



# Integrated Report 2019



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hhe
human health care

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## Period Covered

This Integrated Report covers business performance from April 1, 2018 to March 31, 2019. Some sections may include information on activities as recent as fiscal 2019.

## ■ Reporting Organizations

Eisai Co., Ltd. and domestic and overseas consolidated subsidiaries

#### Forward-Looking Statements and Risk Factors

Materials and information provided in this Integrated Report may contain "forward-looking statements" based on current expectations, forecasts, estimates, business goals and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Moreover, the target values contained in this report merely express medium-term strategies, intended directions and visions and are not an official earnings forecast. For the official earnings forecast, please refer to the annual financial report (Consolidated Financial Statement) in accordance with the rules set by the Tokyo Stock Exchange. Factors that could have a material impact on the future outlook include, but are not limited to, changes in the economic environment and competitive pressures surrounding Eisai's business environment, revisions to laws and regulations, fluctuations in currency exchange rates, uncertainties associated with new drug development and infringements of intellectual property rights by third parties. Although this report contains information on pharmaceuticals (including those under development), the content is not intended for advertising or medical advice purposes. In addition, further details about business risks stated above are described in the Annual Security Report.

This English Report was translated from the original Japanese version. In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.

### Note to Description

•Generic names for drugs are given omitting the base or hydrate.

#### ■ Notes to Icons on Each Page

- Pages that are strongly related to 6 capitals which comprise Eisai's corporate value (intellectual capital, human capital, manufactured capital, social and relationship capital, natural capital and financial capital) are marked with corresponding icons.
- Pages that are strongly related to 17 Sustainable Development Goals (SDGs) are marked with SDGs icons.

# **Materiality**

Eisai's corporate philosophy is to give first thought to patients and their families. Likewise, Eisai provides employees, who are responsible for patient contribution, with opportunities to develop their talents to enrich their careers and cultivate work satisfaction. Eisai's mission is the enhancement of patient satisfaction, then revenue and earnings are generated consequently. We place importance on this sequence of placing mission before the ensuing results.

On the other hand, in order to sustainably maximize corporate value to fulfil every stakeholder's satisfaction, and taking into consideration the corporate philosophy's concept of "mission and the results" in

consideration, it is regarded to be more efficient to focus on long-term investors, beneficiaries of residual income, as the important stakeholder\*1. With the longterm interests of all stakeholders including patients and employees taken into account, it is believed that identifying the concerns relating to the interests of long-term investors and then taking initiatives on a priority basis, is the fast track to the maximization of corporate value.

Business Base (ESG)

Process for Establishing Materiality and Eisai's Materiality Matrix are shown below. Reviews and updates are undertaken as needed.

\*1 Concept derived from Enlightened Value Maximization Theory (Michael C. Jensen, 2001)

#### Process for Establishing Materiality

#### **Process 1: Identification of issues**

We identify issues giving consideration to various types of guidelines (e.g., Sustainability Accounting Standards for Pharmaceuticals by SASB\*2, GRI Guidelines), to Sustainable Development Goals (SDGs)\*3, to communication with stakeholders and to socially responsible investment (SRI) indices (e.g., Dow Jones Sustainability Index).

#### Process 2: Prioritization of issues and creation of materiality matrix

We prioritize issues with a particularly high degree of importance, and then create a matrix, from the perspectives of "impact on Eisai's business considering the corporate philosophy and impact on finances, and of "interest to long-term investors", which includes financial reporting, opportunities to create innovation, and the impact of legal restrictions and industry norms.

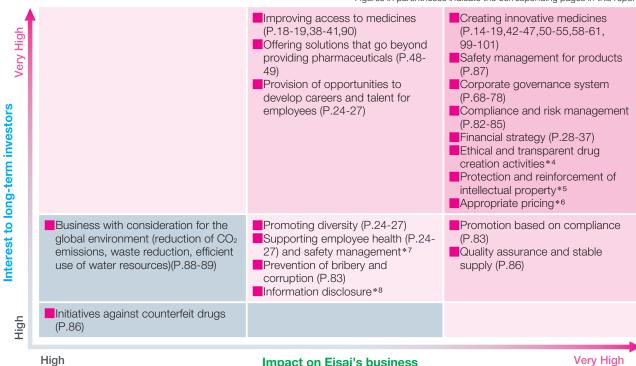
#### **Process 3: Reviews and updates**

Reviews and updates are undertaken as needed taking into consideration the progress of initiatives toward issues and changes in the business environment.

- \*2 SASB (Sustainability Accounting Standards Board) is a U.S.-based non-profit organization that identifies materiality by industry for reasonable investors and develops sustainability disclosure standards
- \*3 Sustainable Development Goals (SDGs) are a set of international goals under the 2030 Agenda for Sustainable Development adopted at the United Nations. Sustainable Development Summit in September 2015. For details, please refer to page 90.

## Eisai's Materiality Matrix

Figures in parentheses indicate the corresponding pages in this report.



\*4-7 Please refer to Eisai's Corporate Website

- \*4 Ethical and Transparent Drug Creation Activities
- \*5 Intellectual Property Initiatives

High

- \*6 Marketing, Aims to Secure Appropriate Pricing
- \*7 Occupational Safety and Health
- Impact on Eisai's business
- https://www.eisai.com/company/business/research/discovery/index.html
- https://www.eisai.com/company/business/research/ip/index.html
- https://www.eisai.com/company/business/marketing/index.html
- https://www.eisai.com/sustainability/employee/health\_safety/index.html
- \*8 Please refer to Article 11 of Eisai's Corporate Governance Guideline
- https://www.eisai.com/company/governance/cgregulations/cgguideline/index.html

# The driving force of Eisai

# "human health care (hhc)"

Established the corporate philosophy in 1992, which is understood and internalized as our core value by employees, both in Japan and overseas

All employees are encouraged to spend 1% of their total business hours to interact with patients

# Socialization with People with Dementia

(Facility for Elderly People in Tokyo)

Directors including outside directors and mid-level employees had conversation with people with dementia and recognized that the patients can still express their thoughts and still want to live satisfying lives.



# Held an Event to Support Patients with Cancer (Medical Center in Philippines)

Together with a patient advocacy group, we held an event to support breast cancer patients in the Philippines. During the event, we held contests such as the most stylish way to wrap a scarf around the head to cover their hair loss due to chemotherapy and making Christmas cards to encourage patients to express their feelings through messages written on the card.



# Laboratory tour with Refractory Disease Patients (Tsukuba Research Laboratories in Ibaraki Prefecture)

We invited patients with refractory disease to Tsukuba Research Laboratories and introduced our research in the upstream area for medicine creation. Through spending time with the patients, we felt patients' difficulties in their daily life and hope for cure, and reconfirmed our motivation to contribute to patients.



# Socialization with People with Intellectual Disability (Facility for People with Disabilities in Shizuoka Prefecture)

Employees from overseas, who came to Japan for training, interacted and empathized with residents of a facility for people with intellectual disabilities. By spending time with people with intellectual disability, we had an experience to look back at the origin of our human health care philosophy to contribute to patients.



Eisai's corporate philosophy reflects our commitment to business activities aiming to increase the benefits to patients, their families, and consumers, who we clearly recognize as the key players in healthcare.

This corporate philosophy is summarized by the term "human health care (hhc)". We believe that, it is important for each employee to first get close to patients and see the situation from their perspectives in order to learn to empathize with their thoughts and feelings that they might not always express in words. Accordingly, all employees are encouraged to spend 1% of their total business hours to interact with patients. Currently, this Corporate Philosophy penetrated in the minds all employees in Eisai group, shared beyond nationality, border, gender and age, and practiced in their daily business. Examples are described below.

#### Socialization with People with Lymphatic (Health Center in India) **Filariasis**

Eisai's employees from all over the world gathered in India to socialize with lymphatic filariasis patients. We directly heard from patients the difficulties they face in their daily life and their mental struggles, such as they cannot do house chores or work to earn a living because of their crippled limbs. They also worry about the social stigma that their children suffer because of the parent's physical deformity. In addition to supplying an anti-filariasis drug DEC (Diethylcarbamazine) tablets at price zero, we sought other ways to assist them in day-to-day life.



Plant Tour with People with Rare Diseases

(Kashima Plant in Ibaraki Prefecture)

We invited people with rare diseases to Kashima Plant. After a facility tour, we had discussions and workshop. Directly sharing the emotions of patients with refractory diseases improved our motivation.



#### **Awareness Activity of Metastatic Breast** (Convention Center in the United States) Cancer

Employees of our U.S. subsidiary launched a website to raise awareness activity of metastatic breast cancer and provide support to patients. On the website, breast cancer patients can find tips and advice for living well and improving vitality.



**New Employees Socialized with People with Dementia** and Their Families (Training Facility in Kanagawa Prefecture)

In the training for new employees conducted in April, these new employees spent time with people with dementia and their families. They learned that it is important to create an environment in the local community that co-exist with dementia, and that by focusing on what can be done, this can be realized with their support and the support of people in the area even if they become demented.



### Incorporated the corporate philosophy into the Company's Articles of Incorporation in June 2005

To commemorate our values and goals with shareholders and to operate business, we incorporated the Corporate Philosophy into the Company's Articles of Incorporation, upon receiving approval at the Annual General Shareholders' Meeting in June 2005.

# **Articles of Incorporation Article 2**

- (1) The Company's Corporate Philosophy is to give first thought to patients and their families, and increase the benefits that health care provides them. Under this Philosophy, the Company endeavors to become a human health care (hhc) company.
- (2) The Company's mission is the enhancement of patient satisfaction. The Company believes that revenues and earnings will be generated by fulfilling this mission. The Company places importance on this sequence of placing the mission before the ensuring results.
- (3) The Company strives to fulfill its social responsibilities by positioning compliance (i.e., the observance of legal and ethical standards) as the basis of all business activities.
- (4) The Company's principal stakeholders are patients, customers, shareholders and employees. The Company endeavors to develop and maintain a good relationship with stakeholders and to enhance the value of their stake through:
  - 1. Satisfying unmet medical needs, ensuring a stable supply of high-quality products, and providing useful information on subjects including drug safety and efficacy;
  - 2. Timely disclosure of corporate management information, enhancement of corporate value, and a positive return to shareholders; and
  - 3. Ensuring stable employment, offering challenging and fulfilling duties, and providing full opportunities for the development of employees' capabilities.

Sequence of Mission and Results Based on the *hhc* Corporate Philosophy



### Initiatives to realize innovation based on the theory of knowledge creation

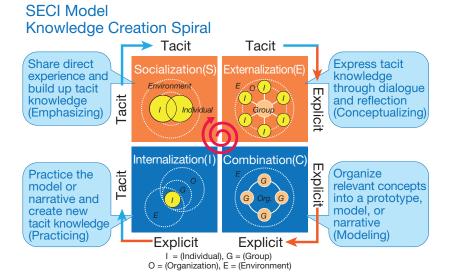
Each employee of Eisai is aiming to realize our Corporate Philosophy "hhc" through daily work by exercising ingenuity based on the **theory of knowledge creation**.

There are two types of knowledge: "tacit knowledge" and "explicit knowledge". The former is subjective and not easily expressible, while the latter is expressible. The "SECI model" is the core framework of knowledge creation, which creates organizational innovation through the repetitive and mutual conversion of tacit and explicit knowledge. In this model, knowledge creation is captured in four phases:

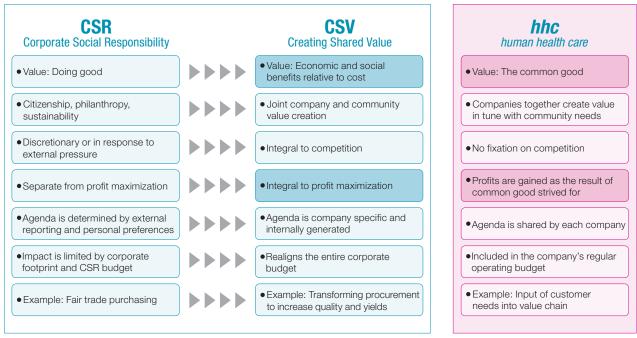
- (1) "Socialization(S)", a process of building up tacit knowledge through directly sharing experience with others.
- (2) "Externalization(E)", a process of expressing tacit knowledge through dialogue between individuals and articulation into concepts or iconography.
- (3) "Combination(C)", a process to combine explicit knowledge of an organizational level into a model, or narrative.
- (4) "Internalization(I)", a process of creating new tacit knowledge through practicing explicit knowledge.

It is important to repeat this spiral of four phases for strategic knowledge creation.

Eisai places particular importance on socialization in understanding the reality of patients (emotions) and encourages all employees around the world to spend 1% of their total business hours to interact with patients.



# **Business model based on hhc**



<sup>\*</sup>Compiled by Deloitte Tohmatsu Consulting based on Michael E. Porter, "Creating Shared Value", Harvard Business Review, and other resources and revised by Eisai. Supervised by Ikuiiro Nonaka, Professor Emeritus of Hitotsubashi University.

Eisai's *hhc* is different from corporate social responsibility (CSR), which mainly involves social contribution activities such as acts of charity that do not directly contribute to business or corporate value. It is relatively close to Creating Shared Value (CSV), a business model that aims to pursue both social value and economic value. Eisai's mission is to create social value by enhancing patient satisfaction, and economic value in the form of revenue and profit is generated as a result. Eisai places importance on this sequence of placing the mission before the ensuring results.

Confirmed the thorough internalization of the corporate philosophy among employees around the world and their high engagement in Eisai through the knowledge creation survey 2017

Eisai began conducting the Knowledge Creation Survey targeting approximately 10,000 employees around the world in September 2017. The survey aims for ascertaining the current conditions of knowledge creation activities at Eisai and its organizational units and realizing the corporate philosophy. To achieve these aims, Eisai has conducted this survey six times since fiscal 1997 under the supervision of Ikujiro Nonaka, Professor Emeritus at Hitotsubashi University.

Eisai confirmed the thorough internalization of the corporate philosophy among employees around the world (Figure 1) and their high engagement (attachment or emotional involvement) in the company (Figure 2) based on its analysis of the answers provided to a total of 172 questions asked in the survey.

At the same time, **employees** recognized the importance of "socialization", a process particularly emphasized by Eisai through which they share time with patients and accumulate tacit knowledge. They also showed a tendency to understand the needs to raise the level of accomplishment of "socialization" (Figure 3). This is presumably because many employees feel the need to understand the true needs of patients through accomplishment of "socialization". We will revitalize our efforts for "socialization"

because "socialization" lies at

the root of Eisai.

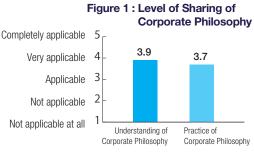


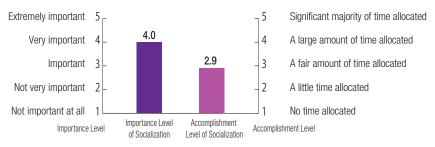
Figure 2 : Engagement in Eisai

3.8 3.8 3.7

3 - 2 - 1

Satisfaction Pride in Current job is rewarding and satisfying

Figure 3: Level of Importance and Accomplishment of Socialization



# **SWOT Analysis Strengths**

Taking on the challenge to promptly expand our contributions to patients by leveraging our strengths

# 1. Thorough internalization of the corporate philosophy and high employee engagement

Confirmed the thorough internalization of the corporate philosophy and high employee engagement in the company worldwide from the results of "Knowledge Creation Survey 2017"

phe

human health care

Reference P4-7, 14

# 2. Industry-leading R&D pipeline in the dementia area

Phase II studies for 2 candidates are underway
Eisai is the only company in the world which leads Phase II studies

of both BACE\* $^1$  inhibitor and anti-A $\beta$  (amyloid beta) antibody Aim for successful development of the world's first potential disease modifier

for Alzheimer's disease



Investigational BACE inhibitor elenbecestat\*2

Banz401-0000-201 0 BANZ401-0000-201 0 364118

Investigational anti-A\$\beta\$ protofibrils antibody BAN2401\*2,3

Lists of Aβ associated pharmaceutical candidates at the stage of Phase II study\*4

## **BACE** inhibitor

#### **Elenbecestat**

- \*1 Beta-site amyloid precursor protein-cleaving enzyme
- \*2 Co-development with Biogen Inc.
- \*3 Licensed-in from BioArctic AB
- \*4 The chart created by Eisai based on the information on ClinicalTrials.gov as of July 11, 2019

## Anti-Aβ antibody

#### **BAN2401**

Gantenerumab (Roche)
Solanezumab (Eli Lilly)

**Reference** P15-16, 42-47

# 3. Abundant experience and knowledge in medicine creation in the dementia and oncology areas

Accumulated abundant experience and knowledge through medicine creation for

more than 35 years (since 1983) in the dementia area and more than 30 years (since 1987) in the oncology area

Reference P12-13, 42-47, 50-55, 58-61, 99-101

# 4. Accumulation of experience and knowledge from global business activities

Drug creation activities • Production activities • Marketing activities

Commenced overseas operation in the late 1960s, and accelerated global operation in mid 1990s Currently established a solid business foundation in Japan, the U.S., Europe, China, and Asia Achieved double-digit growth of revenue (based on local currency) for 8 consecutive years and recorded top-class revenue in China among Japanese companies

Reference P56-67

# 5. Expansion of products developed in-house

Anticancer agent Lenvima®



Revenue in fiscal 2018

62.6 billion yen (YoY 194%) Anticancer agent Halaven®



41.3 billion yen (YoY 104%) Antiepileptic agent Fycompa®



19.3 billion yen (YoY 132%)

**Reference** P50-55, 92-93

# 6. Strategic partnerships in the neurology and oncology areas

Global partnerships that enable increased probability of success and accelerated development with optimization of development and commercialization expenses

Neurology area: Biogen Inc.



Oncology area: Merck & Co., Inc.,
 Kenilworth, N.J., U.S.A.



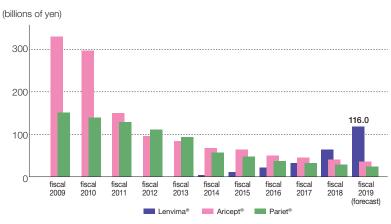
Reference P15-17, 42-47, 50-55, 80-81

# **SWOT Analysis Weaknesses, Opportunities**

# Weaknesses

# 1. Delay in creation of major brands with annual revenue of over 100 billion yen

# Trends in revenue of major brands



- \*1 Co-development with Biogen Inc.
- \*2 Licensed-in from BioArctic AB

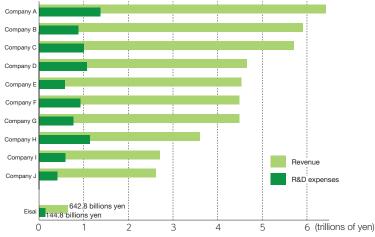
One of our weaknesses is that we have not been able to create major brands since we created the Alzheimer's disease treatment Aricept<sup>®</sup> and proton-pump inhibitor Pariet<sup>®</sup>.

However, in-house developed anticancer agent Lenvima<sup>®</sup> is expected to achieve more than 100 billion yen revenue in fiscal 2019 and have the potential to exceed the peak sales of Aricept<sup>®</sup>. In addition, investigational BACE inhibitor elenbecestat\*1 and anti-A $\beta$  protofibril antibody BAN2401\*1,2 are estimated to have the potential to exceed the peak revenue of Aricept<sup>®</sup>, considering the expected benefits.

▶Reference: P42-47,50-55,58-63

# 2. Limited R&D expenses compared with global large pharmaceutical companies

# Revenue and R&D expenses of top 10 pharmaceutical companies and Eisai in fiscal 2018



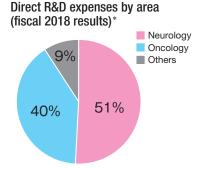
Source: AnswersNews (only available in Japanese) https://answers.ten-navi.com/pharmanews/16219/

In 2018 global ranking of revenue of pharmaceutical campanies, Eisai ranked 5<sup>th</sup> among Japanese pharmaceutical companies and 30<sup>th</sup> in the world. **We have limited R&D expenses compared with large pharmaceutical companies.** In order to overcome this weakness, Eisai promotes strategies to improve productivity and efficiency of drug creation activities.

First, Eisai is thoroughly selecting and concentrating on priority projects. We chose neurology and oncology as the strategic areas of focus that have higher needs from patients and would allow us to utilize our accumulation of knowledge and know-how. We have concentrated R&D resources in those areas.

The second strategy is **utilizing partnerships.** Joint development with partners who have diverse experience and know-how is very effective in increasing the probability of success of new drug development and accelerate it. Also, partnerships greatly contribute to the dispersion of risk in R&D and investment efficiency. In the consolidated income statement for fiscal 2018, our R&D expenses was 144.8 billion yen (ratio to revenue: 22.5%). However, R&D expenses inclusive of partners' share of expenses (46.4 billion yen) was 191.3 billion yen (ratio to revenue: 29.8%).

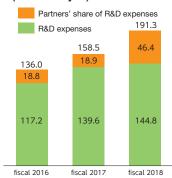
\*Source: NEW Pharma Future No.19 June to July 2019



Concentrate 91% of the direct R&D expenses into two areas

\*Inclusive of partners' share of expenses

# R&D expenses inclusive of partners' share of expenses (billions of yen)



10

;

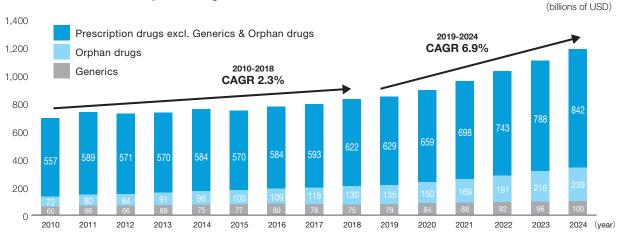
# and Threats

# **Opportunities**

# **Expansion of global pharmaceutical market**

It is thought that population aging, growth in developing and emerging countries, and the creation of ground-breaking drugs will further expand the global pharmaceutical market. The 2019-2024 CAGR (compound annual growth rate) of global prescription drug market is expected to be 6.9%, and the CAGR is to be 11.4% in the oncology area. Expansion of global pharmaceutical market will be **a great business opportunity for Eisai, which conducts business activities globally.** 

# **Worldwide Total Prescription Drug Sales**



Reference: EvaluatePharma® World Preview 2019, Outlook to 2024 ©Evaluate Ltd.

# **Threats**

# 1. Innovative competitive products entering the market

Each pharmaceutical company invests aggressively into R&D to develop new drugs. The launch of an innovative product by a competitor is a large threat for us.

However, it will not necessarily lead to taking growth opportunities from us. Combination therapies are becoming standard, especially in the oncology area. If we demonstrate the scientific rationality of combination therapies of our agents and the new products, we will be able to dramatically increase our growth potential. As for Lenvima®, we are actively developing combination therapies with innovative anti-PD-1 antibodies.

▶ Reference: P50-55

# 2. Increasing pressure to lower drug prices as governments promote policies to reduce healthcare expenditure

Many governments around the world are implementing policies to reduce healthcare expenditure, and as a result, there is increasing pressure to lower drug prices, which is a threat to our business. High priced agents are appearing one after another on the market, especially in oncology area, therefore setting reasonable prices is a very important issue.

Eisai believes that **drug prices should be determined based on the fundamental value provided to patients.** We are striving to create drugs that bring genuine value to patients, but at the same time, we believe that the value of innovation should be appropriately reflected in the price.

# Aiming to Contribute to Patients around the World History of Eisai

## 1941

# Founded Eisai

The founder Toyoji Naito established Eisai and focused on drug creation activities, because he was dissatisfied with how Japan's drug industry at the time remained overly reliant on imports.

1941 Established Nihon Eisai Co., Ltd.

1955 Changed corporate name from Nihon Eisai Co., Ltd. to Eisai Co., Ltd.



Founder: Toyoji Naito



Advertisement for Sampoon contraceptive launched in 1948



# **Late 1960s**

# Commenced full-fledged overseas expansion

Yuji Naito was inaugurated as the second President of Eisai in 1966, and promoted overseas expansion proactively.

Late 1960s to early 1970s Local subsidiaries established in Southeast Asia



Yuji Naito

### 1980s

# Established a foundation for global business expansion

#### Three-hub R&D network established

1982 Tsukuba Research Laboratories (Japan)

1989 Eisai Research Institute of Boston, Inc. (U.S.)

1992 Eisai London Research Laboratories, Ltd. (U.K.)

# Entry into dementia and oncology areas

1983 Commenced drug discovery research on dementia at Tsukuba Research Laboratories

1987 Launched R&D group to develop proprietary anticancer agents at Tsukuba Research Laboratories

1992 Adopted the corporate philosophy of "human health care (hhc)"

At a time when the typical strategy for a Japanese pharmaceutical company to expand business overseas was to license out its products to pharmaceutical companies abroad, Eisai was determined to handle all processes regarding its products on its own, from research, which serves as the fountainhead from which all other product phases flow, through to manufacturing. Driven by this determination, Eisai was one of the first in the industry to establish R&D bases in Japan, the U.S. and Europe and has strived for the creation of global brands.

Additionally, Eisai commenced drug creation activities in the dementia and oncology area at this time.



Tsukuha Research Laboratories



Fisai Research Institute of Boston Fisai London Research Laboratories



Haruo Naito, the current Representative Corporate Officer and CEO, was appointed President of Eisai in 1988. He began transforming the corporate image and challenging employees to adopt new mindsets and attitudes as soon as he began his tenure. Then, in 1990, with clearly recognizing patients, their families and the customers as the key players in healthcare and for pharmaceutical companies, the company announced the concept of "Eisai Innovation." This advocated taking pride in achieving business





## \_ate 1990s

# Growth of two major brands accelerated global business expansion

### Launched Alzheimer's disease treatment Aricept®

1997 in the U.S. and Europe (U.K.)

**1999** in Japan



#### Launched proton-pump inhibitor Pariet®

**1997** in Japan

1998 in Europe (U.K.)

1999 in the U.S.

(brand name: AcipHex®)



# **Peak Sales**

Aricept® ¥322.8 billion (fiscal 2009) Pariet® ¥175.9 billion (fiscal 2007) Total ¥470.8 billion (fiscal 2009)

Two products developed in-house, Aricept® and Pariet®, were launched in late 1990s and expanded globally. Total revenue of these products peaked at ¥470.8 billion in fiscal 2009. Growth of the two major brands accelerated global business expansion, and Eisai established pharmaceutical sales subsidiaries consecutively in major countries overseas.

Additionally, Eisai conducted M&A and established new subsidiaries to strengthen foundation in oncology area.

## Strengthened foundation in oncology area

2007: Acquired Morphotek, Inc. 2008: Acquired MGI Pharma, Inc. 2010: Established H3 Biomedicine Inc.

in the U.S.

## 2010s

# Value creation through new products developed in-house and partnership model

#### LOE (Loss of Exclusivity) in two major brands

Aricept® Pariet® 2010 in the U.S. 2010 in Japan 2011 in Japan 2012 in Europe 2012 in Europe 2013 in the U.S.

#### Launched new products developed in-house

2010: Launched anticancer agent Halaven® in the U.S. 2012: Launched antiepileptic agent Fycompa® in Europe

2015: Launched anticancer agent Lenvima® in the U.S., Japan and Europe

#### Formulated partnerships in the dementia and oncology area

2014: Entered into a collaboration agreement with of Alzheimer's disease treatments

2018: Entered into global strategic oncology collaboration for Lenvima® with Merck & Co., Inc., Kenilworth, N.J., U.S.A.

Eisai went through a tough phase due to the loss of exclusivity in Aricept® and Pariet®. However, new products developed in-house has been expanding continuously. Eisai's financial performance has been improving steadily with the growth of Lenvima® and others

In 'EWAY 2025', a medium-term business plan spanning 10 years and commenced in fiscal 2016, Eisai has selected oncology and neurology as its therapeutic areas of focus. Under the partnership model, development of next generation Alzheimer's disease treatments is advancing in the dementia area. Additionally, development of combination therapy of Lenvima® and immuno-oncology is making remarkable progress in the oncology area.



November 2010: LOE for Aricept® in the U.S. February 2015: Launched Lenvima® in the U.S.



(Billions of yen) 800

**CEO Message** 

# To Our Stakeholders

# Management Based on a Corporate Philosophy

The Company's Corporate Philosophy is to give first thought to patients and their families, and to increase the benefits that health care provides to them. Under this philosophy, we endeavor to become a human health care (hhc) company. Since taking up the role as CEO, I have directed the company's management in accordance with the corporate philosophy. A corporate philosophy is a guide to show, "Who is important to us, and what do we work for", not just for within the company, but also for outside of the company. Our corporate philosophy is stipulated in the Articles of Incorporation, one of the prime documents for the company.

It is not easy to understand patients' true thoughts and feelings. Of course, we cannot ask a patient in the hospital waiting room how they feel. Even for families and relatives, it is actually quite difficult to find out a patient's true pain and needs. Accordingly, approximately 10,000 employees worldwide are encouraged to spend 1% of their total business hours to interact with patients to learn their true thoughts and feelings. We believe that it is important to truly consider the perspectives of patients and their families, and share thoughts and feelings that might not be expressed in words by talking to patients or having meals together with them.



# Create Innovation in Neurology and Oncology Areas under the Medium-Term Business Plan 'EWAY 2025'

Management Strategies

Currently, Eisai is focused on achieving 10-year medium-term business plan 'EWAY 2025', an initiative to create innovation with strong motivation based on the corporate philosophy "hhc". Innovation is not something that necessarily happens in science or technology. Strong motivations of people are essential. 'EWAY 2025' is aimed at creating innovation with strong motivations to find out patients' true needs from socialization with them and to fulfill their needs.

The concept of "Ricchi" is also incorporated into 'EWAY 2025'. "Ricchi" is an area where real patient needs are still unmet and no one has achieved success, or even remained untapped from "hhc" point of view, then Eisai has an opportunity to become a frontrunner there. We aim to play a central role in "Ricchi" and constantly innovate. Determining "Ricchi" means limiting the scope of our activities and involves taking risks. However, we believe that focusing on specific areas will empower the efficiency towards creating innovation.

Among the various areas, we have decided to focus on neurology and oncology since we commenced

#### **Focusing on Neurology and Oncology Areas**

## Neurology Area

Successful case such as launch of Aricept® Abundant knowledge in dementia area Industry-leading pipeline in dementia area

# **Oncology Area**

Successful case such as launch of Halaven® and Lenvima® Tumor microenvironment with experience and knowledge from Halaven® and Lenvima Driver gene mutation and aberrant splicing of H3 Biomedicine 'EWAY 2025' in April 2016.

Business Base (ESG)

In neurology, we had the successful case of launching Aricept® for the treatment of Alzheimer's disease. We have abundant experience and knowledge of medicine creation and disease awareness activities in the dementia area. Also, an industry-leading pipeline is our greatest strength. Despite the estimates that the number of patients is increasing globally, no dementia treatment has been newly approved by the U.S. FDA since 2003. Eisai's priority is to create new medicines to fulfill high unmet needs in the dementia area, and that is the motivation that made us decided to focus on neurology area.

In oncology area, we launched the anticancer agent Halaven® in 2010, and Lenvima® in 2015, and have built experiences and knowledge. Oncology is the area in which the world's large pharmaceutical companies are in fierce competition to develop new treatments. It is extremely challenging to be successful in this area. Under these circumstances, we decided to focus on oncology, since we believe that successful outcome is achieved through these two perspectives: "tumor microenvironment\*1", which we have experience and knowledge from the development of Halaven® and Lenvima®, and "driver gene mutation\*2 and abberant splicing\*3" utilizing technology of H3 Biomedicine, Inc., a precision medicine research & development subsidiary.

- \*1 Specific environment that the immune cells infiltration and angiogenesis induction are occurred around tumor cells. It is considered that various stimulations and nutrition from microenvironment enhance carcinogenesis.
- st 2 Genes that play a direct role in the incidence and progression of cancer
- \*3 Abnormality in activity to remove unnecessary part from genetic information of DNA

# Dementia Area — Phase III Studies Are Ongoing for Two Projects

Regarding investigational anti-amyloid beta  $(A\beta)$ antibody aducanumab\*1, which was being developed under the collaboration with Biogen, Eisai and Biogen announced the decision to discontinue two Phase III studies for patients with early Alzheimer's disease on March 21, 2019. In spite of the great deal of support on this project, we would like to sincerely apologize for this result.

However, we have two Phase II studies ongoing for two projects. Next-generation Alzheimer's disease treatments are expected to slow disease progression from earlier stages and for longer periods of time, and potentially provide new hope for patients. We will strive to deliver new treatments to patients and their families as early as possible.

Regarding investigational BAN2401\*1,2, an antiamyloid beta  $(A\beta)$  protofibrils antibody, the analysis of Phase II study with 856 patients demonstrated reduction of  $A\beta$  accumulation in the brain and subsequent improvement of cerebrospinal fluid (CSF) biomarkers. As a result, this is the first late-stage study data that has successfully demonstrated the slowing in clinical decline. These findings suggested the potential of BAN2401 as a disease modifying treatment. Based on the results of Study 201, the Phase II study (Clarity AD) has been initiated in March 2019. High affinity for A $\beta$  protofibrils which have strong neurotoxicity, is a unique characteristic of BAN2401. The Phase III study is currently ongoing and final readout of Primary endpoint is targeted in the first quarter of fiscal 2022.

As for investigational elenbecestat\*1, a BACE (β -site amyloid precursor protein cleaving enzyme) inhibitor, two Phase II studies (MISSION AD1/2) are ongoing and patient enrollment was completed in March 2019. Final readout of Primary endpoint is targeted in the first quarter of fiscal 2021. The Phase II study (Study 202) conducted in the U.S. was the



Investigational anti-A $\beta$  protofibrils antibody BAN2401

first study of a BACE inhibitor to show a statistically significant difference in  $A\beta$  levels in the brain while suggesting delay of clinical symptom decline.

In addition, these two agents were selected for prevention studies (A3 study and A45 study) for Alzheimer's disease planned by Alzheimer's Clinical Trials Consortium (ACTC), which is one of the world's experts on Alzheimer's disease.

- \*1 Co-development with Biogen Inc. \*2 Licensed-in from BioArctic AB



Investigational BACE inhibitor elenbecestat

# Initiatives to Develop Environment Surrounding Dementia in Japan

In order to deliver next-generation Alzheimer's disease treatments without delay, we need to improve infrastructure on the medical and social environments. Various issues need be addressed; however, establishing environment for early diagnosis and initiation of treatment is particularly important since current studies suggest that accumulation of  $A\beta$ , sleep disorders and behavioral disorders may occur long before cognitive impairment appears.

As for cancer, the Cancer Control Act was established in Japan; therefore, public expenses cover most of the primary cancer screenings. With this Act, substantial progress has been made in prevention and treatment of cancer. On the contrary, the public expense coverage for diagnosis of dementia has not been fully established in Japan. For this reason, the philosophy and basic measures of Basic Act for Dementia are currently under review. Recently, progress has been made for the establishment of the legislation for dementia in Japan; the Basic Act for Dementia was submitted to the Lower House from the Liberal Democratic Party and the Komeito party during the ordinary parliamentary session. The Outline for Promoting the Dementia Plan focusing on co-existence and prevention as pillars, has been summarized in June 2019. Prior to the G20 Summit in June 2019, the Japan Pharmaceuticals Manufacturers Association prepared the proposals regarding global healthcare issues including dementia and submitted these to the Government of Japan. Through these initiatives, we expect that dementia measure in Japan would make a major step forward.

We also need to develop new diagnostic methods, which will enable early diagnosis of dementia as soon as we can. Therefore, Eisai and Sysmex Corporation are jointly pursuing development of minimally invasive and inexpensive high throughput diagnostics (bloodbased diagnostic method).

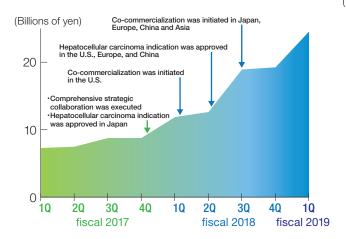
# Oncology Area — Expansion of Lenvima® and Pursuit of Further Maximization of Its Value

Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. (U.S. Merck) agreed upon a global strategic collaboration for Lenvima® in March 2018. The cocommercialization is currently progressing smoothly in major countries. In fiscal 2018, we obtained approval for hepatocellular carcinoma around the world, including the U.S. and China. As a result, the revenue of Lenvima® in fiscal 2018 reached 62.6 billion yen, 194% YoY. In fiscal 2019, we will expand the range of co-commercialization and aim to achieve revenue of 116 billion yen, 185% YoY.

The co-development of combination therapy of Lenvima® and KEYTRUDA® (generic name: pembrolizumab) is also steadily ongoing. In July 2019, we received the Breakthrough Therapy Designation from the U.S. FDA\* for the potential first-line treatment of advanced unresectable hepatocellular carcinoma, following renal cell carcinoma and endometrial carcinoma. 11 of the 13 co-developed studies (12 studies are pivotal) for the combination therapy of Lenvima® and KEYTRUDA® were initiated approximately 1 year after entering the strategic

#### Recent transition of Lenvima® revenue

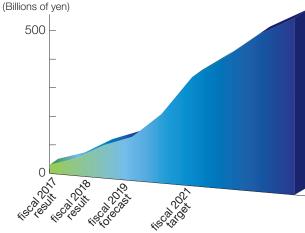
High growth was achieved from approval of Hepatocellular carcinoma indication and initiation of co-commercialization with Merck & Co., Inc., Kenilworth, N.J., U.S.A. in major countries



collaboration, and remaining two studies will be initiated within fiscal 2019.

Furthermore, this collaboration will have a positive impact on Eisai's financial position in the medium to long-terms. Assuming the achievement of all development and commercial goals for all indications, the total amount of upfront, option, regulatory and sales milestone payments have the potential to reach up to \$5.76 billion U.S. dollars (approximately 611.0 billion yen). We have already recognized \$1.38 billion U.S. dollars at the end of March 2019, and recognition of the regulatory and multiple sales milestones are expected

• Mid-to long-term perspective of Lenvima® revenue
Aim to realize innovative value for patients through accelerating development of combination therapies with KEYTRUDA®



in addition to a one-time \$0.2 billion U.S. dollar associated with certain option rights in fiscal 2019. This collaboration enables further proactive investment in R&D in oncology and dementia areas. Accordingly, the achievability of fiscal 2020 target as set in 'EWAY 2025' has been enhanced by enabling operating profit of 100 billion yen level on average and 10% level of ROE. The achievability of ROE target of 15% level in fiscal 2025 has been enhanced through continuous growth in revenue and operating profit beyond fiscal 2021.

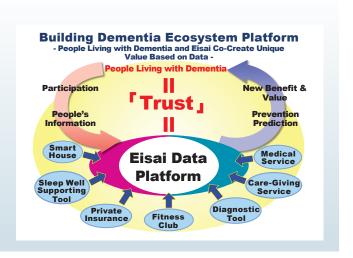
\* An U.S. FDA program intended to expedite development and review of drugs for serious or life-threatening conditions. Preliminary clinical evidence demonstrating the drug may have substantial improvement of at least one clinically significant endpoint over available therapy is required.

# Transformation of Business Model under the Fourth Industrial Revolution – Establishment of Ecosystem

We are currently going through the era of the fourth industrial revolution. Under such circumstances, we believe that it is necessary to focus on predicting what may happen to each patient in the future, and provide new benefit to those living with disease and their families. For example, we aim to provide advice, recommendation and proposals, such as when an onset of disease occurs, and how he/she can avoid risks of developing dementia or cancer five years later.

We aim to develop algorithms related to prevention and prediction utilizing Eisai's own knowledge, expertise, experiences and clinical data, as well as big data from external organizations. Moreover, by establishing platform in which partners who provide contents can participate, we aim to provide enormous benefit to those living with the disease and their families. Especially in dementia area, while pursuing partnership agreements with local governments, we aim to build the "Dementia Ecosystem" along with fitness clubs and insurance companies, in order to contribute to the realization of the well-being of patients and their families who participate in it.

Success of the "Dementia Ecosystem" does not rely on digital technique, but on the prospects of building trust relationship with those living with the disease and their families. In order to gain the credibility of receiving new benefits and values by participating in Eisai platform, through mutually connecting with those living with the disease and their families, we will sincerely make effort to meet their expectations.



# Contribution to Achieve SDGs Through the Initiatives to Eliminate Medical or Care "Gaps"

We are working on eliminating the various medical or care gaps that exist throughout the world to fulfill a mission of enhancement of patient satisfaction. In an ideal world, people would have equal access to the treatment/care they need, however things are different in reality. Due to differences in region or income, or the lack of medical systems, there are huge discrepancies in the level of treatment or care available. We are enhancing our initiatives to eliminate these regional, income, and institutional gaps. We believe that the initiatives to eliminate the gaps lead to achieving the United Nations 17 Sustainability Development Goals (SDGs). We are aiming to contribute to achieving four goals in particular among the 17 goals: "1. No poverty", "3. Good health and well-being", "10. Reduced inequalities" and "17. Partnerships for the qoals".

# Contribution to Achieving SDGs 1

# **Initiative to Eliminate Tropical Diseases** in Impoverished Regions



A representative example of efforts to resolve the gap is to eliminate Neglected Tropical Diseases (NTDs). NTDs, such as lymphatic filariasis\* (LF) are serious medical and social issues. Moreover, due to poverty or other reasons, many people afflicted with NTDs cannot receive the necessary treatments. We are taking proactive initiatives to relieve patients of their fears and sufferings. Initiatives for NTDs are not side work; it is a major area of focus alongside oncology and neurology.

In order to eliminate LF, Eisai initiated manufacturing the LF treatment "DEC (Diethylcarbamazine)" tablets, at our Vizag Plant in India. We have provided these to the World Health Organization (WHO) at Price

Zero. Supply commenced in October 2013, and we have delivered approximately 1.8 billion tablets to 28 countries by the end of June 2019. WHO announced that elimination of LF was achieved in 14 countries. Eisai will continue providing DEC tablets until LF is eliminated in all the endemic countries.



DEC tablets

Socialization between member of Eisai and patients

# • Contribution to Achieving SDGs 3 and 10





# Affordable Pricing Policies in Emerging Countries

We have been formulating various flexible pricing policies that enable patients in emerging countries to purchase our products at affordable prices. For example, we have introduced "HOPE TO HER PROGRAM" in eight Asian countries. In this program, our anticancer agent Halaven® is provided based on tiered pricing model, which is a scheme to reduce the burden for medicine expenses according to the patients' income and health insurance systems. This program has enabled approximately 4,100 patients with breast cancer to receive Halaven® over the past five years.

# • Contribution to Achieving SDGs 17

# 17 PARTNERSHIPS FOR THE GOALS

# **Development for New Treatments for Tropical Diseases Utilizing Partnerships**

Eisai is proactively taking initiatives aimed at developing new treatments for NTDs. We have collaborated with several international research organizations to obtain specific research technologies and experience in running clinical studies and networking with clinical facilities in endemic regions.

Eisai's initiatives for elimination of NTDs are a longterm investment with the aim of eliminating regional gaps and expanding the productive population and middle-income group in developing and emerging countries, and we will continue to proactively engage in these initiatives.

\* A disease caused by thread-like worms (helminths) of a pathogen, known as filarial. It is transmitted to humans by mosquitoes. Infection can cause serious damages to the lymphatic system and may cause physical impairment such as elephantiasis which swells and enlarges the foot resembling that of an elephant. Statistics show that more than 120 million people in 73 tropical and subtropical countries are infected with this disea

# Eisai's Initiatives for ESG Are Highly Evaluated by External Organizations

Management Strategies

Eisai was ranked eighth among large global pharmaceutical companies in the Access to Medicine Index (ATM Index) 2018, as the result of the successful activities for Society (S) focusing on initiatives to eliminate gaps were highly evaluated.

In the Environment (E) category, we have been making efforts to reduce impact on the global environment for years, and as a result, we were awarded a high evaluation of B rating in the CDP Climate Change Report 2018. "Science Based Targets (SBT) Initiative" certified our medium to long-term targets for greenhouse gas reduction and recognized that the targets were based on scientific grounds. We also announced our endorsement of Task Force on Climaterelated Financial Disclosures (TCFD) in June 2019.

For Governance (G), we believe that our approach for Corporate Governance has always been advanced compared to other companies. We adopted a Company with a Nomination Committee, etc., System in June 2004 to clearly divide functions between supervision of management and execution of business, as well as ensuring fairness and transparency in management. At Eisai, the majority of the board members are outside directors with a high degree of independence. The chair of the board, as well as the chairs of the nomination, audit and compensation committees are all outside directors. The CEO is the only board member from the management side. There are always having active discussions concerning business supervision from various perspectives of the outside directors at the board meetings. In the Jefferies Securities' Governance Review Report, Eisai has been awarded the first place among the TOPIX500 companies for the third consecutive year since 2016.

Business Base (ESG)

Additionally, Eisai has been selected as a member of the FTSE4Good Index Series for the 18th consecutive year since 2002. Eisai is selected for membership in all four ESG indices adopted by the Government Pension Investment Fund (GPIF): MSCI Japan ESG Select Leaders Index, FTSE Blossom Japan Index, MSCI Japan Empowering Women Index (WIN) and S&P/JPX Carbon Efficient Index. Furthermore, Eisai supports the United Nations Global Compact. Through undertaking initiatives to embed the Ten principles of the United Nations Global Compact in the four areas of human rights, labor, environment and anti-corruption, we continue to make efforts to increase our corporate value.

# Maximizing Shareholder Value over the Medium- to Long-Term

Eisai believes that proactive investment for growth based on medium to long-term ROE management, a stable dividend policy and a global investor relations (IR) strategy are three important measures that make up our financial strategy for maximizing shareholder value. Eisai achieved the target ROE for fiscal 2020 of over 10%, two years ahead of original schedule which was planned in 'EWAY 2025', and is generating a historical 10-year average ROE of 10.2% and positive equity spread\* of 2.2%. In working to realize medium and long-term growth, we will continue to proactively invest in R&D in dementia and oncology areas. Regarding dividends, we will maintain our policy of paying stable dividends with a dividend on equity (DOE) ratio at the 8% level. At the end of fiscal 2018, Eisai's net debt equity ratio (Net DER) was -0.32, while the ratio of equity attributable to owners of the parent was 58.6%. We sustain our sound financial condition that enables us to invest proactively and maintain stable dividends. As for IR strategy, our activities for years were recognized and we received the "IR Grand Prix Award" at the IR Award 2018 held by the Japan Investor Relations Association (JIRA). We intend to disclose information in a timely and fair manner to fulfill our accountability to investors and work to constantly enhance shareholder value.

\* Equity spread: ROE - Cost of equity. Eisai conservatively assumes cost of equity of 8%.



On the other hand, in addition to financial strategy, we believe that the initiatives to enhance non-financial capital with a focus on ESG are important to maximize corporate value over the medium to long-term. As mentioned above, our initiatives for ESG are highly evaluated by external organizations. We will seek further enhancement of non-financial capital and increase corporate value, through the management based on a corporate philosophy or initiatives to eliminate gaps centered on contribution to eliminate NTDs.

Eisai would like to undertake our stakeholder's mandate by increasing corporate value continuously under the concept of hhc philosophy and compliance. We ask all our stakeholders for their continued support.

July 2019

Haruo Naito Representative Corporate Officer and CEO



# Value Creation Process and Flow

Figures in parentheses indicate the corresponding pages of this report.

# Six Capitals based on the IIRC framework

# **Capital to sustain Eisai**

# **Financial Capital**

Pool of funds for use in corporate activities

- Net DER -0.32\*
- Ratio of equity attributable to owners of the parent 58.6%\*
- •Net Debt/EBITDA -1.70 years\*
- •Credit rating A+ (R&I announced in

(\* end of fiscal 2018)

(P.28-37,94-95)

# **Intellectual Capital**

Knowledge-based intangible assets such as pipelines and intellectual property

•Abundant experience and knowledge of drug creation activities and pipeline in the dementia and oncology area (P.42-61,99-101)

# **Human Capital**

Capabilities and experiences of Eisai's human assets as well as motivation for innovation

- •Thorough internalization of the corporate philosophy
- Globalized human resources
   (More than half of the 10,000-plus employees at Eisai work overseas)

(P.4-7,24-27,56-57)

input of capital for value creation

# **Manufactured Capital**

Facilities for the manufacture of products and provision of services

Own plants at 9 sites in major regions worldwide

(P.56-57.86)

## Social and Relationship Capital

Building relationships of trust with society and stakeholders for the common good

- Initiatives for improving access to medicines highly evaluated
- (ranked 8th at Access to Medicine Index)
- Wide range of partnerships in the world

(P.38-41,48-49,80-81,86-87)

# **Natural Capital**

Environmental resources and processes associated with corporate activities

- •36.4% reduction of CO<sub>2</sub> emission in Japan compared to fiscal 2005 (fiscal 2018)
- Continuation of zero emissions in Japan for eleven consecutive years (fiscal 2018) (P.88-89)

# Eisai's Strategy Map

Financial perspective

Sustainable maximization of shareholder value

Ordinary general meeting of shareholders



Customer perspective

Eisai's mission

Enhancement of patient satisfaction



Output (products and services)

# Creation of innovative medicines in neurology and oncology areas

Anticancer agent Lenvima®

Investigational disease modifying treatment for Alzheimer's disease elenbecestat\*1 Institute 101.8/05 Baccapi-cooper B 14118

Investigational disease modifying treatment for Alzheimer's disease BAN2401\*1,2



Internal business process perspective

# Global business activities



Develop drug creation, production and marketing activities globally over many years

# Utilization of partnerships (P.80-81)



Aim to improve business efficiency and productivity, and to promptly maximize contributions to patients Quality assurance, stable supply, and safety management for products (P.86-87)

Build a complete system globally

Learning & growth perspective

Internalization of human health care (hhc) philosophy (P.4-7)

All employees are encouraged to use 1% of their total business hours to interact with patients

Interaction with dementia patients as part of new-employee training in China



Eisai's mission is the enhancement of patient satisfaction as defined in the Eisai Articles of Incorporation. In order to fulfill this mission, Eisai utilizes many different types of capital as input and converts them into many different forms of output (products and services) through business activities. Creation of social value by enhancing patient satisfaction leads to generation of economic value in the form of revenue and profit as a result. Through the creation of these outcomes, Eisai is aiming to expand its capital to an extent that is greater than the amount of input.

This chart expresses Eisai's continuous value creation process and flow based on a model that incorporates the IIRC (International Integrated Reporting Council) framework and balanced scorecard.

> Creation of ROE that exceeds the cost of capital in the medium- to long-term (P.34-35)

Sustainable and stable shareholder returns (R36)

# Initiatives to eliminate medical or care gaps (P.18-19)

- - ·Regional gaps
  - Income gaps
  - ·Institutional gaps

Contribution to achieve Sustainable Development Goals (SDGs) (P.18-19, 90)









# Initiatives for improving access



Supply DEC tablets to help eliminate lymphatic filariasis free of charge

# Offering solutions that go beyond providing pharmaceuticals (P.48-49)



Medication administration support device "e-OKUSURI-SAN" Expansion of capital to an extent that is greater than the amount of input

#### **Enhancement of corporate governance** (P.68-78)



The seven outside directors supports the effectiveness of the corporate governance system

# Enhancement of compliance & risk management (P.82-85)

·Commenced promotion of fullfledged compliance in fiscal 2000 from the lessons of vitamin lawsuit

Identification of risks and promotion of prompt and efficient response to risks



# Promotion of talents innovation strategy (P.24-27) Promote diversity

E-GOLD

"It's time to embrace Eisai Diversity"

Promote work style reform

Aim for expansion of capital

# Financial Capital

Pursued an optimal capital structure while maintaining financial integrity

- •Net DER: -0.3 to 0.3
- •Ratio of equity attributable to
- owners of the parent: 50-60%
- •Net Debt/EBITDA: 0-3 years
- Maintaining a single A level credit rating

(P.28-37,94-95)

# **Intellectual Capital**

- Aim for successful development of the world's first potential disease modifier for Alzheimer's disease
- •Aim for value maximization of Lenvima® by developing combination therapy with anti-PD-1 antibody

(P.42-61,99-101)

# **Human Capital**

•Aim to develop talents capable of continuously innovating even in a rapidly changing business environment

(P.4-7,24-27,56-57)

# **Manufactured Capital**

•Aim to fulfill the mission and responsibility to supply high quality products stably (P.56-57,86)

# Social and Relationship Capital

- •Contribution to the future growth in developing and emerging countries and improvement in the value of Eisai's corporate brand through initiatives to improve access to medicines
- •Further expansion of useful partnerships (P.38-41,48-49,80-81,86-87)

# **Natural Capital**

•Aiming to Reduce CO2 Emissions across the entire value chain by 30% compared to Fiscal 2016 by Fiscal 2030

# Accumulation of capital for further value creation

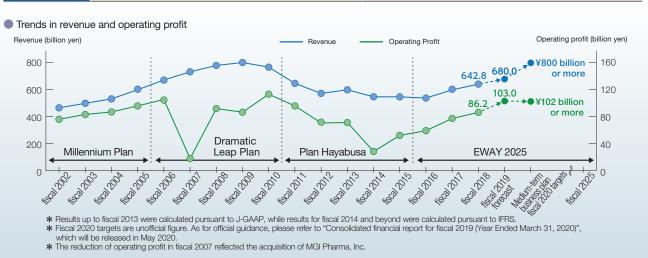
\* Source: Created by Eisai based on Kazunori Ito and Toshiaki Nishihara, "Disclosure and Usability of Information on Integrated Report of Eisai", The KAIKEIGAKU KENKYU (The Annual bulletin of accounting study) No.43, 2017 and advice from Professor Kazunori Ito

# Medium-Term Business Plan 'EWAY 2025'

Eisai began formulating three- to five-year span medium-term business plans in 1957 and executed plan management based on a medium- to long-term perspective. 'EWAY 2025', commenced in April 2016, is Eisai's first medium-term business plan spanning 10 years. For a pharmaceuticals company that has undertaken new drug development over long periods of time, 10 years is not particularly a long time. Eisai will stay keenly focused on the goals, and aim to expand contribution to patients.

# A look back at the past three medium-term business plans

	Key achievements	Key issues
Millennium Plan (FY2002-FY2005)	<ul> <li>Expanded Alzheimer's disease treatment Aricept® and proton-pump inhibitor Pariet®</li> <li>Accelerated expansion of business in overseas</li> <li>Virtually attained key management targets (net revenue of ¥600.0 billion and operating income of ¥100.0 billion) one year ahead of schedule</li> <li>Enhanced corporate governance</li> <li>Adopted a Company with a Nomination Committee, etc., System in 2004</li> <li>Added the corporate philosophy of hhc to the Articles of Incorporation in 2005</li> </ul>	<ul> <li>Unable to launch in-house developed drugs following Aricept® and Pariet®</li> <li>Main development themes unachieved</li> <li>Anticancer agent E7070</li> </ul>
Dramatic Leap Plan (FY2006-FY2010) DRAMATIC LEAP PLAN	<ul> <li>Attained best ever consolidated revenue (fiscal 2009) thanks to expansion of Aricept® and Pariet®</li> <li>Globalization advanced across all functions</li> <li>Strengthened foundation in oncology area</li> <li>Acquired Morphotek, Inc. (2007)</li> <li>Acquired MGI Pharma, Inc. (2008)</li> <li>Launched in-house anticancer agent Halaven® (2010, in the U.S.)</li> </ul>	Unable to achieve consolidated financial targets (revenue of ¥1 trillion and operating income of ¥200 billion) due to delays in obtaining new drug approvals and unachieved development themes  Main development themes unachieved  •Severe sepsis treatment/endotoxin antagonist Eritoran  •Thrombin receptor antagonist E5555  •Aricept® pediatric indications in the U.S. and Europe  •Pariet® long-acting formulation  •AMPA receptor antagonist perampanel for Parkinson's disease
Plan Hayabusa (FY2011-FY2015) 2015 HAYABUSA	<ul> <li>Launched new in-house drugs</li> <li>Antiepileptic agent Fycompa® (2012 in Europe)</li> <li>Anticancer agent Lenvima® (2015 in the U.S., Japan and Europe)</li> <li>Fycompa® (2015 in the U.S., Japan and Europe)</li> <li>Expanded in China and Asia business</li> <li>New market entry</li> <li>Strengthened initiatives for improving access to medicines</li> </ul>	<ul> <li>Unable to achieve consolidated financial targets that aimed for the highest level of results (revenue of ¥800 billion and operating income of ¥200 billion) due to the following factors</li> <li>Insufficient capabilities for responding to changes in business environment resulting from the loss of exclusivities for both Aricept® and Pariet®</li> <li>Delays in product creation</li> <li>Main development themes unachieved</li> <li>Halaven® second-line treatment for breast cancer in the U.S.</li> <li>Halaven® for non-small cell lung cancer</li> </ul>



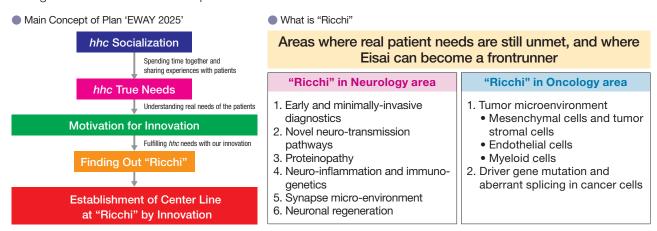
# bhc and "Ricchi": The Core Concepts of Medium-Term Business Plan 'EWAY 2025'

'EWAY 2025' aims to achieve the following three strategic intents:

- 1. Aim to support patients' thought: "I do not want to get sick. I want to know if I get sick, and I want to be cured."
- 2. Aim to support patients' thought: "I want to control my disease in my neighborhood and safely spend the rest of my life with peace of mind."
- 3. Focus on a business domain where Eisai can find out "Ricchi" based on the human health care (hhc) needs and fulfill them with Eisai innovation

The foundation of these strategic intents is the corporate philosophy, human health care (hhc) which reflects the desire to contribute to patients. Since the inauguration of 'EWAY 2025', patient socialization programs have been included into many internal training programs, which has motivated employees to contribute to patients.

In neurology and oncology, the two therapeutic areas of focus in 'EWAY 2025', Eisai finds out "Ricchi", where Eisai can become a frontrunner, and has been focusing efforts there. Establishing a center line at "Ricchi" through innovation is a core concept of 'EWAY 2025'.



# Interim evaluation of 'EWAY 2025'- Toward achievement of fiscal 2020 target in the medium-term business plan for operating profit and ROE ahead of schedule

The current progress of revenue is below the intended target, mainly due to the delay in the growth of key products including Halaven® and Fycompa®. We are aiming for further expansion of revenue, mainly by rapid growth of Lenvima®.

On the other hand, the current progress of operating profit and ROE is over the intended target, mainly due to the positive impact of partnership model (including recognition of one-time payment or milestone payment, sharing of R&D expenses) or selecting and concentrating on priority projects. As for ROE, the fiscal 2020 target in the medium-term business plan was achieved ahead of schedule in fiscal 2018. Regarding operating profit,

the fiscal 2020 target in the mediumterm business plan is planned to be achieved ahead of schedule in fiscal 2019.

	Fiscal 2018 Results	Fiscal 2019 Forecasts	Medium-term Business Plan Fiscal 2020 Targets
Revenue	642.8 billion	680.0 billion	800 billion level
Operating profit	86.2 billion	103.0 billion	102 billion level
ROE	10.4%	11.2%	10% or more

Entered into global strategic oncology collaboration for Lenvima® with Merck & Co., Inc., Kenilworth, N.J., U.S.A. in 2018	The results of revenue in fiscal 2018 were below
<ul> <li>Initiation of Phase II studies for elenbecestat*¹ in 2016</li> <li>Initiation of Phase II study for BAN2401*¹,² in 2018</li> </ul>	the intended target.  Main development theme unachieved  •Alzheimer's disease treatment aducanumab*1

<sup>\*1</sup> Co-development with Biogen Inc. \*2 Licensed-in from BioArctic AB.

# **Human Capital**

# Strategy for Talents Innovation

Aiming to Develop Talents Capable of Continuously Innovating Even in a Rapidly Changing Business Environment

Yosuke Akita
Corporate Officer
Chief Talent Officer (CTO)



# Q: What are the strengths of Eisai's talents?

A: I think that the greatest strength is the deep penetration of our corporate philosophy. I have worked in

hunan health care

the United States and Europe as an expatriate, and when I asked local staff there why they had joined Eisai, many of them expressed their empathy with our *hhc* corporate philosophy. Eisai's corporate philosophy is not a simple subject. All employees around the world are striving to achieve the corporate philosophy in our daily business. I think that our greatest strength is the large pool of employees who are proactively determined to work at Eisai.

**Another strength is globalization.** More than half of the 10,000-plus employees at Eisai work overseas.

Local employees are assigned to senior management positions at most of Eisai's overseas subsidiaries. 6 of our 30 corporate officers are from outside Japan. The Executive Committee Meeting, the highest decision-making body at Eisai, has been conducted in English for nearly twenty years. We are also focusing on the development of leaders who would run the business on a global scale. The programs called "E-GOLD" designed for global leaders and "E-ACE" for next-generation talent are important selective training schemes led by the CEO and CTO, respectively. 15 of the 147 employees who have completed the E-GOLD program currently play active roles as corporate officers.

## Q: What are the challenges Eisai must overcome in its strategy for talents innovation?

**A:** Put simply, our challenge is to develop talents capable of continuously creating innovation even in a rapidly changing business environment. The purpose of the personnel system reform implemented in April 2016 was to achieve this goal.

Eisai's personnel system in Japan in the past had been an ability-based grade system. Salaries were designed to increase as employees'abilities improved every year, and the system assumed the company's steady growth and a relatively unchanging business environment. After the loss of exclusivity for Aricept®, an Alzheimer's disease treatment, and Pariet®, a proton-pump inhibitor, we faced a harsh business environment and these assumptions significantly changed. We therefore implemented a new personnel

system that would encourage drastic changes in the perception and behavior of each of our employees who take leading roles in innovation.

The new personnel system promotes and aims to achieve the development of professionals, achievement of diverse work styles and promotion of maximization of diverse talents as its three focal areas.



## Q: What is your mission in particular to develop professionals?

A: Eisai defines a professional as an individual who is self-reliant and capable of generating expected results and solving challenges and problems. We actively offer various programs to our employees to become professionals regardless of their age or career stage. After launching the new personnel system, the opportunities to develop employees' abilities have significantly improved. We believe that our employees are steadily improving

their abilities using such opportunities.

The system also ensures that employees who have made substantial achievements as professionals are fairly rewarded. As a result of recognizing and evaluating high-performing employees regardless of their age, the ratio of employees in their 30s or younger who are in management positions has been increasing every year.

## Key programs that started after the launch of new personnel system

#### Interview for professional development review (all employees)

All employees make an action plan to fill the gap between their desired future and the present (three year plan), and implement in under the advices and supports of their supervisor.

#### ■EKKYO program (applicants)

The program allows employees to experience operations in other departments in the company (cross-departmental experience). A total of 119 employees participated in the program in three years.

#### ■Mentoring program (applicants)

Executives and employees of other departments provide advice as mentors. A total of 71 employees participated in the program in three years.

#### ■Career development program (all employees aged 30, 40, and 50)

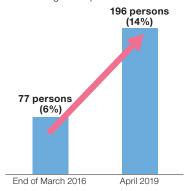
Training to support the autonomous career development of employees is provided at their milestone ages.

# ■Professional milestones (employees aged 45 and 55)

Promotes the activities as professionals by objectively reflecting on their activities in a 360-degree analysis.

An increase in employees in their 30s or younger who are in management positions in Eisai Co., Ltd.

Figures in parentheses are the ratio to all management positions



## Q: What is your mission in particular to achieve diverse work styles?

A: We expanded the options that employees can choose based on their values. We also expanded the range of options for employees having some constraints due to personal reasons such as childcare and caregiving and developed an environment for them to exert their abilities to the fullest.

#### Key systems that started after the launch of new personnel system

#### Mobility selection system

- · A system that allows employees to select the range of their activities based on their life style and/or life events
- · Available options include "global selection", which does not limit the location of work, and "domestic area selection," which limits work location.
- · Employees experiencing life events such as childcare, nursing care or marriage are able to select a limitation of work locations for a certain period of time or request support for living together with their spouses upon getting married.

## Job challenge system

· A system for implementing personnel changes through internal offerings to employees in specific positions or roles

Mobility selection system: status of use			
	fiscal 2016	fiscal 2017	fiscal 2018
Selection of domestic area	35	34	34
Limitation of work locations for a certain period of time	39	33	24
Support for living together upon marriage	0	3	4

Personnel changes through job challenge system				
fiscal 2016	fiscal 2017	fiscal 2018		
3	3	2		

- Change in the system for sick leave to enable employees to take half-day leave for cancer, dialysis or infertility treatment (April 2018)
- Establishment of a system that offers time off for paternity leave, aimed at encouraging male employees to participate in childcare (April 2018) 58 male employees utilized the system in fiscal 2018

# Q: Do you see progress in the promotion of maximization of diverse talents?

A: Eisai believes that diversity is the source of innovation and has been developing a climate that allows employees with a wide range of values to carry out activities regardless of their nationality, gender, age or other characteristics



"It's time to embrace Eisai Diversity"

since the Eisai Diversity Declaration in 2012.

An important issue in promoting diversity is the facilitation of the activities of female employees in Japan. We have been continuously working to offer female employees various programs to support becoming a leader and manager. For instance, introducing E-Win, a selective training program for female employees before promotion to management positions, and a mentoring system, as well as providing career seminars for female employees, including those on childcare leave, to meet role models from both in and outside the company. In addition, we are actively working on the mid-career recruitment of female

managers and manager candidates.

As a result, the **ratio of women in management positions**, which was 3.1% at the end of March 2012, **rose every year to 9.4% in June 2019**, and we are targeting a ratio of 10% by the end of fiscal 2020. Furthermore, Eisai was selected for membership in the MSCI Japan Empowering Women Index (WIN) in June 2018.

We are also providing our employees around the world with opportunities for global work experience. We are growing in line with cross-border talent development and placement of the right people in the right places through the international staffing (global mobility) program within the Eisai Group. Moreover, we are running the Global Challenge Program in our pharmaceutical business division in Japan for employees desiring to work internationally in the future.

Number of participants	fiscal 2016	fiscal 2017	fiscal 2018
in Global Challenge Program	24	28	26

# Q: Why did Eisai implement soliciting voluntary retirement program in 2018?

**A:** Our medium-term business plan 'EWAY 2025' sets out our goal of becoming "a company that changes society through creating medicines and providing solutions." We must acquire leading-edge technologies in each field and implement reforms faster than we have done in the past to build a new business model on a global scale that will change society. The values of working are also changing significantly. We decided to **offer our employees with an option other than to continue working at Eisai.** 

For that reason, we implemented voluntary retirement program with a premium retirement allowance and reemployment support. This program eligible for was employees aged 45 or above who were employees of Eisai as of April 1, 2018 and had been continuously employed for five years or more, with the retirement date of March 31, 2019. There were 300 emploees applied for the program. We are also planning to implement voluntary retirement with retirement dates of March 31, 2020 and March 31, 2021.

## Q: What will Eisai be focusing on in terms of talents development and recruitment?

A: With the hope of contributing to patients through a new business model, we will strengthen talents development to acquire skills of cutting-edge technology in each field, such as artificial intelligence (AI), the Internet of Things (IoT) and big data. We will acquire knowledge and skills in the company through the recruitment of specialist, such as data scientists with extensive experience, and build the foundation of diverse talents responding to change. While we have focused internal talents development in the past and have not actively recruited specialist. We are now actively recruiting specialist and skilled persons.

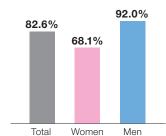
We will also carry out continuous and stable new graduate recruitment in view of a medium- to long-term personnel composition for efficient succession of the talents base from one generation to another. We will further strive to increase our employees' job satisfaction and expand their opportunities for skill development. The job retention rate of employees of newly graduates from college is an important indicator of their satisfaction with the company after joining Eisai. Because the

rate for women tends to be low, we are undertaking developments to improve the work environment. We will continue to strive to raise our employees' job satisfaction and enhance their skill development opportunities.

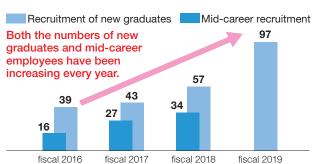


 Retention rates of new graduates after 5 years in Eisai Co., Ltd. (average of last 10 years)

\*See page 96 for retention rates after 3 and 10 years.



Changes in the number of newly hired employees in Eisai Co., Ltd.



# Q: Finally, please describe the progress of work style reforms.

**A:** We introduced a time management system to improve the efficiency of how we work with a greater focus on time and have continuously worked to reduce long working hours. However, one employee in a management position passed away and the demise was certified as a work-related accident in February 2019. We are taking this extremely seriously. We renewed our efforts to eradicate long working hours in March 2019 and have been proactively carrying this out.

As part of our compliance with the Act on the

Arrangement of Related Acts to Promote Work Style Reform, we unified the "36 Agreement" (agreement on overtime and holiday work) at all of our business establishments in April 2019 and established interval substitute holidays and paid leave promotion days.

Our employees' good health is a precondition for the company's sustainable growth, innovation and increased productivity, and the entire company is committed to improving our efforts toward work style reforms.

(Interviewer: Hiroko Shinjo, Public Relations Department)

Business Base (ESG)

# Strengthening efforts to eradicate long working hours (issued March 1, 2019)

Management Strategies

- 1) Reinstitution and company-wide enforcement of compliance with minimum required rules
  - a. Raise awareness of and thoroughly enforce once again the compliance with the "36 Agreement" \*1 as the most important requirement.
  - b. The health management time\*2 is, in principle, up to 80 hours in a single month. If it unavoidably exceeds 80 hours in a month, the advance approval of the corporate officer in charge must be obtained, and the upper limit of health management time (a prohibition of 100 hours or more per month or exceeding 80 hours in two consecutive months) must be established.
  - c. Set appropriate reporting and knowledge of working hours, holidays (taken at least four days per month), and leave (paid leave of at least five days per year) as requirements, and all employees must comply with them.
- 2) Goal setting and personnel appraisal

minimum required rules.

- a. Include the promotion of time management in the goals of all employees and corporate officers in
  - As a quantitative target, set the requirements of all employees as the minimum requirement and set the target above such requirements.
- b. Apply the target of each employee set for the promotion of time management and their level of achievement to their performance evaluation. Evaluate negatively the behavior of any employee in a management position who has violated the
- \*1 Agreement on overtime and holiday works stipulated in Article 36 of the Labor Standard Act. This agreement is applied for general employees.
- \*2 "Health management time" is introduced from the viewpoint of appropriate implementation of measures to ensure health for employees such as managers who are not subject to the regulations stipulated in the Labor Standards Act.

# Efforts to comply with the Act on the Arrangement of Related Acts to Promote Work Style Reform

1) Revise the 36 Agreement to set the number of hours below the maximum time specified by law and unify it across all business establishments.

		Monthly limit	Yearly limit	Special provisions (when resigning the agreement)		
		(hours)	(hours)	Monthly upper limit (hours)	Yearly upper limit (hours)	Limit on the number of times
	Law	45	360	<ul><li>Avg. of multiple months:</li><li>80 or below</li><li>Less than 100/month</li></ul>	720	6
Ī	Eisai	40	360	80	600	6

2) Establishment of interval substitute holidays

To secure adequate living and sleeping hours, establish a system to provide an interval substitute holiday on the following day if office work extends to 23:00 or later.

# Improvement of pension management

To support the stable living of employees after retirement, our pension plan is managed by the Eisai Corporate Pension Fund, which is independent of our company, in an organization consisting of the representatives of the company and labor union while monitoring the asset balance for the pursuit of stable assets and profits. The fund announced the acceptance of the Japanese version of the Stewardship Code\* in February 2018 and launched ESG investment.

\* Principles of behavior required of institutional investors to fulfill their responsibility as an asset management trustee.

## Health promotion activities to protect employees' health

In view of protecting the health of our employees, Eisai and the Eisai Health Insurance Society have established the Collaborative Health Project and support employees' health in cooperation with occupational health physicians, medical staff and other relevant parties. In February 2018, the Ministry of Economy, Trade and Industry selected Eisai as an outstanding Health and Productivity Management Organization in the large enterprise category (White 500) for the second consecutive year. In June 2019, we issued the Eisai Health Declaration and are aiming to achieve no smoking at all offices by October 2020 as one of our key strategies.





Certified as a childcare supporting company by the Tokyo Labor Bureau of the Ministry of Health, Labour and Welfare

# Interview: Progress in Integrating ESG with Corporate Value



Ryohei Yanagi (Left)

Chief Financial Officer, Chief IR Officer

## Kathy Matsui (Right)

Vice Chair of Goldman Sachs Japan Co-head of Macro Research in Asia Chief Japan Equity Strategist

### Kathy Matsui's Biography

Kathy earned an AB, magna cum laude, in Social Studies from Harvard University and an MA from Johns Hopkins University, School of Advanced International Studies. In 1999, Kathy coined the term "Womenomics" and argued widely that diversity is essential for economic growth and innovation. She is a member of several Japanese government-related working groups looking at ways to bring about changes that will unlock the potential of women in Japan.

#### **Growing awareness of ROE**

Matsui I feel that Japanese managements' awareness of ROE has changed radically over the nearly 30 years I have been observing the markets, especially since around 2013-2014. I believe this is because, with the introduction of the Stewardship Code, followed by the Corporate Governance Code, the raison d'etre of public companies is being questioned. Previously, there were major differences between companies in terms of their understanding and ways of thinking about ROE. But now, average ROE has been lifted to a much higher level. I get the impression that since the Ito Review was issued, the issue of why companies should focus on ROE has become a topic of everyday conversation.

In Japan, deflation has continued for over 20 years since the bursting of the country's economic bubble. As "cash is king" was viewed as being axiomatic, few believed that profits should be returned to shareholders via dividend payments and share buybacks. However, I think that due to Japan subsequently moving from deflation to inflation, many are asking why companies hold large amounts of cash and cross-shareholdings.

Yanagi Since managements of listed companies are responsible for boosting corporate value, awareness of ROE and cost of equity is vital. As you say, the Stewardship Code, the Corporate Governance Code, and the Ito Review had an educational effect, boosting corporate awareness, and ROE has improved to around 9%-10% on average, from 4%-5%.

In the investor surveys I conduct every year, I ask whether investors are satisfied with Japanese companies' governance. In the 2019 survey, 21% said they were. This is a major improvement, since only 10% said they were in the 2012 survey, before Abenomics. However, most investors are still not satisfied. Some Japanese companies might now have two outside directors, but this is still far from levels in Europe and the US, where majority of the board is outside directors, and it looks as though investors think that management teams' financial knowledge is insufficient.

It is the same with ROE levels. There has been a big improvement, with 17% saying they were satisfied in the 2019 survey, versus 5% in 2012. However, most

are still not satisfied, probably due to concerns that the improvement is only temporary or that there is insufficient awareness of cost of equity. Companies are still not sufficiently aiming to enhance corporate value on their own initiative rather than because government says they should. In the case of ROE as well, Japanese companies are lagging behind the 15% average at European and US firms, and, as with governance, I think that improvement is only halfway there.

Management Strategies

Most investors say the cost of shareholders equity should be around 8%, and the average is around that level. The idea that if you invest in Japanese stocks, ROE at the target companies should be at least 8% has reigned for 10 years. This result was adopted in the Ito Review, leading to the creation of the so-called "8% rule" and, I think, to a general lifting of ROE at Japanese companies.

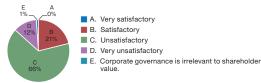
As a pharmaceutical company which develops new drugs at a 10-year span, we view 10-year average ROE as a KPI. We tell investors worldwide that our policy is to secure an equity spread of 2% and achieve a 10-year average ROE of at least 8%, 10% if possible, and avoid short-termism—i.e., striving to boost ROE in the near-term by excessively reducing R&D and personnel expenses and using leverage.

In practice, ROE has fallen below 8% at times. However, our ROE was 10.4% in FY2018 and the FY2019 forecast is 11.2%. We have maintained a high level of R&D investment, even on a global comparison,

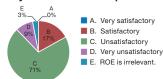
#### Global investor survey 2019

Survey period: February 25-May 29, 2019 Survey targets: 181 major institutional investors globally (100 domestic, 81 overseas)

# Are you satisfied with Japan's corporate governance



### Are you satisfied with Japan's ROE in general?



equivalent to around a quarter of revenue, and we have not cut back investment to secure near-term profits even when times were tough. As a result, we have been able to launch new anti-cancer agent Lenvima®, which we expect to achieve FY2019 revenue of over ¥100 billion, and I think we will be able to maintain stable ROE of over 10% from now on. This is the reason why I think we need to let global investors know that we focus on long-term value creation and will not fall into short-termism.

### On the importance of non-financial information disclosures, including ESG

Matsui The ESG (Environmental, Social and Governance) concept appears to have taken on considerable importance in financial markets of late. Third-party surveys point to dramatic expansion of global assets under management in products that incorporate ESG. Japan in particular has seen ESG assets under management rise from just under ¥27 trillion in 2015 to around ¥232 trillion in 2018, so the ESG debate is not something that can be ignored. Against this backdrop, companies are having to change the way they think about ESG and how they disclose data to shareholders if they are to attract capital from global investors.

From an analyst's perspective, however, companies' ESG disclosures have tended to be insufficient. For example, for many years, I have been involved with diversity, which comes under the Social and Governance components of ESG, and in Japan, even large companies did not disclose basic data such as the gender breakdown of employees or managers until 2016, and there was no mandatory requirement to do so. Even if the ESG concept existed, in most cases there was no data. Disclosure has improved, but we believe companies still do not disclose enough nonfinancial information.

Another concern is that some companies focus too much on their mandatory disclosure obligations for this kind of data, resulting in the content becoming very formulaic. We see differences among companies'



behavior depending on whether their disclosures are based on a real understanding of the value of ESG, or whether they are just going through the motions to meet regulatory requirements.

Yanagi While ROE is essential in terms of financial information, non-financial information is taking on increasing importance amid the rising tide of interest in ESG. Kathy, you have long been an advocate of the creation of value through governance, but also value-creation through diversity in your pioneering work on "Womenomics".

If you ask global investors what they think of ESG at Japanese companies, many will say that in Japan ESG has become ESG for its own sake, and that there is no explanation of its relevance to the value creation as required by investors. What investors require is an explanation of value relevance that combines ROE and ESG, as encapsulated in "ROESG," a concept advocated by Professor Kunio Ito of Hitotsubashi University. As you say, however, company disclosures do not go beyond the superficial, and I also have concerns that value relevance is not being explained.

Every year we ask investors whether ESG should be reflected in corporate value. In this year's survey, 78% of investors said ESG value should be reflected to a large extent, to the portion of PBR above 1X, and of those respondents, 24% said it should be factored in 100%. As such, we see a strong possibility that Japanese companies' PBRs, which tend to be low by global standards, at around 1X, could increase if they are recognized by global investors through enhancing disclosure of ESG value and engaging proactively with investors on ESG topics on an ongoing basis.

Against this backdrop, we have been pursuing ESG-focused IR. In recent years, we believe investors have been recognizing our non-financial value in ESG and other areas, including our drug discovery pipeline, human capital, and our social contribution. As you said, Kathy, we believe deepening dialog with investors through information disclosure and engagement is key

Global investor survey 2019

Period: Feb 25th-May 29th, 2019

Target:181 global major institutional investors (Japan 100, Overseas 81)

# How about the long-term relationship between ESG (non-financials) value and valuation?



- A. The value of ESG should be 100% factored into PBR (part of above 1) via reduction of capital cost or increasing, stabilizing financial performance in future.
- B. The value of ESG should be mostly factored into PBR via reduction of capital cost or increasing, stabilizing financial performance in future.
- C. Some value of ESG should be factored into PBR.
- D. The value of ESG is nothing to do with valuation.
- E. Not interested in the relationship between ESG and valuation at all / Not important at all.

to converting ESG into corporate value.

As CFO, I proposed a synchronized model regarding financial capital and non-financial capital value relevance based on Eisai's corporate philosophy (human health care, or hhc), prior to the announcement of the International Integrated Reporting Council (IIRC) framework in consideration of longer-term capital efficiency (ROE and equity spread) and sustainability (importance of non-financial capital).

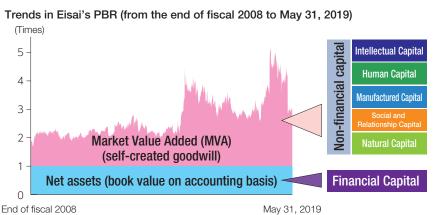
Technically, shareholders' equity is the sum of the book value of shareholders' equity (BV) and market value added (MVA) that exceeds BV. The portion that exceeds PBR of 1X is related to ESG value, or "non-financial capital."

First, under the ① Intrinsic Value Model, MVA is defined as ESG/CSR value (cost of capital reduction effects), customer value, human value, and organizational value.

In contrast to this, the ② IIRC-PBR Model explains the relevance of six capitals under the IIRC framework, by positioning Book Value of Shareholders' Equity (BV) as financial capital, and relating MVA to nonfinancial capital consisting of intellectual capital, human capital, manufactured capital, social and relationship capital and natural capital, based on the assumption that shareholder value equals long-term total market capitalization and also equals BV plus MVA.

From the 3 Residual Income Model (RIM), it is

•IIRC-PBR Model (Value relevance of the six capitals that compose corporate value)
—Net assets (book value on accounting basis) is related to financial capital and Market Value Added (MVA) is related to non-financial capital—



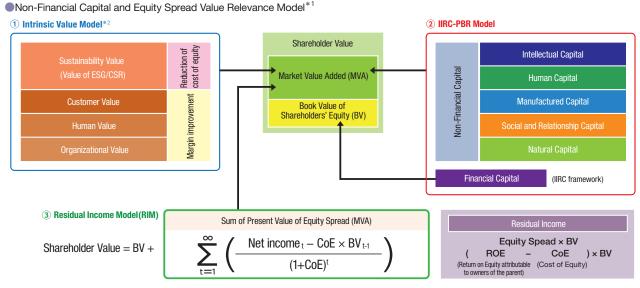
thought that MVA converges in the sum of present value of equity spread. Therefore, it can be considered that future financial value creation based on equity spread over the long term does not conflict with non-financial capital value such as ESG and MVA creation and is not mutually contradictory and can be synchronized.

Management Strategies

In conjunction with the Non-Financial Capital and Equity Spread Value Relevance Model, the Intrinsic Value Model which relates non-financial capital to MVA, the IIRC-PBR Model and the Residual Income Model (RIM) which implicates the relation between MVA and equity spread, are mutually complementary through the creation of MVA. This is the ROESG model.

In the Residual Income Model, it is proven

mathematically that the present value of residual income is a function of ROE. This suggests that the portion corresponding to PBR above 1X is the ESG value-added recognized by investors, and that this should move into line with the relative strength of ROE over the ultra-long term. However, short-termism destroys this balance. For example, an attempt to double EPS and dividends in a single fiscal year by excessively reducing near-term R&D and personnel expenses would undermine long-term sustainability. For that reason, we use an ROESG approach that aims to increase ROE in the long term via investment in R&D, and in people, with a long-term perspectives.



- \*1 Source based on the following reference: "ROE Revolution and Financial Strategies" CHUOKEIZAI-SHA (2017)
- \*2 "Financial Strategies for Maximizing Corporate Value" Doyukan (2009)

Let me introduce one of our initiatives as an example. Improving access to medicines (ATM) is one of our key focuses in the Social component of ESG. In particular, we are implementing measures to combat lymphatic filariasis (LF). LF is a disease transmitted via mosquitoes that causes swelling of the patient's lower limbs until they resemble those of an elephant. This leads to difficulties in working and significant economic damage. Around 860 million people are at risk globally, but market demand for treatments has not emerged since many of these people belong to the poorest income classes. As a result, drugs for LF treatment have not provided by pharmaceutical companies. In view of our corporate philosophy of contributing to patients, we felt that this should not be overlooked, and we therefore teamed up with the WHO on a project to provide 2.2 billion DEC (diethylcarbamazine) tablets free of charge by 2020. We have already provided 1.8 billion tablets, and will continue to provide until LF is completely eliminated. We have received some criticism that this damages shareholder value, but we view the project as a long-term investment.

We are the only Japanese pharmaceutical company that has a plant in India, where production costs are low. The mass production of 2.2 billion tablets raises capacity utilization at the plant and improves the skills and motivation of plant employees. As a result, the employee turnover rate at our Vizag plant has declined to 5%, versus the average rate of 15% at other companies' plants in India. Taking into account also the enhancement of our brand value in emerging countries, we anticipate a positive contribution to net present value (NPV) in the very long term. Having explained the background of the program, which both contributes to patients and enhances corporate value in terms of long-term ROE, we have received support from longterm investors such as overseas pension funds, and in recent years, it appears that the percentage of Eisai shares held by ESG investors has been increasing. Matsui That is a good example.

### Efforts in new drug development and corporate value creation

Matsui What is the current situation in new drug development?

Yanagi As we are smaller in size compared to global mega-pharma companies, we are focusing resources on neurology area and oncology area in order to meet unmet medical needs. New drug development



is a high-risk business that involves spending large amounts of resources over many years. We therefore also use the partnership model. Our consolidated R&D budget in FY2018 was ¥144.8 billion, but adding the ¥46.4 billion from of share of expenses borne by our partners, a huge amount of ¥191.3 billion was invested in order to accelerate development of new drugs. I think this is in line with strengthening the means of implementation and revitalizing the global partnership for sustainable development as called for in the United Nations' Sustainable Development Goals (SDGs).

In addition, Eisai's corporate philosophy stipulates increase of patient satisfaction our mission, committing us to pursuing economic profit and linking this to creating shareholder value after the fact over a long time scale. Also, I think one of Eisai's fundamental characteristics is that as a result of a resolution at the general shareholders meeting in 2005, this philosophy was incorporated into our articles of incorporation and shared with investors. The corporate philosophy in the articles of incorporation itself balances ROE and ESG.

#### Strategic shareholdings

Matsui I feel that the revolution in Japanese corporate governance resembles that which Germany faced in the second half of the 1990s. At that time in Germany, there were solid cross-shareholdings between industry and financial institutions. The German government, ahead of EU unification, told industry that it, "should unwind cross-shareholdings, because it reduces capital efficiency." Most companies would not unwind cross-shareholdings on their own initiative. Progress was made in unwinding cross-shareholdings due partly to tax incentives such as not levying capital gains taxes from the sale of equities, but share prices declined in some cases. Accordingly, share price awareness increased for the first time, causing managements to focus on ROE and shareholder returns, and companies adopted strategies that boosted ROE, including M&A and restructuring. I feel that German and Japanese corporate culture have always had a great deal in common. I therefore expect Japanese corporate governance reforms, which are only halfway there, to also make substantial progress, as Germany's example

Yanagi You have long said that there are things we should learn from Germany, haven't you?

Matsui I have been saying we should reference Germany's restructuring since before Abenomics.

What Germany and Japan have in common is that they had no other way of boosting their competitiveness.

Yanagi Even if stock supply and demand deteriorates

temporarily, the corporate value of companies that make progress in unwinding cross-shareholdings rises in the long term, doesn't it?

Matsui Yes, it does. The event study section of our GS SUSTAIN report, which takes ESG and other topics as themes for analysis, has confirmed that companies whose shares are sold tend to outperform the market after unwinding. Moreover, for the sellers, if the amount of shares sold represents at least 3% of its market capitalization, they were rewarded with outperformance averaging 6.3%.\* This is not easy given long-term relationships, but it would be helpful if these empirical results were used to encourage the further unwinding of cross-shareholdings. The stock market has recently become more focused on the unwinding of crossshareholdings, and if further progress is made, this could lead to long-term value creation. Greater competition in the operating environment and having to make more efficient use of limited resources are challenges shared by both Germany and Japan.

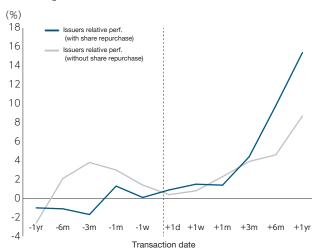
What is the situation with regard to cross-shareholdings at Eisai?

\* Japan Governance Radar: Unwinding of cross-holdings—An event study: Market welcomes improvement in corporate governance," Goldman Sachs, September 13, 2018

Yanagi As CFO, I am leading efforts to unwind crossshareholdings. Due to reductions in recent years, we only cross-held stocks with 25 listed companies as of end-March 2019. My responsibility is to calculate the Repurchasing shares as part of unwinding has bolstered share price performance

Management Strategies

Average TOPIX-relative share price performance before and after the unwindina



We analyzed cases of unwinding of listed shares by corporates based on disclosu in reports of changes in shareholdings (since June 2015). We calculated TOPIXrelative performance indexed to the closing price one day prior to the date on which the transactions are closed

Source: Company data, Bloomberg, Quick Astra Manager

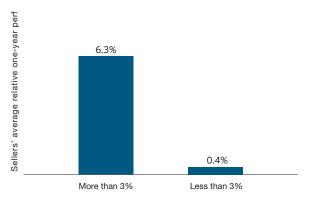
NPV (Net Present Value) for each of the stocks we hold, and ultimately negotiate with issuers with the aim of having zero holdings. The German example is very encouraging and informative.

Eisai is also placing importance on human capital in order to sustainably enhance corporate value in adhering the Corporate Governance Code. That led Eisai's corporate pension fund to adopt the Stewardship Code in 2018 so as to maximize corporate pension returns, which support employees when they have retired. This fund is going to sign the Principles of Responsible Investment (PRI) in FY2019, and plans to strictly exercise voting rights as it pursues ESG based on global standards.

Eisai and Eisai's corporate pension fund are adhering to the Corporate Governance Code and the Stewardship Code, respectively, while we aim to create a virtuous investment chain, albeit on a small

Large strategic share unwinds can lead to outperformance for the seller Sellers' average relative one-year performance by the size of the impact to the

Business Base (ESG)



The size of the impact = the amount of the unwinding/ seller's market cap.

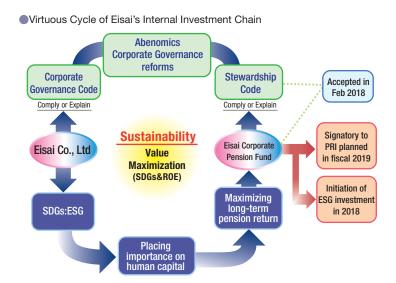
Source: Company data, Bloomberg, Nikkei Astra Manager

scale. To this end, it is necessary on the corporate side to promote the unwinding of cross-shareholdings while avoiding conflicts of interest. I hope that this sort of action eventually becomes commonplace across Japan and improves the whole value.

Matsui Japanese companies overall have been slow to unwind cross-shareholdings.

Yanagi I believe fewer than 10 pension funds at companies in Japan have adopted the Stewardship Code. I strongly hope that the adoption of the Stewardship Code and entry into ESG investing by corporate pension funds will give impetus to ESG investing in the Japanese market and translate into enhanced governance across the board and corporate value.

Thank you for your time today. Matsui Thank you.



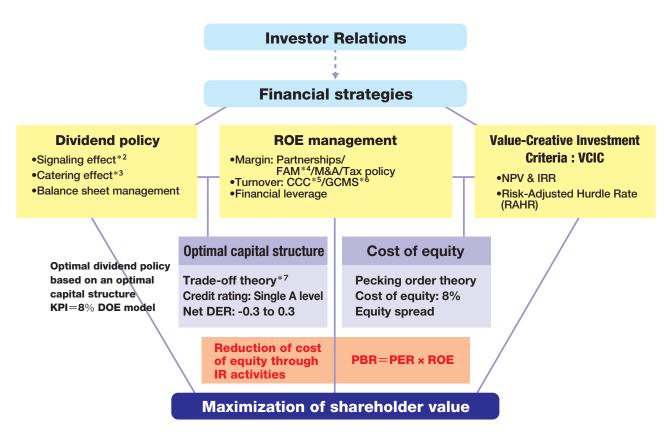
# **Financial Capital**

# **Financial Strategy**

Aiming to continuously maximize shareholder value based on "Medium-to Long-Term ROE Management", "Sustainable and Stable Shareholder Returns" and "Value-Creative Investment Criteria for Growth"

# Financial strategy map\*1 for sustainable maximization of shareholder value

Eisai has set out a financial strategy map as its CFO policy to continuously maximize shareholder value. This strategy consists of three key themes: "ROE management", "Dividend policy" and "Value-Creative Investment Criteria (VCIC)."



- \*1 Source based on the following reference: "Financial and Accounting Literacy to Enhance Corporate Value" (2016) Nikkei Publishing Inc.
- \*2 Signaling effect: Potential impact on stock price by showing management's belief in the achievement of revenue forecast through dividend policy
- \*3 Catering effect: Potential impact on stock price by meeting the expectation of shareholders' preference for dividend
- \*4 FAM: Fixed Asset Monetization
- \*5 CCC: Cash Conversion Cycle
- \*6 GCMS: Global Cash Management System
- \*7 Trade-off theory: Idea to pursue optimal capital structure for debt finance and equity finance to use for balancing the costs and benefits

# ROE management -targets a positive equity spread over the medium- to long-term

Eisai has been working to improve its medium- to long-term ROE since the beginning of the 2000s. **Eisai aims to avoid short-termism and achieve ROE above cost of equity over the medium- to long-term (e.g., 10-year average).** In other words, Eisai aims to create a "positive equity spread (ROE – Cost of shareholders' equity)." Cost of shareholders' equity is the return demanded by shareholders and Eisai has conservatively assumed a cost of shareholders' equity of 8%. Eisai is generating a historical 10-year average ROE of 10.2% and a positive equity spread of 2.2%.

#### Trends in ROE by fiscal year and medium- to long-term value creation



#### Equity spread: ROE - Cost of equity (CoE)

The key indicator of shareholder value creation based on residual income model\*

Eisai conservatively assumes cost of equity of 8% (risk-free rate of 2% + risk premium of 6%)

 $\boldsymbol{\ast}$  "ROE Revolution and Financial Strategies" CHUOKEIZAI-SHA (2015)

#### Historical 10-year equity spread

Historical 10-year average ROE: 10.2% – CoE 8% = 2.2%

\*Results up to fiscal 2012 were calculated pursuant to generally accepted accounting principles in Japan (J-GAAP), while results from fiscal 2013 to 2018 were calculated pursuant to International Financial Reporting Standards (IFRS).



\*1 "Profit for the year attributable to owners of the parent"/"Revenue" \*2 "Revenue"/"Total assets" \*3 "Total assets"/"Equity attributable to owners of the parent"

Under the DuPont method, ROE can be analyzed by three elements consisting of margin (ratio of profit to revenue), turnover (total assets turnover ratio) and financial leverage. Eisai is focusing on optimizing each of these three elements.

## **Increase margins**

Eisai has focused on expanding high-profit global brands discovered and developed in-house, such as Lenvima®, Halaven® and Fycompa®. Eisai is aiming to improve margin by effective operation through utilizing partnerships and emphasizing selection and concentration for priority projects.

## Improve turnover

Eisai has managed the cash conversion cycle (CCC) to control working capital and strived to improve asset efficiency through steps including selling assets encompassing investment securities and streamlining inventory. The Corporate Governance Code, which was revised in June 2018, calls for the validation of benefits and risks of strategically held shares. Before the revision of the Code, Eisai has sold strategically held shares in 7 stocks (selling all of its shares).

#### Use financial leverage

Eisai has pursued an optimal capital structure while maintaining financial integrity. For maintaining a single A level credit rating, we have set the KPls of **Net DER**\*1 **of -0.3 to 0.3, a ratio of equity attributable to owners of the parent of 50%-60% and Net Debt/EBITDA\*2 of 0 to 3 years.** By undertaking business activities based on financial discipline, we are steadily reducing interest-bearing debt, and we secured net cash position as of the end of fiscal 2018. Net DER was negative 0.32, the ratio of equity attributable to owners of the parent was 58.6% and Net Debt/EBITDA was negative 1.70 years. Based on the view that we have secured sufficient financial integrity, we believe we can resume our leverage strategies.

<sup>\*1</sup> Net debt equity ratio (Net DER) = (Interest-bearing debt (bonds and borrowings) - Cash and cash equivalents - Time deposits exceeding three months - Investment securities held by the parent company) / Equity attributable to owners of the parent

<sup>\*2</sup> EBITDA: Earnings Before Interest, Taxes, Depreciation and Amotization

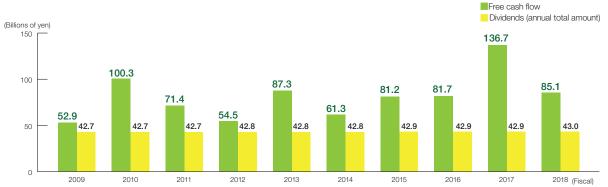
# Dividend policy

Eisai returns profits to all shareholders in a stable and sustainable manner based on factors such as a healthy balance sheet and comprehensive consideration of consolidated financial results, dividend on equity (DOE, ratio of equity attributable to owners of the parent) and free cash flow, as well as consideration of the signaling effect. We strive for an "optimal dividend policy based on an optimal capital structure" that depends on long-term balance sheet management, rather than a dividend payout ratio based on short-term performance. As a KPI for dividends, from the perspective of balance sheet management, Eisai has adopted DOE, which indicates the ratio of dividends to consolidated net assets.

In principle, Eisai strives to maintain dividends within the range of free cash flow over multiple years. Eisai is maintaining a healthy balance sheet under present conditions. Therefore, Eisai plans to **increase dividends** to 160 yen (previous forecast was 150 yen)\* for the first time in 10 years, with an intention to maximize shareholder value. Acquisition of treasury stock will be carried out appropriately after factors such as the market environment and capital efficiency (ROE) are taken into account.

\* Dividents per share subject to approval of Board of Directors

#### • Trends in free cash flow and dividends —Dividends within the range of free cash flow over multiple years—



- \*Results up to end of fiscal 2012 were calculated pursuant to J-GAAP, while results from end of fiscal 2013 and onward were calculated pursuant to IFRS.
- \*Free cash flow ="Net cash from operating activities"-"Capital expenditures (cash basis)
- # Expenditures from purchases of financial assets and proceeds from sale and redemption of financial assets are included in the formula used to calculate capital expenditures.

#### Strong Balance Sheet —Dividend sustainability by maintaining optimal capital structure—



Equity attributable to owners of the parent Net interest-bearing debt\*1 =Ratio of equity attributable to owners of the parent =Net debt equity ratio (Net DER)\*:

- \*Results up to end of fiscal 2012 were calculated pursuant to J-GAAP, while results from end of fiscal 2013 and onward were calculated pursuant to IFRS.

  \*1 Net interest-bearing debt = Interest-bearing debt (bonds and borrowings) Cash and cash equivalents Time deposits exceeding three months, etc. Investment securities held by the parent company\*3
- \*2 Net debt equity ratio (Net DER) = (Interest-bearing debt (bonds and borrowings) Cash and cash equivalents Time deposits exceeding three months, etc.
- Investment securities held by the parent company\*3) / Equity attributable to owners of the parent \*3 Investment securities held by the parent company are included in the formula under IFRS.

#### Eisai's funding policy

Eisai's funding policy is based on the pecking order theory. Eisai prioritizes "cash on hand" over "debt". "Equity financing", which could damage existing shareholder value, is the last option.

As an efficient funding measure, Eisai adopts a Global Cash Management System (GCMS) for the effective cash utilization among group companies.

# VCIC (Value-Creative Investment Criteria)

Management Strategies

Prioritization and selection of investments will become even more important for companies to achieve growth. Therefore, Eisai has determined Value-Creative Investment Criteria (VCIC) for its strategic investments to ensure value creation. When making investments, we use Net Present Value (NPV) and the Internal Rate of Return (IRR) spread using a risk-adjusted hurdle rate as KPIs. In principle, we naturally select only those investments with a positive NPV and set a certain spread for IRR to assure value creation. In setting hurdle rates, we factor in all risk elements, such as the particular investment project, the investee country and liquidity. We have approximately 200 types of hurdle rates and apply the risk-adjusted hurdle rate appropriate for each respective investment project.

The Corporate Governance Code, which was revised in June 2018, calls for the allocation of management resources in consideration of cost of shareholders' equity. Eisai has introduced VCIC in 2013 to ensure corporate value creation.

# Formula of risk-adjusted hurdle rate

Risk-adjusted hurdle rate = Risk free rate +  $\beta$  × Risk premium (+ liquidity premium)

- Risk free rate: 10 year average yield of 10 year government bond
- β: Defined by investment categories (risk profile)

# KPI for finance under medium-term business plan 'EWAY 2025'

Under the medium-term business plan 'EWAY 2025', we aim to attain ROE at the 10% or more and an equity spread at the 2% or more for fiscal 2020, as the midpoint of the plan. For fiscal 2025, the final year of the plan, Eisai is mindful of attaining ROE at the 15% level on the back of dramatic growth spurred by contributions of flagship drugs in the neurology area and oncology area.

With DOE as a KPI, we will pursue an optimal dividend policy based on an optimal capital structure and work to maximize shareholder value.

KPIs	FY2020 Targets
ROE	10% or more
Equity spread*1	2% or more
DOE*2	8% level
Ratio of equity attributable to owners of the parent	50-60%
Net DER*3	-0.3 to 0.3

Business Base (ESG)

# 15% level ROE in FY2025

- \* Dividends per share subject to approval of Board of Directors.
- \*1 Equity spread = ROE Cost of equity. Eisai conservatively assumes cost of equity of 8%
- \*2 DOE = Dividend on equity attributable to owners of the parent
- \*3 Net DER: Net Debt Equity Ratio = (Interest-bearing debts (bonds and borrowings) Cash and cash equivalents Time deposits exceeding 3 months, etc. Investment securities held by the parent company)/Equity attributable to owners of the parent

# Aim to create medium- to long-term corporate value

We believe that promoting an understanding of our non-financial information is essential for realizing the objectives of our engagement, which is to have our corporate value assessed from the perspective of medium- to long-term corporate value creation. This non-financial information covers areas such as intellectual capital centering on our pipeline and patents; human capital that handles our operations; our initiatives for improving access to medicines; and our corporate governance. To attain this objective, Eisai's IR team holds a total of approximately 800 dialogues with investors and analysts on an annual basis. Among these,

the CFO holds approximately 200 dialogues every year, including with overseas investors. The CFO and IR team strive to reduce cost of equity and are committed to promoting engagement based on the idea of "IR is not a cost center and contributes to corporate value creation."

Our activities for years were recognized and we

received the "IR Grand Prix Award" at the IR Prime Business Award 2018 held by the Japan **Investor Relations** Association (JIRA).



# Improving Access to Medicines (ATM)

"We want to deliver as many necessary medicines as possible and nurture hope in as many people as possible." Putting this wish into mind, Eisai is engaged in activities for improving ATM in developing and emerging countries.

Number of countries supplied with lymphatic filariasis treatment DEC tablets and volume supplied (as of June 2019)

28 countries 1.8 billion tablets









# Investing in the Future of Developing and Emerging Countries

Eisai is engaged in activities for improving ATM with the aim of ensuring that people in developing and emerging countries receive the medicines they need. ATM is a basic need for all people regardless of nationality, economic disparities or social standing. Today, approximately 2 billion people around the world do not have adequate access to medicines\*, most of whom are the poor in developing and emerging countries who also lack proper information about

# Efforts to Help Eliminate Lymphatic Filariasis: Supplying DEC Tablets and Implementing Awareness-Raising Activities

Lymphatic filariasis (LF) is a neglected tropical disease (NTD) transmitted to humans via carrier mosquitoes. It is estimated that approximately 860 million people worldwide, mainly those in developing countries, are exposed to the risk of LF.

The World Health Organization (WHO) conducts mass drug administrations (MDAs) in endemic areas

health and diseases.

Eisai believes that improving ATM in developing and emerging countries is a long-term investment that will support the health of the people living in these countries and ultimately lead to the future growth of these nations as a whole. Eisai utilizes many methods including supply of products at affordable prices as well as public-private partnerships, as it continues to implement various ATM initiatives through its unique business models.

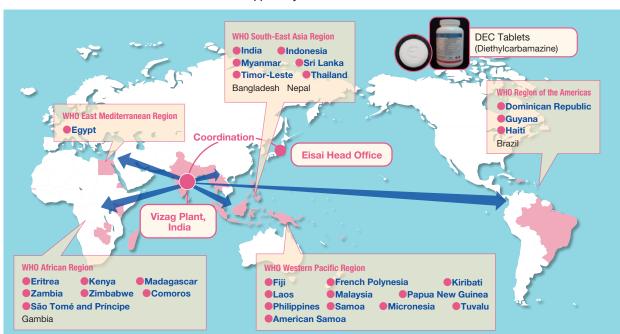
- \* Source: Access to Medicine Index
- https://accesstomedicinefoundation.org/

in order to eliminate LF. Eisai is committed to supplying diethylcarbamazine (DEC) tablets, one of the three types of LF medicines used in the MDAs, to LF endemic countries that need DEC until LF is eliminated in these countries.

In 2013, Eisai obtained WHO prequalification for DEC tablets and commenced production at its Vizag Plant in India. Since then, **Eisai has provided 1.8 billion DEC tablets to 28 endemic countries** through WHO's elimination program (as of June 2019).

Countries where DEC tablets are scheduled to be supplied by 2020

Countries where distribution has commenced



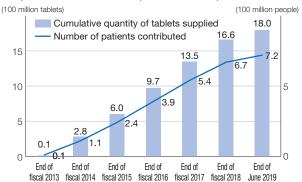
(Distribution status as of June 2019)

Furthermore, to support the smooth implementation of WHO's MDA programs, Eisai is engaging in initiatives to raise public awareness of LF in endemic areas. In order to eliminate LF as early as possible, staff members of Eisai's local subsidiaries cooperate with the relevant representatives in endemic countries, prepare and distribute leaflets in the local languages on the prevention and treatment of LF and support implementation of MDA in endemic countries. For example, since 2015, during MDA programs by Ministry of Public Health and NGOs for LF elimination in Indonesia, Eisai staff members have socialized with LF patients, held workshops, and raised awareness about LF in collaboration with students from Faculty of Medicine as well as Master's Program of Public Health in Gadiah Mada University.

Management Strategies

Eisai's activities are highly appreciated by endemic countries. Token of Remembrance from Antimalaria Unit of Ministry of Health, Government of Andhra Pradesh in India is just one such example.

#### Cumulative quantity of DEC tablets supplied and the number of patients contributed to \* (as of June 2019)



\* The number of patients contributed to is an estimated value, which is converted from the cumulative quantity of tablets supplied based on the assumption that an average of 2.5 tablets is taken per capita in accordance with the definition of WHO.

#### **R&D** Initiatives for Improving Global Health

Eisai proactively undertakes research on pharmaceuticals for treating NTDs and for the three major infectious diseases (malaria, tuberculosis, HIV/ AIDS).

These diseases strike people with low incomes in developing countries, causing them to leave work. This in turn leads to a negative cycle of poverty in which people become incapacitated due to disease and become even poorer, and international efforts are called upon to tackle this significant global health issue. In response, Eisai is currently conducting various projects aimed at developing new treatments for Chagas disease, filariasis, leishmaniasis and mycetoma as well as malaria and tuberculosis. Undertaking research activities for these diseases requires specific expertise, technologies and clinical study experience in addition to networks with clinical facilities in endemic regions. For these reasons, Eisai is actively engaged in external collaborations such as partnerships with global research organizations and is participating in international consortiums to share compound libraries, as Eisai seeks to develop new drugs for NTDs and the three major infectious

# **Received Token of Remembrance from Ministry** of Health, Government of Andhra Pradesh for **Supporting Activities to Eliminate LF**

Business Base (ESG)

In Yarada Village near Eisai's Vizag Plant (located in Andhra Pradesh) which has been manufacturing DEC tablets since 2013, there were patients suffering from LF when Eisai started to manufacture DEC tablets. Eisai supported the larvicidal activities with regular spraying of pesticides in drains without lid as well as in puddle, and repaired the old public toilets to improve hygiene environment in cooperation with Ministry of Health, Government of Andhra Pradesh which supports the elimination activity of vector-borne disease in Yarada Village. Furthermore, Eisai has focused on disease awareness activities by providing explanation about prevention of vector-borne disease to local residents, and has supported the MDA program for LF elimination. The state government evaluated these activities, and Eisai received a token of remembrance in 2015. These activities in Yarada Village still continues, with expansion of



Village in recent years. In Kasimkota Village, as a new activity, Eisai is aiming to improve the quality of life (QOL) of patients by providing custom-made shoes to LF patients who cannot wear normal shoes because of the swelling of feet or have trouble walking due to LF.

the activities in Kasimkota

diseases.

Eisai aims to develop new drugs for Chagas disease, a disease transmitted by the assassin bug which is prevalent in 21 countries in Latin America. For this purpose, Eisai conducted a Phase II study of its in-house developed antifungal agent fosravuconazole (E1224) in partnership with the Drugs for Neglected Diseases initiative (DNDi). This Phase I study is completed and future plans are under review. In Sudan, another Phase II study of the agent is being conducted with DNDi for fungal mycetoma, a highly neglected disease for which there is no effective treatment. Mycetoma is transmitted through pricks in the skin and causes large lesions that can spread to other parts of the body and cause severe disability. Since February 2019, in cooperation with the international non-governmental organization, Association for Aid and Relief, Japan (AAR Japan), Eisai has been implementing awareness activities about knowledge on mycetoma and the importance of early treatment, as well as initiatives that promote patients' early diagnosis and treatment at medical institutions in Sudan which is one of the countries where the disease is most prevalent.

# Visiting Sudan which is One of the Most **Endemic Countries with Mycetoma**

We visited Mycetoma Research Center (MRC) at Khartoum University where the Phase II study for E1224 is being conducted and inspected the status of clinical study and treatments. At MRC, over 8,500 patients have been treated to the present. However, the current treatment requires long-term medication and high economic burden, so more than half of patients cannot complete the treatment. This leads to the recurrence of the disease and results in resection or amputation surgery.

Then we visited a clinic in Wad Onsa Village, an



Photo of Clinic in Wad Onsa Village

endemic area of mycetoma with the MRC medical team. Wad Onsa Village is a remote area 400 km away from the capital and has no medical facilities. Therefore the MRC Medical Team

visits the clinic in Wad Onsa Village several times a year, and provides diagnosis and medical treatments including surgery free of charge for residents of the surrounding 290 villages. A total of more than 700 people have undergone surgery since 2015. However, patients need to go to the capital in case they need major surgery, but not many of them can afford accommodation and treatment costs.

Through this visit, we deeply realized that there are many patients suffering from mycetoma even now. We felt the need to accelerate the development of new treatments for mycetoma and to actively engage in disease awareness activities.

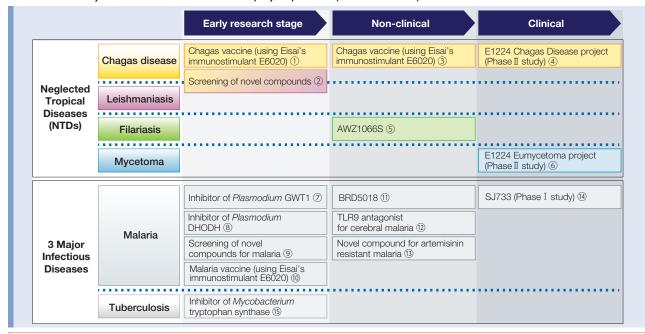


Katsura Hata Director, Global Health Research Section, hhc Data Creation Center



Takavuki Hida Group Leader, ESG Group, Policy, Advocacy & Sustainability Department

### NTDs/Three major infectious diseases research project portfolio (As of June 2019)



Consortium for NTDs and 3 major infectious diseases

①, ⑩, ② Fundação Oswaldo Cruz (Fiocruz) (Brazil)

⑤, ⑬ Liverpool School of Tropical Medicine (U.K.),

2, 4, 6, 10 Drugs for Neglected Disease initiative (DNDi)

■Main partners of the projects

3 Sabin Vaccine Institute (U.S.)

(Switzerland)

University of Liverpool (U.K.)

WIPO Re:Search 16

NTD Drug Discovery Booster 17 TB Drug Accelerator (19)

Macrofilaricide Drug Accelerator ®

(MMV) (Switzerland) 8, (1) Broad Institute (U.S.), Medicines for Malaria Venture

- (MMV) University of Kentucky (U.S.), Medicines for Malaria Venture (Switzerland)
- (B) Broad Institute (U.S.), Colorado State University (U.S.), University of Chicago (U.S.)
- (6) World Intellectual Property Organization (WIPO) (Switzerland), BIO Ventures for Global Health (BVGH) (U.S.)
- 18, 19 Bill & Melinda Gates Foundation (U.S.)

②, ⑨ Medicines for Malaria Venture (MMV) (Switzerland) Please visit the following link for details on projects https://www.eisai.com/sustainability/atm/research.html

# **Pricing Policy that Emphasizes Affordability**

Eisai has formulated various flexible pricing policies that enable patients in developing and emerging countries to purchase Eisai's products at affordable prices. These pricing policies are formulated taking into consideration the social, economic and healthcare environments of developing and emerging countries. For example, Eisai has been providing Aricept® and Pariet® in India since 2005 at affordable prices that

# are best suited to the living standards of the local patients.

Management Strategies

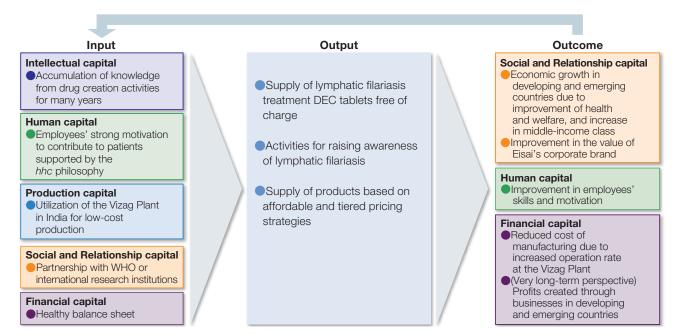
Regarding Fycompa®, we introduced a unique system in India where many patients have to pay the full cost of medical expenses out-of-pocket. The treatment is provided for free to patients for a certain period of time, and a full-scale administration of the treatment is implemented once efficacy is confirmed. In addition, Eisai has introduced tiered pricing, "Hope to Her"program, an affordable pricing model, for the anticancer agent Halaven® in 8 Asian countries. In this model, co-payment is set at several tiers in accordance with the income level and health insurance availability of the patients, ranging from the full price to free of charge depending on the condition. During the fiveyear period, Halaven® was supplied to approximately 4,100 patients cumulatively via tiered pricing.

Business Base (ESG)



Explanation about "Hope to Her" program from Medical Representative to a doctor (India)

# Creating Corporate Value and Solutions to Social Issues Through Initiatives for Improving ATM



For the purpose of facilitating the improvement of ATM, Eisai utilizes many different types of capital as input and converts them into many different forms of output (products and services), such as DEC tablets, through business activities. As a result, we pursue the creation of positive outcomes such as the improvement of health, welfare and economic growth by increasing the number of middle-income populations in developing countries and emerging countries. Eisai also seeks to enhance the value of its corporate brand, improve employees' skills and motivation, and reduce costs by increasing the operation rate of the Vizag Plant as

positive internal outcomes. Eisai believes that efforts to improve ATM will increase capital to an extent that is greater than the amount of input, through the creation of added value. Eisai's initiatives for improving ATM go beyond the framework of CSR activities and aim at creating long-term value. Supplying DEC tablets free of charge will initially be a loss and thus negatively affect profits and ROE in the short term.

However, from a very long-term perspective, we estimate that it will boost our NPV (net present value) to a positive level through the creation of the outcomes described above.

# **Eisai's Initiatives for Improving ATM Highly Evaluated**

The Access to Medicine Foundation, an international non-profit organization which analyses how the world's largest pharmaceutical companies are addressing access to medicine, biennially researches and publishes the Access to Medicine Index. In 2018, Eisai was ranked 8th rising three access to places in the ranking from 11th medicine in 2016. Among Eisai's activities, INDEX

Eisai's continued commitment to combat NTDs was selected as the best practice.

In addition, Eisai has been selected for the MSCI Japan ESG Select Leaders Index as a company with outstanding ESG ratings, and has maintained an AA ranking in the ESG Index for six consecutive years since 2014. In this Index, the area of Access to Health Care was highlighted as one of Eisai's strengths.

# Intellectual Capital

# **Development of Potential Next-Generation Dementia Treatments**

Proactive investment in the industry-leading pipeline to become a top runner for new drug development in dementia area

# **SWOT Analysis of Medicine Creation Activity in Dementia Area**

# **Strengths**

- 2. Expertise acquired through development for more than 35 years
- Global strategic partnerships that potentially increase probability of success and accelerated development with optimization of R&D and commercialization expenses

# Weaknesses

 Focus on dementia, a disease in which developing new drugs is particularly difficult and large-scale clinical studies are required, necessitating a large amount of R&D expenses

# **Opportunities**

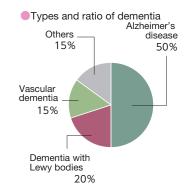
- 1. Expansion of market for dementia treatments as population ages
- 2. Expansion of potential market as diagnosis technology improves

# **Threats**

- 1. Competing products entering the market
- 2. Increasing pressure to lower drug prices as governments promote policies to reduce healthcare expenditure

#### What is Dementia?

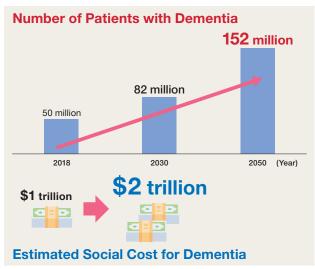
Dementia is a condition characterized by the occurrence of a variety of disorders and the emergence of impediments to everyday life due to the death of brain cells and a worsening of cognitive functions resulting from various causes. There are different types of dementia. Symptoms of Alzheimer's, the most prevalent dementia, are mainly those related to memory impairment (core symptoms), while behavioral and psychological symptoms (BPSD) such as delusions and hallucinations, violence, wandering and depression can also be observed. Other types of the disease include dementia with Lewy bodies and vascular dementia, among others. All of these are characteristically progressive.



Source: "Guide to Understand Dementia with Lewy Bodies" (editorial supervisor: Kenji Kosaka) (Japanese title "Rebi-Shotai Gata Ninchisho Ga Yoku Wakaru Hon")

# An Ever-Increasing Number of Patients with Dementia and Social Cost

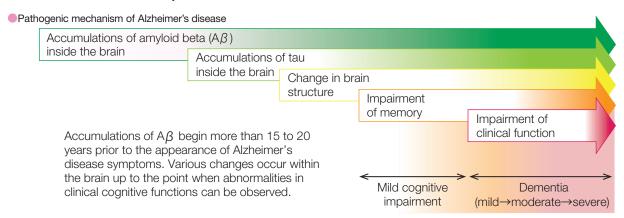
As the aging of the global population gathers pace, the number of patients with dementia is expected to continue an upward trend. In 2018, there were an estimated 50 million patients with dementia worldwide. And the number of the patients will increase to approximately 82 million in 2030, and approximately 152 million, almost tripled in 2050. Based on a calculation, there is one new case of dementia found every 3 seconds worldwide. It is reported that the current social cost of dementia, including medicine, social care, and the care provided by family, is 1 trillion USD, and is expected to double in 2030. Therefore, dementia is a global issue which needs to be addressed and there are expectations for earlier development of treatments that satisfy unmet medical needs.



Value Creation Activities Company Introduction Management Strategies Business Base (ESG) **Appendix** 

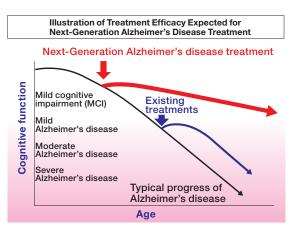
# Pathogenic Mechanism of Alzheimer's Disease (AD)

Alzheimer's disease is associated with the occurrence of neuronal cell death as a result of the gradual accumulation of proteins in the brain, called amyloid beta  $(A\beta)$  long before the onset of the symptoms, such as memory impairment. The accumulation of  $A\beta$  is considered to accelerate the tau pathology and resulting in the neuronal cell death caused by the accumulation of tau.



# Treatment Efficacy Expected for Next-Generation Dementia Treatments

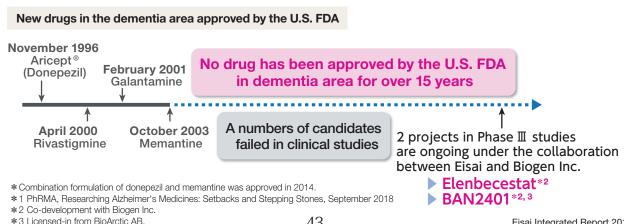
A numbers of treatment for AD are already in the market, including Eisai's in-house developed Aricept®, although the efficacy of these treatments are limited. Worsening of cognitive functions is unavoidable after certain period of time of administration of the drugs. Also, they are not indicated for patients who are in the stage of MCI. Therefore, development of potential next-generation dementia treatments which could potentially suppress the worsening of cognitive functions over a longer period of time from the earlier disease stage, is highly expected.



# Challenging Path Toward the Development of Next-Generation Dementia Treatment

No drug has been approved by the U.S. FDA for the treatment of dementia since 2003. 146 agents under development between 1998 and 2017 did not prove success\*1. This suggests that the development of drug in dementia area to be very challenging.

One reason for the development of treatment of dementia to be challenging is that high-order functions, such as cognition, are unique to humans, and it is difficult to create an applicable experimental scenario using animal models. For example, if accumulation of brain  $A\beta$  or tau were observed in mouse, it is not for sure if mouse develops dementia. It is necessary to accumulate knowledge and confirm the correlation between reactions of animal models and changes that occur inside the brain of patients with dementia or their core symptoms, including biomarkers. Moreover despite the advances made in diagnostic imaging technology such as PET (positron emission tomography), there is no method to directly observe the changes inside a human brain.



# Leveraging Abundant Experience and Knowledge to Create Next-Generation Dementia Treatment

Under the corporate philosophy of *hhc*, we strive to create next-generation dementia treatment. Eisai's **knowledge and know-how in medicine creation activities in dementia area have been accumulated over 35 years** since Aricept<sup>®</sup>. And they will be a great advantage for success in developing next-generation dementia treatments.

# Eisai's Ingenuity in Discovery Research

Eisai possesses facilities for various pharmacological tests, experience and knowledge to study pharmacological effects in central nervous system of animals. In particular, utilizing in-house established behavioral pharmacology studies and the animal models, Eisai evaluates the compounds which act to molecules that regulate synaptic transmission between neuronal cells and Eisai leverages them to develop drugs in central nervous systems and predict efficacy of compounds in clinical studies. With the developments of neuroscience, it has been discovered a variety of target molecule in the brain. Eisai applies the behavioral pharmacology studies that have been established to the discovery of target molecule, and always pursues new possibilities for medicine creation.

#### Example of Eisai's biomarker detection system



For the human pathology and high-order functions unique to human that are difficult to mimic the human condition animal models, Eisai accurately develops compounds from preclinical to clinical studies by combining the biomarker research using detection of the biological molecules as indicators, to the conventional method of research.

For objective measurement of functions in the brain, Eisai focuses on establishing methods (using machine shown in the left) to discover new biomarkers and quantitative measurement.

#### Eisai's Ingenuity in Clinical Research

It is said that there are four elements (right drug discovery target, right patients, right dosage, right clinical evaluation indicators) that are important for a clinical study to meet its primary endpoint. It is assumed that the failed trials may have had an issue in one or more of these factors. For instance, the clinical studies that have failed may have included patients whose  $A\beta$  deposition was unknown or patients whose disease had advanced to a stage beyond which the mechanism of action of the drug was effective. Or they may not have had a sufficient dosage, or the endpoint selected was not sensitive enough for the patient population.

In Eisai's clinical studies, learnings from the past studies were considered and the following factors which are thought to contribute to success were incorporated:

- 1) Identifying A $\beta$  deposition in early stage patients with AD when enrolling for studies
- 2) Setting appropriate doses for antibodies or small molecule compounds
- 3) Selecting a suitable endpoint for evaluating effects for patients with early stage AD

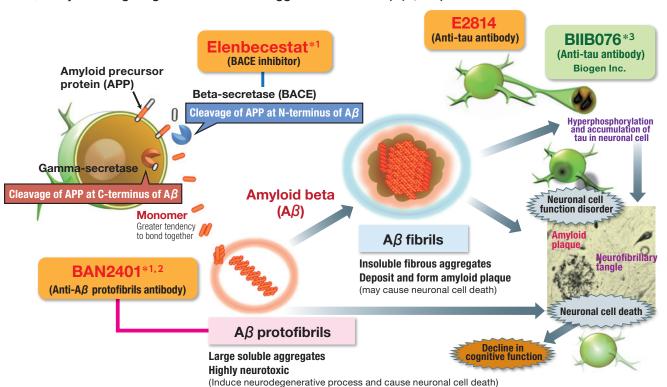
Favorable results were obtained from Phase  ${\mathbb I}$  studies in elenbecestat and BAN2401, and Phase  ${\mathbb I}$  studies are steadily ongoing.

Business Base (ESG)

## **Industry-Leading R&D Pipeline in Dementia Area**

Eisai possesses industry-leading R&D pipeline in dementia area. Under the collaboration with Biogen Inc., 2 projects in Phase II studies are ongoing.

Projects Targeting Accumulation of Aggressive Factors (Aβ, tau)



- \*1 Co-development with Biogen Inc.
- \*2 Licensed-in from BioArctic AB
- \*3 Eisai has an option to jointly develop and commercialize with Biogen Inc.

## Investigational BACE inhibitor elenbecestat developed in-house (co-development with Biogen Inc.)

Discovered at Tsukuba Research Laboratories, this compound inhibits BACE (beta-site amyloid precursor protein cleaving enzyme), an enzyme involved in the production of A\(\beta\). While BACE is generally classified as BACE1 and BACE2, elenbecestat shows relative selectivity to BACE1 which is potentially related to A $\beta$ production in the brain. For the first time in BACE inhibitor, elenbecestat demonstrated the reduction of

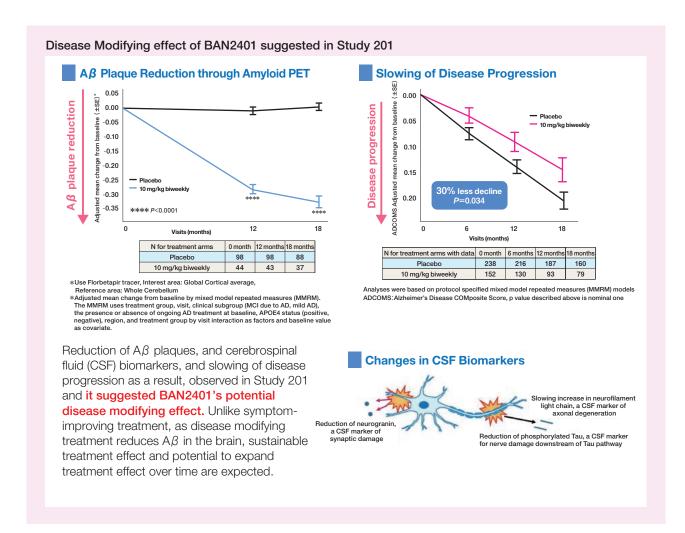
 $A\beta$  accumulated in the brain and suggested the slowing of clinical decline as analyses of exploratory clinical endpoints in Phase II study. Elenbecestat is currently in two Phase II studies (MISSION AD1, MISSION AD2), and has completed patient enrollment in March 2019. Final readout of primary endpoint is targeted in the first quarter of fiscal 2021.



# lacksquare Investigational anti-A $oldsymbol{eta}$ protofibrils antibody BAN2401 (co-development with Biogen Inc.)

This anti-A\(\beta\) protofibrils antibody is in-licensed from BioArctic AB. BAN2401 has a unique characteristic to bind and reduce highly toxic A $\beta$  protofibrils. Phase  $\mathbb{I}$  study (Study 201) demonstrated slowing in clinical decline as well as dose-dependent reduction of  $A\beta$  accumulation in the brain, and open-label extension study is currently ongoing. According to the meetings with the health authorities based on the results of study 201, a single Phase II study was initiated in March 2019 to support filing for BAN2401. Final readout of primary endpoint is targeted in the first guarter of fiscal 2022.





# Evaluation of Elenbecestat and BAN2401 in earlier disease stages

In May 2019, elenbecestat and BAN2401 were selected for two prevention studies by the Alzheimer's Clinical Trials Consortium (ACTC) as treatments to be evaluated in upcoming clinical studies. The A3 Study will target cognitively normal individuals who are currently amyloid negative but are at high risk for AD, and elenbecestat was adopted to evaluate whether it can prevent amyloid build-up in the brain.

The A45 study will target preclinical (pre-symptomatic) stage of AD in who are clinically normal individuals (no/minor cognitive impairment) and have elevated levels of amyloid in brain, and elenbecestat and BAN2401 were adopted to evaluate prevention of cognitive decline. Details are currently under consideration.

#### Investigational anti-tau antibody E2814

This anti-tau antibody was discovered as part of the research collaboration with University College London and is designed to prevent the spreading of tau protein "seeds" which are believed to spread among different areas of the brain and induces tau pathology as the disease advances. This compound is expected to prevent accumulation of neurofibrillary tangles in the brain, and to slow the progression the disease. **We plan to initiate Phase I study in fiscal 2019.** 

# Investigational anti-tau antibody BIIB076 under development by Biogen Inc.

Eisai has an option to jointly develop and commercialize BIIB076. Biogen Inc. is currently conducting a Phase I study for BIIB076. Eisai has a right to exercise its option after the completion of the Phase I study.

#### Discontinuation of the development of investigational anti-A $\beta$ antibody aducanumab

In March 2019, Biogen Inc. and Eisai announced the decision to discontinue the global Phase II studies, ENGAGE and EMERGE, designed to evaluate the efficacy and safety of aducanumab in patients with mild cognitive impairment due to AD and mild AD dementia. The decision was made based on the results of a futility analysis conducted by independent data monitoring committee, which indicated the trial were unlikely to meet the primary endpoint upon completion.

Business Base (ESG)

# Projects Targeting Transformation of Symptoms over Time

Management Strategies

In recent years, it has been increasingly known that various disorders have occurred since 10 to 20 years before the diagnosis of dementia. Eisai sees importance of relieving the symptoms associated with dementia, and has taken various approaches.

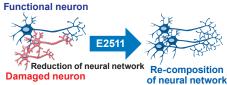
Sleep disorder may accelerate the accumulation of  $A\beta$  and potentially lead to AD. Eisai has filed for lemborexant, an antagonist to dual orexin receptors, which are involved in the regulation of sleep and awakening for insomnia disorder indication in the U.S. and Japan in fiscal 2018. Phase I study for patients with irregular sleep-wake rhythm disorder (ISWRD) due to AD/dementia is also ongoing.

Furthermore, the occurrence of depression, epilepsy, anxiety, dysosmia and other forms of behavioral disorders increases in relation to the accumulation of  $A\beta$  and tau. It is considered that suppression of behavioral disorders would potentially delay the onset of Alzheimer's disease. Eisai also develops new treatments for epilepsy and other neurological disorders. The development of investigational E2027, a PDE9 inhibitor targeting dementia with Lewy bodies is also ongoing.

# Projects in Preclinical Stages

# Investigational Synapse Regenerant E2511

The axon terminal of a neuron is called a synapse and it is thought that the dysfunction of synapse has been occurer in the brain of patients with dementia. Eisai is working on projects to revitalize neurons by restoring synapse function. Currently preclinical study is ongoing for E2511.



Regeneration of synapse by administration of E2511

# Research Focused on Immuno-Dementia at G2D2, a New Research Facility

Eisai has established Eisai Center for Genetics Guided Dementia Discovery (G2D2), a new exploratory research facility in Cambridge, Massachusetts, the U.S. in 2019. AD genetic studies suggest altered immune function of microglia, a cell that exerts immune functions in the central nervous system, is potentially a risk factor of AD. G2D2 engages in drug discovery research focusing on immuno-dementia looking at what comes after drug discovery targeting A $\beta$  and tau.



## Joint Research with Keio University Targeting Brain Maintenance System

It is known that the brain has numerous protective mechanisms. It is reported that the brain's protective mechanisms include functions that phagocytose and remove foreign substances such as A $\beta$  and functions that repair damaged neuronal cells. Eisai sees the brain maintenance system supported by these protective mechanisms, as an important



target for new drug discovery aimed to cure dementia. Therefore, Eisai and Keio University have established the Eisai-Keio Innovation Lab for Dementia (EKID) to advance joint research in this area. This project was selected by the Japan Agency for Medical Research and Development (AMED) for its Cyclic Innovation for Clinical Empowerment (CiCLE) grant program, and run by their support.

# **Development of New Diagnostic Methods**

While diagnosis of AD is sometimes made by using tests such as amyloid PET imaging examinations and cerebrospinal fluid analysis, various issues such as the insufficient number of facilities for examinations and the invasiveness of the testing remain to be addressed.

Eisai is pursuing a new dementia diagnostic method through blood test in collaboration with Sysmex Corporation. HISCL™, an automated immunoassay system developed by Sysmex Corporation, enabled the measurement of Aetain plasma, which had been difficult to measure, and elucidated that A $\beta$ 42/40 ratio in plasma correlates the one in cerebrospinal fluid. Currently, verification of the data is ongoing using blood samples of patients with dementia with amyloid PET images. Sysmex Corporation and Eisai are putting forth every effort for the practical application of the test to precede the time of potential launch schedule of the disease modifying treatment.

Full-automated system immunoassay HISCL™



**Social and Relationship Capital** 

# Initiatives for Dementia Area Offering Solutions that Go Beyond Providing Pharmaceuticals

Undertaking a variety of activities for solving issues faced by patients, their families and the community and for building a foundation for a society that coexists with dementia



Eisai launched the in-house developed dementia treatment Aricept<sup>®</sup> in 1999. The introduction of Aricept<sup>®</sup> as Japan's first Alzheimer's disease treatment provided patients and their families with great hope. In the following section, Dr. Masaaki Matsushita, Professor Emeritus, University of Tokyo, describes the differences between the situation today and the times prior to the launch of Aricept<sup>®</sup> when there were no treatments for dementia.

# "Hopes on Aricept®"

"I have been involved in the treatment of Alzheimer's disease since 1960s. As a doctor, when I was depressed by expectations and hopes for what I can do for patients as well as desperation, Aricept<sup>®</sup> shed light on the future treatment for dementia. With Aricept<sup>®</sup>, part of the walls of hard-to-treat dementia has been destroyed."



Dr. Masaaki Matsushita

Director, Tokyo Metropolitan Geneatric Hospital Professor Emeritus, University of Tokyo

Back then, dementia was still described in Japan as "senility," and the understanding of this disease and its diagnostic methods had not adequately spread throughout society. Eisai was acutely aware that the environment surrounding dementia patients would never change just by providing Aricept<sup>®</sup>. Acting on this recognition, Eisai proactively promoted a variety of initiatives to break through the status quo approach toward dementia. First, Eisai repeatedly carried out disease awareness activities for Alzheimer's disease through civic forums and its website. To date, Eisai has held meetings for dementia disease awareness on approximately 2,000 times in Japan and around 10,000 times globally. For the diagnosis of dementia, Eisai has actively worked to promote the spread of simple diagnostic methods, such as the Hasegawa Dementia Scale and MMSE\*, which are more suitable for clinical practice. These initiatives have produced positive results and have helped significantly increase the awareness of dementia throughout the world. At the same time, Eisai learned that the provision of pharmaceuticals was not enough to solve issues surrounding dementia patients. Dr. Masahiro Shigeta, Director, Department of Psychiatry at Jikei University School of Medicine, describes these issues surrounding dementia patients below.



"I have seen many patients with dementia and their families who have happy life in the clinical settings. The ability that was lost due to dementia is only a small part of that persons. There is no need to be sad even when dementia comes up. When trying to truly respond to anxieties and requests of patients and their families, there is more important thing other than the presence of treatments. I assume that Eisai can honestly confront dementia because Eisai has been with dementia patients since Aricept® went on the market."

# **Dr. Masahiro Shigeta**Director, Department of Psychiatry at Jikei University School of Medicine

Dr. Manabu Ikeda, Professor, Department of Psychiatry, Osaka University Medical School describes Eisai's engaging in dementia area below.

"As a leading company in Japan, I want Eisai to take a challenge on developing new treatments for dementia. Keeping that in mind, I would like to ask Eisai to support for the steadily growing elderly people living alone "to be able to continue to live safely in a familiar area". Further initiatives to realize the measures to avoid various risks are expected so that healthy people as well as patients with mild cognitive impairment (MCI) and dementia can live safer and longer lives while respecting their wills and securing their activeness."



Dr. Manabu Ikeda

Professor, Department of Psychiatry, Osaka University Medical School

<sup>\*</sup> MMSE (Mini Mental State Examination) was developed in the U.S. in 1974 for diagnosing dementia and other diseases. This is an examination mainly for measuring recall, calculation ability, language ability and orientation.

# Enhancement Activities in Communities under Partnership Agreements for Dementia

Taking a cue from the launch of Aricept®, Eisai has conducted disease awareness activities and the provision of information in cooperation with local governments and medical associations. In 2008, we started activities to support the building of communities to coexist with patients with dementia, aiming for more concrete activities based on the accumulation of experience and knowledge.

In 2010, Eisai entered into a community development partnership with Asahi Ward in Yokohama City. This was the first agreement to support dementia patients at the community level in Japan. With that as a start, we will expand our activities to construct various social systems.

Business Base (ESG)

Partnership agreements for dementia were concluded with 158 municipalities/medical associations/pharmacist associations in Japan as of the end of July 2019, and working to build communities that enable patients with dementia to live in peace.

# Developing the hhc Solutions Business: Aiming to Build the Foundation for a Society that Coexists with Dementia

Throughout over 20 years of disease awareness activities in the dementia area, Eisai learned that the provision of pharmaceuticals was not enough to satisfy the truly unmet dementia-related needs. Since 2016, Eisai has engaged in the business of providing a variety of solutions in cooperation with partners including counterparts of the dementia partnership agreements to meet the unmet needs of patients and their families and build the foundation for a society that coexists with dementia. For all people who hope to live in peace in their familiar communities, we continue to work on the activities to support patients with dementia in each community; promotion of

understanding dementia; and early detection and early treatment of dementia.

In March 2019, the website about the hhc solution businesses including specific activity examples has launched in Japan. We introduce our activity examples in each communities with partnership agreement, and information about variety of our solution products.

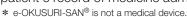
Website about the hhc solution businesses (only available in Japanese) https://hhcs.eisai.jp



# Major Products of hhc Solutions Business

# Medicine administration support device "e-OKUSURI-SAN®"

This device supports medicine administration for patients, families, pharmacists, nurses and caregivers. The device also supports looking after patients remotely by confirming a patient's record of medicine administration.





# A tool to support going out "Me-MAMORIO®"

Me-MAMORIO® is a small tag that utilizes the shortrange wireless Bluetooth communication standard jointly developed and sold by Eisai with Mamorio based on a partnership agreement. Through the short-range communication with the smartphone, it is possible to detect the location of patients with dementia and reduce their anxieties while going out.





# Educational materials on dementia for elementary, junior high and high school students

Eisai handles teaching materials to local governments, educational institutions and medical care worker for elementary, junior high and high school students to learn about dementia, and think and discuss together how

patients with dementia feel and how to deal with them.













#### Interprofessional Collaboration Service "Hikari One Team SP"

This service enables "One Team" consists of interprofessionals to share the care plan for each patient so as to work on care with same point of view.

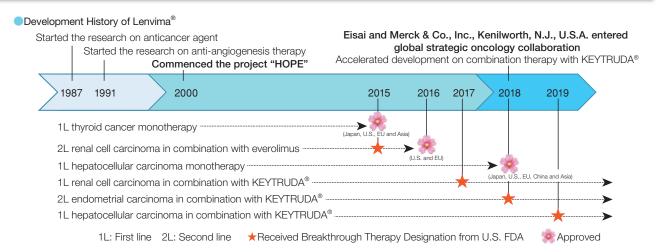
# **Intellectual Capital**

# Special Feature Lenvima®



The Birth Story of Lenvima® and Strategy Toward Value Maximization Through Innovative Partnership





# Project "HOPE" Development of Novel Anti-angiogenic Therapy with the Efforts to Put Ourselves into Patients' Place

Eisai started the research on anticancer agents in 1987. At that time, the main focus in development was cytotoxic anticancer agents that directly attack cancer cells. However, such anticancer agents could not be administered long-term due to their side effects, and their range of appropriate dosage ("therapeutic window") was very narrow, resulting to a burden on patients. Under that circumstances, anti-angiogenic therapy had become the next target for development to potentially lessen the burden on patients. Anti-angiogenetic therapy suppresses angiogenesis of cancer cells, which occur to enhance nutrients and oxygen supply needed for their propagation and metastases.

Eisai started the research on anti-angiogenic therapy in 1991. Eisai's researchers at Tsukuba Research Laboratories in Japan named the project "HOPE", and started the project to fulfill patients' long-cherished needs since 2000.

# **Development Goals of Project "HOPE"**

## Overcoming weakness of cytotoxic anticancer agents

- •Feasible for long-term treatment with fewer side effects
- •Wider range of dosage (therapeutic window)
- •Realize distinct prolongation of lifespan
- •Oral administration form to lessen the burden of administration and minimize the frequency to visit medical facilities for patients

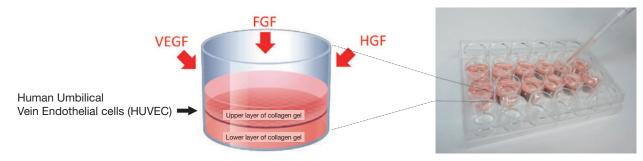
# "Make Haste Slowly"

# Commenced with the Establishment of New Evaluation Model to Reflect Clinical Setting

Eisai started the establishment of an evaluation model for preclinical setting that was more similar to pathology of cancer in clinical setting, with the aim that the compound with strong activity in preclinical would reproduce anticancer activity (efficacy) in

patients. As a result, a groundbreaking model that could induce angiogenesis both *in vitro* and *in vivo* was created, and the system to screen compounds utilizing that model was established. Taking this opportunity, Eisai started a full-scale research.

New in vitro Evaluation Model of Angiogenesis with 24-Well Cell Culture Plate



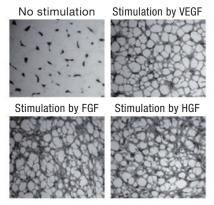
# Careful Evaluation on Compounds with Low-Throughput Screening System

As "HOPE" project progressed, new insights into angiogenesis were being reported gradually. It was suggested that angiogenesis consisted of multiple processes, and each of these process was regulated by multiple angiogenic factors, such as VEGF (vascular endothelial growth factor), FGF (fibroblast growth factor), PDGF (platelet derived growth factor) and HGF (hepatocyte growth factor).

Based on such new insights into angiogenic factors, Eisai developed a unique in vitro evaluation model that induces tube formation of endothelial cells, which was considered to be a process specific to angiogenesis. The mainstream of the method to find seed compounds was high-throughput screening, which could evaluate hundreds of compounds all at once to enhance efficiency in the process at that time. However, Eisai prioritized utilizing a novel in vitro evaluation model, which is believed to reflect tumor environment in human body, and low-throughput screening to evaluate efficacies of compounds for lumen formation induced by three factors of VEGF, FGF and HGF. Although the low-throughput screening could only evaluate 3 to 4 compounds a week, Eisai continuously conducted the screening. In the end, Eisai found the seed compound, which not only had 100 to 1000 times stronger activity than other antiangiogenic agents that inhibited vascular endothelial

Blood vessel induced from stimulation by each factors of angiogenesis

Business Base (ESG)

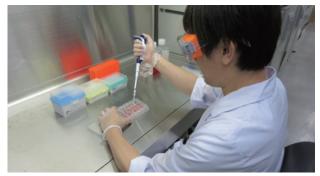


Unique phenomenon of angiogenesis Tube formulation of endothelial cells



growth factor receptors (VEGFR) developed by other companies, but also inhibited fibroblast growth factor receptors (FGFR). As a result of all these processes, Lenvima® was born.

#### Low-throughput screening and High-throughput screening



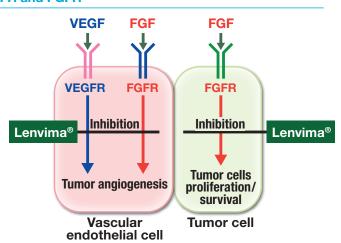
Low-throughput screening (number of compounds to be evaluated at once is limited)



High-throughput screening (evaluate multiple compounds at once)

# Characteristics of Lenvima® Inhibition of both VEGFR and FGFR

Lenvima® is designed to inhibit not only signals for VEGFR in tumor vascular endothelial cell, but also tumor vessels with excessive FGFR signals and FGFdependent tumor cells. Eisai believes that Lenvima® is potentially efficacious for multiple cancer types by inhibiting FGFR, which conventional VEGFR kinase inhibitors would not target upon.



# Establishment of Unique Evaluation Model and Low-Throughput Screening were the Keys for Successful Development of Lenvima®

When Eisai started the research on antiangiogenic therapy in 1990's, rodent cornea and chorioallantoic membrane of chicken eggs, which had no blood vessel, were utilized in the general model to evaluate angiogenesis. However, researchers of Eisai, including myself, initiated the research to establish a novel evaluation model, based on a conviction that both *in vivo* and *in vitro* evaluation models for angiogenesis of tumor that could reflect clinical setting would be essential.

Although we needed human vascular endothelial cell to form *in vitro* evaluation model, available cells were in bad condition at that time. For that reason, we could not reproduce angiogenesis successfully as expected. We visited obstetrics and gynecology clinics repeatedly to obtain umbilical cord through the courtesy of physicians and with consent of donors. As a result of all these efforts, we could establish a novel *in vitro* model utilizing isolated-cultured vascular endothelial cells from umbilical cord, and initiate screening for compounds with the model.

We started to find tumor cell, which would not induce angiogenesis at first to establish *in vivo* model. We finally created artificially modified tumor



Director, Biomarker Research Translational Science Department, Oncology Business Group



cells that produce VEGF and FGF, important factors of tumor angiogenesis, and established a unique evaluation model that could evaluate tumor angiogenesis and tumor proliferation induced by them.

Other organizations conducted evaluations utilizing high-throughput screening focusing on only VEGFR kinase inhibitor. On the other hand, we conducted evaluations utilizing low-throughput screening for *in vitro* evaluation. We evaluated the inhibitory activity in angiogenesis induced by both VEGF and FGF. We paid attention not only to the strength of the activity, but also to the balance of inhibiting VEGF and FGF. In *in vivo* evaluation model, we also evaluated prolongation of lifespan, a primary endpoint in clinical study, to seek for a promising compound in addition to utilizing our unique model.

It took great effort and time. However, it is an honor that our passion and strong will to create better medicine resulted in the birth of an innovative medicine, Lenvima<sup>®</sup>.

## Achieved obtainment of New Indication for Hepatocellular Carcinoma Globally and Accelerated Growth

Indication expansion for Lenvima® is proceeding very smoothly. Lenvima® was first approved for the treatment of thyroid cancer (monotherapy), and then approved in combination with everolimus for the treatment of renal cell carcinoma (second-line) globally. Regarding the third indication of hepatocellular carcinoma (monotherapy), we

# Hepatocellular carcinoma Simultaneous submissions and approvals in Japan, the U.S., Europe, China, and Asia Europe Submitted: July 24, 2017 Approved: August 20, 2018 China Submitted: October 30, 2017 Approved: September 4, 2018 South Korea Submitted: March 6, 2018 Approved: August 29, 2018

obtained approvals in Japan, the U.S., Europe, China and Asia in 2018.

Liver cancer is the fourth-leading cause of cancer death, estimated to be responsible for approximately 780,000 deaths per year globally. Additionally, approximately 840,000 cases are newly diagnosed each year. Hepatocellular carcinoma accounts for

85% to 90% of liver cancer. There are only a few systemic chemotherapies approved for the first line therapy and unmet medical needs remained.

Lenvima® has been growing rapidly since Eisai obtained approvals for hepatocellular carcinoma indication globally. Annual revenue reached 62.6 billion yen in fiscal 2018, which was 194% growth year-on-year. Revenue target for fiscal 2019 is 116.0 billion yen with 185% year-on-year growth.

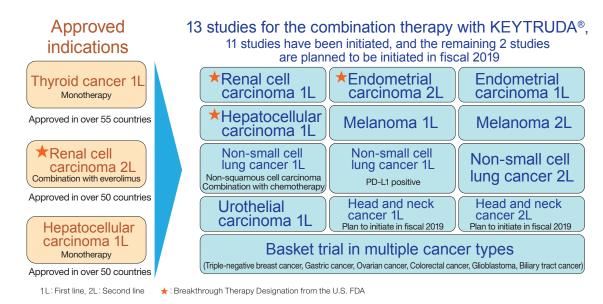
# Maximizing the Value of Lenvima® Through Innovative Partnership Model

In order to maximize the value of Lenvima®, Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. (U.S. Merck) agreed upon a global strategic collaboration for Lenvima® in March 2018. Under the agreement, Eisai and U.S. Merck started co-commercialization of Lenvima® in fiscal 2018 and achieved high growth in major countries around the world. Co-development of the combination therapy with anti-PD-1 antibody KEYTRUDA® is also proceeding smoothly. Eisai has received Breakthrough Therapy Designation from the U.S. FDA for treatment of

hepatocellular carcinoma as first-line treatment in combination with KEYTRUDA  $^{\! \otimes}$  in July 2019 in addition to renal cell carcinoma and endometrial carcinoma.

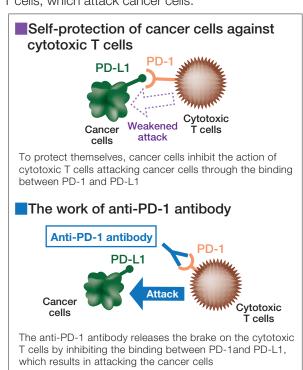
11 clinical studies out of 13 (12 studies are pivotal studies) planned for combination therapies under co-development, have been initiated, and remaining 2 studies will be initiated in fiscal 2019.

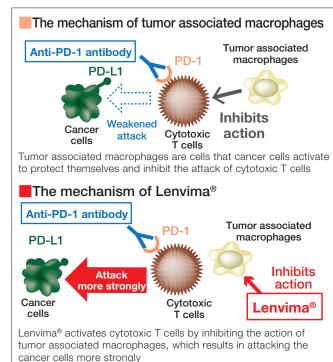
As a result of this agreement, the collaboration will potentially expand contribution to patients and lower the costs and risks in development by sharing R&D expenses.



# Major mechanism of how Lenvima® enhances efficacy of anti-PD-1 antibody

Results from preclinical studies showed that antitumor activity of the anti-PD-1 antibody was enhanced with Lenvima<sup>®</sup> administration by reducing tumor-associated macrophages (TAM) and increasing activated cytotoxic T cells, which attack cancer cells.





Recognition of payments under agreement with U.S. Merck
 The strategic collaboration brings medium- to long-term financial impact on Eisai

# Maximum of up to 5.76 billion U.S. dollars in total (approx. 611.0 billion yen\*)

- ▶ One-time payment: 950 million U.S. dollars (approx. 101.0 billion yen\*)
  - Upfront payment: 300 million U.S. dollars (approx. 32.0 billion yen\*) (Recognized in March 2018)
  - One-time option payments associated with U.S. Merck exercising for certain option rights:
     650 million U.S. dollars (approx. 69.0 billion yen\*)
    - Recognized 325 million U.S. dollars in fiscal 2018. Plan to recognize 200 million U.S. dollars in fiscal 2019 and 125 million U.S. dollars in fiscal 2020.
- Reimbursement for R&D payment: 450 million U.S. dollars (approx. 48.0 billion yen\*)
  - 450 million U.S. dollars of reimbursement for R&D payment was recognized in March 2018 and was booked in deposits. The deposits will be withdrawn as Eisai's share of the R&D expenses concerning Lenvima® occurs, and then booked as the reversal of R&D expenses.
- ▶ Milestone payments: Maximum of up to 4.36 billion U.S. dollars in total (approx. 462.0 billion yen\*)
  - Clinical and regulatory milestones: Up to 385 million U.S. dollars (approx. 41.0 billion yen\*)
     Include regulatory approval of indications in hepatocellular carcinoma or renal cell carcinoma, etc.

     Recognized 225 million U.S. dollars in fiscal 2018
  - Milestones associated with sales of Lenvima<sup>®</sup>: Maximum of up to 3.97 billion U.S. dollars (approx. 421.0 billion yen\*)
  - Recognized 50 million U.S. dollars in fiscal 2018. Plan to recognize multiple sales-based milestone payments in fiscal 2019. \*USD 1=106 yen

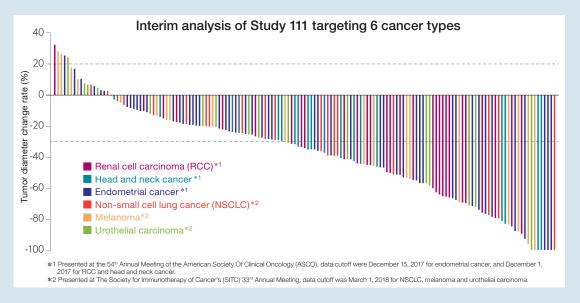
# Strong Bonds between Eisai and Key Opinion Leaders Generated Innovative Partnership

The initiation of the collaboration with U.S. Merck dates back to March 2015 when we first entered into a collaboration on the research. Under the collaboration agreement, we have been conducting Study 111 (Phase Ib/II Study) in multiple cancer types in combination of Lenvima® and KEYTRUDA®. Although Study 111 is still ongoing, significant anti-tumor activity exceeding monotherapy was demonstrated in all six types of cancer (renal cell carcinoma, endometrial carcinoma, head and neck cancer, urothelial cancer, non-small cell lung cancer and melanoma). These significant interim analysis results surprised U.S. Merck, and led to the innovative collaboration agreement in March 2018.

Takashi Owa
Vice President
Chief Medicine Creation Officer,
Oncology Business Group,
Chief Discovery Officer,
Oncology Business Group



Eisai's scientists strongly believed that Lenvima® had a potential to enhance efficacy of anti-PD-1 antibody based on its unique mechanism of action. On the other hand, the scientists of U.S. Merck were not definate about the potential of Lenvima®, since they were conducting clinical studies with numbers of agents in combination with KEYTRUDA®. It is my personal opinion but one of the reasons why the results from Study 111 in combination therapy of Lenvima® and



KEYTRUDA® exceeded the expectation of scientists of U.S. Merck is that two key opinion leaders greatly supported the potential of Lenvima® in light of their experience for clinical use.

Management Strategies

One of the key opinion leaders is a world famous physician. He paid attention to Lenvima®'s unique mechanism of action that clearly differed from other tyrosine kinase inhibitors, and suggested the potential treatment for renal cell carcinoma in combination with everolimus. He also supported us when we had a discussion with U.S. Merck for the strategic collaboration based on his insights for the combination therapy of Lenvima® and immune checkpoint inhibitor.

Another key opinion leader was an up-andcoming physician who believed in the potential of Lenvima® from the experience to lead clinical study of monotherapy treatment in thyroid cancer. We are grateful that he suggested to U.S. Merck that it would be worth to consider this for clinical studies in multiple cancer types (basket trial). The original plan for Study 111 included an option to limit the number of cancer types. I think that we could start the research collaboration with six types of cancer thanks to suggestions from the key opinion leader. If we did not conduct Study 111 with six types of cancer, we might not have been able to enter into the strategic collaboration.

Strategic collaboration of Lenvima® became possible with a lot of luck. However, the key for the collaboration is the strong bond between Eisai and key opinion leaders generated from Lenvima®'s great potential, in addition to the effort of Eisai's scientists to maximize the potential.

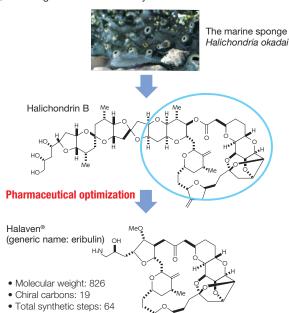
# Pipeline Following Lenvima® Worldwide Product Creation Capability

Halaven® is an in-house microtubule dynamics inhibitor which is a result of Eisai's remarkable capability in synthetic chemistry. The origin of medicine creation of Halaven® is halichondrin B, which showed strong antitumor substances, extracted from Halichondria okadai of marine organism. New project is underway utilizing assets obtained from development of Halaven®.

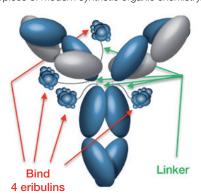
The middle molecule compound, investigational E7130 is synthetically produced from halichondrin through joint research with Harvard University utilizing Eisai's strength in synthetic organic chemistry, and Phase I study is ongoing in solid tumors.

As for biologics (antibody drugs), a Phase I study is ongoing for Eisai's potential first antibodydrug conjugate (ADC) MORAb-202. ADCs are believed to be next-generation antibody drugs, in which antibody drugs and small molecular drugs (payloads) are chemically conjugated via a suitable

Retracing Halaven<sup>®</sup>'s Discovery and Invention



Eisai's First Antibody-Drug Conjugate (ADC) MORAb-202 This ADC is a combination of farletuzumab, an in-house discovered antibody currently in clinical development, and eribulin, a masterpiece of modern synthetic organic chemistry.



linker. Investigational MORAb-202 is Eisai's unique ADC which combines the antibody drug farletuzumab and eribulin (Halaven®). MORAb-202 showed enhanced efficacy and antitumor activity in triple-negative breast cancer and its tumor microenvironment.

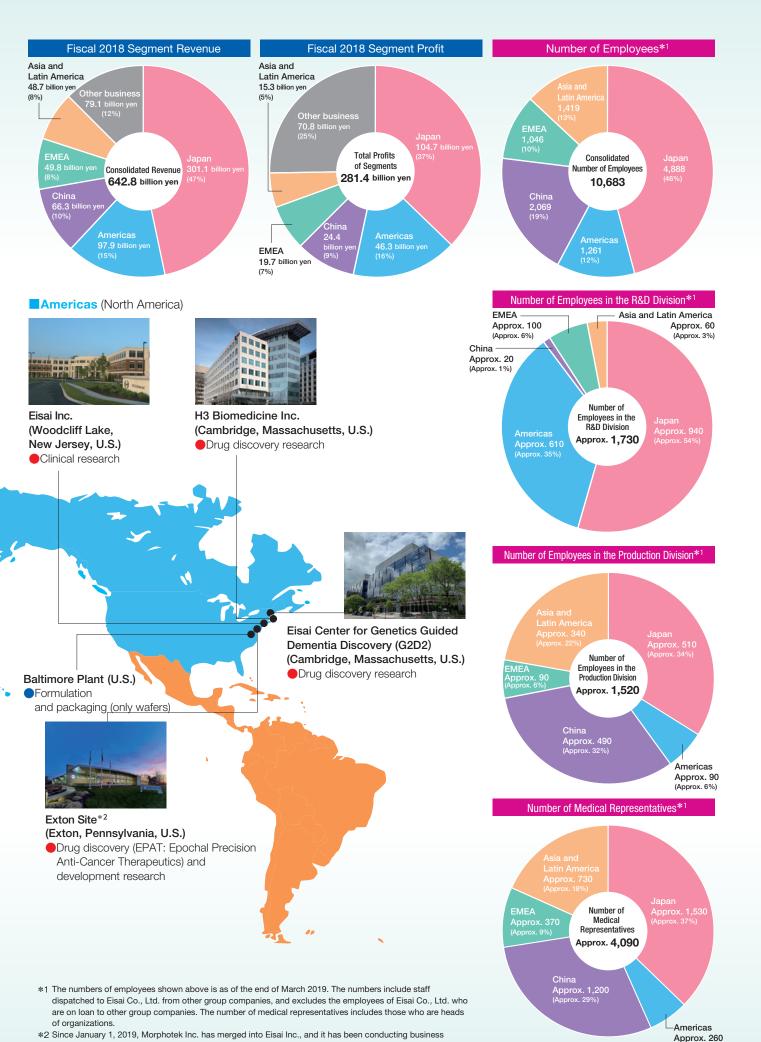
Cutting-edge projects are also underway at H3 Biomedicine, Inc., a subsidiary of Eisai Co., Ltd., aiming to develop next-generation anticancer agents toward precision medicine. Phase I studies are ongoing for investigational splicing modulator H3B-8800 and investigational FGFR4 inhibitor H3B-6527, and Phase I/II study is ongoing for investigational ER $\alpha$  inhibitor H3B-6545. In addition to these projects, H3 Biomedicine, Inc. and Bristol-Myers Squibb Company announced a multi-year research collaboration focused on evaluating whether novel therapeutics leveraging H3's RNA splicing platform can provide a more powerful response against cancer in December 2018.

# **Global Business Activities**

Eisai has been developing global business activities on its own and accumulating experience and knowledge over many years. Eisai's history of overseas operation dates back to the foundation of a local affiliate company in Southeast Asia in the late 1960s. From the 1980s to the early 1990s, Eisai created a three-hub R&D network in Japan, the U.S. and Europe. From the 1990s to the early 2010s, Eisai established pharmaceutical subsidiaries in major countries worldwide in line with the expansion of Alzheimer's disease treatment Aricept® and proton-pump inhibitor Pariet®.

Developing global business activities independently is always associated with difficulties. However, Eisai considers that it is important to overcome any difficulty and accumulate experience and knowledge to leverage for future growth. This is how Eisai has built solid business foundations in Japan, the U.S., Europe, China, and Asia.





57

activities as Exton Site.

# **Intellectual Capital**

# **Global Business Activities**

# **Medicine Creation Activities**

Aiming to create innovation by selection and concentration utilizing researchers' strong sense of mission as well as accumulated experience and knowledge.





# Taro Terauchi (First person from the left)

- 1997 Joined Eisai, Chemistry Unit 2, Tsukuba Research Laboratories
- 2013 Head of Chemistry, Global Discovery Research, Neuroscience and General Medicine Product Creation Unit (PCU), Eisai Product Creation Systems (EPCS)
- 2016 Head of Medicinal Chemistry, Neurology Tsukuba Research Department, Discovery, Medicine Creation, Neurology Business Group (NBG)
- 2018 Head of Neurology Tsukuba Research Department, Discovery, Medicine Creation, NBG (Current)

## Tomoo Ogawa (Second person from the left)

- 1988 Joined Eisai, Section 3, Clinical Development Department, Research and Development Headquarters (HQs)
- 2005 Head of Focused Area Group, Clinical Operations Department, Clinical Research Center
- 2010 Head of Japan, Clinical Development, Neuroscience PCU, EPCS
- 2011 Head of Neuroscience Clinical Development Section, Japan/Asia Clinical Research PCU, EPCS
- 2016 Deputy Head of Japan and Asia Clinical Development Department, Clinical, Medicine Creation, NBG / Head of Neurology Development Group, NBG
- 2017 Head of Japan and Asia Clinical Development Department, Clinical, Medicine Creation, NBG (Officer) (Current)

#### Tomohiro Matsushima (Second person from the right)

- 1994 Joined Eisai, Chemistry, Discovery Research 3 Department, Research and Development HQs
- 2010 Head of Tsukuba Chemistry, Global Chemistry, Global Discovery Research, Oncology PCU, EPCS
- 2016 Head of Oncology Tsukuba Research Department, Discovery, Medicine Creation, Oncology Business Group (OBG)
- 2018 Deputy Chief Discovery Officer, OBG / Head of External Research, Discovery, Medicine Creation, OBG (Current)

#### Akihiko Tsuruoka (First person from the right)

- 1990 Joined Eisai, Section 1, Discovery Research 2 Department, Research and Development HQs
- 2008 Head of Chemistry Group, Discovery Research Laboratories II, Discovery & Development Research HQs of Japan
- 2009 Head of Tsukuba, Discovery, Oncology PCU/Chemistry, Tsukuba, Discovery, Oncology PCU, EPCS
- 2010 Head of Global Chemistry, Global Discovery Research, Oncology PCU, EPCS
- 2016 Head of Oncology Development Group, Japan and Asia Clinical Development Department, Clinical, Medicine Creation, OBG
- 2017 Head of Japan and Asia Clinical Development Department, Clinical, Medicine Creation, OBG / Head of Japan and Asia Planning & Project Management Group. OBG
- 2018 Head of Japan and Asia Clinical Development Department, Clinical, Medicine Creation, OBG (Officer) (Current)

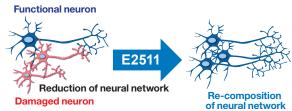
# Q: From your years of experience in medicine creation activities in dementia area, what do you think about Eisai's strength in medicine creation research?

A: Terauchi I think the greatest strength is researchers' commitment to contribute to patients through creating new medicines. At Eisai, researchers' commitment to create new

medicines in dementia field has been inherited for its high unmet medical needs, with the corporate philosophy *hhc* in mind since in-house Alzheimer's disease treatment Aricept® was developed.



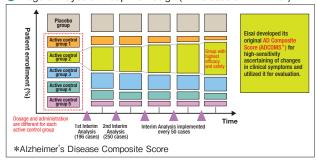
Since brain has advanced order functions, no pharmaceutical companies succeeded in development of next-generation dementia treatments so far for difficulties in target selection and evaluation. Aricept®, our in-house developed treatment for Alzheimer's disease, had contributed to improve symptoms of dementia, but we keenly aware of the necessity to develop basic treatment to fulfill true needs of patients, while actively spending time with patients through socialization activities. Through researchers' every day efforts with the aim to deliver new treatment to the patients as soon as possible, we have possessed industry-leading abundant pipeline in dementia field with accumulated experiences. Currently my team is conducting discovery research for investigational synapse regenerant, E2511. This compound is expected to promote recovery from disease by regenerating damaged functional neurons. Therefore, we believe that we can deliver potential curative treatment to the patients. Due to its innovative concept, we have experienced so many difficulties during the discovery research, such as not being



Regeneration of synapse by administration of E2511

able to obtain the results that we initially expected. We had faced crisis of discontinuation of this project on a number of occasions, but with researchers' commitment to fulfill true needs of patients, we carried on challenging. As a result, we have reached to create new agent after 10 years of discovery research. A: Ogawa I am currently engaged in clinical development in neurology area, and in my opinion, Eisai's strength in clinical development is strong commitment to pursue better development methods. As much were unknown concerning development methods in dementia field, I think Eisai is the one who has been taking the lead in. In the 1990s, when evaluation scales were not yet established, we discovered more objective evaluation method, compared to the subjective evaluation method used by physicians at the time. We introduced ADAScog, a globally standardized scale, to clinical studies for the first time in Japan and trained physicians who were in charge of clinical studies in order to unify the standard of assessment. Furthermore, we have accumulated experience and knowledge by conducting internal operations, such as contrivance in choosing right patients. Recently, we used Bayesian adaptive design to shorten time to determine optimal dose in Phase II Study for investigational BAN2401. We also developed Eisai's original scale ADCOMS, and utilize it to evaluate efficacy of the compound. I believe that these acts of pursuing patient contribution are originated the employees' wish that is fostered through hhc activities conducted from the past.





Frequent interim analyses are conducted and the computer assigns patients to the arm with superior safety and effective dosages to obtain the data for optimal dose in more effective manner

# Q: From your years of experience in medicine creation activities in oncology area, what do you think about Eisai's strength in medicine creation research?

**A:** Matsushima I have been engaging in the discovery research as a synthetic researcher in oncology area for many years, and I think Eisai's strength in medicine creation is that the boundaries among laboratories in and outside Japan are low. Communication between researchers in each laboratory are very active on a daily basis, as well as the global conferences involving decision-making. We feel close, as if they are working in a department next door. We communicate each other based on deep mutual trust that was built



ESAB held at H3 Biomedicine

through collaboration for projects even in English. We have the board system called ESAB (Eisai Scientific Advisory Board), which leaders of global research sites gathers. Famous scientists from the external institutions give objective advice on our projects from scientific view point, and we examine the direction of R&D strategy at Eisai.

**A:** Tsuruoka I am currently in charge of clinical development in oncology, but I was originally a synthetic researcher of discovery research in oncology. Through this broad experience, I would say that the strength in Eisai's medicine creation is promoting precise clinical development conducted globally and regionally, placing IPT (international project team) in the center. Eisai has clinical development functions in Japan, the U.S, Europe, China and Asia,

and structure to pursue global development of new medicines have been well established. IPT is usually formed at the time of clinical introduction. Clinical studies are initiated along clinical study plan to pursue worldwide submissions/approvals since early stage of clinical development after IPT was formed. IPT leader, as well as the lead of each function, such as discovery research, development research, and clinical research are selected. IPT plays a key role to decide developmental plan per indication or regulatory strategies that differ by region, and so on. These strategies are updated in a timely manner depending on the changes in treatment circumstances or competitive landscape, and are applied to clinical development.

# Q: After launching Pariet<sup>®</sup> in 1999, for more than 10 years until the launch of Halaven<sup>®</sup> in 2010, Eisai could not deliver new medicines to patients. What do you think of how "period of frustration" has occurred?



**A:** Terauchi I think the biggest reason for it was that selection and concentration was insufficient.

Eisai used to pursue patient contribution in various areas, resulting in disease areas of target widely spread, not only in dementia or cancer, but also in diabetes, inflammatory diseases, thrombosis, pain, antimicrobial agents and so on. As there was no clear priority, resources dispersed. Sincere learning from this experience, we now carry out selection and concentration in neurology and oncology areas where we can demonstrate our competitive advantage. We believe that this system is effectively functioning. We are now able to approach with various concepts for medicine creation towards hypothesis of dementia pathology by concentrating resource in dementia area, which we have the greatest strength in, in neurology.

Another reason for the stagnation in new medicine creation was insufficiency of human biology perspective, which to verify validity of drug discovery targets from *in vivo* molecules and genetics that potentially have actual influence on disease onset and progression in human. However, we are now able to advance each project after thoroughly verifying validity of drug discovery target and concept from the perspectives of human biology. **A:** Matsushima I think this 10 years of "period of frustration" was the period when new medicine

creation was retained, approximately corresponds to the period that output of discovery research conducted between 1990 to 2000 were expected to bear fruits as new treatments. It was the period when pharmaceutical companies tried to discover medicine creation targets in conjunction with new findings of target molecule for anticancer agent, and science significantly advanced along that. Looking back from now, I think we were focusing too much on efficacy. Even if a compound has strong efficacy, without optimal solubility or metabolic stability that should be installed as an agent, it would not lead to create new treatments. Eisai has developed Halaven<sup>®</sup>, an agent with very complex structure as a compound with necessary profiles installed. Utilizing this experience, we will pursue development of new treatment with feasibility in manufacturing, as well as easy administration for patients.



# Q: What is Eisai's direction in medicine creation going forward?

**A:** Terauchi As the aging of global population gathers pace, needs for the treatment and prevention of dementia are increasing. We are conducting medicine creation projects focusing on tau, synapse microenvironment, neuro-inflammation hypothesis and so on, following BAN2401 and elenbecestat that are under development based on A $\beta$  hypothesis. By successfully developing these medicines, we would like to enrich treatment options for all disease stage for dementia, such as from prevention/pre-emptive medicine to treatment for severe stage. Possessing candidates with various concepts enable us to explore possibility of creating new value by combination use. Moreover, it is suggested that dementia, epilepsy and sleep disorder are potentially involved in disease onset of dementia. By leveraging research foundations and experience built through development of perampanel and lemborexant, we will advance projects in which synergies are expected.

A: Ogawa In neurology area, we pursue shortening clinical study period and improving probability of success by leveraging our knowledge and experiences cultivated over years. For instance, we formulate innovative study designs, such as using biomarkers at early stage of development, to advance the best development strategy for new projects with colleagues worldwide. In particular, we have knowledge and experiences based on the past clinical development of Aricept® for approved indications of mild, moderate and severe AD and for dementia with Lewy bodies. I am proud of the quantity and quality of contribution that we have made as a Japanese pharmaceutical company for global clinical studies. We currently strengthen clinical development in China among Asian countries to promote contribution to patients in a timely manner. Thus, we strive to continue to contribute to patients.

A: Tsuruoka In development of anticancer agent I am involved in, I constantly aim to submit in four global areas of Japan, the U.S., Europe and China at the same time. In the past, there were many cases





Business Base (ESG)

that development in Japan was behind that of the U.S. and Europe. In addition, as there have been difficulties in enrolling specified numbers of patients in China in global clinical studies, local clinical studies specifically for China submission, were conducted separately in the past. However, we accomplished simultaneous submission for Lenvima® in the four regions worldwide for the indication of hepatocellular carcinoma, by overcoming numerous difficulties. We continuously aim to submit at four global regions at the same time.

Currently, we are conducting first-in-human studies in Japan (Phase I study that a compound is administered to human for the first time in the world) in a number of projects. This is very meaningful to pursue simultaneous submission/approval at four global regions, and this is one of Eisai's strengths. Since Japan is the home ground to Eisai, physicians in Japan often give us suggestions and advices with warmth with the aim to develop new anticancer agents from Japan.

It is said that right medicine creation target, right patient, right dose, right timing and right evaluation are important for clinical studies to achieve success.

Going forward, utilization of Al (artificial intelligence) and other methods can be one of the directions in order to advance drug discovery with more subjective and precise manner.

"Period of frustration" we experience in the past, gave us valuable lessons. By consistently introducing new methods of clinical development, we strive to shorten the period for clinical studies and obtain highquality data in order to deliver new treatments to patients as soon as possible.

# **Human Capital**

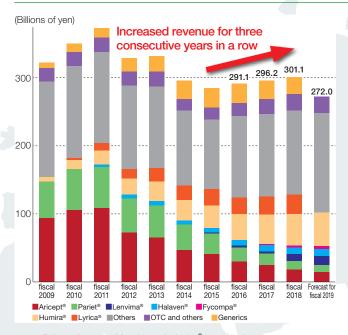
# Global Business Activities Marketing Activities

10-year transition of revenue in each region



Eisai is implementing marketing activities in each region, looking at regional characteristics. 10-year changes in business performance will be introduced in this section.

# Japan pharmaceutical business



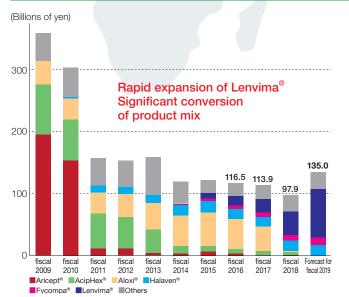
- \* Full year forecast of fiscal 2019 for Lyrica® is not disclosed
- \* Generic business was fully transferred to Nichi-lko Pharmaceutical Co., Ltd. in April 2019.
- \* Although consumer healthcare business was separated from Japan pharmaceutical business in the new segment in fiscal 2019, this section is described based on the segment in fiscal 2018 (consumer healthcare business, namely OTC and others from fiscal 2019, is included in Japan pharmaceutical business).

Japan pharmaceutical business achieved peak sales in fiscal 2011 with the expansion of Alzheimer's disease treatment Aricept® and proton-pump inhibitor Pariet®. However, it experienced decrease of revenue due to the loss of exclusivity for these two products (Pariet®: in 2010, Aricept®: in 2011). Rapid expansion of generics in the market and price revision, which is implemented every two years, also impacted the performance.

After years of stagnant growth, Japan pharmaceutical business got back to growth trajectory and achieved increase in sales for three consecutive years since fiscal 2016 with the growth of new branded products, such as in-house developed anticancer agents of Lenvima® and Halaven®, fully human anti-TNF- $\alpha$  monoclonal antibody Humira® and pain treatment Lyrica®.

Eisai strives for further growth of branded products, such as Lenvima<sup>®</sup>, even though a decrease in sales is forecasted for fiscal 2019 due to transfer of generic business and price revision.

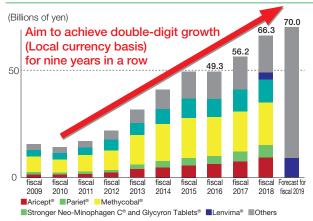
# **Americas pharmaceutical business (North America)**



Performance of business in the U.S., the biggest pharmaceutical market in the world, had declining drastically after loss of exclusivity for Aricept® in 2010. Additionally, loss of exclusivity for AcipHex® (product name of Pariet® in the U.S.) in 2013, and return of the marketing rights for antiemetic agent Aloxi® impacted on the performance. Yet, anticancer agent Halaven® and antiepileptic agent Fycompa® continue to grow steadily. Revenue of anticancer agent Lenvima® rapidly expanded in fiscal 2018 with the additional approval for hepatocellular carcinoma indication.

Eisai aims to achieve increase in revenue with the growth of Lenvima<sup>®</sup> in the U.S. in fiscal 2019.

# China pharmaceutical business



Management Strategies

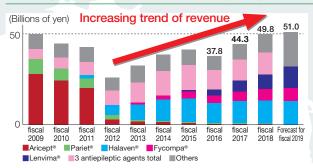
\* Full year forecasts of fiscal 2019 by products in China pharmaceutical business are not disclosed, except for Lenvima

Eisai's pharmaceutical business in China, particularly conventional drugs, such as peripheral neuropathy treatment Methycobal® and Aricept® are continuously growing even if their generic equivalents are already available on the market. In addition, Lenvima® has been launched in November 2018 and recorded 3.1 billion yen of revenue in 5 months.

Business Base (ESG)

New policies along with institutional reforms has accelerated new drug approval process in China, but further expansion of generics is also expected at the same time in China. Eisai aims to achieve double-digit growth for nine consecutive years (local currency basis) with rapid expansion of Lenvima® and stable growth of other products in fiscal 2019.

# EMEA pharmaceutical business (Europe, the Middle East, Africa and Oceania)

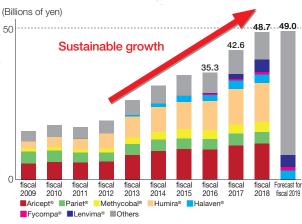


\* Full year forecasts of fiscal 2019 by products in EMEA pharmaceutical business are not disclosed, except for Halaven®, Fycompa® and Lenvima®

Performance has significantly declined after loss of exclusivity of two major products of Aricept® and Pariet® in 2012. Currently, the expansion of Halaven<sup>®</sup>, Fycompa<sup>®</sup> and Lenvima<sup>®</sup> are contributing to the increasing trend in revenue, in addition to the growth of three antiepileptic agents Zonegran®, Zebinix® and

Eisai seeks to achieve record-high revenue of 51.0 billion yen in fiscal 2019 with rapid expansion of Lenvima®.

# Asia and Latin America pharmaceutical business (primarily South Korea, Taiwan, Hong Kong, India, ASEAN, Central and South America)

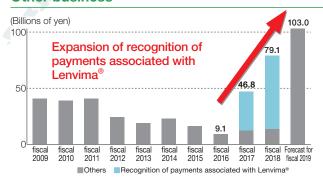


\* Full year forecasts of fiscal 2019 by products in Asia and Latin America pharmaceutical business are not disclosed, except for Halaven®, Fycompa® and Lenvima

Eisai's business in Asia is continuously growing, associated with the expansion of the pharmaceutical market along with economic development in each country. Growth of fully human anti-TNF-α monoclonal antibody Humira<sup>®</sup> is continuously growing, in addition to stable growth of Aricept®, Pariet® and Methycobal<sup>®</sup>, notwithstanding the generics already available on the market. Eisai seeks the opportunity to expand the inhouse developed products in Latin America through partnership with Grupo Biotoscana, which signed an exclusive licensing agreement with in 2017.

Although revenue growth is expected to be slowing down temporarily due to the scheduled return of marketing rights for Humira® scheduled in Taiwan in August 2019, Eisai strives for further growth with Lenvima®, Halaven® and Fycompa® to support sustainable growth in the future.

# Other business



Other business refers to the performance associated with income from licensing to parent company and business for active pharmaceutical ingredients (API). Revenue recorded in fiscal 2017 to fiscal 2018 included the recognition of payments from Merck & Co., Inc., Kenilworth, N.J., U.S.A. in association with strategic collaboration for Lenvima® (34.5 billion yen in fiscal 2017 and 65.5 billion yen in fiscal 2018). Expansion of recognition of payments is expected in conjunction with revenue growth of Lenvima® in fiscal 2019.

# **Intellectual Capital**

# **Special Feature**

# Rapid Growth of the China Business

Aiming for expansion of contribution to patients with new products, and further growth of China Business

**Yanhui Feng**Corporate Officer

President, Eisai China Holdings Ltd.
President, Eisai China Inc.



# **SWOT Analysis of China Business**

# **Strengths**

- 1. Establishment of a business foundation in China for more than 20 years
- 2. Adopted a management system that gives autonomy to local management in China
- 3. Strong growth in anticancer agent Lenvima® and collaboration with MSD\*
- 4. Achieved approval for anticancer agent Halaven<sup>®</sup>, and submitted New Drug Applications for antiepileptic agent Fycompa<sup>®</sup>

# **Opportunities**

- Acceleration of new drug approval process through system reforms by China's regulatory authorities
- Growth in low-tier markets (small and medium-sized cities in inland and regional areas as well as small and medium-sized hospitals) due to rising income levels, and the promotion of hierarchical diagnosis
- \* Merck & Co., Inc., Kenilworth, N.J., U.S.A., known as MSD outside of the United States and Canada

# Weaknesses

 Research and development functions in China consist only of clinical development, with no drug discovery research function

# **Threats**

1. Further market penetration of generic pharmaceuticals

# Q: Could you tell us about your career to the present and your approaches in the daily business?

**A:** I joined Eisai in 2012. Prior to joining Eisai, I built a nearly 20-year experience in sales and marketing fields, mainly at U.S.-affiliated pharmaceutical companies.

My philosophy is "Never give up." This means that no matter how challenging the circumstances are, I act with a strong awareness of achieving high

goals with great determination or bringing out the full strengths of the team.

I expect employees of Eisai China to work efficiently to produce results while avoiding long working hours. I myself try to finish work on time and enjoy dinner together with my family.

### Q: What initiatives have you taken up to the present to grow the business?

A: First, I initiated major changes to the training system for managers and medical representatives (MRs), who contribute to patients at the front lines. Based on an analysis of each person's skills, I transformed this system into customized training to eliminate disparities between the skills expected and the abilities presented by each individual. By revamping the system, I believe the sales skills of employees were significantly elevated. I also changed the incentive scheme which to better reward employees who have achieved good performance.

This has contributed to boost employee motivation.

On top of this, we utilize the comprehensive data analysis to seek more growth opportunities in the market. We analyze data such as market size and market share, and set goals according to each targeted medical institution and facility. Circumstances at the market front lines change every moment. For this reason, we give frontline managers the discretion to adjusting targets depending on the changes in the environments, in order to increase the accuracy of goal attainment.

# Q: How do you think is the Corporate Philosophy human health care (hhc) incorporated in the daily business at Eisai China?

A: Through a more than 20-year history of undertaking business in China, I believe that the employees of Eisai China are deeply familiarized with hhc. Socialization with patients through *hhc* programs represents the starting point of our daily business. Accordingly, hhc activities are incorporated into the performance targets of all employees, and organization managers take the lead in planning hhc activities. Such initiatives by Eisai China were commended in "hhc Initiative 2018," which reports on the outstanding activities of employees worldwide.

Let me introduce one example of our hhc activities. When launching the anticancer agent Lenvima®, we simultaneously implemented a patient assistance program (PAP) to reduce patients' self-payment burden when they purchase this drug. The origin of this program is socialization between employees and patients. Through the conversation with patients diagnosed with hepatocellular carcinoma (HCC), we re-confirmed that this is a disease with significantly

high unmet medical needs due to factors such as limited treatment methods and related information. and that patients have great concerns over continuing treatment while paying expensive treatment costs. In view of this, we changed the originally planned PAP scheme to further reduce the self-payment burden, thus maximizing our contribution to patients.

Business Base (ESG)



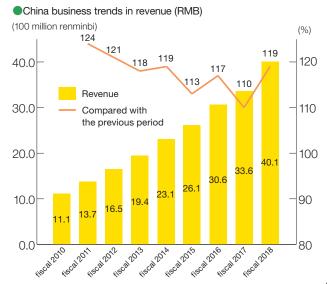
Socialization with patients with HCC held by the Eisai China employees prior to the launch of Lenvima®

# Q: Eisai China has achieved double-digit growth in sales (RMB basis) for eight consecutive years from fiscal 2011. Moreover, Eisai is one of the biggest in terms of sales volume among Japanese pharmaceutical manufactures operating in China. What do you think are Eisai China's strengths?

A: Our first strength is the management system that gives autonomy to local managements. This system was introduced in 2014 along with the establishment of the China Region. With the complete trust of the Head Office management, Eisai China's management has been delegated management-decision authority. This approach allows us to respond quickly to sudden market shifts and maintains the motivation of local management at an extremely high level.

The second strength is **our strong sales force**. As I explained earlier, the improvements we made to our training system and incentive scheme have helped raise employee capabilities and motivation. Furthermore, MR performance targets include

not only individual targets but also incorporate performance targets of Eisai China as a whole. By taking this approach, we are spreading a culture that aims for target attainment with all employees working in unison. I place great importance on our annual meeting as a venue where all sales teams can meet at one location. During this meeting, participants share the company targets and achievements as well as joy when attaining the targets. Thanks to this type of corporate culture, I sense that Eisai appears to be an attractive company in the eyes of employees within China's pharmaceutical industry.





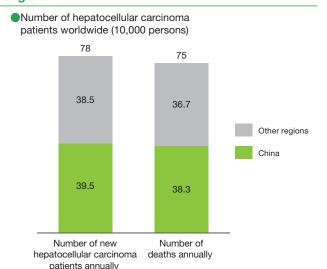
Presentation held by Feng at the Eisai China Fiscal 2019 Annual Meeting where all of the sales team gathered

# Q: In the five months since it was launched in November 2018, revenue of Lenvima® has soared to 3.1 billion yen. What are the factors for Lenvima®'s strong start?

**A:** Liver cancer is the third highest cancer-related cause of death in China. There are approximately 395,000 new cases and 380,000 deaths per year, accounting for **approximately 50% of cases worldwide.** 

The only existing treatment for unresectable hepatocellular carcinoma (uHCC) was sorafenib which was approved for that indication in 2008. Lenvima® thus became the first new therapeutic agent launched in China in approximately 10 years. As it has been almost seven years since we last launched an in-house product in China, and Lenvima® was to be the first in-house cancer agent in China, the entire company was buzzing with energy since before its launch.

On October 30, 2017, a New Drug Application (NDA) for Lenvima® was filed for the indication of HCC, and in December 2017, Lenvima® was designated for Priority Review. On September 4, 2018, Lenvima® was approved as a single agent for the treatment of patients with uHCC who have not received prior systemic therapy. Benefitting from reforms to the new drug approval procedures by China's regulatory authorities, we were able to obtain approval within the very short period of approximately 10 months after filing an application. I will discuss this in more detail later. In China, new drug manufacturing is possible only after obtaining approval, so in general much time is required from approval to product launch. To provide patients with Lenvima® as soon as possible, we proceeded with preparations in unison with relevant departments. This teamwork enabled us to launch Lenvima® on November 12, 2018, two months earlier than planned. Along with the launch, the simultaneous introduction of a PAP to reduce the economic burden on patients, and the commencement of collaboration with MSD enabled Lenvima® to get off to a strong start. Also contributing to the solid start was the recommendation of Lenvima® in two Chinese guidelines for HCC



\* Source: GLOBOCAN2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012, others

through the proactive medical activities prior to launch, as well as the sharing of best practices of HCC patients in Japan. Lenvima® has received good reputation from both patients and doctors, spurring growing calls for the listing on China's National Reimbursement Drug List (NRDL). We are making best efforts to provide even more patients with access to Lenvima® as quickly as possible.



Package of Lenvima® in China

# Q: Could you talk about promising new drugs following Lenvima®?

A: In July 2019, Halaven® was approved as a treatment for locally advanced or metastatic breast cancer. Eisai China has been marketing the breast cancer drug Fareston®\* from 2011 and has been building good relationships with breast cancer specialists for many years. Following the approval of Halaven®, we will promote thoroughgoing preparations to contribute to patients as quickly as possible.

Additionally, we have filed NDA for the antiepileptic agent Fycompa® for the indication

of adjunctive therapy for partial-onset seizures. In January 2019, Fycompa® was designated for Priority Review. I believe, with a novel action mechanism, Fycompa® can make a significant contribution to patients with epilepsy in China. The Neurology Team, which is currently in charge of marketing treatments for Alzheimer's disease and Parkinson's disease, will handle marketing for Fycompa®.

\* Eisai undertakes marketing and distribution in China through a comprehensive marketing agreement with Orion Corporation.

## Q: What areas do you consider are Eisai China's weaknesses?

A: Eisai China is achieving strong growth so it is hard to find weaknesses at this time. If there is any weakness though, I believe it is that R&D functions in China consist of only clinical development and we have no drug discovery research function.

Business Base (ESG)

# Q: Finally, could you describe Eisai China's opportunities and threats? China is undertaking major reforms of its healthcare system. How will this affect Eisai China?

A: I believe that China has huge potential.

Demand for new treatments is rising in tandem with an aging population and increase of diseases such as cancer and chronic diseases including diabetes. Responding to this situation, in recent years, authorities have undertaken reforms of the approval system for pharmaceuticals and others, beginning with the acceleration of new drug approval process. As part of these reforms, the Priority Review procedure was implemented with the aim of accelerating research, development and launch of new medicines with high-unmet medical needs, such as cancer, infectious diseases and pediatrics. Lenvima® and Fycompa® were designated for Priority Review due to their significant clinical benefits



compared with existing treatments. Under these system reforms, Lenvima® received approval within the short span of 10 months after NDA was filed. I believe these reforms will significantly benefit Eisai, which is a research and development based pharmaceutical manufacturer.

Pharmaceutical markets for large cities and large hospitals are now settling toward stable growth. In contrast, strong growth is expected in low-tier markets such as small and medium-sized cities in inland and regional areas as well as small and medium-sized hospitals.

At the same time, the Chinese government is implementing policies for improving quality and promoting the greater use of generic drugs. Eisai China's main products include the Alzheimer's disease treatment Aricept® and peripheral neuropathy treatment Methycobal<sup>®</sup>. However, numerous generic drugs have already been launched and so there is a possibility that those products could be replaced by the generic drugs along with the promotion of the government policies. Therefore, growth in new products such as Lenvima® is essential for Eisai China to sustain growth. The generic pharmaceutical company we acquired in 2015 is promoting projects for providing access for numerous patients, mainly in low-tier markets, by offering high-quality, low-priced generic pharmaceuticals in line with government policies.

Interviewer: Aiko Sakai, Investor Relations Department

# Briof history of Fisai China

	Brief filstory of Elsaf Griffia
1991	The Beijing Representative Office was established. Shenyang Eisai Pharmaceutical Co., Ltd. was established as a pharmaceutical manufacturing and sales subsidiary.
1994	$Methycobal^{\scriptscriptstyle{(\!0\!)}},$ a peripheral neuropathy treatment was launched.
1996	Eisai Suzhou Pharmaceutical Co., Ltd. was established as a pharmaceutical manufacturing and sales subsidiary.
1998	Construction of Suzhou plant was completed.
1999	Aricept®, a treatment for Alzheimer's disease was launched.
2010	Eisai (Suzhou) Trading Co., Ltd. was established as a pharmaceutical trading subsidiary.
2014	Eisai China Holdings Ltd. was established as a holding company. Shifted to autonomy management.
2015	Eisai (Liaoning) Pharmaceutical Co., Ltd. was established as a generic pharmaceutical company (by acquisition).

New Suzhou plant commenced full-scale operation. Lenvima®, an anticancer agent was launched.

# Overview of Eisai China

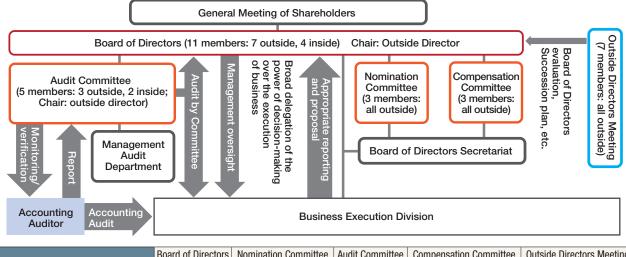
Number of employees	2,069 (as of the end of March 2019)
Number of medical representatives	Approximately 1,200 (as of the end of March 2019)
Major offices for medical representatives	Beijing, Guangzhou, Chengdu, Xi'an, Shenyang, Hangzhou, Qingdao, Tianjin, and Fuzhou
Major products	•Aricept®, a treatment for Alzheimer's disease •Stronger Neo-Minophagen C® / Glycyron® Tablets, liver disease / allergic disease treatment •Selbex®, a gastritis/gastric ulcer treatment •Pariet®, a proton-pump inhibitor •Fareston®, a breast cancer drug •Myonal®, a muscle relaxant •Methycobal®, a peripheral neuropathy treatment •Merislon®, a treatment of vertigo and balance disorder •Lenvima®, an anticancer agent

# **Corporate Governance System**

Management oversight functions and business execution functions have been clearly separated since fiscal 2004 in pursuit of fairness and transparency.

Eisai has pursued the best corporate governance practices and has remained committed to the improvement of governance.

- The Company has adopted a company with a nomination committee, etc., system.
- •The Board of Directors ("the Board") shall delegate to the corporate officers broad power of decision-making for business execution to the extent permitted by the laws and regulations, and it shall exercise the function of management oversight.
- The majority of the Board shall be independent and neutral outside directors.
- •The Representative Corporate Officer and CEO shall be the only director who is concurrently a corporate officer.
- ●To clarify the management oversight function, the positions of the Chair of the Board and the Representative Corporate Officer and CEO shall be separated and performed by different individuals.
- The Nomination Committee and the Compensation Committee shall be entirely composed of outside directors, and the majority of the Audit Committee shall consist of outside directors.
- The Chairs of the Nomination Committee, the Audit Committee and the Compensation Committee shall be outside directors.
- •The Outside Directors Meeting shall be established to ensure the effective function of the role of outside directors.
- •The internal control system and its operation shall be enhanced to ensure such as the credibility of financial reports.



		Board of Directors	Nomination Committee	Audit Committee	Compensation Committee	Outside Directors Meeting
N	umber of meetings held in fiscal 2018	11 times	8 times	12 times	6 times	8 times
	Attendance in fiscal 2018	100%	100%	100%	100%	100%

## Features of Eisai's Corporate Governance

# Clear Separation of the Functions between Oversight of Management and the Execution of Business

The central aspect of the Company's corporate governance is the clear separation of the oversight of management and the execution of business by fully utilizing the fact that it is a company with a nomination committee, etc., system.

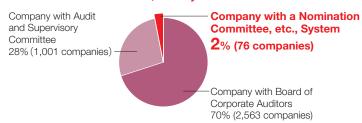
The Board of Directors with outside directors making up the majority is able to enhance the vitality of and devote its attention to management by entrusting a large portion of the decision-making authority over business execution to corporate officers to the extent permitted by laws and regulations. In accordance with the Companies Act, the Board of Directors has passed resolutions on rules for the Systems for Ensuring Proper Business Operations to establish specific internal controls that should be established and operated by corporate officers. In addition to the items set forth in the rules, corporate officers work to enhance and operate the internal controls within the scope of their responsibilities to secure autonomy and increase the speed and flexibility of business execution.

Under this structure, the Board of Directors also checks the status of execution of duties by corporate officers and inspects the appropriateness of the status of internal controls, such as the business execution and decision-making processes, from the perspectives of shareholders and society.

Furthermore, in order to achieve a clear separation between the oversight of management and the execution of business, the Company has established that the chair of the Company's Board of Directors be an outside director and that the Representative Corporate Officer and CEO be the only individual to concurrently serve as a corporate officer and a director.

#### Types of Board of Directors in Japan

# 2% of companies in Japan adopt a Companies with a Nomination Committee, etc. System



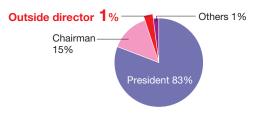
Management Strategies

Subject: 3,640 Tokyo Stock Exchange-listed companies (Aggregated data as of July 15, 2019) Source: "Officer-related survey 2019" IR Japan

#### Attributes of the Chair of the Board in Japan

Business Base (ESG)

## 1% of the Board of Directors in Japan is chaired by outside directors



Subject: 3,640 Tokyo Stock Exchange-listed companies (Aggregated data as of July 15, 2019) Source: "Officer-related survey 2019" IR Japan

# 2A Sustained, Autonomous Mechanism for Enhancement of Corporate Governance Centered on Outside Directors

The presence of 7 independent outside directors, who account for the majority of the Board of Directors, supports the effectiveness of the Company's corporate governance structure. As indicated in the diagram below, the Company has established and is operating a mechanism to enhance sustained, autonomous corporate governance centered on outside directors, including (1) a system of electing neutral and independent outside directors by a Nomination Committee, (2) operating the Board of Directors, etc., through the leadership of a chair who is an outside director, (3) an Outside Directors Meeting for broad discussion of corporate governance, including consideration of a succession plan, etc., and (4) corporate governance evaluations that drive the Plan-Do-Check-Act (PDCA) cycle of the Board of Directors and each committee. We will continue to work to enhance the content of each of those efforts.

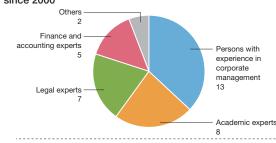
Composition of Eisai's outside directors in fiscal 2018

Persons with experience in corporate management: 3 Finance and accounting experts: 1 Legal experts: 1 Academic experts/Woman: 1 (Area of expertise: Audits/internal control)

Attributes of the 35 Eisai outside directors who were in office since 2000

(Area of expertise: Corporate governance)

Academic experts/Foreign national: 1



Of the 35 outside directors, 3 are women and 6 are of foreign nationality

## A Sustained, Autonomous Mechanism for Enhancement of Corporate Governance Centered on Outside Directors

- 1) The Nomination Committee consists of 3 members, all of whom are outside directors
- 2 Information on candidates is also collected from members of the Nomination Committee and all other directors and former outside directors of the Company
- 3 Candidates are narrowed down after screening for independence and presence of any competitive activities, etc.
- 4 After the order of priority of requests for appointment has been set, the Chair of the Nomination Committee (outside director) submits to candidates requests for acceptance of appointment

Outside director appointment system

Corporate

governance

evaluations

- The Chair of the Board of Directors is appointed from among outside directors
- 2The Chair of the Board of Directors proposes the Board of Directors agenda items for the year, annual themes, etc.
  - 3A week before meetings of the Board of Directors, there is a meeting with the secretariat and Head Office staff regarding the content of agenda items, materials, etc.

Chair of the Board of Directors (Outside director)

Outside

Meetina

**Directors** 

4 The Chair of the Board of Directors draws out knowledge from directors with diverse backgrounds, enhances the quality of the discussions among members of the Board of Directors, and manages Board meetings effectively and efficiently

- 1 Review of Corporate Governance Guidelines and internal control-related rules
- 2The Outside Directors Meeting compiles the results of evaluation of each director, and proposes them, including issues, to the Board of Directors
- 3 Resolutions are passed by the Board of Directors and disclosed in business reports, etc.
- 4 The PDCA cycle is driven by confirming, at Board meetings, implementation status in regard to issues, etc.
- 5 Reviews of Board of Directors evaluations are conducted by an outside organization once every 3 years

- 1) Matters are discussed freely, with only outside directors in attendance
- 2As necessary, the Board of Directors and corporate officers are asked to consider issues, share information, etc.
- 3Corporate governance evaluations (including the evaluations made by each director) are summarized and proposed to the Board of Directors
- 4 Information regarding the succession plan proposed by the CEO is shared

## Fiscal 2018 Efforts Related to Corporate Governance

## Dialogue with Outside Directors and Investors

Up to this point as well, the Company has conducted meetings between institutional investors and outside directors in Japan and overseas.

Outside directors visited multiple institutional investors and carried out dialogues with them between January and February 2018. A Meeting for Exchange of Opinions between Institutional Investors and Outside Directors was held in September 2018. All 7 outside directors attended to carry out dialogue with about 50 institutional investors.

Exchanges of opinion were carried out from various perspectives in regard to the Company's efforts related to corporate governance.

Furthermore, in response to requests from institutional investors, meetings for exchanging opinions have been carried out with the participation of several outside directors. The knowledge gained through such dialogue is used in the discussions held by the Board of Directors, etc. The Outside Directors Meeting has confirmed that outside directors will continue to carry out dialogue with investors in order to deepen mutual understanding of corporate governance efforts aimed at increasing corporate value.



Opinion exchange between institutional investors and outside directors

# Information Sharing and Discussion Regarding the Succession Plan

# View Regarding Selection of the Chief Executive Officer (CEO)

The Company positions the selection of the CEO as one of the most important decisions to be made by the Board of Directors. The CEO's duty is to exhibit strong leadership while also nurturing the next CEO. The Company believes that having outside directors participate in this process with such recognition and having them offer advice, etc., increases the objectivity of the CEO's proposal of successor candidates. It rationally ensures the fairness of the CEO selection process as the Board of Directors.

# Procedures Regarding CEO Selection

Even after becoming a company with a nomination committee, etc., system in 2004, discussions had been repeated under a consistently optimal corporate governance system regarding the CEO succession process. In fiscal 2016, with consideration given to the previous background, discussions were held at an Outside Directors Meeting on ideal information sharing by the Board of Directors in relation to a succession plan formulated by the CEO and preparations for unexpected situations, and succession procedures, etc., were set out as rules. The outline of the procedures are as follows.

- 1) Sharing of Information on the Succession Plan
  - (a) Information on the succession plan proposed by the CEO is shared 2 times a year at the Outside Directors Meeting.
  - (b) The CEO and inside directors also participate in this Outside Directors Meeting, and information on the succession plan is shared among all directors.
- 2) Discussion on the Succession Plan
  - (a) The criteria for evaluating candidates are expected to change in accordance with the business environment, etc. For this reason, criteria will be set appropriately when the CEO proposes candidates.
  - (b) The CEO will evaluate candidates on the criteria that has been set, and present evaluation results in the succession plan.
  - (c) Outside directors provide advice on the succession plan. The CEO considers the advice provided by outside directors, and reflects it in the succession plan as appropriate.

#### Preparations for Unexpected Situations

Circumstances, such as unforeseen accidents, that necessitate the sudden selection of a new CEO by the Board of Directors are also possible. Contingency plans for such unexpected situations are also confirmed when considering the aforementioned succession plan.

## **Corporate Governance Evaluation**

The effectiveness of the Board of Directors' management oversight function is evaluated each year at the Outside Directors Meeting. If any issues related to the operation of the Board of Directors, etc., are identified, a request and proposal for improvement are submitted to the Board of Directors and operational divisions. In the corporate governance evaluation, the status of the activities of the Board of Directors, etc., is inspected and evaluated based on the corporate governance evaluation carried out in the previous fiscal year, issues are identified for the next fiscal year, and improvement measures are presented, thereby implementing the Plan-Do-Check-Act (PDCA) cycle. Beginning in fiscal 2017, we have an outside organization review our processes and results once every 3 years to ensure the appropriateness and suitability of corporate governance evaluations on a continued and periodical basis.

70

# **Fiscal 2018 Corporate Governance Evaluation Results**

With regard to the Corporate Governance Guidelines and Internal Control Regulations, no evidence was found of any operation, etc., that deviates from the rules. It was confirmed that the directors and corporate officers, etc., are executing their duties appropriately to improve corporate governance. In regard to the Board of Directors evaluation, the state of response in fiscal 2018 to the issues identified in the fiscal 2017 Board of Directors evaluation as issues for fiscal 2018 was checked and evaluated, and the issues, etc., for the next fiscal year were recognized. Some of the major issues identified are listed below.

# Major issues identified for fiscal 2019 relating to the roles, proceedings etc. of the Board of Directors through the evaluation

- •In regard to the selection of proposals, it is necessary to continue to take up medium- to long-term business issues and risks faced by the Company in a timely manner for discussion at Outside Directors Meetings and elsewhere.
- •The succession plan will continue to be developed by implementing the Plan, Do, Check, Act (PDCA) cycle. Outside directors must strive to obtain a deeper understanding of the evaluation of each candidate through efforts such as meeting the candidate in person to assess his or her character.
- •It was found that the Board of Directors must recognize important risks that need to be overseen by the Board of Directors from among the wide range of risks identified by corporate officers, and receive periodic reports from corporate officers on the actions taken to prepare for and respond to those risks, and on how the impact and probability of occurrence have changed.
- \* For the further information regarding the corporate governance review, please refer to pages 48-56 of the Notice of Convocation of the 107th Ordinary General Meeting of Shareholders: ▶ https://www.eisai.com/ir/stock/meeting/pdf/einv107 all.pdf

## **Compensation for Directors and Corporate Officers**

Compensation paid to directors is only a fixed base compensation. The duty of directors is to supervise management, and a fixed rate not incorporating performance-based compensation is used to ensure that directors are able to properly perform their oversight functions. The level is intended to be set at the upper middle range for the industry.

The compensation paid to the corporate officers is made up of base compensation, bonuses and stock-based compensation at a ratio of 6:3:1, and performance-based compensation accounts for 40% of total compensation.

Fixed compensation

Performance-based compensation

Compensation Paid to Corporate Officers

Base compensation Bonuses (60%) Stock-based compensation (30%) Stock-based compensation (10%)

The stock-based compensation system, a medium- to long-term incentive plan, was introduced in fiscal 2013. Stock-based compensation involves providing corporate officers with stocks on an annual basis through a trust in accordance with the degree of achievement of company-wide performance objectives. The system motivates the corporate officers to share profit awareness based on the same perspective as that of the shareholders, and to remain aware of performance and stock prices in executing their duties from a medium- to long-term perspective.

The amounts of bonuses provided to corporate officers are calculated in accordance with the degree of the achievement of company-wide performance goal and the corporate officers' performance objectives.

The degree of the achievement of company-wide performance objectives is determined after reviewing consolidated revenue, consolidated operating profit, consolidated profit for the year (attributable to the parent company) and consolidated ROE.

The average rate of bonus payment to corporate officers was 115% in fiscal 2018, because the degree of attainment of Company-wide performance objectives was 107% and the average degree of attainment of individual performance objectives was 107%.

The average rate of stock-based compensation was 107% in fiscal 2018, because the degree of attainment of Company-wide performance objectives was 107%.

	Targets	Results	Degree of attainment	, ,
Consolidated revenue	632.0 billion yen	642.8 billion yen	102%	
Consolidated operating profit	86.0 billion yen	86.2 billion yen	100%	107%
Consolidated profit for the year	57.5 billion yen	63.4 billion yen	110%	107%

-	Bonus payments to Corporate Officers in fiscal 2018
	Basic bonus
٦	×107% (degree of attainment of Company-wide performance objectives)
	×107%*(degree of attainment of individual performance objectives)
	=Basic bonus×115%
	*The degree of attainment of individual performance objectives is determined in a range of 0 to 150%.
	Stock-based compensation in fiscal 2018
	Base number of shares
	×107%(degree of attainment of Company-wide performance objectives)

- \*For details of the compensation system for corporate officers please refer to pages 62-69 of the Notice of Convocation of the 107th Ordinary General Meeting of Shareholders: https://www.eisai.com/ir/stock/meeting/pdf/einv107 all.pdf
- \* Please refer to the corporate website for details about Eisai's Corporate Governance Guideline, the Rules of the Board of Directors, the Rules of the Nomination, Audit and Compensation committees, the Corporate Governance Report and Policy for Protection of Company's Corporate Value and Common interests of Shareholders: https://www.eisai.com/company/governance/index.html

# **Interviews with Outside Directors**

Members of the IR Department ask about the opinions of seven outside directors who support the effectiveness of Eisai's corporate governance.

Date of birth (age) and number of years served as a director are as of June 20, 2019.

# Taking Advantage of the Diversity of Outside Directors to Oversee Management

## Yasuhiko Katoh

Position: Chair of the Board of Directors, Member of the Independent Committee of Outside Directors Date of birth (age): May 19, 1947 (72 years of age)

Served years: 3

Concurrent position: Senior Advisor, Mitsui E&S Holdings

Co., Ltd.

Three years have passed since assuming my duties as an Eisai outside director. I became acquainted with an Eisai director in autumn 2014, when I was serving as Representative Director and Chairman of Mitsui Engineering & Shipbuilding Co., Ltd. (currently Mitsui E&S Holdings Co., Ltd.), and this led to my becoming an Eisai director. I was asked to serve as an Eisai outside director one year later. I had no previous contact with Eisai and met Mr. Naito, CEO of Eisai, for the first time after accepting the request from the Chair of the Nomination Committee (outside director).



After becoming an Eisai Director, one aspect of Eisai that truly impressed me was seeing that the corporate philosophy was deeply instilled in all employees and being put into practice. When we outside directors visited research laboratories, sales bases and plants, I could really sense that each and every employee seriously thought about what he or she should do on their own to realize this corporate philosophy.

#### What I Strive for as Chairman of the Board of Directors

I began serving as Chairman of the Board of Directors from fiscal 2018. I focus on fully leveraging the respective strengths of the seven outside directors, who come from different backgrounds in terms of their expert knowledge, experience and other areas. At the Board of Directors, I do everything I can to encourage directors to voice a diversity of opinions in undertaking discussions. Eisai has also set up the Outside Directors Meeting composed of entire outside directors. At this meeting, we engage in wideranging discussions on topics concerning governance and business. Through this type of framework, outside directors are able to deepen their mutual understanding and this encourages the members to further express their opinions freely.

# Unceasing Efforts to Improve Corporate Governance

I believe Eisai's governance framework and its operation are superb. A particularly outstanding feature is that prior to the convening of the Board of Directors, the Board of Directors Secretariat provides sufficient pre-explanations individually. This helps



the Board to commence discussions immediately on the day of the meeting and leads to efficient discussions. However, it is crucial for directors to work continuously for improvements by rotating the Plan-Do-Check-Action (PDCA) cycle for a variety of issues that are identified through the once-per-year evaluation of the Company's corporate governance system without being satisfied with the status quo.

Additionally, we regard risk management as an extremely important issue in executing bold and quick business activities and in promoting new business models. Besides monitoring the state of business execution for the attainment of targets by corporate officers, the Board of Directors must also ascertain important issues and risks within the areas of its responsibilities and reliably oversee management.

# ■Succession Plan

All directors commonly recognize that the succession of the CEO is one of the important business issues. In fiscal 2017, the Outside Directors Meeting formulated operational rules of the succession plan. Based on these rules, we share and carefully examine the succession plan submitted by the CEO twice a year. There are multiple opportunities for outside directors to meet those candidates in the succession plan, such as at a meeting of the Board of Directors. We provide advice to the CEO based on the information, etc., gained through such opportunities. Outside directors are deeply committing to the process of upbringing a successor by the CEO, which reasonably ensures the fairness of the Board of Directors to nominate the CEO. We believe that developing and operating these mechanisms is what supervision is about.

Interviewer: Koshiro Takei, Investor Relations Department

### **Implementing Proactive Risk Management**

### Tamaki Kakizaki

Position: Member of the Audit Committee, Member of the Independent Committee of Outside Directors Date of birth (age): January 16, 1961 (58 years of age)

Served years: 3

Concurrent positions: Professor, School of Law, Meiji

University

Outside director, Mitsubishi Shokuhin

Co., Ltd.

Outside corporate auditor, Japan Airport Terminal Co., Ltd.

I became an Eisai outside director after attending a Corporate Group Internal Control study workshop together with an Eisai employee. Prior to that time, I had no experience in serving as an outside director. I received the request to serve as a director and I decided to accept the position, thinking that all my research to date on corporate law (the Companies Act) and internal control could be put to good use in practical business.

This is my fourth year as an Eisai director. I am always aware of my standpoint as an independent outside director and work to "perform oversight of business execution from an external viewpoint." The Audit Committee to which I belong is comprised of outside directors possessing expertise and experience in the fields of finance, accounting, law, auditing and internal control, as well as internal directors who have a wealth of in-house experience. Leveraging the diverse expertise and knowledge of Audit Committee members, we make efforts to undertake discussions to go one-step further to root causes to correct any problems, transcending boundaries of auditing.

### Features of Eisai's Corporate Governance

The majority of Eisai's directors are independent outside directors and the Board of Directors is comprised of directors from a diversity of backgrounds. I believe the particularly notable features of Eisai's governance are the extremely high quality of discussions at the Board of Directors in addition to the outstanding openness among directors. It is extremely important to assure opportunities for each director to candidly express their opinions from a variety of viewpoints at the Board of Directors Meeting, and there is even a move in the United States to make this a law. Furthermore, Eisai stands out in terms of the quality and quantity of information provided in advance to outside directors concerning the Board of Directors, and this gives me a sense of Eisai's deep enthusiasm for enhancing governance.



Business Base (ESG)

### ■ Enhancing Our Risk-based Approach to Management

In the future, I would like to further enhance Eisai's risk-based approach to management. In implementing compliance and "proactive risk management" that pick off the buds of any misconduct beforehand as a global company, it is crucial to raise the risk sensitivity of corporate officers continually. Therefore, as an outside director I will pursue initiatives for continuous improvements in the future. These efforts will extend beyond only questioning the risk awareness of corporate officers and will include requiring reports that contain measures for countering risk.

### ■Initiatives for Engagement with Shareholders and Investors

Since 2018, Eisai's outside directors have been promoting dialogue with institutional investors. By providing clear and adequate explanations, I personally have the sense that we have gained a certain degree of understanding from shareholders and investors. In the future, I would like to continue exchanging opinions and promoting deeper mutual understanding across a wide range regarding a variety of themes concerning corporate governance for the enhancement of Eisai's corporate value.

Interviewer: Aiko Sakai, Investor Relations Department

# Aiming for Best Practices for Dialogue between Outside Directors and Shareholders and Investors

### Daiken Tsunoda

Position: Chair of the Independent Committee of Outside Directors, Member of the Audit Committee

Date of birth (age): January 29, 1967 (52 years of age)

Served years: 3

Concurrent positions: Partner, Nakamura, Tsunoda &

Matsumoto (Law Firm)

Outside Director, Culture Convenience

Club Co., Ltd. (unlisted)

Besides any other reason, I guess that a proximate reason why I became an Eisai director is because a partner at my law firm was previously an outside director at Eisai. When I was asked to serve as director, I knew the Chair of the Nomination Committee via business ties at the time, but I had never met with Mr. Naito, CEO of Eisai, and there was almost no acquaintance with other related persons.

After assuming the duties of director as well as from the standpoint of a legal expert specializing in company law, I place most attention on the appropriateness of procedures for exercising duty of care as a director. In other words, this focuses on "whether the company's decision-making is executed in accordance with proper procedures and processes that can be frankly explained to a variety of stakeholders."

### **Continuous Enhancement of Corporate Governance**

The awareness of corporate governance throughout the world changed along with the introduction of the Stewardship Code and the Corporate Governance Code, and then the quality of governance of Japanese companies increased rapidly. I believe that as Eisai is a top runner in corporate governance, it is important for the company not only to maintain confidence in initiatives implemented up to now but also to re-evaluate its current structure and its operation constantly and put them on track for improvement.

### Initiatives for Succession Plan

The strong leadership of the CEO is the wellspring of Eisai's growth. For this reason, I believe the selection of the next CEO is the most crucial management issue for the Board of Directors and one essential decision-making matter. Outside directors provide advice on a succession plan proposed by the CEO who then considers this advice and suitably reflects this in the succession plan. The steady involvement of outside directors in the nurturing and selection of a successor in this manner can ensure the fairness of the CEO selection.



## ■The Importance of Dialogue with Shareholders and Investors

From last year, outside directors have begun focusing on initiatives for dialogue with shareholders and investors. We established venues for dialogue with approximately 50 shareholders and investors that included the participation of all seven outside directors. We also visited institutional investors individually for repeated interviews. I hope to position these types of dialogue between shareholders and investors and outside directors as a Best Practice of a leading runner in corporate governance.

Some institutional investors expressed opposing opinions to our "Policy for Protection of the Company's Corporate Value and Common Interests of Shareholders (Response Policy)." I believe these opposing opinions arose because of our explanation of the Response Policy being insufficient, so we have made efforts to provide more clear explanations.

I am keenly aware of the importance of outside directors proactively engaging in dialogue and building bonds of trust with investors. Going forward, without restricting ourselves to the Response Policy, we will continue our active dialogue over the long term regarding a variety of themes concerning governance toward the enhancement of Eisai's corporate value.

Interviewer: Kyoko Yoshizawa, Investor Relations Department

### **Promoting the Further Globalization of Corporate Governance**

### **Bruce Aronson**

Position: Chair of the Compensation Committee, Member of the Nomination Committee, Member of the Independent Committee of Outside Directors Date of birth (age): May 14, 1952 (67 years of age)

Served years: 2

Concurrent positions: Affiliate Scholar, U.S.-Asia Law Institute, New York University School of Law, Visiting Researcher, Musashino Institute for Global Affairs, Musashino University, Research Associate, Japan Research Centre, SOAS University of London

Management Strategies

I learned that Eisai was an outstanding company in corporate governance while I was in the process of promoting research on corporate governance at a university. Although I was not acquainted with anyone at Eisai, I eventually assumed the duties of Eisai director after being recommended by a person affiliated with the university who previously served as an Eisai outside director.

### ■ Discussions on Executive Compensation from a Global Perspective

This is my third year as an outside director, and last year I began serving as Chair of the Compensation Committee. I am keenly aware of taking a global perspective when engaging in discussions on executive compensation systems. There are differences in executive compensation systems and levels in each country, including in the United States, Europe, and China and other Asian countries. For example, the level of executive compensation in the United States is approximately 10 times that of Japan. I recognize that for Eisai, which undertakes business globally, the question of how we should build a compensation governance framework in response to such circumstances is a crucial issue that the Compensation Committee is facing.

Meanwhile, we have incorporated performancebased stock compensation (bonuses and stock compensation) into our executive compensation system and have set the consolidated performancebased compensation ratio at 40% of total compensation. Regarding this point, some institutional investors have suggested that we should raise the consolidated performance-based compensation ratio. In the future as well, we will consider the appropriate form of our executive compensation system from a variety of perspectives.

Revisions to laws and growing social debate are being accompanied by demand for transparency of executive compensation and the disclosure of details. Eisai's Compensation Committee makes proposals for disclosure of executive compensation, including the compensation system and decision-making process of performance-based compensation, every year in business execution departments. Going forward, we will enhance disclosure for further improving fairness and transparency in deciding compensation and thereby fulfill accountability to Eisai's stakeholders.



Business Base (ESG)

### ■Globalization of Corporate Governance

Eisai's governance has several strong points. I feel the most outstanding feature is that the CEO and other corporate officers possess a mindset for accepting the candid opinions and recommendations of outside directors. I believe this feature is the reason outside directors can execute their roles and duties with a sense of fulfillment and responsibility.

Thinking of corporate governance from a global perspective is also important for Eisai as a company that carries out its business globally. It is necessary to pay close attention to risks that could emerge in each country where regulations and business environments differ. Therefore, as the only foreign-national outside director, I seek to provide opinions and suggestions based on perspectives and ways of thinking from overseas countries, such as the United States. Also, I am making efforts to increase opportunities more than ever before for listening to the direct opinions of overseas corporate officers.

### Perspective of the Company's Social Responsibilities

Through my contact with employees at workshops and visits to business sites, I can sense that the hhc philosophy is deeply embedded in the minds of employees and that there are an extremely large number of highly motivated employees. Recent years have witnessed wide-ranging demands for reforms of working styles and promoting advancement of women in the workplace. The Board of Directors will resolutely undertake discussions on initiatives toward diversity and improving workstyles with the aims of raising company productivity and employee job satisfaction.

Multifaceted perspectives are essential for the oversight of management by the Board of Directors, and as a global company with social responsibilities we will address an array of issues beginning with initiatives toward ESG and the SDGs.

Interviewer: Koshiro Takei, Investor Relations Department

### Aiming for the Optimal Structure of the Board of Directors

### Shuzo Kaihori

Position: Chair of the Nomination Committee, Member of the Compensation Committee, Member of the

Independent Committee of Outside Directors **Date of birth (age)**: January 31, 1948 (71 years of age)

Served year: 1

Concurrent positions: Advisor, Yokogawa Electric Corporation Outside Director, HOYA CORPORATION

At the time I was serving as the Chairman of the Board of Yokogawa Electric Corporation, I was introduced to Eisai by an acquaintance and subsequently became an Eisai outside director.

I currently serve as an outside director at another company besides Eisai. That said, using politics as an example, I realize the importance of speaking out from the standpoint of an opposition party. Leveraging my experience as a former corporate management, I am aware of pointing out matters, regardless of how small they are, that could burgeon into risk as I work to oversee the execution of management.

## ■ Considering the Optimal Configuration of the Board of Directors

I currently serve as Chair of the Nomination Committee. I will strive to increase both the depth and breadth of the Board of Directors' management oversight functions through frank discussions by the outside directors who possess different experience and backgrounds. I believe there is much value in actually discussing numerous matters at venues where a variety of knowledge can be expressed.

The Nomination Committee assumed the heavy responsibility of making proposals to the Board of Directors about the Board's optimal configuration. This fiscal year, the Nomination Committee has identified two important discussion themes, namely the "appropriate term of office for outside directors" and "diversity of the Board of Directors." We will undertake fundamental debate while taking into consideration matters such as investor opinions asking, "Isn't the term of office of outside director too short?" Additionally, even though it is important that the Board of Directors is composed of diverse human resources with different backgrounds in terms of expert knowledge and experience, that alone is still insufficient. Undertaking global activities is accompanied by a variety of risks. Therefore, I believe that besides having diversity, the Board of Directors must also possess the qualities and abilities to identify this type of risk from various angles.



### **CEO Succession Plan**

The selection of the CEO is a matter for resolution not by the Nomination Committee but by the Board of Directors. For this reason, information on the CEO Succession Plan is shared among all members of the Board of Directors. Specifically, the CEO proposes and explains the current evaluation and situations of multiple candidates. In the future, besides undertaking discussions concerning the nurturing and evaluation of successors, I believe that we must also discuss matters such as structures within the operational departments and in the Board of Directors to ensure a seamless succession.

## Importance of Balancing Risk Taking and Investments

Besides risk associated with the success or failure of drug discovery that requires huge amounts of R&D investments, pharmaceutical companies also face numerous risks associated with many regulations compared to other industries. The importance of product quality and information management as well as data integrity is extremely high and utmost attention is essential in undertaking business activities.

When I once considered the spin-off of the medical system business while serving for the previous company, and so I painfully experienced the severity of regulations concerning the handling of data and information in the medical field. In new businesses Eisai is pursuing in the field of dementia, we need to make investments for obtaining new knowledge in the data business while collaborating with insurance companies and local governments. I believe we will need to carry out management that pays more attention than ever before on balancing risks and investments.

Interviewer: Kyoko Yoshizawa, Investor Relations Department

### **Employees Are the Foundation of Company**

### Ryuichi Murata

Position: Member of the Nomination Committee, Member of the Compensation Committee, Member of the Independent Committee of Outside Directors Date of birth (age): April 12, 1948 (71 years of age)

Served year: 1

Concurrent positions: Senior Advisor, Mitsubishi UFJ Lease &

Finance Company Limited Audit & Supervisory Board Member (Outside), NORITAKE CO., LIMITED Outside Director, Kintetsu Group Holdings Co., Ltd.

Management Strategies

I was asked to serve as an Eisai outside director probably because I met the "Requirements for the Independence and Neutrality of Outside Directors" as a person with management experience at a financial institution at the time when Eisai was considering the diversity of its Board of Directors. I assumed the position as an Eisai director after becoming an Advisor to the Board at Mitsubishi UFJ Lease & Finance Company Limited, which was nine years after retiring as a board member at MUFG Bank, Ltd.

### The Role of Outside Directors

The Board of Directors must continually verify whether the company is formulating and executing strategies that can respond to the all changes of global circumstances and the times. The Board has the responsibility for oversight regarding whether important matters are being decided and executed from a long-term perspective in accordance with proper procedures.

Turning to risk management, in the previous fiscal year I proposed the mapping of all potential risks faced by Eisai using the dual axes of "probability of occurrence" and "impacts" and that monitoring be undertaken periodically by the Board of Directors. Upon making this proposal, a report came out immediately. One of the most important roles of Director is to recognize risk and the impact when it occurs.

The pharmaceutical industry is witnessing intense change and competition, and accordingly, we must consider all options such as business alliances, corporate acquisitions. For this reason, the Board of Directors must also adequately pay attention to an appropriate capital structure and financial strategies to take such opportunities.



Business Base (ESG)

### **■**Considering the Feelings of Employees

I resonate with "Yumeshichikun" said to be the motto of Japanese industrialist Eiichi Shibusawa. These teachings begin with, "Those without dreams have no ideals", and this ties in with, "Those who pursue happiness are therefore not without dreams". For a company, increasing revenue and profit, dividends and ROE are of course important. Above that, I think what is ideal is that all employees are with their dreams. I have opportunities to meet Eisai's employees during visits to research laboratories and business sites and at workshops. Each time, I truly have an admiration in perceiving that Eisai's corporate philosophy is deeply ingrained in employees. I will further increase contact with employees in the future, and ensure we all possess dreams together toward the realization of the medium-term business plan 'EWAY 2025'. The foundation of Company is employees. I will contribute to the creation of Company where employees can keep working with dreams without hesitation whatever happens to the company.

At a time when I was making efforts to ensure the smooth operation of businesses and employees as a bank branch manager, I encountered the words of Buddhist monk Dengyo Daishi Saicho, "Light up a corner. Those who light a corner are national treasures." In the same manner that each person continually making efforts is a national treasure, Eisai's treasure is employees. I will keep playing my role caring the mind of employees in every scene, every

Interviewer: Kyoko Yoshizawa, Investor Relations Department

### Not Overlooking Indications of Major Risks That Lurk Within Small Signs

### Hideyo Uchiyama

Position: Chair of Audit Committee, Member of the Independent Committee of Outside Directors

Date of birth (age): March 30, 1953 (66 years of age)

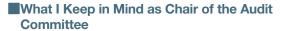
Served year: 1

Concurrent positions: Executive Advisor, ASAHI Tax

Corporation

Audit & Supervisory Board Member (Outside), OMRON Corporation Audit & Supervisory Board Member (Outside), Sompo Holdings, Inc.

I became an Eisai outside director through a connection with a former Eisai outside director who I knew well through The Japanese Institute of Certified Public Accountants and so on. I had absolutely no contact with Eisai until I was sounded out about serving as a director.



Eisai's stakeholders encompass society as a whole and include shareholders, investors and patients. Accordingly, I pay attention to overseeing business execution not just from the perspective of my own specialized field of accounting and management, but also from my standpoint as the representative of a diversity of stakeholders. In auditing, it is crucial not to overlook indications of major risk that lurk within small signs. We engage in open-minded discussions about whether Eisai's frameworks are suited to contemporary society and whether the results of internal audits are proper, and as Chair of the Audit Committee I cite points for improvement. For example, not to mention the importance of work style reform, I believe we need to consider optimal measures and methods that allow each employee to fully exert his or her strengths. To obtain important results in R&D, which is the paramount theme for pharmaceuticals companies, it might be necessary to make investments in relevant departments to realize even more finely tuned working environments.

### ■ Refining Corporate Governance

One key facet of Eisai's governance I believe is that the Chair of the Board of Directors is an outside director. Rather than discussions with foregone conclusions, I truly feel that proper decisions are made after opinions are expressed from a variety of perspectives and adequate discussion is undertaken based on each respective director's expertise, knowledge, experience and governance perspectives. The Outside Directors Meeting comprised only of outside directors is yet one other distinctive feature. The Outside Directors Meeting is convened 7-8 times per year. At this meeting, we share information with corporate officers regarding themes concerning business activities, the business environment and risk



and undertake deep discussions about corporate governance. This meeting provides an environment that facilitates mutual communication among outside directors and helps fostering a sense of solidarity and sense of mission that can be called Team Eisai.

However, we must always be mindful that everything faces the possibility of falling into a rut, becoming a mere façade and deteriorating. Therefore, the Outside Directors Meeting evaluates the effectiveness of the Board of Directors once per year. I believe these evaluations are desirably implemented each time the Board of Directors convened, and the PDCA cycle is driven immediately when there is an issue. I would like to see this continued in the future.

### ■Activities I Wish to Focus on as a Director

Last year I participated in Socialization Programs in which we spend time with patients. This is an extremely meaningful opportunity that enables the implementation of Eisai's corporate philosophy to be experienced directly. I hope to actively participate in such programs in the future and cherish the perspectives of patients. As the secretary of the Certified Public Accountant Outside Directors Network, in November 2018, I served as moderator of a discussion panel entitled "Roles of Independent Outside Directors in Contributing to Corporate Value Improvement." At this discussion, I introduced case examples from Eisai. People there evaluated that Eisai's governance is well established in terms of structure and operation. As an Eisai outside director. I would like to make Eisai's initiatives toward governance widely known throughout the world and also be useful in improving the governance of Japanese companies as a whole. If the opportunity arises, I wish to actively introduce the activities of a front-runner in corporate governance. Interviewer: Koshiro Takei, Investor Relations Department

### Corporate Executives (As of July 31, 2019)

Management Strategies

### **Directors**

Representative Corporate Officer and CEO

### Haruo Naito

Chair of the Board of Directors Member of the Independent Committee of Outside Directors

### Yasuhiko Katoh

Member of the Audit Committee

### Hirokazu Kanai

Member of the Audit Committee Member of the Independent Committee of **Outside Directors** 

### Tamaki Kakizaki

Member of the Audit Committee Chair of the Independent Committee of Outside Directors

### Daiken Tsunoda

Member of the Nomination Committee Chair of the Compensation Committee Member of the Independent Committee of Outside Directors

### **Bruce Aronson**

### Yutaka Tsuchiya

Chair of the Nomination Committee Member of the Compensation Committee Member of the Independent Committee of Outside Directors

### Shuzo Kaihori

Member of the Nomination Committee Member of the Compensation Committee Member of the Independent Committee of Outside Directors

### Ryuichi Murata

Business Base (ESG)

Chair of the Audit Committee Member of the Independent Committee of Outside Directors

### Hideyo Uchiyama

Member of the Audit Committee

### Hideki Hayashi

### **Corporate Officers**

Representative Corporate Officer and CEO

### Haruo Naito

Representative Corporate Officer, COO and Industry Affairs Industry Affairs China Business Data Integrity

### Yasushi Okada

Executive Vice President General Counsel Intellectual Property

### Kenta Takahashi

Executive Vice President Chief Financial Officer Chief IR Officer

### Ryohei Yanagi

Senior Vice President Chief Medical Officer Global Safety Board Chair

### **Edward Stewart Geary**

Senior Vice President President, EMEA Region Chairman & CEO, Eisai Europe Ltd.

### **Gary Hendler**

Senior Vice President President, Oncology Business Group

### Terushige like

Senior Vice President President, Neurology Business Group President, Americas Region Chairman & CEO, Eisai Înc.

### Ivan Cheung

Senior Vice President President, Eisai Japan

### Hidenori Yabune

Senior Vice President Chief Clinical Quality Officer Chief Product Quality Officer Global Product Emergency Management

### Hiroyuki Kato

Vice President

Chief Medicine Creation Officer, Oncology Business Group Chief Discovery Officer, Oncology Business

### Takashi Owa

Vice President

Chief Clinical Officer, Neurology Business Group Chief Medical Officer, Neurology Business Group

### Lynn Kramer

President, Asia and Latin America Region

### Sayoko Sasaki

Vice President Chief Compliance Officer Internal Control

### Junichi Asatani

Vice President President & COO, Eisai Inc.

### Shaji Procida

Vice President Chief Discovery Officer, Neurology Business Group

### Teiji Kimura

Vice President

General Affairs, Environmental and Safety Affairs Japan Subsidiaries

### Masayuki Miyajima

Vice President Global Partnership Development

### Tatsuyuki Yasuno

Vice President President, Eisai China Holdings Ltd. President, Eisai China Inc.

### Yanhui Feng

Vice President President, Eisai Demand Chain Systems

### Yoshiteru Kato

Vice President Chief Planning Officer

### Mitsuaki Tanaka

Vice President President, Consumer hhc Business Division API Solutions

### Shohei Kanazawa

Vice President Corporate Affairs Global Value & Access

### Masatomi Akana

Vice President Chief Medical Officer Japan and Asia

### Hiroyuki Kobayashi

Vice President Head of Medicine Development Center

### Akiko Nakahama

Vice President Chief Strategy Officer

### Kazumasa Nagayama

Vice President Chief Talent Officer

### Yosuke Akita

Vice President Chief Data Officer Head of Tsukuba Research Laboratories

### Kappei Tsukahara

Vice President

Deputy President, Eisai Japan

### Hiroyuki Murayama

Vice President Chief Digital Officer Dementia Total Inclusive Ecosystem

### Keisuke Naito

## **Partnerships**

Aiming to Improve Business Efficiency and Productivity and Promptly Maximize Contribution to Patients by Leveraging Global Partnerships



\* Details of the agreements below are as of the end of June 2019.

### Significance of Partnership in Value Chain for Pharmaceutical Industry

### **Medicine Creation**

- Potentially enhance the probability of success, accelerate development, and accumulate experience and knowledge through joint development with partners with various experience and know-how
- Create opportunities by acquiring the rights to develop promising compounds
- Enhance efficiency by sharing cost for the development with partners

### Manufacturing

- Increase in the volume to be manufactured and enhance the rate of operation of own manufacturing sites by expanding the market through strategic collaboration with partners
- Establish optimal supply structure by utilizing not only in-house manufacturing technology/ facility, but also ones which partners have

### Marketing

- Rapid expansion and accumulate marketing experience of products through co-promotion with partners with various experience and knowhow
- Create opportunities by acquiring sales rights of promising products
- Improve access to medicine by expanding the areas for product sales
- Enhance efficiency in commercialization cost by sharing with partners

Enhance efficiency and productivity in business

Earlier maximization in contribution to patients

### Partnerships aimed at creating innovation in neurology area

Partner	Product/Compound	Region	Purpose			
Arena Pharmaceuticals, Inc. (U.S.)	Antiobesity agent BELVIQ® and BELVIQ XR®	Global	Signed in December 2016 to change licensing agreement in marketing and supply that was originally concluded in November 2013. Based on the change in the agreement, Eisai acquired all development and marketing rights from Arena Pharmaceuticals, Inc.			
BIAL-Portela & Ca., S.A.(Portugal)	Antiepileptic agent Zebinix®	Europe	License and co-promotion agreement			
BioArctic AB (Sweden)	Anti-Aβ protofibrils antibody BAN2401	Global	Exclusive rights to study, develop, manufucture and market			
	<ul> <li>Anti-Aβ protofibrils antibody BAN2401</li> <li>BACE inhibitor Elenbecestat</li> <li>Anti-Aβ antibody Aducanumab</li> </ul>	Global	Co-development and co-commercialization			
Biogen Inc. (U.S.)	Anti-tau antibody BIIB076		Acquisition of option rights related to joint development/joint commercialization			
	Multiple sclerosis treatment Avonex®, Tysabri® and Tecfidera®	Japan	Co-promotion to accounts that Biogen currently does not call upon			
	Three products above and Plegridy®	Asia (excluding China)	Distribution and booking sales			
CY Biotech (Taiwan)	Antiobesity agent BELVIQ® and BELVIQ XR®	China (including Hong Kong and Macau)	Grant exclusive development and marketing rights			
Sumitomo Dainippon Pharma Co., Ltd. (Japan)	Antiepileptic agent Zonegran®	Europe and Asia	License agreement for manufacturing and sales			
Eurofarma Laboratórios S.A. (Brazil)	Antiobesity agent BELVIQ® and BELVIQ XR®	17 countries in Latin America and the Caribbean and Brazil	Grant exclusive development and marketing rights			
Meiji Seika Pharma Co., Ltd. (Japan)	Parkinson's disease treatment Safinamide	Japan and Asia	License agreement for the commercialization			
Novartis AG (Switzerland)	Antiepileptic agent Inovelon®/ Banzel®	Global	License agreement for development, manufacturing and sales			
Pfizer Inc. (U.S.)	Pain treatment Lyrica®	Japan	Co-promotion			
Sunovion Pharmaceuticals Inc. (U.S.)	Insomnia treatment Lunesta®	Japan	Exclusive license for the development and marketing			
Sysmex Corporation (Japan)	_	_	Comprehensive non-exclusive collaboration agreement for creating new diagnostics in the dementia area			
Keio University (Japan)	_	_	New joint research agreement for the discovery and development of new drugs targeting dementia			
University College London (U.K.)	_	_	Agreement to form major drug discovery alliance to develop new therapeutics			

### Partnerships aimed at creating innovation in oncology area

Partner	Product/Compound	Region	Purpose			
Bristol-Myers Squibb (U.S.)	Explore modulating RNA splicing to develop potential immunotherapy	_	Multi-year research collaboration focused on developing immune therapies using H3 Biomedicine, Inc.*'s RNA splicing platform			
Dr. Reddy's Laboratories Ltd.	Anticancer agent E7777	Global (excluding Japan and Asia)	Transfer the exclusive development and marketing rights			
Epizyme, Inc. (U.S.)	Anticancer agent E7438	Japan	Partnership in development and commercialization			
Epizyme, mc. (0.5.)	Anticancer agent E7436	Asia	The rights of first negotiation for licensing rights			
Merck & Co., Inc., Kenilworth, N.J., U.S.A. (U.S.)	Anticancer agent Lenvima®	Global	Joint development and commercialization and in combination with Merck & Co., Inc., Kenilworth, N.J., U.S.A. KEYTRUDA® for multiple cancer types			
Ono Pharmaceutical Co., Ltd.	Anticancer agent Lenvima®	Japan	Collaboration agreement to jointly develop the combination therapy with Opdivo® for the treatment of hepatocellular carcinoma(HCC)			
(Japan)	Anticancer agent eribulin liposomal formulation	Japan	Collaboration agreement to jointly develop the combination therapy with Opdivo®			
PRISM BioLab Co., Ltd. (Japan)	CBP/beta-catenin inhibitor E7386	Global	Joint research and development			
SymBio Pharmaceuticals Ltd.	Anticancer agent Treakisym®/	Japan	Exclusive rights on joint development and marketing			
(Japan)	Anticancer agent Treakisym®/ Symbenda®	Singapore and South Korea	Exclusive development and marketing licenses			

<sup>\*</sup> A subsidiary of Eisai Co., Ltd.

### Partnerships aimed at creating innovation in other areas (gastrointestinal disease, and others)

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Partner	Product/Compound	Region	Purpose			
AbbVie Deutschland GmbH & Co. KG (Germany)	Fully human anti-TNF- α monoclonal antibody Humira®	Japan, Taiwan and South Korea	Development, sales and co-promotion EA Pharma Co., Ltd. and AbbVie GK undetake co-promotion for indications in the area of gastrointestinal disease (ulcerative colitis, Crohn's disease and intestinal Behçet's disease)			
Ajinomoto Co., Inc. (Japan)	_	Japan	Ageement for integrating (absorption type split) Eisai's gastrointestinal disease treatment business with Ajinomoto Pharmaceuticals Co., Ltd. (Establishment of EA Pharma Co., Ltd.)			
Minophagen Pharmaceutical Co.,	Liver disease/allergic disease agents Stronger	Japan and Euro-Asia	Exclusive rights for the development and marketing in countries where the products have not yet been sold			
Ltd. (Japan)	Neo-Minophagen C® and Glycyron®	China and other Euro-Asia	First negotiation rights for exclusive marketing rights in countries where the products are already sold			
Sato Pharmaceutical Co., Ltd., Seren Pharmaceuticals Inc. (Japan)	Oral antifungal agent NAILIN® Capsules 100mg	Japan	Co-promotion between Sato Pharmaceutical Co., Ltd. and Eisai			
FUJIFILM Toyama Chemical Co., Ltd. (Japan)	Anti-rheumatic agent Careram®	Japan	Joint development and marketing alliance			

### Partnerships aimed at building new business models

Partner	Region	Purpose
Grupo Biotoscana (Uruguay)	Latin America	Exclusive license to seek regulatory approvals and commercialize the anticancer agents Halaven® and Lenvima®, as well as antiepileptic agents Fycompa® and Inovelon®
Nichi-Iko Pharmaceutical Co., Ltd. (Japan)	Japan	Strategic alliance agreements including incremental transfer of all shares of Elmed Eisai Co., Ltd., (completed in April 2019), co-operation in building Eisai's Ecosystem, as well as collaboration on the active pharmaceutical ingredient (API) business promoted primarily at Eisai's Vizag Plant in India

### Partnerships aimed at expanding access to medicines

Partnerships aimed at expanding	ig access to medicines
Partner	Purpose
Access Accelerated	Participation in a multi-stakeholder global partnership to advance access to non-communicable diseases (NCDs) prevention, treatment and care in low and lower-middle income countries
Bill & Melinda Gates Foundation (U.S.)	Participation in consortium aimed at the development of macrofilaricide drug and new treatment for tuberculosis
Broad Institute (U.S.)	Joint research aimed at the development of new treatments for Chagas disease, malaria and tuberculosis
Colorado State University, University of Chicago (U.S.)	Joint research agreement to develop a potential new treatment for tuberculosis with the compound identified from Broad Institute's chemical library
Drugs for Neglected Diseases initiative (DNDi)(Switzerland)	Collaboration and licensing agreement for new drug development for Chagas disease and eumycetoma     Participation in the Drug Discovery Booster Consortium formed by DNDi with the aim of accelerating the development of new drugs for leishmaniasis and Chagas disease
Global Health Innovative Technology Fund (GHIT Fund)(Japan)	Participation in public-private partnership aimed at bringing Japanese innovation to accelerate development of new medicines to cure infectious diseases in the developing world
Univerity of Kentucky (U.S.)	Agreement for joint research aimed at developing new antimalarial agent
Liverpool School of Tropical Medicine, University of Liverpool (U.K.)	Agreement for joint research for creating <i>Wolbachia</i> inhibitors (new antifilarial agents)     Agreement for joint research for developing antimalarial drugs
Macrofilaricide Drug Accelerator	Participation in global partnership aimed at developing new drugs for filariasis (especially river blindness)
Medicines for Malaria Venture (MMV) (Switzerland)	Agreement for joint research for the development of new antimalarial drugs
Fundacao Oswaldo Cruz (Fiocruz)(Brazil)	Agreement for joint research and development of compounds developed by Eisai for the treatment of malaria and NTDs
Sabin Vaccine Institute (U.S.)	Agreement for joint research for development of new vaccines for Chagas disease
TB Alliance (U.S.)	Alliance to find faster-acting and affordable drug regimens to fight tuberculosis
Tuberculosis Drug Accelerator (TBDA)	Participation in global partnership aimed at creating innovative new drugs for tuberculosis
World Health Organization (WHO) (Switzerland)	Agreement for providing free of charge DEC (diethylcarbamazine) tablets, a treatment for lymphatic filariasis, and participation in partnership for providing lymphatic filariasis diagnostic kits free of charge to endemic areas
World Intellectual Property Organization (WIPO)(Switzerland)	Participation in consortium sponsored by WIPO for promoting the development of new drugs for tropical diseases

## **Compliance and Risk Management**

Eisai defines compliance as "the observance of the highest legal and ethical standards" and positions it at the core of management activities.

To contain risks within acceptable levels, Eisai is carrying out various initiatives including establishing, developing, and implementing internal control systems as well as conducting internal audits.

Eisai designates a Chief Compliance Officer, who is concurrently the corporate officer responsible for Internal Control, oversees the Corporate Compliance and Risk Management Department and promotes compliance and risk management. Eisai promotes its compliance program that consists of delivering the message of top management, developing the Code of Conduct and other relevant rules, conducting educational activities, establishing a training system as well as providing consultation services by defining compliance as "the observance of the highest legal and ethical standards" and positioning it at the core of management activities.

Regarding the risk management, Eisai defines risks as "the threat or probability that an action or event will adversely affect the achievement of corporate and/or organizational objectives." In order to avoid or keep risks within acceptable levels, Eisai is carrying out various initiatives including establishing, developing, and operating internal control systems as well as conducting internal audits.

### 1. Compliance Promotion

In 1999, Eisai was prosecuted by the U.S. Department of Justice for its involvement in a cartel for synthetic bulk vitamin E products, and penalties and fines were imposed by countries other than the U.S. **Based on the lessons of this vitamin lawsuit, Eisai started to promote full-fledged compliance in fiscal 2000.** These compliance promotion activities periodically undergo objective reviews by a Compliance Committee that consists of outside experts such as lawyers and consultants from Japan and overseas.

### Establishment of Code of Conduct and Other Relevant Rules, and Awareness Activities for Cultivating Compliance Awareness

Eisai has been publishing Compliance Handbook, which outlines Eisai Network Companies (ENW) Charter of Business Conduct and the Code of Conduct, to cultivate the compliance awareness in all officers and employees. For all officers and employees in all Eisai network companies, this handbook is available in 17 languages.

Furthermore, a "Code of Conduct for Business Partners", which covers the behavior expected from all business partners and employees, was issued and expanded globally.

Eisai continues to conduct trainings through a variety of media such as compliance workshops, including those designed for directors and officers, e-learning and distribution of case studies.



The Compliance Handbook



Compliance Training for Directors and Officers

### Use of Compliance Counter

The Compliance Counter serves as a point of contact for the whistle-blowing system in ENW. This counter is set up globally across Japan, the U.S., Europe, China, Asia and other countries and it is available for ENW employees to contact directly to the Compliances Counter at Eisai Headquarters. In Japan, the Compliance Counter also provides resources such as whistle-blowing system operated by outside lawyers and contact desk operated by the external counselors, creating an environment that serves to further promote compliance.

Eisai considers that it is important to receive as much consultation/as possible to make this internal whistle-blowing system function effectively. Thus, the Compliance Counter accepts not only whistle-blowing reports but also all sorts of consultations such as interpretation of laws and rules as well as daily activities regarding compliance. In fiscal 2018, nearly 500 inquiries were received at Eisai Headquarters.

Business Base (ESG)

### Prevention of Bribery and Corruption

In order to promote the genuine business activities without bribery and corruption across ENW, Eisai formulated the Corporate Anti-Bribery and Anti-Corruption (ABAC) for ENW. Based on this policy, Eisai introduced the ABAC due diligence system that receives responses about a globally common questionnaire on the possibility of bribery and corruption from the companies in advance with which we plan to undertake new transactions. Also, Eisai is working on introducing the system to detect signs of potential fraud at overseas ENW by monitoring accounting and financial data.

### Promotion and Information Disclosure Based on Compliance

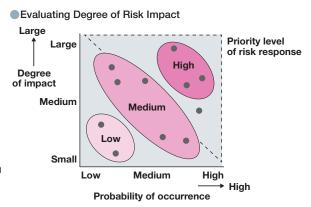
Eisai engages in promotion activities globally based on the compliance. In addition, in order to gain a broad understanding of society that corporate activities are conducted under a high level of ethics, the payments to medical institutions and patients groups are disclosed on the corporate website in accordance with the laws and guidelines established by the Japan Pharmaceutical Manufacturers Association (JPMA) and each country.

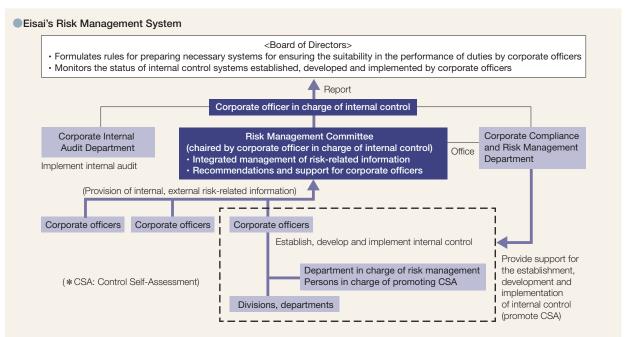
### 2. Risk Management Promotion

In accordance with the Companies Act, Eisai's Board of Directors formulated the "Rules for Preparing Necessary Systems for Ensuring the Suitability in the Performance of Duties by Corporate Officers." These rules stipulate that all corporate officers should identify the risks in their duties and establish, develop, and operate the internal control systems. In response, the corporate officer responsible for internal control established "ENW Internal Control Policy", and is establishing, developing and implementing internal control systems covering all ENW as well as implementing initiatives for containing risk within acceptable levels.

### Promoting Risk Management System and Risk Response

At the Risk Management Committee, critical risks identified by all the corporate officers and department managers through Control Self-Assessment (CSA) by placing the corporate officer responsible for internal control as chair. Also, Eisai quickly detects its own potential similar risks through continuous monitoring for external corporate scandals and responds to risks promptly by the risk avoidance and elicitation prevention activity.





### **2** CSA (Control Self-Assessment)

One of the tools used by Eisai for risk management is CSA. In the CSA activity, all the department managers in ENW identify and evaluate risks in their own structure, and these identified risks are dealt with through workshops and others.

In addition, Eisai enhances the effectiveness of risk management by understanding critical risks and following up on risk response status by corporate officers.

### 3 Internal Audit Activities Based on International Standards

Internal audits are voluntary audits that differ from the audits conducted by the Audit Committee and the accounting audits. **Eisai implements the internal audits globally.** These internal audits independently and objectively assess whether the execution of duties by corporate officers is being undertaken appropriately and efficiently. The results are reported to the Executive Committee and to the Audit Committee.

To assure high-quality audits that conform to global standards, the Corporate Internal Audit Department undergoes an assessment every year by an external assessment committee composed of outside experts in accordance with the standards of The Institute of Internal Auditors (an international professional association for internal auditors based in the U.S.).

### **4** Serious Risks and Measures Taken

The following table outlines the major risks that potentially have a serious impact on Eisai's business activities and measures taken in response to those risks. The risks included in the table are just a selection of those deemed to be serious based on risk assessments.

Risk	Outline	Measures Taken
Risks relating to product safety and quality	Potential impact on patients' health or stable product supplies as well as on business results associated with product recalls, suspension of sales, etc., as a result of concerns regarding the safety or quality of products due to raw materials, manufacturing processes or other factors	▶ Please refer to P.86 (Quality Assurance, Stable Supply).
Risks relating to pharmaceutical safety management (side effect information, etc.)	Potential impact on patients' health due to failure of pharmaceutical company's obligation of scientific evaluation and notification to the regulatory authorities regarding any adverse events or safety precautions associated with Eisai's products	Please refer to P.87 (Safety Information Management for Products).
Risks related to overseas operations	Potential risks that original projected earnings may not be achieved by legal restrictions, socio-political uncertainty, and business environment uncertainty	Eisai has deployed corporate officers at key locations and has built a system to immediately ascertain and share important information, as well as enable a response.      Global risk management activities decrease the risks during implementing business and a backup system in the event when risks are actualized.
Risks relating to outsourcing	Potential serious impact on Eisai's operations and performances in the event of suspension of outsourcing partners or in the event of any issues with research results or manufactured output provided by outsourcing partners	Eisai investigates and accredits the eligibility before selecting outsourcing partners and verifies the suitability of their business by regular audit during outsourcing.     Eisai prepares the responses by a backup system when the risks are actualized.

Risk	Outline	Measures Taken
Risks relating to information management	Potential impact on Eisai's competitiveness and/or reputation and potential disadvantages for concerned stakeholders in the event of a leak involving confidential technical or business information, or personal information held by Eisai	Eisai has established the internal rules for confidential information, and implements continuous trainings.     Eisai has developed and operated the personal information protection system.
Risks relating to financial reporting	Potential risks for stakeholders to sustain unexpected losses and for significant loss of confidence in Eisai due to inaccurate financial reporting	Eisai is compliant with standards for evaluating, auditing and implementing internal controls in relation to financial reporting in accordance with the Financial Instruments and Exchange Act and other applicable legislation. Eisai has put in place effective internal control systems in relation to financial reporting and ensures that they are operated in an appropriate manner.
Risks related to financial market conditions and currency movement	Potential impacts on business results by foreign exchange fluctuations on the yen conversion of sales of overseas consolidated subsidiaries, export and import transactions, losses on sales or devaluation of stocks and other securities due to a decline in the stock market, and an increase in projected benefit obligations due to changes in the interest rate	<ul> <li>Considering the impact on business results, Eisai is always monitoring financial markets and foreign exchange fluctuations.</li> <li>Regarding financial assets, Eisai regularly revises its obligations held, and aims for optimization.</li> <li>Regarding the impact of foreign exchange, Eisai utilizes currency hedges and netting as well as other derivatives in an effort to reduce risk based on the statuses of the Group's transactions and business activities.</li> </ul>
Risks relating to the environment	Potential serious impact on the business results due to factors such as legal action (closure of facilities, etc.), remedial environmental measures or compensation for the local community in the event of environmental contamination stemming from one of Eisai's facilities	Eisai has set out the internal policy as well as discussed and made decisions regarding important matters relating to protecting the environment at a company-wide Environment and Safety Committee.  Individual facilities also establish their own management systems, including obtaining ISO 14001, and carry out their own environmental activities.
Risks related to plant closure or shutdown	Potential serious impact on product supply and business results because of closure or shutdown of plants due to technical problems, raw material shortages, influenza and other pandemics, fire, earthquakes and other natural disasters	Through regular assessment of contract manufacturers and API suppliers, as well as maintenance of reasonable inventories of API and products, etc., Eisai works to reduce risks relating to the supply of products.  Combined with making doubly sure of preparations for every kind of disaster, in order to bring about business continuity as well as early recovery/ restart, Eisai has set a "Business Continuity Plan" for each department. Together with planning responses, Eisai also works to regularly review these plans to increase their effectiveness.
Risks relating to disasters, etc.	Potential large-scale damage to plants, sales offices and other facilities and potential impact on Eisai's activities in the event of a natural disaster such as an earthquake or typhoon, or an accident such as a fire	Together with making doubly sure of preparations for every kind of disaster, each division formulates a "Business Continuity Plan (BCP)" to ensure that business can continue or be quickly restored/reinstated. In addition to BCP measures, Eisai also carries out regular reviews to make plans more effective.

# **Quality Assurance and Stable Supply**

For patients around the world waiting for pharmaceuticals,

Eisai fulfills the mission and responsibility to supply the high quality products stably.



### **Quality Assurance Activities**

Eisai is carrying out quality assurance activities enabling the supply of pharmaceutical products that ensure safe use for patients in every countries and regions. Eisai manages the quality in the manufacturing phase in accordance with the globally unified Good Manufacturing Practice (GMP) standards (international regulations for production and quality management) while placing emphasis on maintaining product quality in the distribution phase.

### Stable Supply

Eisai owns plants in 9 sites in major regions worldwide and has the system to supply products in a timely manner to each market from each region. Also, Eisai has formulated a business continuity plan (BCP) to ensure stable supply in case of any risks such as natural disaster, accident or act of terrorism. Even in the event of large earthquake, we are committed to resuming plant operations as soon as possible and continuing the stable supply of products by consistently ensuring appropriate product inventory. Additionally, we are undertaking initiatives for securing backup sites that enable alternate operations in times of emergency, primarily for specific products with a high degree of urgency and importance.

### **Initiatives against Counterfeit Medicines**

As the globalization of the development and distribution of pharmaceutical products accelerates remarkably, the risk of counterfeit medicines is increasing all over the world. In order to deliver the pharmaceutical products to patients safely and reliably, Eisai is actively participating in monitoring and establishing measures against counterfeit medicines and illegal distribution of medicines. When an actual case is detected, Eisai responds quickly by undertaking investigations, taking various legal steps and assuring stable supplies, with efforts led by the Product Security Execution Committee.



Counterfeits of BELVIQ® (Left: Genuine, Right: Counterfeits)

### List of the functions of each plant and major manufactured items

Plant		APIs	Formulation	Packaging	Major manufactured items
Flaill	Country	AFIS	FUITIUIALIUII	iviajor manuractureu items	
Kashima		0			Lenvima <sup>®</sup> , Halaven <sup>®</sup> , Fycompa <sup>®</sup>
Kawashima	Japan		0	0	Lenvima®, Fycompa®, Lunesta®
Fukushima (EA Pharma)			0	0	Elental®, Moviprep®
Suzhou	China		0	0	Methycobal®, Aricept®, Merislon®
Benxi	Offilia	0	0	0	Transfer factor*
Bogor	Indonesia		0	0	Pariet®, Aricept®, Methycobal®
Vizag	India	0	0	0	Warfarin®, diethylcarbamazine (DEC tablets) API for generics
Hatfield	U.K.		0	0	Lenvima <sup>®</sup> , Halaven <sup>®</sup> , Fycompa <sup>®</sup>
Baltimore	U.S.		0	0	Gliadel <sup>®</sup>

<sup>\*</sup> Product name in Chinese:转移因子口服溶液

### Social and Relationship Capital

# Safety Management for Products

Maximization of Value of Pharmaceutical Products by Promoting Proper Use

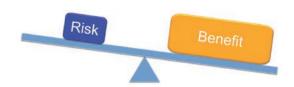


### **Safety Information Management**

The value of pharmaceutical products can be fully maximized through proper usage upon correctly understanding the risks and benefits. Eisai works to ensure that its products are used properly in countries around the world by collecting and evaluating the product safety information, as well as integrates and manages the information globally. Approximately 30,000 safety information were accumulated in fiscal 2018 and more utilized to update product safety information. Eisai promotes the proper use of our products all over the world by providing the updated information to healthcare professionals and patients in a timely manner.

Objective of safety management for pharmaceutical products

Maximization of value by reducing risks and increasing benefits



### **Initiatives for Safety Management**

Fairness and neutrality for the collection, analysis, and evaluation of safety information are secured by advices from outside clinicians as appropriate. In addition, Eisai specifies risks of each product and provides information continuously to minimize the risks through consultation with regulatory authorities in each country.

Eisai proposed the risk control measures for hepatic encephalopathy using the proper usage guidelines, which were prepared accompanying obtainment of the additional indication of hepatocellular carcinoma for anticancer agent Lenvima® in Japan in March 2018. Also, for pneumothorax and interstitial pneumonia that were newly specified as risks, Eisai prepared the documentation for minimizing risks and contributed to adverse event management in medical settings.

### Eisai hhc Hotline

At Eisai in Japan, the "Eisai hhc Hotline" (toll-free customer information service) is open 365 days a year to relieve any concerns that patients, customers, and healthcare practitioners may have in the use of Eisai products, and provide correct information for their proper use.

Inquiries and opinions are shared as valuable information within Eisai and utilized for development and improvement of products as well as provision of information or services.



### **Initiatives for Reinforcing Data Integrity**

Data integrity refers to the completeness of data. For a research and development based pharmaceutical manufacturer, securing the integrity of research data, manufacturing data, and other data is extremely important, thus, Eisai is strengthening the initiatives. Since fiscal 2017, Eisai has been continuously conducting trainings for over 3,000 employees involved in handling important data. Training contents are enhanced by presenting the own cases of each department and adopting the discussion style for global common theme. Furthermore, a new system for reinforcing initiatives to secure data integrity launched in January 2018.

# **Business with Consideration for the Global Environment**





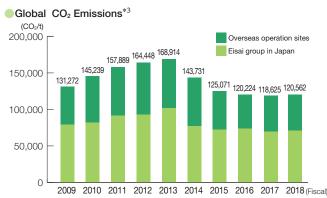
Eisai conducts business operations seeking co-existence with the global environment. Based on the Eisai Network Companies (ENW) Environmental Protection Policy, all employees recognize the importance of environmental protection and incorporate an environmental perspective in working to solve social issues. In promoting business expansion into countries across the world, Eisai will fulfill its corporate social responsibility by focusing on reducing environmental impact at each stage of business.

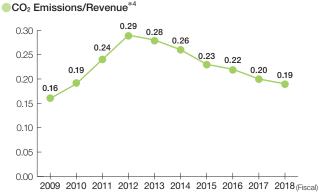
# Formation of a Low-Carbon Society: Aiming to Reduce CO₂ Emissions of Eisai Group in Japan by 30% Compared to Fiscal 2016 by Fiscal 2030

Eisai is promoting initiatives for the formation of a low carbon society to help solve the problem of climate changes. As one of its initiatives, Eisai set the greenhouse gas (GHG) reduction target by fiscal 2030 based on scientific grounds and received the approval from Science Based Targets initiative (SBTi)\*1 in May 2019.

In addition, Eisai is participating in the Commitment to a Low Carbon Society initiated by the Federation of Pharmaceutical Manufacturers' Associations of Japan, and has steadily conducted the target to reduce the domestic  $CO_2$  emissions by 23% compared to fiscal 2005 by fiscal 2020. **Regarding the domestic CO\_2 emission in fiscal 2018, a reduction of 36.4%\*2 was achieved compared to fiscal 2005.** 

- · 30% reduction of GHG emission (Scope 1 and 2) by fiscal 2030 from fiscal 2016
- · 30% reduction of GHG emission (emission based on purchased products and services in Scope 3) by fiscal 2030 from fiscal 2016
- Scope 1: Direct emission of GHG released into the air by the use of fossil fuel
- Scope 2: Indirect emission of GHG with use of electricity and steam purchased from others
- Scope 3: Indirect emission of GHG by supply chain excluding Eisai





- \*1 International joint initiative led by CDP, an international NGO that manages information disclosure programs related to the environment, UN Global Compact (UNGC), World Wildlife Fund for Nature (WWF), and World Resources Institute (WRI)
- \*2 Where the carbon emission factor based on the use of electricity is assumed to be 0.367t-CO2/MWh as in the evaluation of the Eisai group target

\*3 Emissions from business activities at offices outside Japan and vehicles for sales use are not included •The data was revised due to inclusion of Baltimore Plant (U.S.) from fiscal 2011.

• CO<sub>2</sub> emissions from overseas operation sites are calculated based on the International Energy Agency's "CO<sub>2</sub> Emissions from Fuel Combustion (2017 Edition)".

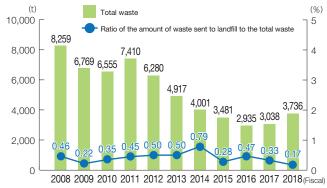
\*4 Global CO<sub>2</sub> emissions (CO<sub>2</sub>/t) / Consolidated revenue (million yen)

## Establishment of a Recycling-Oriented Society:

# Zero Emissions have been Achieved in Japan for Eleven Consecutive Years

Eisai is conducting waste disposal with three goals in mind: reduce the amount of waste generated, increase the rate of recycling, and decrease the amount of waste sent to landfill. We also sort waste for recycling and select the best possible waste disposal contractors possible in a timely manner. Furthermore, we are actively trying to process recycling that has value in the market and to reduce disposal costs.

### Total Waste and Ratio of Amount of Waste Sent to Landfill in Japan



# Improvement of Resilience to Climate-Related Risks Analysis of Effects by Climate Change Using TCFD Framework

Eisai announced its endorsement of final report of Task Force on Climate-related Financial Disclosures (TCFD)\*5 in June 2019. Eisai addresses reduction of risk and creation of opportunity by understanding the med- and long-term effects of climate changes to business using TCFD framework.

### Governance

The company-wide Environment and Safety Committee is established for deliberation and decision-making of important environmental protection issues. Also, regarding the climate-related risks and opportunities, Eisai has launched a cross-organizational project with the corporate officer of General Affairs, Environmental and Safety Affairs as the person in charge.

### Strategy

Eisai recognizes that the climate-related risk and opportunity are the important elements to be considered for planning strategies. WHO predicts that infectious diseases will increase following climate changes. Therefore, Eisai is proceeding to develop medicines for malaria and other neglected tropical diseases (NTDs).

	Major Climate-Related Risks and opportunities	Measures
Physical	Damages to production and procurement activities due to increase in natural disasters.	Analysis of the risks of facilities and suppliers, and promote resilience measures.
cal Risks	Shortage of pharmaceuticals supply when there is an increase of healthcare needs and damage to product activities occur at the same time due to natural disasters.	Reinforcement of the stable supply system during emergency.  *For further details, please refer to page 86.
Transition	Increase in production and logistics costs due to increase in costs for fuel and electricity.	Minimization of the impact by expanding the use of renewable energy.
ition Ri	Impact on operations at factories and of suppliers due to reinforcement of environmental regulations.	Strengthening the environmental management for factories and suppliers by anticipating future environmental regulations.
Risks	Loss of opportunity in case of late response to increased promotion request.	Promotion of steady reduction of GHG for achieving SBT.  *For further details, please refer to page 88.
Opport	Acquisition of market opportunity by responding to increased healthcare needs in accordance with climate changes.	Development of medicines for malaria and NTDs.  *For further details, please refer to pages 38-41.
Opportunities	Improvement of third-party evaluation through consideration for environment.	Promotion of consideration for environment and co-existence with community. Kawashima Industrial Complex and Naito Museum of Pharmaceutical Science and Industry are striving for biodiversity conservation such as protection of depleted plants.  *For further details, please refer to the website of Naito Museum of Pharmaceutical Science and Industry.

### Risk Management

Eisai initiated the analysis of risks to business by mid- and long-term climate changes. In addition to the current risk management activity (Control Self-Assessment, CSA), the climate-related risks will also be uniformly managed by Risk Management Committee.

### **Index and Target**

The climate-related index and target are as shown in the Formation of a Low Carbon Society.

\*5 A private sector-led task force with regard to climate-related financial information disclosure established under the Financial Stability Board (FSB) as per the request of G20 finance ministers and central bank governors. TCFD has announced the recommendation to understand and disclose the financial impacts of climate changes on business.

# Rated "B" in the CDP Climate Change Report 2018 and Ranked Third in WWF Japan's Ranking of Corporations for Effective Efforts to Address Climate and Energy Issues

In 2018, the CDP\*6 evaluation system highly rated Eisai as "B", which is equivalent to the "Management" level. In the Japanese health care sector, only one company achieved "Leadership" level (A), while three companies including Eisai achieved "Management" level (B).



\*6 A non-profit organization based in London, formerly known as Carbon Disclosure Project. It requests information relating to climate change, water, and forests from companies with top ranking market capitalization in principal countries and discloses the information to the government, companies and investors. The CDP evaluation system evaluates the status of implementation of a company's environmental management activities on a scale of one to eight (A, A- to D and D-) on four different levels including leadership, management, recognition and information disclosure.

In June 2018, the non-government organization World Wide Fund for Nature Japan (WWF Japan)\*7 announced its Ranking of Corporations for Effective Efforts to Address Climate and Energy Issues for the pharmaceutical industry. Eisai was ranked 3rd among Japanese pharmaceutical manufacturers.

- \*7 WWF Japan is one of the world's largest conservation non-government organizations, and has published its ranking of corporations for effective efforts to address climate and energy issues by industry since 2014.
- \*For more detailed information, please refer to WWF Japan's website. https://www.wwf.or.jp/activities/activity/3630.html (In Japanese only)
- \* See the Environmental Report for more detailed information about our environmental activities. > https://www.eisai.com/ir/library/annual/index.html

## Initiatives for Achieving Sustainable Development Goals (SDGs) and Contribution to UN Global Compact

Eisai strives to actively address global environmental (E) and social issues (S) under enhanced governance (G) and contribute to the achievement of a sustainable society. In order to realize our *human health care* (*hhc*) corporate philosophy, we strengthen our initiatives for ESG through our daily corporate activities. We acknowledge that these ESG initiatives improve non-financial capital and help us achieve the United Nations (UN) Sustainable Development Goals (SDGs). We aim to promote initiatives through contributing to UN Global Compact.

### **Initiatives for Achieving SDGs**



### 1. No Poverty

 Aim to contribute to patients through improvement of access to medicines in developing and emerging countries, thereby improving health and welfare as well as contributing to economic growth through the expansion of the middle-income class (Page 18)



### 3. Good Health and Well-Being

- Creation of innovative medicines (Pages 42-47, 50-61, 99-101)
- Offering solutions that go beyond providing pharmaceuticals (Pages 48-49)
- Initiatives to eliminate neglected tropical diseases (NTDs) which are endemic in developing countries (Pages 18, 38-41)
  - Provision of diethylcarbamazine (DEC) tablets at Price Zero (free of charge) for elimination of lymphatic filariasis
  - •Initiatives to create new medicines for Chagas disease, filariasis, leishmaniasis, mycetoma, malaria and tuberculosis which spread mainly among people of lower-income classes in developing countries



### 10. Reduced Inequalities

• Provision of Eisai products based on Affordable Pricing Policy in developing and emerging countries (Pages 18, 40-41)



### 17. Partnerships for the Goals

Partnerships with corporations, United Nations organizations, non-profit organizations, research institutions, academia
and other groups for creating innovation in areas of focus and expanding access to medicines (Pages 9, 15-18, 80-81)

### Eisai's Initiatives for the UN Global Compact

**WE SUPPORT** 





	Ten Principles in four areas	Status of initiatives
Human Rights	Principle 1: Businesses should support and respect the protection of human rights; and Principle 2: make sure that they are not complicit in human rights abuses.	In March 2019, Eisai enacted Human Rights Policy for Eisai Network Companies (ENW) and shared it with all ENW employees. The policy was also made available to the public on Eisai's website. In addition, the Charter of Business Conduct of
Labour	Principle 3: Businesses should uphold the freedom of association and the recognition of the right to collective bargaining;  Principle 4: the elimination of all forms of forced and compulsory labour;  Principle 5: the effective abolition of child labour; and Principle 6: the elimination of discrimination in respect of employment and occupation.	ENW, which is shared among all employees across the globe, states that human rights should be respected and child labor, forced and compulsory labor, human trafficking will not be tolerated wherever Eisai conducts business.  *For further details, please refer to page 91.
Environment	Principle 7: Businesses should support a precautionary approach to environmental challenges; Principle 8: undertake initiatives to promote greater environmental responsibility Principle 9: encourage the development and diffusion of environmentally friendly technologies.	Eisai is committed to the formation of a low-carbon society and a recycling-oriented society.  *For further details, please refer to pages 88-89.  *For further details, please refer to the Environmental Report.  https://www.eisai.com/ir/library/annual/index.html
Anti- Corruption	in all its forms, including extortion and bribery.	Aiming to undertake honest business activities, Eisai formulated the Corporate Anti-Bribery and Anti-Corruption (ABAC) Policy for ENW. In addition, we have introduced a prior check system for companies with which we plan to newly undertake transactions. We carry out e-learning programs regarding anti-bribery and anti-corruption for employees.  *For further details, please refer to page 83.

### **Respect for Human Rights**

# Fulfillment of Corporate Responsibility for Human Rights in Accordance with International Human Rights Standards

Eisai believes that it is essential for all business activities to be conducted as the basis of respect for human rights to achieve sustainable development of our business for realization of corporate philosophy. The Eisai network companies (ENW) Charter of Business Conduct, a global internal code of business activity, clearly indicates that human rights should be respected wherever Eisai conducts business activities.

In order to complement the ENW Charter of Business Conduct and to indicate specific policies which Eisai should follow to fulfill its corporate responsibility for human rights, ENW Human Rights Policy was formulated in March 2019. This policy was enacted offer the approval by the Executive Committee and the consent of the Board of Directors.

### **ENW Human Rights Policy**

In the international community, the efforts to prevent complicity against human rights violations by business partners in value chain are requested to companies in addition to the respect of human rights within the companies. The ENW Human Rights Policy implements human rights due diligence in accordance with United Nation's Guiding Principles on Business and Human Rights which is internationally recognized as human rights guidelines, and states to continue to fulfill Eisai's responsibility for respecting human rights in all of its business activities.

- \*Please visit the following website for Eisai Human Rights Policy.
- https://www.eisai.com/sustainability/employee/human\_rights/pdf/Human%20Rights%20Policy\_en.pdf

### Items of ENW Human Rights Policy

- 1. Our Commitment to Respect Human Rights
- 5. Education and Training
- 2. Our Approach to Human Rights Due Diligence
- 6. Remedy
- 3. Respecting Human Rights of Our Stakeholders
- 7. Disclosure

4. Stakeholder Engagement

### **Understanding of Issues and Human Rights Due Diligence**

In fiscal year 2018, the risks were assessed by using the probability of human rights issues and its impact as indices based on the cases of human rights issues occurred in the pharmaceutical industry in the past. As a result, we identified six issues as highly important human rights issues relating to Eisai's business activities. With regard to these issues, the relevant business organizations assessed the risks with potential impacts and conducted the gap analysis with good examples that are already made public. Based on the results of the gap analysis, we will implement measures to prevent or reduce the occurrence of negative impacts, track the effectiveness of efforts, and disclose the results by prioritizing working on high-risk issues. In fiscal year 2019, we plan to prioritize the human rights in supply chain and conduct the due diligence.

### Important Human Rights Issues Related to Businesses

- Ethical Marketing
- Access to Medicines
- Human Rights of Patients
- ♦ Human Rights of Clinical Trial Participants
- Product Safety and Quality
- ♦ Human Rights of Business Partners Including Suppliers

### **Education and Training**

In order to fulfill our responsibility to respect human rights, we understand that it is important to spread the spirit of respect for human rights throughout the company and to retain it as a corporate culture. In fiscal year 2018, 34 human rights awareness training were held at offices, department manager trainings, and new employee trainings at all ENWs, and 5,686 employees participated. Furthermore, we implement awareness activities such as e-learning for compliance, distribution of e-newsletters related to human rights called "Human Rights Plaza", and an employee engagement program calling for slogan submissions for internal human rights message. In addition to the existing education and training contents, we plan a program for spreading the understanding of ENW Human Rights Policy and global human rights standard in fiscal year 2019.

- \*Please visit the following website for human rights initiatives.
- https://www.eisai.com/sustainability/employee/human\_rights/index.html

## **Major Products**

Product lineup mainly consisting of two major focus areas (Neurology and Oncology) Neurology Area Revenue in fiscal 2018 ¥177.4 billion (104% YoY, Composition of consolidated revenue 27.6%)

### **Aricept**® (generic name: donepezil)

n-house

Treatment for Alzheimer's disease/dementia with Lewy bodies Revenue in fiscal 2018 ¥40.2 billion (91% YoY)

A dementia treatment discovered and developed in-house by Eisai that is believed to slow the overall progression of symptoms associated with Alzheimer's disease by inhibiting acetylcholinesterase enzyme which breaks down the neurotransmitter acetylcholine. Currently approved in more than 100 countries worldwide. The agent received additional approval for a indication for the treatment of dementia with

Lewy bodies in Japan, the Philippines and Thailand.

Although revenue is decreasing mainly due to the expansion of generics in Japan, revenues are increasing in China and Asia.



in Ch

**Methycobal**<sup>®</sup> (generic name: mecobalamin)

In-house

### Peripheral neuropathy treatment

Revenue in fiscal 2018 ¥39.3 billion (98% YoY)

A mecobalamin (Vitamin B12 coenzyme) product originally discovered and developed by Eisai. Restores damaged peripheral nerves and is widely used for the treatment of

peripheral neuropathy in Japan and other Asian countries.

Although revenue is decreasing in Japan, revenues are increasing in China and Asia.



Fycompa® (generic name: perampanel)

n-house

### Antiepileptic agent

Revenue in fiscal 2018 ¥19.3 billion (132% YoY)

An AMPA receptor antagonist discovered and developed inhouse by Eisai, Fycompa® has been approved in Japan, the U.S., Europe and Asia for the adjunctive treatment for both partial-onset seizures and primary generalized tonic-clonic seizures.

Revenue is currently increasing worldwide.



Lyrica® (generic name: pregabalin)

In-license

### Pain treatment

Revenue in fiscal 2018 (Co-promotion income) ¥28.3 billion (107% YoY)

A pain treatment originally developed by Pfizer Inc. of the U.S.. Currently approved in more than 130 countries and regions globally\*. Co-promoted in Japan by Pfizer Japan Inc. and Eisai Co., Ltd., with both companies working to provide information on its proper use.

Revenue is successfully increasing in Japan.

\* As of January 2017



**BELVIQ**<sup>®</sup> (generic name: lorcaserin)

In-license

### Treatment for chronic weight management Revenue in fiscal 2018 ¥5.6 billion (118% YoY)

This treatment is believed to encourage decreased food consumption and promote satiety by selectively activating serotonin 2C receptors in the brain. BELVIQ® was the first prescription treatment for obesity approved by the U.S. Food and Drug Administration in 13 years and was launched in June 2013. Additionally, the once-daily formulation was launched in the U.S. in October 2016.

In fiscal 2018, revenue grew globally.

Oncology Area Revenue in fiscal 2018 ¥120.9 billion (96% YoY, Composition of consolidated revenue 18.8%)

### Lenvima<sup>®</sup> (generic name: lenvatinib)

In-house

### Anticancer agent/molecular targeted medicine Revenue in fiscal 2018 ¥62.6 billion (194% YoY)

A selective tyrosine kinase inhibitor (TKI) with a novel binding mode originally discovered and developed in-house by Eisai. Approved as a treatment of refractory thyroid cancer in over 55 countries, renal cell carcinoma (RCC) in combination with everolimus in over 50 countries and hepatocellular carcinoma in over 50 countries worldwide (product name for treatment

of RCC in Europe: Kisplyx®). Revenue is successfully increasing worldwide.



Halaven® (generic name: eribulin)

In-house

BELVIQ

Tablets (

### Anticancer agent/microtubule dynamics inhibitor Revenue in fiscal 2018 ¥41.3 billion (104% YoY)

An anticancer agent discovered and developed in-house

by Eisai. A synthetic analog of halichondrin B derived from the marine sponge *Halichondria okadai*. Shows an antitumor effect by arresting the cell cycle through inhibition of the growth of microtubules. Approved in more than 70 countries for the treatment of breast cancer. Approved in over 60 countries for use in the treatment of liposarcoma (soft tissue sarcoma in

In fiscal 2018, revenue grew globally.



### **Others**

### Pariet® (generic name: rabeprazole)

### Proton-pump inhibitor

### Revenue in fiscal 2018 ¥27.7 billion (87% YoY)

A proton-pump inhibitor originally discovered and developed in-house by Eisai. Indicated for the treatment of gastric and duodenal ulcers, reflux esophagitis and eradication of

Helicobacter pylori infections, etc. Approved in more than 100 countries worldwide.

Although revenues are increasing in China and Asia, revenue is decreasing in Japan mainly due to increasingly severe competition and the expansion of generics.



### Consumer **Healthcare Business**

Revenue in fiscal 2018 ¥24.3 billion (Composition of consolidated revenue 3.8%)

### Chocola BB® Products Revenue in fiscal 2018 ¥15.3 billion (111% YoY)

Ranging from the signature product Chocola BB®

Plus, a Vitamin B2 preparation for rough skin and stomatitis, a variety of products such as third-class OTC drugs, designated quasi-drugs and food with nutrient function claims are available.



Chocola BB<sup>®</sup> Plus: Third-class OTC drug

Chocola BB® Royal 2: Designated quasi-drug

In fiscal 2018, revenue increased due to the launch of new and updated products as well as the effect of television commercials and growth of Chocola BB® tablets from inbound tourism.

Chocola.com ▶ https://www.chocola.com/index.html (Only available in Japanese)

# Revenue of Major Brands (Billions of yen) 300.0 250.0 200.0 150.0 100.0 50.0 0.0 iscal 201A riscal 2016 Aricept® -- Pariet® Lenvima®

\* A major brand is an extremely popular medicine which achieved annual revenue of at least 100 billion yen or which is expected to.

### **Humira**® (generic name: adalimumab)

Business Base (ESG)

### In-license

### Fully human anti-TNF- $\alpha$ monoclonal antibody Revenue in fiscal 2018 ¥59.9 billion (109% YoY)

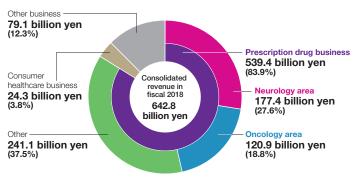
A treatment for autoimmune diseases such as rheumatoid arthritis. In Japan, the agent is manufactured and marketed by AbbVie GK and marketed by Eisai. AbbVie GK and Eisai are co-promoting the agent for the indications in the areas other than gastrointestinal disease, while AbbVie GK and EA Pharma

Co. Ltd., are co-promoting the agent for the indications in the gastrointestinal disease area.

Revenue is increasing in Japan and Asia mainly due to the success of promotion leveraging the strengths of having a wide range of indications.

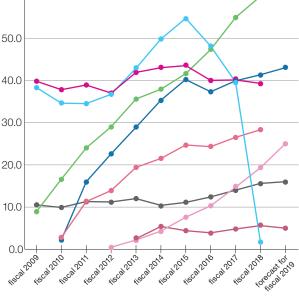


### Revenue of prescription drug business, consumer healthcare business and others





Revenue of Other Major Products



- ---Humira® ★ Revenue of Lyrica® is an alliance income from co-promotion.
- We returned an exclusive license for commercialization of Aloxi in June 2018.

Methycobal<sup>®</sup> -Fycompa<sup>®</sup> -Lyrica<sup>®</sup> -BELVIQ<sup>®</sup>

★ We did not disclose fiscal 2019 forecast for global revenue of Methycobal®, Lyrica®, and Humira®.

--- Aloxi®

---Chocola BB® series

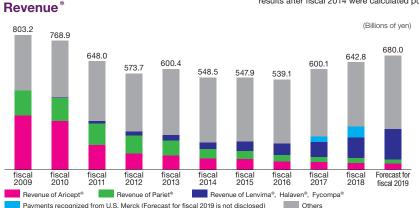
(Billions of yen)

### **Financial Capital**

# **Consolidated Financial Highlights** in the Last 10 Years

Returned to growth trajectory by overcoming revenue decline of major products

\* Results up to fiscal 2013 were calculated pursuant to generally accepted accounting principles in Japan (J-GAAP), while results after fiscal 2014 were calculated pursuant to International Financial Reporting Standards (IFRS)

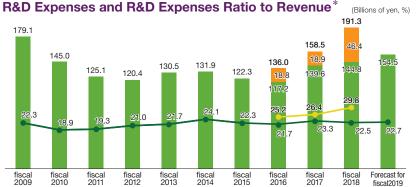


After achieving the peak sales in fiscal 2009, decline trend in revenue continued due to loss of exclusivity of our major products, Aricept®, treatment for Alzheimer's disease and Pariet®/AcipHex®, protonpump inhibitor. At the same time, newly launched in-house products, such as Halaven® (anticancer agent), Fycompa® (antiepileptic agent) and Lenvima® (anticancer agent) are steadily growing. In addition, Eisai recorded the amount recognized in revenue from Merck & Co., Inc., Kenilworth, N.J., U.S.A. (U.S. Merck) associated with strategic collaboration. As a result, Eisai achieved increase in revenue for two consecutive years in fiscal 2018.

### Cost of Sales and Cost of Sales Ratio to Revenue\*



Cost of sales ratio kept increasing due to change in product mix caused by revenue decline of Aricept® and Pariet®/AcipHex® whose cost of sales ratios are relatively low. However, expansion of in-house products with low cost of sales ratios and recording the payments recognized from U.S. Merck associated with strategic collaboration on revenue resulted the decrease in cost of sales ratio since fiscal 2017.

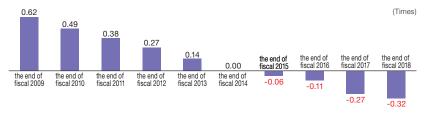


Partner's share of R&D expenses (Results from fiscal 2009 to 2015 and forecast for 2019 are not disclosed to revenue ——R&D expenses ratio to revenue (Including partner's share of R&D expenses)

Eisai continued to invest in R&D proactively towards future growth, even in the period of revenue decrease. R&D expenses remained over 120 billion yen level, which accounted for 19 to 24% of revenue for the past 10 years.

Moreover, Eisai achieved significantly effective investment in R&D by utilizing partnerships. Results for substantial R&D expenses in fiscal 2018 was 191.3 billion yen and R&D expenses ratio was 29.8% including the cost shared by partners.

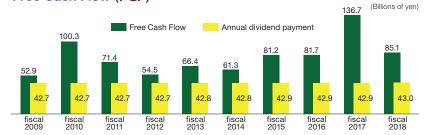
### Net Debt Equity Ratio (Net DER)\*



After the acquisition of MGI Pharma, Inc. in 2008, the amount of borrowing was increased. Nevertheless, Eisai repaid certain amount every year since then, and have been achieving net cash position, which cash and securities exceed interest-bearing debt since fiscal 2015. Eisai strives to maintain financial soundness that enables both proactive investment and stable dividends.

### Free Cash Flow (FCF)\*

R&D expenses



Eisai maintained FCF, exceeding the amount of annual dividend payment by managing working capital and selling assets, even when revenue declined continuously. Payments recognized from U.S. Merck since fiscal 2017 contributes to securing FCF.

					(	Billion yen)	(Reference data)				(E	Billion yen)
Financial Indicators (IFRS)	fiscal 2013	fiscal 2014	fiscal 2015	fiscal 2016	fiscal 2017	fiscal 2018	Financial Indicators (J-GAAP)	fiscal 2009	fiscal 2010	fiscal 2011	fiscal 2012	fiscal 2013
⟨Income Statement Items⟩							⟨Income Statement Items⟩					
Revenue	599.5	548.5	547.9	539.1	600.1	642.8	Net sales	803.2	768.9	648.0	573.7	600.4
Cost of sales	194.7	193.6	194.5	195.9	201.3	184.5	Cost of sales	160.7	167.8	173.4	174.1	188.2
Ratio to revenue (%)	32.5	35.3	35.5	36.3	33.5	28.7	Cost of sales					
Gross profit	404.8	354.9	353.5	343.2	398.8	458.3		20.0	21.8	26.8	30.3	31.3
Ratio to revenue (%)	67.5	64.7	64.5	63.7	66.5	71.3	Gross profit	642.4	601.1	474.6	399.6	412.2
Research and development	136.3	131.9	122.3	117.2	139.6	144.8		80.0	78.2	73.2	69.7	68.7
expenses  Ratio to revenue (%)	22.7	24.1	22.3	21.7	23.3	22.5	Research and development expenses	179.1	145.0	125.1	120.4	130.5
Selling, general and	203.3	194.5	192.8	174.9	183.9	228.2	олропесо	22.3	18.9	19.3	21.0	21.7
administrative expenses  Ratio to revenue (%)	33.9	35.5	35.2	32.5	30.6	35.5	Selling, general and administrative expenses	376.9	343.0	253.7	208.7	210.5
Other income	4.1	1.0	17.7	13.6	3.0	2.6	administrative expenses	46.9	44.6	39.1	36.4	35.1
Ratio to revenue(%)	0.7	0.2	3.2	2.5	0.5	0.4						
Other expenses	2.8	1.1	4.1	5.6	1.1	1.7						
Ratio to revenue (%)	0.5	0.2	0.7	1.0	0.2	0.3						
Operating profit	66.4	28.3	51.9	59.1	77.2	86.2	Operating income	86.4	113.1	95.7	70.5	71.1
Ratio to revenue (%)	11.1	5.2	9.5	11.0	12.9	13.4		10.8	14.7	14.8	12.3	11.8
Profit for the year	38.5	43.5	55.0	42.2	54.4	66.5	Ordinary income	79.7	105.2	90.0	65.6	64.9
Ratio to revenue (%)	6.4	7.9	10.0	7.8	9.1	10.3		9.9	13.7	13.9	11.4	10.8
Profit for the year attributable to owners of the parent	38.3	43.3	54.9	39.4	51.8	63.4	Net income	40.3	67.4	58.5	48.3	33.0
Ratio to revenue (%)	6.4	7.9	10.0	7.3	8.6	9.9		5.0	8.8	9.0	8.4	5.5
Comprehensive income for the year	84.5	114.2	16.5	36.8	53.8	79.5						
<cash flow="" items<="" statement="" td=""><td>i&gt;</td><td></td><td></td><td></td><td></td><td></td><td><cash flow="" item<="" statement="" td=""><td>s&gt;</td><td></td><td></td><td></td><td></td></cash></td></cash>	i>						<cash flow="" item<="" statement="" td=""><td>s&gt;</td><td></td><td></td><td></td><td></td></cash>	s>				
Net cash from operating activities	91.3	76.0	95.6	75.9	149.6	103.7	Net cash from operating activities	107.9	123.2	90.6	73.2	85.7
Net cash from investing activities	20.9	(18.8)	(6.7)	(28.6)	17.0	(7.9)	Net cash from investing activities	(69.8)	(58.8)	(2.6)	21.7	26.2
Net cash from financing activities	(115.1)	(59.7)	(72.9)	(35.4)	(81.9)	(79.2)	Net cash from financing activities	(49.2)	(68.0)	(78.0)	(81.8)	(114.8)
Free cash flow*	87.3	61.3	81.2	81.7	136.7	85.1	Free cash flow*	52.9	100.3	71.4	54.5	66.4

<sup>\*</sup> Free cash flow = "Net cash from operating activities" – "Capital expenditures(cash basis)\*\* "

\*\* Expenditures from purchases of financial assets and proceeds from sale and redemption of financial assets are included in the formula used to calculate capital expenditures in IFRS.

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Total assets	973.8	1,053.8	974.0	1,030.8	1,049.0	1,071.5	Total assets	1,101.9	1,046.3	1,004.7	990.2	945.5
Equity attributable to owners of the parent	526.3	598.7	573.7	584.6	593.6	628.1	Shareholder's equity	415.9	404.2	416.8	469.4	506.8
Non-controlling interests	3.1	3.3	3.2	18.0	20.5	23.9						
Total liabilities	444.4	451.8	397.2	428.2	434.9	419.5						
Return on equity attributable to owners of the parent (ROE) (%)	7.6	7.7	9.4	6.8	8.8	10.4	Return on equity (ROE) (%)	9.6	16.4	14.3	10.9	6.8
Return on sales ratio (%)	6.4	7.9	10.0	7.8	9.1	10.3	Return on sales ratio (%)	5.0	8.8	9.0	8.4	5.5
Leverage (times)	1.9	1.8	1.7	1.8	1.8	1.7	Leverage (times)	2.6	2.6	2.4	2.1	1.9
Total assets turnover ratio (no. of times)	0.6	0.5	0.5	0.5	0.6	0.6	Total assets turnover ratio (no. of times)	0.7	0.7	0.6	0.6	0.6
Ratio of equity attributable to owners of the parent (%)	54.0	56.8	58.9	56.7	56.6	58.6	Shareholders' equity ratio (%)	37.7	38.6	41.5	47.4	53.6
Net debt equity ratio (Net DER)(times)*1	0.08	0.00	(0.06)	(0.11)	(0.27)	(0.32)	Net debt equity ratio (Net DER) (times)	0.62	0.49	0.38	0.27	0.14
Dividend on equity attributable to owners of the parent (DOE)(%)*2	8.5	7.6	7.3	7.4	7.3	7.0	Dividend on equity (DOE) (%)	10.1	10.4	10.4	9.6	8.8
Dividend payout ratio (DPR) (%)	111.8	99.0	78.0	109.0	82.8	67.8	Dividend payout ratio (DPR) (%)	105.9	63.4	73.1	88.6	129.8
Earnings per share (basic) (EPS) (yen)	134.1	151.6	192.2	137.6	181.2	221.3	Earnings per share (EPS) (yen)	141.6	236.5	205.3	169.4	115.6
Dividend per share (DPS) (yen)	150.0	150.0	150.0	150.0	150.0	150.0	Dividend per share (DPS) (yen)	150.0	150.0	150.0	150.0	150.0

<sup>\*1 &</sup>quot;Net debt equity ratio (Net DER)" = ("Interest-bearing debt" ("Bonds and borrowings") – "Cash and cash equivalents" – "Time deposits exceeding three months, etc." – "Investment securities held by the parent company\*\*") / "Equity attributable to owners of the parent"

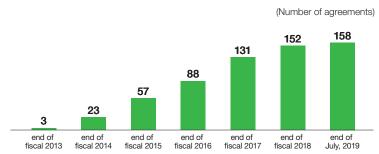
\*\* Investment securities held by the parent company are included in the formula used to calculate liabilities ratio.

\*2 Dividend on equity attributable to owners of the parent (DOE) = Dividend payout ratio (DPR) x Return on equity attributable to owners of the parent (ROE)

## **ESG Indices in the Last 10 Years**

Eisai discloses important indicators on ESG (Environment, Society, Governance), and verifies the activities each year, aiming to enhance non-financial capital contributing to sustainable development.

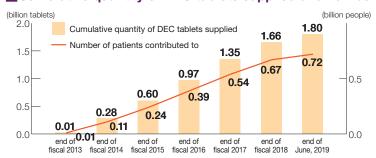
### Number of regional cooperation agreements (Japan)



We have tied dementia cooperation agreements with local governments, medical associations, pharmacist associations, etc. aiming at town planning to co-exist with dementia, and conducted disease awareness activities and provision of information in Japan. The number of agreements increased to 158 in 43 prefectures as of July 2019.

\*For further details, please refer to page 49.

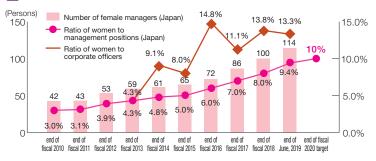
### ■Cumulative quantity of DEC tablets supplied and number of patients contributed to\*



Eisai has been supplying diethylcarbamazine (DEC) tablets to eliminate lymphatic filariasis diseases to 28 countries through WHO and will continue until the diseases are eliminated.

- \* The number of patients contributed to is an estimated value, which is converted from the cumulative quantity of tablets supplied based on the assumption that an average of 2.5 tablets is taken per capita in accordance with the definition of WHO.
- \*For further details, please refer to pages 38-41.

### ■Women advancement indices

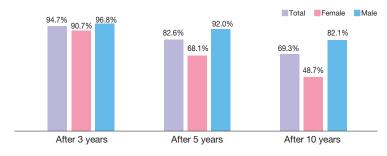


With the belief that the source of innovation is diversity, Eisai is creating a work environment in which people with diverse values can play active roles regardless of their nationality, gender, or age. We have been working on promoting female advancement in Japan.

Female ratio of corporate officers recently reached over 10%. Female ratio of managers is gradually improving to targeted 10% by the end of fiscal 2020.

\*For further details, please refer to pages 24-27.

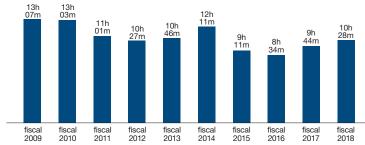
### Retention rate of new graduates (recent 10 years average, Japan)\*



Eisai is aiming at improving retention rate of new graduates assuming it a key indicator of satisfaction with the company after joining. As the rates after 3 years, 5 years and 10 years tend to be lower for women than men, we are improving the working environment.

- \* Retention rate of new graduates indicates the rate at the beginning of the next fiscal year. For example, the number of retention rate after 3 years for fiscal 2018 indicates the rate of retention of the new graduates hired in fiscal 2016 as of April 1, 2019. The retention rate after 3 years of the most recent 10 years is calculated as the average of the rate for new graduates hired from fiscal 2009 to fiscal 2018.
- \* For further details, please refer to pages 24-27, 98.

### Average monthly overtime hours (per non-management employee)



The well-being of employees is the basis of Eisai's sustainable growth, innovation creation, and productivity improvement, so we are strongly promoting efforts to eradicate long working hours. In recent years, the average overtime hours per non-management employee have been around 10 hours.

\*For further details, please refer to pages 24-27.

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Scope of data: Eisai Group (Eisai Co., Ltd. and Group companies in and outside Japan)

Eisai Co., Ltd. Eisai Group in Japan (Eisai Co., Ltd. and Group companies in Japan)

(Data for subsidiaries and businesses transferred is included until the date the transfer was completed)

Future policy: ○ Items that do not require significant improvement at present ✓ Items for improvement

### Corporate Governance and Compliance Indices

	Ir	ndex	Period	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	
0	Ratio of outside direc	tors to directors	At fiscal year end	63.6% 7/11										
0	Ratio of women to dir	rectors	At fiscal year end	9.1% 1/11										
	Ratio of women to co	rporate officers	At fiscal year end	0% 0/26	0% 0/27	0% 0/18	0% 0/18	4.3% 1/23	9.1% 2/22	8% 2/25	14.8% 4/27	11.1% 3/27	13.8% 4/29	
0	Average age of corpo	rate officers	At fiscal year end	56.1	54.8	52.9	52.9	53.0	53.1	53.6	52.9	52.9	53.2	
0	Remuneration	Directors (internal) (millions of yen)	At fiscal year end	129	116	118	118	116	114	113	113	113	113	
Ŏ	(base salary, bonuses, retirement	Directors (outside) (millions of yen)	At fiscal year end	86	87	85	86	82	76	74	74	74	88	
0	benefits)	Corporate officers (millions of yen)	At fiscal year end	1,252	1,138	876	872	1,055	976	1,310	1,247	1,203	1,219	
$\circ$	Niversia au af Alica a a	Number of times offered	Annually	105	70	84	120	65	56	47	62	65	72	
ŏ	Number of times compliance training offered	Number of executive training courses	Annually	2	2	2	2	2	2	2	2	2	3	
O	Ollered	Total participants (approx.)	Annually	9,000	6,000	6,000	8,500	5,800	5,000	4,600	5,800	4,800	6,200	
0	Submission rate of EN	NW compliance oath	At fiscal year end	_	-	-	-	_	_	100.0%	100.0%	100.0%	100.0%	
0	Number of times human rights training	Number of times offered	Annually	16	23	15	28	23	28	30	34	34	34	
0	offered	Participants	Annually	11,647	16,370	5,096	3,123	2,452	2,405	5,001	5,457	5,477	5,686	
0	Number of cases subject authorities due to violation		At fiscal year end	0	0	0	0	0	0	0	0	0	0	*
0	Number of employee disc violation of anti-corruption	i acts	At fiscal year end	0	0	0	0	0	0	0	0	0	0	*
0	Fines, penalties and costs violation of anti-corruption		At fiscal year end	0	0	0	0	0	0	0	0	0	0	*

<sup>\*</sup> The U.S. Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act, the Unfair Competition Prevention Act in Japan, etc.

### Environmental Indices

_													
	Index	Period	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	
0	Amount of CO <sub>2</sub> emissions (t)	Annually	131,272	145,239	157,889	164,448	168,914	143,731	125,071	120,224	118,625	120,562	*1
0	Scope 1 (t)	Annually	51,951	51,254	53,007	52,835	47,095	38,175	31,698	31,726	32,404	34,248	*1
0	Scope 2 (t)	Annually	79,746	94,493	92,486	112,136	121,797	105,532	93,359	88,497	86,221	86,315	*1
0	Amount of electricity consumption (MWh)	Annually	182,124	209,920	203,417	213,993	210,651	209,552	169,608	160,378	158,048	159,235	*2
0	Water consumption (Km³)	Annually	-	-	3,785	3,562	3,820	3,323	3,453	3,149	2,982	3,089	*2
0	Water discharge (Km³)	Annually	_	_	3,262	2,948	3,125	2,694	2,726	2,449	2,446	2,584	*2
0	Amount of waste generated (t)	Annually	6,769	6,555	7,410	6,280	4,917	4,001	3,481	2,935	3,038	3,736	
0	Waste-recycling rate	Annually	53.80%	56.30%	49.70%	50.30%	48.3%	50.6%	57.7%	62.8%	58.7%	47.9%	*2
0	Amount of chemical substances handled subject to the PRTR system (t)	Annually	469	656	885	566	477	499	476	258	267	261	*2
0	Number of administrative penalties and litigation related to the environment	Annually	0	0	0	0	0	0	0	0	0	0	

### Involvement with Patients

		Index	Period	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	
		Japan		2	8	6	5	4	4	3	1	4	2	*
		Americas (North America)		1	3	0	2	0	2	2	3	1	2	*
	Number of prescription drugs approved	EMEA (Europe, Middle East, Africa, Russia and Oceania)	At fiscal year end	0	2	2	2	1	1	2	3	0	1	*
	approved	China		0	0	0	0	0	1	0	0	1	1	*
		Asia		2	1	0	0	0	0	2	1	0	1	*
0	Number of patents (num	ber of patent applications)	Annually	157	151	125	109	88	87	65	55	51	63	
0	Number of inquiries to h	<i>hc</i> Hotline	Annually	92,050	98,650	103,675	108,298	99,471	91,286	97,444	90,742	82,028	71,568	
	Number of complaints	(concerning product quality)	Annually	296	238	256	222	368	336	314	323	309	525	

<sup>\*</sup> Includes additional indications and formulations. The past data was reviewed by recalculation.

### Involvement with Society

	Index	Period	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
0	Number of regional agreements	Annually	_	_	_	_	3	20	34	31	43	21
0	DEC tablets supplied (billion tablets)	Annually	-	-	-	-	0.01	0.26	0.32	0.37	0.37	0.32
0	Cumulative quantity of DEC tablets supplied (billion tablets)	Annually	-	_	_	-	0.01	0.28	0.60	0.97	1.35	1.66
0	Amount of funds donated (millions of yen)	Annually	3,449	3,583	2,185	1,988	2,377	2,073	2,602	2,118	2,505	2,765

### Involvement with Employees

	Inc	dex	Period	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
0		Total		11,415	11,560	10,730	10,495	10,419	10,183	9,877	10,452	10,456	10,683
		Japan		5,675	5,636	5,472	5,320	5,200	4,712	4,523	5,009	4,914	4,888
	Number of employees	Americas (North America)		2,701	2,559	1,843	1,815	1,763	1,719	1,290	1,296	1,240	1,261
	Number of employees by region	EMEA (Europe, Middle East, Africa, Russia and Oceania)	At fiscal year end	1,015	1,015	873	831	811	893	913	983	1,022	1,046
		China		1,114	1,407	1,498	1,454	1,559	1,607	1,875	1,909	1,906	2,069
		Asia and Latin America		910	943	1,044	1,075	1,086	1,252	1,276	1,255	1,374	1,419

<sup>\*\*1</sup> Recalculated including Baltimore Plant from FY2011

Scope 1: Direct emissions of greenhouse gases emitted to the atmosphere by fossil fuel use
Scope 2: Indirect emissions of greenhouse gases associated with the use of electricity and steam supplied by others

\*\*2 As a result of recalculation, the past data was revised.
Amount of electricity consumption: FY2013-2017, Water consumption: FY2011, Water discharge: FY2011,2014,2015 and 2017, Waste-recycling rate and Amount of chemical substances handled subject to the PRTR system: FY2009-2013

	Ind	ex	Period	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	
		Total		4,428	4,415	4,305	4,163	4,130	3,583	3,577	3,508	3,436	3,411	*1
	Number of employees o	f Male	At fiscal year end	3,394	3,393	3,331	3,228	3,202	2,845	2,838	2,775	2,708	2,679	*1
	Eisai Co., Ltd.	Female	The flooding out office	1,034	1,022	974	935	928	738	739	733	728	732	*1
	Number of toponousers or			23.4%	23.1%	22.6%	22.5% 306	22.5%	20.6%	20.7%	20.9%	21.2%	21.5%	
	Number of temporary er Ratio of temporary employees		At fiscal year end	7.5%	6.9%	6.7%	6.8%	5.1%	5.7%	3.7%	4.3%	5.9%	7.4%	*1
	Tiatio of temporary employees	Total		1,372	1,392	1,376	1,369	1,370	1,282	1,292	1,206	1,228	1,250	*2
<b>✓</b>	Number of management	Female		40	42	43	53	59	61	65	72	86	100	*2
1		Total	At fiscal year end	2.9%	3.0%	3.1%	3.9%	4.3%	4.8%	5.0%	6.0%	7.0%	8.0%	
	Ratio of women in mana		ed	9.2%	3.6%	6.5%	16.3%	17.4%	15.4%	11.6%	17.6%	21.3%	23.9%	<b>4</b> 7
		managers		8/87	2/56	3/46	8/49	8/46	6/39	5/43	9/51	13/61	17/71	<b>↑</b> ∠
	Average age		At fiscal year end	41.8	42.3	42.8	43.4	42.5	43.7	44.1	44.8	45.3	45.3	*1
		Total		18.1	18.5	19.0	19.5	20	19.4	19.9	20.4	20.8	21.2	
	Average years of employ		At fiscal year end	18.9	19.3	19.7	20.1	20.7	20.3	20.8	21.4	21.9	22.3	*1
		Female		15.5	16.1	16.8	17.3	17.8	15.9	16.2	16.9	16.9	17.3	*1
	Turnover rate (self-direc	ted retirement)	Annually	1.4%	1.5%	2.4%	1.7%	1.8%	1.4%	2.6%	3.1%	2.5%	2.2%	*1,3
	Total turnover rate	Total	Annually	3.3%	2.5%	4.8%	2.8%	14.2% 78	1.9%	3.0%	3.8%	3.4% 97	11.4%	*1,4 *1,5
	Number of users of child	Total dcare Male	Annually	2	1	0	1	1	1	2	09	5		*1,5
•	leave program	iviaic	Annually	60	69	76	77	<u>'</u> . 77	89	93	89	92	99	
	Normalism of constraints	Female	Annually	00	09	70	11	- 11	09	93	09	92		*1,5
	Number of users of spousal n Number of users of short working	, , ,	Annually re Annually	74	80	79	82	86	73	93	80	75	58 90	*1,6 *1
	Average annual salary (t	· · ·												ar I
	(according to the annual		Annually	10,728	10,936	11,094	11,063	10,401	10,403	10,939	10,389	10,446	10,992	
0	Personal development e (thousands of yen)(per e		Annually	224	192	157	162	177	176	198	210	214	221	<b>*</b> 1,7
$\overline{\bigcirc}$	Percentage of handicap		Annually	1.91%	2.02%	2.03%	2.37%	2.39%	2.56%	2.53%	2.65%	2.84%	2.88%	
0		• • •	,	30.4%	40.8%	28.3%	50.0%	36.9%	14.3%	33.3%	38.2%	44.3%	36.3%	. 4
O	Female rate in the annua	ai nired (Female/ i otal)	Annually	59/194	42/103	17/60	14/28	31/84	2/14	35/105	21/55	31/70	33/91	*1
		Total	Annually	176	98	56	21	76	3	100	39	43	57	
	Number of hired new gra		Annually	122	57	39	12	46	2	66	20	23	32	
		Female	Annually	54	41	17	9	30	1	34	19	20		*1,8
		Total (10 years average 94.7%)	At fiscal year end	95.0% 189/199	95.5% 234/245	94.9% 167/176	93.9% 92/98	98.2% 55/56	90.5% 19/21	94.7% 72/76	100% 3/3	93.0% 93/100	89.7% 35/39	<b>*</b> 1,8,9
	Retention rate of hired new graduates	Male	At fiscal year end	96.8%	98.2%	95.9%	96.5%	97.4%	91.7%	100%	100%	95.5%	90.0%	*1,8,9
	after 3 years	(10 years average 96.8%)	7 te noodi your ond	122/126 91.8%	167/170 89.3%	117/122 92.6%	55/57 90.2%	38/39	11/12 88.9%	46/46 86.7%	2/2 100%	63/66 88.2%	18/20 89.5%	. 1,0,5
		Female (10 years average 90.7%)	At fiscal year end	67/73	67/75	50/54	37/41	17/17	8/9	26/30	1/1	30/34	17/19	*1,8,9
		Total	At fiscal year end	81.5%	77.2%	81.9%	85.3%	88.1%	82.7%	83.9%	81.0%	82.9%	66.7%	*1,8,9
	Retention rate of	(10 years average 82.6%) Male		198/243 95.7%	176/228 94.4%	163/199 92.1%	209/245 92.4%	155/176 89.3%	81/98 89.5%	47/56 92.3%	17/21 75.0%	63/76 91.3%	2/3 50.0%	
	hired new graduates after 5 years	(10 years average 92.0%)	At fiscal year end	110/115	119/126	116/126	157/170	109/122	51/57	36/39	9/12	42/46	1/2	*1,8,9
<b>✓</b>	artor o years	Female (10.100)	At fiscal year end	68.8%	55.9%	64.4%	69.3%	85.2%	73.2%	64.7%	88.9%	70.0%	100%	<b>*</b> 1,8,9
		(10 years average 68.1%) Total	,	88/128 50.0%	57/102 85.7%	47/73 83.1%	52/75 72.8%	46/54 78.0%	30/41 65.4%	11/17 57.9%	8/9 67.3%	21/30 72.2%	72.7%	
	Detection and of	(10 years average 69.3%)	At fiscal year end	1/2	24/28	69/83	59/81	71/91	159/243	132/228	134/199	177/245	128/176	*1,8,9
	Retention rate of hired new graduates	Male (10 years systems 92 1%)	At fiscal year end	100%	85.7%	93.1% 54/58	88.2%	86.7%	86.1%	76.2% 96/126	79.4% 100/126	82.9% 141/170	75.4% 92/122	*1,8,9
	after 10 years	(10 years average 82.1%) Female		1/1	18/21 85.7%	60.0%	45/51 46.7%	52/60 61.3%	99/115 46.9%	35.3%	46.6%	48.0%	66.7%	
<b>~</b>		(10 years average 48.7%)	At fiscal year end	0/1	6/7	15/25	14/30	19/31	60/128	36/102	34/73	36/75	36/54	*1,8,9
0	Average monthly overting (per non-management e		Annually	13h 7m	13h 3m	11h 1m	10h 27m	10h 46m	12h 11m	9h 11m	8h 34m	9h 44m	10h 28m	
1	Number of work-related		Annually	29	35	31	42	16	9	16	23	19		*10
0	Frequency of work-related		Annually	0.18	0.44	0.27	0.19	0.10	0	0	0.10	0.10	0.20	
_	injuries that resulted in n	nore than												
O	4 days of work lost (per hours of actual work)	million Contractor	Annually	0	0	0	0	0	0	0	0	0	0	
$\checkmark$	Number of work related	Employee	Annually	0	0	0	0	0	0	0	1	0	0	<b>*</b> 12
0	Number of work-related	Contractor	Annually	0	0	0	0	0	0	0	0	0	0	
$\checkmark$	Number of cases of wor	k-related Employee	Annually	0	0	0	0	0	0	0	1	0	0	*12
0	occupational illness	Contractor	Annually	0	0	0	0	0	0	0	0	0	0	
0	Percentage of employee		Annually	99.45%	99.76%	99.93%	99.75%	99.83%	99.75%	99.86%	99.48%	99.56%	99.91%	
0	underwent health check	T diffing Thornisc	rs Annually	60.36%	71.88%	73.22%	72.01%	76.57%	74.45%	71.16%	80.57%	78.10%	80.27%	*13
$\checkmark$	Average days of paid ho (per non-management e		Annually	13.4	13.7	13.9	12.7	12.3	12.1	12.1	12.4	12.9	13.5	
	(PS. HOTT Management e													

<sup>\*1</sup> Based on the number of fulltime Eisai Co., Ltd. employees including employees dispatched to ENW companies
\*2 Recalculated based on the number of employees disclosed in Annual Securities Report (Eisai Co., Ltd. employees includes those dispatched from ENW companies and excludes the ones to ENW companies)
Formerly, the numbers were calculated based on the number of fulltime Eisai Co., Ltd. employees including employees dispatched to ENW companies.
\*3 Self-directed retirement only, not including mandatory retirement due to age, voluntary retirement, etc. As a result of recalculation, the past data was revised from 1.4% to 1.5% for FY2010, from 1.6% to 1.7% for FY2012, from 1.6% to 1.8% for FY2013.

FY2010, from 1.6% to 1.7% for FY2012, from 1.6% to 1.8% for FY2013.

4 Covering all retirements such as self-directed retirement, mandatory retirement due to age, death retirement, voluntary retirement, etc.

5 Childcare leave program entitlement: Workers who have served the company for 1 year or more and requested childcare leave for child/children under the age of 3 Period: By the day of the employee's request before the child/children reach the age of 3 Period: By the day of the employee's request before the child/children reach the age of 3 Personal maternity leave program (new program commenced April, 2018) entitlement: Workers whose partner gave birth Period: Up to 5 days of special paid holidays

7 Personal development expenses include training, studying abroad, participation in academic conferences

8 Not including employees who joined the company midway

9 At the beginning of next fiscal year (Eg. The number of retention rate after 3 years for FY2018 indicates the rate of retention of the new graduates hired in FY2016 as of April 1, 2019)

10 As a result of recalculation, the past data was revised from 30 to 29 for FY2009, from 17 to 16 for FY2013, from 10 to 9 for FY2014, from 18 to 16 for FY2015, from 27 to 23 for FY2016 FY2016.

<sup>\*11</sup> As a result of recalculation, the past data was revised from 0 to 0.10 for FY2013, from 0.29 to 0 for FY2015, from 0 to 0.10 for FY2016.
\*12 As a result of recalculation, the past data was revised from 0 to 1 for FY2016.
\*13 Health check eligibility includes dependent spouses and dependent family members aged 40 or older.

### **Intellectual Capital**

## **Major R&D Pipeline**

Robust progress in development in the therapeutic areas of focus: neurology and oncology

(As of the end of July 2019)

Projects which have made progress on development stage since fiscal year 2018

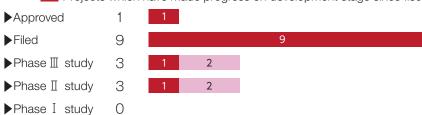
#### Neurology Area **Major R&D Pipeline**

		Development Stage						
Target Disease	Region	Phase I	Phase Ⅱ	Phase Ⅲ	Filed	Approval		
Fycompa® perampanel/E2007 Antieplieptic agent / AMPA receptor antagonist In-hou	se Oral a	gent						
	U.S.					September 201		
Pediatric epilepsy (Additional dosage and administration)	Japan				January 2019			
,	Europe				February 2019			
Adjunctive therapy for partial-onset seizures	China				Accepted October 2018			
Monotherapy for partial-onset seizures (Additional indication)	Japan				January 2019			
Fine granule formulation (Additional formulation)	Japan			_	January 2019			
Lennox-Gastaut syndrome (Additional indication)	Japan/U.S./ Europe							
lemborexant/E2006 Orexin receptor antagonist In-house Oral agent								
Insomnia disorder	U.S.				December 2018			
irisorrilla disorder	Japan				March 2019			
Irregular sleep-wake rhythm disorder (ISWRD) associated with Alzheimer's disease dementia	Japan/U.S.							
Disease modifying treatment for Alzheimer's disease / beta-site amyloid precursor protein Early Alzheimer's disease (Co-development with Biogen Inc.)	Japan/U.S./ Europe/China	enzyme (E	BACE) INNIR	oitor in-no	ouse Orai	agent		
BAN2401 Disease modifying treatment for Alzheimer's disease / anti-A $oldsymbol{eta}$ protofibril antib	ody In-li	cense (Bio	Arctic AB)	Injection				
Early Alzheimer's disease (Co-development with Biogen Inc.)	Japan/U.S./ Europe/China							
safinamide/ME2125 Anti-Parkinson's disease agent / MAO-B inhibitor In-license (Meiji	Seika Ph	arma Co.,	Ltd.) Oral	agent				
Partingan's diagon	Japan				October 2018	3		
Parkinson's disease	Asia (South Korea)				July 2019			
E2027 Treatment fo dementia with Lewy bodies / phosphodiesterase (PDE) 9 inhibitor	In-house	Oral agent	t					
Dementia with Lewy bodies	Japan/U.S./ Europe							
E2730 Antiepileptic agent, treatment for neurological diseases / Synapse function modu	ulator In-	house Or	al agent					
Epilepsy	U.S.							
E2082 Antiepileptic agent, treatment for neurological diseases / AMPA receptor antagor	nist In-ho	ouse Oral	agent					
Epilepsy	U.S.							

 $<sup>\</sup>boldsymbol{\ast}$  All clinical studies of E2082 in Japan and U.S. have been suspended.

### **Number of Projects in Neurology Area**

Projects which have made progress on development stage since fiscal year 2018 Others



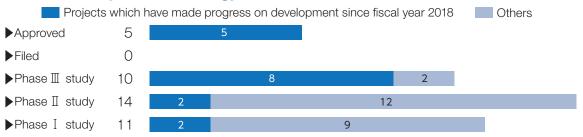
- \* Number of projects that were approved or filed is counted by region.
- \* Number of projects in which Phase I, II or III studies are ongoing is counted by indication. Projects which have been suspended are excluded. 
  \* Number of projects in which Phase I/II studies are ongoing is counted based on the current study stage.

### Oncology Area Major R&D Pipeline

Target Disease	Region	Phase I	Phase I	Phase II	Filed	Approve
Lenvima®/Kisplyx® lenvatinib/E7080 Anticancer agent / kinase inhibitor In-house On		T Habb I	1 11400 1	· · · · · · · · · · · · · · · · · · ·		, lph.ore
	U.S.					August 20
Hepatocellular carcinoma/First-line (Additional indication)	Europe					August 2
Co-development with Merck & Co., Inc., Kenilworth, N.J., U.S.A. (U.S. Merck))	Asia (Korea)					August 2
	China					September
Thyroid cancer (Additional indication) (Co-development with U.S. Merck)	China					
Renal cell carcinoma/First-line (Additional indication) (In combination with anticancer agent everolimus or anti-PD-1 antibody KEYTRUDA®) (Co-development with U.S. Merck)	Japan/U.S./ Europe					
Combination therapy with anti-PD-1 antibody $KEYTRUDA^{\$}$ (Co-development with U.S. Mer	ck)					
Endometrial carcinoma/Second-line	Japan/U.S./ Europe					
Endometrial carcinoma/First-line	Japan/U.S./ Europe/China					
Hepatocellular carcinoma/First-line	Japan/U.S./ Europe/China					
Melanoma/First-line	U.S./Europe/ China					
Nonsquamous non-small cell lung cancer/First-line	Japan/U.S./ Europe/China					
Non-small cell lung cancer, PD-L1 positive /First-line	Japan/U.S./ Europe/China					
Non-small cell lung cancer/Second-line	Japan/U.S./ Europe					
Bladder cancer, cisplatin-ineligible /First-line	Japan/U.S./					
Melanoma/Second-line	Europe U.S./Europe					
Baskect trial for selected solid tumors (Triple negative breast cancer, ovarian cancer, gastric cancer, colorectal cancer, glioblastoma and biliary tract cancer)	U.S./Europe					
Selected solid tumors (Endometrial cancer, renal cell carcinoma, head and neck cancer, urothelial cancer, non-small cell lung cancer, melanoma)	U.S./Europe					
Hepatocellular carcinoma	Japan Japan/U.S.					
Non-small cell lung cancer (RET translocations) (Additional indication)	Japan/U.S./					
Co-development with U.S. Merck)	Europe/Asia					
Biliary tract cancer (Additional indication) (Co-development with U.S. Merck)	Japan					
Hepatocellular carcinoma (In combination with anti-PD-1 antibody nivolumab) Co-development with Ono Pharmaceutical Co., Ltd.)	Japan					
Halaven® eribulin/E7389 Anticancer agent / microtubule dynamics inhibitor In-house	Injection					
Breast cancer	China					July 2
Bladder cancer (Additional indication)	U.S./Europe					
Triple negative breast cancer (In combination with anti-PD-1 antibody KEYTRUDA®)  Co-development with U.S. Merck)	U.S.					
HER2-negative breast cancer (In combination with PEGPH20) Co-development with Halozyme Therapeutics Inc.)	U.S.					
Liposome formulation (Additional formulation) (In combination with anti-PD-1 antibody nivolumab) (Co-development with Ono Pharmaceutical Co., Ltd.)	Japan					
Liposome formulation (Additional formulation)	Japan/Europe					
Farletuzumab/MORAb-003 Anticancer agent / humanized anti-FRA monoclonal antibod	ř –	se Inject	ion			
Platinum-sensitive ovarian cancer	Japan/U.S./ Europe					
MORAb-004 Anticancer agent / humanized anti-endosialin monoclonal antibody In-ho Melanoma	U.S./Europe					
Amatuximab / MORAb-009 Anticancer agent / chimeric anti-mesothelin monoclonal and Mesothelioma	tibody In- U.S./Europe		njection			
E7777 Anticancer agent / a fusion protein that combines the interleukin-2 receptor bindi Peripheral T-cell lymphoma and cutaneous T-cell lymphoma	ng domair Japan	with diph	theria toxin	fragments	In-hous	e Injec
Tazemetostat/E7438 Anticancer agent / EZH2 inhibitor In-license (Epizyme Inc.) Oral Non-Hodgkin B-cell lymphoma	agent Japan					
H3B-6545 Anticancer agent / ERα inhibitor In-house Oral agent  Breast cancer	U.S./Europe					
E7090 In-house Oral agent						

Taxant Diagona	Development Stage								
Target Disease	Region	Phase I	Phase Ⅱ	Phase Ⅱ	Filed	Approved			
H3B-6527 In-house Oral agent									
Hepatocellular carcinoma	U.S./Europe								
H3B-8800 In-house Oral agent									
Blood cancer	U.S./Europe								
E7386 Collaboration (PRISM BioLab Co., Ltd.) Oral agent									
Solid tumors	Japan/Europe								
Solid tumors (In combination with Lenvima®)	Japan								
MORAb-202 In-house Injection									
Solid tumors	Japan								
E7130 Collaboration (Harvard University) Injection									
Solid tumors	Japan								

### **Number of Projects in Oncology Area**



- \* Number of projects that were approved or filed is counted by region.

  \* Number of projects in which Phase I, I or I studies are ongoing is counted by indication.

  \* Number of projects in which Phase I/I studies or Phase I/I studies are ongoing is counted based on the current study stage.

### Gastrointestinal Disease Area Major R&D Pipeline

T 10:			Development Stage			
Target Disease	Region	Phase I	Phase Ⅱ	Phase Ⅲ	Filed	Approved
MOVICOL®/AJG555 Chronic constipation treatment / polyethylene glycol preparation In-	license (N	orgine B.V.	Oral age	nt		
Chronic constipation (Co-development by EA Pharma and Mochida Pharmaceutical Co., Ltd.)	Japan					September 2018
carotegrast methyl/AJM300 Ulcerative colitis treatment / α4 integrin antagonist In-hous	se Oral a	igent				
Ulcerative colitis (Co-development with EA Pharma and Kissei Pharmaceutical Co., Ltd.)	Japan					
E6007 Ulcerative colitis treatment / integrin activation inhibitor In-house Oral agent						
Ulcerative colitis (Development conducted by EA Pharma)	Japan					
E3112 In-house Injection						
Liver disease (Development conducted by EA Pharma)	Japan					

Research and development in the gastrointestinal disease area is mainly conducted by Eisai's subsidiary EA Pharma.

### Other Major R&D Pipeline

Target Disease			Developn	nent Stage		
Taliget Disease	Region	Phase I	Phase I	Phase II	Filed	Approved
Humira® adalimumab/D2E7 Fully human anti-TNFα monoclonal antibody In-license (Ab	obVie GK	Injection	1			
Hidradenitis suppurativa (Additional indication)	Japan					February 2019
E6011 Anti-fractalkine antibody In-house Injection						
Rheumatoid arthritis	Japan					
Crohn's disease (Development conducted by EA Pharma)	Japan/Europe					
E6742 In-house Oral agent						
Autoimmune disease	U.S.					

### Status of Shares (As of March 31, 2019)

Authorized (common stock) 1.100.000.000 shares

Issued 296,566,949 shares (including 10,046,253 shares of treasury stock)

Number of shareholders 53.041

Transfer agent Mitsubishi UFJ Trust and Banking Corporation

### Principal Shareholders

Shareholders	Number of shares held (in thousands)	Percentage held of all shareholder voting rights (%)
The Master Trust Bank of Japan, Ltd. (trust account)	33,741	11.78
Japan Trustee Services Bank, Ltd. (trust account)	31,494	11.00
STATE STREET BANK AND TRUST COMPANY 505001	18,329	6.40
Nippon Life Insurance Company	12,281	4.29
Saitama Resona Bank, Limited	7,300	2.55
Trust & Custody Services Bank, Ltd. as trustee for Mizuho Bank, Ltd. Retirement Benefit Trust Account re-entrusted by Mizuho Trust and Banking Co., Ltd.	5,437	1.89
Japan Trustee Services Bank, Ltd. (trust account 5)	4,697	1.64
Japan Trustee Services Bank, Ltd. (trust account 7)	4,536	1.58
The Naito Foundation	4,207	1.46
JP MORGAN CHASE BANK 385151	4,092	1.42
Total	126,116	44.06

#### (Notes)

- 1 Numbers of shares are rounded down to the nearest thousand.
- 2 Indicates the top 10 shareholders in terms of percentage of the total number of outstanding shares (excluding treasury stock).

  3 The 10,046,000 shares (3.38%) of treasury stock are not included in this table at the de
- table as they do not have voting rights.

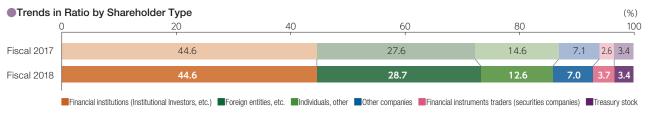
  4 Although the following Large Shareholding Report (revised report) was received before the end of the fiscal year, in cases in which it is impossible to make confirmation with the shareholder registry for the end of the fiscal year, or in which the number of shares held is not ranked among the top 10, it is not included in the table. Further, the holding percentage enclosed in parentheses is the percentage of the total number
- of outstanding shares (rounded down), including treasury stock.
  (1) Including the Mitsubishi UFJ Financial Group, Inc., 4 companies jointly held 16,113,000 shares (5.43%) as of July 13, 2015 (July 21, 2015, Revised Report)
- (2) Including the Wellington Management Company, LLP, 2 companies jointly held 27,087,000 shares (9.13%) as of July 31, 2015 (August 7, 2015, Revised Report)
- (3) Including Mizuho Bank, Ltd., 2 companies jointly held 18,900,000 shares (6.37%) as of October 14, 2016 (October 21, 2016, Large Shareholding Report)
- Report)

  (4) Vanguard Health Care Fund held 14,838,000 shares (5.00%) as of November 24, 2016 (December 15, 2016, Large Shareholding Report)

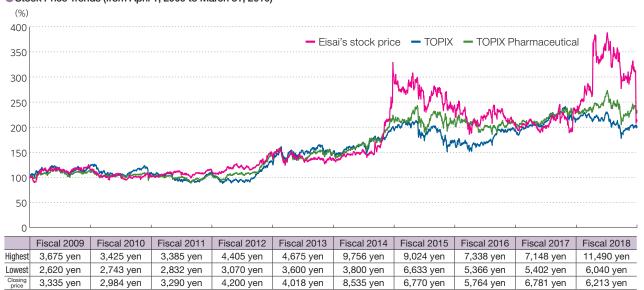
  (5) Including BlackRock Japan Co., Ltd., 11 companies jointly held 18,308,000 shares (6.17%) as of August 15, 2017 (August 21, 2017, Large Shareholding Report)

  (6) Nomura Asset Management Co., Ltd. held 14,963,000 shares (5.05%) as of March 15, 2018 (March 22, 2018, Large Shareholding Report)

  (7) Including Sumitomo Mitsui Trust Bank, Limited, 3 companies jointly held 15,967,000 shares (5.38%) as of December 14, 2018 (December 21, 2018, Large Shareholding Report)







Note: The April 1, 2009, closing prices of Eisai's stock price, TOPIX and TOPIX Pharmaceutical respectively represent the 100 shown in the line graph

### TSR (Total Shareholder Return, %)

Holding period	1 year	3 years	5 years	10 years
Eisai	121.0	129.9	165.6	267.8
Nikkei Stock Average*1	138.5	130.7	198.4	305.7
TOPIX*2	128.5	117.3	172.2	253.3

Note: TSR is based on investment conducted at the closing price on March 31, 2009

https://indexes.nikkei.co.jp/en/nkave/index/profile?idx=nk225tr

https://www.jpx.co.jp/english/markets/statistics-equities/monthly/index.html

Please refer to the Notice of Convocation of the 106th Ordinary General Meeting of Shareholders for the status of shares

<sup>\*1</sup> Source: Nikkei Indexes

<sup>\*2</sup> Source: JAPAN EXCHANGE GROUP

https://www.eisai.com/ir/stock/meeting/index.html

### Corporate Data (As of March 31, 2019)

Corporate Name Eisai Co., Ltd.

Date Founded December 6, 1941 **Head Office Address** 4-6-10, Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan

Paid-in Capital ¥44,986 million Stock Exchange Listings
Eisai common stock is listed on the
Tokyo Stock Exchange. (Securities
Code Number: 4523)

Date for Settlement of Accounts March 31 Annual Shareholders'
Meeting
Held in June

Independent Public Accountants Deloitte Touche Tohmatsu LLC

## **Major External Evaluations**

As of July 2019





Listed as Most Honored Companies, the first place in Health Care & Pharmaceuticals by "Institutional Investor"

> Selected within TOP3 for all ranking categories- Best CEO, Best CFO, Best IR Professionals, Best IR Programs

## Listed as Global 100 Most Sustainable Corporation for the Fourth Time

Highest Ranked Japanese Company in the global ranking by Canada-based media and investment advisory company, Corporate Knights, Inc.

MSCI 🌐

2018 Constituent MSCI Japan ESG Select Leaders Index

MSCI 💮

2018 Constituent MSCI Japan Empowering Women Index (WIN)





FTSE Blossom Japan

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### Editor's Note for Integrated Report 2019

We focused on following two points in this fifth integrated report in order to obtain a better understanding of Eisai in mid-to-long term perspective.

First, we focused on disclosing information for 10-year span. 10 years is not particularly a long period of time for a pharmaceuticals company that has undertaken new drug development over long period, but the last 10 years was a turbulent period for us. After fiscal 2009 when we recorded peak sales, Eisai went through a tough phase due to the loss of exclusivity in major products. However, we came back to a growth trajectory by launching in-house developed anticancer agent Lenvima®, a crystallization of Eisai's wisdom, and by making robust progress in partnership model. I felt proud of our employees who continued their effort to create innovation in the difficult business environment.

Secondly, we focused on describing not only positive elements but also a variety of issues in

our business. We have been making a continuous effort to improve these issues. We believe that it is the best measure for value creation over the midto-long term to share the issues and our effort with our stakeholders in this integrated reporting.



The discontinuation of development of Alzheimer's disease treatment aducanumab, announced in March 2019, was a huge ordeal for us. Eisai will go through more ordeals from now on. However, I believe that Eisai will be able to overcome various ordeals and create much more innovation that contributes to create value for patients, by utilizing our strengths described in the SWOT analysis, under the concept of *hhc* philosophy. I strongly hope that Eisai will be able to make a significant contribution to the creation of next-generation dementia treatments, which has been all humankind's long-cherished wish.

(Chief Editor of Integrated Report 2019)

For further information

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