





Eisai Co., Ltd.

### **Our Response to the Novel Coronavirus Infection**

# Contribution to Stable Drug Supply and Therapeutic Treatment Development

As an "human health care (hhc)" company, we are engaged in stable drug supply even in the social turmoil under the pandemic, research and development of therapeutic drugs, and support activities in each country. We also take measures to prevent the infection spread at all of our facilities.

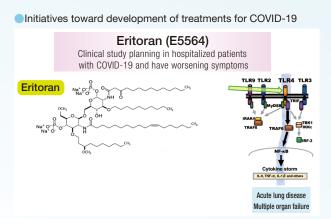
### 1. Stable Supply of Medicines

We secure the necessary inventory for stable supply from normal times, and we are making every possible effort to supply pharmaceuticals through stable production. Our operation of global 9 production sites are all smoothly ongoing with sufficient inventory of raw materials, drug substance and ample stock of final products. We will continue to carefully check the situation and take necessary measures.

### 2. Contribution to Development of Remedies

(1) Regarding the TLR4 (Toll-Like Receptor 4) inhibitor eritoran (E5564), created and developed internally as a sepsis treatment, Eisai is participating in the international network REMAP-CAP (A Randomised, Embedded,

Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia) which aims for novel coronavirus medicine development, and is to begin an international collaborative clinical trial which is designated for the patients hospitalized and in a progressing disease state. It is hoped that through suppressing the most upstream TLR4 activity which controls production of multiple cytokines, the cytokine storm in patients can be suppressed and pneumonia can thus be prevented from becoming severe.



- (2) Eisai is participating in a consortium of life science companies entitled "COVID-19 Therapeutics Accelerator," initiated by the Bill & Melinda Gates Foundation and formed with collaboration from Wellcome Trust (U.K.) and MasterCard (U.S.). This consortium aims for the fast delivery of potentially relevant research results relating to vaccines, medicines, and diagnosis techniques to people affected by COVID-19 across the world. Eisai has provided its unique collection of approximately 2,600 natural product compounds to the Scripps Institute (U.S.) for constructing a compound library for the development of treatments. Eisai is planning to provide its new vaccine adjuvant (E6020) which has possibility to boost antibody production.
- (3) Gimsilumab, the anti-GM-CSF antibody which Eisai has licensed to Roivant Sciences Ltd. (U.K.), is assumed to inhibit activity of GM-CSF that is thought to act on immune pathology which is caused by the novel coronavirus. Eisai is supporting and has provided active pharmaceutical ingredients of Gimsilumab for a placebo-controlled, double-blind study conducted by Roivant in the U.S. on acute respiratory distress syndrome (ARDS) caused by COVID-19.
- (4) Eisai supplied active pharmaceutical ingredients to the National Institute of Infectious Diseases (NIID) in response to a request "for the provision of active pharmaceutical ingredients applicable for screening of remedies for the novel coronavirus" issued on February 7, 2020 through the Ministry of Health, Labour, and Welfare (MHLW) towards the Federation of Pharmaceutical Manufacturers Association of Japan (FPMAJ) and the Japan Pharmaceutical Manufacturers Association (JPMA).
- (5) Eisai is conducting efforts for realizing new remedies that apply its assets and technologies, through collaborations with academia and external organizations.

# 3. Support of Response Efforts to the Spread of the Novel Coronavirus Infection in Different Countries

- (1) In Japan, Eisai is providing supplies such as its own products to patient organizations, municipalities, and non-profit organizations for the impaired.
- (2) In the U.S., our U.S. subsidiary donated more than 1 million USD (approximately 107 million JPY) to medical facilities and non-profit patient groups and provided with Personal Protective Equipment (PPE; masks, goggles, and hazmat suits) to local healthcare providers.





- (3) In Europe, through its EMEA subsidiary, Eisai has provided 945 thousand euros (approximately 111 million JPY) in funding to professional organizations targeting COVID-19 such as the World Health Organization (WHO), as well as to support healthcare providers and supporting communities in the U.K., Italy, Germany, Spain, Belgium, France, Portugal, and the Slovak Republic.
- (4) In China, Eisai donated 1 million yuan (approximately 15 million JPY) to the Wuhan Charity Federation NPO and provided local healthcare providers with medicines and medical relief supplies through its Chinese subsidiary.
- (5) In Asian countries and other countries outside of China, Eisai donated 11.8 million rupees (approximately 17 million JPY) to federal emergency funding in India, and will provide funding and supplies to support organizations such as community chests in South Korea, Thailand, Vietnam, Indonesia, the Philippines, Malaysia, Singapore and Mexico.
- (6) In African countries, Eisai has committed the equivalent of 1 million USD in aid over the next 1 year in order to support the controlling of the spread of COVID-19 along with prevention of delays of elimination activities for neglected tropical diseases (NTDs). As part of this support, in cooperation with the Drugs for Neglected Diseases initiative (DNDi), Eisai has now begun provision of PPE to core hospitals in Africa for research of and countermeasures against infectious diseases. In addition, Eisai makes donation and supports Amref Health Africa for the development and popularization of its mobile health platform Leap for healthcare workers.

### 4. Minimize Impacts on Clinical Trials

With regard to clinical trials of potential next-generation dementia treatments and anti-cancer agent Lenvima®, we see some delays in setting up study sites, patient enrollment and data collection in some countries, but we minimize the impact by adding new sites or changes of evaluation facilities.

### 5. Efforts for Prevention of Spread of Infection and Employees Safety

We regularly review our Business Continuity Plan (BCP), which minimizes human damage in the event of a disaster or emergency and secures a backup manufacturing system, at all facilities around the world, and are taking measures to prevent infectious diseases from expanding through corporate activities.

We will continue to work to prevent the spread of all infectious diseases and support countermeasure activities. We hope the end of COVID-19 pandemic as soon as possible.



### Contents human health care

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### Major External Evaluations As of June 2020

2020 CONSTITUENT MSCI JAPAN **ESG SELECT LEADERS INDEX** 

2020 CONSTITUENT MSCI JAPAN EMPOWERING WOMEN INDEX (WIN)

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FTSE Blossom

FTSE Russell (the trading name of FTSE International Limited and Frank Russell Company) confirms that Eisai has been independently assessed according to the FTSE4Good criteria, and has satisfied the requirements to become a constituent of the FTSE4Good Index Series. Created by the global index provider FTSE Russell, the FTSE4Good Index Series is designed to measure the performance of companies demonstrating strong Environmental, Social and Governance (ESG) practices. The FTSE4Good indices are used by a wide variety of market participants to create and assess responsible investment funds and other products.













### **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 long-term 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.

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**

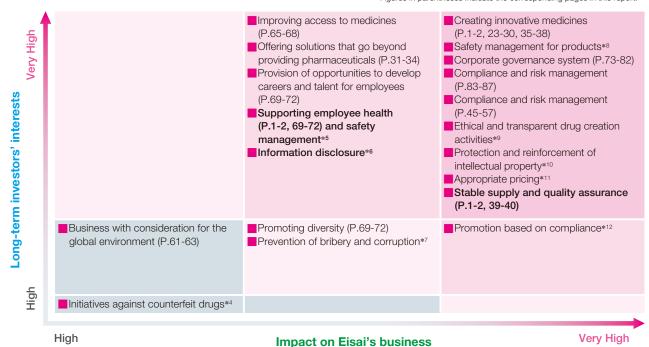
Reviews and updates are undertaken as needed taking into consideration the progress of initiatives toward issues and changes in the business environment.

- \*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

### Eisai's Materiality Matrix

### Updates from Integrated Report 2019 are in bold.

Figures in parentheses indicate the corresponding pages in this report.



- \*4-12 Please refer to Eisai's Corporate Website
  - \*4 Initiatives against Counterfeit Drugs
  - \*5 Occupational Safety and Health
  - \*6 Information Disclosure (Corporate Governance Guidelines Article 11)
  - \*7 Prevention of Bribery and Corruption
  - \*8 Safety Management for Products
  - \*9 Ethical and Transparent Drug Creation Activities
  - \*10 Intellectual Property Initiatives
  - \*11 Realizing Affordable Pricing \*12 Compliance-based Promotion

- https://www.eisai.com/sustainability/atm/product-security.html
- https://www.eisai.com/sustainability/employee/health\_safety/index.html
- https://www.eisai.com/company/governance/cgregulations/cgguideline/index.html https://www.eisai.com/sustainability/management/compliance/index.html
- https://www.eisai.com/sustainability/atm/pharmacovigilance.html
- https://www.eisai.com/company/business/research/discovery/index.html https://www.eisai.com/company/business/research/ip/index.html
- https://www.eisai.com/sustainability/atm/markets/005.html
- https://www.eisai.com/sustainability/management/compliance/index.html

30 years

Number of years since the company announced the concept of "Eisai Innovation" – the origin of "human health care (hhc)"



### Importance of the "SECI Model" from Knowledge Creation Theory and "Socialization"

Takayama: According to your Knowledge Creation
Theory, the process of exchanging and transferring tacit
knowledge and explicit knowledge within an
organization consists of and is theorized in four phases
called SECI; Socialization, Externalization, Combination,
and Internalization. Eisai took Socialization as the most
important phase and has been focusing on it. We
believe that unless we make an effort to emphasize with
each patient, we cannot truly "empathize" and no new
knowledge will be created.

**Prof. Nonaka:** The patient's view of the world is usually not obvious for others. We cannot understand the

 SECI Model Knowledge Creation Spiral Tacit Tacit Express tacit knowledge through dialogue and reflection Share direct experience and build up tacit knowledge (Conceptualizing) (Emphasizing) Practice the Tacit relevant concepts into a prototype, model or narrative and model, or narrative (Modeling) create new tacit knowled (Practicing) (Individual), G = (Gro O = (Organization), E = (Environment)

patients unless we get close to them and feel together with them. The origin is empathy. Socialization begins with empathy, that is to put yourself completely in his or her shoes at the level of unconsciousness. This leads to sympathy, that is, to objectify another person and experience emotions from the point of view of that person.

Then we move to Externalization, that is, to articulate tacit knowledge by words and create concepts by

sharing the essence we sympathized through dialogue. Different people have different feelings even when they see the same thing. I believe that a system of empathy and sympathy interactively creating ideas, concepts, and hypotheses by intelligent combat, thoroughly discussing "this is like that, I felt like that" is the very foundation of sustainable innovation.

### Socialization and "Encounter"

**Takayama:** I feel the necessity for our employees to express their humanity more through Socialization. I want each employee to experience the fact that new values are created through human interaction with patients.

Prof. Nonaka: Empathy is different from sympathy. Empathy is elicited in a selfless state of experiencing the consciousness of others, being oneness in body and soul. The essence of empathy is to "encounter." Encounter means that we, as a unique existence, mutually participate in the dynamic process of life of each other. Through pure encounters, we perceive

character, spirit and unconscious emotional depth of others without alienating, objectifying or manipulating them. In other words, a sincere, open and honest attitude towards people, things, phenomena, environments and everything can help each other's subjectivity to become as one, and build relationships that lead to dialogue. This is called the "I – Thou" relationship. This empathy is the most important starting point in knowledge creation. Because the only way to understand the essence of the pain and sadness of patients is to empathize with them though our whole body and soul as if they were your own.

### **Strategies Based on Patients' Anxieties**

**Takayama:** Eisai's CEO, Haruo Naito, says that empathy and anxieties are important. He suggested that sharing feelings with patients through Socialization may possibly remain only as tacit knowledge conceived superficially. What is truly expected through Socialization is to understand and extract anxieties in the emotional depths of patients, and then to formulate and implement a strategy to eliminate those anxieties.

Prof. Nonaka: By exchanging tacit knowledge derived from subjectivity with each other in the process of Socialization, an empathy naturally arises from the inside and leads us to a state of intersubjectivity, which we ought to call "our subjectivity," and enables us to extract potential anxieties in emotional depths of patients and their families. Such anxieties may be more sorrowful than their feelings conceived superficially, and may be derived from the worries for loved ones such as family members, or the loss of significant values that have shaped one's own life.

In vijnapti-matrata (the theory that everything exists

only in the mind), human consciousness is divided into eight levels. The deepest level is called *alaya-vijnana*, which is the eighth consciousness that corresponds to true unconsciousness. In *alaya-vijnana*, an inexhaustible collection of memories is preserved, such as all memories of what we have experienced in our life and what our ancestors have experienced. This *alaya-vijnana*, underlying unconsciousness, is the origin of true creativity.

When we perceive the serious anxiety that arises from the emotional depth of the patients, it brings motivation that inspires us to devote ourselves to do something helpful for them. This motivation should be the basis for true understanding of the anxieties, the source of the feeling of "for the patient's best benefit," the reason for realizing that no-one but us can undertake this task, and eventually, the meaning of life. It is necessary to begin with the empathy in the whole-hearted and spiritual encounter with each patient who has his or her own history and story of life, and to truly understand the essence of anxiety, explicitly formulate a hypothesis, and put it into practice.

### Relationship between Prof. Nonaka and Eisai

Takayama: After Eisai CEO Haruo Naito established the idea of "human health care (hhc)" in 1989, he struggled for about seven years to find out how to put empathy with the patients, which is the most important phase, into practice. After that, he was impressed when

he found the Knowledge Creation Theory, which posits that new knowledge cannot be created unless empathy is elicited, and he integrated the theory into Eisai's philosophy-based management. I believe you first met CEO Naito in 1996. Could you tell me about your first

encounter with him, please?

**Prof. Nonaka:** I was invited by Mr. Naito to participate in a 2-year project named "Code of the Company for 21st Century" in Keizai Doyukai (Japan Association of Corporate Executives), which Mr. Naito initiated as the

Chair in 1996. Then Mr. Naito took an interest in my book, *The Knowledge-Creating Company* (TOYO KEIZAI INC., 1996) and started the Knowledge Creation Project in Eisai. Surprisingly, he recognized that Socialization was the true origin of the knowledge creation process.

### **30 Years of Knowledge Creation**

Takayama: "hhc" stands for Eisai's corporate philosophy of "human health care," and that means, "to give first thought to patients and their families, and to increase the benefits that health care provides to them." Around the time of the Eisai Innovation Declaration in 1989, we struggled to expand the idea within the company, but it gradually progressed by putting your Knowledge Creation Theory into practice. Giving first thought to patient's emotions, we have developed unique "human health care" activities over the past 30 years based on the Knowledge Creation Theory. For creating the future, we must polish our intuition based on empathy into collective knowledge through thorough dialogue, with no compromises or conjecture. In the "hhc" company, it is necessary for each employee to explore the significance of their existence as human beings and the purpose of life. During that time, you gave us a lot of practical advice.

Prof. Nonaka: Eisai invited me to assist in 1996 and I shared my Knowledge Creation Theory then. The Knowledge Creation Department, which I named, was established as a department directly under CEO in 1997. From then on, the department has made efforts to enhance the "hhc" philosophy among employees and provided opportunities to be intuitive for essence to

empathize with patients and their families through direct experience in Socialization programs. Mr. Naito says "our philosophy urges us to take action." The "hhc," which was presented as a corporate philosophy, shed light on Eisai's strategy concept and the path of execution. As a result, the business domain is enriched and explored, not only for new drug creation, but also for solutions in the community.



### **Incorporating the Corporate Philosophy in the Articles of Incorporation**

Takayama: In 2005, when you were an Outside Director of Eisai, the corporate philosophy was incorporated into the Articles of Incorporation by the Annual General Shareholders' Meeting. And in the following year, in 2006, the Shareholders' Meeting approved the revision of the Articles of Incorporation to state, "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 ensuing results."

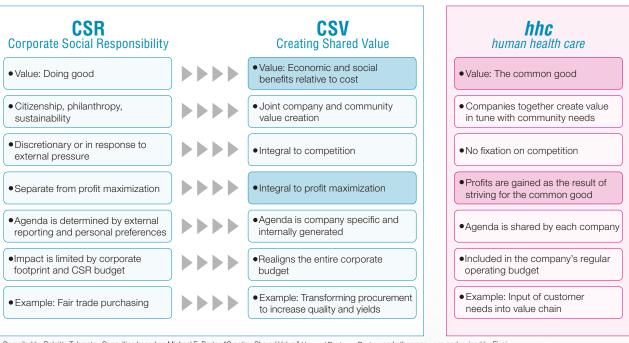
**Prof. Nonaka:** That was an epoch making event. It was innovative to put the proposal of "human health care" into the Articles of Incorporation. It was truly inspiring to see the positive sequence, prioritizing patient contribution (social contribution) over profit, was added to the Articles of Incorporation at the Shareholders' Meeting. I think the action was ahead of the trend of wise capitalism.

### **Eisai's "Societal Innovation"**

**Takayama:** Eisai is currently developing a new business domain called "Societal Innovation" which is to change our society. As a specific example, we are taking on the challenge of social innovation in collaboration with local communities, such as the Living Labs, based on Knowledge Creation Theory, with the

aim of "creating a community where people with dementia can live comfortably."

**Prof. Nonaka:** The Resident-Driven Living Labs, which Eisai initiated in 2015 as a new challenge for knowledge creation activities, is an innovative approach that is



<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.

completely different from living labs such as demonstration experiment conducted based on hypothesis by companies and academia, or national and local governments' policies conducted in other regions of Europe, the United States and Japan.

Eisai's Living Labs is an unprecedented mechanism for creating innovation, in which the local residents themselves put the Knowledge Creation Theory into practice. Eisai has been engaged with this theory in the

business field for many years to realize the "hhc" corporate philosophy as social goodness. By coordinating the practice of Knowledge Creation Theory focusing on the needs of residents, Eisai will be able to obtain answers to healthcare needs and challenges through new solutions as well as medicine. Furthermore, Eisai could build a new ecosystem by linking the creation of Social Capital to Societal Innovation.

### **What Society Requires after COVID-19**

Takayama: Recently, I feel that COVID-19 has been causing not only physical infection, but also social infection by causing people to feel uneasy as an infection in the mind, and inducing prejudice and discriminatory behavior. We have witnessed that human beings are forced to lose their ties with their own self and are driven to inappropriate actions or ideas. How do you see the current world situation under COVID-19?

Prof. Nonaka: Known as "new normal," the impact from COVID-19 changed the world drastically and we can no longer go back to where we were before. Digitalization or digital transformation (DX) will be further enhanced. However, it is human creativity that gives meaning to numbers and data in the digital world. We cannot create the future without striving for creative activity with diverse people, addressing their unconsciousness and the tacit knowledge. This is the universal "royal road" of knowledge creation in any era.

In such a society, wise leadership is becoming increasingly important even in changing and chaotic situations. The leadership can make quick decisions and create the future through interaction between the common good and the reality. The foundation of wise leadership is empathy, which enables us to connect with all people, things, and the environment at "here and now."

Based on the empathy in the field, we will find a breakthrough through a battle of knowledge, and systematically and autonomously accomplish knowledge creation with grit. In addition, we will overcome conflict of interests with the principles of "common good" and bring together the world's network of knowledge, including grass-roots networks. We have many predecessors who have advocated and practiced the dynamic synthesis of altruism and egoism. I think it is time to form an agile scrum together to reconstruct and disseminate the origins of Japanese management represented by "Sampo Yoshi (good for the seller, good for the buyer, and good for society)" to the world.

# 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

### **Late 1960s**

### **Commenced full-fledged overseas expansion**

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

### Late1960s to early1970s

Local subsidiaries established in Southeast Asia



### 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

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

Inauguration of Haruo Naito, Present CEO

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



### Late 1990s~

### Growth of two major brands accelerated global business expansion

#### Launched Alzheimer's disease (AD) 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®)



### Major in-house products

1997



1997 Pariet®



nce of

launch of products developed

in-house

### FY2002 to FY2005

### **Millennium Plan**

### Outcome

Achievement of major KPIs a year ahead (Revenue ¥600 billion, Operating Profit ¥100 billion) Enhancement of corporate governance

2004 Transferred to a company with committees

**2005** Incorporated the Corporate Philosophy into the Company's Articles of Incorporation

### Issue

Dispersion of R&D resources Unable to launch in-house developed products

### FY2006 to FY2010

### **Dramatic Leap Plan**

### Outcome

Strengthened foundation in oncology area

2007: Acquired Morphotek, Inc. in the U.S. 2008: Acquired MGI Pharma, Inc. in the U.S.

2010: Established H3 Biomedicine Inc. in the U.S.

Launched anticancer agent Halaven®

### reach of peak sales of 2 major brands

Aricept® ¥322.8 billion (FY2009) ¥175.9 billion (FY2007) Pariet® ¥470.8 billion (FY2009) Total

Achievement of record revenue (FY2009)

Establishment of product supply system

on affordable pricing Completion of Vizag Plant in India



Vizag Plant (India)

### Issue

Underachivement of performance targets (Revenue ¥1 trillion, Operating profit ¥200 billion)

Dispersion of R&D resources



### Concentration of resources in neurology and oncology area

### 2010s

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

### Formulated partnerships in the neurology and oncology area

2014 : Entered into a collaboration agreement with Biogen Inc. for the development and commercialization of AD treatments

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

•Neurology area Biogen Inc.

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





### FY2011 to FY2015

### **Plan Hayabusa**

#### Outcome

Enhancement of business in China and Asia Strengthened efforts to improve access to medicines

### Launched new products developed in-house

**2012 :** Launched antiepileptic agent Fycompa®

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

#### Issue

Under achievement of performance targets (Revenue over ¥800 billion Operating Profit over ¥200 billion)

Lack of capability to respond to changes in the business environment by LOE of two major brands

Loss of exclusivity (LOE) 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.

### FY2016 to FY2025

### EWAY 2025 → P.21

### FY2019∼

### Development progress in neurology and oncology area

July 2019 The Eisai Center for Genetics Guided Dementia Discovery (G2D2), a new exploratory research facility in Cambridge, Massachusetts, U.S., began full-scale research activities.

September The U.S. Food and Drug Administration (FDA) marked the first approval of Lenvima® (lenvatinib) plus KEYTRUDA® (pembrolizumab) combination treatment for patients with endometrial carcinoma\*

October Regulatory filing planned for investigational aducanumab in early AD

November Launched Parkinson's disease treatment Equfina® tablets in Japan

Lenvima® accepted additional indication for differentiated thyroid cancer in China

December Anti-insomnia drug Dayvigo™ obtained new drug approval in the U.S., followed by Japan in January 2020 January 2020 Launched Fycompa® and Halaven® in China

March Launched digital tool "NouKNOW™" in Japan for self-assessment of brain performance (brain health)

June Launched Dayvigo™ in the U.S. (Japan in July)

July Biogen Inc. completed submission of Biologics License Application (BLA) to the FDA for the approval of aducanumab, an investigational treatment for AD

Initiated new Phase III study (AHEAD 3-45) of investigational BAN2401 preclinical (asymptomatic) AD

\* Advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation

# 2020 Dayvigo™ DAYVIGO (lemborexant) ( ® 5mg. 10mg tablets

2012 Fycompa®

2015

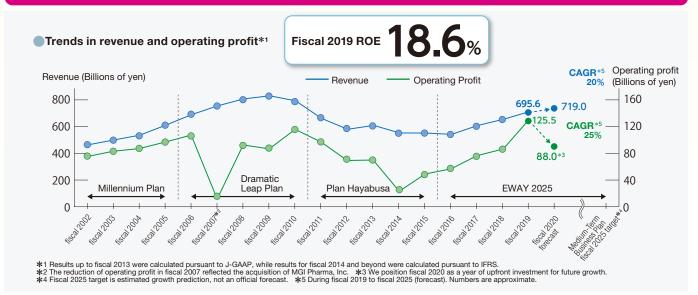
Lenvima®

LENVIMA'
(lenvatinih) cansules

Fycompa<sup>®</sup>

perampanel

### Advancement to Medico Societal Innovator



# **SWOT Analysis** (Business)

Taking on the challenge to promptly expand our contributions to patients with clear understanding of our characteristics

# **Eisai's characteristics**



1 Internalized philosophy of "hhc" and deep engagement of employees

83 points
Employees' empathy toward Corporate Mission and Vision exceeded all industries' average

Reference P69-72

2 Ample knowledge of medicine creation backed by experience





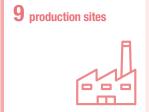


P1-2, Reference 23-30, 35-38

3 Global business activities







Reference P22, 39-40 41-42

4 Strategic partnerships

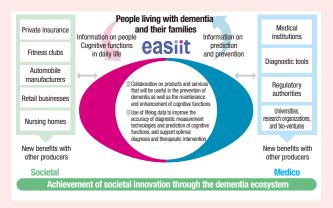




Reference

P43-44

5 Development of the Dementia Ecosystem Platform



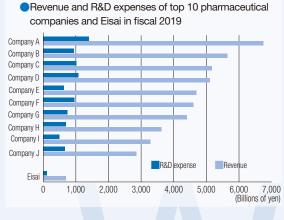
Reference

P31-34



- 1 Limited R&D expenses
  - Utilize partnerships
- 2 Loss of exclusivity (LOE) of major products
  - Preparation of new treatment of Alzheimer's disease
- 3 Slow business development in Africa

Collaboration with international NGOs



Source : AnswersNews (Only available in Japanese) https://answers.ten-navi.com/pharmanews/18365/

# **Environment surrounding pharmaceutical industry**

# pportunities

- 1 Global expansion of pharmaceutical market
- 2 Growing interest in preventive medicine
- 3 Progress of personalized medicine utilizing data science

# hreats

- 1 Market entry of innovative treatments
- 2 Downward pressure on drug prices
- 3 Increasing market share of generic drugs

### Message from CEO

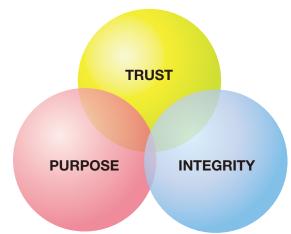
# To Our Stakeholders

We would like to extend our deepest sympathies to those who were infected with the new coronavirus (COVID-19), and thank all the healthcare workers who are fighting against the virus on the front lines day and night, and we hope that the infection will come to an end soon.

I consider "Trust," "Purpose," and "Integrity" as important elements of our business, and we have undertaken initiatives during the COVID-19 pandemic focusing on these. I believe that "Trust" is built when you show that you are constantly considering others. As one of those efforts, we have provided our products and relief goods such as masks to local governments with partnership agreements for dementia and patient groups in Japan, as well as donations to countries around the world. I think the most important things in order to realize "hhc" philosophy, which is "Purpose," are to improve the quality of life (QOL) of patients based on empathy, and to supply life-related products in a stable manner. Even under COVID-19, all of our 9 manufacturing sites around the world are operating smoothly. Based on our Business Continuity Plan



### The Whole Picture of Eisai's Business

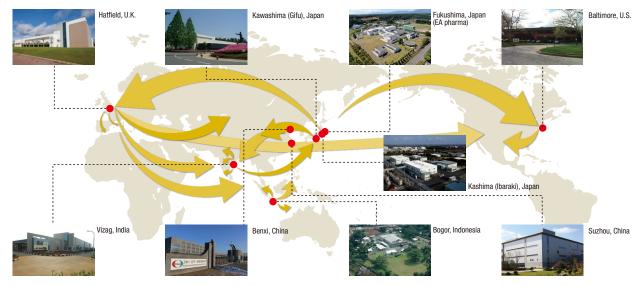


(BCP), we secured sufficient supply of active pharmaceutical ingredient (API), raw and intermediate materials as well as ample stock of final products. As for the safety of employees at the sites, we continue to operate while implementing strict measures to prevent infection in accordance with the COVID-19 Operational Manual established by the company.

Another important "Purpose" is to develop treatment for COVID-19. Eritoran is in-house developed by our former Research Institute of Boston as a treatment candidate\* for severe sepsis, which may suppress upstream of cytokine storm which causes severe lung inflammation or multiple organ failure. Clinical study is currently ongoing in cooperation with international networks with an aim to contribute to patients as soon as possible. We are also involved in the development of immunologic adjuvant (vaccine) and compound candidates (treatments) in collaboration with the Bill & Melinda Gates Foundation as the only Japanese company involved in this project. Although the spread of COVID-19 is affecting people all over the world, the Eisai Group gives first thought to patients, and continues to carry on our business, including stable supply of drugs, through properly managed corporate behavior. We will take every possible measure.

\* The development was discontinued in 2014 after Phase III study was conducted.

### Stable Supply of Life-Related Products: Smooth Operation in Global 9 Sites



# Contribution to Patients Backed by Engagement and Practice of Corporate Philosophy

"We give first thought to patients and their families, and increase the benefits that health care provides them, and fulfil various healthcare needs of the world." This description of "hhc" is easy to understand, but understanding how patients feel joy, what makes them upset or sad, and what they look forward to, is not easy. Accordingly, approximately 10,000 employees worldwide are encouraged to spend 1% of their total business hours interacting with patients to learn their true thoughts and feelings. We believe that it is important to truly consider the perspectives of patients, and share thoughts and feelings that might not be expressed in words, by talking to patients or having meals together with them. I would

like to introduce an example of "Socialization." When a foreign employee from our overseas subsidiary was participating in an inhouse training activity in Tokyo, he visited a



pediatric cancer hospital ward and spent a day with a boy who had cancer. This employee and the boy belonged to different generations and there was a language barrier, but at the end of the day, the employee was in tears, understanding what kind of feelings this boy lived with. This shows what empathy means and this is what we expect from "Socialization." What is more important about the concept of "hhc" is that it is shared not only among us but also with our shareholders. The concept was codified into our Articles of Incorporation at the General Shareholders Meeting in 2005 upon receiving approval. This mutual sharing of our corporate philosophy with shareholders forms a core tenet of the Company.

### **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 ensuing 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:
  - 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.

# Societal Innovation through Establishing the Dementia Ecosystem

We have been spending time with people with

dementia for over 20 years since the launch of

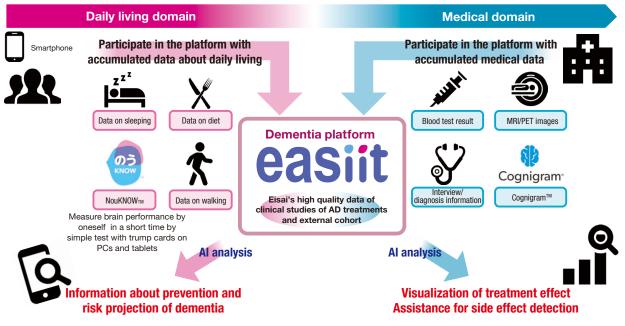
Aricept®, then finally came to understand the following three anxieties that they have after years of "Socialization." The first one is "when will symptoms appear?," the second is "are there any ways to avoid this disease?," and the third is "I don't want to be a burden on my family." Then, based on a hypothesis that if we successfully respond to these three anxieties, we could bring a sense of happiness and assurance to people with dementia, we introduced the Dementia Ecosystem Platform Model, a strategy aimed at realizing Societal Innovation, through repeated brainstorming.

We have initiated a full-fledged effort to form a dementia platform "Easiit" (pronounced "E-Zit"). The core of "Easiit" is a loop of information between people with dementia and our data platform. The core asset of "Easiit" is high-quality data obtained from internal and external clinical studies including the studies for nextgeneration dementia treatments that we have accumulated since the development of Aricept®. We will make various projections and give advice based on the Al analysis of the information of the people with dementia. To realize this, we would like firstly to ask people to share daily living domain information such as how you sleep, walk, eat and so on, and the results from "NouKNOW<sub>TM</sub>" (pronounced "NOH-NOH"). "NouKNOWTM" is a digital tool for self-assessment of brain performance (brain health), and was launched in March 2020 for legal entities such as municipalities and corporations. Based on the data we have



accumulated, we are considering conducting Al analysis and returning information about preventive activities and risk projection of dementia to all parties. This information loop potentially promotes the measurement of brain health and the habit of preventive behavior. At the same time, in the medical domain, we plan to input data of check-ups conducted at medical institutions, and brain performance data measured by "Cognigram™" that shares algorithms with "NouKNOW<sub>TM</sub>," through an application designed for doctors. By analyzing the data, we aim to visualize treatment results and assist with detection of side effects, leading on to treatment as well as greater efficiency in medical consultation or diagnosis. This function of bridging the daily living domain and medical domain is the whole image of "Easiit" through which we aim to realize Societal Innovation.

### Schematic Representation of the Dementia Ecosystem Platform easift



Neurology Area—The time to contribute to patients by next-generation dementia treatments is approaching

Aducanumab\*1 is an investigational next-generation Alzheimer's disease (AD) treatment, and Biogen Inc.,

our partner is currently actively engaging with the U.S. Food and Drug Administration (FDA) and regulators in

Europe and Japan. In the United States in particular, Biogen Inc. completed submission of a Biologics License Application (BLA) to the FDA. Working closely together, Biogen Inc. and we are proceeding to prepare and formulate various initiatives such as establishing go-to-market strategy, building out medical teams, preparing market access, and so on.

As regards BAN2401\*1,2 an investigational antiamyloid beta (A $\beta$ ) protofibrils antibody,

Clarity AD, a pivotal Phase III study in early AD is steadily ongoing and the readout of primary endpoint is targeted for the second quarter of fiscal 2022.

Regarding preclinical (asymptomatic) AD, AHEAD 3-45, a Phase III study to evaluate potential prevention

### World's First Potential Next-Generation Alzheimer's Disease (AD) Treatment

# Anti-amyloid beta (Aß) antibody Aducanumab

# Plan to complete the filing in July 2020 (U.S.)

- Completed submission of Biologics License Application (BLA) to the FDA
- Engagements with regulators in Japan and Europe are progressing

# Anti-amyloid beta $(A\beta)$ protofibrils antibody **BAN2401**

# Plan for final readout of primary endpoint in fiscal 2022

- Confirmed reduction of amyloid in brain and reduction of clinical decline in Phase II study
- Phase II study is progressing to support filing.
- Phase III study targeting pre-clinical (asymptomatic) AD started in July 2020.

Full-scale preparations underway to realize patient contributions with potential world's first next generation AD treatment

of future cognitive decline, has been initiated in July 2020, as a public-private partnership with the ACTC\*3.

- $\pmb{*}$ 1 Co-development with Biogen Inc.  $\pmb{*}$ 2 Licensed-in from BioArctic AB
- \*3 Alzheimer's Clinical Trials Consortium

# Oncology Area-Expanding contribution to patients with Lenvima®

With Merck & Co., Inc., Kenilworth, N.J., U.S.A., co-commercialization activities have been rolled out in 18 major countries. The first indication of Lenvima® and KEYTRUDA® combination was approved and launched for endometrial carcinoma\* in the United States in September 2019. We are expanding contribution to patients globally and recognized all the expected payments of 1,625 million USD by fiscal

2019. Following the recommendations in multiple cancer treatment guidance committees, we believe that the contribution to patients with an oral anticancer agent, Lenvima® may expand further.

We are conducting pivotal studies for 13 indications in 7 cancer types to expand indication of Lenvima® and KEYTRUDA® combination.
Clinical studies of Lenvima® and

KEYTRUDA® combination are being conducted on a large scale with estimated enrollment of a total of approximately 8,200 patients with cancer. By covering wide range of cancer types, we expect that this combination therapy may be established as a backbone therapy.

\* Advanced endometrial carcinoma that is not Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

# Lenvima®: Expanding Contribution to Patients as Oral Formulation Agents on Recommendations from Guidance

### Hepatocellular carcinoma (single agent)

International Liver Cancer Association (ILCA) issued guidance
to recommend oral formulation cancer agents.

Lenvima® is recommended as Category 1 (based upon high-level evidence) treatment option in
National Comprehensive Cancer Network (NCCN) guidelines.

### Renal cell carcinoma in combination with everolimus

European Association of Urology (EAU) issued guidance to recommend oral formulation cancer agents.

### Endometrial carcinoma in combination with KEYTRUDA®

Society of Gynecologic Oncology (SGO) guidance recommends every 6 week administration of KEYTRUDA®, instead of every 3 week, to reduce the number of hospital visits.

Combination therapy of Lenvima® and KEYTRUDA® has been increasingly selected.

# Pursuing Thorough Safety in Drug Discovery Activities, Ensuring Ethics and Transparency

We have been strengthening safety measures for participants in our clinical studies. Particularly for the first clinical study of a compound under development (Fist in Human Study), we ensure greater safety of the participants while in the process of formulating the

clinical study implementation plan, monitoring of clinical studies, and evaluation of the structure of clinical study sites. We will continue to pay the utmost attention to ensuring safety to conduct pharmaceutical research and development with high ethical standards.

### Initiatives for Digital Transformation (DX)

One of the keywords under the new order brought by COVID-19 is digital transformation (DX), and this is an absolute requirement for us in order to realize Societal Innovation. As a pharmaceutical company whose primary purpose is to improve the well-being of patients and consumers, we feel the necessity of linking digital and individual. We are currently establishing a dementia platform "Easiit" to realize this linkage. "Easiit" contains 3 characteristics of DX: 1. Data-driven, 2. Connected, 3. Speed. Nowadays, online medical consultation or remote medicine are provided utilizing digital platforms, and the combination of digital and in-person activities has become a core

strategy in information provision activities at our sales frontline. We will continue to develop new solutions while establishing and operating a robust data management platform. To realize a stable supply regardless of climate change or natural disasters, it is recessary to establish global enterprise resource planning (ERP) to formulate and implement optimal plans, from raw material procurement to manufacturing plans utilizing Al to predict the shift of market demand in a timely manner. To improve our digital capabilities, we will also hire people who possess high skills in this area and establish partnerships with other companies.

### Corporate Value Creation by Enhancing Non-Financial Capital

We are working to eliminate the various medical and care gaps that exist throughout the world to fulfill a mission of enhancement of patient satisfaction. One representative example is an effort to eliminate neglected tropical diseases (NTDs). NTDs, such as lymphatic filariasis\* (LF) are serious social issues concentrated in developing and emerging countries. Moreover, due to poverty and other reasons, the majority of these people cannot receive necessary treatments. With the aim of eliminating LF, we commenced manufacturing of diethylcarbamazine (DEC) tablets, treatment for LF, at our Vizag Plant in India, which is being provided to the World Health Organization (WHO) at Price Zero. Since commencing the provision in October 2013, we have delivered approximately 1.99 billion tablets to 28 countries as of end of March 2020. The WHO announced that the elimination of LF was achieved in 17

countries. We will continue to provide DEC tablets, until LF is eliminated in all the LF-endemic countries.

\* 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 damage to the lymphatic system and may cause physical impairment such as elephantiasis, which swells and enlarges the foot so that it resembles that of an elephant. Statistics show that more than 120 million people in 73 tropical and subtropical countries are infected with this disease.

Regarding human capital, we position employees as important stakeholders in the Articles of Incorporation, and strive to ensure stable employment, provide worthwhile work, and enhance opportunities for developing skills. In the realization of the "hhc" philosophy, employees are an important asset. In order to create an environment in which employees with diverse values can maximize their capabilities, we are implementing various measures to enhance employee motivation, such as promoting "work style reform" represented by telework significantly in Japan.

# Eisai's Initiatives for ESG are Highly Evaluated by External Parties

We were ranked the eighth among the global major pharmaceutical companies in the Access to Medicine Index (ATM Index) 2018, evaluated for the successful activities in Society (S), including initiatives to eliminate NTDs. In the Environment (E) category, we have been making efforts to reduce environmental impact globally over the years, and as a result, a high evaluation of A

list in the CDP Climate Change Report 2019 was granted. We have also set medium- to long-term targets for greenhouse gas reduction, and our emission targets have been recognized as being based on scientific grounds and certified by the "Science Based Targets (SBT) Initiative." In June 2019, we expressed our agreement with the Task Force on

Climate-related Financial Disclosures (TCFD).

In the area of Governance (G), we believe that we have been taking

advanced approaches in Corporate Governance. We adopted a Company with a Nomination Committee, etc., System in June 2004, to clearly separate functions between supervision of management and execution of business, as



**CLIMATE** 

well as ensuring fairness and transparency in management. The majority of the Board of Directors are outside directors with a high degree of independence. The Chairman of the board, as well as the chairs of the nomination, audit, compensation, and *hhc* governance committees, are all outside directors.

The CEO is the only board member from the management side. At the board meetings, various questions are raised and active discussions are held from diverse perspectives with outside directors playing a central role.

Additionally, we have been selected as a member of the FTSE4Good Index Series for the 19th consecutive year since 2002. We have also been selected for membership in four ESG indices adopted by the GPIF (Government Pension Investment Fund): MSCI Japan ESG Select Leaders Index, FTSE Blossom Japan Index, MSCI Japan Empowering Women Index (WIN), and S&P/JPX Carbon Efficient Index. We are participants in the United Nations Global Compact. Through implementing initiatives in ten principles of the United Nations in the four areas of human rights, labor, environment and anti-corruption, we continue to make efforts to enhance our corporate value.

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

We believe 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 to maximize shareholder value. We achieved the target ROE of over 15% set in 'EWAY 2025' initially targeted for fiscal 2025, far ahead of schedule, and we are generating a 10-year historical average ROE of 11.1%, with positive equity spread\* of 3.1%. In working to realize medium- to long-term growth, we will continue proactive investment in R&D in the dementia and oncology areas. As regards dividends, we plan to maintain our policy of paying stable dividends, maintaining the dividend on equity (DOE) ratio at the 8% level. At the end of fiscal 2019, Eisai's net debt equity ratio (Net DER) was -0.29, while the ratio of equity attributable to owners of the parent was 63.8%. We have retained our sound financial condition that enables proactive investment and stable dividends.

 $\pmb{\ast}$  Equity spread: ROE - Cost of equity. We conservatively assume cost of equity of 8%

With regard to IR, our activities over the years led to us being recognized and selected by the US financial information magazine "Institutional Investor" as the "Most Honored Company," and we have been ranked first place overall in the Biotechnology & Pharmaceuticals sector of "The All-Japan Executive Team" with the first place in "Best CEOs" and "Best CFOs" respectively in the sector. Furthermore, the "IR Grand Prix Award" was granted at the IR Award 2018 held by the Japan Investor Relations Association (JIRA). We intend to disclose information in a

disclose information in a timely and fair manner to fulfill our accountability to investors, and continue to work to enhance shareholder value.



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

August 2020 Representative Corporate Officer and CEO



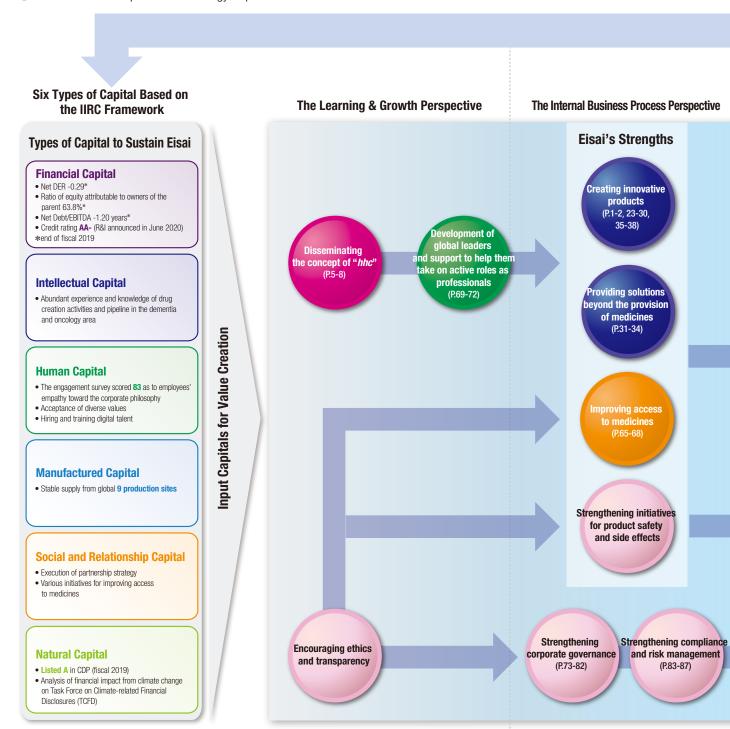
# Value Creation Process and Flow

Eisai seeks to increase corporate value by putting its Corporate Philosophy into practice. Accordingly, Eisai considers it a top priority to: work to build relationships of trust with a wide range of stakeholders including customers, shareholders and local communities; maximize value for patients, shareholders and employees; and strive to be a socially responsible company.

Value generated through corporate activities is built up as "capital," which is increased, decreased and converted through the business model. In this report, based on the framework\*¹ released by the International Integrated Reporting Council (IIRC), the process of investing capital to engage in business and create added value, wherein the increase in capital exceeds the inputs, is considered to be the "value creation process."

Meanwhile, "value creation flow," or how value is generated through business activities, is ultimately an

Eisai's value creation process and strategy map



assessment focused on the financial perspective based on the balanced scorecard's\*2 four perspectives\*3,4. This is also consistent with the thinking (sequence of goals and outcomes) that is based on Eisai's Corporate Philosophy of creating social value by enhancing patient satisfaction, our overriding objective, and thereby generating economic value in the form of sales and profit.

This report expresses Eisai's continuous value generation as a value creation process and flow model based on a new model that incorporates the IIRC framework and balanced scorecard.

- \*1 IIRC, "The International IR Framework," International Integrated Reporting Council, 2013
- \*2 Kaplan, Robert S. and Norton, David P., "Using The Balanced Scorecard as a Strategic Management System," Boston, MA: Harvard Business Review, January-February, 1996 \*3 Jensen, Michael C., "Value Maximization, Stakeholder Theory, and The Corporate Objective Function," Business Ethics Quarterly 12(2), 2002

### \*4 Porter, Michael E. and Kramer, Mark R., "Creating Shared Value," Harvard Business Review, June 2011, pages 8-31

### **Accumulate Capital for Further Value Creation The Customer Perspective** The Financial Perspective **Pursuit of Capital Expansion Financial Capital Expanding long-term** Net DER -0.3 to 0.3 shareholder value · Ratio of equity attributable to owners of (P.4, 51-57) the parent 50-60% • Net Debt/EBITDA 0 to 3 years · Credit rating A level **Intellectual Capital** · Contribution to patients with world's first potential next-generation dementia treatments Value maximization of anti-cancer agent Lenvima® **Enhancing customer** Cultivating Increasing revenue satisfaction new customers (P.45-50) **Expansion of Capita Human Capital** • Human talent able to anticipate change and continuously create innovation · More active engagement with the company Increasing profit (P.45-50) **Manufactured Capital** Stable supply of high quality products to the world even in case of emergency **Social and Relationship Capital** Expansion of partnership strategy Contribution to the growth of developing and emerging countries by improving access to medicines **Improving Natural Capital** social value • Environmentally responsible business operations · Mitigating climate change risk and creating opportunities Figures in parentheses indicate the corresponding pages of this report

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

### Medium-Term Business Plan 'EWAY 2025'

# 10 years

Realize Societal Innovation for Alzheimer's Disease with 'EWAY FUTURE'

Eisai began formulating three- to five-year span medium-term business plans in 1957, and has 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. We have positioned the four years until March 2020 as 'EWAY CURRENT' and the six years from fiscal 2020 to fiscal 2025 as 'EWAY FUTURE.'

### **'EWAY CURRENT'**

### Achieved operating profit target of fiscal 2020 and ROE target of fiscal 2025 ahead of schedule

Eisai established business groups of neurology and oncology as strategically focused areas with 'EWAY 2025,' based on Eisai's corporate philosophy "human health care (hhc)," which embodies a sincere commitment to contributing to patients' well-being. Eisai identified "Ricchi" where we can become a frontrunner and have taken concentrated actions in such areas. In neurology and oncology, we have been able to achieve acceleration of development of innovative new drug creation and meeting of financial targets ahead of time

by steadily developing a partnership model in collaboration with Biogen Inc. and Merck & Co., Inc., Kenilworth, NJ, U.S.A. in each area.

	Fiscal 2019 Results	Medium-term Business Plan (At the time the plan was formulated)
Revenue	¥695.6 billion	¥800 billion level (fiscal 2020)
Operating Profit	¥125.5 billion	¥102 billion level (fiscal 2020)
ROE	18.6%	15% level (fiscal 2025)

Key achievements	Key issues
<ul> <li>Achieved mid-term targets of operating profit and ROE for fiscal 2020 in fiscal 2019</li> <li>Acceleration of development of next-generation Alzheimer's disease treatments</li> <li>Initiation of Phase III study of investigational BAN2401*1.2 in 2019</li> <li>Completed submission of investigational aducanumab*1 based on analysis on large datasets in the U.S. in 2020</li> <li>Approval of Lenvima® (lenvatinib) plus KEYTRUDA® (pembrolizumab) combination treatment for patients with endometrial carcinoma*3 in the U.S. in 2019</li> <li>Launched in-house created Dayvigo<sup>TM</sup> for the indication of insomnia in the U.S. and Japan in 2020</li> </ul>	<ul> <li>Main development theme unachieved</li> <li>Alzheimer's disease treatment investigational elenbecestat*<sup>1</sup></li> </ul>

### **'EWAY FUTURE'**

### The biggest focus is on initiatives for Alzheimer's disease

We believe that the next-generation dementia treatments we are creating will bring great value to society not only by suppressing Alzheimer's disease onset and deterioration of cognitive function, but also reducing the cost of medical care, nursing care services, and care by family. What is most important in maximizing the value of next-generation dementia treatments is the elimination of the chasm (gap) of

disease understanding, preventive behavior, and realizing habits of cognitive function check. To that end, based on the Eisai dementia platform "Easiit," we will prepare various solutions such as acceleration of disease awareness and introduction of digital cognitive function check tools by utilizing our own media tools such as websites, and we will realize Societal Innovation.

### Maximizing Lenvima®'s value and medicine creation based on gene mutation

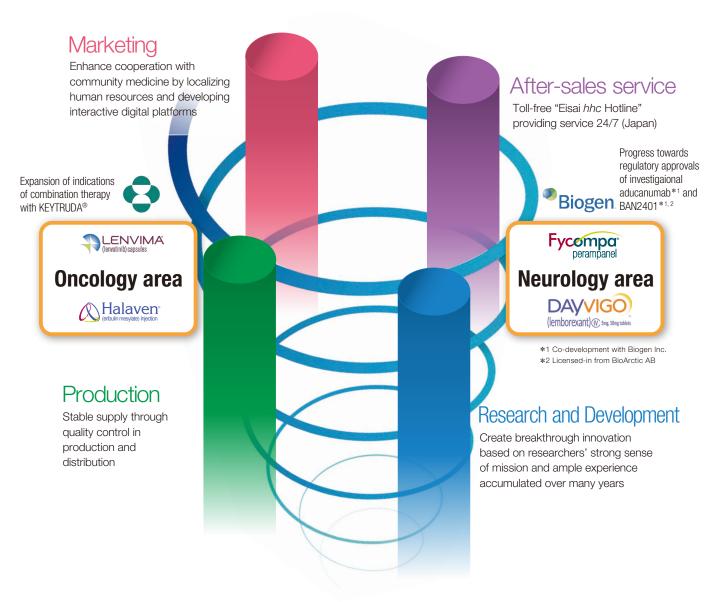
Lenvima® will undergo late-stage clinical trials as combination therapy with KEYTRUDA® aiming to establish a core position in the treatment of various cancer types. In addition, we aim to cure cancer by realizing precision medicine, grasping the gene mutation

related to carcinomatous transformation, proliferation, invasion, recurrence, metastasis, and treatment resistance that occur at each stage of Cancer Continuum\*4 with liquid biopsy\*5.

<sup>\*1</sup> Co-development with Biogen Inc. 
\*2 Licensed-in from BioArctic AB 
\*3 Advanced endometrial carcinoma that is not Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) who have disease progression following prior systemic therapy and are not candidates for curativesurgery or radiation. 
\*4 The continuous progression of disease. Cancer Continuum is classified as precancerous condition/ultra-early cancer, early cancer, and advanced cancer. 
\*5 A biological test using blood as a sample

# **Our Value Chain**

Connecting value creation to future patients with a strong global network



List of the functions of each plant, and major manufactured items

Plant	Country	APIs	Formulation	Packaging	Major manufactured items
Kashima		0			Lenvima®, Dayvigo™, Halaven®, Fycompa®
Kawashima	Japan	×	0)		Lenvima®, Dayvigo™, Fycompa®, Lunesta®
Fukushima (EA Pharma)			250	0	Elental®, Goofice®, Moviprep®
Suzhou	Ohina		0	0	Methycobal®, Merislon®, Aricept®
Benxi	China	0		, 0	Transfer factor *
Bogor	Indonesia	1.0	E-0		Pariet®, Aricept®, Methycobal®
Vizag	India	Ö	0		Warfarin®, diethylcarbamazine (DEC) tablets API for generics
Hatfield	U.K.		0	0	Lenvima®, Dayvigo™, Halaven®, Fycompa®
Baltimore	U.S.		0	0	Gliadel <sup>®</sup>

<sup>\*</sup> Product name in Chinese:转移因子口服溶液

# 152 million people

Estimated number of people with dementia worldwide as of 2050





### SWOT Analysis

# **Strengths**

- 1. Industry-leading rich R&D pipeline along with the continuous disease pathology of Alzheimer's disease (AD Continuum)
  - Investigational anti-Aβ antibody aducanumab: Completed submission of Biologics License Application (BLA) in the U.S., and re-dosing study (EMBARK) is ongoing
  - Investigational anti-Aβ protofibrils antibody BAN2401: Pivotal Phase II study (Clarity AD), re-dosing study, and Phase II study (AHEAD 3-45) in people with preclinical AD are ongoing
  - In fiscal 2020, a total of 6 projects are scheduled for clinical studies
- 2. Expertise acquired over 35 years of medicine creation in this area
- 3. Progress in the "partnership model," a global strategic alliance that enables acceleration of development, increase of probability of success, and streamlining of R&D and commercialization expenses

# Weaknesses

- 1. High degree of difficulty in developing new drugs
- 2. Large-scale and long-term clinical studies are necessary
- 3. Large R&D expenses are incurred

# **Opportunities**

- 1. Increase in the global number of people with dementia as the population ages 2. Enactment of the Basic Law for Dementia in Japan
- 3. Realization of early diagnosis and early intervention with improved diagnostic technologies

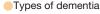
### **Threats**

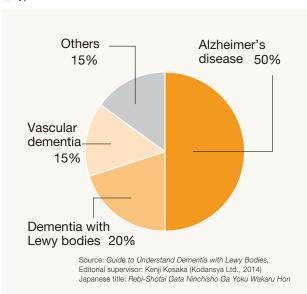
- 1. Competing products entering the market
- 2. Development of treatments other than drugs that directly stimulate and activate the brain
- 3. Increasing pressure to lower drug prices as governments promote policies to reduce healthcare expenditure
- 4. Delay in development of medicines due to pandemic

### **Environment Surrounding Dementia**

### What is Dementia?

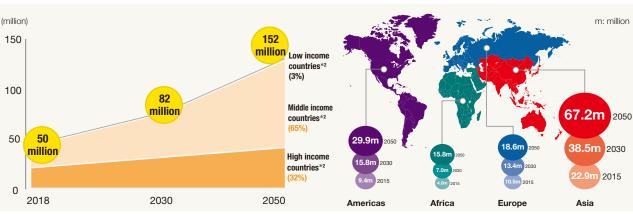
Symptoms such as "getting hard to remember new things" or "can't remember the name of my acquaintances" become more prominent with aging. However, this "forgetting" is due to aging of the brain. By contrast, dementia is completely different from "forgetting" due to aging, and refers to a symptom or condition that occurs due to the death of brain cells resulting from various causes and diseases, or an extreme worsening of cognitive functions. There are various types of dementia. While symptoms of Alzheimer's disease (AD), the most prevalent type of dementia, are mainly related to memory impairment (core symptoms), behavioral and psychological symptoms (BPSD), such as delusions and hallucinations, violence, wandering and depression are also observed. In addition to AD, dementia with Lewy bodies and vascular dementia are well-known, and as the disease progress, comprehension and judgement abilities of people living with dementia deteriorate, which may impair social life and daily living.





### Current Situation of Dementia: Increase in the Number of People with Dementia and Costs Related to Dementia

As the aging of the global population gathers pace, the number of people with dementia is expected to continue an upward trend. In 2018, the number of people with dementia was estimated to be 50 million worldwide. It is estimated that this number will reach 82 million by 2030, and 152 million by 2050. The population living with dementia is expected to increase mainly in Asian countries.



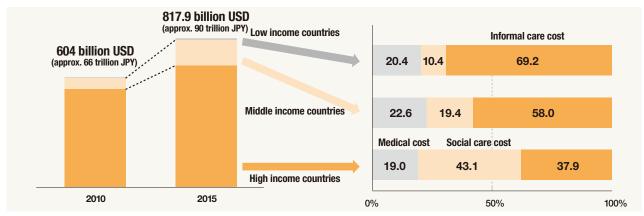
- \* 1 World Alzheimer Report 2018
- \*2 High income countries are defined as those with a GNI (Gross National Income) per capita of \$12,736 or more, Middle income countries are defined as those with a GNI per capita of more than \$1,046 but less than \$12,736 and Low income countries are defined as those with a GNI per capita of \$1,045 or less (World Alzheimer Report 2015)
- \*3 World Alzheimer Report 2015

The costs associated with dementia are estimated to reach approximately 90 trillion JPY in 2015 and 220 trillion JPY in 2030, including the costs of medical care, nursing care, and family care. In addition to medical expenses, the cost of care (social care, family care, etc.) is very high, however, understanding of the disease is still insufficient. People with dementia, their families, or

Estimated number of people with dementia worldwide\*1

people who are associated with them, may fear dementia including AD, or experience a feeling of denying the onset of the disease. There are also cases in which people postpone going to see the doctor despite the presence of symptoms, so that appropriate medical intervention is not provided.

### Estimated cost for dementia

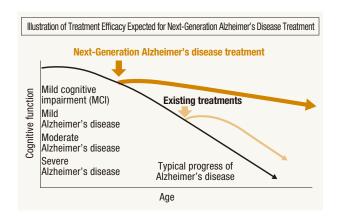


\* High income countries are defined as those with a GNI (Gross National Income) per capita of \$12,736 or more, Middle income countries are defined as those with a GNI per capita of more than \$1,046 but less than \$12,736 and Low income countries are defined as those with a GNI per capita of \$1,045 or less (World Alzheimer Report 2015)

### Limitations of Current Dementia Treatments and Efficacy Expected for Next-generation Dementia Treatments

Regarding dementia treatments, symptomatic treatments including our in-house developed "Aricept®" have over 20 years of history in the market, and their efficacy and safety have been established; however, their limitations have also become clear. Worsening of cognitive functions is unavoidable after a certain period of administration, and there is no effect of radically slowing down or stopping the progression of the disease. Therefore, development of potential next-generation dementia treatment, which could potentially delay the onset of dementia or suppress the worsening of cognitive functions over a longer period of time, is highly anticipated.

In the U.S., it is estimated that a treatment introduced in 2025 that delays the onset of AD, which accounts for the majority of dementia, by five years, would decrease the number of people living with the disease by 42%



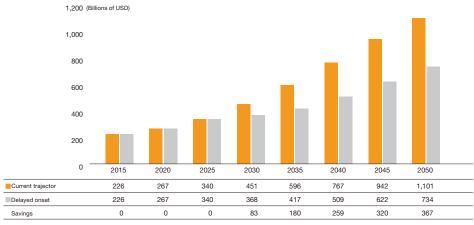
(5.7 million people), and total costs to all payers would decrease by 33% (367 billion USD) compared to the current trajectory. Similarly, in Japan, if a new intervention method that delays the onset of disease by

5 years is introduced, it is estimated that the medical and nursing care costs in fiscal 2025 will decrease by approximately 1.9 trillion JPY in a single year (medical expenses of approximately 1 trillion JPY and nursing care cost of approximately 0.9 trillion JPY).

The next-generation dementia treatments could contribute not only by suppressing the decline of cognitive function of people with dementia, but also by

controlling costs such as medical expenses and nursing care costs, and reducing the disease burden by

Impact of a treatment that delays onset by five years on total costs, 2015-2050 (U.S.)



Source: Alzheimer's Association. Changing the Trajectory of Alzheimer's Disease: How a treatment by 2025 saves lives and dollars Fig6. All

extending the healthy life period. This would be of great benefit to society.

### Challenging Path Toward Creation of Next-Generation Dementia Treatment

No drug has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of dementia since 2003. 146 agents under development between 1998 and 2017 did not prove successful. This suggests that medicine creation in the dementia area is very challenging.

It is extremely difficult to reproduce high-order brain functions such as cognitive function that are unique to humans, and it is difficult to create an applicable

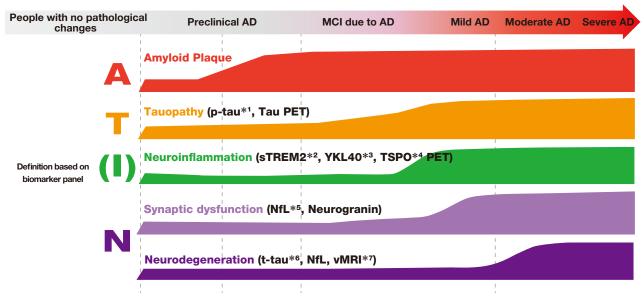
experimental scenario using animal models. Hence, it has been extremely challenging to develop nextgeneration dementia treatments\*. Consequently, it was necessary to understand the progression of the disease by developing biomarkers that accurately reflect changes in the brain of AD, to begin with.

\* Treatments that have the effect of suppressing recurrence rates of the disease or delaying its progression

### Research and Development along with the Continuous Disease Pathology of Alzheimer's Disease (AD Continuum)

### What is AD Continuum?

In AD, a peptide called amyloid beta (A $\beta$ ) aggregates and accumulates in the brain, 10 to 20 years before symptoms such as memory impairment appear. It is thought that, triggered by the aggregation and accumulation of  $A\beta$  in the brain, a tau protein that exists in neuron accumulates in the cells, after which neuronal cell death is caused. This is the AB hypothesis, which Eisai's research for next-generation AD treatments is based upon. The current AD treatments are intended for those with clinical symptoms. By contrast, the



<sup>\*</sup> This figure is created based on the lecture at the 39th Annual Meeting of the Japanese Neuroscience Society by Dr. Makoto Higuchi, National Institute of Quantum and Radiological Science and Technology (Radiological Science and Development Directorate)

\*6 Total tau \*7 Volumetric MRI

<sup>1</sup> Phosphorylated tau \*2 Soluble triggering receptor expressed on myeloid cells 2 \*3 Chitinase-3-like protein 1 \*4 18kDa translocator protein \*5 Neurofilament light chain

next-generation dementia treatments based on the  $A\beta$  hypothesis target early AD (mild cognitive impairment due to AD [MCI due to AD] and mild AD) where  $A\beta$  accumulation in the brain is observed, and preclinical AD where earlier cognitive impairment has not been confirmed.

On the other hand, the development of various biomarkers\* for detecting pathological changes in the

brain and the understanding of AD Continuum are progressing. In particular, utilizing  $A\beta$  (A), tau (T), neuroinflammation (I), and neurodegeneration (N) as biomarkers has made it possible to evaluate neuropathological changes that characterize the pathology of AD.

 $oldsymbol{*}$  Physiological indicators on the presence or absence of disease and the progression

### Investigational Anti-A β Antibody Aducanumab

Investigational aducanumab is an anti-amyloid antibody licensed-in from Neurimmune AG (Switzerland) and developed by Biogen Inc. Eisai exercised its option rights for co-development and co-commercialization in October 2017. A Biological License Application (BLA) to the FDA for AD was

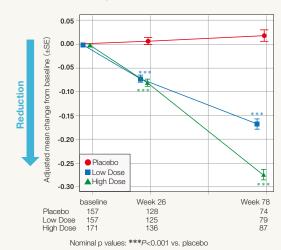
completed in July 2020. The consultation with authorities in Japan and Europe for new drug application are steadily ongoing. In March 2020, the EMBARK study, a re-dosing study of aducanumab for participants of previous studies, was initiated.

### **Progress of BLA Filing for Aducanumab**

The Phase II studies (EMERGE and ENGAGE) of aducanumab in people with early AD (MCI due to AD and mild AD) were discontinued in March 2019.

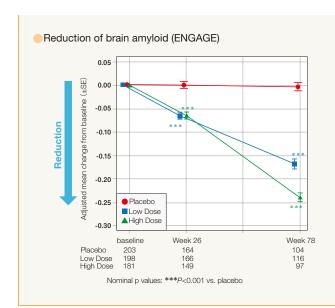
Then, in consultation with the FDA, a larger-scale data set containing additional data from the EMERGE and ENGAGE studies, which became available after the pre-specified futility analysis, went under the final analysis. As a result, the EMERGE study showed reductions of amyloid in the brain and reduction of clinical decline in the high-dose group of aducanumab (primary endpoint was CDR-SB [Clinical Dementia Rating-Sum of Boxes]). In the ENGAGE study, although it did not meet its primary endpoint, the data from the subset of ENGAGE that received high doses of aducanumab support the findings from the EMERGE study, by confirming reductions of brain amyloid and clinical decline. We concluded that the difference between the results predicted by the futility analysis announced in March 2019 and the final results was largely due to the increase in the number of subjects receiving high-dose aducanumab due to the revision of the protocol during the clinical studies. Furthermore, the improvement of pathological conditions was also indicated by the biomarkers related to tau and neurodegeneration other than  $A\beta$ .

### Reduction of brain amyloid (EMERGE)



### Reduction of clinical decline in cognitive function and activities of daily living (EMERGE)

	% Reduction vs Placebo p-value		
	Low dose (N=543)	High dose (N=547)	
CDR-SB	-14% 0.117	-23% 0.010	
MMSE	3% 0.690	-15% 0.062	
ADAS-Cog13	-14% 0.167	-27% 0.010	
ADCS-ADL-MCI	-16% 0.156	-40% 0.001	



### Reduction of clinical decline in cognitive function and activities of daily living (ENGAGE)

	% Reduction vs Placebo p-value		
	Low dose (N=547)	High dose (N=555)	
CDR-SB	-12% 0.236	2% 0.825	
MMSE	-6% 0.488	3% 0.796	
ADAS-Cog13	-11% 0.248	-12% 0.245	
ADCS-ADL-MCI	-18% 0.135	-18% 0.152	

### Investigational Anti-A β Protofibril Antibody BAN2401

Investigational BAN2401 is an anti-A $\beta$  protofibril antibody obtained through collaborative research with BioArctic AB (Sweden), and has the unique features of binding and reducing A $\beta$  protofibrils which are thought to be the most toxic in the formulations of A $\beta$ . Following the discussion with regulatory authorities based on the results of Phase II study (Study 201) that showed suppression of clinical decline as well as dose-dependent reduction of A $\beta$  accumulation in the brain, a single pivotal Phase III study (Clarity AD) is required for a filing for BAN2401, and is currently underway. This Phase III study is targeted to people with early AD, and the results of the primary endpoint are anticipated in the second quarter of fiscal 2022. The

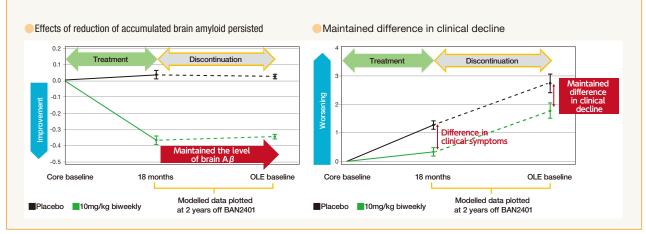
201 Open-Label Extension (OLE) study (Open-label continuous administration study) is also ongoing.

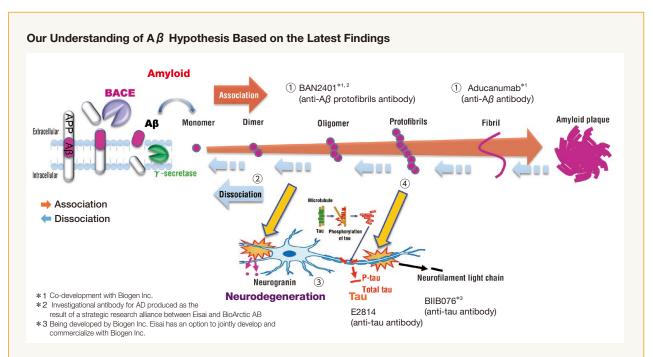


Furthermore, in collaboration with Alzheimer's Clinical Trials Consortium (ACTC), a network of 35 major clinical trial facilities in the U.S., a Phase III study (AHEAD 3-45 study) in people with normal clinical symptoms and pre-clinical levels of brain amyloid accumulation, which is an even earlier stage than early AD, was initiated in July 2020.

### Potential Disease Modifying Effect Suggested at the time of initiation of BAN2401 201 OLE Study

Study 201 (18 month core study) demonstrated that a clinical decline was suppressed and the accumulation of  $A\beta$  plaques in the brain was reduced by BAN2401. At the time of initiation of the OLE study, the degree of brain  $A\beta$  accumulation of the participants was measured. In the BAN2401 administration group, Brain amyloid reduction at the end of core study persisted for an average of two years after administration of BAN2401 was discontinued. Also, regarding the disease progression, the difference between the placebo group and the BAN2401 administration group at the end of Study 201 (18 month core study) was maintained for an average of two years following the discontinuation of BAN2401 administration.





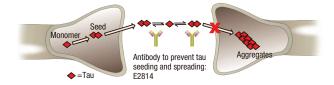
- ① The Study 201 of BAN2401 and the studies of aducanumab (EMERGE, ENGAGE, and Phase Ib study [PRIME]) demonstrated that removal of  $A\beta$  aggregates resulted in reduction of clinical decline and slowed the decline in activities of daily living. From the facts thereof, we have a strong belief in the  $A\beta$  hypothesis and we are confident that these results represent a breakthrough in medicine creation in AD area.
- ② Antibodies targeting aggregates have been shown to remove  $A\beta$  aggregates with higher efficiency compared to anti- $A\beta$  monomer antibodies or BACE inhibitors. The speed of lowering brain  $A\beta$  monomer level, breaking the balance, and dissociating  $A\beta$  aggregates of BACE inhibitors is slow.
- 4 There are various forms of  $A\beta$  aggregates, and among them, many studies have reported that soluble aggregates such as protofibrils have the highest toxicity. It is considered that treatment focused on soluble  $A\beta$  aggregates is important.

### Investigational Anti-tau Antibody "E2814"

Investigational E2814 is an anti-tau antibody developed in research collaboration with University College London (U.K.). The major component of neurofibrils, which is one of the pathological changes in AD, is tau protein that is present in neuron. It is known that the severity of cognitive impairment in AD well correlates with the spread of neurofibrils. E2814 targets tau seed (tau transmission species), which is known to propagate to different areas of the brain as the disease progresses, and cause tau lesions,

and it is expected to prevent further accumulation of neurofibrils in the brain and suppress disease progression. A Phase I study is currently ongoing.

### Intracellular action of E2814



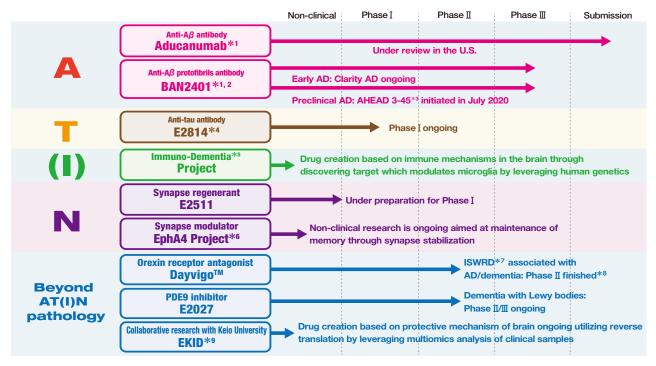
### Discontinuation of the development of investigational BACE inhibitor elenbecestat

The Phase  ${\mathbb I}$  studies (MISSION AD) of the oral  $\beta$ -site-amyloid precursor protein cleaving enzyme (BACE) inhibitor, elenbecestat, which were conducted in people with early AD, were discontinued in September 2019. The decision was made based on the results of a safety review conducted by the Data Safety Monitoring Board (DSMB), which recommended discontinuation of these studies due to an unfavorable risk-benefit ratio. We are currently conducting follow-up of subjects who participated in the study. Detailed data of these studies will be presented at the AD-related conference.

### Series of AD-associated Pipeline: Classification by Biomarker Panel

Eisai possesses an industry-leading R&D pipeline in the dementia area. In fiscal 2020, a total of 6 projects

are scheduled for clinical studies, and multiple projects are underway for preclinical studies.



- \*1 Co-development with Biogen Inc. \*2 Antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic
- \*3 A single preclinical AD study in collaboration with Alzheimer's Clinical Trials Consortium (ACTC) \*4 Co-research with University College London (UCL), U.K.
- \*5 Research at G2D2 (Eisal Center for Genetics Guided Dementia Discovery) \*6 Research at KAN Research Institute \*7 Irregular sleep-waker rhythm disorder
- \*8 Core study of Phase II has been finished.
- \*9 Project aiming to identify and verify novel drug discovery target candidates linked to the development of next-generation treatments and preventative medicines for dementia at Eisai-Keio Innovation Lab for Dementia (EKID) has been selected by Japan Agency for Medical Research and Development (AMED) for the Cyclic Innovation for Clinical Empowerment (CiCLE) program.

Eisai believes that improving the various symptoms experienced by people with dementia is also important, and is developing treatments by various approaches.

Recent studies have revealed that  $A\beta$  excretion from the brain is promoted during sleep. At the same time, it is thought that sleep disorders may trigger  $A\beta$  accumulation in the brain, leading to AD. Eisai has launched lemborexant (product name: Dayvigo<sup>TM</sup>), an antagonist that competitively binds to orexin receptors

which are involved in the regulation of sleep and wakefulness. It is indicated for the treatment of adults with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance in the U.S., and for the treatment of insomnia in Japan. Currently, development is underway for the indication of irregular sleep-wake rhythm disorder (ISWRD) associated with AD.

Furthermore, the development of investigational E2027, a PDE9 inhibitor targeting dementia with Lewy bodies, is ongoing.

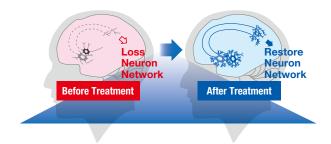
### Projects in Preclinical Stages

### Approach to Nerve Activation

There are more than 100 billion neurons in the human brain, and neurons form a neural network via sites called synapses. It is thought that in the brain of people with dementia, the dysfunction of synapse occurs and neural networks are reduced. Eisai is also working on projects to restore synaptic function and reactivate neurons in the brain.

The synaptic regenerating agent investigational E2511 is a drug candidate designed to activate damaged cholinergic neurons and promote synapse remodeling and neural networks reconstruction. Preparation is ongoing to initiate Phase I study in fiscal 2020. Preclinical studies are currently ongoing

for the EphA4 project, a synapse modifier that we are conducting research on at KAN Research Institute.



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

At G2D2 (Eisai Center for Genetics Guided Dementia Discovery), our exploratory research facility in Cambridge, Massachusetts, we have engaged in drug discovery research focusing on immunedementia to expand Eisai's dementia pipeline beyond  $A\beta$ 

and tau. Studies of genes involved in the onset and progression of AD suggest that modulation of the immune function of microglia, the cells that control immune functions in the central nervous system, is a high risk factor for AD.

### Collaboration with Keio University Targeting Brain Homeostasis System

It is known that the brain has numerous protective mechanisms. Specifically, there are mechanisms to remove accumulated proteins such as  $A\beta$  and others, remove foreign substances, and repair damaged neurons. Eisai and Keio University have established

the Eisai-Keio Innovation Lab for Dementia (EKID) to advance joint research with the aim of creating a new drug discovery target potentially to cure dementia through the homeostasis maintaining system of the brain, one of the protective mechanisms.

### Development of New Diagnostic Method

While the essential diagnostic requirement of dementia is memory loss, some of the diseases do not have memory impairment as the core symptom. Currently, there are no diagnostic criteria that are highly recommended by the Japanese Neurological Society (https://www.neurology-jp.org/guidelinem/degl/sinkei\_degl\_2010\_02.pdf).

Accumulation of  $A\beta$  in the brain in the diagnosis of AD is currently confirmed by amyloid positron emission tomography (PET) or cerebrospinal fluid (CSF) test. In addition to amyloid PET, tau PET is being put to practical use, but there are issues such as insufficient number of facilities and large costs. In addition to  $A\beta$  and tau, the accuracy of diagnosis of disease progression by CSF test has been improved by the progress of research on various biomarkers for neuroinflammation and neurodegeneration.

Since February 2016, Eisai has been collaborating with Sysmex Corporation on research and

development of a new dementia diagnostic method through blood test, aiming for the practical application of a test method for diagnosing people with early-stage AD who are targeted for the next-generation dementia treatment with a test method with less pain. HISCL<sup>TM</sup> Series, an automated immunoassay system developed by Sysmex Corporation, has made it possible to accurately quantify  $A\beta$  in plasma,

which was considered to be difficult to measure. It has been strongly suggested that measuring the plasma  $A\beta$ 1-42/ $A\beta$ 1-40 ratio using HISCL<sup>TM</sup> Series may help to understand the amyloid pathology in the brain.

Full-automated immunoassay system  $\mathsf{HISCL}^\mathsf{TM}$  Series



# Aim to Realize Further Innovation, Not Only in the Medical Field, But Also in Society





Keisuke Naito Corporate Officer President, Dementia Total Inclusive Ecosystem Business Unit Chief Digital Officer

# **Q** What is Dementia Ecosystem?

A. Although an ecosystem generally means an ecological system, we are building a new business model, which is composed of platformers, partners and members as if itself is an ecosystem, to move beyond conventional business model of pharmaceutical

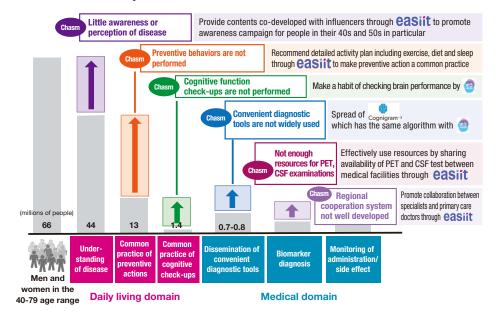
companies. The goal of the dementia ecosystem is that Eisai becomes a platformer to provide solutions through services and contents of partner companies in various sectors with a medicine creation value chain rooted in the true feelings of patients and their families.

### How do you deal with social issues regarding dementia?

A. Various research has found that life style reform, such as regular exercise and balanced diet, may reduce the risk of lower brain performance in recent years. However, there is difficulty in getting people to make a habit of implementing preventive action and checking cognitive function, since there are not many people who are

implementing and understanding preventive actions and checking cognitive function by themselves, based on an in-house survey. So we are expanding our target from the medical domain to the daily living domain to eliminate this chasm and encourage consumers to make behavioral changes in daily living as well. As a result of these actions, we believe that innovation, which is not only maximizing the value of next-generation dementia treatment in the medical domain but also changing society, can be materialized. To achieve this goal, we have established a new department named Dementia Total Inclusive Ecosystem (abbreviated as DTIE), which is responsible for dementia ecosystem, in April 2018.

### Eliminate Chasms by the Dementia Platform **@asiit**



### Q What is the meaning behind the department name "Dementia Total Inclusive Ecosystem (DTIE)"?

A. Novelty in naming was the first priority, since the department would prepare for the launch of next-generation dementia treatment and the spreading of awareness among the public that we were implementing initiatives with a new approach as no one has ever done before. We believe that ensuring "Leaving no one behind" and promoting "inclusive" society mentioned in the Sustainable Development Goals (also known as SDGs) by the United Nations may apply to

dementia. This is the way we came up with the idea of naming the department "Dementia Total Inclusive Ecosystem." Ecosystem is an ecological system that is naturally formed without any deliberate. Therefore, the name symbolizes our aim for social system, which is to allow everyone to access and receive benefits, not creating the ecosystem itself. Also, the name DTIE shows our aim to connect with all stakeholders, since "TIE" means to bond something together.

### Q What is the mission of DTIE?

A. One of the major missions of DTIE is preparation to launch next-generation dementia treatment. At the same time, Eisai strives to contribute to the dementia area in the long run, whether there are treatments or not. Consequently, Eisai's commitment to making a contribution to the dementia area will never stop, even if the development or launch of next-generation dementia treatments has some kind of issues. It is also important for us to contribute to patients through ways other than development of treatments, utilizing the experience that we have gained through commercial activity of Aricept®.



# What was behind the idea that it was important to contribute through ways other than just treatment, even though Eisai is a pharmaceutical company?

A. We believe that we have been establishing a position as a pioneer in the field of dementia since the development of Aricept®. At the same time, we have learned that dementia is not solved with treatment alone. Contributions through tools and solutions other than treatments are expected to come into the market from now on. We have to prepare for digital transformation as mega platformers, such as GAFA (Google, Amazon, Facebook, and Apple) newly enter the healthcare business with an enormous quantity of data. I learned a lot from the failure of the clinical study in the investigational project for MORAb-003 when I worked at Epochal Precision Anti-Cancer Therapeutics (EPAT, formerly Morphotek, Inc., one of Eisai's research

sites in the U.S.) before. Results of a clinical study are completely unpredictable until they are confirmed at the end, although a huge investment is required for research and development for new treatment. Pharmaceutical companies have no choice but to put all their efforts into developing investigational projects on the assumption of success. Thus, we need to prepare other ways of business to contribute to people in need or to monetize, other than selling treatments, considering the major impact that the success or failure of projects can have on companies. Again, Eisai's mission is to realize a new way of making a contribution to patients by seeking a cutting-edge approach other than treatments to remain as a pioneer in the field of dementia.

### Q What are the achievements so far since DTIE was established?

A. We are focusing on preparing biomarkers to diagnose continuous AD disease progression through amyloid positron emission tomography (PET) imaging and cerebrospinal fluid (CSF) examination, taking into account the potential paradigm shift in diagnosis of AD associated with the launch of next-generation dementia treatments. At the same time, cognitive function check-up is a key to establishing the dementia ecosystem. We have entered into a business alliance agreement for exclusive development and commercialization of a cognitive function test Cogstate Brief Battery developed by Cogstate Ltd. (Australia) and launched as "NouKNOW<sub>TM</sub>" for brain performance testing (non-clinical use) in Japan in March 2020. This

is a global standard as a tool to check brain performance, since it is in practical use in more than 55 countries already, including the U.S., and is applied to over 100 languages/dialects. It is very meaningful that we could introduce it in Japan.

Furthermore, we are preparing the dementia platform "Easiit" for practical use, which general users' personal health records directly link to. General users or their family who installed the app would provide information of daily living, such as data on sleeping, diet, exercise and brain performance score, through "NouKNOW<sub>TM</sub>" to "Easiit." General users would receive appropriate advice on prediction/prevention from the algorithm based on a diverse data set of dementia

through the app. Needless to say, compliance with related rules and regulations, such as the Personal Information Protection Law, and complete support in both tangible and intangible aspects are very important. The whole idea with "Easiit" is to expand its function to medical use, which is able to visualize treatment effect with input from electronic medical records, and realize optimal therapy and efficient

diagnosis of disease through interviews eventually, to further contribute to people with dementia and medical staff. In July 2020, we started providing smartphone app "Easiit App" to encourage behavior alteration by collecting lifelog data from daily life by co-development with DeNA Group (Tokyo), our alliance partner. With the beginning of provision of the "Easiit App," the Eisai Dementia Platform "Easiit" has commenced.

### **NouKNOW**<sub>TM</sub>

"NouKNOW<sub>TM</sub>" is conducted through a simple card test using a PC or tablet device to quantitatively measure brain performance in four tests evaluating psychomotor function, attention, learning and memory, and working memory. Users can self-assess independently and in a short time frame (approx. 15 minutes),

enabling regular assessments in instances such as daily life and health checkups. On the results screen, a score (brain performance index [BPI]) — as a measurement of quantified brain performance aspects such as memorization, cognition, and decision — appears along with lifestyle advice for maintaining brain

performance. We started the sales for corporate bodies such as local governments and companies, and we have received many inquiries.





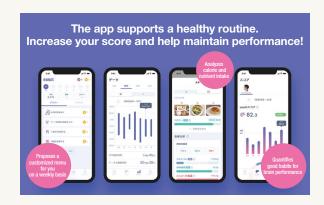


### "Easiit App" (co-development and provision with DeNA Group)

"Easiit App" is designed to support building of habits that are considered good for brain performance in daily life. A menu of individualized recommendations on diet, based on users' footsteps, diet, sleep, and weight records (lifelog) is updated on a weekly basis and displayed. Individualized scoring is conducted based on actions and habits which are good for brain performance. For diet record in particular, easy diet management

is made possible as the "Easiit App" evaluates users' meals via photo upload for calorie intake and eleven essential nutrients, and displays this information in relation to an age-based standard for calorie and nutrient intake. Eisai plans to equip the "Easiit App" with a linkage to the brain performance self-check tool "NouKNOW $_{TM}$ " and a new function is planned for use in families. This app is now free of charge and the high function edition with various additional contents and continuous individual data visualization is to be launched for a charge.

Easiit (Only available in Japanese) ▶ https://www.easiit.com/app



### Community Network Building that Enables Dementia Patients to Live with Peace of Mind

Since 2010, the Company has been promoting the conclusion of regional collaborative agreements with local governments, medical associations, and pharmaceutical associations, etc., throughout Japan (167 organizations in 44 prefectures as of March 31,

2020). The Company proactively participates in the promotion of the understanding of dementia, its early discovery and treatment, and other community-building efforts that allow dementia patients to live with peace of mind.

### Message from Bunkyo-city, Tokyo, collaborating with Eisai under Regional Collaborative Agreement

Ms. Kiyomi Shidehara, Dementia area support promotion member, Elderly Welfare Division

We concluded a community development partnership agreement to promote local dementia support initiatives with Eisai Co., Ltd. in June 2015, whose head office is located in Bunkyo-ward and is promoting initiatives to support local communities for dementia, in addition to conduct research and development for dementia treatments.

We have been working together to disseminate the initiatives rooted in the community to support people

with dementia, such as a project to make the number of missing people due to dementia zero in Bunkyo-ward.

We will continuously promote understanding and awareness of dementia to further develop the community, where people with dementia and their families can live with peace of mind in collaboration with Eisai Co., Ltd.

### Case Example: Bungotakada City, Oita Prefecture

We undertook the building of a community network that enables local residents to acquire a grasp of their cognitive function level as well as the state of their health, and consult healthcare professionals at an early stage. In collaboration with the local government and medical association, salons (meeting places) were set up at 15 locations for about 300 people. Health checkups to confirm such matters as cognitive function and frailty levels were held at the salons. Participants suspected of having mild dementia were asked to visit a specialist hospital for further checks. Activities useful for maintaining good health were also held at salons. They included brain exercise classes, a place for

reminiscing where participants talked about their past memories, lectures on oral care, and cooking classes where participants thought of their own menu and procured needed ingredients.



Brain exercise class (September 2019)

### **Dementia Cafe**

The dementia cafe (Orange Cafe) is a place where dementia patients, their families and people from the community can gather freely. Orange Cafes are regularly held at the Company's Head Office (Tokyo), the Naito Museum of Pharmaceutical Science and Industry (Gifu Prefecture), and the Tsukuba Research Laboratories (Ibaraki Prefecture). In addition to spending an enjoyable time, people who visit the cafe can make new friends, exchange information, and consult healthcare and nursing care professionals. At the same time, they can also participate in brain activation exercises, led by nursing preventive exercise instructors, enjoy musical entertainment as part of music therapy, and other offerings. The Company's employees

participate each time a salon is held, proactively interacting with a variety of individuals.



Brain activation exercise (January 2020)

# 16 types of cancer 12 million people



Number of patients with cancer globally to whom Eisai may be able to contribute through our products and projects under development

### SWOT Analysis

# **Strengths**

- 1. Capability to develop in-house products based on experience and knowledge of medicine creation with human biology evidence as a pillar
- 2. Capability in research and development based on cuttingedge organic synthesis chemistry, which was utilized in the development of Halaven<sup>o</sup>
- 3. Contribution to patients by establishing standard of care through steady progress in development of combination therapy of Lenvima® and KEYTRUDA®
- 4. Fulfilling unmet medical needs through strategic partnership that enables creation of new value
- 5. Progress in the development of projects following Halaven® and Lenvima® targeting cancer microenvironment that is existingtherapy-resistant and immunosuppressive, and cancer driver genes, such as E7386, MORAb-202, E7130, and H3B-6545

# Weaknesses

- 1.Insufficient variety of products for specific cancer types
- 2.Initiatives to provide innovative treatment methods aiming for the curing of cancer are still in non-clinical stage

# **Opportunities**

- 1.Expansion of oncology market along with creation of highvalue-added agents and economic growth in developing/ emerging countries
- 2.Transformation of treatment system along with innovation in technology for diagnosis and artificial intelligence (Al)

### Threats

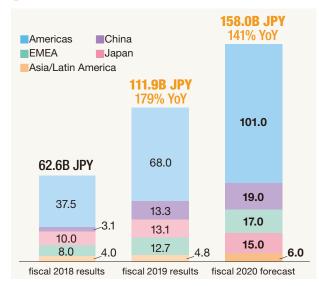
- 1. Authority's approvals for competitive treatments
- 2. Innovative competitive treatments entering the market
- 3.Increasing pressure to lower drug prices to reduce healthcare expenditure
- 4. Delay in development of medicines due to pandemic

### Lenvima®: Progress of Partnership Model

### 1.Steady progress of collaboration and expansion of revenue Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. agreed upon a global strategic collaboration for Lenvima® in March 2018. The co-commercialization is currently progressing smoothly in 18 countries as of June 2020 and revenue forecast of over 150 billion is expected in fiscal 2020.

Since collaboration started, Eisai has recognized accumulated total of 1,625 million USD payment from Merck & Co., Inc., Kenilworth, N.J., U.S.A. including up-front, one-time option, and milestone payment. Besides, in fiscal 2017, Eisai has received 450 million USD as reimbursement of research and development expenditure, separately from milestone payment.

### Revenue of Lenvima® (Billions of yen)



Recognition of payments under agreement with Merck & Co., Inc., Kenilworth, N.J., U.S.A.

### Maximum of up to 5.76 billion USD in total (approx. 611.0 billion JPY\*)

- One-time payment: 950 million USD (approx. 101.0 billion JPY)
- · Upfront payment: 300 million USD (approx. 32.0 billion JPY)
- One-time option payments associated with Merck & Co., Inc., Kenilworth, N.J., U.S.A. exercising certain option rights: 650 million USD (approx. 69.0 billion JPY)
- Reimbursement for R&D payment: 450 million USD (approx. 48.0 billion JPY)

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 USD in total (approx. 462.0 billion JPY)

- Clinical and regulatory milestones: Up to 385 million USD (approx. 41.0 billion JPY) regulatory approval of indications in hepatocellular carcinoma or renal cell carcinoma, etc.
- Milestones associated with sales of Lenvima®: Maximum of up to 3.97 billion USD (approx. 421.0 billion JPY)

\*1 USD=106 JPY

One-time pay (Total 950 millio		Clinical and regulatory mi (Maximum of up to 385 millio	Sales-based milestone (Maximum of up to 3.97 billion USD)			
Up-front payment (Fiscal 2017)	300 million USD	Approval of hepatocellular carcinoma indication in Japan (Fiscal 2017)	25 million USD	When revenue of 500 million USD was achieved in fiscal 2018	50 million USD	
One-time option payment (Fiscal 2018)	325 million USD	Approval of hepatocellular carcinoma indication in the U.S. (Fiscal 2018)	125 million USD	When revenue of 800 million USD was achieved from January to December 2019	150 million USD	
One-time option payment (Fiscal 2019)	200 million USD	Approval of hepatocellular carcinoma indication in Europe (Fiscal 2018)	50 million USD	When revenue of 750 million USD was achieved in fiscal 2019	150 million USD	
		Approval of reimbursement for hepatocellular carcinoma indication in Europe (Fiscal 2018)	25 million USD	When revenue of 1 billion USD was achieved in fiscal 2019	200 million USD	
		Approval of hepatocellular carcinoma indication in China (Fiscal 2018)	25 million USD			
		Total receipts 1,625 milli	on USD			

Received 450 million USD in fiscal 2017, as a reimbursement for research and development expenses

### 2. Obtained first approval for the combination therapy of Lenvima® and KEYTRUDA® for the treatment of endometrial carcinoma\*1

In September 2019, the first combination therapy of Lenvima® and KEYTRUDA® was approved and launched in the U.S. for the treatment of endometrial carcinoma. This is the first new treatment option in approximately 50 years since the U.S. Food and Drug Administration (FDA) last approved existing treatment. This is an accelerated approval reviewed for three months under the FDA's Real-Time Oncology Review (RTOR\*2) pilot program.

In addition, this review was the first case conducted under Project Orbis, an initiative of the FDA Oncology

Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among its international partners. Under this project, the FDA, the Australian Therapeutic Goods Administration (TGA) and Health Canada collaboratively reviewed applications for two oncology drugs, allowing for simultaneous decisions in all three countries.

- \*1 Advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation
- \*2 The FDA's Real-Time Oncology Review (RTOR) pilot program aims to improve the efficiency of the review process for applications to ensure that treatments are available to patients as early as possible. RTOR allows the FDA to review much of the data earlier, before the applicant formally submits the complete application.

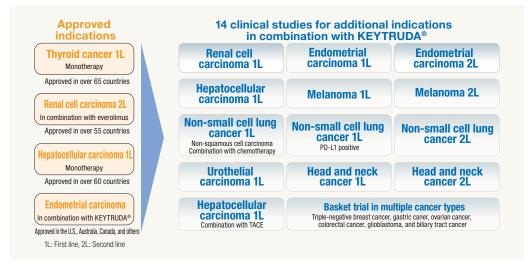
# 3. Clinical studies aimed at obtaining approvals for additional indications are steadily ongoing (LEAP study)

Large-scale later stage clinical studies for combination therapy of Lenvima® and KEYTRUDA® are ongoing with approximately 8,200 patients with 13 types of cancer. In addition to 13 studies, which were originally planned at the time of signing the agreement for strategic partnership with Merck & Co., Inc., Kenilworth, N.J., U.S.A., further expansion of target indication is underway, such as initiating a new study for hepatocellular carcinoma in

combination with TACE\*. Eisai is aiming for this combination therapy to be a core therapy by obtaining indication in multiple types of cancer. Furthermore, we plan to accelerate development, once promising data for earlier submission is observed in basket trial, a study Phase II stage targeting multiple types of cancer.

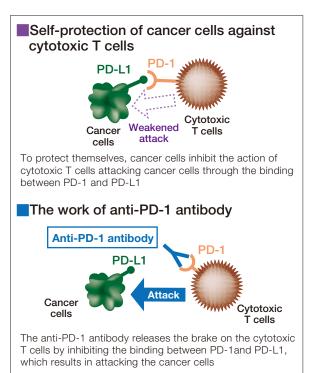
\* Transcatheter Arterial Chemoembolization: A therapy that selectively obstructs blood circulation to induce necrosis in hepatocellular carcinoma (HCC) by injecting embolization material into the hepatic artery that supplies nutrient blood to tumor

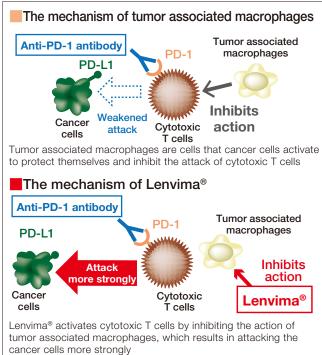
Opproved indications for Lenvima and further expansion of target indications in combination with KEYTRUDA



## Major mechanism of efficacy of anti-PD-1 antibody enhanced by Lenvima® (Non-clinical studies)

Studies showed that antitumor activity of the anti-PD-1 antibody was enhanced with Lenvima by reducing tumor-associated macrophages (TAM) and increasing activated cytotoxic T cells, which attack cancer cells.





#### Honored with PSJ Award for Drug Research and Development

"Drug discovery research of novel anti-tumor agent Lenvima® targeting VEGF and FGF receptors" was honored with The Pharmaceutical Society of Japan (PSJ) Award for Drug Research and Development 2020. The PSJ Award for Drug Research and Development is one of a series of awards presented by the PSJ and is dedicated to researchers who have conducted outstanding research work that has contributed to medicine through the innovative development of a pharmaceutical drug or applicable technology related to the pharmaceutical sciences. Award recipients are evaluated based on the ingenuity of the research itself as well as the effectiveness and safety of the related pharmaceutical products or the innovativeness of the related medical treatment or treatment technology.

# Drug Creation Strategy Based on Progression of Cancer (Cancer Continuum) and Gene Mutation

The progression of cancer is classified as precancerous condition/ultra-early cancer, early cancer, and advanced cancer. At each stage, cancer gene alteration that correspond to canceration, proliferation, infiltration or recurrence, metastasis, treatment resistance and so on, exists. Next-generation drug discovery research strategy is aimed at curing cancer by grasping these alterations through liquid biopsy (a biological test using blood as a sample), leading to the development of

precision medicine suitable for each patient.

In January 2020, Eisai entered into a joint research and development agreement with Personal Genome Diagnostics Inc. (U.S.) for cancer genetics panel test. In this joint research and development, we utilize liquid biopsy to create a cancer gene panel test kit that enables comprehensive analysis of alterations in more than 500 cancer genes, and utilizes them for drug discovery.

# 1. Drug discovery for precancerous condition/ultra-early cancer stage

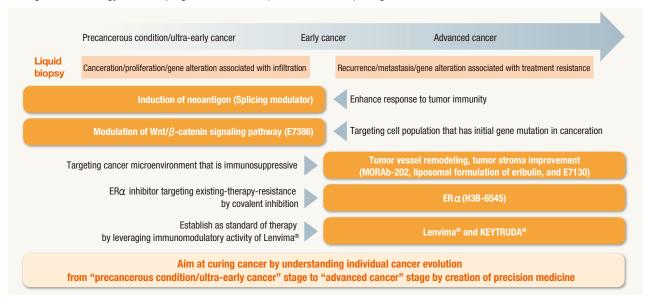
### Induction of neoantigen\*1

H3 Biomedicine Inc. (H3B), our precision medicine research and development subsidiary based in Boston, U.S., and Bristol-Myers Squibb Company (U.S.) are collaborating in research to advance novel therapeutics leveraging H3B's RNA splicing\*<sup>2</sup> platform. The two companies are conducting research to induce

neoantigens in specific cancer cells through antibodydrug conjugate (ADC) using splicing modulator, and increase the reactivity of immuno-checkpoint inhibitors.

- \*1 A mutant antigen born along with cancer cell-specific genetic information and editing abnormalities. It is not expressed in normal cells, but only found in cancer cells. The more neoantigens cancer cells contain, the more immunogenicity is observed, and the greater the likelihood of becoming a target of immune cell attacks.
- \*2 Molecular editing to remove unnecessary parts from genetic information

Drug creation strategy based on progression of cancer (Cancer Continuum) and gene mutation



#### WNT/beta-catenin inhibitor investigational E7386\*

Beta-catenin has long been known to be a factor that rapidly accelerates the malignancy of cancer. Due to the high difficulty of drug discovery, which requires drug design to inhibit protein-protein interactions, it was made a part of the drug discovery target known as Cancer Big 4, along with K-RAS variants, MYC, and p53 variants. By utilizing the drug discovery chemical capability accumulated through experience to date, Eisai successfully developed an oral agent, investigational E7386, which inhibits WNT-signal-dependent canceration and cancer cell proliferation,

by blocking transcription through inhibiting protein-protein interactions of CBP and  $\beta$ -catenin. Phase I study is ongoing for this agent. Abnormalities in WNT/ $\beta$ -catenin signaling pathways have been observed in various types of cancer. Since this abnormality is observed particularly from the early stage of occurrence of hepatocellular carcinoma, E7386 is expected to be a treatment for early hepatocellular carcinoma. Also, in non-clinical studies, a combination effect of Lenvima® and KEYTRUDA® has been confirmed, and a Phase I trial in combination with Lenvima® is ongoing.

\* Co-development with PRISM BioLab Co., Ltd.

### 2. Drug discovery for early to advanced cancer

### Platform originated from in-house developed Halaven®

Halaven® (generic name: eribulin) is an in-house microtubule dynamics inhibitor, which was developed as 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. Development of new drugs is underway utilizing assets obtained from development of this innovative product, Halaven®.

MORAb-202, which conjugated eribulin to an antibody via a suitable linker, is Eisai's unique ADC, which conjugated the in-house developed anti-folate receptor  $\alpha$  antibody, farletuzumab and eribulin that acts to the tumor

microenvironment, and Phase I study is ongoing. This agent is expected to show efficacy in cancers such as ovarian cancer that overexpresses folate receptor  $\alpha$ , and in tumor microenvironment, and to demonstrate antitumor activity.

In addition to MORAb-202, we have a platform originated from eribulin, that is targeted at existing-therapy-resistance and tumor immunosuppressive cancer microenvironments. It includes a liposomal formulation designed to increase the accumulation of cancer by encapsulating eribulin in lipids, and investigational E7130, a total synthetic medium molecular compound halichondrin B, and so on.

# Selective estrogen receptor alpha covalent antagonist investigational H3B-6545

Investigational H3B-6545 is an oral ER receptor  $\alpha$  covalent antagonist developed by H3B, and Phase II study is ongoing in this agent. Hormone receptor positive breast cancer accounts for about 70% of all breast cancers. Through the long-term usage of aromatase inhibitors, one of the hormone treatments, a drug-resistant ER $\alpha$  gene mutations occurs in about 30% of hormone-positive breast cancer.

Investigational H3B-6545 has a new drug profile different from existing ones that covalently binds to both wild-type and mutant  $\text{ER}\alpha$ , to inhibit downstream signals and suppress the growth of breast cancer cells. Therefore, this agent is expected to become an agent that can be administrated by the patients with hormone receptor positives for a longer period.

7.5 billion Number of medicine tablets manufactured at 9 global sites in a year

Fulfill Our Mission and Responsibility to Consistently Supply High Quality Products for Patients around the World



Hiroyuki Kato (Left)
Senior Vice President
Chief Clinical Quality Officer
Chief Product Quality Officer
Global Product Emergency Management
(referred to as Kato (Quality) in the text)

Yoshiteru Kato (Right)
Senior Vice President
President, Eisai Demand Chain Systems
(referred to as Kato (Production) in the text)

Let me ask you about supply chain management in Eisai. How do you handle growing medical needs?

Kato (Production): We have 9 medicine production sites globally. By maximizing the characteristics and technical strengths of the region where the site is located, we are building a supply chain that delivers high quality medicines to patients around the world in a stable manner. Our major products such as Lenvima® are having approvals applied for in more countries immediately after or almost at the same time as when they are launched in Japan, the U.S. and Europe. By utilizing not only our own production sites but also manufacturing contractors (CMOs), we aim to deliver medicines to patients as quickly as possible. When selecting CMOs to do business with, we confirm not only whether it is a company that can provide GMP\* conformity, quality, and a stable supply system, but also whether they share our commitment to quality and the idea of "patient first."

Kato (Quality): The variety of products Eisai handles is steadily increasing. So we select the appropriate inhouse site or CMO for each product at each stage of raw material procurement, drug substance manufacturing, formulation, packaging, and so on. Some

products are outsourced to Eisai. Business is getting more complicated. In order to achieve a stable supply of high quality products under such circumstances, close cooperation at each stage of the supply chain is important regardless of whether the producer is Eisai or a CMO. We believe this cooperation can be realized at a higher level by deep understanding of the true feelings of patients. In addition, in order to deliver our products to patients around the world, we need more and more efforts to respond to the increasing GMP regulatory requirements of national authorities. At the Kawashima Industrial Complex (Gifu Prefecture), we recently had inspections by authorities from several countries in a

short period of time and made an all-out effort to respond properly.

\* Standards for manufacturing control and quality control. In order to manufacture and sell medicines, it is necessary to comply with the GMP set by each country in which the medicines are sold, and to be approved by the national authorities.



### What is your specific method for maintaining a high quality of products?

Kato (Quality): Ensuring the integrity (consistency and accuracy) of data related to manufacturing and quality control is an essential requirement to maintain product quality. In order to strengthen data integrity, Eisai

promotes regular training for employees who handle important data, automation of calculation and recording of important data, and establishment of appropriate segregation of duties. There is a separation of

governance between production and quality management.

**Kato (Production):** On behalf of patients, the quality department strictly checks the products manufactured wholeheartedly by us, the production department. By separating governance, we believe that we can

continue delivering high quality medicines to patients.

Kato (Quality): The production department and the quality department are the closest and the most important partners for achieving a meaningful contribution to the well-being of patients.

# What are your counter-measures in relation to various risk factors such as Brexit, natural disasters, COVID-19, and so on?

Kato (Production): It is our responsibility to ensure stable production of medicines and ensure delivery to patients under any circumstances, so we have formulated a Business Continuity Plan (BCP) and regularly review it. With BCP, we aim to minimize damage in the event of a disaster or an emergency and to immediately undertake activities for business continuity. We maintain a system that ensures continuous product supply, such as backup manufacturing systems.

Kato (Quality): Even under the COVID-19 pandemic, we are able to continue manufacturing with minimal impact. We believe that this is a manifestation of the strong will of our employees around the world who are involved in manufacturing and quality assurance, in addition to responding to BCP and implementing daily actions to minimize their own infection risk in order to contribute to patients' well-being. In addition, taking this pandemic as an opportunity, we will once again examine the ideal form of logistics and make it more

certain that we can contribute to patients' well-being under the new order.

Kato (Production): We have been systematically responding to Brexit from an early stage. Using the warehouse in Antwerp (Belgium) as a transportation base in the EU, we have established a quality assurance system in the EU centered on Eisai GmbH, a German subsidiary of Eisai. In addition, in order to increase the inventory of all products

for EU to more than 6 months, our production site at Hatfield (U.K.) has increased production by operating 24 hours a day. We believe that we can continue to supply products without confusion even after the transition period of Brexit.



## Lastly, please tell us your thoughts on quality assurance and stable supply.

Kato (Quality): Eisai has a policy called "Eisai Quality Policy" that is the basis of all business activities. In our manufacturing and quality assurance departments, we keep the concept of "the quality of every single tablet, capsule and ampoule that we produce is integral to the life of patients" in mind at every single moment we work. In the case of a major quality issue, the existing relationship of trust with the patient or family can be immediately impaired. In order to maintain and improve this relationship of trust, we believe that it is important for each staff member involved in manufacturing and quality to continue their efforts with "Eisai Quality Policy" in mind.

Kato (Production): We frequently have chances to receive words of thanks directly from patients and their families through Socialization\*, such as "The thoughts of Eisai's employees who make medicines help us," "I want to thank you all. It is thanks to medicine that my daughter has continued to grow and stayed healthy," "This medicine keeps children alive." We also listen to the message "The most horrifying event would be discontinuation of this medicine's supply." We pledge that we will never betray the trust that people place in use, and will consistently manufacture high quality medicines and deliver them to patients.

For the details of "initiatives against counterfeit medicines," please visit our website at 🕨 https://www.eisai.com/sustainability/atm/product-security.html

<sup>\*</sup> Activities that involve spending time with patients and their families and sharing true feelings. Please refer to pages 5-8.

# **Marketing Activities**

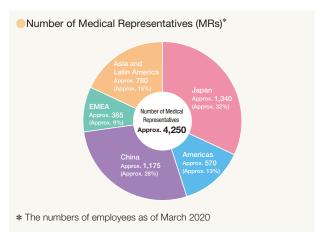
# 69 countries

The number of countries where we conduct marketing activities

# Marketing activities looking at regional characteristics

Based on the "hhc" corporate philosophy, the Company aims to elucidate the true needs that are latent in patients, their families, and medical personnel, and to capture questions raised in the clinical field regarding disease state, evaluation, treatment, risk, prevention, etc., which will then lead to the meeting of unmet medical needs by proposing solutions in cooperation with each business and partner company. Approximately 4,250 medical representatives (MRs) in

the Company are conducting marketing tailored to local characteristics for patients around the world through Socialization in the field of medical care.

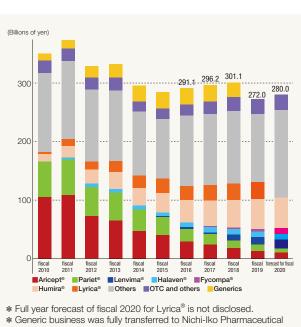


# Japan

Patients with cancer and neurological disorders tend to be concentrated in acute care hospitals which provide advanced medical care. Because communication skills are necessary for MRs to share their thoughts with medical professionals with ample knowledge and propose prescriptions, field trainers assigned to each focus area are working hard on talent development.

Due to the busier schedule of doctors and the stricter security of hospitals, restrictions on visits to medical institutions have been tightened. Information gathering by digital channels is rapidly being common. Therefore, we established the Digital Market Strategy Department, and are working on the construction of a next-generation marketing scheme in parallel with improving the skills of MRs. We are going to realize more effective multi-channel promotion by identifying the true needs of medical personnel by separation of the roles of MRs and digital channels to increase commercial effect and efficiency, instead of simply replacing the MR function with digital contents.

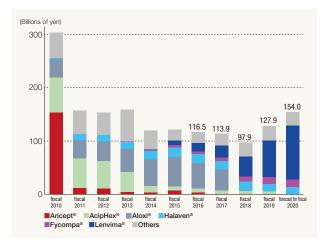
We are aiming at sustainable growth especially with in-house developed anticancer agents Lenvima® and anti-insomnia drug Dayvigo™.



Co., Ltd. in April 2019.

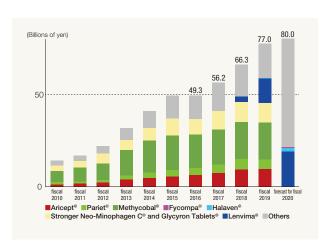
### Americas (North America)

In-house developed anti-cancer agent Lenvima® achieved dramatic growth and led an increase in revenue in fiscal 2019. In-house developed new anti-insomnia drug Dayvigo™ was launched in June 2020. Eisai is implementing marketing/promotional activities utilizing digital tools, such as sending e-mails and holding webinars to medical personnel, in addition to conventional marketing activity, in which MRs visit medical facilities to provide information on the products. Eisai aims to further promote digital marketing activity to establish the structure, which will make it possible to stay connected with medical personnel even in an unexpected situation where marketing activities are restricted.



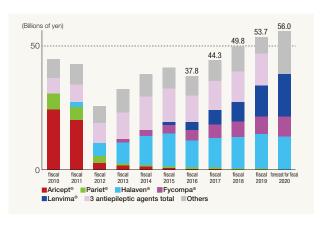
### China

Although long-listed products, such as Methycobal® and Aricept® have supported the growth of business for a long time, in-house developed new products, such as Lenvima®, Halaven® and Fycompa® have been launched and supported the growth since fiscal 2018. We aim to continuously grow by being flexible with changes brought by rapid expansion of online healthcare business with further expansion of new products, market development in inland areas and regional small cities/hospitals, and an up-to-date business model with full-fledged digital technology.



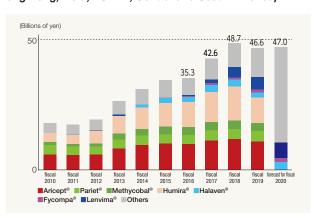
### **EMEA** (Europe, the Middle-East, Africa, and Oceania)

Managers spend most of their time coaching MRs focused on initiatives to improve productivity. MRs improve their marketing skills through the coaching and strive to achieve better performance through mutual communication with medical personnel. Furthermore, in the regions where Eisai implements business through collaboration with partners, such as the Middle-East, Africa, Central and Eastern Europe, and Southern Africa, our in-house marketing team provides the educational program to partners, so that partners can learn high quality information.



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

Asia is the first region where Eisai expanded its business outside Japan in the late 1960s, since when approximately half a century has elapsed. The subsidiary company in Thailand marked its 50th anniversary in 2019, and it has expanded the territory to cover Vietnam, Myanmar, Cambodia, and Laos through collaboration with partners. In addition to the provision of information by MRs, the company hold the event called "Eisai Day" annually where talk shows and events by physicians and pharmacists are provided for patients, their families, and healthcare providers, as well as the general public.



# Number of partnerships 55

Aim to generate societal innovation and maximize contribution to patients, together with partners







# Q Can you discuss the objectives of Eisai's partnership strategy?

A. In order to deliver innovative medicines and solutions to patients and their families as early as possible, we believe that partnerships with companies and research institutes who share strengths in the areas or fields we focus on can potentially help us achieve goals that we would not be able to achieve on our own.

Investing large amounts of resources over the years is often required to develop new medicines; therefore, we believe that partnerships are very important for us to continuously develop innovative medicines and provide solutions that fulfill patients' unmet needs.

Our collaboration with Biogen Inc. (U.S.), which began in 2014 and the collaboration with Merck & Co., Inc., Kenilworth, N.J., U.S.A. (known as MSD outside the U.S. and Canada), which began in 2018 will bring significant impact in the areas of Alzheimer's disease and oncology, respectively, which we are focused on. Thanks to these partnerships, the global development

of potential next-generation dementia treatments is steadily progressing, and the development of combination therapy of Lenvima® (lenvatinib), an inhouse developed anticancer agent, and KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy developed by Merck & Co., Inc., Kenilworth, N.J., U.S.A., is progressing faster in a broad range of cancer types than the original plan and will help maximize the value of Lenvima®.

As regards the development of solutions, we entered into a business alliance agreement with Cogstate Ltd. (Australia) in August 2019, as well as launching "NouKNOW $_{TM}$ ," a digital tool for self-assessment of brain health, on March 31, 2020 in Japan.

All of these partnerships have helped us create value that we could not have achieved on our own, and we aim to transform medical innovation into societal innovation through our partnership model.

# Q How would you evaluate the progress of the partnership strategy so far?

A. While there are certainly some challenges in the process of building partnerships and working together with the partners, I believe the results have exceeded our expectations.

As regards the development of potential nextgeneration dementia treatments, while many major pharmaceutical companies have discontinued the development, with regard to aducanumab, which we co-develop with Biogen Inc., Biogen has completed the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in July 2020. Furthermore, the launch readiness for a potential first therapy to realize clinical decline in Alzheimer's disease is also progressing. I believe this has proven to be a successful example of the partnership model.

In the collaboration with Merck & Co., Inc., Kenilworth, N.J., U.S.A., co-development of combination therapy of Lenvima® and KEYTRUDA® has progressed in multiple types of cancers, and this may dramatically expand the scope of patient contribution that Lenvima® can make.

# Q What are the efforts you have put in place to operate partnerships between the companies?

A. In partnerships with Biogen Inc. and Merck & Co., Inc., Kenilworth, N.J., U.S.A., our CEO closely communicates with each company's CEO on a regular basis. In addition, the decision-making process has dramatically improved by establishing committees

focusing on development, manufacturing, and commercialization functions, as well as regularly holding in-depth discussions.

I feel that identifying the departments that should work together, in accordance with the differences in the

organizational structure among the companies, has worked effectively in helping us make quick decisions.

While there may be a variety of issues to discuss between the companies in project that are currently in progress, if we go back to the common goal of "serving the best interests of our patients" and carry on discussions, a mutual trust can be built.

It is obvious that working in close communication and building trust is essential to operate partnerships smoothly. However, the actual process of resolving difficulties and producing positive results together with the partners has helped us to acquire valuable expertise.

# Q What do you have in mind for any new potential partnerships?

A. To realize our corporate philosophy "hhc" and the medium-term business plan, 'EWAY 2025,' we are constantly seeking partners who have strengths in areas we do not have, and have common interests addressing issues that we believe need to be solved.

We continue to build our global investment business by recently establishing the Corporate Venture Investment (CVI) department in Tokyo in May 2019, as well as Eisai Innovation, Inc. in the U.S. in August 2019. Our focus is not on pursuing profits from investments, but on incorporating external innovations into our business.

Since we seek synergy between in-house research and development and the provision of solutions to

patients, we will continue to invest in companies who possess technologies that will be a foundation of drug discovery and diagnostics related to neurology and oncology drugs, as well as solutions, such as digital technologies, other than drug development.

We will continue to invest to build upon Eisai's ecosystem that focuses on making a contribution to patients' well-being. Various approaches will be considered, including intervention at an earlier stage of the disease, prediction of the progress of the clinical condition, and related services. We aim to contribute to the creation of societal innovation and increase the positive contribution that we make to patients.

### Merck & Co., Inc., Kenilworth, N.J., U.S.A.'s Statement on Collaboration with Eisai

We value our collaboration with Eisai as an excellent example of what can be achieved when two companies work together toward a common goal — in this case, to improve outcomes for patients with cancer. With extensive oncology experience across both companies, we have initiated a broad clinical development program evaluating the combination of KEYTRUDA® plus Lenvima® across many types of cancer, including several registrational Phase III trials. Our joint efforts have already resulted in the first FDA approval for the combination in 2019, addressing a significant unmet medical need for certain patients with endometrial carcinoma. We look forward to pursuing additional indications for the KEYTRUDA® plus Lenvima® combination in the coming years and are excited by its potential to help even more patients.



Rick Hartz Vice President, Commercial Development

### Biogen Inc.'s Statement on Collaboration with Eisai

Biogen Inc. and Eisai share a commitment to science and a common vision to deliver breakthrough therapies for patients and families affected by Alzheimer's disease. This historic collaboration has allowed us to leverage the complementary forces of our organizations to share risk and to create potentially more value together than each company alone. The commitment both companies share to address the urgency in Alzheimer's disease is exemplified by the rapport between the CEOs and the attention and leadership they provide to this collaboration. It requires time and effort to make this collaboration manageable and, despite the time zone challenges, our joint teams are dedicated to bridging the complexities. The success of this partnership comes from the trust and mutual understanding our teams have built and the shared underlying passion to make a difference for Alzheimer's patients. We are optimistic about aducanumab, which promises to become the first therapy to reduce the clinical decline in Alzheimer's disease, and which has completed the regulatory filling in the U.S. Looking ahead, we are committed to advancing our portfolio of potential Alzheimer's therapies and the co-promotion of Multiple Sclerosis treatments.



Satbir Kaur Vice President, Head of Alliance Management and Integration

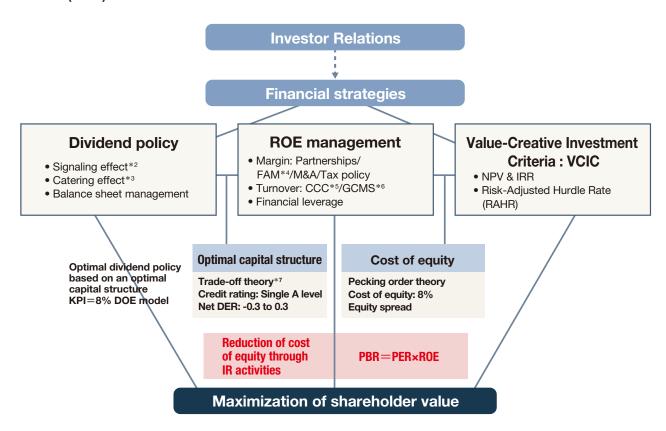


18.6% ROE of fiscal 2019

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)."

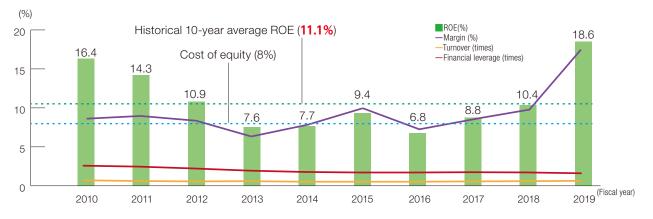


- \*1 Source based on the following reference: Financial and Accounting Literacy to Enhance Corporate Value (Nikkei Publishing Inc., 2016)
- \*2 Signaling effect: Potential impact on stock price by showing management's belief in the achievement of revenue forecast through dividend policy
- \*3 Catering 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 —Target 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 11.1% and a positive equity spread of 3.1%.

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%)

\* "CFO policy" CHUOKEIZAI-SHA (2020)

### Historical 10-year equity spread

Historical 10-year average ROE: 11.1% - CoE 8% = 3.1% \*Results up to fiscal 2012 were calculated pursuant to generally accepted accounting principles in Japan (J-GAAP), while results from fiscal 2013 to

2019 were calculated pursuant to International Financial Reporting Standards



\*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

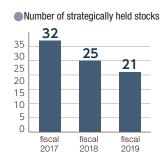
Under the DuPont method, ROE can be analyzed by three elements consisting of margin (ratio of profit to revenue), turnover (total assets turnover ratio) and financial leverage. Eisai is focusing on optimizing each of these three elements.

### **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 had sold strategically held shares. In fiscal 2019, Eisai sold strategically held shares in 6 stocks (all shares of 5 stocks among the 6) and part of 3 deemed holding shares.



## **Use financial leverage**

Eisai has pursued an optimal capital structure while maintaining financial integrity. For maintaining a single A level credit rating as a general rule, we have set the KPIs 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 2019. Net DER was -0.29, the ratio of equity attributable to owners of the parent was 63.8% and Net Debt/EBITDA was -1.20 years. We have secured sufficient financial integrity and liquidity on hand to absorb the impact of COVID-19.

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

parent company) / Equity attributable to owners of the parent \*2 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 strong 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\*1, 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 main 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 maintains a healthy balance sheet under present conditions. Therefore, Eisai increased dividends to 160 yen in fiscal 2019 and intend to keep it in fiscal 2020\*2 with an intention to balance stable dividend payment and investment for corporate growth. Acquisition of treasury stock will be carried out appropriately after factors such as the market environment, theoretical share price, and capital efficiency (ROE) are taken into account.

- \*1 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 on IFRS. \*2 Dividends 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
- \* Dividends per share subject to approval of Board of Directors (reported on the timing of occurrence)

### Strong balance sheet —Dividend sustainability by maintaining optimal capital structure—

finvestment securities held by the parent company are included in the formula under IFRS.



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

### Eisai's Funding Policy

Eisai's funding policy is based on the pecking order theory. Eisai prioritizes cash on hand over debt, and equity financing 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)

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)

# KPIs 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, which is the final year of the plan, we are 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. We achieved all the numerical targets in fiscal 2019 ahead of schedule.

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

KPI	Fiscal 2020 targets*1
ROE	10% or more
Equity spread*2	2% or more
DOE*3	8% level
Ratio of equity attributable to owners of the parent	50-60%
Net DER*4	-0.3 to 0.3

### Fiscal 2025 target\*1: 15% level ROE

- \* Dividends per share subject to approval of Board of Directors
- \*1 Numerical targets as of March 2016 when mid-term business plan was formulated
- \*2 Equity spread = ROE Cost of equity. Eisai conservatively assumes cost of equity of 8%
- \*3 DOE = Dividend on equity attributable to owners of the parent
- \*4 Net DER: Net Debt Equity Natio = (Interest-bearing debts (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 enhance 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



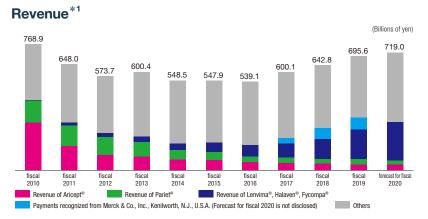
contributes to corporate value creation."

Eisai's activities for years were recognized and the Company was selected by the US financial information magazine "Institutional Investor" as "Most Honored Company" and has been ranked first place overall in the Biotechnology & Pharmaceuticals sector of "The All-Japan Executive Team" with the first place in "Best CEOs" and "Best CFOs" respectively in the sector.

# **Consolidated Financial Highlights in the Last 10 Years**

Achieved Record High Operating Profit and Profit for the Year by Lenvima®'s Expanding Contribution to Patients

\*1 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)



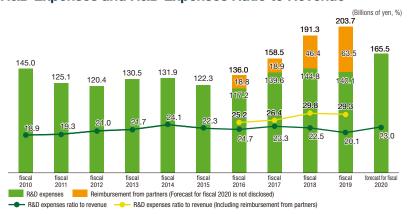
Decline trend in revenue continued due to loss of exclusivity of our major products, Aricept®, treatment for Alzheimer's disease and Pariet®/AcipHex®, protonpump inhibitor. At the same time, newly launched in-house products, such as Lenvima® (anticancer agent) Halaven® (anticancer agent), and Fycompa® (antiepileptic 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 three consecutive years in fiscal 2019.

# Cost of Sales and Cost of Sales Ratio to Revenue\*1



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 Merck & Co., Inc., Kenilworth, N.J., U.S.A. associated with strategic collaboration on revenue resulted in the decrease in cost of sales ratio since fiscal 2017.

# R&D Expenses and R&D Expenses Ratio to Revenue\*1



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.

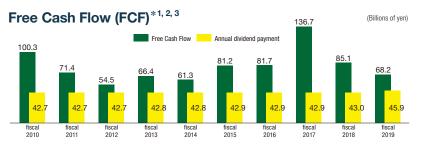
Moreover, Eisai achieved significantly effective investment in R&D by utilizing partnerships. Results for substantial R&D expenses in fiscal 2019 was 203.7 billion yen and R&D expenses ratio was 29.3% including the reimbursement from partners.

# Operating Profit and Operating Profit Ratio to Revenue\*1



We achieved record high operating income due to the expanded contribution of Lenvima® to patients and the recognition of payments from Merck & Co., Inc., Kenilworth, N.J., U.S.A. in association with strategic collaboration for Lenvima® in fiscal 2019. We plan to make

Lenvima® in fiscal 2019. We plan to make aggressive investments in R&D and SG&A expenses, while Lenvima® is expected to expand its contribution to patients in fiscal 2020.



# 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 Merck & Co., Inc.,
Kenilworth, N.J., U.S.A. since fiscal 2017
contributes to securing FCF.

- \*2 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 on IFRS. \*3 Dividends per share subject to approval of Board of Directors
- \*3 Dividends per share subject to approval of Board of Directors (reported on the timing of occurrence)

	ficaci	ficaci	ficoc	fiscal	ficoc		Billion yen)	(Reference data) Financial Indicators	ficaci	ficaci		Billion yen
Financial Indicators (IFRS)	fiscal 2013	fiscal 2014	fiscal 2015	11SCal 2016	fiscal 2017	fiscal 2018	fiscal 2019	(J-GAAP)	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	695.6	Net sales	768.9	648.0	573.7	600.4
Cost of sales	194.7	193.6	194.5	195.9	201.3	184.5	175.7	Cost of sales	167.8	173.4	174.1	188.2
Ratio to revenue (%) Gross profit	32.5 404.8	35.3 354.9	35.5 353.5	36.3 343.2	33.5 <b>398.8</b>	28.7 458.3	25.3 <b>519.9</b>		21.8	26.8	30.3	31.3
Ratio to revenue (%)	67.5	64.7	64.5	63.7	66.5	71.3	74.7	Gross profit	601.1	474.6	399.6	412.2
Research and development expenses	136.3	131.9	122.3	117.2	139.6	144.8	140.1	Research and development	78.2	73.2	69.7	68.7
Ratio to revenue (%)	22.7	24.1	22.3	21.7	23.3	22.5	20.1	expenses	145.0	125.1	120.4	130.5
Selling, general and administrative expenses	203.3	194.5	192.8	174.9	183.9	228.2	256.3	Selling, general and	18.9	19.3	21.0	21.7
Ratio to revenue (%)	33.9	35.5	35.2	32.5	30.6	35.5	36.8	administrative expenses	343.0	253.7	208.7	210.5
Other income	4.1	1.0	17.7	13.6	3.0	2.6	6.4		44.6	39.1	36.4	35.1
Ratio to revenue (%)	0.7	0.2	3.2	2.5	0.5	0.4 <b>1.7</b>	0.9					
Other expenses  Ratio to revenue (%)	2.8 <sub>0.5</sub>	1.1 0.2	4.1 0.7	5.6 1.0	1.1	0.3	<b>4.4</b> 0.6					
Operating profit	66.4	28.3	51.9	59.1	77.2	86.2	125.5	Operating income	113.1	95.7	70.5	71.1
Ratio to revenue (%)	11.1	5.2	9.5	11.0	12.9	13.4	18.0		14.7	14.8	12.3	11.8
Profit for the year	38.5	43.5	55.0	42.2	54.4	66.5	122.5	Ordinary income	105.2	90.0	65.6	64.9
Ratio to revenue (%)  Profit for the year attributable	6.4	7.9	10.0	7.8	9.1	10.3	17.6		13.7	13.9	11.4	10.8
to owners of the parent	38.3	43.3	54.9	39.4	51.8	63.4	121.8	Net income	67.4	58.5	48.3	33.0
Ratio to revenue (%)  Comprehensive income for	6.4	7.9	10.0	7.3	8.6	9.9	17.5		8.8	9.0	8.4	5.5
the year	84.5	114.2	16.5	36.8	53.8	79.5	96.2					
(Cash Flow Statement Items	>							(Cash Flow Statement Items)				
Net cash from operating activities	91.3	76.0	95.6	75.9	149.6	103.7	102.8	Net cash from operating activities	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)	(27.6)	Net cash from investing activities	(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)	(103.5)	Net cash from financing activities	(68.0)	(78.0)	(81.8)	(114.8)
Free cash flow	87.3	61.3	81.2	81.7	136.7	85.1	68.2	Free cash flow	100.3	71.4	54.5	66.4
								(D. L. OL LIII)				
(Financial Position Items)	070.0	4.050.0	0740	1 000 0	1 0 10 0	4 074 5	1 000 1	(Balance Sheet Items)	4.040.0	4 00 4 7	000.0	0.45.5
Total assets  Equity attributable to owners	973.8 526.3	1,053.8 598.7	974.0 573.7	1,030.8				Total assets Shareholder's equity	1,046.3	1,004.7	990.2 469.4	945.5 506.8
of the parent				584.6	593.6	628.1	678.1	Silarenoluer's equity	404.2	416.8	409.4	500.6
Non-controlling interests	3.1	3.3	3.2	18.0	20.5	23.9	24.5					
Total liabilities	444.4	451.8	397.2	428.2	434.9	419.5	359.5					
Return on equity attributable to owners of the parent (ROE) (%)	7.6	7.7	9.4	6.8	8.8	10.4	18.6	Return on equity (ROE) (%)	16.4	14.3	10.9	6.8
Return on sales ratio (%)	6.4	7.9	10.0	7.8	9.1	10.3	17.6	Return on sales ratio (%)	8.8	9.0	8.4	5.5
Leverage (times)	1.9	1.8	1.7	1.8	1.8	1.7	1.6	Leverage (times)	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	0.6	Total assets turnover ratio (no. of times)	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	63.8	Shareholders' equity ratio (%)	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)	(0.29)	Net debt equity ratio (Net DER) (times)	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	7.0	Dividend on equity (DOE) (%)	10.4	10.4	9.6	8.8
Dividend payout ratio (DPR) (%)	111.8	99.0	78.0	109.0	82.8	67.8	37.6	Dividend payout ratio (DPR) (%)	63.4	73.1	88.6	129.8
Earnings per share (basic)	134.13	151.57	192.23	137.63	181.18	221.34	425.01	Earnings per share (EPS) (yen)	236.52	205.33	169.38	115.56
(EPS) (yen)												

<sup>\*1</sup> 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 (ROE) = Dividend payout ratio (DPR) x Return on equity attributable to owners of the parent (ROE)

# CFO Dialogue: Challenge for ESG, Making Invisible Value Visible



Ryohei Yanagi (Left)
Executive Vice President
Chief Financial Officer

Manami Konno (Right) ABeam Consulting Ltd. P&T Digital Business Unit FMC Sector Manager

# 1. Growing Interest in ESG

Yanagi: In global capital markets, ESG investment is now increasing rapidly. The asset balance is about 31 trillion USD (about 3,350 trillion JPY), and about 35% of the capital on the market is currently said to be ESG related. Although Europe is ahead of Japan in this area, the Government Pension Investment Fund (GPIF), which manages public pensions, has signed up to the Principles for Responsible Investment (PRI) and has adopted the ESG index. Since then, the direction has changed dramatically and ESG-related investment balances have grown rapidly by 115% over the past two years. With the increasing importance of non-financial information, the amount of ESG investing assets and the number of investors has increased. If investors are interested in Japanese companies with high potential ESG values, it is highly probable that the corporate value itself will be greatly improved as well. If the value of ESG and nonfinancial capital of a Japanese company that have not been realized at present is evaluated, the Price Bookvalue Ratio (PBR) of Japanese companies will have the chance to approximately double, as has been seen in the U.K. based on the change in PBR over the past 10 years.

Ms. Konno: ABeam Consulting Ltd. places priority on ESG-related information among non-financial information. ESG is the source of future corporate value and is the core of attractiveness for stakeholders to companies. Companies need to not only realize business management

by closely linking visions, management strategies and business plans with ESG, but also to promote external disclosure and dialogue in order to appeal on the basis of such characteristics. On the other hand, companies' initiatives related to ESG sometimes do not directly link ESG to corporate visions, management strategies, and business plans. I regret that there are some disclosures of only qualitative ESG, and settings of key performance indicators (KPIs) with little relation to the corporate vision.

Yanagi: Face-to-face engagement between companies and investors is also important in order to spread understanding of the fact that a significant portion of corporate value is composed of non-financial information and that it must become tangible. Overseas institutional investors have fiduciary responsibility and do not make inefficient investment decisions. In an investor survey I conducted in 2020, about three quarters of investors in the world answered that they would like Japanese companies to explain the relationship between ESG and corporate value. To that end, Eisai's IR team holds 800 one-on-one meetings with domestic and foreign investors annually. There are many short-term related interviews, such as about short-term figures and press release commentary, but recently they have changed to have more ESG focused interviews. In the last five years, the percentage of ESG focused interviews appears to have increased to over 30% from around 5%.

#### 2. Value Relevance Model

Yanagi: In order to realize the value of ESG and nonfinancial information, and link it to corporate value, it is necessary to synchronize ESG and Return on Equity (ROE). As CFO, I proposed a synchronization model (IIRC-PBR Model) regarding financial capital and non-financial capital value relevance based on Eisai's corporate philosophy "human health care (hhc)," at the same time as the announcement of the International

Source: Monthly Capital Market (June 2020), Capital Markets Research Institute, partially reedited

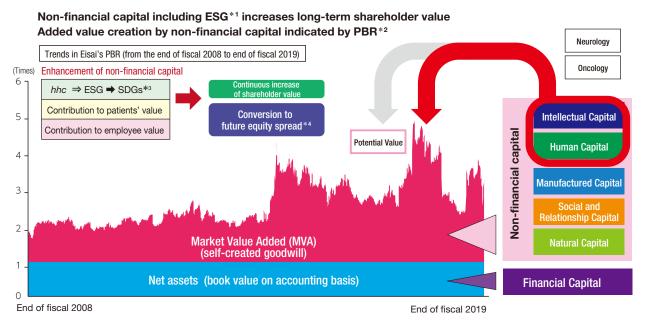
Integrated Reporting Council (IIRC) framework in consideration of longer-term capital efficiency (ROE and equity spread) and sustainability (importance of nonfinancial capital). Technically, shareholders' equity is the sum of the book value of shareholders' equity (BV) and market value added (MVA) that exceeds BV. The portion that exceeds PBR of 1X is related to ESG value, or non-financial capital related. First, under the ① Intrinsic Value Model, I defined MVA 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 the six types of capital under the IIRC framework, by positioning BV as financial capital, and relating MVA to non-financial 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 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 as part of stakeholder capitalism.

IIRC-PBR model (Value relevance of the six types of capital 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

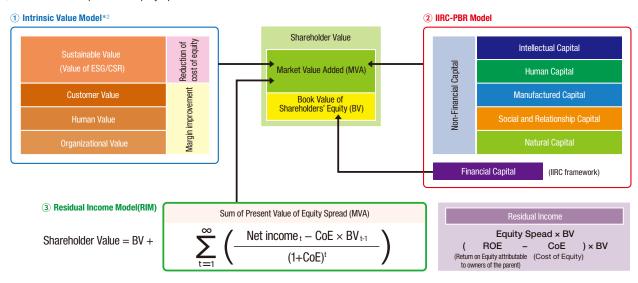


In conjunction with the non-financial capital and equity spread Value Relevance Model, the Intrinsic Value Model, which relates non-financial capital to MVA, the IIRC-PBR Model and the RIM, which implicates the relation between MVA and equity spread, are mutually complementary through the creation of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

In the RIM, it is proven mathematically that the present value of residual income is a function of equity spread (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 reduce R&D and personnel expenses in short term and buy back shares extremely would undermine long-term sustainability. For that reason, I, as CFO, promote an ROESG management that aims to increase ROE in the long term, looking at the average of 10 years via investment in R&D, and in human resources, with a long-term perspective.





Ms. Konno: In order for a company to gain a competitive advantage in the long term and sustainably, it has been a priority to secure management resources and assets that competitors cannot possess, that is core capabilities and values that cannot be easily imitated. Therefore, many companies have traditionally promoted investment as the basis for improving competitiveness and profitability in visible assets such as facilities and their expansion, and disclosed the value.

On the other hand, it is a well-known fact that the elements showing corporate value are shifting from tangible, visible things to human capital, technology, know-how, and intellectual property. From a bird's eye view of the entire value chain, it is becoming more and more widely recognized that human resources and knowledge are the fundamental elements that support a company's competitive advantage and generate innovation. As a result, companies are taking various measures to secure and utilize human resources and knowledge, but at the same time, investment in this invisible capital is becoming an important and difficult management issue.

Because it is necessary to realize comprehensive business management from various aspects, companies need to identify what capital investment is essential to the sustainable growth of the company, allocate and develop resources to strengthen human resources and knowledge with effect measurement, and prepare for risks that such resources cannot be secured or strengthened in parallel. We believe that companies that respond appropriately to these issues strategically sublimate human and intellectual capital to corporate value.

Yanagi: As we not operating on the same scale as the global mega-pharma companies, we are focusing resources on the 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 fiscal 2019 was 140.1 billion JPY, but adding the 63.5 billion JPY from the share of expenses borne by our partners, a huge amount of 203.7 billion JPY 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, from the viewpoint of Eisai's corporate

philosophy of "hhc," improving access to medicines (ATM) is one of our key areas of focus in the Social component of ESG. We teamed up with the World Health Organization (WHO) and will continue to provide diethylcarbamazine (DEC) tablets free of charge until lymphatic filariasis (LF), one of neglected tropical diseases (NTDs), is completely eliminated. The number of DEC tablets we provided by fiscal 2019 is 1.99 billion.

We have received some criticism that this damages shareholder value, but if we calculate net present value (NPV) of the project, taking the enhancement of our brand value in emerging markets into account, the project is creating value from a very long-term perspective. The mass production of DEC tablets in India where production cost is small raises not only capacity utilization at the plant but also the skills and motivation of plant

employees. We have received support from long-term investors such as overseas pension funds for balancing both the positive contribution to patients and long-term creation of corporate value in boosting ESG interest.

Ms.Konno: That is a great project. I think it's very wonderful and distinctive that Eisai not only continues activities that embody the corporate philosophy for a long period of time, but also links them to long-term creation of corporate value. In addition, I feel the fact that various other facts about ESG and qualitative information such as the corporate philosophy, the details of efforts and results are established and disclosed as a value creation story is a factor that gains the support of stakeholders.

# 3. Quantitative Analysis of Non-Financial Value

Ms. Konno: ABeam Consulting Ltd. believes that one of the reasons why ESG has been taking time to be captured as a management issue is the recognition wall of difficulty in quantitatively monitoring ESG-related information. One of the major issues is the difficulty in measuring cost-effectiveness, set KPIs, grasping the achievement rate, and integrating management goals, due to such walls. Therefore, in order to solve this problem and strengthen the competitiveness of Japanese companies, we envisioned the ABeam Digital ESG Platform, which utilizes the latest digital technology

to collect, accumulate, and analyze ESG information scattered inside and outside the company.

Yanagi: I have long felt that quantifying and accurately ascertaining the relationship between various ESG KPIs and corporate value was an issue, so I found the ABeam Digital ESG Platform concept very interesting and decided to conduct joint research. I composed a model for empirical research on the delayed penetration effect of ESG on corporate value and was looking for a partner to digitally process a large amount of ESG data.

● List of positive correlation of Eisai's ESG related KPIs and PBR\*¹(Logarithmic transformation)

Mu	Itiple regression analysis (Logarithmic transform	ation) *2: In(F	PBRi)=α+	-β₁·In(RO	E <sub>i</sub> )+β₂∙In	(ESG KPl <sub>i-t</sub> )	<b>+γ</b> i–t	
	ESG KPI*3	Delayed penetration effect (years before correlation)	Regression coefficient*4	t-statistic*5	p-value	Adjusted R-squared*6	Number of data observations	
Social and Relationship	Number of dispensing pharmacies doing business with Eisai (non-cons.)	0	3.30	4.55	0.001	0.70	12	
Human	Percentage of handicapped employees (non-cons.)	10+	3.35	4.25	0.003	0.72	11	p <
Human	Personnel cost (cons.)	5	1.38	4.40	0.003	0.75	10	Г
Human	Percentage of employees who underwent health checks (non-cons.)	10	38.57	3.26	0.012	0.61	11	
Intellectual	Number of prescription drugs approved (domestic)	4	0.25	3.13	0.017	0.61	10	
Human	Ratio of women in management (non-cons.)	7	0.24	2.96	0.018	0.56	11	
Human	Number of managers (non-cons.)	10+	3.14	2.94	0.019	0.56	11	
Social and Relationship	Number of pharmacies*7 doing business with Eisai (non-cons.)	4	0.48	2.93	0.019	0.56	11	
Intellectual	R&D costs (cons.)	10+	0.82	2.90	0.020	0.55	11	p <
Social and Relationship	Number of inquiries to <i>hhc</i> Hotline*8 (non-cons.)	5	1.08	2.88	0.021	0.55	11	
Human	Number of users of childcare leave program (non-cons.)*9	9	0.33	2.89	0.023	0.57	10	
Intellectual	R&D costs (non-cons.)	10+	0.88	2.78	0.024	0.53	11	
Human	Number of employees in EMEA*10	9	0.33	2.75	0.025	0.53	11	
Human	Number of employees in Americas*11	10	0.29	2.70	0.027	0.52	11	

<sup>\*</sup> The table above shows selected KPIs with positive correlation with PBR indicated from Multiple regression analysis (Logarithmic transformation) with ESG KPIs with 10 or more number of data observations, adjusted R-squared 0.5 or above, t-statistic 2 or above and p-value 0.05 or less on 1088 samples. This analysis is supported by ABeam Consulting Ltd.

Source: CFO policy (CHUOKEIZAI-SHA, 2020), partially reedited

<sup>\*1:</sup> Price Book-value Ratio \*2:  $\alpha$ : A factor affecting PBR rise unexplainable by ROE nor ESG,  $\beta$ 1: A value indicating the strength of the relationship between ROE and PBR,  $\beta$ 2: A value indicating the strength of the relationship between ESG KPI and PBR,  $\gamma$ 1-t: Difference between PBR estimated by regression equation and actual PBR, i: targeted fiscal year \*3: Key Performance Indicator about Environment, Social, Governance \*4: A value indicating the strength of the relationship between explanatory variables (ROE, ESG KPI) and dependent variable (PBR) \*5: A value indicating whether ROE or ESG KPI is statistically correlated with PBR or not \*6: A number that shows the explanatory power of the whole regression model (shown above) \*7: Including pharmacies selling foods \*8: Contact for inquiries and opinions for Eisai \*9: Item with more significant result is listed among those items with significant results. \*10: Europe, Middle East, Africa, Russia, and Oceania \*11: North America

Ms. Konno: ABeam Digital ESG Platform is designed based on the concept of integrating non-financial areas such as ESG with accounting/financial areas and utilizing them for sophisticated business management, information disclosure, and engagement with stakeholders. An overview of Proof of Concept (PoC) was to analyze the correlation between non-financial data and financial data on Yanagi CFO's model, taking Eisai's data as sample. We collected nearly 100 ESG KPIs covering a period of around 10 years and analyzed the impact on PBR putting delayed penetration effect into consideration. As a result, many of the KPIs related to human capital, such as personnel cost, the ratio of women in management, percentage of handicapped employees, and percentage of employees who underwent health checks, were found to have positive correlations with PBR. It has also been proved that R&D costs have a positive correlation after more than 10 years.

Yanagi: Yes. As a result of this empirical study that I designed, we have obtained positive evidence for the relationship between ESG and corporate value. For example, personnel expenses, which are investment for people composing the corporate value, will maximize the corporate value with a retardation effect after 5 years as human capital, and similarly, the ratio of female managers will increase PBR with female participation and the next generation follow-up after 7 years. R&D expenses, which are intellectual capital and sources of patient contribution which is the Company's "Purpose" itself, will contribute to corporate value with a 10-year time lag. In terms of average sensitivity, we can interpret the results as "Increase in personnel expenses by 10% will improve PBR by 13.8% in 5 years," "Increase in R&D

expenses by 10% will improve PBR by 8.2% in 10 years," "Increase in female manager ratio by 10% (e.g. 8% to 8.8%) will improve PBR by 2.4% in 7 years," and "Increase in users of childcare system by 10% will improve PBR by 3.3% in 9 years." These results suggest that each of Eisai's ESG factors may create a corporate value of 50 to 300 billion JPY with a 5-10 year delayed penetration effect. In this way, we were able to demonstrate that enriching Eisai's human and intellectual capital will contribute to the well-being of patients in the medium- to long-term and sustainably increase



# **Empirical Study about Eisai's ESG and Corporate Value Sensitivity Analysis**

(Trial calculation of average value at 95% confidence interval)

Increase in personnel expenses by 10% will improve PBR by 13.8% in 5 years

Increase in R&D expenses by 10% will improve PBR by 8.2% in 10 years

Increase in female manager ratio by 10% (e.g. 8% to 8.8%) will improve PBR by 2.4% in 7 years

Increase in users of childcare system by 10% will improve PBR by 3.3% in 9 years



Each KPI of Eisai's ESG will create a corporate value of ¥50 to ¥300 billion level with a 5-10 year delayed penetration effect

Company Introduction

(Unit: Billion yen)

	Fiscal 2018	Fiscal 2019
Revenue	642.8	695.6
Cost of sales	184.5	175.7
Personnel expenses for production Human capital	13.6	14.2
Gross profit	471.9	534.1
R&D expenses	144.8	140.1
R&D expenses Intellectual capital (of which, personnel expenses)	(45.6)	(46.4)
SG&A expenses	228.2	256.3
Personnel expenses for sales Human capital	87.1	88.0
Other income & expenses	0.9	2.0
Conventional operating profit	86.2	125.5
ESG EBIT	331.6 ←	367.8 ←

ESG EBIT = Operating profit + R&D expenses + Personnel expenses

corporate value through the delayed penetration effect. Although I have to admit that there is no absolute answer, I feel that we have gained further credibility through ESG engagement with investors around the world based on the evidence of empirical research conducted as CFO this year.

### ESG value-based B/S

(Unit : Billion yen, Times)

	Fiscal 2018	Fiscal 2019
Conventional accounting value (Book value net assets)	652.0	702.6
ESG value (Market value added)	1,190.6	1,649.4
Corporate value (Market value)	1,842.6	2,352.1
(Ref.) PBR	2.8	3.4

Based on the correlation of this empirical research, I tried to quantify ESG partially by looking at human capital and intellectual capital, and calculated pro forma "ESG P/L and B/S based on corporate value" as a concept.

Let me talk about ESG value-based P/L first. In normal P/L, operating profit, personnel expenses and R&D expenses are deducted from sales revenue as expenses, and profits are compressed. However, if we consider from the results that personnel expenses and R&D expenses will create value in the future ex-post and delayed integrated with Company's "Purpose," those costs are not expenses but "investment in intangible assets." Then we can say that personnel expenses and R&D expenses should be added back based on corporate value creation theory. So, as CFO, I came across the idea of "ESG EBIT" which is pro forma management accounting profit. It is no doubt important that ESG EBIT exceed the cost of capital; I feel that the increase of ESG EBIT as intrinsic profit leads to the creation of corporate value in the mediumto long-term, eliminating discretionary profit adjustment by short-termed intention. Accounting operating profit in fiscal 2019 was 125.5 billion JPY, and ESG EBIT was 367.8 billion JPY if intangible values were added on.

I also have an idea of ESG value-based B/S based on IIRC-PBR Model. My assumption is that the corporate value is the sum of the net assets, which is the accounting value, and the invisible value of ESG, which is also "self-created goodwill," is based on the simple current market value added. The value of Eisai's ESG evaluated by the market at the end of fiscal 2019 was 1,649.4 billion JPY.

The top materiality in the pharmaceutical industry is no doubt a new drug development. I additionally recognize the analysis result as very convincing with the statistical proof of the importance of the penetration effect of human capital on corporate value in addition to intellectual capital such as the number of approved prescription drugs and R&D expenses. We organized the "Eisai's Materiality Matrix" shown on page 4 of this integrated report by prioritizing the most important factors from the viewpoints of "impact on Eisai's

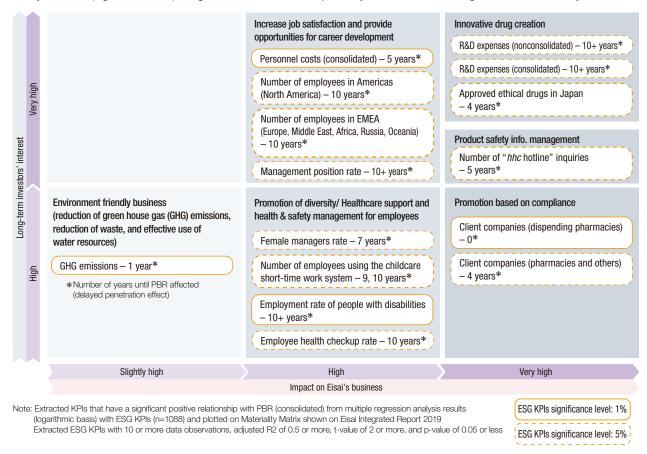
business" and "long-term investors' interests." When we plotted the KPIs that have produced significant results in the analysis this time on the same coordinate axes, we found that they have a high affinity with the "Eisai's Materiality Matrix." The qualitative classifications updated taking investor opinions into account with reference to the Materiality Map of the Sustainability Accounting Standards Board (SASB) and the quantitative evidence obtained in this study generally agree, and that has certain implications. In particular, in addition to investment in human capital, the long-term delayed penetration effect of R&D expenses as the source of growth of pharmaceutical companies on PBR is highly important. It will be an antithesis against short termism, synchronizing with Eisai's corporate philosophy "hhc" (ROESG model). We believe that we will be able to make efforts with stronger support from investors in the longterm and make a sustainable contribution to patients. I think this is one of the mechanisms of accountability in the new era of stakeholder capitalism.

Ms. Konno: We believe that companies should combine quantitative data and digital analysis tools with ESG initiatives to develop a management mechanism

and infrastructure that fuses non-financial and financial aspects. We hope management action will lead to a legitimate evaluation of corporate value if they watch non-financial data regularly, not only when external disclosure is made, and if they make business decisions, engage with stakeholders, and disclose information based on non-financial data.

Yanagi: I agree. In response to the results of this research, we have introduced a tool that analyzes the degree of association between diversity and corporate value in "Cockpit," which is content that constitutes ABeam Digital ESG Platform. We plan to automatically link financial accounting data to "Cockpit" and enhance data analysis that will lead to enhanced ESG activities and productivity in global bases in the future. The number of investors who recognize ESG as a material for investment decisions will keep increasing from now on. By getting a new perspective on the relationship between ESG and corporate value, which has been difficult to quantify so far, we would like to share Eisai's medium- to long-term corporate value with more investors.

Analysis results (logarithmic basis) of significant Eisai's ESG KPIs positively correlated with PBR against Eisai's Materiality Matrix



Source: CFO policy (CHUOKEIZAI-SHA, 2020), cooperation with ABeam Consulting Ltd.

# **Enhancement of Non-Financial Capital for Corporate Strategy**

Practicing ESG Management by Visualizing the Relationship between Non-Financial Capital and Financial Capital

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. We recognize that this is the very essence of ESG management required today. We

believe that it is important to enhance corporate value by enriching human capital by promoting corporate philosophy and diversity, enhancing intellectual capital by investing in R&D, and enhancing social and relationship capital by improving access to medicines.

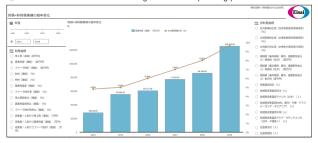
We conducted joint research with ABeam Consulting Ltd. as to the relationship between non-financial capital, financial capital, and improvement of corporate value that many stakeholders have requested proof of. We are also making efforts to realize ESG management while utilizing the digital tool "Cockpit."



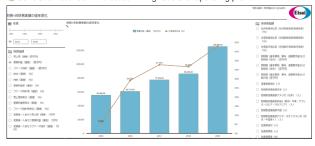
Source: ABeam Consulting Ltd

### **Examining the Relationship between Human Capital and Financial Capital**

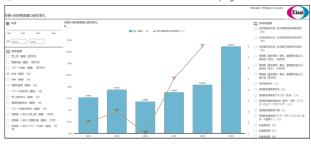
- Correlation analysis between various indicators related to human capital and financial indicators such as revenue, operating profit, Pharma EBIT\*, ROE, and PBR
- \* Operating profit+R&D expenses
- Correlation between Female manager ratio and Operating profit



Correlation between Mid-career hiring ratio and Operating profit

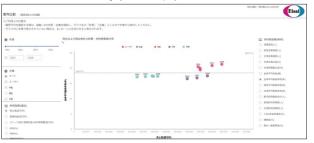


Correlation between Number of male users of childcare leave program and ROE

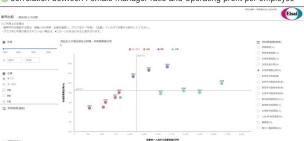


A possibility is indicated that enhancement of diversity through active participation of women and mid-career recruitment, and establishment of a working environment that facilitates male participation in childcare, may lead to sustainable corporate value enhancement.

- 2. Comparison with other companies in the same industry based on disclosed information
- Correlation between Average years of employment and Revenue



Correlation between Female manager ratio and Operating profit per employee



Comparing with other companies in the same industry, we obtained the result that the years of employment can also be an important factor for enhancing the corporate value, indicating a positive impact on our company. At the same time, it was also suggested that a further increase in the ratio of female managers could further enhance corporate value.

If the disclosure of quantitative indicators related to ESG is improved in each company due to the growing interest from stakeholders, it is expected that the accuracy of analysis will be improved and a new perspective will be obtained.

It was indicated that the enhancement of non-financial capital will lead to sustainable enhancement of corporate value in ESG's quantitative analysis efforts. We will continue to analyze the relationship between various types of non-financial capital and financial capital, and place it as a material for formulating strategies that will contribute to patients and sustainably enhance corporate value in the medium- to long-term.

# **SWOT Analysis** (ESG)

Enhancing non-financial capital to meet the long-term growth expectations of stakeholders

# **Eisai's characteristics**





 Rated "A," the highest rating in the CDP Climate Change Report 2019



Reference

P61

Received approval from "Science Based Targets (SBT)
 Initiative" for targets of 30% reduction of greenhouse gas
 (GHG) reduction in May 2019



Reference

P62

 Agreed with Task Force on Climate-related Financial Disclosures (TCFD) in June 2019



Reference

P62-63

Establishment of "Sustainability Advisory Board"

Reference

P61

P65-68



- Acceleration of Access to Medicines
  - Provided treatments in 28 countries at price zero and eliminated lymphatic filariasis (LF) in 17 countries
  - Affordable pricing policies in developing and emerging countries



Explanation about tiered pricing program from MR to a doctor (India)

Deep engagement of global employees

Reference P69-72

Reference

G

The Board of Directors has a majority of outside directors, and is chaired by an outside director

Reference P73-82

 Clear separation of the functions between the monitoring of management and the execution of business

Reference P73-82

W eaknesses

1 Slow business development in Africa

Collaboration with international NGOs

2 Work style reforms are still underway

Improve business efficiency by promoting digital transformation (DX)

3 Insufficient digital talents

Promote the recruitment of talented people and build partnerships with companies in digital business area

# **Surrounding environment**

# pportunities

- 1 Population growth in emerging countries and improving purchasing power
- 2 Increasing disease due to climate change
- 3 Progress of aging population
- 4 Development of manufacturing technology with low environmental impact
- 5 Enriched human resources in line with business globalization

# hreats

- 1 Disruption of production due to climate change
- 2 Increase in natural disasters
- 3 Increase of immigration and terrorism due to shrinking habitable area

# Social and Relationship Capital Initiatives for Achieving Sustainable Development Goals (SDGs)/ESG Indices



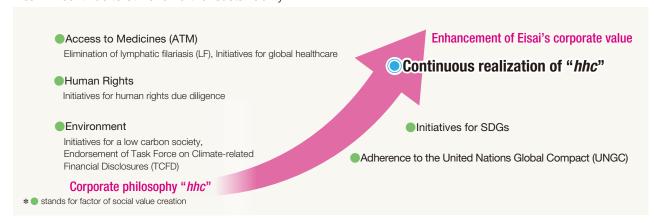




Proactively Work toward the Solution of Global Environment and Social Issues under Well-Established Governance

Eisai aims to enhance corporate value by creating social value. The origin of this idea is "human health care (hhc)," which is Eisai's corporate philosophy. Eisai's corporate activities rely on the idea that economic value is created as a result of social value creation.

We believe that the continuous realization of "hhc" is a mission for all Eisai employees. We are working on this realization, recognizing that it is important to contribute to the unmet medical needs of the world through our business activities and continue to create value for society. As part of these efforts, the CEO, other executives in charge of ESG (Environment, Society, and Governance), and employees gather together and hold a "Sustainability Advisory Board" to discuss sustainability, and receive advice from external advisors once a year. We discussed actions for climate change and human rights in addition to Access to Medicines (ATM) in the Board in fiscal 2019. Eisai will continue to strive for further sustainability.



# Rated "A" in the CDP\*1 Climate Change Report 2019

Eisai conducts business operations seeking coexistence 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.

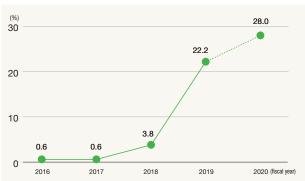
We were rated "A," the highest rating in the CDP

### Expanding use of renewable energy\*2

We are working to switch to renewable energy in production sites and R&D sites that consume the most energy group-wide. In fiscal 2019, we switched to renewable energy with green electricity certificate at the Vizag Plant in India, and at the Suzhou and Benxi Plants in China. In fiscal 2020, we aim to achieve the renewable energy ratio target by switching the energy usage of the headquarters building group and part of the Tsukuba Research Laboratory.

Climate Change Report 2019, based on the evaluation of answers to the CDP Climate Change Questionnaire. In fiscal 2019, 8,400 companies responded worldwide, of which 180 were companies with an "A" rating and 38 were Japanese companies. The A list companies are recognized as taking advanced approaches to climate change issues, and are expected to continue to demonstrate global leadership to respond to environmental risks and contribute the building of a sustainable economy.

### Trend of renewable energy introduction ratio



### Initiatives for a low-carbon society Reduce CO<sub>2</sub> emissions by 30% from fiscal 2016 by fiscal 2030

We are promoting initiatives for the formation of a low carbon society to help solve the problem of climate change. As one of the initiatives, we set the greenhouse gas (GHG) reduction target by fiscal 2030 based on scientific grounds and received the approval from "Science Based Targets initiative (SBTi)"\*<sup>3</sup> in May 2019. We are making efforts to decrease CO<sub>2</sub> emissions by 40,000t globally to realize low carbon society.

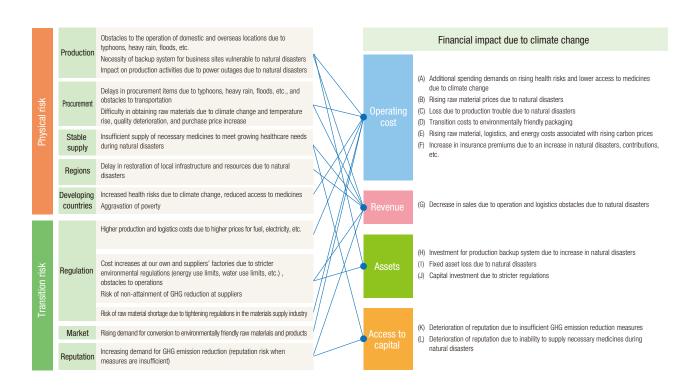
- \*1 CDP (former name: Carbon Disclosure Project) is an NGO founded in London in 2001. It sends inquiries to the world's top companies on behalf of institutional investors with assets under management of 96 trillion USD, analyzes and evaluates the answers, and then represents the results to investors, governments and companies. The information from CDP is considered to be a key factor for ESG investment.
- \*2 Energy that is always present in the natural world, such as sunlight, wind power, and geothermal energy, that "is not exhausted," "is present everywhere," and "does not emit CO<sub>2</sub>."

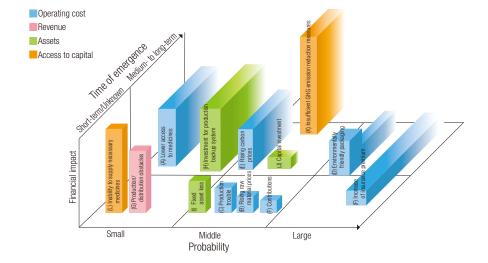
  \*3 SBTi helps companies set reduction targets to keep average global temperature rises below 1.5 degrees Celsius since the Industrial Revolution. CDP, United Nations Global Compact, World
- \*3 SBTi helps companies set reduction targets to keep average global temperature rises below 1.5 degrees Celsius since the Industrial Revolution. CDP, United Nations Global Compact, World Resources Institute (WRI), and World Wildlife Fund (WWF) Japan jointly established SBTi in 2015.

# Improving Resilience to Climate-Related Risks Analysis of Impact of Climate Change Based on TCFD Frameworks

Eisai tried scenario analysis from October 2019 to March 2020 in accordance with the Final Report "Recommendations by the Task Force on Climate Change Disclosure" released by the Financial Stability Board (FSB) Task Force on Climate-related Financial Disclosures (TCFD) in 2017. Setting two scenarios, one with large GHG emissions and a temperature rise of 4

degrees Celsius since the Industrial Revolution in 2100, and one with a strict climate change policy that limits the temperature rise in 2100 to within 1.5 degrees Celsius, we executed financial impact analysis of physical risks and transition risks due to climate change, and did mapping on the three axes of magnitude of financial impact, probability of occurrence, and timing of occurrence.





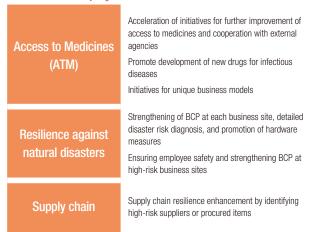
As a result, we detected that the largest physical risk is the decline in access to medicines in developing countries and the need for additional cost spending required for improvement. The second is the loss due to production failures and damage to fixed assets due to natural disasters and the amount of continuous investment in the production backup system. We also evaluated that the decrease in sales by the stagnation of product supply due to the suspension of production and logistics was significant.

In terms of transition risk, we evaluated that the decline in reputation in case GHG reductions were inadequate would have an extremely large impact, and

that the continuous rise in raw material prices due to the continuous rise in carbon prices would also have a large impact. In addition, we evaluated that the replacement cost would be large if we were forced to change the packaging due to increasing environmental demands, including a certain period of time needed for the change as cost.

To manage these risks, in addition to accelerating the initiatives already underway, we establish a medium-to long-term roadmap for setting and achieving higher goals. We also accelerate the implementation and the disclosure of long-term and sustainable initiatives and measures.

### Initiatives for physical risks



#### Initiatives for transition risks

Verify the cost-effectiveness of reduction measures and formulate concrete action plans for the entire value chain globally Science Based Targets (SBT) Clarification of required management resources achievement plan Disclosure of easy-to-understand information on GHG emissions, reduction targets, and results in addition to maintaining CDP evaluation Confirm emission status of major suppliers and Supply chain reduction measures for GHG reduction in the supply chain to achieve SBT Environmentally Early consideration of the priority of switching targets friendly containers Selection of alternative materials and technologies and packaging

### Activities Based on Human Rights Policy

Eisai believes that it is essential for all business activities to be conducted on the basis of respect for human rights, and that this is the foundation of our business activities. The importance of respect for human rights is clearly stated in The Eisai network companies (ENW)

Charter of Business Conduct, which was defined to promote respect for human rights as a company-wide initiative in March 2019. We are promoting activities to fulfill our corporate responsibility for respecting human rights in line with this Charter.

### Human rights due diligence (Initiatives for human rights issues)

Stakeholders	Priority Issues	Actions
Patients and other consumers	Improvement of Access to Medicines (ATM)*1	<ul> <li>Provision of DEC tablets and disease awareness activities to countries with widespread lymphatic filariasis (LF)</li> <li>Participation in Access Accelerated, a global initiative of the International Federation of Pharmaceutical Manufacturers'</li> <li>Associations (IFPMA) to improve access to prevention, diagnosis and treatment of non-communicable diseases in low and middle income countries</li> </ul>
Employees*2	Acceleration of stay/ improve health activities     Support for balancing treatment and work	<ul> <li>Put "Eisai Health Declaration" into effect to promote 100% consultation rate of health checkups, eliminate smoking at all business sites and improve health literacy</li> <li>Established a "Return to Work Support Program" to create an environment in which employees who suffer from illness such as cancer can work while fighting illness. Issued "Guidance for Balancing Treatment and Work"</li> </ul>
Business partners	<ul> <li>Human rights respect and proper working environment in supply chain</li> </ul>	<ul> <li>Formed and started a cross-organizational sustainable procurement project in order to conduct a sustainability assessment that includes consideration of human rights, occupational safety, and the environment of our business partners</li> <li>Adopted system by EcoVadis as suppliers' sustainability evaluation method</li> </ul>

### Internal activities to disseminate respect for human rights

In order for the respect for human rights to become established as a corporate culture, it is necessary for top management to understand it. Eisai held a training lecture for the Board of Directors and Corporate Officers from an outside expert about responsibility for respecting human rights being required by the international community. In addition, we made every effort to make respect for human rights penetrate the Company by holding training for domestic ENW employees (held 29 times, 6,220 people participated), level-specific training for new employees and organizational managers, and e-learning about business and human rights.

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)

**ESG Indices** Altems for improvement in future

Corporate Governance												
	and Compliance Indices	Period	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019
Ratio of outside directors to	directors	At fiscal year end	63.6%	63.6%	63.6%	63.6%	63.6%	63.6%	63.6%	63.6%	63.6%	63.6%
Tiatio of outside directors to	uncolors	At listal year end	7/11	7/11	7/11	7/11	7/11	7/11	7/11	7/11	7/11	7/11
Ratio of female directors to	directors	At fiscal year end	9.1%	9.1%	9.1%	9.1%	9.1%	9.1%	9.1%	9.1%	9.1%	9.1%
Tidilo of formale directors to	uncotors	At hood your ond	1/11	1/11	1/11	1/11	1/11	1/11	1/11	1/11	1/11	1/11
Ratio of female corporate officers to corporate officers		At fiscal year end	0%	0%	0%	4.3%	9.1%	8.0%	14.8%	11.1%	13.8%	10.0%
Thatis of formals corporate o		, , , , , , , , , , , , , , , , , , , ,	0/27	0/18	0/18	1/23	2/22	2/25	4/27	3/27	4/29	3/30
Average age of corporate of	fficers	At fiscal year end	54.8	52.9	52.9	53.0	53.1	53.6	52.9	52.9	53.2	54.2
Number of times	Number of times offered	Annually	70	84	120	65	56	47	62	65	92	172
compliance training	Number of executive training courses	Annually	2	2	2	2	2	2	2	2	3	2
offered	Total participants (approx.)	Annually	6,000	6,000	8,500	5,800	5,000	4,600	5,800	4,800	6,200	7,200
Submission rate of ENW co	mpliance oath	At fiscal year end	_	_	_	_		100.0%	100.0%	100.0%	100.0%	100.0%
Number of times human	Number of times offered	Annually	23	15	28	23	28	30	34	34	34	29
rights training offered	Participants	Annually	16,370	5.096	3,123	2,452	2,405	5,001	5,457	5,477	5,686	6,220
Involvemen	t with Society	Period	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019
Number of regional agreem	•	Annually	112010	-	-	3	20	34	31	43	21	15
			_	_	_							
Cumulative quantity of DEC tal		Annually	-	-	-	0.01	0.28	0.60	0.97	1.35	1.66	1.99
Involvement v	vith Employees	Period	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019
	Total		11,560	10,730	10,495	10,419	10,183	9,877	10,452	10,456	10,683	10,998
	Japan		5,636	5,472	5,320	5,200	4,712	4,523	5,009	4,914	4,888	4,593
Number of employees	Americas (North America)		2,559	1,843	1,815	1,763	1,719	1,290	1,296	1,240	1,261	1,682
by region	EMEA (Europe, Middle East, Africa,	At fiscal year end	1,015	873	831	811	893	913	983	1,022	1,046	1,113
	Russia and Oceania)											
	China		1,407	1,498	1,454	1,559	1,607	1,875	1,909	1,906	2,069	2,087
	Asia and Latin America		943	1,044	1,075	1,086	1,252	1,276	1,255	1,374	1,419	1,523
	Total		4,415	4,305	4,163	4,130	3,583	3,577	3,508	3,436	3,411	3,212
Number of employees of	Male	At Construence of	3,393	3,331	3,228	3,202	2,845	2,838	2,775	2,708	2,679	2,479
Eisai Co., Ltd.		. At fiscal year end	1,022	974	935	928	738	739	733	728	732	733
	Female		23.1%	22.6%	22.5%	22.5%	20.6%	20.7%	20.9%	21.2%	21.5%	22.8%
	Total		1,392	1,376	1,369	1,370	1,282	1,292	1,206	1,228	1,250	1,203
Number of managers	Female		42	43	53	59	61	65	72	86	100	116
	Total	. At fiscal year end	3.0%	3.1%	3.9%	4.3%	4.8%	5.0%	6.0%	7.0%	8.0%	9.6%
Ratio of women in manager		. At hoodi your ond										
natio of wolliell ill illallage	Newly appointed managers		3.6% 2/56	6.5% 3/46	16.3% 8/49	17.4% 8/46	15.4% 6/39	11.6% 5/43	17.6% 9/51	21.3% 13/61	23.9% 17/71	23.1% 15/65
A		At Construence of										
Average age		At fiscal year end	42.3	42.8	43.4	42.5	43.7	44.1	44.8	45.3	45.3	45.0
	Total		18.5	19.0	19.5	20	19.4	19.9	20.4	20.8	21.2	19.9
Average years of employme	nt Male	At fiscal year end	19.3	19.7	20.1	20.7	20.3	20.8	21.4	21.9	22.3	21.3
	Female		16.1	16.8	17.3	17.8	15.9	16.2	16.9	16.9	17.3	15.4
Turnover rate (self-directed	retirement)	Annually	1.5%	2.4%	1.7%	1.8%	1.4%	2.6%	3.1%	2.5%	2.2%	2.1%
Total turnover rate		Annually	2.5%	4.8%	2.8%	14.2%	1.9%	3.0%	3.8%	3.4%	11.4%	7.5%
	Total	Annually	70	76	78	78	90	95	89	97	105	91
Number of users of childca	re 🔺 Male	Annually	1	0	1	1	1	2	0	5	6	8
leave program	Female	Annually	69	76	77	77	89	93	89	92	99	83
Number of users of spousa		Annually	_	-	_	_	-	-	_	-	58	78
· · · · · · · · · · · · · · · · · · ·		Annually	80	79	82	86	73	93	80	75	90	69
Number of users of short worki		,										
Personal development expenses	(thousands of yen)(per employee)	Annually	192	157	162	177	176	198	210	214	221	259
	employees	Annually	2.02%	2.03%	2.37%	2.39%	2.56%	2.53%	2.65%	2.84%	2.88%	2.62%
Percentage of handicapped			40.8%	28.3%	50.0%	36.9%	14.3%	33.3%	38.2%	44.3%	36.3%	39.8%
	ired (Female/Total)	Annually			14/28	31/84	2/14	35/105	21/55	31/70	33/91	74/186
		Annually	42/103	17/60								0.7
Percentage of handicapped Female rate in the annual h	ired (Female/Total)	Annually Annually	98	56	21	76	3	100	39	43	57	97
Female rate in the annual h	Total						3 2	100 66	39 20	43 23	57 32	50
Female rate in the annual h	Total	Annually	98	56	21	76						
Female rate in the annual h  Number of hired new gradu	Total  ates Male  Female	Annually Annually Annually	98 57	56 39	21 12	76 46	2	66	20	23	32	50
Female rate in the annual h  Number of hired new gradu	Total  ates Male  Female	Annually Annually	98 57 41	56 39 17	21 12 9	76 46 30	2 1	66 34	20 19	23 20	32 25	50 47
Female rate in the annual h  Number of hired new gradu  Average monthly overtime I (per non-management emp	Total  ates Male  Female  nours loyee)	Annually Annually Annually	98 57 41 13h	56 39 17 11h	21 12 9 10 h	76 46 30 10h	2 1 12h	66 34 9h	20 19 8h	23 20 9h	32 25 10h	50 47 11h
Female rate in the annual h  Number of hired new gradu  Average monthly overtime I (per non-management emp  Number of work-related ac  Frequency of work-related inju	Total  ates Male  Female  nours loyee)  cidents  Employee	Annually Annually Annually Annually	98 57 41 13h 3m	56 39 17 11h 1m	21 12 9 10 h 27m	76 46 30 10h 46m	2 1 12h 11m	66 34 9h 11m	20 19 8h 34m	23 20 9h 44m	32 25 10h 28m	50 47 11h 10m
Female rate in the annual h  Number of hired new gradu  Average monthly overtime I (per non-management emp  Number of work-related ac  Frequency of work-related injuresuited in more than 4 days of	ates Male Female  nours loyee) cidents ies that Employee work lost	Annually Annually Annually Annually Annually Annually Annually	98 57 41 13h 3m 35 0.44	56 39 17 11h 1m 31 0.27	21 12 9 10 h 27m 42 0.19	76 46 30 10h 46m 16	2 1 12h 11m 9	66 34 9h 11m 16	20 19 8h 34m 23	23 20 9h 44m 19 0.10	32 25 10h 28m 17 0.20	50 47 11h 10m 11 0.15
Female rate in the annual h  Number of hired new gradu  Average monthly overtime I (per non-management emp  Number of work-related ac  Frequency of work-related injuresulted in more than 4 days of	Total  Ates  Male Female  nours loyee)  cidents fies that work lost k)  Contractor	Annually Annually Annually Annually Annually Annually Annually Annually	98 57 41 13h 3m 35 0.44	56 39 17 11h 1m 31 0.27	21 12 9 10 h 27m 42 0.19	76 46 30 10h 46m 16 0.10	2 1 12h 11m 9 0	66 34 9h 11m 16 0	20 19 8h 34m 23 0.10	23 20 9h 44m 19 0.10	32 25 10h 28m 17 0.20	50 47 11h 10m 11 0.15
Female rate in the annual h  Number of hired new gradu  Average monthly overtime	Total  Ates  Male Female  nours loyee)  cidents ries that work lost k)  Contractor  Employee  es	Annually Annually Annually Annually Annually Annually Annually Annually Annually	98 57 41 13h 3m 35 0.44 0	56 39 17 11h 1m 31 0.27 0	21 12 9 10 h 27m 42 0.19 0	76 46 30 10h 46m 16 0.10	2 1 12h 11m 9 0	66 34 9h 11m 16 0	20 19 8h 34m 23 0.10 0	23 20 9h 44m 19 0.10	32 25 10h 28m 17 0.20 0	50 47 11h 10m 11 0.15 0
Female rate in the annual h Number of hired new gradu Average monthly overtime I (per non-management emp Number of work-related ac Frequency of work-related injuresulted in more than 4 days of (per million hours of actual wor Number of work-related fataliti	Total  Adale  Female  Female  Fours  Total  A contractor  A contractor  A contractor  A contractor  Contractor	Annually	98 57 41 13h 3m 35 0.44 0	56 39 17 11h 1m 31 0.27 0	21 12 9 10 h 27m 42 0.19 0	76 46 30 10h 46m 16 0.10 0	2 1 12h 11m 9 0 0	66 34 9h 11m 16 0 0	20 19 8h 34m 23 0.10	23 20 9h 44m 19 0.10 0	32 25 10h 28m 17 0.20 0	50 47 11h 10m 11 0.15 0
Female rate in the annual h  Number of hired new gradu  Average monthly overtime I (per non-management emp  Number of work-related ac  Frequency of work-related injuresulted in more than 4 days of (per million hours of actual work)  Number of work-related fataliti  Number of cases of work-related	Total  Male Female  nours loyee) cidents ries that work lost k)  Employee  Contractor  es  Employee  Contractor  dd  Employee	Annually	98 57 41 13h 3m 35 0.44 0 0	56 39 17 11h 1m 31 0.27 0 0	21 12 9 10 h 27m 42 0.19 0	76 46 30 10h 46m 16 0.10 0	2 1 12h 11m 9 0 0	66 34 9h 11m 16 0 0	20 19 8h 34m 23 0.10 0	23 20 9h 44m 19 0.10 0	32 25 10h 28m 17 0.20 0	50 47 11h 10m 11 0.15 0 0
Female rate in the annual h Number of hired new gradu Average monthly overtime I (per non-management emp Number of work-related ac Frequency of work-related injuresulted in more than 4 days of (per million hours of actual wor Number of work-related fataliti	Total  Male Female  nours loyee) cidents ries that work lost k)  Employee  Contractor  es  Employee  Contractor  ad  Employee  Contractor	Annually	98 57 41 13h 3m 35 0.44 0	56 39 17 11h 1m 31 0.27 0	21 12 9 10 h 27m 42 0.19 0	76 46 30 10h 46m 16 0.10 0	2 1 12h 11m 9 0 0	66 34 9h 11m 16 0 0	20 19 8h 34m 23 0.10 0	23 20 9h 44m 19 0.10 0	32 25 10h 28m 17 0.20 0	50 47 11h 10m 11 0.15 0

<sup>\*1</sup> Based on the number of fulltime Eisai Co., Ltd. employees including employees dispatched to Eisai Network Companies (ENW) \*2 Based on the number of employees disclosed in Annual Securities Report (Eisai Co., Ltd. employees include those dispatched from ENW and exclude the ones to ENW) \*3 Self-directed retirement only, not including mandatory retirement due to age, voluntary retirement, etc. \*4 Covering all types of retirement such as self-directed retirement, mandatory retirement due to age, 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 \*6 Spousal maternity leave program (Commenced in 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

# 28 countries 1.99 billion tablets

Number of countries supplied with lymphatic filariasis treatment DEC tablets and volume supplied (as of March 2020)







"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.

### Contributing the Achievement of SDGs through the Initiatives for ATM

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 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/

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

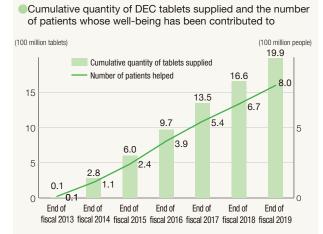
Lymphatic filariasis (LF) is a neglected tropical disease (NTD) transmitted to humans via carrier mosquitoes. It is estimated that approximately 893 million people worldwide, mainly those in developing countries, are exposed to the risk of LF.

The World Health Organization (WHO) conducts mass drug administrations (MDAs) in endemic areas 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 pregualification for DEC tablets and commenced production at its Vizag Plant in India. Since then, Eisai has provided 1.99 billion DEC tablets to 28 endemic countries through the WHO's elimination program (as of March 2020). Furthermore, to support the smooth implementation of the 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 the Faculty of Medicine as well as the Master's Program of Public Health in Gadjah Mada University.



Eisai employees at Vizag Plant socializing with LF patient



\* The number of patients helped 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 WHO's definitions.

# Introduction of Eisai's Efforts to Improve Access to Medicines in the Encyclopedia Britannica's Digital Library "School Edition" for Elementary and Junior High School Children

Encyclopedia Britannica has been known as the world standard in knowledge since 1768. Britannica Japan's "School Edition" is a digital library consisting of abundant multimedia contents based on the encyclopedia. This library supports Japanese elementary and junior high school children's research for study and discussion. Eisai's initiatives to improve access to medicines have been introduced as an example of a company engaged in "support for providing medicines in developing countries" under the discussion theme of "What kind of international cooperation activities should Japan do in particular?" in the "Let's deepen our thinking together!" column. This is the first time that the efforts of a pharmaceutical company have been featured in the "School Edition."

The article highlighted Eisai's mission and long-term initiatives to contribute to patients around the world, in addition to the effects of Eisai's specific activities such as the free provision of DEC tablets for LF, local activities for raising awareness, and support for mass drug administration.



Source: Britannica School Edition, Copyright: Britannica Japan Co., Ltd.

# ■ 10 years of Progress toward LF Elimination

In November 2010, Eisai agreed to provide the WHO with a total of 2.2 billion DEC tablets free of charge by 2020. In 2012, Eisai was the only Japanese company to participate in the "London Declaration," the largest public-private partnership in the field of global health to eliminate 10 NTDs.

Eisai started the development of DEC tablets in 2010 and received prequalification from the WHO in 2013. Since obtaining prequalification, Eisai has been manufacturing and supplying the DEC tablets from its Vizag Plant in India. Eisai announced that it would continue to provide DEC tablets to endemic countries that need DEC until LF is eliminated in these countries, at the 5th Anniversary event of the London Declaration in April 2017. In addition, to commemorate the 5th Anniversary of the London Declaration, efforts by donor companies were officially acknowledged in the form of a Guinness World Record for "Most medication donated in 24 hours." The total number of treatments was 207 million. This was accomplished thanks to the



combined efforts of donor company drug production facilities, including Eisai's Vizag Plant, as well as various NTDs elimination partners.

Eisai has created a short animation to commemorate the 10th anniversary of LF elimination activities in collaboration with global partners. Eisai will continue to collaborate with partners to contribute to LF patients and their families. Eisai will also introduce information about international cooperation activities and the challenges that need to be overcome in an easy to understand way.

Please watch the animation about Eisai's LF elimination activities in 10 years

https://www.eisai.com/sustainability/movie/index.html

### R&D Initiatives for Improving Global Health

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

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

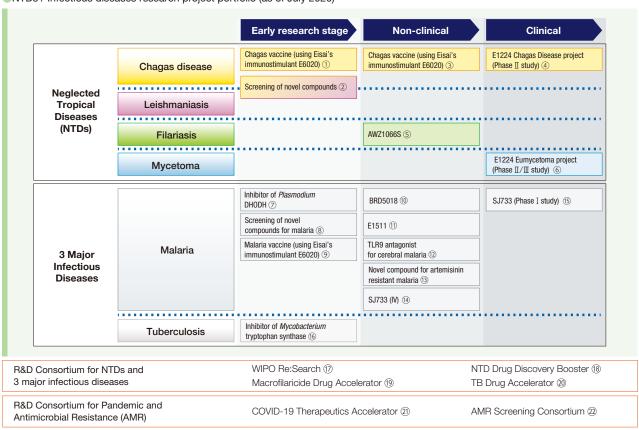
people become incapacitated due to disease and become even poorer, and international efforts are called upon to tackle this significant global health issue. In response, Eisai is currently conducting various projects aimed at developing new treatments for Chagas disease, mycetoma, filariasis, and leishmaniasis 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 diseases. Eisai aims to develop new drugs for fungal mycetoma, a highly neglected disease for which there is no effective treatment.

Currently, Eisai is conducting a Phase II/III study of its in-house developed antifungal agent fosravuconazole (E1224) in partnership with the Drugs for Neglected Diseases *initiative* (DNDi) in Sudan. 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. Eisai also commissioned AAR Japan to conduct patients' medical awareness survey.

Malaria, which infects approximately 230 million people and kills more than 400 thousand people per year, is still a serious infectious disease. In recent years, resistance to existing drugs has been reported, and the development of new drugs has become an urgent task. Eisai is pursuing a Phase I study with the aim of developing a new drug against malaria in partnership with the University of Kentucky in the United States and the Swiss non-profit Medicines for Malaria Venture (MMV).

#### NTDs / Infectious diseases research project portfolio (as of July 2020)



- Main partners of the projects
- ①, ⑨, ⑫ Fundação Oswaldo Cruz (Fiocruz) (Brazil)
- (2), (4), (6), (8) Drugs for Neglected Disease initiative (DNDi) (Switzerland)
- 3 Sabin Vaccine Institute (U.S.)
- (5), (3) Liverpool School of Tropical Medicine (U.K.), University of Liverpool (U.K.)
- (a.s.,) Broad Institute (U.S.), Medicines for Malaria Venture (MMV) (Switzerland)
- (8), (11) Medicines for Malaria Venture (MMV) (Switzerland)

- (4), (5) University of Kentucky (U.S.), Medicines for Malaria Venture (MMV) (Switzerland)
- (U.S.), Colorado State University (U.S.), University of Chicago (U.S.)
- World Intellectual Property Organization (WIPO) (Switzerland), BIO Ventures for Global Health (BVGH) (U.S.)
- (9), (20), (21) Bill & Melinda Gates Foundation (U.S.)
- 20 Global Antibiotic Research and Development Partnership (GARDP) (Switzerland)

Please visit the following link for details on projects  $\blacktriangleright$  https://www.eisai.com/sustainability/atm/research.html

# Pricing Policy that Emphasizes Affordability

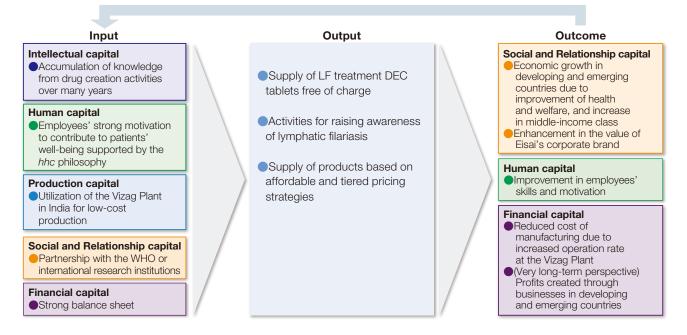
Eisai has formulated various flexible pricing policies that enable patients in developing and emerging countries to purchase Eisai's products at affordable prices.

Regarding Fycompa®, antiepileptic agent, and Aricept®,

a treatment for Alzheimer's disease, we introduced a unique system in India, where in the past many patients have had to pay the full cost of medical expenses out-of-pocket. The treatments are 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. For antiepileptic agent Zonegran®, we have started a patient support program "Livefree" for patients who need financial support for long-term treatment in India in 2017. In this program, we provide various types of support and tools such as treatment

cost subsidies, free examinations, and disease management support for patients. In addition, Eisai has introduced tiered pricing, with the "Patient Access Program" for the anticancer agent Lenvima® 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 conditions. During the four-year period, Lenvima® was supplied to approximately 2,400 patients cumulatively via tiered pricing.

### Enhancement of 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 size of the 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 net present value (NPV) to a positive level through the creation of the outcomes described above.

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

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 places in the ranking from 11th in 2016. Among Eisai's activities, 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 7 consecutive years since 2014. In this Index, the area of Access to Health Care was highlighted as one of Eisai's strengths.

# **Strategy for Talent Innovation**

# 83 points Employees' empathy toward Corporate Mission and Vision exceeded all industries' average



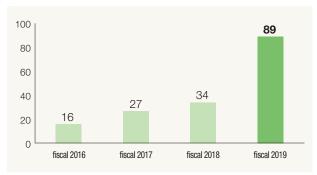
Result from Employee Engagement Survey "wevox" in May 2020

Eisai's strategy is to develop human resources who cultivate confidence and pride through proactive and challenging work, and voluntarily contribute to creation of new value with empathy toward corporate philosophy. We renewed the definition of global human resources who work on the global stage. We would like to form a borderless group of talents who can actively engage with people regardless of time difference or location, build trust, and continue to create innovation while adapting to changes. Toward this end, we will further promote reforms to create a better work environment so that diverse human resources can work actively, and realize a flexible work style.

## ■ Hiring and Training Digital Talent in 'EWAY 2025' FUTURE

Under the current medium-term business plan 'EWAY 2025,' we are promoting drug creation using digital technology which we call "5D (Data Driven Drug Discovery and Development) drug creation," establishment of a dementia ecosystem platform, and enhancement of the link between daily living domain and medical domain using digital technology. In 'EWAY FUTURE,' the latter part of the 10-year business plan 'EWAY 2025,' the digital transformation will be in full-scale operation. We focus on fostering leaders who promote digital transformation, and increasing the digital literacy of employees. In addition, we will promote mid-career recruitment of digital talent such as data scientists and engineers, to prepare for the creation of new business models.

#### The number of mid-career recruitment



# Voice of a Mid-Career Employee with Expertise in the Digital Field

### Q Why did you decide to join Eisai?

**A.** Generating innovation through data science was one of the hottest areas in the IT industry in 2016, when I joined Eisai. At that time, I had responsibility for setting up a data science team. While gaining such experiences, I started to have a strong desire to "help people with the power of data," then I found Eisai. I decided to join the company since I felt empathy toward Eisai's vision of "contribute to patients' well-being with data."



Keishi Akada hDAC 5D Integration Unit

### **Q** What is your impression of the Company since you have joined?

**A.** I felt the strong determination of the company to bring innovation with big data and Al. I had opportunities to experience many challenging projects, including one that was recognized and led to the invaluable experience of receiving an award directly from the CEO.

### **Q** What do you hope to achieve at Eisai?

**A.** The pharmaceutical industry is facing the necessity to achieve discontinuous growth, utilizing data to create new drugs. This situation is the same as what I had expected before joining the company, and I am reaffirming my determination to realize self-innovation, and innovation in drug discovery, as well as innovation at Eisai.

# Fair Opportunities and Rewards

We offer various programs to support employees' professional growth at every age and career stage. Employees can improve their abilities by actively taking advantage of such opportunities to achieve results. The remuneration and appointment system ensures that employees who have made substantial achievements are fairly rewarded regardless of their age. As a result, the number of employees in management who are in their 30s or younger is increasing every year.

# The number of employees in management who are in their 30s or younger



### Progress of Work Style Reform

We position the objectives of work style reform as "realizing work styles that allow employees to maximize their independence, and increase productivity by improving engagement and maximizing output." To do so, we are promoting various initiatives. We are creating an environment which enables employees to adopt work styles that balance both life and work, in which each employee's life events and diverse values are accepted. We also have introduced systems that offer a wider choice of work styles from the perspective of supporting employees to maximize their performance by balancing work and childcare, nursing care, and illness.

For the details of positive work environment, please visit our website at

https://www.eisai.com/sustainability/employee/environment/index.html

On the other hand, we are taking extremely seriously the fact that the Company underwent certification of a work-related accident in February 2019. In response to this, we have been pro-actively making efforts to eliminate long working hours, in line with the organizational or individual situations since March 2019. Currently, average monthly overtime hours per non-

management employee are around 10 hours. We also manage working hours of managers and employees with deemed working hours and discretionary labor by monitoring "health management time," which was introduced with the aim of securing employees' health appropriately. The initiatives to eliminate long overtime work are making steady progress.

As our efforts to comply with the Act on the Arrangement of Related Acts to Promote Work Style Reform, which came into effect in 2019, we have implemented the following measures;

- Revision of the "36 Agreement" to set the number of hours below the maximum time specified by law and unify it across all business establishments
- 2) Establishment of "interval hours"

Furthermore, as a next step in work style reform that goes beyond just reducing overtime work, we are considering a new work style making full use of digital technology. This will include how the ideal office environment should be, based on the lessons learned from the situations caused by COVID-19.

### Promoting Diversity in Human Resources (Acceleration of Diversity)

Eisai believes that diversity is a source of innovation, and has developed a climate that allows employees with a wide range of values to carry out activities regardless of their nationality, gender, age or other characteristics, since the "Eisai Diversity Declaration" was issued in 2012.

Sharing of global values, and facilitation of participation and advancement of female employees in the workplace in Japan, were addressed as issues in promoting diversity.

As regards sharing of global values, we are fostering a sense of unity and human resource development across countries through the "E-GOLD program" led by the CEO, and the "E-ACE program" led by the CTO (Chief Talent Officer), which are selective development programs to develop global leaders across the regions and functions, and the international employee exchange program of "Global Mobility Program" within the Eisai

Group. Moreover, we are running the "Global Challenge Program" in the pharmaceutical business division in Japan, for selected employees who wish to work in an international setting in the future, to develop intercultural skills.

# The number of participants in "Global Challenge Program" (cumulative)



# Voice of an Employee with Foreign Nationality

# Q Why did you decide to join Eisai?

A. I chose to work in the pharmaceutical industry since I wanted to take part in improving access to medicine. Attracted to the company's strong determination to contribute to patients by creating medicine from scratch and proving them free of charge, and the ability to execute projects, I decided to join Eisai.

# Q What is your impression of the Company since you have joined?

A. My workplace has a culture that encourages challenges and allows a new employee to take on important tasks. I learned a great deal while feeling nervous in the first year at Eisai, such as when I was assigned as a contact point for the diethylcarbamazine (DEC) tablets provision program, I held telephone conferences with colleagues in India and the U.K., and gave a presentation at a conference in front of executives including the CEO, and external advisors. I would like to contribute to the elimination of LF, by working closely with the World



Wei Wang Sustainability Department

# What do you hope to achieve at Eisai?

A. I have learned from my current assignments that issues of access to medicine cannot be solved fundamentally just by the provision of medicine. Under the ownership of the governments of each country, maintenance of the environment of local areas and disease awareness are also essential. In the future, I would like to contribute to the development of developing countries through improving sustainable healthcare standards, by formulating strategies that meet the needs of those countries.

Health Organization (WHO) and internal personnel to steadily deliver DEC tablets to those who are in need.

# Voice of an Employee who Applied for Talent Development Programs

# Which talent development program did you use?

A. I used "Job Challenge," which was recruited for internally. As a medical representative (MR), I was taking pride in handling our global products, and started to have a strong interest in overseas business through an opportunity to take part in the "Global Challenge Program" at our Thai subsidiary. This experience led to me moving from being an MR to taking up my current duties as a result of internal transfer.



Kiyoto Miyamori Asia and Latin America Region Department

# Q Has your motivation changed through participation in the program?

A. Through the internal training program at our Thai subsidiary, I saw treatment disparities in Asian countries, and started to have a strong desire to solve this, which prompted me to apply for "Job Challenge." This has led to me having great motivation for my current duties. I feel joy when working to realize "hhc" through engaging in a wide range of duties from business management to business development.

## What do you hope to achieve at Eisai?

A. I am currently in charge of management operations in countries in the Asia and Latin America Region (ALA), mainly South Korea and Malaysia. By expanding new products in the market and realizing affordable pricing, I would like to take initiatives to achieve a further contribution to patients' well-being.

As regards the facilitation of the participation and advancement of female employees in the workplace, we have been continuously working to encourage female employees to take on challenges to become leaders or managers. Such initiatives include



participation in mentoring programs with external mentors and selective leader development program, or holding seminars by inviting various female role models from outside. We are also actively working to support all employees who are participating in childcare, including male employees, by holding seminars regarding "Ikubosses" (managers who willingly let their subordinates participate in childcare regardless of gender), promoting awareness of the childcare leave system among managers, and so on. 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 has steadily risen from 3.1% at the end of March 2012 to 10.4% in April 2020, and we have achieved the target of 10% set in April 2016.

Ratio of female employees in management (as of April 1, each year\*)



\* Calculated based on the number of employees disclosed in the Securities Report

# Employee Engagement

In order to create a work environment in which all employees work proactively, voluntarily challenging themselves with a high level of engagement, we conduct an engagement survey "wevox," a tool developed and operated by Atrae, Inc., as an index to grasp the issues and areas for improvement.

In the results of "wevox" conducted in May 2020, the total engagement score was 74, which was 3 points higher than the all-industry average. In particular, in the survey item of "empathy for corporate mission and

vision," the score was 83, which was 9 points higher than all-industry average, and it was confirmed that the management policies and strategies based on the "hhc" philosophy have achieved high penetration among the employees. By contrast, the score of the survey item of "workload" was 59, which was 5 points lower than the all-industry average, which has driven the Company to try to understand the current situation and to make efforts to accelerate work style reform.

# Initiatives to Support Employees' Health and Life after Retirement

# (1) Health-focused management and company-wide prohibition of smoking

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. The Ministry of Economy, Trade and Industry selected Eisai as an outstanding Health and Productivity Management Organization in the large enterprise category (White 500) because Eisai had been practicing initiatives in line with local health issues and initiatives to improve health for the third consecutive year. In June

2019, we issued the Eisai Health Declaration, and we are aiming to achieve no smoking at all offices by October 2020 as key strategies with improvement of employees' healthcare literacy.



# (2) Enhancement 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\*1 in February 2018 and signed the PRI\*2 in December 2019, and has been executing ESG investment.

\*1 Principles of behavior required of institutional investors to fulfill their responsibility as an

asset management trustee
\*2 Principles for Responsible Investment

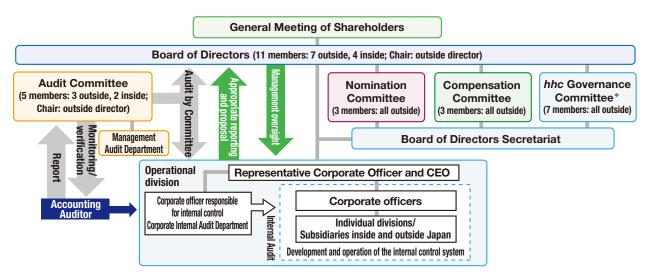
# **Corporate Governance System**

In 2004

Adoption of company with a nomination committee, etc., system

Eisai has Pursued the Best Corporate Governance Practices and has Remained Committed to the Improvement of Governance.

### Corporate Governance System



	Board of Directors	Nomination Committee	Audit Committee	Compensation Committee	Outside Directors Meeting*
Number of meetings held in fiscal 2019	12 times	9 times	13 times	8 times	8 times
Attendance in fiscal 2019	100%	100%	100%	100%	100%

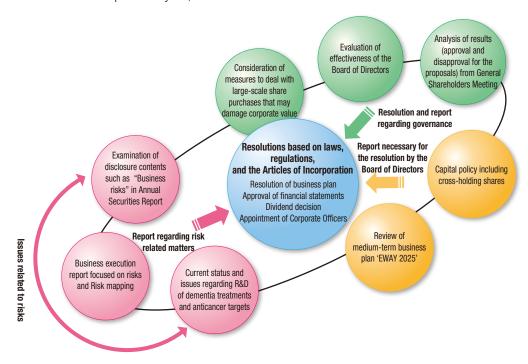
<sup>\*</sup> In fiscal 2020, the Outside Directors Meeting was renamed the "hhc Governance Committee," which is clearly positioned as a committee within the Board of Directors.

# Main Agenda Items of the Board of Directors

The annual agenda of the Board of Directors is decided based on the issues discussed by the *hhc* Governance Committee and the issues extracted by the Board of Directors evaluation in the previous year, such as

matters to be resolved and reports based on laws, regulations, and the Articles of Incorporation.

Multiple risk related issues were discussed in fiscal 2019 as shown below.



# 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, chaired and made up the majority by outside directors specifies rules on internal control for corporate officers

to develop and operate, and devote its attention to management. Corporate officers secure autonomy by developing and operating the internal controls within the scope of their responsibilities and increase the speed and flexibility of business execution. CEO is the only individual to concurrently serve as a corporate officer and a director.

# Orporate Governance System Centered on Outside Directors

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 *hhc* Governance Committee for

broad discussion of corporate governance, including engagement with stakeholders and 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.

### hhc Governance Committee

In fiscal 2020, the Outside Directors Meeting was renamed the "hhc Governance Committee" and charged with the task of taking steps to further enhance the Company's corporate governance with a clear positioning as a committee organization under the Board of Directors. The Composition and Roles of the hhc Governance Committee are as follows.

- 1 The hhc Governance Committee consists of all of the outside directors.
- 2 The *hhc* Governance Committee works to improve the management oversight function of the Board of Directors by proactively engaging in dialogues with stakeholders and using the findings from those dialogues to enrich discussions by the Board of Directors.
- 3 The *hhc* Governance Committee shares information and provides advice, etc., regarding the Representative Corporate Officer and CEO's proposal for plans to nurture candidates to fill the role of Representative Corporate Officer and CEO in the future. The *hhc* Governance Committee rationally ensures the fairness of the CEO selection process on the Board of Directors by involving outside directors in the process.
- 4 The *hhc* Governance Committee evaluates the effectiveness of the management oversight function of the Board of Directors on an annual basis. If any issues emerge in the operations of the Board of Directors, etc., the *hhc* Governance Committee proposes relevant improvements to the Board of Directors.
- 5 The *hhc* Governance Committee carries out broad discussions on the Company's corporate governance and business matters and works to make continuing improvements to the Company's corporate governance.
- 6 The *hhc* Governance Committee reports to the Board of Directors or notifies the corporate officers as necessary about the items it has discussed.

The activities of Outside Directors Meeting in fiscal 2019 are as follows.

# Dialogues with Stakeholders

- The Outside Directors Meeting held an opinion exchange between outside directors and approximately 50 institutional investors, etc. (October 2019).
- Outside directors visited individual institutional investors (April, May, November, and December 2019).
- Outside directors visited KAN Research Institute and the sales office in Kobe to share information and hold discussions with young and middle-ranking employees (February 2020).

# ② CEO Succession

• The Outside Directors Meeting shared information on and discussed the succession plan (September 2019 and March 2020).

# Sevaluation of the Effectiveness of the Board of Directors

• The Outside Directors Meeting conducted a corporate governance evaluation (a Self-review of the Corporate Governance Guidelines and the Internal Control Regulations, as well as a Board of Directors evaluation by individual directors) (April 2020).

# Others

- The Outside Directors Meeting discussed Board of Directors agenda items (July 2019).
- The Outside Directors Meeting shared information on various issues related to the selection of directors by the Nomination Committee (July 2019).
- The Outside Directors Meeting discussed items to be resolved and reported at meetings of the Board of Directors (December 2019).
- The Outside Directors Meeting discussed ways of enhancing corporate governance (December 2019 to April 2020).

# Dialogue with Outside Directors and Investors

Eisai has conducted meetings between institutional investors and outside directors in Japan and overseas. As it did last fiscal year, the Company held an opinion exchange between outside directors and over 50 institutional investors, etc., in fiscal 2019. Based on the requests from institutional investors in the questionnaire following last year's exchange, this year's gathering included an approximately 2-hour Q-and-A session as well as a discussion.

Outside directors also made a total of 12 visits to 9 different companies to share information and exchange opinions with institutional investors. Open, frank exchanges of opinion on the Company's corporate governance-related efforts and the status of outside director activities took place in small-group dialogues, bringing a variety of perspectives together in fruitful

discussion. The Board of Directors uses the findings and knowledge that come out of these dialogues to enhance their discussions and provide better management oversight.



# Summary of the Q-and-A Session "Opinion Exchange between Institutional Investors, etc., and Outside Directors"

Q: What kinds of discussions are taking place about corporate governance?

A: << Member of the Audit Committee>> We are discussing the importance of fortifying risk management. We will make improvements for corporate officers to report to the Board of Directors with a greater focus on risk.

A: <<Chair of the Nomination Committee>>> We are looking at the Board's composition and discussing the diversity and numbers of the outside directors on the Board. For example, if we need outside directors with experience at IT companies or not, what we want to gain from differences in nationality in the Board, and so on.

Q: What kinds of discussions are taking place about the CEO succession plan?

A: <<Chair of the Board of Directors>> We believe that keeping outside directors involved in discussions on the succession plan will help make the process of selecting the next CEO a fair one, by the Company giving us numerous opportunities to connect with candidates and letting us make comments on their performance and personality.

A: << Chair of the Audit Committee>> Our current CEO has led the Company with strong leadership for more than 30 years. For the Company to continue improving its corporate value, it will need to go more than simply selecting the right next CEO, to building the optimal top-management framework, building a team of corporate officers with the right composition and with appropriate duties.

A: <<Chair of the Nomination Committee>> The ultimate responsibility for reaching a resolution on the selection of the CEO rests with the Board of Directors, as the CEO is a corporate officer. All of the Company's directors share information on the succession plan twice a year, and the Company's outside directors meet with the CEO for succession-related discussions at the Outside Directors Meeting.

# Succession Plan

# 1 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
  - Information on the succession plan proposed by the CEO is shared 2 times a year at the Outside Directors Meeting.

- 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
  - 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.
  - The CEO evaluates candidates on the criteria that have been set, and presents evaluation results in the succession plan.
  - 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.

# Execution of Board of Directors Evaluation

The effectiveness of the Board of Directors' management oversight function is evaluated each year at the *hhc* Governance Committee. 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. The Board of Directors evaluation is based on evaluations by individual directors. In fiscal 2019, the Company introduced a framework that enables each director to evaluate and record the discussions,

operations, etc., at every meeting of the Board of Directors. Aiming to "guarantee the suitability of the Board of Directors evaluation," a mechanism to improve and guarantee the Board of Directors evaluation through an outside organization was adopted in fiscal 2017. This examination, evaluation, improvement proposal, and inspection, etc., of evaluation results by an outside organization take place once every 3 years and fiscal 2020 corresponds to the third year of the cycle.

# Fiscal 2019 Corporate Governance Evaluation Results

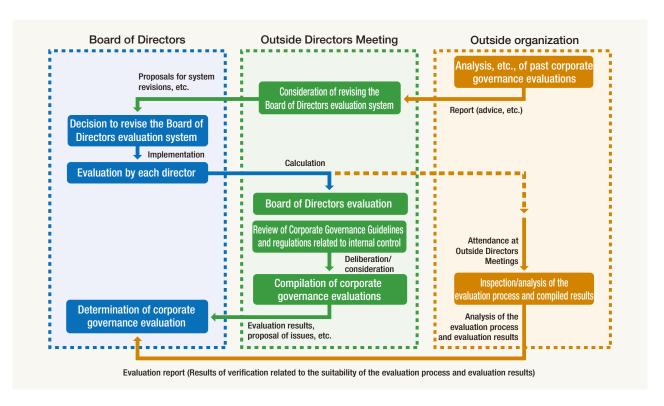
With regard to the Corporate Governance Guidelines and Internal Control Regulations, no evidence was found of any operation, etc., that deviates from the rules. It was confirmed that the directors and corporate

officers, etc., are executing their duties appropriately to improve corporate governance.

Some of the major issues identified in fiscal 2019 evaluation are listed below.

- In order to fulfill its responsibility for providing a management oversight function, one of its key roles, the Board of Directors will work to understand medium- to long-term management issues, monitor changes in the business environment surrounding Company management, select appropriate agenda items such as ways of going beyond defensive risk management through more aggressive approaches, and enhance the efficiency of meeting operations. As part of the effort to provide the information that outside directors need to exercise their oversight function, opportunities for outside directors and corporate officers to engage in closer communication and deepen their mutual understanding will be provided.
- The Outside Directors Meeting's wide-ranging roles, functions, and operations pertaining to corporate governance, such as (1) dialoguing with institutional investors, (2) discussing the CEO succession plan, and (3) performing Board of Directors evaluations, will be organized and optimized, and approaches to making further enhancements to the Company's corporate governance will be discussed.
- The Board of Directors will oversee response to the disclosed "Risk Factors." To facilitate that oversight process, the Board of Directors will receive sufficient reports on efforts in and progress on digital transformation—a key element in achieving the 'EWAY 2025' goals—this fiscal year.

For the further information regarding the corporate governance review, please refer to pages 52-58 of the Notice of Convocation of the 108th Ordinary General Meeting of Shareholders: https://www.eisai.com/ir/stock/meeting/pdf/einv108\_all.pdf



### Activities of Nomination Committee

The Company had previously set relatively short terms for its outside directors, seeing the element of independence as the most crucial factor for selection. In the interest of ensuring the continuity of discussions and operations on the Board of Directors and committees, however, both the Nomination Committee and the Outside Directors Meeting discussed extending the terms for the Company's outside directors. The discussions prompted the Company to make partial revisions to its

basic approach to outside director terms and amend its internal regulations to enable flexible responses.

Aiming to better the Company's corporate governance structure, the Nomination Committee will continue to perform medium- to long-term simulations of terms for outside directors, discuss the composition and diversity of the Board of Directors, etc., and select director candidates with the right qualities for enhancing the Board's functions.

### Skill matrix of outside directors in fiscal 2020

Name	Corporate management experience	Finance & accounting expertise	Legal expertise	Academic background (discipline)	Gender & nationality
Yasuhiko Katoh	0				
Daiken Tsunoda			0		
Bruce Aronson			0	(Corporate Governance)	(Foreign Nationality)
Shuzo Kaihori	0				
Ryuichi Murata	0				
Hideyo Uchiyama	0	0			
Yumiko Miwa				(ESG, Corporate Governance)	(Female)

Attributes of the outside directors who were/are in office since 2000



Of the 36 outside directors, 4 are women and 6 are foreigners.

# Activities of Audit Committee

The Audit Committee conducts activities in accordance with an audit plan formulated each fiscal year. This fiscal year's audit plan included audits of the execution of duties by directors and corporate officers, audits of business reports and annexed detailed statements, and audits of financial statements, etc., as items stipulated by laws and regulations. In terms of theme-based audits, which we specify every fiscal year, we focused on (1) auditing internal control related to information

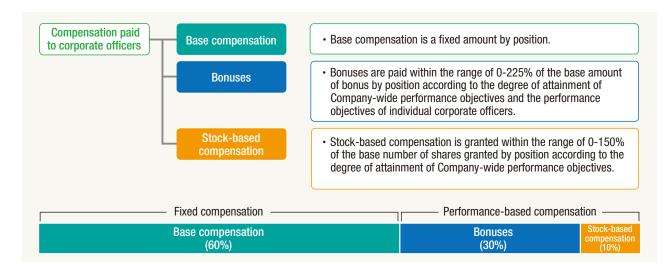
disclosure, (2) auditing internal control in the promotional activities of overseas subsidiaries, and (3) auditing the Business Continuity Plan (BCP) for the pharmaceutical supply chain.

Our efforts for internal audit activities were highly evaluated, and we received the 33rd "IIA Japan Chairman's Award" of the Institute of Internal Auditors in September 2019.

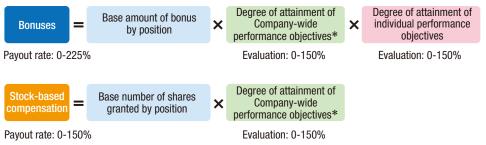
# Activities of Compensation Committee

The Compensation Committee has the authority to determine the content of compensation, etc. of individual directors and corporate officers of the Company. It determines (1) policy concerning decisions on the content of compensation of individual directors and corporate officers, (2) the content of compensation of individual directors and corporate officers, and (3) the evaluation of the level of attainment of Company-wide

performance targets and the individual performance targets of each corporate officer for the performance-based compensation of corporate officers. The Committee confirmed that, in fiscal 2020, it would continue to discuss certain issues that have come to light in relation to the compensation system for corporate officers.



### Process of determining performance-based compensation



\*Consolidated revenue, consolidated operating profit, consolidated profit for the year (attributable to the parent company), and consolidated ROE

# ■ The Independent Committee of Outside Directors and the "Policy for Protection of the Company's Corporate Value and Common Interests of Shareholders"

The Independent Committee of Outside Directors considers the maintenance, revision, and abolition of the "Policy for Protection of the Company's Corporate Value and Common Interests of Shareholders" (hereinafter "the Policy") after gathering and discussing the necessary information, such as examples of activism and corporate acquisition as well as the latest information and trends pertaining to takeover defense measures every year. In the Company's case, from the perspective of the management team, the mechanism of the Policy makes it harder to issue stock acquisition rights (imposition of so-called takeover defense measures) because Independent Committee of Outside Directors decides to issue or not issue stock

acquisition rights prior to the board of directors with this Policy. The results of the exercise of voting rights on proposals for the selection of directors at the Ordinary General Meeting of Shareholders indicated that in fiscal 2019, as has been the case in past years, some shareholders opposed the idea of continuing the Policy without putting it to a vote at the General Meeting of Shareholders. However, the results also showed that some of the shareholders who had voted in opposition the previous year were now in favor of the idea—the efforts and approaches of the Independent Committee of Outside Directors, evidently, have gotten through to the shareholders to some extent.

For the reason that the Independent Committee of Outside Directors has judged continuation of the Policy to be appropriate, please refer to pages 68-69 of the Notice of Convocation of the 108th Ordinary General Meeting of Shareholders: hhttps://www.eisai.com/ir/stock/meeting/pdf/einv108\_all.pdf

# Interview with an Outside Director (Chair of the Board of Directors)



### Yasuhiko Katoh

Position: Chair of the Board of Directors, Chair of the *hhc* Governance Committee, Member of the Independent Committee of Outside Directors Concurrent positions:

Special Advisor, Mitsui E&S Holdings Co., Ltd.

# Q Please tell us about the outcomes of the Board of Directors in fiscal 2019 and the recognition of challenges in relation to fiscal 2020.

**A.** The important roles of the Board of Directors in a company with a nomination committee, etc. are to inspect the appropriateness and efficiency of decision-making processes by corporate officers and to assess business performance and ensure management adequacy and transparency. In the Board of Directors, directors with diverse backgrounds make remarks based on their experience and expertise, and very active discussions take place. I make various efforts to encourage directors to engage in active discussion.

I can summarize the activities and outcomes of the Board of Directors in fiscal 2019 as "strived to exert the management supervision function, which is an important role of the Board of Directors, by picking up medium- to long-term management issues and risks and adding them to the agenda." The agenda of the Board of Directors was also set with a focus on themes related to risks. Those were, for example, based on the reports on the current status and issues on the development of dementia treatments and anticancer agents including the competitive environment, and reports and discussions on disclosure items such as

"business risks" in the securities report. The Board of Directors actively requests executive officers to report on risks, and the quarterly business execution reports submitted by the executive officers are also concisely compiled focusing on risks and countermeasures. This has helped with making risks visible and establishing habits of sound risk management.

As activities of outside directors following fiscal 2018, we engaged in an exchange of opinions with over 50 institutional investors and made individual visits in fiscal 2019. We also engaged with employees by visiting research institutes, production sites, and the front line of marketing.

The challenges for the Board of Directors in relation to fiscal 2020 include supervision of digital transformation (DX), an essential initiative to achieve 'EWAY 2025,' understanding and responding to environmental changes surrounding management including measures after COVID-19, and promotion of proactive risk management. The outside directors will continue to exercise leadership to enhance corporate value and meet the expectations of all stakeholders.

# Q Please tell us how the "hhc Governance Committee" was established, about its role, and about future initiatives.

**A.** Eisai has been evaluated as being a front-runner in corporate governance. I think one of our key features is that we have the "Outside Directors Meeting." The Meeting started as an opportunity to foster mutual understanding among outside directors in 2008. Since then, the Meeting has played an important role in continuous enhancement of our corporate governance. Examples include information sharing and discussion regarding the CEO succession plan, summarizing corporate governance evaluation results, and engagement with stakeholders such as patients,

investors, and employees.

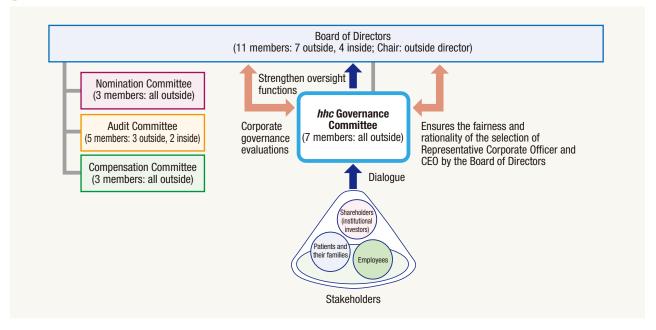
At the same time, since the establishment of "Japan's Corporate Governance Code" by Tokyo Stock Exchange, Inc. (TSE), companies in Japan are working to enhance their corporate governance with a sense of speed. Seeingt that, outside directors discussed how we can maintain a solid advantage in this field and continuously meet the expectations of our stakeholders. Then we decided to rename the "Outside Directors Meeting" as "hhc Governance Committee" and clearly positioned it as a committee within the Board of

Directors as a component of the governance system. We aim to further enhance the governance framework and operation.

The "hhc Governance Committee" works to enhance corporate value while listening to the voices of

shareholders, capturing discussions regarding corporate governance that is globally deployed in a prompt manner, and carrying out broad discussions on the Company's corporate governance and business.

### The framework of the hhc Governance Committee



# Q What do you think the role of Eisai will be in the "New Normal" after COVID-19?

**A.** Eisai's corporate philosophy is to give first thought to patients and their families. So the most important thing is that, even under COVID-19, we keep patients who need our drugs free from inconvenience and anxieties. What is important for us is to adequately manufacture and the supply of safe, high-quality drugs, and not to disrupt the supply route nor stop the production sites. Also, it is very important to minimize delays in R&D and clinical trials, and not to delay processes directed towards new drug approvals. In addition, we ought to contribute to the development of drugs and vaccines for COVID-19.

Eisai not only delivers treatments for illness, but is also actively engaged in prevention and prediction of diseases. One example is the establishment of the "Dementia Ecosystem." With this, we provide tools to understand and habituate appropriate actions to

prevent dementia, and information on what to do to prevent dementia and how to deal with it when diagnosed. We aim to introduce this platform and establish an ecosystem based on collaboration with partners such as pharmaceutical companies, administrative offices, medical institutions, care facilities, companies developing diagnostics, IT companies, private insurance agencies, and so on.

To realize these goals, it is necessary to utilize Al and IoT. Eisai is actively promoting DX. COVID-19 has elucidated the necessity of changes in society and organizations, such as work style reform. We recognized the necessity of implementing DX companywide with a sense of speed not only in the field of dementia but also in all the departments in Eisai. The Board of Directors will closely monitor the ongoing status of activities.

# **Interview with an Outside Director (New Director)**



# Yumiko Miwa

Position: Member of the Audit Committee, Member of the *hhc* Governance Committee, Member of the Independent Committee of Outside Directors Concurrent positions:

Professor, School of Commerce, Meiji University Part-time Lecturer, College of Commerce, Nihon University Member, Fund Management Committee, National Federation of Mutual Aid Associations for Municipal Personnel

# Q Please tell us how you come to serve as an outside director of Eisai.

**A.** When a research society of corporate governance was launched in the Meiji Institute for Global Affairs (MIGA) in 2012, I was serving as a co-chairperson (the other chair was Mr. Sumitaka Fujita, Chairman of Japan Association for Chief Financial Officers). Board members of Japanese companies, lawyers, CPAs, and researchers participated in the research society to seek the ideal way of Japanese corporate governance. There I met Mr. Bruce Aronson, who is currently an outside

director of Eisai. We mainly discussed how Japanese corporate governance should be, what was the ideal way of separating supervision and execution while Japanese companies were having difficulty while transitioning to become companies with a nominating committee, etc., and how Japanese corporate governance was viewed by institutional investors. I assume that Mr. Aronson recommended me for the position of Eisai's outside director.

# Q Please tell us about your aspirations as a new outside director.

**A.** In 1996, I took up a post to teach "Institutional investors theory," at Meiji University, which was a rare subject in Japanese universities at that time. Foreign institutional investors came to be qualified to become asset managers of Japanese pension funds in the mid 1990s. This course was arranged by the Faculty of Commerce of Meiji University, foreseeing the coming era of widespread activity by institutional investors in Japan.

I have conducted research about the influence of institutional investors on corporate governance in the U.S. since 1991 when I was enrolled in a master's program at graduate school. Nearly 30 years have passed since then. We have seen big changes in corporate governance in Japan, such as exercise of voting rights by institutional investors, and initiatives for engagement. My recent research focus is on ESG investment by institutional investors.

The impression of Eisai I had from outside was that it had a strong leadership structure and good corporate governance. The Company recently conducted direct engagement between outside directors and institutional investors, and that made me recognize Eisai as a top runner. Dialogue with stakeholders and engagement will

become even more important in the future. So I think that the positioning of Board of Directors as a creator of Social Value that goes beyond the role of a supervisor is very important. I consider my role to be an outside director who contributes to the creation of the Company's Social Value. I would like to contribute to management supervision and Social Value creation from the perspective of a woman and a researcher, and also contribute to dialogue with institutional investors, individual investors, and ESG.

The corporate philosophy of "human health care (hhc)" is a way of knowledge creation through Socialization with patients, their families, and our employees. The creation of opportunities for Socialization between self and others can be applied to engagement with various stakeholders. I understand engagement with stakeholders as an interaction to further enhance corporate value and would like to contribute to its activation.

As a female outside director, I have a strong interest in the realization of diversity. The society in the 1950s when the United States had overwhelming economic power was really homogeneous in the sense that only white males were allowed to participate. In that society,

where the maximum income tax rate was as high as 90%, a uniform image of white, middle-income people was dominant. We can easily understand the homogeneousness by looking at members of Boards of Directors at the time. The background behind this was that there was no full-fledged price competition for American companies.

Then American manufacturing industry dropped out of its No. 1 position in less than 20 years, since price competition was in full swing, and Japan came to take over this position. Ironically, in a period of low economic growth, the labor force liquidation and "work style reform" has advanced, promoting the advancement of women into society. Under such circumstances, diversity has been receiving attention also in Japan, some time after it began to be focused on in the Western countries. I think this is because knowledge creation based on diverse values is needed when

economic growth is slow. We have achieved economic growth at the expense of the global environment and safe living. Issues that were not related to economic growth have been postponed or abandoned. We are now facing severe realities that this attitude has brought upon us. I think this lies behind the increasing importance of ESG.

We need value creation unmeasurable on the criteria of economic growth, which is measured with money. Value is created through engaging with people with diverse values. Institutional investors require companies to recognize long-term risks, and companies have to be prepared for ESG related issues such as disclosure in integrated reports and specification of ESG materiality. I think we also need to understand what underlies things, what you might call a knowledge creation from diverse values.

# Q What do you think the role of Eisai will be in the "New Normal" after COVID-19?

**A.** In connection with the values created by diversity that I mentioned earlier, we have recognized problems that growth in money cannot solve under COVID-19. Reflecting this awareness, overseas institutional investors and NGOs are showing greater concern on issues of climate change, business, and human rights than ever before.

Stocks of listed companies are traded in the secondary market, so anonymous individuals will become shareholders. Since there is an individual who is the ultimate source of funds behind institutional investors, someone who is anonymous is a shareholder in this sense, too. So we can say that companies are

public entities from the point of view that the shares are held by the general public.

As a public entity, Eisai needs to focus more on ESG issues than ever. Due to the spread of COVID-19, employment is being discussed worldwide. As we are a global company, I think we need to consider employment and strengthening initiatives of employees' engagement globally. As a pharmaceutical company, we have announced that we are participating in a global cooperation system for the development of a vaccine for COVID-19. I believe Eisai will play an extremely large role in this global movement.

# **Personal history**

April 1988	Joined Nomura Securities Co., Ltd.
April 1996	Full-time Assistant, School of Commerce, Meiji University
April 1997	Full-time Lecturer, School of Commerce, Meiji University
April 2000	Assistant Professor, School of Commerce, Meiji University
April 2002	Member, Fund Management Committee, Pension Fund Association for Local Government Officials
October 2005	Professor, School of Commerce, Meiji University (current)
April 2006	Visiting Professor, Stephen M. Ross School of Business, University of Michigan
April 2013	Part-time Lecturer, College of Economics, Rikkyo University
April 2020	Part-time Lecturer, College of Commerce, Nihon University (current)
April 2020	Member, Fund Management Committee, National Federation of Mutual Aid Associations for Municipal
	Personnel (current)

# Compliance, Risk Management, and Internal Audit

# 17 Languages

Number of languages into which the Compliance Handbook has been translated

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.

Regarding internal audit, the corporate officer responsible for internal audit oversees the Internal Audit Department and promote audits from a position independent of the business execution division.

# 1. Compliance Promotion

Eisai promotes its compliance program, which 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. Based on a lesson from an international cartel for synthetic bulk vitamin E products, Eisai started to promote full-fledged compliance in fiscal 2000. These compliance promotion programs 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 a Compliance Handbook, which outlines the Eisai Network Companies (ENW) Charter of Business Conduct and the Code of Conduct, to cultivate compliance awareness. For all officers and employees in all Eisai network companies, this handbook is available in 17 languages.

In addition, various training programs are continuously held utilizing different formats, such as a compliance workshop for Corporate Officers, e-learning, and workshops utilizing special training materials in each department.



The Compliance Handbook in 17 languages

A campaign was held by members of the

Compliance Risk Management department to improve the credibility of Compliance Counter and enhance compliance awareness among employees through visiting 14 major sites and ENW in Japan in December 2019.

# 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 at each ENW company and it is available for ENW employees to directly contact the Compliances Counter at Eisai Headquarters. The Compliance Counter also provides resources, such as contact with independent lawyers and outside contact operated by the ombudsperson who handles issues at workplaces or works to improve the environment for compliance promotion. 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 2019, more than 500 inquiries were received at the Compliance Counter at Eisai Headquarters.

# Certified as a Consumer Affairs Agency's Whistleblowing Compliance Management System



The Eisai Headquarters Compliance Counter has been certified as a "Whistleblowing Compliance Management System" set up by the Consumer Affairs Agency in April 2020.

This certification is the self-evaluating system of the whistleblowing system in accordance with the Consumer Affairs Agency "Guidelines for Private Business Operators regarding the maintenance and operation of the whistle-blowing system based on the Whistleblower Protection Act." The company self-evaluates

and submits the results to the Consumer Affairs Agency and, after its deliberation, obtains the certification. Compliance is becoming more and more important, and the importance of the whistleblowing system is increasing. This registration gives all ENW executives and employees increased confidence in the whistleblowing system (the Compliance Counter), and they are working to promote corporate activities with an emphasis on compliance.

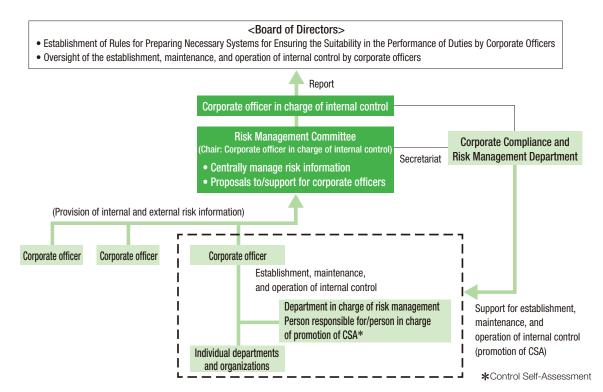
# 2. Risk Management Promotion

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 and evaluate the risks in their duties and establish, develop, and operate the internal control systems. Regarding 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 risks or keep risks within acceptable levels, Eisai has developed the "ENW Internal Control Policy" and is carrying out various initiatives including establishment, development, and operation of internal control systems throughout ENW.

# 1 Promoting Risk Management System and Risk Response

At the Risk Management Committee, critical risks are managed in a united way by the Corporate Officer responsible for internal control, acting as chair. Also, Eisai quickly detects its own potential similar risks through continuous monitoring of external corporate scandals and responds to risks promptly by risk avoidance and elicitation prevention activity.

### Eisai's Risk Management System



# OSA (Control Self-Assessment)

One of the tools used by Eisai for risk management is CSA. In CSA activity, all department managers in ENW identify and evaluate risks in their own structure every year, and work to address the identified risks.

In addition, Eisai enhances the effectiveness of risk management by developing an understanding of critical risks and following up of risk response status by corporate officers.

### 3. Internal Audit Activities Based on International Standards

Eisai implements internal audits focusing on the themes selected by the internal audit departments in each region on a risk basis. The results of internal audits assessed independently and objectively are reported to the Board of Directors and to the Audit Committee.

To assure high-quality audits that conform to global standards, the Corporate Internal Audit Department undergoes an assessment 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.).

# "IIA Japan Chairman's Award" of the Institute of Internal Auditors was granted

Eisai received the 33rd "IIA Japan Chairman's Award" of the Institute of Internal Auditors for its efforts related to internal audit activities in September 2019.

The following initiatives were highly evaluated: emphasis on contribution for achieving the corporate objectives, implementation of audit with full consideration of business operation risks and socially focused matters and selecting the theme for audit, emphasis on cause analysis of problems, and implementation of regular internal and external evaluations for continuous audit quality improvement.

# 4. Risk Factors

Risks and uncertainties that could cause significant fluctuations in the results of the Group or have a material effect on investment decisions are outlined below. However, these do not cover all of the risks and uncertainties faced by the Group, and it is possible that they will be affected in the future by other factors that cannot be foreseen, or are not deemed to be important, at this point in time.

The Group's Executive Board and other decision-making bodies regularly discuss the risks and uncertainties faced by the Group, and consider measures to turn these risks and uncertainties into opportunities, or to mitigate them. The results of such consideration are reported to the Board of Directors, which in turn discusses them. Accordingly, the risks and uncertainties indicated below do not only include the input from the Executive Board, but also reflect the discussions of the Board of Directors.

# (1) Corporate Philosophy

# Management based on the Corporate Philosophy

Insufficient permeation of the Corporate Philosophy throughout the Group, stagnation of the implementation of management aimed at implementing the Philosophy, and other factors that hinder the full increase of benefit to patients and their families may have significant impact

# (3) Pharmaceutical Research and Development, Production, and Sales Activities

New drug development
Product quality and stable supply
Litigation and other proceedings
Trend to contain medical costs

Side effects
Intellectual property
Data reliability

# (2) Business Strategy

**Establishment of AD franchise** 

Maximization of the value of Lenvima®

Partnership model

**Digital transformation** 

Any delays in efforts to execute our important business strategies or factors that hinder the achievement

# (4) Others

Succession Information security
COVID-19 Climate change
Impairment of goodwill and intangible assets

### (1) Corporate Philosophy

### Management based on the Corporate Philosophy

The Company has adopted the Corporate Philosophy of giving first thought to patients and their families, and to increasing the benefits health care provides. These aims are stipulated in our Articles of Incorporation as well and have been shared with stakeholders. Collectively, they constitute our "Purpose." We believe that the increased benefit to patients and their families resulting from achievement of these aims will lead to improved performance of the Group and increased corporate value in the long term. The strategic intent of the medium-term business plan 'EWAY 2025' is also dependent on the Corporate Philosophy of "hhc," and the powerful motivation generated by understanding the true needs of patients is the source of the Group's innovation. In addition, we view the importance of promoting the information management/provision, etc., needed to promote further the research and development of new drugs, produce and sell high-quality products, and achieve safe use of pharmaceuticals, on a foundation of controls, aimed at creating patient value, as "Integrity." This Philosophy is also the building block of our ESG efforts, such as provision of a lymphatic filariasis treatment free of charge, improvement of access to medicines, and building of a community that coexists

Accordingly, insufficient permeation of the Corporate Philosophy throughout the Group, stagnation of the implementation of management aimed at implementing the Philosophy, and other factors that hinder the full increase of benefit to patients and their families may have significant impact not only on the Group's business performance, but also on the improvement of corporate value, including nonfinancial value.

### (2) Business Strategy

### Establishment of AD franchise

The Group has established maximization of the value of next-generation Alzheimer's disease (AD) treatments as one of the most important strategies in the medium-term business plan 'EWAY 2025.' However, considering the patients to whom the treatment would be directed, it is possible that it will not be possible to provide next-generation AD treatments to patients in a broad manner by using conventional sales and promotion strategies. In short, it may not be possible to obtain the anticipated future revenue without the permeation of education on the illness that is aligned with the patient journey of Alzheimer's patients, from new recognition of the illness to diagnosis, treatment, and subsequent daily living, establishment of diagnosis methods that utilize cognitive function testing, positron emission tomography (PET), and cerebrospinal fluid (CSF), etc., establishment of a follow-up structure to ensure safety, and the establishment of an AD franchise, or in other words, an ecosystem that takes into consideration the fostering of a culture that measures cognitive function in society in general.

Maximization of the value of Lenvima®
The Group and Merck & Co., Inc., Kenilworth, N.J., U.S.A. are conducting trials of combination therapy using anticancer agent Lenvima® and the anti-PD-1 antibody KEYTRUDA® for 13 indications for 7 types of cancer. However, it is possible that we will not be able to achieve the sales plan for Lenvinna® due to changes in positioning resulting from unanticipated trial results for competing products or approval timing, preventing the acquisition of approval of additional indications for Lenvima® at the originally expected timing, and weakening the competitiveness of the product. One-time payments for certain option rights, development milestones, and sales milestones, etc., have been set in the revenue obtained through the Lenvima® partnership model, and if they are not achieved due to a failure to achieve sales targets or acquire approval, it may not be possible to obtain the revenue anticipated for the future.

# Partnership model

The Group considers partnerships to be an effective means of improving efficiency and productivity. Partnerships may be established with the aim of accelerating new drug development through utilization of the latest science and technology, or with the aim of efficient resource usage and maximization of business value in each

If there are differences of opinion with partners in pharmaceutical research and development, production, and sales activities that utilize partnerships, the aforementioned activities may be delayed or become inefficient. It is also possible that unanticipated partnership expenses will be generated, thereby reducing the planned and anticipated profits, or otherwise hindering the maximization of business value. In addition, in the event of differences in interpretation of contracts, it is possible that such differences will develop into litigation or mediation between the Group and partners, ultimately leading to dissolution of the partnership. In such cases, business performance may be significantly affected, including the prevention of the creation of new drugs or achievement of revenue in the future as expected.

# Digital transformation

The Group has established the goal of becoming a Medico Societal Innovator as a major theme in the medium-term business plan 'EWAY 2025,' in an aim to convert from a value chain model to an ecosystem platform model. As the "Fourth Industrial Revolution" moves steadily forward, one of our important issues will be to achieve a digital transformation aimed at causing a paradigm shift in all aspects, from drug discovery to providing patients with medicines, through the use of Al. The Company assigned a Chief Digital Officer and will accelerate the Group-wide digital strategy.

The changes in the business environment caused by the recent outbreak of a novel coronavirus (COVID-19) make the need for a digital transformation clear. Any delays in efforts to achieve it or factors that hinder the achievement may have significant impact not only on the Group's business performance, but also on the improvement of corporate value, including non-financial value.

### (3) Pharmaceutical Research and Development, Production, and Sales Activities

### New drug development

The Group is developing candidates for the next-generation AD treatments and many other new drugs. In regard to candidates for the next-generation AD treatments, the Group is taking the lead in the Phase III trial of BAN2401. In addition, the Group's partner Biogen Inc. was taking the lead in the Phase III trials of aducanumab.

Drug development requires a long period of time and a large investment of capital. Development of a drug candidate substance may be discontinued due to shortcomings in its effectiveness or safety profile. For example, on September 13, 2019, Biogen Inc. and the Company announced that the Phase III trials to verify the efficacy and safety of elenbecestat for early-stage AD would be discontinued.

Moreover, even if clinical trials yield expected results, it is possible that the new drug approval may not be granted as a result of a stringent regulatory process of a country. Currently, Biogen Inc. completed the submission of a Biologics License Application (BLA) for the approval of aducanumab in the United States. Further, due to the delay or discontinuation of development of a new drug or other reasons, revenue expected of a new drug may not be realized.

### Side effects

Even when pharmaceuticals have been approved and sold, subsequent data and events may cause the benefit and risk profile of the pharmaceuticals to differ from that of the time when they were approved. Changes to product package inserts, suspension of sales, recall of products, or implementation of other measures in response to the discovery and collection of serious side effects, may significantly impact business performance.

The Group has established a Safety Executive Committee consisting of the safety administrators, etc., of all regions, and a Global Safety Board consisting of the persons responsible for medical evaluation of safety for each product, etc., as a structure for scientific evaluation of information on all adverse events and safety related to products, and to report on such to the regulatory authorities. The Group has established a global product safety monitoring structure with these structures at the center, and are working to thoroughly ensure proper use of products.

### Product quality and stable supply

It is necessary to provide patients with high-quality pharmaceutical products in a stable manner, but if there are concerns regarding product quality in relation to the raw materials used in products, the manufacturing process, or other factors, or if suspension of supply of those raw materials, technical problems in the manufacturing process, or serious disasters, etc., causing plant operation to stop, result in the supply chain being cut off, not only is it possible that the health of patients may be adversely affected, but it is also possible that product recalls,

of patients may be adversely affected, but it is also possible that product recalls, suspension of sales, or other events may impact business performance.

The Group conducts quality assurance activities that make it possible to provide high-quality pharmaceuticals that can be used without worry, and implements manufacturing control and quality control that comply with the GMP global standards (standards related to manufacturing control and quality control). In regard to manufacturing subcontractors as well, we conduct activities such as dispatching technicians to inspect manufacturing sites, in addition to periodic GMP audits. Further, we are working to ensure quality at the distribution stage. In addition, the Group has its own plants in major regions around the world, and has established a structure under which products can be supplied in a timely manner established a structure under which products can be supplied in a timely manner from each plant. Moreover, we have established a Business Continuity Plan (BCP), and are striving to maintain a structure that ensures stable supply even in the case of a serious disaster, etc.

### Intellectual property

Ordinarily, it is possible for generic manufacturers to launch generic products upon the expiration of the patent and data protection period of the originator drug. However, if an acquired patent cannot be properly protected due to dismissal of a patent application or as a result of an invalidation trial after the patent has been issued, generic products and biosimilar products may enter the market earlier than expected, which could potentially lead to a decrease in revenue. For example, an invalidation trial has been requested regarding the Japanese method-of-use patent for the pain treatment agent Lyrica® (being jointly promoted with Pfizer Inc.) that is scheduled to expire in 2022.

In addition, there are some countries, such as the United States, in which drug applications for generics and biosimilar products can be submitted even during the patent period. In such countries, it is possible that there will be patent infringement lawsuits against companies that submit drug applications for generics or biosimilar products. Depending on the results of such patent infringement lawsuits, it is possible that generics or biosimilar products will be placed on the market prior to the end of the patent period, thereby significantly and rapidly shrinking the Group's share of the market in that country. For example, in 2018, a federal court of appeals in the United States finalized the ruling that the patent for the antiemetic Aloxi® was invalid, and generic versions were placed on the market. In addition, if a substance patent that protects the Group's pharmaceuticals is judged to be invalid, the product's market value in that country may be lost, resulting in a significant impact on the Group's business performance.

Meanwhile, although the Group always uses caution to avoid infringing upon the intellectual property rights of third parties, in the unlikely event that the Group's business activities do violate the intellectual property rights of a third party, it is possible that the third party will request termination of those business activities or demand compensation for damage.

### Litigation and other proceedings

In the ordinary course of the Group's business activities, the Group is and may be, from time to time, involved in litigations, arbitrations or any other legal, regulatory, or administrative proceedings in connection with various matters, including product liability and other product-related matters (e.g., personal injury), consumer protection, regulation of trade, securities law, data protection, breach of contract, violation of laws and regulations and environmental regulation that arise through claims, investigations, or other actions by third parties, including governments. Litigation and other legal proceedings are inherently unpredictable. Although the Group believes that its defenses and counterclaims in matters in which it is or may become a defendant are substantial, it could in the future be the subject of judgments or enter into settlements, and such developments could have a material adverse effect on the Group's business, financial condition, results of operations or reputation.

For example, with regard to the proton pump inhibitor "Pariet®/Aciphex®," claims for personal injury have been filed against the Group as well as other claims against other manufacturers of other types of proton pump inhibitors. Cases filed in U.S. federal courts have been consolidated as a multi-district litigation in the U.S. District Court for the District of New Jersey. The number of pending lawsuits is expected to fluctuate significantly because certain lawsuits against the Group may be consolidated with other lawsuits that have been brought in federal and state courts in the United States involving multiple plaintiffs against multiple pharmaceutical companies claiming that they have been diagnosed with various injuries following treatment with various types of proton pump inhibitors and because certain lawsuits may be settled or dismissed, or additional lawsuits may be filed. It is not currently possible to estimate potential liability in connection with claims concerning "Pariet®/Aciphex®."

### Data reliability

One of the most critical concerns for a pharmaceutical company is ensuring the integrity of its research- and production-related data (the completeness, consistency, and accuracy of the data), which establishes a basis for the safety and reliability of the company's products. If the Company cannot guarantee the integrity of those key data sets, it could find itself grappling with delays and stoppages in new drug development, product recalls, suspensions of product sales, and other circumstances with the potential to devastate business performance.

The Group has thus created a Data Integrity Promotion Committee and a Data Integrity Planning and Coordination organization, set up a systematic framework for the recording, verification, approval, and storage of data, and established and operated, etc., an appropriate internal-control structure, all of which help the Group meet integrity needs. Not only does the Group's approach strengthen the integrity of data that corroborates product quality and data on clinical trials, both key concerns, but it also includes ongoing training programs for employees—in Japan and overseas as well—whose responsibilities involve working with important data.

### Trend to contain medical costs

Governments around the world are exploring and implementing a variety of measures to contain drug costs in hopes of controlling rising medical expenses. In Japan, for example, the government has taken steps to reduce the prices for prescription drugs and promote the use of generic drugs. Meanwhile, the Chinese authorities have slashed drug prices under a price negotiation system and moved to encourage the use of generic pharmaceuticals via a centralized bulk-buy program. Similar developments are occurring in Europe as well. In some cases, a product that has already secured new-drug approval may not be eligible for health insurance reimbursement at the expected price. The promotion of these types of policies and the implementation of new measures may prevent the Group from earning the revenue that it originally anticipated for certain products.

While it continues to track changes in governmental systems and policy trends worldwide, the Group is exploring ways not only to ensure that its new drugs are effective and safe but also to demonstrate that they offer unique forms of value, such as the ability to alleviate nursing-care needs and address the severity of target diseases. Together with the entire pharmaceuticals industry, the Group is also appealing to governmental organizations and other relevant parties to ensure that drug prices reflect those levels of quality and value.

### (4) Others

### Succession

For over 30 years, the Group's current Representative Corporate Officer and CEO has used his strong leadership skills to help the Group develop its business activities and grow on a global scale.

Looking forward, it will be important for the Representative Corporate Officer and CEO to take a planned, systematic approach to helping potential successors hone the abilities that they will need to thrive as future company leaders. The Group will also need to prepare as thoroughly as possible for any disruptions that may occur and ensure that the Board of Directors selects the future Representative Corporate Officer and CEO from an objective, fair perspective. Falling to take these types of vital steps, however, may impede the Group in its quest to fulfill its Corporate Philosophy and deal a serious blow to Group management.

The Board of Directors, recognizing the selection of the Representative Corporate Officer and CEO as one of the most important decisions it makes as an official body, has thus established rules and procedures relating to the Group's succession plan. The Group's independent outside directors also play a role in the processes for nurturing promising candidates for the position, among other initiatives, thereby serving a supervisory function for succession. Specifically, the Outside Directors Meeting receives a proposal for a succession plan from the Representative Corporate Officer and CEO twice a year, shares information on the succession plan with all directors, and engages in discussions on the proposal.

In addition to pursuing the above initiatives for ensuring an optimal succession process for the Representative Corporate Officer and CEO, the Group also engages in succession planning on a yearly basis to facilitate the transfer of leadership for corporate officer posts and other important positions across the company

organization by selecting candidates for positions, helping those potential future leaders develop their skills, monitoring the progress of retention measures, and carrying out other relevant tasks.

### Information security

The Group, whose digital-platform strategy, 5D (Data Driven Drug Discovery & Development) strategy, Eisai Data Lake vision, and other forward-looking initiatives are ushering business forward, now has more and more opportunities to utilize elements of the IT infrastructure such as AI, big data, and the cloud. As business in cyberspace makes strides forward, however, the Group is also confronting progressively sophisticated cyber attacks and grappling with increasingly serious security threats. The current circumstances thus elevate the possibility of a cyber attack triggering a suspension of business or other outcome that would impact business activity. As a result, the need for an even stronger information-security framework is growing.

Considering the personal information, undisclosed information, and other types of important information in its possession, the Group could also see its credibility and competitive advantages suffer if a data breach were to result in a leak of sensitive information. In recent years, the corporate community is also dealing with the growing need to respond appropriately to global demands for the protection of personal information. The Group is also fully aware that leaks of unreleased structural formulas for projects in the drug discovery phase would have a negative impact on the processes for filing and acquiring patents. For the Group, a loss of credibility in the public eye or competitive advantages in the business sphere could have a major impact on business results.

To prevent cyber-attacks and other threats from interfering with important business, as well as safeguard against leaks of personal or confidential information, etc., the Group's newly appointed "Chief Information Security Officer" (CISO) leads the effort to bolster the Group's security framework, establish regulations on information management, etc., and work to ensure that all officers and employees fully recognize the importance of information management in their day-to-day business activities. Through these and other similar measures, the Group is enhancing governance over and implementing measures for global information security on an ongoing basis.

### COVID-19

Since beginning to spread in early 2020, the novel coronavirus infection (COVID-19) has become a global pandemic in a matter of several months and may impact the Group's business activity in a variety of ways. The outbreak has the potential to affect numerous areas. R&D, for example, may see delays in the registration of patients for clinical trials and slower progress in actual testing processes. COVID-19 could also disrupt the Group's production activities, as suspensions of plant operations (both within the Group and at its suppliers) and other developments have the potential to interfere with supply chains and thereby endanger stable product supplies. Another area that stands to feel the effects of the pandemic is sales, as medical representatives may find themselves unable to collect information from and provide information to medical professionals in a timely, appropriate fashion.

The Company has thus established a Crisis Countermeasure Team to handle the Company's response to the COVID-19 outbreak. Working with its subsidiaries around the world, the Company is also gathering accurate information, working to keep its employees safe, and actively encouraging the use of ICT technologies and other resources in hopes of minimizing the disease's impact on business activity. The Group's plants, which consistently stock the necessary inventory levels for ensuring stable product supplies, are also adapting frameworks and operating under the predetermined Business Continuity Plan (BCP).

### Climate change

The Group recognizes that climate change is a crucial issue with a substantial impact on corporate activities. Climate change has the potential to make natural disasters like large-scale typhoons, heavy rainfalls, and floods more and more common, which could interfere with operations at the Group's manufacturing sites and other locations around the world, delay the procurement of raw materials, etc., and rupture transportation channels. These types of obstacles may have a negative effect on stable product supplies. Measures to facilitate the shift to a low-carbon society, such as the implementation of carbon taxes and stricter environmental regulations, may also elevate costs at Group locations worldwide and the Group's procurement sources.

The Group announced its endorsement of the Task Force on Climate-Related Financial Disclosures (TCFD) in June 2019 and launched a cross-organization project that now uses the TCFD framework to perform scenario analyses on the long-term effects of climate change.

# Impairment of goodwill and intangible assets

The Group records goodwill and intangible assets obtained as a result of merger and acquisition and the licensing-in of products and pipelines. If the fair values of these types of assets fall below the corresponding carrying amounts due to deviations in plans and actual performance, market changes, or other factors, the Group needs to book impairment losses accordingly. Such circumstances may have a negative impact on the Group's financial results and financial positions.

For example, the Group's goodwill (168.7 billion JPY as of the end of fiscal 2019) is mainly allocated to the Americas pharmaceutical business. Fair values are calculated using a variety of assumptions such as projected cash flows and growth rates for the Americas pharmaceutical business, determined based on management-approved business plans. These assumptions are affected by factors ranging from the possibility of future approvals and additional indications for new drugs, the timing of those changes, and post-marketing drug prices to sales volume, competing products, and interest-rate fluctuation.

# Corporate Executives (As of June 30, 2020)

### **Directors**

Director, Representative Corporate Officer and CEO

### Haruo Naito

Chair of the Board of Directors, Chair of the *hhc* Governance Committee and 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 *hhc* Governance Committee and Chair of the Independent Committee of Outside Directors

# Daiken Tsunoda

Member of the Nomination Committee, Chair of the Compensation Committee, Member of the *hhc* Governance Committee and 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 *hhc* Governance Committee and Member of the Independent Committee of Outside Directors

### Shuzo Kaihori

Member of the Nomination Committee, Member of the Compensation Committee, Member of the *hhc* Governance Committee and Member of the Independent Committee of Outside Directors

### Ryuichi Murata

Chair of the Audit Committee, Member of the *hhc* Governance Committee and Member of the Independent Committee of Outside Directors

# Hideyo Uchiyama

Member of the Audit Committee

# Hideki Hayashi

Member of the Audit Committee, Member of the *hhc* Governance Committee and Member of the Independent Committee of Outside Directors

### Yumiko Miwa

### **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

# Ryohei Yanagi

Senior Vice President Global Safety Officer

# **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 Chairman, Eisai Inc.

# 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

Senior Vice President President, Americas Region President, Fisai Inc.

# Tatsuyuki Yasuno

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

### Yanhui Feng

Senior Vice President President, Eisai Demand Chain Systems

# Yoshiteru Kato

Senior Vice President Chief Government Relations Officer Global Value & Access

# Masatomi Akana

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

# Takashi Owa

Vice President Chief Clinical Officer, Neurology Business Group

# Lynn Kramer

Vice President Chief IR Officer Stakeholder Communications

# Sayoko Sasaki

Vice President Internal Audit

### Junichi Asatani

Vice President

# Chief Discovery Officer, Neurology Business Group **Teiji Kimura**

Vice President General Affairs, Environmental and Safety Affairs Japan Subsidiaries

# Masayuki Miyajima

Vice President

Executive Vice President, Integrity, Eisai Inc.

### **Alexander Scott**

Vice President Chief Compliance Officer Internal Control Chief Information Security Officer

# Mitsuaki Tanaka

Vice President President, Asia and Latin America Region API Solutions

# Shohei Kanazawa

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 Head of Medical Headquarters

# Hiroyuki Murayama

Vice President President, Dementia Total Inclusive Ecosystem Business Unit Chief Digital Officer

### Keisuke Naito

Vice President

President, Consumer hhc Business Division

# Eriko Naito

# **Major Products**

Product lineup mainly consisting of two major focus areas (Neurology and Oncology)



Neurology Area Revenue in fiscal 2019 ¥183,3 billion (103% YoY, Composition of consolidated revenue 26.3%)

Fycompa® (generic name: perampanel)

In-house

Antiepileptic agent

Revenue in fiscal 2019 ¥25.3 billion (131% YoY)

An AMPA receptor antagonist discovered and developed inhouse by Eisai, Fycompa® has been approved in more than 60 countries such as Japan, the U.S., and countries in Europe and Asia for the adjunctive treatment of both partial-onset seizures and primary generalized tonic-clonic seizures. It obtained the approvals for an additional indication for monotherapy of partial-onset seizures and an additional indication for partial-onset seizures in pediatric patients aged 4 years and older, as well as a new fine granule formulation in Japan in January 2020. Revenue is currently increasing worldwide.



**Dayvigo**<sup>TM</sup> (generic name: lemborexant)

In-house

Anti-insomnia drug

Launched in the U.S. in June 2020, in Japan in July 2020

Dayvigo™ is an in-house developed dual orexin receptor antagonist, which inhibits orexin neurotransmission regulating sleep-wake rhythm by binding competitively to the two subtypes of orexin receptors. It



acts on the orexin neurotransmitter system and is believed to facilitate sleep onset, sleep maintenance, and better waking by regulating sleep-wake rhythm. Launched for the treatment of adults with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance in the U.S., for the treatment of insomnia in Japan.

Aricept® (generic name: donepezil)

In-house

Treatment for Alzheimer's disease/dementia with Lewy bodies Revenue in fiscal 2019 ¥34.9 billion (87% 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 an indication for the treatment of dementia with Lewy bodies in Japan, the Philippines and Thailand.

Methycobal® (generic name: mecobalamin)

In-house

Peripheral neuropathy treatment Revenue in fiscal 2019 ¥38.0 billion (97% 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.



Lyrica® (generic name: pregabalin)

In-license

Pain treatment

Revenue in fiscal 2019 (Co-promotion income) ¥28.6 billion (101% YoY)

A pain treatment originally developed by Pfizer Inc. (U.S.). Currently approved in more than 100 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 December 2019



Oncology Area Revenue in fiscal 2019 ¥165.9 billion (137% YoY, Composition of consolidated revenue 23.9%)

Lenvima® (generic name: lenvatinib)

In-house

In-house

Anticancer agent/molecular targeted medicine Revenue in fiscal 2019 ¥111.9 billion (179% YoY)

A selective tyrosine kinase inhibitor (TKI) with a novel binding mode originally discovered and developed in-house by Eisai. Approved as a treatment for refractory thyroid cancer in over 65 countries, renal cell carcinoma (RCC) in combination

with everolimus in over 55 countries and hepatocellular carcinoma in over 60 countries worldwide (product name for treatment of RCC in Europe: Kisplyx®). Revenue is successfully increasing worldwide.



Halaven® (generic name: eribulin)

Anticancer agent/microtubule dynamics inhibitor Revenue in fiscal 2019 ¥40.2 billion (97% 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 75 countries for the treatment of breast cancer. Approved in over 65 countries for use in the treatment of liposarcoma (soft tissue sarcoma in Japan).



Pariet® (generic name: rabeprazole)

In-house

Proton-pump inhibitor

Revenue in fiscal 2019 ¥24.1 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.

Revenue is increasing in Asia, although decreasing in Japan due to intensifying competition and the expansion of generics.

**Humira**® (generic name: adalimumab)

In-license

Fully human anti-TNF- $\alpha$  monoclonal antibody Revenue in fiscal 2019 ¥61.4 billion (103% 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 areas other than gastrointestinal disease, while AbbVie GK and EA Pharma Co. Ltd., are co-promoting the agent for indications in the gastrointestinal disease area.

Revenue is increasing in Japan, mainly due to the success of promotion leveraging the strengths of having a wide range of indications.



# ■ Consumer Healthcare Business Revenue in fiscal 2019 ¥24.9 billion (Composition of consolidated revenue 3.6%)

# Chocola BB® Products Revenue in fiscal 2019 ¥15.5 billion (101% YoY)

Including the signature product Chocola B8® 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.

BB SECTION OF THE PROPERTY OF

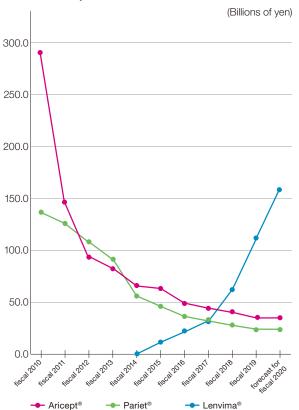
Chocola BB® Plus: Third-class OTC drug

Chocola BB® Royal 2: Designated quasi-drug

In fiscal 2019, revenue Third-class OTC drug Designated quincreased due to the launch of new and updated products as well as growth of Chocola BB® tablets from the effect of television commercials.

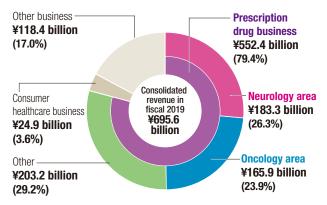
Chocola.com ► https://www.chocola.com/index.html (Only available in Japanese)

# Revenue of major brands

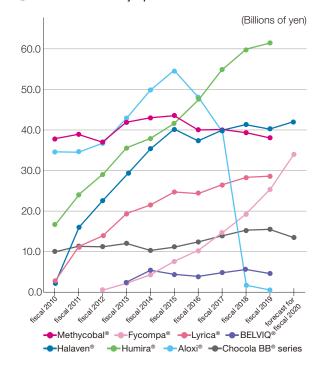


\* A major brand is an extremely popular medicine which achieved annual revenue of at least 100 billion JPY or which is expected to.

 Revenue of prescription drug business, consumer healthcare business and others



# Revenue of other major products



- \* Revenue of Lyrica® is an alliance income from co-promotion.
- \* We returned an exclusive license for commercialization of Aloxi® in June 2018.
- \* We did not disclose fiscal 2020 forecast for global revenue of Methycobal®, Lyrica®, and Humira®.

### Status of Shares (As of March 31, 2020)

Issued 296,566,949 shares (including 9,903,184 shares of treasury stock)

Number of shareholders

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)	35,394	12.36
Japan Trustee Services Bank, Ltd. (trust account)	32,611	11.38
State Street Bank and Trust Company 505001	20,639	7.20
Nippon Life Insurance Company	12,281	4.28
Saitama Resona Bank, Limited	6,800	2.37
Japan Trustee Services Bank, Ltd. (trust account 7)	6,284	2.19
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)	4,876	1.70
JP Morgan Chase Bank 385151	4,623	1.61
The Naito Foundation	4,207	1.46
Total	133,154	46.49

- 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 9,903,000 shares (3.34%) of treasury stock are not included in this table as they
- 3 The 9,903,000 shares (3.34%) of treasury stock are not included in this 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., all 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, all 2 companies jointly held 27,087,000 shares (9.13%) as of July 31, 2015 (August 7, 2015, Revised Report)

  (3) Including BlackRock Japan Co., Ltd., all 11 companies jointly held 18,308,000 shares (6.17%) as of August 15, 2017 (August 21, 2017, Revised Report)

  (4) Including Sumitomo Mitsui Trust Bank, Limited, all 3 companies jointly held 15,967,000 shares (5.38%) as of December 14, 2018 (December 21, 2018, Revised Report)

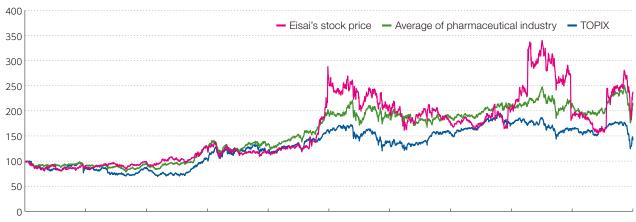
- Report)

  (5) Including Nomura Securities Co., Ltd., all 2 companies jointly held 17,993,000 shares (6.07%) as of September 13, 2019 (September 20, 2019, Revised Report)

  (6) Including Mizuho Bank, Ltd., all 2 companies jointly held 15,777,000 shares (5.32%) as of January 15, 2020 (January 22, 2020, Revised Report)

### Trends in ratio by shareholder type (%) 40 80 100 Fiscal 2018 44.6 28.7 12.6 Fiscal 2019 44.9 ■ Financial institutions (Institutional Investors, etc.) ■ Foreign entities, etc. ■ Individuals, other ■ Other companies ■ Treasury stock ■ Financial instruments traders (securities companies)

# Stock price trends (from April 1, 2010 to March 31, 2020)\*



	Fiscal 2010	Fiscal 2011	Fiscal 2012	Fiscal 2013	Fiscal 2014	Fiscal 2015	Fiscal 2016	Fiscal 2017	Fiscal 2018	Fiscal 2019
Highest	3,425 yen	3,385 yen	4,405 yen	4,675 yen	9,756 yen	9,024 yen	7,338 yen	7,148 yen	11,490 yen	9,433 yen
Lowest	2,743 yen	2,832 yen	3,070 yen	3,600 yen	3,800 yen	6,633 yen	5,366 yen	5,402 yen	6,040 yen	5,205 yen
Closing	2.984 ven	3.290 ven	4.200 ven	4.018 ven	8.535 ven	6.770 ven	5.764 ven	6.781 ven	6.213 ven	7.931 ven

<sup>\*</sup> The April 1, 2010, closing prices of Eisai's stock price, Average of pharmaceutical industry, and TOPIX respectively represent the 100 shown in the line graph.

### TSR (Total Shareholder Return, %)\*1

Holding period	1 year	3 years	5 years	10 years	
Eisai	94.0	139.4	278.4	283.1	
Nikkei Stock Average*2	89.5	118.1	187.8	200.4	
TOPIX*3	90.8	113.1	175.2	178.4	

<sup>\*1</sup> TSR is based on investment conducted at the closing price on March 31, 2010

https://indexes.nikkei.co.jp/en/nkave/index/profile?idx=nk225tr

Please refer to the Notice of Resolution of the 108th Ordinary General Meeting of Shareholders for the status of shares

<sup>\*2</sup> Source: Nikkei 225 Total Return Index

<sup>\*3</sup> Source: JAPAN EXCHANGE GROUP Monthly Statistics Report https://www.jpx.co.jp/english/markets/statistics-equities/monthly/index.html

# Corporate Data (As of March 31, 2020)

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

### Period Covered

This Integrated Report covers business performance from April 1, 2019 to March 31, 2020. Some sections may include information on activities as recent as fiscal 2020.

### 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.

We maintained proper social distance in interviews and dialogs for this Integrated Report 2020.

### ■ Note to Description

 $\bullet\mbox{Generic}$  names for drugs are given omitting the base or hydrate.

### ■ Notes to Icons on Each Page

- Pages that are strongly related to the 6 types of capital 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 the 17 Sustainable Development Goals (SDGs) are marked with SDGs icons.

# On the Issuance of the Integrated Report 2020

We prepared this integrated report on the theme of "sustainable growth of the Company by enhancing non-financial capital." We would like the readers to understand that our corporate activities do not confine ESG matters to a limited range of issues, but place importance on connecting them to corporate value creation activities as a management strategy.

In 30 years after the company announced the concept of "Eisai Innovation" which is the origin of "hhc," all Eisai employees put importance on the time needed to understand the true feelings of the patient, and motivation to respond to these feelings has been the source of growth for the Company. We are confident that the investment in human capital and intellectual capital based on the philosophy of "hhc" realizes both value creation for patients and the Company's growth.

The year 2020 is the 10th year for the partnership with the World Health Organization (WHO) aiming at the elimination of lymphatic filariasis (LF) after the signing of a joint statement in November 2010. Our diethylcarbamazine (DEC) tablets, treatments for LF, are distributed in 28 countries. We have seen steady progress with the elimination in of LF 17 countries, but are keenly

aware of the difficulties and the long way to go before the total elimination. The situation is the same with the initiative for COVID-19. Issues about global health are not issues where a single company can bring solutions, but essentially need partnership with reliable partners, as promoted by the SDGs. We are committed to continuing all related activities as a long term investment.



Sayoko Sasaki Corporate Officer Chief IR Officer Stakeholder Communications

We are at the forefront of the creation of nextgeneration Alzheimer's disease treatments, and we are working to deliver them to people with dementia as soon as possible. With the rapid aging of the population, dementia is a global public health issue of high social priority, and we aim to realize not only Medical Innovation but also Societal Innovation.

We hope this integrated report will help you understand that our initiatives for ESG are paving the way to mediumto long-term enhancement of corporate value.

For further information

Investor Relations Eisai Co., Ltd.

4-6-10, Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan

TEL: 0120-745-040