

Annual Report 2014

Creating and Sustaining Corporate Value

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#### **Creating Corporate Value**

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Further details on financial information can be found in the Consolidated Financial Statements Under IFRSs and Independent Auditor's Report http://www.takeda.com/investor-information/

#### Inclusion Status in SRI (Socially Responsible Investment) Indexes (as of May 31, 2014)

- Dow Jones Sustainability Asia Pacific Index (S&P Dow Jones Indices LLC of the U.S.)
- FTSE4Good (FTSE International Limited of the U.K.)
- Ethibel Excellence (Forum ETHIBEL of Belgium)
- Morningstar Socially Responsible Investment Index (MS-SRI) (Morningstar Inc., Japan)









The Ministry of Economy, Trade and Industry and the Tokyo Stock Exchange have recognized Takeda as a Nadeshiko Brand, a listed enterprise that is "exceptional in encouraging women's success in the workplace" (March 2014)



See → P.56 Labor

### Reference Guidelines for Disclosure of Non-Financial Information

- The International Integrated Reporting Council (IIRC) International Framework for Integrated Reporting
- United Nations Global Compact Advanced Level Criteria
- GRI's Fourth Generation of Sustainability Reporting Guidelines (G4)

#### **Precautions Regarding Forward-Looking Statements**

This annual report includes forward-looking statements regarding Takeda's plans, prospects, strategies and performance, etc. These prospects are the result of assessments obtained from information currently available, and since actual performance is subject to various risks and uncertainties, it should be noted that outcomes could differ substantially from those prospects.

Factors that could affect future prospects would include, but are not limited to, economic circumstances in Takeda's business domains, competitive pressures, relevant laws and regulations, change in the status of product development, exchange rate risk and so on.

#### Standardized Wording in This Report

Generic names for drugs are given omitting the base, except for the section explaining pipeline drugs.

Note: The contents of this annual report are based on information for fiscal 2013 (April 1, 2013 to March 31, 2014), with some activities of significant relevance in fiscal 2014 also included.

Statements about market scales and shares in this Annual Report are based on the company's analysis of IMS data in "IMS Market Prognosis Global 2014-2018."

#### Integrated Annual Report Editorial Policy

This report offers an integrated explanation of Takeda's strategies and performance based on its corporate philosophy, from a perspective of creating and sustaining corporate value.

#### **Integrated Thinking**

Since its foundation in 1781, Takeda has conducted its business of providing pharmaceuticals with integrity, which is at the core of the unchanging values of "Takeda-ism" (Integrity: Fairness, Honesty and Perseverance). We believe that the essence of CSR for Takeda lies in developing outstanding pharmaceutical products in accordance with these values. From another perspective, we are very aware that our sustainability can exist only when a sustainable and healthy society is assured. As a corporate citizen, we aim to take the initiative to address social issues in fields where we can leverage our strengths. In this way, Takeda's relationships with society are an integral part of its business development.

the IIRC, the United Nations Global Compact Advanced level criteria, and GRI's Fourth Generation of Sustainability Reporting Guidelines (G4) to create a comprehensive report targeting a broad range of stakeholders, especially shareholders and other investors.

#### Creating and Sustaining Corporate Value

Takeda has formulated "Vision 2020" to articulate the aspiration of where the company wants to be in the future. Guided by this vision, the entire Group is implementing strategies aimed at transformation into a truly global pharmaceutical company capable of responding to diverse medical needs. Throughout all of its business activities, Takeda is committed to promoting corporate value creation by developing outstanding pharmaceutical products and conducting corporate citizenship activities. At the same time, we also work to sustain corporate value through business processes that are grounded in integrity.

In this report we have attempted to highlight our strategies for creating and sustaining corporate value, and the ways in which they are interlinked.

See → P.12 Mid-Range Growth Strategy

P.16 Financial Strategy

P.18 R&D Strategy

P.20 Marketing Strategy

P.22 CSR Strategy

P.24 Corporate Governance Strategy

P.28 Corporate Philosophy

1781 Takeda's Foundation

#### Integrated Reporting/Integrated Report

Since fiscal 2006, Takeda has conducted integrated reporting, incorporating non-financial information about our initiatives on human rights, the environment, and communities, etc., in addition to financial information. Based on this, we have been publishing integrated annual reports. Since fiscal 2009, we have published the CSR Data Book making reference to the Global Reporting Initiative (GRI) Guidelines. In 2011, we participated in a pilot program of the International Integrated Reporting Council (IIRC), which is proposing an international framework for integrated reporting. In this report, we have referred to the international framework for integrated reporting of



**IIRC** 

The International Integrated

was established in 2010 by

private-sector companies,

associations, government

agencies, and others, as an

organization for developing

an international corporate

reporting framework.

investors, accounting

Reporting Council (IIRC)

#### Relationship between CSR and Sustainability at Takeda



Annual Reports and CSR Data Books are available on Takeda's corporate website (PDF/E-book).

http://www.takeda.com/

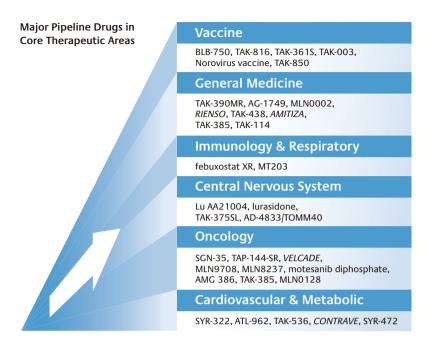


We will maximize the strengths of our global presence to deliver outstanding pharmaceutical products to people worldwide.



# Takeda Snapshot

Creating Corporate Value through the Pharmaceutical Business



#### Building a Highly Competitive Product Portfolio Tailored to the Characteristics of Mature and Emerging Markets

Takeda formulated "Vision 2020" to articulate where we aspire to be as a global company by the year 2020. The objective of Takeda's business is to "pursue innovative medicines as well as high-quality branded generics, life-saving vaccines, and OTC medicines – to help as many people as we can, as soon as we can." In particular, Takeda is focusing on the penetration of a diverse portfolio of products and the swift increase of new product sales in a broad range of markets, and also on the steady progression of our highly competitive late stage pipeline.

#### (See →

P.18 R&D Strategy P.20 Marketing Strategy P.34 R&D Pipeline P.40 Core Products



6

#### **Core Therapeutic Areas**

- Cardiovascular & Metabolic
- Oncology
- Central Nervous System
- Immunology & Respiratory
- General Medicine
- Vaccine

19

Number of R&D Sites

25% by FY2017

Core Earnings Ratio Target (fiscal 2013-2017)

¥1,691.7<sub>bn</sub>

#### Fiscal 2013 Revenue

Ethical Drug Business ¥1,529.1bn Consumer Healthcare Business ¥72.9bn Other Businesses ¥93.8bn Takeda participates in the creation of global CSR guidelines, helping to identify materiality and promoting its activities.



Takeda declared its support for the United Nations Global Compact in 2009 and became a member of the LEAD program in 2011. We are now cooperating with activities to promote the implementation and widespread adoption of the United Nations Global Compact principles.

**51**/7,000

No. of participating companies in the United Nations Global Compact LEAD program / No. of participating companies in the United Nations Global Compact As of May 2014



Since 2012, Takeda has been participating in the BSR Healthcare Working Group, and is cooperating with activities to jointly draft the BSR "Guiding Principles on Access to Healthcare," among other initiatives.

**15**/250

No. of participating companies in BSR Healthcare Working Group / No. of participating companies in BSR As of May 2014



Since 2006, Takeda has been publishing integrated annual reports. In 2011, we participated in the IIRC Pilot Program. Since then, we have been assisting with the development of an international integrated reporting framework.

3/100

No. of participating pharmaceutical companies in the IIRC Pilot Program / No. of participating companies in the IIRC Pilot Program As of May 2014

## Proactive Participation in the International Community

Takeda actively participates in international communities of global corporations and international NGOs. Our main channels of participation are the United Nations Global Compact LEAD program, as well as the BSR Healthcare Working Group, which is a global association of member companies for CSR, and the International Integrated Reporting Council (IIRC) Pilot Program. Our discussions in these forums help us to develop an awareness of issues, which we use to identify materiality within our CSR activities.



At the IIRC's Pilot Program Conference



P.22 CSR Strategy
P.49 Takeda's CSR Activities

## Takeda Snapshot

Sustaining Corporate Value through CSR



## Promotion and Disclosure of CSR Activities as Required by the International Community

Takeda is stepping up its CSR activities by reflecting insight gained from the international community to help it identify materiality, and then utilizing the United Nations Global Compact's 10 principles and the ISO 26000 framework of guidance standards for social responsibility. Furthermore, we disclose the details of our activities, referring to the IIRC's International Integrated Reporting Framework, the United Nations GC Advanced level criteria, and GRI's Fourth Generation of Sustainability Reporting Guidelines (G4). We strive to provide disclosure of information that is easy to understand by organizing the information into five categories: Human Rights, Labor, Environment, Anti-Corruption (including the core subjects in ISO 26000 of Fair Operating Practices and Consumer Issues), and Corporate Citizenship Activities.

#### See →

P.54 Human Rights
P.56 Labor
P.58 Environment
P.60 Anti-Corruption/
Fair Operating Practices/
Consumer Issues
P.62 Corporate
Citizenship Activities

¥1.55bn

Amount Pledged to Support Healthcare Access (2009-2019)

¥3.9<sub>bn</sub>

Donation Amount for Great East Japan Earthquake Assistance

(Period of recovery support program operation by NGOs and NPOs due to donations from Takeda: 2011 – 2020)

5%

Target Percentage of Women in Managerial Positions in Japan by Fiscal 2015

18%

Fiscal 2015 CO<sub>2</sub> Emissions Reduction Target

from fiscal 2005 levels)

#### Financial and Non-Financial Highlights

#### Takeda Pharmaceutical Company Limited and Subsidiaries Each Consolidated Fiscal Year Ended March 31

Takeda has adopted International Financial Reporting Standards (IFRS) from fiscal 2013, ended March 31, 2014, and the disclosure information in this material is based on IFRS. According to this adoption, the previous year's information is also based on IFRS.

| Fiscal year end  | ded March 31                   | Millions of yen 2014 | Millions of yen<br>2013 | Millions of yen<br>2012 | Millions of yen<br>2011 | Millions of yen<br>2010 | % change<br>2014/2013 | Thousands of U.S. dollars *1 |
|--|--------------------------------|----------------------|-------------------------|-------------------------|-------------------------|-------------------------|-----------------------|------------------------------|
|  |                                | IFRS                 | IFRS                    | J-GAAP                  | J-GAAP                  | J-GAAP                  |                       | IFRS                         |
| Revenue  |                                | ¥ 1,691,685          | ¥ 1,557,005             | ¥ 1,508,932             | ¥ 1,419,385             | ¥ 1,465,965             | 8.6%                  | \$ 16,424,126                |
| Research a developme   | nd<br>ent expenses             | 341,560              | 321,323                 | 281,885                 | 288,874                 | 296,392                 | 6.3                   | 3,316,117                    |
| Operating  | profit                         | 139,274              | 64,994                  | 265,027                 | 367,084                 | 420,212                 | 114.3                 | 1,352,175                    |
| Profit befor   |                                | 158,851              | 133,068                 | 252,478                 | 371,572                 | 415,829                 | 19.4                  | 1,542,243                    |
| Net profit a<br>owners of t                                  | attributable to<br>the Company | 106,658              | 148,583                 | 124,162                 | 247,868                 | 297,744                 | (28.2)                | 1,035,515                    |
| Core earnir  | ngs                            | 314,202              | 285,470                 | _                       | _                       | _                       | 10.1                  | 3,050,505                    |
| Net cash from  | om (used in)<br>activities     | ¥ 148,335            | ¥ 332,579               | ¥ 336,570               | ¥ 326,938               | ¥ 381,168               | (55.4)%               | \$ 1,440,146                 |
| Net cash fro<br>(used in) in                                 | om<br>vesting activities       | (158,611)            | (131,077)               | (1,093,964)             | (99,255)                | (117,521)               | 21.0                  | (1,539,913)                  |
| Net cash from (used in) fire                                 | om<br>nancing activities       | 101,441              | (152,202)               | 393,789                 | (146,544)               | (148,046)               | _                     | 984,864                      |
| Total assets   | s                              | ¥ 4,569,144          | ¥ 4,052,556             | ¥ 3,577,030             | ¥ 2,786,402             | ¥ 2,823,274             | 12.7%                 | \$ 44,360,621                |
| Total equit  | у                              | 2,540,635            | 2,338,286               | 2,071,866               | 2,136,656               | 2,164,746               | 8.7                   | 24,666,359                   |
| Treasury sh  | ares                           | (621)                | (587)                   | (808)                   | (1,014)                 | (980)                   | _                     | (6,029)                      |
| Return on equity attributable to owners of the Company (ROE) |                                | 4.5%                 | 6.8%                    | 6.1%                    | 11.8%                   | 14.4%                   |                       |                              |
| Basic earni  | ngs per share                  | ¥ 135.10             | ¥ 188.21                | ¥ 157.29                | ¥ 314.01                | ¥ 377.19                | (28.2)%               | \$ 1.31                      |
| Cash divide  | ends per share                 | 180.00               | 180.00                  | 180.00                  | 180.00                  | 180.00                  | _                     | 1.75                         |
| Revenue<br>by region<br>*2                                   | Japan                          | ¥ 733,882            | ¥ 734,311               | _                       | _                       | _                       | (0.1)%                | \$ 7,125,068                 |
|  | North America                  | 374,532              | 360,540                 | _                       | _                       | _                       | 3.9                   | 3,636,233                    |
|  | [U.S.]                         | [352,065]            | [343,828]               | _                       | _                       | _                       | [2.4]                 | [3,418,107]                  |
|  | Europe                         | 297,548              | 246,514                 | _                       | _                       | _                       | 20.7                  | 2,888,816                    |
|  | Russia/CIS                     | 89,571               | 68,339                  | _                       | _                       | _                       | 31.1                  | 869,621                      |
|  | Latin America                  | 81,245               | 62,921                  | _                       | _                       | _                       | 29.1                  | 788,786                      |
|  | Asia                           | 85,371               | 60,094                  | _                       | _                       | _                       | 42.1                  | 828,845                      |
|  | Other                          | 29,536               | 24,285                  | _                       | _                       | _                       | 21.6                  | 286,757                      |
| Number of<br>employees<br>*3                                 | Total                          | 31,225               | 30,481                  | 30,305                  | 18,498                  | 19,585                  | 2.4%                  |                              |
|  | Japan                          | 9,554                | 9,525                   | 9,530                   | 9,467                   | 9,305                   | 0.3                   |                              |
|  | Overseas                       | 21,671               | 20,956                  | 20,775                  | 9,031                   | 10,280                  | 3.4                   |                              |
|  | Pharmaceutical business        | 29,133               | 28,397                  | 28,284                  | 16,470                  | 17,568                  | 2.6                   |                              |
|  | Ethical drugs                  | 28,672               | 27,947                  | 27,844                  | 16,035                  | 17,125                  | 2.6                   |                              |
|  | Consumer healthcare            | 461                  | 450                     | 440                     | 435                     | 443                     | 2.4                   |                              |
|  | Other businesses               | 2,092                | 2,084                   | 2,021                   | 2,028                   | 2,016                   | 0.4                   |                              |
| Total input e  | energies (million MJ)          | 9,278                | 9,428                   | 9,156                   | 6,582                   | 6,215                   | (1.6) %               |                              |
| CO <sub>2</sub> emissio                                      | ns (kilotons of CO2)           | 434                  | 439                     | 435                     | 292                     | 280                     | (1.1)                 |                              |
| Fresh water used (thousand m <sup>3</sup> )                  |                                | 7,944                | 8,373                   | 8,598                   | 7,309                   | 7,461                   | (5.1)                 |                              |

<sup>\*1</sup>The U.S. dollar amounts in this report represent translations of Japanese yen, solely for the reader's convenience, at the rate of ¥103=US\$1, the approximate exchange rate on March 31, 2014.

Note: Account names under IFRS. Names in J-GAAP correspond to names in IFRS as follows: •Net sales/Revenue •Operating income/Operating profit •Income before income taxes and minority interests/Profit before tax -Net income/Net profit attributable to owners of the Company -Net assets/Total equity -Return on equity/Return on equity attributable to owners of the Company -Earnings per share/Basic earnings per



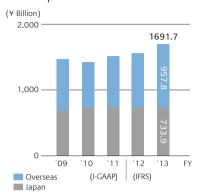
See → P.72 Financial Information

P.77 Key Social Responsibility Data

<sup>\*2</sup> We revised the geographical segments from fiscal 2013, ended March 31, 2014. The country groupings for fiscal 2012 have been restated using this revised segmentation. Figures have been omitted for the previous years.

<sup>\*3</sup> Employees working in Takeda Pharmaceutical Company Limited and its consolidated subsidiaries. From fiscal 2010, ended March 31, 2011, the numbers are indicated on a full time equivalent basis. For fair comparison, the numbers of fiscal 2009, ended March 31, 2010, are modified according to the new basis.

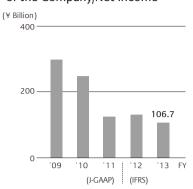
#### Revenue/Net Sales



#### Operating Profit and Operating Margin



#### Net Profit Attributable to Owners of the Company/Net Income



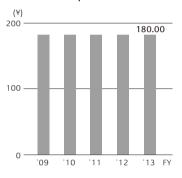
#### **R&D** Expenses and Ratio to Revenue



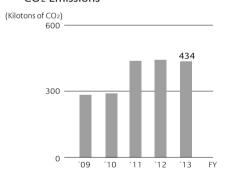
#### **EPS and ROE**



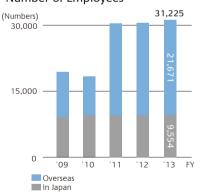
#### Cash Dividends per Share



#### CO<sub>2</sub> Emissions



#### Number of Employees



#### **Proportion of Shareholders**



#### **Performance Overview**

#### Revenue

Revenue increased year on year as growth in sales of core products, including new products, more than offset the negative impact of generic competition on sales of ACTOS in the U.S. market.

+8.6%

#### Operating profit

Operating profit increased in line with an increased gross profit and rigorous cost controls in all aspects of operations.

+114.3%

#### Net profit for the year (attributable to owners of the Company)

Net profit for the year (attributable to owners of the Company) declined, mainly due to a decrease in gains on sales of financial assets and the inclusion last year of a tax refund relating to the correction for transfer pricing

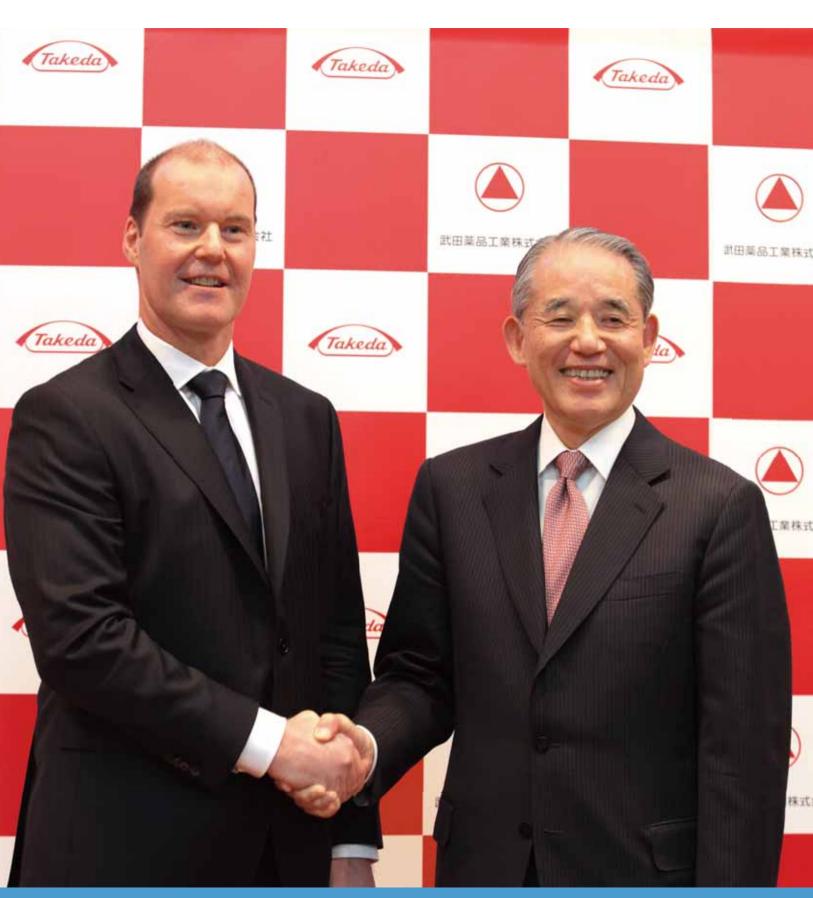
taxation.

#### Core earnings

Core earnings are calculated by deducting any temporary factors, such as impacts from business combination accounting and from amortization/impairment loss of intangible assets, etc., from operating profit.

See 

P.10 Performance Overview and Mid-Range Growth Strategy P.16 Financial Strategy



## Message from the CEO

# We, Takeda, continue to transform ourselves towards better health and a brighter future.

Following a series of transformational integrations, including both Millennium and Nycomed, last year Takeda formulated "Vision 2020" to articulate where we aspire to be as a global company by the year 2020. Providing a clear direction and goals for the invigorated "New Takeda," Vision 2020 will be achieved through the execution of our Mid-Range Growth Strategy during fiscal 2013-2017. This roadmap is centered around the principles of "Globalization," "Diversity," and "Innovation."

Throughout fiscal 2013, we leveraged our strength as a Group to develop and implement our strategies more deeply based upon the foundations of our Mid-Range Growth Strategy. On the commercial front, double-digit growth in the emerging and U.S. markets contributed strongly as we realized substantial growth in all major countries and regions. In Research and Development, we are concentrating our efforts on the progress of our highly competitive late stage pipeline, where we are seeing steady results. Simultaneously, we are implementing "Project Summit," a company-wide strategic initiative to speed up our transformation into a company with a robust and efficient operating model that is globally competitive in every aspect of its business. In the first year, this initiative already delivered cost savings and efficiencies which exceeded the initial target. We are proactively employing individuals with rich global experience and a wealth of knowledge to further invigorate our corporate culture through diversity of talent.

At the same time, Takeda is making every effort to improve its corporate value through enhancing CSR activities even further. This includes adopting a holistic approach to improving access to healthcare for people around the world.

Christophe Weber officially assumed responsibility for execution of all operations under the title of Chief Operating Officer (COO) in April 2014, and as of June 27, 2014, he has also become Representative Director, and President. Mr. Weber has demonstrated his leadership for over 20 years within the global pharmaceutical industry, and I firmly believe him to be the most suitable person to lead the next generation of transformation within Takeda. My role as

Representative Director, Chairman of the Board and CEO will be to take responsibility for the mid- to long-term strategy. Mr. Weber has experience in a variety of countries and regions as well as a track record of success in a broad range of therapeutic areas that will be indispensable to Takeda's sustainable growth in the global market. Under his strong leadership, I firmly believe that Takeda will continue to grow and flourish.

With regard to a series of issues surrounding the results of the CASE-J study, an investigator-led clinical research related to the hypertension medicine *BLOPRESS* (candesartan) in Japan, we sincerely apologize to patients, healthcare professionals and all the concerned parties for multiple incidences of involvement and encouragement by Takeda employees. Takeda will implement measures to prevent recurrences of this kind of event in the future. These measures include ensuring transparency through clarifying the role of each department and strengthening each department's checking systems, as well as thoroughly ensuring that Takeda employees are completely uninvolved in investigator-led clinical research related to Takeda products.

Takeda will return to the basic focus on its deeply embedded corporate philosophy of "Takeda-ism" (Integrity: Fairness, Honesty and Perseverance) which has been fostered through generations of history, as we undertake a radical overhaul and rebuilding of the entire Group's compliance system. Our corporate mission states, "We strive towards better health for people worldwide through leading innovation in medicine," and we are making continual efforts to realize this every day. We are transforming ourselves into a truly global pharmaceutical company so that we can fulfill a wide range of medical needs around the world, as we blaze a new trail in our efforts to help people realize better health and a brighter future.

Yasuchika Hasegawa Representative Director, Chairman of the Board & CEO

### Takeda will make a collective effort across the Group to realize Vision 2020, working to promote its business with a sense of urgency and dedication.

[Performance Overview and Mid-Range Growth Strategy]



Performance Overview

# Takeda has steadily executed measures to increase its ability to compete globally.

Takeda has adopted International Financial Reporting Standards (IFRS) for reporting its consolidated operating results instead of Japanese Generally Accepted Accounting Principles (J-GAAP) from fiscal 2013. In this document, all financial information is based on IFRS, except the items which are specified as J-GAAP.

Our consolidated revenue in fiscal 2013 grew 8.6% year on year to ¥1,691.7 billion, including an increase in ethical drug revenues of 9.1% to ¥1,529.1

billion. The increase was driven by higher sales of core products such as antihypertensive agent AZILVA (azilsartan) in Japan, and multiple myeloma treatment VELCADE (bortezomib), gastro-esophageal reflux disease treatment DEXILANT (dexlansoprazole), and COLCRYS (colchicine) for treatment of acute gout flares in the U.S. Furthermore, in Europe, sales of malignant lymphoma treatment ADCETRIS (brentuximab vedotin) expanded strongly, and sales in emerging markets also increased mainly due to the sales contribution of peptic ulcer treatment pantoprazole. Such positive factors and the yen's depreciation absorbed a drastic decrease in sales of type 2 diabetes treatment ACTOS (pioglitazone), which was strongly affected by the introduction of generic versions, mainly in the U.S. As a result, we recorded an overall increase in consolidated revenue. On a like-for-like basis,\*1 revenue increased by 5.1% compared to the previous year.

Consolidated operating profit increased 114.3% year on year to ¥139.3 billion. Consolidated net profit for the year (attributable to owners of the Company) declined by 28.2% year on year to ¥106.7 billion. The decline was mainly due to a decrease in gains on sales of non-core financial assets and the inclusion in fiscal 2012 of a tax refund relating to the correction for transfer pricing taxation between the U.S. and Japan. Core earnings,\*2 an underlying profit indicator widely used in the pharmaceutical industry which has been introduced as a profit measure at Takeda from fiscal 2013, increased 10.1% year on year to ¥314.2 billion.

In fiscal 2013, Takeda initiated a Mid-Range Growth Strategy for achieving "Vision 2020," which articulates the aspiration of where the company wants to be in the year 2020.

In R&D, Takeda strives to address the unmet medical needs of people worldwide by focusing on initiatives to quickly obtain new drug approvals for its promising late-stage pipeline. As a result, in fiscal 2013, the company was able to secure approvals and advance many of its pipeline products. In September 2013, Takeda obtained approval from the U.S. Food

and Drug Administration for *BRINTELLIX* (vortioxetine), a treatment for major depressive disorder, and in January 2014, obtained a new drug application approval in Japan for *ADCETRIS*. Furthermore, we have stepped up our efforts to strengthen our vaccine business globally, obtaining a vaccine for dengue fever with the acquisition of U.S.-based Inviragen, Inc. in May 2013.

In our commercial activities, we have been working to build highly competitive product portfolios optimized to meet the respective market needs in mature and emerging markets while also implementing optimal marketing strategies. In Japan, Takeda managed to increase sales of the NESINA (alogliptin) family for the treatment of type 2 diabetes and AZILVA. In the U.S., Takeda focused on maximizing sales of new products launched in June 2013: NESINA, KAZANO (fixed-dose combination of NESINA and metformin), and OSENI (fixed-dose combination of NESINA and ACTOS). In Europe, efforts to strengthen the specialty care business saw sales of ADCETRIS grow rapidly in its first year on the market. In emerging markets, with a specific focus on Russia/CIS, China, and Brazil, we continued to achieve business growth that exceeds the growth of each market in which we operate. Takeda is also striving to further expand its commercial platform in growing markets, with activities such as the establishment of new subsidiaries.

- \*1 Constant forex and excluding exceptional items (Non-recurring items to be excluded in view of normal business performance such as M&A related transactions, business divestments, patent expirations and working day differences)
- 2 Core earnings are calculated by deducting any temporary factors, such as impacts from business combination accounting and from amortization/impairment loss of intanable assets, etc., from operating profit.

#### Financial Forecasts for Fiscal 2014

In our operating results forecasts for fiscal 2014, we are projecting consolidated revenue of ¥1,725.0 billion, an increase of 2.0% year on year, operating profit of ¥150.0 billion, up 7.7%, and net profit for the year (attributable to owners of the Company) of ¥85.0 billion, a decrease of 20.3% year on year. These forecasts include the negative impact of the assumption of a slight further depreciation of the yen against major currencies.

The main factors behind the projected increase in consolidated revenue are expected sales increases for *AZILVA* in Japan, and *BRINTELLIX* and *ENTYVIO* (vedolizumab) for the treatment of ulcerative colitis and Crohn's disease in the U.S., as well as sales growth in emerging markets.

Although we are projecting an increase in consolidated operating profit from the previous year, net profit (attributable to owners of the Company) for the year is expected to decrease, mainly because of a significant decrease in financial income. Core earnings are expected to marginally decrease from the previous year, mainly as a result of increased R&D expenses and sales expenses related to the launch of new products, particularly in the U.S.

#### **Shareholder Returns**

The annual dividend per share for fiscal 2013 was the same as the previous year at ¥180. With regard to profit distribution in accordance with the steady implementation of the Mid-Range Growth Strategy, we are committed to our policy of maintaining annual dividends of ¥180 per share for fiscal 2014 and 2015. With an emphasis on returns to shareholders, we will also strive for a stable dividend for the future.

| (Announced in May 2014)   | FY2012 (Actual) | FY2013 (Actual) | (¥ Billion<br>FY2014 (Forecast) |
|---|-----------------|-----------------|---------------------------------|
|   | ,               | IFRS            | , ,                             |
| Revenue   | 1,557.0         | 1,691.7         | 1,725.0                         |
| R&D expenses  | 321.3           | 341.6           | 350.0                           |
| Operating profit  | 65.0            | 139.3           | 150.0                           |
| Net profit for the year (attributable to owners of the Company) | 148.6           | 106.7           | 85.0                            |
| EPS (¥)   | 188             | 135             | 108                             |
| Core earnings   | 285.5           | 314.2           | 280.0                           |
| % of Revenue  | 18.3%           | 18.6%           | 16.2%                           |

Note: The foreign exchange rate assumptions for fiscal 2014 are US\$1 = ¥100 and 1 euro = ¥140

#### Mid-Range Growth Strategy

## Takeda will make a Group-wide effort to further strengthen its initiatives based on the Mid-Range Growth Strategy initiated in fiscal 2013.

Under "Vision 2020," the long-term objective of Takeda's business is to "pursue innovative medicines as well as high-quality branded generics, life-saving vaccines, and OTC medicines - to help as many people as we can, as soon as we can." To realize Vision 2020, Takeda initiated a Mid-Range Growth Strategy, starting from fiscal 2013, that is further deepening and expanding previous strategies, centered around the principles of "Globalization," "Diversity," and "Innovation."

Takeda positions fiscal 2014 as a year of investment. It will strengthen and accelerate the Mid-Range Growth Strategy under a new management structure with a Chief Executive Officer responsible for mid- to long-term corporate strategy and decisions related to important global policies and a Chief Operating Officer responsible for the execution of Takeda's global business.

#### Globalization

- Ensure early market penetration and maximized sales of new products in mature markets
- Achieve faster sales growth than the market growth rate and increased profitability in emerging markets

#### **Diversity**

- Attract and develop diverse talent
- Create a culture that encourages creativity
- Tailor a product portfolio to meet medical needs

#### **Innovation**

#### **Scientific Innovation**

 Propose new healthcare solutions that meet a diverse array of medical needs from prevention to care and cure

#### **Business Process Innovation**

 Improve business processes and establish new business models to succeed in a globally competitive environment (Project Summit)

#### 1. Globalization

#### ■ Mature Markets

Takeda will build a strong commercial model in each therapeutic area, quickly maximizing the value of its diverse product portfolio and attractive pipeline assets.

#### [The Japanese Market]

Takeda will realize maximized sales of new and key products, centered on the strategic product families of *NESINA* and *AZILVA*. We will maintain our No.1 share position in Japan through a higher level of specialization in our information distribution activities by shifting to a therapeutic area-based MR (Medical Representative) system, and further initiatives to maximize the value of new products.

#### [The U.S. Market]

Takeda will actively invest in marketing in the U.S. in order to grow the NESINA family and BRINTELLIX, and to realize the early uptake and market penetration of new products for which marketing approvals are expected soon or have been granted in fiscal 2014, such as ENTYVIO. In addition, we will pursue an optimal commercial model and formulate and execute optimal sales strategies in each therapeutic area to maximize the value of various products.

#### [The European Market]

While maintaining and expanding existing products, Takeda will strengthen its specialty care business by focusing on the market penetration of new products, including oncology products such as *ADCETRIS*, and will develop a business structure that can realize steady sales and high profitability despite challenging market environments.

#### ■ Emerging Markets

With the main focus on Russia/CIS, Brazil and China, Takeda will maximize sales of its existing portfolio, including branded generics and OTC medicines. Moreover, we will realize top-line growth that exceeds the growth of each market by continuing to launch and penetrate the market with a diverse portfolio of new products, including innovative medicines and vaccines that meet the increasing needs of each market, and by implementing a sales strategy that strives for efficient investment.

See → P.20 Marketing Strategy

#### 2. Diversity

Takeda will build a corporate culture that continuously produces creative ideas by having employees from various countries, cultures, and backgrounds work together to improve our organizational strength and global competitiveness through mutual understanding and respect.

See → P.22 CSR Strategy

#### 3. Innovation

Takeda defines and categorizes innovation in two ways: "Scientific Innovation," which meets a variety of medical needs by providing new healthcare solutions from prevention to care and cure, and "Business Process Innovation," which improves business processes and establishes new business models to succeed in the highly competitive market environment.

#### ■ Scientific Innovation Strengthening of Our Competitive R&D Pipeline

In order to strengthen its competitive R&D pipeline, Takeda will focus on the six therapeutic areas of "Cardiovascular & Metabolic," "Oncology," "Central Nervous System," "Immunology & Respiratory," "General Medicine," and "Vaccine." We will continue to concentrate R&D activities on innovative medicines

and vaccines targeting unmet medical needs, while pursuing further value creation projects across each therapeutic area.

#### Improvement of R&D Productivity

Takeda will continue working to improve R&D productivity by bringing its promising late-stage pipeline to market and maximizing its value, enriching the mid-stage portfolio, and strengthening research competitiveness and productivity.

See → P.18 R&D Strategy

#### ■ Business Process Innovation

Takeda will further enhance Project Summit, a company-wide strategic initiative to pursue transformation into a company that is globally competitive in every aspect of its business. With the addition of leaders possessing vast global experience, Takeda is strengthening efforts to build a robust and efficient operating model in terms of its sales and marketing functions, production and supply chain operations, and general and administration functions, such as finance & accounting, IT, and human resources.

See → P.16 Financial Strategy

#### **Guidance for Sustainable Growth**

| Growth                | Revenue growth in emerging markets,<br>mature markets<br>+<br>Steady launch of pipeline drugs | Revenue                  | FY2013-17 | Mid-single-<br>digit<br>CAGR  |
|-----------------------|---|--------------------------|-----------|-------------------------------|
| Efficiency            | Establishment of a robust and efficient operating model                                       | Core<br>earnings<br>(CE) | FY2013-17 | 25% CE<br>ratio*<br>by FY2017 |
| Shareholder<br>Return | Stable dividend   | Dividend<br>per share    | FY2013-15 | Maintain<br>¥180<br>annually  |

<sup>\*</sup> Achieve with at least 20% FY2013-17 CAGR of operating profit

## Message from the COO

# "Leading through Change" I will devote all my energy to transforming Takeda into a Japan-based global best-in-class company.

Takeda possesses a variety of strengths that constitute a solid foundation for further growth as a global pharmaceutical company. The foremost of these strengths is Takeda's heritage and values. Throughout our long history as a pharmaceutical company, Takeda has placed "Takeda-ism (Integrity: Fairness, Honesty, and Perseverance)" as the heart of its business. This is critically important for us as a company that serves society by delivering pharmaceutical products to people suffering from illness and disease, to maintain trust with society. I strongly identify with this set of values and I steadfastly stand by the spirit of Takeda-ism that we have inherited from our founder and the generations that followed him.

Furthermore, with a global footprint in more than 70 countries, a promising R&D pipeline, a diverse product portfolio, talented and passionate employees, as well as a sound financial position, Takeda possesses all the necessary components to achieve sustainable growth.

Takeda must continue to develop its competitiveness in every aspect of its business. This is a challenge and an opportunity. Takeda's scale of operations is optimal for us to be able to act with agility - a key factor in order to continue to flourish in our highly competitive operating environment.

Additionally, in order to be successful it is important

to fully grasp the diverse nature of the markets within this industry. We will be very local and customercentric to appropriately reflect the unique attributes of each country, such as healthcare systems, medical needs, and business models.

I have spent over 20 years in the global pharmaceutical industry, with experience in all of Takeda's six core therapeutic areas, including the vaccine field, ranging across both the emerging and reimbursed markets. Moving forward, I will fully leverage all of these experiences to realize growth for Takeda.

In traveling to Takeda locations across the world since my appointment as COO in April 2014, it became very clear that Takeda's strengths support our aspiration: we will steer Takeda towards becoming a global leader in every aspect of its business. In other words, we intend for Takeda to be perceived as best-in-class in the eyes of the world's patients and their healthcare professionals, our employees, as well as our shareholders and investors. To achieve these high ambitions, I will devote all my energy to leading Takeda through change.

Christophe Weber

Representative Director, President & COO



We continue to work steadily to realize sustainable growth by achieving the goals of our Mid-Range Growth Strategy that include increasing efficiency and profitability as we support the financial needs of Takeda's business operations.

François-Xavier Roger Director and Chief Financial Officer (CFO)

#### **Core Management Policies**

- Pursue Project Summit to improve profitability
- Optimize our balance sheet to achieve strong cash flow generation



# Financial Strategy

## Improving Profitability – Pursuing Project Summit –

Takeda is vigorously pursuing Project Summit, a Group-wide strategic initiative to increase the effectiveness and efficiency of all our operations. Through this initiative, we are strengthening our business models with more efficient operating structures and improving profitability in order to achieve our sustainable growth guidance of 25% core earnings ratio by fiscal 2017.

During fiscal 2013, the first year of the initiative, among other achievements, we have taken the first steps to consolidate our manufacturing and R&D bases, realign our sales and marketing organization, optimize distribution in Europe, and leverage procurement on a global basis. As a result, we achieved cost reductions of ¥34 billion,\*1 exceeding our target. While continuing implementation of existing initiatives, we will generate new initiatives for even greater effectiveness and efficiency.

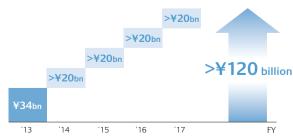
Meanwhile, we will also implement a multi-year program to redesign core business processes in R&D, commercial and G&A as global, unified, and best-inclass.

\*1 Compared to actual fiscal 2012 costs

#### **Cost Saving Performance and Targets**



Note: All cost saving figures are compared to actual costs for fiscal 2012



#### **CFO**

The senior officer responsible for oversight of all the company's financial activities and a member of the senior management team that develops and executes strategy in ways that maximize corporate value.

#### **Consolidated Balance Sheets**

(¥ Billion)

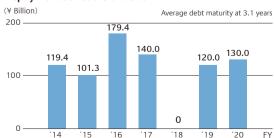
| IFRS           Total non-current assets         2,544.6         2,821.2         2,976.6         155.5           Total current assets         1,061.7         1,231.4         1,592.5         361.1           Total assets         3,606.2         4,052.6         4,569.1         516.6           Total non-current liabilities         679.2         1,080.4         1,225.8         145.3           Total current liabilities         759.2         633.8         802.8         168.9 |                     | vs Fiscal 2012 End |
|---|---------------------|--------------------|
| Total current assets         1,061.7         1,231.4         1,592.5         361.1           Total assets         3,606.2         4,052.6         4,569.1         516.6           Total non-current liabilities         679.2         1,080.4         1,225.8         145.3   |                     |                    |
| Total assets         3,606.2         4,052.6         4,569.1         516.6           Total non-current liabilities         679.2         1,080.4         1,225.8         145.3  | current assets      | 155.5              |
| Total non-current liabilities 679.2 1,080.4 <b>1,225.8</b> 145.3  | nt assets           | 361.1              |
|   | S                   | 516.6              |
| Total current liabilities         759.2         633.8         802.8         168.9   | current liabilities | 145.3              |
|   | nt liabilities      | 168.9              |
| Total liabilities         1,438.4         1,714.3         2,028.5         314.2   | ties                | 314.2              |
| Total equity 2,167.8 2,338.3 <b>2,540.6</b> 202.3   | у                   | 202.3              |

## Cash Flow Generation - Balance Sheet Optimization -

To drive strong cash flow generation, Takeda is optimizing its balance sheet, specifically by reducing the level of working capital and strengthening cash management. In addition, we will continue to steadily repay interest-bearing debt while establishing and implementing flexible financial strategies, thereby realizing continuous investment for growth and a stable dividend. In this way we will maintain and enhance a strong and sound financial base that will support the implementation of the Mid-Range Growth Strategy.

| Net Cash                    | (¥ Billion |            |  |
|-----------------------------|------------|------------|--|
| Net cush                    | March 2013 | March 2014 |  |
|                             | IF         | RS         |  |
| Gross debt*2                | (542.1)    | (790.3)    |  |
| Cash and cash equivalents*3 | 547.7      | 805.7      |  |
| Net cash                    | 5.6        | 15.4       |  |

#### Repayment schedule of debt\*2



- \*2 Debt figures in this chart represent bonds and loans on an FX rate hedged basis.
- \*3 Cash and cash equivalents include short-term investments which mature or become due within one year from the reporting date.

The balance sheet as of the end of fiscal 2013 indicates the ratio of equity attributable to owners of the Company was 54.1%, down 2.0 percentage points year on year. Overall, the company continues to maintain a very high level of financial strength.

Cash flow for fiscal 2013 was a net inflow of ¥91.2 billion. Net cash inflow from operating activities was ¥148.3 billion, net cash outflow from investing activities was ¥158.6 billion, and net cash inflow from financing activities was ¥101.4 billion.

Net cash, which represents cash and cash equivalents minus gross debt, was ¥15.4 billion, meaning we have liquidity.

| Consolidated Statement of<br>Cash Flows                            | Fiscal 2012 | (¥ Billion)<br>Fiscal 2013 |
|--|-------------|----------------------------|
|  | IF          | RS                         |
| Net cash from operating activities                                 | 332.6       | 148.3                      |
| Net cash from (used in) investing activities                       | (131.1)     | (158.6)                    |
| Net cash from (used in) financing activities                       | (152.2)     | 101.4                      |
| Net increase (decrease) in cash and cash equivalents               | 49.3        | 91.2                       |
| Cash and cash equivalents at beginning of year                     | 454.2       | 545.6                      |
| Effect of movements in exchange rates on cash and cash equivalents | 42.0        | 29.3                       |
| Cash and cash equivalents at end of year                           | 545.6       | 666.0                      |

See → P.72 Financial Information

Takeda will lead the pharmaceutical industry in providing meaningful solutions to patients with unmet medical needs.

Tadataka Yamada, M.D. Director and Chief Medical & Scientific Officer (CMSO)

#### **Core Management Policies**

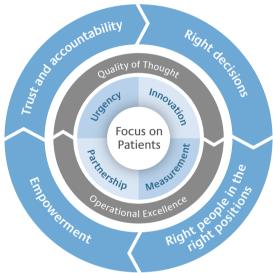
- Deliver innovative solutions that address unmet medical needs through a patient-centered approach to R&D
- Create new value by building a competitive R&D pipeline in core therapeutic areas
- Focus on increasing R&D productivity by advancing initiatives for the short, medium and long terms



## R&D Strategy

#### A Patient-Centered Approach to R&D

In order to meet the unmet medical needs of patients around the world, Takeda has made steady progress to improve R&D productivity and continue to discover and deliver innovative medicines, with the R&D strategy focusing on two key initiatives, Quality of Thought and Operational Excellence. These initiatives build upon the four R&D guiding principles: Urgency, Innovation, Measurement and Partnership.



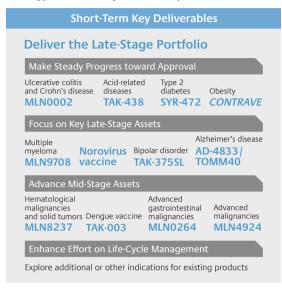
## Building a Competitive R&D Pipeline Portfolio in Core Therapeutic Areas

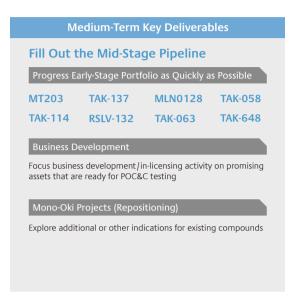
Takeda is focusing resources on the core therapeutic areas of "Cardiovascular & Metabolic," "Oncology," "Central Nervous System," "Immunology & Respiratory," "General Medicine," and "Vaccine." In addition to promoting R&D in new drugs and vaccines in therapeutic areas where medical needs are not adequately met, we also will build a competitive pipeline by creating important treatments that span multiple therapeutic areas.

#### **CMSO**

The Chief Medical & Scientific Officer (CMSO) makes the final decisions for all Takeda's R&D activities.

#### Strategy for Increasing R&D Activity





Long-Term Key Deliverables

**Invigorate Discovery Research** 

- Invest in Cutting-Edge Science and Technology
- Maximize Drug Discovery Potential
- · Advance Experimental/Translational Medicine Capability

#### POC&C

Under the Proof of Concept & Competitiveness (POC&C) model, Takeda aims to prove through clinical trials that a compound is safe and effective for use with humans, and to verify its competitive advantage in the market.

#### NCDs

Non-communicable diseases (NCDs) is a collective term to describe diseases such as diabetes, cardiovascular diseases, cancer, and pulmonary diseases. In 2011, the United Nations Summit declared NCDs to be a priority issue to be tackled at a global level.

#### Improvement of R&D Productivity

Under the Mid-Range Growth Strategy, we have implemented various measures to boost R&D productivity.

In the short term, Takeda will focus on key late-stage assets, and on making steady progress toward regulatory approval. We will strive to maximize the value of the late-stage pipeline, including life-cycle management initiatives.

In the medium term, Takeda will progress the early-stage portfolio as quickly as possible, and will pursue opportunities to in-license promising assets that are ready for POC&C (Proof of Concept & Competitiveness) testing and for new and additional indications for existing assets.

In the long term, Takeda will continue to invest in cutting-edge science and technology that will invigorate future drug discovery, and will strengthen collaborations with external consortia and research institutions. In addition, we will further improve our R&D productivity, maximizing our drug discovery potential by empowering our talented scientists and conducting critical experiments that allow the right decisions to be made at an early stage. We will also advance our capabilities in experimental and translational medicine.

See → P.30 R&D

#### **Global Health Project**

Takeda brings a true sense of urgency to improving people's lives and meeting important medical needs all over the world. To this end, we are promoting the "Global Health Project," aimed at providing people around the world with better access to medicines. As part of this initiative, we are also an active partner in Japan's Global Health Innovative Technology Fund (GHIT Fund).\* In addition, we entered into agreements with the Medicines for Malaria Venture (MMV) to study anti-malarial compounds in December 2013 as one of the projects selected to receive assistance.

Takeda is already a leader in innovative treatments for non-communicable diseases (NCDs) such as diabetes and cardiovascular disease. In this field and in areas including vaccines, we continue to engage in activities that go beyond monetary donations to promote lasting change.

The GHIT Fund is a pioneering non-profit public-private partnership established in Japan in April 2013 by the Government of Japan, a consortium of five Japanese pharmaceutical companies including Takeda, and the Bill & Melinda Gates Foundation, aimed at promoting the discovery and development of new drugs to fight communicable diseases (CDs) in developing countries.

See → P.22 CSR Strategy
P.63 Initiatives to Improve Access to Healthcare

We will maximize our strengths as a global pharmaceutical company to meet wide-ranging medical needs throughout the world.

#### **Core Management Policies**

- Optimize marketing operations to maximize strengths as a global pharmaceutical company
- Achieve global growth by building highly competitive product portfolios optimized to meet market needs



# Marketing Strategy

#### **Optimization of Marketing Operations**

Takeda is pursuing a global brand strategy, and optimizing marketing operations through more efficient sales activities on both a global and a local level. We are seeking to maximize our strengths as a global pharmaceutical company with operations in over 70 countries.

The process of integration with Nycomed is continuing smoothly, and at the beginning of fiscal 2013 we finished consolidating commercial subsidiaries in overlapping areas in Europe. In emerging countries, we are striving to further expand our commercial platform in growing markets, and since fiscal 2012 we have established sales subsidiaries in Ecuador, Peru, and Israel, among other countries.

### Building a Highly Competitive Product Portfolio

While innovative drugs are positioned at the core of Takeda's business model, the company is building a highly competitive product portfolio tailored to the specific market characteristics of each country in both mature and emerging markets. Takeda will realize growth on a global scale under optimal marketing strategies.

In mature markets, Takeda will build a strong commercial model in each therapeutic area, quickly maximizing the value of its diverse product portfolio and increasing the number of attractive pipeline assets.

In emerging markets, in addition to existing portfolios consisting of branded generics (branded ethical products for which patents have expired) and OTC medicines, Takeda will launch a multitude of innovative prescription drugs and vaccines in response to increasing market needs. Our aim is to outpace the growth of each market.

## Targeting Contributions to Revenue through Fiscal 2017

Takeda's revenue growth will be driven by rapidly growing emerging markets and the U.S., where we have launched several promising new products. We plan on emerging markets contributing over 40% of our revenue growth from fiscal 2013 up until fiscal 2017, with North America contributing over 30%. Our domestic business, with its consistently high profit margin, will also continue to make an important contribution.

Mid-Range Growth Strategy: Globalization Achieve sustainable growth **Emerging Markets Innovative Medicines Emerging Markets Branded Generics Branded Generics** & OTC Medicines & OTC Medicines Mature Markets Mature Markets **Mature Markets Innovative** Innovative **Innovative Medicines Medicines Medicines** (Present=Transformation period) (Past) (Future)

Emerging Markets\* Year-on-year growth in revenue (fiscal 2013)

\* Emerging markets is the total for Russia ICIS Latin America Asia, and Other, including currency translation effects

See → P.76

Ethical Drugs: Revenue by Region

#### **Core Management Policies in Fiscal 2014**

In the Japanese market, Takeda will maximize sales of new products such as the NESINA (alogliptin) family\*1 of type 2 diabetes treatments and the AZILVA (azilsartan) family\*2 of hypertension treatments. We will maintain our No.1 share of the Japanese market through a higher level of specialization in our promotional activities under a realigned sales force

In the U.S. market, Takeda will actively invest in marketing new products including the NESINA family, BRINTELLIX (vortioxetine) for the treatment of major depressive disorder, and also a product for obesity for which marketing approval is expected in fiscal 2014. In addition, Takeda will formulate effective sales strategies in each therapeutic area to maximize the value of various products over the long term.

In the European market, Takeda will accelerate its presence in specialty care by maintaining and expanding the sales of existing products and by focusing its efforts on the early penetration of new products, including those in the therapeutic area of oncology such as ADCETRIS (brentuximab vedotin) for the treatment of malignant lymphomas.

In emerging markets, Takeda will expand further and capitalize on its strengths in Russia/CIS, Brazil and China, working to maximize sales of its existing portfolio. At the same time, we will outpace the growth of the market by continuing to launch a diverse array of new products tailored to local needs.

- \*1 NESINA family: NESINA and LIOVEL(combination tablets of NESINA and ACTOS) \*2 AZILVA family: AZILVA and ZACRAS (combination tablets of AZILVA and calcium
- channel blocker)

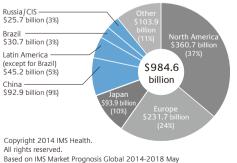
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#### **Pharmaceutical Market and Industry Trends**

The projected compound average growth rate (CAGR) in mature markets over the 2014-2017 period is about 3%. These pharmaceutical markets are as large as ever, and are therefore important for Takeda. In particular, new medicines that target unmet medical needs are expected to offer considerable potential.

The projected CAGR in emerging markets over the 2014-2017 period is about 10%. While branded generics and OTC products are driving growth in emerging markets in the short and medium terms, Takeda's view is that sales opportunities for new drugs will expand over the longer term.

#### Global Pharmaceutical Market Sales (2013)



We are working to sustain our corporate value while responding to the demands of international society.

#### **Core Management Policies**

- comprehended the changes and diversity of the global
- · Make a concerted effort across the Group to improve access to healthcare in order to promote smooth business operations in emerging markets



## **CSR** Strategy

#### **Holistic Approach**

The core rationale for corporate social responsibility (CSR) at Takeda is in the corporate mission of "striving towards better health for people worldwide through leading innovation in medicine." We believe it is important to recognize the various effects of the pharmaceutical business value chain on society. We therefore strive to maintain and improve sound business processes throughout our operations, and to engage in activities to promote a sustainable society as a good corporate citizen. We engage in CSR activities taking this holistic approach.

#### Holistic Approach

Pharmaceutical business (products and services)

**Business** processes

Corporate citizenship activities

#### **Sustaining Corporate Value**

Takeda recognizes that to steadily implement its medium- to long-term growth strategies it needs to seriously reconsider the meaning of sincere business processes, having first understood the social aspects of the changes and diversity of the global markets. Through this approach we aim to avoid social risks and work to sustain our corporate value. In particular, we recognize that healthcare access is a material issue when it comes to smoothly developing business in emerging economies.

See → P.4 Sustaining Corporate Value through CSR P.49 Takeda's CSR Activities

P.52 CSR Activity Targets and Results

#### **Healthcare Access Governance** 2012 Integrated Initiatives to Improve Access to Healthcare • Launched Global Health Project (2012) • Signatory to BSR Guiding Principles on Access to Healthcare (GPAH) (2013) • Global Health Project responded to the Access to Medicine Index survey 2012 R&D and collaboration with partners to address unmet medical needs • Strengthened vaccine business (2012) • Participated in the Global Health Innovative Technology Fund (GHIT Fund) (2013)2011 Business in emerging markets to address unmet medical needs • Integrated Nycomed (2011) • Acquisition of Multilab (Brazil) (2012) 2009 Corporate citizenship activities to address social issues in emerging and developing countries • Established the Takeda-Plan Healthcare Access Program (2009) • Established the Takeda Initiative (2010) • Commenced support for the IDEEL Program (2013) 1781 Business processes with integrity Research and development activities · CRO management to conduct global clinical studies sensitive to human rights • Three-Year Plan for Anti-Counterfeit Measures (2012)

### Integrated Initiatives to Improve Access to Healthcare

Takeda is working to support better access to healthcare for people around the world, including emerging and developing countries with the aim of realizing Vision 2020 (Better Health, Brighter Future) for all, making reference to the BSR's Guiding Principles on Access to Healthcare (GPAH), which Takeda helped to draft.

Specific initiatives are centered around the Global Health Project, which comprises members from divisions across the company, including those involved in R&D, pharmaceutical production, emerging markets, the vaccine business, corporate planning, industry negotiations, intellectual property, and CSR. The project discusses Takeda's initiatives from the aspects of both business and corporate citizenship activities, reporting the content of these discussions to management when appropriate. The project is also discussing the formulation of a basic policy on healthcare access to integrate the entire Group's initiatives and further enhance its activities.

See → P.19 Global Health Project
P. 63 Initiatives to Improve Access to Healthcare

#### Organization Chart of Functions in the Global Health Project



We are working to ensure sound and transparent management.

#### **Core Management Policies**

- Strengthen the management framework suitable for a global pharmaceutical company to maximize strengths
- Ensure rigorous compliance throughout the Group to fulfill responsibilities as a global company



# Corporate Governance Strategy

#### Strengthen the Management Framework

Takeda is establishing a management framework to facilitate rapid decision-making that is sound and transparent in order to maximize its strengths as a global pharmaceutical company with a business infrastructure that spans the world.

In 2011, we introduced outside directors who bring perspectives from other industries to create a structure that ensures the appropriate execution of business operations. Then, in 2012, Takeda also established a Global Leadership Committee, composed mainly of internal directors, which deliberates and makes decisions on the important issues facing the Group from an optimal company-wide perspective. Furthermore, a Nomination Committee and a Compensation Committee were established as advisory bodies to the Board of Directors. These committees are each chaired by an outside director. Together, the committees serve to ensure transparency and objectivity in decision-making processes and results relating to personnel matters for internal directors and to the compensation system.

#### **Rigorously Promoting Compliance**

Takeda has formulated the Takeda Global Code of Conduct, which contains specific guidelines on global compliance with policies related to anti-corruption, anti-bribery, fair competition, and anti-trust set out in the compliance promotion codes in every country where the company has operations. Looking ahead, the company will implement even stronger Group-wide initiatives to promote compliance even more rigorously.

#### **Takeda's Globalization Progress**

Takeda has been supplying pharmaceuticals since its foundation in 1781, during which time we have developed a strong commitment to the highest ethical standards and a strong sense of mission. We began our full-scale entry into the global market in the 1960s, and since then we have significantly widened the field of our business activities by bringing innovative new medicines to the world. As our journey continues into the 21st century we have increased the pace of our progress, and we will continue the challenge of becoming a truly global pharmaceutical company that can contribute to realizing better health and a brighter future for people worldwide.

#### Committee Concerned with Business Execution

#### Global Leadership Committee

The Global Leadership Committee is comprised mainly of internal directors, along with business division heads and corporate division heads. The committee meets twice a month in principle, to deliberate and make decisions on important issues relating to strategy, management, and business execution.

#### See →

P.26 Board of Directors, Auditors and Corporate Officers P.66 Corporate Governance P.67 Compliance

#### **Advisory Bodies to the Board of Directors**

#### Nomination Committee

The Nomination Committee has been established as an advisory body to the Board of Directors and is chaired by an outside director. The committee serves to ensure transparency and objectivity in decision-making processes and results relating to personnel matters for internal directors (appropriate standards and procedures for appointment and reappointment, and having and administering appropriate succession plans).

## Compensation Committee

The Compensation Committee has been established as an advisory body to the Board of Directors and is chaired by an outside director. The committee serves to ensure transparency and objectivity in decision-making processes and results relating to the compensation system (appropriate levels of compensation for the directors, appropriate performance targets within the director bonus system, and appropriate bonuses based on business results).

| 1962  | 2008   | 2009  | 2011   |
|---|--|---|--|
| Entry into the<br>Global Market   | Millennium Pharmaceuti-<br>cals, Inc. Acquired   | Participation in UN<br>Global Compact   | Nycomed Acquired   |
| Takeda began full-scale entry into the global market with the goal of contributing to the health of patients throughout the world. After an initial step into Asia, the company then expanded its overseas activities by entering Europe and the U.S. | Takeda acquired Millennium Pharmaceuticals to serve as the core of its global oncology strategy. In 2013, Millennium Pharmaceuticals' R&D functions were integrated with Takeda's R&D organization under the CMSO to achieve even greater synergies. | Takeda supports the United Nations Global Compact's 10 principles relating to "Human Rights," "Labour," "Environment" and "Anti-Corruption," and has incorporated them into its business activities. Moreover, Takeda has enhanced its CSR activities by establishing a dedicated CSR organization. | The integration of legacy Nycomed expanded the Group's sales channels in fast-growing emerging markets, while strengthening its business base across Europe. |

#### **Board of Directors**



Yasuchika Hasegawa

Representative Director, Chairman of the Board & CEO

1970 Joined the Company

1998 Senior Vice President,

Pharmaceutical International Division 1998 Corporate Officer

2001 Senior Vice President, Corporate Planning Department 2002 Senior Vice President, Corporate Strategy &

Planning Department

2003 President and Representative Director 2011 Chairman, KEIZAI DOYUKAI

(Japan Association of Corporate Executives) (to present) 2014 Chairman of the Board and Representative Director and Chief Executive Officer (to present)



Christophe Weber

Representative Director, President & COO

2003 Chairman and CEO, GlaxoSmithKline France

2008 Senior Vice President and Regional Director, Asia Pacific, GlaxoSmithKline
2011 President and General Manager Designate,

GlaxoSmithKline Vaccines

2012 President and General Manager, GlaxoSmithKline Vaccines

2012 CEO, GlaxoSmithKline Biologicals

2012 Member of GlaxoSmithKline Corporate Executive Team 2014 Chief Operating Officer of the Company (to present)

2014 Corporate Officer

2014 President and Representative Director (to present)



Shinji Honda

Senior Managing Director, Corporate Strategy Department

1981 Inined the Company

2001 Executive Vice President, TAP Pharmaceutical Products Inc.

2001 Executive vice resident, 178 - 100-1222 2008 Senior Vice President, Overseas Business Planning Department

2009 President, Takeda Pharmaceuticals North America, Inc. (currently Takeda Pharmaceuticals U.S.A., Inc.)

2011 Corporate Officer

2011 Chief Integration Officer,

Takeda Pharmaceuticals International, Inc.

2012 Senior Vice President.

Corporate Strategy Department (to present)

2013 Director

2013 President, Takeda Pharmaceuticals International, Inc.

2014 Senior Managing Director (to present)



Yasuhiko Yamanaka

Managing Director and Special Missions

1979 Joined the Company 2003 Senior Vice President, Corporate Strategy &

Planning Department Corporate Officer

2007 Senior Vice President, Pharmaceutical Marketing Division

2007 Director

2011 Managing Director (to present) 2012 Assistant to CEO, Globalization

2013 Special Missions assigned by President 2014 Special Missions (to present)



#### Tadataka Yamada, M.D.

Director and Chief Medical & Scientific Officer

2004 Member of the Board of Directors, GlaxoSmithKline 2006 President, Global Health Program,

Bill and Melinda Gates Foundation

2011 Member of the Board of Directors, Agilent Technologies, Inc. (to present)

2011 Chairman, Management and Operations Committee

3 of the Company

2011 Medical and Scientific Advisor to the CEO

2011 Executive Vice President,

2011 Director (to present) Takeda Pharmaceuticals International, Inc. (to present) 2011 Chief Medical & Scientific Officer (to present)



Masato Iwasaki, Ph.D.

Director and Senior Vice President. Pharmaceutical Marketing Division

1985 Joined the Company 2002 Director, Diabetes, Ethical Products Marketing

Department, Pharmaceutical Marketing Division

2008 Senior Vice President, Strategic Product Planning Department

2010 Corporate Officer

2012 Head of CMSO Office,

Takeda Pharmaceuticals International, Inc.

2012 Senior Vice President,

Pharmaceutical Marketing Division (to present)

2012 Director (to present)



François-Xavier Roger

Director and Senior Vice President, Chief Financial Officer

1998 Chief Financial Officer, Asia Pacific, Hoechst Marion Roussel (currently Sanofi S.A.) 1999 Vice President, Finance, International Division,

Aventis Pharma Ltd. (currently Sanofi S.A.)
1999 Chief Financial Officer, Asia Pacific, Danone S.A.

2005 Vice President, Corporate Finance and Group Treasurer, Danone S A

2008 Chief Financial Officer, Millicom International Cellular

2013 Chief Financial Officer of the Company (to present) 2013 Corporate Officer

2014 Senior Vice President (to present)

2014 Director (to present)



#### Fumio Sudo

Outside Director

1964 Joined Kawasaki Steel Corporation

(currently JFE Steel Corporation) President and Representative Director, Kawasaki Steel Corporation

2003 President and Representative Director,

JFE Steel Corporation

2005 President and Representative Director, JFE Holdings, Inc.
2010 Honorary Advisor to JFE Holdings, Inc. (to present)

2010 Outside Director, JS Group Corporation (currently LIXIL Group Corporation) (to present)

2010 Outside Director, New Otani Co., Ltd. (to present)

2011 Outside Director, Taisei Corporation (to present) 2011 Outside Director of the Company (to present)

2012 Outside Director of Tokyo Electric Power Company,

Incorporated (to present)
2014 Chairman of the Board, Tokyo Electric Power Company, Incorporated (to present)



Yorihiko Kojima

Outside Director

1965 Joined Mitsubishi Corporation2001 Executive Vice President and Operating Officer, Mitsubishi Corporation

2004 President and Representative Director, Mitsubishi Corporation

2010 Outside Director, Sony Corporation

2010 Chairman of the Board, Mitsubishi Corporation (to present)

2010 Outside Director, Mitsubishi Heavy Industries Ltd. (to present)

Vice Chairman, Keidanren

(Japan Business Federation) (to present)
Outside Director of the Company (to present)

2011

2013 Outside Director of The Shoko Chukin Bank, Ltd. (to present)



#### Masahiro Sakane

Outside Director

1963 Joined Komatsu Ltd.

1989 Director, Komatsu Ltd.

2001 President and Representative Director, Komatsu Ltd.

2007 Chairman of the Board and Representative Director, Komatsu I td.

2008 Outside Director, Nomura Holdings, Inc. (to present) 2008 Outside Director, Nomura Securities Co., Ltd.

(to present)

2008 Outside Director, Tokyo Electron Limited (to present)

2010 Vice Chairman, Keidanren (Japan Business Federation) 2010 Chairman of the Board, Komatsu Ltd.

2011 Outside Director, Asahi Glass Co., Ltd. (to present) 2013 Director and Councilor, Komatsu Ltd.

2013 Councilor, Komatsu Ltd. (to present)

2014 Outside Director of the Company (to present)

Note: Fumio Sudo, Yorihiko Kojima and Masahiro Sakane are Outside Directors as provided in Article 2, Item 15 of the Companies Act of Japan.

#### Corporate Auditors



Naohisa Takeda

Corporate Auditor

1972 Joined the Company

2000 General Manager, Department of Europe, Pharmaceutical International Division

2003 General Manager, Department of Europe and Asia

2005 Corporate Officer

2007 General Manager, Overseas Business

Planning Department

2008 Corporate Auditor (to present)



Teruo Sakurada

Corporate Auditor

1970 Joined the Company

2000 General Manager, Tohoku Branch, Pharmaceutical Marketing Division

2005 General Manager, Osaka Branch,

Pharmaceutical Marketing Division 2006 Corporate Officer

2009 Corporate Auditor (to present)



Tsuguoki Fujinuma

Corporate Auditor

1974 Registered as a certified public accountant (to present) 1991 Representative Partner of Asahi Shinwa & Co.

1993 Representative Partner, Showa Ota & Co.

(currently Ernst & Young ShinNihon) Chairman and President of the

Japanese Institute of Certified Public Accountants

2008 Outside Corporate Auditor of the Company (to present) 2008 Outside Corporate Auditor of Sumitomo Corporation

(to present)

2008 Outside Director of Nomura Holdings, Inc. (to present)

2008 Outside Director of

Sumitomo Life Insurance Company (to present) 2010 Outside Corporate Auditor of

Seven & i Holdings Co., Ltd. (to present)

2010 Vice-Chairman, IFRS Foundation Trustees (to present)

Note: Corporate auditors Tsuquoki Fujinuma and Shiro Kuniya are Outside Corporate Auditors as provided in Article 2, Item 16 of the Companies Act of Japan.



Shiro Kuniya

Corporate Auditor

1982 Registered as an attorney-at-law (Osaka Bar Association) 1982 Joined Oh-Ebashi Law Offices

1987 Registered as an attorney-at-law

at New York Bar Association
1997 Outside Corporate Auditor, Sunstar Inc.

2002 Managing Partner, Oh-Ebashi LPC & Partners (to present)

2006 Outside Corporate Auditor, NIDEC CORPORATION 2011 Chairman, Inter-Pacific Bar Association

2012 Outside Director, NEXON Co., Ltd. (to present)
2012 Outside Director, EBARA CORPORATION (to present)

2013 Outside Director, Sony Financial Holdings Inc.

2013 Outside Corporate Auditor of the Company (to present)

#### Corporate Officers

#### Haruhiko Hirate

Senior Vice President, Head of North Asia

#### Nancy Joseph-Ridge, M.D.

General Manager, Pharmaceutical Development Division

#### Anna Protopapas

President, Millennium Pharmaceuticals, Inc. Executive Vice President, Global Business Department, Takeda Pharmaceuticals International, Inc.

#### Trevor Smith

Chief Executive Officer, Takeda Pharmaceuticals Europe Limited Head of Europe and Canada Commercial Operations, Takeda Pharmaceuticals International GmbH

#### Tadao Hirouchi

Vice President, Pharmaceutical Marketing Division

#### Douglas Cole

President, Takeda Pharmaceuticals U.S.A., Inc.

#### David Osborne

Senior Vice President, Global HR Officer

#### Junichi Handa

Senior Vice President, Human Resources Department

#### Tetsuyuki Maruyama, Ph.D.

General Manager, Pharmaceutical Research Division

#### Takeda Global Advisory Board (TGAB)\*

Outside Advisors

#### Karen Katen

Former Vice Chairman of Pfizer Inc. and currently Senior Advisor for Essex Woodlands Health Ventures

#### Sidney Taurel

Former Chairman and CEO of Eli Lilly and Company and currently Chairman Emeritus of Eli Lilly and Company

#### Bruno Angelici

Former Executive Vice President, International, AstraZeneca plc and currently Chairman of Vectura Group plc

#### William W. Chin, M.D.

Former Executive Dean of Harvard Medical School, and currently Executive Vice President of Science and Regulatory Affairs, PhRMA

 The Takeda Global Advisory Board (TGAB) is a body comprised of four external advisors with executive-level experience at global pharmaceutical companies.
 The TGAB conducts vigorous exchanges of opinion with management about various management issues.

As of June 30, 2014

Our Corporate Philosophy begins with Takeda-ism, and brings together the highest ethical standards and a strong sense of mission that is kept alive in our management activities.

#### **Mission**

We strive towards better health for people worldwide through leading innovation in medicine.

#### Vision 2020

## Better Health, Brighter Future

For more than 230 years, we have been serving society with innovative medicines and helping patients reclaim valuable moments of life from illness. Now, with new healthcare solutions from prevention to care and cure, we are determined to help even more people enjoy their lives to the fullest.

We continue to transform the future of healthcare by unifying our strengths as "Global One Takeda." We are

a diverse organization committed to working with local communities to fully understand their needs and deliver industry-leading solutions with a sense of urgency, dedication and unparalleled efficiency.

Our passion for healthcare and commitment to improving lives will enable us to make the next 230 years healthier and brighter for people around the world.

Committed to Improving Health

Our Organization
Strength
from Diversity

Our People
Powered
by Passion

#### **Takeda-ism and Values**

Takeda-ism is the unchanging set of **core values** that guides all our activities. We pledge to act with **Integrity**—comprising **Fairness**, **Honesty** and **Perseverance**—at all times, especially when facing difficulties or challenges.

In our day-to-day work, we focus on the following **values** while upholding the highest ethical standards:

- Diversity
- · Teamwork
- Commitment
- · Transparency
- · Passion
- · Innovation





# Creating Corporate Value

through the Pharmaceutical Business

Taking on the challenge of developing innovative pharmaceutical products

– that is the role Takeda is committed to fulfill for the sake of people worldwide.

We will continue to diligently create pharmaceutical products, guided by the philosophy of Takeda-ism.

- 30 R&D
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- 34 R&D Pipeline Current Status of Major Pipeline Drugs
- 37 In-Licensing and Alliance Activities
- 38 Production and Supply Chain
- 39 Quality Management System
- 40 Marketing

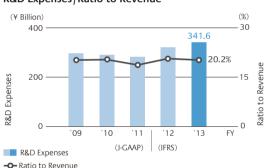
We will focus on activities to obtain new drug approvals quickly for our rich late-stage pipeline, as we continue to refine our global R&D organization.

#### **Achievements in Fiscal 2013**

Takeda steadily implemented its strategies to improve R&D productivity and, in terms of measurement, substantially exceeded all of its value creation goals for fiscal 2013 as measured by progress in the development of pipeline assets and the number of regulatory filings and approvals. The main achievements by core therapeutic area were as follows.

In the Cardiovascular & Metabolic area, in July 2013, Takeda obtained an Import Drug License from the China Food and Drug Administration for *NESINA* (alogliptin) for the treatment of type 2 diabetes, and in September 2013, marketing authorization was granted by the European Commission for *VIPIDIA*,\*1 *VIPDOMET*,\*2 and *INCRESYNC*.\*3 In addition, in March 2014, Takeda filed a New Drug Application (NDA) in

R&D Expenses/Ratio to Revenue



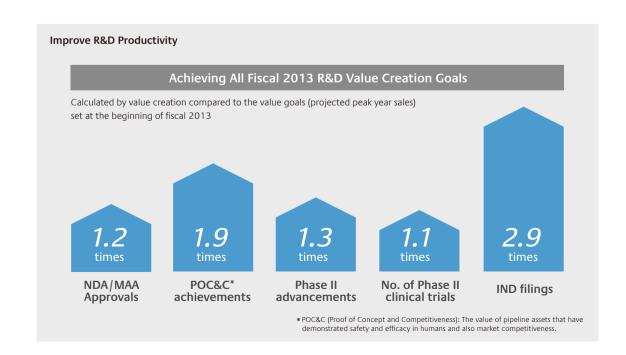
Japan for the once-weekly type 2 diabetes treatment SYR-472 (trelagliptin).

In Oncology, in January 2014 Takeda obtained NDA approval in Japan for *ADCETRIS* (brentuximab vedotin) for the treatment of malignant lymphoma.

In the Central Nervous System area, in September 2013 Takeda obtained approval in the U.S. for *BRINTELLIX* (vortioxetine) for the treatment of major depressive disorder. In addition, in March 2014 Marketing Authorisation was granted by the European Commission for atypical antipsychotic *LATUDA* (lurasidone) for the treatment of schizophrenia.

In General Medicine, positive opinions were issued for the approval of *ENTYVIO* (vedolizumab) for the treatment of ulcerative colitis and Crohn's disease in a December 2013 advisory committee meeting of a joint panel of members from the U.S. Food and Drug Administration, and in a March 2014 meeting of the Committee for Medicinal Products for Human Use of the European Medicines Agency. In May 2014, Takeda received permission to market the treatment in both the U.S. and EU. In Japan, in February 2014, Takeda submitted an NDA for TAK-438 (vonoprazan) for the treatment of acid-related diseases.

In Vaccines, Takeda acquired Inviragen, Inc. in May 2013, thereby expanding its pipeline assets including a vaccine for dengue fever. In March 2014, Takeda



20.2%

R&D expenses / ratio to revenue (fiscal 2013)

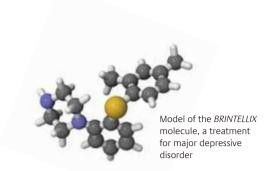
obtained NDA approval in Japan for cell-cultured influenza vaccine H5N1 "TAKEDA" 1mL and cell-cultured influenza vaccine (prototype\*4) "TAKEDA" 1mL for the prevention of pandemic influenza to be manufactured in the Hikari Plant.

- \*1 Japan and U.S. product name: NESINA
- \*2 U.S. product name: KAZANO (fixed-dose combination of NESINA with metformin)
- \*3 Japan product name: LIOVEL, U.S. product name: OSENI (fixed-dose combination of NESINA with ACTOS)
- \*4 To facilitate registration of a vaccine for use in the event of a pandemic caused by an influenza strain other than H5N1

#### Consolidation of the Global R&D Network

To build a more robust and efficient operating model, Takeda is rationalizing its business operation structure by consolidating its R&D facilities.

In May 2013, the R&D functions of Millennium Pharmaceuticals were integrated with Takeda's global R&D organization under the CMSO. In August 2013, Takeda concluded an agreement with its whollyowned subsidiary, Takeda Bio Development Center Limited, to transfer Takeda Bio's development activities to the Japan Development Center. It was decided that after the completion of the transfer in April 2014, Takeda Bio would be dissolved. We also reached an agreement to consolidate R&D facilities in Europe.



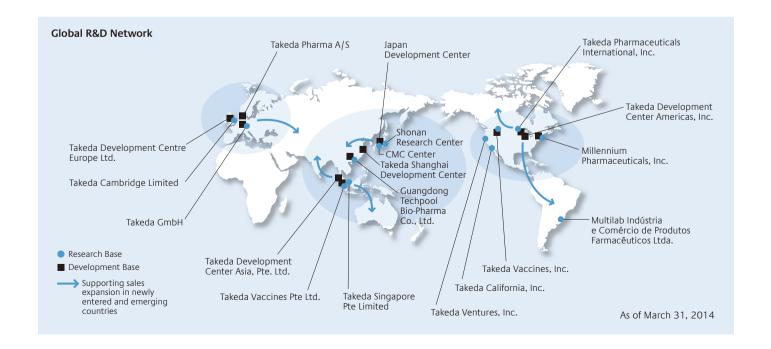
We are committed to achieving our goals under Project Summit and are taking bold and transformative steps to make every one of our R&D functions more efficient and competitive.

#### **Promotion of In-Licensing and Alliances**

Takeda uses in-licensing and R&D alliances to reinforce the pipeline as an important strategy for complementing in-house R&D activities.

Over the past year, we have obtained marketing approval for several in-licensed assets, including the aforementioned *ADCETRIS* (in-licensed from Seattle Genetics), *BRINTELLIX* (in-licensed from Lundbeck), and *LATUDA* (in-licensed from Sumitomo Dainippon Pharma). We have also progressed the development of other in-licensed assets, including TAK-816 for prevention of infectious disease caused by Haemophilus influenza type b (Hib) (in-licensed from Novartis), and an extended release formulation of *ULORIC* (febuxostat) (in-licensed from Teijin).

See → P.37 In-Licensing and Alliance Activities



We will work to create new corporate value by promoting the global vaccine business, pursuing innovative technologies to develop new products, and strengthening our IP strategies.

#### Vaccine Business

#### **Building a Global Vaccine Business**

Takeda established the Vaccine Business Division in January 2012 to expand its contributions to public health from Japan to the rest of the world. Through the Vaccine Business Division, we are developing new vaccines that address important unmet medical needs in global public health, building upon the vaccine business we have successfully operated in Japan for more than 60 years. We have expanded our pipeline through acquisitions of LigoCyte Pharmaceuticals, Inc. and Inviragen, Inc., and are advancing their promising vaccine candidates against dengue and norovirus, both of which are responsible for a significant burden of disease around the world. Takeda will continue to work through the vaccine business to contribute to better global public health, disease prevention, and improved access to healthcare.

See → P.22 CSR Strategy

200,000

Number of people who die from norovirus each year around the world

Source: Patel MM, et al. Systematic literature review of role of noroviruses in sporadic gastroenteritis. Emerg Infect Dis. 2008;14:1224–31.



Computer-generated image of the norovirus

400m

Number of people worldwide infected with dengue virus each year Source: Centers for Disease Control and Prevention

http://www.cdc.gov/dengue/

#### **Norovirus Vaccine**

During Infectious Disease (ID) Week in October 2013, Takeda announced results of Phase II trials of its norovirus vaccine candidate. The trials demonstrated for the first time that the norovirus vaccine was able to reduce symptoms in test subjects who had been administered the most commonly occurring norovirus genotype. We believe that if the clinical trials continue to be successful and all regulatory requirements are met, Takeda's norovirus vaccine could be the first of its kind on the market.

#### **Dengue Vaccine**

In May 2013, Takeda acquired Inviragen, Inc., bringing various promising vaccine candidates into Takeda's pipeline, including a tetravalent dengue vaccine.

Dengue is the most important mosquito-borne viral illness in the world, and is one of four World Health Organization future vaccine priorities. TAK-003 is a recombinant vaccine that targets all four strains of the virus, and is built on the genetic backbone of the dengue type 2 virus, which is an important dengue strain in many parts of the world. TAK-003 is currently being evaluated in Phase II studies.

#### **Hib Vaccine**

Takeda has submitted a New Drug Application (NDA) in Japan for TAK-816, a vaccine against infections caused by Haemophilus influenzae type b (Hib). TAK-816 is licensed from Novartis. Hib meningitis can be fatal or have long-term health effects; however, these outcomes are preventable through immunization. The vaccine is expected to provide a new option for Hib vaccination in Japan.

#### Pandemic Influenza Vaccine

In March 2014, Takeda obtained approval for cell-cultured influenza vaccine H5N1 "TAKEDA" 1mL and cell-cultured influenza vaccine (prototype\*) "TAKEDA" 1mL, for prevention of pandemic influenza. The vaccines were developed jointly with Baxter International Inc. In April 2014, Takeda was selected as a recipient of a supplemental subsidy from the Japanese Government to expand production capacity for its cell-cultured pandemic influenza vaccine.

\* To facilitate registration of a vaccine for use in the event of a pandemic caused by an influenza strain other than H5N1.

#### Varicella Vaccine

In January 2014, Takeda entered into an agreement with the Research Foundation for Microbial Diseases of Osaka University for the sale of its *BIKEN* freezedried live attenuated varicella vaccine in Japan, and launched the vaccine in February. The varicella vaccine's importance is increasingly recognized by public health authorities, and it is planned to include varicella vaccination in the national routine immunization program in Japan in autumn 2014.

#### Other Vaccines Currently under Development in Japan

Our work on vaccines for the Japanese market is focused on infectious diseases affecting children and adults. Currently, our vaccine development program includes TAK-361S, which is a quadruple combination vaccine including an inactivated poliovirus vaccine to help support the global eradication of polio, and the Kanda HPV (human papillomavirus) vaccine.

#### CMC Center

**CMC** Research

CMC (Chemistry,

Manufacturing and

Controls) research is a

comprehensive approach

to supporting compound

characterization, process

development, pharmaceu-

quality control, and quality

assurance. CMC efforts

include the research and

innovative approaches to

manufacturing methods,

the planning of formula-

supply chain management,

analytical testing methods.

tical manufacturing.

implementation of

pharmaceutical

tions, packaging development, clinical

and the design of

#### **Establishing a Global CMC Structure**

The Chemistry, Manufacturing and Controls (CMC) Center's mission is to maximize product value to patients through our innovative CMC technologies and operational excellence. The CMC Center seeks to establish platform technologies that add value to Takeda products, and to develop new technologies in-house or through partnerships to ensure that CMC continues to provide value in the future.

We have developed a function-based global organization and operational model that integrates the functions of the entire global CMC framework. Our headquarters are based in Osaka, Japan where the global heads of the Chemical Development Laboratories, the Pharmaceutical Technology R&D Laboratories, and the Analytical Development Laboratories are located. We also have established Hikari Bio-Manufacturing Technology Laboratories, an antibody drug substance manufacturing site, in Hikari, Yamaguchi Prefecture.

Overseas sites include the Cambridge Biologics CMC Group, the Chicago Pharmaceutical Science Group, Takeda Boston Pharmaceutical Sciences, Takeda-California CMC Group and the Innovation Technology Laboratories located in the U.S. We also have staff located in Singen (Germany) and London (U.K.). All CMC research and development activities are driven forward through the combined efforts of global functions and local site staff.

#### Intellectual Property

## Intellectual Property Protecting Takeda's Business

The Intellectual Property department supports the business of the Group by protecting scientific ideas and inventions using patents, goodwill capitalized in product brands using trademark rights, and also by promoting the proper usage of such intellectual property (IP) rights.

It is generally assumed that patent protection of pharmaceutical products is achieved solely by a basic substance patent covering the original new active ingredient. In fact, a medicine relies on a patent portfolio that protects not only the ingredient, but also its use, manufacturing process, formulation,

production intermediates, any related derivatives, and the methods for evaluating biomarkers. The IP department strives to effectively manage all of these patent portfolios.

Takeda's IP operations must also address the important issue of how to construct patent portfolios to protect new businesses based on new state-of-the-art technologies developed in recent years, including regenerative medicine, cell-based therapies and gene therapy. In addition, there has been an increase in the importance of companion diagnostics using biomarkers, and addressing this topic has become an important new issue for IP in the pharmaceutical industry.

#### Helping to Realize the Mid-Range Growth Strategy

The IP department aims to help realize the Mid-Range Growth Strategy by supporting Takeda's increasingly global business activities, specifically by ensuring appropriate protection of the Group's scientific ideas and inventions, and the goodwill of its products. At present, the IP department has offices in Japan (Tokyo and Shonan), Chicago, San Diego, Boston, Cambridge (U.K.) and Zurich. Each member of these teams supports Takeda's business in their respective regions, and we are also constructing an organization capable of operating on a global scale under a shared management policy and strategy as a global IP department. In terms of external activities, we are actively conveying our opinions regarding revisions to legal systems through a range of external organizations, so as to quickly respond to increasingly borderless IP regulatory systems worldwide surrounding the company's business. Global IP activities organized in this way support the Group's entire business from R&D to sales and marketing by focusing on the three key tasks defined below.

- [1] Enhancement of the product portfolio and R&D pipeline and protection of related rights
- [2] Facilitation of more dynamic and appropriate in-licensing and out-licensing activities through partner alliance support
- [3] Securing and protection of IP rights around the world

For further details about Takeda's intellectual property, please see the CSR Data Book

https://www.takeda.com/csr/reports/

Pipeline Drugs (Phase II and above: Overview) The indications are mainly those for which Takeda will actively pursue approval.

Development Code Generic Name Brand Name Indications Brand Name Indications

| Development Code   | Generic Name                      | Brand Name          | Indications   | Stage of Development Phase I   Phase II   Phase III   Filed   Appro |
|--------------------|-----------------------------------|---------------------|---|---|
| Cardiovascular &   | Metabolic                         |                     |   |   |
| SYR-322            | alogliptin benzoate               | NESINA, etc.        | Diabetes mellitus   |   |
|                    |                                   |                     | Diabetes mellitus (Fixed-dose combination with pioglitazone)  |   |
|                    |                                   |                     | Diabetes mellitus (Fixed-dose combination with metformin)   |   |
| ATL-962            | cetilistat                        |                     | Obesity   |   |
| TAK-536            | azilsartan                        | AZILVA              | Hypertension (Fixed-dose combination with amlodipine besilate)  |   |
| Contrave®          | naltrexone SR/bupropion SR        | CONTRAVE            | Obesity   | U   |
| SYR-472            | trelagliptin succinate            |                     | Diabetes mellitus   |   |
|                    |                                   |                     |   |   |
| Central Nervous    | -                                 |                     |   |   |
| ∟u AA21004         | vortioxetine                      | BRINTELLIX          | Major depressive disorder   | ,   |
|                    |                                   |                     | Generalized anxiety disorder  | U   |
| urasidone          | lurasidone hydrochloride          | LATUDA              | Schizophrenia   |   |
|                    |                                   |                     | Bipolar disorder  | E   |
| TAK-375SL          | ramelteon                         | ROZEREM             | Bipolar disorder (sublingual formulation)   | U   |
| AD-4833/TOMM40     |                                   |                     | Delay of onset of mild cognitive impairment due to Alzheimer's disease  | U/E   |
| mmunology & Re     | espiratory                        |                     |   |   |
| JLORIC®            | febuxostat                        | ULORIC              | Hyperuricemia and gout (Extended-release formulation)   | U   |
| MT203              | namilumab                         |                     | Psoriasis   | E   |
|                    |                                   | 1                   |   |   |
| General Medicine   | 2                                 |                     |   |   |
| TAK-390MR          | dexlansoprazole                   | DEXILANT            | Erosive esophagitis (healing and maintenance) and non-erosive gastro-esophageal reflux disease  |   |
| \G-1749            | lansoprazole                      | TAKEPRON, etc.      | Fixed-dose combination with low-dose aspirin  |   |
| MLN0002            | vedolizumab                       | ENTYVIO             | Ulcerative colitis  | J I   |
|                    |                                   |                     | Crohn's disease   | J I   |
| Feraheme®/Rienso®  | ferumoxytol                       | FERAHEME/<br>RIENSO | Iron deficiency anemia from all causes in patients who have a history of unsatisfactory oral iron therapy or in whom oral iron cannot be used | E   |
| ΓAK-438            | vonoprazan                        |                     | Acid-related diseases (GERD, Peptic ulcer, etc.)  | J.  |
|                    | fomepizole                        |                     | Ethylene glycol and methanol poisonings   | J.  |
| AMITIZA®           | lubiprostone                      | AMITIZA             | Liquid formulation  | U   |
|                    |                                   |                     | Pediatric functional constipation   | U   |
| TAK-385            | relugolix                         |                     | Endometriosis   |   |
|                    |                                   |                     | Uterine fibroids  | J J   |
| TAK-114            |                                   |                     | Ulcerative colitis  |   |
| Vaccina            | 1                                 |                     |   |   |
| Vaccine            |                                   |                     |   |   |
| BLB-750            |                                   |                     | Prevention of pandemic influenza  |   |
| ГАК-816            |                                   |                     | Prevention of infectious disease caused by Hib  | ,   |
| TAK-361S           |                                   |                     | Prevention of infectious disease caused by Diphtheria, Pertussis, Tetanus, Polio  | 1   |
| ΓΑK-003            |                                   |                     | Prevention of dengue fever caused by dengue virus   |   |
| Norovirus vaccine  |                                   |                     | Prevention of acute gastroenteritis (AGE) caused by norovirus   |   |
| TAK-850            |                                   |                     | Prevention of influenza disease caused by influenza virus   |   |
|                    |                                   |                     | subtype A and B contained in the vaccine  |   |
| Oncology           |                                   |                     |   |   |
| Oncology<br>SGN-35 | brentuximab vedotin               | ADCETRIS            | Relapsed or refractory Hodgkin lymphoma   |   |
| 10N-22             | PIEHRAVIIIAD AGGORIII             | ADCEINIS            | Relapsed or refractory modgkin lymphoma  Relapsed or refractory anaplastic large cell lymphoma  |   |
|                    |                                   |                     | Relapsed cutaneous T-cell lymphoma  |   |
|                    |                                   |                     | 7 1   | E F   |
|                    |                                   |                     | Post-ASCT Hodgkin lymphoma  |   |
|                    |                                   |                     | Front line Hodgkin lymphoma   | J/E   |
| FAD 144 CD         | louprorolin acetata               | I ELIDIINI a+-      | Front line mature T-cell lymphoma   | J/E   |
| TAP-144-SR         | leuprorelin acetate<br>bortezomib | VELCADE             | Prostate cancer and premenopausal breast cancer (6-month formulation)   |   |
| /ELCADE®           | DOLLEZOTTID                       | VELCADE             | Front line mantle cell lymphoma   | U   |
| ALNOZOO            | ivazomih                          |                     | Relapsed diffuse large B-cell lymphoma  | U   |
| MLN9708            | ixazomib                          |                     | Previously untreated multiple myeloma   | J/U/E   |
|                    |                                   |                     | Relapsed or refractory multiple myeloma   | J/U/E   |
|                    | 12                                |                     | Relapsed or refractory primary (AL) amyloidosis   | U/E   |
| MLN8237            | alisertib                         |                     | Relapsed or refractory peripheral T-cell lymphoma   | U/E   |
|                    |                                   |                     | Small cell lung cancer, ovarian cancer  | U/E   |
|                    | motesanib diphosphate             |                     | Advanced non-squamous non-small cell lung cancer  | J. Company  |
| AMG 386            | trebananib                        |                     | Ovarian cancer  |   |
| TAK-385            | relugolix                         |                     | Prostate cancer   | U   |
| MLN0128            |                                   |                     | Breast cancer   | U   |

For further details on the status of the development pipeline, please see Takeda's website

J: Japan, U: U.S., E: Europe

# 9-17

The number of years required for development of a new drug, from basic research to approval

Source: Pharmaceutical Industry Textbook 2014-2015 (Japan Pharmaceutical Manufacturers Association)

### **Current Status of Major Pipeline Drugs**

### Cardiovascular & Metabolic

Treatment for Type 2 Diabetes: SYR-322 (alogliptin benzoate)

(U.S./Europe/Japan: Approved)

Originally discovered by Takeda California, Inc., SYR-322 treats type 2 diabetes by inhibiting the action of the DPP-4\*1 enzyme. SYR-322 obtained regulatory approval in Japan in April 2010, the U.S. in January 2013, and Europe in September 2013, and was launched under the brand name NESINA.\*2 Takeda is continuing development activities and submission toward regulatory approvals in emerging markets.

- \*1 DPP-4 breaks down glucagon-like peptide-1 (GLP-1), a hormone that stimulates the secretion of insulin.
- \*2 Marketed as VIPIDIA in Europe

# Treatment for Type 2 Diabetes: SYR-472 (trelagliptin succinate) (Japan: Filed)

SYR-472 is a once-weekly DPP-4 inhibitor that is anticipated to be a new treatment option for patients who require more effective control of their blood glucose levels. In March 2014, Takeda filed a New Drug Application in Japan.

### **Central Nervous System**

Treatment for Major Depressive Disorder: Lu AA21004 (vortioxetine) (U.S.: Approved, Japan: Phase III)

In-licensed from H. Lundbeck A/S of Denmark, Lu AA21004's mechanism of action is different from antidepressants that are currently available. Lu AA21004 obtained regulatory approval in the U.S. in September 2013 and was launched under the brand name *BRINTELLIX*. Lu AA21004 is currently in Phase III in Japan.

# Atypical Antipsychotic: lurasidone hydrochloride (Europe: Approved)

Lurasidone is an atypical antipsychotic created by Sumitomo Dainippon Pharma Co., Ltd. of Japan. It received regulatory approval by Swissmedic in August 2013 and by the European Commission in March 2014 for the treatment of schizophrenia in adult patients. Lurasidone is also in Phase III in Europe for Bipolar disorder.

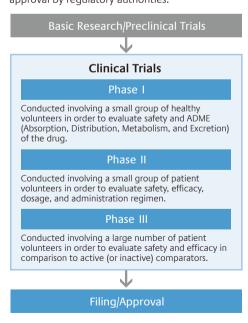
### **Immunology & Respiratory**

# Treatment for Hyperuricemia and Gout: febuxostat XR (U.S.: Phase III)

Discovered by Teijin Pharma Limited, febuxostat is a treatment for hyperuricemia in patients with gout. It is marketed in the U.S. under the brand name *ULORIC*. Febuxostat XR has been developed as an extended-release formulation to increase user convenience, and is currently undergoing Phase III clinical trials in the U.S.

### **R&D** Pipeline

The R&D pipeline means drugs under development, from the start of research through approval and launch. Clinical trials are conducted in humans for drugs for which basic research and preclinical trials have been completed. Medicines that have undergone safety and efficacy evaluation via three phases of clinical trials are launched onto the market as new drugs after approval by regulatory authorities.



See → P.54 Human Rights P.67 Compliance

# 8.2m

Deaths worldwide due to cancer (2012)

Source: World Cancer Report 2014 (International Agency for Research on Cancer)

### **General Medicine**

### Treatment for Ulcerative Colitis and Crohn's Disease: MLN0002 (vedolizumab) (U.S./ Europe: Approved, Japan: Phase III)

Developed by Millennium Pharmaceuticals, MLN0002 is a monoclonal antibody against  $\alpha 4 \beta 7$  integrin.\* In May 2014, Takeda obtained regulatory approval in the U.S. and Europe for the treatment of ulcerative colitis and Crohn's disease. It is currently undergoing Phase III clinical trials in Japan.

\*  $a4\beta$ 7 integrin is a protein present on the surface of lymphocytes and is involved in immunological reaction in the intestinal tract.

# Treatment for Acid-Related Diseases: TAK-438 (vonoprazan) (Japan: Filed)

TAK-438 is an in-house developed potassium-competitive acid blocker (P-CAB) that suppresses gastric acid secretion by inhibiting the binding of potassium ions to the proton pump.\* It has a different mechanism of action from proton pump inhibitors (PPIs). In February 2014, Takeda filed a New Drug Application in Japan.

 Proton pump: an enzyme that functions in the final stages of acid secretion in gastric parietal cells.

### Vaccine

### Influenza Vaccine BLB-750 (Japan: Approved)

BLB-750 is a cell culture-based pandemic influenza vaccine developed using cell culture technology licensed from Baxter International Inc. of the U.S. The vaccine was granted approval in Japan in March 2014. The vaccine will be manufactured at a newlyestablished facility at Takeda's Hikari Plant that was partially funded by a subsidy from the Japanese Government.

### Hib Vaccine TAK-816 (Japan: Filed)

In-licensed from Novartis AG of Switzerland, TAK-816 is a vaccine for the prevention of infections caused by Haemophilus influenzae type b (Hib), one of the most significant causes of pneumonia, meningitis, and otitis in children. In September 2013, Takeda filed a New Drug Application in Japan.

### Norovirus Vaccine (Phase II)

The norovirus vaccine developed by LigoCyte (currently Takeda Vaccines, Inc.) is designed to cover a broad range of genetic strains of norovirus, a leading cause of acute gastroenteritis in adults and children around the globe. A vaccine for norovirus does not currently exist. Phase II studies of an intramuscular formulation are in progress.

### Oncology

# Treatment for Lymphoma: SGN-35 (brentuximab vedotin) (Europe/Japan: Approved)

In-licensed from Seattle Genetics, Inc. of the U.S., the anti-cancer agent SGN-35 is an antibody-drug conjugate that targets the CD30 antigen expressed by some tumor cells. SGN-35 obtained regulatory approval in Europe in October 2012 and Japan in January 2014 for relapsed/refractory Hodgkin lymphoma and relapsed/refractory anaplastic large cell lymphoma,\* and was launched under the brand name ADCETRIS. Takeda is currently conducting several additional trials to expand the approved indications.

\* In Europe, relapsed/refractory systemic anaplastic large cell lymphoma

# Treatment for Multiple Myeloma: MLN9708 (ixazomib) (U.S./Europe/Japan: Phase III)

Discovered by Millennium, MLN9708 builds on our leadership in proteasome inhibition that began with *VELCADE*. MLN9708 is the oral proteasome inhibitor in the furthest stage of development, and it is currently in Phase III clinical trials for relapsed/refractory and previously untreated multiple myeloma and relapsed/refractory primary (AL) amyloidosis in Japan, the U.S., and Europe. Takeda is also investigating MLN9708 in a broad range of other cancers.

### In-Licensing and Alliance Activities

# Advances in In-Licensing and Alliance Activities from April 2013 Onward

### Zinfandel Pharmaceuticals, Inc. (U.S.)

• In August 2013, Takeda initiated a Phase III clinical trial for AD-4833 (pioglitazone)/TOMM40, which uses the TOMM40 biomarker for Alzheimer's disease, in-licensed from Zinfandel.

### Sumitomo Dainippon Pharma Co., Ltd. (Japan)

- In August 2013, Takeda obtained approval from Swissmedic in Switzerland for the atypical antipsychotic *LATUDA* (lurasidone), which is in-licensed from Sumitomo Dainippon Pharma.
- In March 2014, the European Commission granted Marketing Authorisation for *LATUDA*.

### H. Lundbeck A/S (Denmark)

• In September 2013, Takeda obtained marketing approval from the U.S. FDA for *BRINTELLIX* (vortioxetine), a treatment for major depressive disorder in-licensed from Lundbeck, and launched it in January 2014.

### Novartis AG (Switzerland)

 In September 2013, Takeda submitted an NDA in Japan for Haemophilus influenzae type b vaccine TAK-816, which Takeda in-licensed from Novartis.

### Natrogen Therapeutics International, Inc. (U.S.)

• In December 2013, Takeda entered an agreement with Natrogen to acquire an exclusive license to develop Natrogen's Natura-alpha compound (currently TAK-114) for treatment of ulcerative colitis, as well as an option to acquire Natrogen. TAK-114 is currently in Phase II.

### Tri-Institutional Therapeutics Discovery Institute, Inc. (Tri-I-TDI) (U.S.)

• In October 2013, Takeda partnered with Tri-I-TDI, a novel collaboration of academic institutions (Memorial Sloan-Kettering Cancer Center, The Rockefeller University and Weill Cornell Medical College). This industry-academic partnership will combine the spirit of innovation in academia with the resources and talents of industry to expedite early-stage drug discovery into innovative treatments and therapies for patients.

For further details on in-licensing and alliance activities, please see Takeda's website http://www.takeda.com/partnership/

### Paladin Labs Inc. (Canada)

• In December 2013, Takeda submitted an NDA in Japan for fomepizole, which Takeda in-licensed from Paladin Labs for the treatment for ethylene glycol and methanol poisonings. Fomepizole is one of the compounds that the Ministry of Health, Labour and Welfare requested pharmaceutical companies to develop in Japan in accordance with the result of the conference "Unapproved New Drugs and New Indications with High Medical Needs." Takeda received a grant for development expenditures of the drug from the Pharmaceutical Development Support Center.

### Seattle Genetics, Inc. (U.S.)

• In January 2014, Takeda received regulatory approval in Japan for *ADCETRIS* (brentuximab vedotin), which Takeda in-licensed from Seattle Genetics for treatment of malignant lymphoma, and launched it in April 2014.

### Trianni, Inc. (U.S.)

• In March 2014, Takeda entered into a license agreement with Trianni for the use of the "Trianni Mouse," a monoclonal antibody discovery platform. The agreement allows Takeda to access Trianni's next generation transgenic mouse platform for the generation of human monoclonal antibodies against disease targets in all therapeutic areas Takeda is pursuing.

### Baxter International Inc. (U.S.)

- In March 2014, Takeda received regulatory approval in Japan for cell-cultured influenza vaccine H5N1 "TAKEDA" 1mL and cell-cultured influenza vaccine (prototype\*) "TAKEDA" 1mL for prevention of pandemic influenza, to be manufactured in the Hikari Plant using technologies that Takeda in-licensed from Baxter.
- \* To facilitate registration of a vaccine for use in the event of a pandemic caused by an influenza strain other than H5N1.

### Teva Pharmaceutical Industries Ltd. (Israel)

 In April 2014, Takeda entered into an agreement with Teva, for commercializing Teva's Parkinson's disease treatment rasagiline in Japan.
 Takeda will develop rasagiline tablets for the Japanese market and submit an NDA for registration of the product in Japan.

### MacroGenics (U.S.)

• In May 2014, Takeda entered into an option agreement with MacroGenics for the development and commercialization of MGD010, a product candidate currently in preclinical development for the treatment of autoimmune diseases.

As of June 30, 2014

### Partner's Voice



The Tri-Institutional Therapeutics Discovery Institute (Tri-I TDI) is an unprecedented collaboration established to enhance discovery and translational research for the betterment of human health. The collaboration includes Weill Cornell Medical College, Memorial Sloan-Kettering Cancer Center and The Rockefeller University with Takeda as the industry partner.

Tri-I TDI will build a stronger bridge between early-stage research discoveries and the development of new diagnostic and therapeutic agents for a number of diseases that afflict both the developing and Western world.

The partnership with Takeda is initially focused on developing small chemical molecules, and we are very excited to have medicinal chemists and pharmacologists from Takeda bringing their private sector experience to the academic setting by helping to conduct drug discovery research in the institute's laboratories.

### Michael A. Foley, Ph.D.

Sanders Director, Tri-Institutional Therapeutics Discovery Institute & The Sanders Innovation and Education Initiative

### **Production and Supply Chain**

We are accelerating measures to strengthen our global production and supply chain functions as part of our effort to build a robust and efficient operating model.

# Strengthening the Global Production and Supply Chain Network

In order to respond to the rapid geographical expansion of its sales activities, Takeda is taking steps to strengthen its global production and supply chain network and quality assurance system. In July 2014, we established the position of Global Manufacturing Officer (GMO) and appointed Dr. Thomas Wozniewski, who has accumulated abundant experience in a global pharmaceutical corporation. The GMO will work closely with the global leadership teams in production and supply chain divisions to drive forward Takeda's global manufacturing strategy.

Takeda currently has 27\* production sites in 18 countries and supply chain operations on a global scale, and the GMO will be responsible for all of Takeda's manufacturing facilities, including the Osaka and Hikari plants in Japan. Looking ahead, the GMO will lead our efforts to maximize the capability of our global production network, further reduce costs through global procurement of raw materials, and more effectively integrate and increase the efficiency of our global supply chain.

 Takeda plans to close the Roskilde Plant in Denmark and the Elverum Plant in Norway by early 2015.

See → P.61 Global Purchasing Incorporating CSR

18
Number of countries where Takeda has production sites







### **Quality Management System**

For patients who take our high-quality products around the world, Takeda is establishing a comprehensive quality management system to meet the requirements and expectations of a global pharmaceutical company, recognizing that safety takes priority over everything in this industry.

# Establishing and Operating the New Quality Management System

Takeda is taking steps to support the rapid globalization of its business. As part of this, under the initiative of the Global Quality Assurance Department (GQAD), Takeda has combined existing quality management systems and established a next generation system suitable for the needs of a global pharmaceutical company.

GQAD has established document architecture to show the concept of a quality management system, including risk management and crisis management, placing "Takeda Corporate Quality Policy" as a top document. GQAD is calling for the entire Group to comply with the system.

GQAD, as a cornerstone of quality assurance of Takeda, is responsible for dissemination of the quality management system to Group companies, while seriously reviewing the system for further improvement by diligently assessing the status of compliance through internal audits and other relevant measures.

**Global Quality Assurance** President & COO Structure of Takeda GOAD Cross Functional Risk and Crisis Management **Audit and Monitoring** and Coaching Information/Intelligence • TRIP • Database construction QA Dept **QA** Dept **QA** Dept **QA** Dept and operation GCP Initiative • Religious and Cultural **GDP** Points of Attention • Global Recall Anti-Counterfeit Develop-Manufac-• Nuclear Reactor Risk Marketing Research turing · Supply Chain Management

Applicable Regulations: GLP, GCP, GPP, GMP, GDP

Risk Management as a Part of Ouality Assurance Activities

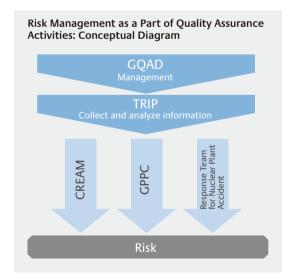
As a part of quality assurance activities, Takeda is establishing a risk management system on a global scale by promoting the Takeda Risk Intelligence Program (TRIP). The purpose of this program is to centrally collect information on risks that could affect quality assurance of Takeda products, such as pharmaceutical regulations, religion and culture,

counterfeit medicines and nuclear reactors, and convert it to intelligence. Based on the intelligence created by TRIP, potential risks associated with plans for expansion into new territories and clinical trials in emerging and developing countries have been identified so far.

### Types of Risks Handled by TRIP

- Legislative changes in manufacturing, quality and import and export
- Impacts of Halal\*
- Counterfeiting
- Cargo theft, theft of products
- Illegal diversion
- Corruption including bribery
- Actions, campaigns and threats against pharmaceutical companies and executives
- Cultural, religious, and other social actions that could negatively impact Takeda's reputation
- \* Halal is the word used to describe compliance with Islamic law.

If a significant risk is identified, Takeda will take an immediate countermeasure against it. For instance, religious and cultural points of attention represented by Halal are being controlled by a cross-functional team, the Council for Risk Evaluation And Mitigation (CREAM). Furthermore, as counterfeit drugs have become a major issue worldwide, the Global Product Protection Committee (GPPC) has given careful consideration to the individual risk profiles of each product and each region by utilizing TRIP and taken steps to strengthen our global countermeasures. This activity includes strengthening of Group-wide supply chain management to prevent illegal diversion and theft.



See → P.60 Global Anti-Counterfeit Measures

For further details about Takeda's quality management system, please see the CSR Data Book

http://www.takeda.com/csr/reports/

Tailored to individual market needs in mature and emerging markets, we aim to provide high-quality medicines to patients worldwide.

### **Takeda's Core Products**

Takeda conducts activities according to the corporate mission to "strive towards better health for people worldwide through leading innovation in medicine." We offer a diverse range of pharmaceutical products tailored to characteristics of mature and emerging markets. Along with the innovative medicines that

make up the core of our business, we also provide high-quality branded generics (branded ethical products for which patents have expired), life-saving vaccines, and OTC medicines, to help as many people as we can, as soon as we can.

### Cardiovascular & Metabolic



For Type 2 Diabetes

Pioglitazone

FY2013 net sales

GLUSTIN (Europe)

¥36.6billion
Main in-house sales regions:
Japan, U.S., Europe and Asia
Brand Names:
ACTOS (Japan, U.S.,
Europe and Asia),



For Type 2 Diabetes

Alogliptin

FY2013 net sales

¥40.4billion
Main in-house sales regions:
Japan, U.S. and Europe
Brand Names:
NESINA (Japan and U.S.),

VIPIDIA (Europe)



For Hypertension

### Candesartan

FY2013 net sales

¥155.0billion
Main in-house sales regions:
Japan, Europe and Asia
Brand Names:
BLOPRESS (Japan,
Europe and Asia),
AMIAS, KENZEN, etc. (Europe)



For Hypertension

Azilsartan

FY2013 net sales

¥25.3 billion
Main in-house sales regions:
Japan
Brand Names:
AZILVA (Japan)

### Immunology & Respiratory



For Hyperuricemia and Gout

**Febuxostat** 

FY2013 net sales

¥26.9billion

Main in-house sales regions:

Brand Names: ULORIC (U.S.)

U.S.



For Hyperuricemia and Gout Colchicine

FY2013 net sales

¥51.9billion

Main in-house sales regions: U.S.

Prand Names:

Brand Names: COLCRYS (U.S.)

# General Medicine



For Peptic Ulcers

### Lansoprazole

FY2013 net sales

¥118.4billion

Main in-house sales regions: Japan, U.S., Europe and Asia Brand Names: TAKEPRON (Japan and Asia), PREVACID (U.S. and Asia),

PREVACID (U.S. and Asia), OGAST, LANSOX, AGOPTON, etc. (Europe)



Acid Reflux Disease

### Dexlansoprazole

FY2013 net sales

¥50.3billion

Main in-house sales regions:

U.S. and Asia
Brand Names:

DEXILANT (U.S. and Asia)





### Oncology



For Multiple Myeloma **Bortezomib** 

FY2013 net sales

¥95.1 billion

Main in-house sales regions:

Brand Names: VELCADE (U.S.)



For Prostate Cancer, Breast Cancer and Endometriosis

### Leuprorelin

FY2013 net sales

¥124.3billion

Main in-house sales regions: Japan, Europe and Asia Brand Names: LEUPLIN (Japan), ENANTONE, etc. (Europe and Asia)



For Colorectal Cancer

### **Panitumumab**

FY2013 net sales

¥19.4billion

Main in-house sales regions: Japan Brand Names: VECTIBIX (Japan)



For Malignant Lymphoma **Brentuximab** 

# Vedotin

FY2013 net sales

¥13.6billion

Main in-house sales regions: Japan and Europe Brand Names: ADCETRIS (Japan and Europe)

### Central Nervous System



For Peptic Ulcers **Pantoprazole** 

FY2013 net sales

¥103.1billion

Main in-house sales regions: Europe, Asia and Latin America

Brand Names: PANTOZOL (Europe and Latin America) PANTORC, PANTOLOC, PANTOPRAZOL NYC, etc. (Europe and Asia)



For Insomnia

### Ramelteon

FY2013 net sales

¥10.1 billion

Main in-house sales regions: Japan, U.S. and Asia Brand Names: ROZEREM (Japan, U.S. and Asia)



For Alzheimer's-Type Dementia

### **Galantamine**

FY2013 net sales

¥12.3billion

Main in-house sales regions: Japan

Brand Names: REMINYL (Japan)



For Major Depressive Disorders **Vortioxetine** 

Launched in January 2014

**New Product** 

Main in-house sales regions: U.S.

Brand Names: BRINTELLIX (U.S.)



Takeda Key Figures

Fiscal 2013 revenue

The Japanese Market (Ethical Drug)

¥582.1<sub>bn</sub>

30%+

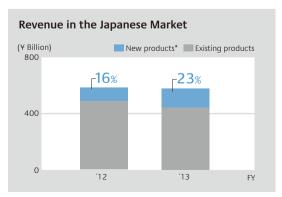
Target CAGR for new products\* and core

\* In-house products that have been on the market for

Salos (V Billion) (VoV)

# Fiscal 2013 Sales of Core Products

| Core Froducts                             | sales (* Billion) | (101)  |
|---|-------------------|--------|
| BLOPRESS hypertension treatment           | 125.8             | 6.1%↓  |
| TAKEPRON peptic ulcer treatment           | 67.6              | 2.1%↓  |
| LEUPLIN prostate and breast cancer treatm | nent <b>64.5</b>  | 2.3%↓  |
| NESINA type 2 diabetes treatment          | 38.0              | 0.6%†  |
| AZILVA hypertension treatment             | 25.3              | -      |
| VECTIBIX cancer treatment                 | 19.4              | 2.8% † |



\* In-house products that have been on the market for 5 years after launch (6 years including the year of launch)

### **Performance Overview**

Takeda's revenue of ethical drugs in Japan in fiscal 2013 fell slightly by 1.0% year-on-year to ¥582.1 billion, mainly due to termination of some products for distribution sales. However, sales contributions from new products such as the type 2 diabetes treatment *NESINA* (alogliptin) family and the antihypertension treatment *AZILVA* (azilsartan) helped to offset the decline.

### **Business Environment**

The shift towards generic medicines is progressing further in Japan as the government steps up its efforts to encourage their use to curb increasing healthcare expenditure. Under these circumstances, Takeda plans to strengthen its business base in Japan by concentrating its resources on new products to drive future growth.

### Takeda's Strategy

Takeda will accelerate the value maximization of new products across a broad range of therapeutic areas to consolidate our No. 1 share of the Japanese market.

In the diabetes area, we aim to increase total sales with lineups that can be tailored to individual patients. With regard to our core strategic products, the *NESINA* family, we are conducting promotional activities based on the latest evidence to secure our position as the leading choice among the DPP-4 inhibitors.

In the hypertension area, the new product AZILVA has been rapidly gaining market share as an ARB that has stronger potency in lowering blood pressure than any other existing angiotensin II receptor blockers and can deliver stable 24-hour control of blood pressure. Now, we will maximize the sales of the AZILVA family including ZACRAS, a fixed-dose combination of AZILVA and a calcium channel blocker launched for marketing in June 2014.

In other therapeutic areas, in July 2013, Takeda and Pfizer Japan Inc. launched *XELJANZ* (tofacitinib), a rheumatoid arthritis treatment. We also started commercialization of the varicella vaccine *BIKEN* and the malignant lymphoma treatment *ADCETRIS* (brentuximab vedotin) in February and April 2014, respectively.













Main new products launched from fiscal 2010 to fiscal 2013

# 49%

Projected share of new products within ethical drug\* revenue in Japan in fiscal 2017

 In-house products that have been on the market for 5 years after launch (6 years including the year of launch)

# No.1

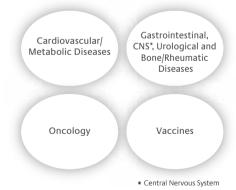
MR Productivity in Japan

Ethical drug revenue in Japan for fiscal 2013 divided by the number of MRs as of June 2013 yielded approximately ¥291.1 million per MR – the highest of all brand-drug companies in Japan.

Source: Monthly Mix July, 2014 (Elsevier Japan) From April 2014, Takeda has re-aligned the MR sales force structure, where each MR is responsible for one of the following therapeutic areas:

"Cardiovascular/Metabolic Diseases," "Gastrointestinal, Central Nervous System, Urological and Bone/Rheumatic Diseases," "Oncology," and "Vaccines." This new structure will enable us to ensure a higher level of specialization in our promotional activities and meet the needs of medical professionals.

### New MR Sales Force Structure



# Consumer Healthcare Business (Consumer Healthcare Drugs and Quasi-Drugs)

### **Performance Overview**

The consumer healthcare business generated revenue of ¥72.9 billion (up 8.9% year on year) in fiscal 2013, reflecting higher sales of core brands such as *ALINAMIN* and *BENZA*.

### Fiscal 2013 Sales of

| Core Brands      | Sales (¥ Billion) (YoY) |        |  |
|------------------|-------------------------|--------|--|
| ALINAMIN tablets | 19.6                    | 25.2%† |  |
| ALINAMIN drinks  | 15.1                    | 5.2%†  |  |
| The BENZA range  | 10.4                    | 7.2% † |  |

### **Business Environment and Takeda's Strategy**

With the promotion of self-medication being positioned as one of the important objectives of Japan's health insurance program reform initiatives, and the expected increase of awareness of health issues among consumers, Consumer Healthcare Drugs (OTC products) are expected to play an increasingly important role in Japanese society.

In the Mid-Range Growth Strategy, Takeda will continue to focus resources on core brands which offer a high return on investment, while actively seeking to diversify the consumer healthcare business and obtain in-licensed products to create avenues for sustainable growth.

In our efforts to diversify the business, we have been expanding our online retail business in Japan, and we will enhance the lineup of products in our online store. We have also been accelerating our overseas business promotion, and we continue to expand the number of export destination countries throughout Asia and our overseas product lineups.



Consumer Healthcare Business Core Brand Products



### **Performance Overview**

Revenue in the U.S. in fiscal 2013 declined to ¥318.9 billion, a year-on-year decrease of 2.4%. The decline reflects the first full year of type 2 diabetes treatment *ACTOS*' (pioglitazone) loss of exclusivity and slightly lower sales of existing products. This was partially offset by growth in diverse core products including the new *NESINA* (alogliptin) family of products for the treatment of type 2 diabetes.

# 14<sub>m</sub>

Number of patients in the U.S. affected by major depressive disorder each year

Source: Estimates by the National Comorbidity Survey Replication (NCS-R) (conducted from February 2001 to December 2002)



Note: Excluding royalty and service income

### **Business Environment**

While patient access is expanding due to the implementation in 2014 of several health insurance system reforms under the Affordable Care Act (ACA), price pressures see a continued shift away from branded medicines unless they are highly differentiated. As the ACA moves closer to full implementation, we are adapting our business to address emerging healthcare delivery systems as we bring to market new medicines that address unmet medical needs.

### **Takeda's Strategy**

In the U.S., based on our diverse product portfolio, we will propose and execute optimal sales strategies for each core therapeutic area to strengthen our franchises in each field.

Looking at core products, our new offerings include the *NESINA* family, *BRINTELLIX* (vortioxetine), for the treatment of major depressive disorder, and *ENTYVIO* (vedolizumab), for the treatment of ulcerative colitis and Crohn's disease.

We will also strive to maximize the value of our diverse products, including *COLCRYS* (colchicine) for the treatment of acute gout flares and *ULORIC* (febuxostat) for hyperuricemia in adult gout patients, and will expand sales of the gastroesophageal reflux disease treatment *DEXILANT* (dexlansoprazole), and *VELCADE* (bortezomib), a drug for multiple myeloma.

We are also making plans to launch a few pipeline products that are expected to receive approvals and additional indications moving forward, such as *CONTRAVE* (naltrexone SR/bupropion SR), a treatment for chronic weight management in adults and MLN9708 (ixazomib), a treatment for multiple myeloma. These additions will strengthen our franchise in a number of core therapeutic areas.

# Fiscal 2013 Net Sales of Core Products

| Net Sales | (¥ | Billion' | ) ( | (YoY) |
|-----------|----|----------|-----|-------|

|  | ,    | , , ,  |
|--|------|--------|
| VELCADE multiple myeloma treatment       | 95.1 | 30.5%† |
| COLCRYS hyperuricemia and gout treatment | 51.9 | 54.8%† |
| DEXILANT acid reflux disease treatment   | 50.3 | 53.6%† |
| ULORIC hyperuricemia and gout treatment  | 26.9 | 51.6%† |



### **Performance Overview**

Revenue in Europe in fiscal 2013 rose 15.2% year-onyear to ¥243.8 billion. Sales of an innovative new drug, *ADCETRIS* (brentuximab vedotin) for the treatment of malignant lymphoma grew rapidly and the base of mature products has also been very resilient. In addition to these factors, the effect of depreciation of the yen helped absorb the decline in sales of products subjected to loss of exclusivity (pioglitazone and candesartan).



Note: Excluding royalty and service income

### **Business Environment**

There are early signs that the European economy might be starting to recover from a long period of stagnation. Although governments across Europe are seeking to constrain public spending in healthcare and pharmaceutical markets, they are also tending to prioritize innovative medicines.

### Takeda's Strategy

Takeda has been successfully deploying a new operating model, designed to increase its focus especially on specialty care medicine (including oncology and central nervous system diseases, etc.), while still maintaining a strong base of primary care medicines. This redeployment has led to increased profitability, as well as preparing the region for new business platforms in the near future by establishing distinctive customer-facing capabilities.

In the specialty care field, the new oncology product *ADCETRIS* is performing extremely well. We will continue to promote it actively and prepare for further oncology assets. In fiscal 2014 we will also launch new specialty care products such as *ENTYVIO* (vedolizumab), for the treatment of ulcerative colitis and Crohn's disease, and *LATUDA* (lurasidone), an atypical antipsychotic in the central nervous system field.

In the primary care field, we will focus on growing *VIPIDIA*\*1 (alogliptin), *VIPDOMET*,\*2 and *INCRESYNC*,\*3 which are new drugs for type 2 diabetes, launched in November 2013. In addition to this, Takeda will seek to maintain and expand the sales of its key assets such as pantoprazole, a treatment for peptic ulcers.

Moving forward, Takeda will steadily bring its diverse pipeline products to market, in order to improve its growth trajectory from fiscal 2014 onward - transforming the region into a diverse specialty care business with a strong base of primary care medicines.

- \*1 Japan and U.S. product name: NESINA
- \*2 U.S. product name: KAZANO (fixed-dose combination of NESINA with metformin)
- \*3 Japan product name: LIOVEL, U.S. product name: OSENI (fixed-dose combination of NESINA with ACTOS)

# Fiscal 2013 Net Sales of Core Products

| Net Sales (¥ Billion) | (YoY) |
|-----------------------|-------|
|                       |       |

ADCETRIS malignant lymphoma 13.6 —

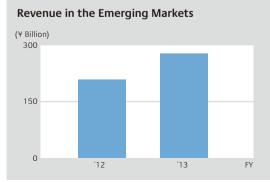


Emerging markets are expected to contribute over 60% of total global pharmaceutical market growth between 2014 and 2017, and Takeda is rapidly developing its business in those countries; it continuously strengthens its platform through enhanced commercial capabilities, new product launches and territorial expansion. Takeda has adopted a flexible and targeted approach for each individual market, combining innovative products with well-established, branded generics and OTC products. Our principal focus remains on Russia/CIS, Brazil, and China.

10.92m

Russia ranks fifth in the world for the number of adults suffering from diabetes (2013)

Source: *IDF Diabetes Atlas 6th Edition*, International Diabetes Federation



Note: Excluding royalty and service income

### Russia/CIS

### **Performance Overview**

Revenue in Russia/CIS for fiscal year 2013 was ¥89.5 billion, reflecting a year-on-year increase of 31.1%. Despite tougher generic competition and pricing pressure, Takeda continued to outpace market growth.

### **Business Environment**

The projected compound annual growth rate (CAGR) for Russia/CIS over the 2014-2017 period is approximately 9%. The nationwide health insurance/reimbursement schemes have not yet been finalized, but the Russian government has made a public commitment on healthcare reforms that include a broader reimbursement scheme with more transparent and evidence based rules.

### **Takeda's Strategy**

The key success factor in this region is a balanced portfolio with branded generics, original products and selective OTC that qualify for retail sales and innovative medicines with potential inclusion into state procurement programs. Localization, through our Yaroslavl Plant and innovation, through the progressive launch of the Takeda portfolio, have become increasingly important to sustain future growth. At the same time Takeda continues to maximize sales of core products such as *CONCOR* (bisoprolol), an antihypertensive agent, and *ACTOVEGIN*, an agent for cerebral vascular disorders and stroke, which is Takeda's leading product in the region.



Note: Excluding royalty and service income

### Brazil

### **Performance Overview**

Revenue in fiscal year 2013 in Brazil grew year-onyear by more than 25%, driven mainly by the growth of various core products.

### **Business Environment**

The projected CAGR for the Brazilian market over the 2014-2017 period is approximately 11%. This increase is mainly attributed to a growing middle income class and the aging of the Brazilian population.

### Takeda's Strategy

To ensure future growth, we are launching innovative medicines from our own pipeline and promoting life-cycle management for existing products with the addition of new indications. We expect to generate at least 45% of regional sales by 2018 with new products.

The acquisition of Multilab in 2012 has reinforced Takeda's presence in the Brazilian OTC and branded generics sector, which accounts for 55% of the country's total pharmaceutical market. We continue maximizing synergies from the acquisition, while utilizing Multilab's strong regional distribution network and geographical coverage.

### China

### **Performance Overview**

Revenue in China grew year-on-year by more than 40% in fiscal year 2013 - this has been driven by steady growth in core products thanks to sales force strengthening and increased promotional efforts.

### **Business Environment**

The projected CAGR for the Chinese market over the 2014-2017 period is approximately 14%. The Chinese government has set a long-term goal of creating a universal health insurance scheme by 2020, and is pressing ahead with other healthcare system reforms.

### Takeda's Strategy

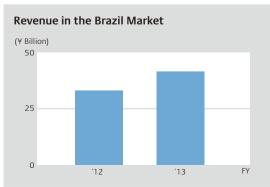
Takeda Shanghai Development Center (TSDC) and the commercial organization collaborate closely to enhance our product portfolio for the Chinese market. The aim is to achieve faster development of products that address China's specific unmet medical needs, in line with market demands. In December 2013, we launched the type 2 diabetes treatment *NESINA* (alogliptin). Moving forward, we will launch a series of innovative new drugs including *DAXAS* (roflumilast) for chronic obstructive pulmonary disease and TAK-390MR (dexlansoprazole) for gastroesophageal reflux disease.

As part of our response to China's healthcare system reforms, we introduced a Business Unit (BU) system that enables us to conduct more effective planning, more efficient coaching and better sales management.

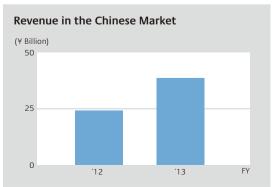
# 98.4m

China ranks first in the world for the number of adults suffering from diabetes (2013)

Source: *IDF Diabetes Atlas 6th Edition*, International Diabetes Federation



Note: Excluding royalty and service income



Note: Excluding royalty and service income

# Sustaining Corporate Value

through CSR

As a company committed to improving people's lives,

Takeda considers the various impacts of its business operations on society and strives to sustain its corporate value throughout every part of its business processes.

At the same time we also focus on being an active corporate citizen.

- 49 Takeda's CSR Activities
- 54 Human Rights
- 56 Labor
- 58 Environment
- 60 Anti-Corruption/Fair Operating Practices/ Consumer Issues
- 62 Corporate Citizenship Activities



### Takeda's CSR Activities

Recognizing companies are part of society, Takeda conducts activities with a holistic approach to not only create but also sustain corporate value.

The core rationale for corporate social responsibility (CSR) at Takeda is in the pharmaceutical business.

We therefore strive to maintain and improve sound business processes throughout our operations, and to engage in activities to promote a sustainable society as a good corporate citizen.

We engage in CSR activities taking this holistic approach.

We refer to internationally recognized guidelines

such as the United Nations Global Compact's 10 principles in promoting CSR activities.

At the same time, we take into consideration various opportunities

to create and sustain value for society and enterprises.

See → P.4 Sustaining Corporate Value through CSR P.22 CSR Strategy

### UNGC

United Nations Global Compact The UNGC is a worldwide framework for promoting voluntary actions by corporations as responsible corporate citizens. Participating businesses and organizations are asked to support and implement its 10 principles.

### **IIRC**

The International Integrated Reporting Council The IIRC was established as an organization for developing an international corporate reporting framework.

### Global Fund

The Global Fund to Fight AIDS, Tuberculosis and Malaria We cooperate with the Global Fund to implement the "Takeda Initiative," an endowment program designed to aid in developing and strengthening the capacity of healthcare workers in Africa.

### **IFPMA**

International Federation of Pharmaceutical Manufacturers & Associations

### **BSR**

A global association of member companies for CSR.

### FTSE4Good

An SRI (Socially Responsible Investment) index developed by FTSE International Limited of the

### **DJS Indexes**

SRI (Socially Responsible Investment) indexes developed by S&P Dow Jones Indices LLC of the U.S.

### ATM Index

The Access to Medicine (ATM) Index was developed by the Access to Medicine Foundation to independently rank pharmaceutical companies' efforts to improve access to medicine.

### CSR Activities through Dialogue with a Diverse Range of Communities

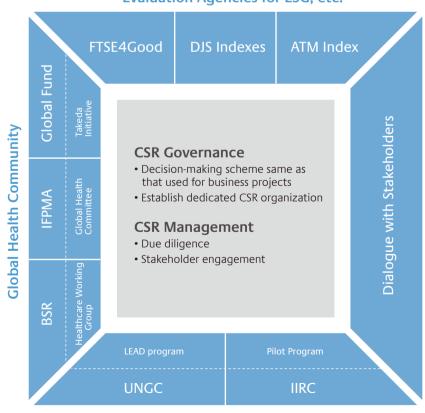
Based on a holistic approach, Takeda strives to understand expectations for the company in the present and the future through dialogue with a diverse range of communities and stakeholders. By reflecting

these dialogues in CSR management, we are working to create and sustain corporate value.

### Conceptual Diagram:

Implementing CSR Activities through Dialogue with a Diverse Range of Communities

### **Evaluation Agencies for ESG, etc.**



**CSR Community** 

### Participation in the CSR Community

To enhance future corporate value and avoid risks, it is crucial to develop an in-depth understanding of global standards and trends concerning CSR and respond to them properly. Takeda has participated in the United Nations Global Compact LEAD program and the IIRC Pilot Program since the inception of each program, and actively participates in the programs' new initiatives and projects to develop new rules.

# Activities within the Global Health Community

We have identified material issues specific to pharmaceutical companies and studied management techniques and response measures through activities led by the BSR Healthcare Working Group, the IFPMA Global Health Committees, and others.

Specifically, we discussed crucial issues in the value chain such as initiatives to improve access to health-care, contract research organization (CRO) management, and the issue of counterfeit drugs. In anti-counterfeiting measures, we are also conducting collaborative activities with the International Criminal Police Organization (ICPO). Furthermore, we are increasing understanding of access to healthcare by implementing the Takeda Initiative, a joint program with the Global Fund.

### **CSR Governance**

Material and associated issues identified through the abovementioned processes are handled by the departments responsible for global governance of quality, human rights, labor, the environment, procurement, and community, according to each project. A team specialized in promoting CSR activities set up inside the Corporate Communications Department provides tangential support for implementation and disclosure activities carried out by the department responsible for global governance, while referring to ISO 26000, United Nations GC Advanced level criteria, and GRI's Fourth Generation of Sustainability Reporting Guidelines (G4). Notably, it identifies any impacts business activities have on society and the environment, including potential impacts, and takes appropriate measures to handle them, with the aim of sustaining corporate value. As with business projects, important projects related to CSR are handled by the Global Leadership Committee and the Board of Directors.

Insights and issues identified through dialogue with a diverse range of communities

# United Nations Global Compact LEAD program

- · Long-term goal setting
- Post-2015 development agenda



Guidelines for promoting post-2015 CSR activities announced in September 2013 at the UN Global Compact Leaders Summit

### **IIRC Pilot Program**

- Relationship between integrated thinking and integrated reporting
- Independent assurance of non-financial information



### **IFPMA**

- Seriousness of non-communicable diseases (NCDs) in developing countries
- Anti-counterfeit measures



# Takeda Initiative in cooperation with the Global Fund

- Problems facing frontline medical staff
- Logistics problems for pharmaceuticals



### CRO

Contract research organizations

### ISO 26000

Issued by the International Organization for Standardization (ISO), ISO 26000 is an international standard that provides guidance on social responsibility.

### The United Nations Global Compact Advanced Level Criteria

Disclosure criteria for Communication on Progress (COP), an annual activity report requested by the United Nations Global Compact.

### GRI's Fourth Generation of Sustainability Reporting Guidelines (G4)

Guidelines issued by the Global Reporting Initiative (GRI) related to sustainability reports.

### Due Diligence

In the context of social responsibility, due diligence is the process of identifying and avoiding or reducing the negative impacts of an organization's decisions and activities.

### Stakeholder Engagement

For Takeda, stakeholder engagement means understanding the position and concerns of stakeholders and then reflecting these in corporate activities and decision making.

### AA1000

Issued by British firm AccountAbility, these are guidelines relating to accountability.

### **Due Diligence**

As a pharmaceutical company committed to improving people's lives, Takeda is engaged in identifying any impacts its business activities have on society and the environment, including potential impacts, and takes appropriate measures to handle them, with the aim of sustaining corporate value. Takeda sees this process as a series of activities ranging from "Recognition," which refers to identifying negative impacts on society, to "Preservation," which refers to avoiding situations that could decrease corporate value.

### **Stakeholder Engagement**

Based on ISO 26000, Takeda identifies stakeholders and focuses on stakeholder engagement as the basic practices underpinning social responsibility. We also refer to the AA1000 standards, a set of international guidelines for accountability to enhance our stakeholder engagement efforts.

### **Evaluation Agencies for ESG, etc.**

We monitor the expectations of investors and other stakeholders of the company, and CSR trends, in the process of replying to surveys from SRI indexes such as the Dow Jones Sustainability Indexes and surveys carried out by agencies evaluating pharmaceutical companies on their activities related to access to healthcare, such as the Access to Medicine Index. Furthermore, we confirm the areas where the company should improve its activities through feedback information obtained from the evaluation agencies.





### **Dialogue with Stakeholders**

Takeda enhances the quality of dialogue with stakeholders using the AA1000 standards, based on appropriate information disclosures and dissemination.

We have also established a contact point for consultations and complaints, which we respond to appropriately in our drive to improve our corporate activities.

| Stakeholders                          | Method of Dialogue   | Responsible<br>Organizational Body   |
|---------------------------------------|--|--|
| Patients and<br>Medical Professionals | Pharmaceutical information providing activities       Provide information through customer relations and through our website, etc.       Hold seminars on healthcare, etc.     Provide information through advertising                 | Customer Relations<br>Contact Center, etc.                                 |
| Shareholders and Investors            | Provide information through our Annual Report, website, and other media Shareholders' meetings and investors' briefings Respond to CSR surveys by socially responsible investors   | Corporate<br>Communications<br>Department, etc.                            |
| Society                               | Implement programs in cooperation with NGOs and NPOs   | Corporate<br>Communications<br>Department, etc.                            |
| Environment                           | Dialogue with local residents living near manufacturing and research facilities     Disclosure of information through Annual Report and website, etc.  | Organizational<br>bodies of each<br>manufacturing and<br>research facility |
| Business Partners                     | Honest purchasing activities based on the Takeda Global Code of Conduct and the Guidelines for Socially Responsible Purchasing     Surveys of business partners     Exchange of views, explanations, study sessions     Inquiries desk | Organizational bodies handling procurement, etc.                           |
| Employees                             | Company intranets  | Human<br>resources-related<br>departments, etc.                            |

Stakeholders comprise all parties that are influenced by, and/or have an influence on, corporate activities.

Takeda uses the framework of the core subjects in the ISO 26000 standard to promote its activities. This section explains Takeda's activities in accordance with the disclosure standards of the United Nations Global Compact.

| CSR Activity Targets and Results                                |                              |   |  |  |  |  |
|---|------------------------------|---|--|--|--|--|
| The United Nations<br>Global Compact<br>Advanced Level Criteria | ISO 26000<br>Core Subjects   | Targets for Fiscal 2013   | Results for Fiscal 2013  |  |  |  |
| Criteria<br>1-2 and 19-21                                       | Organizational<br>Governance | Continue to increase knowledge and awareness of CSR among employees   | Published pages to explain about CSR in the In-house magazine, four times in the year  |  |  |  |
| •   |                              | Continue to hold stakeholder dialogues (stakeholder engagement)   | Held "expanded stakeholder dialogue" involving all groups that have received support through the Takeda Well-Being Program over the past five years  |  |  |  |
| Human Rights Criteria 3-5                                       | Human<br>Rights              | Ensure strict adherence to company rules on human rights in all operational processes, including research, development, procurement, and marketing      | Promoted awareness in and outside the company of the Guiding Principles on Access to Healthcare (GPAH) created by BSR, including items relating to human rights, to which Takeda is a signatory  |  |  |  |
| ON O  | Labor<br>Practices           | Continue to strengthen the promotion of diversity   | Distributed exclusive newsletters to all employees on diversity-related issues featuring interviews with division managers relating to initiatives to strengthen diversity in each division (Japan)  |  |  |  |
| WW  |                              | Promote accelerated development of global leaders   | Organized Leadership Development Trustees at Takeda Pharmaceutical to take responsibility for developing leaders (management) capable of driving global business development through the management team in the workplace (Japan)                                |  |  |  |
| Labor<br>Criteria 6-8   |                              | Continue to promote work-life balance   | Conducted company-wide initiatives to reduce overtime work hours including sending continuous messages from management and provided a checklist for promoting work effectiveness including items that were collected from successful internal activities (Japan) |  |  |  |
|   | The<br>Environment           | Continue to promote the Takeda Group Environmental Action Plan  | Each Group company and division set targets based on the plan and worked to achieve them   |  |  |  |
|   |                              | Formulate the Global EHS Guideline  | Formulated the guideline and a checklist to promote awareness in every division worldwide  |  |  |  |
|   |                              | Continue to strengthen and improve environmental protection and accident prevention management systems  | Each Group company and division set targets based on the plan and worked to achieve them   |  |  |  |
| Environment<br>Criteria 9-11                                    |                              | Continue to promote full employee participation in energy conservation  | Continued power-saving activities including appropriate temperature setting and frequent turning off of lights. Continued the in-house eco-point system  |  |  |  |
|   |                              | Continue to improve awareness raising, education, and training for environmental protection and accident prevention                                     | Held environmental protection and accident prevention training according to plan and engaged in educational activities via the intranet  |  |  |  |
|   |                              | Continue to promote initiatives for biodiversity conservation   | Continued to cultivate over 100 species of endangered herbal plants at<br>Takeda Garden for Medicinal Plant Conservation (Kyoto) to ensure their<br>ongoing preservation   |  |  |  |
|   | Fair Operating<br>Practices  | Continue to instill the Takeda Global Code of Conduct and the Takeda Anti-Corruption Global Policy in employees   | Conducted global-level policy dissemination activities in cooperation with overseas subsidiaries   |  |  |  |
|   |                              | Continue to follow up with suppliers on improvement items identified through fiscal 2012 survey; initiate use of survey with more suppliers             | Conducted the CSR survey and provided evaluation and feedback for 27 firms that completed it   |  |  |  |
|   |                              | Continue to promote green procurement   | Continued steady promotion of green procurement  |  |  |  |
| Anti-Corruption Criteria 12-14                                  | Consumer<br>Issues           | Conduct interim review of Three-Year Plan for Anti-Counterfeit<br>Measures in light of environmental changes; continue steady<br>implementation of plan | Measured the effect of anti-counterfeit measures focused mainly on investigating and closing down illegal online pharmacies by conversion into monetary terms  |  |  |  |
| Citteria 12 11  |                              | Raise disease awareness through Takeda website and advertising  | Created a website for Communication with Patients on the company's website for healthcare professionals, and prepared information for them to provide to patients (Japan)  |  |  |  |
|   |                              | Continue to provide information spanning treatments and preventative measures   | Provided information on treatments and preventative therapies through website, seminars, and various other media   |  |  |  |
|   | Community<br>Involvement     | Continue to provide ongoing support for areas affected by the<br>Great East Japan Earthquake  | Created a recovery support scheme aimed at providing long-term, continuous support until 2020  |  |  |  |
| •   | and<br>Development           | Continue to promote corporate citizenship activities in the healthcare field  | Extended the countries to be supported under the IDEEL Program from India to include Mexico among other steps to ensure continuous, effective management of healthcare-related programs  |  |  |  |
|   |                              | Continue to provide research grants in a wide range of fields that contribute to healthcare progress  | Joined the Global Health Innovative Technology Fund (GHIT Fund), which aims to promote the discovery of new drugs to fight communicable diseases in developing countries   |  |  |  |
| Corporate   |                              | Continue partnerships with NGOs and NPOs  | Conducted monitoring visits of programs in Tanzania and China. Recognized frontline challenges and strengthened framework for collaboration with NGOs  |  |  |  |
| Citizenship<br>Activities<br>Criteria 15-18                     |                              | Continue to raise awareness throughout the company about the Basic Policies on Corporate Citizenship Activities   | Completed renewal of information on the company intranet, but recognized the need to improve the content further   |  |  |  |
|   |                              | Continue to implement activities to publicize the Global Donation Guidelines throughout the company   | Continued activities to raise awareness including renewal of information on the company intranet   |  |  |  |
|   |                              | Continue to provide opportunities for volunteer activities to employees in Japan  | Provided volunteer opportunities for a large number of employee<br>participants, including through the Great East Japan Earthquake Area Support<br>Program operated by Global Compact Japan Network  |  |  |  |

Evaluations: O:Target achieved \times: Progress made, but target not yet achieved \times: Target not achieved

| Evaluation | Targets for Fiscal 2014  | Page in Annual Report  |   |  |
|------------|--|--|---|--|
|            | Continue to increase knowledge and awareness of CSR among employees  | ₱ P.49 Takeda's CSR Activities   | <ul><li>P.4 Snapshot</li><li>P.22 CSR Strategy</li></ul>                    |  |
| $\bigcirc$ | Continue to engage with stakeholders   |  | → P.66 Corporate Governance   |  |
| $\circ$    | Continue to ensure strict adherence to company rules on human rights in all operational processes, including research, development, procurement, and marketing | P.54 Human Rights Management   | <ul><li>P.56 Labor</li><li>P.67 Compliance</li></ul>                        |  |
| $\bigcirc$ | Continue to strengthen the promotion of diversity  |  |   |  |
|            | Continue to promote accelerated development of global leaders  | Global Talent Manageme<br>Promotion of Diversity<br>Union Relationship | nt  |  |
| $\bigcirc$ | Continue to promote work-life balance  | ·  |   |  |
| 0          | Continue to promote the Takeda Group Environmental Action Plan   | <ul><li>₱ P.58</li><li>Environmental Managem</li></ul>                 | ent   |  |
| $\bigcirc$ | Conduct internal audit based on the Global EHS Guideline and the checklist   | Holding of the Global EH. The Environmental Impac Entire Value Chain   | S Meeting   |  |
|            | Continue to strengthen and improve environmental protection and accident prevention management systems   | Initiatives to Deal with C<br>Water Resources Conserv                  | 3   |  |
|            | Continue to promote full employee participation in energy conservation   | Waste Reduction  |   |  |
|            | Continue to improve awareness raising, education, and training for environmental protection and accident prevention  | _  |   |  |
| $\circ$    | Continue to promote initiatives for biodiversity conservation  |  |   |  |
|            | Continue to instill the Takeda Global Code of Conduct and the Takeda Anti-Corruption Global Policy in employees  | ⇒ P.60<br>Anti-Corruption  | <ul><li>P.33 Intellectual Property</li><li>P.67 Compliance</li></ul>        |  |
|            | Plan to conduct the CSR survey for new suppliers   | Transparency Guideline<br>Global Purchasing<br>Incorporating CSR       | The resimpliance  |  |
| 0          | Continue to promote green procurement  | Fair Promotion Activities  |   |  |
|            | Assess the effectiveness of the Three Year Plan by employing numerical indicators  | <ul><li>⇒ P.60</li><li>Global Anti-Counterfeit</li></ul>               | P.38 Production and<br>Supply Chain   |  |
|            | Continue to raise disease awareness through Takeda website and advertising   | Measures   | <ul><li>P.39 Quality Management<br/>System</li><li>P.40 Marketing</li></ul> |  |
| 0          | Continue to provide information spanning treatments and preventative measures  |  | F.40 Marketing  |  |
| <u> </u>   | Continue to provide ongoing support for areas affected by the Great East Japan Earthquake  | • P.62 Corporate Citizenship   | <ul><li>P.22 CSR Strategy</li><li>P.32 Vaccine Business</li></ul>           |  |
| <u> </u>   | Continue to promote corporate citizenship activities in the healthcare field   | Activities Management Partnership with                                 | 7.52 vaccine business   |  |
| <u> </u>   | Continue to provide research grants in a wide range of fields that contribute to healthcare progress   | NGOs and NPOs<br>Initiatives to Improve<br>Access to Healthcare        |   |  |
| <u> </u>   | Continue partnerships with NGOs and NPOs   | Support for Areas Affected by the<br>Great East Japan Earthquake       |   |  |
|            | Continue to raise awareness throughout the company about the Basic Policies on Corporate Citizenship Activities  |  |   |  |
|            | Continue to implement activities to publicize the Global Donation Guidelines throughout the company  |  |   |  |
| 0          | Continue to provide opportunities for volunteer activities to employees in Japan   |  |   |  |





# Clinical Trial Process Management Emphasizing the Human Rights of Trial Participants

Takeda conducts clinical trials globally while giving the utmost consideration to the human rights of trial participants. Accordingly, when selecting contract research organizations (CROs) to perform various operations in our global clinical trials, we take particular care to conduct rigorous pre-contractual quality assurance audits. After contracting with CROs, we take responsibility for oversight of all CRO activities and evaluate CROs on an ongoing basis in line with our policies and standards.

Number of global CROs contracted after conducting pre-contractual quality assurance audits

2

### Human Rights Management

Takeda has prepared internal standards in the form of policies and guidelines based on international human rights standards, and strives to be socially responsible at every stage of the value chain from research and development to procurement, production, distribution, and sales and marketing as it conducts its activities. We also recognize that one of our key priorities is to support the needs of people who do not have adequate access to pharmaceuticals. Takeda has announced its basic stance on tackling the issue of improving access to healthcare by signing the "Guiding Principles on Access to Healthcare" drafted by BSR.\*

\* A global association of member companies for CSR

### Future Outlook.

**Issues and Initiatives Going Forward** 

Global pharmaceutical companies that conduct business in emerging markets and developing countries must give consideration and care to human rights issues in various processes in the course of providing medicines. Takeda will continue to fulfill its responsibilities as a company involved in improving people's lives by bolstering its initiatives, drawing on a variety of insights gained through proactive participation in international community forums, such as BSR's Healthcare Working Group.

For further details about our activities, please see the CSR Data Book. https://www.takeda.com/csr/reports/

### Major Human Rights Issues and Initiatives throughout the Value Chain

### Research

### Issues

 Obtaining the voluntary agreement (informed consent) of all individuals who provide human-derived specimens beforehand

### Initiatives

 Conduct research activities based on a framework of policies and rules that respect the dignity of life and human rights

### Development (Clinical Trials)

### Issues

 Obtaining the voluntary agreement (informed consent) of all individuals who participate in clinical trials beforehand

### **Initiatives**

 Follow the International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) guidelines, which are international standards consistent with the spirit of the Declaration of Helsinki

### Procurement

### Iccupa

 Human rights problems for workers at suppliers in emerging and developing countries

### Initiatives

• Strengthen response across the entire value chain based on "Global Purchasing Policy" and "Guidelines for Socially Responsible Purchasing"

See →

P.68 Promotion of Compliance in Research

P.60 Transparency Guideline

P.61 Global Purchasing Incorporating CSR

### Guidelines for Reference and Issues and Initiatives across the Entire Value Chain

### **International Human Rights Standards**

Number of companies that jointly drafted the BSR "Guiding Principles on Access to Healthcare"

Takeda participated in drafting the principles along with 10 other global pharmaceutical companies, and played a leading role in their formulation.

### Universal Declaration of Human Rights

A declaration adopted by the United Nations General Assembly in 1948, as a common standard of achievement for all peoples and all nations

### The Declaration of Helsinki

A statement of ethical principles for research and clinical trials involving human-derived specimens, adopted by the World Medical Association (WMA) in 1964

### 10 Principles of the United Nations Global Compact

A voluntary set of principles for corporations to realize sustainable development of society, advocated by the Secretary-General of the United Nations in 1999

# The BSR "Guiding Principles on Access to Healthcare"

A set of principles for improving access to healthcare globally, set out in 2013 by the BSR, a global association of member companies for CSR

### Takeda's Internal Standards

Number of committee meetings concerning human rights-related rules (fiscal 2013)



### Production Distribution Sales and Marketing

• Concerns for the safety and health of people who live near our facilities

### **Initiatives**

• Strengthen response based on the "Global EHS Policy" and "Global EHS Guideline"

### Issues

• Prevention of health problems to patients due to counterfeit drugs

### **Initiatives**

• Strengthen countermeasures at a global level based on the Three-Year Plan for Anti-Counterfeit Measures

### Initiatives

Issues

• Compliance with the JPMA Code of Practice and the Fair Competition Code for Ethical Drug Production and Sales

· Appropriate provision, collection and

communication of information related to

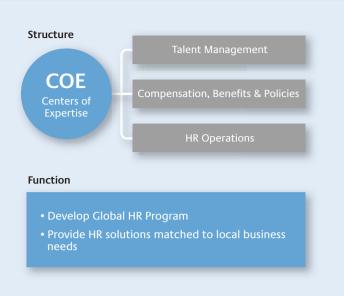
See → P.58 Environmental Management

P.60 Global Anti-Counterfeit Measures

P.61 Fair Promotion Activities

pharmaceutical products

### Structure and Functions of the Specialist COE Teams





Measures to Sustain Corporate Value

### **Establishment of Global HR Functions**

Takeda is making further enhancements to its HR functions in each country and region under the supervision of the Global HR Officer. In January 2014, we established a new global HR System, under which HR Business Partners (HRBPs) and Centers of Expertise (COEs) will take leadership roles. The HRBPs will support head office functions for each business division. The COEs are specialist teams responsible for developing an efficient, effective global HR program.

Number of Centers of Expertise teams

3

### Global Talent Management

### **Attraction and Development of Diverse Talent**

Takeda has made the attraction and development of global talent an important part of its Mid-Range Growth Strategy. Not only will we continue active recruitment of diverse employees, we are also focused on developing professionals capable of leading Takeda's global business.

In Japan, Takeda Pharmaceutical Company is primarily responsible for developing leaders under the concept of having the current management raise the next generation. Takeda Pharmaceutical has organized the TPC Leadership Development Trustees, who take responsibility for this important task. The trustees discuss the human resource development plan and have already begun to move some of it into the execution phase. In one of these initiatives, from fiscal 2014 we started a new leader development program targeting human resources who have the potential to be management class leaders in the future. The program features top-level business school professors from outside the company as well as lecturers from among our own current directors and division heads.

We have also created the Schola Cogito program for all employees who have a desire to learn, regardless of the geographical area in which they work. In this program, the business site where the course is conducted serves as a hub connecting key business sites and mobile PCs via a network to conduct live lessons in order to help employees to enhance their business skills.



Schola Cogito



### Takeda-ism e-Learning

Takeda shares its corporate philosophy comprising "Takeda-ism" (Integrity: Fairness, Honesty and Perseverance), as well as its Mission, the Vision 2020, and its values, throughout the entire Group in order to foster a dynamic and active corporate culture.

In January 2014, Takeda launched a Takeda-ism e-learning program to enable employees all over the world to receive training through the company intranet that would deepen their understanding of the corporate philosophy. The program comprises three sections entitled, "Takeda's Tradition," "Takeda Today," and "The Practice of Takeda-ism." Together they explain in detail the elements that all Takeda employees should hold in

### Schola Cogito

The two words are Latin. Schola means school. Cogito comes from Rene Descartes' famous quote "Cogito ergo sum" (I think, therefore I am), where cogito means to think.



Takeda-ism e-learning slide

Women's

**Empowerment** 

Empowerment refers to

the ability of women to

participate in decision-

exert power autono-

mously, both as

making processes and to

individuals and within the

context of social groups.

Target percentage of

women in managerial

positions in Japan by

Nadeshiko Brand logo

fiscal 2015

common in order to make Takeda a true global pharmaceutical company. The program has an innovative visual design and includes entries into the Vision 2020 Photography Contest from employees around the world.

### Promotion of Diversity

### Support for Women's Empowerment Principles (WEPs)

The Women's Empowerment Principles (WEPs) are a set of principles for businesses offering guidance on how to empower women in the workplace. These principles are the result of a collaboration between the United Nations Entity for Gender Equality and the Empowerment of Women (UN Women) and the United Nations Global Compact. Takeda signed the CEO Statement of Support for the WEPs in 2012 and follows the seven principles to enhance its initiatives for promoting the active participation of women in corporate activities. In Japan, Takeda is taking steps to develop and produce female managers and has set specific numerical targets to help achieve this aim. In fiscal 2013, the percentage of women in managerial positions was 2.9%.\*1

In March 2014, Takeda was selected by the Ministry of Economy, Trade and Industry (METI) and the Tokyo Stock Exchange (TSE) as a Nadeshiko Brand, a listed enterprise that is "exceptional in encouraging women's success in the workplace." The Nadeshiko Brand Program is a joint effort by METI and TSE to publicly acknowledge and promote enterprises that proactively encourage women to play more active roles in the



"WILL" Female Leadership Acceleration Program

workplace by providing an environment that enables women to further their careers.

\*1 Employee basis

| Status of Women's Empowerment Initiatives | 5 |
|---|---|
|   |   |

| V | П |          |  |
|---|---|----------|--|
|   | П | <b>W</b> |  |
|   | П |          |  |
|   |   |          |  |

|  |        | FY2012 | FY2013 |
|--|--------|--------|--------|
| Employee   | Female | 1,806  | 1,809  |
| composition  | Male   | 4,738  | 4,769  |
| Number of participants in  | Female | 36     | 32     |
| leadership develop-<br>ment programs*2   | Male   | 38     | 3      |
| Ratio of women in managerial positions   |        | 2.5%   | 2.9%   |
| Child care leave users   |        | 74     | 165    |
| Cilia care leave users   | Male   | 61     | 69     |
| Ratio of women receiving<br>health examination for<br>gender-related health issues |        | 56%    | 49%    |
| Number of users of on-site child care facilities                                   |        | 55     | 58     |

Data collection sites: Takeda Pharmaceutical Company Limited

### Union Relationship

### **Development of Healthy Industrial Relations**

By communicating with workers unions and employee representatives of each company in accordance with the laws of each respective country, we maintain a healthy relationship with workers unions. For example, in Japan, by having a collective bargaining agreement with the Takeda Pharmaceutical Workers Union we conduct regular dialogues regarding various topics, such as conditions of employment or human resource activities currently practiced at Takeda.

### Future Outlook

**Issues and Initiatives Going Forward** 

Takeda is promoting a policy under Vision 2020 of unifying our strengths as "Global One Takeda" to achieve an organization where diversity thrives. Our initiative to build a new global HR system is an effort to make Vision 2020 a reality. We will share common goals throughout the entire company across divisional and regional borders, and undertake even further alignment activities to optimize our HR functions. In this way, we are accelerating our endeavor to become a truly global pharmaceutical company.

Data assured by a third party

See > P.78 Independent Assurance of Environmental and Social Performance Indicators

For further details about our activities, please see the CSR Data Book http://www.takeda.com/csr/reports/

<sup>\*2</sup> Includes overseas employees in the program in fiscal 2012





### Holding of the Global EHS Meeting

With the integration with Nycomed, Takeda's global presence has expanded to around 70 countries. In response to the rapid change, we strive to share information and expertise. In 2013, the first Global EHS Meeting was held by representatives in charge of environment, occupational health and accident prevention. Network Meetings, which aim to deepen cooperation between manufacturing sites and laboratory sites respectively, were successfully held.

Countries of participants at the First Global EHS Meeting and Network Meeting (2013)

22

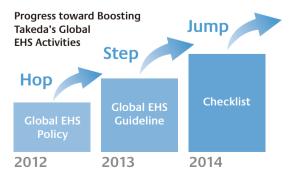
# 1970

Established the Environmental Protection Measures Committee

### Environmental Management

# Reorganizing the Group-Wide Management Structure

Since establishing the Environmental Protection Measures Committee in 1970, Takeda has engaged in environmental protection activities from a long-term perspective. Under the Takeda Group Environmental Action Plan, Takeda has set targets for measures to combat global warming, waste reduction, and other initiatives over the mid- and long-term. We review and evaluate our progress each year, and plan our future activities. In order to make concerted efforts as a Global One Takeda on environment as well as health and safety, we formulated the Global EHS Policy in 2012, the Global EHS Guideline which sets out specific measures for the policy in 2013, and a checklist which ascertains our EHS implementation progress in 2014. Combining these three guiding documents gives our EHS activities a dramatic boost.



### **Validation of Activities Using an Index**

Takeda recognizes the importance of quantitative assessments of the impact of business activities on the environment. In fiscal 2012, we undertook environmental impact assessments for our operations in Japan and overseas by LIME.\*1 Based on the results of these assessments, we identified issues to be addressed and we are now using the expertise we have acquired in Japan to reduce our environmental impact globally.

\*1 LIME (Life-cycle Impact assessment Method based on Endpoint modeling) was developed as a national project in Japan for making a quantitative overall assessment of various environmental impacts, including CO<sub>2</sub>, waste, and chemical substances.

# Trends in Environmental Impacts Due to Business Operations



Environmental impact cost CO2 SOx Others

-O- Environmental efficiency index (Net sales/environmental impact cost)

Data collection sites: Takeda production and research sites ('05-'13, unconsolidated), including indirect emissions associated with purchased electricity. Group production and research sites in Japan and overseas ('12-'13 Group sites in Japan and overseas), including indirect emissions associated with purchased electricity.

Ratio of Scope\*2 3 CO2 emissions at the Takeda parent company across the entire value chain (fiscal 2013)

\*2 Refers to the scope for calculation and reporting on emissions as stipulated by the GHG Protocol, an international standard for calculating GHG emissions.

Reduction in the Group's CO<sub>2</sub> emissions in Japan and overseas from fiscal 2005 level (fiscal 2013)

# reduction

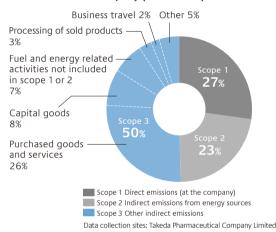
Reduction in the volume of the Group's final waste disposal in Japan from fiscal 2010 level (fiscal 2013)

Reduction in the Group's reported atmospheric release of PRTR substances in Japan from fiscal 2010 level (fiscal 2013)

### The Environmental Impact throughout the Entire Value Chain

Since fiscal 2012, Takeda has been calculating the greenhouse gas (GHG) emissions at the parent company not only for its own activities (Scope 1 and 2) but for the entire value chain including the activities of is suppliers, customers and others (Scope 3).

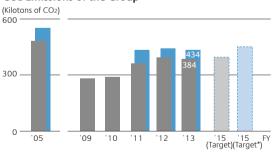
### CO<sub>2</sub> Emission Ratios across the Entire Value Chain at Takeda Parent Company (Fiscal 2013)



### Environmental Performance

### Initiatives to Deal with Climate Change

### CO<sub>2</sub> Emissions of the Group



Total for Group in Japan and Overseas (Excl. Legacy Nycomed) Total for Group in Japan and Overseas (Incl. Legacy Nycomed) Target\* includes values for legacy Nycomed operations.

Data collection sites: Group production and research sites in Japan and overseas (Takeda Pharmaceutical Company includes headquarters and sales offices.)

### Calculation Method

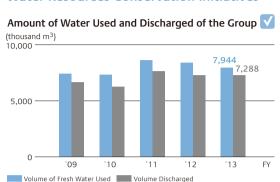
• Emissions included in the calculation

CO<sub>2</sub> emissions refer to direct emissions generated by combustion of fossil fuels and indirect emissions from energy sources.

### CO<sub>2</sub> emission factor

Emissions of the Group in Japan are calculated based on the "Law Concerning the Rational Use of Energy," and the CO2 emission factor for purchased electricity is the adjusted emission factor for each electric power provider in each fiscal year (figures for fiscal 2013) are the actual figures from fiscal 2012). The CO2 emission factors for electricity purchased outside Japan are based on country-specific factors stipulated in the GHG Protocol. Due to changes in factors, past data has been restated

### **Water Resources Conservation Initiatives**

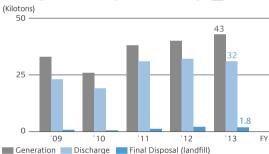


Data collection sites: Group production and research sites in Japan and overseas

### Waste Reduction

### Trends in Waste Generation, Discharge and Final Disposal of the Group





Data collection sites: Group production and research sites in Japan and overseas Waste: The total sum of hazardous and non-hazardous waste and valuable resources

### **Future Outlook**

**Issues and Initiatives Going Forward** 

Takeda will continue working to fulfill its social responsibilities for EHS on a Group-wide basis, in accordance with the Global EHS Policy and the Global EHS Guideline. We will promote EHS-related activities spanning various issues of concern to the global community such as the use of water resources and climate change. At the same time, we will continue to ascertain the global environmental impact of our operations through Scope 3 calculation and independent assurance, and to conduct highly transparent and reliable disclosure.

Data assured by a third party

See → P.78 Independent Assurance of Environmental and Social Performance Indicators

For further details about our activities, please see the CSR Data Book http://www.takeda.com/csr/reports/





### Global Anti-Counterfeit Measures

Takeda has formulated the Three-Year Plan for Anti-Counterfeit Measures (fiscal 2012 through 2014). The specialized team called Global Product Security (GPS) is responsible for executing the initiatives stipulated in the plan. Specific measures are developed and applied in consideration of the risk profile and level of each product and the country in which it is sold, considering corruption levels as well. Takeda is also gathering and investigating information regarding counterfeit medicines on a global scale in cooperation with international organizations, including the ICPO (International Criminal Police Organization). A total of 8,044 rogue online pharmacies illegally selling Takeda products were shut down as a result of Takeda's investigations in fiscal 2013.

Estimated quantifiable ROI to the legitimate supply chain by shutting down rogue online pharmacies illegally selling Takeda products (fiscal 2013) Approx.

60

Number of countries where the Takeda Global Code of Conduct has been disseminated in brochures or on the intranet

### Anti-Corruption

### The Takeda Global Code of Conduct/ The Takeda Anti-Corruption Global Policy

The Takeda Global Code of Conduct is a set of basic rules governing compliance across the entire Group. All Group executives and employees are expected to understand, comply with, and implement the Code in their daily business activities.

Moreover, to prevent corruption, the Takeda Global Code of Conduct has a clear guideline on prohibiting corruption and bribery, and more detailed guidelines are set out in the Takeda Anti-Corruption Global Policy.

### Transparency Guideline

### Relationship with Medical Institutions and Patient Groups

International society is calling for greater transparency and disclosure of information from pharmaceutical companies about their activities in every country. In the U.S., the Affordable Care Act (ACA) of 2010 stipulated the "Sunshine Act," while in Japan in 2011 a guideline was formulated for ensuring transparency in the relationship between corporate activities and medical institutions, and in 2012 a guideline was formulated on transparency in the relationship between corporate activities and patient groups.

Takeda's Main Policies/Guidelines/Action Plans on Anti-Corruption

• Basic Rules of Compliance for the Entire Group

The Takeda Global Code of Conduct

• Specific Conduct Guidelines for Anti-Corruption
The Takeda Anti-Corruption Global Policy

Policy Framework for Respecting the Dignity of Life and Human Rights

Rules for the Research Ethics Investigation Committee, etc. Guidelines for Implementing CSR throughout the Value Chain, Including Business Partners

Global Purchasing Policy/Guidelines for Socially Responsible Purchasing

Guidelines for Reducing Environmental Risks

Global EHS Policy Global EHS Guideline

Research and Development

Procuremen

**Production** 

Takeda referred to these guidelines to form its own Transparency Guideline for the Relation between Corporate Activities and Medical Institutions as well as the Transparency Guideline for the Relation between Corporate Activities and Patient Groups. We have disclosed related information such as provision of funds.

Global Purchasing Incorporating CSR

### Global Purchasing Policy/Guidelines for **Socially Responsible Purchasing**

Takeda has formulated the "Global Purchasing Policy" to support the enhancement of its global production and supply network. The policy sets out basic guidelines for purchasing activities, with a focus on quality, cost, delivery date, social acceptability, and the environment. Takeda strives to implement this policy not only in its business activities, but also shares the "Guidelines for Socially Responsible Purchasing" with its suppliers and encourages them to make their own efforts to solve social and environmental issues across the supply chain, including suppliers of raw/packaging materials and equipment, contract manufacturers as well as construction companies.

### **Supplier Survey**

Takeda asks suppliers to participate in a "CSR Survey" based on the "Guidelines for Socially Responsible Purchasing." The survey allows us to ascertain suppliers' CSR implementation performance, establishment of their quality assurance system, sustainability of stable supply, compliance with laws, labor management systems, and environmental preservation

• Transparency Guideline

Transparency Guideline for the Relation between **Corporate Activities and Medical Institutions** Transparency Guideline for the Relation between **Corporate Activities and Patient Groups** 

Quality Assurance Standard for Pharmaceutical Products Distribution

Takeda Global GDP Standard Global Anti-Counterfeit Measures

Three-Year Plan for **Anti-Counterfeit Measures**  Code for Promoting Drugs

The Policy on Promotion of the JPMA Code of Practice

Sales and Marketing

activities. The outcome collected from the surveys is fed back to the respective suppliers.

### Fair Promotion Activities

### The Policy on Promotion of the JPMA Code of Practice

Takeda's activities are governed by the Takeda Global Code of Conduct, which includes guidelines on fair promotion activities, and ensures strict adherence to laws relating to the pharmaceutical business in each country, and to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code. Moreover, in Japan, in order to ensure strict adherence to the JPMA Code of Practice, Takeda has created the Policy on Promotion of the JPMA Code of Practice and detailed SOP to implement the Policy by incorporating the existing Takeda Promotion Code for Prescription Drugs. With regard to a series of issues surrounding the Candesartan Antihypertensive Survival Evaluation in Japan (CASE-J study), Takeda will implement measures to prevent recurrences of this kind of event in the future. These measures include ensuring transparency through clarifying the role of each department and strengthening each department's checking systems, as well as thoroughly ensuring that Takeda employees are completely uninvolved in investigator-led clinical research related to Takeda products.

See → P.68 Issues Surrounding the Candesartan Antihypertensive Survival Evaluation in Japan (CASE-J Study)

### Future Outlook

**Issues and Initiatives Going Forward** 

Takeda has established a policy framework that includes the Takeda Global Code of Conduct and the Takeda Anti-Corruption Global Policy, and is upholding a tradition that Takeda has developed since its foundation of providing pharmaceuticals with integrity. Now, as part of our responsibility as a global pharmaceutical company, we also recognize the growing importance of implementing CSR initiatives not just internally, but throughout the entire supply chain. Going forward, we will take even further measures to ensure rigorous compliance, and to ensure fair operating practices across our entire value chain.

For further details about our activities, please see the CSR Data Book http://www.takeda.com/csr/reports/





Measures to Sustain Corporate Value

### **IDEEL\* Program**

In developing countries, diabetes, hypertension, cancer, and other non-communicable diseases (NCDs) are becoming an increasingly serious issue along with communicable diseases (CDs). Since 2012, in partnership with the international NGO "Project HOPE," Takeda has been supporting the expansion of an online diabetes educator course known as International Diabetes Educator E-Learning (IDEEL), from India in to other countries. From 2013, Takeda is supporting the program development for Spanish-speaking countries where there are considerable numbers of diabetes patients. Takeda will assist in the translation of the program into Spanish and in the launch of the program to developing countries in the Americas, mainly Mexico, which has many sufferers from diabetes.

\* IDEEL: International Diabetes Education E-Learning Program

\* IDEL: International Diabetes Education E-Learning Program

Number of trainees the program aims to reach by the end of June 2015

# 188

Number of participants in the GC-JN\* Collective Action for Recovery from the Great East Japan Earthquake Disaster (As of December 2013)

Global Compact Japan Network

Number of In-House Marketplace events held for earthquake recovery support (As of March 2014)

### **Corporate Citizenship** Activities Management

### **Basic Policy and Value Chain Concept**

As part of its CSR activities, Takeda carries out corporate citizenship activities with a particular focus on support activities to solve social problems. Takeda has set out its Basic Policies on Corporate Citizenship Activities as a global pharmaceutical company, as a set of common basic principles shared by all Group companies. We have focused our activities in the area of healthcare, where we leverage our expertise in the pharmaceutical industry.

In the course of implementing these activities, we believe it is important to reevaluate each process using a value-chain framework, and to then take on the stakeholder's perspective with an emphasis on outcomes and impacts.

### Partnership with NGOs and NPOs

### **Long-Term Ongoing Corporate Citizenship Activities**

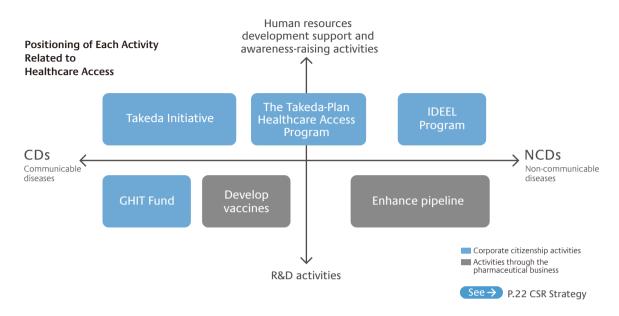
When addressing social issues in the field of health and medicine, we believe that it is important to establish a framework for long-term, ongoing support. Takeda is implementing an ongoing support program based on links developed with NGOs and NPOs who have a deep understanding of frontline social issues.

### Support for Areas Affected by the **Great East Japan Earthquake**

Since immediately after the Great East Japan Earthquake, Takeda has been conducting activities to support the recovery of areas affected by the disaster. Examples include the contribution of pharmaceuticals and donations. Including our "Support for Japan's Vitality and Recovery" project, under which we donate part of the profits from sales of ALINAMIN, we approved donations totaling ¥3.9 billion (as of January 2014). Through these donations, we will continue to assist recovery support programs by NGOs and NPOs through to 2020. Furthermore, we are conducting a broad range of other activities to assist with post-quake recovery efforts, such as support for employees who have an intention to serve as volunteers and our In-House Marketplace events, where local specialties from the disaster-affected areas are sold within the company.

For further details about Takeda's activities to support the recovery from the Great East Japan Earthquake, please see its website.

http://www.takeda.com/earthquake/



# 10<sub>vears</sub>

Duration of the "Takeda Initiative" healthcare support program in Africa

# Initiatives to Improve Access to Healthcare

### **Takeda Initiative**

The "Takeda Initiative" is a 10-year grant program running from 2010 to 2019 to support the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) in developing the capacity of healthcare providers in three African countries. In addition to providing donations, Takeda proactively visits project sites to gain an on the ground understanding of the local situation and contribute to improving access to healthcare. In 2013, a trip to Tanzania, one of the countries supported by the "Takeda Initiative," allowed firsthand exposure to monitoring logistics in delivering medicine and learning about hygiene practices. The visit drove home the importance of

investing in personnel training to ensure efficient delivery and maintenance of quality in providing medicine to hospitals.

# The Global Health Innovative Technology Fund (GHIT Fund)

The GHIT Fund is a pioneering non-profit public-private partnership established in Japan in April 2013 by the Government of Japan, a consortium of five Japanese pharmaceutical companies including Takeda, and the Bill & Melinda Gates Foundation, aimed at promoting the discovery and development of new drugs to fight communicable diseases (CDs) in developing countries. Takeda has entered into agreements with Medicines for Malaria Venture ("MMV") to develop DSM265 and formulate ELQ300, two anti-malarial compounds. MMV was selected in December 2013 as the first project to be subsidized by the GHIT Fund.

### Stakeholder's Voice



We are extremely grateful for the commitment from Takeda. At the core of the Global Fund is the realization that we all must work together if we are to defeat AIDS, tuberculosis and malaria. Working with partners like Takeda, we have an historic opportunity to seize new advances in science and apply practical experience to defeat these diseases and remove them as threats to public health. Working together, we can do great things.

### Mark Dybul

Executive Director, the Global Fund to Fight AIDS, Tuberculosis and Malaria



Plan Japan is a member of Plan International, a global NGO recognized by the United Nations that is active in 70 countries throughout the world.

### The Takeda-Plan Healthcare Access Program

In 2009, we established the Takeda-Plan Healthcare Access Program in collaboration with Plan Japan. The program is providing support for improved access to healthcare services for children in China, Indonesia, the Philippines, and Thailand. The program has achieved various results, as shown in the table below. Besides providing donations, Takeda has visited all the



A project site visit in China Photograph: Plan Japan

See → P.22 CSR Strategy

### Future Outlook

Issues and Initiatives Going Forward

The United Nations and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) have expressed an expectation to pharmaceutical companies around the world for action toward the prevention and control of non-communicable diseases (NCDs) in developing countries. We have therefore been promoting corporate citizenship activities focused on NCDs and developing countries, such as support for the IDEEL program. We have also declared our support for BSR's Guiding Principles on Access to Healthcare (GPAH) and are enhancing our practical activities based on the principles. Takeda will continue to contribute fully to community development through a holistic approach that incorporates both business and corporate citizenship perspectives.

For further details about our activities, please see the CSR Data Book http://www.takeda.com/csr/reports/

### Progress on the Takeda-Plan Healthcare Access Program (July 2009 – June 2013)



| •   |                  | • ,  | ,  |  |
|---|------------------|--|--|--|
| Country/Activity  | Input            | Output   | Outcome  | Impact   |
| Indonesia Community-led total sanitation to create open defecation-free villages Targeted MDGs: Goals 4 and 7 | ¥9.8<br>million  | Trained facilitators (156 people in 36 villages). Conducted implementation workshops (about 1,100 people in 20 villages). Conducted follow-up monitoring of open defecation-free villages (5 villages in year two, 2 villages in year three, and 10 villages in year four)   | 12 out of 20 villages achieved open defecation-free villages within one year of implementation.     The number of diarrhea patients at clinics decreased by about 90%.     Toilets were installed at own cost (2,829 households).  | Of the 20 target villages, 2 adopted the five articles for achieving an open defecation-free village as village by-laws. The activity was recognized as a successfue example case and has been promoted throughout the Lembata District and to neighboring districts also.   |
| China<br>Improvement of child<br>nutrition<br>Targeted MDGs:<br>Goals 1 and 2                                 | ¥10.1<br>million | Supplied nutrition booklets for students and instructors (12,300 copies).  Supplied food materials (for a total of about 5,900 individuals at 4 schools).  Conducted awareness-raising activities led by a Children's Committee through essay writing contests (for 3,400 individuals at 3 schools), skit, song, and dance contests (1,874 individuals at 4 schools), and sports events (over 600 individuals at 3 schools). | About 65% of all the children said that they have started to give more thought to nutrition when choosing snacks.     Provision of sterilizers has enabled children to have meals in a hygienic environment. Students also learned how to use the sterilizers and practiced putting them away after use.                                       | The central government began supplying food materials for students, starting from the fourth quarter of the third year.  A study tour was planned for a visit to Taiwan, where nutritional education in schools is well advanced. The district education board project team members and teachers from the 4 target schools, numbering 8 individuals in total, visited a junior high school and an elementary school in Taiwan. |
| Philippines Healthcare support for children Targeted MDGs: Goals 2 and 8                                      | ¥10.3<br>million | Conducted consultations, treatment, hospitalization, and surgery (87 individuals).     Supplied assistive medical equipment (28 individuals).  | Donation activities for sick children have begun on a voluntary basis at schools.     Certain doctors offered discounted fees for consultations and assistive medical equipment.     Promoted understanding of the importance of early treatment, and increase in the number of medical consultations.   | Budget proposals for medical support at the town and village levels were submitted.     Village councils approved financial support for part of the transportation expenses of children from villages to hospitals, as well as part of the transportation expenses for the children's parents and relatives, and for meals for children during transit.  |
| Thailand Prevention of the spread of HIV/AIDS among young people Targeted MDGs: Goal 6                        | ¥9.0<br>million  | Comprehensive sexuality education provided to a total of 10,186 people at 16 schools, including students, teachers, and guardians, as part of the regular curriculum or extra-curricular programs.  A student representative group was formed to increase awareness of comprehensive sexuality education within school (approx. 480 individuals at 16 schools).  | Increased acceptance of the topic of sexuality to enable instruction to be provided on the risks of pregnancy, abortion, and sexual diseases including HIV/AIDS among young people, as well as correct knowledge of sexuality, as part of the curriculum.  Consultation offices for students were voluntarily set up within 16 target schools. | A sustainable implementation system based on stronger stakeholder relationships was established by enhancing networks with hospital personnel and HIV patient groups.     Based on the results of this project, Sisaket Province has decided to try introducing the sexuality education in more schools.   |

project sites and

conducts activities

such as stakeholder

dialogues aimed at

improving project

quality.





See → P.78 Independent Assurance of Environmental and Social Performance Indicators



# **Corporate Governance**

Takeda will work to establish a management framework befitting a world-class pharmaceutical company that operates on a global scale, and make steady progress towards realizing "Vision 2020."

- 66 Fundamental Policy and Structure
- 67 Compliance
- 68 Messages from Outside Directors
- 69 Crisis Management
- 70 Risk Factors in Business

### Fundamental Policy and Structure

### **Policy toward Corporate Governance**

Takeda's management mission is to "strive towards better health for people worldwide through leading innovation in medicine." In line with this mission, Takeda is working to establish a management framework befitting a world-class pharmaceutical company that operates on a global scale. We are strengthening internal controls, including rigorous compliance and risk management, and establishing a structure to facilitate rapid decision-making that is sound and transparent. Through these initiatives, we will further enhance our corporate governance, thereby maximizing corporate value.

### **Management Structure**

At Takeda, the Board of Directors determines the fundamental policies for the Group, and management and business operations are then conducted in accordance with their decisions. Transparency of the Board of Directors is achieved through audits conducted by corporate auditors. At the same time, the company also has outside directors who bring perspectives from other industries to help ensure the appropriate execution of business operations.

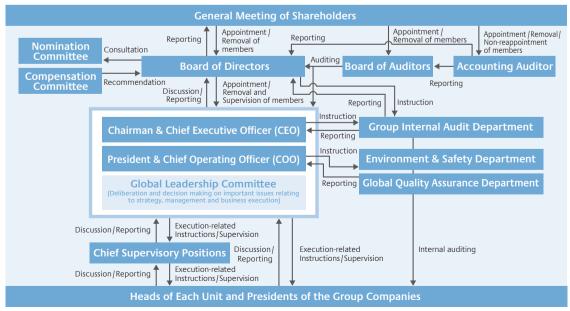
Moreover, as management tasks continue to diversify, the Group has appointed special officers to ensure a

flexible and swift response: the Chief Executive Officer (CEO), Chief Operating Officer (COO) and oversight positions related to accounting and financial functions, human resources functions, R&D functions, and ethical-drug manufacturing functions. Takeda has also established a Global Leadership Committee, composed mainly of internal directors, which responds to the global business risks that have accompanied the expansion of the scope of our business. The Global Leadership Committee assembles to deliberate and make decisions on the important issues facing the Group, from an optimal company-wide perspective.

Takeda has given its Board of Directors the primary functions of observing and overseeing business execution as well as decision-making for company management. The Board of Directors consists of 10 directors (all male), seven Japanese and three non-Japanese, including three outside directors, and meets in principle once per month to make resolutions and receive reports on important matters regarding management.

Furthermore, a Nomination Committee and a Compensation Committee have been established as advisory bodies to the Board of Directors. Each Committee consists of one Outside Director as a Chairman, one Outside Auditor and one Internal Director. Together, the committees serve to ensure transparency and objectivity in decision-making processes and results relating to personnel matters for

### Schematic Diagram of Takeda's Corporate Governance System, Including the Internal Control System



internal directors (appropriate standards and procedures for appointment and reappointment, and having and administering appropriate succession plans) and to the compensation system (appropriate levels of compensation for the directors, appropriate performance targets within the director bonus system, and appropriate bonuses based on business results).

Any risks we may face in the course of global business operations are managed by the personnel responsible for risk management in each organization within the relevant domain. We therefore have set a system in place to prevent or mitigate risks, according to their degree and nature.

Furthermore, based on the "Takeda Group's Management Policy" and the "Management Policy for Affiliated Companies," we work to clarify the roles and responsibilities of all Group companies. We ensure compliance and appropriate business operations through implementation of periodic internal audits and the Control Self Assessment (CSA) program.\*

• Under the CSA program, personnel responsible for internal control assess the status of internal control in their particular company or division and pledge to implement a program of improvement. They then take an oath to confirm that the proposed program of improvement is appropriate. The CSA program forms the basis for evaluation and confirmation of financial reporting by management.

### **Auditing System**

Takeda is a "Company with Auditors" as defined in Japan's Companies Act. Takeda has established a system to ensure the effective implementation of audits, under the "Audit Rules by Corporate Auditors" which prescribe the activities of auditors, including attendance at important meetings and authority to review important documents. The company also ensures the soundness and transparency of business

management by means of an audit by the Board of Corporate Auditors and by the internal and outside Corporate Auditors. In addition, KPMG AZSA LLC serves as the accounting auditor.

### Compliance

# The Takeda Global Code of Conduct and Promotion of the Global Compliance Program

In order to fulfill social expectations, gain trust and achieve recognition for its value to society, Takeda believes that, in addition to complying with laws and regulations, it is essential for Group employees and executives to conduct business from a high ethical and moral standard through the practical implementation of the corporate philosophy, "Takeda-ism." In line with this perspective, Takeda has instituted the Takeda Global Code of Conduct as a baseline standard of compliance commonly applicable to Group companies to help promote an integrated approach to compliance issues across Takeda operations worldwide. In fiscal 2011, Takeda formulated the Takeda Anti-Corruption Global Policy to deal with tightening regulations of anti-bribery globally.

To promote compliance throughout the entire Group, Takeda has appointed a Global Compliance Officer and established the Global Compliance Committee. The Global Compliance Office, which is in the Legal Department of Takeda Pharmaceutical Company Limited, supports these efforts to promote compliance.

The Takeda Global Code of Conduct and the Takeda Global Code of Conduct (Japan edition) can be viewed on Takeda's corporate website. http://www.takeda.com/company/compliance/

# Compensation of Directors and Corporate Auditors Amount and Type of Compensation for Each Class of Director and Corporate Auditor, and Number of Recipients

| Class of director/auditor                             | Total amount of                   | Total amount of comp | No. of  |               |            |
|---|-----------------------------------|----------------------|---------|---------------|------------|
| Class of director/addition                            | compensation<br>(millions of yen) | Basic compensation   | Bonuses | Stock options | recipients |
| Directors<br>(excl. outside directors)                | 621                               | 212                  | 260     | 149           | 8          |
| Corporate auditors (excl. outside corporate auditors) | 104                               | 104                  | _       | _             | 2          |
| Outside directors and outside corporate auditors      | 66                                | 66                   | _       | _             | 5          |

Note: The figures above include two Directors and one Corporate Auditor who retired as of the conclusion of the 137th Ordinary General Meeting of Shareholders held on June 26, 2013, and one Director who retired as of the conclusion of the 138th Ordinary General Meeting of Shareholders held on June 27, 2014.

Takeda's Corporate Governance Report can be viewed on the corporate website. (Available in Japanese only)

http://www.takeda.co.jp/investor-information/governance/

Up-to-date information on major subsidiaries and affiliates can be viewed on the corporate website.

http://www.takeda.com/worldwide

# Promotion of Compliance at Group Companies

Under the global compliance organizational structure, each Group company continues to reinforce their compliance programs in line with the Takeda Global Code of Conduct.

The Global Compliance Office works with Regional Compliance Officers when a coordinated global approach is required to manage certain compliance issues.

# Promoting Compliance at Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited instituted the Takeda Compliance Program in April 1999, appointing its Compliance Officer and establishing the Compliance Promotion Committee. To implement the Takeda Global Code of Conduct in Japan, Takeda Pharmaceutical Company Limited has created the Takeda Global Code of Conduct (Japan edition) that all of its employees and executives are expected to follow. Takeda Pharmaceutical Company Limited raises compliance awareness among its employees and executives through various training courses, including e-learning programs, discussion seminars at each business unit, and other programs.

In addition, an in-house hotline system called the Voice of Takeda System (VTS) and an external hotline system called the External VTS (for which outside counsel acts as a VTS contact) have been established to provide employees with a means of reporting compliance-related issues, while ensuring that employees who report the issues are protected.

### **Promotion of Compliance in Research**

In pursuing its research activities, Takeda complies with relevant laws, such as the Pharmaceutical Affairs Law, as well as in-house regulations in order to develop outstanding pharmaceutical products.

When conducting experiments with animals, which are essential to the research and development of new drugs, we establish committees within our research facilities (such as the Laboratory Animal Ethics Committee, etc.), and we observe laws and regulations, including the Act on Welfare and Management of Animals. We make every effort to practice the 3Rs,\*1 the fundamental ethical and scientific principles for respecting life and caring for animals. Shonan Research Center, Millennium Pharmaceuticals, Inc. and Takeda California, Inc. received Full Accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).\*2

In addition, when dealing with biohazards and chemical hazards we take all possible measures to protect people and the environment.

- \*1 The 3Rs are Reduction (of the number of animals in experiments), Replacement (of animal-based experiments with non-animal-based ones) and Refinement (of methods to reduce animal suffering).
- \*2 AAALAC International is a private, non-profit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

### Issues Surrounding the Candesartan Antihypertensive Survival Evaluation in Japan (CASE-J Study)

In March 2014, Takeda held a press conference to address the concerns surrounding the results of the CASE-J study, a clinical study related to the hypertension medicine *BLOPRESS* (candesartan). While the results of the internal investigation did not confirm "data falsification" or "possible conflicts of interest," it was

# Message



The ability of a company to thrive and survive lies in maintaining its ability to continue to create new value. Takeda has been resolutely striving to achieve this in recent years. In the economic environment of sudden change and a highly competitive world, while the company must hold steadfastly to the tradition of Takeda-ism, it must also embrace customers from every part of a diverse and heterogeneous world. This is the way to ensure the company's growth and sustainability. Moreover, in any industry, if management is to be successful, all employees from top management to workers on the front lines, must retain their shared sense of crisis as well as a positive outlook. Takeda has been also working on these aspects.

The responsibility of an outside director is primarily to supervise the execution of business (under the CEO), and as such it is the essence of corporate governance and compliance. Secondly, the outside director should give opinions and advice through their own experience and knowledge from a different perspective for management when they participate in the Board of Directors' meetings at Takeda.

At this time of transformation, my value as an outside director will be tested. I will make a sincere effort to perform my role.

Fumio Sudo Outside Director

found that "a portion of promotional activities were inappropriate" in their use of the CASE-J study results. Takeda explained this and apologized to patients and healthcare professionals. Furthermore, as a continuation of the internal investigation, Takeda announced the appointment of a third-party organization to conduct an investigation to address points that were insufficiently clear.

Over the course of the three-month third-party's investigation, Takeda has not issued objections to any part of the methods or scope as specified, and has been fully cooperating with the investigation.

The third-party's investigation uncovered new facts that were not identified through our internal investigations conducted in November 2013 and February 2014. These facts confirmed multiple incidences of involvement and encouragement by Takeda employees in the investigator-led clinical research CASE-J study. Facts confirmed regarding the inappropriate use of research results for portions of the promotional activities were the same as those previously announced by Takeda.

However, the third-party's investigation did not find any indications that Takeda was involved in "accessing the research data," "data falsification or fabrication," nor had "direct involvement in the statistical analysis work."

We take these results very seriously and sincerely regret the multiple incidences of inappropriate involvement and encouragement that may not only raise doubts as to the impartiality of this study, but also may potentially lower the credibility of Takeda as well as the entire pharmaceutical industry.

Based on the investigation results, Takeda will implement measures to prevent recurrences of this kind of event in the future. These measures include ensuring

transparency through clarifying the role of each department and strengthening each department's checking systems, as well as thoroughly ensuring that Takeda employees are completely uninvolved in investigator-led clinical research related to Takeda products.

The investigation report (public version) by a third-party organization can be viewed on the corporate website. (Available in Japanese only)

http://www.takeda.co.jp/update/files/20140620.pdf

### Crisis Management

### Takeda's Approach to Crisis Management

The prevention of emergency situations that could result in a considerable impact on our management, or responding immediately when such a situation occurs, is an important aspect of the Group's corporate governance. Takeda has therefore been working to strengthen its crisis management function even further, in addition to ensuring adequate audits and other internal controls and promoting compliance on a Group-wide basis.

When implementing crisis management initiatives, it is important to act with fairness and integrity to ensure the Group's employees and finances are safeguarded. This is also a responsibility that Takeda must fulfill toward its stakeholders, who include shareholders, customers, suppliers, employees, communities, and society at large. Takeda has therefore formulated the "Takeda Group Global Business Continuity Plan (BCP) Policy," as part of its response, to prevent the interruption of business activities in the event of any accident or disaster, or, where interruption is unavoidable, to resume business at the earliest opportunity, in addition to the existing "Takeda Group Global Crisis Management Policy."

Through these initiatives, Takeda will continue to fulfill its mission of maintaining a reliable supply of products.

## Message



Improving corporate governance goes beyond simply introducing and retaining outside directors. The important thing is whether these outside directors actually function in their roles. Takeda has taken steps to ensure that its outside directors can perform their functions adequately by enhancing the provision of information and by appointing outside director(s) as the chair for the Nomination Committee and Compensation Committee. I strive to actively offer opinions and ideas from an external perspective, as is expected.

As Takeda works to promote "Globalization," "Diversity," and "Innovation" under its Mid-Range Growth Strategy, it will need to rebuild its management structure with strong leadership and consistent policies. My own experience as the head of a major sogo shosha (global integrated business enterprise) has familiarized me with the challenges of globalization and evolving business models. I intend to leverage that experience to check on the development of this management structure and give practical advice and ideas. In this way, I hope to contribute to Takeda's continued growth going forward.

Yorihiko Kojima Outside Director

### **Takeda Group Global Crisis Management Policy**

Takeda strives to ensure that all possible preventive measures are taken to avoid potential crises in accordance with the "Takeda Group Global Crisis Management Policy," which comprises basic policies, rules and standards for crisis management. The policy also underpins systems and operations we have put in place to respond to each type of crisis swiftly and appropriately. In this way, we aim to minimize any potential harm to employees, any impact on the Group's finances, and any effect on society at large in the event of a crisis.

### **Takeda's Crisis Management Structure**

Takeda Pharmaceutical Company Limited and its Group companies are responsible for establishing their own crisis management systems, implementing preventive measures, and taking appropriate action if a crisis occurs. In the case of a crisis that has a major impact on the Group and requires Group-wide action, a "Global Crisis Management Committee" chaired by the President of Takeda coordinates a common understanding of the situation and any relevant information. The Committee directs each Group company to take countermeasures, later following up on the implementation of the countermeasures.

### Risk Factors in Business

Takeda's business performance is subject to various present and future risks, and may experience unexpected fluctuations due to the occurrence of risk events. Below is a discussion of the main assumed risks that Takeda faces in its business activities. Takeda works to fully identify potential risks and takes all possible steps to prevent them from materializing. Moreover, Takeda will ensure a precise response if risk events occur.

The future events contained in these items are envisioned as of the end of fiscal 2013.

### 1) Risk in R&D

While Takeda strives for efficient R&D activities aimed at launching new products in each market of Japan, the United States, Europe and Asia as early as possible, marketing of ethical drugs, whether in-house developed or licensed compounds, is allowed only when they have been approved through rigorous investigations of efficacy and safety as stipulated by the competent authorities.

If the efficacy and safety of compounds Takeda is preparing to bring to market do not meet the required level for

approval, or if the reviewing authorities express concern regarding the conformity of such compounds, Takeda will have to give up R&D activities for such compounds at that point, or conduct additional clinical or non-clinical testing. As a result, Takeda risks the inability to recoup the costs incurred, a delay in launching new products, or being obliged to revise its R&D strategy.

### 2) Risk in intellectual property rights

Each of Takeda's products is protected for a certain period by various patents covering substance, processes, formulations and uses.

While Takeda strictly manages intellectual property rights, including patents, and always keeps careful watch for potential infringement by a third party, expected earnings may be lost if the intellectual property rights held by Takeda are infringed by a third party. Moreover, if Takeda's in-house product is proven to have infringed a third party's intellectual property rights, Takeda may be required to pay compensations.

# Risk of sales decrease following patent expirations

While Takeda takes active measures to extend product life cycles, including the addition of new indications and formulations, generic drugs inevitably penetrate the market following patent expirations of most branded products. In addition, the increasing use of generic drugs and prescription-to-OTC switches also intensifies competition, both in domestic and overseas markets, especially in the U.S. market. Takeda's sales of ethical drugs may drop sharply as a result of these trends.

### 4) Risk of side effects

Although ethical drugs are only allowed to be marketed after approval for production and marketing following rigorous investigation by the competent authorities around the world, accumulated data during the post-marketing period may reveal side effects that were not known at the time of launch. If new side effects are identified for a product, Takeda will be required to describe the side effects in a "precaution" section of the package insert, or restrict usage of the product. Takeda may also be obliged to either discontinue sale of the product or recall it. The company can potentially be liable for damages and liabilities if such events occur.

# 5) Risk of price-reduction due to movements to curtail drug costs

In the U.S. market, which is the world's largest, authorities are promoting the use of low-price generic drugs, and pressure to reduce brand drug prices is increasing as a result of strong demand from the federal and state governments and Managed Care programs. In Japan, authorities have been reducing National Health Insurance (NHI) prices for drugs every other year and are also promoting the use of generic drugs. In the European market, drug prices have been reduced in a similar fashion, due to measures implemented in

each country to control drug costs and the expansion of parallel imports. Price reduction as a result of efforts to curtail drug costs in each country can significantly influence the business performance and financial standing of the Takeda Group.

### 6) Influence of exchange fluctuations

The Takeda Group's overseas revenue in fiscal 2013 amounted to ¥957.8 billion, which accounted for 56.6% of total consolidated revenue. Revenue in North America was ¥374.5 billion, which accounted for 22.1% of total consolidated revenue. For this reason, the Takeda Group's business performance and financial standing are considerably affected by fluctuations in foreign exchange rates. Most of such risks are pure translation risks and as such cannot be mitigated.

### 7) Risk related to corporate acquisitions

As part of its global business development in order to realize sustainable growth, Takeda engages in corporate acquisitions. However, there is a possibility that the intended result or profit expected from such acquisitions may not be realized, as business activities in countries around the world are confronted by many risks including, but not limited to, changes in law and regulations, political unrest, economic uncertainty and differences in business practices. In addition, there may be an impact on the financial results and financial condition of Takeda if write-downs, etc., occur due to a decrease in the value of acquired assets resulting from investment activities such as corporate acquisitions.

# Country risk in the countries and regions in operation

With developing its business globally, Takeda establishes its risk management structure to reduce the damage from and cope with the risks, including governmental, social and economic risks in the countries and regions in operation. However, Takeda may face unexpected situations. As a result, there may be an impact on the financial results and financial condition of Takeda.

### 9) Risk related to stable supply

In parallel with rapid international expansion of its sales network, Takeda is strengthening its global supply chain. However, in the event of technical or legal / regulatory problems in Takeda's production or distribution facilities, or other disruption due to natural disasters or accidental reasons, Takeda may have a suspension of or substantial delay in the supply of products. As a result, there may be an impact on the financial results and financial condition of Takeda.

# 10) Risk related to litigation and other legal matters

Regarding Takeda's operational activities, in addition to the existing litigations, there is a possibility that a suit may be brought to court relating to an adverse effect of a pharmaceutical product, product liability, labor issues, fair trade, etc.

As a result, there may be an impact on the financial results and financial condition of Takeda.

### **Litigation and Other Legal Matters**

### 1) U.S. AWP litigation

In the U.S., civil lawsuits have been filed by patients, insurance companies and state governments against numerous pharmaceutical companies, including major enterprises, over the sale of certain pharmaceutical products. The complaints seek, among other things, damages resulting from price discrepancies between the average wholesale price (AWP) as published and the actual selling prices. Thus, these types of lawsuits are sometimes called "AWP Litigation." Actions are pending against TAP Pharmaceutical Products Inc.\* in three state courts over lansoprazole (U.S. product name: *Prevacid*). In one case, the Company is also named as a defendant.

Takeda is diligently defending itself in each of the remaining aforementioned lawsuits.

 TAP was merged into Takeda Pharmaceuticals North America, Inc. (hereinafter "TPNA") in June 2008 and TPNA changed its name to Takeda Pharmaceuticals U.S.A., Inc. ("TPUSA") in January 2012. TAP marketed *Prevacid* before its merger with TPNA.

# Product liability litigation regarding pioglitazone-containing products

The Company, TPUSA, and certain Company affiliates located in the U.S. have been named as defendants in lawsuits pending in U.S. federal and state courts in which plaintiffs allege to have developed bladder cancer as a result of taking pioglitazone-containing products (and in some cases alleged other injuries). Eli Lilly & Co. ("Eli Lilly") is a defendant in many of these lawsuits. Also, proposed personal injury class action lawsuits have been filed in Canada, and a lawsuit seeking compensation for bladder cancer has been filed in France.

The Company is vigorously defending these lawsuits. In 2013, jury trials were conducted in three cases in state courts in Los Angeles, California, Baltimore, Maryland, and Las Vegas, Nevada. All three trials resulted in judgments at the trial court level in favor of Takeda. The plaintiffs in these cases have challenged the judgments in post-trial proceedings and appeals. In 2014, the first trial was conducted in the federal multi district litigation ("MDL"),\* in the case of Terrence Allen, et al. v. TPNA, et al, On April 7, 2014, the jury reached a verdict in favor of plaintiffs and awarded \$1,475 thousand in compensatory damages against Takeda defendants and Eli Lilly, allocating liability 75% to Takeda defendants and 25% to Eli Lilly. The jury also assessed \$6 billion in punitive damages against Takeda defendants and \$3 billion in punitive damages against Eli Lilly. Takeda defendants intend to challenge this outcome through all available means, including post-trial motions and an appeal. Many additional state court trials are scheduled to take place during the remainder of 2014 and

 An MDL consolidates similar cases filed in federal courts under one federal jurisdiction primarily for pre-trial and discovery purposes.

2015.

### Consolidated Statement of Income

Takeda Pharmaceutical Company Limited and Subsidiaries Years ended March 31, 2014 and 2013

| - Cars chace march 5 1, 25 1 1 and 25 15   |             | Millions of yen | Thousands of U.S. dollars |
|--|-------------|-----------------|---------------------------|
|  | 2014        | 2013            | 2014                      |
|  | IFRS        | IFRS            | IFRS                      |
| Revenue  | ¥ 1,691,685 | ¥ 1,557,005     | \$ 16,424,126             |
| Cost of sales  | (490,263)   | (463,845)       | (4,759,835)               |
| Gross profit   | 1,201,422   | 1,093,159       | 11,664,291                |
| Selling, general and administrative expenses                                       | (556,210)   | (512,922)       | (5,400,097)               |
| Research and development expenses Amortization and impairment losses on intangible | (341,560)   | (321,323)       | (3,316,117)               |
| assets associated with products  | (143,202)   | (173,772)       | (1,390,311)               |
| Other operating income   | 23,861      | ` 24,127        | 231,660                   |
| Other operating expenses   | (45,038)    | (44,277)        | (437,262)                 |
| Operating profit   | 139,274     | 64,994          | 1,352,175                 |
| Finance income   | 49,297      | 87,668          | 478,612                   |
| Finance expenses   | (30,720)    | (20,455)        | (298,252)                 |
| Share of profit of associates accounted for using                                  |             |                 |                           |
| the equity method  | 1,000       | 861             | 9,709                     |
| Profit before tax  | 158,851     | 133,068         | 1,542,243                 |
| Income tax expenses  | (49,292)    | 17,627          | (478,563)                 |
| Net profit for the year  | ¥ 109,558   | ¥ 150,695       | \$ 1,063,670              |
| Attributable to:   |             |                 |                           |
| Owners of the Company  | ¥ 106,658   | ¥ 148,583       | \$ 1,035,515              |
| Non-controlling interests  | 2,900       | 2,113           | 28,155                    |
| Net profit for the year  | ¥ 109,558   | ¥ 150,695       | \$ 1,063,670              |
| Earnings per share   |             | Yen             | U.S. dollars              |
| Basic earnings per share   | ¥ 135.10    | ¥ 188.21        | \$ 1.31                   |
| Diluted earnings per share   | 134.95      | 188.17          | 1.31                      |

Note: •The U.S. dollar amounts in this report represent translations of Japanese yen, solely for the reader's convenience, at the rate of ¥103=US\$1, the approximate exchange rate on March 31, 2014.

For consolidated financial statements and notes to consolidated financial statements, please see the "Consolidated Financial Statements Under IFRSs and Independent Auditor's Report"

http://www.takeda.com/investor-information/

<sup>•</sup>Takeda has adopted International Financial Reporting Standards (IFRS) from fiscal 2013 ended March 31, 2014 and the disclosure information in this material is based on IFRS. According to this adoption, the previous year's information is also based on IFRS.

### Consolidated Statement of Financial Position

| Years ended March 31, 2014 and 2013                                   |                      |                      | Millions of yen      | Thousands o<br>U.S. dollar |
|---|----------------------|----------------------|----------------------|----------------------------|
|   | 2014                 | 2013                 | Transition date      | 2014                       |
|   | IFRS                 | IFRS                 | As of April 1, 2012  | IFR                        |
| ASSETS  |                      |                      |                      |                            |
| NON-CURRENT ASSETS  | V = 42 2=2           | V = 46 011           | V 520 01 4           | 6 = 264 = 6                |
| Property, plant and equipment   | ¥ 542,253            | ¥ 546,811            | ¥ 530,814            | \$ 5,264,597               |
| Goodwill  | 814,671              | 714,024              | 582,257              | 7,909,42                   |
| Intangible assets   | 1,135,597            | 1,095,806<br>36,691  | 1,026,772            | 11,025,21<br>311,48        |
| Investment property Investments accounted for using the equity method | 32,083<br>d 10,001   | 9,171                | 33,465<br>8,285      |                            |
| Other financial assets  | 192,806              | 211,753              | 182,835              | 97,09<br>1,871,90          |
| Other non-current assets  | 40,772               | 27,526               | 17,845               | 395,84                     |
| Deferred tax assets   | 208,424              | 179,368              | 162,296              | 2,023,53                   |
| Total non-current assets  | 2,976,607            | 2,821,151            | 2,544,569            | 28,899,09                  |
|   |                      |                      |                      |                            |
| CURRENT ASSETS  |                      |                      |                      |                            |
| Inventories   | 254,329              | 229,258              | 196,000              | 2,469,21                   |
| Trade and other receivables   | 430,620              | 374,977              | 357,148              | 4,180,77                   |
| Other financial assets  | 184,981              | 16,240               | 6,274                | 1,795,93                   |
| Income taxes recoverables   | 12,044               | 12,040               | 4,724                | 116,93                     |
| Other current assets  | 43,510               | 49,336               | 40,835               | 422,42                     |
| Cash and cash equivalents Subtotal                                    | 666,048<br>1,591,531 | 545,580<br>1,227,432 | 454,247<br>1,059,229 | 6,466,48<br>15,451,75      |
| Assets held for sale  | 1,005                | 3,974                | 2,449                | 9,75                       |
| Total current assets  | 1,592,536            | 1,231,405            | 1,061,677            | 15,461,51                  |
|   |                      |                      |                      |                            |
| Total assets  | ¥ 4,569,144          | ¥ 4,052,556          | ¥ 3,606,247          | \$ 44,360,62               |
| LIABILITIES AND EQUITY  |                      |                      |                      |                            |
| LIABILITIES   |                      |                      |                      |                            |
| NON-CURRENT LIABILITIES   |                      |                      |                      |                            |
| Bonds and loans   | ¥ 704,580            | ¥ 582,623            | ¥ 300,948            | \$ 6,840,58                |
| Other financial liabilities   | 110,129              | 96,419               | 31,619               | 1,069,21                   |
| Net defined benefit liabilities                                       | 76,497               | 66,641               | 53,136               | 742,68                     |
| Provisions  | 14,399               | 21,828               | 16,139               | 139,79                     |
| Other non-current liabilities   | 39,555               | 41,115               | 14,916               | 384,02                     |
| Deferred tax liabilities  | 280,595              | 271,797              | 262,477              | 2,724,22                   |
| Total non-current liabilities   | 1,225,755            | 1,080,423            | 679,234              | 11,900,53                  |
| CURRENT LIABILITIES   |                      |                      |                      |                            |
| Bonds and loans   | 155,404              | 1,945                | 241,411              | 1,508,77                   |
| Trade and other payables  | 184,900              | 169,871              | 176,109              | 1,795,14                   |
| Other financial liabilities   | 48,817               | 38,556               | 11,536               | 473,95                     |
| Income taxes payables   | 52,332               | 129,358              | 34,860               | 508,07                     |
| Provisions  | 125,349              | 100,806              | 110,429              | 1,216,98                   |
| Other current liabilities   | 235,953              | 193,311              | 184,856              | 2,290,80                   |
| Total current liabilities   | 802,754              | 633,847              | 759,200              | 7,793,72                   |
| Total liabilities   | 2,028,509            | 1,714,270            | 1,438,435            | 19,694,26                  |
| EQUITY  |                      |                      |                      |                            |
| Share capital   | 63,562               | 63,541               | 63,541               | 617,10                     |
| Share premium   | 39,866               | 40,257               | 50,142               | 387,04                     |
| Treasury shares   | (621)                | (587)                | (808)                | (6,029                     |
| Retained earnings   | 1,901,307            | 1,927,795            | 1,920,537            | 18,459,29                  |
| Other components of equity  | 466,624              | 243,097              | 73,706               | 4,530,33                   |
| Equity attributable to owners of the Company                          | 2,470,739            | 2,274,103            | 2,107,117            | 23,987,75                  |
| Non-controlling interests   | 69,896               | 64,183               | 60,695               | 678,60                     |
| Total equity  | 2,540,635            | 2,338,286            | 2,167,812            | 24,666,35                  |
| Total liabilities and equity  |                      |                      |                      | \$ 44,360,62               |
| Total liabilities and equity  | ¥ 4,569,144          | ¥ 4,052,556          | ¥ 3,606,247          | \$ 44,300,62               |

For consolidated financial statements and notes to consolidated financial statements, please see the "Consolidated Financial Statements Under IFRSs and Independent Auditor's Report"

### ■ Eleven-Year Summary of Selected Financial Data

Takeda Pharmaceutical Company Limited and Subsidiaries

| 2014       | 2013  | 2012   | 2011  |  |
|------------|---|--|---|--|
| IFRS       | IFRS  | J-GAAP   | J-GAAP  |  |
| ¥1,691,685 | ¥1,557,005  | ¥1,508,932   | ¥1,419,385  |  |
| 341,560    | 321,323   | 281,885  | 288,874   |  |
| 139,274    | 64,994  | 265,027  | 367,084   |  |
| 158,851    | 133,068   | 252,478  | 371,572   |  |
| 106,658    | 148,583   | 124,162  | 247,868   |  |
|            |   |  |   |  |
| ¥135.10    | ¥188.21   | ¥157.29  | ¥314.01   |  |
| 134.95     | 188.17  | 157.26   | 313.96  |  |
| 180.00     | 180.00  | 180.00   | 180.00  |  |
|            |   |  |   |  |
| ¥2,976,607 | ¥2,821,151  | ¥2,298,034   | ¥1,200,150  |  |
| 1,592,536  | 1,231,405   | 1,278,996  | 1,586,252   |  |
| 4,569,144  | 4,052,556   | 3,577,030  | 2,786,402   |  |
| 1,225,755  | 1,080,423   | 753,433  | 213,150   |  |
| 802,754    | 633,847   | 751,731  | 436,596   |  |
| 2,540,635  | 2,338,286   | 2,071,866  | 2,136,656   |  |
|            |   |  |   |  |
| 308,360    | 278,845   | 304,628  | 256,291   |  |
| 31,225     | 30,481  | 30,305   | 18,498  |  |
|            | ¥1,691,685 341,560 139,274 158,851 106,658  ¥135.10 134.95 180.00  ¥2,976,607 1,592,536 4,569,144 1,225,755 802,754 2,540,635 | IFRS         IFRS           ¥1,691,685         ¥1,557,005           341,560         321,323           139,274         64,994           158,851         133,068           106,658         148,583           ¥135.10         ¥188.21           134.95         188.17           180.00         180.00           ¥2,976,607         ¥2,821,151           1,592,536         1,231,405           4,569,144         4,052,556           1,225,755         1,080,423           802,754         633,847           2,540,635         2,338,286           308,360         278,845 | IFRS         IFRS         J-GAAP           ¥1,691,685         ¥1,557,005         ¥1,508,932           341,560         321,323         281,885           139,274         64,994         265,027           158,851         133,068         252,478           106,658         148,583         124,162           ¥135.10         ¥188.21         ¥157.29           134.95         188.17         157.26           180.00         180.00         180.00           ¥2,976,607         ¥2,821,151         ¥2,298,034           1,592,536         1,231,405         1,278,996           4,569,144         4,052,556         3,577,030           1,225,755         1,080,423         753,433           802,754         633,847         751,731           2,540,635         2,338,286         2,071,866           308,360         278,845         304,628 | IFRS         IFRS         J-GAAP         J-GAAP           ¥1,691,685         ¥1,557,005         ¥1,508,932         ¥1,419,385           341,560         321,323         281,885         288,874           139,274         64,994         265,027         367,084           158,851         133,068         252,478         371,572           106,658         148,583         124,162         247,868           ¥135.10         ¥188.21         ¥157.29         ¥314.01           134.95         188.17         157.26         313.96           180.00         180.00         180.00         180.00           1,592,536         1,231,405         1,278,996         1,586,252           4,569,144         4,052,556         3,577,030         2,786,402           1,225,755         1,080,423         753,433         213,150           802,754         633,847         751,731         436,596           2,540,635         2,338,286         2,071,866         2,136,656           308,360         278,845         304,628         256,291 |

Note: •The U.S. dollar amounts in this report represent translations of Japanese yen, solely for the reader's convenience, at the rate of ¥103=US\$1, the approximate exchange rate on March 31, 2014.

rate on March 31, 2014.
•Employees working in Takeda Pharmaceutical Company Limited and its consolidated subsidiaries. From fiscal 2010, ended March 31, 2011, the numbers are indicated on a full time equivalent basis.

on a full fille equivalent basis.

Takeda has adopted International Financial Reporting Standards (IFRS) from fiscal 2013 ended March 31, 2014 and the disclosure information in this material is based on IFRS. According to this adoption, the previous year's information is also based on IFRS.

<sup>•</sup>Account names under IFRS. Names in FGAAP correspond to names in IFRS as follows: •Net sales/Revenue •Operating Income/Operating profit •Income before income taxes and minority interests/Profit before tax •Net income/Net profit attributable to owners of the Company •Earnings per share/Basic earnings per share •Diluted net income per share/Diluted earnings per share •Net assets/Equity

| Thousands of U.S. dollars | Millions of yen |            |            |            |            |            |            |
|---------------------------|-----------------|------------|------------|------------|------------|------------|------------|
| 2014                      | 2004            | 2005       | 2006       | 2007       | 2008       | 2009       | 2010       |
| IFRS                      | J-GAAP          | J-GAAP     | J-GAAP     | J-GAAP     | J-GAAP     | J-GAAP     | J-GAAP     |
| \$16,424,126              | ¥1,086,431      | ¥1,122,960 | ¥1,212,207 | ¥1,305,167 | ¥1,374,802 | ¥1,538,336 | ¥1,465,965 |
| 3,316,117                 | 129,652         | 141,453    | 169,645    | 193,301    | 275,788    | 453,046    | 296,392    |
| 1,352,175                 | 371,633         | 385,278    | 402,809    | 458,500    | 423,123    | 306,468    | 420,212    |
| 1,542,243                 | 446,144         | 441,102    | 517,957    | 625,379    | 576,842    | 398,546    | 415,829    |
| 1,035,515                 | 285,264         | 277,438    | 313,249    | 335,805    | 355,454    | 234,385    | 297,744    |
|                           |                 |            |            |            |            |            |            |
| \$1.31                    | ¥321.86         | ¥313.01    | ¥353.47    | ¥386.00    | ¥418.97    | ¥289.82    | ¥377.19    |
| 1.31                      | _               | _          | _          | _          | _          | 289.80     | 377.14     |
| 1.75                      | 77.00           | 88.00      | 106.00     | 128.00     | 168.00     | 180.00     | 180.00     |
|                           |                 |            |            |            |            |            |            |
| \$28,899,097              | ¥605,513        | ¥575,520   | ¥670,324   | ¥714,788   | ¥605,487   | ¥1,284,604 | ¥1,250,400 |
| 15,461,515                | 1,730,147       | 1,969,915  | 2,371,970  | 2,357,713  | 2,243,792  | 1,475,584  | 1,572,874  |
| 44,360,621                | 2,335,660       | 2,545,435  | 3,042,294  | 3,072,501  | 2,849,279  | 2,760,188  | 2,823,274  |
| 11,900,534                | 141,628         | 133,685    | 158,444    | 168,978    | 98,035     | 234,242    | 230,051    |
| 7,793,728                 | 370,562         | 365,500    | 488,227    | 442,407    | 428,711    | 472,106    | 428,477    |
| 24,666,359                | 1,823,470       | 2,046,250  | 2,395,623  | 2,461,116  | 2,322,533  | 2,053,840  | 2,164,746  |
|                           |                 |            |            |            |            |            |            |
| _                         | 116,343         | 118,042    | 108,111    | 112,113    | 149,478    | 196,437    | 236,480    |
| _                         | 14,592          | 14,510     | 15,069     | 14,993     | 15,487     | 19,362     | 19,654     |

### Ethical Drugs: Revenue by Region

Takeda Pharmaceutical Company Limited and Subsidiaries

| Years ended March 31, 2014 and 2013     |                     |              |         | (Billions of Yen)     |
|---|---------------------|--------------|---------|-----------------------|
| -                                       | <b>2014</b><br>IFRS | 2013<br>IFRS | YoY     | % change<br>2014/2013 |
| Revenue in Japan                        | 583.0               | 589.9        | (6.9)   | (1.2)%                |
| Revenue Overseas                        | 863.3               | 763.8        | 99.5    | 13.0                  |
| North America                           | 340.8               | 343.2        | (2.5)   | (0.7)                 |
| [U.S.]                                  | [318.9]             | [326.8]      | [(7.9)] | [(2.4)]               |
| Europe                                  | 243.8               | 211.6        | 32.1    | 15.2                  |
| Russia/CIS                              | 89.5                | 68.3         | 21.2    | 31.1                  |
| Latin America                           | 80.6                | 62.3         | 18.3    | 29.4                  |
| Asia                                    | 80.5                | 55.5         | 25.1    | 45.2                  |
| Other                                   | 28.1                | 22.9         | 5.2     | 22.7                  |
| Royalty income and service income       | 85.8                | 50.8         | 35.0    | 68.9                  |
| Japan                                   | 2.1                 | 1.3          | 0.8     | 66.9                  |
| Overseas                                | 83.7                | 49.5         | 34.2    | 68.9                  |
| Total ethical drugs revenue             | 1,532.1             | 1,404.5      | 127.6   | 9.1                   |
| Ratio of overseas ethical drugs revenue | 61.8%               | 57.9%        | 3.9pt   |                       |
|   |                     |              |         |                       |

 $<sup>\</sup>ensuremath{^{\bullet}}$  Revenue amount is classified into countries or regions based on the customer location.

### Ethical Drugs: Global Major Products' Sales

Takeda Pharmaceutical Company Limited and Subsidiaries

| Years ended March 31, 2014 and 2013 |       |       |        | (Billions of Yen) |
|-------------------------------------|-------|-------|--------|-------------------|
| Product —                           | 2014  | 2013  | YoY    | % change          |
|                                     | IFRS  | IFRS  |        | 2014/2013         |
| CANDESARTAN                         | 155.0 | 169.6 | (14.6) | (8.6)%            |
| LEUPRORELIN                         | 124.3 | 116.5 | 7.9    | 6.8               |
| LANSOPRAZOLE                        | 118.4 | 110.2 | 8.1    | 7.4               |
| PANTOPRAZOLE                        | 103.1 | 78.0  | 25.1   | 32.2              |
| VELCADE                             | 95.1  | 72.9  | 22.2   | 30.5              |
| COLCRYS                             | 51.9  | 33.6  | 18.4   | 54.8              |
| DEXILANT                            | 50.3  | 32.7  | 17.6   | 53.6              |
| NESINA                              | 40.4  | 37.8  | 2.6    | 6.8               |
| PIOGLITAZONE                        | 36.6  | 122.9 | (86.2) | (70.2)            |
| ULORIC                              | 26.9  | 17.7  | 9.2    | 51.6              |
| ACTOVEGIN                           | 26.4  | 19.6  | 6.8    | 34.7              |
| AMITIZA                             | 25.7  | 22.3  | 3.3    | 15.0              |
| CALCIUM                             | 19.1  | 15.4  | 3.8    | 24.6              |
| TACHOSIL                            | 16.9  | 13.2  | 3.6    | 27.6              |
| ADCETRIS                            | 13.6  | 4.5   | 9.1    |                   |

<sup>•••</sup> Revenue amount includes intersegment sales.
••• Revenue in emerging markets is the total of "Russia/CIS," "Latin America," "Asia," and "Other."

<sup>\*\*\*\*</sup> Other region includes Middle East, Oceania and Africa.

# Key Social Responsibility Data Takeda Pharmaceutical Company Limited and Subsidiaries

| Labor        |  | 2014   | 2013   | 2012   |  |
|--------------|--|--------|--------|--------|--|
| Number of    | Total  | 31,225 | 30,481 | 30,305 |  |
| employees*   | Japan  | 9,554  | 9,525  | 9,530  |  |
|              | Overseas                                       | 21,671 | 20,956 | 20,775 |  |
|              | Pharmaceutical business                        | 29,133 | 28,397 | 28,284 |  |
|              | Ethical drugs                                  | 28,672 | 27,947 | 27,844 |  |
|              | Consumer healthcare                            | 461    | 450    | 440    |  |
|              | Other businesses                               | 2,092  | 2,084  | 2,021  |  |
| Number of pa | rticipants in the global leadership<br>program | _      | 36     | 28     |  |

<sup>\*</sup> Employees working in Takeda Pharmaceutical Company Limited and its consolidated subsidiaries on a full time equivalent basis

### **Environment**

| Total input energies  | 9,278 million MJ                | 9,428 million MJ                | 9,156 million MJ                |
|---|---------------------------------|---------------------------------|---------------------------------|
| Fresh water used  | 7,944 thousand m <sup>3</sup>   | $8,373$ thousand $m^3$          | $8,598 \; \text{thousand m}^3$  |
| CO <sub>2</sub> emissions                                       | 434 kilotons of CO <sub>2</sub> | 439 kilotons of CO <sub>2</sub> | 435 kilotons of CO <sub>2</sub> |
| SOx (sulfur oxide) emissions                                    | 112 tons                        | 122 tons                        | 105 tons                        |
| NOx (nitrogen oxide) emissions                                  | 341 tons                        | 328 tons                        | 287 tons                        |
| Dust emissions  | 38 tons                         | 40 tons                         | 26 tons                         |
| Amount of waste generated                                       | 43 kilotons                     | 40 kilotons                     | 38 kilotons                     |
| PRTR-designated substances released into the atmosphere (Japan) | 38 tons                         | 35 tons                         | 56 tons                         |

### **Corporate Citizenship Activities**

| Cash donations                                     | ¥3 | 3,220 million (IFRS)  | ¥2  | 2,839 million (IFRS) | ¥! | 5,324 million<br>(J-GAAP) |
|--|----|-----------------------|-----|----------------------|----|---------------------------|
| Takeda Science Foundation research grants          | ¥  | <b>1,</b> 520 million | ¥ 2 | 2,261 million        | ¥  | 2,266 million             |
| Shoshisha Foundation scholarships                  | ¥  | 102 million           | ¥   | 78 million           | ¥  | 70 million                |
| Institute for Fermentation, Osaka, research grants | ¥  | 407 million           | ¥   | 400 million          | ¥  | 408 million               |

### Independent Assurance of Environmental and Social Performance Indicators



### Independent Assurance Report

To the President and COO of Takeda Pharmaceutical Company Limited

We were engaged by Takeda Pharmaceutical Company Limited (the "Company") to undertake a limited assurance engagement of the environmental and social performance indicators marked with of the period from April 1, 2013 to March 31, 2014 included in its Annual Report 2014 (the "Report") for the fiscal year ended March 31, 2014, except for the Input, Output and Outcome indicators in the "Progress on the Takeda-Plan Healthcare Access program", whose figures from July 1, 2009 to June 31, 2013 are the subject of this assurance engagement (the "Indicators").

### The Company's Responsibility

The Company is responsible for the preparation of the Indicators in accordance with its own reporting criteria (the "Company's reporting criteria"), as described in the Report, which are derived, among others, from the Sustainability Reporting Guidelines Version 4 of the Global Reporting Initiative and Environmental Reporting Guidelines of Japan's Ministry of the Environment.

### Our Responsibility

Our responsibility is to express a limited assurance conclusion on the Indicators based on the procedures we have performed. We conducted our engagement in accordance with 'International Standard on Assurance Engagements (ISAE) 3000, Assurance Engagements other than Audits or Reviews of Historical Financial Information', issued by the International Auditing and Assurance Standards Board, and the 'Practical Guidelines for the Assurance of Sustainability Information' of the Japanese Association of Assurance Organizations for Sustainability Information. The limited assurance engagement consisted of making inquiries, primarily of persons responsible for the preparation of information presented in the Report, and applying analytical and other procedures, and the procedures performed vary in nature from, andare less in extent than for, a reasonable assurance engagement. The level of assurance provided is thus not as high as that provided by a reasonable assurance engagement. Our assurance procedures included:

- Interviewing with the Company's responsible personnel to obtain an understanding of its policy for the preparation of the Report and reviewing the Company's reporting criteria.
- Inquiring about the design of the systems and methods used to collect and process the Indicators.
- Performing analytical reviews of the Indicators.
- Examining, on a test basis, evidence supporting the generation, aggregation and reporting of the Indicators in conformity with the Company's reporting criteria, and also recalculating the Indicators.
- Visiting to the Company's Osaka factory selected on the basis of a risk analysis.
- Evaluating the overall statement in which the Indicators are expressed.

### Conclusion

Based on the procedures performed, as described above, nothing has come to our attention that causes us to believe that the Indicators in the Report are not prepared, in all material respects, in accordance with the Company's reporting criteria as described in the Report.

### Our Independence and Quality Control

We have complied with the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants, which includes independence and other requirements founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior. In accordance with International Standard on Quality Control 1, we maintain a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

KPMG A25A Sustamability Co. Ltd.

KPMG AZSA Sustainability Co., Ltd.

Tokyo, Japan

July 15, 2014

### Corporate Information As of March 31, 2014

### **Takeda Pharmaceutical Company Limited**

Founded June 12, 1781 January 29, 1925 Date of Incorporation ¥63,562 million Share Capital Number of Shareholders 308,360 Common Shares Issued 789,680,595 Independent Certified KPMG AZSA LLC

**Public Accountants** Ginsen Bingomachi Bldg. 3-6-5, Kawara-machi, Chuo-ku,

Osaka-shi, Osaka 541-0048, Japan

Stock Exchange Listings (#4502) Tokyo, Nagoya, Fukuoka, Sapporo Administrator of the Mitsubishi UFJ Trust and Banking Corporation

Shareholders' Register 4-5 Marunouchi 1-chome Chiyoda-ku, Tokyo 100-8212, Japan

### American Depositary Receipts (ADR):

Ratio (ADR:ORD): 2:1

Exchange: OTC (Over-the-Counter)

Symbol: TKPYY CUSIP: 874060205

### Depositary:

The Bank of New York Mellon 101 Barclay Street, New York,

NY 10286, USA

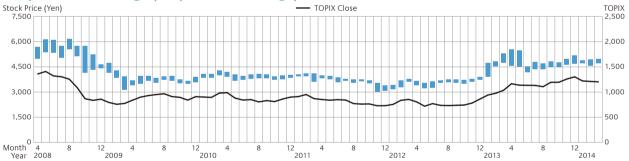
DR Shareowner Contact: Non-U.S. Callers: 201-680-6825

U.S. Callers: (888) 269-2377 URL: http://www.adrbnymellon.com

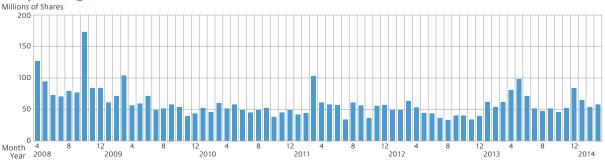
### **Principal Shareholders (10 largest shareholders)**

| Shareholders   | No. of shares held (1,000) | % of shares outstanding |
|--|----------------------------|-------------------------|
| Nippon Life Insurance Company                        | 53,580                     | 6.79                    |
| The Master Trust Bank of Japan, Ltd. (Trust account) | 32,728                     | 4.14                    |
| Japan Trustee Services Bank, Ltd. (Trust account)    | 29,887                     | 3.78                    |
| Takeda Science Foundation                            | 17,912                     | 2.27                    |
| Barclays Securities Japan Limited                    | 15,000                     | 1.90                    |
| The Bank of New York 133522                          | 10,680                     | 1.35                    |
| State Street Trust & Banking Co., Ltd. 505225        | 9,582                      | 1.21                    |
| State Street Bank West Client-Treaty                 | 9,315                      | 1.18                    |
| Japan Trustee Services Bank, Ltd. (Trust account 6)  | 8,179                      | 1.04                    |
| Japan Trustee Services Bank, Ltd. (Trust account 5)  | 8,169                      | 1.03                    |

### Monthly Stock Price Range (Tokyo Stock Exchange)



### **Monthly Trading Volume**



<sup>\*</sup> TOPIX (Tokyo Stock Price Index) is an intellectual property that belongs to the Tokyo Stock Exchange, Inc. (TSE). All the rights to calculate, publicize, disseminate, and use the index value are reserved by the TSE.

For further information, please contact

**Head Office** 

**Tokyo Head Office** 

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