

# Summary of Financial Statements for the Nine Month Period Ended December 31, 2015 (IFRS, Consolidated)

February 3, 2016

## Takeda Pharmaceutical Company Limited

Stock exchange listings: Tokyo, Nagoya, Fukuoka, Sapporo

TSE Code: 4502

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Supplementary materials for the financial statements: Yes

Presentation to explain for the financial statements: Yes

(Million JPY, rounded to the nearest million)

## 1. Consolidated Financial Results for the Nine Month Period Ended December 31, 2015 (April 1 to December 31, 2015)

### (1) Consolidated Operating Results (year to date)

(Percentage figures represent changes over the same period of the previous year)

	Revenue		Operating profit		Profit before tax		Net profit for the period	
	(Million JPY)	(%)	(Million JPY)	(%)	(Million JPY)	(%)	(Million JPY)	(%)
Nine month period ended December 31, 2015	1,393,257	4.0	167,480	(15.9)	154,607	(17.6)	116,364	41.3
Nine month period ended December 31, 2014	1,339,985	4.1	199,052	12.6	187,566	(5.8)	82,345	(39.8)

	Net profit attributable to owners of the Company		Total comprehensive income for the period		Basic earnings per share	Diluted earnings per share
	(Million JPY)	(%)	(Million JPY)	(%)	(JPY)	(JPY)
Nine month period ended December 31, 2015	113,646	42.5	115,780	(38.6)	144.94	143.88
Nine month period ended December 31, 2014	79,745	(40.2)	188,600	(53.6)	101.39	101.16

### (2) Consolidated Financial Position

	Total assets (Million JPY)	Total equity (Million JPY)	Equity attributable to owners of the Company (Million JPY)	Ratio of equity attributable to owners of the Company to total assets (%)	Equity attributable to owners of the Company per share (JPY)
As of December 31, 2015	4,189,879	2,162,371	2,098,862	50.1	2,679.00
As of March 31, 2015	4,296,192	2,206,176	2,137,047	49.7	2,719.27

## 2. Dividends

	Annual dividends per share (JPY)				
	1st quarter end	2nd quarter end	3rd quarter end	Year-end	Total
Fiscal 2014	—	90.00	—	90.00	180.00
Fiscal 2015	—	90.00	—	—	—
Fiscal 2015 (Projection)	—	—	—	90.00	180.00

(Note) Modifications in the dividend projection from the latest announcement: None

## 3. Forecasts for Consolidated Operation Results for Fiscal 2015 (April 1, 2015-March 31, 2016)

(Percentage figures represent changes from previous fiscal year)

	Revenue		Operating profit		Profit before tax		Net profit attributable to owners of the Company		Basic earnings per share
	(Million JPY)	(%)	(Million JPY)	(%)	(Million JPY)	(%)	(Million JPY)	(%)	(JPY)
Fiscal 2015	1,820,000	2.4	120,000	—	115,000	—	68,000	—	86.53

(Note) Modifications in forecasts of consolidated operating results from the latest announcement: Modified

## Additional Information

- (1) Changes in significant subsidiaries during the period : No  
(changes in specified subsidiaries resulting in the change in consolidation scope)
- (2) Changes in accounting policies and changes in accounting estimates
- 1) Changes in accounting policies required by IFRS : Yes
- 2) Changes in accounting policies other than 1) : No
- 3) Changes in accounting estimates : No
- (Note) For details, refer to "2. Additional Information in Summary" in page 15.
- (3) Number of shares outstanding (common stock)
- 1) Number of shares outstanding (including treasury stock) at term end:
- |                   |                    |
|-------------------|--------------------|
| December 31, 2015 | 790,194,695 shares |
| March 31, 2015    | 789,923,595 shares |
- 2) Number of shares of treasury stock at term end:
- |                   |                  |
|-------------------|------------------|
| December 31, 2015 | 6,743,866 shares |
| March 31, 2015    | 4,032,165 shares |
- 3) Average number of outstanding shares (for the nine month period ended December 31):
- |                   |                    |
|-------------------|--------------------|
| December 31, 2015 | 784,060,957 shares |
| December 31, 2014 | 786,554,842 shares |

### \* Implementation status about the audit

- This summary of financial statements is exempt from quarterly review procedures required by Financial Instruments and Exchange Act. A part of quarterly review for securities report based on Financial Instruments and Exchange Act has not completed at the time of disclosure of this summary of financial statements. The securities report for the nine month period ended December 31, 2015 is scheduled to be disclosed on February 10, 2016 after completion of the quarterly review.

### \* Note to ensure appropriate use of forecasts, and other comments in particular

- All forecasts in this document are based on information currently available to the management, and do not represent a promise or guarantee to achieve those forecasts. Various uncertain factors could cause actual results to differ, such as changes in the business environment and fluctuation of foreign exchange rates. If a significant event occurs that requires the forecasts to be revised, the Company will disclose it in a timely manner.
- For details of the financial forecast, and the management guidance indicators for actual business performance, please refer to "1. Qualitative Information for the Nine Month Period Ended December 31, 2015 (3) Outlook for Fiscal 2015" on page 13.
- Supplementary materials for the financial statements (presentation materials for the earnings release conference to be held on February 3, 2016) and the audio of the conference including question-and-answer session will be promptly posted on the Company's website.  
(Website of the Company)  
<http://www.takeda.com/investor-information/results/>

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## 1. Qualitative Information for the Nine Month Period Ended December 31, 2015

### (1) Consolidated Operating Results

#### (i) Operating Results

Consolidated results (April 1 to December 31, 2015):

*Billion JPY*

	<u>Amount</u>	<u>Change over the same period of the previous year</u>	
Revenue	1,393.3	+ 53.3	+ 4.0%
R&D expenses	253.9	+ 4.7	+ 1.9%
Operating profit	167.5	- 31.6	- 15.9%
Profit before tax	154.6	- 33.0	- 17.6%
Net profit for the period (attributable to owners of the Company)	113.6	+33.9	+42.5%
EPS (JPY)	144.94	+ 43.56	+ 43.0%

#### [Revenue]

Consolidated revenue was 1,393.3 billion JPY, an increase of 53.3 billion JPY (+4.0%) compared to the same period of the previous year.

- ENTYVIO (for ulcerative colitis and Crohn's disease), first marketed in the U.S. and Europe in June 2014, has experienced strong sales uptake, and in the U.S. there was also an increase in sales of VELCADE (for multiple myeloma), DEXILANT (for acid reflux disease), and BRINTELLIX (for major depression disorder). ADCETRIS (for malignant lymphoma) experienced sales growth in Japan, Europe, and emerging markets, which are the regions where Takeda has marketing rights. In Japan, sales of AZILVA (for hypertension) and LOTRIGA (for hyperlipidemia) significantly increased compared to the same period of the previous year.

On the other hand, negative factors impacting revenue included the decrease of sales of large products such as CANDESARTAN (for hypertension), mainly due to the penetration of generic products.

The depreciation of the yen contributed to a 19.8 billion JPY increase in revenue due to foreign exchange effects, and in total, consolidated revenue increased by 53.3 billion JPY.

- Consolidated revenue of Takeda's major ethical drugs:

*Billion JPY*

Indications / Product Name	Amount	Change over the same period of the previous year	
Multiple myeloma / VELCADE	126.5	+ 12.2	+10.6%
Prostate cancer, breast cancer and endometriosis / LEUPRORELIN (Japan product name: LEUPLIN)	95.8	+ 1.1	+1.2%
Peptic ulcer / PANTOPRAZOLE	78.7	+ 1.2	+1.5%
Peptic ulcer / LANSOPRAZOLE (Japan product name: TAKEPRON)	70.4	- 7.7	-9.9%
Hypertension / CANDESARTAN (Japan product name: BLOPRESS)	67.1	- 34.8	-34.2%
Ulcerative colitis and Crohn's disease / ENTYVIO	59.3	+ 42.9	+261.2%
Acid reflux disease / DEXILANT	56.6	+ 11.4	+25.3%
Hypertension / AZILVA	45.3	+ 12.3	+37.2%
Diabetes / NESINA	38.3	+ 4.4	+12.9%
Gout / COLCRYS	34.2	- 9.6	-21.9%
Malignant Lymphoma / ADCETRIS	21.4	+ 3.9	+22.5%
Major depressive disorder / BRINTELLIX	18.1	+ 8.9	+98.0%

(Note) Revenue amount includes royalty income and service income.

- In the U.S., in December 2015, Takeda launched NINLARO (for relapsed or refractory multiple myeloma), the first and only oral proteasome inhibitor. Since clinical research started for the first proteasome inhibitor, VELCADE, 20 years ago, Takeda's Oncology Unit has advanced scientific understanding of multiple myeloma, which culminated in the introduction of NINLARO, an efficacious once-weekly pill with a tolerable safety profile. This highly innovative product is expected to provide a significant contribution to Takeda's mid- to long-term sustained growth.  
 In Japan, TAKECAB (for acid-related diseases) was launched in February 2015, and activities of providing information to healthcare professionals have been continuing in co-promotion with Otsuka Pharmaceutical Company, Limited. Also in Japan, in May 2015, Takeda launched ZAFATEK, the world's first once weekly oral type 2 diabetes treatment option.
- In November 2015, Takeda announced the establishment of a new business venture in Japan with Teva, the global leader in generics. The new business venture, to be established in or after April 2016, will deliver Teva's high-quality generic medicines and Takeda's long listed products to patients. It is expected to meet wide-range of needs and correspond to the growing importance of generics in Japan.  
 In December 2015, Takeda announced the sale of its respiratory portfolio to AstraZeneca.  
 Focusing on its core therapeutic areas, Takeda will further strengthen its initiatives to lead innovation in medicine and provide innovative new drugs.

[Operating profit]

Consolidated operating profit was 167.5 billion JPY, a decrease of 31.6 billion JPY (-15.9%) compared to the same period of the previous year.

- Gross profit increased by 37.2 billion JPY (+3.9%) due to revenue increase.
- Selling, general and administrative expenses increased by 37.5 billion JPY (+8.6%) mainly due to the increase in sales expenses related to new products in the U.S.
- R&D expenses were 253.9 billion JPY, an increase of 4.7 billion JPY (+1.9%).
- Amortization and impairment losses on intangible assets associated with products decreased by 33.4 billion JPY (-26.4%), mainly due to 30.5 billion JPY of COLCRYS impairment loss being recognized in the same period of the previous year.
- Other operating income decreased by 73.8 billion JPY (-77.9%), mainly due to 56.4 billion JPY of reversal of COLCRYS contingent consideration and 25.4 billion JPY (\*) of the gains on sales of property, plant and equipment being recognized in the same period of the previous year.  
(\* ) Ethical Drug Business: 10.1 billion JPY, Other Business: 15.3 billion JPY
- Other operating expenses decreased by 13.7 billion JPY (-38.7%), mainly due to the decrease in restructuring expenses.

[Net profit for the period (attributable to owners of the Company)]

Consolidated net profit for the period was 113.6 billion JPY, an increase of 33.9 billion JPY (+42.5%) compared to the same period of the previous year. Despite the decrease in operating profit, this increase was mainly due to the decrease in income tax expenses by 67.0 billion JPY (-63.7%).

- In the same period of the previous year, the reversal of a deferred tax asset for R&D tax credits was recognized as the result of Takeda adopting a tax method which allows for R&D expenditures to be expensed in the year incurred. Further, in the current period ended December 31, 2015, income was subject to a lower tax rate in Japan and tax cost was decreased on capital redemption from a subsidiary. As a result, income tax expenses significantly decreased compared to the same period of the previous year.
- Basic earnings per share was 144.94 JPY, an increase of 43.56 JPY (+43.0%) compared to the same period of the previous year.

Underlying growth (Note1) (April 1 to December 31, 2015):

*Billion JPY*

	<u>Change over the same period of the previous year</u>	
Revenue	+ 3.8%	+51.2
Core Earnings (Note2)	+ 1.5%	+ 4.0
Core EPS (JPY) (Note3)	+ 17.3 %	+38.19

(Note1) "Underlying Growth", comparing two periods of financial results under a common basis, shows the real performance of the business. It excludes the impact of foreign exchange and exceptional items such as product divestments and acquisitions, impact of purchase accounting, amortization and impairment loss of intangible assets, restructuring costs and major litigation costs. Takeda adopts "Underlying Growth" of revenue, Core Earnings and Core EPS as its indicators for management guidance.

(Note2) Core Earnings is calculated from operating profit by excluding the impact of exceptional items, such as purchase accounting, amortization and impairment loss of intangible assets, restructuring costs and major litigation costs.

(Note3) Core EPS is earnings per share based on Core Net Profit, which is calculated from Net profit for the period by excluding the impact of exceptional items, similar to those listed above, and the tax effects on them.

- Underlying revenue growth was +3.8% (+51.2 billion JPY) compared to the same period of the previous year.
- Underlying Core Earnings growth was +1.5 % (+4.0 billion JPY) compared to the same period of the previous year. Underlying selling, general and administrative expenses increased by 4.3% due to the increase of investment for new products, and underlying R&D expenses increased by 3.0%.
- Underlying Core EPS growth was +17.3% (+38.19 JPY) compared to the same period of the previous year.

## (ii) Results by Segment

Revenue and operating profit by business segment (April 1 to December 31, 2015):

*Billion JPY*

Type of Business	Revenue		Operating profit	
	Amount	Change over the same period of the previous year	Amount	Change over the same period of the previous year
Ethical Drug	1,272.0	+57.4	136.2	-14.9
<Japan>	<428.4>	< -8.7>		
<Outside of Japan >	<843.6>	< +66.0>		
Consumer Healthcare	63.8	+5.6	21.0	+3.3
Other	57.4	-9.7	10.3	-20.0
Total	1,393.3	+53.3	167.5	-31.6

[Ethical Drug Business]

Revenue in the Ethical Drug Business was 1,272.0 billion JPY, an increase of 57.4 billion JPY (+4.7%) compared to the same period of the previous year, and operating profit was 136.2 billion JPY, a decrease of 14.9 billion JPY (-9.9%) compared to the same period of the previous year.

- Revenue in Japan was 428.4 billion JPY, a decrease of 8.7 billion JPY (-2.0%). Contribution from the sales increase of products such as AZILVA and LOTRIGA could not fully offset the sales decrease of products such as BLOPRESS mainly due to the penetration of generic products.
- The following table shows revenue results of major products in Japan:

*Billion JPY*

Product Name (Indications)	Amount	Change over the same period of the previous year	
BLOPRESS (Hypertension)	47.3	- 31.5	-40.0%
AZILVA (Hypertension)	45.3	+ 12.3	+37.2%
LEUPLIN (Prostate cancer, breast cancer and endometriosis)	42.2	- 2.5	-5.7%
TAKEPRON (Peptic ulcer)	33.0	- 8.2	-19.8%
NESINA (Diabetes)	29.2	- 0.6	-1.9%
LOTRIGA (Hyperlipidemia)	16.9	+ 7.8	+86.4%
VECTIBIX (Colorectal cancer)	14.2	+ 0.2	+1.1%
REMINYL (Alzheimer-type dementia)	12.4	+ 2.0	+19.4%

- Revenue in outside of Japan was 843.6 billion JPY, an increase of 66.0 billion JPY (+8.5%) compared to the same period of the previous year. Some products decreased in sales due to the penetration of generic products, but this impact was greatly exceeded by the positive factors driving sales such as the favorable sales growth of ENTYVIO and the stable sales increase of VELCADE and DEXILANT in the U.S.
- The following table shows revenue results of major products in outside of Japan:

*Billion JPY*

Product Name (Indications)	Amount	Change over the same period of the previous year	
VELCADE (Multiple myeloma)	122.7	+ 13.7	+12.6%
PANTOPRAZOLE (Peptic ulcer)	78.7	+ 1.2	+1.5%
ENTYVIO (Ulcerative colitis and Crohn's disease)	59.3	+ 42.9	+261.2%
DEXILANT (Acid reflux disease)	56.6	+ 11.4	+25.3%
LEUPRORELIN (Prostate cancer, breast cancer and endometriosis)	53.6	+ 3.7	+7.4%
LANSOPRAZOLE (Peptic ulcer)	37.3	+ 0.4	+1.2%
COLCRYS (Gout)	34.2	- 9.6	-21.9%
CANDESARTAN (Hypertension)	19.7	- 3.3	-14.3%

(Note) Revenue amount includes royalty income and service income.



[Consumer Healthcare Business]

Revenue in the Consumer Healthcare Business was 63.8 billion JPY, an increase of 5.6 billion JPY (+9.7%) compared to the same period of the previous year, mainly due to the increase in sales of ALINAMIN tablets (vitamin-containing products). Operating profit increased by 3.3 billion JPY (+18.6%) to 21.0 billion JPY, mainly due to the increase in gross profit resulting from revenue increase.

[Other Business]

Revenue in Other Business was 57.4 billion JPY, a decrease of 9.7 billion JPY (-14.5%) compared to the same period of the previous year, mainly due to the end of sales contribution from the Mizusawa Group as a result of the sale of all shares of Mizusawa Industrial Chemicals, Ltd. in April, 2015. Operating profit was 10.3 billion JPY, a decrease of 20.0 billion JPY (-66.0%), mainly due to 15.3 billion JPY of gains on sales of property, plant and equipment being recognized in the same period of the previous year.

### **(iii) Activities and Results of Research & Development**

Takeda has announced that its top priorities are to be a leader in Oncology, Gastroenterology and CNS emphasizing psychiatry. Second, it will deliver maximum, targeted value in Specialty CV and an innovative business and global health approach in Vaccines.

As a patient-centric, innovation-driven, R&D-based company, Takeda will focus and strengthen its pipeline in these Therapeutic Areas, broaden its therapeutic modality expertise and ensure it has the right mix of capabilities to drive continued success well into the future. These capabilities include:

- A balanced expertise in therapeutic modalities beyond small molecules, including biologics and a strong commitment to regenerative medicine centered around its “Takeda-CiRA Joint Program for iPS Cell Applications” (T-CiRA) collaboration
- Expertise in bioinformatics and genomic research
- Translational medicine as a foundational capability
- A deep, strong commitment to meaningful external partnerships and collaborations, as these are a key source of innovation

Major R&D events and business development contracts, press released from April 2015 to date, are listed as follows (chronologically by therapeutic area):

#### **Oncology**

##### **[NINLARO]**

- In May 2015, Takeda announced that it has started the Phase III maintenance study (TOURMALINE-MM4 study) of NINLARO (generic name: ixazomib), an oral proteasome inhibitor, in patients with newly diagnosed multiple myeloma who have responded to initial therapy and have not undergone an autologous stem cell transplant.
- In July 2015, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) granted an accelerated assessment (\*) to NINLARO for the treatment of patients with relapsed and/or refractory multiple myeloma. In August 2015, the EMA accepted the Marketing Authorization Application (MAA) for NINLARO for the treatment of patients with relapsed and/or refractory multiple myeloma.  
(\* ) The EMA awards an accelerated assessment to those medicines deemed to be of major public health interest and, in particular, therapeutic innovation.

- In November 2015, Takeda received approval from the U.S. Food and Drug Administration (FDA) for NINLARO indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. The FDA approval of NINLARO is based on results from the Phase III study (TOURMALINE-MM1 study), the first double-blind, placebo-controlled trial with a proteasome inhibitor. In December 2015, data from TOURMALINE-MM1 study was presented at the 57<sup>th</sup> Annual Meeting of the American Society of Hematology (ASH).

[MLN8237 (alisertib)]

- In May 2015, Takeda announced that it has decided to discontinue the Phase III trial of MLN8237 (generic name: alisertib), an inhibitor of Aurora A kinase, for patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) following the results of a pre-specified interim analysis that indicated the study is unlikely to meet the primary endpoint over the standard-of-care in this treatment setting. Takeda continues to investigate the utility of MLN8237 in small cell lung cancer.

[LEUPLIN]

- In September 2015, Takeda received approval from the Japanese MHLW for LEUPLIN (generic name: leuprorelin) 24 week depot, for the treatment of prostate cancer and premenopausal breast cancer.

[ADCETRIS]

- In October 2015, Takeda and Seattle Genetics, Inc. of the U.S. announced that the companies have achieved completion of target patient enrollment in the Phase III ECHELON-1 trial of ADCETRIS (generic name: brentuximab vedotin), a treatment for malignant lymphoma which Takeda in-licensed from Seattle Genetics. ECHELON-1 is a randomized trial evaluating ADCETRIS as part of a frontline combination chemotherapy regimen in patients with previously untreated advanced classical Hodgkin lymphoma. The expected timing of data readout from the trial is in the 2017 to 2018 timeframe.

- In December 2015, post-treatment follow up data from the pivotal Phase II study of single-agent ADCETRIS for the treatment of relapsed or refractory Hodgkin lymphoma following autologous stem cell transplantation (ASCT), was presented at the 57<sup>th</sup> ASH.

- In January 2016, Takeda announced that the European Commission (EC) has approved a Type II variation for ADCETRIS to include data on the retreatment of adult patients with relapsed or refractory Hodgkin lymphoma or relapsed or refractory systemic anaplastic large cell lymphoma who previously responded to ADCETRIS and who later relapse.

[Partnership/Business Development]

- In April 2015, Takeda and the National Cancer Center (NCC) of Japan signed a partnership agreement with the goal to discover and develop anti-cancer agents. Takeda and the NCC have agreed to share information and hold regular discussions in order to collaborate and transition findings from basic research to clinical research and development activities.
- In August 2015, Takeda and Gencia LLC of the U.S. signed a partnership agreement to develop a new class of small molecule drugs, called Mitochondrial Agonists of the Glucocorticoid Receptor, as potential treatments for hematological and inflammatory diseases. The initial aim of the collaboration will be joint research and development leading to two preclinical drug candidates, one each in the areas of inflammation and oncology.

## **Gastroenterology**

### **[ENTYVIO]**

- In October 2015, data highlighting the efficacy and safety of ENTYVIO (generic name: vedolizumab) for the treatment of ulcerative colitis and Crohn's disease, was presented during the 2015 American College of Gastroenterology (ACG) Annual Scientific Meeting and during the United European Gastroenterology Week (UEGW).

### **[Partnership/Business Development]**

- In December 2015, Takeda and Cour Pharmaceutical Development Company, Inc. of the U.S. entered into a partnership to research and develop novel immune modulating therapies for the potential treatment of celiac disease. The collaboration will explore the potential of Tolerizing Immune Modifying nanoParticle (TIMP) therapy to allow celiac patients to tolerate gluten in their diet.
- In January 2016, Takeda and Enterome Bioscience SA of France entered into a strategic drug discovery collaboration to research and develop potential new therapeutics directed at microbiome targets thought to play crucial roles in gastrointestinal disorders, including inflammatory bowel diseases (e.g. ulcerative colitis) and motility disorders (e.g. irritable bowel syndrome).
- In January 2016, Takeda and enGene, Inc. of Canada entered into a strategic alliance to discover, develop and commercialize novel therapies for specialty gastrointestinal diseases using enGene's "Gene Pill" gene delivery platform. Takeda will also collaborate with enGene in developing Gene Pill into a platform for oral delivery of antibodies.

## **CNS**

### **[LATUDA]**

- In May 2015, Takeda announced that it has reached an agreement with Sumitomo Dainippon Pharma Co., Ltd. to terminate the license agreement for the joint development and exclusive commercialization in Europe of LATUDA (generic name: lurasidone), an atypical antipsychotic agent. The companies have started discussions in an effort to finalize and execute a mutual agreement establishing a transition plan for the orderly transfer of all development and commercialization rights and activities with respect to LATUDA to Sumitomo Dainippon Pharma.

### **[BRINTELLIX]**

- In August 2015, the FDA accepted a supplemental New Drug Application (sNDA) for review to add clinical data to the current product label regarding the effect of BRINTELLIX (generic name: vortioxetine), which Takeda licensed from H. Lundbeck A/S of Denmark, on certain aspects of cognitive function in adults with Major Depressive Disorder.

### **[Partnership/Business Development]**

- In January 2016, Takeda and NsGene, Inc. of the U.S. signed a research agreement to develop encapsulated cell therapies for the potential treatment of Parkinson's disease. The partnership will focus on the delivery of recombinant Glial Cell Line-Derived Neurotrophic Factor (GDNF) to affected brain regions by way of implanted, encapsulated cell therapy devices.

## **Vaccines**

### **[Organization]**

- In June 2015, Takeda announced that it will consolidate its Vaccine Business Unit (VBU) operations by establishing global and regional hubs, as well as consolidating the U.S. vaccine sites, as the organization continues to grow and advance its important vaccine programs. The Boston/Cambridge, Massachusetts area, and Zurich, Switzerland will serve as VBU's global hubs for the vaccine business outside of Japan. VBU will maintain regional hubs in Singapore and in Brazil. Takeda will close its vaccine site in Bozeman, Montana as well as the Madison, Wisconsin and Fort Collins, Colorado sites. In addition, vaccine activities in Deerfield, Illinois, which currently serves as the global headquarters for VBU, will shift to the Boston/Cambridge area. This transition will occur in phases over the next two years, with the completion of U.S. consolidation by mid-2017.

### **[Seasonal Influenza Vaccine]**

- In August 2015, Takeda reached an agreement with Nanotherapeutics, Inc. of the U.S. providing Takeda with expanded commercialization and technology access rights related to Nanotherapeutics' Vero cell technology platform – a cell culture-based platform for vaccine production which Nanotherapeutics acquired from Baxalta, formerly Baxter International's BioScience division. Takeda gains rights to commercialize its pandemic and seasonal influenza vaccine products based on the Vero cell technology platform in certain regions outside of Japan and will have access to Vero cell technology and reagents for the development of vaccines beyond influenza.

### **[VAXEM Hib]**

- In January 2016, Takeda received approval from the Japanese MHLW for VAXEM Hib, which Takeda in-licensed from Novartis(\*) of Switzerland, for a conjugate vaccine to prevent infections caused by Haemophilus influenzae type b (Hib) in children aged from 2 months to under 5 years of age.

(\*) In April 2014, GlaxoSmithKline plc (GSK) announced a transaction with Novartis which closed in March 2015. As result of this transaction, GSK acquired Novartis' non-influenza global vaccines business including VAXEM Hib.

### **[Partnership/Business Development]**

- In June 2015, Takeda and the Drugs for Neglected Diseases *initiative* (DND<sup>i</sup>) of Switzerland signed an agreement to collaborate in the "Lead Optimization Program" aimed at identifying the best compound among aminopyrazole series for developing an innovative drug for the treatment of visceral leishmaniasis. The program is being funded by Global Health Innovative Technology Fund.

## **Others**

- In April 2015, Takeda and the Center for iPS Cell Research Application (CiRA) of Kyoto University entered into a 10-year collaboration on iPS cell research. Takeda and CiRA will work together to develop clinical applications of induced pluripotent stem cells. In December 2015, the T-CiRA began research in six core directions to explore clinical applications of stem cells in therapeutic areas including cancer, heart failure, diabetes mellitus, neuro-degenerative disorders and intractable muscle diseases.

- In April 2015, Takeda announced that it has signed an agreement to undertake collaborative research with Keio University School of Medicine and Niigata University at Takeda's Shonan Research Center regarding the search for, and functional analysis of, disease-related RNA-binding proteins.

- In April 2015, the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the FDA convened to review EXAMINE, a global cardiovascular safety outcomes trial of type 2 diabetes treatment NESINA (generic name: alogliptin), and voted that the use of alogliptin in patients with Type 2 diabetes has an acceptable CV risk profile. In June 2015, a post hoc analysis and additional post hoc analyses of data from EXAMINE were presented at the American Diabetes Association's (ADA) 75<sup>th</sup> Scientific Sessions.
- In July 2015, Takeda announced the completion of the study to fulfill the post-marketing commitment and submissions of data to regulatory authorities from the Pan European Multi-Database Bladder Cancer Risk Characterization Study, a large multi-database retrospective matched cohort study, conducted in four European countries, for pioglitazone containing medicines, including ACTOS (generic name: pioglitazone) with up to 10 years of follow-up. Findings demonstrate that there is no association between the use of pioglitazone and the risk of bladder cancer.
- In September 2015, Takeda received approval from the Japanese MHLW for COPAXONE (generic name: glatiramer), which Takeda in-licensed from Teva Pharmaceutical Industries Ltd. of Israel, for the treatment of multiple sclerosis.
- In September 2015, Takeda submitted a New Drug Application ("NDA") to the Japanese Ministry of Health, Labour and Welfare (MHLW) for the fixed-dose combination of NESINA and metformin for the treatment of type 2 diabetes.

## **(2) Consolidated Financial Position**

### **[Assets]**

Total assets as of December 31, 2015 were 4,189.9 billion JPY, a decrease of 106.3 billion JPY compared to the previous fiscal year end, mainly due to a decrease in intangible assets as a result of amortization and a decrease in cash and cash equivalents resulting from dividend payments.

### **[Liabilities]**

Total liabilities as of December 31, 2015 were 2,027.5 billion JPY, a decrease of 62.5 billion JPY compared to the previous fiscal year end, mainly due to bonus payments and revaluation of share-based payments accrual. Non-current liabilities and current liabilities decreased by 56.9 billion JPY and 5.6 billion JPY, respectively.

### **[Equity]**

Total equity as of December 31, 2015 was 2,162.4 billion JPY, a decrease of 43.8 billion JPY compared to the previous fiscal year end. Despite net profit for the period, this decrease was mainly due to the acquisition of treasury shares related to the Board Incentive Plan (BIP) and the Employee Stock Ownership Plan (ESOP), in addition to dividend payments.

The ratio of equity attributable to owners of the Company to total assets increased by 0.4 pt. from the previous fiscal year end to 50.1%.

### (3) Outlook for Fiscal 2015

The outlook for consolidated results for the full year of fiscal 2015 has been revised from the previous forecast (announced at the 2<sup>nd</sup> quarter of fiscal 2015 financial results announcement on October 30, 2015) as follows, considering the current results and foreign exchange rates.

#### Forecast

	<i>Billion JPY</i>			
	Previous forecast (A)	Revised forecast (B)	Change (B-A)	Change
Revenue	1,820.0	1,820.0	—	—
R&D expenses	330.0	330.0	—	—
Operating profit	105.0	120.0	+15.0	+14.3%
Profit before income taxes	115.0	115.0	—	—
Net profit for the year (attributable to owners of the Company)	68.0	68.0	—	—
EPS	86.53 yen	86.53 yen	—	—

#### Management Indicators – Underlying growth (\*)

Revenue	Low single digit
Core Earnings (*)	Higher than revenue growth
Core EPS (*)	Higher than Core Earnings growth

(\*) Please refer to the (Underlying growth) on page 5.

#### [Assumptions used in preparing the Outlook]

The foreign exchange rates assumptions for fiscal 2015 are 1 USD = 121 JPY and 1 EUR = 133 JPY.

#### [Forward looking statement]

All forecasts in this document are based on information currently available to the management, and do not represent a promise or guarantee to achieve those forecasts. Various uncertain factors could cause actual results to differ, such as changes in the business environment and fluctuation of foreign exchange rates. If a significant event occurs that requires the forecasts to be revised, the Company will disclose it in a timely manner.

#### **(4) Litigation**

##### Product liability litigation regarding pioglitazone-containing products

Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and certain affiliates located in the U.S. (collectively, "Takeda" in this section (4)) have been named as defendants in lawsuits in U.S. federal and state courts in which plaintiffs allege to have developed bladder cancer or other injuries as a result of taking products containing type 2 diabetes treatment pioglitazone (U.S. brand name: ACTOS) (hereafter, "ACTOS" is used to refer generally to Takeda products containing pioglitazone). Eli Lilly & Co. has been named as a defendant in many of these lawsuits. Outside the U.S., lawsuits and claims have also been brought by persons claiming similar injuries.

On April 29, 2015 (U.S. time April 28), Takeda reached an agreement with the lead plaintiffs' lawyers that was expected to resolve the vast majority of ACTOS product liability lawsuits pending against Takeda in the U.S. The settlement would cover all bladder cancer claims pending in any U.S. court as of the date of settlement, and claimants with unfiled claims in the U.S. represented by counsel as of the date of settlement and within three days thereafter would also be eligible to participate. The settlement would become effective if 95% of litigants and claimants opted in, and once that threshold was achieved, Takeda agreed to pay 2.37 billion USD into a settlement fund. That figure would rise to 2.4 billion USD if more than 97% of the current litigants and claimants opted to participate in the settlement. Under the settlement, litigants and claimants who met prescribed criteria would receive payouts from the fund.

On September 12, 2015 (U.S. time September 11), Takeda announced that more than 96% of eligible litigants and claimants have opted into the ACTOS product liability resolution program. On October 7, 2015 (U.S. time), it was verified that more than 97% of eligible litigants and claimants have opted into the resolution program, and that the resolution program had become effective, which triggers a 2.4 billion USD payment by Takeda into the settlement fund.

Takeda believes that the claims made in this litigation are without merit, and does not admit liability. Takeda believes that the company acted responsibly with regard to ACTOS. Takeda will continue to vigorously defend through all available legal means any cases that continue or are newly filed after the settlement.



## 2. Additional Information in Summary

### (1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in the change in consolidation scope):

No applicable event occurred during the period.

### (2) Changes in accounting policies and changes in accounting estimates

The significant accounting policies adopted for the condensed interim consolidated financial statements are the same as those for the fiscal year ended March 31, 2015 with the exception of the items described below.

(Changes in accounting policies)

The accounting standard applied by the Companies effective from the first quarter ended June 30, 2015 is as follows.

IFRS		Description of new standards, interpretations and amendments
IAS 19	Employee Benefits	Amendment to the accounting for contributions from employees and third parties to defined benefit plans

The above standard does not have a material impact on the condensed interim consolidated financial statements.

### 3. Condensed Interim Consolidated Financial Statements [IFRS]

#### (1) Condensed Interim Consolidated Statement of Operations

(Million JPY)

	Nine month period ended December 31, 2014	Nine month period ended December 31, 2015
Revenue	1,339,985	1,393,257
Cost of sales	(386,407)	(402,440)
Gross profit	953,578	990,817
Selling, general and administrative expenses	(438,036)	(475,526)
Research and development expenses	(249,227)	(253,898)
Amortization and impairment losses on intangible assets associated with products	(126,478)	(93,065)
Other operating income	94,664	20,899
Other operating expenses	(35,449)	(21,746)
Operating profit	199,052	167,480
Finance income	14,912	17,263
Finance expenses	(27,719)	(30,577)
Share of profit of associates accounted for using the equity method	1,321	440
Profit before tax	187,566	154,607
Income tax expenses	(105,222)	(38,242)
Net profit for the period	82,345	116,364
Attributable to:		
Owners of the Company	79,745	113,646
Non-controlling interests	2,600	2,719
Net profit for the period	82,345	116,364
Earnings per share (JPY)		
Basic earnings per share	101.39	144.94
Diluted earnings per share	101.16	143.88

#### (2) Condensed Interim Consolidated Statement of Operations and Other Comprehensive Income

(Million JPY)

	Nine month period ended December 31, 2014	Nine month period ended December 31, 2015
Net profit for the period	82,345	116,364
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurements of defined benefit plans	(6,412)	6,818
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	105,091	(14,131)
Net changes on revaluation of available-for-sale financial assets	8,436	7,551
Cash flow hedges	(860)	(823)
	112,667	(7,402)
Other comprehensive income for the period, net of tax	106,255	(584)
Total comprehensive income for the period	188,600	115,780
Attributable to:		
Owners of the Company	182,994	114,050
Non-controlling interests	5,606	1,729
Total comprehensive income for the period	188,600	115,780

**(3) Condensed Interim Consolidated Statement of Financial Position**

(Million JPY)

	As of March 31, 2015	As of December 31, 2015
<b>ASSETS</b>		
<b>NON-CURRENT ASSETS</b>		
Property, plant and equipment	526,162	516,718
Goodwill	821,911	818,741
Intangible assets	939,381	798,335
Investment property	30,218	29,964
Investments accounted for using the equity method	10,425	10,743
Other financial assets	241,323	255,127
Other non-current assets	52,192	51,993
Deferred tax assets	154,506	158,546
Total non-current assets	2,776,120	2,640,166
<b>CURRENT ASSETS</b>		
Inventories	262,354	268,741
Trade and other receivables	444,681	483,877
Other financial assets	61,275	99,558
Income taxes recoverable	22,148	9,857
Other current assets	63,225	61,094
Cash and cash equivalents	652,148	560,952
Subtotal	1,505,830	1,484,078
Assets held for sale	14,243	65,634
Total current assets	1,520,072	1,549,712
Total assets	4,296,192	4,189,879

(Million JPY)

	As of March 31, 2015	As of December 31, 2015
<b>LIABILITIES AND EQUITY</b>		
<b>LIABILITIES</b>		
<b>NON-CURRENT LIABILITIES</b>		
Bonds and loans	629,416	630,121
Other financial liabilities	70,105	66,103
Net defined benefit liabilities	91,686	82,908
Provisions	47,075	33,588
Other non-current liabilities	78,778	74,331
Deferred tax liabilities	156,132	129,209
Total non-current liabilities	1,073,191	1,016,260
<b>CURRENT LIABILITIES</b>		
Bonds and loans	99,965	99,997
Trade and other payables	170,782	170,420
Other financial liabilities	42,105	39,038
Income taxes payable	41,071	59,120
Provisions	418,587	414,969
Other current liabilities	238,469	212,284
Subtotal	1,010,978	995,828
Liabilities held for sale	5,846	15,420
Total current liabilities	1,016,824	1,011,248
Total liabilities	2,090,016	2,027,508
<b>EQUITY</b>		
Share capital	64,044	64,588
Share premium	59,575	64,785
Treasury shares	(18,203)	(35,967)
Retained earnings	1,601,326	1,581,564
Other components of equity	430,305	423,892
Equity attributable to owners of the Company	2,137,047	2,098,862
Non-controlling interests	69,129	63,509
Total equity	2,206,176	2,162,371
Total liabilities and equity	4,296,192	4,189,879

#### (4) Condensed Interim Consolidated Statement of Changes in Equity

Nine month period ended December 31, 2014 (From April 1 to December 31, 2014)

(Million JPY)

	Equity attributable to owners of the Company					
	Share capital	Share premium	Treasury shares	Retained earnings	Other components of equity	
					Exchange differences on translation of foreign operations	Net changes on revaluation of available-for-sale financial assets
As of April 1, 2014	63,562	39,866	(621)	1,901,307	406,151	60,771
Net profit for the period				79,745		
Other comprehensive income					102,139	8,369
Comprehensive income for the period				79,745	102,139	8,369
Issuances of new shares	178	178				
Acquisitions of treasury shares			(17,569)			
Disposals of treasury shares		(0)	1			
Dividends				(141,781)		
Changes in the ownership interest in subsidiaries				(7,901)		
Transfers from other components of equity				(6,399)		
Share-based payments		5,359	3			
Put options written on non-controlling interests		11,277				
Total transactions with owners	178	16,814	(17,565)	(156,081)		
As of December 31, 2014	63,740	56,681	(18,185)	1,824,972	508,290	69,141

	Equity attributable to owners of the Company				Non-controlling interests	Total equity
	Other components of equity			Total		
	Cash flow hedges	Remeasurements of defined benefit plans	Total			
As of April 1, 2014	(298)	—	466,624	2,470,739	69,896	2,540,635
Net profit for the period				79,745	2,600	82,345
Other comprehensive income	(860)	(6,399)	103,249	103,249	3,006	106,255
Comprehensive income for the period	(860)	(6,399)	103,249	182,994	5,606	188,600
Issuances of new shares				357		357
Acquisitions of treasury shares				(17,569)		(17,569)
Disposals of treasury shares				1		1
Dividends				(141,781)	(2,035)	(143,816)
Changes in the ownership interest in subsidiaries				(7,901)	(4,079)	(11,980)
Transfers from other components of equity		6,399	6,399	—		—
Share-based payments				5,362		5,362
Put options written on non-controlling interests				11,277		11,277
Total transactions with the owners	—	6,399	6,399	(150,254)	(6,114)	(156,368)
As of December 31, 2014	(1,159)	—	576,272	2,503,479	69,387	2,572,867

Nine month period ended December 31, 2015 (From April 1 to December 31, 2015)

(Million JPY)

	Equity attributable to owners of the Company					
	Share capital	Share premium	Treasury shares	Retained earnings	Other components of equity	
					Exchange differences on translation of foreign operations	Net changes on revaluation of available-for-sale financial assets
As of April 1, 2015	64,044	59,575	(18,203)	1,601,326	355,692	75,685
Net profit for the period				113,646		
Other comprehensive income					(13,243)	7,653
Comprehensive income for the period				113,646	(13,243)	7,653
Issuances of new shares	543	544				
Acquisitions of treasury shares			(22,338)			
Disposals of treasury shares		0	2			
Dividends				(141,585)		
Changes in the ownership interest in subsidiaries				1,359		
Transfers from other components of equity				6,818		
Share-based payments		4,666	4,573			
Put options written on non-controlling interests						
Total transactions with owners	543	5,210	(17,764)	(133,408)		
As of December 31, 2015	64,588	64,785	(35,967)	1,581,564	342,449	83,338

	Equity attributable to owners of the Company				Non-controlling interests	Total equity
	Other components of equity			Total		
	Cash flow hedges	Remeasurements of defined benefit plans	Total			
As of April 1, 2015	(1,073)	—	430,305	2,137,047	69,129	2,206,176
Net profit for the period				113,646	2,719	116,364
Other comprehensive income	(823)	6,818	405	405	(989)	(584)
Comprehensive income for the period	(823)	6,818	405	114,050	1,729	115,780
Issuances of new shares				1,087		1,087
Acquisitions of treasury shares				(22,338)		(22,338)
Disposals of treasury shares				2		2
Dividends				(141,585)	(1,868)	(143,453)
Changes in the ownership interest in subsidiaries				1,359	(5,481)	(4,122)
Transfers from other components of equity		(6,818)	(6,818)	—		—
Share-based payments				9,239		9,239
Put options written on non-controlling interests				—		—
Total transactions with the owners	—	(6,818)	(6,818)	(152,236)	(7,350)	(159,585)
As of December 31, 2015	(1,895)	—	423,892	2,098,862	63,509	2,162,371

## (5) Notes to Condensed Interim Consolidated Financial Statements

(Going Concern Assumption)

Nine month period ended December 31, 2015 (April 1 to December 31, 2015)

No events to be noted for this purpose.

(Significant Changes in Equity Attributable to Owners of the Company)

Nine month period ended December 31, 2015 (April 1 to December 31, 2015)

No events to be noted for this purpose.

(Segment Information)

### 1. Revenues and operating profit by reportable segment and other information

Nine month period ended December 31, 2014 (April 1 to December 31, 2014)

(Million JPY)

	Reportable Segments			Total	Condensed interim consolidated financial statements
	Ethical Drugs	Consumer Healthcare	Other		
Revenues	1,214,676	58,207	67,101	1,339,985	1,339,985
Operating profit	151,086	17,717	30,249	199,052	199,052
	Finance income				14,912
	Finance expenses				(27,719)
	Share of profit of associates accounted for using the equity method				1,321
	Profit before tax				187,566

Nine month period ended December 31, 2015 (April 1 to December 31, 2015)

(Million JPY)

	Reportable Segments			Total	Condensed interim consolidated financial statements
	Ethical Drugs	Consumer Healthcare	Other		
Revenues	1,272,031	63,843	57,383	1,393,257	1,393,257
Operating profit	136,195	21,006	10,278	167,480	167,480
	Finance income				17,263
	Finance expenses				(30,577)
	Share of profit of associates accounted for using the equity method				440
	Profit before tax				154,607

### 2. Geographic Information

Revenues

(Million JPY)

	Japan	United States	Europe and Canada	Russia/ CIS	Latin America	Asia	Others	Total
Nine month period ended December 31, 2014	553,437	300,375	247,675	64,009	66,612	81,791	26,085	1,339,985
Nine month period ended December 31, 2015	541,078	382,779	238,157	49,661	55,203	96,266	30,113	1,393,257

(Note) 1. Revenues are attributable to countries or regions based on the customer location.

2. "Others" region includes Middle East, Oceania and Africa.

(Breakdown of Revenues)

Nine month period ended December 31, 2014 (April 1 to December 31, 2014)

(Million JPY)

Ethical Drugs			Consumer healthcare	Other	Condensed interim consolidated statement of income	[Royalties]
(Japan)	(Overseas)	Subtotal				
437,052	777,625	1,214,676	58,207	67,101	1,339,985	[45,152]

Nine month period ended December 31, 2015 (April 1 to December 31, 2015)

(Million JPY)

Ethical Drugs			Consumer healthcare	Other	Condensed interim consolidated statement of income	[Royalties]
(Japan)	(Overseas)	Subtotal				
428,401	843,630	1,272,031	63,843	57,383	1,393,257	[40,503]

(Significant Subsequent Events)

No events to be noted for this purpose.

## 4. Supplemental Information

### (1) Ethical Drugs Revenues [Consolidated]

(Billion JPY)

	Nine month period ended December 31, 2014	Nine month period ended December 31, 2015	Change over the same period of the previous year		Three month period ended December 31, 2014	Three month period ended December 31, 2015	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
Domestic revenues	430.6	423.1	(7.5)	(1.7%)	151.2	154.6	3.5	2.3%
Overseas revenues	724.0	803.7	79.7	11.0%	269.4	277.5	8.1	3.0%
United States	284.1	367.6	83.6	29.4%	109.4	128.6	19.2	17.6%
Europe and Canada	216.7	216.9	0.2	0.1%	77.5	74.1	(3.4)	(4.4%)
Russia/CIS	62.5	49.3	(13.2)	(21.1%)	24.9	17.5	(7.4)	(29.7%)
Latin America	63.4	53.3	(10.1)	(15.9%)	24.2	16.9	(7.3)	(30.1%)
Asia	74.8	89.2	14.4	19.3%	27.8	31.3	3.5	12.5%
Others	22.4	27.3	4.9	21.7%	5.6	9.0	3.5	61.9%
Royalty Income and Service Income	60.1	45.3	(14.9)	(24.7%)	24.0	14.4	(9.6)	(40.2%)
Domestic	6.5	5.3	(1.1)	(17.5%)	2.7	1.8	(0.9)	(34.0%)
Overseas	53.7	39.9	(13.7)	(25.6%)	21.3	12.6	(8.7)	(40.9%)
Total revenues	1,214.7	1,272.0	57.4	4.7%	444.5	446.5	2.0	0.4%

(Note) "Others" region includes Middle East, Oceania and Africa.

Ratio of Overseas sales	64.0%	66.3%
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	65.4%	65.0%
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### Foreign exchange rates (Reference)

(JPY)

	Nine month period ended December 31, 2014	Nine month period ended December 31, 2015
USD average rate	105.7	121.7
EUR average rate	139.7	133.6

	Three month period ended December 31, 2014	Three month period ended December 31, 2015
	112.1	121.2
	141.1	132.6

### (2) Ethical Drugs Revenues [Emerging Markets]

(Billion JPY)

	Nine month period ended December 31, 2014	Nine month period ended December 31, 2015	Change over the same period of the previous year		Three month period ended December 31, 2014	Three month period ended December 31, 2015	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
Total Revenues in Emerging Markets	234.3	227.4	(6.8)	(2.9%)	87.8	77.1	(10.7)	(12.2%)
China	40.0	49.7	9.7	24.3%	15.7	18.4	2.7	17.2%
Russia	45.8	35.0	(10.8)	(23.6%)	18.5	12.6	(5.9)	(31.9%)
Brazil	35.9	29.2	(6.7)	(18.6%)	12.7	9.5	(3.1)	(24.8%)

(Note) 1. Revenue amount includes royalty income and service income.

2. "Total Revenues in Emerging Markets" includes the revenue amounts in Emerging Markets other than "China", "Russia" and "Brazil."

Takeda Pharmaceutical Company Limited (4502)  
Summary of Financial Statements for the Nine Month  
Period Ended December 31, 2015 (Consolidated)

**(3) Ethical Drugs: Global major products' sales**

(Billion JPY)

Product name	Regional	Nine month period ended December 31, 2014	Nine month period ended December 31, 2015	Change over the same period of the previous year		Three month period ended December 31, 2014	Three month period ended December 31, 2015	Change over the same period of the previous year	
				Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
<i>Velcade</i> (Multiple myeloma)	United States	80.7	101.1	20.4	25.2%	26.3	33.2	6.9	26.3%
	Other than United States	33.6	25.4	(8.2)	(24.5%)	15.3	7.5	(7.7)	(50.7%)
	Total	114.4	126.5	12.2	10.6%	41.6	40.7	(0.8)	(2.0%)
<i>Leuprorelin</i> (Prostate cancer, breast cancer and endometriosis)	Japan	44.7	42.2	(2.5)	(5.7%)	15.0	14.8	(0.2)	(1.4%)
	United States	11.9	13.1	1.1	9.6%	5.2	4.4	(0.8)	(15.7%)
	Europe and Canada	27.5	26.9	(0.6)	(2.3%)	9.5	9.2	(0.3)	(3.2%)
	Emerging Markets	10.4	13.6	3.2	30.4%	3.6	5.0	1.4	40.2%
Total	94.6	95.8	1.1	1.2%	33.3	33.4	0.1	0.3%	
<i>Pantoprazole</i> (Peptic ulcers)	United States	7.4	8.9	1.5	20.9%	3.9	4.2	0.3	6.5%
	Europe and Canada	37.8	34.8	(3.0)	(7.8%)	13.4	11.2	(2.2)	(16.5%)
	Emerging Markets	32.4	34.9	2.6	8.0%	9.7	11.5	1.8	18.8%
	Total	77.6	78.7	1.2	1.5%	27.0	26.8	(0.1)	(0.5%)
<i>Lansoprazole</i> (Peptic ulcers)	Japan	41.2	33.0	(8.2)	(19.8%)	13.7	11.2	(2.6)	(18.7%)
	United States	20.6	21.8	1.2	5.8%	8.6	6.8	(1.8)	(20.9%)
	Europe and Canada	8.9	7.9	(1.0)	(10.8%)	3.1	2.5	(0.6)	(20.6%)
	Emerging Markets	7.5	7.7	0.2	2.6%	2.6	2.4	(0.2)	(6.1%)
Total	78.1	70.4	(7.7)	(9.9%)	28.0	22.8	(5.2)	(18.4%)	
<i>Candesartan</i> (Hypertension)	Japan	78.8	47.3	(31.5)	(40.0%)	22.6	16.0	(6.5)	(28.9%)
	United States	1.5	1.0	(0.5)	(34.9%)	0.4	0.3	(0.1)	(22.0%)
	Europe and Canada	13.4	9.6	(3.8)	(28.1%)	4.0	3.2	(0.8)	(19.5%)
	Emerging Markets	8.2	9.2	1.0	11.8%	2.5	2.8	0.3	14.0%
Total	101.8	67.1	(34.8)	(34.2%)	29.4	22.4	(7.0)	(23.9%)	
<i>Entyvio</i> (Ulcerative colitis and Crohn's disease)	United States	12.1	44.0	31.8	—%	7.2	16.7	9.5	131.9%
	Europe and Canada	4.3	14.5	10.2	—%	2.7	6.2	3.6	132.9%
	Emerging Markets	0.0	0.9	0.9	—%	0.0	0.4	0.4	—%
	Total	16.4	59.3	42.9	—%	9.9	23.4	13.5	136.0%
<i>Dexilant</i> (Acid reflux disease)	United States	38.9	48.4	9.6	24.6%	15.3	18.3	3.0	19.5%
	Europe and Canada	3.6	4.0	0.4	11.2%	1.5	1.5	0.0	2.2%
	Emerging Markets	2.7	4.2	1.5	54.5%	1.2	1.4	0.2	20.8%
	Total	45.2	56.6	11.4	25.3%	17.9	21.2	3.3	18.2%
<i>Azilva</i> (Hypertension)	Japan	33.0	45.3	12.3	37.2%	12.7	16.7	4.0	31.5%
	Total	33.0	45.3	12.3	37.2%	12.7	16.7	4.0	31.5%
<i>Nesina</i> (Diabetes)	Japan	29.7	29.2	(0.6)	(1.9%)	10.1	10.1	0.0	0.1%
	United States	2.9	4.4	1.4	49.9%	1.3	1.4	0.2	14.2%
	Europe and Canada	0.3	2.4	2.1	—%	0.2	1.2	1.0	—%
	Emerging Markets	0.9	2.3	1.4	151.6%	0.4	0.8	0.4	114.0%
Total	33.9	38.3	4.4	12.9%	12.0	13.6	1.6	13.4%	
<i>Colcrys</i> (Gout)	United States	43.7	34.2	(9.6)	(21.9%)	14.0	11.3	(2.7)	(19.4%)
	Total	43.7	34.2	(9.6)	(21.9%)	14.0	11.3	(2.7)	(19.4%)
<i>Uloric</i> (Gout and Hyperuricemia)	United States	23.4	31.2	7.8	33.4%	9.5	11.3	1.8	18.7%
	Europe and Canada	0.4	0.5	0.1	19.9%	0.2	0.2	0.0	15.9%
	Total	23.8	31.7	7.9	33.2%	9.7	11.5	1.8	18.6%
<i>Amitiza</i> (Constipation)	United States	22.8	28.9	6.1	26.7%	8.9	9.8	0.9	10.2%
	Europe and Canada	0.0	0.1	0.1	—%	0.0	0.0	0.0	25.3%
	Total	22.9	29.0	6.1	26.9%	8.9	9.8	0.9	10.2%
<i>Adcetris</i> (Malignant Lymphoma)	Japan	2.1	2.4	0.3	15.5%	0.8	0.8	0.1	7.0%
	Europe and Canada	12.3	13.3	1.0	8.2%	3.9	4.2	0.3	8.8%
	Emerging Markets	2.9	5.7	2.8	97.2%	1.1	1.8	0.7	62.7%
	Total	17.4	21.4	3.9	22.5%	5.8	6.9	1.1	18.9%
<i>Brintellix</i> (Major depressive disorder)	United States	9.1	18.1	8.9	98.0%	3.8	6.8	3.1	81.2%
	Total	9.1	18.1	8.9	98.0%	3.8	6.8	3.1	81.2%

(Note) Sales amount includes royalty income and service income.



Takeda Pharmaceutical Company Limited (4502)  
Summary of Financial Statements for the Nine Month  
Period Ended December 31, 2015 (Consolidated)

**(4) Ethical Drugs: US major products' sales (in USD)**

(Million USD)

Product name	Launched Year	Indication	Nine month period ended December 31, 2014	Nine month period ended December 31, 2015	Change over the same period of the previous year		Three month period ended December 31, 2014	Three month period ended December 31, 2015	Change over the same period of the previous year	
					Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
<i>Velcade</i>	2008	Multiple myeloma	765	809	44	5.7%	261	266	5	2.0%
<i>Dexilant</i>	2009	Acid reflux disease	366	398	32	8.8%	136	151	15	11.1%
<i>Entyvio</i>	2014	Ulcerative colitis and Crohn's disease	112	361	249	—%	64	138	74	114.6%
<i>Colcrys</i>	2012	Gout	416	281	(135)	(32.5%)	125	93	(32)	(25.8%)
<i>Uloric</i>	2009	Gout and Hyperuricemia	220	256	36	16.5%	85	93	8	10.0%
<i>Amiiza</i>	2006	Constipation	215	238	22	10.4%	79	81	2	2.2%
<i>Prevacid (lansoprazole)</i>	1995	Peptic ulcers	188	174	(14)	(7.3%)	74	55	(20)	(26.6%)
<i>Brintellix</i>	2014	Major depressive disorder	86	148	62	72.3%	34	56	22	66.4%
<i>Contrave</i>	2014	Obesity	7	42	36	—%	7	13	7	102.7%
<i>Ninlaro</i>	2015		—	4	4	—%	—	4	4	—%

(Note) Sales amount does not include royalty income and service income.

**(5) Ethical Drugs: Japan major products' sales**

(Billion JPY)

Product name	Launched Year/Month	Indication	Nine month period ended December 31, 2014	Nine month period ended December 31, 2015	Change over the same period of the previous year		Three month period ended December 31, 2014	Three month period ended December 31, 2015	Change over the same period of the previous year	
					Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
<i>Blopress (candesartan)</i>	1999/6	Hypertension	78.8	47.3	(31.5)	(40.0%)	22.6	16.0	(6.5)	(28.9%)
<i>Aziva</i>	2012/5	Hypertension	33.0	45.3	12.3	37.2%	12.7	16.7	4.0	31.5%
<i>Leuplin (leuprorelin)</i>	1992/9	Prostate cancer, breast cancer and endometriosis	44.7	42.2	(2.5)	(5.7%)	15.0	14.8	(0.2)	(1.4%)
<i>Takepron (lansoprazole)</i>	1992/12	Peptic ulcers	41.2	33.0	(8.2)	(19.8%)	13.7	11.2	(2.6)	(18.7%)
<i>Enbrel</i>	2005/3	Rheumatoid arthritis	31.4	31.9	0.5	1.5%	11.1	10.8	(0.2)	(2.1%)
<i>Nesina</i>	2010/6	Diabetes	29.7	29.2	(0.6)	(1.9%)	10.1	10.1	0.0	0.1%
<i>Lotriga</i>	2013/1	Hyperlipidemia	9.1	16.9	7.8	86.4%	4.1	6.3	2.3	55.9%
<i>Vectibix</i>	2010/6	Colorectal cancer	14.1	14.2	0.2	1.1%	4.9	4.8	(0.1)	(1.9%)
<i>Reminyl</i>	2011/3	Alzheimer-type dementia	10.4	12.4	2.0	19.4%	4.0	4.5	0.5	12.4%
<i>Benet</i>	2002/5	Osteoporosis	8.0	7.7	(0.3)	(4.3%)	2.7	2.7	(0.1)	(2.9%)
<i>Basen</i>	1994/9	Diabetes	8.9	7.0	(1.9)	(20.8%)	2.9	2.3	(0.5)	(18.5%)
<i>Actos (pioglitazon)</i>	1999/12	Diabetes	8.6	6.9	(1.7)	(19.8%)	2.8	2.3	(0.5)	(17.0%)
<i>Rozerem</i>	2010/7	Insomnia	5.0	5.7	0.7	15.0%	1.8	2.0	0.2	12.1%
<i>Adcetris</i>	2014/4	Malignant Lymphoma	—	4.2	4.2	—%	—	2.2	2.2	—%
<i>Takecab</i>	2015/2	Acid-related Diseases	2.1	2.4	0.3	15.5%	0.8	0.8	0.1	7.0%

**(6) Consumer Healthcare: Major products' sales**

(Billion JPY)

Product name	Nine month period ended December 31, 2014	Nine month period ended December 31, 2015	Change over the same period of the previous year		Three month period ended December 31, 2014	Three month period ended December 31, 2015	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
<i>Alinamin tablets</i>	16.3	20.5	4.3	26.2%	6.4	7.4	1.0	15.6%
<i>Alinamin health tonics</i>	12.3	12.4	0.1	0.8%	3.9	4.3	0.3	8.7%
<i>Biofermin</i>	8.5	8.5	0.0	0.6%	2.5	3.0	0.4	17.4%
<i>Benza</i>	6.3	6.7	0.4	6.5%	2.2	2.4	0.2	7.1%
<i>Borraginol</i>	3.2	3.5	0.3	8.7%	1.3	1.4	0.1	5.7%

## (7) Development activities

This table primarily shows the indications for which we will actively pursue approval. We are also conducting additional studies of certain assets to examine their potential for use in further indications.

### ■ US/EU/Jpn

Development in regions where compound is not yet approved. Additional indications/formulations/important label updates in regions where compound is already approved are shown in the table "Additional indications/formulations/important label updates of approved compounds"

Development code <generic name> Brand name (country / region)	Drug Class (administration route)	Indications	Stage	
<glatiramer acetate> COPAXONE® (Jpn)	Immunomodulator (injection)	Relapse prevention of multiple sclerosis	Jpn	Approved (Sep '15)
MLN9708 <ixazomib> NINLARO® (US)	Proteasome inhibitor (oral)	Relapsed or refractory multiple myeloma	US EU Jpn	Approved (Nov '15) Filed (Jul '15) P-III
		Previously untreated multiple myeloma	US EU Jpn	P-III P-III P-III
		Maintenance therapy in patients with newly diagnosed multiple myeloma following autologous stem cell transplant	US EU Jpn	P-III P-III P-III
		Maintenance therapy in patients with newly diagnosed multiple myeloma not treated with stem cell transplant	US EU Jpn	P-III P-III P-III
		Relapsed or refractory primary (AL) amyloidosis	US EU	P-III P-III
		Solid tumors	US	P-I
		TAK-816 VAXEM Hib® (Jpn)	Hib vaccine (injection)	Prevention of infectious disease caused by Haemophilus influenzae type b (Hib)
MLN0002 <vedolizumab> ENTYVIO® (US, EU)	Humanized monoclonal antibody against α4β7 integrin (injection)	Ulcerative colitis Crohn's disease	Jpn Jpn	P-III P-III
Lu AA21004 <vortioxetine> BRINTELLIX® (US)	Multimodal anti-depressant (oral)	Major depressive disorder	Jpn	P-III
AMG 386 <trebananib>	Anti-angiopoietin peptibody (injection)	Ovarian cancer	Jpn	P-III
TVP-1012*1 <rasagiline>	Monoamine oxidase B (MAO-B) inhibitor (oral)	Parkinson's disease	Jpn	P-III
MLN8237 <alisertib>	Aurora A kinase inhibitor (oral)	Small cell lung cancer	US EU	P-II(b) P-II(b)
TAK-385 <relugolix>	LH-RH antagonist (oral)	Prostate cancer	US EU Jpn	P-II(b) P-II(b) P-I
		Endometriosis	Jpn	P-II(b)
		Uterine fibroids	Jpn	P-II(b)
TAK-228*2 <- - >	mTORC1/2 inhibitor (oral)	Breast cancer	US EU	P-II(b) P-II(b)
		Renal cancer	US	P-II(b)
		Endometrial cancer	US	P-II(b)
MT203 <namilumab>	GM-CSF monoclonal antibody (injection)	Psoriasis	EU	P-II(b)
		Rheumatoid arthritis	EU Jpn	P-II(b) P-II(b)
			Jpn	P-II(b)
TAK-272 <- - >	Direct renin inhibitor (oral)	Early stage diabetic nephropathy	Jpn	P-II(b)

\*1 Brand name in Teva territories: AZILECT®

\*2 Formerly known as MLN0128

Development code/product name <generic name>	Drug Class (administration route)	Indications	Stage	
<b>TAK-003</b>	Tetravalent dengue vaccine (injection)	Prevention of dengue fever caused by dengue virus	-	P-II(b)
<b>TAK-214</b>	Norovirus vaccine (injection)	Prevention of acute gastroenteritis (AGE) caused by norovirus	-	P-II(b)
<b>TAK-924<sup>*3</sup></b> <b>&lt;pevonedistat&gt;</b>	NEDD 8 activating enzyme inhibitor (injection)	High risk myelodysplastic syndromes  Solid tumors	US EU -	P-II(a) P-II(a) P-I
<b>TAK-063</b> <b>&lt; - &gt;</b>	PDE10A inhibitor (oral)	Schizophrenia	US	P-II(a)
<b>TAK-850</b>	Seasonal influenza vaccine (injection)	Prevention of influenza disease caused by influenza virus subtype A and B contained in the vaccine	Jpn	P-II(a)
<b>TAK-117<sup>*4</sup></b> <b>&lt; - &gt;</b>	PI3K $\alpha$ isoform inhibitor (oral)	Non-small cell lung cancer  Gastric cancer	US EU -	P-I/II P-I/II P-I
<b>TAK-659</b> <b>&lt; - &gt;</b>	SYK kinase inhibitor (oral)	Solid tumors, Hematologic malignancies	-	P-I
<b>TAK-233</b> <b>&lt; - &gt;</b>	(oral)	Women's health	-	P-I
<b>TAK-935</b> <b>&lt; - &gt;</b>	CH24H inhibitor (oral)	Epilepsy	-	P-I
<b>TAK-058</b> <b>&lt; - &gt;</b>	5-HT <sub>3</sub> receptor antagonist (oral)	Schizophrenia, especially cognitive impairment associated with schizophrenia	-	P-I
<b>TAK-079</b> <b>&lt; - &gt;</b>	Cytolytic monoclonal antibody (injection)	Rheumatoid arthritis, Systemic lupus erythematosus	-	P-I
<b>TAK-020</b> <b>&lt; - &gt;</b>	Bruton's tyrosine kinase inhibitor (oral)	Rheumatoid arthritis	-	P-I
<b>TAK-021</b>	EV71 vaccine (injection)	Prevention of hand, foot and mouth disease caused by enterovirus 71	-	P-I
<b>TAK-243<sup>*5</sup></b> <b>&lt; - &gt;</b>	UAE inhibitor (injection)	Solid tumors	-	P-I
<b>TAK-648</b> <b>&lt; - &gt;</b>	PDE4 inhibitor (oral)	Diabetic nephropathy	-	P-I
<b>TAK-915</b> <b>&lt; - &gt;</b>	PDE2A inhibitor (oral)	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
<b>TAK-653</b> <b>&lt; - &gt;</b>	AMPA receptor potentiator (oral)	Psychiatric disorders, Neurological diseases	-	P-I
<b>TAK-831</b> <b>&lt; - &gt;</b>	D-amino acid oxidase (DAAO) inhibitor (oral)	Cerebellar ataxia, Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
<b>TAK-580<sup>*6</sup></b> <b>&lt; - &gt;</b>	pan-Raf kinase inhibitor (oral)	Solid tumors	-	P-I
<b>AMG 403</b> <b>&lt;fulranumab&gt;</b>	Human monoclonal antibody against human Nerve Growth Factor (NGF) (injection)	Pain	Jpn	P-I

\*3 Formerly known as MLN4924

\*4 Formerly known as MLN1117

\*5 Formerly known as MLN7243

\*6 Formerly known as MLN2480

■ Additional indications/formulations/important label updates of approved compounds

Development code <generic name> Brand name (country / region)	Drug Class	Indications or formulations	Stage	
<b>TAP-144-SR</b> <leuprorelin acetate> LEUPLIN® (Jpn) LUPRON DEPOT® (US) ENANTONE®, etc. (EU)	LH-RH agonist	Prostate cancer, Premenopausal breast cancer (6-month formulation)	Jpn	Approved (Sep '15)
<b>TAK-390MR</b> <dexlansoprazole> DEXILANT® (US)	Proton pump inhibitor	Acid-related diseases (orally disintegrating tablet) Acid-related diseases in adolescents	US US EU	Approved (Jan '16) Filed (Sep '15) Filed (Sep '15)
<b>SGN-35</b> <brentuximab vedotin> ADCETRIS® (EU, Jpn)	CD30 monoclonal antibody-drug conjugate	Post-ASCT Hodgkin lymphoma Relapsed cutaneous T-cell lymphoma Front line Hodgkin lymphoma Front line mature T-cell lymphoma	EU EU Jpn EU Jpn	Filed (Mar '15) P-III P-III P-III P-III
<b>Lu AA21004</b> <vortioxetine> BRINTELLIX® (US)	Multimodal anti-depressant	Addition of clinical data to the product label regarding the effect of vortioxetine on certain aspects of cognitive function in adults with Major Depressive Disorder Attention Deficit Hyperactivity Disorder (ADHD) in adult patients	US US	Filed (May '15) P-II(a)
<b>SYR-322</b> <alogliptin> NESINA® (US, Jpn) VIPIDIA® (EU)	DPP-4 inhibitor	Type 2 diabetes (fixed-dose combination with metformin)	Jpn	Filed (Sep '15)
<b>MLN0002</b> <vedolizumab> ENTYVIO® (US, EU)	Humanized monoclonal antibody against α4β7 integrin	Ulcerative colitis, Crohn's disease (subcutaneous formulation)	US EU Jpn	P-III P-III P-III
<b>AD-4833/TOMM40</b>	Insulin sensitizer/ Biomarker assay	Delay of onset of mild cognitive impairment due to Alzheimer's disease	US EU	P-III P-III
<lubiprostone> AMITIZA® (US)	Chloride channel activator	New formulation Pediatric functional constipation	US US	P-III P-III
<febuxostat XR> ULORIC® (US)	Non-purine, selective xanthine oxidase inhibitor	Hyperuricemia (extended-release formulation)	US	P-III
<b>TAK-536</b> <azilsartan> AZILVA® (Jpn)	Angiotensin II receptor blocker	Hypertension (fixed-dose combination with amlodipine and hydrochlorothiazide)	Jpn	P-III
<b>NE-58095NF</b> <risedronate> BENET® (Jpn)	Bone resorption inhibitor	Osteoporosis (additional formulation; change of the dosage and administration)	Jpn	P-II/III

■ **Recent progress in stage** Progress in stage disclosed since release of FY2014 results (May 15<sup>th</sup>, 2015)

Development code <generic name>	Indications	Country/Region	Progress in stage
<glatiramer acetate>	Relapse prevention of multiple sclerosis	Jpn	Approved (Sep '15)
<b>TAP-144-SR</b> <leuprorelin acetate>	Prostate cancer, Premenopausal breast cancer (6-month formulation)	Jpn	Approved (Sep '15)
<b>Lu AA21004</b> <vortioxetine>	Addition of clinical data to the product label regarding the effect of vortioxetine on certain aspects of cognitive function in adults with Major Depressive Disorder	US	Filed (May '15)
<b>MLN9708</b> <ixazomib>	Relapsed or refractory multiple myeloma	US	Filed (Jul '15)
<b>MLN9708</b> <ixazomib>	Relapsed or refractory multiple myeloma	EU	Filed (Jul '15)
<b>TAK-390MR</b> <dexlansoprazole>	Acid-related diseases in adolescents	US, EU	Filed (Sep '15)
<b>SYR-322</b> <alogliptin>	Type 2 diabetes (fixed-dose combination with metformin)	Jpn	Filed (Sep '15)
<b>TAK-228</b> <->	Renal cancer	US	P-II(b)
<b>TAK-228</b> <->	Endometrial cancer	US	P-II(b)
<b>MT203</b> <namilumab>	Rheumatoid arthritis	Jpn	P-II(b)
<b>TAK-063</b> <->	Schizophrenia	US	P-II(a)
<b>TAK-850</b>	Prevention of influenza disease caused by influenza virus subtype A and B contained in the vaccine	Jpn	P-II(a)
<b>TAK-648</b> <->	Diabetic nephropathy	-	P-I
<b>TAK-915</b> <->	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
<b>TAK-653</b> <->	Psychiatric disorders, Neurological diseases	-	P-I
<b>TAK-831</b> <->	Cerebellar ataxia, Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
<b>MLN9708</b> <ixazomib>	Relapsed or refractory multiple myeloma	US	Approved (Nov '15)
<b>TAK-390MR</b> <dexlansoprazole>	Acid-related diseases (orally disintegrating tablet)	US	Approved (Jan '16)
<b>TAK-816</b>	Prevention of infectious disease caused by Haemophilus influenzae type b (Hib)	Jpn	Approved (Jan '16)
<b>MLN0002</b> <vedolizumab>	Ulcerative colitis, Crohn's disease (subcutaneous formulation)	US, EU, Jpn	P-III
<b>TAK-924</b> <pevonedistat>	High risk myelodysplastic syndromes	US, EU	P-II(a)
<b>TAK-117</b> <->	Non small cell lung cancer	US, EU	P-I/II

Progress in stage disclosed since the announcement of FY2015 Q2 results (October 30<sup>th</sup>, 2015) are listed under the bold dividing line

■ **Discontinued projects** Discontinuation disclosed since release of FY2014 results (May 15<sup>th</sup>, 2015)

Development code <generic name>	Indications (Stage)	Reason
<b>TAK-137</b> < - >	Psychiatric disorders, Neurological diseases (P-I)	Pharmacokinetic variability led to decrease in safety margin.
<b>TAK-733</b> < - >	Solid tumors (P-I)	Development terminated based on a strategic portfolio decision.
<b>TAK-264<sup>*7</sup></b> < - >	Gastric cancer, Pancreatic cancer (US, EU P-II)	Development terminated due to lack of efficacy.
<b>TAK-272</b> < - >	Hypertension (P-I)	Reconsideration of the development program for TAK-272.
<b>Lu AA24530</b> < - >	Major depressive disorder, Generalized anxiety disorder (P-I)	Lu AA24530 was investigated for major depression but has not been in active clinical development since 2009, and following the success of Brintellix (vortioxetine), it has been decided to discontinue further development.
<b>TAK-114</b> < - >	Ulcerative colitis (US, EU P-II(a))	Potential for a better product profile with a similar candidate compound.
<b>Lu AA21004</b> <vortioxetine>	Generalized anxiety disorder (US P-III)	Discontinued due to re-evaluation of the lifecycle management development program.

\*7 Formerly known as MLN0264

Discontinued projects disclosed since the announcement of FY2015 Q2 results (October 30<sup>th</sup>, 2015) are listed under the bold dividing line

■ **Filings and Approvals in Brazil, China & Russia**

Takeda is steadily progressing its pipeline assets through the filing and approval process on a global scale, including in emerging markets. This table shows filings and approvals in the key emerging markets of Brazil, China & Russia.

Country	Development code/generic name (stage)
<b>Brazil</b>	alogliptin/metformin (Filed Jul '13), alogliptin/pioglitazone (Filed Dec '13), ramelteon <sup>*8</sup> (Filed Mar '14), vedolizumab (Approved May '15)
<b>China</b>	brentuximab vedotin (Filed May '13)
<b>Russia</b>	alogliptin/metformin (Filed Mar '14), brentuximab vedotin (Filed May '14), vedolizumab (Filed Jun '15)

\*8 TAK-375 <ramelteon> MT1/MT2 receptor agonist (oral) for the treatment of insomnia

■ **Clinical study protocol summaries**

All clinical study protocol summaries are disclosed on the English-language web-site (<http://www.takeda.com/c-t/>) and all clinical study protocol information in the Japanese-language is disclosed on the Japanese-language web-site (<http://www.takeda.co.jp/c-t/>).

We anticipate that this disclosure assure transparency of information on the clinical trials for the benefit of healthcare professionals, their patients and other stakeholders, which we believe will contribute to the appropriate use of Takeda's products worldwide.