Better Health, Brighter Future

Financial Results for 1st Half FY2014

DATA BOOK

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Takeda-ism

We, the members of the Takeda Group, pledge to act with integrity at all times, especially when facing difficulties or challenges. "Integrity" refers to our compliance with the highest ethical standards, our fairness and honesty in conducting every activity, and our perseverance in pursuing the ideal forms for our operations and management. Through the demonstration of these qualities, we show our commitment to building trust and confidence in all the people around us, and our determination to continue to expand the business. These empower our progress in our global endeavors to fulfill our mission to "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.

- **Our Business: Committed to Improving Health**

  With countless people in desperate need of new healthcare solutions, there's no time to wait. That's why we 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.

- **Our Organization: Strength from Diversity**

  A common set of values, Takeda-ism, unites us as one. Using our diverse skills and ideas, we develop fresh solutions to meet the needs of people around the world. Each one of us is empowered to act swiftly and decisively in our quest to improve quality of life.

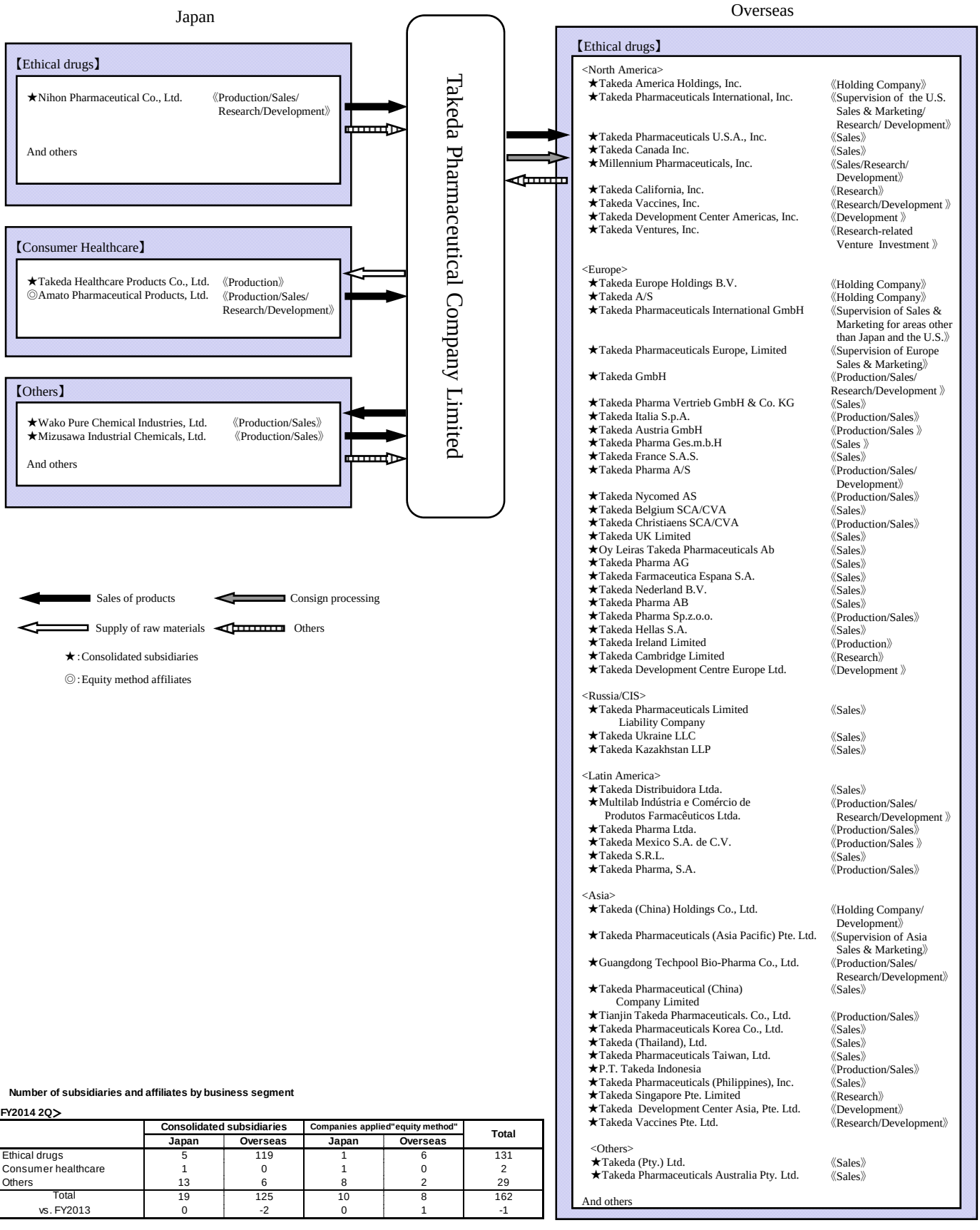
- **Our People: Powered by Passion**

  Our people are our greatest asset. Driven by passion to learn and contribute more, we embrace new challenges with confidence and open minds. We are determined to lead the change for a better world.

Contents

I. Overview of Takeda group

The Takeda Group consists of 163 companies, including the parent company submitting these consolidated financial statements, 144 consolidated subsidiaries and 18 affiliates accounted for by the equity method. The following chart shows the main business areas of the Takeda Group, the position of the companies that make up the Group within their respective areas of business, and relationships with each business segment.



■ **Number of subsidiaries and affiliates by business segment**

< FY2014 2Q>

	Consolidated subsidiaries		Companies applied"equity method"		Total
	Japan	Overseas	Japan	Overseas	
Ethical drugs	5	119	1	6	131
Consumer healthcare	1	0	1	0	2
Others	13	6	8	2	29
Total	19	125	10	8	162
vs. FY2013	0	-2	0	1	-1

II. Financial Results

1. Financial highlights (more detail will be available in Page 3 and onward)

Consolidated operating results (Billions of Yen)	FY12	FY13	FY14 Forecasts	FY13 H1	FY14 H1	vs. PrY	increase/ decrease
Revenue	1,557.0	1,691.7	1,725.0	828.1	851.4	23.3	2.8%
Overseas revenue	822.7	957.8	1,011.0	462.7	492.0	29.4	6.3%
<% of Revenue>	<52.8%>	<56.6%>	<58.6%>	<55.9%>	<57.8%>	<1.9pt>	
Revenue of ethical drugs segment	1,401.5	1,529.1	1,564.0	748.7	770.1	21.4	2.9%
R&D expenses	321.3	341.6	350.0	155.9	156.5	0.6	0.4%
<% of Revenue>	<20.6%>	<20.2%>	<20.3%>	<18.8%>	<18.4%>	<-0.4pt>	
Operating profit	65.0	139.3	150.0	109.9	116.7	6.8	6.2%
<% of Revenue>	<4.2%>	<8.2%>	<8.7%>	<13.3%>	<13.7%>	<0.4pt>	
Profit before income taxes	133.1	158.9	140.0	120.2	113.1	-7.1	-5.9%
<% of Revenue>	<8.5%>	<9.4%>	<8.1%>	<14.5%>	<13.3%>	<-1.2pt>	
Net profit for the year	150.7	109.6		80.5	63.2	-17.4	-21.6%
<% of Revenue>	<9.7%>	<6.5%>		<9.7%>	<7.4%>	<-2.3pt>	
Profit attributable to owners of the Company	148.6	106.7	85.0	78.7	61.4	-17.3	-22.0%
<% of Revenue>	<9.5%>	<6.3%>	<4.9%>	<9.5%>	<7.2%>	<-2.3pt>	
Core earnings *	285.5	314.2	280.0	182.0	169.3	-12.7	-7.0%
<% of Revenue>	<18.3%>	<18.6%>	<16.2%>	<22.0%>	<19.9%>	<-2.1pt>	

* Profit from regular business 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.

Consolidated financial position (Billions of Yen)	FY12 End	FY13 End	FY13 H1 End	FY14 H1 End	vs. FY13 End
Total assets	4,052.6	4,569.1		4,571.8	2.7
Total liabilities	1,714.3	2,028.5		2,040.9	12.4
Total equity	2,338.3	2,540.6		2,530.9	-9.7
Equity attributable to owners of the Company	2,274.1	2,470.7		2,463.9	-6.9
Ratio of equity attributable to owners of the Company to total assets	56.1%	54.1%		53.9%	-0.2pt

Shares	FY12 End	FY13 End	FY13 H1 End	FY14 H1 End
Number of shares outstanding (1,000)	789,666	789,681	789,681	789,735
Treasury stock（1,000）	206	213	209	4,028
Stock price at year-end (Yen)	5,030	4,892	4,635	4,768
Total market value (Billions of Yen)	3,972.0	3,863.1	3,660.2	3,765.5

ROE・EPS・Dividend (Yen)	FY12	FY13	FY13 H1	FY14 H1	vs. PrY
Return on equity attributable to owners of the Company	6.8%	4.5%		5.0%	
Basic earnings per share	188.21	135.10	99.75	78.07	-21.67
Annual dividends per share	180.00	180.00	90.00	90.00	-
Dividend pay-out ratio	95.6%	133.2%	90.2%	115.3%	25.0pt

Exchange rate(Yen)	FY12	FY13	FY14 Assumptions	FY13 H1	FY14 H1
US$ Average (Apr.-Mar.)	82	100	105	98	102
Euro Average (Apr.-Mar.)	106	133	140	128	139

2. Consolidated Statement of Income

(Billions of Yen)

	FY12	FY13	FY14 Forecasts	FY13 H1	FY14 H1	vs. PrY	increase/ decrease
Revenue	1,557.0	1,691.7	1,725.0	828.1	851.4	23.3	2.8%
Royalty income	45.2	77.4		37.5	28.5	-9.0	-23.9%
Cost of sales	463.8	490.3		238.1	247.0	8.9	3.8%
<% of revenue>	<29.8%>	<29.0%>		<28.7%>	<29.0%>	<0.3pt>	
Gross Profit	1,093.2	1,201.4		590.0	604.4	14.4	2.4%
<% of revenue>	<70.2%>	<71.0%>		<71.3%>	<71.0%>	<-0.3pt>	
SG&A expenses	512.9	556.2		260.6	283.1	22.6	8.7%
<% of revenue>	<32.9%>	<32.9%>		<31.5%>	<33.3%>	<1.8pt>	
Advertising and Sales promotion expenses	86.2	105.3		48.6	52.6	3.9	8.1%
Personnel expenses	208.5	228.7		108.9	113.6	4.7	4.3%
R&D expenses	321.3	341.6	350.0	155.9	156.5	0.6	0.4%
<% of revenue>	<20.6%>	<20.2%>	<20.3%>	<18.8%>	<18.4%>	<-0.4pt>	
Amortization and impairment losses on intangible assets associated with products	173.8	143.2		58.6	63.2	4.6	7.8%
Other operating income	24.1	23.9		11.1	38.7	27.7	-
Government grant income	2.9	2.6		1.3	1.6	0.3	25.8%
Rental income	4.7	4.3		2.2	2.0	-0.2	-10.6%
Gains on sales of assets held for sale	4.1	6.6		-	25.4	25.4	-
Royalty income on transfer of operations	4.3	4.7		4.2	6.4	2.2	53.1%
Others	8.1	5.6		3.4	3.4	-0.0	-0.7%
Other operating expenses	44.3	45.0		16.1	23.5	7.4	46.4%
Expenses directly attributable to rental income	2.3	5.0		2.5	1.2	-1.3	-50.9%
Donations and contributions	2.8	3.2		0.6	0.8	0.1	19.1%
Restructuring expenses *	25.2	21.7		10.0	13.9	3.9	39.0%
Others	13.9	15.1		2.9	7.6	4.7	164.4%
Operating profit	65.0	139.3	150.0	109.9	116.7	6.8	6.2%
<% of revenue>	<4.2%>	<8.2%>	<8.7%>	<13.3%>	<13.7%>	<0.4pt>	
Financial income	87.7	49.3		22.2	10.1	-12.1	-54.4%
Interest income	1.2	1.4		0.4	1.0	0.5	121.0%
Dividends income	4.0	3.3		1.8	1.6	-0.2	-12.4%
Gains on sales of available-for-sale financial assets	56.3	40.5		18.1	3.3	-14.8	-81.6%
Foreign exchange gains including gains on valuation of derivatives	11.1	4.1		1.8	4.0	2.2	126.6%
Interest on tax refund	15.1	-		-	-	-	-
Others	0.1	0.0		0.0	0.2	0.2	-
Financial expenses	20.5	30.7		12.4	14.7	2.4	19.2%
Interest expenses	3.4	4.9		2.1	2.8	0.6	29.8%
Fair value adjustments of contingent considerations	6.5	11.0		5.2	8.1	2.9	54.6%
Impairment losses on available-for-sale financial assets	0.9	0.8		0.3	0.8	0.4	121.0%
Foreign exchange losses including losses on valuation of derivatives	6.7	11.8		3.9	-	-3.9	-
Others	2.9	2.3		0.7	3.1	2.4	-
Share of profit of associates accounted for using the equity method	0.9	1.0		0.5	1.1	0.6	121.6%
Profit before tax	133.1	158.9	140.0	120.2	113.1	-7.1	-5.9%
Income tax expenses	-17.6	49.3		39.7	50.0	10.3	25.9%
Net profit for the period	150.7	109.6		80.5	63.2	-17.4	-21.6%
<% of revenue>	<9.7%>	<6.5%>		<9.7%>	<7.4%>	<-2.3pt>	
Attributable to Owners of the Company	148.6	106.7	85.0	78.7	61.4	-17.3	-22.0%
<% of revenue>	<9.5%>	<6.3%>	<4.9%>	<9.5%>	<7.2%>	<-2.3pt>	
Total comprehensive income for the period	323.3	343.7		214.1	78.0	-136.1	-63.5%
<% of revenue>	<20.8%>	<20.3%>		<25.9%>	<9.2%>	<-16.7pt>	
Attributable to Owners of the Company	318.8	339.2		211.7	75.2	-136.5	-64.5%
<% of revenue>	<20.5%>	<20.0%>		<25.6%>	<8.8%>	<-16.7pt>	
Effective tax rate							
Japanese statutory tax rate	38.0%	38.0%		38.0%	35.6%	-2.4pt	
Effective tax rate	-13.2%	31.0%		33.0%	44.2%	11.2pt	

* Expenses from reorganization, such as the consolidation of a number of sites and functions (including the potential merger or liquidation of subsidiaries) and the reduction of the workforce to build an efficient operating model. The major item in these expenses was the early retirement payments for the workforce.

3. Revenue / Product Sales

◆ Revenue by Regions

(Billions of Yen)

	FY12	FY13	FY13 H1	FY14 H1	vs. PrY	increase/ decrease
Total net revenue	1,557.0	1,691.7	828.1	851.4	23.3	2.8%
Japan	734.3	733.9	365.4	359.3	-6.1	-1.7%
Overseas	822.7	957.8	462.7	492.0	29.4	6.3%
<% of revenue>	<52.8%>	<56.6%>	<55.9%>	<57.8%>	<1.9pt>	
North America	360.5	374.5	180.2	197.6	17.4	9.7%
<% of revenue>	<23.2%>	<22.1%>	<21.8%>	<23.2%>	<1.5pt>	
[U.S.]	[343.8]	[352.1]	[169.0]	[185.8]	[16.8]	[9.9%]
Europe	246.5	297.5	147.9	144.8	-3.1	-2.1%
<% of revenue>	<15.8%>	<17.6%>	<17.9%>	<17.0%>	<-0.9pt>	
Russia/CIS	68.3	89.6	41.3	38.0	-3.3	-7.9%
<% of revenue>	<4.4%>	<5.3%>	<5.0%>	<4.5%>	<-0.5pt>	
Latin America	62.9	81.2	38.2	41.2	3.0	7.8%
<% of revenue>	<4.0%>	<4.8%>	<4.6%>	<4.8%>	<0.2pt>	
Asia	60.1	85.4	40.3	51.2	10.9	27.1%
<% of revenue>	<3.9%>	<5.0%>	<4.9%>	<6.0%>	<1.2pt>	
Other	24.3	29.5	14.8	19.2	4.4	29.6%
<% of revenue>	<1.6%>	<1.7%>	<1.8%>	<2.3%>	<0.5pt>	
Royalty income	45.2	77.4	37.5	28.5	-9.0	-23.9%
Ethical drugs	44.8	77.3	37.5	28.5	-9.0	-23.9%
Japan	0.4	0.2	0.1	2.9	2.8	-
Overseas	44.4	77.1	37.4	25.6	-11.7	-31.4%

* Revenue amount is classified into countries or regions based on the customer location.
** Other region includes Middle East, Oceania and Africa.

◆ Ethical Drugs Revenue

(Billions of Yen)

	FY12	FY13	FY13 H1	FY14 H1	vs. PrY	increase/ decrease
Net Sales in Japan	586.9	580.0	290.0	279.4	-10.6	-3.6%
Net Sales Overseas	763.8	863.3	417.3	454.6	37.3	8.9%
North America	343.2	340.8	166.0	185.4	19.4	11.7%
[U.S.]	[326.8]	[318.9]	[155.2]	[174.7]	[19.5]	[12.6%]
Europe	211.6	243.8	119.9	128.5	8.6	7.1%
Russia/CIS	68.3	89.5	41.3	37.6	-3.6	-8.8%
Latin America	62.3	80.6	37.8	39.2	1.4	3.7%
Asia	55.5	80.5	38.1	47.0	8.8	23.2%
Other	22.9	28.1	14.2	16.8	2.6	18.4%
Royalty income and service income	50.8	85.8	41.5	36.2	-5.3	-12.8%
Japan	1.3	2.1	1.0	3.8	2.8	-
Overseas	49.5	83.7	40.5	32.3	-8.1	-20.1%
Total ethical drugs revenue	1,401.5	1,529.1	748.7	770.1	21.4	2.9%
Ratio of overseas ethical drugs revenue	58.0%	61.9%	61.1%	63.2%	2.1pt	

* Revenue amount is classified into countries or regions based on the customer location.
** Other region includes Middle East, Oceania and Africa.

◆ Major Subsidiaries *

(Billions of Yen)

	FY12	FY13	FY13 H1	FY14 H1	vs. PrY	increase/ decrease
Takeda Pharmaceuticals U.S.A., Inc.	234.9	213.0	101.4	115.9	14.5	14.3%
[Millions of US$]	[2,856]	[2,126]	[1,033]	[1,132]	[99]	[9.5%]
Millennium Pharmaceuticals, Inc.	108.4	144.3	70.3	76.8	6.5	9.3%
[Millions of US$]	[1,318]	[1,440]	[716]	[749]	[33]	[4.6%]
Wako Pure Chemical Industries, Ltd.	60.3	60.8	31.7	33.1	1.4	4.5%

* Revenue amounts for TPC group's intercompany transaction are subtracted.

◆ **Ethical Drugs: Global major products' sales**

(Billions of Yen)

Product	FY12	FY13*	FY14 Forecasts*	FY13 H1*	FY14 H1*	vs. PrY	increase/ decrease
Velcade	72.9	131.3	141.0	64.2	72.8	8.6	13.3%
Candesartan	169.6	157.1	118.0	83.4	72.5	-11.0	-13.1%
Leuprorelin	116.5	126.8	121.0	65.4	61.3	-4.1	-6.2%
Pantoprazole	78.0	103.7	91.0	48.2	50.6	2.4	4.9%
Lansoprazole	110.2	119.7	91.0	60.7	50.1	-10.6	-17.4%
Colcrys	33.6	51.9	61.0	25.7	29.8	4.0	15.7%
Dexilant	32.7	50.3	57.0	23.6	27.2	3.6	15.3%
Nesina	37.8	40.4	45.5	18.4	21.9	3.5	19.0%
Pioglitazone	122.9	36.8	34.0	20.1	18.3	-1.8	-8.9%
Uloric	17.7	26.9	31.5	12.5	14.1	1.6	13.1%
Amitiza	22.3	25.7	28.0	12.0	13.9	1.9	15.8%
Adcetris	4.5	13.6	20.5	6.1	11.7	5.5	90.8%
Calcium	15.4	19.7	22.0	9.0	9.9	0.9	10.3%
Actovegin	19.6	26.4	25.5	12.5	9.9	-2.6	-21.1%
Tachosil	13.2	17.0	18.5	8.1	8.5	0.4	5.0%

*Royalty income and service income are included in FY13, FY14 Forecasts, FY13 H1 and FY14 H1.

◆ **Ethical Drugs: Overseas major products' sales (Regional basis)**

(Billions of Yen)

	FY12	FY13*	FY14 Forecasts*	FY13 H1*	FY14 H1*	vs. PrY	increase/ decrease
Candesartan							
North America, Latin America, Europe, Russia/CIS, Asia and Others	35.6	31.3	23.0	17.8	16.2	-1.6	-8.9%
Leuprorelin							
North America and Latin America	14.9	18.3	16.0	10.1	8.3	-1.8	-17.7%
Europe and Russia/CIS	27.8	34.0	36.5	16.4	17.4	1.0	6.0%
Asia and Other	7.8	10.1	11.0	5.1	5.9	0.8	15.5%
Lansoprazole							
North America and Latin America	24.5	30.8	16.5	14.7	12.2	-2.5	-16.7%
Europe and Russia/CIS	10.5	13.0	11.5	6.5	5.8	-0.8	-11.8%
Asia and Other	6.1	8.3	9.0	4.3	4.7	0.4	8.1%
Pantoprazole							
North America and Latin America	28.9	40.0	25.5	17.4	14.1	-3.3	-18.9%
Europe and Russia/CIS	29.9	36.5	37.5	17.8	19.5	1.7	9.7%
Asia and Other	19.2	27.2	28.0	13.0	16.9	3.9	30.1%
Pioglitazone							
North America and Latin America	90.9	6.2	9.5	4.8	5.2	0.4	7.3%
Europe and Russia/CIS	8.2	7.9	7.5	3.7	3.8	0.1	2.5%
Asia and Other	4.7	7.1	6.0	3.2	3.5	0.3	9.0%

* This chart shows the major overseas products sales classified as "North America and Latin America", "Europe and Russia/CIS" and "Asia and Other" and does not include sales in Japan.

** The sales of Candesartan are shown in one area (North America, Latin America, Europe, Russia/CIS, Asia and Other), because export sales of Candesartan to licensees are recorded under a single route.

*Royalty income and service income are included in FY13, FY14 Forecasts, FY13 H1 and FY14 H1.

◆ Ethical Drugs: Japan major products' sales

(Billions of Yen)

Product	Launched	Therapeutic Class	FY12	FY13	**FY14 Forecasts ****	FY13 H1	**FY14 H1**	vs PrY	increase/ decrease
Blopress * (candesartan)	(99. 6)	Hypertension	134.0	125.8	**95.0**	65.6	**56.2**	-9.4	-14.3%
Leuplin (leuprorelin)	(92. 9)	Prostate cancer, breast cancer and endometriosis	66.0	64.5	**57.5**	33.8	**29.7**	-4.1	-12.0%
Takepron * (lansoprazole)	(92.12)	Peptic ulcers	69.1	67.6	**54.0**	35.1	**27.5**	-7.7	-21.9%
Enbrel	(05. 3)	Rheumatoid arthritis	43.2	45.4		22.5	**20.4**	-2.1	-9.4%
Azilva *	(12. 5)	Hypertension	3.4	25.3	**49.0**	8.0	**20.3**	12.4	155.9%
Nesina *	(10. 6)	Diabetes	37.8	38.0	**39.5**	17.9	**19.6**	1.7	9.7%
Vectibix	(10. 6)	Colorectal cancer	18.8	19.4	**18.5**	9.6	**9.2**	-0.3	-3.5%
Reminyl	(11. 3)	Alzheimer-type dementia	8.4	12.3		5.7	**6.4**	0.7	12.4%
Basen	(94. 9)	Diabetes	19.3	16.1	**12.5**	8.6	**6.0**	-2.6	-30.0%
Actos (pioglitazone)	(99.12)	Diabetes	19.1	15.5	**11.0**	8.3	**5.8**	-2.5	-30.2%
Benet	(02. 5)	Osteoporosis	13.3	11.6	**9.5**	6.0	**5.3**	-0.7	-11.6%
Lotriga	(13. 1)	Hyperlipidemia	1.1	5.2	**12.0**	1.8	**5.0**	3.2	180.6%
Rozerem	(10. 7)	Insomnia	4.5	6.0	**8.0**	2.8	**3.2**	0.3	12.2%

* The figures include the amounts of compound drugs.

** The figures for "FY14 Forecasts" are partially undisclosed due to disclosure policy of alliance partners.

◆ Consumer Healthcare: Major products' sales

(Billions of Yen)

	FY12	FY13	**FY14 Forecasts**	FY13 H1	**FY14 H1**	vs PrY	increase/ decrease
Alinamin tablet	15.7	19.6	**17.9**	9.4	**9.9**	0.5	5.6%
Alinamin drink	14.3	15.1	**14.7**	8.3	**8.4**	0.0	0.4%
Benza	9.7	10.4	**10.7**	6.0	**5.9**	-0.1	-0.0
Biofermin	8.1	8.4	**8.4**	4.1	**4.1**	-0.0	-1.0%
Borraginol	4.3	4.4	**4.2**	2.0	**1.9**	-0.1	-5.0%

4. Consolidated Statement of Financial Position

＜Assets＞ (Billions of Yen)

	FY12 End	FY13 End	FY14 H1 End	% of Total	vs. FY13 End
Total non-current assets	2,821.2	2,976.6	2,938.2	64.3%	△38.4
Property, plant and equipment	546.8	542.3	535.3	11.7%	-7.0
acquisition cost	1,109.0	1,167.7	1,176.8		9.1
Accumulated depreciation and impairment losses	-562.2	-625.4	-641.5		-16.1
Goodwill	714.0	814.7	821.5	18.0%	6.8
Intangible assets	1,095.8	1,135.6	1,099.2	24.0%	-36.4
Investment property	36.7	32.1	30.4	0.7%	-1.7
Investments accounted for using the equity method	9.2	10.0	10.5	0.2%	0.5
Other financial assets	211.8	192.8	204.5	4.5%	11.7
Investment securities	160.3	141.6	137.9		-3.7
Other non-current assets	27.5	40.8	39.1	0.9%	-1.7
Prepaid pension costs	23.3	35.8	35.6		-0.2
Deferred tax assets	179.4	208.4	197.7	4.3%	-10.7
Total current assets	1,231.4	1,592.5	1,633.6	35.7%	41.1
Inventories	229.3	254.3	277.4	6.1%	23.1
Trade and other receivables	375.0	430.6	455.2	10.0%	24.6
Other financial assets	16.2	185.0	159.9	3.5%	-25.1
Income tax receivables	12.0	12.0	6.5	0.1%	-5.5
Other current assets	49.3	43.5	51.3	1.1%	7.8
Cash and cash equivalents	545.6	666.0	681.5	14.9%	15.4
Assets held for sale	4.0	1.0	1.7	0.0%	0.7
Total Assets	4,052.6	4,569.1	4,571.8	100.0%	2.7

＜Liabilities and equity＞

(Billions of Yen)

	FY12 End	FY13 End	FY14 H1 End	% of Total	vs. FY13 End
Total liabilities	1,714.3	2,028.5	2,040.9	44.6%	12.4
Total non-current liabilities	1,080.4	1,225.8	1,261.7	27.6%	36.0
Bonds	471.3	463.3	473.5	10.4%	10.2
Long-term loans	111.3	241.3	241.3	5.3%	-
Other financial liabilities	96.4	110.1	116.9	2.6%	6.8
Retirement benefit liabilities	66.6	76.5	83.2	1.8%	6.7
Provisions	21.8	14.4	12.5	0.3%	-1.9
Other non-current liabilities	41.1	39.6	68.2	1.5%	28.6
Deferred tax liabilities	271.8	280.6	266.2	5.8%	-14.4
Total current liabilities	633.8	802.8	779.2	17.0%	-23.6
Bonds	-	154.1	164.2	3.6%	10.0
Short-term loans	1.9	1.3	1.2	0.0%	-0.1
Trade and other payables	169.9	184.9	155.2	3.4%	-29.7
Other financial liabilities	38.6	48.8	51.4	1.1%	2.6
Income tax payables	129.4	52.3	80.1	1.8%	27.8
Provisions	100.8	125.3	127.5	2.8%	2.2
Other current liabilities	193.3	236.0	199.5	4.4%	-36.4
Total equity	2,338.3	2,540.6	2,530.9	55.4%	-9.7
Share capital	63.5	63.6	63.7		0.1
Capital surplus	40.3	39.9	54.2		14.3
Treasury shares	-0.6	-0.6	-18.2		-17.6
Retained earnings	1,927.8	1,901.3	1,879.2		-22.1
Other components of equity	243.1	466.6	485.0		18.4
Equity attributable to owners of the company	2,274.1	2,470.7	2,463.9		-6.9
Non-controlling interests	64.2	69.9	67.1		-2.8
Total liabilities and equity	4,052.6	4,569.1	4,571.8	100.0%	2.7

5. Consolidated Statement of Cash Flows

(Billions of Yen)

	FY12	FY13	FY13 H1	FY14 H1	vs. PrY
Net cash from (used in) operating activities	332.6	148.3	-0.9	84.7	85.6
Net cash from (used in) investing activities	-131.1	-158.6	-14.5	25.5	40.0
Net cash from (used in) financing activities	-152.2	101.4	173.1	-106.1	-279.2
Net increase in cash and cash equivalents	49.3	91.2	157.7	4.0	-153.6
Cash and cash equivalents at beginning of year	454.2	545.6	545.6	666.0	120.5
Effect of movements in exchange rates on cash and cash equivalents	42.0	29.3	14.4	11.4	-3.0
Cash and cash equivalents at end of year	545.6	666.0	717.7	681.5	-36.2

6. Segment Information

(Billions of Yen)

	FY12	FY13	FY13 H1	**FY14 H1**	vs. PrY	increase/ decrease
Revenue	1,557.0	1,691.7	828.1	**851.4**	23.3	2.8%
Ethical drugs	1,401.5	1,529.1	748.7	**770.1**	21.4	2.9%
Japan	588.2	582.1	291.0	**283.2**	-7.7	-2.7%
Overseas	813.3	947.0	457.8	**486.9**	29.1	6.4%
Consumer healthcare	66.9	72.9	36.7	**37.7**	0.9	2.6%
Others	93.0	93.8	42.6	**43.6**	1.0	2.2%
Adjustments	-4.4	-4.0				
Operating Income	65.0	139.3	109.9	**116.7**	6.8	6.2%
Ethical drugs	34.1	112.1	91.4	**80.4**	-11.0	-12.1%
<% of Ethical drugs revenue>	<2.4%>	<7.3%>	<12.2%>	**<10.4%>**	<-1.8pt>	
Consumer healthcare	12.9	16.4	10.5	**11.3**	0.8	7.8%
<% of Consumer healthcare revenue>	<19.3%>	<22.5%>	<28.5%>	**<30.0%>**	<1.4pt>	
Others	17.9	10.8	8.1	**25.0**	17.0	-
<% of Others revenue>	<19.3%>	<11.5%>	<18.9%>	**<57.5%>**	<38.6pt>	
Adjustments	0.1	-0.0				

7. Capital expenditure, depreciation and amortization and impairment losses

(Billions of Yen)

	FY12	FY13	FY13 H1	FY14 H1	vs. PrY	increase/ decrease
Capital expenditures						
Tangible assets *	72.3	43.9	19.0	**26.5**	7.5	39.3%
Intangible assets **	194.4	60.0	29.5	**21.9**	-7.6	-25.8%

* Excluding increase due to acquisition.

** Including increase (including goodwill) due to acquisition.

Depreciation and Amortization	176.2	188.2	92.0	**96.5**	4.5	4.9%
Amortization associated with products	112.2	120.1	58.6	**62.0**	3.4	5.8%
Impairment losses	71.0	27.5	-	**1.2**	1.2	-
Impairment losses associated with products	62.4	23.1	-	**1.2**	1.2	-

8. Number of employees

	FY12 End	FY13 End	FY14 H1 End	% of total	vs. FY13 End
Total (①－②)＋③	30,481	31,225	31,815	100.0%	590
< Overseas >	<20,956>	<21,671>	<22,277>	<70.0%>	<606>
Ethical drugs	27,947	28,672	29,206	91.8%	534
Consumer healthcare	450	461	477	1.5%	16
Others	2,084	2,092	2,132	6.7%	40
Takeda Pharmaceutical Company Limited ①	6,671	6,716	6,838		122
Temporarily transferred employees & Temporarily accepted employees (net) ②	127	138	104		-34
Employees working in Takeda Pharmaceutical Company Limited ①－②	6,544	6,578	6,734	21.2%	156
Consolidated subsidiaries ③	23,937	24,647	25,081	78.8%	434

* Employees on the full time equivalent basis

9. Shareholders

【By ownership】

		FY12 End	FY13 End	FY14 H1 End	vs. FY13 End
Financial Institutions	No. of shareholders	311	313	297	-16
	No. of shares(1000)	250,440	235,354	231,394	-3,960
	% of shares outstanding	31.71	29.80	29.30	-0.50
Registered Financial Instruments Firms	No. of shareholders	59	67	57	-10
	No. of shares(1000)	37,273	38,582	45,321	6,739
	% of shares outstanding	4.72	4.88	5.74	0.86
Other institutions	No. of shareholders	1,772	1,890	1,781	-109
	No. of shares(1000)	41,596	41,626	42,903	1,276
	% of shares outstanding	5.27	5.27	5.43	0.16
Foreign investors	No. of shareholders	861	883	913	30
	No. of shares(1000)	221,281	223,377	224,306	930
	% of shares outstanding	28.02	28.29	28.40	0.12
Private investors and others	No. of shareholders	275,841	305,206	304,352	-854
	No. of shares(1000)	238,953	250,612	245,679	-4,933
	% of shares outstanding	30.26	31.74	31.11	-0.63
Takeda	No. of shares(1000)	123	130	133	2
	% of shares outstanding	0.02	0.02	0.02	0.00

【By number of shares held each】

		FY12 End	FY13 End	FY14 H1 End	vs. FY13 End
5,000,000～	No. of shareholders	25	21	23	2
	No. of shares(1000)	300,172	267,568	278,274	10,706
	% of shares outstanding	38.01	33.88	35.24	1.35
1,000,000～ 4,999,999	No. of shareholders	79	91	82	-9
	No. of shares(1000)	176,679	203,000	189,652	-13,348
	% of shares outstanding	22.37	25.71	24.01	-1.69
100,000～ 999,999	No. of shareholders	288	273	284	11
	No. of shares(1000)	92,399	85,950	91,422	5,472
	% of shares outstanding	11.70	10.88	11.58	0.69
10,000～ 99,999	No. of shareholders	2,373	2,472	2,441	-31
	No. of shares(1000)	49,309	50,889	50,742	-147
	% of shares outstanding	6.25	6.46	6.43	-0.03
1,000～ 9,999	No. of shareholders	60,392	63,080	61,712	-1,368
	No. of shares(1000)	120,618	126,265	123,907	-2,358
	% of shares outstanding	15.28	16.00	15.69	-0.31
100～ 999	No. of shareholders	206,147	232,953	233,418	465
	No. of shares(1000)	50,234	55,762	55,493	-269
	% of shares outstanding	6.36	7.06	7.03	-0.03
Less than 99	No. of shareholders	9,541	9,470	9,441	-29
	No. of shares(1000)	255	247	246	-1
	% of shares outstanding	0.03	0.03	0.03	-0.00
Total	No. of shareholders	278,845	308,360	307,401	-959
	No. of shares(1000)	789,666	789,681	789,735	55

【10 largest shareholders】

	Shareholders	FY14 H1 End		Change from FY13 End	
		No. of shares held (1,000)	% of shares outstanding	No. of shares increase/decrease (1,000)	Previous ranking
1	Nippon Life Insurance Company	50,760	6.43	-2,820	<1>
2	The Master Trust Bank of Japan, Ltd. (Trust account)	30,841	3.91	-1,887	<2>
3	Japan Trustee Services Bank, Ltd. (Trust account)	27,771	3.52	-2,116	<3>
4	Takeda Science Foundation	17,912	2.27	-	<4>
5	Barclays Securities Japan Limited	15,000	1.90	-	<5>
6	State Street Trust & Banking Co., Ltd. 505225	10,004	1.27	422	<7>
7	State Street Bank West Client-Treaty	9,537	1.21	221	<8>
8	JP Morgan Chase Bank 385147	9,210	1.17	4,058	<20>
9	Japan Trustee Services Bank, Ltd. (Trust account 1)	8,281	1.05	345	<13>
10	Japan Trustee Services Bank, Ltd. (Trust account 6)	8,255	1.05	76	<9>

10. Financial ratios

	FY12	FY13	FY13 H1	FY14 H1
[Growth rates]				
Revenue (%)		8.6		2.8
Operating profit (%)		114.3		6.2
Net profit (%) *		-28.2		-22.0
[Profitability ratios]				
Gross profit margin (%)	70.2	71.0	71.3	71.0
Operating margin (%)	4.2	8.2	13.3	13.7
Net margin (%) *	9.5	6.3	9.5	7.2
Return on total assets (%) *	3.9	2.5		2.7
Return on equity attributable to owners of the Company (ROE) (%)	6.8	4.5		5.0
[Stability ratios]				
Ratio of equity attributable to owners of the Company to total assets (%)	56.1	54.1		53.9
Current ratio (%)	194.3	198.4		209.7
Non-current assets to long-term capital (%) *	84.1	80.5		78.9
[Efficiency ratios]				
Asset turnover (times)	0.38	0.37		0.37
Fixed-asset turnover (times)	0.55	0.57		0.58
Notes and accounts receivable turnover (times)	4.50	4.45		4.10
[Other ratios]				
R&D expenses to revenue (%)	20.6	20.2	18.8	18.4
Equity attributable to owners of the Company per share (Yen)	2,881	3,130		3,136
Basic earnings per share (EPS) (Yen) *	188.21	135.10	99.75	78.07
Growth Rate of EPS (%)		-28.2		-21.7
Payout ratio (%)	95.6	133.2	90.2	115.3
Dividend on equity attributable to owners of the Company (DOE) (%)	6.5	6.0		5.7

* Ratios are calculated based on amounts attributable to owners of the Company.

** "Notes and accounts receivable turnover" are after adjustment of outstanding balance at each fiscal year end and/or 1st half of fiscal year if the ending day falls on weekend or holiday, and to be paid on the beginning day of the following fiscal term.

III. Pipeline

1. Development Activities

Note: 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 code/product name <generic name>	Drug Class (administration route)	Indications	Stage		In-house/ In-license
MLN0002 <vedolizumab>	Humanized monoclonal antibody against α4β7 integrin (injection)	Ulcerative colitis	US EU Jpn	Approved (May 14) Approved (May 14) P-III	In-house
		Crohn's disease	US EU Jpn	Approved (May 14) Approved (May 14) P-III	
		Subcutanous formulation	-	P-I	
Contrave® <naltrexone XR /bupropion XR>	Mu-opioid receptor antagonist and dopamine/norepinephrine re-uptake inhibitor (oral)	Obesity	US	Approved (Sep 14)	In-license (Orexigen)
<fomepizole>	Alcohol dehydrogenase inhibitor (injection)	Ethylene glycol and methanol poisonings	Jpn	Approved (Sep 14)	In-license (Paladin Labs)
TAK-438 <vonoprazan>	Potassium-competitive acid blocker (oral)	Acid-related diseases (GERD, Peptic ulcer, etc.)	Jpn	Filed (Feb 14)	In-house
SYR-472 <trelagliptin>	DPP-4 inhibitor (oral)	Type 2 diabetes	Jpn	Filed (Mar 14)	In-house
TAK-816	Hib vaccine (injection)	Prevention of infectious disease caused by Haemophilus influenzae type b (Hib)	Jpn	Filed (Sep 13)	In-license (Novartis)
MLN9708 <ixazomib>	Proteasome inhibitor (oral)	Previously untreated multiple myeloma	US EU Jpn	P-III P-III P-III	In-house
		Relapsed or refractory multiple myeloma	US EU Jpn	P-III P-III P-III	
		Relapsed or refractory primary (AL) amyloidosis	US EU	P-III P-III	
		Maintenance therapy in patients with multiple myeloma following autologous stem cell transplant	US EU	P-III P-III	
		Solid tumors	US	P-I	
MLN8237 <alisertib>	Aurora A kinase inhibitor (oral)	Relapsed or refractory peripheral T-cell lymphoma	US EU	P-III P-III	In-house
		Small cell lung cancer, Ovarian cancer	US EU	P-II P-II	
		Non-Hodgkin lymphoma	Jpn	P-I	
		Solid tumors	Jpn	P-I	
Lu AA21004 <vortioxetine>	Multimodal anti-depressant (oral)	Major depressive disorder	Jpn	P-III	In-license (Lundbeck)
		Generalized anxiety disorder	US	P-III	
<motesanib diphosphate>	VEGFR1-3, PDGFR, c-Kit inhibitor (oral)	Advanced non-squamous non-small cell lung cancer	Jpn	P-III	In-license (Amgen)
AMG 386 <trebananib>	Anti-angiopoietin peptibody (injection)	Ovarian cancer	Jpn	P-III	In-license (Amgen)
MLN0264 < - >	Antibody-Drug Conjugate targeting GCC (injection)	Gastric cancer, Pancreatic cancer	US EU	P-II P-II	In-house
TAK-385 <relugolix>	LH-RH antagonist (oral)	Endometriosis	Jpn	P-II	In-house
		Uterine fibroids	Jpn	P-II	
		Prostate cancer	US EU Jpn	P-II P-II P-I	

Development code/product name <generic name>	Drug Class (administration route)	Indications	Stage		In-house/ In-license
MLN0128 < - >	mTORC1/2 inhibitor (oral)	Breast cancer	US EU	P-II P-II	In-house
		Solid tumors	-	P-I	
TAK-003*1	Tetravalent dengue vaccine (injection)	Prevention of dengue fever caused by dengue virus	-	P-II	In-house
Norovirus vaccine	Norovirus vaccine (injection)	Prevention of acute gastroenteritis (AGE) caused by norovirus	-	P-II	In-house
TAK-114*2	Pro-inflammatory cytokine inhibitor (oral)	Ulcerative colitis	US EU Jpn	P-II P-II P-I	In-license (Natrogen)
TAK-361S	Tetravalent vaccine (injection)	Prevention of infectious disease caused by diphtheria, pertussis, tetanus, poliomyelitis	Jpn	P-II	In-license (Biken)
MT203 <namilumab>	GM-CSF monoclonal antibody (injection)	Psoriasis	EU	P-II	In-licence (Amgen)
		Rheumatoid arthritis	EU	P-I	
TAK-850	Influenza vaccine (injection)	Prevention of influenza disease caused by influenza virus subtype A and B contained in the vaccine	Jpn	P-I/II	In-license (Baxter)
TAK-733 < - >	MEK inhibitor (oral)	Solid tumors	-	P-I	In-house
TAK-272 < - >	Direct renin inhibitor (oral)	Hypertension	-	P-I	In-house
TAK-063 < - >	PDE10A inhibitor (oral)	Schizophrenia	-	P-I	In-house
TAK-137 < - >	AMPA receptor potentiator (oral)	Psychiatric disorders and neurological diseases	-	P-I	In-house
TAK-659 < - >	SYK kinase inhibitor (oral)	Solid tumors, Hematologic malignancies	-	P-I	In-house
TAK-233 < - >	(oral)	-	-	P-I	In-house
TAK-935 < - >	CH24H inhibitor (oral)	Diseases related to glutamate excitotoxicity	-	P-I	In-house
TAK-058 < - >	5-HT3 receptor antagonist (oral)	Schizophrenia, especially cognitive impairment associated with schizophrenia	-	P-I	In-house
TAK-079 < - >	Cytolytic monoclonal antibody (injection)	Rheumatoid arthritis, Systemic lupus erythematosus	-	P-I	In-house
INV21	EV71 vaccine (injection)	Prevention of hand, foot and mouth disease caused by enterovirus 71	-	P-I	In-house
MLN3126 < - >	CCR9 antagonist (oral)	Sjogren's syndrome	-	P-I	In-house
MLN4924 < - >	NEDD 8 activating enzyme inhibitor (injection)	Advanced malignancies, Acute myeloid leukemia	-	P-I	In-house
MLN1117 < - >	PI3Kα isoform inhibitor (oral)	Solid tumors	-	P-I	In-house
MLN7243 < - >	UAE Inhibitor (injection)	Solid tumors	-	P-I	In-house
MLN2480 < - >	pan-Raf kinase inhibitor (oral)	Solid tumors	-	P-I	In-license (Sunesis)
ITI-214 < - >	PDE1 inhibitor (oral)	Cognitive impairment associated with schizophrenia	-	P-I	In-license (Intra-Cellular)

*1 Formerly known as DENVax

*2 Formerly known as Natura-alpha

Development code/ product name <generic name>	Drug Class (administration route)	Indications	Stage		In-house/ In-license
Lu AA24530 < - >	Multimodal anti-depressant (oral)	Major depressive disorder, Generalized anxiety disorder	US Jpn	P-I P-I	In-license (Lundbeck)
AMG 403 <fulranumab>	Human monoclonal antibody against human Nerve Growth Factor (NGF) (injection)	Pain	Jpn	P-I	In-license (Amgen)
<rasagiline>	Monoamine oxidase B (MAO-B) inhibitor (oral)	Parkinson's disease	Jpn	P-I	In-license (Teva)

■ Additional indications/formulations of approved compounds

Development code <generic name> Brand name (country / region)	Drug Class	Indications or formulations	Stage		In-house/ In-license
<bortezomib> Velcade® (US)	Proteasome inhibitor	Retreatment of multiple myeloma Front line mantle cell lymphoma Relapsed diffuse large B-cell lymphoma	US US US	Approved (Aug 14) Approved (Oct 14) P-III	In-house
TAP-144-SR <leuprorelin acetate> Leuplin® (Jpn) Lupron Depot® (US) Enantone®, etc. (EU)	LH-RH agonist	Prostate cancer, Premenopausal breast cancer (6-month formulation)	Jpn	Filed (Sep 14)	In-house
<ferumoxytol> Rienso® (EU) Feraheme® (Canada)	IV iron	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	EU	Filed (Jun 13)	In-license (AMAG)
TAK-375SL <ramelteon> Rozerem® (US, Jpn)	MT1/MT2 receptor agonist	Bipolar (sublingual formulation)	US	P-III	In-house
SYR-322 <alogliptin> Nesina® (US, Jpn) Vipidia® (EU)	DPP-4 inhibitor	Type 2 diabetes (fixed-dose combination with metformin)	Jpn	P-III	In-house
AD-4833/TOMM40	Insulin sensitizer/ Biomarker assay	Delay of onset of mild cognitive impairment due to Alzheimer's disease	US EU	P-III P-III	In-license (Zinfandel)
SGN-35 <brentuximab vedotin> Adcetris® (EU, Jpn)	CD30 monoclonal antibody-drug conjugate	Relapsed cutaneous T-cell lymphoma Post-ASCT Hodgkin lymphoma Front line Hodgkin lymphoma Front line mature T-cell lymphoma	EU EU EU Jpn EU Jpn	P-III P-III P-III P-III P-III P-III	In-license (Seattle Genetics)
<lubiprostone> Amitiza® (US)	Chloride channel activator	Liquid formulation Pediatric functional constipation	US US	P-III P-III	In-license (Sucampo)
<febuxostat XR> Uloric® (US)	Non-purine, selective xanthine oxidase inhibitor	Extended-release formulation	US	P-III	In-license (Teijin)
<lurasidone hydrochloride> Latuda® (EU)	Atypical antipsychotic agent	Bipolar disorder	EU	P-III	In-license (Sumitomo Dainippon Pharma)
TAK-390MROD <dexlansoprazole> Dexilant® (US)	Proton pump inhibitor	Orally disintegrating tablet	-	P-I	In-house

■ Recent progress in stage **Progress in stage since release of FY2013 results (May 8th, 2014)**

Development code <generic name>	Indications	Country/Region	Progress in stage
MLN0002 <vedolizumab>	Ulcerative colitis	US	Approved (May 14)
MLN0002 <vedolizumab>	Crohn's disease	US	Approved (May 14)
MLN0002 <vedolizumab>	Ulcerative colitis	EU	Approved (May 14)
MLN0002 <vedolizumab>	Crohn's disease	EU	Approved (May 14)
MLN9708 <ixazomib>	Maintenance therapy in patients with multiple myeloma following autologous stem cell transplant	US, EU	P-III
SYR-322 <alogliptin>	Type 2 diabetes (fixed-dose combination with metformin)	Jpn	P-III
MLN0264 < - >	Gastric cancer, Pancreatic cancer	US, EU	P-II
MLN0002 <vedolizumab>	Subcutaneous formulation	-	P-I
TAK-935 < - >	Diseases related to glutamate excitotoxicity	-	P-I
TAK-058 < - >	Schozophrenia, especially cognitive impairment associated with schizophrenia	-	P-I
<bortezomib>	Retreatment of multiple myeloma	US	Approved (Aug 14)
Contrave® <naltrexone XR / bupropion XR>	Obesity	US	Approved (Sep 14)
<fomepizole>	Ethylene glycol and methanol poisonings	Jpn	Approved (Sep 14)
<bortezomib>	Front line mantle cell lymphoma	US	Approved (Oct 14)
TAP-144-SR <leuprorelin acetate>	Prostate cancer, Premenopausal breast cancer (6-month formulation)	Jpn	Filed (Sep 14)
TAK-385 <relugolix>	Prostate cancer	EU	P-II
MLN0128 < - >	Breast cancer	EU	P-II
TAK-385 <relugolix>	Prostate cancer	Jpn	P-I
MLN4924 < - >	Acute myeloid leukemia	-	P-I
TAK-079 < - >	Rheumatoid arthritis, Systemic lupus erythematosus	-	P-I
MLN3126 < - >	Sjogren's syndrome	-	P-I

Progress in stage since the announcement of FY2014 Q1 results (August 1st, 2014) are listed under the bold dividing line

■ Discontinued projects **Discontinued since release of FY2013 results (May 8th, 2014)**

Development code <generic name>	Indications (Stage)	Reason
SYR-472 <trelagliptin>	Type 2 diabetes (US, EU P-II)	Discontinued in the US and EU after consideration of the development costs that would be necessary in order to obtain approval.
TAK-700 <orteronel>	Prostate cancer (US, EU, Jpn P-III)	Takeda decided to end the development program for orteronel (TAK-700) based on the results of two Phase 3 clinical trials. The studies found that while orteronel plus prednisone could extend the time patients lived before their cancer progressed, it did not extend overall survival in these patients.
<peginesatide>	Anaemia associated with chronic kidney disease in adult patients undergoing dialysis (EU P-III)	In February 2013, all lots of peginesatide were voluntarily recalled in the US following postmarketing reports of serious hypersensitivity reactions. A detailed investigation of these reactions has confirmed that no quality or manufacturing issues were present but has not identified a specific root cause for the reactions. Based on these findings, further clinical development of peginesatide will not be pursued.

■ 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)
Brazil	TAK-491*[3]/chlorthalidone (Approved Jul 14), SGN-35 (Approved Sep 14), SYR-322/metformin (Filed Jul 13), SYR-322/pioglitazone (Filed Dec 13), TAK-375*[4] (Filed Mar 14), MLN0002 (Filed Sep 14)
China	roflumilast*[5] (Filed Dec 11), SGN-35 (Filed May 13)
Russia	TAK-390MR*[6] (Approved May 14), SYR-322 (Approved Oct 14), SYR-322/metformin (Filed Mar 14), SGN-35 (Filed May 14), TAK-491/chlorthalidone (Filed May 14)

*3 **TAK-491 <azilsartan medoxomil>** Angiotensin II receptor blocker (oral) for the treatment of hypertension

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

*5 **<roflumilast>** PDE4 inhibitor (oral) for the treatment of Chronic Obstructive Pulmonary Disease

*6 **TAK-390MR <dexlansoprazole>** Proton pump inhibitor (oral) for the treatment of erosive esophagitis and gastro-esopageal reflux disease

■ Characteristics of projects

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MLN0002 <vedolizumab>	ENTYVIO™ (US, EU)	Humanized monoclonal antibody against α4β7 integrin	Ulcerative colitis, Crohn's disease	Injection
[Mode of action / Supplemental] MLN0002 is a humanized monoclonal antibody that specifically antagonizes the α4β7 integrin, inhibiting the binding of α4β7 integrin to intestinal mucosal addressin cell adhesion molecule (MAdCAM-1). MAdCAM-1 is preferentially expressed on blood vessels and lymph nodes of the gastrointestinal tract. The α4β7 integrin is expressed on a subset of circulating white blood cells, and these cells have been shown to play a role in mediating the inflammatory process in ulcerative colitis and Crohn's disease.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
<naltrexone XR /bupropion XR>	CONTRAVE® (US)	Mu-opioid receptor antagonist and dopamine/norepinephrine re-uptake inhibitor	Obesity	Oral
[Mode of action / Supplemental] The two components of CONTRAVE act in a complementary manner in the central nervous system. The central pathways targeted by this treatment are involved in controlling the balance of food intake and metabolism, and regulating reward-based eating behavior. In clinical trials, CONTRAVE was shown to help obese patients initiate and sustain significant weight loss, improve important markers of cardiometabolic risk and increase the ability to control eating.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
<fomepizole>	Fomepizole Intravenous Infusion 1.5g "Takeda"	Alcohol dehydrogenase inhibitor	Ethylene glycol and methanol poisonings	Injection
[Mode of action / Supplemental] Fomepizole is an antidote to inhibit the metabolism of ethylene glycol and methanol by inhibiting alcohol dehydrogenase (ADH) competitively and thereby inhibiting production of toxic metabolites (organic acids).				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-438 <vonoprazan>	Not decided yet	Potassium-competitive acid blocker	Acid-related diseases (GERD, Peptic ulcer, etc.)	Oral
[Mode of action / Supplemental] TAK-438 is a potassium-competitive acid blocker (P-CAB) that suppresses gastric acid secretion by inhibiting the proton pump, the final step of acid secretion from gastric parietal cells. PPIs are activated in an acid environment and bind irreversibly to the proton pump whereas TAK-438 suppresses acid secretion by directly competing with potassium ions and reversibly inhibiting the proton pump The results of non-clinical and P-I studies show that this drug has a stronger inhibitory effect on acid secretion compared with PPIs as well as an earlier onset and longer duration of action.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
SYR-472 <trelagliptin>	Not decided yet	DPP-4 inhibitor	Type 2 diabetes	Oral
[Mode of action / Supplemental] SYR-472 is a DPP-4 inhibitor, taken orally once weekly, that works by blocking Glucagon Like Peptide-1 (GLP-1) degradation to keep its concentration for a longer period of time. GLP-1, which is secreted within the digestive tract, stimulates pancreatic beta cells to increase the secretion of insulin, and GLP-1 has the potential to improve beta cell function itself.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-816	Not decided yet	Hib vaccine	Prevention of infectious disease caused by Haemophilus influenza Type b (Hib)	Injection
[Mode of action / Supplemental] TAK-816 is a vaccine to prevent infection caused by Haemophilus Influenza Type b (Hib). Hib vaccine is developed by combining it with detoxified diphtheria toxin in order to increase immunogenicity, assuring the potential to induce the production of antibodies in infants.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MLN9708 <ixazomib>	Not decided yet	Proteasome inhibitor	Relapsed or refractory multiple myeloma, Previously untreated multiple myeloma, Maintenance therapy in patients with multiple myeloma following autologous stem cell transplant, Relapsed or refractory primary (AL) amyloidosis, Solid tumors	Oral
[Mode of action / Supplemental] MLN9708 is an investigational oral, proteasome inhibitor, which constitutes a unique approach to targeted therapy. Inhibition of the proteasome prevents the degradation of numerous regulatory proteins, affecting multiple signaling cascades within the cell. In vitro, non-clinical studies have shown that proteasome inhibition can be cytotoxic to a variety of cancer cell types.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MLN8237 <alisertib>	Not decided yet	Aurora A kinase inhibitor	Relapsed or refractory peripheral T-cell lymphoma, Small cell lung cancer, Ovarian cancer, Non-Hodgkin lymphoma, Solid tumors	Oral
[Mode of action / Supplemental] MLN8237 is an oral highly-specific small molecule Aurora A kinase inhibitor. Both Aurora A kinase and Aurora B kinase play important roles in cell mitosis, but they have different distributions in the cell and different roles in the process of mitosis. Aurora A kinase is a serine/threonine kinase that exists in the centrosome and spindle poles and is known to play an important role in the formation of spindles at the time of mitosis.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
Lu AA21004 <vortioxetine>	BRINTELLIX® (US)	Multimodal anti-depressant	Major depressive disorder, Generalized anxiety disorder	Oral
[Mode of action / Supplemental] Lu AA21004 is an inhibitor of serotonin (5-HT) reuptake and that is thought to be a mechanism of its action. It is also an agonist at 5-HT1A receptors, a partial agonist at 5-HT1B receptors and an antagonist at 5-HT3, 5-HT1D and 5-HT7 receptors. In vivo nonclinical studies have demonstrated that Lu AA21004 enhances levels of the neurotransmitters serotonin, noradrenaline, dopamine, acetylcholine and histamine in specific areas of the brain.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
<motesanib diphosphate>	Not decided yet	VEGFR1-3, PDGFR, c-Kit inhibitor	Advanced non-squamous non-small cell lung cancer	Oral
[Mode of action / Supplemental] Motesanib is an orally administered inhibitor targeting vascular endothelial growth factor (VEGF) receptor 1,2 and 3, platelet derived growth factor (PDGF) receptor and c-kit (Stem Cell Factor) receptors intending to inhibit angiogenesis and tumor growth.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
AMG 386 <trebananib>	Not decided yet	Anti-angiopoietin peptibody	Ovarian cancer	Injection
[Mode of action / Supplemental] AMG 386 is a peptibody (Fc-peptide fusion protein) which binds to and inhibit Angiopoietin 1 and 2. Angiopoietins are known to be one of the cytokines which stimulate angiogenesis of vascular endothelial cells related to tumor growth and metastasis through different pathways from vascular endothelial growth factors (VEGF). AMG386 inhibits vascular angiogenesis through binding to angiopoietin 1 and 2.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MLN0264	Not decided yet	Antibody-drug conjugate targeting GCC	Gastric cancer, Pancreatic cancer	Injection

[Mode of action / Supplemental]
MLN0264 is a novel, first in class antibody drug conjugate (ADC) that selectively binds Guanylate Cyclase C (GCC) and kills GCC-expressing cells at sub-nanomolar concentrations. Its toxic payload, monomethyl auristatin E (MMAE; a very potent microtubulin inhibitor) is linked to a target specific monoclonal antibody (developed by Millennium), via a cleavable linker (utilizing proprietary technology licensed from Seattle Genetics).
GCC is a transmembrane receptor localized on the apical, but not the basolateral, membrane of epithelial tissues primarily in the gastrointestinal (GI) tract. Malignant transformation results in loss of this anatomically privileged GCC expression profile and tumor, but not normal, tissue becomes accessible to systemically administered agents targeting GCC. GCC is expressed across various cancers, including gastric, pancreatic and colorectal cancer.

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-385 <relugolix>	Not decided yet	LH-RH antagonist	Endometriosis, Uterine fibroids, Prostate cancer	Oral

[Mode of action / Supplemental]
TAK-385 is a nonpeptidic oral LH-RH antagonist. It antagonizes LH-RH in the LH-RH receptor that exists in the anterior pituitary basophil (secretory cell), and lowers blood concentration of sex hormones by inhibiting secretion of LH and FSH caused by the stimulation of LH-RH. It is expected to become a treatment for sex hormone-dependent diseases such as endometriosis and uterine fibroids.

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MLN0128	Not decided yet	mTORC1/2 inhibitor	Breast cancer, Solid tumors	Oral

[Mode of action / Supplemental]
MLN0128, a novel mTORC1/2 inhibitor, has generated encouraging data in multiple P-I studies and entered P-II studies for breast cancer in 2014.

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-003	Not decided yet	Tetravalent Dengue vaccine	Prevention of dengue fever caused by dengue virus	Injection

[Mode of action / Supplemental]
Takeda's Tetravalent Dengue Vaccine Candidate (Takeda's TDV) is a live virus (attenuated tetravalent) vaccine, including the four serotypes of the dengue virus. The chimeric, attenuated vaccine strains for dengue serotypes 1, 3 and 4 were engineered by replacing the DENV-2 PDK-53 structural genes, premembrane (prM) and envelope (E), with the prM and E genes of the respective with virus strains that cause disease in humans. In preclinical models, this candidate stimulates both types of acquired immunity: humoral (antibody) and cell-mediated (T-cell) immune responses. In Phase 1 and 2 clinical studies, Takeda's Tetravalent Dengue Vaccine Candidate (Takeda's TDV) induced immune responses to all dengue virus serotypes after two vaccinations with no safety concerns in multiple age groups and in dengue endemic and dengue non-endemic countries.

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
Norovirus vaccine	Not decided yet	Norovirus vaccine	Prevention of acute gastroenteritis (AGE) caused by norovirus	Injection

[Mode of action / Supplemental]
The norovoris vaccine includes virus-like particle (VLP) antigens representing each of the two genogroups that predominantly cause illness in humans, and is formulated with alum and MPL adjuvants. Takeda's product candidate is the only clinical-stage vaccine against norovirus in the world. Phase I and I/II studies showed the vaccine to be generally well tolerated, and a reduction in mild, moderate or severe vomiting and diarrhea symptoms was demonstrated in vaccinees upon oral challenge with live norovirus. The norovirus vaccine is administered by the intramuscular route.

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-114	Not decided yet	Pro-inflammatory cytokine inhibitor	Ulcerative colitis	Oral

[Mode of action / Supplemental]
TAK-114 is a synthetic small molecule that is believed to inhibit expression of pro-inflammatory cytokines (IL-1β, IL-6, IL-12 and TNF-α), which can increase inflammation and worsen the disease, and stimulate expression of a cytokine (IL-10) which further suppresses proinflammatory responses. These anti-inflammatory responses may limit unnecessary tissue disruptions caused by inflammation.

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-361S	Not decided yet	Tetravalent vaccine	Prevention of infectious disease caused by Diphtheria, Pertussis, Tetanus, Poliomyelitis	Injection
[Mode of action / Supplemental] TAK-361S is a combined vaccine with a Diphtheria-Tetanus-acellular Pertussis (DTaP) vaccine and Sabin inactivated polio vaccine (sIPV). sIPV is an inactivated poliovirus vaccine (IPV) derived from the Sabin strains poliovirus (attenuated poliovirus). Compared to the inactivated poliovirus vaccine produced from wild-type poliovirus that is used in many countries, sIPV does not require an advanced safe management site for its production.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MT203 <namilumab>	Not decided yet	GM-CSF monoclonal antibody	Psoriasis, Rheumatoid arthritis	Injection
[Mode of action / Supplemental] MT203 works by neutralizing GM-CSF (a fully human monoclonal antibody neutralizing Granulocyte macrophage colony-stimulating factor) signaling by binding the soluble cytokine. GM-CSF, a pro-inflammatory cytokine, has been shown to play a significant role in various autoimmune and inflammatory disease and supports development of MT203 for the treatment of psoriasis and rheumatoid arthritis.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-850	Not decided yet	Influenza vaccine	Prevention of influenza disease caused by influenza virus subtype A and B contained in the vaccine	Injection
[Mode of action / Supplemental] TAK-850 is an inactivated, cell-culture seasonal influenza vaccine based on Baxter's Vero cell culture technology. It is expected to be suitable for people with allergies because of the absence of eggs, preservatives, adjuvant or antibiotics.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-733	Not decided yet	MEK inhibitor	Solid tumors	Oral
[Mode of action / Supplemental] TAK-733 is a highly selective, allosteric, non-ATP competitive inhibitor of MEK kinase. MEK signaling plays an essential role in regulating both mitogenic and survival signals within tumor cells. This pathway is activated in 50 percent of human cancers, including colon, lung, breast, pancreas, melanoma, ovary and kidney. Inhibition of MEK by TAK-733 as a single agent and in combination with other drugs has a significant effect on the progression of tumor growth in pre-clinical models.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-272	Not decided yet	Direct renin inhibitor	Hypertension	Oral
[Mode of action / Supplemental] TAK-272 is a direct renin inhibitor (DRI), which is at the top of the enzymatic cascade of renin-angiotensin system (RAS). Non-clinical pharmacology studies have shown that TAK-272 selectively inhibited human renin and efficiently lowered blood pressure. Additionally TAK-272 has shown strong organ protective effects.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-063	Not decided yet	PDE10A inhibitor	Schizophrenia	Oral
[Mode of action / Supplemental] TAK-063 is a PDE10A inhibitor. An alternative approach to treating schizophrenia may be to selectively inhibit the enzyme PDE10A, thereby modulating the dopaminergic and glutamatergic second messenger pathways in the striatum. Inhibition of PDE10A in vivo has been reported to be associated with behavioral effects consistent with antipsychotic activity. Based on the potential effects of TAK-063 on striatal function, the initial nonclinical and clinical programs for TAK-063 are focused on the treatment of schizophrenia.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-137	Not decided yet	AMPA receptor potentiator	Psychiatric disorders and neurological diseases	Oral
[Mode of action / Supplemental] TAK-137 is an AMPA receptor (AMPA-R) potentiator. Glutamate is the major excitatory neurotransmitter in the brain and it produces its effects by binding to different receptors such as the AMPA receptor. In fact, AMPA receptors mediate most of the excitatory neurotransmission in the human central nervous system and are also involved in processes thought to underlie memory and learning, and the formation of neural networks during brain development. Published preclinical and clinical data have suggested that positive modulation of AMPA receptors may be therapeutically effective in the treatment of various psychiatric disorders and neurological diseases. The potential for AMPA-R potentiators to ameliorate cognitive deficits, a symptom commonly associated with many CNS condition, is particularly promising.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-659	Not decided yet	SYK kinase inhibitor	Solid tumors, Hematologic malignancies	Oral
[Mode of action / Supplemental] TAK-659 is an orally bioavailable, selective inhibitor of SYK (Spleen Tyrosine Kinase) and FLT3 (FMS-like tyrosine kinase-3). SYK is a non-receptor protein tyrosine kinase that is widely expressed in hematopoietic cells. It is involved in coupling activated immuno-receptors (B-cell and Fc receptors) to downstream signaling events that mediate diverse cellular responses including proliferation, differentiation and phagocytosis. SYK is known to be activated in lymphomas and leukemias. Tumor populations enriched for activated SYK expression include B-cell tumors that require signaling through BcR, myeloid tumors that signal through FcgR and EBV-associated heme and solid tumor malignancies.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-233	Not decided yet	-	-	Oral
[Mode of action / Supplemental] TAK-233 is a novel and orally available drug.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-935	Not decided yet	CH24H inhibitor	Diseases related to glutamate excitotoxicity	Oral
[Mode of action / Supplemental] TAK-935 is a small molecule that potently inhibits cholesterol 24-hydroxylase (CH24H), a CNS-specific enzyme dominantly responsible for cholesterol catabolism in the brain. Recent literature indicates CH24H is involved in over-activation of the glutamatergic pathway, implying its potential role in CNS diseases such as epilepsy, traumatic brain injury and Alzheimer’s disease.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-058	Not decided yet	5-HT3 receptor antagonist	Schizophrenia, especially cognitive impairment associated with schizophrenia	Oral
[Mode of action / Supplemental] TAK-058 is a potent and highly selective 5-HT3 antagonist optimized for CNS target engagement. Parvalbumin-positive (PV+) interneurons in the prefrontal cortex regulate a key circuit involved in memory and perception, and these neurons are significantly affected in the schizophrenic brain. Blocking 5-HT3 receptors disinhibits PV+ interneurons providing an opportunity to restore the cortical excitation-inhibition imbalance and improve cognitive performance in schizophrenic patients.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-079	Not decided yet	Cytolytic monoclonal antibody	Rheumatoid arthritis, Systemic lupus erythematosus	Injection
[Mode of action / Supplemental] TAK-079 is a cytolytic monoclonal antibody.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
INV21	Not decided yet	EV71 vaccine	Prevention of hand, foot and mouth disease caused by enterovirus 71	Injection
[Mode of action / Supplemental] INV21 is an inactivated whole virus particle formulated with aluminum hydroxide adjuvant, produced in Vero cells. The vaccine is based on a common strain of EV71 (the B2 sub-genogroup). In a P-I study in 36 healthy adults in Singapore, INV21 induced robust, neutralizing antibody responses against the EV71 virus in every individual. There were no safety concerns in the trial.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MLN3126	Not decided yet	CCR9 antagonist	Sjogren's syndrome	Oral
[Mode of action / Supplemental] MLN3126 is an oral, small molecule chemokine C-C motif receptor 9 (CCR9) antagonist for the treatment of primary Sjögren syndrome (SjS). A published study showed that CCR9+ T cell are increased in the peripheral blood of SjS patients and in the salivary glands of mice with SjS-like disease. Further information will be gathered in a series of translational studies to evaluate the expression and correlation of CCR9 and CCR9 ligand, CCL25, expression in SjS patient tissues/ peripheral blood and changes with disease progression and severity.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MLN4924	Not decided yet	NEDD 8 activating enzyme inhibitor	Advanced malignancies, Acute myeloid leukemia	Injection
[Mode of action / Supplemental] MLN4924 is a first-in-class small molecule inhibitor of a Millennium-discovered target, NEDD 8 activating enzyme (NAE). MLN4924 inhibits NAE, which controls key components of the ubiquitin proteasome pathway that are important for cancer cell growth and survival. In pre-clinical models, MLN4924 suppresses cancer cell growth leading to cell death. MLN4924 is currently being studied in patients with solid tumors and hematologic malignancies.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MLN1117	Not decided yet	PI3Kalpha isoform inhibitor	Solid tumors	Oral
[Mode of action / Supplemental] MLN1117, a novel and selective inhibitor of the PI3Kalpha isoform, entered human clinical testing in 2011. A P-I dose escalation study is underway to evaluate the safety, tolerability and pharmacokinetics of single-agent MLN1117 in patients with advanced solid malignancies who have tumors characterized by the presence of a PIK3CA mutation.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MLN7243	Not decided yet	UAE Inhibitor	Solid tumors	Injection
[Mode of action / Supplemental] MLN7243 is a first-in-class selective inhibitor of Ubiquitin Activating Enzyme（UAE）. MLN7243 inhibits UAE driven ubiquitination resulting in ER (Endoplasmic Reticulum) stress, defective DNA repair, cell cycle arrest and apoptosis.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
MLN2480	Not decided yet	pan-Raf kinase inhibitor	Solid tumors	Oral
[Mode of action / Supplemental] MLN2480 is a selective pan-Raf kinase inhibitor. The Raf kinases (A-Raf, B-Raf and C-Raf) are key regulators of cell proliferation and survival within the mitogen-activated protein kinase (MAPK) pathway. The MAPK pathway is frequently disregulated in human cancers, often via activating mutations of Ras or Raf. Following treatment with MLN2480, significant antitumor activity was observed in both tumor xenograft models that had B-Raf$^{V600E/D}$ mutations or were wild type for B-Raf. MLN2480 exhibited a promising preclinical profile and has potential to be a therapeutic agent for solid tumors.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
ITI-214	Not decided yet	PDE1 inhibitor	Cognitive impairment associated with schizophrenia	Oral
[Mode of action / Supplemental] ITI-214 potently inhibits the phosphodiesterase1 (PDE1) enzyme and with that amplifies dopamine D1 receptor signaling in the prefrontal cortex of the brain, leading to improvement of cognition. This mode of action is unique compared to currently available drugs to treat schizophrenia, most of which work on blocking dopamine D2 receptors to relieve positive symptom. PDE1 inhibitors, including ITI-214, have been shown to enhance cognition in animal models.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
Lu AA24530	Not decided yet	Multimodal anti-depressant	Major depressive disorder, Generalized anxiety disorders	Oral
[Mode of action / Supplemental] In pre-clinical studies, Lu AA24530 has demonstrated activities as a multi-modal enhancer with reuptake inhibition at monoamine transporters, and antagonist activity at 5-HT_3 and 5-HT_{2c} receptors. In vivo rat studies have demonstrated that treatment with Lu AA24530 leads to increases in acetylcholine, noradrenaline, dopamine and 5-HT levels in brain regions that play a key role in the regulation of mood.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
AMG 403 <fulranumab>	Not decided yet	Human monoclonal antibody against human Nerve Growth Factor (NGF)	Pain	Injection
[Mode of action / Supplemental] AMG 403 is a human monoclonal antibody that has the specific capacity to neutralize the biologic actions of human NGF. NGF has been shown to contribute to persistent pain in a variety of animal models of inflammatory and neuropathic pain, and is known to be elevated in the knee joints of humans with chronic arthritis and possibly other chronic painful conditions in humans.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
<rasagiline>	Not decided yet	Monoamine oxidase B (MAO-B) inhibitor	Parkinson's disease	Oral
[Mode of action / Supplemental] Rasagiline is an innovative treatment for Parkinson's disease, and Takeda has signed an agreement with Teva allowing Takeda to commercialize it in Japan. Rasagiline is a monoamine oxidase B (MAO-B) inhibitor which is presumed to act by increasing available synaptic dopamine in the brain which may improve the motor symptoms characteristic of Parkinson’s disease.				

[Additional indications/formulations]

Development Code <generic name>	Brand Name	Drug Class	Additional indications/formulations	Administration
<bortezomib>	VELCADE®	Proteasome inhibitor	Front line mantle cell lymphoma, Retreatment of multiple myeloma, Relapsed diffuse large B-cell lymphoma	Injection
[Mode of action / Supplemental] VELCADE blocks the activity of proteasomes, which are enzymes found inside all human cells and necessary for their growth and survival. By inhibiting proteasomes activity, VELCADE causes a buildup of proteins, thereby inducing apoptosis/cell death. Proteasomes break down the resultant proteins which are created through the division and growth of cancer cells as well as other misfolded intracellular proteins. Proteasomes also break down the proteins that are responsible for angiogenesis and cell proliferation.				

Development Code <generic name>	Brand Name	Drug Class	Additional indications/formulations	Administration
TAP-144-SR <leuprorelin acetate>	LEUPLIN® (Jpn), LUPRON DEPOT® (US), ENANTONE®, etc. (EU, Asia)	LH-RH agonist	Prostate cancer, Premenopausal breast cancer (6-month formulation)	Injection
[Mode of action / Supplemental] TAP-144-SR is a long-acting sustained releasing LH-RH agonist product, and is marketed in over 80 countries world-wide. It is a standard treatment of prostate cancer, and in the US and Europe, a 6-month formulation was approved which makes it possible to provide treatment from one to six months with one injection. A 3-month formulation was authorized in Japan for prostate cancer (PC) in August 2002 and for premenopausal breast cancer (BC) in August 2005. In Japan, Takeda filed an NDA submission of the 6-month formulation with both PC and BC indications in September 2014.				

Development Code <generic name>	Brand Name	Drug Class	Additional indications/formulations	Administration
<ferumoxytol>	RIENSO® (EU), FERAHEME® (Canada)	IV iron	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	Infusion
[Mode of action / Supplemental] Treatment with RIENSO provides the following benefits: rapid repletion of iron stores in anemic patients; greater flexibility in the amount of iron that can be given to a patient in a single administration; fewer physician visits required for the administration of 1g of iron. RIENSO was approved for iron deficiency anemia in adult patients with chronic kidney disease in the EU in June 2012, and is currently under review for 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.				

Development Code <generic name>	Brand Name	Drug Class	Additional indications/formulations	Administration
TAK-375SL <ramelteon>	ROZEREM® (US, Jpn)	MT_1/MT_2 receptor agonist	Bipolar disorder	Sublingual
[Mode of action / Supplemental] TAK-375SL is highly specific to the MT_1/MT_2 receptor. Abnormalities on circadian rhythms are prominent features of bipolar I disorder. Normalization or resynchronization of circadian rhythms with exogenous melatonin agonists is expected to become a treatment for either acute bipolar episodes or to prevent recurrence.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
SYR-322 <alogliptin>	NESINA® (Jpn, US) VIPIDIA® (EU)	DPP-4 inhibitor	Diabetes mellitus	Oral
[Mode of action / Supplemental] SYR-322 is a DPP-4 inhibitor, taken orally once a day. DPP-4 inhibitors work by blocking Glucagon Like Peptide-1 (GLP-1) degradation to maintain its blood concentration for a longer period of time. GLP-1, which is secreted within the digestive tract, stimulates pancreatic beta cells to increase the secretion of insulin, and GLP-1 has the potential to improve beta cell function itself. SYR-322 was approved in Japan in April 2010, in the US in January 2013, and in the EU in September 2013. Clinical/registration activities are currently ongoing in other regions to support the approval of SYR-322 globally. SYR-322 has also been approved in fixed-dose combinations with pioglitazone (in Japan as LIOVEL®, in the US as OSENI® and in the EU as INCRESYNC®), and metformin (in the US as KAZANO® and in the EU as VIPDOMET®).				

Development Code <generic name>	Brand Name	Drug Class	Additional indications/formulations	Administration
AD-4833/TOMM40	-	Insulin sensitizer/ Biomarker assay	Delay of onset of mild cognitive impairment due to Alzheimer's disease	Oral
[Mode of action / Supplemental] The TOMM40 biomarker, discovered by a team led by Zinfandel's founder Allen Roses, M.D., together with APOE and age, is being developed to identify older adults at high risk of developing Mild Cognitive Impairment (MCI) due to Alzheimer's disease (AD) within the subsequent five years. Recent studies have demonstrated that TOMM40 mutations may be associated with loss of mitochondrial function in neurons, which has been implicated in the etiology of AD.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
SGN-35 <brentuximab vedotin>	ADCETRIS® (EU, Jpn)	CD30 monoclonal antibody-drug conjugate	Relapsed or refractory Hodgkin lymphoma, Front line Hodgkin lymphoma, Post-ASCT Hodgkin lymphoma, Relapsed or refractory systemic anaplastic large cell lymphoma, Front line mature T-cell lymphoma, Relapsed cutaneous T-cell lymphoma	Injection
[Mode of action / Supplemental] SGN-35 is an antibody-drug conjugate (ADC) comprising an anti-CD30 monoclonal antibody attached by an enzyme cleavable linker to a potent, synthetic drug, monomethyl auristatin E (MMAE) utilizing Seattle Genetics' proprietary technology. The ADC employs a novel linker system that is designed to be stable in the bloodstream but to release MMAE upon internalization into CD30-expressing tumor cells. This approach is intended to spare non-targeted cells and thus may help minimize the potential toxic effects of traditional chemotherapy while allowing for the selective targeting of CD30-expressing cancer cells, thus potentially enhancing the antitumor activity.				

Development Code <generic name>	Brand Name	Drug Class	Additional indications/formulations	Administration
<lubiprostone>	AMITIZA® (US)	Chloride channel activator	Liquid formulation, Pediatric functional constipation	Oral
[Mode of action / Supplemental] Amitiza has a novel mechanism of action as a chloride channel activator, which causes an increase in intestinal fluid secretion, thereby increasing the passage of the stool and additionally stimulates recovery of mucosal barrier function and reduces intestinal permeability via the restoration of tight junction protein complexes, improving symptoms associated with chronic idiopathic constipation (CIC), irritable bowel syndrome with constipation (IBS-C) and opioid-induced constipation (OIC).				

Development Code <generic name>	Brand Name	Drug Class	Additional indications/formulations	Administration
<febuxostat XR>	ULORIC® (US)	Non-purine, selective xanthine oxidase inhibitor	Extended release formulation	Oral
[Mode of action / Supplemental] Febuxostat is a non-purine selective inhibitor of xanthine oxidase which causes gout, maketed by Takeda in the U.S. as ULORIC. An extended release formulation is in development.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
<lurasidone hydrochloride>	LATUDA® (EU)	Atypical antipsychotic agent	Schizophrenia, Bipolar disorder	Oral
[Mode of action / Supplemental] Lurasidone is an atypical antipsychotic agent with an affinity for dopamine D2, serotonin 5-HT_{2A} and serotonin 5-HT_7 receptors where it has antagonist effects. In addition, lurasidone is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine or muscarinic receptors. In March 2014, lurasidone was approved in the EU for the treatment of schizophrenia.				

Development Code <generic name>	Brand Name	Drug Class	Indications	Administration
TAK-390MR <dexlansoprazole>	DEXILANT® (US, Canada) DEXIVANT® (Mexico)	Proton pump inhibitor	Erosive esophagitis (healing and maintenance), Non-erosive gastro-esophageal reflux disease	Oral
[Mode of action / Supplemental] TAK-390MR was originally developed by Takeda and is launched in the US, Canada and Mexico, and has been appoved in 16 countries in the EU by the decentralized procedure. It is taken once-daily, and employs a new modified release technology on an enantiomer of lansoprazole. TAK-390MR is the first proton pump inhibitor with a Dual Delayed Release™ formulation designed to provide two separate releases of medication in order to maintain its gastric antisecretory activity.				

■ 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.

2. Research Activities

■ Main joint research activities

(1) Joint researches with domestic research organizations and companies

Partner	Research subject	Schedule
Kirin Brewery Company Ltd. (Now Kyowa Hakko Kirin Ltd.)	Licensing-in of the human antibody technology	2003/7-
Kyoto University	Research collaboration for basic and clinical research project of discovering treatments for obesity and schizophrenia based on CNS control	2011/1-2016/3
Osaka University	Joint research on development of platform for practical application and commercialization of nano-particle vaccines	2012/2-2015/1

(2) Joint research with overseas research organizations and companies

Partner	Country	Research subject	Schedule
XOMA Ltd.	US	Joint research on discovery, development and production technologies of monoclonal antibody	2006/11-
Seattle Genetics	US	Research collaboration on Antibody-Drug Conjugate	2009/3-
University College London	UK	Research collaboration on development of novel cancer treatment	2010/3-2014/3
Sage Bionetworks	US	Research collaboration on discovering effective therapeutic targets for Central Nervous System (CNS) disease	2010/11-2015/6
Florida Hospital, Sanford-Burnham Medical Research Institute	US	Research collaboration to target obesity	2010/12-2015/2
Zinfandel Pharmaceuticals	US	Licensing agreement for Alzheimer's Disease Biomarker TOMM40 for the risk of Alzheimer's disease	2010/12-
Structural Genomics Consortium	Canada	Participation in consortium to advance basic research on selected drug targets based on three-dimensional structures of human proteins	2011/7-2015/6 *Takeda joined 2012/4
BC Cancer Agency	Canada	Research collaboration to explore new drug targets based on gene analysis	2012/8-2015/7
Advinus Therapeutics Limited	India	Discovery collaboration focused on novel targets for major therapeutic areas, including Inflammation, CNS, and Metabolic diseases	2012/10-2015/9
Resolve Therapeutics	US	Collaboration to develop compounds for the treatment of Systemic Lupus Erythematosus (SLE)	2013/2-
Tri-Institutional Therapeutics Discovery Institute	US	Collaboration of academic institutions and industry to more effectively develop innovative treatments and therapies	2013/10 -2016/9
Trianni, Inc.	US	Agreement for use of Trianni's next generation transgenic mouse platform for the generation of human monoclonal antibodies against disease targets in all therapeutic areas	2014/3-
MacroGenics	US	Collaboration to research and develop product candidates that will be directed against jointly selected pairs of molecular targets and using MacroGenics' Dual-Affinity Re-Targeting (DART®) proprietary platform.	2014/9-

Takeda Pharmaceutical Company Limited