



# Financial Results for 1<sup>st</sup> Q of FY2016 DATA BOOK

Takeda Pharmaceutical Company Limited (TSE code 4502)

Contact: Global Finance, IR TEL: +81-3-3278-2306 http://www.takeda.com/

Quarterly Announcements / Presentations <a href="http://www.takeda.com/investor-information/results/">http://www.takeda.com/investor-information/results/</a>

Co	nte	nts
$\sim$	1166	1113

I. Financial Results	
1. Revenue / Product Sales	
<ul><li>Prescription Drugs Revenue [Consolidated]</li></ul>	1
<ul> <li>Prescription Drugs: Global major products' sales</li> </ul>	2
<ul><li>Prescription Drugs: US major products' sales (in US\$)</li></ul>	3
<ul><li>Prescription Drugs: Japan major products' sales</li></ul>	4
◆ Consumer Healthcare: Major products' sales	5
2. Exchange Rate	6
II. Pipeline	
1. Development Activities	7-10
Oncology	
■ Gastroenterology	
■ CNS	
■ Vaccines	
■ Others	
■ Recent progress in stage	
■ Discontinued projects	
■ Revised collaboration agreement	
■ Clinical study protocol summaries	
2. Research Activities	11
■ Main joint research activities	

## I. Financial Results

#### 1. Revenue / Product Sales

## ◆ Prescription Drugs Revenue [Consolidated]

(Billion JPY)

	FY14	FY15	FY15	FY16	vs. F	)rV	Underlying
	Annual	Annual	Q1	Q1	V5. I	-11	Growth
Net sales	1,527.6	1,592.8	392.1	381.8	-10.3	-2.6%	10.9%
Japan	553.2	535.1	133.1	123.9	-9.2	-6.9%	10.3%
United States	394.9	495.3	118.6	126.7	8.1	6.9%	16.5%
Europe and Canada	287.1	283.5	70.7	71.4	0.6	0.9%	7.9%
Emerging Markets	292.3	279.0	69.7	59.9	-9.8	-14.1%	5.2%
Russia/CIS	79.5	61.5	15.4	12.5	-2.9	-18.7%	8.0%
Russia	56.2	43.3	10.6	8.8	-1.8	-17.0%	10.7%
Latin America	80.1	66.0	17.6	14.6	-3.0	-17.0%	11.6%
Brazil	46.2	37.4	9.8	7.9	-1.9	-18.9%	2.4%
Asia	102.4	116.6	28.6	25.3	-3.2	-11.2%	1.8%
China	53.0	63.2	13.4	13.2	-0.1	-1.1%	12.9%
Other	30.3	34.9	8.1	7.4	-0.7	-9.0%	0.8%
Royalty income and service income	86.9	55.8	15.8	12.2	-3.5	-22.3%	-20.3%
Japan	8.1	6.6	2.0	2.8	0.8	43.2%	-22.8%
Overseas	78.8	49.3	13.8	9.4	-4.4	-31.6%	-20.0%
Total prescription drugs revenue	1,614.5	1,648.7	407.8	394.0	-13.8	-3.4%	9.7%
Ratio of overseas prescription drugs revenue	65.2%	67.1%	66.9%	67.9%	1.0 pt		

<sup>\*1</sup> Revenue amount is classified into countries or regions based on the customer location. \*2 Other region includes Middle East, Oceania and Africa.

(Billion JPY)

Volicade   Private   Pr	Frescription	on Drugs: Global majo			···]					(Billion JPY)
Velicade							vs.	PrY		
Other than United States         41.9         30.4         9.1         6.7         2.4         28.1%         17.9%           Total         Total         57.6         53.8         13.3         13.1         -0.3         2.0%         2.0%           Leuprorelin Luried States         15.9         17.3         17.7         7.7         10.0         20.4%         2.25 %           Europe and Canada         36.4         35.3         8.7         8.3         -0.4         -4.9%         -0.8%           Fortal         124.0         124.4         30.9         30.8         -0.1         -0.4%         2.5%           Pantoprazole Luried States         11.0         13.5         1.7         3.4         1.7         94.9%         -19.8%           Europe and Canada         49.3         43.4         11.0         3.0         -2.7         -24.9%         -11.7%           Total         103.7         10.8         1.7         3.4         1.7         94.9%         -11.9%           Emerging Markets         20.7         10.8         3.1         1.0         2.1         -8.9         -80.8%         12.0%           Lansoprazole         Japan *2         52.5         41.3         11.0 <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>Forecasts *3</td>										Forecasts *3
Total	Velcade									
Leuprorelin	=									A. A.
United States										3 3
Europe and Canada   36.4   35.3   8.7   8.3   -0.4   -4.9%   -0.2%	Leuprorelin									
Emerging Markets										
Total										
Pantoprazole   United States	=	<u> </u>								•
Europe and Canada										
Emerging Markets	Pantoprazole									
Total										
Lansoprazole   Japan   2   52.5   41.3   11.0   2.1   -8.9   -80.8%   12.0%	=	Emerging Markets			10.7					
United States			103.7	100.8	24.3	20.1	-4.2	-17.3%		
Europe and Canada   11.7   10.5   3.1   2.3   -0.9   -28.1%   -22.9 %   Emerging Markets   10.1   10.2   2.7   2.4   -0.3   -11.0%   0.5%   10.8	Lansoprazole	Japan *2			11.0	2.1	-8.9	-80.8%	12.0%	
Emerging Markets		United States	28.7	27.5	9.1	6.6	-2.5	-27.3%	-20.7%	
Total		Europe and Canada	11.7	10.5	3.1	2.3	-0.9	-28.1%	-23.9%	
Total		Emerging Markets	10.1	10.2	2.7	2.4	-0.3		0.5%	
Entyvio	=		102.9	89.5						222
Europe and Canada   7.7   21.9   3.9   8.8   4.9   124.4%   137.3%   Total   27.8   86.2   16.2   32.0   15.9   98.2%   113.9%   113.9%   137.3%	Entyvio									
Emerging Markets	•									
Total								-	_	
Candesartan	=	Ţ Ţ						98.2%	113.9%	
United States	Candesartan									• •
Europe and Canada   17.7   12.5   3.2   3.0   -0.2   -7.0%   -1.2%   11.0%   12.57   84.8   22.7   11.3   -11.4   50.4%   -18.9	our racourtur.	•								
Emerging Markets										
Total   125.7   84.8   22.7   11.3   -11.4   -50.4%   -18.9%										
Dexilant         United States         53.5         64.0         16.3         13.0         -3.3         -20.2%         -13.3%           Europe and Canada         4.9         5.4         1.3         1.5         0.1         10.9%         24.9%           Total         62.3         75.1         18.8         16.2         -2.7         -14.3%         -5.9%           Azilva         Japan         45.4         59.0         14.1         17.7         3.6         25.6%         25.6%           Nesina         Japan         38.4         36.9         9.5         9.3         -0.2         -1.6%         -1.6%           Lurope and Canada         0.6         3.5         0.5         1.5         1.0         - <td>-</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>	-									
Europe and Canada   4.9   5.4   1.3   1.5   0.1   10.9%   24.9%   Emerging Markets   3.9   5.7   1.2   1.6   0.5   38.9%   66.5%   1.2   1.6   0.5   38.9%   66.5%   1.2   1.6   0.5   38.9%   66.5%   1.2   1.6   0.5   38.9%   66.5%   1.2   1.6   0.5   38.9%   66.5%   1.2   1.2   1.2   1.3   1.2   1.3   1.5   0.1   1.0   1.2   1.2   1.3   1.2   1.3   1.2   1.3   1.2   1.3   1.2   1.3   1.2   1.3   1	Devilant									
Emerging Markets   3.9   5.7   1.2   1.6   0.5   38.9%   66.5%   Total   62.3   75.1   18.8   16.2   -2.7   -14.3%   -5.9%	Doxilarit									
Total										
Azilva         Japan         45.4         59.0         14.1         17.7         3.6         25.6%         25.6%           Total         45.4         59.0         14.1         17.7         3.6         25.6%         25.6%           Nesina         Japan         38.4         36.9         9.5         9.3         -0.2         1.6%         -1.6%           Europe and Canada         0.6         3.5         0.5         1.5         1.0         -         -         -           Emerging Markets         1.3         3.3         0.7         1.0         0.3         35.1%         55.9%           Total         44.3         48.9         12.2         13.3         1.2         9.5%         11.6%           Colcrys         United States         58.8         46.5         11.2         10.5         -0.7         -5.9%         2.1%           Uloric         United States         32.6         41.8         9.8         9.5         -0.3         -2.7%         5.6%           Europe and Canada         0.6         0.7         0.2         0.2         0.0         4.7%         17.9%           Europe and Canada         0.0         0.1         0.0         0.0	=									$\rightarrow$
Total	Δzilva									
Nesina         Japan United States Europe and Canada Europe and Canada         38.4   36.9   3.5   3.5   1.5   1.5   0.0   3.0%   10.9%   10.	Aziiva	-								$\rightarrow$
United States	Nocina									
Europe and Canada   0.6   3.5   0.5   1.5   1.0   -     -	INESITIA									
Emerging Markets								J.U /0 -	10.870	
Total         44.3         48.9         12.2         13.3         1.2         9.5%         11.6%           Colcrys         United States         58.8         46.5         11.2         10.5         -0.7         -5.9%         2.1%           Total         58.8         46.5         11.2         10.5         -0.7         -5.9%         2.1%           Uloric         United States         32.6         41.8         9.8         9.5         -0.3         -2.7%         5.6%           Europe and Canada         0.6         0.7         0.2         0.2         0.0         4.7%         17.9%           Emerging Markets         -         -         -         0.0         0.0         -         -         -           Amitiza         United States         31.9         37.2         9.4         8.9         -0.5         -5.6%         2.5%           Europe and Canada         0.0         0.1         0.0         0.0         -0.0         -18.7%         -9.0%           Adcetris         Japan         2.8         3.1         0.8         0.9         0.1         9.1%         9.1%           Europe and Canada         16.3         17.4         4.3         5.0 <td></td> <td>-</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>- 25 10/</td> <td>55 OO/</td> <td></td>		-						- 25 10/	55 OO/	
Colcrys         United States         58.8         46.5         11.2         10.5         -0.7         -5.9%         2.1%           Total         58.8         46.5         11.2         10.5         -0.7         -5.9%         2.1%           Uloric         United States         32.6         41.8         9.8         9.5         -0.3         -2.7%         5.6%           Europe and Canada         0.6         0.7         0.2         0.2         0.0         4.7%         17.9%           Emerging Markets         -         -         -         -         0.0         0.0         -         -         -           Amitiza         United States         31.9         37.2         9.4         8.9         -0.5         -5.6%         2.5%           Europe and Canada         0.0         0.1         0.0         0.0         -0.0         -18.7%         -9.0%           Adcetris         Japan         2.8         3.1         0.8         0.9         0.1         9.1%           Europe and Canada         16.3         17.4         4.3         5.0         0.7         17.4%         24.5%           Emerging Markets         3.6         7.2         1.7         1.	-									
Total	Colonie									
Uloric   United States   32.6   41.8   9.8   9.5   -0.3   -2.7%   5.6%     Europe and Canada   0.6   0.7   0.2   0.2   0.0   4.7%   17.9%     Emerging Markets     -   0.0   0.0   -   -     Total   33.2   42.5   10.0   9.7   -0.2   -2.4%   6.0%     Amitiza   United States   31.9   37.2   9.4   8.9   -0.5   -5.6%   2.5%     Europe and Canada   0.0   0.1   0.0   0.0   -0.0   -18.7%   -9.0%     Total   32.0   37.3   9.4   8.9   -0.5   -5.7%   2.5%     Adcetris   Japan   2.8   3.1   0.8   0.9   0.1   9.1%   9.1%     Europe and Canada   16.3   17.4   4.3   5.0   0.7   17.4%   24.5%     Emerging Markets   3.6   7.2   1.7   1.9   0.1   8.7%   46.9%     Total   22.9   27.6   6.8   7.8   1.0   14.3%   27.2%     Trintellix *4   United States   13.6   24.5   5.0   6.4   1.4   27.6%   38.2%     Total   13.6   24.5   5.0   6.4   1.4   27.6%   38.2%     Total   3.2   8.4   0.5   6.4   5.8   -   -     Total   3.2   8.4   0.5   6.4   5.8   -   -     Total   United States   -   4.0   -   6.0   6.0   -   -     Emerging Markets   -   0.0   -   0.0   0.0   -   -     United States   -   4.0   -   6.0   6.0   -   -     Emerging Markets   -   0.0   -   0.0   0.0   -   -	COICI ys									
Europe and Canada Emerging Markets         0.6         0.7         0.2         0.2         0.0         4.7%         17.9% Inches Inc	Lllorio									
Emerging Markets         -         -         -         -         0.0         0.0         -         -           Total         33.2         42.5         10.0         9.7         -0.2         -2.4%         6.0%           Amitiza         United States         31.9         37.2         9.4         8.9         -0.5         -5.6%         2.5%           Europe and Canada         0.0         0.1         0.0         0.0         -0.0         -18.7%         -9.0%           Adcetris         Japan         2.8         3.1         0.8         0.9         0.1         9.1%         9.1%           Europe and Canada         16.3         17.4         4.3         5.0         0.7         17.4%         24.5%           Emerging Markets         3.6         7.2         1.7         1.9         0.1         8.7%         46.9%           Trintellix *4         United States         13.6         24.5         5.0         6.4         1.4         27.6%         38.2%           Takecab         Japan         3.2         8.4         0.5         6.4         5.8         -         -           Total         3.2         8.4         0.5         6.4         5.8<	OIOIIC									
Total         33.2         42.5         10.0         9.7         -0.2         -2.4%         6.0%           Amitiza         United States         31.9         37.2         9.4         8.9         -0.5         -5.6%         2.5%           Europe and Canada         0.0         0.1         0.0         0.0         -0.0         -18.7%         -9.0%           Adcetris         Japan         2.8         3.1         0.8         0.9         0.1         9.1%         9.1%           Europe and Canada         16.3         17.4         4.3         5.0         0.7         17.4%         24.5%           Emerging Markets         3.6         7.2         1.7         1.9         0.1         8.7%         46.9%           Total         22.9         27.6         6.8         7.8         1.0         14.3%         27.2%           Trintellix *4         United States         13.6         24.5         5.0         6.4         1.4         27.6%         38.2%           Takecab         Japan         3.2         8.4         0.5         6.4         5.8         -         -           Total         3.2         8.4         0.5         6.4         5.8         <		•		0.7	0.2			4.7%	17.9%	
Amitiza         United States Europe and Canada         31.9         37.2 Europe and Canada         9.4         8.9         -0.5         -5.6% -9.0%	=	Ţ Ţ		40.5	10.0			0.40/	6.00/	
Europe and Canada   0.0   0.1   0.0   0.0   -0.0   -18.7%   -9.0%	A :4:									
Total   32.0   37.3   9.4   8.9   -0.5   -5.7%   2.5%	Amitiza									
Adcetris         Japan Europe and Canada Europe and Canada Emerging Markets         16.3 17.4 4.3 5.0 0.7 17.4% 24.5% 24.	-									
Europe and Canada   16.3   17.4   4.3   5.0   0.7   17.4%   24.5%	A 1									-
Emerging Markets   3.6   7.2   1.7   1.9   0.1   8.7%   46.9%     Total   22.9   27.6   6.8   7.8   1.0   14.3%   27.2%     Trintellix *4   United States   13.6   24.5   5.0   6.4   1.4   27.6%   38.2%     Total   13.6   24.5   5.0   6.4   1.4   27.6%   38.2%     Takecab   Japan   3.2   8.4   0.5   6.4   5.8   -   -     Total   3.2   8.4   0.5   6.4   5.8   -   -     Ninlaro   United States   -   4.0   -   6.0   6.0   -   -     Emerging Markets   -   0.0   -   0.0   0.0   -   -	Adcetris									
Total   22.9   27.6   6.8   7.8   1.0   14.3%   27.2%										
Trintellix *4         United States         13.6         24.5         5.0         6.4         1.4         27.6%         38.2%           Total         13.6         24.5         5.0         6.4         1.4         27.6%         38.2%           Takecab         Japan         3.2         8.4         0.5         6.4         5.8         -         -           Total         3.2         8.4         0.5         6.4         5.8         -         -           Ninlaro         United States         -         4.0         -         6.0         6.0         -         -           Emerging Markets         -         0.0         -         0.0         0.0         -         -	=									
Total         13.6         24.5         5.0         6.4         1.4         27.6%         38.2%           Takecab         Japan         3.2         8.4         0.5         6.4         5.8         -         -           Total         3.2         8.4         0.5         6.4         5.8         -         -           Ninlaro         United States         -         4.0         -         6.0         6.0         -         -           Emerging Markets         -         0.0         -         0.0         0.0         -         -										
Takecab         Japan         3.2         8.4         0.5         6.4         5.8         -         -           Total         3.2         8.4         0.5         6.4         5.8         -         -           Ninlaro         United States         -         4.0         -         6.0         6.0         -         -           Emerging Markets         -         0.0         -         0.0         0.0         -         -	Trintellix *4									
Total         3.2         8.4         0.5         6.4         5.8         -         -           Ninlaro         United States         -         4.0         -         6.0         6.0         -         -           Emerging Markets         -         0.0         -         0.0         0.0         -         -								27.6%	38.2%	
Ninlaro         United States         -         4.0         -         6.0         6.0         -         -           Emerging Markets         -         0.0         -         0.0         -         -         -	Takecab	Japan		8.4	0.5	6.4	5.8	-	-	
Emerging Markets - 0.0 - 0.0 0.0			3.2	8.4	0.5	6.4	5.8		-	
	Ninlaro	United States	-		-	6.0	6.0	-	-	
			-	0.0	-	0.0	0.0	-	-	
	=		-	4.1	-	6.0	6.0	-	-	

<sup>\*1</sup> Sales amount includes royalty income and service income.

± <10% +10%~20 +20%~30% +>30% -10%~20% -20%~30% ->30%

<sup>\*2</sup> Products excluding fixed dose combinations were transferred to the Joint Venture with Teva in Japan in April, 2016.

<sup>\*3</sup> FY16 Forecasts: Arrows show growth from FY15 results (reported basis).

<sup>\*4</sup> Trintellix is the brand name used since June 2016 for the product previously marketed as Brintellix. The formulations, indication and dosages of Trintellix remain the same as that of Brintellix.

## ◆ Prescription Drugs: US major products' sales (in US\$) \*1

(Millions of US\$)

				(101	(ΨΟΟ 10 ΘΟΨ)		
	FY14 Annual	FY15 Annual	FY15 Q1	FY16 Q1	vs. PrY	Increase/ decrease	
Velcade	1,017	1,079	276	247	-29	-10.6%	
Entyvio	179	524	99	201	102	103.4%	
Dexilant	488	530	135	117	-18	-13.3%	
Colcrys	542	386	92	94	2	2.1%	
Uloric	297	347	81	85	5	5.6%	
Amitiza	291	308	77	79	2	2.5%	
Trintellix*2	124	203	42	58	16	38.2%	
Prevacid (lansoprazole)	254	222	73	57	-15	-20.9%	
Ninlaro	-	34	-	54	54	-	
Contrave*3	19	56	16	13	-3	-21.6%	

<sup>\*1</sup> Product sales (royalty income and service income are excluded).

<sup>\*2</sup> Trintellix is the brand name used since June 2016 for the product previously marketed as Brintellix.

The formulations, indication and dosages of Trintellix remain the same as that of Brintellix.

<sup>\*3</sup> In March 2016, Takeda and Orexigen announced they have agreed to terminate the collaboration.

#### ◆ Prescription Drugs: Japan major products' sales

(Billions JPY) FY15 FY16 FY14 FY15 Therapeutic Increase/ Launched vs PrY Class decrease Q1 Q1 Annual Annual Azilva \* (12.5)45.4 59.0 14.1 17.7 3.6 25.6% Hypertension Prostate cancer, Leuplin (92.9)57.6 53.8 13.3 13.1 -0.3 -2.0% breast cancer and (leuprorelin) endometriosis Rheumatoid Enbrel 41.2 40.8 10.4 11.0 5.9% (05.3)0.6 arthritis Nesina \* (10.6)Diabetes 38.4 36.9 9.5 9.3 -0.2 -1.6% Lotriga (13. 1)Hyperlipidemia 13.2 22.3 5.0 6.8 1.8 36.8% Acid-related Takecab \* 6.4 (15.2)3.2 8.4 0.5 5.8 Diseases Vectibix 4.7 4.9 (10.6)Colorectal cancer 18.3 18.4 0.2 5.1% Alzheimer-type Reminyl (11.3) 13.9 16.0 3.9 4.6 8.0 19.3% dementia **Benet** (02.5)Osteoporosis 10.4 9.7 2.5 2.3 -0.2 -6.4% (10.7)Rozerem Insomnia 6.6 7.4 1.8 2.1 0.3 17.8% Malignant 8.0 0.9 9.1% Adcetris (14.4)2.8 0.1 3.1 Lymphoma

<sup>\*</sup> The figures include the amounts of fixed dose combinations and blister packs.

# ♦ Consumer Healthcare: Major products' sales

(Billions JPY)

	FY14	FY15		FY15	FY16	vs PrY	Increase/	
	Annual	Annual		Q1	Q1	V5 F11	decrease	
Alinamin tablet	20.7	25.2	-	6.9	6.1	-0.8	-11.8%	
Alinamin drink	14.9	14.9	-	4.0	5.1	1.1	27.3%	
Biofermin	8.1	8.6	-	2.2	2.2	-0.0	-0.2%	
Benza	9.7	9.8		1.2	1.3	0.1	8.3%	
Borraginol	4.1	4.5		1.1	1.1	0.0	3.0%	

## 2. Exchange Rate

Average Exchange Rate (JPY)

	FY14	FY15	FY15	FY16	FY16
	April-March	April-March	April-June	April-June	Assumptions
USD	109	121	121	112	110
EUR	139	132	132	126	125
RUB	2.6	1.9	2.2	1.7	1.6
CNY	17.6	19.0	19.5	17.1	17.4
BRL	45.3	34.1	39.1	31.3	31.2

## II. Pipeline

#### 1. 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 and in additional formulations. The listings in this table are limited to the US, EU and Japan, but we are also actively conducting development activities in other regions, including in Emerging Markets.

#### Oncology

Development code <generic name=""> BRAND NAME</generic>	Drug Class (administration route)	Indications / additional formulations	Stage	1
		D-1	EU	Filed (Jul '15)
		Relapsed or refractory multiple myeloma	Jpn	Filed (Jul '16)
			US	P-III
		Previously untreated multiple myeloma	EU	P-III
			Jpn	P-III
MI NO700		Maintenance therapy in patients with newly diagnosed	US	P-III
MLN9708 <ixazomib></ixazomib>	Proteasome inhibitor (oral)	multiple myeloma following autologous stem cell	EU	P-III
NINLARO® (US)	Froteasome inhibitor (oral)	transplant	Jpn	P-III
THILD III (OO)		Maintenance therapy in patients with newly diagnosed	US EU	P-III P-III
		multiple myeloma not treated with stem cell transplant	Jpn	P-III
			US	P-III
		Relapsed or refractory primary (AL) amyloidosis	EU	P-III
		Solid tumors	US	P-I
		Post-autologous stem cell transplant Hodgkin lymphoma	EU	Approved (Jul '16)
SGN-35 <bre>strentuximab</bre>	CD30 monoclonal antibody-drug	Relapsed cutaneous T-cell lymphoma	EU	P-III
vedotin>	conjugate (injection)	Front line Hodgkin lymphoma	EU	P-III
ADCETRIS® (EU, Jpn)			Jpn	P-III
		Front line mature T-cell lymphoma	EU	P-III
MLN8237			Jpn US	P-III
<alisertib></alisertib>	Aurora A kinase inhibitor (oral)	Small cell lung cancer	EU	P-II(b) P-II(b)
\alisertib>	mTORC1/2 inhibitor (oral)		US	P-II(b)
		Breast cancer	EU	P-II(b)
TAK-228 <->		Renal cancer	US	P-II(b)
		Endometrial cancer	US	P-II(b)
TAK-385 <relugolix></relugolix>	LH-RH antagonist (oral)	Prostate cancer	Jpn	P-I
TAK-924	NEDD 8 activating enzyme inhibitor	High risk myelodysplastic syndromes	US EU	P-II(a) P-II(a)
<pevonedistat></pevonedistat>	(injection)	Solid tumors	-	P-I
TAK-117	Pl3Kα isoform inhibitor (oral)	Non-small cell lung cancer	US EU	P-I/II P-I/II
<->	i iota isolomi imilibilor (olai)	Gastric cancer	-	P-I
TAK-202 <plozalizumab></plozalizumab>	CCR2 antagonist (injection)	Solid tumors	<u>-</u>	P-I
TAK-243 <->	UAE inhibitor (injection)	Solid tumors	-	P-I
TAK-580 <->	pan-Raf kinase inhibitor (oral)	Solid tumors	-	P-I
TAK-659	SYK kinase inhibitor (oral)	Solid tumors, Hematologic malignancies	-	P-I
TAK-931	CDC7 inhibitor (oral)	Solid tumors	-	P-I

## ■ Gastroenterology

Development code <generic name=""> BRAND NAME</generic>	Drug Class (administration route)	Indications / additional formulations	Stage	
TAK-390MR <dexlansoprazole> DEXILANT® (US, EU)</dexlansoprazole>	Proton pump inhibitor (oral)	Acid-related diseases in adolescents	US EU	Approved (Jul '16) Approved (May '16)
Cx601 <->	A suspension of allogeneic expanded adipose-derived stem cells (injection)	Complex perianal fistulas in patients with Crohn's disease	EU	Filed (Mar '16)
		Ulcerative colitis	Jpn	P-III
MLN0002 <vedolizumab> ENTYVIO<sup>®</sup> (US, EU)</vedolizumab>	Humanized monoclonal antibody against α4β7 integrin (injection)	Crohn's disease	Jpn	P-III
		Subcutaneous fomulation (for Ulcerative colitis, Crohn's disease)	US EU Jpn	P-III P-III P-III
		Graft-versus-host disease (GvHD) prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	US	P-I
<lubiprostone></lubiprostone>		New formulation	US	P-III
AMITIZA® (US)	Chloride channel activator (oral)	Pediatric functional constipation	US	P-III
TAK-438 <vonoprazan> TAKECAB® (Jpn)</vonoprazan>	Potassium-competitive acid blocker (oral)	Gastro-esophageal reflux disease in patients who have a partial response following treatment with a proton pump inhibitor	-	P-II(b)
TD-8954 <->	5-HT4 receptor agonist (injection)	Enteral feeding intolerance	-	P-I/II
TAK-828 <->	RORyt inverse agonist (oral)	Crohn's disease	-	P-I
ATC-1906* <sup>1</sup>	Dopamine D2/D3 receptor antagonist (oral)	Gastroparesis	-	P-I

<sup>\*1</sup> Agreement with Altos Therapeutics LLC for an exclusive option for Takeda to acquire Althos beginning on the date of the agreement and continuing for a period of time following the completion of ongoing Phase 1 studies. Altos will be responsible for successfully completing Phase 1 clinical trials

#### ■ CNS

Development code <generic name=""> BRAND NAME</generic>	Drug Class (administration route)	Indications / additional formulations	Stage	
Lu AA21004		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	FDA Complete Response Letter (Mar '16)
<pre><vortioxetine> TRINTELLIX® (US)</vortioxetine></pre>	Multimodal anti-depressant (oral)	Major depressive disorder	Jpn	P-III
THINTELLIA (OO)		Attention Deficit Hyperactivity Disorder (ADHD) in adult patients	US	P-II(a)
AD-4833/TOMM40	Mitochondrial growth modulator (oral) / Biomarker assay	Delay of onset of mild cognitive impairment due to Alzheimer's disease	US EU	P-III P-III
TVP-1012* <sup>2</sup> <rasagiline></rasagiline>	Monoamine oxidase B (MAO-B) inhibitor (oral)	Parkinson's disease	Jpn	P-III
TAK-063 <->	PDE10A inhibitor (oral)	Schizophrenia	US	P-II(a)
TAK-041 <->	GPR139 agonist (oral)	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
TAK-058 <->	5-HT3 receptor antagonist (oral)	Cognitive impairment associated with schizophrenia	-	P-I
TAK-071 <->	M1 positive allosteric modulator (M1PAM) (oral)	Alzheimer's disease, Lewy body dementia	-	P-I
TAK-653 <->	AMPA receptor potentiator (oral)	Psychiatric disorders, Neurological diseases	-	P-I
TAK-831 <->	D-amino acid oxidase (DAAO) inhibitor (oral)	Cerebellar ataxia, Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
TAK-915 <->	PDE2A inhibitor (oral)	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
TAK-935 <->	CH24H inhibitor (oral)	Epilepsy	=	P-I

<sup>\*2</sup> Brand name in Teva territories: AZILECT®

#### ■ Vaccines

<b>Development code</b> BRAND NAME	Type of vaccine (administration route)	Indications / additional formulations		
TAK-003	Tetravalent dengue vaccine (injection)	Prevention of dengue fever caused by dengue virus	-	P-II(b)
TAK-214	Norovirus vaccine (injection)	Prevention of acute gastroenteritis (AGE) caused by norovirus	-	P-II(b)
TAK-850	Seasonal influenza vaccine (injection)	Prevention of influenza disease caused by influenza virus subtype A and B contained in the vaccine	Jpn	P-II(a)
TAK-021	EV71 vaccine (injection)	Prevention of hand, foot and mouth disease caused by enterovirus 71	-	P-I

#### ■ Others

Development code <generic name=""> BRAND NAME</generic>	Drug Class (administration route)	Indications / additional formulations	Stage	•
SYR-322 <alogliptin> NESINA® (US, Jpn) VIPIDIA® (EU)</alogliptin>	DPP-4 inhibitor (oral)	Fixed-dose combination with metformin (for Type 2 diabetes)	Jpn	Filed (Sep '15)
TAK-536 <azilsartan> AZILVA<sup>®</sup> (Jpn)</azilsartan>	Angiotensin II receptor blocker (oral)	Fixed-dose combination with amlodipine and hydrochlorothiazide (for Hypertension)	Jpn	Filed (Jun '16)
TAK-385	LH-RH antagonist (oral)	Uterine fibroids	Jpn	P-III
<relugolix></relugolix>		Endometriosis	Jpn	P-II(b)
MT203	GM-CSF monoclonal antibody (injection)	Psoriasis	EU	P-II(b)
<namilumab></namilumab>		Rheumatoid arthritis	EU Jpn	P-II(b) P-II(a)
TAK-272 <->	Direct renin inhibitor (oral)	Early stage diabetic nephropathy	Jpn	P-II(b)
TAK-020 <->	Bruton's tyrosine kinase inhibitor (oral)	Rheumatoid arthritis	-	P-I
TAK-079 <->	Cytolytic monoclonal antibody (injection)	Rheumatoid arthritis, Systemic lupus erythematosus	-	P-I

#### ■ Recent progress in stage [Progress in stage disclosed since release of FY2015 results (May 10th, 2016)]

Development code <generic name=""></generic>	Indications / additional formulations	Country/Region	Progress in stage
TAK-390MR <dexlansoprazole></dexlansoprazole>	Acid-related diseases in adolescents	EU	Approved (May '16)
TAK-390MR <dexlansoprazole></dexlansoprazole>	Acid-related diseases in adolescents	US	Approved (Jul '16)
SGN-35   vedotin>	Post-autologous stem cell transplant Hodgkin lymphoma	EU	Approved (Jul '16)
TAK-536 <azilsartan></azilsartan>	Fixed-dose combination with amlodipine and hydrochlorothiazide (for Hypertension)	Jpn	Filed (Jun '16)
MLN9708 <ixazomib></ixazomib>	Relapsed or refractory multiple myeloma	Jpn	Filed (Jul '16)
TAK-438 <vonoprazan></vonoprazan>	Gastro-esophageal reflux disease in patients who have a partial response following treatment with a proton pump inhibitor	-	P-II(b)
MLN0002 <vedolizumab></vedolizumab>	Graft-versus-host disease (GvHD) prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	US	P-I
TAK-041 <->	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
TAK-071 <->	Alzheimer's disease, Lewy body dementia	-	P-I
TAK-202 <plozalizumab></plozalizumab>	Solid tumors	-	P-I

#### Discontinued projects [Discontinuation disclosed since release of FY2015 results (May 10th, 2016)]

Development code <generic name=""></generic>	Indications (Stage)	Reason
<febuxostat xr=""></febuxostat>	Extended release formulation (for Hyperuricemia) (US P-III)	Discontinued based on P-III results
NE-58095NF	Additional formulation; change of the dosage and	Development terminated for strategic reasons based upon the outcome of
<risedronate></risedronate>	administration (for Osteoporosis) (Jpn P-II/III)	the clinical study

#### ■ Revised collaboration agreement [Revision disclosed since release of FY2015 results (May 10th, 2016)]

Development code <pre><generic name=""></generic></pre>	Indications (Stage)	Reason
AMG 386 <trebananib></trebananib>	Ovarian cancer (Jpn P-III)	P-III results of AMG 386 did not meet the pre-defined criteria. The rights for this molecule have been returned to Amgen.
TAK-385 <relugolix></relugolix>	Prostate cancer (US, EU P-II(b))	In June 2016, Takeda granted Myovant an exclusive, worldwide license to relugolix, excluding Japan and certain other Asian countries
AMG 403 <fulranumab></fulranumab>	Pain (Jpn P-I)	The rights for AMG 403 have been returned to Amgen due to a revision of development strategy.

#### ■ 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

Oncology

Partner	Country	Research subject	Schedule
Seattle Genetics	US	Antibody-Drug Conjugate technology	Mar '09 -
Mersana Therapeutics	US	Antibody-Drug Conjugate technology	Apr '14 -
ImmunoGen, Inc.	US	Antibody-Drug Conjugate technology	Mar '15 -
National Cancer Center of Japan	Japan	A partnership to develop basic research to clinical development by promoting exchanges among researchers, physicians, and others engaged in anti-cancer drug discovery and cancer biology research	Apr '15 - Apr '18
M2Gen	US	Genomic data from cancer patients	Jun '16 -

Gastroenterology

Partner	Country	Research subject	Schedule
Cour Pharmaceutical Development Company	US	Immune modulating therapies for the potential treatment of celiac disease and other gastrointestinal diseases, utilizing Cour's Tolerizing Immune Modifying nanoParticle (TIMP) platform	Dec '15 -
Enterome	France	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).	Jan '16 -
enGene	Canada	Novel therapies for specialty gastrointestinal (GI) diseases using enGene's "Gene Pill" gene delivery platform	Jan '16 -

## CNS

Partner	Country	Research subject	Schedule
Zinfandel Pharmaceuticals	US	Alzheimer's Disease Biomarker TOMM40	Dec '10 -
Kyoto University	Japan	Treatments for obesity and schizophrenia based on CNS control	Jan '11 - Mar '16
NsGene	US	Encapsulated cell therapies for the potential treatment of Parkinson's disease	Jan '16 -

Other / Multiple Therapeutic Area

Partner	Country	Research subject	Schedule
Tri-Institutional Therapeutics Discovery Institute	US	Collaboration of academic institutions and industry to more effectively develop innovative treatments and therapies	Oct '13 - Jun '17
Trianni, Inc.	US	Trianni's transgenic mouse platform to identify fully human monoclonal antibodies against disease targets in all therapeutic areas	Mar '14 -
MacroGenics	US	Product candidates that will be directed against jointly selected pairs of molecular targets and using MacroGenics' Dual-Affinity Re-Targeting (DART®) proprietary platform.	Sep '14 -
Keio University, Niigata University	Japan	The search for and functional analysis of disease-related RNA-binding proteins, that may lead to treatments in the areas such as CNS and oncology.	Mar '15 - Mar '18
Center for iPS Cell Research Application (CiRA), Kyoto University	Japan	Clinical applications of iPS cells in areas such as heart failure, diabetes mellitus, neuro-psychiatric disorders and cancer	Apr '15 - Mar '25
Gencia LLC	US	Mitochondrial Associated Glucocorticoid Receptors (MAGR) agonists for potential use primarily in hematological and inflammatory diseases	Aug '15 -
Astellas, Daiichi Sankyo	Japan	Fundamental biomarker data on healthy adult volunteers in order to optimize and accelerate the development of innovative medicines	May '16 -
Ultragenyx	US	Rare genetic diseases	Jun '16 - May '21

