



*Better Health, Brighter Future*

# 1<sup>st</sup> Quarter Results for FY2017 DATA BOOK

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Quarterly Announcements / Presentations

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# I. Financial Results

## 1. Segment Information

								(Billion JPY)
	FY14	FY15	FY16	FY16 Q1	FY17 Q1	YOY		FY17 Forecasts
Revenue	1,777.8	1,807.4	1,732.1	434.0	448.2	14.2	3.3%	1,680.0
Prescription drugs	1,614.5	1,648.7	1,568.9	394.0	427.2	33.2	8.4%	
Consumer healthcare	73.6	80.1	82.6	20.4	20.9	0.5	2.3%	
Other	89.7	78.6	80.6	19.6	0.1	-19.4	-99.3%	
Operating Profit	-129.3	130.8	155.9	152.9	195.0	42.0	27.5%	180.0
Prescription drugs	-178.9	102.8	128.4	142.2	66.8	-75.4	-53.0%	
<% of Prescription drugs revenue>	<-11.1%>	<6.2%>	<8.2%>	<36.1%>	<15.6%>	<20.4pt>		
Consumer healthcare	17.2	18.9	20.5	7.4	6.6	-0.8	-10.4%	
<% of Consumer healthcare revenue>	<23.4%>	<23.6%>	<24.9%>	<36.2%>	<31.7%>	<-4.5pt>		
Other	32.4	9.1	6.9	3.3	121.5	118.2	-	
<% of Other revenue>	<36.2%>	<11.5%>	<8.6%>	<17.1%>	-	-		

◆Segment Information (Quarterly)

(Billion JPY)

	FY16				FY17							
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
Revenue	434.0	416.8	465.0	416.2	448.2	3.3%						
Prescription drugs	394.0	375.6	421.0	378.1	427.2	8.4%						
Consumer healthcare	20.4	22.0	23.1	17.1	20.9	2.3%						
Others	19.6	19.2	20.9	20.9	0.1	-99.3%						
Operating Profit	152.9	9.1	55.4	-61.6	195.0	27.5%						
Prescription drugs	142.2	4.1	46.3	-64.2	66.8	-53.0%						
<% of Prescription drugs revenue>	<36.1%>	<1.1%>	<11.0%>	<-17.0%>	<15.6%>							
Consumer healthcare	7.4	4.7	6.9	1.6	6.6	-10.4%						
<% of Consumer healthcare revenue>	<36.2%>	<21.4%>	<29.8%>	<9.1%>	<31.7%>							
Others	3.3	0.4	2.1	1.1	121.5	-						
<% of Others revenue>	<17.1%>	<2.0%>	<10.2%>	<5.2%>	-							

## 2. Revenue by Region

### ◆ Consolidated Revenue (Prescription drugs + Consumer healthcare + Other)

(Billion JPY)

	FY14	FY15	FY16	FY16	FY17	YOY	
				Q1 YTD	Q1 YTD		
Total revenue	1,777.8	1,807.4	1,732.1	434.0	448.2	14.2	3.3%
Japan	712.8	688.1	655.3	163.8	160.3	-3.5	-2.1%
<% of revenue>	<40.1%>	<38.1%>	<37.8%>	<37.7%>	<35.8%>	<-2.0pt>	
United States	426.1	514.4	520.2	130.5	148.6	18.1	13.9%
<% of revenue>	<24.0%>	<28.5%>	<30.0%>	<30.1%>	<33.1%>	<3.1pt>	
Europe and Canada	325.3	309.3	279.7	76.5	73.6	-2.9	-3.8%
<% of revenue>	<18.3%>	<17.1%>	<16.1%>	<17.6%>	<16.4%>	<-1.2pt>	
Emerging Markets	313.6	295.6	276.9	63.3	65.8	2.5	4.0%
<% of revenue>	<17.6%>	<16.4%>	<16.0%>	<14.6%>	<14.7%>	<0.1pt>	
Russia/CIS	81.3	61.8	57.5	12.8	17.0	4.2	33.1%
<% of revenue>	<4.6%>	<3.4%>	<3.3%>	<3.0%>	<3.8%>	<0.9pt>	
Latin America	85.4	68.4	72.5	15.0	17.0	2.0	13.3%
<% of revenue>	<4.8%>	<3.8%>	<4.2%>	<3.4%>	<3.8%>	<0.3pt>	
Asia	111.4	126.0	112.8	27.5	25.2	-2.4	-8.6%
<% of revenue>	<6.3%>	<7.0%>	<6.5%>	<6.3%>	<5.6%>	<-0.7pt>	
Other	35.5	39.4	34.0	8.0	6.6	-1.4	-17.0%
<% of revenue>	<2.0%>	<2.2%>	<2.0%>	<1.8%>	<1.5%>	<-0.4pt>	
Royalty income and service income	87.5	56.5	60.1	12.4	30.3	17.9	144.1%

\*1 Revenue amount is classified into countries or regions based on the customer location.

\*2 Other region includes Middle East, Oceania and Africa.

### ◆ Consolidated Prescription Drugs Revenue

(Billion JPY)

	FY14	FY15	FY16	FY16	FY17	YOY		Underlying Growth
				Q1	Q1			
Total prescription drugs revenue	1,614.5	1,648.7	1,568.9	394.0	427.2	33.2	8.4%	6.9%
Japan	561.3	541.7	504.7	126.7	139.3	12.6	10.0%	1.6%
United States	419.5	511.0	516.7	129.7	148.6	18.9	14.6%	13.5%
Europe and Canada	326.7	305.6	276.0	75.5	73.6	-2.0	-2.6%	4.6%
Emerging Markets	307.0	290.4	271.5	62.1	65.8	3.6	5.9%	6.0%
Russia/CIS	81.2	61.8	57.5	12.8	17.0	4.2	33.1%	19.8%
Russia	57.6	43.5	41.9	9.1	12.5	3.4	37.6%	18.8%
Latin America	85.0	68.2	72.5	15.0	17.0	2.0	13.4%	12.7%
Brazil	47.6	38.1	39.0	8.1	10.0	1.9	23.5%	12.3%
Asia	106.6	121.2	107.8	26.4	25.2	-1.3	-4.8%	-1.6%
China	55.2	66.0	57.6	13.9	12.3	-1.6	-11.2%	-4.7%
Other	34.3	39.2	33.7	8.0	6.6	-1.3	-16.7%	-7.5%
Royalty income and service income	86.9	55.8	59.5	12.2	30.2	17.9	146.5%	-4.4%
Japan	8.1	6.6	18.7	2.8	18.1	15.3	-	10.3%
Overseas	78.8	49.3	40.9	9.4	12.1	2.6	28.1%	-8.7%
Ratio of overseas prescription drugs	65.2%	67.1%	67.8%	67.9%	67.4%	<-0.5pt>		

\*1 Revenue amount is classified into countries or regions based on the customer location.

\*2 Other region includes Middle East, Oceania and Africa.

◆ Consolidated Revenue (Quarterly: Prescription drugs + Consumer healthcare + Other)

(Billion JPY)

	FY16				FY17								
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY	
Total revenue	434.0	416.8	465.0	416.2	448.2	3.3%							
Japan	163.8	163.3	187.3	141.0	160.3	-2.1%							
<% of revenue>	<37.7%>	<39.2%>	<40.3%>	<33.9%>	<35.8%>								
United States	130.5	121.4	130.4	137.8	148.6	13.9%							
<% of revenue>	<30.1%>	<29.1%>	<28.1%>	<33.1%>	<33.1%>								
Europe and Canada	76.5	66.3	69.9	67.1	73.6	-3.8%							
<% of revenue>	<17.6%>	<15.9%>	<15.0%>	<16.1%>	<16.4%>								
Emerging Markets	63.3	65.7	77.5	70.4	65.8	4.0%							
<% of revenue>	<14.6%>	<15.8%>	<16.7%>	<16.9%>	<14.7%>								
Russia/CIS	12.8	12.7	16.1	16.0	17.0	33.1%							
<% of revenue>	<3.0%>	<3.0%>	<3.5%>	<3.8%>	<3.8%>								
Latin America	15.0	16.7	23.4	17.5	17.0	13.3%							
<% of revenue>	<3.4%>	<4.0%>	<5.0%>	<4.2%>	<3.8%>								
Asia	27.5	28.0	30.7	26.7	25.2	-8.6%							
<% of revenue>	<6.3%>	<6.7%>	<6.6%>	<6.4%>	<5.6%>								
Other	8.0	8.4	7.4	10.3	6.6	-17.0%							
<% of revenue>	<1.8%>	<2.0%>	<1.6%>	<2.5%>	<1.5%>								
Royalty income and service income	12.4	16.7	19.8	11.2	30.3	144.1%							

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

◆ Consolidated Prescription Drugs Revenue (Quarterly)

(Billion JPY)

	FY16				FY17								
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY	
Total prescription drugs revenue	394.0	375.6	421.0	378.1	427.2	8.4%							
Japan	126.7	125.1	146.5	106.4	139.3	10.0%							
United States	129.7	120.6	129.7	136.7	148.6	14.6%							
Europe and Canada	75.5	65.5	68.9	66.1	73.6	-2.6%							
Emerging Markets	62.1	64.5	75.9	68.9	65.8	5.9%							
Russia/CIS	12.8	12.7	16.1	16.0	17.0	33.1%							
Russia	9.1	9.5	12.0	11.3	12.5	37.6%							
Latin America	15.0	16.7	23.4	17.5	17.0	13.4%							
Brazil	8.1	9.9	10.4	10.6	10.0	23.5%							
Asia	26.4	26.8	29.1	25.5	25.2	-4.8%							
China	13.9	14.7	16.1	12.9	12.3	-11.2%							
Other	8.0	8.4	7.3	10.0	6.6	-16.7%							
Royalty income and service income	12.2	16.6	19.6	11.1	30.2	146.5%							
Japan	2.8	9.5	4.2	2.2	18.1	-							
Overseas	9.4	7.1	15.4	8.9	12.1	28.1%							
Ratio of overseas prescription drugs revenue	67.9%	66.7%	65.2%	71.9%	67.4%								

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

◆ Prescription Drugs: Global major products' sales \*1

(Billion JPY)

		FY14	FY15	FY16	FY17	FY16	FY17	YOY		Underlying
		Forecasts*3				Q1	Q1			Growth
Entyvio	U.S.	20.1	63.1	99.6		22.5	31.0	8.5	37.9%	38.2%
	EUCAN	7.7	21.9	39.5		8.8	13.5	4.7	53.1%	60.8%
	EM	0.0	1.3	4.0		0.8	1.4	0.7	90.1%	85.5%
	Total	27.8	86.2	143.2	↗↗↗	32.0	45.9	13.9	43.3%	45.4%
Ninlaro	Japan	-	-	-		-	0.2	0.2	-	-
	U.S.	-	4.0	29.1		6.0	9.0	3.1	51.0%	51.3%
	EUCAN	-	-	0.2		-	0.6	0.6	-	-
	EM	-	0.0	0.1		0.0	0.1	0.1	-	-
	Total	-	4.1	29.4	↗↗↗	6.0	10.0	4.0	67.1%	67.6%
Velcade	U.S.	110.8	131.6	112.9		28.9	30.7	1.9	6.4%	6.7%
	Other than U.S.	41.9	30.4	24.7		6.7	5.5	-1.2	-17.7%	-17.5%
	Total	152.7	162.0	137.6	↘↘↘	35.5	36.2	0.7	1.9%	2.2%
Adcetris	Japan	2.8	3.1	3.3		0.9	1.0	0.2	19.1%	19.1%
	Europe	16.3	17.4	17.5		5.0	4.7	-0.3	-6.7%	-1.8%
	EM	3.6	7.2	9.3		1.9	3.6	1.7	91.3%	85.2%
	Total	22.9	27.6	30.1	→	7.8	9.3	1.5	19.0%	22.0%
Takecab	Japan	3.2	8.4	34.1		6.4	12.5	6.1	95.7%	95.7%
	Total	3.2	8.4	34.1	↗↗↗	6.4	12.5	6.1	95.7%	95.7%
Trintellix	U.S.	13.6	24.5	31.9		6.4	11.2	4.8	74.1%	74.8%
	Total	13.6	24.5	31.9	↗↗↗	6.4	11.2	4.8	74.1%	74.8%
Leuprorelin	Japan	57.6	53.8	48.6		13.1	12.4	-0.7	-5.3%	-5.3%
	U.S.	15.9	17.3	18.3		5.7	5.2	-0.4	-7.6%	-14.3%
	EUCAN	36.4	35.3	31.1		8.3	8.1	-0.2	-2.7%	-5.0%
	EM	14.2	18.0	16.3		3.8	3.0	-0.7	-19.0%	12.0%
	Total	124.0	124.4	114.2	→	30.8	28.7	-2.1	-6.7%	-5.4%
Dexilant	U.S.	53.5	64.0	49.7		13.0	12.8	-0.2	-1.8%	-1.5%
	EUCAN	4.9	5.4	5.7		1.5	1.4	-0.1	-3.7%	0.5%
	EM	3.9	5.7	7.3		1.6	2.1	0.5	27.9%	29.4%
	Total	62.3	75.1	62.6	→	16.2	16.3	0.2	1.0%	1.8%
Azilva	Japan	45.4	59.0	66.9		17.7	18.7	1.0	5.6%	5.6%
	Total	45.4	59.0	66.9	→	17.7	18.7	1.0	5.6%	5.6%
Nesina	Japan	38.4	36.9	32.9		9.3	8.0	-1.3	-13.8%	-13.8%
	U.S.	4.1	5.3	5.2		1.5	1.2	-0.3	-16.8%	-16.4%
	EUCAN	0.6	3.5	6.1		1.5	2.0	0.5	32.9%	40.8%
	EM	1.3	3.3	4.9		1.0	1.4	0.4	42.1%	39.6%
	Total	44.3	48.9	49.1	→	13.3	12.7	-0.6	-4.7%	-4.2%
Uloric	U.S.	32.6	41.8	41.4		9.5	11.2	1.7	17.3%	17.7%
	EUCAN	0.6	0.7	0.7		0.2	0.2	0.0	4.6%	10.0%
	EM	-	-	0.1		0.0	0.1	0.0	-	-
	Total	33.2	42.5	42.2	→	9.7	11.4	1.7	17.5%	17.9%
Colcrys	U.S.	58.8	46.5	38.9		10.5	9.6	-0.9	-8.3%	-8.1%
	Total	58.8	46.5	38.9	↘	10.5	9.6	-0.9	-8.3%	-8.1%
Amitiza	U.S.	31.9	37.2	33.7		8.9	8.6	-0.3	-3.0%	-2.7%
	EUCAN	0.0	0.1	0.1		0.0	0.0	0.0	0.3%	8.5%
	Total	32.0	37.3	33.8	→	8.9	8.6	-0.3	-3.0%	-2.7%
Pantoprazole	U.S.	11.0	13.6	10.1		3.4	1.9	-1.5	-45.5%	-45.3%
	EUCAN	49.3	43.4	30.5		8.6	7.9	-0.8	-9.0%	-6.0%
	EM	43.4	43.7	33.7		8.0	7.0	-1.0	-12.2%	-10.8%
	Total	103.7	100.8	74.2	→	20.1	16.7	-3.3	-16.5%	-14.7%
Lansoprazole	Japan *2	52.5	41.3	8.1		2.1	1.6	-0.6	-26.1%	-20.7%
	U.S.	28.7	27.5	20.0		6.6	3.8	-2.8	-42.9%	-42.8%
	EUCAN	11.7	10.5	7.1		2.3	1.9	-0.3	-13.9%	-11.3%
	EM	10.1	10.2	9.2		2.4	2.5	0.1	2.3%	1.6%
	Total	102.9	89.5	44.4	↘↘↘	13.4	9.7	-3.6	-27.2%	-26.6%
Candesartan	Japan *2	94.6	58.5	14.8		4.8	1.8	-3.0	-62.3%	-
	U.S.	2.1	1.3	0.6		0.2	0.2	-0.0	-3.1%	-3.0%
	EUCAN	17.7	12.5	9.3		3.0	2.6	-0.4	-14.0%	-11.8%
	EM	11.4	12.4	9.5		3.2	2.6	-0.5	-16.9%	-16.3%
	Total	125.7	84.8	34.2	↘↘↘	11.3	7.3	-4.0	-35.4%	-10.6%

U.S.: United States, EUCAN: Europe and Canada, EM: Emerging Markets

\*1 Sales amount includes royalty income and service income.

\*2 Products were transferred to the Joint Venture with Teva in Japan (monotherapy in April 2016 and fixed dose combinations in May 2017). Supply sales of these products to the JV is currently recognized.

\*3 FY17 Forecasts: Arrows show growth from FY16 results (reported basis).

→ ± <10% ↗ +10%~20% ↗↗ +20%~30% ↗↗↗ +>30% ↘ -10%~20% ↘↘ -20%~30% ↘↘↘ ->30%

◆ Prescription Drugs: Global major products' sales \*1 (Quarterly)

(Billion JPY)

		FY16			
		Q1	Q2	Q3	Q4
Entyvio	U.S.	22.5	23.2	25.7	28.3
	EUCAN	8.8	9.3	10.7	10.7
	EM	0.8	0.9	1.0	1.5
	Total	32.0	33.3	37.4	40.4
Ninlaro	Japan	-	-	-	-
	U.S.	6.0	6.8	8.0	8.3
	EUCAN	-	-	0.0	0.2
	EM	0.0	0.0	0.0	0.0
Total	6.0	6.8	8.0	8.6	
Velcade	U.S.	28.9	26.7	27.4	29.9
	Other than U.S.	6.7	7.1	6.8	4.0
	Total	35.5	33.8	34.2	34.0
Adcetris	Japan	0.9	0.7	0.9	0.8
	Europe	5.0	3.8	4.2	4.4
	EM	1.9	2.1	2.3	3.0
	Total	7.8	6.6	7.4	8.3
Takecab	Japan	6.4	7.5	10.8	9.5
	Total	6.4	7.5	10.8	9.5
Trintellix	U.S.	6.4	7.8	8.5	9.1
	Total	6.4	7.8	8.5	9.1
Leuprorelin	Japan	13.1	11.7	13.6	10.2
	U.S.	5.7	3.8	4.9	3.9
	EUCAN	8.3	7.8	7.0	8.0
	EM	3.8	4.2	4.4	3.9
	Total	30.8	27.5	29.9	26.1
Dexilant	U.S.	13.0	12.4	12.3	12.0
	EUCAN	1.5	1.3	1.5	1.4
	EM	1.6	1.6	1.8	2.3
	Total	16.2	15.3	15.6	15.6
Azilva	Japan	17.7	15.6	18.5	15.0
	Total	17.7	15.6	18.5	15.0
Nesina	Japan	9.3	7.7	9.2	6.6
	U.S.	1.5	1.2	1.1	1.4
	EUCAN	1.5	1.4	1.5	1.7
	EM	1.0	1.3	1.1	1.5
	Total	13.3	11.6	13.0	11.2
Uloric	U.S.	9.5	9.6	11.3	11.0
	EUCAN	0.2	0.2	0.2	0.2
	EM	0.0	0.0	0.0	0.0
	Total	9.7	9.8	11.6	11.2
Colcrys	U.S.	10.5	9.7	9.3	9.4
	Total	10.5	9.7	9.3	9.4
Amitiza	U.S.	8.9	8.0	9.3	7.6
	EUCAN	0.0	0.0	0.0	0.0
	Total	8.9	8.0	9.3	7.6
Pantoprazole	U.S.	3.4	2.0	2.3	2.4
	EUCAN	8.6	7.2	7.8	6.8
	EM	8.0	9.1	8.2	8.3
	Total	20.1	18.3	18.4	17.5
Lansoprazole	Japan *2	2.1	2.0	2.1	1.8
	U.S.	6.6	4.2	4.8	4.4
	EUCAN	2.3	1.5	1.7	1.6
	EM	2.4	2.2	2.4	2.2
	Total	13.4	10.0	11.0	10.1
Candesartan	Japan *2	4.8	3.7	3.6	2.6
	U.S.	0.2	0.1	0.2	0.1
	EUCAN	3.0	1.8	2.6	1.9
	EM	3.2	1.9	2.4	2.0
	Total	11.3	7.5	8.8	6.6

U.S.: United States, EUCAN: Europe and Canada, EM: Emerging Markets

\*1 Sales amount includes royalty income and service income.

\*2 Products were transferred to the Joint Venture with Teva in Japan (monotherapy in April 2016 and fixed dose combinations in May 2017). Supply sales of these products to the JV is currently recognized.

		FY17							
		Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
Entyvio	U.S.	31.0	37.9%						
	EUCAN	13.5	53.1%						
	EM	1.4	90.1%						
	Total	45.9	43.3%						
Ninlaro	Japan	0.2	-						
	U.S.	9.0	51.0%						
	EUCAN	0.6	-						
	EM	0.1	-						
	Total	10.0	67.1%						
Velcade	U.S.	30.7	6.4%						
	Other than U.S.	5.5	-17.7%						
	Total	36.2	1.9%						
Adcetris	Japan	1.0	19.1%						
	Europe	4.7	-6.7%						
	EM	3.6	91.3%						
	Total	9.3	19.0%						
Takecab	Japan	12.5	95.7%						
	Total	12.5	95.7%						
Trintellix	U.S.	11.2	74.1%						
	Total	11.2	74.1%						
Leuprorelin	Japan	12.4	-5.3%						
	U.S.	5.2	-7.6%						
	EUCAN	8.1	-2.7%						
	EM	3.0	-19.0%						
	Total	28.7	-6.7%						
Dexilant	U.S.	12.8	-1.8%						
	EUCAN	1.4	-3.7%						
	EM	2.1	27.9%						
	Total	16.3	1.0%						
Azilva	Japan	18.7	5.6%						
	Total	18.7	5.6%						
Nesina	Japan	8.0	-13.8%						
	U.S.	1.2	-16.8%						
	EUCAN	2.0	32.9%						
	EM	1.4	42.1%						
	Total	12.7	-4.7%						
Uloric	U.S.	11.2	17.3%						
	EUCAN	0.2	4.6%						
	EM	0.1	-						
	Total	11.4	17.5%						
Colcrys	U.S.	9.6	-8.3%						
	Total	9.6	-8.3%						
Amitiza	U.S.	8.6	-3.0%						
	EUCAN	0.0	0.3%						
	Total	8.6	-3.0%						
Pantoprazole	U.S.	1.9	-45.5%						
	EUCAN	7.9	-9.0%						
	EM	7.0	-12.2%						
	Total	16.7	-16.5%						
Lansoprazole	Japan *2	1.6	-26.1%						
	U.S.	3.8	-42.9%						
	EUCAN	1.9	-13.9%						
	EM	2.5	2.3%						
	Total	9.7	-27.2%						
Candesartan	Japan *2	1.8	-62.3%						
	U.S.	0.2	-3.1%						
	EUCAN	2.6	-14.0%						
	EM	2.6	-16.9%						
	Total	7.3	-35.4%						

U.S.: United States, EUCAN: Europe and Canada, EM: Emerging Markets

\*1 Sales amount includes royalty income and service income.

\*2 Products were transferred to the Joint Venture with Teva in Japan (monotherapy in April 2016 and fixed dose combinations in May 2017). Supply sales of these products to the JV is currently recognized.

### 3. FX

<b>Average Exchange Rate</b>	<b>(yen)</b>				
	USD	EUR	RUB	CNY	BRL
FY14	109	139	2.6	17.6	45.3
FY15	121	132	1.9	19.0	34.1
FY16	109	120	1.7	16.2	32.9
FY16 Q1	112	126	1.7	17.1	31.3
FY17 Q1	111	121	2.0	16.1	34.8
FY17 Assumption	110	120	1.9	16.6	36.4

#### **Impact of 1% depreciation of yen**

	USD	EUR	RUB	CNY	BRL
Revenue	+42.2	+13.6	+3.7	+4.5	+3.4
Core Earnings	+6.4	+2.6	+2.0	+0.8	+0.5
Operating Profit	-1.1	-0.9	+1.5	+0.6	+0.4
Net Profit	-0.7	-0.7	+1.0	+0.4	+0.2

## 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. This listing only shows regional activity for pivotal programs, or regional in-licensing deals.
- Stage-ups are recognized in the table upon achievement of First Subject In.

#### ■ Oncology

Development code <generic name> BRAND NAME	Drug Class (administration route)	Indications / additional formulations	Stage	
<brigatinib> ALUNBRIG™ (US)	ALK inhibitor (oral)	ALK-positive metastatic non-small cell lung cancer in patients who have been previously treated with crizotinib	EU	Filed (Feb '17)
		Front line ALK-positive non-small cell lung cancer	US	P-III
			EU	P-III
		ROS1-positive non-small cell lung cancer	-	P-I
SGN-35 <brentuximab vedotin> ADCETRIS® (EU, Jpn)	CD30 monoclonal antibody-drug conjugate (injection)	Relapsed cutaneous T-cell lymphoma	EU	Filed (Apr '17)
		Front line Hodgkin lymphoma	Jpn	P-III
		Front line mature T-cell lymphoma	EU	P-III
MLN9708 <ixazomib> NINLARO® (US, EU, Jpn)	Proteasome inhibitor (oral)	Previously untreated multiple myeloma	US	P-III
			EU	P-III
			Jpn	P-III
		Maintenance therapy in patients with newly diagnosed multiple myeloma following autologous stem cell transplant	US	P-III
			EU	P-III
			Jpn	P-III
<ponatinib> ICLUSIG® (US)	BCR-ABL inhibitor (oral)	Imatinib-resistant chronic phase chronic myeloid leukemia	US	P-III
		Dose ranging study for second-line patients with chronic-phase chronic myeloid leukemia	US	P-II(b)
		Philadelphia chromosome-positive acute lymphoblastic leukemia	-	P-II(b)
TAK-385 <relugolix>	LH-RH antagonist (oral)	Prostate cancer	Jpn	P-III
TAK-228 <sapanisertib>	mTORC1/2 inhibitor (oral)	Breast cancer	US	P-II(b)
			EU	P-II(b)
		Renal cell cancer	US	P-II(b)
		Endometrial cancer	US	P-II(b)
TAK-924 <pevonedistat>	NEDD 8 activating enzyme inhibitor (injection)	High risk myelodysplastic syndromes	-	P-II(a)
TAK-202 <plozalizumab>	CCR2 antagonist (injection)	Solid tumors	-	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/FLT3 kinase inhibitor (oral)	Solid tumors, Hematologic malignancies	-	P-I
TAK-788 <->	EGFR/HER2 inhibitor (oral)	Non-small cell lung cancer	-	P-I
TAK-931 <->	CDC7 inhibitor (oral)	Solid tumors	-	P-I
XMT-1522* <sup>1</sup> <->	HER2 dolaflexin antibody-drug conjugate (injection)	HER2 positive solid tumors	-	P-I
<cabozantinib>	Multi-targeted kinase inhibitor (oral)	Solid tumors	Jpn	P-I

\*1 Takeda and Mersana Therapeutics, Inc. will co-develop XMT-1522, and Mersana will lead execution of the Phase 1 trial.

## ■ Gastroenterology

Development code <generic name> BRAND NAME	Drug Class (administration route)	Indications / additional formulations	Stage	
<b>Cx601</b> < - >	A suspension of allogeneic expanded adipose-derived stem cells (injection)	Complex perianal fistulas in patients with Crohn's disease	EU	Filed (Mar '16)
<b>MLN0002</b> <vedolizumab> ENTYVIO® (US, EU)	Humanized monoclonal antibody against α4β7 integrin (injection)	Ulcerative colitis	Jpn	P-III
		Crohn's disease	Jpn	P-III
		Subcutaneous fomulation (for Ulcerative colitis, Crohn's disease)	US	P-III
			EU	P-III
			Jpn	P-III
		Graft-versus-host disease (GvHD) steriod refractory (SR)	-	P-II(a)
		Graft-versus-host disease (GvHD) prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	-	P-I
<b>SPI-0211</b> <lubiprostone> AMITIZA® (US)	Chloride channel activator (oral)	New formulation (initially for Chronic Idiopathic Constipation and Opioid-Induced Constipation)	US	P-III
		Pediatric functional constipation	US	P-III
<b>TAK-438</b> <vonoprazan> TAKECAB® (Jpn)	Potassium-competitive acid blocker (oral)	Non-erosive reflux disease (NERD) in patients with gastroesophageal reflux disease	Jpn	P-III
		Gastro-esophageal reflux disease in patients who have a partial response following treatment with a proton pump inhibitor	-	P-II(b)
<b>TAK-906</b> < - >	Dopamine D2/D3 receptor antagonist (oral)	Gastroparesis	-	P-I
<b>TAK-954</b> < - >	5-HT4 receptor agonist (injection)	Enteral feeding intolerance	-	P-I

## ■ CNS

Development code <generic name> BRAND NAME	Drug Class (administration route)	Indications / additional formulations	Stage	
<b>TVP-1012*<sup>2</sup></b> <rasagiline>	Monoamine oxidase B (MAO-B) inhibitor (oral)	Parkinson's disease	Jpn	Filed (Jun '17)
<b>Lu AA21004</b> <vortioxetine> TRINTELLIX® (US)	Multimodal anti-depressant (oral)	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 (Jun '17)
		Major depressive disorder	Jpn	P-III
		Attention Deficit Hyperactivity Disorder (ADHD) in adult patients	US	P-II(a)
<b>AD-4833/TOMM40</b>	Mitochondrial growth modulator (oral) / Biomarker assay	Delay of onset of mild cognitive impairment due to Alzheimer's disease	US EU	P-III P-III
<b>TAK-041</b> < - >	GPR139 agonist (oral)	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
<b>TAK-058</b> < - >	5-HT3 receptor antagonist (oral)	Cognitive impairment associated with schizophrenia	-	P-I
<b>TAK-071</b> < - >	M1 positive allosteric modulator (M1PAM) (oral)	Alzheimer's disease	-	P-I
<b>TAK-653</b> < - >	AMPA receptor potentiator (oral)	Treatment resistant depression	-	P-I
<b>TAK-831</b> < - >	D-amino acid oxidase (DAAO) inhibitor (oral)	Cerebellar ataxia, Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
<b>TAK-935*<sup>3</sup></b> < - >	CH24H inhibitor (oral)	Rare pediatric epilepsies	-	P-I

\*2 Brand name in Teva territories: AZILECT®

\*3 Co-development with Ovid Therapeutics

## ■ Vaccines

Development code BRAND NAME	Type of vaccine (administration route)	Indications / additional formulations	Stage	
TAK-003	Tetravalent dengue vaccine (injection)	Prevention of dengue fever caused by dengue virus	-	P-III
TAK-214	Norovirus vaccine (injection)	Prevention of acute gastroenteritis (AGE) caused by norovirus	-	P-II(b)
TAK-195	Sabin inactivated polio vaccine (injection)	Prevention of poliomyelitis	-	P-I/II
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	Drug Class (administration route)	Indications / additional formulations	Stage	
TAK-385 <relugolix>	LH-RH antagonist (oral)	Uterine fibroids	Jpn	P-III
		Endometriosis	Jpn	P-II(b)
MT203 <namilumab>	GM-CSF monoclonal antibody (injection)	Rheumatoid arthritis	EU	P-II(b)
			Jpn	P-II(a)
TAK-020 <->	Bruton's tyrosine kinase inhibitor (oral)	Rheumatoid arthritis	-	P-I
TAK-079 <->	Cytolytic monoclonal antibody (injection)	Systemic lupus erythematosus	-	P-I

## ■ Recent progress in stage [Progress in stage disclosed since release of FY2016 results (May 10th, 2017)]

Development code <generic name>	Indications / additional formulations	Country/Region	Progress in stage
TVP-1012 <rasagiline>	Parkinson's disease	Jpn	Filed (Jun '17)
MLN0002 <vedolizumab>	Graft-versus-host disease (GvHD) steroid refractory (SR)	-	P-II(a)
TAK-195	Prevention of poliomyelitis	-	P-I/II

## ■ Discontinued projects [Update disclosed since release of FY2016 results (May 10th, 2017)]

Development code <generic name>	Indications (Stage)	Reason
MLN9708 <ixazomib>	Solid Tumors (P-I)	Insufficient response observed to support company sponsored development

## 2. Externalized assets in which Takeda retains a financial interest

Partner	Nature of Partnership
Biological E. Limited	Takeda agreed to transfer existing measles and acellular pertussis vaccine bulk production technology to develop low-cost combination vaccines for India, China and low- and middle-income countries.
Cerevance	Takeda provided a 25-person neuroscience research team from its Cambridge (UK) site, fully equipped laboratory space, and licenses to a portfolio of undisclosed preclinical and clinical stage drug programs.
Myovant Sciences	Takeda granted Myovant an exclusive, worldwide license (excluding Japan and certain other Asian countries) to relugolix (TAK-385) and an exclusive, worldwide license to MVT-602 (TAK-448).
Outpost Medicine	Takeda granted an exclusive license to Outpost for the worldwide development and commercialization rights to OP-233 (TAK-233).
Ovid Therapeutics	Takeda collaborates with Ovid on the clinical development and commercialization of TAK-935 in Rare Pediatric Epilepsies.
Scohia Pharma	Takeda granted Scohia Pharma exclusive rights for the research, development, manufacture, marketing, etc. of eight of Takeda's R&D projects, including TAK-272, TAK-792 and TAK-094.
Ultragenyx	Takeda granted an exclusive license to one undisclosed preclinical product candidate in a pre-determined field of use, with an exclusive option to co-develop and co-commercialize the candidate in additional therapeutic areas.

## 3. Research & Development collaborations

### Oncology

Partner	Country	Subject
Crescendo Biologics	UK	The discovery, development and commercialization of Humabody <sup>®</sup> -based therapeutics for cancer indications
GammaDelta Therapeutics	UK	Novel T cell platform, based on the unique properties of gamma delta (γδ) T cells derived from human tissues, to discover and develop new immunotherapies in oncology
Gencia LLC	US	Mitochondrial Associated Glucocorticoid Receptors (MAGR) agonists for potential use primarily in hematological and inflammatory diseases
ImmunoGen, Inc.	US	Antibody-Drug Conjugate technology
Maverick Therapeutics	US	T-cell engagement platform created specifically to improve the utility of T-cell redirection therapy for the treatment of cancer
Mersana Therapeutics	US	Antibody-Drug Conjugate technology
Nektar Therapeutics	US	Research collaboration to explore combination cancer therapy with five Takeda oncology compounds and Nektar's lead immuno-oncology candidate, the CD122-biased agonist NKTR-214
Seattle Genetics	US	Antibody-Drug Conjugate technology
Tesaro	US	Exclusive licensing agreement to develop and commercialize novel cancer therapy niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in South Korea, Taiwan, Russia and Australia

### Gastroenterology

Partner	Country	Subject
Arcturus	US	Collaboration to develop RNA-based therapeutics for the treatment of NASH and other gastrointestinal (GI) related disorders
BioSurfaces, Inc.	US	Research program designed to develop innovative medical devices to treat patients with GI diseases using BioSurfaces' proprietary nanomaterial technology.
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
enGene	Canada	Novel therapies for specialty gastrointestinal (GI) diseases using enGene's "Gene Pill" gene delivery platform
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)
Finch Therapeutics	US	Global agreement to develop FIN-524, a live biotherapeutic product composed of cultured bacterial strains linked to favorable clinical outcomes in studies of microbiota transplantations in IBD
NuBiyota	Canada	Development of Microbial Ecosystem Therapeutic products for gastroenterology indications
PvP Therapeutics	US	Global agreement to develop KumaMax, a novel enzyme designed to break down the immune-reactive parts of gluten in the stomach

### CNS

Partner	Country	Subject
Affilic	France	Affilic's proprietary Nanofitins <sup>®</sup> platform in therapies targeting the central nervous system
Cerevance	US, UK	Discovery and development of novel therapeutics for neurological and psychiatric disorders
Ovid Therapeutics	US	Development of TAK-935, an oral CH24H inhibitor for rare pediatric epilepsies. Takeda and Ovid Therapeutics will share in the development and commercialization costs of TAK-935 on a 50/50 basis and, if successful, share in the profits on a 50/50 basis.
Ultragenyx	US	Collaboration to develop and commercialize therapies for rare genetic diseases
Zinfandel Pharmaceuticals	US	Alzheimer's Disease Biomarker TOMM40

## Vaccines

Partner	Country	Subject
U.S. Government - The Biomedical Advanced Research and Development Authority (BARDA)	US	Partnership to develop TAK-426, a Zika vaccine candidate, to support the Zika response in the US and affected regions around the world
Bill & Melinda Gates Foundation	US	Partnership to develop TAK-195, a Sabin-strain Inactivated Polio vaccine (sIPV) candidate, to support polio eradication in developing countries
Zydus Cadila	India	Partnership to develop TAK-507, a Chikungunya vaccine candidate, to tackle an emerging and neglected infectious disease in the world

## Other / Multiple Therapeutic Area

Partner	Country	Subject
Arix Bioscience	UK	Value creation through venture and biotech partnerships
Astellas, Daiichi Sankyo	Japan	Fundamental biomarker data on healthy adult volunteers in order to optimize and accelerate the development of innovative medicines
BioMotiv	US	Therapeutic accelerator to identify and develop pioneering medical innovations specifically in the therapeutic areas of immunology & inflammation and cardio-metabolic diseases
Bridge Medicines	US	Building upon Tri-I TDI, Bridge Medicines will give financial, operational and managerial support to move projects seamlessly from a validating, proof-of-concept study to an in-human clinical trial
Center for iPS Cell Research Application, Kyoto University	Japan	Clinical applications of iPS cells in areas such as heart failure, diabetes mellitus, neuro-psychiatric disorders and cancer
Dementia Discovery Fund (DDF)	Global	New global investment fund to support discovery and development of novel dementia treatments
Harrington Discovery Institute at University Hospitals in Cleveland, Ohio	US	Collaboration for the advancement of medicines for rare diseases, within Takeda's strategic R&D focus in its therapeutic areas of oncology, gastroenterology and central nervous system disorders
Keio University, Niigata University, Kyoto 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
M2Gen	US	Genomic data from cancer patients
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
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
Presage Biosciences	US	Access to Presage's proprietary CIVO™ technology platform to enable identification of novel oncology drug combinations in solid tumors
Schrödinger	US	Multi-target research collaboration combining Schrödinger's in silico platform-driven drug discovery capabilities with Takeda's deep therapeutic area knowledge and expertise in structural biology.
Trianni, Inc.	US	Trianni's transgenic mouse platform to identify fully human monoclonal antibodies against disease targets in all therapeutic areas
Tri-Institutional Therapeutics Discovery Institute (Tri-I TDI)	US	Collaboration of academic institutions and industry to more effectively develop innovative treatments and therapies

Note: List is not inclusive of all Takeda R&D collaborations

### ■ Clinical study protocol summaries

Clinical study protocol summaries are disclosed on the English-language web-site (<https://takedaclinicaltrials.com/>) and clinical study protocol information in the Japanese-language is disclosed on the Japanese-language web-site (<http://www.takeda.co.jp/research/ct/>).

We anticipate that this disclosure will assure transparency of information on Takeda's 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.

## Appendix

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

(Million US\$)

	FY14	FY15	FY16	FY16 Q1	FY17 Q1	YOY	
Entyvio	179	524	913	201	278	77	38.2%
Velcade	1,017	1,079	1,000	247	268	21	8.5%
Dexilant	488	530	457	117	115	-2	-1.5%
Trintellix	124	203	294	58	101	43	74.8%
Uloric	297	347	380	85	101	15	17.7%
Colcrys	542	386	358	94	87	-8	-8.1%
Ninlaro	-	34	267	54	81	28	51.3%
Amitiza	291	308	310	79	77	-2	-2.7%
Iclusig	-	-	22	-	40	40	-
Prevacid (lansoprazole)	254	222	179	57	33	-25	-42.8%
Alunbrig	-	-	-	-	2	2	-

\*1 Product sales (royalty income and service income are excluded).

◆ Prescription Drugs: US major products' sales (in US\$) \*<sup>1</sup> (Quarterly)

(Million US\$)

	FY16				FY17							
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
Entyvio	201	224	241	247	278	38.2%						
Velcade	247	250	253	250	268	8.5%						
Dexilant	117	120	116	104	115	-1.5%						
Trintellix	58	75	81	80	101	74.8%						
Uloric	85	92	107	95	101	17.7%						
Colcrys	94	93	88	83	87	-8.1%						
Ninlaro	54	65	75	73	81	51.3%						
Amitiza	79	77	87	66	77	-2.7%						
Iclusig	-	-	-	22	40	-						
Prevacid (lansoprazole)	57	40	44	37	33	-42.8%						
Alunbrig	-	-	-	-	2	-						

\*1 Product sales (royalty income and service income are excluded).

◆ Prescription Drugs: Japan major products' sales

(Billion JPY)

	Launched	Therapeutic Class	FY14	FY15	FY16	FY16	FY17	YOY	
						Q1	Q1		
Azilva *	(12. 5)	Hypertension	45.4	59.0	66.9	17.7	18.7	1.0	5.6%
Takecab *	(15. 2)	Acid-related Diseases	3.2	8.4	34.1	6.4	12.5	6.1	95.7%
Leuplin (leuprorelin)	(92. 9)	Prostate cancer, breast cancer and endometriosis	57.6	53.8	48.6	13.1	12.4	-0.7	-5.3%
Enbrel	(05. 3)	Rheumatoid arthritis	41.2	40.8	40.4	11.0	10.3	-0.7	-6.0%
Nesina *	(10. 6)	Diabetes	38.4	36.9	32.9	9.3	8.0	-1.3	-13.8%
Lotriga	(13. 1)	Hyperlipidemia	13.2	22.3	27.5	6.8	7.9	1.1	15.6%
Vectibix	(10. 6)	Colorectal cancer	18.3	18.4	18.8	4.9	5.0	0.0	1.0%
Reminyl	(11. 3)	Alzheimer-type dementia	13.9	16.0	17.4	4.6	4.7	0.0	0.3%
Rozerem	(10. 7)	Insomnia	6.6	7.4	8.1	2.1	2.3	0.2	8.0%
Benet	(02. 5)	Osteoporosis	10.4	9.7	8.3	2.3	2.0	-0.3	-12.5%
Adcetris	(14. 4)	Malignant Lymphoma	2.8	3.1	3.3	0.9	1.0	0.2	19.1%

\* The figures include the amounts of fixed dose combinations and blister packs.

◆ Prescription Drugs: Japan major products' sales (Quarterly)

(Billion JPY)

Launched	Therapeutic Class	FY16				FY17							
		Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
Azilva *	(12. 5)	Hypertension	17.7	15.6	18.5	15.0	18.7	5.6%					
Takecab *	(15. 2)	Acid-related Diseases	6.4	7.5	10.8	9.5	12.5	95.7%					
Leuplin (leuprorelin)	(92. 9)	Prostate cancer, breast cancer and endometriosis	13.1	11.7	13.6	10.2	12.4	-5.3%					
Enbrel	(05. 3)	Rheumatoid arthritis	11.0	10.0	10.9	8.6	10.3	-6.0%					
Nesina *	(10. 6)	Diabetes	9.3	7.7	9.2	6.6	8.0	-13.8%					
Lotriga	(13. 1)	Hyperlipidemia	6.8	6.6	7.8	6.3	7.9	15.6%					
Vectibix	(10. 6)	Colorectal cancer	4.9	4.6	5.1	4.2	5.0	1.0%					
Reminyl	(11. 3)	Alzheimer-type dementia	4.6	4.1	4.8	3.8	4.7	0.3%					
Rozerem	(10. 7)	Insomnia	2.1	1.9	2.2	1.8	2.3	8.0%					
Benet	(02. 5)	Osteoporosis	2.3	2.0	2.3	1.7	2.0	-12.5%					
Adcetris	(14. 4)	Malignant Lymphoma	0.9	0.7	0.9	0.8	1.0	19.1%					

\* The figures include the amounts of fixed dose combinations and blister packs.

◆ Consumer Healthcare: Japan major products' sales

(Billion JPY)

	FY14	FY15	FY16	FY16 Q1	FY17 Q1	YOY	
Alinamin tablet	20.7	25.2	24.1	6.1	7.6	1.5	23.8%
Alinamin drink	14.9	14.9	16.1	5.1	4.0	-1.1	-21.9%
Biofermin	8.1	8.6	9.1	2.2	2.5	0.2	10.3%
Benza	9.7	9.8	10.0	1.3	1.2	-0.0	-2.3%
Borraginol	4.1	4.5	4.5	1.1	1.1	-0.0	-1.4%
Mytear	4.4	4.2	3.9	0.8	0.8	0.0	5.2%

\* This table shows sales amount of Takeda Consumer Healthcare Company Limited (TCHC) in Japan.

Takeda Consumer Healthcare Company Limited succeeded the business of Takeda's Japan Consumer Healthcare Business Unit (JCHBU), and started its business on April 1, 2017 as the new company.

◆ Consumer Healthcare: Japan major products' sales (Quarterly)

(Billion JPY)

	FY16				FY17							
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
Alinamin tablet	6.1	6.2	6.8	4.9	7.6	23.8%						
Alinamin drink	5.1	4.0	4.2	2.8	4.0	-21.9%						
Biofermin	2.2	2.3	2.6	2.0	2.5	10.3%						
Benza	1.3	4.2	3.2	1.4	1.2	-2.3%						
Borraginol	1.1	1.1	1.3	1.0	1.1	-1.4%						
Mytear	0.8	0.9	0.9	1.3	0.8	5.2%						

\* This table shows sales amount of Takeda Consumer Healthcare Company Limited (TCHC) in Japan.

Takeda Consumer Healthcare Company Limited succeeded the business of Takeda's Japan Consumer Healthcare Business Unit (JCHBU), and started its business on April 1, 2017 as the new company.



**Takeda Pharmaceutical Company Limited**