



Better Health, Brighter Future

FY2019 Q2 DATABOOK

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Quarterly Announcements / Presentations

<https://www.takeda.com/investors/reports/>

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I. Financial Results

1. Revenue by Region

■ Year To Date

(Bn JPY)	Reported				Underlying
	FY18 Q2 YTD	FY19 Q2 YTD	YOY		YOY
Total revenue	880.6	1,660.2	779.6	88.5%	-0.2%
Japan	274.2	299.4	25.2	9.2%	-1.1%
% of revenue	31.1%	18.0%	-13.1pt		
United States	321.1	805.9	484.8	151.0%	-4.0%
% of revenue	36.5%	48.5%	12.1pt		
Europe and Canada	158.6	321.8	163.2	102.9%	2.1%
% of revenue	18.0%	19.4%	1.4pt		
Growth and Emerging Markets	126.7	233.0	106.4	84.0%	11.8%
% of revenue	14.4%	14.0%	-0.3pt		
Russia/CIS	27.5	36.9	9.4	34.2%	8.8%
% of revenue	3.1%	2.2%	-0.9pt		
Latin America	34.7	75.8	41.1	118.5%	11.9%
% of revenue	3.9%	4.6%	0.6pt		
Asia	51.9	83.9	32.0	61.6%	20.9%
% of revenue	5.9%	5.1%	-0.8pt		
Other	12.6	36.5	23.9	189.4%	-2.2%
% of revenue	1.4%	2.2%	0.8pt		
Of which royalty / service income	24.9	47.1	22.3	89.4%	

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

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

1. Revenue by Region (continued)

◆Quarterly

(Bn JPY)	Reported											
	FY18				FY19							
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
Total revenue	449.8	430.8	499.4	717.2	849.1	88.8%	811.0	88.3%				
Japan	144.3	130.0	169.8	127.0	152.3	5.6%	147.1	13.2%				
% of revenue	32.1%	30.2%	34.0%	17.7%	17.9%		18.1%					
United States	161.1	160.0	174.3	333.6	415.7	158.0%	390.2	143.9%				
% of revenue	35.8%	37.1%	34.9%	46.5%	49.0%		48.1%					
Europe and Canada	79.1	79.5	86.3	160.8	165.2	108.8%	156.6	97.0%				
% of revenue	17.6%	18.5%	17.3%	22.4%	19.5%		19.3%					
Growth and Emerging Markets	65.4	61.3	69.1	95.8	115.9	77.3%	117.2	91.0%				
% of revenue	14.5%	14.2%	13.8%	13.4%	13.6%		14.4%					
Russia/CIS	14.1	13.4	16.8	15.4	19.0	34.6%	17.9	33.7%				
% of revenue	3.1%	3.1%	3.4%	2.2%	2.2%		2.2%					
Latin America	18.5	16.2	19.8	33.6	37.4	102.2%	38.4	137.3%				
% of revenue	4.1%	3.8%	4.0%	4.7%	4.4%		4.7%					
Asia	26.9	25.0	24.0	29.6	41.0	52.4%	42.9	71.5%				
% of revenue	6.0%	5.8%	4.8%	4.1%	4.8%		5.3%					
Other	5.8	6.8	8.5	17.2	18.5	-	18.0	165.9%				
% of revenue	1.3%	1.6%	1.7%	2.4%	2.2%		2.2%					
Of which royalty / service income	13.0	11.9	21.7	24.4	27.1	108.5%	20.0	68.6%				

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

2. Product Sales Analysis (vs PY Reported Actual)

(Sales amount includes royalty income and service income)

■ Year To Date

(Bn JPY)	Reported			US	YOY	Japan	YOY	EUCAN	YOY	GEM*3	YOY	Ex-US	YOY
	FY18Q2 YTD	FY19Q2 YTD	YOY										
GI	252.1	341.6	35.5%	200.7	46.0%	38.1	32.4%	64.7	13.9%	30.1	3.6%	7.9	-
Entyvio	128.4	168.4	31.2%	117.7	34.7%	2.5	-	41.6	14.8%	6.6	38.0%		
Dexilant	34.9	31.1	-10.9%	20.8	-18.8%			3.8	8.3%	6.6	12.3%		
Pantoprazole	30.7	24.4	-20.4%	1.3	-61.8%			11.2	-18.6%	12.0	-11.9%		
Takecab-F	27.2	35.0	28.3%			34.7	27.9%			0.2	161.8%		
Gattex/Revestive		29.3	-	25.1	-			4.0	-	0.2	-		
Pentasa		13.0	-	13.0	-								
Lialda/Mezavant*1		12.2	-	4.3	-							7.9	-
Amitiza	16.3	15.1	-7.2%	15.0	-7.8%			0.0	-93.6%	0.1	-		
Resolor/Motegrity		2.7	-	1.1	-			1.5	-	0.1	-		
Other	14.6	10.3	-29.2%	2.5	-48.8%	0.8	-48.6%	2.6	-20.3%	4.3	-8.1%		
Rare Metabolic		92.1	-	28.7	-	1.5	-	21.1	-	15.3	-	25.5	-
Elaprase		35.5	-	9.7	-	0.7	-	12.6	-	12.5	-		
Replagal *1		25.5	-									25.5	-
Vpriv		18.7	-	8.0	-	0.8	-	7.2	-	2.7	-		
Natpara		12.4	-	11.0	-			1.3	-	0.1	-		
Rare Hematology		174.7	-	72.4	-	14.0	-	43.7	-	44.6	-		
Advate		83.2	-	35.7	-	4.0	-	23.4	-	20.1	-		
Adynovate		29.8	-	15.6	-	7.5	-	5.2	-	1.4	-		
FEIBA *2		27.8	-	5.0	-	0.9	-	7.6	-	14.3	-		
Hemofil/mmunate/ Immunine *2		12.1	-	2.5	-			3.2	-	6.4	-		
Other PDT Products *2		1.1	-	-0.0	-			0.9	-	0.3	-		
Other		20.6	-	13.5	-	1.5	-	3.4	-	2.2	-		
Hereditary Angioedema		60.3	-	48.7	-	0.3	-	9.7	-	1.6	-		
Firazyr		15.3	-	8.9	-	0.3	-	4.6	-	1.5	-		
Takhzyro		30.7	-	28.9	-			1.8	-	0.0	-		
Kalbitor		2.4	-	2.4	-			0.0	-		-		
Cinryze *2		12.0	-	8.5	-			3.4	-	0.1	-		

*1 License-out product : Regional breakdown is not available due to contract.

*2 PDT products

*3 GEM: Growth and Emerging Markets, which include Russia/CIS, Latin America, Asia, Middle East, Oceania and Africa

Other PDT products in Rare Hematology include Bebulin and Prothrombin.

Other in Rare Hematology include Vonvendi, Obizur, Rixubis, Agrylin/Xagrid, Recombinate, Other Hemophilia.

■ Year To Date

(Bn JPY)	Reported			US	YOY	Japan	YOY	EUCAN	YOY	GEM*3	YOY	Ex-US	YOY
	FY18Q2 YTD	FY19Q2 YTD	YOY										
PDT Immunology	8.0	191.7	-	127.1	-							64.6	-
Immunoglobulin *2	5.9	146.5	-	109.7	-							36.8	-
Albumin *2	0.8	34.1	-	7.9	-							26.2	-
Other *2	1.3	11.1	-	9.6	-							1.6	25.5%
Oncology	198.5	214.8	8.3%	111.7	9.3%	38.7	10.8%	33.5	6.1%	22.6	35.7%	8.3	-36.4%
Velcade *1	64.9	63.6	-1.9%	57.1	7.2%							6.5	-44.1%
Leuprorelin	55.1	56.6	2.8%	12.4	11.3%	20.6	2.5%	15.1	-10.1%	8.6	20.8%		
Ninlaro	29.4	38.3	30.2%	26.5	16.3%	2.5	21.7%	5.5	59.0%	3.7	-		
Adcetris	21.1	25.8	22.1%			3.9	80.2%	11.6	7.8%	9.8	20.8%		
Iclusig *1	14.2	14.7	3.7%	12.8	1.4%							1.8	23.0%
Alunbrig	2.3	3.4	48.3%	2.4	8.2%		-	0.8	-	0.2	-		
Vectibix	10.5	11.6	10.2%			11.6	10.2%						
Other	1.0	0.9	-12.1%	-0.0	-			0.6	-6.2%	0.3	-10.8%		
Neuroscience	46.4	213.9	-	167.1	-	20.6	48.0%	22.9	-	3.3	-		
Vyvanse		131.5	-	113.2	-			15.1	-	3.2	-		
Trintellix	27.1	34.6	27.6%	34.6	27.6%								
Adderall XR		10.6	-	9.8	-			0.8	-				
Rozerem	10.1	8.7	-14.2%	3.1	-42.6%	5.6	18.1%			0.0	-22.8%		
Reminyl	8.4	9.0	7.4%			9.0	7.1%	0.0	-				
Intuniv		8.0	-	0.8	-	3.6	-	3.6	-	0.1	-		
Other	0.8	11.4	-	5.6	-	2.5	-	3.3	-	0.0	-		
Other	375.6	371.0	-1.2%										
Azilva	35.2	38.7	9.9%			38.7	9.9%						
Nesina	26.8	28.6	6.6%	3.2	14.4%	14.3	0.2%	5.3	4.5%	5.8	23.9%		
Uloric	26.5	14.1	-46.9%	13.5	-48.0%			0.3	-21.8%	0.3	71.0%		
Colcrys	16.3	13.1	-19.5%	13.1	-19.5%								
Enbrel	18.1	15.9	-11.9%			15.9	-11.9%						
Lotriga	15.2	16.0	4.9%			16.0	4.9%						

*1 License-out product : Regional breakdown is not available due to contract.

*2 PDT products

*3 GEM: Growth and Emerging Markets, which include Russia/CIS, Latin America, Asia, Middle East, Oceania and Africa

Other in PDT Immunology include Aralast, Glassia, Kenktsu-Nonthron and others

Other in Neuroscience include Copaxone, Rasagiline, Mydayis, Buccolam, Daytrana/Equasym and Carbatrol/Equetro

2. Product Sales Analysis (vs PY Reported Actual) (continued)

■ Quarterly (Bn JPY)	Reported											
	FY18				FY19							
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
GI	124.0	128.1	140.8	146.5	171.6	38.4%	169.9	32.7%				
Entyvio	61.3	67.1	72.6	68.2	83.9	36.9%	84.5	26.0%				
Dexilant	17.4	17.5	20.0	14.3	15.8	-9.0%	15.3	-12.8%				
Pantoprazole	16.2	14.5	16.2	14.7	11.6	-28.5%	12.8	-11.3%				
Takecab-F	14.3	13.0	17.1	13.9	18.3	28.1%	16.7	28.6%				
Gattex/Revestive				12.8	15.1	-	14.1	-				
Pentasa				4.7	6.5	-	6.5	-				
Lialda/Mezavant				3.3	5.6	-	6.7	-				
Amitiza	7.9	8.4	9.6	7.1	7.8	-0.7%	7.3	-13.2%				
Resolor/Motegrity				0.7	1.4	-	1.3	-				
Other	7.0	7.6	5.2	6.8	5.6	-19.4%	4.7	-38.2%				
Rare Metabolic				42.3	48.9	-	43.2	-				
Elaprase				15.1	18.8	-	16.7	-				
Replagal				11.4	12.9	-	12.6	-				
Vpriv				8.7	9.3	-	9.4	-				
Natpara				7.1	7.9	-	4.5	-				
Rare Hematology				66.7	89.9	-	84.8	-				
Advate				32.1	42.7	-	40.5	-				
Adynovate				10.7	16.7	-	13.1	-				
FEIBA *1				9.6	13.1	-	14.8	-				
Hemofil/Immunate/ Immunine*1				5.5	6.6	-	5.6	-				
Other PDT Products *1				0.5	0.6	-	0.5	-				
Other				8.3	10.3	-	10.3	-				
Hereditary Angioedema				20.4	31.9	-	28.5	-				
Firazyr				6.4	9.0	-	6.3	-				
Takhzyro				9.7	14.5	-	16.2	-				
Kalbitor				1.2	1.1	-	1.3	-				
Cinryze *1				3.1	7.3	-	4.7	-				

*1 PDT products

Other PDT products in Rare Hematology include Bebulin and Prothrombin.

Other in Rare Hematology include Vonvendi, Obizur, Rixubis, Agrylin/Xagrid, Recombinate, Other Hemophilia.

■ Quarterly (Bn JPY)	Reported											
	FY18				FY19							
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
PDT Immunology	4.2	3.8	4.5	81.0	90.2	-	101.5	-				
Immunoglobulin *1	3.1	2.8	3.2	64.3	68.0	-	78.5	-				
Albumin *1	0.4	0.4	0.5	15.6	16.1	-	17.9	-				
Other *1	0.6	0.6	0.8	1.1	6.0	-	5.1	-				
Oncology	98.9	99.5	108.2	92.8	106.5	7.6%	108.4	8.9%				
Velcade	31.4	33.5	35.4	27.5	31.7	1.0%	31.9	-4.7%				
Leuprorelin	28.6	26.5	29.5	25.4	28.4	-0.9%	28.3	6.7%				
Ninlaro	14.0	15.4	17.1	15.7	18.3	30.8%	20.0	29.7%				
Adcetris	11.0	10.1	10.9	10.9	12.7	16.4%	13.0	28.3%				
Iclusig	7.0	7.2	7.4	7.1	7.6	9.2%	7.0	-1.7%				
Alunbrig	1.1	1.2	1.5	1.4	1.7	52.8%	1.7	44.2%				
Vectibix	5.4	5.1	5.7	4.3	5.6	3.5%	6.0	17.3%				
Other	0.5	0.5	0.6	0.4	0.4	-9.6%	0.5	-14.4%				
Neuroscience	24.3	22.1	27.3	81.0	111.9	-	102.0	-				
Vyvanse				49.4	68.8	-	62.7	-				
Trintellix	14.1	13.0	17.5	12.9	17.4	23.4%	17.2	32.2%				
Adderall XR				5.4	5.7	-	4.9	-				
Rozerem	5.2	4.9	4.8	4.2	5.1	-1.6%	3.6	-27.4%				
Reminyl	4.5	3.9	4.6	3.7	4.8	6.5%	4.2	8.4%				
Intuniv				1.3	4.1	-	4.0	-				
Other	0.5	0.3	0.4	4.1	6.0	-	5.4	-				
Other	198.4	177.2	218.7	188.6	198.3	-0.1%	172.8	-2.5%				
Azilva	19.4	15.8	20.5	15.0	20.5	5.4%	18.2	15.5%				
Nesina	14.1	12.7	15.6	12.3	14.6	3.3%	14.0	10.3%				
Uloric	14.1	12.4	14.0	10.6	12.2	-13.1%	1.8	-85.3%				
Colcrys	9.2	7.1	7.3	6.4	7.2	-22.4%	6.0	-15.8%				
Enbrel	9.9	8.2	9.8	7.3	8.7	-12.1%	7.2	-11.6%				
Lotriga	8.1	7.1	9.0	6.6	8.8	8.1%	7.2	1.2%				

*1 PDT products

Other in PDT Immunology include Aralast, Glassia, Kenktsu-Nonthron and others

Other in Neuroscience include Copaxone, Rasagiline, Mydayis, Buccolam, Daytrana/Equasym and Carbatrol/Equetro

3. Product Sales Analysis (vs FY2018 Pro-forma)

Pro-forma includes 12-month (April 2018 – March 2019) revenue of legacy Shire as if the acquisition of Shire had occurred on April 1, 2018. This pro-forma revenue may not represent what sales would have been had the acquisition of Shire had occurred on April 1, 2018.

(Bn JPY)	FY18 Reported Pro-forma*2				FY19 Reported (Financial Reported Base)											
	Q1	Q2	Q3	Q4	Q1	YOY		Q2	YOY		Q3	YOY		Q4	YOY	
						Reported	Underlying		Reported	Underlying		Reported	Underlying		Reported	Underlying
GI	159.4	160.4	177.1	146.5	171.6	7.7%	7.9%	169.9	5.9%	9.9%						
Entyvio	61.3	67.1	72.6	68.2	83.9	36.9%	36.8%	84.5	26.0%	31.3%						
Dexilant	17.4	17.5	20.0	14.3	15.8	-9.0%	-9.4%	15.3	-12.8%	-9.3%						
Pantoprazole	16.2	14.5	16.2	14.7	11.6	-28.5%	-25.0%	12.8	-11.3%	-6.0%						
Takecab-F	14.3	13.0	17.1	13.9	18.3	28.1%	28.1%	16.7	28.6%	28.6%						
Gattex/Revestive	14.5	10.8	13.9	12.8	15.1	4.5%	3.3%	14.1	31.2%	35.9%						
Pentasa	8.4	7.3	9.4	4.7	6.5	-22.4%	-23.7%	6.5	-11.1%	-8.4%						
Lialda/Mezavant	11.7	13.6	11.2	3.3	5.6	-52.5%	-51.7%	6.7	-50.9%	-48.5%						
Amitiza	7.9	8.4	9.6	7.1	7.8	-0.7%	-3.0%	7.3	-13.2%	-10.5%						
Resolor/Motegrity	0.7	0.7	1.8	0.7	1.4	85.1%	103.8%	1.3	94.4%	91.9%						
Other	7.0	7.6	5.2	6.8	5.6	-19.4%	-18.4%	4.7	-38.2%	-35.7%						
Rare Metabolic	49.4	47.9	51.0	42.3	48.9	-1.2%	3.9%	43.2	-9.8%	-2.1%						
Elaprase	19.1	18.9	19.1	15.1	18.8	-1.4%	3.6%	16.7	-11.7%	-4.8%						
Replagal	13.6	13.6	13.4	11.4	12.9	-5.3%	3.5%	12.6	-7.8%	2.7%						
Vpriv	9.7	9.7	10.7	8.7	9.3	-4.6%	0.6%	9.4	-3.0%	5.7%						
Natpara	7.0	5.7	7.9	7.1	7.9	11.8%	10.2%	4.5	-20.1%	-17.9%						
Rare Hematology	105.2	102.1	107.6	66.7	89.9	-14.5%	-12.6%	84.8	-17.0%	-12.7%						
Advate	53.7	49.5	53.8	32.1	42.7	-20.4%	-18.1%	40.5	-18.1%	-13.5%						
Adynovate	13.2	15.4	15.4	10.7	16.7	26.4%	25.9%	13.1	-15.1%	-12.3%						
FEIBA *1	21.5	17.2	16.3	9.6	13.1	-39.4%	-36.8%	14.8	-13.9%	-9.2%						
Hemofil/Immunate/ Immune *1	5.5	5.7	7.2	5.5	6.6	18.3%	23.0%	5.6	-2.5%	3.4%						
Other PDT Products *1	1.0	0.6	0.8	0.5	0.6	-34.6%	-32.3%	0.5	-18.5%	-15.0%						
Other	10.2	13.7	14.1	8.3	10.3	0.8%	-1.1%	10.3	-24.5%	-21.6%						
Hereditary Angioedema	39.7	36.5	32.8	20.4	31.9	-19.8%	-19.9%	28.5	-22.0%	-18.4%						
Firazyr	23.0	15.6	24.4	6.4	9.0	-61.0%	-60.4%	6.3	-59.6%	-56.5%						
Takhzyro		5.7	1.2	9.7	14.5	-	-	16.2	184.5%	194.4%						
Kalbitor	1.9	2.3	2.1	1.2	1.1	-41.5%	-42.7%	1.3	-43.6%	-41.8%						
Cinryze *1	14.8	13.0	5.1	3.1	7.3	-50.7%	-50.8%	4.7	-63.8%	-62.0%						

*1 PDT products

*2 Pro-forma based product sales and therapeutic area sales which include Legacy Shire's products. Shire's 12 months (April 2018-March 2019) revenue under U.S. GAAP, excluding the oncology business which was divested in August 2018, converted to JPY using FY2018 actual rate for the period.

Other PDT products in Rare Hematology include Bebulin and Prothrombin.

Other in Rare Hematology include Vonvendi, Obizur, Rixubis, Agrylin/Xagrid, Recombinate, Other Hemophilia.

(Bn JPY)	FY18 Reported Pro-forma*2				FY19 Reported (Financial Reported Base)											
	Q1	Q2	Q3	Q4	Q1	YOY		Q2	YOY		Q3	YOY		Q4	YOY	
						Reported	Underlying		Reported	Underlying		Reported	Underlying		Reported	Underlying
PDT Immunology	89.1	100.0	101.9	81.0	90.2	1.2%	1.6%	101.5	1.5%	5.3%						
Immunoglobulin *1	69.5	75.5	77.4	64.3	68.0	-2.2%	-1.9%	78.5	4.0%	7.6%						
Albumin *1	12.9	17.3	17.0	11.0	16.1	25.6%	27.5%	17.9	3.8%	9.0%						
Other *1	6.7	7.2	7.5	5.6	6.0	-10.1%	-11.3%	5.1	-29.3%	-27.3%						
Oncology	98.9	99.5	108.2	92.8	106.5	7.6%	8.1%	108.4	8.9%	12.9%						
Velcade	31.4	33.5	35.4	27.5	31.7	1.0%	-1.3%	31.9	-4.7%	-1.7%						
Leuprorelin	28.6	26.5	29.5	25.4	28.4	-0.9%	0.6%	28.3	6.7%	9.4%						
Ninlaro	14.0	15.4	17.1	15.7	18.3	30.8%	29.8%	20.0	29.7%	35.4%						
Adcetris	11.0	10.1	10.9	10.9	12.7	16.4%	26.6%	13.0	28.3%	39.0%						
Iclusig	7.0	7.2	7.4	7.1	7.6	9.2%	6.7%	7.0	-1.7%	1.3%						
Alunbrig	1.1	1.2	1.5	1.4	1.7	52.8%	51.1%	1.7	44.2%	50.2%						
Vectibix	5.4	5.1	5.7	4.3	5.6	3.5%	3.5%	6.0	17.3%	17.3%						
Other	0.5	0.5	0.6	0.4	0.4	-9.6%	2.5%	0.5	-14.4%	-3.9%						
Neuroscience	100.8	104.2	118.4	81.0	111.9	11.1%	10.1%	102.0	-2.2%	1.1%						
Vyvanse	60.4	66.0	71.0	49.4	68.8	13.9%	12.8%	62.7	-5.0%	-1.5%						
Trintellix	14.1	13.0	17.5	12.9	17.4	23.4%	20.7%	17.2	32.2%	36.2%						
Adderall XR	8.8	8.6	11.3	5.4	5.7	-35.6%	-36.6%	4.9	-42.5%	-40.9%						
Rozerem	5.2	4.9	4.8	4.2	5.1	-1.6%	-2.8%	3.6	-27.4%	-26.9%						
Reminyl	5.0	4.3	5.3	3.7	4.8	-4.4%	-4.7%	4.2	-0.5%	-0.1%						
Intuniv	2.7	2.9	2.9	1.3	4.1	53.3%	60.2%	4.0	34.2%	41.9%						
Other	4.5	4.5	5.6	4.0	6.0	33.4%	34.6%	5.4	18.3%	22.8%						
Other																
Azilva	19.4	15.8	20.5	15.0	20.5	5.4%	5.4%	18.2	15.5%	15.5%						
Nesina	14.1	12.7	15.6	12.3	14.6	3.3%	5.0%	14.0	10.3%	13.6%						
Uloric	14.1	12.4	14.0	10.6	12.2	-13.1%	-15.0%	1.8	-85.3%	-84.8%						
Colcrys	9.2	7.1	7.3	6.4	7.2	-22.4%	-24.1%	6.0	-15.8%	-13.3%						
Enbrel	9.9	8.2	9.8	7.3	8.7	-12.1%	-12.1%	7.2	-11.6%	-11.6%						
Lotriga	8.1	7.1	9.0	6.6	8.8	8.1%	8.1%	7.2	1.2%	1.2%						

*1 PDT products

*2 Pro-forma based product sales and therapeutic area sales which include Legacy Shire's products. Shire's 12 months (April 2018-March 2019) revenue under U.S. GAAP, excluding the oncology business which was divested in August 2018, converted to JPY using FY2018 actual rate for the period.

Other in PDT Immunology include Aralast, Glassia, Kenktsu-Nonthron and others

Other in Neuroscience include Copaxone, Rasagiline, Mydayis, Buccolam, Daytrana/Equasym and Carbatrol/Equetro

4. FY2018 Pro-forma and Product Forecasts

Pro-forma includes 12-month (April 2018 – March 2019) revenue of legacy Shire as if the acquisition of Shire had occurred on April 1, 2018. This pro-forma revenue may not represent what sales would have been had the acquisition of Shire had occurred on April 1, 2018.

(Bn JPY)	FY18 Reported Pro-forma *2					FY19 Forecasts*3
	Q1	Q2	Q3	Q4	Annual	Annual
GI	159.4	160.4	177.1	146.5	643.4	
Entyvio	61.3	67.1	72.6	68.2	269.2	↕↕
Dexilant	17.4	17.5	20.0	14.3	69.2	↕
Pantoprazole	16.2	14.5	16.2	14.7	61.6	↕
Takecab-F	14.3	13.0	17.1	13.9	58.2	↕↕
Gattex/Revestive	14.5	10.8	13.9	12.8	51.9	↕
Pentasa	8.4	7.3	9.4	4.7	29.8	↕
Lialda/Mezavant	11.7	13.6	11.2	3.3	39.9	↕↕↕
Amitiza	7.9	8.4	9.6	7.1	33.0	↕
Resolor/Motegrity	0.7	0.7	1.8	0.7	3.9	↕
Other	7.0	7.6	5.2	6.8	26.6	↕↕
Rare Metabolic	49.4	47.9	51.0	42.3	190.7	
Elaprase	19.1	18.9	19.1	15.1	72.2	↕
Replagal	13.6	13.6	13.4	11.4	52.0	↕
Vpriv	9.7	9.7	10.7	8.7	38.8	↕
Natpara	7.0	5.7	7.9	7.1	27.6	↕↕↕
Rare Hematology	105.2	102.1	107.6	66.7	381.6	
Advate	53.7	49.5	53.8	32.1	189.1	↕
Adynovate	13.2	15.4	15.4	10.7	54.7	↕
FEIBA *1	21.5	17.2	16.3	9.6	64.6	↕↕
Hemofil/Immunate/Immuline *1	5.5	5.7	7.2	5.5	24.0	↕
Other PDT Products *1	1.0	0.6	0.8	0.5	2.8	↕
Other	10.2	13.7	14.1	8.3	46.3	↕↕
Hereditary Angioedema	39.7	36.5	32.8	20.4	129.5	
Firazyr	23.0	15.6	24.4	6.4	69.3	↕↕↕
Takhzyro		5.7	1.2	9.7	16.7	↕↕↕
Kalbitor	1.9	2.3	2.1	1.2	7.4	↕↕↕
Cinryze *1	14.8	13.0	5.1	3.1	36.0	↕↕↕

*1 PDT products

*2 Pro-forma based product sales and therapeutic area sales which include Legacy Shire's products.

Shire's 12 months (April 2018-March 2019) revenue under U.S. GAAP, excluding the oncology business which was divested in August 2018, converted to JPY using FY2018 actual rate for the period.

*3 The respective arrow symbols indicate management's growth rate forecasts as denoted below as compared to FY18 revenue on a pro-forma basis

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

Other PDT products in Rare Hematology include Bebulin and Prothrombin.

Other in Rare Hematology include Vonvendi, Obizur, Rixubis, Agrylin/Xagrid, Recombinate, Other Hemophilia.

(Bn JPY)	FY18 Reported Pro-forma *2					FY19 Forecasts*3
	Q1	Q2	Q3	Q4	Annual	Annual
PDT Immunology	89.1	100.0	101.9	81.0	371.9	
Immunoglobulin *1	69.5	75.5	77.4	64.3	286.7	➔
Albumin *1	12.9	17.3	17.0	11.0	58.2	➔
Other *1	6.7	7.2	7.5	5.6	27.1	➔
Oncology	98.9	99.5	108.2	92.8	399.4	
Velcade	31.4	33.5	35.4	27.5	127.9	➔
Leuprorelin	28.6	26.5	29.5	25.4	110.1	➔
Ninlaro	14.0	15.4	17.1	15.7	62.2	➔
Adcetris	11.0	10.1	10.9	10.9	42.9	➔
Iclusig	7.0	7.2	7.4	7.1	28.7	➔
Alunbrig	1.1	1.2	1.5	1.4	5.2	➔
Vectibix	5.4	5.1	5.7	4.3	20.5	➔
Other	0.5	0.5	0.6	0.4	2.0	➔
Neuroscience	100.8	104.2	118.4	81.0	404.3	
Vyvanse	60.4	66.0	71.0	49.4	246.8	➔
Trintellix	14.1	13.0	17.5	12.9	57.6	➔
Adderall XR	8.8	8.6	11.3	5.4	34.1	➔
Rozerem	5.2	4.9	4.8	4.2	19.1	➔
Reminyl	5.0	4.3	5.3	3.7	18.3	➔
Intuniv	2.7	2.9	2.9	1.3	9.8	➔
Other	4.5	4.5	5.6	4.0	18.7	➔
Other						
Azilva	19.4	15.8	20.5	15.0	70.8	➔
Nesina	14.1	12.7	15.6	12.3	54.8	➔
Uloric	14.1	12.4	14.0	10.6	51.1	➔
Colcrys	9.2	7.1	7.3	6.4	30.0	➔
Enbrel	9.9	8.2	9.8	7.3	35.2	➔
Lotriga	8.1	7.1	9.0	6.6	30.9	➔

*1 PDT products

*2 Pro-forma based product sales and therapeutic area sales which include Legacy Shire's products.

Shire's 12 months (April 2018-March 2019) revenue under U.S. GAAP, excluding the oncology business which was divested in August 2018, converted to JPY using FY2018 actual rate for the period.

*3 The respective arrow symbols indicate management's growth rate forecasts as denoted below as compared to FY18 revenue on a pro-forma basis

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

Other in PDT Immunology include Aralast, Glassia, Kenktsu-Nonthron and others

Other in Neuroscience include Copaxone, Rasagiline, Mydayis, Buccolam, Daytrana/Equasym and Carbatrol/Equetro

5. Exchange Rate

(yen)

Average Exchange Rates vs. JPY			
CURRENCY	FY18 Q2 (Apr-Sep)	FY19 Q2 (Apr-Sep)	FY19 Assumption
USD	110	109	109
EUR	130	122	121
RUB	1.8	1.7	1.7
CNY	16.7	15.9	15.5
BRL	29.7	27.7	26.9

(100 million yen)

Impact of 1% depreciation of yen from October 2019 to March 2020			
REVENUE	CORE OPERATING PROFIT	OPERATING PROFIT	NET PROFIT
+80.3	+28.3	-4.8	-8.1
+21.0	+4.7	-1.0	-1.3
+2.6	+1.4	+1.1	+0.8
+4.0	+1.1	+1.0	+0.7
+2.4	+0.8	+0.6	+0.4

6. CAPEX, depreciation and amortization and impairment losses

						(Bn JPY)
	FY18	FY18Q2 YTD	FY19Q2 YTD	YOY		FY19 Forecasts
Capital expenditures	244.6					180.0 - 230.0
Tangible assets*	188.4					
Intangible assets*	56.2					
* Excluding increase due to acquisition.						
Depreciation and amortization	271.9	77.8	342.0	264.2	-	
Depreciation of tangible assets*	63.3	25.4	72.3	46.9	184.2%	
Amortization of intangible assets	208.6	52.3	269.7	217.3	-	
Amortization associated with products	194.7	47.6	256.3	208.7	-	516.0
* Excluding depreciation for investment assets.						
Impairment losses	10.1	0.6	18.6	18.0	-	
Impairment losses associated with products	8.6	0.6	17.3	16.7	-	121.0
Amortization and impairment losses on intangible assets associated with products	203.4	48.3	273.7	225.4	-	637.0

7. Reconciliation from Reported Revenue to Underlying Revenue

(Bn JPY)	FY2018 ^{*1} H1	FY2019 H1	vs. PY	
Revenue	880.6	1,660.2	+779.6	+88.5%
Shire Revenue	848.9	-		
Pro-forma Revenue	1,729.5	1,660.2	-69.3	-4.0%
FX effects ^{*2}				+2.8pp
Divestitures ^{*3}				+1.0pp
Techpool & Multilab				+0.4pp
XIIDRA & TACHOSIL				+0.7pp
Others				-0.1pp
Underlying Revenue Growth				-0.2%

*1 FY2018 H1 revenue is a pro-forma which adds Legacy Shire's 6 month (April - September 2018) revenue previously reported under US GAAP and conformed to IFRS without material differences, excluding Legacy Shire's oncology business, which was sold in August 2018, and converted to JPY using FY2018 actual rate for the period.

*2 FX adjustment applies constant FY2018 actual full year average rate to both years (1USD=111 yen, 1EUR=129 yen).

*3 Major adjustments are the exclusion of FY2018 H1 revenue of former subsidiaries, Guangdong Techpool Bio-Pharma Co., Ltd., and Multilab Indústria e Comércio de Produtos Farmacêuticos Ltda., both divested in FY2018, and FY2018 H1 and FY2019 H1 revenue of XIIDRA which was divested in July 2019 and TACHOSIL as Takeda agreed in May 2019 to divest this product, with completion of divestiture expected to occur within FY2019.

8. Reconciliation from Reported to Core/Underlying Core – FY2019 H1

(Bn JPY)	REPORTED	REPORTED TO CORE ADJUSTMENTS						CORE	CORE TO UNDERLYING CORE ADJ.		UNDERLYING CORE
		Amortization & impairment of intangible assets	Other operating income/expense	Shire acquisition related costs	Shire purchase accounting adjustments	Swiss Tax Reform	Others		FX	Divestitures	
Revenue	1,660.2							1,660.2	44.2	-21.2	
Cost of sales	-572.3				137.8			-434.5	-11.0	3.0	
Gross Profit	1,087.9				137.8			1,225.7	33.1	-18.2	
SG&A expenses	-462.5			1.4	2.3			-458.8	-11.9		
R&D expenses	-230.4			5.2	-0.1			-225.3	-3.0		
Amortization of intangible assets	-256.3	45.0			211.3			-			
Impairment losses on intangible assets	-17.3	17.3						-			
Other operating income	11.3		-11.3					-			
Other operating expenses	-82.4		23.6	58.8				-			
Operating profit Margin	50.3 3.0%	62.3	12.3	65.3	351.4			541.6 32.6%	18.2	-18.2	32.2%
Financial income/expenses	-81.9			3.5	8.4		-0.4	-70.3	4.2		
Equity income/loss	4.0						1.2	5.3	0.0		
Profit before tax	-27.6	62.3	12.3	68.8	359.8		0.9	476.5	22.4	-18.2	
Tax expense	60.8	-11.1	1.6	-13.1	-68.1	-56.3	-9.9	-96.1	-1.4	4.3	
Non-controlling interests	-0.1							-0.1	-0.0		
Net profit	33.2	51.3	14.0	55.7	291.6	-56.3	-9.0	380.4	21.0	-13.9	
EPS (yen)	21							244	14	-9	249
Number of shares (millions)	1,557							1,557			1,555

9. Reconciliation from Reported to Core – FY2018 H1

(Bn JPY)	REPORTED	REPORTED TO CORE ADJUSTMENTS				CORE
		Amortization & impairment of intangible assets	Other operating income/expense	Shire acquisition related costs	Others	
Revenue	880.6					880.6
Cost of sales	-231.3					-231.3
Gross Profit	649.3					649.3
SG&A expenses	-293.8			7.9		-285.9
R&D expenses	-151.4					-151.4
Amortization of intangible assets	-47.6	47.6				-
Impairment losses on intangible assets	-0.6	0.6				-
Other operating income	32.3		-32.3			-
Other operating expenses	-16.1		13.0	3.2		-
Operating profit	172.0	48.3	-19.3	11.1		212.0
Margin	19.5%					24.1%
Financial income/expenses	-15.2			8.8	1.4	-5.1
Equity income/loss	4.0				1.8	5.8
Profit before tax	160.8	48.3	-19.3	19.8	3.1	212.7
Tax expense	-34.3	-11.6	2.1	-3.4	-0.6	-47.7
Non-controlling interests	0.2					0.2
Net profit	126.7	36.7	-17.2	16.5	2.6	165.2
EPS (yen)	162					211
Number of shares (millions)	783					783

10. Reconciliation from Net Profit to EBITDA/Adjusted EBITDA

(Bn JPY)	FY2019 H1	FY2019 LTM ^{*1}
Net profit for the year	33.3	15.8
Income tax expenses	-60.8	-109.2
Depreciation and amortization	342.0	536.4
Interest expense, net	71.0	109.1
EBITDA	385.4	552.1
Impairment losses	18.6	28.0
Other operating expense (income), net, excluding depreciation and amortization	69.7	28.7
Finance expense (income), net, excluding interest income and expense, net	10.9	24.0
Share of loss on investments accounted for under the equity method	-4.0	43.6
Other adjustments:		
Impact on profit related to fair value step up of inventory in Shire acquisition	132.1	214.3
Acquisition costs related to Shire	1.2	17.1
Other costs ^{*2}	19.0	31.3
Adjusted EBITDA	632.9	939.1
Legacy Shire's Adjusted EBITDA ^{*3}	-	192.1
Pro-forma Adjusted EBITDA	632.9	1,131.2

*1 LTM represents Last Twelve Months (October 2018 – September 2019).

*2 Includes adjustment for non-cash equity based compensation expense starting from FY2019 Q1.

*3 Represents Legacy Shire's adjusted EBITDA based on its financial information converted to IFRS for the corresponding period.

There was no significant difference in the definition of and methodology for adjusted EBITDA between Legacy Takeda and Legacy Shire.

Pipeline

1. Clinical Development Activities

- The following table lists the pipeline assets that we are developing as of October 31, 2019. The assets in our pipeline are in various stages of development, and the contents of the pipeline may change as compounds currently under development drop out and new compounds are introduced. Whether the compounds listed below are ever successfully released as products depends on various factors, including the results of pre-clinical and clinical trials, market conditions for various drugs and regulatory approvals.
- 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 U.S., EU and Japan and China, but we are also actively conducting development activities in other regions, including in Emerging Markets. Country/region in the "Stage" column denote where a clinical study is ongoing or a filing has been made with our specific intention to pursue approval in any of the U.S., EU, Japan or China. 'Global' refers to U.S., EU, Japan and China.
- Brand name and country/region indicate the brand name and country in which the specific asset has already been approved for any indication in any of the U.S., EU, Japan or China and Takeda has commercialization rights for such asset.
- Stage-ups are recognized in the table upon achievement of First Subject In.

■ Oncology Pipeline

Development code <generic name> Brand name (country/region)	Drug Class (administration route)	Indications / additional formulations	Stage
SGN-35*1 <brentuximab vedotin> ADCETRIS (EU, Japan)	CD30 monoclonal antibody-drug conjugate (injection)	Front line Peripheral T-cell Lymphoma	EU Japan Filed (June 2019) Filed (March 2019)
		Relapsed/refractory Hodgkin Lymphoma	China Filed (March 2019)
		Relapsed/refractory systemic Anaplastic large-cell lymphoma	China Filed (March 2019)
<brigatinib> ALUNBRIG (U.S., EU)	ALK inhibitor (oral)	1L ALK-positive Non-Small Cell Lung Cancer	EU U.S. Japan China P-III P-III P-III
		2L ALK-positive Non-Small Cell Lung Cancer (head-to-head with alectinib)	Global P-III
		2L ALK-positive Non-Small Cell Lung Cancer in patients previously treated with ALK inhibitors	Japan China P-II(a) P-II(a)
		2L ALK-positive Non-Small Cell Lung Cancer in patients progressed on 2nd generation Tyrosine Kinase Inhibitors	Global P-II
MLN9708 <ixazomib> NINLARO (Global)	Proteasome inhibitor (oral)	Maintenance therapy in patients with newly diagnosed Multiple Myeloma following autologous stem cell transplant	Japan U.S. EU China Filed (April 2019) P-III P-III P-III
		Newly diagnosed Multiple Myeloma	Global P-III
		Maintenance therapy in patients with newly diagnosed Multiple Myeloma not treated with stem cell transplant	Global P-III
		Relapsed/refractory Multiple Myeloma (doublet regimen with dexamethasone)	U.S. EU Japan P-III P-III P-III
		Relapsed/refractory Multiple Myeloma (triplet regimen with daratumumab and dexamethasone)	Global P-II
<cabozantinib>*2	Multi-targeted kinase inhibitor (oral)	2L Renal cell carcinoma	Japan Filed (April 2019)
		1L Renal cell carcinoma in combination with nivolumab	Japan P-III
		2L Hepatocellular carcinoma	Japan P-II(a)
<ponatinib> ICLUSIG (U.S.)	BCR-ABL inhibitor (oral)	Front line Philadelphia chromosome-positive Acute Lymphoblastic Leukemia	U.S. P-III
		Dose ranging study for Tyrosine Kinase Inhibitor-resistant patients with chronic-phase Chronic Myeloid Leukemia	U.S. P-II(b)
TAK-924 <pevonedistat>	NEDD 8 activating enzyme inhibitor (injection)	High-risk Myelodysplastic Syndromes, Chronic Myelomonocytic Leukemia, Low-blast Acute Myelogenous Leukemia	U.S. EU Japan P-III P-III P-III
TAK-385 <relugolix>	LH-RH antagonist (oral)	Prostate cancer	Japan China P-III P-I
<niraparib>*3	PARP1/2 inhibitor (oral)	Ovarian cancer – maintenance	Japan P-II
		Ovarian cancer – salvage	Japan P-II

TAK-788	EGFR/HER2 exon 20 inhibitor (oral)	Non-Small Cell Lung Cancer with Exon-20 insertion	Global	P-II
TAK-931	CDC7 inhibitor (oral)	Squamous esophageal cancer, Squamous Non-Small Cell Lung Cancer		P-II(a)
TAK-079	Anti-CD38 monoclonal antibody (injection)	Relapsed/refractory Multiple Myeloma Systemic lupus erythematosus	-	P-I P-I
TAK-164	Anti-guanylyl cyclase C antibody drug conjugate (injection)	GI malignancies	-	P-I
TAK-573*4	CD38-targeted IgG4 genetically fused with an attenuated IFN α (injection)	Relapsed/refractory Multiple Myeloma	-	P-I
TAK-981	SUMO inhibitor (injection)	Multiple cancers	-	P-I
TAK-252 / SL-279252*5	PD-1-Fc-OX40L (injection)	Solid tumors		P-I

*1 Partnership with Seattle Genetics, Inc.

*2 Partnership with Exelixis, Inc.

*3 Partnership with GlaxoSmithKline

*4 Partnership with Teva Pharmaceutical Industries Ltd.

*5 Partnership with Shattuck Labs, Inc.

Removals since FY2019 Q1: TAK-659 – for DLBCL and hematologic malignancies – discontinued

TAK-228 – for endometrial cancer - discontinued

■ GI Pipeline

Development code		Drug Class (administration route)	Indications / additional formulations	Stage	
<generic name> Brand name (country/region)					
MLN0002 <vedolizumab> <i>ENTYVIO</i> (U.S., EU, Japan)	Humanized monoclonal antibody against $\alpha 4\beta 7$ integrin (injection)	Crohn's disease	China	Filed (May 2019)	
		Ulcerative colitis	China	Filed (May 2019)	
		Subcutaneous formulation for ulcerative colitis	U.S.	Filed (March 2019)	
			EU	Filed (March 2019)	
			Japan	Filed (August 2019)	
		Subcutaneous formulation for Crohn's disease	EU	Filed (March 2019)	
			U.S. Japan	P-III P-III	
Graft-versus-Host Disease prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	EU Japan	P-III P-III			
Pediatrics Study (ulcerative colitis, Crohn's disease)	Global	P-II			
TAK-438 <vonoprazan> <i>TAKECAB</i> (Japan)	Potassium-competitive acid blocker (oral)	Acid-related diseases	China	Filed (February 2018)	
TAK-633/SHP633 <teduglutide> <i>GATTEX</i> (U.S.) <i>REVESTIVE</i> (EU)	GLP-2 analogue (injection)	Short bowel syndrome (pediatric indication)	Japan	P-III	
		Short bowel syndrome (in adults)	Japan	P-III	
Cx601 <darvadstrocel> <i>ALOFISEL</i> (EU)	A suspension of allogeneic expanded adipose-derived stem cells (injection)	Refractory complex perianal fistulas in patients with Crohn's disease	U.S. Japan	P-III P-III	
TAK-721/SHP621*1 <budesonide>	Glucocorticosteroid (oral)	Eosinophilic esophagitis	U.S.	P-III	
TAK-906	Dopamine D2/D3 receptor antagonist (oral)	Gastroparesis	-	P-II(b)	
TAK-954*2	5-HT $_4$ - hydroxytryptamine receptor agonist (injection)	Post-operative gastrointestinal dysfunction	-	P-II(b)	
TAK-101*3	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Celiac disease	-	P-II(a)	
TAK-951	Peptide agonist	Nausea and vomiting	-	P-I	
TAK-671	Protease inhibitor (injection)	Acute pancreatitis	-	P-I	
TAK-018/EB8018*4	FimH antagonist (oral)	Crohn's disease (post-operative and ileitis)	-	P-I	
TAK-681	GLP-2 long-acting analogue (injection)	Short bowel syndrome		P-I	

Kuma062*5	Glutenase (oral)	Celiac disease	-	P-I
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*1 Partnership with UCSD and Fortis Advisors

*2 Partnership with Theravance Biopharma, Inc.

*3 Acquired license for TAK-101 from Cour Pharmaceutical Development Company. Previously known as TIMP-GLIA.

*4 Partnership with Enterome Bioscience SA

*5 Partnership with PVP Biologics, Inc. PVP leads Phase 1 development.

Additions since FY2019 Q1: MLN0002 Pediatrics Study (ulcerative colitis, Crohn's disease) (Global P-II)

■ Rare Diseases Pipeline

Development code				
<generic name> Brand name (country/region)	Drug Class (administration route)	Indications / additional formulations	Stage	
TAK-743/SHP643 <lanadelumab> TAKHZYRO (U.S., EU)	Plasma kallikrein inhibitor (injection)	Hereditary angioedema	China	Filed (December 2018)
TAK-577/SHP677 VONVENDI (U.S.), VEYVONDI (EU)	von Willebrand factor [recombinant] (injection)	von Willebrand disease	Japan	Filed (July 2019)
		Prophylactic treatment of von Willebrand disease	Global	P-III
		Pediatric on-demand treatment of von Willebrand disease	Global	P-III
TAK-672/SHP672*1 OBIZUR (U.S., EU)	Antihemophilic factor [recombinant], porcine sequence (injection)	Congenital hemophilia A with inhibitors	U.S. EU	P-III P-III
TAK-660/SHP660 ADYNOVATE (U.S., Japan), ADYNOVI (EU)	Antihemophilic factor [recombinant], PEGylated (injection)	Pediatric Hemophilia A	EU	P-III
TAK-755/SHP655*2	Replacement of the deficient-ADAMTS13 enzyme (injection)	Congenital Thrombotic Thrombocytopenic Purpura	U.S. EU	P-III P-III
		Immune Thrombotic Thrombocytopenic Purpura	U.S. EU	P-II P-II
		Sickle cell disease	U.S.	P-I/II
TAK-620/SHP620*3 <maribavir>	Benzimidazole riboside inhibitor (oral)	Cytomegalovirus infection in transplant patients	U.S. EU	P-III P-III
TAK-607/SHP607	Insulin-like Growth Factor / IGF Binding Protein (injection)	Chronic lung disease	-	P-II
TAK-609/SHP609	Recombinant human iduronate-2-sulfatase for intrathecal administration (injection)	Hunter syndrome CNS	U.S. EU	P-II P-II
TAK-611/SHP611	Recombinant human arylsulfatase A (injection)	Metachromatic leukodystrophy	-	P-II
TAK-754/SHP654*4	Gene therapy to restore endogenous FVIII expression	Hemophilia A	-	P-I/II
TAK-531/SHP631*5	Fusion protein of iduronate- 2-sulfatase+antibody (injection)	Hunter syndrome CNS	-	P-I
TAK-834/SHP634 NATPARA (U.S.), NATPAR (EU)	Parathyroid hormone (injection)	Hypoparathyroidism	Japan	P-I*6

*1 Partnership with Ipsen

*2 Partnership with KM Biologics

*3 Partnership with GlaxoSmithKline

*4 Partnership with Asklepios Biopharmaceuticals

*5 Partnership with ArmaGen

*6 NATPARA P-I study in Japan completed; P-III study to start in H2 FY2019

Additions since FY2019 Q1: TAK-755 for Immune Thrombotic Thrombocytopenic Purpura (P-II)

TAK-755 for Sickle cell disease (P-I/II)

■ Neuroscience Pipeline

Development code <generic name> Brand name (country/region)	Drug Class (administration route)	Indications / additional formulations	Stage	
TAK-815/SHP615 <midazolam> BUCCOLAM (EU)	GABA Allosteric Modulator (oral)	Status epilepticus (seizures)	Japan	P-III
TAK-831	D-amino acid oxidase (DAAO) inhibitor (oral)	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-II(a)
TAK-935*1	CH24H inhibitor (oral)	Rare pediatric epilepsies	-	P-II(a)
WVE-120101*2	mHTT SNP1 antisense oligonucleotide (injection)	Huntington's disease	-	P-I/II
WVE-120102*2	mHTT SNP2 antisense oligonucleotide (injection)	Huntington's disease	-	P-I/II
TAK-041	GPR139 agonist (oral)	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
MEDI1341*3	Alpha-synuclein antibody (injection)	Parkinson's disease	-	P-I
TAK-418	LSD1 inhibitor (oral)	Kabuki syndrome	-	P-I
TAK-653	AMPA receptor potentiator (oral)	Treatment resistant depression	-	P-I
TAK-925	Orexin 2R agonist (injection)	Narcolepsy	-	P-I
TAK-994	Orexin 2R agonist (oral)	Narcolepsy	-	P-I

*1 Co-development with Ovid Therapeutics Inc.

*2 50:50 co-development and co-commercialization option with Wave Life Sciences Ltd.

*3 Partnership with AstraZeneca. AstraZeneca leads Phase 1 development

Additions since FY2019 Q1: TAK-994 – Narcolepsy (P-I)

Removals since FY2019 Q1: TRINTELLIX – Major depressive disorder – (Japan, Approved Sept 2019)

■ Plasma-Derived Therapies Pipeline

Development code <generic name> Brand name (country/region)	Drug Class (administration route)	Indications / additional formulations	Stage	
TAK-616/SHP616 CINRYZE (U.S., EU)	C1 esterase inhibitor [human] (injection)	Hereditary angioedema	Japan	P-III
TAK-771/SHP671*1 <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase> HYQVIA (U.S., EU)	Immunoglobulin (IgG) + recombinant hyaluronidase replacement therapy (injection)	Pediatric indication for primary immunodeficiency	U.S.	P-III
		Chronic inflammatory demyelinating polyradiculoneuropathy	U.S. EU	P-III P-III

*1 Partnership with Halozyme

■ Vaccines Pipeline

Development code Brand name (country/region)	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-021	EV71 vaccine (injection)	Prevention of hand, foot and mouth disease caused by enterovirus 71	-	P-I
TAK-426*1	Zika vaccine (injection)	Prevention of zika virus infection	-	P-I

*1 Partnership with The Biomedical Advanced Research and Development Authority (BARDA) - U.S. Government

2. Recent Progress in stage [Progress in stage disclosed since release of FY2018 results (May 14th, 2019)]

Development code <generic name>	Indications / additional formulations	Country/Region	Progress in stage
MLN0002 <vedolizumab>	Crohn's disease	Japan	Approved (May 2019)
TAK-633/SHP633 <teduglutide>	Short bowel syndrome (pediatric indication)	U.S.	Approved (May 2019)
MLN0002 <vedolizumab>	Crohn's disease	China	Filed (May 2019)
MLN0002 <vedolizumab>	Ulcerative colitis	China	Filed (May 2019)
SGN-35 <brentuximab vedotin>	Front line Peripheral T-cell Lymphoma	EU	Filed (June 2019)
<brigatinib>	1L ALK-positive Non-Small Cell Lung Cancer	EU	Filed (June 2019)
TAK-577 / SHP677	von Willebrand disease	Japan	Filed (July 2019)
Lu AA21004 <vortioxetine>	Depression and depressed state	Japan	Approved (Sept 2019)
MLN0002 <vedolizumab>	Subcutaneous formulation for ulcerative colitis	Japan	Filed (August 2019)
MLN0002 <vedolizumab>	Graft-versus-Host Disease prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	Japan	P-III
<brigatinib>	1L ALK-positive Non-Small Cell Lung Cancer	Japan, China	P-III
MLN0002 <vedolizumab>	Pediatrics Study (ulcerative colitis, Crohn's disease)	Global	P-II
TAK-755	Immune Thrombotic Thrombocytopenic Purpura	U.S., EU	P-II
TAK-755	Sickle cell disease	U.S.	P-I/II
TAK-994	Narcolepsy	-	P-I

Progress in stage disclosed since the announcement of FY2019 Q1 results (July 31, 2019) are listed under the bold dividing line

3. Discontinued projects [Update disclosed since release of FY2018 results (May 14th, 2019)]

Development code <generic name>	Indications (Stage)	Reason
MLN9708 <ixazomib>	Relapsed/refractory primary amyloidosis (Global P-III)	Failed primary endpoint; encouraging secondary endpoint data will be submitted for presentation at an upcoming scientific meeting
TAK-659	DLBCL, hematologic malignancies	Despite promising data from current and completed studies, TAK-659 does not meet the high innovation bar we have established
TAK-228 <sapanisertib>	Endometrial cancer	Clinical results do not justify continued development in an indication outside of the therapeutic area strategy

Updates disclosed since the announcement of FY2019 Q1 results (July 31, 2019) are listed under the bold dividing line

4. Exploring Alternative Value Creation [Update disclosed since release of FY2018 results (May 14th, 2019)]

Development code <generic name>	Indications (Stage)	Reason
TAK-438 <vonoprazan>	Gastro esophageal reflux disease in patients who have a partial response following treatment with a proton pump inhibitor (EU, P-II(b))	Takeda has granted a license to Phathom Pharmaceuticals for the development and exclusive commercialization rights to vonoprazan in the U.S., Europe and Canada in exchange for upfront cash and equity, as well as future cash milestones and royalties on net sales.

5. Main Research & Development collaborations*

Oncology

Partner	Country	Subject
Adimab	U.S.	Agreement for the discovery, development and commercialization of three mAbs and three CD3 Bi-Specific antibodies for oncology indications.
Centre d'Immunologie de Marseille-Luminy	France	Collaboration agreement to bring together expertise and knowledge in innate biology with Takeda's BacTrap capabilities to identify novel targets and pathways in myeloid cells.
ASKA Pharmaceutical Co., Ltd	Japan	Takeda granted exclusive commercialization rights for uterine fibroids and exclusive development and commercialization rights for endometriosis for Japan to maximize the product value of relugolix (TAK-385).
Crescendo Biologics	U.K.	Collaboration and licensing agreement for the discovery, development and commercialization of Humabody [®] -based therapeutics for cancer indications.
CuraDev‡	U.K.	Curadev has licensed its novel lead small molecule Stimulator of Interferon Genes (STING) agonist (referred to by Curadev as CRD5500) and associated patents to Takeda.
Exelixis, Inc.	U.S.	Exclusive licensing agreement to commercialize and develop novel cancer therapy cabozantinib and all potential future cabozantinib indications in Japan, including advanced renal cell carcinoma and hepatocellular carcinoma.
GammaDelta Therapeutics	U.K.	Collaboration agreement to discover and develop new immunotherapies in oncology using GammaDelta Therapeutics' novel T cell platform based on the unique properties of gamma delta T cells derived from human tissues.
Haemalogix	Australia	Research collaboration and licensing agreement for the development of new therapeutics to novel antigens in multiple myeloma.
Heidelberg Pharma	Germany	Antibody-Drug-Conjugate (ADC) research collaboration on 2 targets and licensing agreement (α -amanitin payload and proprietary linker).
ImmunoGen, Inc.	U.S.	Licensing agreement for rights to use ImmunoGen's Inc. ADC technology to develop and commercialize targeted anticancer therapeutics (TAK-164).
Maverick Therapeutics	U.S.	Collaboration agreement for the development of Marveric Therapeutics' T-cell engagement platform created specifically to improve the utility of T-cell redirection therapy for the treatment of cancer. Under the agreement, Takeda have the exclusive option to acquire Marverick Therapeutics after 5 years.
Memorial Sloan Kettering Cancer Center	U.S.	Alliance to discover and develop novel Chimeric Antigen Receptor T (CAR-T) cell products for the potential treatment of hematological malignancies and solid tumors.
Molecular Templates	U.S.	Initial collaboration agreement applied Molecular Templates' engineered toxin bodies (ETBs) technology platform to potential therapeutic targets. The second collaboration agreement is for the joint development of CD38-targeted ETBs for the treatment of patients with diseases such as multiple myeloma. [‡]
Myovant Sciences	Switzerland	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).
National Cancer Center of Japan	Japan	Partnership agreement 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.
Nektar Therapeutics	U.S.	Research collaboration agreement to explore combination cancer therapy with five Takeda oncology compounds and Nektar's lead immuno-oncology candidate, the CD122-biased agonist NKTR-214.
Noile-Immune Biotech	Japan	Collaboration agreement for the development of next generation CAR-T cell therapy, developed by Professor Koji Tamada at Yamaguchi University. Takeda has exclusive options to obtain licensing rights for the development and commercialization of Noile-Immune Biotech's pipeline and products resulting from this partnership. Due to the success of the collaboration, Takeda licensed NIB-102 and NIB-103.
Seattle Genetics	U.S.	Agreement for the joint development of ADCETRIS, an ADC technology which targets CD30 for the treatment of HL. Approved in 67 countries with ongoing clinical trials for additional indications.
Shattuck Labs	U.S.	Collaboration agreement to explore and develop checkpoint fusion proteins utilizing Shattuck's unique Agonist Redirected Checkpoint (ARC) [™] platform which enables combination immunotherapy with a single product. Takeda will have the option to take an exclusive license to further develop and commercialize TAK-252/SL-279252
GlaxoSmithKline	U.K.	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.
Teva	Israel	Agreement for worldwide License to TEV-48573 (TAK-573) (CD38-Attenukine) and multi-target discovery collaboration accessing Teva's attenukine platform.

‡ Executed since April 1, 2019

Gastroenterology

Partner	Country	Subject
Ambys Medicines	U.S.	Collaboration agreement for the application of novel modalities, including cell and gene therapy and gain-of-function drug therapy, to meet the urgent need for treatments that restore liver function and prevent the progression to liver failure across multiple liver diseases. Under the terms of the agreement, Takeda has an option to ex-U.S. commercialization rights for the first 4 products that reach an investigational new drug application.
Arcturus	U.S.	Collaboration agreement to develop RNA-based therapeutics for the treatment of non-alcoholic steatohepatitis and other gastrointestinal related disorders using Arcturus' wholly-owned LUNAR™ lipid-mediated delivery systems and UNA Oligomer chemistry.
Beacon Discovery	U.S.	Collaboration agreement for the G-protein coupled receptor drug discovery and development program to identify drug candidates for a range of gastrointestinal disorders. The agreement grants Takeda worldwide rights to develop, manufacture and commercialize products resulting from the collaboration.
Cour Pharmaceutical Development Company‡	U.S.	Takeda has acquired an exclusive global license to develop and commercialize the investigational medicine TIMP-GLIA (TAK-101), an immune modifying nanoparticle containing gliadin proteins.
Enterome	France	Collaboration agreement to research and develop microbiome targets thought to play crucial roles in gastrointestinal disorders, including inflammatory bowel diseases (e.g. ulcerative colitis). The agreement includes a global license and co-development of EB8018/TAK-018 in Crohn's disease.
Finch Therapeutics	U.S.	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 inflammatory bowel disease. Under the terms of the agreement, Takeda obtains the exclusive worldwide rights to develop and commercialize FIN-524 and rights to follow-on products in inflammatory bowel diseases.
Hemoshear Therapeutics	U.S.	Collaboration agreement for novel target and therapeutic development for liver diseases, including nonalcoholic steatohepatitis using Hemoshear's proprietary REVEAL-Tx drug discovery platform.
Janssen	Belgium	Exclusive license agreement to develop and market prucalopride as a treatment for chronic constipation in the U.S. Motegrity, approved in December 2018.
NuBiyota	Canada	Agreement for the development of Microbial Ecosystem Therapeutic products for gastroenterology indications.
PvP Biologics	U.S.	Global agreement to develop Kuma062, a novel enzyme designed to break down the immune-reactive parts of gluten in the stomach. Under the terms of the agreement, Takeda obtains an exclusive option to acquire PvP Biologics following receipt of a pre-defined data package.
Phathom Pharmaceuticals‡	U.S.	Takeda has granted a license to Phathom Pharmaceuticals for the development and exclusive commercialization rights to vonoprazan in the U.S., Europe and Canada in exchange for upfront cash and equity, as well as future cash milestones and royalties on net sales.
Samsung Bioepis	Korea	Strategic collaboration agreement to jointly fund and co-develop multiple novel biologic therapies in unmet disease areas. The program's first therapeutic candidate is TAK-671, which is intended to treat severe acute pancreatitis.
Theravance Biopharma	U.S.	Global license, development and commercialization agreement for TAK-954, a selective 5-HT4 receptor agonist for motility disorders.
UCSD/Fortis Advisors	U.S.	Technology license for the development of oral budesonide formulation (TAK-721/SHP621) for treatment of eosinophilic esophagitis.

‡ Executed since April 1, 2019

Rare Diseases

Partner	Country	Subject
AB Biosciences	U.S.	Research collaboration agreement to potentially develop assets for rare disease with pan-receptor interacting molecules targeted for specific immunological conditions with a focus on autoimmune modulated inflammatory diseases
ArmaGen	U.S.	Worldwide licensing and collaboration agreement to develop AGT-182 (TAK-531/SHP631), an investigational enzyme replacement therapy for potential treatment of both the central nervous system (CNS) and somatic (body-related) manifestations of Hunter syndrome.
Asklepios Biopharmaceuticals	U.S.	Agreement for multiple research and development collaborations using FVIII Gene Therapy for the treatment of Hemophilia A and B.
BioMarin	U.S.	Agreement for the in-license of enabling technology for the exogenous replacement of iduronate-2-sulfatase with Idursulfase-IT in patients via direct delivery to the CNS for the long-term treatment of Hunter Syndrome in patients with cognitive impairment in order to slow progression of cognitive impairment (TAK-609/SHP609).
GlaxoSmithKline	U.K.	In-license agreement between GSK and University of Michigan for TAK-620/SHP620 (marabivir) in the treatment of human cytomegalovirus.
Harrington Discovery Institute at University Hospitals in Cleveland, Ohio	U.S.	Collaboration agreement for the advancement of medicines for rare diseases.
IPSEN	France	Purchase agreement for the development of Obizur for the treatment of Acquired Hemophilia A including for patients with Congenital Hemophilia A with inhibitors indication in elective or emergency surgery.
KM Biologics	Japan	Agreement for the development collaboration of TAK-755/SHP655 to overcome the ADAMTS13 deficiency, induce clinical remission thus reducing cTTP and aTTP related morbidity and mortality.
NanoMedSyn	France	Pre-clinical research collaboration agreement to evaluate a potential enzyme replacement therapy using NanoMedSyn's proprietary synthetic derivatives named AMFA
Novimmune	Switzerland	Agreement for the exclusive worldwide rights to develop and commercialize an innovative, bi-specific antibody in pre-clinical development for the treatment of hemophilia A

Rani Therapeutics	U.S.	Research collaboration agreement to evaluate a micro tablet pill technology for oral delivery of FVIII therapy in hemophilia
Ultragenyx	U.S.	Collaboration agreement to develop and commercialize therapies for rare genetic diseases.
Xenetic Biosciences	U.S.	Exclusive R & D license agreement for PolyXen delivery technology for hemophilia factors VII, VIII, IX, X.

Neuroscience

Partner	Country	Subject
AstraZeneca	UK	Agreement for the joint development and commercialization of MEDI1341, an alpha-synuclein antibody currently in development as a potential treatment for Parkinson's disease.
Denali Therapeutics	U.S.	Strategic option and collaboration agreement to develop and commercialize up to three specified therapeutic product candidates for neurodegenerative diseases, incorporating Denali's ATV platform for increased exposure of biotherapeutic products in the brain.
Lundbeck	Denmark	Collaboration agreement to develop and commercialize vortioxetine.
Mindstrong Health	U.S.	Agreement to explore development of digital biomarkers for selected mental health conditions, in particular schizophrenia and treatment-resistant depression.
Ovid Therapeutics	U.S.	Agreement for the 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.
Skyhawk Therapeutics‡	U.S.	Collaboration and licensing agreement to develop and commercialize RNA modulation therapies targeting neurodegenerative diseases.
StrideBio	U.S.	Collaboration and license agreement to develop <i>in vivo</i> AAV based therapies for Friedreich's Ataxia (FA) and two additional undisclosed targets.
Wave Life Sciences	Singapore	Research, development and commercial collaboration and multi-program option agreement to develop antisense oligonucleotides for a range of neurological diseases.

‡ Executed since April 1, 2019

Plasma Derived Therapies

Partner	Country	Subject
Halozyme	U.S.	Agreement for the in-license of Halozyme's proprietary ENHANZE™ platform technology to increase dispersion and absorption of HyQvia. Ongoing development work for a U.S. pediatric indication to treat primary immunodeficiencies and a Phase 3 indication in Chronic Inflammatory Demyelinating Polyradiculoneuropathy.
Kamada	Israel	In-license agreement to develop and commercialize Alpha-1 proteinase inhibitor (Glassia) ; Exclusive supply and distribution of Glassia in the U.S., Canada, Australia and New Zealand; Development of protocol for post market commitment trial ongoing.

Vaccines

Partner	Country	Subject
Biological E. Limited	India	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.
U.S. Government - The Biomedical Advanced Research and Development Authority (BARDA)	U.S.	Partnership to develop TAK-426, a Zika vaccine candidate, to support the Zika response in the U.S. and affected regions around the world.
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
Bridge Medicines	U.S.	Partnership with Tri-Institutional Therapeutics Discovery Institute, Bay City Capital and Deerfield Management in the establishment of Bridge Medicines. 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	Collaboration agreement for clinical applications of iPS cells in Takeda strategic areas including applications in neurosciences, oncology and GI as well as discovery efforts in additional areas of compelling iPSC translational science.
HiFiBio	U.S.	Collaboration agreement for functional therapeutics high-throughput antibody discovery platform that enables identification of antibodies for rare events for discovery of therapeutic antibodies for GI & Oncology therapeutic areas.
HitGen	China	Agreement that HitGen will apply its advanced technology platform, based on DNA-encoded library design, synthesis and screening, to discover novel leads which will be licensed exclusively to Takeda.
Isogenica	UK	Agreement for the access to a sdAb platform to generate a toolbox of VHH to various immune cells and targets for pathway validation and pipeline development across Oncology and GI portfolio.
Numerate	U.S.	Agreement for joint-discovery programs aimed at identifying clinical candidates for use in Takeda's core therapeutic areas: oncology, gastroenterology, and central nervous system disorders, which is using its AI-driven platform, from hit finding and expansion through lead design/optimization and ADME toxicity modeling.
Portal Instruments	U.S.	Agreement for the development and commercialization of Portal's jet injector drug delivery device for potential use with Takeda's investigational or approved biologic medicines.
Recursion Pharmaceuticals	U.S.	Agreement to provide pre-clinical candidates for Takeda's TAK-celerator™ development pipeline.
Schrödinger	U.S.	Agreement for the 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.
Seattle Collaboration	U.S.	Agreement for SPRInT (Seattle Partnership for Research on Innovative Therapies) to accelerate the translation of Fred Hutchinson Cancer Research Center's and University of Washington's cutting-edge discoveries into treatments for human disease (focusing on Oncology, GI and Neuroscience).
Stanford University	U.S.	Collaboration agreement with Stanford University to form the Stanford Alliance for Innovative Medicines to more effectively develop innovative treatments and therapies.
Tri-Institutional Therapeutics Discovery Institute (Tri-I TDI)	U.S.	Agreement for the collaboration of academic institutions and industry to more effectively develop innovative treatments and therapies.

‡ Executed since April 1, 2019; * List is not inclusive of all Takeda R&D collaborations.

Completed Partnerships [Update disclosed since release of FY2018 results (May 14th, 2019)]

Partner	Country	Subject
Max Planck Institute	Germany	Agreement for the exclusive worldwide license under certain intellectual property to develop and commercialize the licensed products in rare disease field.
Bill & Melinda Gates Foundation	U.S.	Partnership to develop TAK-195, a Sabin-strain Inactivated Polio vaccine (sIPV) candidate, to support polio eradication in developing countries.

■ 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 (<https://www.takeda.com/jp/what-we-do/research-and-development/takeda-clinical-trial-transparency/>).

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.



Takeda Pharmaceutical Company Limited