Better Health, Brighter Future

FY2020 Q1 DATABOOK

Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK)

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

Quarterly Announcements / Presentations
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Forward-Looking Statements

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I. Financial Results

1. Revenue by Region

■Year To Date

	Reported				Underlying
(Bn JPY)	FY19 Q1	FY20 Q1	YOY		YOY
Total revenue	849.1	801.9	-47.3	-5.6%	0.9%
Japan	152.3	144.0	-8.3	-5.4%	-3.8%
% of revenue	17.9%	18.0%	0.0pt		
United States	415.7	402.6	-13.1	-3.1%	1.9%
% of revenue	49.0%	50.2%	1.3pt		
Europe and Canada	165.2	157.6	-7.7	-4.6%	2.5%
% of revenue	19.5%	19.6%	0.2pt		
Growth and Emerging Markets	115.9	97.6	-18.2	-15.7%	1.2%
% of revenue	13.6%	12.2%	-1.5pt		
Russia/CIS	19.0	13.0	-6.0	-31.4%	5.5%
% of revenue	2.2%	1.6%	-0.6pt		
Latin America	37.4	30.8	-6.6	-17.7%	10.0%
% of revenue	4.4%	3.8%	-0.6pt		
Asia	41.0	36.9	-4.1	-10.0%	-7.0%
% of revenue	4.8%	4.6%	-0.2pt		
Other	18.5	16.9	-1.6	-8.4%	-0.9%
% of revenue	2.2%	2.1%	-0.1pt		
Of which royalty / service income	27.1	18.1	-9.0	-33.4%	

*1 Revenue amount is classified into countries or regions based on the customer location.
*2 GEM: Growth and Emerging Markets, which include Russia/CIS, Latin America, Asia, Middle East, Oceania and Africa
*3 Other region includes Middle East, Oceania and Africa.

1. Revenue by Region (continued)

■ **Quarterly**

	Reported											
	FY19				FY20							
(Bn JPY)	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
Total revenue	849.1	811.0	859.3	771.7	801.9	-5.6%						
Japan	152.3	147.1	168.0	125.4	144.0	-5.4%						
% of revenue	17.9%	18.1%	19.5%	16.2%	18.0%							
United States	415.7	390.2	409.8	380.3	402.6	-3.1%						
% of revenue	49.0%	48.1%	47.7%	49.3%	50.2%							
Europe and Canada	165.2	156.6	161.7	162.0	157.6	-4.6%						
% of revenue	19.5%	19.3%	18.8%	21.0%	19.6%							
Growth and Emerging Markets	115.9	117.2	119.8	104.1	97.6	-15.7%						
% of revenue	13.6%	14.4%	13.9%	13.5%	12.2%							
Russia/CIS	19.0	17.9	22.4	17.6	13.0	-31.4%						
% of revenue	2.2%	2.2%	2.6%	2.3%	1.6%							
Latin America	37.4	38.4	35.9	31.7	30.8	-17.7%						
% of revenue	4.4%	4.7%	4.2%	4.1%	3.8%							
Asia	41.0	42.9	43.4	38.1	36.9	-10.0%						
% of revenue	4.8%	5.3%	5.1%	4.9%	4.6%							
Other	18.5	18.0	18.1	16.7	16.9	-8.4%						
% of revenue	2.2%	2.2%	2.1%	2.2%	2.1%							
Of which royalty / service income	27.1	20.0	19.0	20.9	18.1	-33.4%						

*1 Revenue amount is classified into countries or regions based on the customer location.
*2 GEM: Growth and Emerging Markets, which include Russia/CIS, Latin America, Asia, Middle East, Oceania and Africa.
*3 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 FY19Q1	Reported FY20Q1	Reported YOY	US	US YOY	Japan	Japan YOY	EUCAN	EUCAN YOY	GEM*4	GEM*4 YOY	Ex-US	Ex-US YOY
GI	**171.6**	**186.9**	**8.9%**	**113.8**	**12.3%**	**22.1**	**11.3%**	**34.6**	**8.5%**	**13.0**	**-11.8%**	**3.5**	**-10.0%**
ENTYVIO	83.9	101.2	20.7%	71.5	21.0%	2.0	96.4%	24.1	17.3%	3.6	12.5%		
DEXILANT	15.8	13.6	-14.0%	8.8	-19.4%			1.9	2.7%	3.0	-5.0%		
pantoprazole	11.6	9.2	-20.9%	0.5	58.8%			4.9	-8.2%	3.8	-36.0%		
TAKECAB-F *3	18.3	20.2	10.6%			19.9	9.4%			0.3	271.5%		
GATTEX/REVESTIVE	15.1	17.5	15.5%	15.4	18.5%			1.9	-7.8%	0.2	74.9%		
PENTASA	6.5	6.2	-5.6%	6.2	-5.6%								
LIALDA/MEZAVANT *1	5.6	5.5	-0.8%	2.0	21.1%							3.5	-10.0%
AMITIZA	7.8	6.3	-19.6%	6.2	-19.6%			0.0	-100.0%	0.1	-12.6%		
RESOLOR/MOTEGRITY	1.4	2.7	100.4%	2.0	274.0%			0.7	-13.8%	0.0	-9.6%		
Other	5.6	4.5	-19.8%	1.2	-21.7%	0.2	-72.5%	1.2	-14.2%	1.9	-5.9%		
Rare Diseases	**168.8**	**155.0**	**-8.2%**	**74.1**	**-5.6%**	**7.7**	**-4.5%**	**34.5**	**-11.1%**	**26.5**	**-13.3%**	**12.2**	**-5.4%**
Rare Metabolic	**48.9**	**39.9**	**-18.3%**	**8.9**	**-44.5%**	**0.8**	**-4.4%**	**10.1**	**-8.0%**	**8.0**	**-2.5%**	**12.2**	**-5.4%**
ELAPRASE	18.8	17.6	-6.4%	5.0	2.3%	0.4	7.3%	5.9	-9.2%	6.3	-10.7%		
REPLAGAL *1	12.9	12.2	-5.4%									12.2	-5.4%
VPRIV	9.3	9.3	1.0%	3.9	-2.7%	0.3	-17.1%	3.5	-8.0%	1.7	49.4%		
NATPARA	7.9	0.7	-90.7%	0.0	-99.9%			0.7	2.8%	0.0	-49.4%		
Rare Hematology	**88.1**	**76.8**	**-12.9%**	**33.4**	**-7.8%**	**6.6**	**-7.3%**	**19.1**	**-17.2%**	**17.7**	**-18.6%**		
ADVATE	42.7	33.7	-21.3%	17.0	-4.1%	1.7	-18.4%	8.1	-35.0%	6.9	-34.3%		
ADYNOVATE *6	14.5	15.3	5.7%	7.2	-4.3%	3.8	0.1%	3.4	38.0%	0.8	36.4%		
FEIBA *2	13.1	12.9	-1.5%	2.4	-10.5%	0.3	-42.1%	3.3	-19.8%	6.9	18.5%		
HEMOFIL/IMMUNATE/IMMUNINE*2	6.6	4.4	-32.5%	0.8	-41.4%			1.6	-6.9%	2.0	-41.8%		
Other PDT Products *2 *6	1.0	0.9	-11.5%	-0.0	-			0.7	-8.7%	0.2	-18.0%		
Other	10.3	9.7	-6.2%	6.0	-13.4%	0.8	5.6%	2.0	32.2%	0.8	-22.9%		
Hereditary Angioedema	**31.9**	**38.3**	**20.2%**	**31.8**	**21.1%**	**0.3**	**130.6%**	**5.4**	**10.9%**	**0.9**	**27.8%**		
FIRAZYR	9.0	8.1	-9.8%	5.2	-10.3%	0.3	130.6%	1.9	-18.6%	0.6	-5.1%		
TAKHZYRO	14.5	23.2	60.7%	21.1	54.3%			2.1	158.1%	0.1	-		
KALBITOR	1.1	1.1	-4.4%	1.1	-4.4%								
CINRYZE *2	7.3	5.9	-19.2%	4.3	-22.1%			1.4	-17.1%	0.1	521.0%		

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

*2 PDT products

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

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

*6 The classification of therapeutic area for product sales has been reviewed. For comparison, the classification of certain products has been changed from the previous fiscal year.

Other PDT products in Rare Hematology include BEBULIN, PROTHROMPLEX and Factor VII.

Other in Rare Hematology include VONVENDI, OBIZUR, RIXUBIS, AGRYLIN/XAGRID, RECOMBINATE, Other Hemophilia.

(Bn JPY)	Reported FY19Q1	Reported FY20Q1	Reported YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*4	YOY	Ex-US	YOY
PDT Immunology	**91.7**	**105.3**	**14.8%**	**74.3**	**28.2%**							**30.9**	**-8.4%**
immunoglobulin *2	68.0	85.1	25.2%	66.1	37.7%							19.0	-5.0%
albumin *2	16.1	13.0	-19.6%	2.6	-38.5%							10.4	-12.8%
Other *2 *6	7.6	7.2	-5.5%	5.6	-2.0%							1.6	-16.0%
Oncology	**106.5**	**108.0**	**1.4%**	**50.1**	**-7.1%**	**23.6**	**18.8%**	**18.4**	**9.8%**	**13.4**	**18.6%**	**2.5**	**-46.6%**
VELCADE *1	31.7	24.2	-23.7%	23.1	-17.8%							1.1	-69.5%
leuprorelin	28.4	27.4	-3.4%	2.1	-60.4%	12.8	15.6%	8.2	5.7%	4.3	1.8%		
NINLARO	18.3	22.9	25.4%	15.6	23.5%	1.2	-6.0%	3.3	23.2%	2.8	68.2%		
ADCETRIS	12.7	15.1	18.4%			2.9	49.4%	6.1	10.1%	6.1	15.8%		
ICLUSIG *1	7.6	9.2	20.7%	7.9	17.7%							1.3	42.0%
ALUNBRIG	1.7	2.0	21.9%	1.4	19.2%			0.4	10.4%	0.2	145.0%		
VECTIBIX	5.6	6.2	10.6%			6.2	10.6%						
Other	0.4	0.9	110.9%	0.0	-100.0%	0.5	-	0.2	-14.2%	0.2	-5.8%		
Neuroscience	**111.9**	**106.9**	**-4.5%**	**80.3**	**-8.4%**	**12.5**	**19.8%**	**11.6**	**-2.2%**	**2.5**	**24.0%**		
VYVANSE	68.8	66.0	-4.1%	55.9	-5.2%			7.8	-2.1%	2.4	23.2%		
TRINTELLIX	17.4	16.9	-3.1%	16.6	-4.8%	0.3	-						
ADDERALL XR	5.7	5.3	-7.7%	4.8	-9.4%			0.4	18.1%				
ROZEREM	5.1	3.0	-40.8%	0.0	-99.3%	3.0	5.3%			0.0	180.2%		
REMINYL *5	4.8	4.2	-11.9%			4.2	-11.9%	0.0	-26.0%				
INTUNIV	4.1	5.6	38.8%	0.4	-38.0%	3.3	107.8%	1.9	2.3%	0.1	89.7%		
Other	6.0	5.8	-3.6%	2.6	-15.4%	1.7	38.0%	1.5	-11.8%	0.0	-77.5%		
Other	**198.6**	**139.8**	**-29.6%**										
AZILVA-F *3	20.5	20.9	1.9%			20.9	1.9%						
NESINA-F *3	14.6	15.5	6.1%	2.4	48.8%	7.4	-2.4%	2.8	5.3%	2.9	5.6%		
ULORIC	12.2	0.9	-92.8%	0.7	-93.7%			0.1	-69.3%	0.1	-54.2%		
COLCRYS	7.2	3.2	-55.9%	3.2	-55.9%								
LOTRIGA	8.8	8.1	-7.9%			8.1	-7.9%						

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

*2 PDT products

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

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

*5 Reminyl sales in Japan include royalty income from the partner.

*6 The classification of therapeutic area for product sales has been reviewed. For comparison, the classification of certain products has been changed from the previous fiscal year.

Other in PDT Immunology include ARALAST, GLASSIA, CEPROTIN, ANTITHROMBIN III, KENKTSU-NONTHRON and others

Other in Neuroscience include COPAXONE, rasagiline, MYDAYIS, BUCCOLAM, DAYTRANA/EQUASYM and CARBATROL/EQUETRO

3. Product Sales Analysis (vs PY Actual) (continued)

(Bn JPY)	FY19 Reported				FY20 Reported & Underlying Growth													
						YOY			YOY				YOY				YOY	
	Q1	Q2	Q3	Q4	Q1	Reported	Underlying	Q2	Reported	Underlying	YTD Underlying	Q3	Reported	Underlying	YTD Underlying	Q4	Reported	Underlying	YTD Underlying
GI	**171.6**	**169.9**	**191.6**	**164.7**	**186.9**	**8.9%**	**13.6%**												
ENTYVIO	83.9	84.5	95.1	83.7	101.2	20.7%	25.5%												
DEXILANT	15.8	15.3	16.9	14.8	13.6	-14.0%	-7.2%												
pantoprazole	11.6	12.8	13.9	11.1	9.2	-20.9%	-9.8%												
TAKECAB-F *2	18.3	16.7	20.7	17.1	20.2	10.6%	10.7%												
GATTEX/REVESTIVE	15.1	14.1	17.7	14.9	17.5	15.5%	19.2%												
PENTASA	6.5	6.5	7.2	5.4	6.2	-5.6%	-3.0%												
LIALDA/MEZAVANT	5.6	6.7	6.0	5.2	5.5	-0.8%	3.6%												
AMITIZA	7.8	7.3	7.0	6.0	6.3	-19.6%	-17.2%												
RESOLOR/MOTEGRITY	1.4	1.3	2.0	1.9	2.7	100.4%	105.3%												
Other	5.6	4.7	5.1	4.8	4.5	-19.8%	-16.3%												
Rare Diseases	**168.8**	**156.8**	**157.7**	**149.4**	**155.0**	**-8.2%**	**-2.0%**												
Rare Metabolic	**48.9**	**43.2**	**40.2**	**38.5**	**39.9**	**-18.3%**	**-9.9%**												
ELAPRASE	18.8	16.7	16.8	15.6	17.6	-6.4%	1.2%												
REPLAGAL	12.9	12.6	13.1	12.7	12.2	-5.4%	6.5%												
VPRIV	9.3	9.4	9.7	9.6	9.3	1.0%	9.5%												
NATPARA	7.9	4.5	0.6	0.6	0.7	-90.7%	-89.8%												
Rare Hematology	**88.1**	**85.1**	**83.8**	**75.0**	**76.8**	**-12.9%**	**-7.0%**												
ADVATE	42.7	40.5	39.9	34.8	33.7	-21.3%	-14.5%												
ADYNOVATE *3	14.5	13.1	15.1	13.9	15.3	5.7%	9.4%												
FEIBA *1	13.1	14.8	11.7	11.9	12.9	-1.5%	5.4%												
HEMOFIL/IMMUNATE/ IMMUNINE*1	6.6	5.6	5.8	4.4	4.4	-32.5%	-26.1%												
Other PDT Products *1*3	1.0	0.8	1.1	0.8	0.9	-11.5%	-5.0%												
Other	10.3	10.3	10.2	9.3	9.7	-6.2%	-2.5%												
Hereditary Angioedema	**31.9**	**28.5**	**33.7**	**35.8**	**38.3**	**20.2%**	**24.5%**												
FIRAZYR	9.0	6.3	7.5	9.9	8.1	-9.8%	-4.7%												
TAKHZYRO	14.5	16.2	18.2	19.4	23.2	60.7%	65.8%												
KALBITOR	1.1	1.3	1.1	1.0	1.1	-4.4%	-1.6%												
CINRYZE *1	7.3	4.7	6.9	5.4	5.9	-19.2%	-16.0%												

*1 PDT products

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

*3 The classification of therapeutic area for product sales has been reviewed. For comparison, the classification of certain products has been changed from the previous fiscal year.

Other PDT products in Rare Hematology include BEBULIN, PROTHROMPLEX and Factor VII.

Other in Rare Hematology include VONVENDI, OBIZUR, RIXUBIS, AGRYLIN/XAGRID, RECOMBINATE, Other Hemophilia.

(Bn JPY)	FY19 Reported				FY20 Reported & Underlying Growth													
						YOY			YOY			YOY			YOY			
	Q1	Q2	Q3	Q4	Q1	Reported	Underlying	Q2	Reported	Underlying	YTD Underlying	Q3	Reported	Underlying	YTD Underlying	Q4	Reported	Underlying	YTD Underlying
PDT Immunology	**91.7**	**102.9**	**101.9**	**97.6**	**105.3**	**14.8%**	**19.4%**												
immunoglobulin *1	68.0	78.5	78.9	73.3	85.1	25.2%	29.8%												
albumin *1	16.1	17.9	15.7	17.5	13.0	-19.6%	-14.3%												
Other *1 *3	7.6	6.5	7.3	6.8	7.2	-5.5%	-2.7%												
Oncology	**106.5**	**108.4**	**103.1**	**103.0**	**108.0**	**1.4%**	**5.4%**												
VELCADE	31.7	31.9	27.2	27.5	24.2	-23.7%	-21.4%												
leuprorelin	28.4	28.3	26.0	26.4	27.4	-3.4%	-1.1%												
NINLARO	18.3	20.0	19.8	19.5	22.9	25.4%	31.0%												
ADCETRIS	12.7	13.0	13.7	13.2	15.1	18.4%	31.1%												
ICLUSIG	7.6	7.0	8.2	9.0	9.2	20.7%	24.2%												
ALUNBRIG	1.7	1.7	1.8	2.1	2.0	21.9%	26.4%												
VECTIBIX	5.6	6.0	6.0	4.9	6.2	10.6%	10.6%												
Other	0.4	0.5	0.4	0.4	0.9	110.9%	14.7%												
Neuroscience	**111.9**	**102.0**	**116.7**	**108.0**	**106.9**	**-4.5%**	**-0.8%**												
VYVANSE	68.8	62.7	75.3	67.3	66.0	-4.1%	0.3%												
TRINTELLIX	17.4	17.2	19.7	16.4	16.9	-3.1%	-0.3%												
ADDERALL XR	5.7	4.9	4.4	9.3	5.3	-7.7%	-4.4%												
ROZEREM	5.1	3.6	3.1	2.7	3.0	-40.8%	-40.8%												
REMINYL	4.8	4.2	4.9	3.5	4.2	-11.9%	-11.5%												
INTUNIV	4.1	4.0	2.9	3.7	5.6	38.8%	46.1%												
Other	6.0	5.3	6.5	5.2	5.8	-3.6%	-1.2%												
Other	**198.6**	**171.1**	**188.4**	**149.0**	**139.8**	**-29.6%**	**-21.0%**												
AZILVA-F *2	20.5	18.2	20.4	17.6	20.9	1.9%	1.9%												
NESINA-F *2	14.6	14.0	15.5	13.9	15.5	6.1%	8.5%												
ULORIC	12.2	1.8	1.4	1.4	0.9	-92.8%	-93.1%												
COLCRYS	7.2	6.0	6.6	2.7	3.2	-55.9%	-54.6%												
LOTRIGA	8.8	7.2	8.8	7.0	8.1	-7.9%	-7.9%												

*1 PDT products

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

*3 The classification of therapeutic area for product sales has been reviewed. For comparison, the classification of certain products has been changed from the previous fiscal year.

Other in PDT Immunology include ARALAST, GLASSIA, CEPROTIN, ANTITHROMBIN III, KENKTSU-NONTHRON and others

Other in Neuroscience include COPAXONE, rasagiline, MYDAYIS, BUCCOLAM, DAYTRANA/EQUASYM and CARBATROL/EQUETRO

4. FY2020 Product Forecasts (Disclosed on May 13, 2020)

(Bn JPY)	FY19 Reported Actual					FY20 Reported Forecasts	
	Q1	Q2	Q3	Q4	Annual	Annual	YOY
GI	**171.6**	**169.9**	**191.6**	**164.7**	**697.9**	**765.0**	**9.6%**
ENTYVIO	83.9	84.5	95.1	83.7	347.2	430.0	23.8%
DEXILANT	15.8	15.3	16.9	14.8	62.8	54.0	-14.0%
pantoprazole	11.6	12.8	13.9	11.1	49.5	39.0	-21.2%
TAKECAB-F *2	18.3	16.7	20.7	17.1	72.7	82.0	12.8%
GATTEX/REVESTIVE	15.1	14.1	17.7	14.9	61.8	66.0	6.8%
PENTASA	6.5	6.5	7.2	5.4	25.6	23.0	-10.1%
LIALDA/MEZAVANT	5.6	6.7	6.0	5.2	23.4	18.0	-23.1%
AMITIZA	7.8	7.3	7.0	6.0	28.1	23.0	-18.3%
RESOLOR/MOTEGRITY	1.4	1.3	2.0	1.9	6.6	8.0	21.9%
Other	5.6	4.7	5.1	4.8	20.2	22.0	8.8%
Rare Diseases	**168.8**	**156.8**	**157.7**	**149.4**	**632.7**		
Rare Metabolic	**48.9**	**43.2**	**40.2**	**38.5**	**170.8**	**161.0**	**-5.8%**
ELAPRASE	18.8	16.7	16.8	15.6	67.9	68.0	0.1%
REPLAGAL	12.9	12.6	13.1	12.7	51.3	51.0	-0.5%
VPRIV	9.3	9.4	9.7	9.6	38.0	38.0	-0.0%
NATPARA	7.9	4.5	0.6	0.6	13.6	4.0	-70.7%
Rare Hematology	**88.1**	**85.1**	**83.8**	**75.0**	**332.0**	**283.0**	**-14.8%**
ADVATE	42.7	40.5	39.9	34.8	157.9	184.0	-14.2%
ADYNOVATE *3	14.5	13.1	15.1	13.9	56.5		
FEIBA *1	13.1	14.8	11.7	11.9	51.5	36.0	-30.1%
HEMOFIL/IMMUNATE/IMMUNINE*1	6.6	5.6	5.8	4.4	22.3	20.0	-10.5%
Other PDT Products *1*3	1.0	0.8	1.1	0.8	3.7	4.0	8.6%
Other	10.3	10.3	10.2	9.3	40.2	39.0	-2.9%
Hereditary Angioedema	**31.9**	**28.5**	**33.7**	**35.8**	**129.8**		**-10%~0%**
FIRAZYR	9.0	6.3	7.5	9.9	32.7	21.0	-35.7%
TAKHZYRO	14.5	16.2	18.2	19.4	68.3		+20%~+30%
KALBITOR	1.1	1.3	1.1	1.0	4.5	4.0	-12.0%
CINRYZE *1	7.3	4.7	6.9	5.4	24.3	18.0	-26.1%

*1 PDT products

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

*3 The classification of therapeutic area for product sales has been reviewed. For comparison, the classification of certain products has been changed from the previous fiscal year.

Other PDT products in Rare Hematology include BEBULIN, PROTHROMPLEX and Factor VII.

Other in Rare Hematology include VONVENDI, OBIZUR, RIXUBIS, AGRYLIN/XAGRID, RECOMBINATE, Other Hemophilia.

Assumption of FX rates for FY20 Reported Forecasts: 1 USD = 109 JPY, 1 Euro = 120 JPY, 1 RUB = 1.6 JPY, 1 BRL = 23.3 JPY, 1 CNY = 15.5 JPY

(Bn JPY)	FY19 Reported Actual					FY20 Reported Forecasts	
	Q1	Q2	Q3	Q4	Annual	Annual	YOY
PDT Immunology	**91.7**	**102.9**	**101.9**	**97.6**	**394.2**		**+10%~+20%**
immunoglobulin *1	68.0	78.5	78.9	73.3	298.7		+10%~+20%
albumin *1	16.1	17.9	15.7	17.5	67.2		+10%~+20%
Other *1 *3	7.6	6.5	7.3	6.8	28.2		0%~+10%
Oncology	**106.5**	**108.4**	**103.1**	**103.0**	**421.0**	**418.0**	**-0.7%**
VELCADE	31.7	31.9	27.2	27.5	118.3	92.0	-22.2%
leuprorelin	28.4	28.3	26.0	26.4	109.0	106.0	-2.8%
NINLARO	18.3	20.0	19.8	19.5	77.6	85.0	9.6%
ADCETRIS	12.7	13.0	13.7	13.2	52.7	60.0	13.9%
ICLUSIG	7.6	7.0	8.2	9.0	31.8	34.0	6.9%
ALUNBRIG	1.7	1.7	1.8	2.1	7.2	11.0	52.0%
VECTIBIX	5.6	6.0	6.0	4.9	22.5	23.0	2.0%
Other	0.4	0.5	0.4	0.4	1.8	7.0	298.3%
Neuroscience	**111.9**	**102.0**	**116.7**	**108.0**	**438.5**	**459.0**	**4.7%**
VYVANSE	68.8	62.7	75.3	67.3	274.1	290.0	5.8%
TRINTELLIX	17.4	17.2	19.7	16.4	70.7	82.0	16.0%
ADDERALL XR	5.7	4.9	4.4	9.3	24.3	23.0	-5.4%
ROZEREM	5.1	3.6	3.1	2.7	14.5	12.0	-17.1%
REMINYL	4.8	4.2	4.9	3.5	17.3	8.0	-53.9%
INTUNIV	4.1	4.0	2.9	3.7	14.6	19.0	29.9%
Other	6.0	5.3	6.5	5.2	23.1	25.0	8.4%
Other	**198.6**	**171.1**	**188.4**	**149.0**	**706.9**		**-20%~-10%**
AZILVA-F *2	20.5	18.2	20.4	17.6	76.7	78.0	1.6%
NESINA-F *2	14.6	14.0	15.5	13.9	58.0	57.0	-1.7%
ULORIC	12.2	1.8	1.4	1.4	16.9	3.0	-82.2%
COLCRYS	7.2	6.0	6.6	2.7	22.5	14.0	-37.8%
LOTRIGA	8.8	7.2	8.8	7.0	31.8	30.0	-5.5%

*1 PDT products

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

*3 The classification of therapeutic area for product sales has been reviewed. For comparison, the classification of certain products has been changed from the previous fiscal year.

Other in PDT Immunology include ARALAST, GLASSIA, CEPROTIN, ANTITHROMBIN III, KENKTSU-NONTHRON and others

Other in Neuroscience include COPAXONE, rasagiline, MYDAYIS, BUCCOLAM, DAYTRANA/EQUASYM and CARBATROL/EQUETRO

Assumption of FX rates for FY20 Reported Forecasts: 1 USD = 109 JPY, 1 Euro = 120 JPY, 1 RUB = 1.6 JPY, 1 BRL = 23.3 JPY, 1 CNY = 15.5 JPY

5. Exchange Rate

(yen)

CURRENCY	Average Exchange Rates vs. JPY		
	FY19Q1	FY20Q1	FY20 Assumption
USD	111	107	109
EUR	124	118	120
RUB	1.7	1.5	1.6
CNY	16.3	15.1	15.5
BRL	28.0	20.2	23.3

(100 million yen)

Impact of 1% depreciation of yen from July 2020 to March 2021			
REVENUE	CORE OPERATING PROFIT	OPERATING PROFIT	NET PROFIT
+123.7	+49.7	+13.9	+5.2
+32.1	-13.9	-20.1	-15.1
+2.5	+1.5	+1.2	+0.9
+7.4	+4.1	+4.1	+2.8
+5.1	+3.0	+2.9	+2.0

6. CAPEX, depreciation and amortization and impairment losses

(Bn JPY)

	FY19	FY19Q1	FY20Q1	YOY		FY20 Forecasts
Capital expenditures*	217.7	43.0	40.5	-2.5	-5.8%	180.0 - 230.0
Tangible assets	127.1	29.9	23.1	-6.7	-22.5%	
Intangible assets	90.6	13.1	17.3	4.2	32.2%	
* Cash flow base						
Depreciation and amortization	583.6	176.3	141.6	-34.7	-19.7%	
Depreciation of tangible assets* (A)	156.0	38.0	31.5	-6.5	-17.1%	
Amortization of intangible assets (B)	427.6	138.4	110.1	-28.2	-20.4%	
Of which Amortization associated with products (C)	412.1	132.2	102.3	-29.8	-22.6%	407.0
Of which Amortization excluding intagible assets associated with products (D)	15.5	6.2	7.8	1.6	25.1%	
* Excluding depreciation for investment assets.						
Depreciation and amortization (excluding intangible assets associated with products) (A)+(D)	171.6	44.2	39.2	-4.9	-11.2%	150.0
Impairment losses	101.9	17.4	7.5	-10.0	-57.2%	
Impairment losses associated with products	43.3	16.1	1.9	-14.2	-88.2%	50.0
Amortization and impairment losses on intangible assets associated with products	455.4	148.3	104.3	-44.0	-29.7%	457.0

(Notes) During FY2019, Takeda completed the purchase price allocation for the assets acquired and the liabilities assumed as part of the Shire acquisition. Accordingly, PL statements for FY2019 and FY2019 Q1 were retrospectively adjusted.

7. Reconciliation from Reported Revenue to Underlying Revenue FY2020 Q1 (Apr-Jun) vs. PY

(BN JPY)	FY2019 Q1 (Apr-Jun)	FY2020 Q1 (Apr-Jun)	vs. PY	
Revenue	**849.1**	**801.9**	**-47.2**	**-5.6%**
FX effects[*1]				+4.4pp
Divestitures[*2]				+2.1pp
XIIDRA				+1.1pp
NEMEA & Russia/CIS				+0.8pp
TACHOSIL				+0.1pp
Others				-0.1pp
Underlying Revenue Growth				**+0.9%**

[*1] FX adjustment applies FY2019 plan rate to both periods (1USD=111JPY, 1EUR=129JPY).

[*2] Major adjustments are as follow;

- Net sales from XIIDRA, a treatment for dry eye disease, the divestiture of which was completed in July 2019, are excluded from FY2019 Q1.
- Revenue of select over-the-counter and non-core products in a number of Near East, Middle East and Africa countries, is excluded from FY2019 Q1 as the divestiture was completed in March 2020. Likewise, revenue of select over-the-counter and non-core products in Russia, Georgia, and a number of countries from within the Commonwealth of Independent States, is excluded from FY2019 Q1 as the divestiture was also completed in March 2020.
- Net sales from TACHOSIL, a surgical patch, that Takeda agreed in May 2019 to divest are excluded from both FY2020 Q1 and FY2019 Q1. Although the agreement to divest the product to Ethicon was terminated in April 2020, it is still adjusted as Takeda continues to explore opportunities to divest TACHOSIL as part of its ongoing divestiture and deleveraging strategy.
- Revenue of products related to divestiture agreements that were publicly announced and expected to complete within the calendar year 2020 are excluded from both FY2020 Q1 and FY2019 Q1.

8. Reconciliation from Reported to Core/Underlying CORE FY2020 Q1 (Apr-Jun)

(BN JPY)	REPORTED	REPORTED TO CORE ADJUSTMENTS						CORE	CORE TO UNDERLYING CORE ADJ.		UNDERLYING GROWTH
		Amortization & impairment of intangible assets	Other operating income/ expense	Shire integration costs	Shire purchase accounting adjustments	Teva JV related accounting adjustments	Others		FX	Divestitures	
Revenue	801.9							801.9	49.2	-16.3	**+0.9%**
Cost of sales	-238.1				26.6			-211.5	-13.6	4.7	
Gross Profit	563.8				26.6			590.3	35.6	-11.6	
SG&A expenses	-202.4			0.0	-0.3			-202.6	-11.4		
R&D expenses	-106.8			-0.1	0.1			-106.8	-3.5		
Amortization of intangible assets	-102.3	22.5			79.8			-			
Impairment losses on intangible assets	-1.9	1.9						-			
Other operating income	63.7		-3.2		-60.2	-0.4		-			
Other operating expenses	-46.8		7.4	20.8			18.6	-			
Operating profit	167.3	24.4	4.2	20.7	46.0	-0.4	18.6	280.9	20.7	-11.6	**+11.2%**
Margin	20.9%							35.0%			**34.7%***
Financial income/expenses	-27.2				2.7		-3.8	-28.3	-0.9		
Equity income/loss	-9.8					10.6		0.8	-0.1		
Profit before tax	130.3	24.4	4.2	20.7	48.7	10.2	14.8	253.4	19.7	-11.6	
Tax expense	-47.8	-5.9	0.9	-3.6	-3.3	-3.1	0.0	-62.7	-2.6	2.8	
Non-controlling interests	-0.0							-0.0	0.0		
Net profit	82.5	18.5	5.1	17.2	45.4	7.1	14.8	190.6	17.0	-8.8	
EPS (yen)	53							122	11	-6	**+8.7%**
Number of shares (millions)	1,559							1,559			1,558

* Underlying Core Operating Profit Margin.

9. Reconciliation from Reported to Core/Underlying CORE FY2019 Q1 (Apr-Jun)

(BN JPY)	REPORTED *1	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 *1 purchase accounting adjustments	Teva JV related accounting adjustments	Others		FX	Divestitures	
Revenue	849.1							849.1	11.7	-33.6	
Cost of sales	-291.8				75.7			-216.1	-3.0	6.2	
Gross Profit	557.3				75.7			633.0	8.7	-27.4	
SG&A expenses	-239.2			0.8	1.1			-237.4	-3.0		
R&D expenses	-116.9			4.3	-0.1			-112.7	-0.5		
Amortization of intangible assets	-105.6	23.0			82.6			-			
Impairment losses on intangible assets	-16.1	16.1						-			
Other operating income	6.7		-6.0			-0.7		-			
Other operating expenses	-41.0		9.4	31.6				-			
Operating profit	45.2	39.1	3.4	36.7	159.2	-0.7		283.0	5.1	-27.4	
Margin	5.3%							33.3%			**31.5%**
Financial income/expenses	-37.4				4.5		0.3	-32.6	1.1		
Equity income/loss	2.3					0.6		3.0	-0.0		
Profit before tax	10.1	39.1	3.4	36.7	163.7	-0.1	0.3	253.3	6.2	-27.4	
Tax expense	-3.1	-7.1	-8.1	-7.0	-29.6	0.0	-0.0	-54.9	-1.0	6.6	
Non-controlling interests	-0.0							-0.0	-0.0		
Net profit	7.0	32.0	-4.7	29.7	134.1	-0.0	0.3	198.4	5.2	-20.8	
EPS (yen)	5							128	3	-13	**117**
Number of shares (millions)	1,556							1,556			1,558

*1 During FY2019, Takeda completed the purchase price allocation for the assets acquired and the liabilities assumed as part of the Shire acquisition. Accordingly, PL statements for FY2019 Q1 were retrospectively adjusted.

10. Reconciliation from Net Profit to EBITDA/Adjusted EBITDA

(BN JPY)	FY2019 Q1 (Apr-Jun)[*1]	FY2020 Q1 (Apr-Jun)	FY2020 LTM[*2]
Net profit for the year	7.0	82.5	119.8
Income tax expenses	3.1	47.8	-60.4
Depreciation and amortization	150.4	141.6	574.8
Interest expense, net	36.8	30.7	131.7
EBITDA	197.3	302.6	766.0
Impairment losses	17.4	7.5	91.9
Other operating expense (income), net, excluding depreciation and amortization and other miscellaneous expenses (non-cash item)	32.8	-24.4	66.9
Finance expense (income), net, excluding interest income and expense, net	0.6	-3.5	-4.7
Share of loss on investments accounted for under the equity method	-2.3	9.8	36.1
Other adjustments:			
Impact on profit related to fair value step up of inventory in Shire acquisition	71.9	26.5	145.6
Acquisition costs related to Shire	0.6	0.0	4.8
Other costs[*3]	8.8	9.2	27.9
Adjusted EBITDA	327.1	327.6	1,134.4

[*1] During FY2019, Takeda completed the purchase price allocation for the assets acquired and the liabilities assumed as part of the Shire acquisition. Accordingly, PL statements for FY2019 Q1 were retrospectively adjusted.
[*2] LTM represents Last Twelve Months (July 2019 – June 2020).
[*3] Includes adjustments for non-cash equity-based compensation expense, non-recurring wind-down costs related to pipeline de-prioritization after Shire acquisition and EBITDA for divested products.

II. Pipeline

1. Clinical Development Activities

- The following table lists the pipeline assets that we are developing as of July 31, 2020. 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, China)	CD30 monoclonal antibody-drug conjugate (injection)	Cutaneous T cell lymphoma	China	Filed (June 2020)
<brigatinib> *ALUNBRIG* (U.S., EU)	ALK inhibitor (oral)	1L ALK-positive Non-Small Cell Lung Cancer	Japan China	Filed (February 2020) P-III
		2L ALK-positive Non-Small Cell Lung Cancer in patients previously treated with ALK inhibitors	Japan	Filed (February 2020)
		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 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 not treated with stem cell transplant	Japan U.S. EU China	Filed (May 2020) P-III P-III P-III
		Maintenance therapy in patients with newly diagnosed Multiple Myeloma following autologous stem cell transplant	U.S. EU	P-III P-III
		Relapsed/refractory Multiple Myeloma (doublet regimen with dexamethasone)	U.S. EU	P-II P-II
		Relapsed/refractory Multiple Myeloma (triplet regimen with daratumumab and dexamethasone)	U.S. EU	P-II P-II
<cabozantinib>*2 *CABOMETYX* (Japan)	Multi-targeted kinase inhibitor (oral)	2L Hepatocellular carcinoma	Japan	Filed (January 2020)
		1L Renal cell carcinoma in combination with nivolumab	Japan	P-III
<niraparib>*3	PARP1/2 inhibitor (oral)	Ovarian cancer – maintenance	Japan	Filed (November 2019)
		Ovarian cancer – salvage	Japan	Filed (November 2019)
<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
		Unfit Acute Myelogenous Leukemia	Global	P-III
TAK-788 <mobocertinib>	EGFR/HER2 exon 20 inhibitor (oral)	Treatment Naïve Non-Small Cell Lung Cancer with Exon-20 insertion	Global	P-III
		Previously treated Non-Small Cell Lung Cancer with Exon-20 insertion	Global	P-II
TAK-385 <relugolix>	LH-RH antagonist (oral)	Prostate cancer	Japan China	P-III P-III

TAK-007*4	CD19 CAR-NK (injection)	Relapsed/refractory B-cell malignancies	-	P-I/II
TAK-169*5	CD38-SLTA (injection)	Relapsed/refractory Multiple Myeloma	-	P-I
TAK-573*6	CD38-targeted IgG4 genetically fused with an attenuated IFNα (injection)	Relapsed/refractory Multiple Myeloma	-	P-I
TAK-981	SUMO inhibitor (injection)	Multiple cancers	-	P-I
TAK-252 / SL-279252*7	PD-1-Fc-OX40L (injection)	Solid tumors or lymphomas	-	P-I

*1 Partnership with Seattle Genetics, Inc.
*2 Partnership with Exelixis, Inc.
*3 Partnership with GlaxoSmithKline
*4 Partnership with The University of Texas MD Anderson Cancer Center
*5 Partnership with Molecular Templates
*6 Partnership with Teva Pharmaceutical Industries Ltd.
*7 Partnership with Shattuck Labs, Inc.

Additions since FY2019 Q4: SGN-35 for Cutaneous T cell lymphoma (China, filed June 2020)
Removals since FY2019 Q4: SGN-35 for previously untreated systemic Anaplastic Large Cell Lymphoma (EU, approved May 2020)
SGN-35 for relapsed / refractory Hodgkin Lymphoma (China, approved May 2020)
SGN-35 for relapsed / refractory systemic Anaplastic Large Cell Lymphoma (China, approved May 2020)
Brigatinib for 1L ALK-positive Non-Small Cell Lung Cancer (U.S., approved May 2020)

■ Rare Diseases Pipeline

Development code <generic name> Brand name (country/region)	Drug Class (administration route)	Indications / additional formulations	Stage	
TAK-743 <lanadelumab> *TAKHZYRO* (U.S., EU)	Plasma kallikrein inhibitor (injection)	Hereditary Angioedema	China Japan	Filed (December 2018) P-III
		Pediatric Hereditary Angioedema	Global	P-III
TAK-577 *VONVENDI* (U.S., Japan), *VEYVONDI* (EU)	von Willebrand factor [recombinant] (injection)	Adult prophylactic treatment of von Willebrand disease	Global	P-III
		Pediatric on-demand treatment of von Willebrand disease	Global	P-III
TAK-672*1 *OBIZUR* (U.S., EU)	Antihemophilic factor [recombinant], porcine sequence (injection)	Congenital hemophilia A with inhibitors during surgery	U.S. EU	P-III P-III
TAK-660 *ADYNOVATE* (U.S., Japan), *ADYNOVI* (EU)	Antihemophilic factor [recombinant], PEGylated (injection)	Pediatric Hemophilia A	EU	P-III
TAK-755*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*3 <maribavir>	Benzimidazole riboside inhibitor (oral)	Cytomegalovirus infection in transplant patients	U.S. EU	P-III P-III
TAK-607	Insulin-like Growth Factor / IGF Binding Protein (injection)	Complications of prematurity	-	P-II
TAK-609	Recombinant human iduronate-2-sulfatase for intrathecal administration (injection)	Hunter syndrome CNS	U.S. EU	P-II P-II
TAK-611	Recombinant human arylsulfatase A for intrathecal administration (injection)	Metachromatic leukodystrophy	-	P-II
TAK-754*4	Gene therapy to restore endogenous FVIII expression (injection)	Hemophilia A	-	P-I/II
TAK-079*5	Anti-CD38 monoclonal antibody (injection)	Myasthenia gravis	-	P-I/II
		Systemic lupus erythematosus	-	P-I/II

TAK-834 *NATPARA* (U.S.), *NATPAR* (EU)	Parathyroid hormone (injection)	Hypoparathyroidism	Japan	P-I*6

*1 Partnership with Ipsen
*2 Partnership with KM Biologics for coexclusive license for commercialization in Japan only
*3 Partnership with GlaxoSmithKline
*4 Partnership with Asklepios Biopharmaceuticals
*5 Relapsed/refractory Multiple Myeloma will continue until trial completion. TAK-079 to be developed in Rare Diseases indications myasthenia gravis (MG) and immune thrombocytopenic purpura (ITP); First-Patient-In expected H1 FY20
*6 P-I study in Japan completed; P-III study start timing under review.

■ Neuroscience Pipeline

Development code <generic name> Brand name (country/region)	Drug Class (administration route)	Indications / additional formulations		Stage
TAK-815 **<midazolam>** *BUCCOLAM* (EU)	GABA Allosteric Modulator (oromucosal)	Status epilepticus (seizures)	Japan	Filed (February 2020)
TAK-935 **<soticlestat>**	CH24H inhibitor (oral)	Dravet Syndrome, Lennox-Gastaut syndrome*1	-	P-II
		15q duplication syndrome, CDKL5 deficiency disorder*1		P-II
		Complex Regional Pain Syndrome		P-II
TAK-994	Orexin 2R agonist (oral)	Narcolepsy	-	P-II
TAK-831*2	D-amino acid oxidase (DAAO) inhibitor (oral)	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-II(a)
WVE-120101*3	mHTT SNP1 antisense oligonucleotide (injection)	Huntington's disease	-	P-I/II
WVE-120102*3	mHTT SNP2 antisense oligonucleotide (injection)	Huntington's disease	-	P-I/II
TAK-041*4	GPR139 agonist (oral)	Anhedionia in major depressive disorder (MDD)	-	P-I
TAK-341/MEDI1341*5	Alpha-synuclein antibody (injection)	Parkinson's disease	-	P-I
TAK-653*4	AMPA receptor potentiator (oral)	Treatment resistant depression	-	P-I
TAK-925	Orexin 2R agonist (injection)	Narcolepsy, other sleep disorders	-	P-I

*1 Co-development with Ovid Therapeutics Inc.
*2 50:50 co-development and co-commercialization option with Neurocrine
*3 50:50 co-development and co-commercialization option with Wave Life Sciences Ltd.
*4 50:50 co-development and co-commercialization with Neurocrine
*5 Partnership with AstraZeneca. AstraZeneca leads Phase 1 development

Removals since FY2019 Q4: TAK-418 for Kabuki syndrome (P-I, discontinued)

■ GI Pipeline

Development code <generic name> Brand name (country/region)	Drug Class (administration route)	Indications / additional formulations	Stage	
MLN0002 <vedolizumab> *ENTYVIO* (Global)	Humanized monoclonal antibody against α4β7 integrin (injection)	Subcutaneous formulation for ulcerative colitis	U.S. Japan	CRL received (Dec 2019)*9 Filed (August 2019)
		Subcutaneous formulation for Crohn's disease	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> *TAKECAB* (Japan) *VOCINTI* (China)	Potassium-competitive acid blocker (oral)	Acid related diseases (Reflex Esophagitis Maintenance)	China	Filed (March 2020)
		Acid related diseases (Duodenal Ulcer)	China	Filed (April 2020)
		Acid related diseases (adjunct to Helicobacter pylori eradication)	China	P-III
		Oral disintegrated tablet formulation	Japan	P-III
TAK-633 <teduglutide> *GATTEX* (U.S.) *REVESTIVE* (EU)	GLP-2 analogue (injection)	Short bowel syndrome (pediatric indication)	Japan	P-III
		Short bowel syndrome (in adults)	Japan	P-III
Cx601 <darvadstrocel> *ALOFISEL* (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*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-018/EB8018*4	FimH antagonist (oral)	Crohn's disease (post-operative and ileitis)	-	P-II
TAK-951	Peptide agonist (sub-cutaneous)	Nausea and vomiting	-	P-I
TAK-671*5	Protease inhibitor (injection)	Acute pancreatitis	-	P-I
TAK-062*6	Glutenase (oral)	Celiac disease	-	P-I
TAK-039*7	Bacterial consortium (oral)	Clostridium difficile infections*8	-	P-I

*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 Samsung Bioepis
*6 Acquired PvP Biologics, Inc. including TAK-062. Previously known as Kuma062.
*7 Partnership with with NuBiyota
*8 Phase 1 study in clostridium difficile infections completed; strategic intention is to take the program forward in hepatic encephalopathy.
*9 Complete Response Letter (CRL) is unrelated to the clinical safety and efficacy data, and included queries related to the design and labelling of the SC product. Takeda is working to resolve CRL and expects an updated timeline within H1 CY2020.

■ Plasma-Derived Therapies Pipeline

Development code <generic name> Brand name (country/region)	Drug Class (administration route)	Indications / additional formulations		Stage
TAK-616 *CINRYZE* (U.S., EU)	C1 esterase inhibitor [human] (injection)	Hereditary angioedema	Japan	P-III*1
TAK-771 *2 **<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 Based on the withdrawal of orphan drug designation by the Japanese Ministry of Health Labour and Welfare (MHLW), termination of development has now been initiated

*2 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-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

Removals since FY2019 Q4: TAK-021 Prevention of hand, foot and mouth disease caused by enterovirus 71 (P-I, discontinued)

2. Recent Progress in stage [Progress in stage disclosed since release of FY2019 results (May 13th, 2020)]

Development code <generic name>	Indications / additional formulations	Country/Region	Progress in stage
<brigatinib>	1L ALK-positive Non-Small Cell Lung Cancer	U.S.	Approved (May 2020)
SGN-35 <brentuximab vedotin>	Previously untreated systemic Anaplastic Large Cell Lymphoma	EU	Approved (May 2020)
SGN-35 <brentuximab vedotin>	Relapsed / refractory Hodgkin Lymphoma	China	Approved (May 2020)
SGN-35 <brentuximab vedotin>	Relapsed / refractory systemic Anaplastic Large Cell Lymphoma	China	Approved (May 2020)
SGN-35 <brentuximab vedotin>	Relapsed / refractory cutaneous T-cell Lymphoma	China	Filed (June 2020)
MLN9708 <ixazomib>	Maintenance therapy in patients with newly diagnosed Multiple Myeloma not treated with stem cell transplant	Japan	Filed (May 2020)
TAK-438 <vonoprazan>	Acid related diseases (Duodenal Ulcer)	China	Filed (April 2020)
TAK-438 <vonoprazan>	Acid related diseases adjunct to Helicobacter pylori eradication	China	P-III
TAK-994	Narcolepsy	-	P-II

3. Discontinued projects [Update disclosed since release of FY2019 results (May 13th, 2020)]

Development code <generic name>	Indications (Stage)	Reason
TAK-418	Kabuki syndrome (P-I)	Clinical data do not justify further development
TAK-021	Prevention of hand, foot and mouth disease caused by enterovirus 71 (P-I)	Strategic decision to externalize development. Program discontinued until partner identified.

4. 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.
Egle Therapeutics‡	France	Identify novel tumor-specific regulatory T-cell targets and develop unique anti-suppressor-based immunotherapies.
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.
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.
Heidelberg Pharma	Germany	Antibody-Drug-Conjugate (ADC) research collaboration on 2 targets and licensing agreement (α-amanitin payload and proprietary linker).
Maverick Therapeutics	U.S.	Collaboration agreement for the development of Maverick 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 has the exclusive option to acquire Maverick Therapeutics 5 years after partnership initiation in 2017.
MD Anderson Cancer Center, University of Texas	U.S.	Exclusive license agreement and research agreement to develop cord blood-derived chimeric antigen receptor-directed natural killer (CAR NK)-cell therapies, 'armored' with IL-15, for the treatment of B-cell malignancies and other cancers
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 (TAK-169) 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.
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
Teva	Israel	Agreement for worldwide License to TEV-48573 (TAK-573) (CD38-Attenukine) and multi-target discovery collaboration accessing Teva's attenukine platform.
Turnstone Biologics	U.S.	Collaboration to co-develop TAK-605 (RIVAL-01) (novel oncolytic virus expressing aCTLA4, IL12-mb, flt3L) via a worldwide partnership and also conduct collaborative discovery efforts to identify additional novel product candidates based on a Turnstone's vaccinia virus platform.

‡ Executed since April 1, 2020

* List is not inclusive of all Takeda R&D collaborations.

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
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).
Carmine Therapeutics‡	Singapore	Research collaboration agreement to discover, develop and commercialize transformative non-viral gene therapies for two rare disease targets using Carmine's REGENT(TM) technology, based on red blood cell extracellular vesicles.
Codexis, Inc.	U.S.	Strategic collaboration and license for the research and development of novel gene therapies for certain disease indications, including the treatment of lysosomal storage disorders and blood factor deficiencies.
Evox Therapeutics	U.K.	Collaboration for developing novel protein replacement and mRNA therapies and targeted delivery using Evox's proprietary exosome technology. Partnership for up to five rare disease targets with Takeda assuming responsibility for its clinical development
GlaxoSmithKline	U.K.	In-license agreement between GSK and University of Michigan for TAK-620 (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 to overcome the ADAMTS13 deficiency, induce clinical remission thus reducing cTTP 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
Xenetic Biosciences	U.S.	Exclusive R&D license agreement for PolyXen delivery technology for hemophilia factors VII, VIII, IX, X.

‡ Executed since April 1, 2020

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.
Neurocrine Biosciences‡	U.S.	Collaboration to develop and commercialize compounds in Takeda's early-to-mid stage neuroscience pipeline, including TAK-041, TAK-653 and TAK-831. Takeda will be entitled to certain development milestones, commercial milestones and royalties on net sales. At certain development events, Takeda may elect to opt in or out of a 50:50 profit share on all clinical programs on an asset-by-asset basis. For any asset in which Takeda is participating in a 50:50 profit share arrangement, Takeda will not be eligible to receive development or commercial milestones.
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 *in vivo* 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, 2020

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.
Cerevance	U.S.	Multi-year research alliance to identify novel target proteins expressed in the central nervous system and to develop new therapies against them for certain GI disorders. Goal of the collaboration is to select, confirm and validate targets from gene expression data sets generated by Cerevance's NETSseq technology.
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.
NuBiyota	Canada	Agreement for the development of Microbial Ecosystem Therapeutic products for gastroenterology indications.
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.
Silence Therapeutics	U.K.	Technology Evaluation Agreement with Silence Therapeutics to access their GalNAc-siRNA technology platform. The objective of the evaluation is to identify a GalNAc-conjugated siRNA that inhibits expression of a proprietary Takeda target.
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) for treatment of eosinophilic esophagitis.

Plasma Derived Therapies

Partner	Country	Subject
CoVig-19 Plasma Alliance	-	Cross sector alliance formed by Takeda and CSL Behring to develop a potential plasma-derived therapy for treating COVID-19. The alliance goal is the development of one, unbranded anti-SARS-CoV-2 polyclonal hyperimmune immunoglobulin medicine with the potential to treat individuals with serious complications from COVID-19.
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 IV 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.
ProThera Biologics‡	U.S.	Global licensing agreement to develop a novel plasma-derived Inter-alpha Inhibitor Proteins (IAIP) therapy for the treatment of acute inflammatory conditions.

‡ Executed since April 1, 2020

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.
Charles River Laboratories	U.S.	Collaboration on multiple integrated programs across Takeda's core therapeutic areas using Charles River Laboratories' end-to-end drug discovery and safety assessment platform to progress these programs towards candidate status.
Evotec GT	Germany	Research alliance to support Takeda's growing number of research stage gene therapy discovery programms.
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.
Massachusetts Institute of Technology	U.S.	MIT-Takeda Program to fuel the development and application of artificial intelligence (AI) capabilities to benefit human health and drug development. Centered within the Abdul Latif Jameel Clinic for Machine Learning in Health (J-Clinic), the new program will leverage the combined expertise of both organizations, and is supported by Takeda's three-year investment (with the potential for a two-year extension).
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, 2020

Completed Partnerships [Update disclosed since release of FY2019 results (May 13th, 2020)]

Partner	Country	Subject
ImmunoGen, Inc.	U.S.	Licensing agreement for rights to use ImmunoGen's Inc. ADC technology to develop and commercialize targeted anticancer therapeutics (TAK-164).
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.
Haemalogix	Australia	Research collaboration and licensing agreement for the development of new therapeutics to novel antigens in multiple myeloma.
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.
Ultragenyx	U.S.	Collaboration agreement to develop and commercialize therapies for rare genetic diseases.

■ 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