Supplementary Documents [IFRS]

Financial results for the first three months of the fiscal year 2020 (FY2020)

Astellas Pharma Inc.

- Q1/FY2020 Financial Results
- Pipeline list

Cautionary Notes

In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

to constitute an advertisement or medical advice.

1. Consolidated Results (Full Basis)

	Unit: B¥			
	FY19	FY20	Change	Change
	APR JUN.	APR JUN.		(%)
Revenue	334.1	307.0	-27.2	-8.1%
Cost of sales	70.5	59.7	-10.9	-15.4%
Ratio to Revenue	21.1%	19.4%		
Gross profit	263.6	247.3	-16.3	-6.2%
SG&A expenses	117.5	120.8	3.3	2.8%
Ratio to Revenue	35.2%	39.3%		
Advertising and Sales Promotion	41.3	42.0	0.7	1.8%
Personnel expenses	43.6	45.7	2.1	4.8%
Other	32.6	33.1	0.5	1.5%
R&D expenses	53.5	57.3	3.8	7.1%
Ratio to Revenue	16.0%	18.7%		
Amortisation of intangible assets	7.2	5.9	-1.3	-18.4%
Share of profit (loss) of investments accounted for using equity method	-0.7	-0.0	0.7	
Other income	4.5	2.2	-2.3	-50.4%
Net foreign exchange gains	0.5	1.1	0.7	131.6%
Other expenses	12.2	4.8	-7.4	-60.6%
Impairment losses	-	3.3	3.3	
Fair value remeasurements on contingent consideration	11.4	0.2	-11.2	-98.5%
Operating profit	77.1	60.8	-16.3	-21.1%
Ratio to Revenue	23.1%	19.8%		
Finance income	0.8	0.4	-0.4	-50.5%
Finance expenses	1.3	1.0	-0.4	-27.8%
Profit before tax	76.5	60.2	-16.3	-21.3%
Ratio to Revenue	22.9%	19.6%		
Income tax expense	18.0	9.8	-8.2	-45.4%
Profit	58.5	50.4	-8.1	-13.9%
Ratio to Revenue	17.5%	16.4%		
Comprehensive income	27.0	55.4	28.4	104.9%

	Initial Forecasts	Revised Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
1,300.8	1,282.0	1,256.5	-3.4%
276.7			
21.3%			
1,024.1			
499.3			
38.4%			
172.4			
179.8			
147.0			
224.2	239.0	233.5	4.1%
17.2%	18.6%	18.6%	
21.2			
-1.7			
12.2			
-			
45.9			
13.8			
11.2			
244.0	252.0	246.5	1.0%
18.8%	19.7%	19.6%	
4.4			
3.0			
245.4	251.0	245.5	0.1%
18.9%	19.6%	19.5%	
49.9			
195.4	202.0	197.5	1.1%
15.0%	15.8%	15.7%	
156.7			

2. Consolidated Results (Core Basis)			Unit: B¥	
	FY19	FY20	Change	Change
	APR JUN.	APR JUN.		(%)
Revenue	334.1	307.0	-27.2	-8.1%
Cost of sales	70.5	59.7	-10.9	-15.4%
Ratio to Revenu	e 21.1%	19.4%		
Gross profit	263.6	247.3	-16.3	-6.2%
SG&A expenses	117.5	120.8	3.3	2.8%
Ratio to Revenu	e 35.2%	39.3%		
Advertising and Sales Promotion	41.3	42.0	0.7	1.8%
Personnel expenses	43.6	45.7	2.1	4.8%
Other	32.6	33.1	0.5	1.5%
R&D expenses	53.5	57.3	3.8	7.1%
Ratio to Revenu	e 16.0%	18.7%		
Amortisation of intangible assets	7.2	5.9	-1.3	-18.4%
Share of profit (loss) of investments accounted for using equity method	-0.7	-0.0	0.7	-
Operating profit	84.7	63.4	-21.4	-25.2%
Ratio to Revenu	e 25.4%	20.6%		
Finance income	0.8	0.4	-0.4	-50.5%
Finance expenses	1.3	1.0	-0.4	-27.8%
Profit before tax	84.2	62.8	-21.4	-25.4%
Ratio to Revenu	e 25.2%	20.5%		
Income tax expense	17.1	10.8	-6.3	-36.7%
Profit	67.1	52.0	-15.1	-22.5%
Ratio to Revenu	e 20.1%	16.9%		

	Initial Forecasts	Revised Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
1,300.8	1,282.0	1,256.5	-3.4%
276.7			
21.3%			
1,024.1			
499.3			
38.4%			
172.4			
179.8			
147.0			
224.2	239.0	233.5	4.1%
17.2%	18.6%	18.6%	
21.2			
-1.7			
277.8	257.0	251.0	-9.6%
21.4%	20.0%	20.0%	
4.4			
3.0			
279.1			
21.5%			
55.9			
223.2	206.0	200.5	-10.2%
17.2%	16.1%	16.0%	

3. Exchange Rate

3. Exchange Rate				Unit: yen
	FY19	FY20	FY19	FY20
	APR JUN.Ave.	APR JUN.Ave.	End	Q1 End
USD/Yen	110	108	109	108
EUR/Yen	123	118	120	121

	Initial Forecasts	Revised Forecasts
FY19	FY20	FY20
Full Year	Full Year	Full Year
109	110	109
121	120	120

* Fx impacts: Revenue -7.1 billion yen and Core operating profit -5.8 billion yen

* Fx impact on elimination of unrealized gain: COGs ratio +1.1ppt

4. Reconciliation of Full Basis to Core Basis

						Unit: B¥
		FY19			FY20	
	APR JUN.			APR JUN.		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Revenue	334.1	-	334.1	307.0	-	307.0
Cost of sales	70.5	-	70.5	59.7	-	59.7
Gross profit	263.6	-	263.6	247.3	-	247.3
SG&A expenses	117.5	-	117.5	120.8	-	120.8
R&D expenses	53.5	-	53.5	57.3	-	57.3
Amortisation of intangible assets	7.2	-	7.2	5.9	-	5.9
Share of profit (loss) of investments accounted for using equity method	-0.7	-	-0.7	-0.0	-	-0.0
Other income *	4.5	-4.5	-	2.2	-2.2	-
Other expenses *	12.2	-12.2	-	4.8	-4.8	-
Operating profit	77.1	7.7	84.7	60.8	2.6	63.4
Finance income	0.8	-	0.8	0.4	-	0.4
Finance expenses	1.3	-	1.3	1.0	-	1.0
Profit before tax	76.5	7.7	84.2	60.2	2.6	62.8
Income tax expense	18.0	-0.9	17.1	9.8	1.0	10.8
Profit	58.5	8.6	67.1	50.4	1.6	52.0

* "Other income" and "Other expenses" are excluded from Full basis results. "Other income" and "Other expenses" include gain/loss on sale and disposal of property, plant and equipment, impairment losses, restructuring costs, litigation costs and foreign exchange gains/losses, etc.

5. Revenue by Regio	n				Unit: B¥	
			FY19	FY20	Change	Change
			APR JUN.	APR JUN.	-	(%)
Revenue			334.1	307.0	-27.2	-8.1%
	Japan		98.5	77.8	-20.7	-21.0%
		Ratio to Revenue	29.5%	25.3%		
Ľ	United States		105.3	117.2	11.9	11.3%
		Ratio to Revenue	31.5%	38.2%		
	Established Market		75.8	64.0	-11.7	-15.5%
		Ratio to Revenue	22.7%	20.9%		
	Greater China		14.7	14.2	-0.5	-3.4%
		Ratio to Revenue	4.4%	4.6%		
In	International		34.2	30.2	-4.0	-11.8%
		Ratio to Revenue	10.2%	9.8%		
	Others		5.6	3.6	-2.0	-36.4%
		Ratio to Revenue	1.7%	1.2%		

	Initial Forecasts	Revised Forecasts	Change from FY19
FY19	FY20 FY20		Change
Full Year	Full Year	Full Year	(%)
1,300.8	1,282.0	1,256.5	-3.4%
345.4	289.1	281.7	-18.4%
26.6%	22.6%	22.4%	
443.5	 490.9	486.4	9.7%
34.1%	38.3%	38.7%	
296.1	 299.0	287.5	-2.9%
22.8%	23.3%	22.9%	
60.4	 67.6	67.2	11.4%
4.6%	5.3%	5.4%	
134.8	 120.1	117.1	-13.1%
10.4%	9.4%	9.3%	
20.7	 15.3	16.5	-20.5%
1.6%	1.2%	1.3%	

- Established Market: Europe, Canada, Australia

- Greater China: China, Hong Kong, Taiwan

- International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

6. Addition to Property, Plant and Equipment

Depreciation/Amortisation

Depreciation/Amortisation	Unit: B¥			
	FY19	FY20	Change	Change
	APR JUN.	APR JUN.		(%)
Addition to Property, Plant and Equipment				
Consolidated	12.6	7.1	-5.5	-43.8%
Depreciation (PP&E)				
Consolidated	8.0	10.0	2.0	24.5%
Amortisation of Intangible Assets (incl. software, etc.)				
Consolidated	9.0	8.0	-1.0	-10.9%

	Initial Forecasts	Revised Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
41.8	29.0	29.0	-30.6%
37.5	41.0	41.0	9.3%
28.9	30.0	30.0	3.9%

- Addition to Property, Plant and Equipment does not include right-of-use asset.

7. Sales of major products

1) Global				Unit: B¥	
		FY19	FY20	Change	Change
		APR JUN.	APR JUN.	-	(%)
XTANDI		96.0	112.0	16.0	16.6%
	United States	46.9	62.7	15.8	33.7%
	ex-US	49.1	49.3	0.2	0.3%
	Japan	9.3	10.1	0.8	9.1%
	Established Market	33.6	31.5	-2.1	-6.4%
	Greater China	0.5	0.7	0.2	31.4%
	International	5.7	6.9	1.3	22.7%
XOSPATA		2.5	5.6	3.2	128.3%
	Japan	0.6	1.0	0.4	70.3%
	United States	1.9	3.6	1.7	92.3%
	Estabilished Market	-	1.0	1.0	-
PADCEV		-	3.0	3.0	-
	United States	-	3.0	3.0	-
Betanis/Myrabetr	iq/BETMIGA	39.9	40.4	0.5	1.2%
	Japan	9.4	8.4	-1.0	-10.5%
	United States	21.3	22.9	1.6	7.7%
	Estabilished Market	6.8	6.6	-0.2	-2.3%
	Greater China	0.4	0.4	0.0	12.3%
	International	2.1	2.0	-0.1	-2.5%
Vesicare		13.6	7.7	-5.8	-43.0%
	Japan	5.7	4.9	-0.8	-13.8%
	United States	0.2	0.4	0.2	85.7%
	Estabilished Market	6.1	1.3	-4.8	-79.2%
	Greater China	0.5	0.2	-0.3	-52.9%
	International	1.1	0.9	-0.2	-14.3%
Prograf		50.4	45.3	-5.1	-10.2%
	Japan	12.2	11.1	-1.1	-9.1%
	United States	3.2	3.6	0.3	10.1%
	Estabilished Market	17.7	13.8	-3.9	-21.9%
	Greater China	7.7	7.8	0.1	1.3%
	International	9.6	9.0	-0.6	-6.0%
Harnal/Omnic		10.9	10.6	-0.3	-3.1%
Funguard/MYCA	MINE	9.0	7.1	-1.9	-21.6%
Eligard		3.6	3.1	-0.6	-16.0%

Unit: B¥	Initial Forecasts	Revised Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
400.0	459.3	464.6	16.1%
203.5	238.3	249.5	22.6%
196.5	221.0	215.1	9.5%
35.8	39.3	38.9	8.8%
135.4	148.3	142.9	5.5%
3.2	6.9	6.9	115.0%
22.1	26.5	26.4	19.5%
14.3	23.2	23.1	61.9%
2.8	3.2	3.2	16.3%
10.5	13.8	13.8	30.8%
0.9	5.6	5.5	486.2%
1.8		13.0	619.6%
1.8		13.0	619.6%
161.6	172.5	167.9	3.9%
34.3	34.9	34.2	-0.5%
89.2	93.0	90.8	1.7%
28.2	31.4	30.5	8.4%
1.4	3.1	3.1	125.0%
8.4	10.1	9.3	10.6%
44.7	32.4	30.0	-32.9%
20.2	17.2	17.1	-15.4%
5.4	3.1	2.2	-59.0%
13.1	6.5	5.2	-60.3%
1.8	1.2	1.2	-34.7%
4.2	4.5	4.3	3.1%
192.9	186.3	182.0	-5.7%
44.3	41.1	40.5	-8.7%
13.2	12.2	12.1	-8.2%
71.5	65.3	62.6	-12.4%
32.2	35.4	35.1	9.2%
31.7	32.4	31.6	-0.4%
42.7	40.5	39.1	-8.3%
35.2	25.1	23.1	-34.4%
14.2	12.9	12.3	-13.3%

- Sales of products in Japan are shown in a gross sales basis

- EM(Established Market): Europe, Canada, Australia

- Greater China: China, Hong Kong, Taiwan

- International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

2) Revenue by region

(1) Japan			Unit: B¥		Unit: B¥	Initial Forecasts	Revised Forecasts	Change from FY19
	FY19	FY20	Change	Change	FY19	FY20	FY20	Change
<global></global>	APR JUN.	APR JUN.	-	(%)	Full Year	Full Year	Full Year	(%)
XTANDI	9.3	10.1	0.8	9.1%	35.8	39.3	38.9	8.8%
XOSPATA	0.6	1.0	0.4	70.3%	2.8	3.2	3.2	16.3%
Betanis	9.4	8.4	-1.0	-10.5%	34.3	34.9	34.2	-0.5%
Vesicare	5.7	4.9	-0.8	-13.8%	20.2	17.2	17.1	-15.4%
Prograf (Including Graceptor)	12.2	11.1	-1.1	-9.1%	44.3	41.1	40.5	-8.7%
Harnal	1.2	0.8	-0.4	-30.5%	4.1	2.6	2.6	-36.2%
Funguard	2.0	1.5	-0.5	-24.5%	7.6	3.6	3.6	-53.0%
<main products=""></main>								
Suglat [Family]	6.0	7.1	1.1	18.3%	23.9	32.3	30.3	26.7%
Sujanu	2.1	2.8	0.7	34.9%	8.9			
Repatha	0.8	1.2	0.4	52.5%	3.1			
Linzess	1.4	1.6	0.2	12.3%	5.6	6.6	6.6	19.4%
BLINCYTO	1.0	1.2	0.1	12.0%	4.5			
EVENITY	3.5	6.9	3.4	96.1%	23.6			
Celecox	13.1	11.6	-1.6	-11.9%	49.2	20.9	20.9	-57.4%
Symbicort	11.0	-	-11.0	-	14.1			
Geninax	2.2	0.6	-1.6	-72.6%	7.7	7.1	5.0	-35.6%
Vaccines	3.3	0.0	-3.3	-99.9%	11.2	7.4	7.4	-34.0%
Gonax	1.3	1.6	0.3	23.2%	5.1	5.5	5.5	8.0%
Cimzia	2.4	2.5	0.1	4.4%	9.3	9.4	9.4	1.6%
Micardis [Family]	5.3	-	-5.3	-	17.7			
Bonoteo	1.8	1.1	-0.7	-40.4%	6.0	3.2	3.2	-46.3%
Lipitor	3.7	2.9	-0.8	-21.2%	12.7	10.0	10.2	-19.3%
Myslee	2.5	2.1	-0.4	-17.3%	9.0	7.2	7.2	-20.3%
Total Rx Sales In Japanese market	97.9	76.9	-21.0	-21.5%	342.1	283.0	275.6	-19.5%

- Sales of products in Japan are shown in a gross sales basis.

(2) United	States			Unit: M\$	
		FY19	FY20	Change	Change
		APR JUN.	APR JUN.	-	(%)
Revenue		958	1,089	131	13.6%
	XTANDI	427	583	156	36.5%
	XOSPATA	17	33	16	96.4%
	PADCEV	-	27	27	-
	Myrbetriq	194	213	19	10.0%
	VESIcare	2	4	2	89.6%
	Prograf	29	33	4	12.4%
	MYCAMINE	26	24	-3	-10.5%
	AmBisome	27	22	-4	-16.3%
	CRESEMBA	37	36	-1	-2.3%
	Scan	185	111	-74	-40.1%
	Tarceva	15	3	-12	-82.4%

	Initial Forecasts	Revised Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
4,078	4,463	4,446	9.0%
1,871	2,166	2,280	21.8%
97	125	126	30.0%
17		119	615.2%
821	845	830	1.1%
50	28	20	-59.3%
122	111	111	-8.7%
106	78	62	-41.8%
116	118	106	-8.7%
155	167	155	0.0%
694	708	626	-9.8%
30			

(3) Established Market			Unit: M€	
	FY19	FY20	Change	Change
	APR JUN.	APR JUN.		(%)
Revenue	613	540	-73	-11.9%
XTANDI	272	266	-7	-2.4%
XOSPATA	-	9	9	-
BETMIGA	55	56	1	1.8%
Vesicare	49	11	-39	-78.4%
Prograf	143	117	-27	-18.5%
Omnic	17	15	-2	-11.8%
MYCAMINE	15	13	-1	-10.0%
Eligard	25	21	-3	-13.3%

FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
2,451	2,492	2,403	-1.9%
1,121	1,236	1,195	6.6%
8	47	46	492.1%
233	262	255	9.4%
108	54	43	-59.9%
592	544	524	-11.5%
71	68	63	-11.1%
56	40	40	-27.9%
98	85	81	-17.1%

- Established Market: Europe, Canada, Australia

(4) Greater China			Unit: B¥	
	FY19	FY20	Change	Change
	APR JUI	I. APR JUN.	_	(%)
Revenue	14	.7 14.2	-0.5	-3.4%
XTANDI	C	.5 0.7	0.2	31.4%
BETMIGA	C	.4 0.4	0.0	12.3%
Vesicare	C	.5 0.2	-0.3	-52.9%
Prograf	7	.7 7.8	0.1	1.3%
Harnal	3	.3 3.7	0.4	12.6%
MYCAMINE	C	.9 0.5	-0.4	-45.6%
Eligard	C	.1 0.1	0.0	16.8%
Feburic	C	.6 0.6	-0.0	-2.6%

	Initial Forecasts	Revised Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
60.4	67.6	67.2	11.4%
3.2	6.9	6.9	115.0%
1.4	3.1	3.1	125.0%
1.8	1.2	1.2	-34.7%
32.2	35.4	35.1	9.2%
13.1	11.4	11.4	-13.1%
3.8	3.7	3.7	-2.4%
0.3	0.4	0.4	19.3%
2.5	4.0	3.9	56.0%

- Greater China: China, Hong Kong, Taiwan

(5) International	Unit: B¥				
	FY19	FY20	Change	Change	
	APR JUN.	APR JUN.		(%)	
Revenue	34.2	30.2	-4.0	-11.8%	
XTANDI	5.7	6.9	1.3	22.7%	
BETMIGA	2.1	2.0	-0.1	-2.5%	
Vesicare	1.1	0.9	-0.2	-14.3%	
Prograf	9.6	9.0	-0.6	-6.0%	
Harnal	4.3	4.2	-0.1	-1.4%	
MYCAMINE	1.4	1.0	-0.4	-31.2%	

		Initial Forecasts	Revised Forecasts	Change from FY19
FY19	Γ	FY20	FY20	Change
Full Year		Full Year	Full Year	(%)
134.8	Γ	120.1	117.1	-13.1%
22.1		26.5	26.4	19.5%
8.4		10.1	9.3	10.6%
4.2		4.5	4.3	3.1%
31.7		32.4	31.6	-0.4%
16.9		18.2	17.6	4.1%
5.5		4.4	4.2	-23.2%

- International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

8. Consolidated statements of financial position

			Unit: E
	FY19	FY20	Change
	End	Q1 End	Change
sets	2,315.2	2,256.0	-59.
Non-current assets	1,447.7	1,460.1	12.
Property, plant and equipment	268.6	267.1	-1.
Goodwill	278.3	276.9	-1.
Intangible assets	724.8	729.4	4.
Trade and other receivables	34.0	34.0	0.
Investments accounted for using equity method	4.7	4.9	0.
Deferred tax assets	52.9	55.5	2.
Other financial assets	74.3	82.0	7.
Other non-current assets	10.2	10.3	0.
Current assets	867.5	796.0	-71.
Inventories	151.0	155.1	4.
Trade and other receivables	347.0	360.7	13.
Income tax receivable	23.6	16.1	-7.
Other financial assets	9.5	4.6	-4.
Other current assets	18.0	19.6	1.
Cash and cash equivalents	318.4	239.9	-78.

			Unit: E
	FY19	FY20	Change
	End	Q1 End	Change
uity and Liabilities	2,315.2	2,256.0	-59.
Equity	1,289.2	1,306.7	17
Equity attributable to owners of the parent	1,289.2	1,306.7	17
Share capital	103.0	103.0	
Capital surplus	177.5	177.2	-0
Treasury shares	-7.2	-7.4	-0
Retained earnings	905.9	918.9	13
Other components of equity	110.0	115.0	5
Liabilities	1,026.0	949.4	-76
Non-current liabilities	227.3	301.7	74
Trade and other payables	3.1	2.8	-0
Deferred tax liabilities	24.7	20.8	-3
Retirement benefit liabilities	38.1	38.6	0
Provisions	6.1	7.6	1
Other financial liabilities	129.3	208.3	79
Other non-current liabilities	26.0	23.6	-2
Current liabilities	798.7	647.7	-151
Trade and other payables	172.0	132.6	-39
Income tax payable	4.0	12.1	8
Provisions	14.2	14.5	0
Other financial liabilities	345.7	235.7	-110
Other current liabilities	262.8	252.7	-10

In the first three months of FY2020, the consolidated statement of financial position as of March 31, 2020 was retroactively revised due to adjustments of fair value of assets acquired and liabilities assumed for Audentes Therapeutics, Inc., which was acquired in January 2020. For the details, refer to Note "Business Combinations" in Financial Results.

R&D Pipeline

The list shows the development status in the target diseases for which we aim to obtain approval in Japan, the United States, Europe and/or China.

As of Aug 2020

Underlined items indicate changes from the previous announcement on May 2020.

Key post-POC projects and projects to maximize their VALUE (1/2)

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Licensor **	Remarks
	enzalutamide MDV3100 (XTANDI [®])	Small molecule	Androgen receptor inhibitor	Non-metastatic castration-resistant prostate cancer	China Filed (Oct 2019)	Pfizer	
	(XTANDI)			Metastatic castration-sensitive prostate cancer	<u>Japan</u> <u>Approved (May 2020)</u> Europe Filed (Jul 2019) China P-III		
				Non-metastatic castration-sensitive prostate cancer	P-III		
	gilteritinib ASP2215	Small molecule	FLT3 inhibitor	Relapsed or refractory acute myeloid leukemia	China Filed (Mar 2020)	In-house	
	(XOSPATA [®])			Post-chemotherapy maintenance acute myeloid leukemia	P-III	-	
				Post-hematopoietic stem cell transplant maintenance acute myeloid leukemia	P-III		
				Newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy	P-III		
				Newly diagnosed acute myeloid leukemia with high intensity induction of chemotherapy	P-III		
				Acute myeloid leukemia in pediatric patients	<u>P-III</u>		
	enfortumab vedotin Antiboo ASG-22ME (PADCEV [®])	Antibody-drug conjugate (ADC)	Nectin-4 targeted ADC	Metastatic urothelial cancer, PD-1/PD-L1 inhibitor and platinum-containing chemotherapy pretreated	P-III	In-house [Co-development with Seattle	
	(FADCEV)		Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)	P-III	Genetics]		
		Metastatic urothelial cancer, PD-1/PD-L1 inhibitor pretreated		P-II			
				Other solid tumors	P-II		
	zolbetuximab IMAB362	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III	In-house (Ganymed)	
				Pancreatic adenocarcinoma	P-II]	

Key post-POC projects and projects to maximize their VALUE (2/2)

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Licensor **	Remarks
	roxadustat ASP1517/FG-4592	Small molecule		Anemia associated with chronic kidney disease in patients on dialysis	Europe Filed (Apr 2020)	FibroGen	Astellas has rights in Japan, Europe, the
				Anemia associated with chronic kidney disease in patients not on dialysis	Japan Filed (Jan 2020) Europe Filed (Apr 2020)		Commonwealth of Independent States, the
				Chemotherapy-induced anemia	P-11		Middle East, and South Africa.
	fezolinetant ESN364	Small molecule	NK3 receptor antagonist	Menopause-related vasomotor symptoms		In-house (Ogeda)	

* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region. The list specifies the area if the compound is developed in limited areas. ** Compounds with "In-house" in this column include ones discovered by collaborative research.

Updates from the previous announcement (May 2020):

enzalutamide (MDV3100): Approved in Japan for prostate cancer with distant metastasis in May 2020.

roxadustat (ASP1517/FG-4592): Filed in Europe for anemia in adult patients with chronic kidney disease in Apr 2020.

gilteritinib (ASP2215): Initiated a new Phase 3 study for acute myeloid leukemia in pediatric patients.

Projects with Focus Area approach (1/2)

Target (Biology)	Generic Name Code No. (Brand Name)	Modality / Technology	Therapeutic Area	Classification	Target Disease	Phase *	Licensor **	Remarks
Immuno- oncology	ASP8374/PTZ-201	Antibody	Oncology	Anti-TIGIT antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	ASP1948/PTZ-329	Antibody	Oncology	Anti-NRP1 antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	ASP1951/PTZ-522	Antibody	Oncology	GITR agonistic antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	ASP9801	Oncolytic virus	Oncology	Oncolytic virus carrying IL-7 and IL-12	Cancer	P-I	Tottori University [Discovered through collaborative research]	
	ASP7517	Cell therapy (artificial adjuvant vector cells)	Oncology	WT1 loaded artificial adjuvant vector cell	Cancer	P-I	RIKEN [Discovered through collaborative research]	
Regeneration	ASP7317	Cell therapy	Ophthalmology	Retinal pigment epithelium cells	Dry age-related macular degeneration, Stargardt disease	P-II	In-house (Astellas Institute for Regenerative Medicine)	
	FX-322	Small molecule	Otology	Inner ear progenitor cell activator (combination of GSK-3 inhibitor and HDAC inhibitor)	Sensorineural hearing loss	P-II	Frequency Therapeutics	Astellas has rights in Ex-US markets
	ASP0598	Recombinant protein	Otology	Recombinant human heparin-binding epidermal growth factor-like growth factor	Chronic tympanic membrane perforation	P-I	Auration Biotech	
specific immuno-	ASP0892	Next generation vaccine (LAMP- vax technology)	Immunology		Peanut allergy	P-I	Immunomic Therapeutics	
	ASP2390	New generation vaccine (LAMP- vax technology)	Immunology		House dust mite-induced allergic rhinitis	P-I	Immunomic Therapeutics [Discovered through collaborative research]	

Projects with Focus Area approach (2/2)

Target (Biology)	Generic Name Code No. (Brand Name)	Modality / Technology	Therapeutic Area	Classification	Target Disease	Phase *	Licensor **	Remarks
Mitochondria	ASP1128/MA-0217	Small molecule	Nephrology	PPARδ modulator	Acute kidney injury		In-house (Mitobridge)	
	ASP0367/MA-0211	Small molecule	Muscle disease		Duchenne muscular dystrophy		In-house (Mitobridge)	
Genetic regulation	bilparvovec	Gene therapy (AAV-based gene therapy)		MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy		In-house (Audentes)	
	AT845	Gene therapy (AAV-based gene therapy)		GAA gene replacement to express GAA enzyme	Pompe disease		In-house (Audentes)	
Others	ASP3772	Next generation vaccine (MAPS technology)	disease	Pneumococcal vaccine based on a multiple antigen- presenting system (MAPS) platform	Prevention of pneumococcal disease	P-II	Affinivax	

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Others

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Licensor **	Remarks
Oncology	ASP1650	Antibody	Anti-Claudin 6 monoclonal antibody	Testicular cancer	P-II	In-house (Ganymed)	
	ASP1235/AGS62P1	Antibody-drug conjugate (ADC)		Acute myeloid leukemia	P-I	In-house [ADC technology, EuCODE license from Ambrx]	
Urology and Nephrology	solifenacin YM905 (<u>VESIcare LS</u>)	Small molecule	Muscarine M ₃ receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	US Approved (May 2020)	In-house	
	mirabegron YM178	Small molecule	β_3 receptor agonist	Overactive bladder and neurogenic detrusor overactivity in pediatric patients	P-III	In-house	
	ASP8302	Small molecule	Muscarine M ₃ receptor positive allosteric modulator	Underactive bladder	P-II	In-house	
Immunology	peficitinib ASP015K	Small molecule	JAK inhibitor	Rheumatoid arthritis	China P-III	In-house	
	bleselumab ASKP1240	Antibody	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients	P-II	Kyowa Kirin	
	ASP1617	Small molecule		Systemic lupus erythematosus	P-I	In-house	
Others	isavuconazole	Small molecule	Azole antifungal	Invasive aspergillosis and mucormycosis in pediatric patients	US P-II	Basilea	
	ASP8062	Small molecule	GABA _B receptor positive allosteric modulator	Substance use disorders	P-I	In-house	

* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region. The list specifies the area if the compound is developed in limited areas. ** Compounds with "In-house" in this column include ones discovered by collaborative research.

Update from the previous announcement (May 2020):

fidaxomicin: Removed the description of the approval in Europe for *clostridium difficile* infection in pediatric patients in Feb 2020. solifenacin (YM905): Approved in US for neurogenic detrusor overactivity in pediatric patients aged 2 years and older in May 2020.

As of August 2020

Underlined item indicates changes from the previous announcement on May 2020

Sphere (Business area)	Project	Concept	Status	Partner	Remarks
	Smartphone application		Implementing medical and health research	BANDAI NAMCO Entertainment	
	Fitness service (Fit-eNce)		Preparing to begin sales through fitness clubs in limited regions		
	BlueStar	Digital therapeutics for adults with diabetes	Under development	Welldoc, Inc.	
Patient outcome maximization	ASP5354	Precision surgery-guide enabling identification of ureter in hysterectomy and colorectal surgery etc.	P- II		

Update from the previous announcement (May 2020): Fitness service (Fit-eNce) : Added as a new project