

## 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. Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.*

1. Consolidated Results (Full Basis)

					Unit: B¥			
	FY19	FY20	Change	Change	FY19	Initial Forecasts	Revised Forecasts	Change from
	APR. - JUN.	APR. - JUN.		(%)	Full Year	FY20	FY20	FY19
						Full Year	Full Year	(%)
Revenue	334.1	307.0	-27.2	-8.1%	1,300.8	1,282.0	1,256.5	-3.4%
Cost of sales	70.5	59.7	-10.9	-15.4%	276.7			
Ratio to Revenue	21.1%	19.4%			21.3%			
Gross profit	263.6	247.3	-16.3	-6.2%	1,024.1			
SG&A expenses	117.5	120.8	3.3	2.8%	499.3			
Ratio to Revenue	35.2%	39.3%			38.4%			
Advertising and Sales Promotion	41.3	42.0	0.7	1.8%	172.4			
Personnel expenses	43.6	45.7	2.1	4.8%	179.8			
Other	32.6	33.1	0.5	1.5%	147.0			
R&D expenses	53.5	57.3	3.8	7.1%	224.2	239.0	233.5	4.1%
Ratio to Revenue	16.0%	18.7%			17.2%	18.6%	18.6%	
Amortisation of intangible assets	7.2	5.9	-1.3	-18.4%	21.2			
Share of profit (loss) of investments accounted for using equity method	-0.7	-0.0	0.7	-	-1.7			
Other income	4.5	2.2	-2.3	-50.4%	12.2			
Net foreign exchange gains	0.5	1.1	0.7	131.6%	-			
Other expenses	12.2	4.8	-7.4	-60.6%	45.9			
Impairment losses	-	3.3	3.3	-	13.8			
Fair value remeasurements on contingent consideration	11.4	0.2	-11.2	-98.5%	11.2			
Operating profit	77.1	60.8	-16.3	-21.1%	244.0	252.0	246.5	1.0%
Ratio to Revenue	23.1%	19.8%			18.8%	19.7%	19.6%	
Finance income	0.8	0.4	-0.4	-50.5%	4.4			
Finance expenses	1.3	1.0	-0.4	-27.8%	3.0			
Profit before tax	76.5	60.2	-16.3	-21.3%	245.4	251.0	245.5	0.1%
Ratio to Revenue	22.9%	19.6%			18.9%	19.6%	19.5%	
Income tax expense	18.0	9.8	-8.2	-45.4%	49.9			
Profit	58.5	50.4	-8.1	-13.9%	195.4	202.0	197.5	1.1%
Ratio to Revenue	17.5%	16.4%			15.0%	15.8%	15.7%	
Comprehensive income	27.0	55.4	28.4	104.9%	156.7			

2. Consolidated Results (Core Basis)

		Unit: B¥						Initial Forecasts		Revised Forecasts		Change from FY19
		FY19 APR. - JUN.	FY20 APR. - JUN.	Change	Change (%)	FY19 Full Year	FY20 Full Year	FY20 Full Year	FY20 Full Year	Change (%)		
Revenue		334.1	307.0	-27.2	-8.1%	1,300.8		1,282.0	1,256.5	-3.4%		
Cost of sales		70.5	59.7	-10.9	-15.4%	276.7						
	Ratio to Revenue	21.1%	19.4%			21.3%						
Gross profit		263.6	247.3	-16.3	-6.2%	1,024.1						
SG&A expenses		117.5	120.8	3.3	2.8%	499.3						
	Ratio to Revenue	35.2%	39.3%			38.4%						
Advertising and Sales Promotion		41.3	42.0	0.7	1.8%	172.4						
Personnel expenses		43.6	45.7	2.1	4.8%	179.8						
Other		32.6	33.1	0.5	1.5%	147.0						
R&D expenses		53.5	57.3	3.8	7.1%	224.2		239.0	233.5	4.1%		
	Ratio to Revenue	16.0%	18.7%			17.2%		18.6%	18.6%			
Amortisation of intangible assets		7.2	5.9	-1.3	-18.4%	21.2						
Share of profit (loss) of investments accounted for using equity method		-0.7	-0.0	0.7	-	-1.7						
Operating profit		84.7	63.4	-21.4	-25.2%	277.8		257.0	251.0	-9.6%		
	Ratio to Revenue	25.4%	20.6%			21.4%		20.0%	20.0%			
Finance income		0.8	0.4	-0.4	-50.5%	4.4						
Finance expenses		1.3	1.0	-0.4	-27.8%	3.0						
Profit before tax		84.2	62.8	-21.4	-25.4%	279.1						
	Ratio to Revenue	25.2%	20.5%			21.5%						
Income tax expense		17.1	10.8	-6.3	-36.7%	55.9						
Profit		67.1	52.0	-15.1	-22.5%	223.2		206.0	200.5	-10.2%		
	Ratio to Revenue	20.1%	16.9%			17.2%		16.1%	16.0%			

3. Exchange Rate

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

		Initial Forecasts		Revised Forecasts	
		FY20 Full Year	FY20 Full Year	FY20 Full Year	FY20 Full Year
FY19 Full Year		109	110	109	109
		121	120	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 APR. - JUN.			FY20 APR. - JUN.		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
<b>Revenue</b>	<b>334.1</b>	-	<b>334.1</b>	<b>307.0</b>	-	<b>307.0</b>
Cost of sales	70.5	-	70.5	59.7	-	59.7
<b>Gross profit</b>	<b>263.6</b>	-	<b>263.6</b>	<b>247.3</b>	-	<b>247.3</b>
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	-
<b>Operating profit</b>	<b>77.1</b>	<b>7.7</b>	<b>84.7</b>	<b>60.8</b>	<b>2.6</b>	<b>63.4</b>
Finance income	0.8	-	0.8	0.4	-	0.4
Finance expenses	1.3	-	1.3	1.0	-	1.0
<b>Profit before tax</b>	<b>76.5</b>	<b>7.7</b>	<b>84.2</b>	<b>60.2</b>	<b>2.6</b>	<b>62.8</b>
Income tax expense	18.0	-0.9	17.1	9.8	1.0	10.8
<b>Profit</b>	<b>58.5</b>	<b>8.6</b>	<b>67.1</b>	<b>50.4</b>	<b>1.6</b>	<b>52.0</b>

\* "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 Region

		Unit: B¥			
		FY19 APR. - JUN.	FY20 APR. - JUN.	Change	Change (%)
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%		
	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%		
	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%		

- 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.

	Initial Forecasts	Revised Forecasts	Change from FY19
FY19 Full Year	FY20 Full Year	FY20 Full Year	Change (%)
33.3	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%	

## 6. Addition to Property, Plant and Equipment Depreciation/Amortisation

		Unit: B¥			
		FY19 APR. - JUN.	FY20 APR. - JUN.	Change	Change (%)
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%

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

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

7. Sales of major products

1) Global

		Unit: B¥				Unit: B¥			
		FY19	FY20	Change	Change	FY19	Initial Forecasts	Revised Forecasts	Change from
		APR. - JUN.	APR. - JUN.		(%)	Full Year	FY20	FY20	FY19
							Full Year	Full Year	(%)
XTANDI		96.0	112.0	16.0	16.6%	400.0	459.3	464.6	16.1%
	United States	46.9	62.7	15.8	33.7%	203.5	238.3	249.5	22.6%
	ex-US	49.1	49.3	0.2	0.3%	196.5	221.0	215.1	9.5%
	Japan	9.3	10.1	0.8	9.1%	35.8	39.3	38.9	8.8%
	Established Market	33.6	31.5	-2.1	-6.4%	135.4	148.3	142.9	5.5%
	Greater China	0.5	0.7	0.2	31.4%	3.2	6.9	6.9	115.0%
	International	5.7	6.9	1.3	22.7%	22.1	26.5	26.4	19.5%
XOSPATA		2.5	5.6	3.2	128.3%	14.3	23.2	23.1	61.9%
	Japan	0.6	1.0	0.4	70.3%	2.8	3.2	3.2	16.3%
	United States	1.9	3.6	1.7	92.3%	10.5	13.8	13.8	30.8%
	Established Market	-	1.0	1.0	-	0.9	5.6	5.5	486.2%
PADCEV		-	3.0	3.0	-	1.8		13.0	619.6%
	United States	-	3.0	3.0	-	1.8		13.0	619.6%
Betanis/Myrbetriq/BETMIGA		39.9	40.4	0.5	1.2%	161.6	172.5	167.9	3.9%
	Japan	9.4	8.4	-1.0	-10.5%	34.3	34.9	34.2	-0.5%
	United States	21.3	22.9	1.6	7.7%	89.2	93.0	90.8	1.7%
	Established Market	6.8	6.6	-0.2	-2.3%	28.2	31.4	30.5	8.4%
	Greater China	0.4	0.4	0.0	12.3%	1.4	3.1	3.1	125.0%
	International	2.1	2.0	-0.1	-2.5%	8.4	10.1	9.3	10.6%
Vesicare		13.6	7.7	-5.8	-43.0%	44.7	32.4	30.0	-32.9%
	Japan	5.7	4.9	-0.8	-13.8%	20.2	17.2	17.1	-15.4%
	United States	0.2	0.4	0.2	85.7%	5.4	3.1	2.2	-59.0%
	Established Market	6.1	1.3	-4.8	-79.2%	13.1	6.5	5.2	-60.3%
	Greater China	0.5	0.2	-0.3	-52.9%	1.8	1.2	1.2	-34.7%
	International	1.1	0.9	-0.2	-14.3%	4.2	4.5	4.3	3.1%
Prograf		50.4	45.3	-5.1	-10.2%	192.9	186.3	182.0	-5.7%
	Japan	12.2	11.1	-1.1	-9.1%	44.3	41.1	40.5	-8.7%
	United States	3.2	3.6	0.3	10.1%	13.2	12.2	12.1	-8.2%
	Established Market	17.7	13.8	-3.9	-21.9%	71.5	65.3	62.6	-12.4%
	Greater China	7.7	7.8	0.1	1.3%	32.2	35.4	35.1	9.2%
	International	9.6	9.0	-0.6	-6.0%	31.7	32.4	31.6	-0.4%
Harnal/Omnic		10.9	10.6	-0.3	-3.1%	42.7	40.5	39.1	-8.3%
Funguard/MYCAMINE		9.0	7.1	-1.9	-21.6%	35.2	25.1	23.1	-34.4%
Eligard		3.6	3.1	-0.6	-16.0%	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¥			
	FY19 APR. - JUN.	FY20 APR. - JUN.	Change	Change (%)
<Global>				
XTANDI	9.3	10.1	0.8	9.1%
XOSPATA	0.6	1.0	0.4	70.3%
Betanis	9.4	8.4	-1.0	-10.5%
Vesicare	5.7	4.9	-0.8	-13.8%
Prograf (Including Gracaptor)	12.2	11.1	-1.1	-9.1%
Harnal	1.2	0.8	-0.4	-30.5%
Funguard	2.0	1.5	-0.5	-24.5%
<Main products>				
Suglat [Family]	6.0	7.1	1.1	18.3%
Sujanu	2.1	2.8	0.7	34.9%
Repatha	0.8	1.2	0.4	52.5%
Linzess	1.4	1.6	0.2	12.3%
BLINCYTO	1.0	1.2	0.1	12.0%
EVENITY	3.5	6.9	3.4	96.1%
Celecox	13.1	11.6	-1.6	-11.9%
Symbicort	11.0	-	-11.0	-
Geninax	2.2	0.6	-1.6	-72.6%
Vaccines	3.3	0.0	-3.3	-99.9%
Gonax	1.3	1.6	0.3	23.2%
Cimzia	2.4	2.5	0.1	4.4%
Micardis [Family]	5.3	-	-5.3	-
Bonoteo	1.8	1.1	-0.7	-40.4%
Lipitor	3.7	2.9	-0.8	-21.2%
Myslee	2.5	2.1	-0.4	-17.3%
Total Rx Sales In Japanese market	97.9	76.9	-21.0	-21.5%

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

	Unit: B¥		
	Initial Forecasts	Revised Forecasts	Change from FY19
	FY20 Full Year	FY20 Full Year	Change (%)
FY19 Full Year	35.8	39.3	8.8%
	2.8	3.2	16.3%
	34.3	34.9	-0.5%
	20.2	17.2	-15.4%
	44.3	41.1	-8.7%
	4.1	2.6	-36.2%
	7.6	3.6	-53.0%
	23.9	32.3	26.7%
	8.9	30.3	
	3.1		
	5.6	6.6	19.4%
	4.5		
	23.6		
	49.2	20.9	-57.4%
	14.1	20.9	
	7.7	7.1	5.0
	11.2	7.4	7.4
	5.1	5.5	5.5
	9.3	9.4	9.4
	17.7		
	6.0	3.2	3.2
	12.7	10.0	10.2
	9.0	7.2	7.2
	342.1	283.0	275.6
			-19.5%

(2) United States

Unit: M\$

	FY19 APR. - JUN.	FY20 APR. - JUN.	Change	Change (%)
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 Full Year	FY20 Full Year	FY20 Full Year	Change (%)
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 APR. - JUN.	FY20 APR. - JUN.	Change	Change (%)
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%
Omnice	17	15	-2	-11.8%
MYCAMINE	15	13	-1	-10.0%
Eligard	25	21	-3	-13.3%

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

- Established Market: Europe, Canada, Australia



## (4) Greater China

Unit: B¥

	FY19 APR. - JUN.	FY20 APR. - JUN.	Change	Change (%)
Revenue	14.7	14.2	-0.5	-3.4%
XTANDI	0.5	0.7	0.2	31.4%
BETMIGA	0.4	0.4	0.0	12.3%
Vesicare	0.5	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	0.9	0.5	-0.4	-45.6%
Eligard	0.1	0.1	0.0	16.8%
Feburic	0.6	0.6	-0.0	-2.6%

- Greater China: China, Hong Kong, Taiwan

	Initial Forecasts	Revised Forecasts	Change from FY19
FY19 Full Year	FY20 Full Year	FY20 Full Year	Change (%)
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%

## (5) International

Unit: B¥

	FY19 APR. - JUN.	FY20 APR. - JUN.	Change	Change (%)
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%

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

	Initial Forecasts	Revised Forecasts	Change from FY19
FY19 Full Year	FY20 Full Year	FY20 Full Year	Change (%)
134.8	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%

## 8. Consolidated statements of financial position

Unit: B¥

	FY19 End	FY20 Q1 End	Change
<b>Assets</b>	<b>2,315.2</b>	<b>2,256.0</b>	<b>-59.1</b>
<b>Non-current assets</b>	<b>1,447.7</b>	<b>1,460.1</b>	<b>12.4</b>
Property, plant and equipment	268.6	267.1	-1.5
Goodwill	278.3	276.9	-1.4
Intangible assets	724.8	729.4	4.6
Trade and other receivables	34.0	34.0	0.0
Investments accounted for using equity method	4.7	4.9	0.2
Deferred tax assets	52.9	55.5	2.6
Other financial assets	74.3	82.0	7.7
Other non-current assets	10.2	10.3	0.1
<b>Current assets</b>	<b>867.5</b>	<b>796.0</b>	<b>-71.5</b>
Inventories	151.0	155.1	4.1
Trade and other receivables	347.0	360.7	13.7
Income tax receivable	23.6	16.1	-7.5
Other financial assets	9.5	4.6	-4.9
Other current assets	18.0	19.6	1.5
Cash and cash equivalents	318.4	239.9	-78.5

Unit: B¥

	FY19 End	FY20 Q1 End	Change
<b>Equity and Liabilities</b>	<b>2,315.2</b>	<b>2,256.0</b>	<b>-59.1</b>
<b>Equity</b>	<b>1,289.2</b>	<b>1,306.7</b>	<b>17.5</b>
<b>Equity attributable to owners of the parent</b>	<b>1,289.2</b>	<b>1,306.7</b>	<b>17.5</b>
Share capital	103.0	103.0	-
Capital surplus	177.5	177.2	-0.3
Treasury shares	-7.2	-7.4	-0.2
Retained earnings	905.9	918.9	13.0
Other components of equity	110.0	115.0	5.0
<b>Liabilities</b>	<b>1,026.0</b>	<b>949.4</b>	<b>-76.7</b>
<b>Non-current liabilities</b>	<b>227.3</b>	<b>301.7</b>	<b>74.4</b>
Trade and other payables	3.1	2.8	-0.3
Deferred tax liabilities	24.7	20.8	-3.9
Retirement benefit liabilities	38.1	38.6	0.5
Provisions	6.1	7.6	1.5
Other financial liabilities	129.3	208.3	79.0
Other non-current liabilities	26.0	23.6	-2.4
<b>Current liabilities</b>	<b>798.7</b>	<b>647.7</b>	<b>-151.0</b>
Trade and other payables	172.0	132.6	-39.3
Income tax payable	4.0	12.1	8.1
Provisions	14.2	14.5	0.3
Other financial liabilities	345.7	235.7	-110.0
Other current liabilities	262.8	252.7	-10.1

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
Oncology	enzalutamide MDV3100 (XTANDI®)	Small molecule	Androgen receptor inhibitor	Non-metastatic castration-resistant prostate cancer	China Filed (Oct 2019)	Pfizer	
				Metastatic castration-sensitive prostate cancer	<u>Japan Approved (May 2020)</u> Europe Filed (Jul 2019) China P-III		
				Non-metastatic castration-sensitive prostate cancer	P-III		
Oncology	gilteritinib ASP2215 (XOSPATA®)	Small molecule	FLT3 inhibitor	Relapsed or refractory acute myeloid leukemia	China Filed (Mar 2020)	In-house	
				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>		
Oncology	enfortumab vedotin 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 Genetics]	
				Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)	P-III		
				Metastatic urothelial cancer, PD-1/PD-L1 inhibitor pretreated	P-II		
				Other solid tumors	P-II		
Oncology	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
Urology and Nephrology	roxadustat ASP1517/FG-4592	Small molecule	HIF-PH inhibitor	Anemia associated with chronic kidney disease in patients on dialysis	Europe Filed (Apr 2020)	FibroGen	Astellas has rights in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.
				Anemia associated with chronic kidney disease in patients not on dialysis	Japan Filed (Jan 2020) Europe Filed (Apr 2020)		
				Chemotherapy-induced anemia	P-II		
Others	fezolinetant ESN364	Small molecule	NK3 receptor antagonist	Menopause-related vasomotor symptoms	P-III	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	
Antigen-specific immunomodulation (ASIM)	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	PPAR $\delta$ modulator	Acute kidney injury	P-II	In-house (Mitobridge)	
	ASP0367/MA-0211	Small molecule	Muscle disease		Duchenne muscular dystrophy	P-I	In-house (Mitobridge)	
Genetic regulation	resamirigene bilparovvec AT132	Gene therapy (AAV-based gene therapy)	Muscle disease	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy	P-II	In-house (Audentes)	
	AT845	Gene therapy (AAV-based gene therapy)	Muscle disease	GAA gene replacement to express GAA enzyme	Pompe disease	P-I	In-house (Audentes)	
Others	ASP3772	Next generation vaccine (MAPS technology)	Infectious disease	Pneumococcal vaccine based on a multiple antigen-presenting system (MAPS) platform	Prevention of pneumococcal disease	P-II	Affinivax	

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\*\* Compounds with "In-house" in this column include ones discovered by collaborative research.

## 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 (VESicare LS)	Small molecule	Muscarine M <sub>3</sub> receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	US <u>Approved (May 2020)</u>	In-house	
	mirabegron YM178	Small molecule	β <sub>3</sub> receptor agonist	Overactive bladder and neurogenic detrusor overactivity in pediatric patients	P-III	In-house	
	ASP8302	Small molecule	Muscarine M <sub>3</sub> 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 <sub>B</sub> receptor positive allosteric modulator	Substance use disorders	P-I	In-house	

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\*\* 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.

## Rx+ Program

As of August 2020

Underlined item indicates changes from the previous announcement on May 2020

Sphere (Business area)	Project	Concept	Status	Partner	Remarks
Chronic disease progression prevention	Smartphone application	Offer smartphone application to support exercise using wearable device to people who needs regular exercise	Implementing medical and health research	BANDAI NAMCO Entertainment	
	<u>Fitness service (Fit-eNce)</u>	<u>Scientifically evidenced exercise programs and systems which support regular exercise</u>	<u>Preparing to begin sales through fitness clubs in limited regions</u>		
	BlueStar	Digital therapeutics for adults with diabetes	<u>Under development</u>	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