

Supplementary Documents [IFRS]

Financial results for the first three months of the fiscal year 2021 (FY2021)

Astellas Pharma Inc.

- Q1/FY2021 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¥

	FY20 APR. - JUN.	FY21 APR. - JUN.	Change	Change (%)
Revenue	307.0	326.1	19.2	6.2%
Cost of sales	59.7	62.2	2.6	4.3%
Ratio to Revenue	19.4%	19.1%		
Gross profit	247.3	263.9	16.6	6.7%
SG&A expenses	120.8	137.1	16.3	13.5%
Ratio to Revenue	39.3%	42.0%		
Advertising and Sales Promotion	10.5	14.1	3.6	34.2%
XTANDI co-promotion fee in the United States	31.5	34.5	3.0	9.4%
Personnel expenses	45.7	49.0	3.3	7.3%
Other	33.1	39.5	6.4	19.5%
R&D expenses	57.3	58.3	1.0	1.8%
Ratio to Revenue	18.7%	17.9%		
Amortisation of intangible assets	5.9	6.0	0.1	1.8%
Share of profit (loss) of investments accounted for using equity method	-0.0	0.3	0.3	-
Other income	2.2	0.4	-1.8	-82.0%
Net foreign exchange gains	1.1	0.3	-0.8	-70.5%
Other expense	4.8	27.1	22.3	465.2%
Impairment losses	3.3	26.1	22.8	690.7%
Operating profit	60.8	36.1	-24.7	-40.7%
Ratio to Revenue	19.8%	11.1%		
Finance income	0.4	1.5	1.1	284.3%
Finance expenses	1.0	1.7	0.8	79.6%
Profit before tax	60.2	35.8	-24.4	-40.5%
Ratio to Revenue	19.6%	11.0%		
Income tax expense	9.8	5.1	-4.7	-47.7%
Profit	50.4	30.7	-19.7	-39.1%
Ratio to Revenue	16.4%	9.4%		
Comprehensive income	55.4	36.2	-19.2	-34.7%

	Initial Forecasts	Revised Forecasts	Change from FY20
FY20 Full Year	FY21 Full Year	FY21 Full Year	Change (%)
1,249.5	1,323.0	1,323.0	5.9%
246.1			
19.7%			
1,003.5			
504.3	541.0	541.0	7.3%
40.4%	40.9%	40.9%	
60.6			
120.2			
182.2			
141.4			
224.5	242.0	242.0	7.8%
18.0%	18.3%	18.3%	
23.8			
0.5			
7.6			
-			
123.0			
101.7			
136.1	265.0	227.0	66.8%
10.9%	20.0%	17.2%	
11.6			
2.3			
145.3	263.0	225.0	54.8%
11.6%	19.9%	17.0%	
24.7			
120.6	209.0	183.0	51.8%
9.7%	15.8%	13.8%	
181.5			

2. Consolidated Results (Core Basis)

Unit: B¥

	FY20 APR. - JUN.	FY21 APR. - JUN.	Change	Change (%)
Revenue	307.0	326.1	19.2	6.2%
Cost of sales	59.7	62.2	2.6	4.3%
Ratio to Revenue	19.4%	19.1%		
Gross profit	247.3	263.9	16.6	6.7%
SG&A expenses	120.8	137.1	16.3	13.5%
Ratio to Revenue	39.3%	42.0%		
Advertising and Sales Promotion	10.5	14.1	3.6	34.2%
XTANDI co-promotion fee in the United States	31.5	34.5	3.0	9.4%
Personnel expenses	45.7	49.0	3.3	7.3%
Other	33.1	39.5	6.4	19.5%
R&D expenses	57.3	58.3	1.0	1.8%
Ratio to Revenue	18.7%	17.9%		
Amortisation of intangible assets	5.9	6.0	0.1	1.8%
Share of profit (loss) of investments accounted for using equity method	-0.0	0.3	0.3	-
Operating profit	63.4	62.8	-0.6	-0.9%
Ratio to Revenue	20.6%	19.3%		
Finance income	0.4	1.5	1.1	284.3%
Finance expenses	1.0	1.7	0.8	79.6%
Profit before tax	62.8	62.6	-0.2	-0.4%
Ratio to Revenue	20.5%	19.2%		
Income tax expense	10.8	13.3	2.5	23.3%
Profit	52.0	49.2	-2.7	-5.3%
Ratio to Revenue	16.9%	15.1%		

	FY20 Full Year	Initial Forecasts FY21 Full Year	Change from FY20 Change (%)
Revenue	1,249.5	1,323.0	5.9%
Cost of sales	246.1		
Ratio to Revenue	19.7%		
Gross profit	1,003.5		
SG&A expenses	504.3	541.0	7.3%
Ratio to Revenue	40.4%	40.9%	
Advertising and Sales Promotion	60.6		
XTANDI co-promotion fee in the United States	120.2		
Personnel expenses	182.2		
Other	141.4		
R&D expenses	224.5	242.0	7.8%
Ratio to Revenue	18.0%	18.3%	
Amortisation of intangible assets	23.8		
Share of profit (loss) of investments accounted for using equity method	0.5		
Operating profit	251.4	270.0	7.4%
Ratio to Revenue	20.1%	20.4%	
Finance income	11.6		
Finance expenses	2.3		
Profit before tax	260.6		
Ratio to Revenue	20.9%		
Income tax expense	50.7		
Profit	209.9	213.0	1.5%
Ratio to Revenue	16.8%	16.1%	

3. Exchange Rate

Unit: yen

	FY20 APR. - JUN.Ave.	FY21 APR. - JUN.Ave.	FY20 End	FY21 Q1 End
USD/Yen	108	109	111	111
EUR/Yen	118	132	130	132

	FY20 Full Year	Initial Forecasts FY21 Full Year
USD/Yen	106	110
EUR/Yen	124	130

* Fx impacts: Revenue +13.6 billion yen and Core operating profit +6.1 billion yen

* Fx impact on elimination of unrealized gain: COGs ratio +0.1ppt

4. Reconciliation of Full Basis to Core Basis

Unit: B¥

	FY20 APR. - JUN.			FY21 APR. - JUN.		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Revenue	307.0	-	307.0	326.1	-	326.1
Cost of sales	59.7	-	59.7	62.2	-	62.2
Gross profit	247.3	-	247.3	263.9	-	263.9
SG&A expenses	120.8	-	120.8	137.1	-	137.1
R&D expenses	57.3	-	57.3	58.3	-	58.3
Amortisation of intangible assets	5.9	-	5.9	6.0	-	6.0
Share of profit (loss) of investments accounted for using equity method	-0.0	-	-0.0	0.3	-	0.3
Other income *	2.2	-2.2	-	0.4	-0.4	-
Other expenses *	4.8	-4.8	-	27.1	-27.1	-
Operating profit	60.8	2.6	63.4	36.1	26.7	62.8
Finance income	0.4	-	0.4	1.5	-	1.5
Finance expenses	1.0	-	1.0	1.7	-	1.7
Profit before tax	60.2	2.6	62.8	35.8	26.7	62.6
Income tax expense	9.8	1.0	10.8	5.1	8.2	13.3
Profit	50.4	1.6	52.0	30.7	18.6	49.2

* "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¥				Initial Forecasts		Change from
		FY20	FY21	Change	Change	FY20	FY21	FY20
		APR. - JUN.	APR. - JUN.		(%)	Full Year	Full Year	(%)
Revenue		307.0	326.1	19.2	6.2%	1,249.5	1,323.0	5.9%
	Japan	77.8	67.5	-10.3	-13.2%	279.1	249.8	-10.5%
	Ratio to Revenue	25.3%	20.7%			22.3%	18.9%	
	United States	117.2	133.6	16.5	14.1%	473.2	544.6	15.1%
	Ratio to Revenue	38.2%	41.0%			37.9%	41.2%	
	Established Markets	64.0	78.0	14.0	21.8%	293.2	331.9	13.2%
	Ratio to Revenue	20.9%	23.9%			23.5%	25.1%	
	Greater China	14.2	16.4	2.2	15.5%	59.3	63.8	7.7%
	Ratio to Revenue	4.6%	5.0%			4.7%	4.8%	
	International Markets	30.2	27.8	-2.4	-8.1%	111.1	122.7	10.4%
	Ratio to Revenue	9.8%	8.5%			8.9%	9.3%	
	Others	3.6	2.8	-0.8	-21.9%	33.6	10.1	-70.1%
	Ratio to Revenue	1.2%	0.9%			2.7%	0.8%	

- Established Markets: Europe, Canada, Australia

- Greater China: China, Hong Kong, Taiwan

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

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

		Unit: B¥				Initial Forecasts		Change from
		FY20	FY21	Change	Change	FY20	FY21	FY20
		APR. - JUN.	APR. - JUN.		(%)	Full Year	Full Year	(%)
Addition to Property, Plant and Equipment								
	Consolidated	7.1	5.2	-1.9	-27.3%	33.7	36.0	6.8%
Depreciation (PP&E)								
	Consolidated	10.0	9.9	-0.1	-0.6%	40.0	43.0	7.5%
Amortisation of Intangible Assets (incl. software, etc.)								
	Consolidated	8.0	8.2	0.2	2.6%	32.7	39.0	19.4%

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

7. Sales of major products

1) Global

Unit: B¥

	FY20 APR. - JUN.	FY21 APR. - JUN.	Change	Change (%)
XTANDI	112.0	132.9	21.0	18.7%
United States	62.7	68.4	5.7	9.1%
ex-US	49.3	64.5	15.3	31.0%
Japan	10.1	12.0	1.9	18.5%
Established Markets	31.5	42.8	11.4	36.1%
Greater China	0.7	1.9	1.2	165.1%
International Markets	6.9	7.8	0.8	12.2%
XOSPATA	5.6	8.3	2.7	47.7%
Japan	1.0	1.1	0.1	6.6%
United States	3.6	4.6	1.0	26.9%
Established Markets	1.0	2.0	1.0	99.4%
Greater China	-	0.5	0.5	-
International Markets	-	0.1	0.1	-
PADCEV	3.0	4.2	1.2	41.9%
United States	3.0	4.2	1.2	41.9%
Evrenzo	0.2	0.6	0.5	282.9%
Japan	0.2	0.6	0.5	282.9%
Betanis/Myrabetriq/BETMIGA	40.4	44.0	3.6	8.8%
Japan	8.4	9.8	1.4	16.2%
United States	22.9	22.8	-0.1	-0.5%
Established Markets	6.6	8.5	1.9	29.4%
Greater China	0.4	0.7	0.2	56.9%
International Markets	2.0	2.2	0.1	5.8%
Vesicare	7.7	7.4	-0.3	-4.4%
Japan	4.9	4.6	-0.4	-7.7%
United States	0.4	0.2	-0.2	-39.4%
Established Markets	1.3	1.4	0.2	14.4%
Greater China	0.2	0.3	0.1	22.3%
International Markets	0.9	0.9	-0.0	-3.9%
Prograf	45.3	45.2	-0.1	-0.3%
Japan	11.1	10.2	-0.9	-7.9%
United States	3.6	2.1	-1.4	-40.8%
Established Markets	13.8	16.2	2.4	17.0%
Greater China	7.8	9.6	1.8	22.9%
International Markets	9.0	7.0	-1.9	-21.7%
Eligard	3.1	-	-3.1	-

	FY20 Full Year	Initial Forecasts FY21 Full Year	Change from FY20 Change (%)
	458.4	557.2	21.5%
	238.6	288.0	20.7%
	219.8	269.2	22.5%
	40.2	45.4	12.8%
	149.3	183.0	22.6%
	4.9	7.0	43.6%
	25.5	33.8	32.7%
	23.8	36.7	53.8%
	3.8	4.4	16.0%
	15.5	20.0	29.3%
	4.4	9.8	123.2%
	0.0	1.6	-
	0.2	0.9	488.4%
	12.8	20.1	57.1%
	12.8	19.1	49.3%
	1.1	8.6	661.0%
	1.1	4.1	262.8%
	163.6	175.2	7.1%
	35.1	35.8	2.2%
	88.0	94.2	7.0%
	29.9	35.6	19.1%
	2.2	2.5	15.0%
	8.5	7.1	-15.9%
	31.6	16.1	-49.2%
	18.5	5.5	-70.4%
	2.2	1.2	-43.3%
	6.2	4.9	-21.5%
	1.0	0.8	-23.4%
	3.7	3.7	-1.1%
	182.7	192.6	5.5%
	40.7	38.5	-5.5%
	11.8	11.1	-6.1%
	64.2	69.8	8.8%
	34.2	37.1	8.4%
	31.7	36.2	14.1%
	9.5	-	-

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

- Established Markets: Europe, Canada, Australia

- Greater China: China, Hong Kong, Taiwan

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

2) Revenue by region

(1) Japan

Unit: B¥

<Global>	FY20 APR. - JUN.	FY21 APR. - JUN.	Change	Change (%)
XTANDI	10.1	12.0	1.9	18.5%
XOSPATA	1.0	1.1	0.1	6.6%
Evrenzo	0.2	0.6	0.5	282.9%
Betanis	8.4	9.8	1.4	16.2%
Vesicare	4.9	4.6	-0.4	-7.7%
Prograf (Including Graceptor)	11.1	10.2	-0.9	-7.9%
Harnal	0.8	0.7	-0.2	-20.2%
Funguard	1.5	0.4	-1.1	-70.7%

FY20 Full Year
40.2
3.8
1.1
35.1
18.5
40.7
3.0
4.4

Initial Forecasts	Change from FY20
FY21 Full Year	Change (%)
45.4	12.8%
4.4	16.0%
4.1	262.8%
35.8	2.2%
5.5	-70.4%
38.5	-5.5%
2.1	-28.9%
1.8	-58.3%

<Main products>

Suglat [Family]	7.1	7.9	0.8	10.9%
Sujanu	2.8	3.2	0.4	13.6%
Repatha	1.2	1.5	0.3	25.3%
Linzess	1.6	1.8	0.2	12.9%
BLINCYTO	1.2	1.4	0.2	17.6%
EVENITY	6.9	7.0	0.1	1.6%
Smyraf	0.2	0.6	0.4	179.6%
Celecox	11.6	-	-11.6	-
Geninax	0.6	0.7	0.1	15.4%
Vaccines	0.0	0.0	0.0	0.0%
Gonax	1.6	1.3	-0.3	-20.3%
Cimzia	2.5	2.8	0.3	12.3%
Lipitor	2.9	-	-2.9	-
Myslee	2.1	1.8	-0.2	-11.4%
Total Rx Sales In Japanese market	76.9	67.0	-9.9	-12.9%

27.9
11.3
5.1
6.4
4.5
24.8
1.7
18.9
2.5
7.9
5.1
10.0
10.6
7.8
276.6

30.3	8.6%
6.9	7.9%
3.1	89.5%
4.5	79.8%
7.7	-3.2%
5.0	-1.7%
6.7	-15.0%
247.6	-10.5%

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

(2) United States

Unit: M\$

	FY20 APR. - JUN.	FY21 APR. - JUN.	Change	Change (%)
Revenue	1,089	1,221	132	12.1%
XTANDI	583	625	42	7.2%
XOSPATA	33	42	8	24.7%
PADCEV	27	38	11	39.5%
Myrbetriq	213	208	-5	-2.2%
VESicare	4	2	-1	-40.4%
Prograf	33	19	-14	-41.8%
MYCAMINE	24	14	-10	-40.4%
AmBisome	22	30	8	35.9%
CRESEMBA	36	45	9	25.8%
Lexiscan	111	196	85	77.1%

	FY20 Full Year	Initial Forecasts FY21 Full Year	Change from FY20 Change (%)
	4,462	4,951	11.0%
	2,250	2,618	16.4%
	146	182	24.6%
	121	174	43.9%
	829	856	3.2%
	20	11	-45.3%
	112	101	-9.5%
	83	17	-78.9%
	114	115	1.0%
	160	176	10.6%
	623	700	12.5%

(3) Established Markets

Unit: M€

	FY20 APR. - JUN.	FY21 APR. - JUN.	Change	Change (%)
Revenue	540	591	51	9.4%
XTANDI	266	325	59	22.2%
XOSPATA	9	15	7	79.0%
BETMIGA	56	65	9	16.2%
Vesicare	11	11	0	2.7%
Prograf	117	123	6	5.1%
Omnice	15	17	2	12.2%
MYCAMINE	13	7	-6	-47.6%
Eligard	21	-	-21	-

	FY20 Full Year	FY21 Full Year	Change (%)
	2,370	2,553	7.7%
	1,207	1,408	16.7%
	36	75	112.3%
	241	274	13.3%
	50	38	-25.3%
	519	537	3.5%
	65	63	-3.7%
	45	22	-51.2%
	64	-	-

- Established Markets: Europe, Canada, Australia

(4) Greater China

Unit: B¥

	FY20 APR. - JUN.	FY21 APR. - JUN.	Change	Change (%)
Revenue	14.2	16.4	2.2	15.5%
XTANDI	0.7	1.9	1.2	165.1%
XOSPATA	-	0.5	0.5	-
BETMIGA	0.4	0.7	0.2	56.9%
Vesicare	0.2	0.3	0.1	22.3%
Prograf	7.8	9.6	1.8	22.9%
Harnal	3.7	2.0	-1.7	-46.8%
MYCAMINE	0.5	0.6	0.1	25.3%
Feburic	0.6	0.6	0.1	9.7%

- Greater China: China, Hong Kong, Taiwan

	Initial Forecasts	
	FY21 Full Year	Change from FY20 Change (%)
FY20 Full Year	59.3	
	63.8	7.7%
	4.9	43.6%
	0.0	-
	2.2	15.0%
	1.0	-23.4%
	34.2	8.4%
	10.8	-26.4%
	2.5	37.7%
	2.6	12.9%

(5) International Markets

Unit: B¥

	FY20 APR. - JUN.	FY21 APR. - JUN.	Change	Change (%)
Revenue	30.2	27.8	-2.4	-8.1%
XTANDI	6.9	7.8	0.8	12.2%
XOSPATA	-	0.1	0.1	-
BETMIGA	2.0	2.2	0.1	5.8%
Vesicare	0.9	0.9	-0.0	-3.9%
Prograf	9.0	7.0	-1.9	-21.7%
Harnal	4.2	4.3	0.1	2.1%
MYCAMINE	1.0	1.6	0.6	64.6%

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

	Initial Forecasts	
	FY21 Full Year	Change from FY20 Change (%)
FY20 Full Year	111.1	
	122.7	10.4%
	25.5	32.7%
	0.2	488.4%
	8.5	-15.9%
	3.7	-1.1%
	31.7	14.1%
	15.1	6.6%
	4.7	7.3%

8. Consolidated statements of financial position

Unit: B¥

	FY20 End	FY21 Q1 End	Change
Assets	2,273.6	2,249.5	-24.2
Non-current assets	1,401.0	1,380.7	-20.3
Property, plant and equipment	264.6	269.7	5.1
Goodwill	284.0	284.1	0.1
Intangible assets	651.4	630.3	-21.1
Trade and other receivables	33.9	32.8	-1.1
Investments accounted for using equity method	7.1	8.0	0.9
Deferred tax assets	54.2	54.6	0.4
Other financial assets	95.9	91.5	-4.3
Other non-current assets	9.9	9.7	-0.3
Current assets	872.6	868.7	-3.9
Inventories	164.1	157.3	-6.8
Trade and other receivables	343.2	364.2	21.1
Income tax receivable	14.0	17.3	3.3
Other financial assets	5.6	4.1	-1.5
Other current assets	19.7	23.9	4.3
Cash and cash equivalents	326.1	301.9	-24.2

Unit: B¥

	FY20 End	FY21 Q1 End	Change
Equity and Liabilities	2,273.6	2,249.5	-24.2
Equity	1,386.1	1,382.9	-3.2
Equity attributable to owners of the parent	1,386.1	1,382.9	-3.2
Share capital	103.0	103.0	-
Capital surplus	177.8	177.7	-0.2
Treasury shares	-15.4	-15.7	-0.3
Retained earnings	953.3	946.0	-7.3
Other components of equity	167.4	171.9	4.5
Liabilities	887.5	866.6	-20.9
Non-current liabilities	295.1	285.0	-10.1
Trade and other payables	0.4	0.3	-0.1
Deferred tax liabilities	18.2	8.2	-10.0
Retirement benefit liabilities	39.0	38.4	-0.5
Provisions	5.8	7.6	1.8
Other financial liabilities	199.0	201.4	2.3
Other non-current liabilities	32.8	29.1	-3.7
Current liabilities	592.4	581.6	-10.8
Trade and other payables	124.8	108.5	-16.3
Income tax payable	8.4	14.6	6.2
Provisions	22.2	19.7	-2.5
Other financial liabilities	148.2	147.5	-0.7
Other current liabilities	288.9	291.3	2.4

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 Jul 2021

Underlined items indicate changes from the previous announcement in Apr 2021.

XTANDI and Strategic products (1/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
enzalutamide MDV3100 (XTANDI)	Small molecule	Androgen receptor inhibitor	Metastatic castration-sensitive prostate cancer	Europe China	<u>Approved (Apr 2021)</u> P-III	Pfizer
			Non-metastatic castration-sensitive prostate cancer	P-III		
gilteritinib ASP2215 (XOSPATA)	Small molecule	FLT3 inhibitor	Post-chemotherapy maintenance acute myeloid leukemia	P-III	In-house	
			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	P-III		
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	Europe	Filed (Mar 2021)	In-house [Co-development with Seagen]
			Metastatic urothelial cancer, cisplatin-ineligible and <u>who have previously received one or more therapy</u>	US	<u>Approved (Jul 2021)</u>	
			Metastatic urothelial cancer, progressed after anti-cancer medication	Japan	Filed (Mar 2021)	
			Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)	P-III		
			Muscle-invasive bladder cancer (combo with pembrolizumab)	P-III		
			Other solid tumors	P-II		
			<u>Non-muscle-invasive bladder cancer</u>	<u>P-I</u>		

XTANDI and Strategic products (2/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
zolibetuximab IMAB362	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III	In-house (Ganymed)	
			Pancreatic adenocarcinoma	P-II		
roxadustat ASP1517/FG-4592	Small molecule	HIF-PH inhibitor	Anemia associated with chronic kidney disease	Europe Filed (Apr 2020)	FibroGen	Astellas has rights in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.
			Chemotherapy-induced anemia	P-II		
fezolinetant ESN364	Small molecule	NK3 receptor antagonist	Vasomotor symptoms associated with menopause	P-III	In-house (Ogeda)	
resamirigene bilparovvec AT132	Gene therapy (AAV-based gene therapy)	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy	P-II	In-house (Audentes Therapeutics)	

* 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 (Apr 2021):

gilteritinib (ASP2215): Removed the description of the approval in China in Jan 2021 for relapsed or refractory acute myeloid leukemia with a FLT3 mutation.

enzalutamide (MDV3100): Obtained the approval in Europe in Apr 2021 for metastatic hormone-sensitive prostate cancer.

enfortumab vedotin (ASG-22ME): Obtained the approval in US in Jul 2021 for metastatic urothelial cancer, cisplatin-ineligible and who have previously received one or more therapy. Entered into Phase 1 for non-muscle-invasive bladder cancer.

Projects with Focus Area approach (1/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
Immunology	ASP1948/PTZ-329	Antibody	Anti-NRP1 antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	ASP1951/PTZ-522	Antibody	GITR agonistic antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	ASP9801	Oncolytic virus	Oncolytic virus carrying IL-7 and IL-12	Cancer	P-I	Tottori University [Discovered through collaborative research]	
	ASP7517	Cell therapy (artificial adjuvant vector cells)	WT1 loaded artificial adjuvant vector cell	Cancer	P-I	RIKEN [Discovered through collaborative research]	
	ASP0739	Cell therapy (artificial adjuvant vector cells)	NY-ESO-1 loaded artificial adjuvant vector cell	Cancer	P-I	RIKEN [Discovered through collaborative research]	
	ASP1570	Small molecule		Cancer	P-I	In-house	
Blindness and Regeneration	ASP7317	Cell therapy	Retinal pigment epithelium cells	Geographic atrophy secondary to age-related macular degeneration, Stargardt disease	P-I	In-house (Ocata Therapeutics)	
Mitochondria Biology	ASP1128/MA-0217	Small molecule	PPAR δ modulator	Acute kidney injury	P-II	In-house (Mitobridge)	
	ASP0367/MA-0211	Small molecule	PPAR δ modulator	Primary mitochondrial myopathies	P-II	In-house (Mitobridge)	
				Duchenne muscular dystrophy	P-I		
Genetic regulation	resamirigene bilparvovec AT132 ***	Gene therapy (AAV-based gene therapy)	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy	P-II	In-house (Audentes Therapeutics)	
	AT845	Gene therapy (AAV-based gene therapy)	GAA gene replacement to express GAA enzyme	Pompe disease	P-I	In-house (Audentes Therapeutics)	

Projects with Focus Area approach (2/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
(Other projects with Focus Area approach)	ASP3772	Next generation vaccine (MAPS technology)	Pneumococcal vaccine based on a multiple antigen-presenting system (MAPS) platform	Prevention of pneumococcal disease	P-II	Affinivax	
	FX-322	Small molecule	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	Recombinant human heparin-binding epidermal growth factor-like growth factor	Chronic tympanic membrane perforation	P-I	Auration Biotech	
	ASP2390	New generation vaccine (LAMP-Vax technology)		House dust mite-induced allergic rhinitis	P-I	Immunomic Therapeutics [Discovered through collaborative research]	

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

*** AT132 is also listed in "XTANDI and Strategic products".

Updates from the previous announcement (Apr 2021):

ASP1570: Entered into Phase 1 for cancer.

ASP0892: Discontinued Phase 1 program for peanut allergy.

Others

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
tacrolimus FK506 (Prograf)	Small molecule	Immunosuppressant	Prevention of rejection after lung transplantation	US <u>Approved (Jul 2021)</u>	In-house	
mirabegron YM178	Small molecule	β_3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	Europe P-III	In-house	
			Overactive bladder in pediatric patients	Europe P-III		
peficitinib ASP015K	Small molecule	JAK inhibitor	Rheumatoid arthritis	China P-III	In-house	
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	Opioid use disorder	P-II	In-house	
			Alcohol use disorder	P-I		
ASP1617	Small molecule		Systemic lupus erythematosus	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 (Apr 2021):

mirabegron (YM178): Removed the description of the approval in US in Mar 2021 for neurogenic detrusor overactivity in pediatric patients aged three years and older.

tacrolimus (FK506): Obtained the approval in US in Jul 2021 for prevention of organ rejection in adult and pediatric patients receiving lung transplantation.

bleselumab (ASKP1240): Discontinued the development for recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients because Phase 2 study did not meet its primary endpoint.

Rx+ Program

As of Jul 2021

Sphere (Business area)	Program	Concept	Status *	Partner	Remarks
Chronic disease progression prevention	Game application for exercise support	Smartphone application to support exercise using wearable device for people who needs regular exercise	Under development	BANDAI NAMCO Entertainment	
	Fit-eNce	Scientifically evidenced exercise programs and systems which support regular exercise	Launched in limited areas New service model under development		
	BlueStar	Digital therapeutics for adults with diabetes	Under development	Welldoc	
Patient outcome maximization	ASP5354	Precision surgery-guide enabling identification of ureter in hysterectomy and colorectal surgery etc.	P-II		

* The list shows the most advanced stage if the stages are different depending on the region.

Updates from the previous announcement (Apr 2021)

My Holter II: Removed the description of the program which obtained certification in Mar 2021.