

Supplementary Documents [IFRS]

Financial results for the first three months of the fiscal year 2023 (FY2023)

Astellas Pharma Inc.

- Q1/FY2023 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.

[Three months ended June 30, 2023]

1. Consolidated Results (Full Basis)

	Unit: B¥				FY22 Full Year	Initial Forecasts		Revised Forecasts		Change from FY22
	FY22 APR. - JUN.	FY23 APR. - JUN.	Change	Change (%)		FY23 Full Year	FY23 Full Year	Change (%)		
Revenue	381.8	375.0	-6.8	-1.8%	1,518.6	1,520.0	1,520.0	0.1%		
Cost of sales	88.9	68.9	-19.9	-22.4%	288.4					
Ratio to Revenue	23.3%	18.4%			19.0%					
Gross profit	292.9	306.0	13.1	4.5%	1,230.3					
SG&A expenses	153.4	168.2	14.8	9.6%	630.3	661.0	661.0	4.9%		
Ratio to Revenue	40.2%	44.8%			41.5%	43.5%	43.5%			
XTANDI co-promotion fee in the United States	43.1	44.6	1.4	3.4%	175.5	176.0	176.0	0.3%		
Personnel expenses	51.2	57.4	6.1	12.0%	211.4					
Advertising and Sales Promotion and Other	59.1	66.3	7.2	12.2%	243.4					
R&D expenses	74.0	64.6	-9.4	-12.7%	276.1	251.0	251.0	-9.1%		
Ratio to Revenue	19.4%	17.2%			18.2%	16.5%	16.5%			
Amortisation of intangible assets	10.7	9.1	-1.7	-15.6%	38.4					
Gain on divestiture of intangible assets	0.2	0.1	-0.1	-68.5%	0.2					
Share of profit (loss) of investments accounted for using equity method	0.3	0.7	0.3	96.2%	1.3					
Other income	16.3	3.9	-12.4	-76.0%	3.6					
Net foreign exchange gains	14.1	-	-14.1	-	-					
Other expenses	38.4	23.1	-15.4	-40.0%	157.5					
Impairment losses	22.0	10.5	-11.5	-52.2%	84.6					
Fair value remeasurements on contingent consideration	15.8	10.1	-5.7	-35.8%	53.1					
Operating profit	33.1	45.8	12.6	38.2%	133.0	288.0	259.0	94.7%		
Ratio to Revenue	8.7%	12.2%			8.8%	18.9%	17.0%			
Finance income	0.9	3.8	2.8	307.2%	8.1					
Finance expenses	2.4	2.7	0.3	13.5%	8.8					
Profit before tax	31.7	46.8	15.2	47.9%	132.4	289.0	260.0	96.4%		
Ratio to Revenue	8.3%	12.5%			8.7%	19.0%	17.1%			
Income tax expense	6.9	13.7	6.9	99.8%	33.6					
Profit	24.8	33.1	8.3	33.5%	98.7	227.0	204.0	106.7%		
Ratio to Revenue	6.5%	8.8%			6.5%	14.9%	13.4%			
Comprehensive income	134.4	134.5	0.1	0.1%	205.3					

2. Consolidated Results (Core Basis)

Unit: B¥

	Unit: B¥				FY22 Full Year	Forecasts	
	FY22 APR. - JUN.	FY23 APR. - JUN.	Change	Change (%)		FY23 Full Year	Change from FY22
Revenue	381.8	375.0	-6.8	-1.8%	1,518.6	1,520.0	0.1%
Cost of sales	88.9	68.9	-19.9	-22.4%	288.4		
Ratio to Revenue	23.3%	18.4%			19.0%		
Gross profit	292.9	306.0	13.1	4.5%	1,230.3		
SG&A expenses	153.4	168.2	14.8	9.6%	630.3	661.0	4.9%
Ratio to Revenue	40.2%	44.8%			41.5%	43.5%	
XTANDI co-promotion fee in the United States	43.1	44.6	1.4	3.4%	175.5	176.0	0.3%
Personnel expenses	51.2	57.4	6.1	12.0%	211.4		
Advertising and Sales Promotion and Other	59.1	66.3	7.2	12.2%	243.4		
R&D expenses	74.0	64.6	-9.4	-12.7%	276.1	251.0	-9.1%
Ratio to Revenue	19.4%	17.2%			18.2%	16.5%	
Amortisation of intangible assets	10.7	9.1	-1.7	-15.6%	38.4		
Gain on divestiture of intangible assets	0.2	0.1	-0.1	-68.5%	0.2		
Share of profit (loss) of investments accounted for using equity method	0.3	0.7	0.3	96.2%	1.3		
Operating profit	55.3	64.9	9.6	17.4%	286.9	290.0	1.1%
Ratio to Revenue	14.5%	17.3%			18.9%	19.1%	
Finance income	0.9	3.8	2.8	307.2%	8.1		
Finance expenses	2.4	2.7	0.3	13.5%	8.8		
Profit before tax	53.8	66.0	12.2	22.6%	286.2		
Ratio to Revenue	14.1%	17.6%			18.8%		
Income tax expense	8.0	14.2	6.2	77.7%	61.6		
Profit	45.8	51.8	6.0	13.0%	224.6	228.0	1.5%
Ratio to Revenue	12.0%	13.8%			14.8%	15.0%	

3. Exchange Rate

Unit: yen

	Unit: yen				FY22 Full Year	Forecasts
	FY22 APR. - JUN.Ave.	FY23 APR. - JUN.Ave.	FY22 End	FY23 Q1 End		FY23 Full Year
USD/Yen	130	137	133	144	135	130
EUR/Yen	138	150	144	157	141	140

* Fx impacts: Revenue +17.5 billion yen and Core operating profit +5.4 billion yen

4. Reconciliation of Full Basis to Core Basis

Unit: B¥

	FY22 APR. - JUN.			FY23 APR. - JUN.		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Revenue	381.8	-	381.8	375.0	-	375.0
Cost of sales	88.9	-	88.9	68.9	-	68.9
Gross profit	292.9	-	292.9	306.0	-	306.0
SG&A expenses	153.4	-	153.4	168.2	-	168.2
R&D expenses	74.0	-	74.0	64.6	-	64.6
Amortisation of intangible assets	10.7	-	10.7	9.1	-	9.1
Gain on divestiture of intangible assets	0.2	-	0.2	0.1	-	0.1
Share of profit (loss) of investments accounted for using equity method	0.3	-	0.3	0.7	-	0.7
Other income *	16.3	-16.3	-	3.9	-3.9	-
Other expenses *	38.4	-38.4	-	23.1	-23.1	-
Operating profit	33.1	22.1	55.3	45.8	19.1	64.9
Finance income	0.9	-	0.9	3.8	-	3.8
Finance expenses	2.4	-	2.4	2.7	-	2.7
Profit before tax	31.7	22.1	53.8	46.8	19.1	66.0
Income tax expense	6.9	1.1	8.0	13.7	0.5	14.2
Profit	24.8	21.0	45.8	33.1	18.7	51.8

* "Other income" and "Other expenses" are excluded from Core 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¥

		FY22 APR. - JUN.	FY23 APR. - JUN.	Change	Change (%)	FY22 Full Year	Forecasts FY23 Full Year	Change from FY22 Change (%)
Revenue		381.8	375.0	-6.8	-1.8%	1,518.6	1,520.0	0.1%
	Japan	66.8	68.3	1.5	2.2%	262.3	278.6	6.2%
	Ratio to Revenue	17.5%	18.2%			17.3%	18.3%	
	United States	160.9	150.0	-10.9	-6.8%	652.4	655.3	0.4%
	Ratio to Revenue	42.1%	40.0%			43.0%	43.1%	
	Established Markets	86.6	96.8	10.3	11.8%	359.8	364.5	1.3%
	Ratio to Revenue	22.7%	25.8%			23.7%	24.0%	
	Greater China	23.2	22.5	-0.6	-2.7%	80.0	78.1	-2.3%
	Ratio to Revenue	6.1%	6.0%			5.3%	5.1%	
	International Markets	33.9	34.7	0.8	2.4%	143.3	137.7	-3.9%
	Ratio to Revenue	8.9%	9.3%			9.4%	9.1%	
	Others	10.4	2.6	-7.8	-75.1%	20.7	5.7	-72.3%
	Ratio to Revenue	2.7%	0.7%			1.4%	0.4%	

- Established Markets: Europe, Canada, etc.

- Greater China: China, Hong Kong, Taiwan

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

- From FY2022 Q3, the commercial segment of Australia was changed from Established Markets to International Markets. All figures above reflect this change.

6. Investment in Property, Plant and Equipment

Depreciation/Amortisation

Unit: B¥

	FY22 APR. - JUN.	FY23 APR. - JUN.	Change	Change (%)	FY22 Full Year	Forecasts FY23 Full Year	Change from FY22 Change (%)
Investment in Property, Plant and Equipment	11.7	9.3	-2.3	-20.1%	36.6	39.0	6.7%
Depreciation (PP&E)	9.8	10.2	0.3	3.5%	40.0	43.0	7.4%
Amortisation of Intangible Assets (incl. software, etc.)	27.0	13.1	-14.0	-51.7%	65.7	48.0	-27.0%

- Investment in Property, Plant and Equipment does not include right-of-use asset.

7. Sales of major products

1) Global

Unit: B¥

	FY22 APR. - JUN.	FY23 APR. - JUN.	Change	Change (%)	FY22 Full Year	Change from FY22	
						Forecasts FY23 Full Year	Change (%)
XTANDI	162.4	174.1	11.7	7.2%	661.1	669.9	1.3%
United States	83.9	86.8	2.9	3.4%	341.8	342.6	0.2%
ex-US	78.5	87.3	8.8	11.2%	319.3	327.3	2.5%
Japan	14.1	14.4	0.3	2.3%	54.7	58.2	6.3%
Established Markets	46.8	54.6	7.8	16.7%	197.9	198.7	0.4%
Greater China	3.6	4.4	0.8	22.6%	11.1	14.5	30.9%
International Markets	14.0	13.8	-0.1	-1.0%	55.6	55.9	0.5%
PADCEV	10.6	15.2	4.7	44.2%	44.4	66.7	50.1%
Japan	2.0	2.2	0.3	13.1%	8.4	9.9	17.6%
United States	7.3	10.5	3.2	43.0%	29.2	44.3	52.1%
Established Markets	1.2	2.4	1.2	94.2%	6.8	11.5	68.9%
International Markets	-	0.1	0.1	-	0.1	0.9	887.0%
XOSPATA	10.5	13.0	2.5	24.2%	46.6	49.3	6.0%
Japan	1.1	1.2	0.1	6.6%	4.3	4.1	-4.6%
United States	5.9	7.1	1.2	20.2%	25.5	26.7	4.4%
Established Markets	2.7	3.3	0.6	24.4%	12.1	13.0	7.8%
Greater China	0.5	0.6	0.1	22.9%	2.5	2.2	-11.9%
International Markets	0.3	0.9	0.5	155.3%	2.2	3.4	54.4%
VEOZAH	-	0.6	0.6	-	-	49.3	-
United States	-	0.6	0.6	-	-	48.7	-
EVRENZO	0.7	1.0	0.2	31.0%	3.2	8.0	150.2%
Japan	0.7	0.6	-0.1	-12.1%	2.4	2.8	17.7%
Established Markets	0.1	0.3	0.3	382.8%	0.6	4.0	538.8%
International Markets	-	0.0	0.0	-	0.2	1.2	609.7%
Betanis/Myrbetriq/BETMIGA	47.9	49.2	1.3	2.7%	188.6	179.5	-4.8%
Japan	9.3	7.3	-2.0	-21.3%	33.5	29.7	-11.4%
United States	24.7	26.1	1.4	5.6%	96.5	90.7	-6.0%
Established Markets	10.1	11.5	1.4	14.0%	42.9	44.8	4.6%
Greater China	1.0	1.0	-0.0	-3.4%	3.9	2.7	-31.6%
International Markets	2.8	3.4	0.5	19.3%	11.8	11.6	-1.5%
Prograf	51.8	49.1	-2.7	-5.3%	198.8	187.9	-5.5%
Japan	9.6	8.0	-1.6	-16.4%	35.6	30.0	-15.7%
United States	2.5	2.4	-0.2	-6.4%	10.7	10.2	-5.3%
Established Markets	17.9	17.8	-0.1	-0.6%	69.8	67.8	-2.8%
Greater China	13.6	12.9	-0.7	-5.1%	46.8	45.8	-2.2%
International Markets	8.2	8.0	-0.2	-2.6%	35.8	34.1	-5.0%
Vesicare	4.0	3.7	-0.3	-8.4%	15.9	13.5	-14.7%

- FY2022 sales of products in Japan are shown in a gross sales basis. FY2023 sales and forecasts are shown in a net sales basis, as in other regions.

- Established Markets: Europe, Canada, etc.

- Greater China: China, Hong Kong, Taiwan

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

- From FY2022 Q3, the commercial segment of Australia was changed from Established Markets to International Markets. All figures above reflect this change.

- PADCEV (United States): Co-promotion revenue from Seagen

- Astellas' EVRENZO territories: Japan, Europe, the Commonwealth of Independent States, Middle East, South Africa, etc.

2) Revenue by region - FY2022 sales of products in Japan are shown in a gross sales basis. FY2023 sales and forecasts are shown in a net sales basis, as in other regions.

(1) Japan

<Global>	Unit: B¥				FY22 Full Year	Forecasts	
	FY22 APR. - JUN.	FY23 APR. - JUN.	Change	Change (%)		FY23 Full Year	Change from FY22 (%)
XTANDI	14.1	14.4	0.3	2.3%	54.7	58.2	6.3%
PADCEV	2.0	2.2	0.3	13.1%	8.4	9.9	17.6%
XOSPATA	1.1	1.2	0.1	6.6%	4.3	4.1	-4.6%
EVRENZO	0.7	0.6	-0.1	-12.1%	2.4	2.8	17.7%
Betanis	9.3	7.3	-2.0	-21.3%	33.5	29.7	-11.4%
Prograf (Including Gracaptor)	9.6	8.0	-1.6	-16.4%	35.6	30.0	-15.7%
Vesicare	1.2	0.7	-0.5	-38.5%	3.9	2.8	-29.4%
Harnal	0.5	0.4	-0.1	-20.9%	1.8	1.3	-29.5%
<Main products>							
Suglat [Family]	8.0	7.4	-0.7	-8.3%	30.3	29.7	-2.1%
Sujanu	3.3	2.9	-0.4	-11.1%	12.3		
Repatha	1.6	1.7	0.0	1.5%	6.4		
Linzess	1.8	1.7	-0.2	-9.1%	7.0	7.3	4.0%
BLINCYTO	1.8	2.4	0.6	33.4%	7.9		
EVENITY	10.0	11.5	1.5	15.1%	42.1		
Smyraf	0.6	0.6	0.0	0.2%	2.5	2.7	10.4%
Vaccines	0.0	0.0	0.0	0.9%	5.5	5.1	-5.9%
Cimzia	3.0	2.6	-0.4	-12.7%	11.2		
Total Rx Sales In Japanese market	66.4	68.0	1.5	2.3%	260.1	277.5	6.7%

(2) United States

Revenue	Unit: M\$				FY22 Full Year	Forecasts	
	FY22 APR. - JUN.	FY23 APR. - JUN.	Change	Change (%)		FY23 Full Year	Change from FY22 (%)
	1,240	1,092	-148	-11.9%	4,816	5,041	4.7%
XTANDI	647	632	-15	-2.3%	2,523	2,635	4.4%
PADCEV	57	76	20	35.1%	215	341	58.5%
XOSPATA	46	52	6	13.6%	188	205	8.8%
VEOZAH	-	4	4	-	-	375	-
Myrbetriq	190	190	-1	-0.3%	712	698	-2.0%
Prograf	19	17	-2	-11.6%	79	78	-1.3%
AmBisome	29	25	-4	-13.9%	118	128	8.2%
CRESEMBA	53	62	10	18.6%	228	291	27.7%
Lexiscan	194	29	-165	-84.9%	725	274	-62.1%

(3) Established Markets

	Unit: M€				FY22 Full Year	Forecasts	
	FY22 APR. - JUN.	FY23 APR. - JUN.	Change	Change (%)		FY23 Full Year	Change from FY22 (%)
Revenue	627	647	21	3.3%	2,554	2,604	2.0%
XTANDI	339	365	26	7.7%	1,405	1,419	1.0%
PADCEV	9	16	7	79.3%	48	82	70.0%
XOSPATA	19	22	3	14.9%	86	93	8.5%
EVRENZO	0	2	2	345.9%	4	29	542.9%
BETMIGA	73	77	4	5.2%	304	320	5.3%
Prograf	130	119	-11	-8.2%	495	485	-2.2%
Vesicare	11	9	-2	-19.2%	39	36	-6.8%
Omnice	17	16	-1	-7.8%	69	67	-3.7%

- Established Markets: Europe, Canada, etc.

- From FY2022 Q3, the commercial segment of Australia was changed from Established Markets to International Markets. All figures above reflect this change.

(4) Greater China

	Unit: B¥				FY22 Full Year	Forecasts	
	FY22 APR. - JUN.	FY23 APR. - JUN.	Change	Change (%)		FY23 Full Year	Change from FY22 (%)
Revenue	23.2	22.5	-0.6	-2.7%	80.0	78.1	-2.3%
XTANDI	3.6	4.4	0.8	22.6%	11.1	14.5	30.9%
XOSPATA	0.5	0.6	0.1	22.9%	2.5	2.2	-11.9%
BETMIGA	1.0	1.0	-0.0	-3.4%	3.9	2.7	-31.6%
Prograf	13.6	12.9	-0.7	-5.1%	46.8	45.8	-2.2%
Vesicare	0.3	0.4	0.1	24.2%	1.0	1.0	-5.1%
Harnal	2.4	2.0	-0.4	-15.4%	8.2	8.4	1.8%
Feburic	0.8	0.8	0.0	0.4%	3.4	2.7	-19.0%

- Greater China: China, Hong Kong, Taiwan

(5) International Markets

	Unit: B¥				FY22 Full Year	Forecasts	
	FY22 APR. - JUN.	FY23 APR. - JUN.	Change	Change (%)		FY23 Full Year	Change from FY22 (%)
Revenue	33.9	34.7	0.8	2.4%	143.3	137.7	-3.9%
XTANDI	14.0	13.8	-0.1	-1.0%	55.6	55.9	0.5%
PADCEV	-	0.1	0.1	-	0.1	0.9	887.0%
XOSPATA	0.3	0.9	0.5	155.3%	2.2	3.4	54.4%
EVRENZO	-	0.0	0.0	-	0.2	1.2	609.7%
BETMIGA	2.8	3.4	0.5	19.3%	11.8	11.6	-1.5%
Prograf	8.2	8.0	-0.2	-2.6%	35.8	34.1	-5.0%
Vesicare	1.1	1.2	0.0	2.3%	4.8	4.0	-16.4%
Harnal	4.1	4.3	0.2	5.0%	17.9	17.5	-2.5%

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

- From FY2022 Q3, the commercial segment of Australia was changed from Established Markets to International Markets. All figures above reflect this change.

8. Consolidated statements of financial position

Unit: B¥

	FY22 End	FY23 Q1 End	Change
Assets	2,456.5	2,798.0	341.4
Non-current assets	1,406.6	1,480.5	73.9
Property, plant and equipment	286.5	290.8	4.3
Goodwill	328.4	355.7	27.3
Intangible assets	562.5	590.4	27.9
Trade and other receivables	24.2	23.0	-1.2
Investments accounted for using equity method	12.7	14.7	2.0
Deferred tax assets	84.2	100.6	16.5
Other financial assets	97.9	95.8	-2.1
Other non-current assets	10.3	9.5	-0.8
Current assets	1,050.0	1,317.5	267.5
Inventories	174.4	200.2	25.8
Trade and other receivables	428.0	462.5	34.5
Income tax receivable	17.8	14.7	-3.1
Other financial assets	19.8	41.3	21.5
Other current assets	32.4	36.0	3.6
Cash and cash equivalents	376.8	561.5	184.6
Assets held for sale	0.7	1.2	0.5

Unit: B¥

	FY22 End	FY23 Q1 End	Change
Equity and Liabilities	2,456.5	2,798.0	341.4
Equity	1,508.0	1,578.4	70.5
Equity attributable to owners of the parent	1,508.0	1,578.4	70.5
Share capital	103.0	103.0	-
Capital surplus	181.3	180.6	-0.6
Treasury shares	-25.1	-34.5	-9.4
Retained earnings	908.2	884.5	-23.6
Other components of equity	340.6	444.7	104.1
Liabilities	948.6	1,219.5	271.0
Non-current liabilities	222.5	228.0	5.5
Bonds and borrowings	50.0	50.0	-
Trade and other payables	4.2	2.4	-1.8
Deferred tax liabilities	6.0	6.5	0.5
Retirement benefit liabilities	24.8	27.1	2.3
Provisions	6.5	9.6	3.1
Other financial liabilities	89.9	92.8	2.9
Other non-current liabilities	41.0	39.6	-1.4
Current liabilities	726.0	991.5	265.5
Bonds and borrowings	75.0	309.0	234.0
Trade and other payables	140.2	138.4	-1.8
Income tax payable	5.1	16.3	11.1
Provisions	17.9	17.6	-0.2
Other financial liabilities	105.1	100.0	-5.2
Other current liabilities	382.7	410.2	27.5

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 2023

Underlined items indicate changes from the previous announcement in Apr 2023.

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	China P-III	Pfizer	
			Non-metastatic castration-sensitive prostate cancer	<u>US</u> <u>Submitted (Jun 2023)</u> <u>Europe</u> P-III		
enfortumab vedotin ASG-22ME (PADCEV)	Antibody-drug conjugate (ADC)	Nectin-4 targeted ADC	Metastatic urothelial cancer, platinum-containing chemotherapy and PD-1/L1 inhibitor pretreated	China Filed (Mar 2023)	In-house [Co-development with Seagen]	
			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		
			Non-muscle-invasive bladder cancer	P-I		
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 high intensity induction of chemotherapy	P-III		
			Newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy	P-I		
			Acute myeloid leukemia in pediatric patients	P-III		

XTANDI and Strategic products (2/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensors **	Remarks
zolibetuximab IMAB362	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	Japan Filed (Jun 2023) US Filed (Jul 2023) Europe Filed (Jul 2023) China Filed (Jul 2023)	In-house (Ganymed)	
			Pancreatic adenocarcinoma	P-II		
fezolinetant ESN364 (VEOZAH)	Small molecule	NK3 receptor antagonist	Vasomotor symptoms due to menopause	US Approved (May 2023) Europe Filed (Sep 2022) China P-III Japan P-II	In-house (Ogeda)	
avacincaptad pegol	Pegylated RNA aptamer	Complement C5 inhibitor	Geographic atrophy secondary to age-related macular degeneration	US Filed (Feb 2023) Europe Submitted (Jul 2023)	In-house (Iveric Bio)	
			Stargardt disease	P-I		
resamirigene bilparovect 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 2023):

enzalutamide: sNDA submitted in US in Jun 2023 for non-metastatic hormone-sensitive prostate cancer with high-risk biochemical recurrence.

enfortumab vedotin: Removed the description of the approval in US in Apr 2023 for unresectable locally advanced or metastatic urothelial cancer who are ineligible to receive cisplatin-based chemotherapy in the first-line setting.

zolibetuximab: Filed in Japan in Jun 2023, US, Europe, and China in Jul 2023 for gastric and gastroesophageal junction adenocarcinoma.

fezolinetant: Approved in US in May 2023 for vasomotor symptoms due to menopause.

avacincaptad pegol: Added a program.

Projects with Focus Area approach (1/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
Immuno-oncology	ASP1570	Small molecule	DGKζ inhibitor	Cancer	P-I	In-house	
	ASP2138	Antibody	Anti-Claudin 18.2 and anti-CD3 bispecific antibody	Gastric and gastroesophageal junction adenocarcinoma, pancreatic adenocarcinoma	P-I	Xencor [Discovered through collaborative research]	
	ASP2074	Antibody	Bispecific antibody	Cancer	P-I	In-house	
	ASP1002	Antibody	Bispecific antibody	Cancer	P-I	In-house	
Blindness and Regeneration	ASP7317	Cell therapy	Retinal pigment epithelium cells	Geographic atrophy secondary to age-related macular degeneration	P-I	In-house (Ocata Therapeutics)	
Mitochondria	bocidelpar ASP0367/MA-0211	Small molecule	PPARδ modulator	Primary mitochondrial myopathies	P-II	In-house (Mitobridge)	
				Duchenne muscular dystrophy	P-I		

Projects with Focus Area approach (2/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
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)	
Targeted Protein Degradation	ASP3082	Small molecule	KRAS G12D degrader	Cancer	P-I	In-house	

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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 2023):

ASP7317: In accordance with the current status of the project, the description of Stargardt disease in the Phase 1 has been removed as its development is now in the research phase.

ASP0598: Discontinued the Phase 1 program for chronic tympanic membrane perforation.

Others

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
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 Filed (Aug 2022)	In-house	
isavuconazole	Small molecule	Azole antifungal	Invasive aspergillosis and mucormycosis in pediatric patients	US <u>Submitted (Jun 2023)</u>	Basilea	
ASP8062	Small molecule	GABA _B receptor positive allosteric modulator	Alcohol use disorder	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.

Updates from the previous announcement (Apr 2023):

isavuconazole: sNDA submitted in Jun in the US for invasive aspergillosis and mucormycosis in pediatric patients.

Rx+ Program

As of July 2023

Category	Program	Concept	Status*	Partner	Remarks
Digital health Other services	Fit-eNce	Service to provide scientifically evidenced exercise programs and systems supporting regular exercise	Under feasibility study		
	Fit-eNce Home	Service to provide scientifically evidenced exercise programs and systems supporting regular exercise at home	Under feasibility study		
	BlueStar	Digital therapeutics for adults with diabetes	Under clinical trial preparation	Welldoc Roche Diabetes Care Japan	
Drug-device combination	pudexacianinium chloride ASP5354	Intraoperative ureter visualization for use in patients undergoing minimally invasive and open abdominopelvic surgeries	P-III	Stryker	
		Visualization and localization of lymph nodes in patients with breast cancer or melanoma undergoing lymphatic mapping	P-II		

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