

Supplementary Documents [IFRS]

Financial results for the first three months of the fiscal year 2024 (FY2024)

Astellas Pharma Inc.

- Q1/FY2024 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, 2024]

1. Consolidated Results (Full Basis)

	Unit: B¥				FY23 Full Year	Forecasts	
	FY23 APR. - JUN.	FY24 APR. - JUN.	Change	Change (%)		FY24 Full Year	Change from FY23 (%)
Revenue	375.0	473.1	98.1	26.2%	1,603.7	1,650.0	2.9%
Cost of sales	68.9	91.1	22.2	32.2%	292.5	326.0	11.5%
	Ratio to Revenue	18.4%	19.3%		18.2%	19.8%	
Gross profit	306.0	382.0	75.9	24.8%	1,311.2	1,324.0	1.0%
SG&A expenses	168.2	206.9	38.7	23.0%	740.1	757.0	2.3%
	Ratio to Revenue	44.8%	43.7%		46.2%	45.9%	
XTANDI co-promotion fee in the United States	44.6	61.6	17.0	38.2%	194.9	189.0	-3.0%
SG&A excl. the above	123.6	145.3	21.7	17.5%	545.2	568.0	4.2%
R&D expenses	64.6	86.8	22.2	34.4%	294.2	317.0	7.8%
	Ratio to Revenue	17.2%	18.4%		18.3%	19.2%	
Amortisation of intangible assets	9.1	35.0	25.9	285.9%	98.8		
Gain on divestiture of intangible assets	0.1	0.9	0.9	-	9.7		
Share of profit (loss) of investments accounted for using equity method	0.7	1.9	1.2	181.2%	-3.2		
Other income	3.9	4.9	1.0	25.2%	8.7		
Net foreign exchange gains	-	1.9	1.9	-	-		
Other expenses	23.1	10.4	-12.7	-55.0%	167.8		
Impairment losses	10.5	0.6	-9.9	-94.1%	78.9		
Restructuring costs	1.4	2.6	1.2	89.9%	25.4		
Fair value remeasurements on contingent consideration	10.1	5.7	-4.4	-43.7%	24.7		
Replacement awards with business combination*	-	-	-	-	33.4		
Operating profit	45.8	50.7	4.9	10.6%	25.5	48.0	88.1%
	Ratio to Revenue	12.2%	10.7%		1.6%	2.9%	
Finance income	3.8	4.3	0.6	14.7%	11.5		
Finance expenses	2.7	4.5	1.8	65.2%	12.0		
Profit before tax	46.8	50.5	3.6	7.8%	25.0	43.0	72.2%
	Ratio to Revenue	12.5%	10.7%		1.6%	2.6%	
Income tax expense	13.7	12.9	-0.8	-6.0%	7.9		
Profit	33.1	37.6	4.5	13.5%	17.0	30.0	76.0%
	Ratio to Revenue	8.8%	7.9%		1.1%	1.8%	
Comprehensive income	134.5	149.5	14.9	11.1%	205.6		

* Payment for Iveric Bio's unvested share-based payments, such as share options

2. Consolidated Results (Core Basis)

Unit: B¥

	Unit: B¥				FY23 Full Year	Forecasts	
	FY23 APR. - JUN.	FY24 APR. - JUN.	Change	Change (%)		FY24 Full Year	Change from FY23 (%)
Revenue	375.0	473.1	98.1	26.2%	1,603.7	1,650.0	2.9%
Cost of sales	68.9	91.1	22.2	32.2%	292.5	326.0	11.5%
Ratio to Revenue	18.4%	19.3%			18.2%	19.8%	
Gross profit	306.0	382.0	75.9	24.8%	1,311.2	1,324.0	1.0%
SG&A expenses	168.2	206.9	38.7	23.0%	740.1	757.0	2.3%
Ratio to Revenue	44.8%	43.7%			46.2%	45.9%	
XTANDI co-promotion fee in the United States	44.6	61.6	17.0	38.2%	194.9	189.0	-3.0%
SG&A excl. the above	123.6	145.3	21.7	17.5%	545.2	568.0	4.2%
R&D expenses	64.6	86.8	22.2	34.4%	294.2	317.0	7.8%
Ratio to Revenue	17.2%	18.4%			18.3%	19.2%	
Operating profit	73.3	88.3	15.0	20.5%	276.9	250.0	-9.7%
Ratio to Revenue	19.5%	18.7%			17.3%	15.2%	
Finance income	3.8	4.3	0.6	14.7%	11.5		
Finance expenses	2.7	4.5	1.8	65.2%	12.0		
Profit before tax	74.3	88.1	13.8	18.6%	276.3		
Ratio to Revenue	19.8%	18.6%			17.2%		
Income tax expense	16.4	21.0	4.6	27.8%	53.1		
Profit	57.9	67.2	9.2	15.9%	223.2	186.0	-16.7%
Ratio to Revenue	15.4%	14.2%			13.9%	11.3%	

3. Exchange Rate

Unit: yen

	Unit: yen				Forecasts	
	FY23 APR. - JUN.Ave.	FY24 APR. - JUN.Ave.	FY23 End	FY24 Q1 End	FY23 Full Year	FY24 Full Year
USD/Yen	137	156	151	161	145	145
EUR/Yen	150	168	163	172	157	155

* Fx impacts: Revenue +45.4 billion yen and Core operating profit +11.6 billion yen

4. Reconciliation of Full Basis to Core Basis

Unit: B¥

	FY23 APR. - JUN.			FY24 APR. - JUN.		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Revenue	375.0	-	375.0	473.1	-	473.1
Cost of sales	68.9	-	68.9	91.1	-	91.1
Gross profit	306.0	-	306.0	382.0	-	382.0
SG&A expenses	168.2	-	168.2	206.9	-	206.9
R&D expenses	64.6	-	64.6	86.8	-	86.8
Amortisation of intangible assets *	9.1	-9.1	-	35.0	-35.0	-
Gain on divestiture of intangible assets *	0.1	-0.1	-	0.9	-0.9	-
Share of profit (loss) of investments accounted for using equity method *	0.7	-0.7	-	1.9	-1.9	-
Other income *	3.9	-3.9	-	4.9	-4.9	-
Other expenses *	23.1	-23.1	-	10.4	-10.4	-
Operating profit	45.8	27.5	73.3	50.7	37.6	88.3
Finance income	3.8	-	3.8	4.3	-	4.3
Finance expenses	2.7	-	2.7	4.5	-	4.5
Profit before tax	46.8	27.5	74.3	50.5	37.6	88.1
Income tax expense	13.7	2.7	16.4	12.9	8.1	21.0
Profit	33.1	24.8	57.9	37.6	29.5	67.2

* The definition of core-basis is changed from Q1/FY2024. In addition to the old definition's adjustments, 'Amortisation of intangible assets', 'Gain on divestiture of intangible assets' and 'Share of profit (loss) of investments accounted for using equity method' are newly excluded as new adjustment items. All figures above reflect this change.

"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¥

		FY23 APR. - JUN.	FY24 APR. - JUN.	Change	Change (%)
Revenue		375.0	473.1	98.1	26.2%
	Japan	68.3	66.7	-1.7	-2.4%
	Ratio to Revenue	18.2%	14.1%		
	United States	150.0	212.1	62.1	41.4%
	Ratio to Revenue	40.0%	44.8%		
	Established Markets	96.8	121.0	24.2	25.0%
	Ratio to Revenue	25.8%	25.6%		
	China	18.2	18.7	0.4	2.4%
	Ratio to Revenue	4.9%	3.9%		
	International Markets	39.1	52.0	13.0	33.2%
	Ratio to Revenue	10.4%	11.0%		
	Others	2.6	2.7	0.1	2.9%
	Ratio to Revenue	0.7%	0.6%		

		Forecasts	
		FY23	Change from FY23
		FY24 Full Year	Change (%)
		1,603.7	
		1,650.0	2.9%
		270.1	3.2%
		16.8%	
		663.1	1.0%
		41.3%	
		415.6	5.2%
		25.9%	
		70.6	-0.1%
		4.4%	
		177.0	5.7%
		11.0%	
		7.3	-11.2%
		0.5%	

- Established Markets: Europe, Canada, etc.

- China: China, Hong Kong

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

- From Q1/FY2024, the commercial segment of Taiwan is changed from China to International Markets. All figures above reflect this change.

6. Investment in Property, Plant and Equipment

Depreciation/Amortisation

Unit: B¥

	FY23 APR. - JUN.	FY24 APR. - JUN.	Change	Change (%)
Investment in Property, Plant and Equipment	9.3	13.5	4.2	44.8%
Depreciation (PP&E)	10.2	10.9	0.7	6.9%
Amortisation of Intangible Assets (incl. software, etc.)	13.1	39.4	26.3	201.7%

		Forecasts	
		FY23	Change from FY23
		FY24 Full Year	Change (%)
		35.4	
		55.0	55.2%
		42.4	-1.0%
		115.4	39.5%

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

7. Sales of major products

1) Global

Unit: B¥

	Unit: B¥				FY23 Full Year	Forecasts	
	FY23 APR. - JUN.	FY24 APR. - JUN.	Change	Change (%)		FY24 Full Year	Change from FY23 (%)
XTANDI	174.1	224.2	50.2	28.8%	750.5	757.0	0.9%
Japan	14.4	14.9	0.4	2.9%	56.7	58.9	3.9%
United States	86.8	119.8	33.0	38.0%	379.7	369.1	-2.8%
Established Markets	54.6	65.7	11.1	20.3%	231.6	236.4	2.1%
China	3.3	3.0	-0.3	-9.2%	12.2	14.7	20.5%
International Markets	14.9	20.9	6.0	40.3%	70.3	77.9	10.9%
PADCEV	15.2	38.4	23.2	152.3%	85.4	151.2	77.2%
Japan	2.2	2.5	0.3	13.1%	8.5	11.3	33.2%
United States	10.5	27.2	16.7	158.9%	60.7	107.5	77.3%
Established Markets	2.4	7.5	5.1	211.9%	14.7	28.2	91.4%
China	-	0.1	0.1	-	0.1	0.7	664.5%
International Markets	0.1	1.1	1.0	-	1.3	3.4	156.1%
IZERVAY	-	12.7	12.7	-	12.1	46.4	282.6%
United States	-	12.7	12.7	-	12.1	46.1	280.0%
VEOZAH	0.6	6.6	6.0	972.0%	7.3	28.3	287.8%
United States	0.6	6.1	5.5	895.9%	7.2	25.8	260.3%
Established Markets	-	0.4	0.4	-	0.1	2.0	-
VYLOY	-	0.3	0.3	-	-	3.7	-
Japan	-	0.3	0.3	-	-	2.1	-
XOSPATA	13.0	17.3	4.3	32.8%	55.1	60.0	8.9%
Japan	1.2	1.3	0.1	5.8%	4.4	5.0	14.2%
United States	7.1	8.9	1.8	25.9%	28.6	29.2	2.2%
Established Markets	3.3	4.6	1.3	39.5%	15.2	16.8	11.0%
China	0.5	1.4	0.9	162.0%	3.1	3.5	12.2%
International Markets	0.9	1.1	0.2	23.8%	3.9	5.5	40.6%
BETANIS/MYRBETRIQ/BETMIGA	49.2	46.1	-3.1	-6.4%	198.1	118.0	-40.4%
Japan	7.3	6.6	-0.7	-9.6%	27.4	25.7	-6.1%
United States	26.1	18.7	-7.4	-28.2%	101.3	16.6	-83.6%
Established Markets	11.5	15.4	3.9	34.1%	51.3	57.1	11.4%
China	0.4	0.4	0.0	8.2%	1.6	1.2	-23.4%
International Markets	3.9	4.9	1.0	24.5%	16.6	17.4	4.8%
PROGRAF	49.1	53.9	4.8	9.8%	203.1	191.8	-5.6%
Japan	8.0	6.4	-1.7	-20.7%	29.5	25.3	-14.4%
United States	2.4	2.7	0.3	14.6%	10.0	10.1	0.9%
Established Markets	17.8	19.2	1.4	8.0%	73.8	69.6	-5.8%
China	11.5	11.2	-0.3	-2.3%	43.5	41.3	-4.9%
International Markets	9.4	14.4	5.0	52.8%	46.3	45.5	-1.6%

- Established Markets: Europe, Canada, etc.

- China: China, Hong Kong

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

- From Q1/FY2024, the commercial segment of Taiwan is changed from China to International Markets. All figures above reflect this change.

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

- VEOZAH: Approved as "VEOZA" in ex-US

2) Revenue by region

(1) Japan

Unit: B¥

	FY23		FY24		Change	Change (%)	FY23 Full Year	Forecasts	
	APR. - JUN.		APR. - JUN.					FY24 Full Year	Change (%)
Revenue	68.3		66.7		-1.7	-2.4%	270.1	278.7	3.2%
XTANDI	14.4		14.9		0.4	2.9%	56.7	58.9	3.9%
PADCEV	2.2		2.5		0.3	13.1%	8.5	11.3	33.2%
VYLOY	-		0.3		0.3	-	-	2.1	-
XOSPATA	1.2		1.3		0.1	5.8%	4.4	5.0	14.2%
EVRENZO	0.6		0.5		-0.1	-16.3%	2.1	1.7	-17.4%
BETANIS	7.3		6.6		-0.7	-9.6%	27.4	25.7	-6.1%
PROGRAF (Including GRACEPTOR)	8.0		6.4		-1.7	-20.7%	29.5	25.3	-14.4%
SUGLAT [Family]	7.4		7.0		-0.4	-4.8%	27.9	27.3	-2.2%
SUJANU	2.9		2.8		-0.1	-4.6%	11.0		
BLINCYTO	2.4		3.2		0.8	34.1%	11.2		
EVENITY	11.5		13.8		2.2	19.6%	48.8		
CIMZIA	2.6		2.5		-0.1	-2.5%	10.0		

(2) United States

Unit: M\$

	FY23		FY24		Change	Change (%)	FY23 Full Year	Forecasts	
	APR. - JUN.		APR. - JUN.					FY24 Full Year	Change (%)
Revenue	1,092		1,360		269	24.6%	4,587	4,621	0.7%
XTANDI	632		768		136	21.6%	2,627	2,545	-3.1%
PADCEV	76		174		98	128.1%	420	742	76.7%
IZERVAY	-		82		82	-	84	318	278.8%
VEOZAH	4		39		35	777.6%	50	178	259.2%
XOSPATA	52		57		6	10.9%	198	201	1.9%
MYRBETRIQ	190		120		-70	-36.7%	701	114	-83.7%
PROGRAF	17		17		0	1.0%	69	70	0.6%
CRESEMBA	62		70		8	12.4%	259	310	19.7%

(3) Established Markets

Unit: M€

	FY23		FY24		Change	Change (%)	FY23 Full Year	Forecasts	
	APR. - JUN.		APR. - JUN.					FY24 Full Year	Change (%)
Revenue	647		721		74	11.4%	2,651	2,822	6.4%
XTANDI	365		391		26	7.2%	1,477	1,525	3.2%
PADCEV	16		45		29	178.0%	94	182	93.5%
VEOZA	-		3		3	-	1	13	-
XOSPATA	22		27		5	24.3%	97	109	12.3%
EVRENZO	2		5		3	119.2%	13	17	33.3%
BETMIGA	77		92		15	19.5%	327	368	12.7%
PROGRAF	119		115		-4	-3.7%	471	449	-4.7%

- Established Markets: Europe, Canada, etc.

(4) China

Unit: B¥

	FY23 APR. - JUN.	FY24 APR. - JUN.	Change	Change (%)
Revenue	18.2	18.7	0.4	2.4%
XTANDI	3.3	3.0	-0.3	-9.2%
PADCEV	-	0.1	0.1	-
XOSPATA	0.5	1.4	0.9	162.0%
BETMIGA	0.4	0.4	0.0	8.2%
PROGRAF	11.5	11.2	-0.3	-2.3%

FY23 Full Year
70.6
12.2
0.1
3.1
1.6
43.5

Forecasts		Change from FY23
FY24 Full Year	Change (%)	
70.5	-0.1%	
14.7	20.5%	
0.7	664.5%	
3.5	12.2%	
1.2	-23.4%	
41.3	-4.9%	

- China:China, Hong Kong

- From Q1/FY2024, the commercial segment of Taiwan is changed from China to International Markets. All figures above reflect this change.

(5) International Markets

Unit: B¥

	FY23 APR. - JUN.	FY24 APR. - JUN.	Change	Change (%)
Revenue	39.1	52.0	13.0	33.2%
XTANDI	14.9	20.9	6.0	40.3%
PADCEV	0.1	1.1	1.0	-
XOSPATA	0.9	1.1	0.2	23.8%
EVRENZO	0.0	0.1	0.0	100.3%
BETMIGA	3.9	4.9	1.0	24.5%
PROGRAF	9.4	14.4	5.0	52.8%
HARNAL	4.9	5.3	0.4	9.1%

FY23 Full Year
177.0
70.3
1.3
3.9
0.5
16.6
46.3
20.8

Forecasts		Change from FY23
FY24 Full Year	Change (%)	
187.0	5.7%	
77.9	10.9%	
3.4	156.1%	
5.5	40.6%	
0.3	-26.7%	
17.4	4.8%	
45.5	-1.6%	
20.9	0.8%	

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

- From Q1/FY2024, the commercial segment of Taiwan is changed from China to International Markets. All figures above reflect this change.

8. Consolidated statements of financial position

Unit: B¥

	FY23 End	FY24 Q1 End	Change
Assets	3,569.6	3,735.5	165.9
Non-current assets	2,374.9	2,494.8	120.0
Property, plant and equipment	293.7	309.7	15.9
Goodwill	418.7	443.7	25.0
Intangible assets	1,453.8	1,503.2	49.3
Trade and other receivables	20.0	22.0	2.0
Investments accounted for using equity method	15.7	19.5	3.8
Deferred tax assets	45.6	54.2	8.6
Other financial assets	108.7	113.4	4.7
Other non-current assets	18.6	29.2	10.6
Current assets	1,194.7	1,240.7	45.9
Inventories	248.7	256.0	7.3
Trade and other receivables	535.0	587.7	52.7
Income tax receivable	13.1	12.3	-0.7
Other financial assets	28.8	35.7	6.9
Other current assets	32.2	46.0	13.7
Cash and cash equivalents	335.7	302.9	-32.8
Assets held for sale	1.2	-	-1.2

Unit: B¥

	FY23 End	FY24 Q1 End	Change
Equity and Liabilities	3,569.6	3,735.5	165.9
Equity	1,596.0	1,676.4	80.5
Equity attributable to owners of the parent	1,596.0	1,676.4	80.5
Share capital	103.0	103.0	-
Capital surplus	184.1	182.6	-1.5
Treasury shares	-33.8	-38.5	-4.7
Retained earnings	809.4	783.8	-25.6
Other components of equity	533.3	645.6	112.3
Liabilities	1,973.6	2,059.1	85.5
Non-current liabilities	687.9	685.3	-2.6
Bonds and borrowings	447.7	443.1	-4.7
Trade and other payables	2.2	8.5	6.3
Income tax payable	-	0.2	0.2
Deferred tax liabilities	51.3	45.1	-6.3
Retirement benefit liabilities	24.7	25.4	0.7
Provisions	7.4	10.0	2.6
Other financial liabilities	105.6	105.8	0.2
Other non-current liabilities	49.0	47.3	-1.6
Current liabilities	1,285.7	1,373.8	88.1
Bonds and borrowings	472.3	549.6	77.3
Trade and other payables	185.2	173.1	-12.0
Income tax payable	38.5	29.7	-8.8
Provisions	15.7	14.1	-1.6
Other financial liabilities	97.6	104.2	6.7
Other current liabilities	476.5	503.0	26.5

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 2024

Underlined items indicate changes from the previous announcement in Apr 2024.

XTANDI and Strategic Brands (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 <u>Approved (Jun 2024)</u>	Pfizer	
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 Pfizer]	
			Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)	Europe Filed (Jan 2024) Japan Filed (Jan 2024) China Filed (Mar 2024)		
			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 Brands (2/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
zolibetuximab IMAB362 (VYLOY)	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma (combo with chemotherapy)	US Filed (May 2024) Europe Filed (Jul 2023) China Filed (Jul 2023)	In-house (Ganymed)	
			<u>Gastric and gastroesophageal junction adenocarcinoma (combo with checkpoint inhibitor and chemotherapy)</u>	P-III		
			Pancreatic adenocarcinoma	P-II		
fezolinetant ESN364 (VEOZAH***)	Small molecule	NK3 receptor antagonist	Vasomotor symptoms due to menopause	China P-III Japan P-III	In-house (Ogeda)	
			Induced vasomotor symptoms in breast cancer patients on adjuvant endocrine therapy	P-III		
avacincaptad pegol (IZERVAY)	Pegylated RNA aptamer	Complement C5 inhibitor	Geographic atrophy secondary to age-related macular degeneration	Europe Filed (Aug 2023)		
			Stargardt disease	P-II		

* 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.

*** Approved as "VEOZA" in ex-US.

Updates from the previous announcement (Apr 2024):

enzalutamide: Approved in China in Jun 2024 for metastatic castration-sensitive prostate cancer. Removed the description of the approval in Europe for high risk biochemical recurrent non-metastatic hormone sensitive prostate cancer that is unsuitable for salvage radiotherapy in Apr 2024.

zolibetuximab: Removed the description of the approval in Japan for CLDN18.2 positive, unresectable, advanced or recurrent gastric cancer in Mar 2024. Resubmission filed in US in May 2024 for gastric and gastroesophageal junction adenocarcinoma (combo with chemotherapy). Entered into Phase 3 for gastric and gastroesophageal junction adenocarcinoma (combo with checkpoint inhibitor and chemotherapy).

Projects with Focus Area approach (1/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensors **	Remarks
Immuno-oncology	ASP1570	Small molecule	DGK ζ 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]	
	ASP1002	Antibody	<u>Anti-Claudin 4 and anti-CD137 bispecific antibody</u>	Cancer	P-I	In-house	
	ASP1012	Oncolytic virus	Oncolytic virus encoding leptin-IL-2	Cancer	P-I	KaliVir	
	ASP2802	Cell therapy	CD20 autologous <i>convertible</i> CAR-T	B-cell lymphoma	P-I	In-house (Xyphos Biosciences)	
Targeted Protein Degradation	ASP3082	Small molecule	KRAS G12D degrader	Cancer	P-I	In-house	
	ASP4396	Small molecule	KRAS G12D degrader	Cancer	P-I	In-house	

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)	
	zocaglusagene nuzaparvovec AT845	Gene therapy (AAV-based gene therapy)	GAA gene replacement to express GAA enzyme	Pompe disease	P-I	In-house (Audentes Therapeutics)	
	ASP2016	Gene therapy (AAV-based gene therapy)	FXN gene replacement to express frataxin	Cardiomyopathy associated with Friedreich ataxia	P-I	In-house (Audentes Therapeutics)	
Blindness and Regeneration	ASP7317	Cell therapy	Retinal pigment epithelium cells	Geographic atrophy secondary to age-related macular degeneration	P-I	In-house (Ocata Therapeutics)	
Immune Homeostasis ***	ASP5502	Small molecule	STING inhibitor	Primary Sjogren's syndrome	P-I	In-house	

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

*** Primary Focus Candidate.

Updates from the previous announcement (Apr 2024):

ASP1002: Described the classification.

ASP5502: Entered into Phase 1.

Others

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensors **	Remarks
mirabegron YM178	Small molecule	β_3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients (aged 3 to less than 18 years)	Europe Filed	In-house	
			Neurogenic detrusor overactivity in pediatric patients (aged 6 months to less than 3 years)	Europe P-III		
peficitinib ASP015K	Small molecule	JAK inhibitor	Rheumatoid arthritis	China Filed (Aug 2022)	In-house	
roxadustat ASP1517/FG-4592	Small molecule	HIF-PH inhibitor	Anemia associated with chronic kidney disease in pediatric patients	Europe P-III	FibroGen	Astellas has rights in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.
abiraterone decanoate PRL-02/ASP5541	Small molecule	CYP17 lyase inhibitor	Prostate cancer	P-I	In-house (Propella Therapeutics)	

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

Rx+ Program

As of Jul 2024

Category	Program	Concept	Status*	Partner	Remarks
Digital health Other services	BlueStar	Digital therapeutics for adults with diabetes	Pivotal study (Japan)	Welldoc Roche Diabetes Care Japan	
	Z1608	Digital therapeutic plus remote patient monitoring for heart failure	Under development	Welldoc Eko	
Drug-device combination	pudexacianinium chloride ASP5354	Intraoperative ureter visualization for use in patients undergoing minimally invasive and open abdominopelvic surgeries	P-III	Stryker	

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