Supplementary Documents [IFRS]

Financial results for the first three months of the fiscal year 2019 (FY2019)

Astellas Pharma Inc.

- Q1/FY2019 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.

Classification of revenue by region

The Company changed its commercial organizational structure at the beginning of FY2019, and its revenue by region is reported based on the new classification; namely Japan, United States, Established Markets, Greater China and International.
The following table presents the new classification.

Region	Main constitutes of revenue
Japan	Product sales in Japan Licensing revenue for Japan local products
United States	Product sales in United States
Established Markets	Product sales in Europe, Canada, and Australia
Greater China	Product sales in China, Hong Kong, and Taiwan
International	Product sales in Russia, Latin America, Middle East, Africa, South East Asia, South Asia, and, Korea Export sales, etc.
Others	Amortisation of deferred revenue for business transfer, etc. ex-US Tarceva royalty

1. Consolidated Results (Full Basis)

Unit: B¥

	FY18 APR. - JUN.	FY19 APR. - JUN.	Change	Change (%)	Forecasts FY19 Full Year	Change from FY18 Change (%)
Revenue	329.1	334.1	5.0	1.5%	1,224.0	-6.3%
Cost of sales	70.7	70.5	-0.2	-0.3%		
Ratio to Revenue	21.5%	21.1%				
Gross profit	258.3	263.6	5.3	2.0%		
SG&A expenses	112.9	117.5	4.6	4.1%		
Ratio to Revenue	34.3%	35.2%				
Advertising and Sales Promotion	36.8	41.3	4.5	12.2%		
Personnel expenses	44.4	43.6	-0.8	-1.8%		
Other	31.7	32.6	0.9	2.9%		
R&D expenses	52.1	53.5	1.4	2.6%	211.0	1.1%
Ratio to Revenue	15.8%	16.0%			17.2%	
Amortisation of intangible assets	9.0	7.2	-1.9	-20.6%		
Share of profit (loss) of investments accounted for using equity method	-0.3	-0.7	-0.5	-		
Other income	4.2	4.5	0.3	6.7%		
Gain on sales of property, plant and equipment	3.6	0.0	-3.6	-99.7%		
Net foreign exchange gains	-	0.5	0.5	-		
Other expense	24.7	12.2	-12.6	-50.8%		
Fair value remeasurements on contingent consideration	0.1	11.4	11.3	-		
Impairment losses	3.0	-	-3.0	-		
Restructuring costs	8.8	-	-8.8	-		
Net foreign exchange losses	1.6	-	-1.6	-		
Litigation costs	11.0	0.2	-10.8	-98.0%		
Operating profit	63.5	77.1	13.5	21.3%	229.0	-6.1%
Ratio to Revenue	19.3%	23.1%			18.7%	
Finance income	1.2	0.8	-0.4	-34.3%		
Finance expense	0.2	1.3	1.1	504.1%		
Profit before tax	64.5	76.5	12.0	18.7%	230.0	-7.6%
Ratio to Revenue	19.6%	22.9%			18.8%	
Income tax expense	9.9	18.0	8.1	81.3%		
Profit	54.6	58.5	4.0	7.3%	182.0	-18.1%
Ratio to Revenue	16.6%	17.5%			14.9%	
Comprehensive income	70.9	27.0	-43.8	-61.8%		

2. Consolidated Results (Core Basis)

Unit: B¥

	FY18 APR. - JUN.	FY19 APR. - JUN.	Change	Change (%)	Forecasts FY19 Full Year	Change from FY18 Change (%)
Revenue	329.1	334.1	5.0	1.5%	1,224.0	-6.3%
Cost of sales	70.7	70.5	-0.2	-0.3%		
Ratio to Revenue	21.5%	21.1%				
Gross profit	258.3	263.6	5.3	2.0%		
SG&A expenses	112.9	117.5	4.6	4.1%		
Ratio to Revenue	34.3%	35.2%				
Advertising and Sales Promotion	36.8	41.3	4.5	12.2%		
Personnel expenses	44.4	43.6	-0.8	-1.8%		
Other	31.7	32.6	0.9	2.9%		
R&D expenses	52.1	53.5	1.4	2.6%	211.0	1.1%
Ratio to Revenue	15.8%	16.0%			17.2%	
Amortisation of intangible assets	9.0	7.2	-1.9	-20.6%		
Share of profit (loss) of investments accounted for using equity method	-0.3	-0.7	-0.5	-		
Operating profit	84.0	84.7	0.7	0.8%	240.0	-13.8%
Ratio to Revenue	25.5%	25.4%			19.6%	
Finance income	1.2	0.8	-0.4	-34.2%		
Finance expense	0.2	1.3	1.1	504.1%		
Profit before tax	85.0	84.2	-0.8	-0.9%		
Ratio to Revenue	25.8%	25.2%				
Income tax expense	14.6	17.1	2.4	16.7%		
Profit	70.4	67.1	-3.2	-4.6%	194.0	-22.2%
Ratio to Revenue	21.4%	20.1%			15.8%	

3. Exchange Rate

Unit: yen

	FY18 APR. - JUN.Ave.	FY19 APR. - JUN.Ave.	FY18 End	FY19 Q1 End	Forecasts FY19 Full Year
USD/Yen	109	110	111	108	110
EUR/Yen	130	123	125	122	125

* Fx impacts:Revenue -5.1 billion yen and Core operating profit +0.4 billion yen
* Fx impact on elimination of unrealized gain: COGs ratio -1.1ppt

4. Reconciliation of Full Basis to Core Basis

Unit: B¥

	FY18 APR. - JUN.			FY19 APR. - JUN.		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Revenue	**329.1**	**-**	**329.1**	**334.1**	**-**	**334.1**
Cost of sales	70.7	-	70.7	70.5	-	70.5
Gross profit	**258.3**	**-**	**258.3**	**263.6**	**-**	**263.6**
SG&A expenses	112.9	-	112.9	117.5	-	117.5
R&D expenses	52.1	-	52.1	53.5	-	53.5
Amortisation of intangible assets	9.0	-	9.0	7.2	-	7.2
Share of profit (loss) of investments accounted for using equity method	-0.3	-	-0.3	-0.7	-	-0.7
Other income *	4.2	-4.2	-	4.5	-4.5	-
Other expense *	24.7	-24.7	-	12.2	-12.2	-
Operating profit	**63.5**	**20.5**	**84.0**	**77.1**	**7.7**	**84.7**
Finance income	1.2	-	1.2	0.8	-	0.8
Finance expense	0.2	-	0.2	1.3	-	1.3
Profit before tax	**64.5**	**20.5**	**85.0**	**76.5**	**7.7**	**84.2**
Income tax expense	9.9	4.7	14.6	18.0	-0.9	17.1
Profit	**54.6**	**15.8**	**70.4**	**58.5**	**8.6**	**67.1**

* “Other income” and “Other expense” are excluded from Full basis results.
“Other income” and “Other expense” 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¥

		FY18 APR. - JUN.	FY19 APR. - JUN.	Change	Change (%)	Forecasts FY19 Full Year	Change from FY18 Change (%)
Revenue		329.1	334.1	5.0	1.5%	1,224.0	-6.3%
	Japan	94.1	98.5	4.3	4.6%	316.8	-14.3%
	Ratio to Revenue	28.6%	29.5%			25.9%	
	United States	102.7	105.3	2.6	2.5%	404.7	-4.0%
	Ratio to Revenue	31.2%	31.5%			33.1%	
	Established Markets	76.9	75.8	-1.1	-1.4%	286.8	-4.4%
	Ratio to Revenue	23.4%	22.7%			23.4%	
	Greater China	13.7	14.7	1.0	7.4%	70.9	13.6%
	Ratio to Revenue	4.2%	4.4%			5.8%	
	International	32.1	34.2	2.1	6.6%	124.4	1.4%
	Ratio to Revenue	9.8%	10.2%			10.2%	
	Others	9.5	5.6	-3.9	-41.0%	20.4	-32.4%
	Ratio to Revenue	2.9%	1.7%			1.7%	

- Established Markets: Europe, Canada, Australia
- Greater China: China, Hong Kong, Taiwan
- International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

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

Unit: B¥

		FY18 APR. - JUN.	FY19 APR. - JUN.	Change	Change (%)	Forecasts FY19 Full Year	Change from FY18 Change (%)
Addition to Property, Plant and Equipment							
	Consolidated	6.2	13.3	7.1	114.2%	41.0	47.8%
Depreciation (PP&E)							
	Consolidated	5.2	8.0	2.8	53.5%	22.5	7.1%
Amortisation (Intangible Assets (Including amortisation of software, etc.))							
	Consolidated	10.9	9.0	-1.9	-17.2%	27.5	-35.2%

- The impact of application of IFRS 16 "Leases"
  Addition to Property, Plant and Equipment : +0.7 billion yen, Depreciation (PP&E) : +3.2 billion yen

7. Sales of major products

1) Global

Unit: B¥

	FY18 APR. - JUN.	FY19 APR. - JUN.	Change	Change (%)	Forecasts FY19 Full Year	Change from FY18 (%)
XTANDI	81.2	96.0	14.8	18.2%	364.2	9.3%
United States	39.3	46.9	7.6	19.3%	178.9	8.6%
ex-US	41.9	49.1	7.2	17.3%	185.3	10.1%
Japan	8.5	9.3	0.8	9.2%	35.5	9.7%
Established Markets	29.4	33.6	4.2	14.5%	128.4	7.9%
Greater China	0.4	0.5	0.1	24.1%	3.1	41.5%
International	3.6	5.7	2.1	58.7%	18.3	23.6%
XOSPATA	-	2.5	2.5	-	15.1	-
Japan	-	0.6	0.6	-	3.9	-
United States	-	1.9	1.9	-	11.3	-
Betanis/Myrabetriq/BETMIGA	34.4	39.9	5.5	16.1%	160.6	9.1%
Japan	8.1	9.4	1.3	16.6%	33.9	3.6%
United States	18.3	21.3	3.0	16.4%	88.1	9.1%
Estabilished Markets	6.2	6.8	0.6	9.6%	27.4	8.1%
Greater China	0.3	0.4	0.1	52.0%	2.4	92.5%
International	1.6	2.1	0.5	29.2%	8.8	23.2%
Vesicare	24.9	13.6	-11.4	-45.6%	41.8	-56.0%
Japan	6.1	5.7	-0.3	-5.3%	19.1	-14.2%
United States	9.5	0.2	-9.3	-97.8%	2.7	-92.7%
Estabilished Markets	7.8	6.1	-1.8	-22.4%	13.8	-53.1%
Greater China	0.4	0.5	0.1	14.6%	2.0	4.9%
International	1.1	1.1	-0.1	-6.6%	4.3	-6.7%
Prograf	52.2	50.4	-1.8	-3.4%	187.7	-4.1%
Japan	12.2	12.2	0.0	0.2%	42.4	-6.6%
United States	3.8	3.2	-0.6	-15.9%	10.3	-26.6%
Estabilished Markets	19.7	17.7	-2.0	-10.1%	68.6	-7.9%
Greater China	6.8	7.7	0.9	13.2%	35.3	12.7%
International	9.7	9.6	-0.1	-1.0%	31.1	2.1%
Harnal/Omnic	11.4	10.9	-0.5	-4.7%	46.9	-1.1%
Funguard/MYCAMINE	8.8	9.0	0.3	3.2%	32.1	-6.9%
Eligard	4.1	3.6	-0.5	-11.7%	14.6	-1.6%

- Sales of products in Japan are shown in a gross sales basis
- Established Markets: 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¥

<Global>	FY18 APR. - JUN.	FY19 APR. - JUN.	Change	Change (%)	Forecasts FY19 Full Year	Change from FY18 Change (%)
XTANDI	8.5	9.3	0.8	9.2%	35.5	9.7%
XOSPATA	-	0.6	0.6	-	3.9	-
Betanis	8.1	9.4	1.3	16.6%	33.9	3.6%
Vesicare	6.1	5.7	-0.3	-5.3%	19.1	-14.2%
Prograf（Including Graceptor）	12.2	12.2	0.0	0.2%	42.4	-6.6%
Harnal	1.5	1.2	-0.3	-17.2%	4.1	-20.5%
Funguard	1.8	2.0	0.2	9.5%	7.0	-7.0%
<Main products>						
Suglat [Family]	4.9	6.0	1.1	22.2%	25.4	42.5%
Sujanu	1.5	2.1	0.6	43.9%		
Repatha	0.6	0.8	0.2	30.1%		
Linzess	0.8	1.4	0.6	76.4%	6.6	68.5%
BLINCYTO	-	1.0	1.0	-		
EVENITY	-	3.5	3.5	-		
Celecox	12.8	13.1	0.3	2.2%	49.6	0.4%
Symbicort	10.5	11.0	0.4	4.0%		
Geninax	2.1	2.2	0.1	5.4%	8.0	-4.3%
Vaccines	3.2	3.3	0.1	2.9%	10.1	-66.0%
Gonax	1.2	1.3	0.1	8.8%	5.2	9.7%
Cimzia	2.4	2.4	0.0	1.6%	10.9	16.2%
Micardis [Family]	6.7	5.3	-1.4	-21.2%	13.5	-40.0%
Bonoteo	3.3	1.8	-1.5	-46.2%	5.5	-38.3%
Lipitor	4.2	3.7	-0.5	-12.6%	12.5	-17.4%
Myslee	2.9	2.5	-0.3	-11.9%	9.5	-11.6%
Total Rx Sales In Japanese market	93.0	97.9	4.9	5.3%	313.8	-14.3%

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

(2) United States

Unit: M$

	FY18 APR. - JUN.	FY19 APR. - JUN.	Change	Change (%)	Forecasts FY19 Full Year	Change from FY18 Change (%)
Revenue	942	958	16	1.7%	3,679	-3.2%
XTANDI	361	427	66	18.4%	1,627	9.5%
XOSPATA	-	17	17	-	102	-
Myrbetriq	168	194	26	15.5%	801	10.0%
VESIcare	87	2	-85	-97.8%	25	-92.6%
Prograf	35	29	-6	-16.6%	94	-26.0%
MYCAMINE	22	26	4	19.0%	89	-8.0%
AmBisome	27	27	-0	-1.2%	111	0.9%
CRESEMBA	29	37	8	27.7%	143	21.0%
Scan	182	185	3	1.7%	669	-3.0%
Tarceva	32	15	-17	-54.0%		

(3) Established Markets

Unit: M€

	FY18 APR. - JUN.	FY19 APR. - JUN.	Change	Change (%)	Forecasts FY19 Full Year	Change from FY18 Change (%)
Revenue	591	613	23	3.8%	2,294	-1.8%
XTANDI	226	272	46	20.6%	1,027	10.8%
BETMIGA	47	55	7	15.4%	219	11.1%
Vesicare	60	49	-11	-18.3%	110	-51.9%
Prograf	151	143	-8	-5.3%	549	-5.4%
Omnic	17	17	-0	-2.2%	66	-5.8%
MYCAMINE	17	15	-2	-11.2%	50	-15.9%
Eligard	27	25	-2	-8.3%	96	-5.4%

- Established Markets: Europe, Canada, Australia

(4) Greater China

Unit: B¥

	FY18 APR. - JUN.	FY19 APR. - JUN.	Change	Change (%)	Forecasts FY19 Full Year	Change from FY18 Change (%)
Revenue	13.7	14.7	1.0	7.4%	70.9	13.6%
XTANDI	0.4	0.5	0.1	24.1%	3.1	41.5%
BETMIGA	0.3	0.4	0.1	52.0%	2.4	92.5%
Vesicare	0.4	0.5	0.1	14.6%	2.0	4.9%
Prograf	6.8	7.7	0.9	13.2%	35.3	12.7%
Harnal	3.2	3.3	0.1	3.0%	16.4	8.1%
MYCAMINE	0.8	0.9	0.1	10.9%	3.7	5.2%
Eligard	0.1	0.1	0.0	21.1%	0.3	24.8%
Feburic	0.6	0.6	-0.0	-2.4%	4.4	74.3%

- Greater China: China, Hong Kong, Taiwan

(5) International

Unit: B¥

	FY18 APR. - JUN.	FY19 APR. - JUN.	Change	Change (%)	Forecasts FY19 Full Year	Change from FY18 Change (%)
Revenue	32.1	34.2	2.1	6.6%	124.4	1.4%
XTANDI	3.6	5.7	2.1	58.7%	18.3	23.6%
BETMIGA	1.6	2.1	0.5	29.2%	8.8	23.2%
Vesicare	1.1	1.1	-0.1	-6.6%	4.3	-6.7%
Prograf	9.7	9.6	-0.1	-1.0%	31.1	2.1%
Harnal	4.5	4.3	-0.2	-4.8%	18.0	0.2%
MYCAMINE	1.5	1.4	-0.1	-7.9%	5.2	5.8%

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

8. Consolidated statements of financial position

Unit: B¥

	FY18 End	FY19 Q1 End	Change
Assets	**1,897.6**	**1,927.0**	**29.4**
Non-current assets	**1,040.5**	**1,106.9**	**66.4**
Property, plant and equipment	173.5	251.9	78.4
Goodwill	225.9	220.1	-5.7
Intangible assets	429.7	423.7	-6.0
Trade and other receivables	25.2	23.6	-1.6
Investments accounted for using equity method	3.7	5.1	1.5
Deferred tax assets	93.0	90.9	-2.1
Other financial assets	81.5	81.2	-0.2
Other non-current assets	8.1	10.3	2.2
Current assets	**857.2**	**820.1**	**-37.0**
Inventories	151.5	150.5	-1.0
Trade and other receivables	342.6	358.8	16.2
Income tax receivable	20.1	22.7	2.6
Other financial assets	2.6	3.9	1.3
Other current assets	25.1	24.8	-0.3
Cash and cash equivalents	311.1	259.4	-51.7
Assets held for sale	4.1	0.0	-4.1

Unit: B¥

	FY18 End	FY19 Q1 End	Change
Equity and Liabilities	**1,897.6**	**1,927.0**	**29.4**
Equity	**1,258.4**	**1,249.7**	**-8.7**
Equity attributable to owners of the parent	**1,258.4**	**1,249.7**	**-8.7**
Share capital	103.0	103.0	-
Capital surplus	177.3	177.1	-0.2
Treasury shares	-164.6	-4.6	160.0
Retained earnings	992.0	854.4	-137.5
Other components of equity	150.8	119.8	-30.9
Liabilities	**639.3**	**677.3**	**38.1**
Non-current liabilities	**141.6**	**213.2**	**71.6**
Trade and other payables	1.6	1.6	0.0
Deferred tax liabilities	5.2	5.1	-0.1
Retirement benefit liabilities	40.2	41.1	0.9
Provisions	5.4	6.2	0.8
Other financial liabilities	52.9	129.6	76.7
Other non-current liabilities	36.4	29.6	-6.8
Current liabilities	**497.7**	**464.2**	**-33.5**
Trade and other payables	185.3	140.0	-45.2
Income tax payable	17.6	24.4	6.8
Provisions	22.8	10.9	-11.9
Other financial liabilities	14.1	43.5	29.4
Other current liabilities	255.9	245.3	-10.7
Liabilities directly associated with assets held for sale	1.9	-	-1.9

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 2019

Underlined items indicate changes from the previous announcement on Apr 25, 2019.

Key post-POC projects and projects to maximize their VALUE

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Dosage Form	Licensor **	Remarks
Oncology	**enzalutamide MDV3100 (XTANDI®)**	Small molecule	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer	China Filed (Mar 2018)	Oral	Pfizer	
				Metastatic hormone-sensitive prostate cancer	US Filed (Jun 2019) Europe Filed (Jul 2019) Japan P-III			
				Non-metastatic hormone-sensitive prostate cancer	P-III			
	gilteritinib ASP2215 (XOSPATA®)	Small molecule	FLT3 inhibitor	Relapsed or refractory acute myeloid leukemia	Europe Filed (Feb 2019) China P-III	Oral	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			
	enfortumab vedotin ASG-22ME	Antibody-drug conjugate (ADC)	Nectin-4 targeted ADC	Locally advanced or metastatic urothelial cancer in patients who have received prior treatment with a PD-1/PD-L1 inhibitor and platinum-containing chemotherapy	US Filed (Jul 2019)	Injection	In-house [Co-development with Seattle Genetics]	
				Urothelial cancer	P-III			
	zolbetuximab IMAB362	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III	Injection	In-house (Ganymed)	
				Pancreatic adenocarcinoma	P-II			
Urology and Nephrology	**roxadustat ASP1517/FG-4592**	Small molecule	HIF stabilizer	Anemia associated with chronic kidney disease in patients on dialysis	Japan Filed (Sep 2018) Europe P-III	Oral	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 P-III Europe P-III			
				Chemotherapy-induced anemia	P-II			
Others	**fezolinetant ESN364**	Small molecule	NK3 receptor antagonist	Menopause-related vasomotor symptoms	P-III	Oral	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 (Apr 2019):

enzaltamide (MDV3100): Filed for metastatic hormone-sensitive prostate cancer in US in Jun 2019 and in Europe in Jul 2019.

enfortumab vedotin (ASG-22ME): Filed in US for locally advanced or metastatic urothelial cancer in patients who have received prior treatment with a PD-1/PD-L1 inhibitor and platinum-containing chemotherapy in Jul 2019.

fezolinetant (ESN364): Clinical development for menopause-related vasomotor symptoms has been progressed to Phase 3.

Projects with Focus Area approach

Target (Biology)	Generic Name Code No. (Brand Name)	Modality / Technology	Therapeutic Area	Classification	Target Disease	Phase *	Dosage Form	Licensor **	Remarks
Immuno-oncology	**ASP8374/PTZ-201**	Antibody	Oncology	Anti-TIGIT antibody	Cancer	P-I	Injection	In-house (Potenza Therapeutics)	
	ASP1948/PTZ-329	Antibody	Oncology	Anti-NRP1 antibody	Cancer	P-I	Injection	In-house (Potenza Therapeutics)	
	ASP1951/PTZ-522	Antibody	Oncology	GITR agonistic antibody	Cancer	P-I	Injection	In-house (Potenza Therapeutics)	
	ASP9801	Oncolytic virus	Oncology		Cancer	P-I	Injection	Tottori University [Discovered through collaborative research]	
	ASP7517	Cell therapy (artificial adjuvant vector cells)	Oncology		Cancer	P-I	Injection	Option agreement with RIKEN	
Regeneration	**ASP7317**	Cell therapy	Ophthalmology	Retinal pigment epithelium cells	Dry age-related macular degeneration, Stargardt's disease	P-II	Injection	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	Injection	Frequency Therapeutics	Astellas has rights in Ex-US markets
Antigen-specific immuno-modulation (ASIM)	**ASP0892**	Next generation vaccine (LAMP-Vax technology)	Immunology		Peanut allergy	P-I	Injection	Immunomic Therapeutics	
	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	Injection	Affinivax	
Mitochondria	**ASP1128/MA-0217**	Small molecule	Nephrology	PPARδ modulator	Acute kidney injury	P-II	Injection	In-house (Mitobridge)	
	ASP0367/MA-0211	Small molecule	Muscle disease		Duchenne muscular dystrophy	P-I	Oral	In-house (Mitobridge)	
Others	**reldesemtiv CK-2127107**	Small molecule	Muscle disease	Fast skeletal muscle troponin activator	Spinal muscular atrophy	P-II	Oral	Cytokinetics	
					Amyotrophic lateral sclerosis	P-II			

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Updates from the previous announcement (Apr 2019):
ASP7517: Entered into Phase 1 for cancer.
FX-322: Added a Phase 2 program for sensorineural hearing loss.
ASP3772: Clinical development for prevention of pneumococcal disease has been progressed to Phase 2.

Others (1/2)

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Dosage Form	Licensor **	Remarks
Oncology	**AGS-16C3F**	Antibody-drug conjugate (ADC)	Anti-ENPP3 ADC	Renal cell carcinoma	P-II	Injection	In-house [ADC technology in-licensed from Seattle Genetics]	
	ASP1650	Antibody	Anti-Claudin 6 monoclonal antibody	Testicular cancer	P-II	Injection	In-house (Ganymed)	
	ASP1235/AGS62P1	Antibody-drug conjugate (ADC)		Acute myeloid leukemia	P-I	Injection	In-house [ADC technology, EuCODE license from Ambrx]	
Urology and Nephrology	**solifenacin YM905**	Small molecule	Muscarine M_3 receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	US Filed (Feb 2017)	Oral	In-house	
	mirabegron YM178	Small molecule	β_3 receptor agonist	Overactive bladder and neurogenic detrusor overactivity in pediatric patients	P-III	Oral	In-house	
	ASP6294	Antibody	Nerve Growth Factor (NGF) neutralization antibody	Bladder pain syndrome / Interstitial cystitis	P-II	Injection	In-house	
	ASP8302	Small molecule	Muscarine M_3 receptor positive allosteric modulator	Underactive bladder	P-II	Oral	In-house	
Immunology	**peficitinib ASP015K**	Small molecule	JAK inhibitor	Rheumatoid arthritis	China P-III	Oral	In-house	
	bleselumab ASKP1240	Antibody	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients	P-II	Injection	Kyowa Kirin	

Others (2/2)

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Dosage Form	Licensor **	Remarks
Others	**evolocumab AMG 145 (Repatha®)**	Antibody	Anti-PCSK9 monoclonal antibody	Familial hypercholesterolemia or hypercholesterolemia in patients who are not suitable for statin therapy	Japan Approved (Jun 2019)	Injection	Amgen [Co-development with Amgen Astellas]	
	fidaxomicin	Small molecule	Macrocyclic antibiotic	*Clostridium difficile* infection in pediatric patients	Europe Filed (Jan 2019)	Oral	Merck	
	micafungin	Small molecule	Echinocandin antifungal	Invasive candidiasis in neonates and young infants less than 120 days of life	US Filed (Jun 2019)	Injection	In-house	
	isavuconazole	Small molecule	Azole antifungal	Invasive aspergillosis and mucormycosis in pediatric patients	US P-II	Injection	Basilea	
	ASP0819	Small molecule	Ca^{2+} activated K^+ channel opener	Fibromyalgia	P-II	Oral	In-house	
	ASP4345	Small molecule	Dopamine D_1 receptor positive allosteric modulator	Cognitive impairment associated with schizophrenia	P-II	Oral	In-house	
	MucoRice-CTB	Next generation vaccine		Prophylaxis of diarrhea caused by *Vibrio cholerae*	P-I	Oral	The Institute of Medical Science, the University of Tokyo	
	ASP8062	Small molecule	$GABA_B$ receptor positive allosteric modulator	Substance use disorders	P-I	Oral	In-house	

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Update from the previous announcement (Apr 2019):
peficitinib (ASP015K): Removed the description of the approval in Japan for rheumatoid arthritis (including prevention of structural joint damage) in patients who have an inadequate response to conventional therapies in Mar 2019.
evolocumab (AMG 145): Approved in Japan for familial hypercholesterolemia or hypercholesterolemia in patients who are not suitable for statin therapy in Jun 2019.
micafungin: Filed in US for invasive candidiasis in neonates and young infants less than 120 days of life in Jun 2019.
ASP8062: Entered into Phase 1 for substance use disorders.

Patient Journey	New Technology	Content	Code Number/ Program Name	Business Concept	Status	Partner
Prevention/Therapy	Digital health	Excercise program with scientific evidence				
			Smartphone application	Offer smartphone application to support exercise using wearable device to people who needs regular exercise	Under development	BANDAI NAMCO Entertainment, Moff
Therapy support	Fluorescence	Image-guided precision surgery				
			ASP5354	Precision surgery-guide enabling identification of ureter in hysterectomy etc.	Phase I stage	
Diagnosis/Therapy	Radioisotope	Theranostics using antibody with radioisotope label				