Supplement Documents for Results 2Q/FY2013

Astellas Pharma Inc.

- Financial Results of 2Q/FY2013
- Pipeline list

Cautionary statement regarding forward-looking information

This material includes forward-looking statements based on a number of assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors, including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launches, the pricing and product initiatives of competitors, the inability of the company to market existing and new product effectively, interruptions in production, infringement of the company's intellectual property rights and the adverse outcome of material litigation.

1. Consolidated Results

rounddown under 0.1 billion yen　　Fiscal Year: From April to March

billion yen

	FY12 APR. - SEP.	FY13 APR. - SEP.	Change	Change (%)	FY12 Full Year	Initial Forecasts FY13 1H	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year	Change from FY12 Change (%)
Net Sales	476.8	556.7	79.8	16.7%	1,005.6	567.0	1,170.0	1,155.0	14.9%
Cost of Sales	150.2	169.4	19.1	12.8%	324.1				
Ratio to Net Sales	31.5%	30.4%			32.2%				
Gross Profit	326.5	387.2	60.6	18.6%	681.4				
SG&A	238.2	302.7	64.5	27.1%	527.6				
Ratio to Net Sales	50.0%	54.4%			52.5%				
Research and Development	83.5	102.2	18.6	22.3%	181.9	105.0	212.0	212.0	16.5%
SG&A excluding R&D	154.6	200.5	45.9	29.7%	345.6				
Advertising and Sales Promotion	33.9	53.0	19.1	56.3%	86.4				
Salaries, Bonuses and Allowances	66.2	78.4	12.1	18.3%	139.7				
Other	54.4	69.0	14.6	27.0%	119.4				
Operating Income	88.3	84.5	-3.8	-4.4%	153.8	83.0	170.0	170.0	10.5%
Ratio to Net Sales	18.5%	15.2%			15.3%	14.6%	14.5%	14.7%	
Non-Operating Income	2.2	1.5	-0.6	-30.5%	4.0				
Exchange Gain	0.7	-	-0.7	-	1.4				
Non-Operating Expenses	0.2	3.0	2.7	-	0.7				
Exchange Loss	-	2.6	2.6	-	-				
Ordinary Income	90.3	83.0	-7.2	-8.0%	157.1	83.0	170.0	170.0	8.2%
Ratio to Net Sales	18.9%	14.9%			15.6%	14.6%	14.5%	14.7%	
Special Gains	0.4	1.5	1.1	244.0%	5.8				
Gain on sales of fixed assets	0.2	0.2	0.0	8.6%	0.2				
Gain on sales of investment securities	0.1	1.2	1.1	-	5.4				
Special Losses	11.4	15.4	3.9	35.0%	38.2				
Loss on sale and disposal of fixed assets	0.3	0.2	-0.1	-33.6%	0.7				
Loss on impairment of fixed assets	9.8	7.2	-2.5	-26.3%	34.7				
Restructuring Costs	-	7.0	7.0	-	-				
Income before Income Taxes	79.3	69.2	-10.1	-12.8%	124.6				
Income Taxes	21.9	21.0	-0.9	-4.3%	41.8				
Net Income	57.4	48.1	-9.2	-16.0%	82.8	52.0	110.0	100.0	20.7%
Ratio to Net Sales	12.0%	8.7%			8.2%	9.2%	9.4%	8.7%	
Comprehensive income	14.9	89.7	74.7	498.8%	152.8				

2. Segment Information by Region

billion yen

		FY12 APR. - SEP.	FY13 APR. - SEP.	Change	Change (%)	FY12 Full Year	Initial Forecasts FY13 1H	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year	Change from FY12 (%)
Net Sales		476.8	556.7	79.8	16.7%	1,005.6	567.0	1,170.0	1,155.0	14.9%
	Japan	269.4	264.6	-4.8	-1.8%	557.5	279.8	582.5	556.8	-0.1%
	Ratio to Net Sales	56.5%	47.5%			55.4%	49.4%	49.8%	48.2%	
	Americas	93.6	140.4	46.7	50.0%	208.7	134.5	267.2	280.4	34.4%
	Ratio to Net Sales	19.6%	25.2%			20.8%	23.7%	22.8%	24.3%	
	Europe	93.3	123.7	30.3	32.5%	196.4	123.5	260.6	260.7	32.7%
	Ratio to Net Sales	19.6%	22.2%			19.5%	21.8%	22.3%	22.6%	
	Asia and Oceania	20.3	27.9	7.5	37.2%	42.9	28.9	59.5	56.9	32.7%
	Ratio to Net Sales	4.3%	5.0%			4.3%	5.1%	5.1%	4.9%	
Operating Income		88.3	84.5	-3.8	-4.4%	153.8	83.0	170.0	170.0	10.5%
	Japan	41.5	25.9	-15.5	-37.5%					
	Ratio to Net Sales	47.0%	30.7%							
	Americas	10.0	19.8	9.8	97.9%					
	Ratio to Net Sales	11.4%	23.5%							
	Europe	33.2	42.7	9.5	28.6%					
	Ratio to Net Sales	37.6%	50.5%							
	Asia and Oceania	2.4	3.6	1.1	46.7%					
	Ratio to Net Sales	2.8%	4.3%							
	Eliminations	1.1	-7.5	-8.7						

- Calculated according to locations of sellers.
- Europe: Including Middle and Near East and Africa

3. Exchange Rate

yen

	FY12 APR. - SEP.Ave.	FY13 APR. - SEP.Ave.	FY12 End	FY13 2Q End	FY12 Full Year	Initial Forecasts FY13 1H	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year
Yen/USD	79	99	94	98	83	100	100	99
Yen/EUR	101	130	121	132	107	130	130	130

∗ Exchange rate fluctuations had positive impact by 61.3 billion yen on net sales and positive impact by 7.7 billion yen on operating income in 2Q/FY2013

4. Per Share Information

	FY12 APR. - SEP.	FY13 APR. - SEP.	FY12 Full Year	Initial Forecasts FY13 1H	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year
The number of share issued (thousand)*	467,964	456,964	467,964			
Treasury Stock (thousand)*	6,030	5,746	16,788			
The number of share issued after deducting Treasury Stock (thousand)*	461,934	451,217	451,176			
Earnings per share (Yen)	124.27	106.82	180.40	115.25	243.81	221.63
Dividend per share (Yen)	65	65	130	65	135	135

*The number of share is shown as of 2Q End.

5. Research and Development Expenses

billion yen

	FY12 APR. - SEP.	FY13 APR. - SEP.	Change	Change (%)	FY12 Full Year	Initial Forecasts FY13 1H	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year	Change from FY12 Change (%)
Research and Development	83.5	102.2	18.6	22.3%	181.9	105.0	212.0	212.0	16.5%
Ratio to Net Sales	17.5%	18.4%			18.1%	18.5%	18.1%	18.4%	

6. Addition to Property, Plant and Equipment

Depreciation/Amortization

billion yen

	FY12 APR. - SEP.	FY13 APR. - SEP.	Change	Change (%)	FY12 Full Year	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year	Change from FY12 Change (%)
Addition to Property, Plant and Equipment								
Consolidated	15.7	14.2	-1.4	-9.5%	32.0	27.0	29.0	-9.6%
Depreciation(Tangible)								
Consolidated	8.2	10.8	2.5	30.5%	17.6	21.0	22.0	24.5%
Amortization(Intangible)								
Consolidated	14.0	19.0	5.0	35.6%	29.7	37.0	38.0	27.6%
Amortization of Goodwill	5.7	2.9			10.3	5.8	5.8	
Agensys	3.4	-			5.3	-	-	
OSI	2.3	2.8			4.8	5.8	5.8	

7. Employee

Number of employees

	FY12 2Q End	FY13 2Q End	FY12 FY End
Total	17,387	17,455	17,454
Japan	8,251	8,186	8,153
Americas	2,958	2,855	2,980
Europe	4,281	4,355	4,356
Asia and Oceania	1,897	2,059	1,965
Total Medical Representatives	6,300	6,280	6,350

- Europe: Including Middle and Near East and Africa

8. Shareholders

	FY12 2Q End	FY13 2Q End
Banks	33.1%	30.2%
Securities	6.2%	4.2%
Other companies	4.2%	3.7%
Foreign companies	46.3%	52.2%
Individuals and others	8.8%	8.6%
Treasury Stock	1.3%	1.3%

9. Sales of major products

1)Sales of global products

billion yen

	FY12 APR. - SEP.	FY13 APR. - SEP.	Change	Change (%)
Prograf	78.4	89.7	11.3	14.4%
Sales by Astellas	76.1	87.0	10.8	14.3%
Japan (Including Graceptor)	24.4	25.3	0.8	3.5%
Americas	15.1	14.8	-0.3	-2.1%
Europe	27.3	34.9	7.5	27.6%
Advagraf	8.3	11.6	3.3	39.8%
Asia and Oceania	9.0	11.8	2.7	30.6%
Exports to third parties	2.2	2.6	0.4	20.5%
Harnal	27.1	29.4	2.3	8.5%
Sales by Astellas	25.1	27.1	2.0	8.2%
Japan	11.8	10.4	-1.3	-11.8%
Europe	7.7	9.3	1.6	21.1%
Asia and Oceania	5.1	7.1	1.9	36.9%
Bulk and Royalties	2.0	2.3	0.2	11.9%
Vesicare	51.8	64.0	12.1	23.5%
Japan	14.8	13.9	-0.8	-5.8%
Americas	21.2	27.5	6.3	29.9%
Europe	14.3	20.2	5.9	41.2%
Asia and Oceania	1.4	1.9	0.5	40.6%
Betanis/Myrbetriq/BETMIGA	1.2	10.6	9.3	723.4%
Japan	1.2	4.8	3.5	272.3%
Americas	-	5.3	5.3	-
Europe	-	0.4	0.4	-
Funguard/Mycamine	14.9	17.6	2.6	18.0%
Japan	6.5	6.0	-0.5	-8.3%
Americas	4.5	5.9	1.3	30.0%
Europe	2.6	4.1	1.4	53.9%
Asia and Oceania	1.0	1.5	0.4	37.8%
Protopic	8.5	12.0	3.4	40.9%
Japan	1.8	1.7	-0.0	-2.9%
Americas	3.5	5.7	2.1	59.7%
Europe	2.1	3.1	0.9	43.0%
Asia and Oceania	0.9	1.3	0.4	49.8%
XTANDI	1.1	20.5	19.4	-
US	1.1	18.8	17.7	-
ex-US	-	1.6	1.6	-
Americas (ex-US)	-	0.1	0.1	-
Europe*	-	1.5	1.5	-
Eligard	7.0	9.0	2.0	28.8%
Europe	7.0	9.0	2.0	28.8%
Asia and Oceania	-	0.0	0.0	-

billion yen

FY12 Full Year	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year	Change from FY12 Change (%)
161.7	182.3	177.8	10.0%
157.3	177.7	173.4	10.3%
49.4	53.4	50.8	2.9%
31.4	29.1	28.9	-8.1%
57.5	68.9	68.9	19.8%
18.0			
18.9	26.2	24.7	31.0%
4.4	4.6	4.3	-0.8%
54.0	58.6	59.7	10.6%
50.0	54.6	54.9	9.7%
22.9	21.4	20.8	-9.1%
15.4	17.7	18.5	20.5%
10.8	14.4	14.7	35.5%
3.9	3.9	4.7	22.3%
109.9	131.7	130.0	18.3%
29.8	32.4	30.4	2.1%
46.8	53.5	54.7	17.0%
30.1	40.8	40.1	33.4%
2.9	4.6	4.1	41.0%
6.9	22.9	26.0	274.7%
5.3	10.9	11.1	109.4%
1.6	10.2	13.0	701.0%
0.0	1.6	1.8	-
30.7	37.2	36.1	17.8%
12.9	13.2	12.8	-0.6%
9.4	11.0	11.0	16.2%
5.9	9.1	9.1	52.6%
2.3	3.8	3.1	36.4%
17.8	23.2	23.7	33.1%
3.4	3.6	3.5	2.5%
7.9	10.6	11.0	39.4%
4.6	6.1	6.3	37.2%
1.7	2.6	2.6	55.8%
12.2			
12.2	40.0	39.7	225.8%
0.0			
-			
0.0			
14.9			
14.9	20.1	19.1	28.1%
-			

*Including "Temporary authorization for use" in France.

- Sales of products in Japan are shown in a gross sales basis.
- Europe: Including Middle and Near East and Africa

2)Sales of products in Japan

billion yen

<Global products>	FY12 APR. - SEP.	FY13 APR. - SEP.	Change	Change (%)	FY12 Full Year	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year	Change from FY12 FY13 Full Year Change (%)
Prograf（Including Graceptor）	24.4	25.3	0.8	3.5%	49.4	53.4	50.8	2.9%
Harnal	11.8	10.4	-1.3	-11.8%	22.9	21.4	20.8	-9.1%
Vesicare	14.8	13.9	-0.8	-5.8%	29.8	32.4	30.4	2.1%
Betanis	1.2	4.8	3.5	272.3%	5.3	10.9	11.1	109.4%
Funguard	6.5	6.0	-0.5	-8.3%	12.9	13.2	12.8	-0.6%
Protopic	1.8	1.7	-0.0	-2.9%	3.4	3.6	3.5	2.5%
<Domestic Products>								
Lipitor [Family]	36.6	32.0	-4.5	-12.5%	70.6	65.1	63.0	-10.8%
Caduet	4.7	5.2	0.5	11.7%	9.6			
Micardis [Family]	44.0	47.3	3.3	7.5%	89.6	100.6	98.0	9.3%
Micombi	5.6	5.8	0.1	2.1%	11.5			
Micamlo	7.2	10.0	2.8	39.2%	15.6			
Gaster	15.6	13.3	-2.2	-14.7%	30.2	27.3	26.7	-11.7%
Myslee	17.2	14.3	-2.8	-16.7%	32.2	29.8	27.3	-15.1%
Seroquel	15.1	10.3	-4.7	-31.5%	28.5	22.9	19.6	-31.1%
Vaccines	8.0	10.5	2.5	32.0%	28.8	34.1	34.1	18.5%
Cefzon	3.6	3.2	-0.4	-12.0%	7.1	6.5	6.4	-10.8%
Frandol	4.4	4.0	-0.3	-7.6%	8.6	8.2	8.1	-6.1%
Celecox	18.6	20.6	2.0	10.8%	37.4	48.5	44.8	19.7%
Geninax	4.9	4.9	0.0	0.5%	12.3	13.8	13.8	12.2%
Bonoteo	4.6	6.4	1.7	37.8%	10.6	17.5	14.0	31.8%
Symbicort	12.0	15.1	3.1	25.8%	27.7	35.6	35.6	28.6%
Argamate	3.0	3.0	0.0	1.7%	6.1	7.2	6.2	2.1%
Kiklin	0.1	0.6	0.4	331.8%	0.5	2.0	1.4	156.2%
Gonax	-	1.0	1.0	-	0.6	3.1	2.9	351.3%
Cimzia	-	1.3	1.3	-			4.5	-
Total Rx Sales In Japan	261.8	257.2	-4.6	-1.8%	535.7	567.3	540.4	0.9%

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

3)Sales of products in Americas and Europe

billion yen

	FY12 APR. - SEP.	FY13 APR. - SEP.	Change	Change (%)	FY12 Full Year	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year	Change from FY12 FY13 Full Year Change (%)
Scan* (Americas)	25.7	33.0	7.2	28.2%	53.1	50.8	59.0	11.2%
Lexiscan	23.0	30.4	7.4	32.1%	47.5			
AmBisome (Americas)	2.8	4.0	1.2	45.8%	6.3	6.8	7.3	16.4%
Tarceva	17.4	22.8	5.4	31.5%	36.5			
(US)	11.0	15.0	4.0	36.7%	23.6			
(ex-US)	6.3	7.8	1.4	22.5%	12.9			
Qutenza (Europe)	0.3	0.6	0.2	69.6%	0.8			

* Adenoscan + Lexiscan

4)Sales in Americas and Europe(Local currency)

Unit:M$

Americas	FY12 APR. - SEP.	FY13 APR. - SEP.	Change	Change (%)	FY12 Full Year	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year	Change from FY12 FY13 Change (%)
Net Sales	1,179	1,420	241	20.5%	2,511	2,672	2,820	12.3%
Prograf	191	150	-40	-21.4%	378	291	291	-23.2%
Scan*	324	334	9	3.0%	639	508	594	-7.1%
Lexiscan	290	308	17	6.1%	572			
AmBisome	35	41	6	17.1%	76	68	74	-2.7%
Protopic	44	57	12	28.3%	95	106	110	16.5%
VESIcare	267	279	11	4.3%	563	535	550	-2.2%
Myrbetriq	-	54	54	-	19	102	131	569.5%
Mycamine	57	60	2	4.4%	114	110	111	-2.8%
Tarceva	219	231	12	5.7%	439			
US	138	152	13	9.9%	284			
ex-US	80	79	-1	-1.6%	155			
XTANDI	14	192	178	-	146			
US	14	190	176	-	146	400	400	172.3%
Americas (ex-US)	-	1	1	-	-			

* Adenoscan + Lexiscan

Unit:M€

Europe	FY12 APR. - SEP.	FY13 APR. - SEP.	Change	Change (%)	FY12 Full Year	Initial Forecasts FY13 Full Year	Revised Forecasts FY13 Full Year	Change from FY12 FY13 Change (%)
Net Sales	927	951	24	2.6%	1,833	2,004	2,005	9.4%
Harnal	97	89	-7	-7.8%	180	166	179	-0.4%
Sales by Astellas	76	71	-4	-6.3%	143	136	143	-0.7%
Capsule	34	32	-1	-4.8%	63	64	70	11.5%
OCAS	42	39	-3	-7.4%	80	72	72	-10.3%
Bulk and Royalties	20	17	-2	-13.4%	36	30	36	0.8%
Prograf	293	288	-5	-1.7%	577	565	563	-2.3%
Sales by Astellas	272	268	-3	-1.2%	536	530	530	-1.3%
Advagraf	82	89	6	8.2%	168			
Exports to third parties	21	20	-1	-7.7%	40	35	33	-16.7%
Vesicare	142	155	13	9.3%	280	314	309	10.0%
BETMIGA	-	3	3	-	0	12	14	-
Protopic	21	24	2	10.7%	43	47	49	13.1%
Mycamine	26	31	5	19.2%	55	70	70	25.8%
Eligard	69	69	-0	-0.3%	139	155	147	5.6%
Qutenza	3	4	1	31.3%	8			
XTANDI*	-	11	11	-	0			

*Including "Temporary authorization for use" in France.

- Europe: Including Middle and Near East and Africa

10.Consolidated Balance Sheets

rounddown under 0.1 billion yen

Billion yen

	31-Mar-13	30-Sep-13	
	Amount	Amount	Change
Assets	**1,445.5**	**1,497.1**	**51.5**
Current assets	**827.1**	**884.3**	**57.1**
Cash on hand and in banks	233.8	258.6	24.8
Trade notes and accounts receivable	286.0	289.0	2.9
Marketable securities	78.8	89.2	10.3
Inventories	128.1	147.9	19.7
Other	102.1	101.5	-0.6
Allowance for doubtful receivables	-1.9	-2.0	-0.1
Fixed assets	**618.3**	**612.7**	**-5.5**
Property, plant and equipment	**218.4**	**218.9**	**0.4**
Intangible fixed assets	**294.8**	**283.4**	**-11.4**
Goodwill	95.9	95.9	-0.0
Patents	138.0	130.4	-7.6
Other	60.7	57.0	-3.7
Investments and other assets	**105.0**	**110.3**	**5.3**
Investment securities	61.6	64.3	2.7
Other	43.4	46.0	2.5
Allowance for doubtful receivables	-0.0	-0.0	0.0

rounddown under 0.1 billion yen

Billion yen

	31-Mar-13	30-Sep-13	
	Amount	Amount	Change
Liabilities and Net assets	**1,445.5**	**1,497.1**	**51.5**
Liabilities	**383.5**	**374.4**	**-9.0**
Current liabilities	**313.5**	**307.6**	**-5.8**
Trade notes and accounts payable	102.8	108.3	5.5
Provision	4.4	4.3	-0.1
Other	206.2	194.9	-11.2
Long-term liabilities	**69.9**	**66.8**	**-3.1**
Accrued retirement benefits for employees	18.2	18.2	-0.0
Other	51.7	48.6	-3.1
Net assets	**1,062.0**	**1,122.6**	**60.6**
Common stock	103.0	103.0	-
Capital surplus	176.8	176.8	-
Retained earnings	917.5	888.9	-28.5
Treasury stock	-72.2	-24.7	47.5
Unrealized holding gains on securities	15.9	19.7	3.8
Foreign currency translation adjustments	-80.9	-43.2	37.7
Stock subscription rights	1.9	2.0	0.1

R&D Pipeline (November 2013)

1. Global Development

(1) Filed

Stage in the most advanced territory

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin*	Remarks
MDV3100 enzalutamide	Androgen receptor inhibitor	Prostate cancer	Japan Filed (May 2013)	Oral	Medivation	
		Metastatic castration-resistant prostate cancer in chemotherapy-naive patients	US Phase-III Europe Phase-III Japan Phase-III Asia Phase-III			New indication
		Non-Metastatic castration-resistant prostate cancer	US Phase-III Europe Phase-III Asia Phase-III			New indication
		Breast cancer	US/Europe Phase-II			New indication

*In-house: Including compounds discovered by collaborative research. (The same applicable hereafter.)

(2) Phase-lll / Phase-ll (1/2)

Stage in the most advanced territory

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
erlotinib	HER1/EGFR tyrosine kinase inhibitor	Non-small cell lung cancer (Adjuvant, combination with MetMAb), Pediatric ependymoma*	US Phase-III	Oral	In-house (co-development with Roche/ Genentech)	New indication
isavuconazole	Azole antifungal	Invasive aspergillosis	US/Europe Phase-III	Injection Oral	Basilea	
		Candidemia / Invasive candidiasis	US/Europe Phase-III			
ASP0113 (VCL-CB01)	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic cell transplant recipients	US/Europe Phase-III Japan Phase-II	Injection	Vical	
		Cytomegalovirus infection or reactivation in solid organ transplant recipients	US/Europe Phase-II			
YM905 solifenacin	Muscarine M_3 receptor antagonist	Neurogenic detrusor overactivity and idiopathic overactive bladder in pediatric patients	US/Europe Phase-III	Oral	In-house	New indication
EB178 solifenacin/ mirabegron	Concomitant use of solifenacin and mirabegron	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	Europe/US/Asia Phase-III	Oral	In-house	
ASP1517 (FG-4592) roxadustat	HIF stabilizer	Anemia associated with chronic kidney disease in patients not on dialysis and on dialysis	Europe Phase-III Japan Phase-II	Oral	FibroGen	
YM311 (FG-2216)	HIF stabilizer	Renal anemia	Europe Phase-II Japan Phase-I	Oral	FibroGen	

*Pediatric ependymoma is not a new indication, rather a supplement whose results are planned to submit to the FDA.

(2) Phase-lll / Phase-ll (2/2)

Stage in the most advanced territory

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
ASP4130 tivozanib	Inhibitor of vascular endothelial growth factor (VEGF) receptors 1, 2 and 3	Colorectal cancer, Breast cancer	US/Europe Phase-II	Oral	AVEO	
ASP7487 (OSI-906) linsitinib	IGF-1R/IR tyrosine kinase inhibitor	Ovarian cancer	US Phase-II	Oral	In-house	
ASP015K	JAK inhibitor	Rheumatoid arthritis	Japan Phase-II (US/Europe Phase-II*)	Oral	In-house	
ASKP1240	Anti-CD40 antagonist	Prevention of organ transplant rejection	US Phase-II Japan Phase-I	Injection	Kyowa Hakko Kirin	
ASP3652	Inhibition of afferent nerve activity	Bladder pain syndrome / Interstitial cystitis	Europe Phase-II Japan Phase-I	Oral	In-house	
ASP1707	GnRH antagonist	Endometriosis	Europe/Japan Phase-II	Oral	In-house	
		Prostate cancer	Europe Phase-I			
ASP4901 (AKP-002)	PDE9 inhibitor	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Japan Phase-II	Oral	ASKA	
ASP8477	Inhibition of central sensitization	Neuropathic pain	Europe Phase-II	Oral	In-house	

*A license agreement was executed with Janssen Biotech, Inc. for the development and commercialization worldwide except for Japan.
Phase-IIb studies will be completed by Astellas.

2. Local Development: Japan

(1) Approved

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
YM060 ramosetron	Irribow OD Tablets (Aug. 2013)	5-HT3 receptor antagonist	Diarrhea-predominant irritable bowel syndrome in males (Orally-disintegrating tablet)	Japan	Oral	In-house	New formulation

(2) Filed

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
midazolam	Benzodiazepine sedative	Conscious sedation in dentistry and dental surgery	Japan Filed (Feb. 2013)	Injection	Roche	New indication
ASP1941 ipragliflozin	SGLT2 inhibitor	Type 2 diabetes	Japan Filed (Mar. 2013)	Oral	In-house (co-development with Kotobuki)	

(3) Phase-lll / Phase-ll (1/2)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
YM060 ramosetron	5-HT3 receptor antagonist	Diarrhea-predominant irritable bowel syndrome Female patients	Japan Phase-III	Oral	In-house	New indication
YM533 beraprost sodium	Prostacyclin receptor stimulator	Chronic renal failure (primary, nephrosclerosis)	Japan/Asia Phase-III	Oral	Toray	New indication New formulation
FK949E quetiapine	Serotonin/dopamine antagonist	Depressive episode in bipolar disorders	Japan Phase-III	Oral	AstraZeneca	New indication New formulation
		Major depressive disorder	Japan Phase-II			
certolizumab pegol	PEGylated anti-tumor necrosis factor-alpha antibody	Methotrexate-naive rheumatoid arthritis	Japan Phase-III	Injection	UCB	New indication
ASP1585 (AMG223) bixalomer	Amine-functional polymer	Hyperphosphatemia in patients not on dialysis with chronic kidney disease	Japan Phase-III	Oral	Ilypsa/Amgen	New indication
nateglinide	Fast acting insulin secretion enhancer	Type 2 diabetes Combination with DPP-4 inhibitors	Japan Phase-III	Oral	Ajinomoto	New indication
ASP3550 degarelix	GnRH antagonist	Prostate cancer (Three-month formulation)	Japan Phase-III	Injection	Ferring	New formulation
AMG 785 romosozumab	Anti-Sclerostin monoclonal antibody	Osteoporosis	Japan Phase-III	Injection	Amgen (co- development with Amgen Astellas)	

(3) Phase-lll / Phase-ll (2/2)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
AMG 145	Anti-PCSK-9 monoclonal antibody	Hyperlipidemia	Japan Phase-III	Injection	Amgen (co-development with Amgen Astellas)	
ASP7374	Influenza vaccine	Prophylaxis of seasonal influenza	Japan Phase-III	Injection	UMN Pharma	
ASP7373	Influenza vaccine	Prophylaxis of H5N1 influenza	Japan Phase-II	Injection	UMN Pharma	
ASP0456 linaclotide	Guanylate cyclase type-C receptor agonist	Irritable bowel syndrome	Japan Phase-II	Oral	Ironwood	

3. Local Development: Europe

(1) Phase-lll / Phase-ll

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
NGX-4010 capsaicin	TRPV1 agonist	Peripheral diabetic neuropathy	Europe Phase-III	Patch	NeurogesX	New indication

4. Phase-I

Code No. Generic Name	Target Disease	Dosage Form	Origin
AGS-16M8F/ AGS-16C3F	Cancer (ADC technology)	Injection	In-house (ADC technology in-licensed from Seattle Genetics)
ASP0306	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Oral	In-house
ASP3026	Cancer	Oral	In-house
ASG-22ME	Cancer (ADC technology)	Injection	In-house (co-development with Seattle Genetics)
ASP9226	Neuropathic pain	Oral	In-house
ASP7991	Secondary hyperparathyroidism	Oral	In-house
ASP6432	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Oral	In-house
ASP9853	Cancer	Oral	In-house
ASP8232	Diabetic nephropathy	Oral	In-house
fidaxomicin*	Clostridium difficile associated diarrhea	Oral	Optimer
ASP3662	Alzheimer's disease	Oral	In-house
ASG-15ME	Cancer (ADC technology)	Injection	In-house (co-development with Seattle Genetics)
ASP2215	Cancer	Oral	In-house
ASP3325	Hyperphosphatemia	Oral	In-house
CK-2127107	Skeletal muscle disease (non-neuromuscular indications)	Oral	Cytokinetics
AMG 102 rilotumumab	Gastric cancer	Injection	Amgen (co-development with Amgen Astellas)
ASP5878	Cancer	Oral	In-house

*Japanese development

5. Project Discontinued

Code No. Generic Name	Area / Phase	Target Disease	Reason
ASP2408	Phase-I	Rheumatoid arthritis	Discontinued due to strategic reasons.
ASP2409	Phase-I	Prevention of organ transplant rejection	Discontinued due to strategic reasons.

<Changes from the Previous Announcement on August 1, 2013> (Changed underlined items)

Launched

-Erlotinib: Removed the previous item below for new indication in the US.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
erlotinib	Tarceva (May 2013)	HER1/EGFR tyrosine kinase inhibitor	First-line treatment of people with metastatic non-small cell lung cancer whose tumors have certain epidermal growth factor receptor activating mutations as detected by an FDA-approved test	US	Oral	In-house (co-development with Roche/ Genentech)	New indication

-Tacrolimus: Removed the previous items below for new indication in Japan and new formulation in the US. ASTAGRAF XL was launched in the US in August 2013.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
FK506 tacrolimus	Prograf (Jun. 2013)	Immunosuppressant	Interstitial pneumonia associated with polymyositis/dermatomyositis	Japan	Oral	In-house	New indication
	ASTAGRAF XL (Jul. 2013)		Prophylaxis of organ rejection in adult kidney transplant recipients (Extended release capsules)	US	Oral		New formulation

-Enzalutamide: Removed the previous item below. XTANDI was launched in Europe in July 2013.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
MDV3100 enzalutamide	XTANDI (Jun. 2013)	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer in patients whose disease has progressed on or after docetaxel therapy	Europe	Oral	Medivation	

-Micafungin: Removed the previous item below for new indication in the US.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
FK463 micafungin	Mycamine (Jun. 2013)	Candin-type antifungal agent	Treatment of pediatric patients four months and older with Candidemia, acute disseminated candidiasis, Candida peritonitis and abscesses, esophageal candidiasis, prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplants	US	Injection	In-house	New indication

-Solifenacin/tamsulosin: Removed the previous item below. VESOMNI was launched in Europe (Netherlands) in September 2013.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
EC905 solifenacin/ tamsulosin	VESOMNI (May 2013)	Fixed dose combination of solifenacin and tamsulosin	Moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy	Europe	Oral	In-house	

Approved

-Ramosetron (Orally-disintegrating tablet): Approved in Japan in August 2013.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
YM060 ramosetron	Irribow OD Tablets (Aug. 2013)	5-HT3 receptor antagonist	Diarrhea-predominant irritable bowel syndrome in males (Orally-disintegrating tablet)	Japan	Oral	In-house	New formulation

Filed

-Enzalutamide [Non-Metastatic castration-resistant prostate cancer]: Entered into Phase-III in the US, Europe and Asia.

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
MDV3100 enzalutamide	Androgen receptor inhibitor	Prostate cancer	Japan Filed (May 2013)	Oral	Medivation	
		Metastatic castration-resistant prostate cancer in chemotherapy-naive patients	US Phase-III Europe Phase-III Japan Phase-III Asia Phase-III			New indication
		Non-Metastatic castration-resistant prostate cancer	US Phase-III Europe Phase-III Asia Phase-III			New indication
		Breast cancer	US/Europe Phase-II			New indication

Phase-III / Phase-II

-Linsitinib: Deleted non-small cell lung cancer from the target disease because the development was discontinued.

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
ASP7487 (OSI-906) linsitinib	IGF-1R/IR tyrosine kinase inhibitor	Ovarian cancer~~,~~ ~~Non-small cell lung cancer~~	US Phase-II	Oral	In-house	

-ASP8477 [Neuropathic pain]: Entered into Phase-II in Europe.

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
ASP8477	Inhibition of central sensitization	Neuropathic pain	Europe Phase-II	Oral	In-house	

-AMG 145 [Hyperlipidemia]: Entered into Phase-III in Japan.

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
AMG 145	Anti-PCSK-9 monoclonal antibody	Hyperlipidemia	Japan Phase-III	Injection	Amgen (co-development with Amgen Astellas)	

Phase-I

-ASP5878 [Cancer]: Entered into Phase-I.

Project Discontinued

-ASP2408 [Rheumatoid arthritis] in Phase-I: Discontinued the development.

-ASP2409 [Prevention of organ transplant rejection] in Phase-I: Discontinued the development.