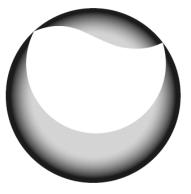
Reference Data

TSE:4568

(Consolidated Financial Results for Q2 FY2015)



Daiichi-Sankyo

October 30, 2015 Daiichi Sankyo Co., Ltd. http://www.daiichisankyo.com

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1. Consolidated Statement of Profit or Loss

	FY2014	Q2 YTD		F	Y2015 Q2 YT	D						FY2015			
JPY Bn	to revenue	Results	to revenue	Results	(vs. Forecast (%))	YoY	YoY (%)		to revenue	Forecast (as of Jul.)	to revenue	Forecast (as of Oct.)	vs. Forecast (as of Jul.)	YoY	YoY (%)
Revenue	100.0%	429.6	100.0%	478.8	(48.9%)	49.2	+11.4%	Forex impact: +23.8 (USD:+22.2, EUR:-1.1, ASCA:+2.7)	100.0%	950.0	100.0%	980.0	30.0	60.6	+6.6%
Cost of sales	30.4%	130.8	31.1%	148.9	(47.4%)	18.1	+13.9% 🥿	Forex impact: +6.0]] 31.8%	302.0	32.0%	314.0	12.0	-9.1	-2.8%
(excl. Special items)	30.4%	130.8	31.8%	152.4		21.6	+16.5%	(USD:+5.1, ASCA:+1.0)							
(Special items)	-	-	-0.7%	-3.5		-3.5	- 1	FY2015: Gain on sales of subsidiary]						
Gross Profit	69.6%	298.8	68.9%	329.8	(49.5%)	31.0	+10.4%	-2.4, Gain on sales of fixed assets -1.1	68.2%	648.0	68.0%	666.0	18.0	69.7	+11.7%
SG&A expenses	35.8%	153.7	30.2%	144.5	(40.8%)	-9.2	-6.0%	Forex impact: +8.9 (USD: +8.6, EUR: -0.6, ASCA: +0.9)	35.6%	338.0	36.1%	354.0	16.0	22.8	+6.9%
(excl. Special items)	34.8%	149.6	31.9%	152.7		3.0	+2.0%								
(Special items)	0.9%	4.0	-1.7%	-8.2		-12.2	-304.5%	Department of Justice +4.0							
R&D expenses	19.8%	84.9	18.5%	88.4	(46.0%)	3.5	+4.1%	FY2015: Gain on sales of fixed assets -8.2	20.0%	190.0	19.6%	192.0	2.0	1.3	+0.7%
(excl. Special items)	19.8%	84.9	18.5%	88.4		3.5	+4.1%	-0.2							
(Special items)	-	-	-	-		-	-	Forex impact: +4.5 (USD:+4.6, EUR:-0.1)							
Operating Profit	14.0%	60.2	20.3%	97.0	(80.8%)	36.8	+61.0%		12.6%	120.0	12.2%	120.0	0.0	45.6	+61.2%
(Operating Profit before Special items)	15.0%	64.3	17.8%	85.3		21.1	+32.8%	Forex impact: +4.4 (USD:+4.0, EUR:-0.4, ASCA:+0.8)							
Financial income/expenses		2.8		-5.9		-8.6			1						
Share of profit or loss of investments accounted for using the equity method		-0.8		-0.3		0.5		FY2015: Expenses relating to sale of Sun Pharma shares etc.							
Profit before tax	14.5%	62.2	19.0%	90.8	(79.0%)	28.6	+46.1%		12.1%	115.0	11.7%	115.0	0.0	35.1	+43.9%
Income taxes		26.9		21.4		-5.6	-20.6%								
Profit for the year	8.2%	35.2	14.5%	69.4		34.2	+97.1%								
Profit attributable to owners of the Company	y 8.5%	36.7	1 4.8 %	70.7	(94.3%)	34.0	+92.8%		7.9%	75.0	7.7%	75.0	0.0	28.5	+61.4%
								Increase in R&D tax credit							
Tax rate		43.3%		23.5%				-							
Overseas sales ratio		43.1%		46.5%											
Currency Rate (Average) USD/JPY		103.05		121.80					Currency	<u>/ Rate (Avera</u> 120.34	ige)	120.90			
EUR/JPY		138.91		135.07						131.04		132.53			

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*At the time of disclosure of this report, the audit procedures for financial statements are in progress in accordance with the Financial Instruments and Exchange Act.

*The figures for FY2014 have been restated and indicated as only the values for continuing operations excluding Ranbaxy.

*Special items : Items having a transitory and material impact on operating profit are defined as "Special items".

Specifically, gains and losses related to: sale of fixed assets, restructuring, impairment, litigation, etc. amounting to 1 billion JPY or more are defined as "Special items".

Annual impact of one yen change

	Forecast	(as of Jul.)	Forecast (as of Oct.)			
	USD	EUR	USD	EUR		
Revenue	2.1 Bn Yen	0.6 Bn Yen	2.2 Bn Yen	0.6 Bn Yen		
Operating Profit	minor	minor	0.2 Bn Yen	0.1 Bn Yen		

FY	20	15
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2. Revenue of Global Products	FY2014 Q2 YTD		FY2015 Q2	YTD	FY2015			
JPY Bn	Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Jul.)	Forecast (as of Oct.)	vs. Forecast (as of Jul.)
Olmesartan antihypertensive	142.2	147.5	(52.0%)	5.3	+3.7%	283.0	284.0	1.0
Olmetec (JPN)	37.8	36.2	(45.8%)	-1.6	-4.3%	79.0	79.0	0.0
Rezaltas (JPN)	9.0	8.9	(46.9%)	-0.1	-1.0%	19.0	19.0	0.0
Benicar/Benicar HCT (US)	34.0	40.3	(55.3%)	6.4	+18.8%	73.0	73.0	0.0
Azor (US)	8.0	10.4	(61.5%)	2.4	+30.1%	17.0	17.0	0.0
Tribenzor (US)	5.2	6.3	(63.4%)	1.1	+22.1%	10.0	10.0	0.0
Olmetec/Olmetec Plus (EU)	20.4	17.1	(53.3%)	-3.3	-16.3%	32.0	32.0	0.0
Sevikar (EU)	9.6	8.5	(53.3%)	-1.0	-10.9%	15.0	16.0	1.0
Sevikar HCT (EU)	5.4	4.6	(51.6%)	-0.8	-14.7%	9.0	9.0	0.0
Other subsidiaries, export, etc	12.9	15.0	(51.9%)	2.2	+16.9%	29.0	29.0	0.0
Prasugrel antiplatelet	11.7	15.3	-	3.6	+30.7%	not disclosed	not disclosed	-
Effient alliance revenue (US)	8.5	10.6	-	2.1	+25.1%	not disclosed	not disclosed	-
Efient alliance revenue and others (EU)	2.3	2.2	-	-0.1	-5.2%	not disclosed	not disclosed	-
Efient (JPN)	0.3	1.8	(35.3%)	1.5	+461.0%	5.0	5.0	0.0
Other subsidiaries, export, etc	0.6	0.7		0.1	+22.2%	not disclosed	not disclosed	-
Edoxaban anticoagulant	0.2	5.3	(36.4%)	5.2	+2602.9%	14.7	14.7	0.0
Lixiana (JPN)	0.2	5.4	(48.8%)	5.2	+2612.0%	11.0	11.0	0.0
Savaysa (US)	-	-0.2	-	-0.2	-	2.0	2.0	0.0
Lixiana (EU)	-	0.2	(9.4%)	0.2	-	1.7	1.7	0.0

. Revenue by	Business Units and Products (1)	FY2014 Q2 YTD		FY2015 Q2	YTD		FY2015			
PY Bn		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Jul.)	Forecast (as of Oct.)	vs. Forecast (as of Jul.)	
apan		222.6	227.8	(46.4%)	5.2	+2.3%	488.0	491.0	3.0	
Olmetec	antihypertensive	37.8	36.2	(45.8%)	-1.6	-4.3%	79.0	79.0	0.0	
Nexium	proton pump inhibitor	32.1	38.7	(50.2%)	6.6	+20.6%	74.0	77.0	3.0	
Memary	treatment for Alzheimer's Disease	16.8	20.5	(43.6%)	3.7	+22.2%	47.0	47.0	0.0	
Loxonin	analgesic and anti-inflammatory	25.4	24.4	(55.4%)	-1.0	-3.9%	44.0	44.0	0.0	
Cravit	antibacterial	14.2	9.0	(52.9%)	-5.2	-36.5%	17.0	17.0	0.0	
Rezaltas	antihypertensive	9.0	8.9	(46.9%)	-0.1	-1.0%	19.0	19.0	0.0	
Artist	antihypertensive	9.4	7.9	(46.4%)	-1.5	-16.3%	17.0	17.0	0.0	
Omnipaque	contrast medium	8.6	8.5	(52.8%)	-0.1	-1.7%	16.0	16.0	0.0	
Mevalotin	antihyperlipidemic	8.3	7.0	(49.7%)	-1.3	-16.1%	14.0	14.0	0.0	
Ranmark	anti-RANKL antibody	4.7	5.9	(45.2%)	1.2	+25.8%	13.0	13.0	0.0	
Inavir	anti-influenza	0.3	0.0	(0.3%)	-0.3	-86.3%	12.0	12.0	0.0	
Urief	treatment for dysuria	5.6	5.7	(51.8%)	0.1	+2.0%	11.0	11.0	0.0	
Pralia	anti-RANKL antibody	3.0	5.4	(53.5%)	2.4	+79.6%	10.0	10.0	0.0	
Lixiana	anticoagulant	0.2	5.4	(48.8%)	5.2	+2612.0%	11.0	11.0	0.0	
Efient	antiplatelet	0.3	1.8	(35.3%)	1.5	+461.0%	5.0	5.0	0.0	
Teneria	type 2 diabetes	3.3	5.3	-	2.0	+61.8%	not disclosed	not disclosed	-	
Daiichi Sankyo	Espha products	6.8	8.6	-	1.8	+25.7%	not disclosed	not disclosed	-	
Vaccines busin	ess	12.5	14.4	-	1.9	+15.1%	not disclosed	not disclosed	-	
aiichi Sankyo H	ealthcare (OTC)	22.7	24.6	(50.3%)	2.0	+8.7%	48.0	49.0	1.0	

3. Revenue by	Business Units and Products (2)	FY2014 Q2 YTD		FY2015 Q2	YTD		FY2015			
JPY Bn		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Jul.)	Forecast (as of Oct.)	vs. Forecast (as of Jul.)	
Daiichi Sankyo, Ir	nc. (US)	78.1	93.4	(53.0%)	15.2	+19.5%	166.0	176.0	10.0	
Olmesartan	antihypertensive	47.2	57.1	(56.6%)	9.9	+21.1%	101.0	101.0	0.0	
Benicar/Beni	icar HCT	34.0	40.3	(55.3%)	6.4	+18.8%	73.0	73.0	0.0	
Azor		8.0	10.4	(61.5%)	2.4	+30.1%	17.0	17.0	0.0	
Tribenzor		5.2	6.3	(63.4%)	1.1	+22.1%	10.0	10.0	0.0	
Welchol	antihyperlipidemic / type 2 diabetes	21.8	24.2	(51.5%)	2.4	+11.0%	37.0	47.0	10.0	
Effient	antiplatelet	8.5	10.6	; -	2.1	+25.1%	not disclosed	not disclosed	-	
Savaysa	anticoagulant	-	-0.2	-	-0.2	-	2.0	2.0	0.0	
Movantik	opioid-induced constipation	-	0.6	; -	0.6	-	not disclosed	not disclosed	-	
Luitpold Pharmac	ceuticals, Inc. (US)	26.8	46.4	(54.0%)	19.6	+73.4%	76.0	86.0	10.0	
Venofer	iron deficiency anemia	14.2	16.0) (53.4%)	1.8	+12.7%	28.0	30.0	2.0	
Injectafer	iron deficiency anemia	2.9	7.9	(46.4%)	5.0	+169.4%	17.0	17.0	0.0	
Daiichi Sankyo Eu	urope GmbH	44.5	39.2	(51.6%)	-5.3	-11.9%	75.0	76.0	1.0	
Olmesartan	antihypertensive	35.4	30.2	(52.1%)	-5.2	-14.6%	57.0	58.0	1.0	
Olmetec/Olm	netec Plus	20.4	17.1	(53.3%)	-3.3	-16.3%	32.0	32.0	0.0	
Sevikar		9.6	8.5	(53.3%)	-1.0	-10.9%	15.0	16.0	1.0	
Sevikar HCT	-	5.4	4.6	(51.6%)	-0.8	-14.7%	9.0	9.0	0.0	
Efient	antiplatelet	2.3	2.2		-0.1	-5.2%	not disclosed	not disclosed	-	
Lixiana	anticoagulant	-	0.2	(9.4%)	0.2	-	1.7	1.7	0.0	
Asia, South and C	Central America (ASCA)	30.0	42.7	(48.5%)	12.8	+42.6%	88.0	88.0	0.0	
Daiichi Sankyo	China	11.5	16.4	-	4.9	+42.6%	not disclosed	not disclosed	-	
Daiichi Sankyo	Taiwan	2.3	2.7	-	0.4	+16.3%	not disclosed	not disclosed	-	
Daiichi Sankyo	Korea	4.4	4.8	; -	0.4	+8.9%	not disclosed	not disclosed	-	
Daiichi Sankyo	Thailand	1.6	1.8	} -	0.2	+11.6%	not disclosed	not disclosed	-	
Daiichi Sankyo	Brasil Farmacêutica	4.3	4.5	; -	0.3	+6.1%	not disclosed	not disclosed	-	
Daiichi Sankyo	Venezuela	3.0	5.5	; -	2.5	+82.1%	not disclosed	not disclosed	-	

3. Revenue by Business Units and Products (3)	FY2014 Q2 YTD		FY2015 Q2	YTD		FY2015			
[Reference] Revenue in Local Currency	Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Jul.)	Forecast (as of Oct.)	vs. Forecast (as of Jul.)	
USD Mn									
Daiichi Sankyo, Inc. (US)	758	766	(52.4%)	8	+1.1%	1,379	1,462	83	
Olmesartan antihypertensive	458	469	(55.7%)	11	+2.4%	842	842	0	
Benicar/Benicar HCT	330	331	(54.5%)	2	+0.5%	608	608	0	
Azor	78	86	(60.6%)	8	+10.1%	142	142	0	
Tribenzor	50	52	(62.5%)	2	+3.3%	83	83	0	
Welchol antihyperlipidemic / type 2 diabetes	211	199	(50.9%)	-13	-6.1%	307	390	83	
Effient antiplatelet	82	87	-	5	+5.9%	not disclosed	not disclosed	-	
Savaysa anticoagulant	-	-1	-	-1	-	17	17	0	
Movantik opioid-induced constipation	-	5	-	5	-	not disclosed	not disclosed	-	
USD Mn									
Luitpold Pharmaceuticals, Inc. (US)	260	381	(53.3%)	121	+46.7%	632	714	83	
Venofer iron deficiency anemia	138	132	(52.8%)	-6	-4.7%	233	249	17	
Injectafer iron deficiency anemia	28	65	(45.8%)	36	+127.9%	141	141	0	
EUR Mn									
Daiichi Sankyo Europe GmbH	321	290	(49.7%)	-30	-9.4%	577	584	8	
Olmesartan antihypertensive	255	224	(50.2%)	-31	-12.2%	438	446	8	
Olmetec/Olmetec Plus	147	126	(51.3%)	-20	-13.9%	246	246	0	
Sevikar	69	63	(51.3%)	-6	-8.3%	115	123	8	
Sevikar HCT	39	34	(49.7%)	-5	-12.2%	69	69	0	
Efient antiplatelet	17	16	-	-0	-2.5%	not disclosed	not disclosed	-	
Lixiana anticoagulant	-	1	(9.1%)	1	-	13	13	0	

4. Consolidated Statement of Financial Position

<asse< th=""><th>ets></th><th></th><th></th><th>(JPY Bn)</th><th colspan="3">u)</th></asse<>	ets>			(JPY Bn)	u)		
		Mar. 2015	Sep. 2015	vs. Mar. 2015			
Assets	3						
С	current assets						
	Cash and cash equivalents	189.4	235.4	46.0			
	Trade and other receivables	241.5	250.5	9.0	Increase due to sale of Sun Pharma shares		
	Other financial assets	186.5	470.0	283.6			
	Inventories	150.1	153.3	3.2			
	Other current assets	14.7	14.8	0.1			
	Subtotal	782.2	1,123.9	341.8			
	Assets held for sale	3.2	-	-3.2			
	Total current assets	785.3	1,123.9	338.6			
N	lon-current assets						
	Property,plant and equipment	266.5	265.4	-1.1			
	Goodwill	71.4	71.2	-0.2			
	Intangible assets	199.4	212.1	12.7	Acquired +20.9, Amorization -8.1		
	Investments accounted for using the equity method	1.3	1.0	-0.3			
	Other financial assets	593.9	162.9	-431.0	Sale of Sun Pharma shares -424.3		
	Deferred tax assets	45.3	45.4	0.0	(Sale: -378.5, Evaluation difference -45.8)		
	Other non-current assets	19.1	18.9	-0.2			
	Total non-current assets	1,197.0	776.9	-420.0			
Т	otal assets	1,982.3	1,900.9	-81.4			
*	Liquidity on hand	374.3	703.9	329.5			
	Debt with interest	224.6	224.2	-0.4			
	Net Cash	149.7	479.7	329.9			

abilities and equity>			(JPY Bn)	
	Mar. 2015	Sep. 2015	vs. Mar. 2015	
bilities				
Current liabilities				
Trade and other payables	235.5	217.6	-17.9	
Bonds and borrowings	20.0	20.0	-0.0	
Other financial liabilities	7.6	1.0	-6.6	
Income taxes payable	7.8	6.9	-0.9	
Provisions	19.4	21.1	1.7	
Other current liabilities	6.7	4.5	-2.3	
Subtotal	297.1	271.1	-26.0	
Liabilities directly associated with assets held for sale	0.4	-	-0.4	
Total current liabilities	297.5	271.1	-26.4	
Non-current liabilities				
Bonds and borrowings	201.0	201.0	0.0	
Other financial liabilities	8.3	8.4	0.1	
Post employment benefit liabilities	11.6	11.9	0.2	
Provisions	2.7	2.6	-0.1	
Deferred tax liabilities	88.4	74.0	-14.4	
Other non-current liabilities	65.7	61.7	-4.0	
Total non-current liabilities	377.7	359.6	-18.2	
Total liabilities	675.2	630.6	-44.6	
Jity				
Equity attributable to owners of the Company				
Share capital	50.0	50.0	0.0	
Capital surplus	105.3	103.9	-1.3	Acqui
Treasury shares	-14.2	-64.2	-50.0	
Other components of equity	169.0	171.5	2.5	
Retained earnings	994.0	1,006.2	12.2	
Total equity attributable to owners of the Company	1,304.1	1,267.5	-36.6	
Non-controlling interests				Profit Divide
Non-controlling interests	3.0	2.8	-0.2	Trans
Total equity	1,307.0	1,270.2	-36.8	
tal liabilities and equity	1,982.3	1,900.9	-81.4	

Acquisiion -50.0 (21 million shares) Profit for the period +70.7, Dividends -21.1, Transfer from comprehensive income -30.8

5. Consolidated Statement of Cash Flows

			(JPY Bn)	
	FY2014 Q2 YTD	FY2015 Q2 YTD	YoY	
Cash flows from operating activities	QZTID	QZIID		
Profit before tax from continuing operations	62.2	90.8	28.6	
Depreciation and amortization	20.4	21.8	1.5	
(Increase) decrease in receivables and payables	-16.4	-16.6	-0.2	
Other, net	-16.7	-14.9	1.8	
Income taxes paid	-4.2	-20.3	-16.0	
Cash flows from operating activities of discontinued operations	11.5	-	-11.5	
Net cash flows from operating activities	56.8	60.9	4.1	
Cash flows from investing activities				
Net (increase) decrease in time deposits and securities	67.3	-281.6	-349.0	Increase in time deposits and securitie
(Acquisition of) proceeds from sales of fixed assets	-38.4	-41.1	-2.7	
Proceeds from sale of subsidiary	-	7.0	7.0	
Net (increase) decrease in investment securities	-0.9	374.2	375.1	Sale of Sun Pharma shares +378.5
Other, net	-0.1	0.0	0.1	
Cash flows from investing activities of discontinued operations	-2.1	-	2.1	
Net cash flows from investing activities	25.8	58.5	32.7	
Cash flows from financing activities				
Net (increase) decrease in borrowings	-10.0	-0.0	10.0	
Repayments of bonds	-60.0	-	60.0	
Purchase of treasury shares	-0.0	-50.2	-50.2	
Dividends paid	-21.1	-21.1	0.0	
Other, net	-0.5	-0.7	-0.2	
Cash flows from financing activities of discontinued operations	-0.3	-	0.3	
Net cash flows from financing activities	-92.0	-72.0	19.9	
Net increase (decrease) in cash and cash equivalents	-9.4	47.3	56.7	
Cash and cash equivalents at the beginning of the period	183.1	189.4	6.3	
Effect of exchange rate changes on cash and cash equivalents	6.6	-1.4	-8.0	
Cash and cash equivalents at the end of the period	180.3	235.4	55.1	
* Free cash flows (Cash flows from operating activities and investing activities)	82.6	119.4	36.8	

6. Number of Employees

		Sep. 2014	Mar. 2015	Sep. 2015
		Results	Results	Results
Consolidated		17,298	16,428	16,377
	Japan	9,201	8,543	8,598
	North America	3,502	3,322	3,295
	Europe	2,116	2,094	2,063
	Others	2,479	2,469	2,421

7. Capital Expenditure and Depreciation and Amortization

		FY2014 Q2 YTD	FY2014	FY2015 Q2 YTD	FY2015
	(JPY Bn)	Results	Results	Results	Forecast
Capital expenditure		15.0	36.3	14.2	30.3
Depreciation and amortization		20.4	42.0	21.8	41.9
Property,plant and equipment		13.1	27.0	13.8	-
Intangible assets		7.3	15.1	8.1	-

8. Summary of Product Outlines

Brand Name Generic Name		Therapeutic Category	Launched	Origin
Japan				
Olmetec	olmesartan	antihypertensive	2004	Daiichi Sankyo
Nexium	esomeprazole	proton pump inhibitor	2011	AstraZeneca
Memary	memantine	treatment for Alzheimer's disease	2011	Merz
Loxonin			1986	Daiichi Sankyo
Loxonin Poultice	lovoprofon	analyzatic and anti-inflammatory	2006	Lead Chemical
Loxonin Tape	loxoprofen	analgesic and anti-inflammatory	2008	Lead Chemical
Loxonin Gel			2010	Daiichi Sankyo
Cravit	levofloxacin	antibacterial	1993	Daiichi Sankyo
Rezaltas	olmesartan / azelnidipine	antihypertensive	2010	Daiichi Sankyo
Artist	carvedilol	antihypertensive	1993	Roche
Omnipaque	iohexol	contrast medium	1987	GE Healthcare
Mevalotin	pravastatin	antihyperlipidemic	1989	Daiichi Sankyo
Ranmark	denosumab	anti-RANKL antibody	2012	Amgen
Inavir	laninamivir	anti-influenza	2010	Daiichi Sankyo
Urief	silodosin	treatment for dysuria	2006	Kissei
Pralia	denosumab	anti-RANKL antibody	2013	Amgen
Lixiana	edoxaban	anticoagulant Direct Oral Factor Xa Inhibitor	2011	Daiichi Sankyo
Efient	prasugrel	antiplatelet	2014	Daiichi Sankyo Ube Industries
Tenelia	teneligliptin	type 2 diabetes	2012	Mitsubishi Tanabe
Daiichi Sankyo, Inc. (US) Olmesartan				
Benicar	olmesartan		2002	
Benicar HCT	olmesartan / hydrochlorothiazide		2003	
Azor	olmesartan / amlodipine	antihypertensive	2007	Daiichi Sankyo
Tribenzor	olmesartan / amlodipine / hydrochlorothiazide		2010	
Welchol	colesevelam	antihyperlipidemic / type 2 diabetes	2000	Genzyme
Effient	prasugrel	antiplatelet	2009	Daiichi Sankyo Ube Industries
Savaysa	edoxaban	anticoagulant Direct Oral Factor Xa Inhibitor	2015	Daiichi Sankyo
Movantik	naloxegol	opioid-induced constipation	2015	Nektar AstraZeneca
uitpold Pharmaceuticals, Inc. (US)				
Venofer	iron sucrose injection	iron deficiency anemia	2000	Vifor Pharma
Injectafer	ferric carboxymaltose injection	iron deficiency anemia	2013	Vifor Pharma
Daiichi Sankyo Europe GmbH				
Olmesartan				
Olmetec	olmesartan		2002	
Olmetec Plus	olmesartan / hydrochlorothiazide	antihuportopoliyo	2005	Daiichi Sankyo
Sevikar	olmesartan / amlodipine	antihypertensive	2009	Danchi Sankyu
Sevikar HCT	olmesartan / amlodipine / hydrochlorothiazide		2010	
Efient	prasugrel	antiplatelet	2009	Daiichi Sankyo Ube Industries
Lixiana	edoxaban	anticoagulant Direct Oral Factor Xa Inhibitor	2015	Daiichi Sankyo

Marketing Alliance	Type of Alliance
AstraZeneca	Co-promotion (DS: Sales)
Kissei	Co-marketing
Mitsubishi Tanabe	Co-marketing
Lilly	Co-promotion (DS: Co-pro revenue)
AstraZeneca	Co-promotion (DS: Co-pro revenue)
Fresenius	Co-marketing
Menarini Pfizer Nycomed	Co-marketing
Lilly	Co-promotion (DS: Co-pro revenue)

	FY2014 Q1	FY2014 Q2	FY2014 Q3	FY2014 Q4		FY20	14		FY2015 Q1	FY2015 Q2	FY2 Q
JPY Bn	Results	Results	Results	Results	to revenue	Results	YoY	YoY (%)	Results	Results	Res
Revenue	213.7	215.9	264.8	225.0	100.0%	919.4	20.2	+2.3%	238.4	240.4	
Cost of sales	64.6	66.2	90.1	102.2	35.1%	323.1	40.2	+14.2%	74.0	75.0	
(excl. Special items)	64.6	66.2	87.9	67.2	31.1%	285.9	7.1	+2.6%	76.3	76.1	
(Special items)	-	-	2.2	35.0	4.0%	37.2	33.1	+813.2%	-2.4	-1.1	
Gross Profit	149.1	149.7	174.7	122.8	64.9%	596.3	-20.0	-3.2%	164.5	165.4	
SG&A expenses	74.9	78.7	84.1	93.4	36.0%	331.2	8.5	+2.6%	71.6	72.8	
(excl. Special items)	74.9	74.7	79.4	89.6	34.7%	318.6	-4.1	-1.3%	75.6	77.1	
(Special items)	-	4.0	4.7	3.8	1.4%	12.6	12.6	-53017.5%	-3.9	-4.3	
R&D expenses	41.4	43.5	50.8	55.0	20.7%	190.7	10.0	+5.5%	43.7	44.7	
(excl. Special items)	41.4	43.5	46.4	54.9	20.3%	186.2	5.6	+3.1%	43.7	44.7	
(Special items)	-	-	4.4	0.0	0.5%	4.4	4.4	-	-	-	
Operating Profit	32.8	27.4	39.7	-25.6	8.1%	74.4	-38.5	-34.1%	49.1	47.9	
(Operating Profit before Special items)	32.8	31.5	51.1	13.3	14.0%	128.6	11.6	+9.9%	42.9	42.5	
Financial income/expenses	0.2	2.5	5.5	-1.8		6.4	5.8		-3.7	-2.1	
Share of profit or loss of investments accounted for using the equity method	-0.3	-0.5	0.1	-0.2		-0.9	-0.3		-0.2	-0.1	
Profit before tax	32.7	29.5	45.3	-27.5	8.7%	79.9	-33.0	-29.2%	45.2	45.6	
Income taxes	11.8	15.1	14.0	-4.6		36.4	-10.8	-22.9%	11.1	10.3	
Profit for the year	20.9	14.3	31.3	-22.9	4.7%	43.6	-22.2	-33.8%	34.1	35.3	
Profit attributable to owners of the Company	21.6	15.1	32.3	-22.5	5.1%	46.5	-22.3	-32.5%	34.9	35.8	
Tax rate	36.1%	51.3%	31.0%	16.7%		45.5%			24.6%	22.5%	
Overseas sales ratio	45.2%	41.1%	39.7%	45.3%		42.7%			46.8%	46.2%	
Currency Rate (Average) USD/JPY	102.16	103.05	106.88	109.94		109.94			121.37	121.80	
EUR/JPY	140.06	138.91	140.31	138.78		138.78			134.16	135.07	

Y2015	FY2015		
Q3	Q4	FY2	2015
Results	Results	to revenue	Results
		100.0%	478.8
		31.1%	148.9
	·	31.8%	152.4
		-0.7%	-3.5
		68.9%	329.8
		30.2%	144.5
	·	31.9%	152.7
		-1.7%	-8.2
		18.5%	88.4
		18.5%	88.4
		-	-
		20.3%	97.0
		17.8%	85.3
			-5.9
			-0.3
		19.0%	90.8
			21.4
		14.5%	69.4
		1 4.8 %	70.7

23.5% 46.5%

121.80 135.07

<9. Quarterly Data>

2. Revenue of Global Products	FY2014 Q1	FY2014 Q2	FY2014 Q3	FY2014 Q4	F	Y2014		FY2015 Q1	
JPY Bn	Results	Results	Results	Results	Results	YoY	YoY (%)	Results	
Olmesartan	75.8	66.5	77.6	73.7	293.5	-6.6	-2.2%	75.6	
Olmetec (JPN)	18.7	19.1	20.6	17.9	76.3	-2.8	-3.5%	18.5	
Rezaltas (JPN)	4.5	4.5	5.0	4.3	18.4	-0.0	-0.3%	4.6	
Benicar/Benicar HCT (US)	18.9	15.1	21.0	22.0	77.0	-8.9	-10.3%	19.8	
Azor (US)	4.1	3.9	5.4	4.9	18.3	0.9	+4.9%	5.8	
Tribenzor (US)	2.7	2.5	3.3	2.8	11.3	2.3	+25.3%	3.1	
Olmetec/Olmetec Plus (EU)	11.1	9.3	8.6	8.7	37.8	-6.8	-15.2%	8.9	
Sevikar (EU)	5.3	4.2	3.9	4.1	17.6	4.1	+30.2%	4.5	
Sevikar HCT (EU)	3.3	2.1	2.2	2.2	9.9	2.3	+29.9%	2.5	
Other subsidiaries, export, etc	7.1	5.8	7.4	6.7	27.0	2.3	+9.4%	7.9	
Prasugrel	5.8	5.9	6.7	6.6	24.9	2.6	+11.7%	7.8	
Effient alliance revenue (US)	4.2	4.2	4.6	4.5	17.6	2.1	+13.7%	5.2	
Efient alliance revenue and others (EU)	1.2	1.2	1.3	1.1	4.8	0.1	+1.7%	1.1	
Efient (JPN)	0.2	0.1	0.2	0.2	0.7	0.7	-	1.2	
Other subsidiaries, export, etc	0.2	0.4	0.5	0.8	1.9	-0.3	-12.2%	0.3	
Edoxaban	0.1	0.1	1.9	2.1	4.3	3.9	+967.0%	1.8	
Lixiana (JPN)	0.1	0.1	1.9	1.4	3.6	3.2	+792.8%	2.1	
Savaysa (US)				0.7	0.7	0.7	-	-0.3	
Lixiana (EU)					-	-	-	0.0	

FY2015 Q2	FY2015 Q3	FY2015 Q4	FY2015
Results	Results	Results	Results
74.0			4 47 5
			147.5
			36.2
			8.9
20.5			40.3
4.6			10.4
3.2			6.3
8.2			17.1
4.1			8.5
2.2			4.6
7.1			15.0
7.4			15.3
5.4			10.6
1.1			2.2
0.6			1.8
0.4			0.7
3.5			5.3
3.2			5.4
0.1			-0.2
0.1			0.2
	71.9 17.7 4.3 20.5 4.6 3.2 8.2 4.1 2.2 7.1 7.4 5.4 1.1 0.6 0.4 3.5 3.2	Results Results 71.9	Results Results Results 71.9

3. Revenue b	y Business	Units and	Products	(1))
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JPY Bn

Japan

Olmetec

Nexium

Memary

Loxonin

Cravit

FY2014 Q1 FY2014 Q2

108.0

18.7

15.3

7.9

12.2

6.9

Results

114.6

19.1

16.8

8.9

13.2

7.3

Results

FY2014 Q3 FY2014 Q4

145.2

20.6

23.7

10.8

13.3

8.8

Results

112.7

17.9

13.6

9.3

10.9

4.9

Results

480.5

76.3

69.3

36.8

49.5

27.8

Results

F	Y2014		FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	FY2015
	YoY	YoY (%)	Results	Results	Results	Results	Results
.5	-5.5	-1.1%	114.2	113.6			227.8
.3	-2.8	-3.5%	18.5	17.7			36.2
.3	15.1	+27.9%	19.1	19.6			38.7
.8	3.5	+10.5%	10.2	10.2			20.5
.5	-9.8	-16.5%	12.6	11.8			24.4
.8	-5.7	-16.9%	4.6	4.4			9.0
.4	-0.0	-0.3%	4.6	4.3			8.9
.1	-4.3	-19.1%	4.1	3.8			7.9
.2	-2.5	-12.5%	4.2	4.2			8.5
.2	-5.3	-24.8%	3.6	3.4			7.0
.2	2.1	+26.1%	2.9	3.0			5.9
.6	3.1	+23.4%	0.0	0.0			0.0
.5	0.1	+0.7%	2.9	2.8			5.7
.3	4.2	+131.8%	2.6	2.8			5.4
.6	3.2	+792.8%	2.1	3.2			5.4
.7	0.7	-	1.2	0.6			1.8
.6	6.0	+390.5%	2.4	3.0			5.3
.9	2.4	+19.4%	4.3	4.3			8.6
.2	-5.3	-14.1%	6.4	8.0			14.4
.8	-0.3	-0.5%	10.8	13.8			24.6

Rezaltas	4.5	4.5	5.0	4.3	18.4	-0.0 -0.3%	4
Artist	4.8	4.7	4.7	4.0	18.1	-4.3 -19.1%	4
Omnipaque	4.2	4.4	4.7	3.9	17.2	-2.5 -12.5%	4
Mevalotin	4.2	4.1	4.3	3.6	16.2	-5.3 -24.8%	3
Ranmark	2.1	2.6	2.9	2.6	10.2	2.1 +26.1%	2
Inavir	0.3	0.0	7.9	8.4	16.6	3.1 +23.4%	0
Urief	2.7	2.9	3.1	2.8	11.5	0.1 +0.7%	2
Pralia	1.3	1.7	2.1	2.2	7.3	4.2 +131.8%	2
Lixiana	0.1	0.1	1.9	1.4	3.6	3.2 +792.8%	2
Efient	0.2	0.1	0.2	0.2	0.7	0.7 -	1
Teneria	1.5	1.8	2.2	2.1	7.6	6.0 +390.5%	2
Daiichi Sankyo Espha products	3.5	3.3	4.8	3.3	14.9	2.4 +19.4%	4
Vaccines business	5.8	6.7	13.1	6.6	32.2	-5.3 -14.1%	6
iichi Sankyo Healthcare (OTC)	9.4	13.3	14.3	10.8	47.8	-0.3 -0.5%	10

3. Revenue by Business Units and Products (2)	FY2014 Q1	FY2014 Q2	FY2014 Q3	FY2014 Q4	F	Y2014		FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	FY2015
JPY Bn	Results	Results	Results	Results	Results	YoY	YoY (%)	Results	Results	Results	Results	Results
Daiichi Sankyo, Inc. (US)	41.6	36.5	48.1	46.8	173.0	1.2	+0.7%	48.0	45.4			93.4
Olmesartan	25.7	21.5	29.7	29.6	106.6	-5.7	-5.1%	28.8	28.3			57.1
Benicar/Benicar HCT	18.9	15.1	21.0	22.0	77.0	-8.9	-10.3%	19.8	20.5			40.3
Azor	4.1	3.9	5.4	4.9	18.3	0.9	+4.9%	5.8	4.6			10.4
Tribenzor	2.7	2.5	3.3	2.8	11.3	2.3	+25.3%	3.1	3.2			6.3
Welchol	11.3	10.5	13.4	12.3	47.4	5.1	+12.1%	13.5	10.6			24.2
Effient	4.2	4.2	4.6	4.5	17.6	2.1	+13.7%	5.2	5.4			10.6
Savaysa				0.7	0.7	0.7	-	-0.3	0.1			-0.2
Movantik					-	-	-	0.2	0.4			0.6
Luitpold Pharmaceuticals, Inc. (US)	12.5	14.3	16.2	14.4	57.4	17.8	+44.8%	21.5	24.9			46.4
Venofer	7.2	7.0	8.6	5.8	28.6	3.7	+14.9%	9.1	6.9			16.0
Injectafer	1.5	1.5	2.2	2.6	7.6	6.3	+483.4%	3.9	4.0			7.9
Daiichi Sankyo Europe GmbH	24.5	20.0	20.1	18.9	83.5	-0.4	-0.5%	20.2	19.0			39.2
Olmesartan	19.7	15.7	14.8	15.0	65.2	-0.4	-0.6%	15.8	14.4			30.2
Olmetec/Olmetec Plus	11.1	9.3	8.6	8.7	37.8	-6.8	-15.2%	8.9	8.2			17.1
Sevikar	5.3	4.2	3.9	4.1	17.6	4.1	+30.2%	4.5	4.1			8.5
Sevikar HCT	3.3	2.1	2.2	2.2	9.9	2.3	+29.9%	2.5	2.2			4.6
Efient	1.2	1.2	1.3	1.1	4.8	0.1	+1.7%	1.1	1.1			2.2
Lixiana					-	-	-	0.0	0.1			0.2
Asia, South and Central America (ASCA)	15.1	14.8	18.9	18.6	67.5	8.8	+14.9%	21.4	21.3			42.7
Daiichi Sankyo China	5.4	6.1	7.3	8.5	27.4	6.1	+28.8%	7.9	8.6			16.4
Daiichi Sankyo Taiwan	1.2	1.1	1.2	1.3	4.9	0.4	+8.8%	1.4	1.3			2.7
Daiichi Sankyo Korea	2.7	1.7	2.0	2.5	8.9	-0.2	-2.0%	2.4	2.4			4.8
Daiichi Sankyo Thailand	0.7	0.9	1.0	1.0	3.7	1.2	+47.1%	0.8	1.0			1.8
Daiichi Sankyo Brasil Farmacêutica	2.3	2.0	2.6	1.5	8.4	0.9	+12.0%	2.6	1.9			4.5
Daiichi Sankyo Venezuela	1.2	1.8	2.9	2.1	8.1	1.2	+17.6%	3.1	2.4			5.5

3. Revenue by Business Units and Products (3)	FY2014 Q1	FY2014 Q2	FY2014 Q3	FY2014 Q4	F	Y2014		FY2015 Q1	FY2015 Q2	FY2015 Q3	FY2015 Q4	FY2015
[Reference] Revenue in Local Currency	Results	Results	Results	Results	Results	YoY	YoY (%)	Results	Results	Results	Results	Results
USD Mn												
Daiichi Sankyo, Inc. (US)	407	351	423	393	1,574	-140	-8.2%	396	371			766
Olmesartan	251	207	262	249	969	-151	-13.5%	237	232			469
Benicar/Benicar HCT	185	145	185	186	700	-156	-18.2%	163	168			331
Azor	40	38	48	41	166	-8	-4.4%	48	38			86
Tribenzor	26	24	30	23	103	13	+14.3%	26	26			52
Welchol	111	101	117	102	431	9	+2.2%	112	87			199
Effient	42	41	40	37	160	6	+3.7%	43	44			87
Savaysa				6	6	6	-	-2	1			-1
Movantik					-	-	-	1	3			5
USD Mn												
Luitpold Pharmaceuticals, Inc. (US)	122	137	142	120	522	127	+32.1%	177	204			381
Venofer	70	68	75	47	260	12	+4.7%	75	57			132
Injectafer	14	14	19	22	69	56	+431.9%	32	33			65
EUR Mn												
Daiichi Sankyo Europe GmbH	175	146	140	141	602	-23	-3.6%	151	140			290
Olmesartan	141	114	103	112	470	-19	-3.8%	118	106			224
Olmetec/Olmetec Plus	79	68	60	65	272	-59	-17.9%	66	60			126
Sevikar	38	31	27	30	127	26	+26.1%	33	30			63
Sevikar HCT	24	15	15	17	71	15	+25.8%	18	16			34
Efient	8	8	9	8	34	-1	-1.6%	8	8			16
Lixiana					-	-	-	0	1			1

<10. Historical Data>

< 10. HIStorical Data> 1. Revenue of Global Products	FY2010	FY2011	FY2012	FY2013	FY2014
JPY Bn	Results	Results	Results	Results	Results
Olmesartan	241.5	249.7	258.9	300.2	293.5
Olmetec (JPN)	82.3	80.9	78.3	79.1	76.3
Rezaltas (JPN)	4.7	13.5	16.9	18.5	18.4
Benicar/Benicar HCT (US)	79.7	71.3	73.2	85.9	77.0
Azor (US)	13.3	12.0	14.8	17.4	18.3
Tribenzor (US)	1.5	4.6	6.8	9.0	11.3
Olmetec/Olmetec Plus (EU)	36.7	36.6	32.6	44.5	37.8
Sevikar (EU)	8.4	11.0	10.8	13.5	17.6
Sevikar HCT (EU)	1.1	3.4	4.7	7.6	9.9
Other subsidiaries, export, etc	13.9	16.5	20.7	24.7	27.0
rasugrel	5.2	10.9	14.4	22.3	24.9
Effient alliance revenue (US)	3.4	7.9	10.5	15.4	17.6
Efient alliance revenue and others (EU)	1.8	2.9	3.9	4.7	4.8
Efient (JPN)					0.7
Other subsidiaries, export, etc				2.2	1.9
doxaban				0.4	4.3
Lixiana (JPN)				0.4	3.6
Savaysa (US)					0.7

Lixiana (EU)

2. Revenue by Business Units and Products (1)	FY2010	FY2011	FY2012	FY2013	FY2014
JPY Bn	Results	Results	Results	Results	Results
Japan	416.0	409.8	442.5	486.0	480.5
Olmetec	82.3	80.9	78.3	79.1	76.3
Nexium		3.9	21.6	54.2	69.3
Memary		9.8	23.8	33.3	36.8
Loxonin	54.2	61.0	59.6	59.3	49.5
Cravit	32.4	36.3	35.9	33.5	27.8
Rezaltas	4.7	13.5	16.9	18.5	18.4
Artist	23.7	24.5	22.4	22.4	18.1
Omnipaque	25.0	23.5	20.2	19.7	17.2
Mevalotin	38.1	33.1	25.8	21.5	16.2
Ranmark			4.4	8.1	10.2
Inavir	6.6	10.7	11.1	13.4	16.6
Urief	10.1	11.0	11.1	11.4	11.5
Pralia				3.2	7.3
Lixiana		0.3	0.3	0.4	3.6
Efient					0.7
Teneria			1.3	1.5	7.6
Daiichi Sankyo Espha products	4.6	9.9	11.1	12.5	14.9
Vaccines business	17.8	21.2	39.1	37.5	32.2
Daiichi Sankyo Healthcare (OTC)	44.8	45.9	47.1	48.1	47.8

2. Revenue by Business Units and Products (2)	FY2010	FY2011	FY2012	FY2013	FY2014
JPY Bn	Results	Results	Results	Results	Results
Daiichi Sankyo, Inc. (US)	130.5	127.1	142.3	171.8	173.0
Olmesartan	94.5	87.9	94.9	112.3	106.6
Benicar/Benicar HCT	79.7	71.3	73.2	85.9	77.0
Azor	13.3	12.0	14.8	17.4	18.3
Tribenzor	1.5	4.6	6.8	9.0	11.3
Welchol	28.5	26.9	33.1	42.3	47.4
Effient	3.4	7.9	10.5	15.4	17.6
Savaysa					0.7
Movantik					
Luitpold Pharmaceuticals, Inc. (US)	53.9	44.7	38.6	39.6	57.4
Venofer	30.7	24.8	23.6	24.9	28.6
Injectafer				1.3	7.6
Daiichi Sankyo Europe GmbH	66.4	70.2	64.4	83.9	83.5
Olmesartan	46.2	51.0	48.0	65.6	65.2
Olmetec/Olmetec Plus	36.7	36.6	32.6	44.5	37.8
Sevikar	8.4	11.0	10.8	13.5	17.6
Sevikar HCT	1.1	3.4	4.7	7.6	9.9
Efient		2.9	3.9	4.7	4.8
Lixiana					
Asia, South and Central America (ASCA)	27.4	28.6	45.4	58.8	67.5
Daiichi Sankyo China	10.8	9.7	16.4	21.2	27.4
Daiichi Sankyo Taiwan	3.4	3.1	3.3	4.5	4.9
Daiichi Sankyo Korea	4.0	4.6	5.3	9.1	8.9
Daiichi Sankyo Thailand	1.2	1.2	1.4	2.5	3.7
Daiichi Sankyo Brasil Farmacêutica	5.2	5.5	6.6	7.5	8.4
Daiichi Sankyo Venezuela	2.9	4.2	6.7	6.9	8.1

2. Revenue by Business Units and Products (3) [Reference] Revenue in Local Currency	FY2010 Results	FY2011 Results	FY2012 Results	FY2013 Results	FY2014 Results
USD Mn					
Daiichi Sankyo, Inc. (US)	1,522	1,608	1,713	1,714	1,574
Olmesartan	1,102	1,112	1,142	1,120	969
Benicar/Benicar HCT	930	901	881	857	700
Azor	155	152	179	174	166
Tribenzor	17	58	82	90	103
Welchol	333	340	399	422	431
Effient	40	100	127	154	160
Savaysa					6
Movantik					
USD Mn					
Luitpold Pharmaceuticals, Inc. (US)	629	566	465	395	522
Venofer	358	314	284	248	260
Injectafer				13	69
EUR Mn					
Daiichi Sankyo Europe GmbH	587	644	601	624	602
Olmesartan	408	468	448	488	470
Olmetec/Olmetec Plus	324	336	304	331	272
Sevikar	74	101	100	100	127
Sevikar HCT	10	31	44	57	71
Efient		27	36	35	34

Lixiana

♦ Launched/Approved

Generic Name	Class	Indication	Regi	on Status	Remarks	
		Atrial fibrillation (AF)	EU	Approved <u>Launched</u>	Launched in UK (15/7*) and obtained recommendation by National Institute for Health and Care Excellence (NICE) (15/9), Launched in Germany (15/8) * means Jul, 2015, ditto	
Edoxaban	Factor Xa inhibitor		<u>S. Korea</u>	<u>Approved</u>	Approved in Aug 2015	
		Venous thromboembolism (VTE)	EU		Launched in UK (15/7) and obtained recommendation by NICE (15/8), Launched in Germany (15/8)	
			<u>S. Korea</u>	<u>Approved</u>	Approved in Aug 2015	
The once daily oral anti coagulant (FXa inhib venous thromboembolism (VTE) in patients w	vith total knee arthroplasty, total hip arthro	aban specifically, reversibly and directly inhibits the enzyme, Factor oplasty and hip fracture surgery. Additional indications for AF/VTE w 15, respectively. Approved in South Korea in August 2015.				
Levofloxacin	New quinolone	Infection disease	<u>JP</u>	Approved Launched	Additional indication: Injection: urology, surgery, and gynecology (15/9) Tablets&Granules: tuberculosis (15/8)	
<summary> Levofloxacin injection formation, which was la</summary>	aunched in 2011for the treatment in respi	ratory tract infection. As LCM programme, the trials for urinary tract i	nfection, s	urgical infecti	on and gynecological infection are completed.	
Carvedilol	β adrenergic receptor blocker	Tachycardiac atrial fibrillation	JP	<u>Approved</u> Launched	Additional indiation. Approved in Aug 2015	
Summary> Non-selective beta blocker with alpha-1 blockade property. Carvedilol was launched for indications of essential hypertension, renal parenchymal hypertension, and angina in May 1993. Indication of chronic heart failure was approved in October, 2002. Regarding atrial fibrillation indication, the clinical trial was conducted to respond to a request from academic societies, and the approval was obtained in August 2015.						
[Brand Name: Squarekids] Precipitated and purified pertussis- diphtheria-tetanus-inactivated polio vaccine	DPT-IPV vaccine	Prevention of pertussis, diphtheria, tetanus and poliomyelitis	JP	Approved	Approved in July 2014 (KDSV)	
<summary></summary>		us (DPT vaccine) of Kitasato Daiichi Sankyo and inactivated polio va	accine (Sa	lk vaccine) of	Sanofi Pasteur in a prefilled syringe, and is the first 4-valent	
Underline: change after FY2015 Q1 Financia	I Announcement in Jul 2015					
◆ Filed						

Product Code Number/Generic Name	Class	
		Atrial fibrillation (AF)
Edoxaban	Factor Xa inhibitor	Venous thromboemb
<summary> The once daily oral anti coagulant (FXa inhib</summary>		
VN-100	Intradermal influenza HA vaccine	
<summary> The Vaccine is a pre-filled syringe type, intra- vaccine is developed by Terumo. This device peripheral blood vessels and nerves within th</summary>	dermal influenza HA vaccine co-develope e, which offers a more easy-to-use, surefir	ed by four companies [Dai
VN-101	Cell-culture H5N1 flu vaccine	Prevention of H5N1 influ
<summary> This vaccine is a cell-culture H5N1 flu vaccin</summary>	e that has developped by Daiichi Sankyo	

Underline: change after FY2015 Q1 Financial Announcement in Jul 2015

Target indication	Region	Filing year/month				
)	ASCA etc	BR (14/6), TW (14/7), TH(15/7) <u>AU(15/8), HK(15/8), CN(15/8), CA(15/8)</u>				
bolism (VTE)	ASCA etc	BR (14/6), TW (14/7), TH(15/7) <u>AU(15/8), HK(15/8), CN(15/8)</u> , <u>CA(15/8)</u>				
bly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood.						
Influenza	JP	Submitted by Japan Vaccine in April 2015				
aiichi Sankyo, Terumo, Japan Vaccine and Kitasato Daiichi Sankyo Vaccine Co., Ltd.]. The intradermal injection device for this the vaccine than current methods. The device is also expected to ease patient hesitation to be injected and lower the risk of damaging						
luenza	JP	Submitted in August 2015 for pediatric use with optimal dose				
nkyo Vaccine(KDSV). KDSV was submitted a supplemental application for optimization of pediatric use.						

Under development (Phase1-3)

Generic Name / Project Code Number	Class	Target indication		Stage	target FY for approval/launch basically for P3	Remarks
Prasugrel	Anti-platelet agent	Ischemic stroke	JP	P3	2017	additional indication
Tasagrei	Anti platelet agent	Sickle cell disease	US	P3	2016	additional indication
Denosumab	Anti-RANKL antibody	Breast cancer adjuvant	JP	P3	2017 →2020	additional indication
Denosumab		Rheumatoid arthritis	JP	P3	2017	additional indication
Tivantinib	MET inhibitor	Hepatocellular cancer	US/EU	P3	2018	
Nimotuzumab	Anti-EGFR antibody	Gastric cancer	JP	P3	2019 -	
		Esophageal cancer	JP	P1	-	
Vemurafenib	BRAF inhibitor	Melanoma adjuvant	US/EU	P3	_	additional indication. Licensee Roche is conducting the study. Submission in 2016 is planned.
Quizartinib	FLT3-ITD inhibitor	Acute myeloid leukemia	US/EU	P3	2018	Relapsed and refractory AML patients
		Tenosynovial Giant Cell Tumor (TGCT)	US/EU	P3	2019	including pigmented villonodular synovitis
		Glioblastoma	US	P2	-	
Pexidartinib/PLX3397	FMS/KIT/FLT3-ITD inhibitor	Melanoma	US	P2	-	
		Melanoma, solid tumor	US	P1/2	-	combination with pembrolizumab in collaboration with Merck
	α2δ ligand	Fibromyalgia	US/EU	P3	2019	
Mirogabalin		Diabetic peripheral neuropathic pain	JP/Asia	1 P3	2018	
		Postherpetic neuralgia	JP/Asia	1 P3	2018	
Hydromorphone	Opioid mu-receptor agonist	Cancer pain	JP	P3	2017	
CHS-0214	$TNF\alpha$ inhibitor	Rheumatoid Arthritis	JP	P3	2017	etanercept biosimilar
CL-108	Opioid mu-receptor agonist combination	Acute pain	US	P3	2016	co-develop with Charleston Laboratories
VN-0107/MEDI3250	Live attenuated influenza vaccine	Prevention of seasonal influenza	<u>JP</u>	<u>P3</u>	<u>2017</u>	In-licensed from AZ/MedImmune. US tradename is FluMist Quadrivalent.
VN-0105	DPT-IPV/Hib vaccine	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib	JP	P3	-	co-develop with Sanofi K.K.and KDSV
CS-3150	MR antagonist	Hypertension	JP	P2b	-	
	in tamagemet	Diabetic nephropathy	JP	P2b	-	
DS-8500	GPR119 agonist	Diabetes	JP	P2	-	
		Non small cell lung cancer	US/EU		-	
		Non small cell lung cancer	JP	P1		
Patritumab	Anti-HER3 antibody	Breast cancer	US	P2		
		Breast cancer	JP	P1	-	
		Head & Neck cancer	EU	P1	-	
SUN13837	Modulator of bFGF signaling system	Spinal cord injury	US/EU	P2	-	
Laninamivir	Neuraminidase inhibitor	Influenza	US/EU <u>JP</u>	P2 P1	-	out-licensing with Biota nebulizer formulation
DS-1040	TAFIa inhibitor	Acute ischemic stroke	-	 P1		
DS-8312	Hypertriglyceridemia treatment	Hypertriglyceridemia	-	P1		
DS-2330	Hyperphosphatemia treatment	Hyperphosphatemia in chronic kindney disease (CKD)	_	<u>P1</u>		
DS-9231/TS23	<u>α2 plasmin inhibitor-inactivating</u> antibody	Thrombosis (cardiovascular diseases, ischemic stroke)	-	<u>P1</u>	_	In-licensed from Translational Sciences Inc
U3-1565	Anti-HB-EGF antibody	Solid cancer	US/JP	D1		

Underline: change after FY2015 Q1 Financial Announcement in Jul 2015

Under development (Phase1-3)

Generic Name / Project code number	Class	Target indication		Stage	Remarks
	MDM2 inhibitor	Solid cancer, lymphoma	US/JP	P1	-
DS-3032	MDM2 inhibitor	Leukemia	US	P1	-
PLX7486	FMS/TRK inhibitor	Solid cancer	US	P1	-
DS-8895	Anti-EPHA2 antibody	Solid cancer	JP	P1	-
DS-8273	Anti-DR5 antibody	Solid cancer	US	P1	-
PLX8394	BRAF inhibitor	Solid cancer, leukemia	US	P1	-
DS-6051	NTRK/ROS1 inhibitor	Solid cancer	US	P1	-
DS-5573	Anti-B7-H3 antibody	Solid cancer	JP	P1	-
PLX9486	KIT inhibitor	Solid cancer	US	P1	-
DS-8201	Anti-HER2 antibody drug conjugat	e Solid cancer	<u>JP</u>	<u>P1</u>	-
DS-1093	HIF-PH inhibitor	Anemia of chronic kidney disease	-	P1	-
DS-3801	GPR 38 agonist	Chronic obstipation	-	P1	-
DS-1971	Analgesic agent	Chronic pain	-	P1	-
DS-1501	Anti-Siglec-15 antibody	Osteoporosis	-	P1	-
DS-7080	Angiogenesis inhibitor	Neovascular age-related macular degeneration (AMD)		<u>P1</u>	-
/N-0102/JVC-001	Measles-Mumps-Rubela vaccine	Prevention of Measles, Mumps and Rubela	<u>JP</u>	<u>P1/2</u>	Japan vaccine company is conducting the phase 1/2 study

Underline: change after FY2015 Q1 Financial Announcement in Jul 2015

Stage-up (major changes from the FY2015 Q1 financial announcement in July 2015)

Generic Name / Project code number	Class	Target indication		Current stage	Remarks
		Atrial Fibrillation (AF)		Launched	Recommended by NICE in Sep/Aug 2015, Launched in Germany (15/8)
Edoxaban	FXa inhibitor	Venous thromboembolism (VTE)	KR	Approved	Approved in Aug 2015
			ASCA e	etc. Submitted	Submitted in AU, HK, CN and CA (15/8)
Levofloxacin	New quinolone	Infection disease	JP	Approved Launched	Additional indication: Injection: urology, surgery, and gynecology (15/9) Tablets&Granules: tuberculosis (15/8)
Carvedilol	eta blocker	Tachycardiac atrial fibrillation	JP	Approved Launched	Additional indication Approved and launced in Aug 2015
VN-101	Cell-culture H5N1 flu vaccine	Prevention of H5N1 influenza	JP	Filed	Submitted in August 2015 for pediatric use with optimal dose
VN-0107/MEDI3250	Live attenuated influenza vaccine	Prevention of seasonal influenza	JP	P3	In-licensed from AZ/MedImmune. US tradename is FluMist Quadrivalent.
DS-2330	Hyperphosphatemia treatment	Hyperphosphatemia in chronic kindney disease (CKD)	-	P1	
DS-9231/TS23	α2 plasmin inhibitor-inactivating antibody	Thrombosis (cardiovascular diseases, ischemic stroke)	-	P1	In-licensed from Translational Sciences Inc.
DS-8201	Anti-HER2 antibody drug conjugate	e Solid cancer	JP	P1	
DS-7080	Angiogenesis inhibitor	Neovascular age-related macular degeneration (AMD)	-	P1	
Laninamivir	Neuraminidase inhibitor	Influenza	JP	P1	Nebulizer formulation
VN-0102/JVC-001	Measles-Mumps-Rubela vaccine	Prevention of Measles, Mumps and Rubela	JP	P1/2	Japan vaccine company is conducting the phase 1/2 study

• Discontinue (major changes from the FY2015 Q1 financial announcement in July 2015)

Generic Name / Project code number	Class	Target indication		Stage
loforminol / GE-145	X-ray contrast media	Angiography	JP	P2
< Reason for discontinuation>				

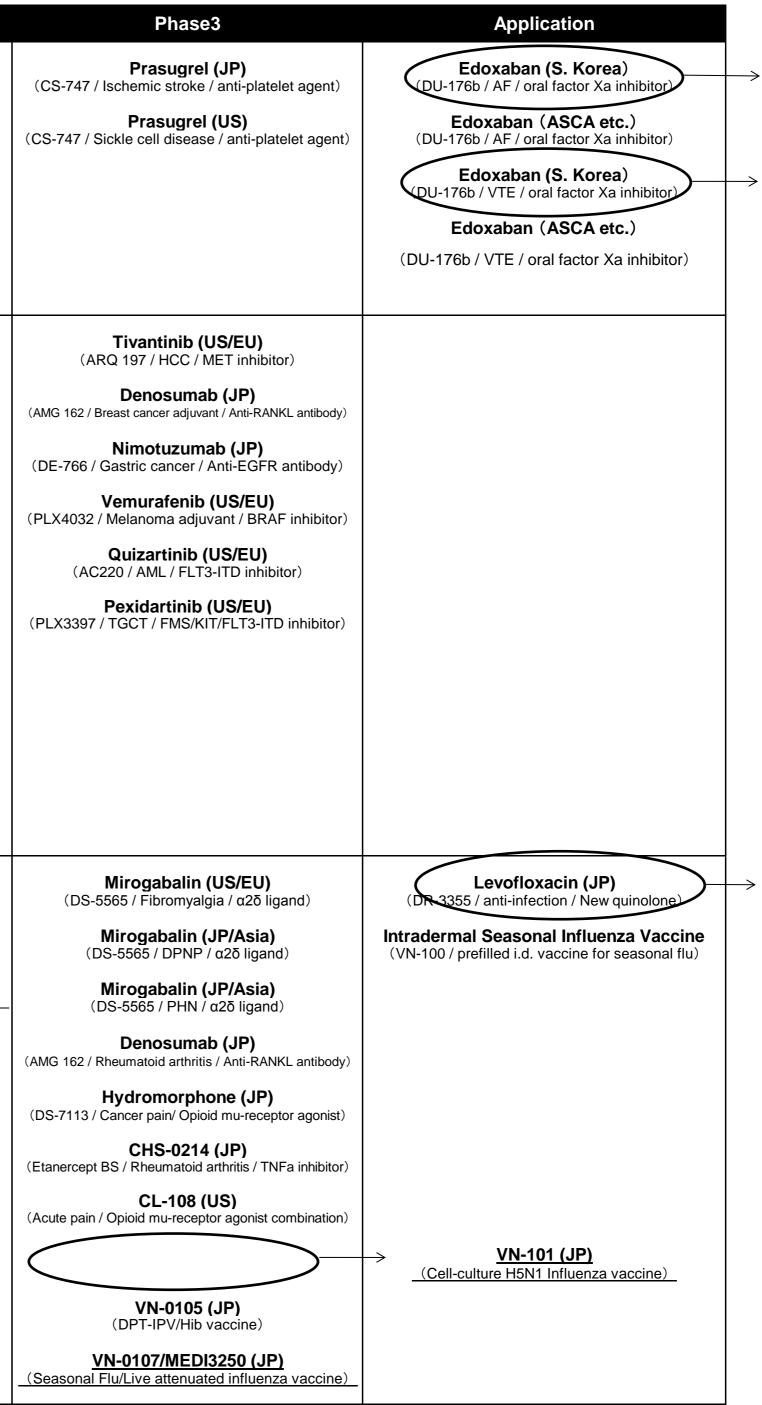
Daiichi Sankyo decided to discontinue the development after reviewing its study results.

Major R&D Pipeline Table

Therapeutic Area	Phase1	Phase2
	DS-1040 (Acute ischemic stroke / TAFIa inhibitor)	CS-3150 (JP) (Hypertension / MR antagonist)
	DS-8312 (Hypertriglyceridemia)	CS-3150 (JP) (Diabetic nephropathy / MR antagonist)
Cardiovascular - Metabolics	DS-2330 (Hyperphosphatemia)	DS-8500 (JP) (Diabetes / GPR119 agonist)
	DS-9231/TS23 (Thrombosis (cardiovascular diseases, ischemic stroke)/α2	
	plasmin inhibitor-inactivating antibody)	
	U3-1565 (US/JP) (Anti-HB-EGF antibody)	Patritumab (US/EU) (U3-1287 / Anti-HER3 antibody)
	DS-3032 (US/JP) (MDM2 inhibitor)	Pexidartinib (US) (PLX3397 / FMS/KIT/FLT3-ITD inhibitor)
	PLX7486 (US) (FMS/TRK inhibitor)	
	DS-8895 (JP) (Anti-EPHA2 antibody)	
Oncology	DS-8273 (US) (Anti-DR5 antibody)	
Uncology	PLX8394 (US) (BRAF inhibitor)	
	DS-6051 (US) (NTRK/ROS1 inhibitor)	
	DS-5573 (JP) (Anti-B7-H3 antibody)	
	PLX9486 (US) (KIT inhibitor)	
	DS-8201 (JP) (Anti-HER2 ADC)	
	DS-1093 (Anemia of chronic kidney disease/HIF-PH inhibitor)	SUN13837 (US/EU) (Spinal cord injury / Modulator of bFGF signaling system)
	DS-3801 (Chronic obstipation/GPR38 agonist)	Laninamivir (US/EU) (CS-8958 / anti-influenza / Out licensing with Biota)
	DS-1971 (Chronic pain)	- Ioforminol (JP)
	DS-1501 (Osteoporosis / Anti-Siglec-15 antibody)	
	DS-7080 (AMD / Angiogenesis inhibitor)	
Others	VN-0102/JVC-001 (JP) (Measles/Mumps/Rubela vaccine)	
		Underline: change after FY2015 Q1 Financial A

Underline: change after FY2015 Q1 Financial Announcement in Jul 2015

As of October 2015



Cardiovascular-Metabolics

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Edoxaban	DU-176b	Oral	Factor Xa inhibitor	 Atrial fibrillation (AF) Venous thromboembolism (VTE) 	Daiichi Sankyo	Lixiana (JP) LIXIANA (EU) SAVAYSA (US)
ummary> e once daily oral anti coagulant omboembolism (VTE) in patient		-		y inhibits the enzyme, Factor Xa, a clotting factor in the blood. Launched in Japan in	n July 2011 as the pre	evention of venous

thromboembolism (VIE) in patients with total knee arthroplasty, total hip arthroplasty and hip tracture surgery.

- Top line results of Hokusai-VTE (VTE) P3 study was presented at ESC 2013.

Top line results of ENGAGE AF-TIMI 48 (AF) P3 study was presented at AHA 2013.
AF/VTE indication: Launched (JP: Sep 2014 (Dec 2014 for 60 mg tablet), US: Feb 2015, Switzerland: May 2015, UK: Jul 2015, Germany: Aug 2015), Approved in South Korea in Aug 2015.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Prasugrel	CS-747	Oral	Anti-platelet agent	- Ischemic stroke - Sickle cell disease	Daiichi Sankyo Ube Industries	Effient (US, Asia) Efient (JPN, EU)
<summary></summary>						
The oral antiplatelet agent. Prasug	rel helps to keep b	lood platelet	s from clumping together an	d developing a blockage in an artery.		
 Co-development with Eli Lilly in t [JP] Approved in Mar-2014 for th [US] P3 study in pediatric sickle of 	e ischemic heart d	isease unde	rgoing PCI and launched in I	May-2014. P3 studies for ischemic stroke are on-going.		

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name		
-	CS-3150	Oral	MR antagonist	- Hypertension - Diabetic nephropathy	Exelixis	TBD		
<summary></summary>	adina ta Minaralaca	rticoid Pocon	stor(MP) which stimulate the	sodium absorption into kidney. This agent is expected antihypertensive and organ-	protoctive offect			
				source and organ-				
P2 study in essential hypertens	ion in Japan was co	mpleted.						
 P2 study in diabetes with albun 	ninuria in Japan wa	s completed.	. On January 2015, Ph.2bs	of HTN and DN started.				
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name		
- DS-8500 Oral GPR119 agonist - Diabetes Daiichi Sankyo TBD								
<summary></summary>								
The agent agonistically acts on GPR119 which is expressed in small intestine and spleen cells, stimulates insulin secretion, and lowers blood sugar concentration.								

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name		
-	CS-3150	Oral	MR antagonist	- Hypertension - Diabetic nephropathy	Exelixis	TBD		
-Summary> The agent inhibits aldosterone binding to Mineralocorticoid Receptor(MR) which stimulate the sodium absorption into kidney. This agent is expected antihypertensive and organ-protective effect.								
P2 study in diabetes with albur	•	•	On January 2015, Ph.2bs	of HTN and DN started.				
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name		
- DS-8500 Oral GPR119 agonist - Diabetes Daiichi Sankyo TBD								
<summary> The agent agonistically acts on GPR119 which is expressed in small intestine and spleen cells, stimulates insulin secretion, and lowers blood sugar concentration.</summary>								

[Project after Phase 2]

Oncology

onoology						
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Tivantinib	ARQ 197	Oral	MET inhibitor	- Hepatocellular cancer	ArQule	TBD
<summary></summary>	hibit HGE(benator	vte growth fa	actor) recentor. Met which ha	as multiple roles in intracellular signal transductions such as cancer cell proliferatior	, angiogenesis inva	sion and apontosis induction
A P3 clinical study for HCC with						
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Nimotuzumab	DE-766	Injection	Anti-EGFR antibody	- Gastric cancer - Esophageal cancer	InnoCIMAb	TBD
<summary> The humanized monoclonal antibo antibodies.</summary>	ody to target Epide	rmal Growth	Factor Receptor(EGFR). Thi	s antibody is expected to be a best in class EGFR, safety against the skin toxicity a	and the efficacy comp	arable to the other
 P3 in Japan for Gastric cancer s 	tarted in April 2013	3.				
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Quizartinib	AC220	Oral	FLT3-ITD inhibitor	- Acute myeloid leukemia	Daiichi Sankyo	TBD

onoology						
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Tivantinib	ARQ 197	Oral	MET inhibitor	- Hepatocellular cancer	ArQule	TBD
<summary></summary>	•	-				
The molecular-targeted agent to in	hibit HGF(hepatod	cyte growth f	actor) receptor, Met which ha	as multiple roles in intracellular signal transductions such as cancer cell proliferation	n, angiogenesis, invas	sion, and apoptosis induction.
A P3 clinical study for HCC with	MET high patients	was started	in Jan-2013.			
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Nimotuzumab	DE-766	Injection	Anti-EGFR antibody	- Gastric cancer - Esophageal cancer	InnoCIMAb	TBD
<summary> The humanized monoclonal antibo antibodies.</summary>	dy to target Epide	rmal Growth	Factor Receptor(EGFR). Thi	s antibody is expected to be a best in class EGFR, safety against the skin toxicity a	nd the efficacy comp	arable to the other
 P3 in Japan for Gastric cancer st 	tarted in April 2013	3.				
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Quizartinib	AC220	Oral	FLT3-ITD inhibitor	- Acute myeloid leukemia	Daiichi Sankyo	TBD

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name	
Tivantinib	ARQ 197	Oral	MET inhibitor	- Hepatocellular cancer	ArQule	TBD	
Summary> The molecular-targeted agent to inhibit HGF(hepatocyte growth factor) receptor, Met which has multiple roles in intracellular signal transductions such as cancer cell proliferation, angiogenesis, invasion, and apoptosis induction A P3 clinical study for HCC with MET high patients was started in Jan-2013.							
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name	
Nimotuzumab	DE-766	Injection	Anti-EGFR antibody	- Gastric cancer - Esophageal cancer	InnoCIMAb	TBD	
<summary> The humanized monoclonal antibo antibodies. • P3 in Japan for Gastric cancer st</summary>			Factor Receptor(EGFR). This	s antibody is expected to be a best in class EGFR, safety against the skin toxicity a	nd the efficacy comp	arable to the other	
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name	
Quizartinib	AC220	Oral	FLT3-ITD inhibitor	- Acute myeloid leukemia	Daiichi Sankyo (Ambit)	TBD	

<Summary>

Kinase inhibitor against a receptor-type tyrosine kinase, FLT3.

Therapeutic effect for patients with acute myeloid leukemia harboring FLT-ITD3 mutation is expected.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Patritumab	U3-1287	Injection	Anti-HER3 antibody	- Non small cell lung cancer - Breast cancer - Head and neck cancer	Daiichi Sankyo (U3 Pharma)	TBD
-			Epidermal Growth Factor Re	eceptor (EGFR) family of proteins. HER 3 is overexpressed in many tumors of epithe	elial origin and HER2/	HER3 dimers and

EGFR/HER3 dimers are more potent to induce tumor cell proliferation than homodimers of HER2 or EGFR.

Generic Name	Project code Number	Dosage Form	Class	
Vemurafenib	PLX4032	Oral	BRAF inhibitor	- Melanoma adjuvant

<Summary>

The molecular-targeted agent to inhibit BRAF V600E mutation. Launched since 2011 as personalized treatment for patients with unrespectable or metastatic melanoma. NDA for combination therapy with MEK inhibitor cobimetinib was submitted in US and EU by Roche. A Phase 1 study of a combination with anti PD-L1 monoclonal antibody atezolizumab is investigated by Roche. Another phase 1 study for triple combination with cobimetinib and atezolizumab is also conducted by Roche.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Pexidartinib	PLX3397	Oral	FMS/KIT/FLT3-ITD inhibitor	- Tenosynovial Giant Cell Tumor - Glioblastoma - Melanoma	Daiichi Sankyo (Plexxikon)	TBD
<summary> The molecular-targeted agent to inl</summary>	nibit Fms, Kit and	Flt3-ITD. Thi	s agent is expected to reduc	ce tumor cell proliferation and expansion of metastases.		

Target Indication	Origin	Brand Name
	Daiichi Sankyo (Plexxikon)	Zelboraf

Others

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Precipitated and purified pertussis-diphtheria-tetanus- inactivated polio vaccine (Salk vaccine) vaccine	DD-687	Injection	DPT-IPV vaccine	- Prevention of pertussis, diphtheria, tetanus and poliomyelitis	Daiichi Sankyo (KDSV) Sanofi Pasteur	Squarekids subcutaneous injection syringe
<summarv></summarv>						

<Summary>

This vaccine is a product made of precipitated and purified pertussis, diphtheria, tetanus (DPT vaccine) of Kitasato Daiichi Sankyo and inactivated polio vaccine (Salk vaccine) of Sanofi Pasteur in a prefilled syringe, and is the first 4-valent combination vaccine in Japan that contains inactivated polio vaccine (Salk vaccine).

Approved in Jul 2014.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Levofloxacin	DR-3355	Injection	New quinolone	- Infection disease	Daiichi Sankyo	Cravit (JP) Levaquin (US) Tavanic (EU)

<Summary>

Levofloxacin injection formation, which was launched in 2011 for the treatment in respiratory tract infection. As LCM programme, the trials for urinary tract infection, surgical infection and gynecological infection are completed.

• A P3 comparative study for urinary tract infection and 4 open studies completed. sNDA submitted in Nov 2014. sNDA approved in Sep 2015.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Intradermal Seasonal Influenza Vaccine	VN-100	Injection (prefilled syringe)	Sesonal flu vaccine	- Prevention of seasonal influenza	Daiichi Sankyo (KDSV) Terumo	TBD
<summary></summary>			version of developed by fea	ur companies [Deijshi Sankus, Taruma, Japan Vacsing and Kitapata Deijshi Sankus		he introdurned injection

The Vaccine is a pre-filled syringe type, intradermal influenza HA vaccine co-developed by four companies [Daiichi Sankyo, Terumo, Japan Vaccine and Kitasato Daiichi Sankyo Vaccine Co., Ltd.]. The intradermal injection device for this vaccine is developed by Terumo. This device, which offers a more easy-to-use, surefire method to administer the vaccine than current methods. The device is also expected to ease patient hesitation to be injected and lower the risk of damaging peripheral blood vessels and nerves within the subcutaneous tissue.

NDA submission in Apr 2014 by Japan Vaccine

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	VN-101	Injection	Cell culture H5N1 flu vaccine	- Prophylaxis of H5N1 influenza infection	Daiichi Sankyo (KDSV)	TBD
<summary> Optimization of cell-culture H5N1 fl</summary>	u vaccine approve	ed in Mar. 20	014 for pediatric use.			
•Ph3 study in Japan started in Jul.	2014. Submitted	sNDA in Au	g 2015.			

Generic Name	Project code Number	Dosage Form	Class	
Denosumab	AMG 162	Injection	Anti-RANKL antibody	 Breast cancer adjuvant Rheumatoid arthritis

<Summary>

The fully human monoclonal antibody to target RANK Ligand, an essential mediator of osteoclast formation. Launched in Jap metastases from solid tumors, in June 2013 as treatment for osteoporosis, and in May 2014 as treatment for giant cell tumo

July, 2007 In-licensed from Amgen.

P3 : Breast cancer adjuvant, Rheumatoid arthritis.

Generic Name	Project code Number	Dosage Form	Class	
-	CHS-0214	Injection	TNFα inhibitor	- Rheumatoid arthritis

<Summary>

Biosimilar product for etanercept

• Phase 3 study for patients with rheumatoid arthritis in Japan was started in August 2014.

Target Indication	Origin	Brand Name
		SRE, GCTB:
	Amgen	Ranmark(JP)
		Osteoporosis: Pralia(JP)
oan in April 2012 as treatment for bone complications or of bone.	stemming from mul	tiple myeloma and bone
Target Indication	Origin	Brand Name
	Coherus	TBD

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	CL-108	Oral	opioid mu-receptor regulator	- Acute pain	Charleston Laboratories	TBD
<summary></summary>						
Combination product of immedia	te-release prometha	zine, hydrod	codone and acetaminophen. R	eduction of Opioid-Induced Nausea and Vomiting is expected.		
•Under phase 3 development in	collaboration with C	harleston La	boratories			
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Mirogabalin	DS-5565	Oral	α2δ ligand	- Fibromyalgia - Diabetic peripheral neuropathic pain - Postherpetic neuralgia	Daiichi Sankyo	TBD
<summary></summary>						
The pain therapy agent to reduce	e the neurotransmitte	er release fr	om nerve terminals. This ager	nt is expected to show the good balanced efficacy and safety profile.		
 Ph2 studies for diabetic periphe Ph3 studies for diabetic periphe Ph3 studies for fibromyalgia are 	ral neuropathic pain	•		on .		
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Hydromorphone	DS-7113	Oral/ Injection	opioid mu-receptor regulator	- Cancer pain	-	TBD
<summary></summary>						
Unapproved and Off-label Drugs	of High Medical Nee	ed."		recommended in WHO guideline as a standard analgesia for cancer pain. It is des release tablet, and Ph2/3 studies for injection formulation are ongoing.	ignated as unapprove	d drug by "Study Group on

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	CL-108	Oral	opioid mu-receptor regulator	- Acute pain	Charleston Laboratories	TBD
<summary></summary>	release prometha	zine hydroc	odone and acetaminophen. R	eduction of Opioid-Induced Nausea and Vomiting is expected.		
•Under phase 3 development in co	·					
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Mirogabalin	DS-5565	Oral	α2δ ligand	- Fibromyalgia - Diabetic peripheral neuropathic pain - Postherpetic neuralgia	Daiichi Sankyo	TBD
<summary> The pain therapy agent to reduce the Ph2 studies for diabetic periphera Ph3 studies for diabetic periphera Ph3 studies for fibromyalgia are in</summary>	I neuropathic pain I neuropathic pain	were compl	eted.	nt is expected to show the good balanced efficacy and safety profile.		
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Hydromorphone	DS-7113	Oral/ Injection	opioid mu-receptor regulator	- Cancer pain	-	TBD
Unapproved and Off-label Drugs of	High Medical Nee	ed."		recommended in WHO guideline as a standard analgesia for cancer pain. It is desi release tablet, and Ph2/3 studies for injection formulation are ongoing.	jnated as unapprove	d drug by "Study Group on

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	CL-108	Oral	opioid mu-receptor regulator	- Acute pain	Charleston Laboratories	TBD
<summary></summary>						
Combination product of immediate	-release prometha	zine, hydroc	odone and acetaminophen. R	eduction of Opioid-Induced Nausea and Vomiting is expected.		
•Under phase 3 development in co	ollaboration with Cl	narleston La	boratories			
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Mirogabalin	DS-5565	Oral	α2δ ligand	- Fibromyalgia - Diabetic peripheral neuropathic pain - Postherpetic neuralgia	Daiichi Sankyo	TBD
<summary> The pain therapy agent to reduce t •Ph2 studies for diabetic periphera •Ph3 studies for diabetic periphera •Ph3 studies for fibromyalgia are in</summary>	al neuropathic pain al neuropathic pain	were comp	leted.	nt is expected to show the good balanced efficacy and safety profile.		
Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Hydromorphone	DS-7113	Oral/ Injection	opioid mu-receptor regulator	- Cancer pain	-	TBD
Unapproved and Off-label Drugs o	f High Medical Nee	ed."		recommended in WHO guideline as a standard analgesia for cancer pain. It is desi release tablet, and Ph2/3 studies for injection formulation are ongoing.	gnated as unapprove	d drug by "Study Group on

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
-	VN-0107 MEDI3250	Nasal spray	Seasonal flu vaccine	- Prevention of seasonal influenza	AZ/MedImmune	TBD
<summarv></summarv>						

<Summary>
The US brand name of this vaccine is FluMist Quadrivalent that is a live attenuated influenza vaccine which is administered as a nasal spray and contains four protective strains. Phase III safety and efficacy studies were conducted for FluMist Quadrivalent in Japanese children over the 2014-2015 influenza season and a regulatory submission is being prepared in Japan.

In preparation for NDA submission

Generic Name	Project code Number	Dosage Form	Class	
-	VN-0105	Injection	DPT-IPV/Hib vaccine	- Prevention of pertussis, diph

<Summary> A combination vaccine reconstituting Hib with precipitated and purified pertussis-diphtheria-tetanus-inactivated polio vaccine (Svaccine (DPT-IPV/Hib).

•Ph3 study in Japan started in Oct 2014.

Generic Name	Project code Number	Dosage Form	Class	- Target Indication	Origin	Brand Name
-	SUN13837	Injection	Modulator of bFGF signaling system	- Spinal cord injury	Daiichi Sankyo (Asubio Pharma)	TBD
<summary> By accelerating self-regeneration of mproved.</summary>	capabilities (nerve	cell protectior	n, nerve axon elongation) w	th bFGF like cell differentiation actions, the perceptional and motor	r-functional dysfunctions caused by cord i	njuries are to be

Target Indication	Origin	Brand Name
theria, tetanus, poliomyelitis and Hib	Daiichi Sankyo (KDSV) Sanofi Pasteur	TBD
(Salk vaccine) vaccine previoursly licensed and launched in Japan, as 1st in the class of pentavalent		