TSE:4568

# Reference Data

(Consolidated Financial Results for Q3 FY2015)



January 29, 2016

Daiichi Sankyo Co., Ltd.

http://www.daiichisankyo.com

# Contents

1.	Consolidated Statement of Profit or Loss	P1
2.	Revenue of Global Products	P2
3.	Revenue by Business Units and Products	P3
4.	Consolidated Statement of Financial Position	P6
5.	Consolidated Statement of Cash Flows	P8
6.	Number of Employees	P9
7.	Capital Expenditure and Depreciation and Amortization	P9
8.	Summary of Product Outlines	P10
9.	Quarterly Data	P11
10.	Historical Data	P16
11.	Major R&D Pipeline (Innovative pharmaceuticals)	P20



#### 1. Consolidated Statement of Profit or Loss

	FY2014	Q3 YTD		FY	/2015 Q3 YT	D						FY2015			
JPY Bn	to revenue	Results	to revenue	Results (	vs. Forecast (%))	YoY	YoY (%)	<u> </u>	to revenue	Forecast (as of Oct.)	to revenue	Forecast (as of	vs. Forecast (as of Oct.)	YoY	YoY (%)
Revenue	100.0%	694.4	100.0%	758.6	(77.4%)	64.2	+9.2%	Forex impact: +25.9 (USD:+26.9, EUR:-2.5, ASCA:+1.5)	100.0%	980.0	100.0%	980.0	0.0	60.6	+6.6%
Cost of sales	31.8%	220.9	31.3%	237.7	(75.2%)	16.8	+7.6%	Forex impact: +6.6 (USD:+6.1, EUR:-0.1, ASCA:+0.6)	32.0%	314.0	32.2%	316.0	2.0	-7.1	-2.2%
(excl. Special items)	31.5%	218.7	31.8%	241.2		22.5	+10.3%	(00D.+0.1, E0K0.1, A00A.+0.0)							
(Special items)	0.3%	2.2	-0.5%	-3.5		-5.7	-257.8%								
Gross Profit	68.2%	473.5	68.7%	520.8	(78.4%)	47.4	+10.0%		68.0%	666.0	67.8%	664.0	-2.0	67.7	+11.4%
SG&A expenses	34.2%	237.8	30.6%	232.3	(68.9%)	<b>.</b>	-2.3% <	Forex impact: +10.0	36.1%	354.0	34.4%	337.0	-17.0	5.8	+1.8%
(excl. Special items)	33.0%	229.0	30.0%	234.4	(66.9%)	-5.5 5.3		USD:+10.8, EUR:-1.3, ASCA:+0.5)	30.1%	354.0	34.4%	337.0	-17.0	3.0	+1.0%
(Special items)	1.3%	8.7	-0.3%	-2.1		-10.8			_						
,	40.5%		40.00/		(70.40/)			Forex impact: +5.2	10.0%	400.0	00.40/	407.0	5.0	0.0	. 0. 00/
R&D expenses	19.5%	135.7	18.2%	138.1	(70.1%)	2.4		(USD:+5.4, EUR:-0.2)	19.6%	192.0	20.1%	197.0	5.0	6.3	+3.3%
(excl. Special items)	18.9% 0.6%	131.3 4.4	18.2% 0.0%	137.8 0.3		6.6 -4.1			J						
(Special items)	0.0%	4.4	0.076	0.3		-4.1	-93.7 /0	<b>5</b>	7						
Operating Profit	14.4%	100.0	19.8%	150.4	(115.7%)	50.4	+50.4%	Forex impact: +4.0 (USD:+4.6, EUR:-0.9, ASCA:+0.3)	12.2%	120.0	13.3%	130.0	10.0	55.6	+74.7%
(Operating Profit before Special items)	16.6%	115.3	19.1%	145.1		29.8	+25.8%	FY0045	] ]						
Financial income/expenses		8.2		-4.9		-13.1	4	FY2015:    Expenses relating to sale of Sun							
Share of profit or loss of investments accounted for using the equity method		-0.8		-0.1		0.6		Pharma shares etc.							
Profit before tax	15.5%	107.5	19.2%	145.4	(121.2%)	38.0	+35.3%		11.7%	115.0	12.2%	120.0	5.0	40.1	+50.1%
Income taxes		41.0		36.1		-4.8	-11.8%								
Profit for the year	9.6%	66.5	14.4%	109.3		42.8	+64.4%								
Profit attributable to owners of the Compar	ny <i>9.9%</i>	68.9	14.6%	110.7	(147.6%)	41.8	+60.6%		7.7%	75.0	7.7%	75.0	0.0	28.5	+61.4%
<u></u>	,	33.3			(,	1110		Increase in R&D tax credit		7 0.10		1010	0.0		
Tax rate		38.1%		24.8%											
Overseas sales ratio		41.8%		44.3%	Special item	<u>1S</u>		EV2044 EV204	<u> </u>	٦					
					Cost of	Sales F	Restructuring cos	FY2014 FY201 s in Japan 2.2 Gain on sales of subsiderations	diary	<u></u>	ov Doto (A				
Currency Rate (Average) USD/JPY		106.88		121.70	-		Settlement expens	Gain on sales of fixed	l assets	Cullen	cy Rate (A	<u>verage)</u> 121.28			
EUR/JPY		140.31		134.37	SG&A e		Restructuring cost			1		133.27			
201001 1		170.01		107.01		·	Gain on sales of fi	ked assets -2.9				100.21			
					R&D ex	penses F	Restructuring cost	s in Japan 4.4 Restructuring costs in 15.4	R&D 0.:	Annuai imi	act of one ye	en change			
			u procedure					•	-0	<u> </u>	F	orecast (as of	Oct.) Forec	ast (as of Jan	1.)

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

	Forecast (	as of Oct.)	Forecast (	as of Jan.)
	USD EUR		USD	EUR
Revenue	2.2 Bn Yen	0.6 Bn Yen	2.3 Bn Yen	0.6 Bn Yen
Operating Profit	0.2 Rn Yen	∩ 1 Rn Yen	0.3 Rn Ven	0.1 Rn Yen

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<sup>\*</sup>The figures for FY2014 have been restated and indicated as only the values for continuing operations excluding Ranbaxy.

<sup>\*</sup>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".

2. Revenue of Global Products	FY2014 Q3 YTD	FY2015 Q3 YTD				FY2015	
JPY Bn	Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Oct.)	
<b>Olmesartan</b> antihypertensive	219.9	228.5	(80.4%)	8.5	+3.9%	284.0	
Olmetec (JPN)	58.4	60.5	(76.6%)	2.1	+3.6%	79.0	
Rezaltas (JPN)	14.1	14.1	(74.2%)	0.0	+0.3%	19.0	
Benicar/Benicar HCT (US)	55.0	63.1	(86.5%)	8.1	+14.8%	73.0	
Azor (US)	13.4	15.7	(92.2%)	2.3	+16.9%	17.0	
Tribenzor (US)	8.5	9.6	(96.2%)	1.1	+12.6%	10.0	
Olmetec/Olmetec Plus (EU)	29.0	24.9	(77.7%)	-4.1	-14.3%	32.0	
Sevikar (EU)	13.5	12.1	(75.4%)	-1.4	-10.5%	16.0	
Sevikar HCT (EU)	7.7	7.4	(82.8%)	-0.2	-2.8%	9.0	
Other subsidiaries, export, etc	20.4	21.1	(72.6%)	0.7	+3.4%	29.0	
Prasugrel antiplatelet	18.4	24.0	-	5.6	+30.4%	not disclosed	
Effient alliance revenue (US)	13.1	16.4	-	3.3	+25.4%	not disclosed	
Efient alliance revenue and others (EU)	3.7	3.3	-	-0.4	-10.0%	not disclosed	
Efient (JPN)	0.5	3.3	(65.6%)	2.8	+552.8%	5.0	
Other subsidiaries, export, etc	1.1	1.0	-	-0.1	-13.0%	not disclosed	
Edoxaban anticoagulant	2.1	10.5	(71.7%)	8.4	+391.8%	14.7	
Lixiana (JPN)	2.1	9.6	(87.2%)	7.5	+347.7%	11.0	
Savaysa (US)	-	0.3	(14.5%)	0.3	-	2.0	
Lixiana (EU)	-	0.7	(38.5%)	0.7	-	1.7	

3. Revenue by	Business Units and Products (1)	FY2014 Q3 YTD		FY2015 Q3	YTD		FY2015
JPY Bn		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Oct.)
Japan		367.8	377.5	(76.9%)	9.6	+2.6%	491.0
Olmetec	antihypertensive	58.4	60.5	(76.6%)	2.1	+3.6%	79.0
Nexium	proton pump inhibitor	55.7	62.0	(80.5%)	6.2	+11.2%	77.0
Memary	treatment for Alzheimer's Disease	27.5	32.7	(69.6%)	5.2	+18.8%	47.0
Loxonin	analgesic and anti-inflammatory	38.7	38.2	(86.9%)	-0.4	-1.1%	44.0
Cravit	antibacterial	23.0	14.6	(85.8%)	-8.4	-36.5%	17.0
Rezaltas	antihypertensive	14.1	14.1	(74.2%)	0.0	+0.3%	19.0
Artist	antihypertensive	14.1	12.1	(71.2%)	-2.0	-14.5%	17.0
Omnipaque	contrast medium	13.3	13.2	(82.6%)	-0.1	-0.9%	16.0
Mevalotin	antihyperlipidemic	12.6	10.8	(77.0%)	-1.8	-14.3%	14.0
Ranmark	anti-RANKL antibody	7.6	9.4	(71.9%)	1.8	+23.6%	13.0
Inavir	anti-influenza	8.2	2.5	(21.1%)	-5.6	-69.0%	12.0
Urief	treatment for dysuria	8.7	9.0	(82.2%)	0.3	+4.0%	11.0
Pralia	anti-RANKL antibody	5.1	9.0	(90.3%)	3.9	+76.6%	10.0
Lixiana	anticoagulant	2.1	9.6	(87.2%)	7.5	+347.7%	11.0
Efient	antiplatelet	0.5	3.3	(65.6%)	2.8	+552.8%	5.0
Teneria	type 2 diabetes	5.5	11.9	-	6.4	+117.6%	not disclosed
Daiichi Sankyo	Espha products	11.6	14.2	-	2.6	+22.1%	not disclosed
Vaccines busin	ess	25.6	30.0	-	4.4	+17.2%	not disclosed
Daiichi Sankyo H	ealthcare (OTC)	37.0	39.9	(81.3%)	2.9	+7.8%	49.0

3. Revenue by Business Units and Products (2)		FY2014 Q3 YTD		FY2015			
JPY Bn		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Oct.)
Daiichi Sankyo, Ir	nc. (US)	126.2	145.5	(82.7%)	19.3	+15.3%	176.0
Olmesartan	antihypertensive	76.9	88.4	(87.5%)	11.5	+14.9%	101.0
Benicar/Ben	icar HCT	55.0	63.1	(86.5%)	8.1	+14.8%	73.0
Azor		13.4	15.7	(92.2%)	2.3	+16.9%	17.0
Tribenzor		8.5	9.6	(96.2%)	1.1	+12.6%	10.0
Welchol	antihyperlipidemic / type 2 diabetes	35.1	37.7	(80.2%)	2.5	+7.2%	47.0
Effient	antiplatelet	13.1	16.4	-	3.3	+25.4%	not disclosed
Savaysa	anticoagulant	-	0.3	(14.5%)	0.3	-	2.0
Movantik	opioid-induced constipation	-	1.3	-	1.3	-	not disclosed
Luitpold Pharmad	ceuticals, Inc. (US)	42.9	69.0	(80.3%)	26.1	+60.8%	86.0
Venofer	iron deficiency anemia	22.8	24.4	(81.3%)	1.6	+7.0%	30.0
Injectafer	iron deficiency anemia	5.1	12.9	(75.7%)	7.8	+152.9%	17.0
Daiichi Sankyo Eı	urope GmbH	64.6	58.1	(76.4%)	-6.5	-10.1%	76.0
Olmesartan	antihypertensive	50.2	44.4	(76.5%)	-5.8	-11.5%	58.0
Olmetec/Oln	netec Plus	29.0	24.9	(77.7%)	-4.1	-14.3%	32.0
Sevikar		13.5	12.1	(75.4%)	-1.4	-10.5%	16.0
Sevikar HCT	-	7.7	7.4	(82.8%)	-0.2	-2.8%	9.0
Efient	antiplatelet	3.7	3.3	-	-0.4	-10.0%	not disclosed
Lixiana	anticoagulant	-	0.7	(38.5%)	0.7	-	1.7
Asia, South and C	Central America (ASCA)	48.9	62.6	(71.1%)	13.7	+28.1%	88.0
Daiichi Sankyo	China	18.9	24.8	-	5.9	+31.3%	not disclosed
Daiichi Sankyo	Taiwan Taiwan	3.6	4.0	-	0.4	+11.2%	not disclosed
Daiichi Sankyo	Korea	6.4	7.2	-	0.7	+11.6%	not disclosed
Daiichi Sankyo	Thailand	2.6	2.9	-	0.3	+10.7%	not disclosed
Daiichi Sankyo	Brasil Farmacêutica	6.9	6.7	-	-0.2	-3.0%	not disclosed
Daiichi Sankyo	Venezuela	6.0	7.1	-	1.1	+19.0%	not disclosed

3. Revenue by	Business Units and Products (3)	FY2014 Q3 YTD		FY2015 Q3	YTD		FY2015
[Reference] Re	Reference] Revenue in Local Currency		Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Oct.)
USD Mn							
Daiichi Sankyo, In	c. (US)	1,181	1,196	(81.8%)	15	+1.3%	1,462
Olmesartan	antihypertensive	720	727	(86.3%)	7	+0.9%	842
Benicar/Beni	car HCT	514	519	(85.3%)	4	+0.8%	608
Azor		125	129	(90.9%)	3	+2.7%	142
Tribenzor		80	79	(94.8%)	-1	-1.1%	83
Welchol	antihyperlipidemic / type 2 diabetes	329	310	(79.4%)	-19	-5.8%	390
Effient	antiplatelet	123	135	-	12	+10.1%	not disclosed
Savaysa	anticoagulant	-	2	(14.4%)	2	-	17
Movantik	opioid-induced constipation	-	10	-	10	-	not disclosed
USD Mn							
Luitpold Pharmac	euticals, Inc. (US)	402	567	(79.4%)	165	+41.2%	714
Venofer	iron deficiency anemia	213	200	(80.4%)	-13	-6.0%	249
Injectafer	iron deficiency anemia	48	106	(74.9%)	58	+122.1%	141
EUR Mn							
Daiichi Sankyo Eu	ırope GmbH	460	432	(73.9%)	-28	-6.1%	584
Olmesartan	antihypertensive	357	330	(74.1%)	-27	-7.6%	446
Olmetec/Olm	netec Plus	207	185	(75.2%)	-22	-10.5%	246
Sevikar		96	90	(73.0%)	-6	-6.6%	123
Sevikar HCT		55	55	(80.1%)	1	+1.5%	69
Efient	antiplatelet	26	24	-	-2	-6.0%	not disclosed
Lixiana	anticoagulant		5	(37.4%)	5		13

### **4. Consolidated Statement of Financial Position**

<Assets> (JPY Bn)

		Mar. 2015	Dec. 2015	vs. Mar. 2015
ssets				
Cu	rrent assets			
	Cash and cash equivalents	189.4	240.1	50.7
	Trade and other receivables	241.5	301.3	59.7
	Other financial assets	186.5	430.0	243.6
	Inventories	150.1	153.6	3.5
	Other current assets	14.7	15.5	0.8
	Subtotal	782.2	1,140.6	358.4
	Assets held for sale	3.2	-	-3.2
	Total current assets	785.3	1,140.6	355.2
No	n-current assets			
	Property,plant and equipment	266.5	265.8	-0.7
	Goodwill	71.4	82.3	11.0
	Intangible assets	199.4	211.1	11.7
	Investments accounted for using the equity method	1.3	1.5	0.1
	Other financial assets	593.9	186.8	-407.2
	Deferred tax assets	45.3	43.5	-1.8
	Other non-current assets	19.1	17.6	-1.5
	Total non-current assets	1,197.0	808.6	-388.3
Tot	tal assets	1,982.3	1,949.2	-33.1
<b>k</b>	Liquidity on hand	374.3	668.6	294.3
	Debt with interest	224.6	207.3	-17.4
		149.7	461.4	

Increase due to sale of Sun Pharma shares

Increase due to acquisition of Im etc.

Acquisition +21.5, Amortization -12.0

Sale of Sun Pharma shares -424.3 (Sale: -378.5, Evaluation difference -45.8)

Liabilities and equity>			(JPY Bn)
	Mar. 2015	Dec. 2015	vs. Mar. 2015
iabilities			
Current liabilities			
Trade and other payables	235.5	232.1	-3.5
Bonds and borrowings	20.0	20.9	0.9
Other financial liabilities	7.6	1.0	-6.6
Income taxes payable	7.8	7.8	-0.0
Provisions	19.4	26.7	7.2
Other current liabilities	6.7	10.1	3.4
Subtotal	297.1	298.5	1.5
Liabilities directly associated with assets held for sale	0.4	1	-0.4
Total current liabilities	297.5	298.5	1.0
Non-current liabilities			
Bonds and borrowings	201.0	183.1	-17.9
Other financial liabilities	8.3	8.8	0.4
Post employment benefit liabilities	11.6	11.9	0.3
Provisions	2.7	2.6	-0.1
Deferred tax liabilities	88.4	84.5	-3.9
Other non-current liabilities	65.7	63.6	-2.1
Total non-current liabilities	377.7	354.4	-23.3
Total liabilities	675.2	653.0	-22.3
quity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Capital surplus	105.3	103.9	-1.3
Treasury shares	-14.2	-64.2	-50.0
Other components of equity	169.0	184.9	15.9
Retained earnings	994.0	1,018.9	24.9
Total equity attributable to owners of the Company	1,304.1	1,293.6	-10.5
Non-controlling interests			
Non-controlling interests	3.0	2.7	-0.3
Total equity	1,307.0	1,296.2	-10.8
otal liabilities and equity	1,982.3	1,949.2	-33.1

Acquisition -50.0 (21 million shares)

Profit for the period +110.7, Dividends -48.5, Transfer from comprehensive income -37.3

### 5. Consolidated Statement of Cash Flows

(JPY Bn)

			(JP ) DII
	FY2014	FY2015	YoY
Cook flows from an existing a still the	Q3 YTD	Q3 YTD	-
Cash flows from operating activities			
Profit before tax from continuing operations	107.5	145.4	
Depreciation and amortization	31.4	33.0	
(Increase) decrease in receivables and payables	-40.1	-52.0	-11.9
Other, net	2.3	-4.2	-6.
Income taxes paid	-13.7	-29.3	-15.0
Cash flows from operating activities of discontinued operations	9.0	-	-9.0
Net cash flows from operating activities	96.4	93.0	-3.4
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	149.7	-243.1	-392.8
(Acquisition of) proceeds from sales of fixed assets	-57.4	-49.3	8.
Proceeds from sale of subsidiary	-	7.0	7.0
Net (increase) decrease in investment securities	-0.5	374.6	375.2
Other, net	-30.7	-10.4	20.3
Cash flows from investing activities of discontinued operations	-3.2	-	3.2
Net cash flows from investing activities	57.9	78.8	20.9
Cash flows from financing activities			
Net (increase) decrease in borrowings	-30.0	-20.0	10.0
Repayments of bonds	-60.0	-	60.0
Purchase of treasury shares	-0.0	-50.2	-50.2
Dividends paid	-42.3	-48.5	-6.3
Other, net	-0.7	-1.0	-0.3
Cash flows from financing activities of discontinued operations	1.0	-	-1.0
Net cash flows from financing activities	-132.0	-119.8	12.2
Net increase (decrease) in cash and cash equivalents	22.3	52.0	29.
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	21.7	-1.3	-23.0
Cash and cash equivalents at the end of the period	227.0	240.1	13.
* Free cash flows (Cash flows from operating activities and investing activities)	154.3	171.8	17.
- 15 Carrier (Carrier of the first operating activities and investing activities)			

Increase in time deposits and securities

Sale of Sun Pharma shares +378.5

FY2014: Acquisition of Ambit shares -33.5 FY2015: Acquisition of Im shares -11.8

### **6. Number of Employees**

	Dec. 2014	Mar. 2015	Dec. 2015
	Results	Results	Results
solidated	17,239	16,428	16,075
Japan	9,171	8,543	8,602
North America	3,481	3,322	3,043
Europe	2,111	2,094	2,066
Others	2,476	2,469	2,364
	North America Europe	Results           solidated         17,239           Japan         9,171           North America         3,481           Europe         2,111	Results         Results           solidated         17,239         16,428           Japan         9,171         8,543           North America         3,481         3,322           Europe         2,111         2,094

### 7. Capital Expenditure and Depreciation and Amortization

		FY2014 Q3 YTD	FY2014	FY2015 Q3 YTD	FY2015
	(JPY Bn)	Results	Results	Results	Forecast
Capital expenditure		24.4	36.3	20.3	30.3
Depreciation and amortization		31.4	42.0	33.0	41.9
Property,plant and equipme	ent	20.0	27.0	21.0	-
Intangible assets		11.4	15.1	12.0	-

### 8. Summary of Product Outlines

Brand Name	Generic Name	Therapeutic Category	Launched	Origin	Marketing Alliance	Type of Alliance
Japan						
Olmetec	olmesartan	antihypertensive	2004	Daiichi Sankyo		
Nexium	esomeprazole	proton pump inhibitor	2011	AstraZeneca	AstraZeneca	Co-promotion (DS: Sales)
Memary	memantine	treatment for Alzheimer's disease	2011	Merz		
Loxonin			1986	Daiichi Sankyo		
Loxonin Poultice	lovoprofon	analgesic and anti-inflammatory	2006	Lead Chemical		
Loxonin Tape	loxoprofen	analgesic and anti-milammatory	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	Kissei	Co-marketing
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	Mitsubishi Tanabe	Co-promotion (DS: Sales)
Daiichi Sankyo, Inc. (US)  Olmesartan  Benicar  Benicar HCT  Azor	olmesartan olmesartan / hydrochlorothiazide olmesartan / amlodipine	antihypertensive	2002 2003 2007	Daiichi Sankyo		
Tribenzor	olmesartan / amlodipine / hydrochlorothiazide		2007			
	<u> </u>			0.0000000000000000000000000000000000000		
Welchol	colesevelam	antihyperlipidemic / type 2 diabetes	2000	Genzyme  Daiichi Sankyo	1:0	On the section (DO: On the section)
Effient	prasugrel	antiplatelet anticoagulant	2009	Ube Industries	Lilly	Co-promotion (DS: Co-pro revenue)
Savaysa	edoxaban	Direct Oral Factor Xa Inhibitor	2015	Daiichi Sankyo		
Movantik	naloxegol	opioid-induced constipation	2015	Nektar AstraZeneca	AstraZeneca	Co-promotion (DS: Co-pro revenue)
Luitpold Pharmaceuticals, Inc. (US)						
Venofer	iron sucrose injection	iron deficiency anemia	2000	Vifor Pharma	Fresenius	Co-marketing
Injectafer	ferric carboxymaltose injection	iron deficiency anemia	2013	Vifor Pharma		
Daiichi Sankyo Europe GmbH						
Olmesartan						
Olmetec	olmesartan		2002			
Olmetec Plus	olmesartan / hydrochlorothiazide	antihynortonsiyo	2005	Daiichi Sankyo	Menarini Pfizer	Co-marketing
Sevikar	olmesartan / amlodipine	antihypertensive	2009	Dallolli Sallkyu	Nycomed	Co-marketing
Sevikar HCT	olmesartan / amlodipine / hydrochlorothiazide		2010		<u> </u>	
Efient	prasugrel	antiplatelet	2009	Daiichi Sankyo Ube Industries	Lilly	Co-promotion (DS: Co-pro revenue)
Lixiana	edoxaban	anticoagulant Direct Oral Factor Xa Inhibitor	2015	Daiichi Sankyo		

### <9. Quarterly Data>

1. Consolidated Statement of Profit or Loss FY2015 FY2015 FY2014 FY2014 FY2014 FY2015 FY2015 FY2014 FY2014 FY2015 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Results Results Results to revenue Results YoY YoY (%) Results Results to revenue Results Results Results Results JPY Bn 213.7 215.9 264.8 225.0 919.4 +2.3% 238.4 240.4 279.8 758.6 Revenue 100.0% 20.2 100.0% Cost of sales 64.6 66.2 90.1 102.2 35.1% 323.1 40.2 +14.2% 74.0 75.0 8.88 31.3% 237.7 66.2 76.3 (excl. Special items) 64.6 87.9 67.2 31.1% 285.9 7.1 +2.6% 76.1 8.88 31.8% 241.2 (Special items) 2.2 35.0 4.0% 37.2 33.1 +813.2% -2.4 -3.5 -1.1 -0.5% **Gross Profit** 149.1 149.7 174.7 122.8 64.9% 596.3 -20.0 -3.2% 164.5 165.4 191.0 68.7% 520.8 74.9 93.4 SG&A expenses 78.7 84.1 331.2 +2.6% 71.6 72.8 87.8 232.3 36.0% 8.5 30.6% 74.9 (excl. Special items) 74.7 79.4 89.6 34.7% 318.6 -4.1 -1.3% 75.6 77.1 81.7 30.9% 234.4 (Special items) 4.0 4.7 3.8 1.4% 12.6 12.6 -53017.5% -3.9 6.1 -0.3% -2.1 -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 49.8 18.2% 138.1 (excl. Special items) 41.4 43.5 46.4 54.9 20.3% 186.2 5.6 +3.1% 43.7 44.7 49.5 18.2% 137.8 (Special items) 4.4 0.0 0.5% 4.4 4.4 0.3 0.3 0.0% 27.4 **Operating Profit** 32.8 39.7 -25.6 8.1% 74.4 -38.5 -34.1% 49.1 47.9 53.4 19.8% 150.4 (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 59.8 19.1% 145.1 0.2 2.5 -3.7 Financial income/expenses 5.5 -1.8 6.4 5.8 -2.1 1.0 -4.9 0.1 -0.2 0.2 Share of profit or loss of investments -0.3 -0.5 -0.2 -0.9 -0.3 -0.1 -0.1 accounted for using the equity method **Profit before tax** 32.7 29.5 45.3 -27.5 8.7% 79.9 -33.0 -29.2% 45.2 45.6 54.6 19.2% 145.4 Income taxes 11.8 15.1 14.0 -4.6 36.4 -10.8 -22.9% 11.1 10.3 14.7 36.1 Profit for the year 20.9 14.3 31.3 -22.9 4.7% 43.6 -22.2 -33.8% 34.1 35.3 39.9 14.4% 109.3 15.1 32.3 -22.5 5.1% 46.5 -22.3 -32.5% 34.9 35.8 40.0 14.6% 110.7 Profit attributable to owners of the Company 21.6 Tax rate 36.1% 51.3% 31.0% 16.7% 45.5% 24.6% 22.5% 27.0% 24.8% Overseas sales ratio 45.2% 41.1% 39.7% 45.3% 42.7% 46.8% 46.2% 40.6% 44.3% Currency Rate (Average) USD/JPY 102.16 103.05 106.88 109.94 109.94 121.37 121.80 121.70 121.70 **EUR/JPY** 140.06 138.91 140.31 138.78 138.78 134.16 135.07 134.37 134.37

11

### <9. Quarterly Data>

2. Revenue of Global Products	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
Olmesartan	75.8	66.5	77.7	73.6	293.5	-6.6	-2.2%	75.6	71.9	80.9		228.5
Olmetec (JPN)	18.7	19.1	20.6	17.9	76.3	-2.8	-3.5%	18.5	17.7	24.3		60.5
Rezaltas (JPN)	4.5	4.5	5.0	4.3	18.4	-0.0	-0.3%	4.6	4.3	5.2		14.1
Benicar/Benicar HCT (US)	18.9	15.1	21.0	22.0	77.0	-8.9	-10.3%	19.8	20.5	22.8		63.1
Azor (US)	4.1	3.9	5.4	4.9	18.3	0.9	+4.9%	5.8	4.6	5.2		15.7
Tribenzor (US)	2.7	2.5	3.3	2.8	11.3	2.3	+25.3%	3.1	3.2	3.3		9.6
Olmetec/Olmetec Plus (EU)	11.1	9.3	8.6	8.7	37.8	-6.8	-15.2%	8.9	8.2	7.8		24.9
Sevikar (EU)	5.3	4.2	3.9	4.1	17.6	4.1	+30.2%	4.5	4.1	3.5		12.1
Sevikar HCT (EU)	3.3	2.1	2.2	2.2	9.9	2.3	+29.9%	2.5	2.2	2.8		7.4
Other subsidiaries, export, etc	7.1	5.8	7.5	6.7	27.0	2.3	+9.4%	7.9	7.1	6.0		21.1
Prasugrel	5.8	5.9	6.7	6.6	24.9	2.6	+11.7%	7.8	7.4	8.7		24.0
Effient alliance revenue (US)	4.2	4.2	4.6	4.5	17.6	2.1	+13.7%	5.2	5.4	5.8		16.4
Efient alliance revenue and others (EU)	1.2	1.2	1.3	1.1	4.8	0.1	+1.7%	1.1	1.1	1.1		3.3
Efient (JPN)	0.2	0.1	0.2	0.2	0.7	0.7	-	1.2	0.6	1.5		3.3
Other subsidiaries, export, etc	0.2	0.4	0.5	0.8	1.9	-0.3	-12.2%	0.3	0.4	0.3		1.0
Edoxaban	0.1	0.1	1.9	2.1	4.3	3.9	+967.0%	1.8	3.5	5.2		10.5
Lixiana (JPN)	0.1	0.1	1.9	1.4	3.6	3.2	+792.8%	2.1	3.2	4.2		9.6
Savaysa (US)	-	-	-	0.7	0.7	0.7	-	-0.3	0.1	0.5		0.3
Lixiana (EU)	-	-	-	-	-	-	-	0.0	0.1	0.5		0.7

3. Revenue by Business Units and Products (1	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
Japan	108.0	114.6	145.2	112.7	480.5	-5.5	-1.1%	114.2	113.6	149.6		377.5
Olmetec	18.7	19.1	20.6	17.9	76.3	-2.8	-3.5%	18.5	17.7	24.3		60.5
Nexium	15.3	16.8	23.7	13.6	69.3	15.1	+27.9%	19.1	19.6	23.3		62.0
Memary	7.9	8.9	10.8	9.3	36.8	3.5	+10.5%	10.2	10.2	12.2		32.7
Loxonin	12.2	13.2	13.3	10.9	49.5	-9.8	-16.5%	12.6	11.8	13.9		38.2
Cravit	6.9	7.3	8.8	4.9	27.8	-5.7	-16.9%	4.6	4.4	5.6		14.6
Rezaltas	4.5	4.5	5.0	4.3	18.4	-0.0	-0.3%	4.6	4.3	5.2		14.1
Artist	4.8	4.7	4.7	4.0	18.1	-4.3	-19.1%	4.1	3.8	4.2		12.1
Omnipaque	4.2	4.4	4.7	3.9	17.2	-2.5	-12.5%	4.2	4.2	4.8		13.2
Mevalotin	4.2	4.1	4.3	3.6	16.2	-5.3	-24.8%	3.6	3.4	3.8		10.8
Ranmark	2.1	2.6	2.9	2.6	10.2	2.1	+26.1%	2.9	3.0	3.5		9.4
Inavir	0.3	0.0	7.9	8.4	16.6	3.1	+23.4%	0.0	0.0	2.5		2.5
Urief	2.7	2.9	3.1	2.8	11.5	0.1	+0.7%	2.9	2.8	3.3		9.0
Pralia	1.3	1.7	2.1	2.2	7.3	4.2	+131.8%	2.6	2.8	3.7		9.0
Lixiana	0.1	0.1	1.9	1.4	3.6	3.2	+792.8%	2.1	3.2	4.2		9.6
Efient	0.2	0.1	0.2	0.2	0.7	0.7	-	1.2	0.6	1.5		3.3
Teneria	1.5	1.8	2.2	2.1	7.6	6.0	+390.5%	2.4	3.0	6.6		11.9
Daiichi Sankyo Espha products	3.5	3.3	4.8	3.3	14.9	2.4	+19.4%	4.3	4.3	5.6		14.2
Vaccines business	5.8	6.7	13.1	6.6	32.2	-5.3	-14.1%	6.4	8.0	15.6		30.0
Daiichi Sankyo Healthcare (OTC)	9.4	13.3	14.3	10.8	47.8	-0.3	-0.5%	10.8	13.8	15.2		39.9

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	52.1		145.5
Olmesartan	25.7	21.5	29.7	29.6	106.6	-5.7	-5.1%	28.8	28.3	31.3		88.4
Benicar/Benicar HCT	18.9	15.1	21.0	22.0	77.0	-8.9	-10.3%	19.8	20.5	22.8		63.1
Azor	4.1	3.9	5.4	4.9	18.3	0.9	+4.9%	5.8	4.6	5.2		15.7
Tribenzor	2.7	2.5	3.3	2.8	11.3	2.3	+25.3%	3.1	3.2	3.3		9.6
Welchol	11.3	10.5	13.4	12.3	47.4	5.1	+12.1%	13.5	10.6	13.5		37.7
Effient	4.2	4.2	4.6	4.5	17.6	2.1	+13.7%	5.2	5.4	5.8		16.4
Savaysa	-		-	0.7	0.7	0.7	-	-0.3	0.1	0.5		0.3
Movantik	-	-	-	-	-	-	-	0.2	0.4	0.7		1.3
Luitpold Pharmaceuticals, Inc. (US)	12.5	14.3	16.2	14.4	57.4	17.8	+44.8%	21.5	24.9	22.6		69.0
Venofer	7.2	7.0	8.6	5.8	28.6	3.7	+14.9%	9.1	6.9	8.4		24.4
Injectafer	1.5	1.5	2.2	2.6	7.6	6.3	+483.4%	3.9	4.0	5.0		12.9
Daiichi Sankyo Europe GmbH	24.5	20.0	20.1	18.9	83.5	-0.4	-0.5%	20.2	19.0	18.8		58.1
Olmesartan	19.7	15.7	14.8	15.0	65.2	-0.4	-0.6%	15.8	14.4	14.2		44.4
Olmetec/Olmetec Plus	11.1	9.3	8.6	8.7	37.8	-6.8	-15.2%	8.9	8.2	7.8		24.9
Sevikar	5.3	4.2	3.9	4.1	17.6	4.1	+30.2%	4.5	4.1	3.5		12.1
Sevikar HCT	3.3	2.1	2.2	2.2	9.9	2.3	+29.9%	2.5	2.2	2.8		7.4
Efient	1.2	1.2	1.3	1.1	4.8	0.1	+1.7%	1.1	1.1	1.1		3.3
Lixiana	-	-	-	-	-	-	-	0.0	0.1	0.5		0.7
Asia, South and Central America (ASCA)	15.1	14.8	18.9	18.6	67.5	8.8	+14.9%	21.4	21.3	19.9		62.6
Daiichi Sankyo China	5.4	6.1	7.3	8.5	27.4	6.1	+28.8%	7.9	8.6	8.3		24.8
Daiichi Sankyo Taiwan	1.2	1.1	1.2	1.3	4.9	0.4	+8.8%	1.4	1.3	1.3		4.0
Daiichi Sankyo Korea	2.7	1.7	2.0	2.5	8.9	-0.2	-2.0%	2.4	2.4	2.4		7.2
Daiichi Sankyo Thailand	0.7	0.9	1.0	1.0	3.7	1.2	+47.1%	0.8	1.0	1.1		2.9
Daiichi Sankyo Brasil Farmacêutica	2.3	2.0	2.6	1.5	8.4	0.9	+12.0%	2.6	1.9	2.1		6.7
Daiichi Sankyo Venezuela	1.2	1.8	2.9	2.1	8.1	1.2	+17.6%	3.1	2.4	1.6		7.1

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	429		1,196
Olmesartan	251	207	262	249	969	-151	-13.5%	237	232	257		727
Benicar/Benicar HCT	185	145	185	186	700	-156	-18.2%	163	168	187		519
Azor	40	38	48	41	166	-8	-4.4%	48	38	43		129
Tribenzor	26	24	30	23	103	13	+14.3%	26	26	27		79
Welchol	111	101	117	102	431	9	+2.2%	112	87	111		310
Effient	42	41	40	37	160	6	+3.7%	43	44	48		135
Savaysa				6	6	6	-	-2	1	4		2
Movantik				-	-	-	-	1	3	6		10
USD Mn												
Luitpold Pharmaceuticals, Inc. (US)	122	137	142	120	522	127	+32.1%	177	204	186		567
Venofer	70	68	75	47	260	12	+4.7%	75	57	69		200
Injectafer	14	14	19	22	69	56	+431.9%	32	33	41		106
EUR Mn												
Daiichi Sankyo Europe GmbH	175	146	140	141	602	-23	-3.6%	151	140	142		432
Olmesartan	141	114	103	112	470	-19	-3.8%	118	106	106		330
Olmetec/Olmetec Plus	79	68	60	65	272	-59	-17.9%	66	60	59		185
Sevikar	38	31	27	30	127	26	+26.1%	33	30	27		90
Sevikar HCT	24	15	15	17	71	15	+25.8%	18	16	21		55
Efient	8	8	9	8	34	-1	-1.6%	8	8	8		24
Lixiana	-	-	-	-	-	-	-	0	1	4		5

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

## 11. Major R&D Pipeline (Innovative pharmaceuticals)

**♦** Launched/Approved

Remarks
Launched in Ireland (15/9*), Netherlands (15/11)  * means Sep, 2015, ditto
Approved in Aug 2015
Launched in Ireland (15/9), Netherlands (15/11)
Approved in Aug 2015
e blood. Launched in Japan in July 2011 as the prevention of er 2014 and 60 mg tablet was launched in December 2014. ugust 2015.
Approved in July 2014 (KDSV) <u>Launched in December 2015</u>
<u>:hed</u> 

Underline: change after FY2015 Q2 Financial Announcement in Oct 2015

### ◆ Filed

Product Code Number/Generic Name	Class	Target indication	Region	Filing year/month
= db_	"	Atrial fibrillation (AF)	ASCA etc.	BR (14/6), TW (14/7), TH(15/7) AU(15/8), HK(15/8), CN(15/8), CA(15/8), <u>TR(15/10)</u>
Edoxaban	Factor Xa inhibitor	Venous thromboembolism (VTE)	ASCA etc.	BR (14/6), TW (14/7), TH(15/7) AU(15/8), HK(15/8), CN(15/8), CA(15/8), <u>TR(15/10)</u>
<summary> Γhe once daily oral anti coagulant (FXa inhi</summary>	bitor) discovered by Daiichi Sankyo. Ed	loxaban specifically, reversibly and directly inhibits the enzyn	ne, Factor Xa, a clotting factor in tl	he blood.
/N-100	Intradermal influenza HA vaccine	Prevention of seasonal Influenza	JP	Submitted by Japan Vaccine in April 2015
	offers a more easy-to-use, surefire me	oped by four companies [Daiichi Sankyo, Terumo, Japan Vac thod to administer the vaccine than current methods. The dev	•	Vaccine Co., Ltd.]. The intradermal injection device for this vaccion that it is the state of th
/N-101	Cell-culture H5N1 flu vaccine	Prevention of H5N1 influenza	JP	Submitted in August 2015 for pediatric use with optimal dose
<summary> This vaccine is a cell-culture H5N1 flu vacci</summary>	ne that has developed by Daiichi Sank	o and Kitasato Daiichi Sankyo Vaccine(KDSV). KDSV was s	submitted a supplemental application	on for optimization of pediatric use.

Underline: change after FY2015 Q2 Financial Announcement in Oct 2015

◆ 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
Denosumab	Anti-RANKL antibody	Breast cancer adjuvant	JP	P3	2020	Additional indication
Denosumab	Anti-NAINIL antibody	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 -	
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/Asia	<u>a</u> P3	2018	Relapsed and refractory AML patients
Quizartimo			<u>JP</u>	<u>P1</u>	-	
		Tenosynovial Giant Cell Tumor (TGCT)	US/EU	P3	2019	Including pigmented villonodular synovitis
		Glioblastoma	US	P2	-	
Pexidartinib/PLX3397	CSF-1R/KIT/FLT3-ITD inhibitor	Melanoma	US	P2	-	
		Melanoma, solid tumor	US	P1/2	-	Combination with pembrolizumab in collaboration with Merck
		Fibromyalgia	US/EU	P3	2019	
Mirogabalin	α2δ ligand	Diabetic peripheral neuropathic pain	JP/Asia	P3	2018	
		Postherpetic neuralgia	JP/Asia	P3	2018	
Hydromorphone	Opioid mu-receptor agonist	Cancer pain	JP	P3	2017	
CHS-0214	TNFlpha 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	JP	P3	2017	In-licensed from AZ/MedImmune. US trade name 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	-	
CS-3130	wit antagonist	Diabetic nephropathy	JP	P2b	-	
DS-8500	GPR119 agonist	Diabetes	JP/ <u>US</u>	P2	-	
		Non small cell lung cancer	US/EU	P2	-	
		Non small cell lung cancer	JP	P1	-	
Patritumab	Anti-HER3 antibody	Breast cancer	US	P2	-	
		Breast cancer	JP	P1	-	
		Head & neck cancer	EU	P1	-	
	NI		US/EU	P2	-	Out-licensing with Biota
Laninamivir	Neuraminidase inhibitor	Influenza	JP	P1	<u>-</u>	Nebulizer formulation
DS-1040	TAFla inhibitor	Acute ischemic stroke	-	P1	-	
DS-2330	Hyperphosphatemia treatment	Hyperphosphatemia in chronic kidney disease (CKD)	-	P1	-	
DS-9231/TS23	α2 plasmin inhibitor-inactivating antibody	Thrombosis (cardiovascular diseases, ischemic stroke)	-	P1	-	In-licensed from Translational Sciences Inc.
DS-9001	Anti-PCSK9 Anticalin-Albumod	<u>Dyslipidemia</u>	-	<u>P1</u>	-	
				<u></u>		

Underline: change after FY2015 Q2 Financial Announcement in Oct 2015

## ◆ Under development (Phase1-3)

Generic Name / Project code number	Class	Target indication		Stage	Remarks
DS-3032	MDM2 inhibitor	Solid cancer, lymphoma	US/JP	P1	-
D3-3032		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 conjugate	e Solid cancer	JP	P1	-
<u>U3-1784</u>	Anti-FGFR4 antibody	Solid cancer	<u>EU</u>	<u>P1</u>	-
<u>DS-1123</u>	Anti-FGFR2 antibody	Solid cancer	<u>JP</u>	<u>P1</u>	-
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>US</u>	P1	-
DS-2969	GyrB inhibitor	Clostridium difficile infection (CDI)	-	<u>P1</u>	-
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

Underline: change after FY2015 Q2 Financial Announcement in Oct 2015

◆ Stage-up (major changes from the FY2015 Q2 financial announcement in October 2015)

Generic Name / Project code number	Class	Target indication		Current stage	Remarks
E describe a	EV a l'abilité au	Atrial Fibrillation (AF)	EU	Launched	Ireland (15/9), Netherlands (15/11)
Edoxaban	FXa inhibitor	Venous thromboembolism (VTE)	ASCA etc.	Submitted	Turkey (15/10)
Precipitated and purified pertussis- diphtheria-tetanus-inactivated polio vaccine (Salk vaccine) vaccine [Brand Name: Squarekids]	DPT-IPV vaccine	Prevention of pertussis, diphtheria, tetanus and poliomyelitis	JP	Launched	Launched in December 2015
Quizartinib	FLT3-ITD inhibitor	A outo myoloid loukomio	Asia	P3	Relapsed and refractory AML patients
Quizartinio	FL13-11D INNIDITOR	Acute myeloid leukemia		P1	
DS-8500	GPR119 agonist	Diabetes	US	P2	
DS-9001	Anti-PCSK9 Anticalin-Albumod	Dyslipidemia	_	P1	
U3-1784	Anti-FGFR4 antibody	Solid cancer	EU	P1	
DS-1123	Anti-FGFR2 antibody	Solid cancer	JP	P1	
DS-2969	GyrB inhibitor	Clostridium difficile infection (CDI)	-	P1	

Note: Regarding prasugrel, results of the phase 3 study for the pediatric patients with sickle cell diseases were submitted to FDA as a sNDA in January 2016.

# ◆ Discontinue (major changes from the FY2015 Q2 financial announcement in October 2015)

Generic Name / Project code number	Class	Target indication		Stage
DS-1093	HIF-PH inhibitor	Anemia of chronic kidney disease	<b>"-</b>	P1
<reason> Daiichi Sankyo decided to discontinue the d</reason>	evelopment after reviewing its study result	S.		
DS-3801	GPR 38 agonist	Chronic obstipation	-	P1
Reason> Daiichi Sankyo decided to discontinue the d	evelopment after reviewing its study result	S.		
SUN13837	Modulator of bFGF signaling system	Spinal cord injury	US/EU	P2
<reason> Daiichi Sankyo decided to discontinue the d</reason>	evelopment after reviewing its study result	s.		
DS-8312	Hypertriglyceridemia treatment	Hypertriglyceridemia	-	P1
<reason> Daiichi Sankyo decided to discontinue the d</reason>	evelopment considering the portfolio.			
Nimotuzumab	Anti-EGFR antibody	Esophageal cancer	JP	P1
<reason> Daiichi Sankyo decided to discontinue the d</reason>	evelopment considering the portfolio.			
U3-1565	Anti-HB-EGF antibody	Solid cancer	US/JP	P1
U3-1565 <reason> Daiichi Sankyo decided to continue Investiga</reason>	<u> </u>		US/JP	Р

3

Therapeutic Area	Phase 1	Phase 2	Phase 3	Application
	DS-1040 (Acute ischemic stroke / TAFla inhibitor)  DS-8312	CS-3150 (JP) (Hypertension / MR antagonist)  CS-3150 (JP)	Prasugrel (JP) (CS-747 / Ischemic stroke / Anti-platelet agent)  Prasugrel (US)	Edoxaban (ASCA etc.) (DU-176b / AF / Oral factor Xa inhibitor)  Edoxaban (ASCA etc.)
Cardiovascular	—(Hypertriglyceridemia)—  DS-2330 (Hyperphosphatemia)	(Diabetic nephropathy / MR antagonist)  DS-8500 (JP/US)  (Diabetes / GPR119 agonist)	-(CS-747 / Sickle cell disease / Anti-platelet agent)	(DU-176b / VTE / Oral factor Xa inhibitor)
	DS-9231/TS23 (Thrombosis (cardiovascular diseases, ischemic stroke)/α2 plasmin inhibitor-inactivating antibody)			
	DS-9001 (Dyslipidemia / Anti-PCSK9 Anticalin-Albumod)			
	<del>U3-1565</del> (US/JP) (Anti-HB-EGF antibody)	Patritumab (US/EU) (U3-1287 / Anti-HER3 antibody)	<b>Tivantinib (US/EU)</b> (ARQ 197 / HCC / MET inhibitor)	
	DS-3032 (US/JP) (MDM2 inhibitor)	Pexidartinib (US) (PLX3397 / CSF-1R/KIT/FLT3-ITD inhibitor)	<b>Denosumab (JP)</b> (AMG 162 / Breast cancer adjuvant / Anti-RANKL antibody)	
	PLX7486 (US) (FMS/TRK inhibitor)		Nimotuzumab (JP) (DE-766 / Gastric cancer / Anti-EGFR antibody)	
	<b>DS-8895 (JP)</b> (Anti-EPHA2 antibody)		Vemurafenib (US/EU) (PLX4032 / Melanoma adjuvant / BRAF inhibitor)	
	<b>DS-8273 (US)</b> (Anti-DR5 antibody)		Quizartinib (US/EU/ <u>Asia</u> ) (AC220 / AML / FLT3-ITD inhibitor)	
	PLX8394 (US) (BRAF inhibitor)		Pexidartinib (US/EU) (PLX3397 / TGCT / CSF1R/KIT/FLT3-ITD inhibitor)	
Oncology	<b>DS-6051 (US)</b> (NTRK/ROS1 inhibitor)			
	<b>DS-5573 (JP)</b> (Anti-B7-H3 antibody)			
	PLX9486 (US) (KIT inhibitor)			
	<b>DS-8201 (JP)</b> (Anti-HER2 ADC)			
	U3-1784 (EU) (Anti-FGFR4 antibody)			
	DS-1123 (JP) (Anti-FGFR2 antibody)			
	DS-1093  (Anemia of chronic kidney disease/HIF-PH inhibitor)	SUN13837 (US/EU)  -(Spinal cord injury / Modulator of bFGF signaling system)	<b>Mirogabalin (US/EU)</b> (DS-5565 / Fibromyalgia / α2δ ligand)	Intradermal Seasonal Influenza Vaccine (VN-100 / prefilled i.d. vaccine for seasonal flu)
	DS-3801  (Chronic obstipation/GPR38 agonist)	Laninamivir (US/EU) (CS-8958 / Anti-influenza / Out licensing with Biota)	<b>Mirogabalin (JP/Asia)</b> (DS-5565 / DPNP / α2δ ligand)	VN-101 (JP) (Cell-culture H5N1 Influenza vaccine)
	<b>DS-1971</b> (Chronic pain)		<b>Mirogabalin (JP/Asia)</b> (DS-5565 / PHN / α2δ ligand)	
	<b>DS-1501</b> (Osteoporosis / Anti-Siglec-15 antibody)		<b>Denosumab (JP)</b> (AMG 162 / Rheumatoid arthritis / Anti-RANKL antibody)	
Others	<b>DS-7080 (<u>US</u>)</b> (AMD / Angiogenesis inhibitor)		Hydromorphone (JP) (DS-7113 / Cancer pain/ Opioid mu-receptor agonist)	
	DS-2969 (CDI / GyrB inhibitor)		CHS-0214 (JP) (Etanercept BS / Rheumatoid arthritis / TNFa inhibitor)	
	VN-0102/JVC-001 (JP) (Measles/Mumps/Rubela vaccine)		CL-108 (US) (Acute pain / Opioid mu-receptor agonist combination)	
			VN-0105 (JP) (DPT-IPV/Hib vaccine)	
			VN-0107/MEDI3250 (JP) (Seasonal Flu/Live attenuated influenza vaccine)	

### **Cardiovascular-Metabolics**

[ Project after Phase 2 ]

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)

#### <Summary>

The once daily oral anti coagulant (FXa inhibitor). Edoxaban specifically, reversibly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood. Launched in Japan in July 2011 as the prevention of venous thromboembolism (VTE) in patients with total knee arthroplasty, total hip arthroplasty and hip fracture 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, Ireland: Sep 2015, Netherlands: Nov 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	Daiichi Sankyo Ube Industries	Effient (US, Asia) Efient (JPN, EU)

#### <Summary>

The oral antiplatelet agent. Prasugrel helps to keep blood platelets from clumping together and developing a blockage in an artery.

- Co-development with Eli Lilly in the US and EU, development by Daiichi Sankyo in Japan.
- [JP] Approved in Mar-2014 for the ischemic heart disease undergoing PCI and launched in May-2014. P3 studies for ischemic stroke are on-going.
- [US] P3 study in pediatric sickle cell disease patients was conducted. The study data was provided to US FDA as supplemental NDA (sNDA).

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.

- Ph2a study in essential hypertension in Japan was completed.
- Ph2a study in diabetes with albuminuria in Japan was completed. On January 2015, Ph2bs 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.

Oncology

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	InnoCIMAb	TBD

#### <Summary>

The humanized monoclonal antibody to target Epidermal Growth Factor Receptor(EGFR). This antibody is expected to be a best in class EGFR, safety against the skin toxicity and the efficacy comparable to the other antibodies.

P3 in Japan for Gastric cancer started in April 2013.

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	<ul><li>Non small cell lung cancer</li><li>Breast cancer</li><li>Head and neck cancer</li></ul>	Daiichi Sankyo (U3 Pharma)	TBD

#### <Summary>

The fully human monoclonal antibody to target HER3, one of the Epidermal Growth Factor Receptor (EGFR) family of proteins. HER 3 is overexpressed in many tumors of epithelial 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	Target Indication	Origin	Brand Name
Vemurafenib	PLX4032	Oral	BRAF inhibitor	- Melanoma adjuvant	Daiichi Sankyo (Plexxikon)	Zelboraf

#### <Summarv>

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 approved in US on November 11, 2015. 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	CSF-1R/KIT/FLT3-ITD inhibitor	- Tenosynovial Giant Cell Tumor - Glioblastoma - Melanoma	Daiichi Sankyo (Plexxikon)	TBD

#### <Summary>

The molecular-targeted agent to inhibit CSF-1R, Kit and Flt3-ITD. This agent is expected to reduce tumor cell proliferation and expansion of metastases.

### **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

#### <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).

Marketed in Dec 2015.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Intradermal Seasonal Influenza Vaccine	VN-100	Injection (prefilled syringe)	Seasonal flu vaccine	- Prevention of seasonal influenza	Daiichi Sankyo (KDSV) Terumo	TBD

#### <Summary>

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 flu vaccine approved in Mar. 2014 for pediatric use.

•Ph3 study in Japan started in Jul. 2014. Submitted sNDA in Aug 2015.

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Denosumab	AMG 162	Injection	Anti-RANKL antibody	- Breast cancer adjuvant - Rheumatoid arthritis	Amgen	SRE, GCTB: Ranmark(JP) Osteoporosis: Pralia(JP)

#### <Summary>

The fully human monoclonal antibody to target RANK Ligand, an essential mediator of osteoclast formation. Launched in Japan in April 2012 as treatment for bone complications stemming from multiple myeloma and bone metastases from solid tumors, in June 2013 as treatment for osteoporosis, and in May 2014 as treatment for giant cell tumor of bone.

- July, 2007 In-licensed from Amgen.
- P3: Breast cancer adjuvant, Rheumatoid arthritis.

code Number Form		Brand Name
- CHS-0214 Injection TNFα inhibitor - Rheumatoid arthritis	Coherus	TBD

#### <Summary>

Biosimilar product for etanercept

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

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>

Combination product of immediate-release promethazine, hydrocodone and acetaminophen. Reduction of Opioid-Induced Nausea and Vomiting is expected.

Under NDA preparation in collaboration with Charleston Laboratories

Generic Name	Project code Number	Dosage Form	Class	Target Indication	Origin	Brand Name
Mirogabalin	DS-5565	Oral	α2δ ligand	<ul><li>Fibromyalgia</li><li>Diabetic peripheral neuropathic pain</li><li>Postherpetic neuralgia</li></ul>	Daiichi Sankyo	TBD

#### <Summary>

The pain therapy agent to reduce the neurotransmitter release from nerve terminals. This agent is expected to show the good balanced efficacy and safety profile.

- •Ph2 studies for diabetic peripheral neuropathic pain were completed.
- Ph3 studies for diabetic peripheral neuropathic pain and postherpetic neuralgia are in execution .
- Ph3 studies for fibromyalgia are in execution .

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>

The opiate, narcotic analgesic that has been available outside of Japan for over 80 years and recommended in WHO guideline as a standard analgesia for cancer pain. It is designated as unapproved drug by "Study Group on Unapproved and Off-label Drugs of High Medical Need."

•Ph2 and Ph3 studies for immediate-release tablet and Ph3 studies for extended-release tablet were completed. Ph2/3 studies for injection formulation are ongoing.

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

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	Target Indication	Origin	Brand Name
-	VN-0105	Injection	DPT-IPV/Hib vaccine	- Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib	Daiichi Sankyo (KDSV) Sanofi Pasteur	TBD

A combination vaccine reconstituting Hib with precipitated and purified pertussis-diphtheria-tetanus-inactivated polio vaccine (Salk vaccine) vaccine previously licensed and launched in Japan, as 1st in the class of pentavalent vaccine (DPT-IPV/Hib).

Ph3 study in Japan started in Oct 2014.