

Results Briefing

Results for Q1 FY2015 (April 1 – June 30, 2015)

DAIICHI SANKYO CO., LTD

Joji Nakayama
President and CEO

July 31, 2015

- ◆ FY2015 Q1 Results
- ◆ FY2015 revised consolidated forecast
- ◆ Edoxaban update
- ◆ R&D Topics

FY2015 Q1 Results

Overview of FY2015 Q1 Results

(JPY Bn)



	FY2014 Q1 Results *1	FY2015 Q1 Results	YoY	
Revenue	213.7	238.4	+11.6% +24.7	
Cost of Sales	64.6	74.0	+9.4	
SG&A Expenses	74.9	71.6	-3.3	
R&D Expenses	41.4	43.7	+2.3	
Operating Profit	32.8	49.1	+49.8% +16.3	
Profit before tax	32.7	45.2	+12.5	
Profit attributable to owners of the Company	21.6	34.9	+61.9% +13.4	
Currency Rate	USD/JPY	102.16	121.37	+19.21
	EUR/JPY	140.06	134.16	-5.9

*1 FY2014 Q1 Results have been restated and indicated as only the values for continuing operations excluding Ranbaxy.

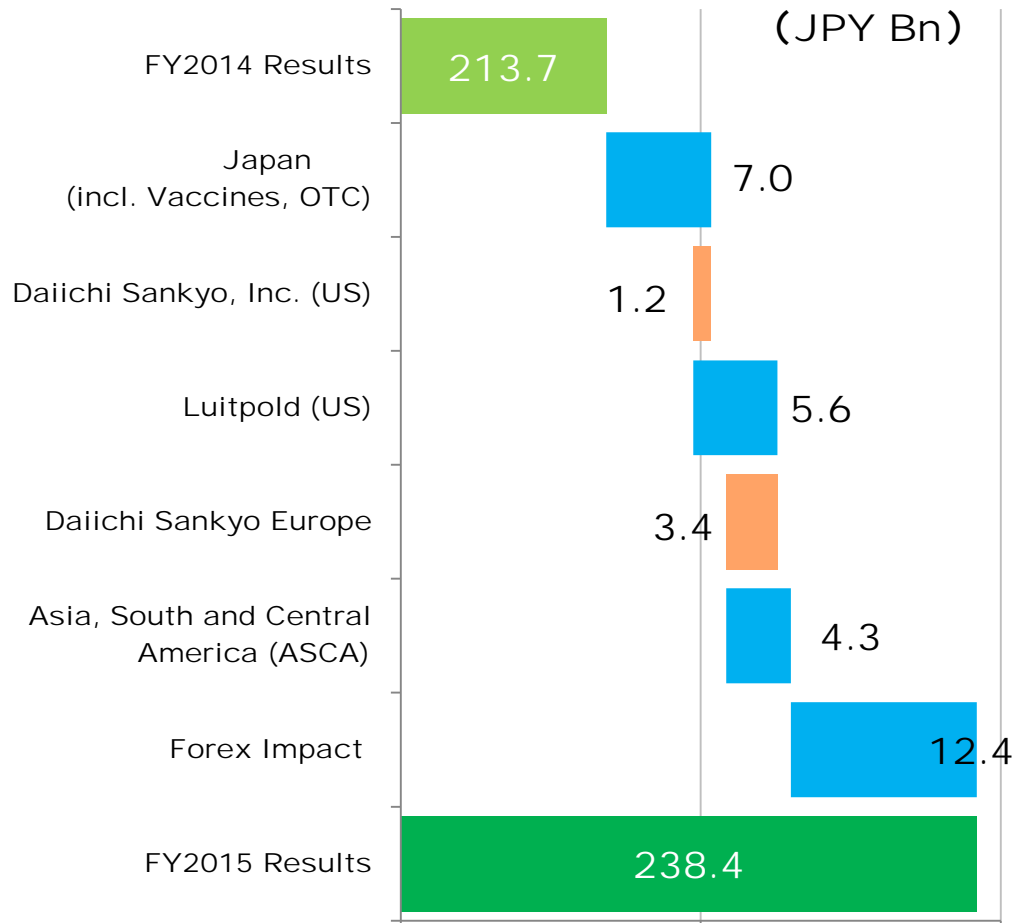
FY2015 Q1 Revenue

Positive Factors

Negative Factors



Increased by 24.7 JPY Bn
Decline in Daiichi Sankyo Inc. and Daiichi Sankyo Europe
offsetted by growth of Japan, Luitpold and ASCA with Forex



Japan
 Positive: Nexium +3.8 Memary +2.4
 Lixana +2.0 Pralia +1.3
 Efient +1.0
 Negative: Cravit -2.3 Artist -0.7

Global (excl. Forex Impact)
 Daiichi Sankyo Inc. : Olmesartan -1.4
 Luitpold : Venofer +0.5
 Injectafer +1.8
 Daiichi Sankyo Europe : Olmesartan -3.3

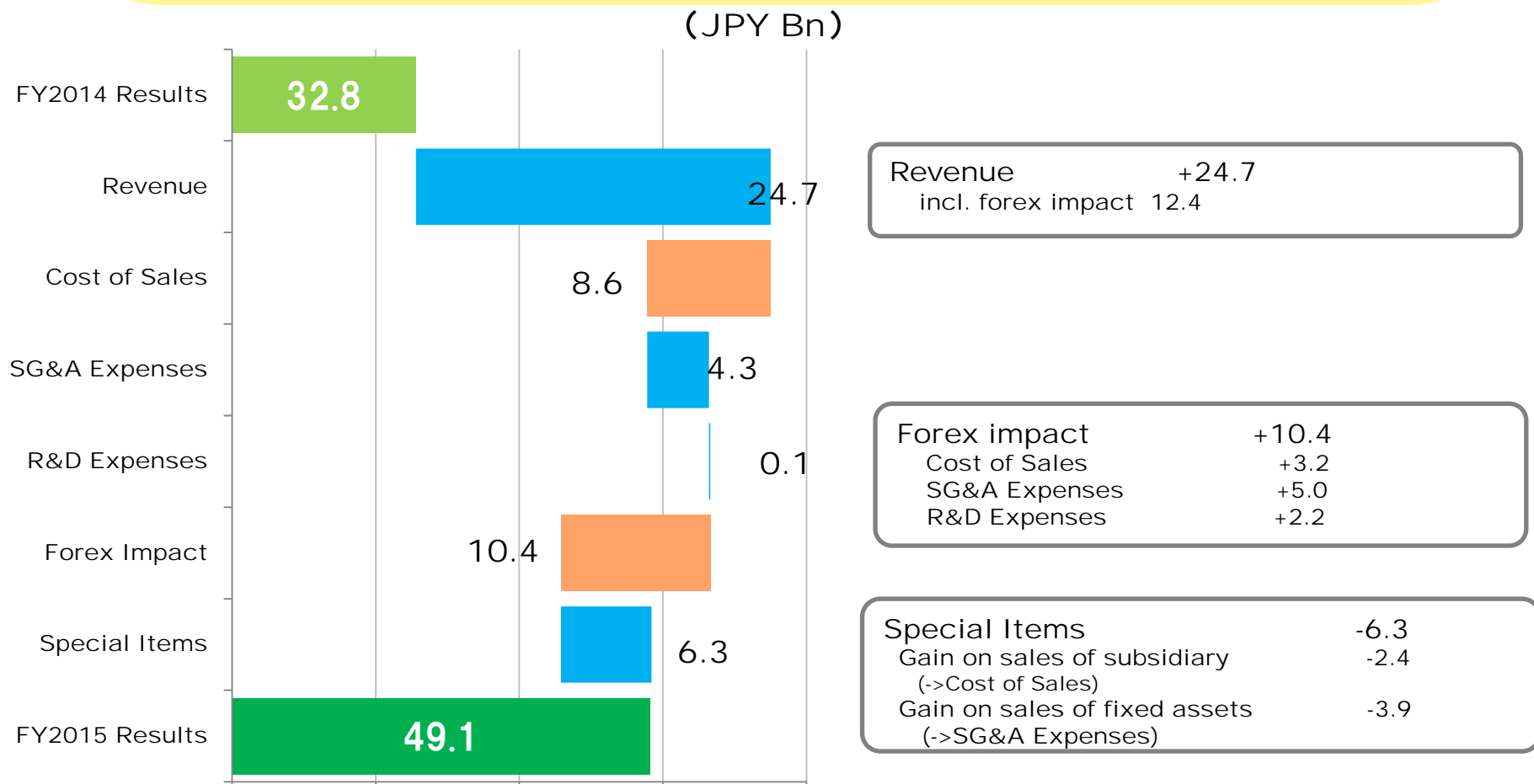
FY2015 Q1 Operating Profit

Positive
Factors

Negative
Factors



Increased by 16.3 JPY Bn
due to increased revenue and decreased R&D and SG&A expenses
absorbing increased cost of sales and forex impact



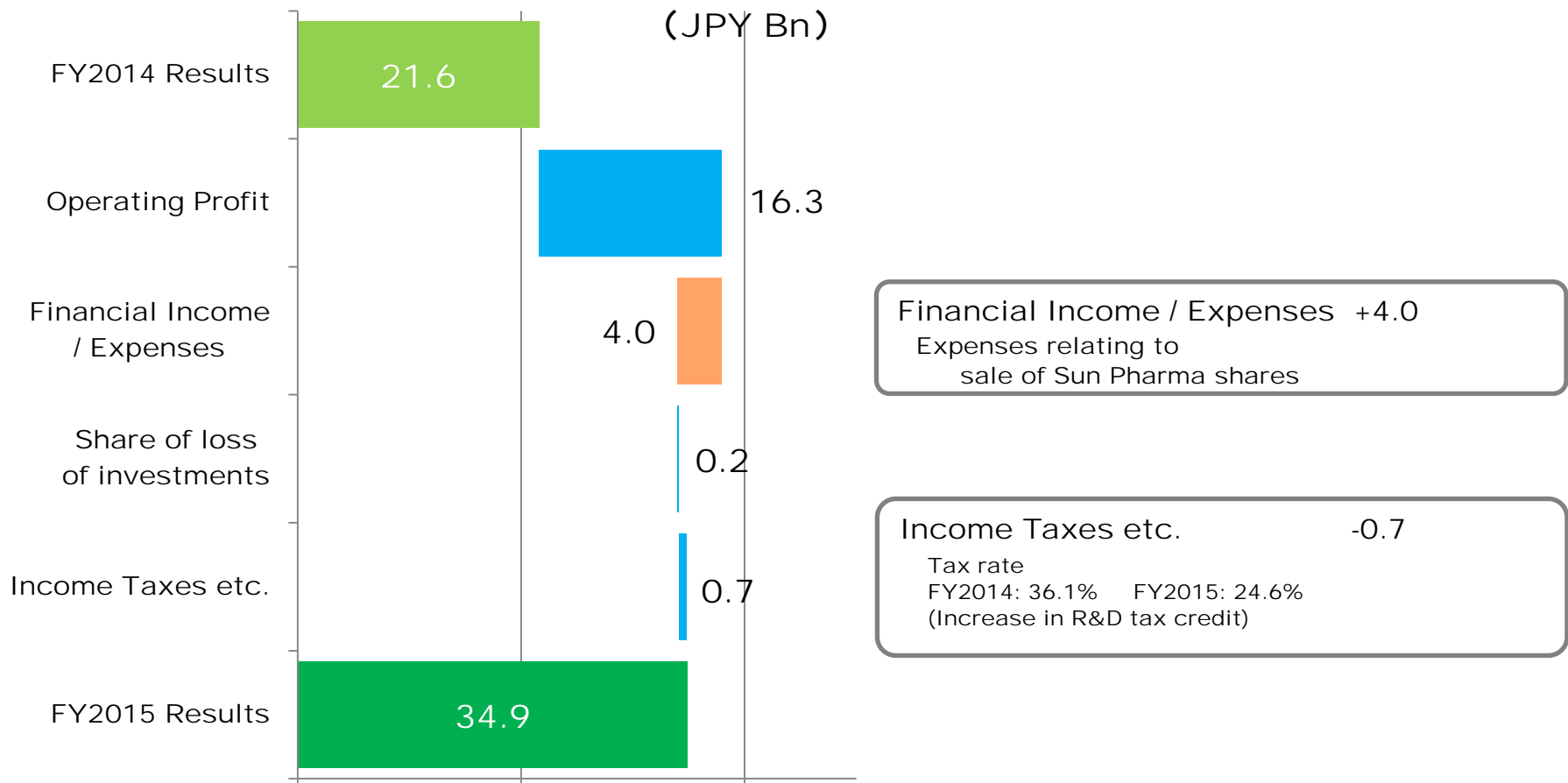
FY2015 Q1 Profit attributable to owners of the Company

Positive Factors

Negative Factors



Increased by 13.4 JPY Bn due to increased operating profit
 Expenses relating to the sales of the Sun Pharma shares is booked as financial expenses



Major business units

(JPY Bn)



	FY2014 Q1 Results	FY2015 Q1 Results	YoY	vs. Forecast (%)
Japan	108.0	114.2	+6.2	23%
Daiichi Sankyo Healthcare	9.4	10.8	+1.4	23%
Daiichi Sankyo Inc.	41.6	48.0	+6.4	29%
Olmesartan	25.7	28.8	+3.1	29%
Welchol	11.3	13.5	+2.2	37%
Effient	4.2	5.2	+1.0	-
Savaysa	-	-0.3	-0.3	-
Movantik	-	0.2	+0.2	-
Luitpold	12.5	21.5	+9.1	28%
Venofer	7.2	9.1	+1.9	33%
Injectafer	1.5	3.9	+2.4	23%
Daiichi Sankyo Europe	24.5	20.2	-4.3	27%
Olmesartan	19.7	15.8	-3.9	28%
Efient	1.2	1.1	-0.0	-
Lixiana	-	0.0	+0.0	1%
Asia, South and Central America (ASCA)	15.1	21.4	+6.3	24%

Major products in Japan

		(JPY Bn)			
		FY2014 Q1 Results	FY2015 Q1 Results	YoY	vs. Forecast (%)
Olmetec	anti-hypertension	18.7	18.5	-0.3	23%
Nexium	anti-ulcer (Proton Pump Inhibitor)	15.3	19.1	+3.8	26%
Memary	treatment for Alzheimer	7.9	10.2	+2.4	22%
Loxonin	analgesic and anti-inflammatory	12.2	12.6	+0.3	29%
Cravit	antibacterial	6.9	4.6	-2.3	27%
Rezaltas	anti-hypertension	4.5	4.6	+0.1	24%
Artist	anti-hypertension	4.8	4.1	-0.7	24%
Omnipaque	contrast medium	4.2	4.2	-0.0	26%
Mevalotin	anti-hyperlipidemia	4.2	3.6	-0.6	26%
Ranmark	treatment for bone metastasis	2.1	2.9	+0.8	22%
Urief	treatment for dysuria	2.7	2.9	+0.1	26%
Pralia	osteoporosis	1.3	2.6	+1.3	26%
Lixiana	anticoagulant	0.1	2.1	+2.0	19%
Efient	antiplatelet	0.2	1.2	+1.0	23%
Teneria	treatment for type 2 diabetes	1.5	2.4	+0.9	-

FY2015 revised consolidated forecast

FY2015 revised consolidated forecast

(JPY Bn)

	FY 2015 Original Forecast (May)	FY 2015 Revised Forecast (July)	vs. Original Forecast
Revenue	920.0	950.0	+30.0
Cost of Sales	300.0	302.0	+2.0
SG&A Expenses	330.0	338.0	+8.0
R&D Expenses	190.0	190.0	0.0
Operating Profit	100.0	120.0	+20.0
Profit before tax	95.0	115.0	+20.0
Profit attributable to owners of the Company	60.0	75.0	+15.0

Due to delay of launch of GE products for Welchol and further expansion in some products including Injectafer

Due to further investment for increasing sales in the U.S.

Currency Rate	USD/JPY	120.00	120.34
	EUR/JPY	130.00	131.04

Forecast for Q2, Q3 and Q4
USD/JPY:120 EUR/JPY:130

Summary of revised revenue forecast

(JPY Bn)

	FY 2015 Original Forecast (May)	FY 2015 Revised Forecast (July)	vs. Original Forecast
Japan	488.0	488.0	-
Olmotec	80.0	79.0	-1.0
Cravit	21.0	17.0	-4.0
Lixiana	5.0	11.0	+6.0
Daiichi Sankyo Inc.	140.0	166.0	+26.0
Welchol	9.0	37.0	+28.0
Savaysa	4.0	2.0	-2.0
Luitpold	72.0	76.0	+4.0
Venofer	27.0	28.0	+1.0
Injectafer	15.0	17.0	+2.0

Sales forecast in Japan remains the same as May, although some products has been revised

Welchol;
Due to delay of GE products entry


Savaysa;
Taking the situation of negotiation with payers into account

Venofer and Injectafer;
Further growth


Edoxaban update

Edoxaban update

Launch and development
for making Edoxaban a flagship product after olmesartan
Global sales forecast in FY2015: 14.7 JPY Bn

-  JPN
 - Making a good start (especially in VTE)
 - Revised sales forecast (5.0 JPY Bn→11.0 JPY Bn)

-  US
 - Negotiation with payers to be listed in formularies of Part-D is on going
 - Revised sales forecast (4.0 JPY Bn→2.0 JPY Bn)

-  EU
 - Launched in Switzerland in May
 - Approved by EC/EMA in June and positively recommended for VTE by NICE in July
 - Launch readiness in Germany, Ireland and UK
 - Sales forecast: 1.7 JPY Bn

- ◆ Other region
 - Applications for approval are underway in Taiwan, Korea and Brazil, and an application for approval was filed in Thailand in July

- ◆ LCM
 - The Hokusai-VTE Cancer study for patients with venous thromboembolism associated with cancer was initiated in June

R&D Topics

Major R&D pipeline

As of July 2015



Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular-Metabolics	<ul style="list-style-type: none"> ■ DS-1040 (Acute ischemic stroke / TAFIA inhibitor) ■ DS-8312 (Hypertriglyceridemia) 	<ul style="list-style-type: none"> ■ CS-3150 (JP) (Hypertension • DM nephropathy / MR antagonist) ■ DS-8500 (JP) (Diabetes / GPR119 agonist) 	<ul style="list-style-type: none"> ■ Prasugrel (JP) (CS-747 / ischemic stroke / anti-platelet agent) ■ Prasugrel (US) (CS-747 / sickle cell disease / anti-platelet agent) 	<ul style="list-style-type: none"> ■ Edoxaban (ASCA) (DU-176b / AF / oral factor Xa inhibitor) ■ Edoxaban (ASCA) (DU-176b / VTE / oral factor Xa inhibitor)
Oncology	<ul style="list-style-type: none"> ■ U3-1565 (US/JP) (Anti-HB-EGF antibody) ■ DS-3032 (US/JP) (MDM2 inhibitor) ■ PLX7486 (US) (FMS / TRK inhibitor) ■ DS-8895 (JP) (Anti-EPHA2 antibody) ■ DS-8273 (US) (Anti-DR5 antibody) ■ PLX8394 (US) (BRAF inhibitor) ■ DS-6051 (US) (NTRK / ROS1 inhibitor) ■ DS-5573 (JP) (Anti-B7-H3 antibody) ■ PLX9486 (US) (KIT inhibitor) 	<ul style="list-style-type: none"> ■ Patritumab (US/EU) (U3-1287 / anti-HER3 antibody) ■ PLX3397 (US) (FMS/KIT/FLT3-ITD inhibitor) 	<ul style="list-style-type: none"> ■ Tivantinib (US/EU) (ARQ 197 / HCC / MET inhibitor) ■ Denosumab (JP) (AMG 162 / breast cancer adjuvant / anti-RANKL antibody) ■ Nimotuzumab (JP) (DE-766 / gastric cancer / anti-EGFR antibody) ■ Vemurafenib (US/EU) (PLX4032 / melanoma adjuvant / BRAF inhibitor) ■ Quizartinib (US/EU) (AC220 / AML / FLT3-ITD inhibitor) ■ PLX3397 (US/EU) (TGCT / FMS/KIT/FLT3-ITD inhibitor) 	
Others	<ul style="list-style-type: none"> ■ DS-1093 (Anemia of chronic kidney disease / HIF-PH inhibitor) ■ DS-3801 (Chronic obstipation / GPR38 agonist) ■ DS-1971 (Chronic pain) ■ DS-1501 (Osteoporosis / Anti-Siglec-15 antibody) 	<ul style="list-style-type: none"> ■ SUN13837 (US/EU) (Spinal cord injury / modulator of bFGF signaling system) ■ Laninamivir (US/EU) (CS-8958 / anti-influenza / out-licensing with Biota) ■ Ioforninol (JP) (GE-145 / X-ray contrast media / angiography) 	<ul style="list-style-type: none"> ■ Mirogabalin (US/EU) (DS-5565 / fibromyalgia / α2δ ligand) ■ Mirogabalin (JP/Asia) (DS-5565 / DPNP/ α2δ ligand) ■ Mirogabalin (JP/Asia) (DS-5565 / PHN / α2δ ligand) ■ Denosumab (JP) (AMG 162 / rheumatoid arthritis / anti-RANKL anti-body) ■ Hydromorphone (JP) (DS-7113 / cancer pain / opioid μ-receptor regulator) ■ CHS-0214 (JP) (Etanercept BS / rheumatoid arthritis / TNFα inhibitor) ■ CL-108 (US) (Acute pain / opioid μ-receptor regulator) ■ VN-101 (JP) (Cell-culture H5N1 Influenza vaccine) ■ VN-0105 (JP) (DPT-IPV/Hib vaccine) 	<ul style="list-style-type: none"> ■ Levofloxacin (JP) (DR-3355 / anti-infection / New quinolone) ■ Intradermal Seasonal Influenza Vaccine (JP) (VN-100 /prefilled i.d. vaccine for seasonal flu)

Initiated new clinical trials

- ◆ Tenosynovial Giant Cell Tumor (TGCT) Phase 3 study
 - Initiated in May 2015
 - Result of the Phase 1 study was published in NEJM in July 2015
 - ✓ 12 out of 23 patients (52 %) achieved a partial response (PR) and 7 patients (30 %) had stable disease (SD)
 - NDA targeted for FY2018 and approval for FY2019 in US/EU

- ◆ Combination with PD-1 inhibitor pembrolizumab Phase 1/2 study in collaboration with Merck
 - Initiated in July 2015
 - Rationale: to attack cancer cells in different immune-related systems
 - Target cancer: advanced melanoma and multiple other solid tumors
 - Part1: investigation of safety of PLX3397 in combination
Part 2: extension cohort at the RP2D

Update on major late stage products

Quizartinib: FLT3-ITD inhibitor

QuANTUM-R* Phase 3 study in progress

* Quizartinib Advancement into the Next Generation of Trial for Unmet Needs in AML

- Second-line therapy for relapsed or refractory FLT3-ITD-positive acute myeloid Leukemia
- Determine overall survival rate (primary outcome measure) and event-free survival rate (secondary outcome) with quizartinib vs. salvage chemotherapy
- Expect high efficacy and safety with low dose
- US/EU: NDA targeted for FY2017 and approval targeted for FY2018

<Reference> increased safety at lower dose without affecting efficacy

	Phase 2b low dose		Phase 2		
	30 mg/day (N=38)	60 mg/day (N=38)	90 mg/day (N=57)	135 mg/day (N=67)	200 mg/day (N=12)
Best response					
CRc rate	47 %	47 %	47 %	45 %	42 %
PR rate	13 %	24 %	25 %	28 %	50 %
Maximum change in QTcF from baseline (msec)					
≤30	50 %	44 %	9 %	9 %	0 %
>30 to ≤ 60	47 %	36 %	46 %	51 %	8 %
>60	3 %	19 %	46 %	39 %	92%

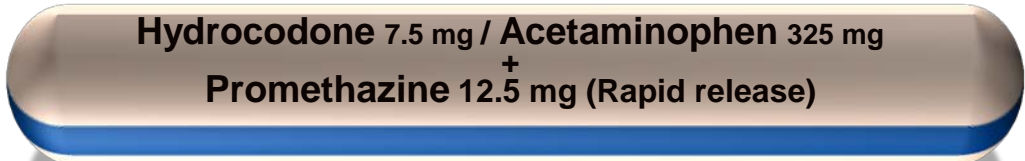
CRc=CR+CRp+CRi (CRc: composite complete response, CR: complete remission, CRp: complete remission with incomplete platelet recovery, CRi: complete remission with incomplete hematologic recovery), PR: partial response

Update on major late stage products

CL-108*: Hydrocodone combination with less Opioid-Induced Nausea and Vomiting, OINV

Phase 3 studies on track, NDA in FY2015

- ◆ Novel, bi-layered tablet provides anti-emetic activity prior to hydrocodone effect



Hydrocodone 7.5 mg / Acetaminophen 325 mg
+
Promethazine 12.5 mg (Rapid release)

- ◆ Phase 3 studies to confirm effect on moderate to severe acute pain as well as the reduction of OINV
 - Post tooth extraction pain: completed
 - ✓ CL-108, compared to HC/APAP demonstrated a significant reduction in OINV
CL-108 36% vs. HC/APAP 58% (p<0.001)
 - Osteoarthritis of the knee or hip pain
 - ✓ completed enrollment in April 2015
 - Pain associated with bunionectomy : on schedule
- ◆ US NDA: Targeted for FY2015
US Approval: Targeted for FY2016

**Exclusive license for US commercialization from Charleston Laboratories Inc.*

Update on major late stage products

Mirogabalin: **α2δ** ligand

Phase 3 studies in each region : on track

◆ US/EU: Fibromyalgia

- Three phase 3 studies for fibromyalgia: in progress
- NDA: targeted for FY2017
Approval: targeted for FY2019

◆ JP/Asia: Peripheral Neuropathic Pain

- Phase 3 studies for diabetic peripheral neuropathic pain and postherpetic neuralgia: in progress
- NDA: targeted for FY2017
Approval: targeted for FY2018

Contact address regarding this material

Daiichi Sankyo Co., Ltd.
Corporate Communications Department

TEL: +81-3-6225-1126

Financial forecasts, future projections and R&D information that Daiichi Sankyo discloses may include information that might be classified as "Forward Looking Statement". These forward looking statements represent our current assumptions basis on information currently available. Please note that such are subject to a number of known and unknown risk and uncertainties and our future performance may differ from the expectations as expressed in such statements.