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Compassion for Patients.™



# Top Management Presentation

## Financial Results of FY2016 Q1

**DAIICHI SANKYO CO., LTD**

**Joji Nakayama**  
President and CEO

**July 29, 2016**

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- ◆ **FY2016 Q1 Financial Results**
  
- ◆ **Major Management Topics**
  - **Edoxaban Update**
  - **Expansion of Product Portfolio in Japan**
  - **Enrichment of Shareholder Returns**
  - **Securing Stable, Low Cost Funding**
  - **R&D Topics**

# FY2016 Q1 Financial Results

# Overview of FY2016 Q1 Results

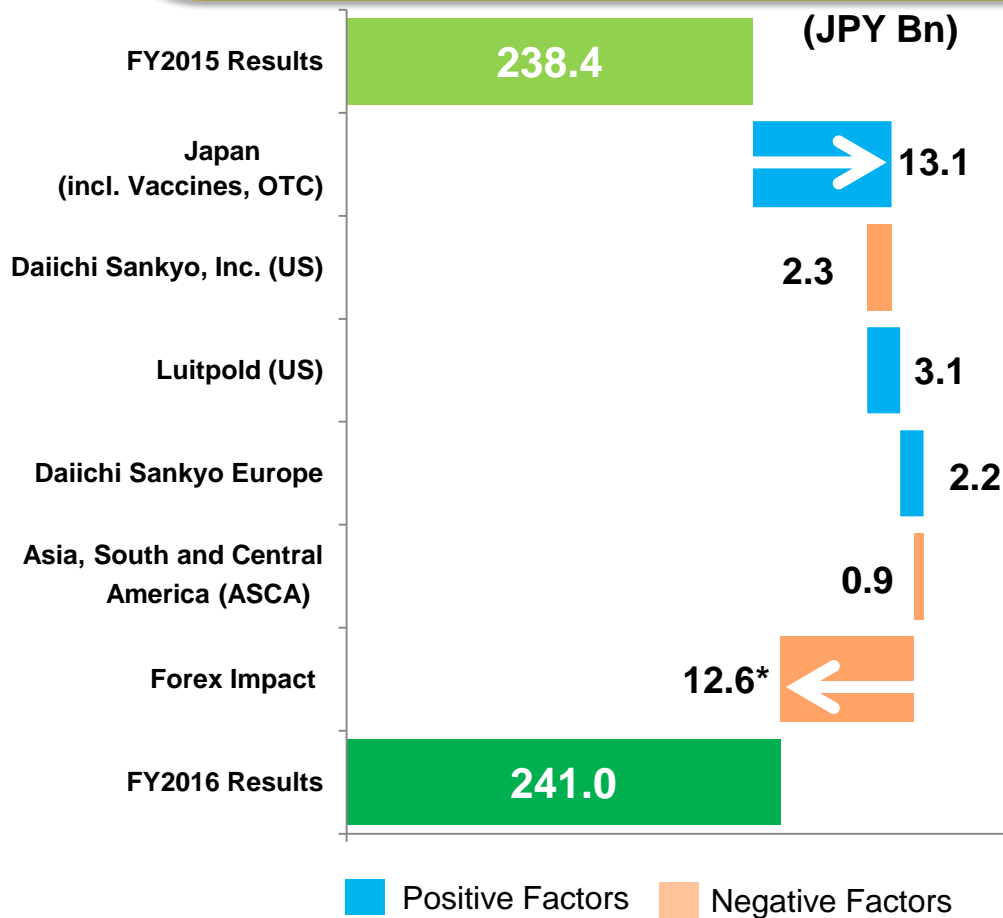
(JPY Bn)

	FY2015 Q1 Results	FY2016 Q1 Results	YoY
Revenue	238.4	241.0	+1.1% <b>+2.6</b>
Cost of Sales	74.0	77.6	<b>+3.7</b>
SG&A Expenses	71.6	69.5	<b>-2.1</b>
R&D Expenses	43.7	46.6	<b>+2.9</b>
Operating Profit	49.1	47.3	-3.8% <b>-1.9</b>
Profit before Tax	45.2	45.2	<b>0.0</b>
Profit attributable to owners of the Company	34.9	30.6	-12.4% <b>-4.3</b>

Currency Rate	USD/JPY	121.37	108.25	-13.12
	EUR/JPY	134.16	122.17	-11.99

# Revenue

**Increased by 2.6 Bn JPY**  
**despite negative effects of NHI price revision, growing numbers of generic drug prescriptions, and yen appreciation, revenue increased due to growth in sales of mainstay products in Japan, US, Europe and Asia**



**Japan**

Positive :	Tenelia	+4.3	Lixiana	+3.4
	Nexium	+1.9	Memary	+1.9
	Pralia	+1.6	Effient	+1.3
	Ranmark	+0.5	DSHC	+4.0
Negative :	Loxonin	-2.3	Artist	-1.0
	Cravit	-0.9	Mevalotin	-0.6

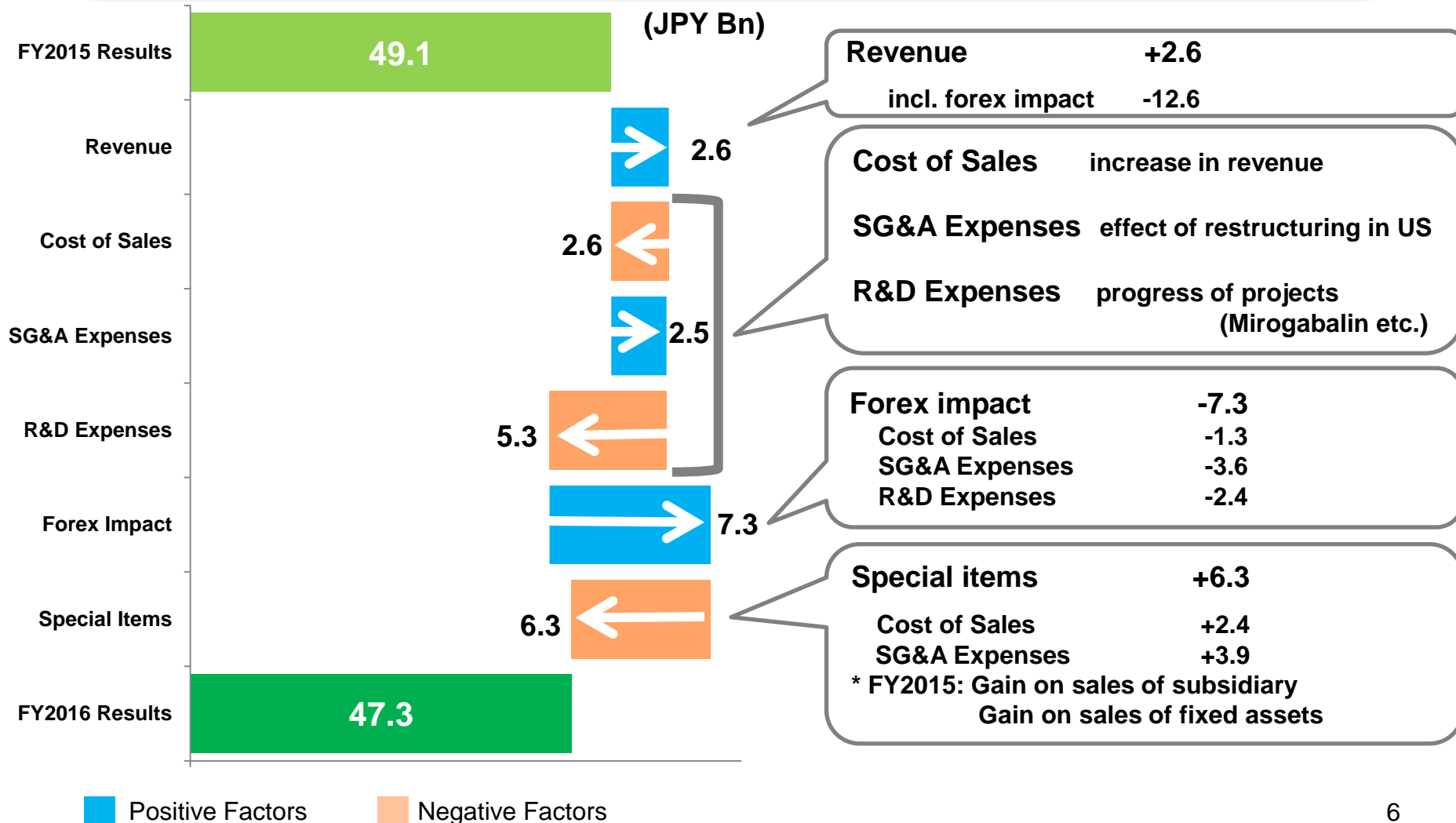
**Global (excl. Forex Impact)**

Daiichi Sankyo, Inc. :	Olmesartan	-2.8
	Welchol	-2.4
	Effient	+1.5
	Movantik	+0.8
Luitpold :	Injectafer	+2.8
Daiichi Sankyo Europe :	Olmesartan	-0.5
	Lixiana	+1.6
	Effient	+1.4

\*Forex impact USD: -7.8, EUR: -2.0, ASCA: -2.8

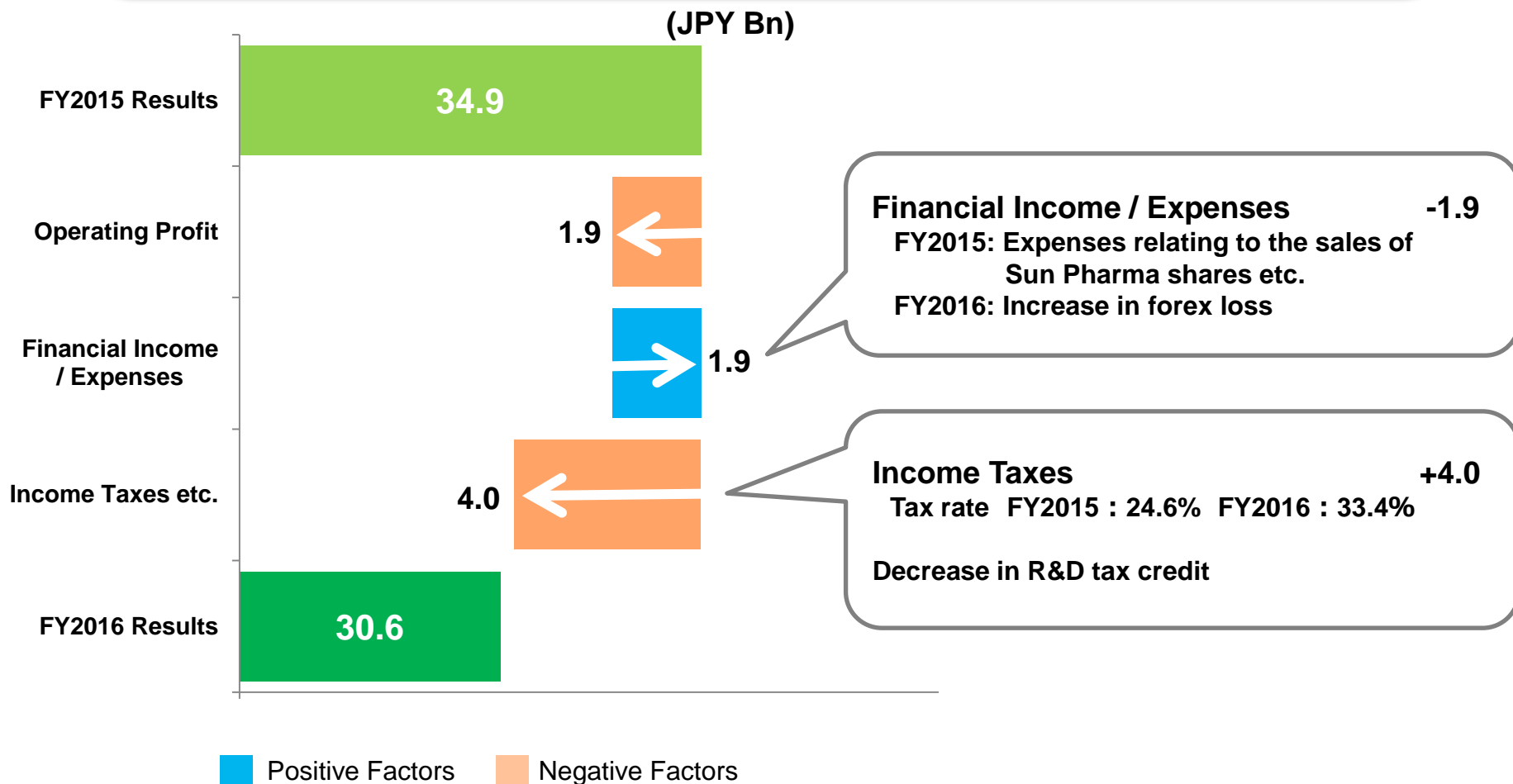
# Operating Profit

**Slightly decreased by 1.9 Bn JPY  
as special items (Gain on sale of fixed assets etc.) were included in FY2015,  
despite of US sales operation's cost reduction and positive forex impact**



# Profit Attributable to Owners of the Company

**Decreased by 4.3 Bn JPY  
due to increase of income taxes caused by decrease in R&D tax credit**



\*Excl. increase and decrease of share of profit or loss of investments accounted for using the equity method and non-controlling interests



# Major Business Units

(JPY Bn)



	FY2015 Q1 Results	FY2016 Q1 Results	YoY	vs. Forecast (%)
<b>Japan</b>	<b>114.2</b>	<b>123.4</b>	<b>+9.2</b>	<b>24.9%</b>
<b>Daiichi Sankyo Healthcare</b>	<b>10.8</b>	<b>14.8</b>	<b>+4.0</b>	<b>24.7%</b>
<b>Daiichi Sankyo Inc.</b>	<b>48.0</b>	<b>40.7</b>	<b>-7.3</b>	<b>33.1%</b>
Olmesartan	28.8	23.2	-5.6	40.0%
Welchol	13.5	10.0	-3.6	27.0%
Effient	5.2	6.0	+0.8	-
Savaysa	-0.3	0.3	+0.6	14.9%
Movantik	0.2	0.9	+0.7	-
<b>Luitpold</b>	<b>21.5</b>	<b>22.0</b>	<b>+0.4</b>	<b>23.9%</b>
Venofer	9.1	7.4	-1.7	29.5%
Injectafer	3.9	5.9	+2.0	21.9%
<b>Daiichi Sankyo Europe</b>	<b>20.2</b>	<b>20.4</b>	<b>+0.2</b>	<b>27.6%</b>
Olmesartan	15.8	14.0	-1.8	30.4%
Efient	1.1	2.3	+1.2	-
Lixiana	0.0	1.4	+1.4	16.1%
<b>Asia, South and Central America (ASCA)</b>	<b>21.4</b>	<b>17.7</b>	<b>-3.7</b>	<b>25.0%</b>

# Major Products in Japan

(JPY Bn)

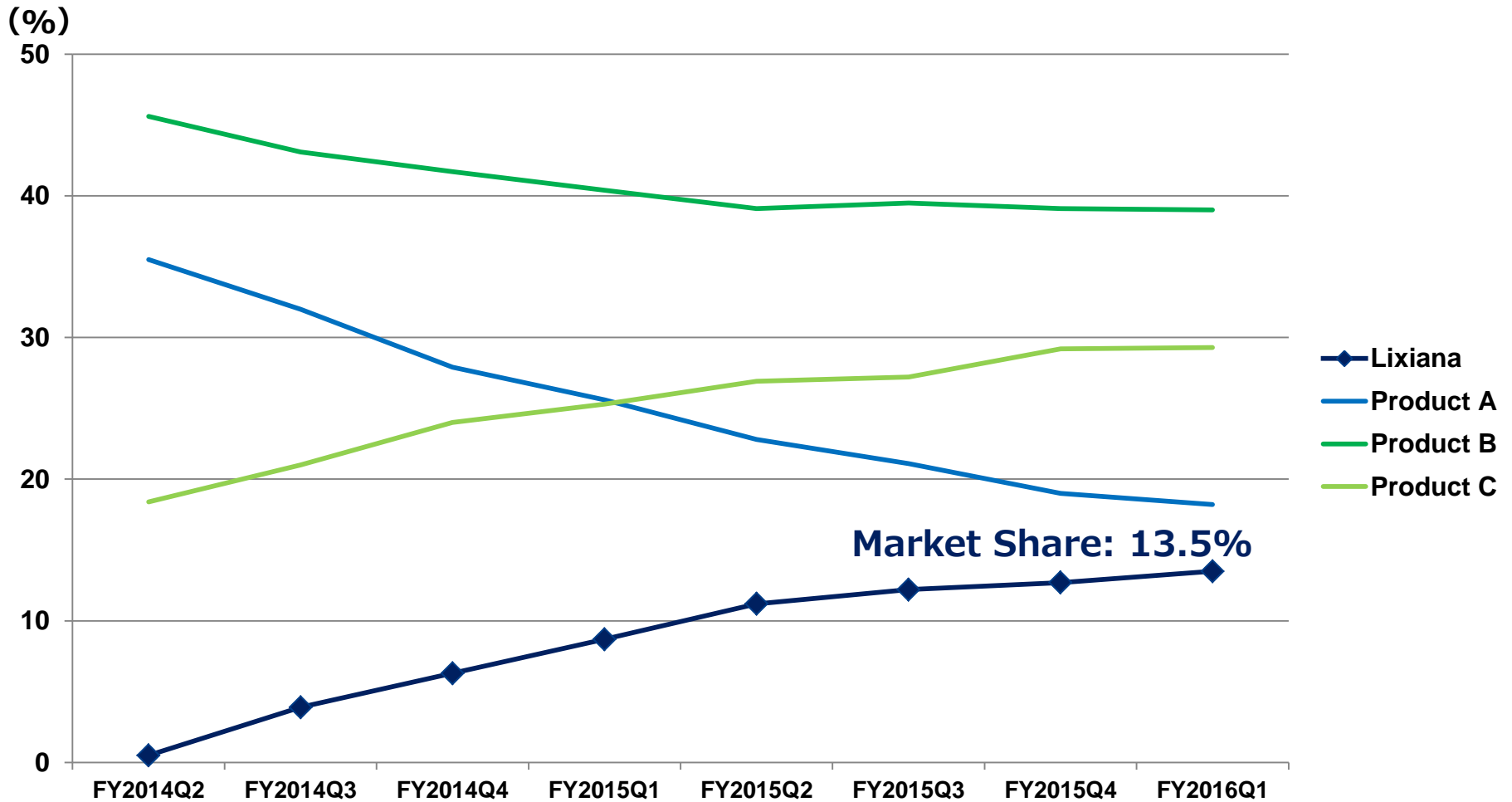


		FY2015 Q1 Results	FY2016 Q1 Results	YoY	vs. Forecast (%)
<b>Nexium</b>	ulcer treatment	19.1	21.0	+1.9	26.3%
<b>Olmotec</b>	antihypertensive agent	18.5	18.3	-0.2	26.8%
<b>Memary</b>	Alzheimer's disease treatment	10.2	12.1	+1.9	23.8%
<b>Loxonin</b>	anti-inflammatory analgesic	12.6	10.3	-2.3	27.8%
<b>Tenelia</b>	type 2 diabetes mellitus inhibitor	2.4	6.7	+4.3	23.8%
<b>Lixiana</b>	anticoagulant agent	2.1	5.5	+3.4	22.0%
<b>Rezaltas</b>	antihypertensive agent	4.6	4.7	+0.0	24.5%
<b>Pralia</b>	treatment for osteoporosis	2.6	4.1	+1.6	25.7%
<b>Ranmark</b>	treatment for bone complications caused by bone metastases from tumors	2.9	3.4	+0.5	25.9%
<b>Inavir</b>	anti-influenza treatment	0.0	0.6	+0.5	4.2%
<b>Cravit</b>	synthetic antibacterial agent	4.6	3.8	-0.9	28.9%
<b>Omnipaque</b>	contrast medium	4.2	3.7	-0.6	30.5%
<b>Urief</b>	treatment for dysuria	2.9	3.0	+0.1	27.3%
<b>Artist</b>	treatment for hypertension, angina pectoris and chronic heart failure	4.1	3.1	-1.0	28.3%
<b>Mevalotin</b>	antihyperlipidemic agent	3.6	2.9	-0.6	29.3%
<b>Efient</b>	antiplatelet agent	1.2	2.5	+1.3	30.9%

# Major Management Topics

# Edoxaban: Japan

Latest market share reached: 13.5% (Apr. 2016 ~ Jun. 2016)



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# Edoxaban: Status in Other Regions

- ◆ Launched countries  
Japan, U.S., Switzerland, the U.K, Germany, Ireland, the Netherlands, South Korea
- ◆ Approved countries (currently preparing for launch)  
Taiwan, Hong Kong
- ◆ Countries where applications for approval are underway  
Brazil, Thailand, Australia, China, Canada, Turkey
- ◆ Market share is steadily growing in Germany (3.2%\* as of Apr. 2016)
- ◆ Partner with Servier Canada inc.\*\* in Canada

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\*\*Subsidiary of LES LABORATOIRES SERVIER in Canada

## Approval for anti epilepsy VIMPAT (lacosamide)

### ◆ Indications

- As an adjunctive therapy in the treatment of partial onset seizures with or without secondary generalization in adult patients with epilepsy who have not obtained sufficient response to other antiepileptic drugs.

### ◆ The terms of agreement

- UCB Japan will manufacture and supply the product; Daiichi Sankyo will manage distribution and book sales in Japan, with both companies promoting in Japan.

## Biosimilars licensed in from Amgen

### ◆ Licensed-in products

- 9 biosimilars, including adalimumab (Humira), bevacizumab (Avastin) and trastuzumab (Herceptin)

### ◆ The terms of agreement

- Amgen will be responsible for the development and manufacturing. Daiichi Sankyo will file for marketing approval and be responsible for distribution and commercialization in Japan, while Amgen will have a limited right to co-promote the products.

## Shareholder Returns Policy during 5YBP\*

- ◆ Total return ratio: 100% or more
- ◆ Annual ordinary dividend: more than 70 JPY
- ◆ Flexible acquisition of own shares

\* 5YBP: 5-year Business Plan (FY2016 - FY2020)

## Based on the policy, acquisition of own shares is ongoing

- ◆ Acquisition period: From June 21, 2016, to October 28, 2016
- ◆ Aggregate amount of acquisition cost: 50.0 billion JPY (maximum)
- ◆ Total number of shares to be acquired: 28 million shares (maximum)
- ◆ Status of acquisition:  
2.85 million shares, 7.3 billion JPY (as of June 30, 2016)

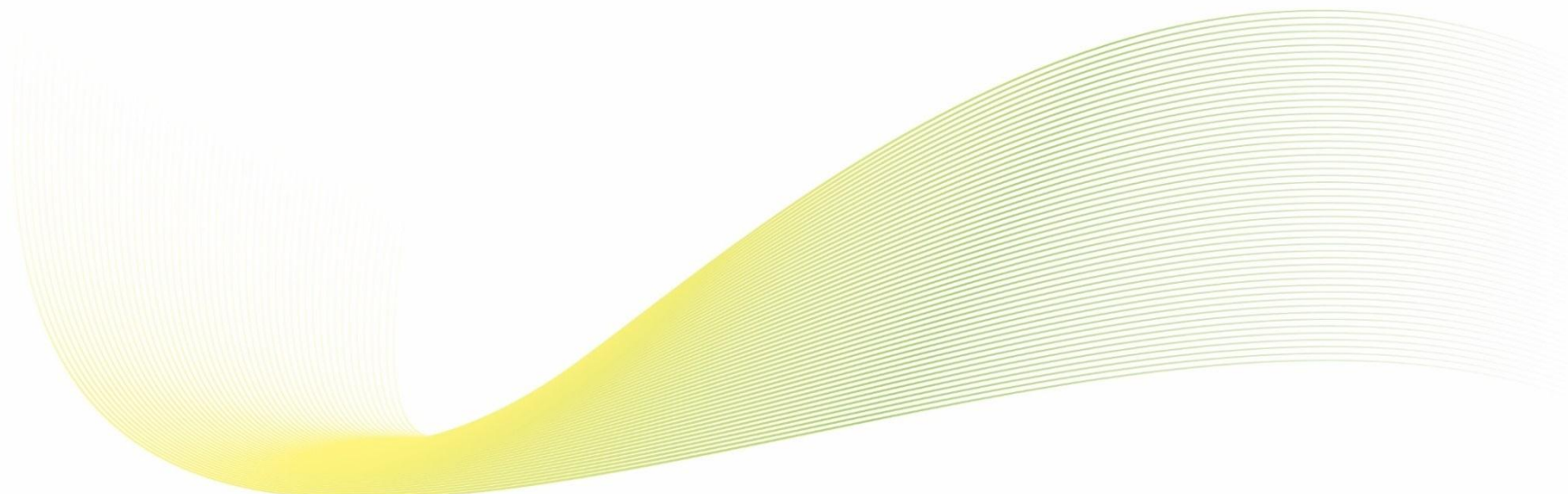
**Under the environment of continuous low interest rates, became the first Japanese healthcare sector's company to secure stable, low cost funds by issuing super-long-term bonds**

## Issuance of unsecured straight bonds

- ◆ Total amount of issue: 100.0 billion JPY  
(75.0 billion JPY: 20 years, 25.0 billion JPY: 30 years)
- ◆ Interest rate: 0.810% per annum (20 years, fixed rate)  
1.200% per annum (30 years, fixed rate)
- ◆ Payment date: July 25, 2016
- ◆ Underwriters: Daiwa Securities Co. Ltd., Mizuho Securities Co., Ltd.  
and Goldman Sachs Japan Co., Ltd.



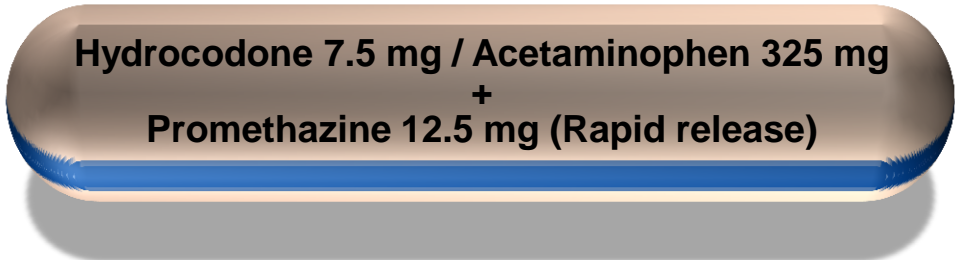
# R&D Topics



# Steady progress of pipeline in late development phase: **CL-108**

## CL-108

- ◆ Novel, bi-layered tablet containing hydrocodone, acetaminophen and promethazine to treat moderate to severe pain and prevent or reduce opioid-induced nausea and vomiting (OINV)
- ◆ **NDA was submitted to FDA in March 2016 and currently under FDA review**
- ◆ **PDUFA date: January 31, 2017**



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

### Update

- Full results of pivotal study in patients with moderate to severe pain following bunionectomy were presented at the American Pain Society Scientific Meeting in May 2016

# CL-108: Phase 3 study results

The study confirmed that CL-108 is a safe and effective analgesic while reducing or preventing OINV in patients with moderate to severe pain following bunionectomy

Patients taking CL-108 experienced significant pain relief compared with placebo ( $p < 0.001$ )

Patients taking CL-108 experienced significantly less OINV compared with HC/APAP ( $p < 0.001$ )

Figure 1. Summed pain intensity differences over 48 hours (SPID<sub>48</sub>)

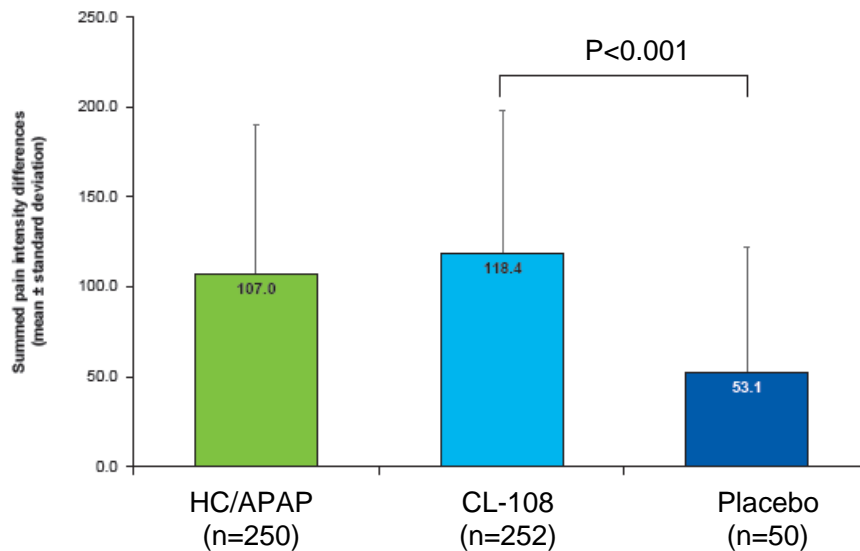
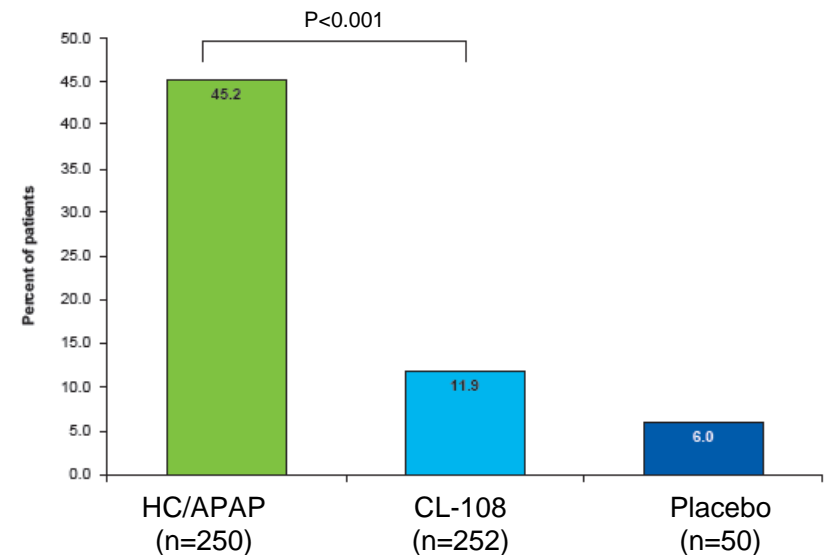


Figure 2. Incidence of OINV over 48 hours



CL-108: hydrocodone 7.5 mg / acetaminophen 325 mg / promethazine 12.5 mg  
HC/APAP: hydrocodone 7.5 mg / acetaminophen 325 mg

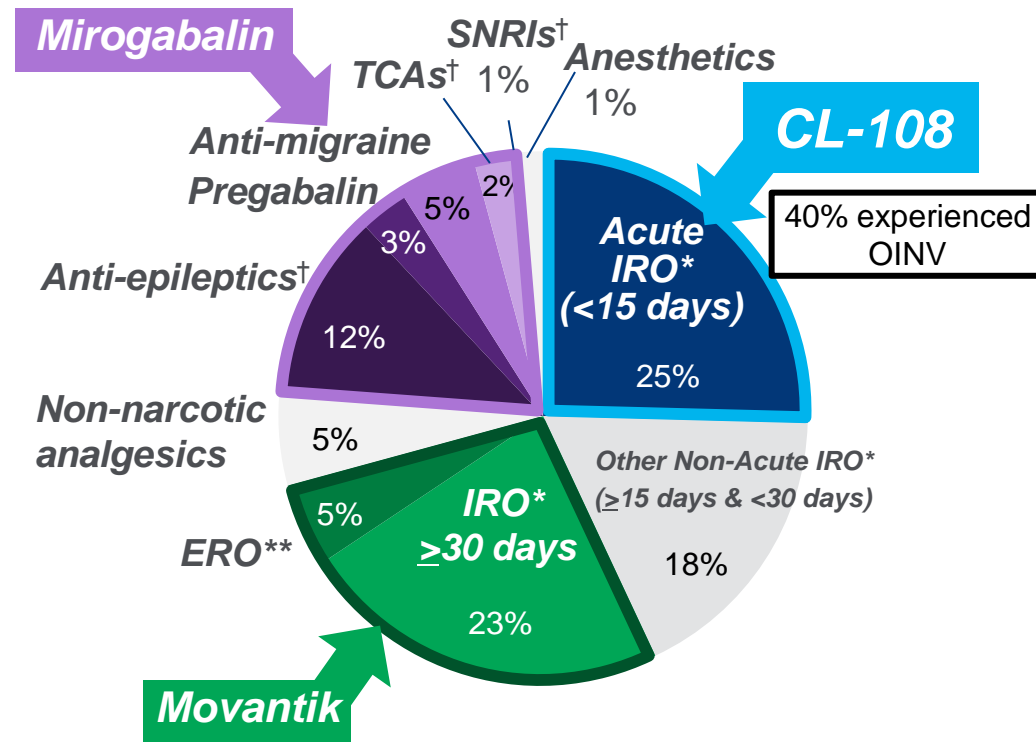
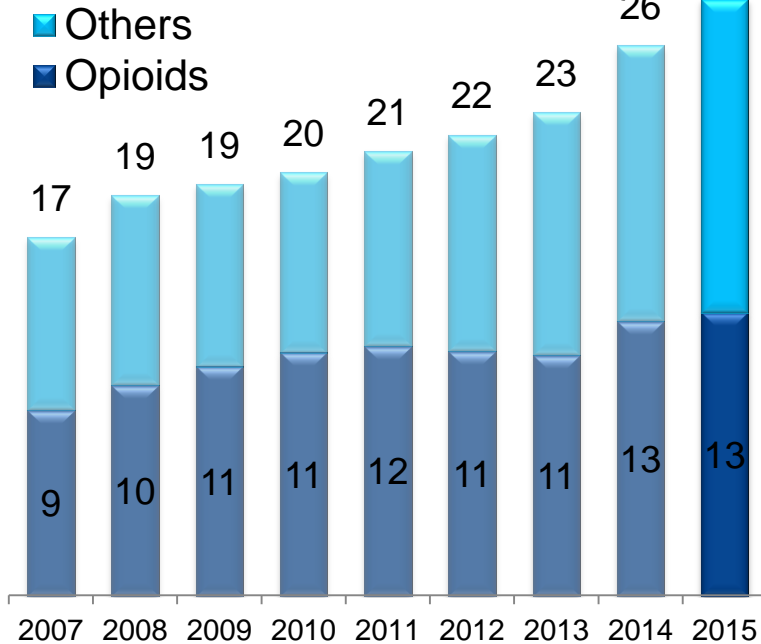
# U.S. Pain Market Holds Great Opportunity

## Large, Growing Market with Diverse Segments

U.S. Pain Market Gross Sales  
(US\$ Billion)

2015: **\$28 Billion**

'07-'15 CAGR 6.6%



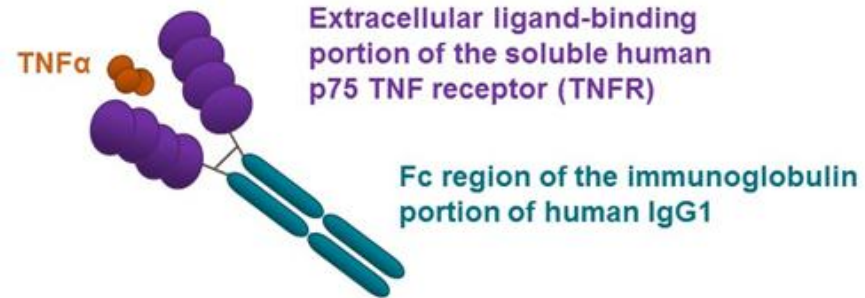
**330~ Million TRx**

\* Immediate-Release Opioid, \*\* Extended-Release Opioid  
† Pain management use only

# Steady progress of pipeline in late development phase: CHS-0214

## CHS-0214

- ◆ CHS-0214 is a proposed biosimilar of etanercept (Embrel)
- ◆ CHS-0214 is fusion protein comprising the soluble human TNF receptor and the Fc region of human IgG1
- ◆ Competitive binder of tumor necrosis factor
- ◆ Phase 1 studies have demonstrated that CHS-0214 is similar to etanercept with regard to pharmacokinetics (PK) and toxicity
- ◆ **Completed the global phase 3 study in patients with active rheumatoid arthritis (RA) co-developing with Coherus, the originator of CHS-0214**
- ◆ **A regulatory application in Japan targeted for FY2016, in preparation**



### Update

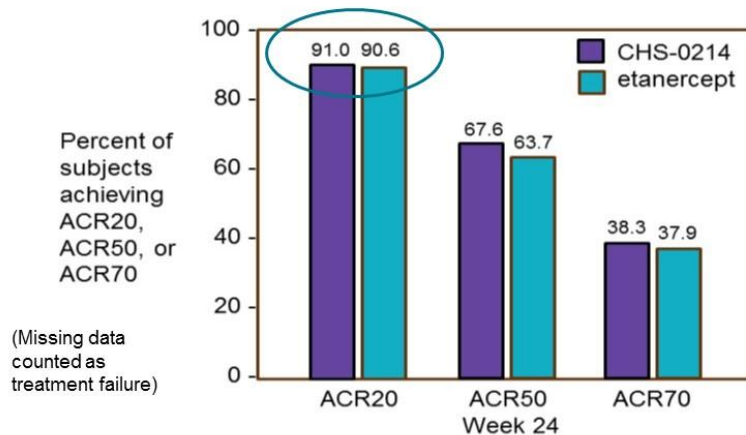
- Results of the global phase 3 study were presented at the European League Against Rheumatism (EULAR) in June 2016

# CHS-0214: Results of the phase 3 study

Confirmed bioequivalence btw CHS-0214 and etanercept

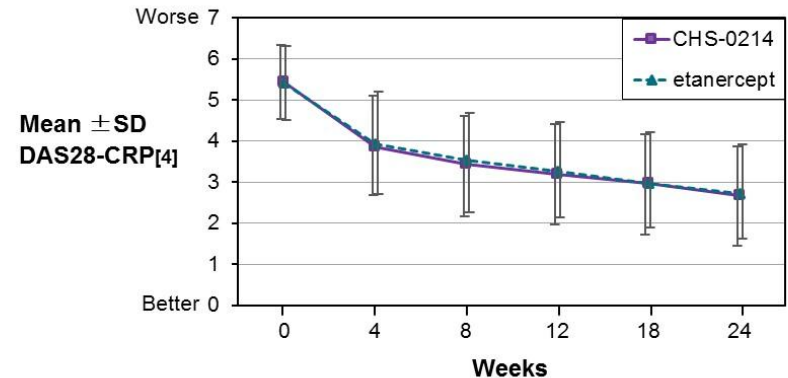
- ◆ Efficacy: CHS-0214 met the predefined criteria of equivalency in terms of ACR20\* and DAS28-CRP\*\*

## ACR20, ACR50 and ACR70 at Week 24



CHS-0214 and etanercept were highly similar  
Primary Endpoint: ACR20 at week 24:  
Treatment Difference (95% CI): 0.41% (-4.55%, 5.37%)

## Disease Activity Score (DAS28-CRP)



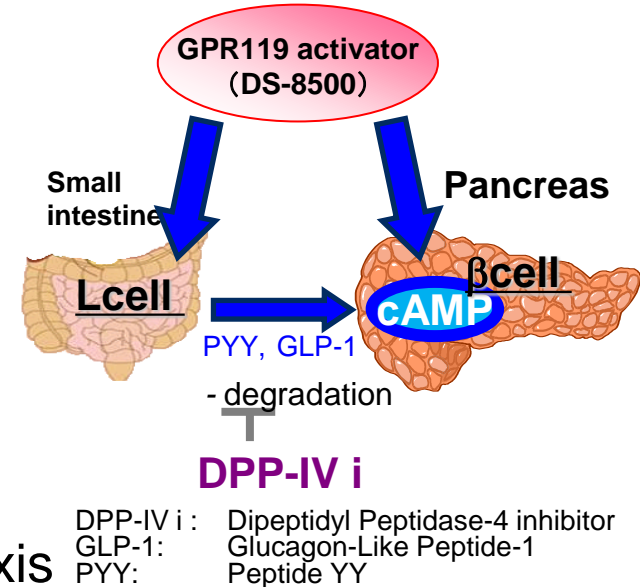
Remission (defined as DAS28-CRP[4] <2.6) in 40.6% and 42.4% subjects in the CHS-0214 and etanercept groups, respectively

- \*ACR20 and \*\*DAS28-CRP are the measures to evaluate disease activity for RA
- ◆ Safety and Immunogenicity: CHS-0214 and etanercept exhibited the same profile

# Steady progress of pipeline in late development phase: DS-8500

## DS-8500

- ◆ Anti-diabetic agent
- ◆ GPR119 agonist
  - Amplify glucose-stimulated insulin secretion
  - Improve  $\beta$ -cell function
  - Stimulate GLP-1 secretion
- ◆ Competitors discontinued projects because of reasons such as tachyphylaxis
- ◆ **Phase 2b studies in Japan and US are ongoing**
  - **Anticipated schedule for Top Line Results: FY2016Q4 for Japan, FY2017H1 for US**
- ◆ Partnering discussion ongoing



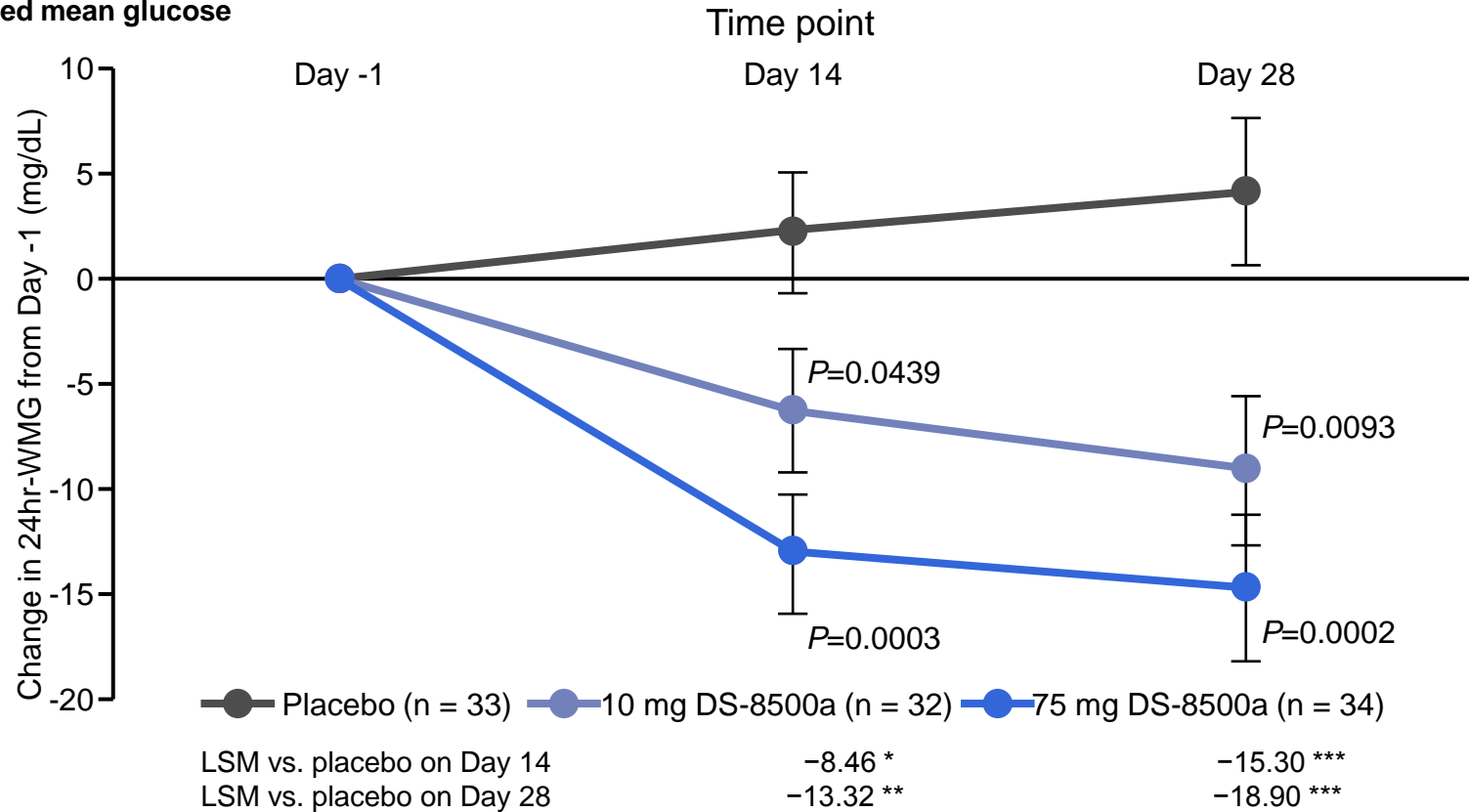
### Update

- Results of the phase 2a study in Japan were presented at the American Diabetes Association in June 2016

# DS-8500: Results of the Japan phase 2a study

No tachyphylaxis was observed during the treatment for 28 days

Change of twenty-four-hour weighted mean glucose



\*P < 0.05, \*\*P < 0.01, and \*\*\*P < 0.001 vs. placebo.

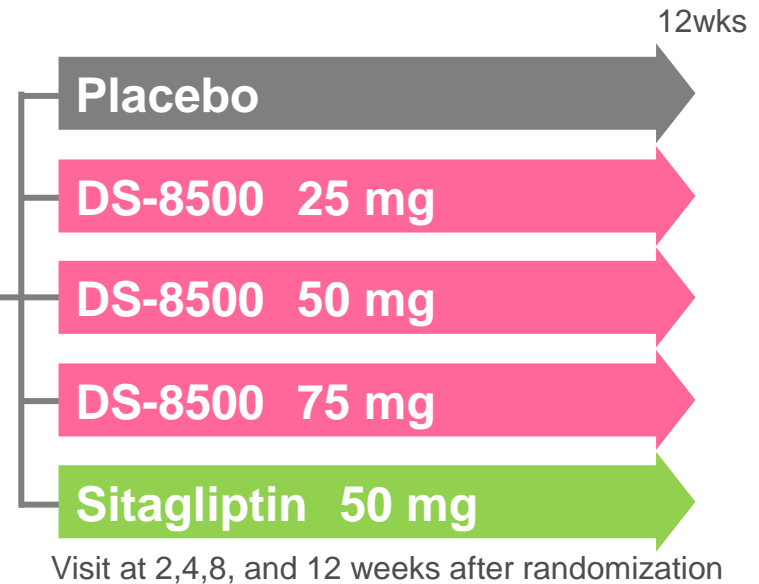
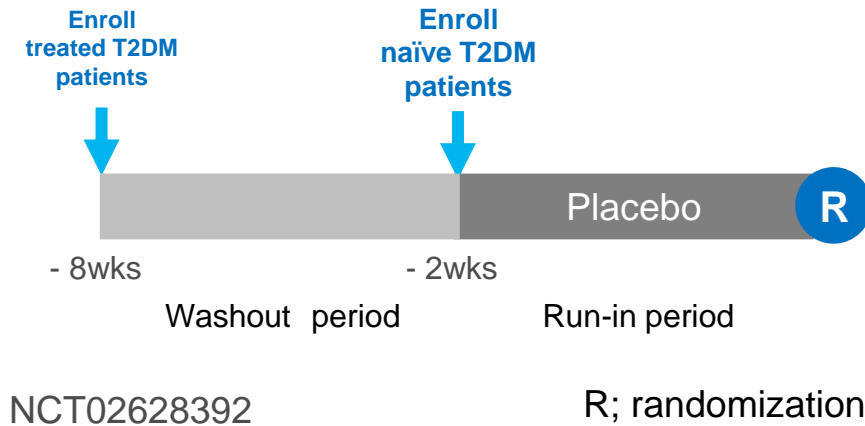
Values are shown as the least squares mean change from Day -1, with P-values versus placebo. The least squares mean differences for 10 or 75 mg DS-8500a versus placebo are also given. LSM, least squares mean



# DS-8500: Ongoing Phase 2b study design

## Japan monotherapy

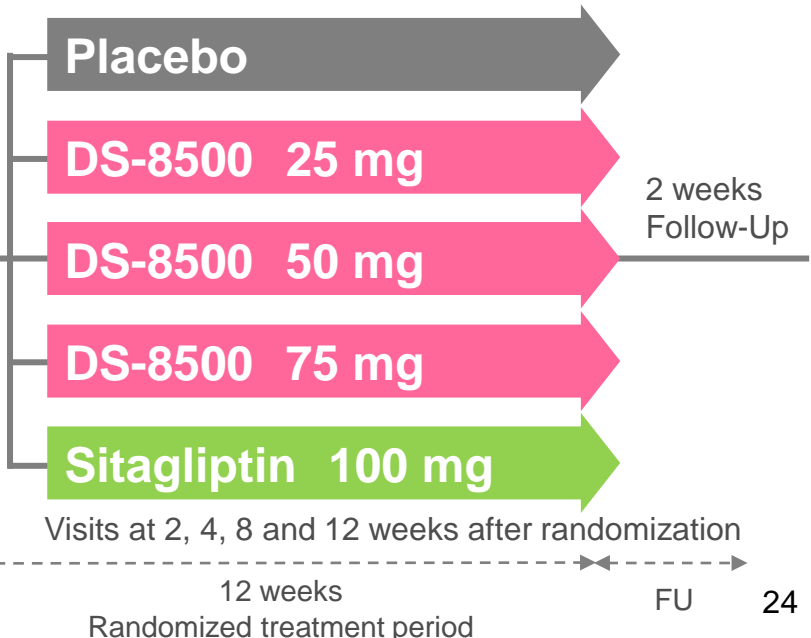
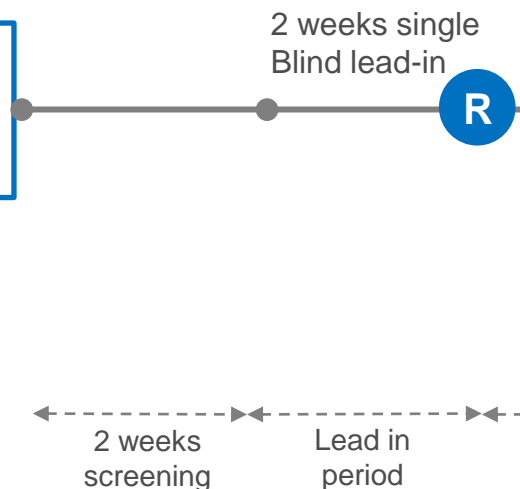
TLR: FY2016 Q4



## US add on to metformin

TLR: FY2017 H1

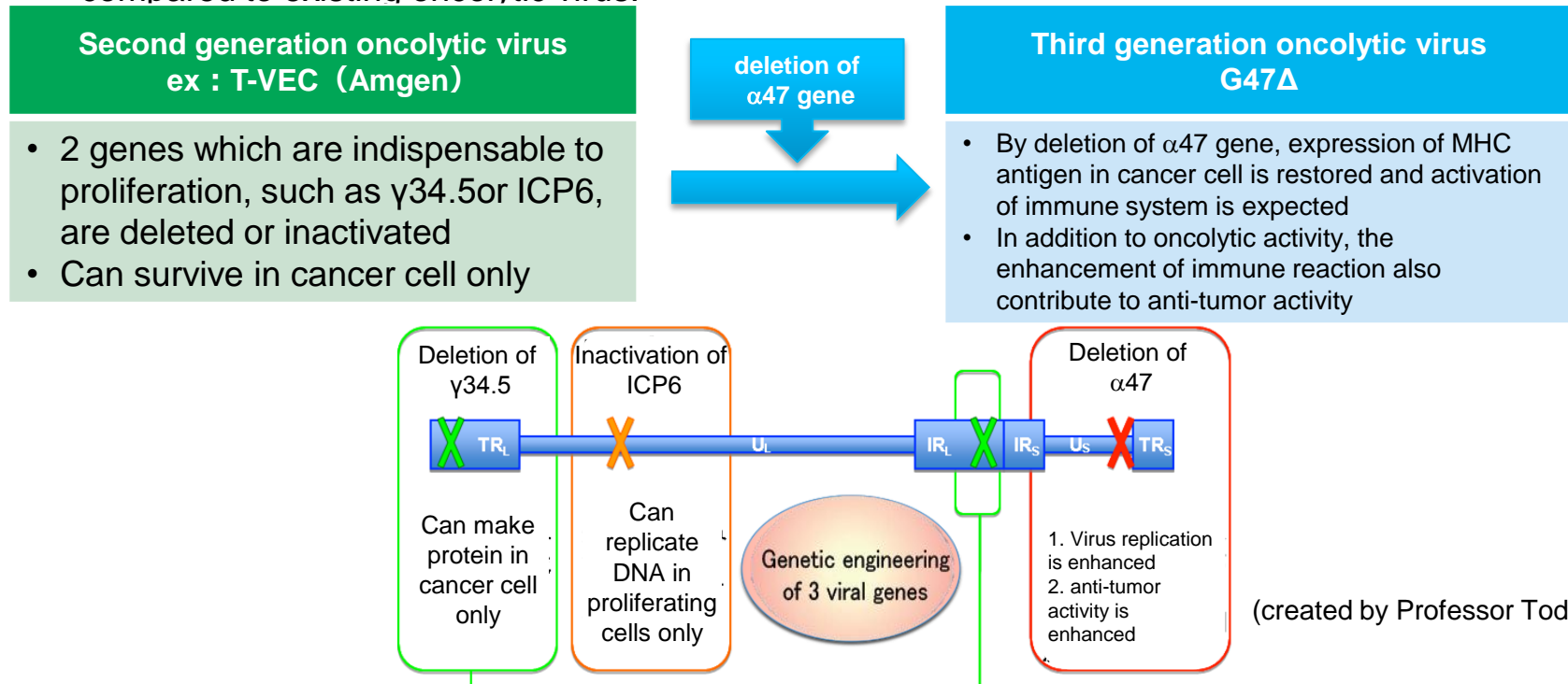
T2DM adult patients on stable Metformin monotherapy with HbA1c 7.0–10.0%



# Application of advanced technologies to create innovative medicine: G47Δ (DS-1647)

Initiate in earnest the development of treatment by oncolytic virus, G47Δ (DS-1647)

- ◆ In collaboration with Professor Todo of Institute of Medical Science, the University of Tokyo, DS has initiated the development of the treatment using G47Δ against solid tumor including glioblastoma
- ◆ G47Δ: Third generation of genetically modified herpes simplex virus type 1 (HSV-1) to treat tumor, which is genetically modified so that the virus can grow selectively in cancer cells. G47Δ is expected to have more potent anti-tumor activity with equal or more safety profile as compared to existing oncolytic virus.



# Application of G47Δ virus for cancer treatment

## ◆ History

- CY2009 - 14 Phase 1/2 study to treat progressive glioblastoma\* conducted by Prof. Todo. Confirmed safety of the treatment of G47Δ
- CY2015 Initiated investigator-initiated phase 2 by Prof. Todo which could be a registration study to treat glioblastoma
- Feb. 2016 Designated as a SAKIGAKE product for medical device, diagnostics and regenerative medicine, which was applied together with Daiichi Sanyo

## ◆ Phase 2 study ongoing:

- No control arm, open label
- Residual or recurrent glioblastoma after standard care of therapy (temozolomid and radiation)
- To enroll around 30 patients

### \*Glioblastoma

Glioma is a typical malignant brain tumor which accounts for 25 % of brain tumor. Among glioma, glioblastoma is most popular with very high malignant potential. 5-year survival rate after receiving standard of care is under 10% and incurable. New breakthrough therapy has been awaited. New patients per a year in Japan are around thousand.

# Major R&D milestone events

Project	Indication/Study	Event	Target
<b>CL-108</b>	Pain/Opioid-induced nausea and vomiting (US)	Approval	PDUFA date Jan. 31, 2017
<b>CHS-0214</b> (etanercept BS)	Rheumatoid arthritis (JP)	NDA	FY2016
<b>Denosumab</b>	Rheumatoid arthritis (JP)	NDA	FY2016
<b>Prasugrel</b>	Ischemic cerebrovascular disease Phase 3 study (JP)	TLR*	FY2016 H1
<b>Tivantinib</b>	METIV·HCC Hepatocellular carcinoma Phase 3 study (US/EU)	TLR	CY2017 H1
<b>Mirogabalin</b>	Fibromyalgia Phase 3 study (US/EU)	TLR	CY2017 H1
<b>Quizartinib</b>	QuANTUM-R AML 2 <sup>nd</sup> line treatment Phase 3 study (US/EU/Asia)	TLR	<b>FY2017 H2</b>
<b>DS-8500</b>	Type 2 Diabetes phase 2b study (JP) (US)	TLR	FY2016 Q4 FY2017 H1

TLR\*: Top Line Results

# Major R&D Pipeline

As of July 2016



Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Oncology	<ul style="list-style-type: none"> <li>■ <b>DS-3032 (US/JP)</b> (MDM2 inhibitor)</li> <li>■ <b>PLX7486 (US)</b> (FMS / TRK inhibitor)</li> <li>■ <b>PLX8394 (US)</b> (BRAF inhibitor)</li> <li>■ <b>DS-6051 (US/JP)</b> (NTRK/ROS1 inhibitor)</li> <li>■ <b>PLX9486 (US)</b> (KIT inhibitor)</li> <li>■ <b>DS-3201 (JP)</b> (EZH1/2 inhibitor)</li> <li>■ <b>PLX73086 (US)</b> (CSF-1R inhibitor)</li> <li>■ <b>PLX51107 (US)</b> (BRD4 inhibitor)</li> <li>■ <b>DS-8895 (JP)</b> (Anti-EPHA2 antibody)</li> <li>■ <b>DS-8273 (US)</b> (Anti-DR5 antibody)</li> <li>■ <b>DS-5573 (JP)</b> (Anti-B7-H3 antibody)</li> <li>■ <b>DS-8201 (JP)</b> (Anti-HER2 ADC)</li> <li>■ <b>U3-1784 (EU)</b> (Anti-FGFR4 antibody)</li> <li>■ <b>DS-1123 (JP)</b> (Anti-FGFR2 antibody)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Patritumab (EU)</b> (U3-1287 / Anti-HER3 antibody)</li> <li>■ <b>Pexidartinib (US)</b> (PLX3397 / CSF-1R/KIT/FLT3-ITD inhibitor)</li> <li>■ <b>DS-1647 (JP)</b> (Glioblastoma / G47A virus)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Tivantinib (US/EU)</b> (ARQ 197 / HCC / MET inhibitor)</li> <li>■ <b>Denosumab (JP)</b> (AMG 162 / Breast cancer adjuvant / Anti-RANKL antibody)</li> <li>■ <b>Nimotuzumab (JP)</b> (DE-766 / Gastric cancer / Anti-EGFR antibody)</li> <li>■ <b>Vemurafenib (US/EU)</b> (PLX4032 / Melanoma Adjuvant / BRAF inhibitor)</li> <li>■ <b>Quizartinib (US/EU/Asia)</b> (AC220 / AML-2<sup>nd</sup> / FLT3-ITD inhibitor)</li> <li>■ <b>Quizartinib (US)</b> (AC220 / AML-1<sup>st</sup> / FLT3-ITD inhibitor)</li> <li>■ <b>Pexidartinib (US/EU)</b> (PLX3397 / TGCT / CSF-1R/KIT/FLT3-ITD inhibitor)</li> </ul>	
Cardiovascular- Metabolics	<ul style="list-style-type: none"> <li>■ <b>DS-1040</b> (Acute ischemic stroke / TAF1a inhibitor)</li> <li>■ <b>DS-2330</b> (Hyperphosphatemia)</li> <li>■ <b>DS-9231/TS23</b> (Thrombosis / α2-PI inactivating antibody)</li> <li>■ <b>DS-9001</b> (Dyslipidemia / Anti-PCSK9 Anticalin-Albumod)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>CS-3150 (JP)</b> (Hypertension · DM nephropathy / MR antagonist)</li> <li>■ <b>DS-8500 (JP/US)</b> (Diabetes / GPR119 agonist)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Prasugrel (JP)</b> (CS-747 / Ischemic stroke / Anti-platelet agent)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Edoxaban (ASCA etc.)</b> (DU-176b / AF / oral factor Xa inhibitor)</li> <li>■ <b>Edoxaban (ASCA etc.)</b> (DU-176b / VTE / oral factor Xa inhibitor)</li> </ul>
Others	<ul style="list-style-type: none"> <li>■ <b>DS-1971</b> (Chronic pain)</li> <li>■ <b>DS-1501</b> (Osteoporosis / Anti-Siglec-15 antibody)</li> <li>■ <b>DS-7080 (US)</b> (AMD / Angiogenesis inhibitor)</li> <li>■ <b>DS-2969</b> (<i>Clostridium difficile</i> infection /GyrB inhibitor)</li> <li>■ <b>DS-5141 (JP)</b> (DMD / ENA oligonucleotide)</li> <li>■ <b>VN-0102/JVC-001 (JP)</b> (MMR vaccine)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Laninamivir (US/EU)</b> (CS-8958 / Anti-influenza / out-licensing with Biota)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Mirogabalin (US/EU)</b> (DS-5565 / Fibromyalgia / α2δ ligand)</li> <li>■ <b>Mirogabalin (JP/Asia)</b> (DS-5565 / DPNP/ α2δ ligand)</li> <li>■ <b>Mirogabalin (JP/Asia)</b> (DS-5565 / PHN / α2δ ligand)</li> <li>■ <b>Denosumab (JP)</b> (AMG 162 / Rheumatoid arthritis / Anti-RANKL antibody)</li> <li>■ <b>Hydromorphone (JP)</b> (DS-7113 / Cancer pain / Opioid μ-receptor regulator) &lt;Injection&gt;</li> <li>■ <b>CHS-0214 (JP)</b> (Etanercept BS / Rheumatoid arthritis / TNFα inhibitor)</li> <li>■ <b>VN-0105 (JP)</b> (DPT-IPV / Hib vaccine)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Hydromorphone (JP)</b> (DS-7113 / Cancer pain / Opioid μ-receptor agonist)&lt;Oral&gt;</li> <li>■ <b>CL-108 (US)</b> (Acute pain / Opioid μ-receptor agonist)</li> <li>■ <b>Intradermal Seasonal Influenza Vaccine (JP)</b> (VN-100 / prefilled i.d. vaccine for seasonal flu)</li> <li>■ <b>VN-0107/MEDI3250 (JP)</b> (Nasal spray flu vaccine)</li> </ul>

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