

# Top Management Presentation

## Financial Results of FY2015

DAIICHI SANKYO CO., LTD

Joji Nakayama  
President and CEO

May 12, 2016

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- ◆ **FY2015 Consolidated Results**
- ◆ **FY2016 Consolidated Forecast,  
Shareholder Returns**
- ◆ **Major Management Topics**
  - **Edoxaban**
  - **Daiichi Sankyo, Inc. (DSI)**
  - **R&D Topics**

# FY2015 Consolidated Results

# Overview of FY2015 Results

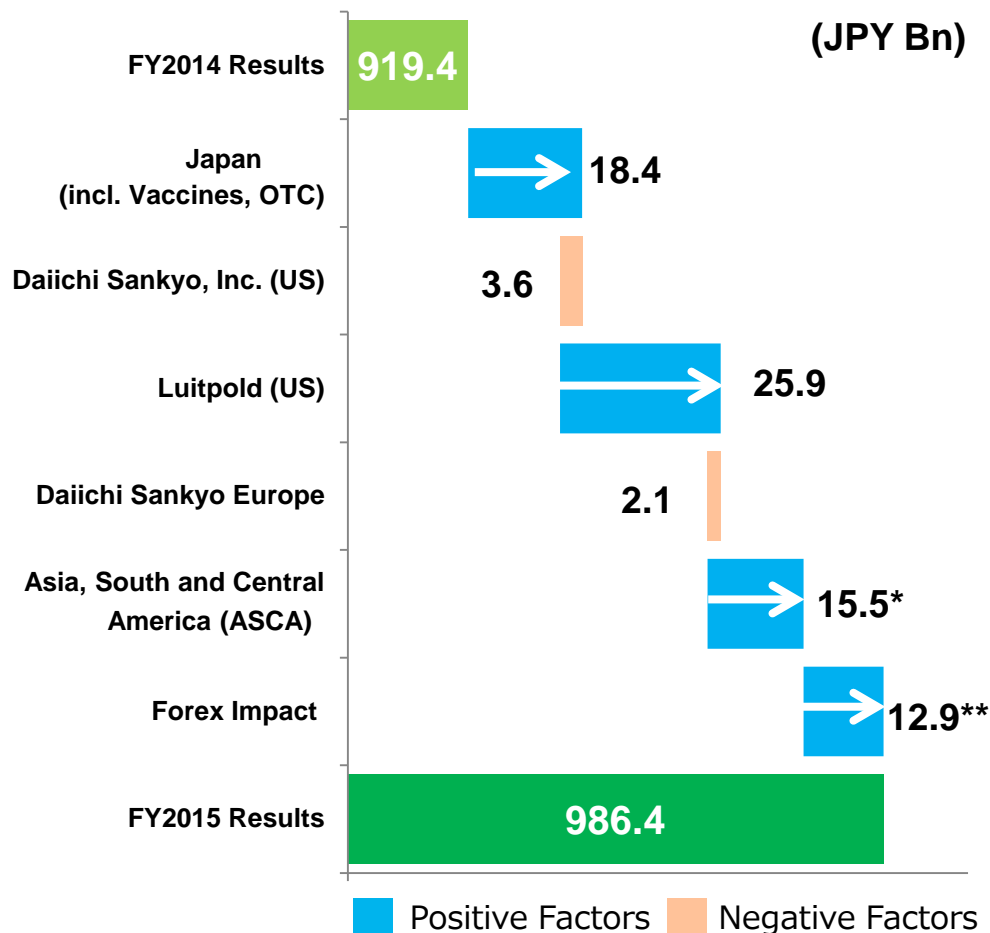
(JPY Bn)

	FY2014 Results*	FY2015 Results	YoY
Revenue	919.4	986.4	<div>+7.3%</div> <b>+67.1</b>
Cost of Sales	323.1	318.6	-4.5
SG&A Expenses	331.2	328.8	-2.4
R&D Expenses	190.7	208.7	+18.0
Operating Profit	74.4	130.4	<div>+75.2%</div> <b>+56.0</b>
Profit before Tax	79.9	122.4	<b>+42.5</b>
Profit attributable to owners of the Company	46.5	82.3	<div>+77.1%</div> <b>+35.8</b>

Currency Rate	USD/JPY	109.94	120.14	+10.20
	EUR/JPY	138.78	132.57	-6.21

\*FY2014 Results have been restated and indicated as only the values for continuing operations.

**Increased by 67.1 JPY Bn  
due to the growth of Luitpold, Japan and ASCA with Forex**



## Japan

Positive :	Nexium	+13.1	Lixiana	+9.4
	Teneria	+9.0	Memary	+5.6
	Pralia	+5.1	Effient	+4.2
	Ranmark	+2.2		
Negative :	Cravit	-9.5	Artist	-3.0
	Mevalotin	-2.7	Inavir	-2.6

## Global (excl. Forex Impact)

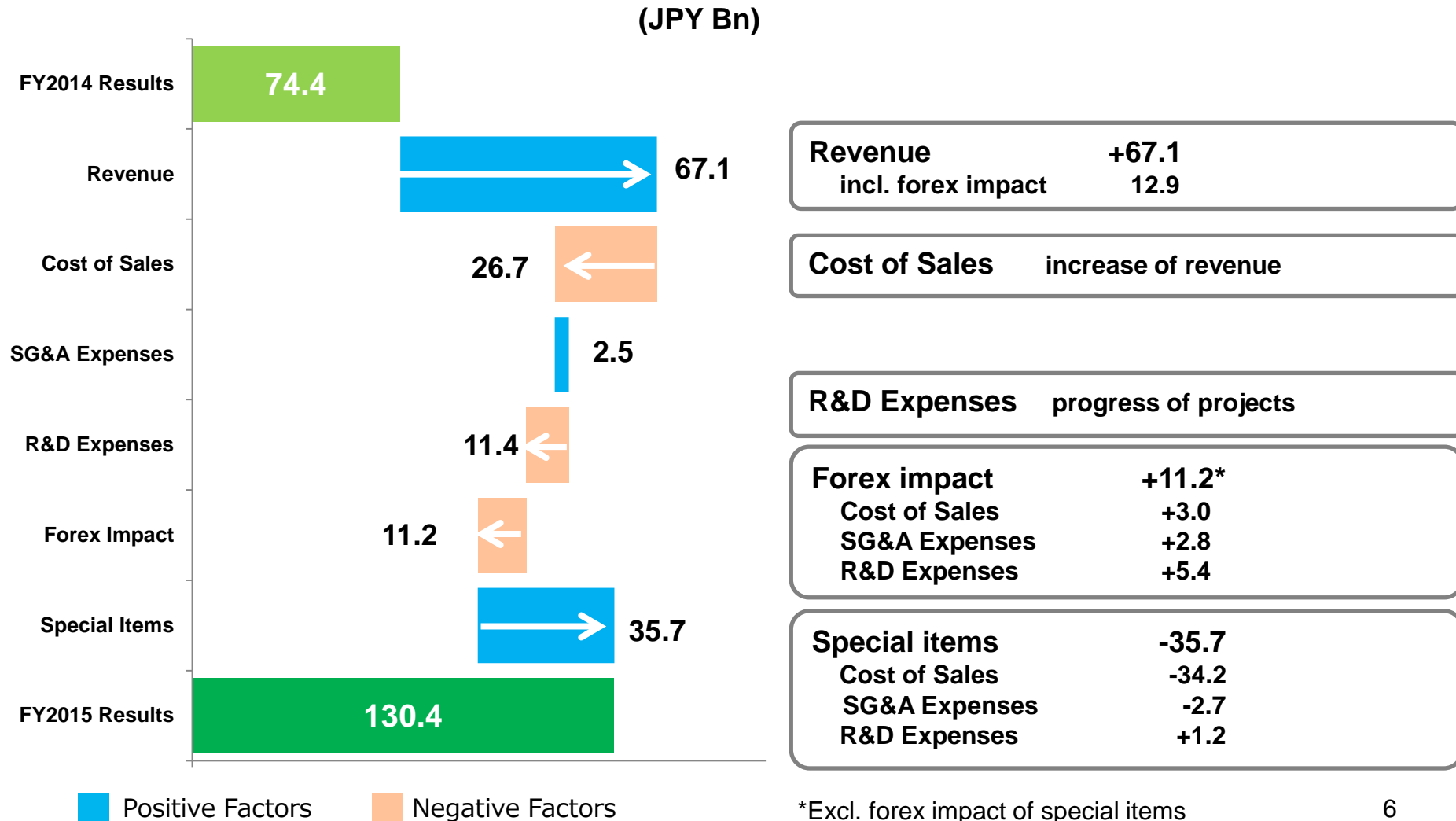
Daiichi Sankyo, Inc. :	Olmesartan	-4.4
	Welchol	-3.1
	Effient	+1.4
	Movantik	+1.8
Luitpold :	Injectafer	+9.4
Daiichi Sankyo Europe :	Olmesartan	-3.5
	Lixiana	+1.6

\*7.7bn negative impact due to the change of exchange rate of Venezuela etc. is included in "Forex Impact."

\*\*Forex impact USD:+24.1, EUR:-3.5, ASCA (incl. Venezuela):-7.7

# Operating Profit

**Increased by 56.0 JPY Bn**  
**due to increased revenue and decreased expenses of special items**



\*Excl. forex impact of special items

# Special Items

(JPY Bn)

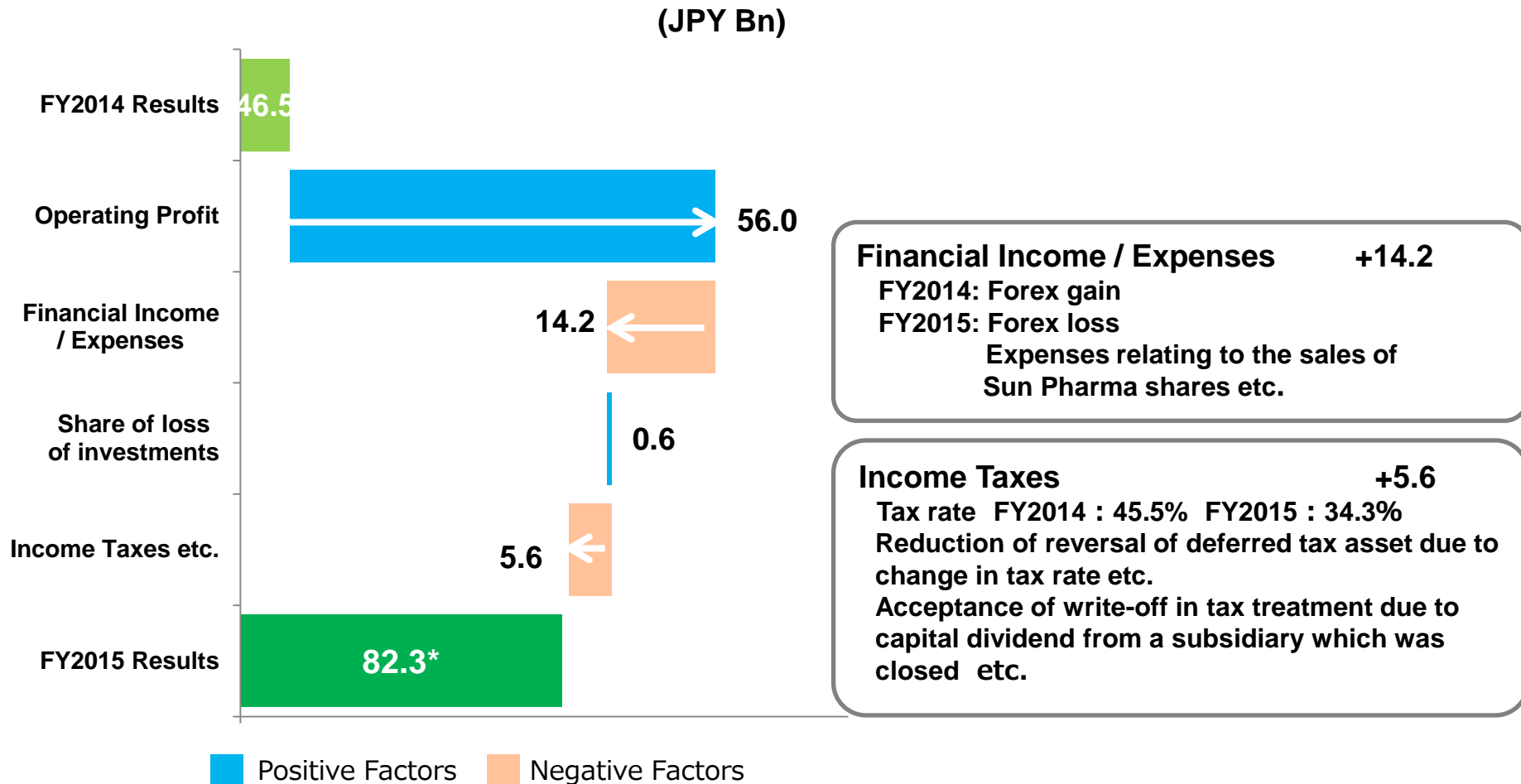
	FY2014 Results		FY2015 Results		YoY
<b>Cost of Sales</b>	Restructuring costs in Japan	<b>2.2</b>	Gain on sales of subsidiary	<b>-2.4</b>	<b>-34.2</b>
	Impairment loss (Intangible)	<b>35.0</b>	Gain on sales of fixed assets	<b>-1.1</b>	
			Impairment loss (Intangible)	<b>1.9</b>	
			Restructuring costs in supply chain	<b>4.6</b>	
<b>SG&amp;A Expenses</b>	Settlement expenses with US Department of Justice	<b>4.7</b>	Restructuring costs in US	<b>15.2</b>	<b>-2.7</b>
	Restructuring costs in Japan	<b>7.3</b>	Restructuring costs in EU	<b>2.9</b>	
	Restructuring costs in US	<b>1.7</b>	Gain on sales of fixed assets	<b>-8.2</b>	
	Impairment loss (Tangible)	<b>1.8</b>			
	Gain on sales of fixed assets	<b>-2.9</b>			
<b>R&amp;D Expenses</b>	Restructuring costs in Japan	<b>4.4</b>	Restructuring costs in R&D	<b>5.6</b>	<b>1.2</b>
<b>Total</b>		<b>54.2</b>		<b>18.5</b>	<b>-35.7</b>

- : Cost decrease items



# Profit Attributable to Owners of the Company

**Increased by 35.8 JPY Bn due to increased operating profit**  
**Forex loss due to strong Yen are booked as financial expenses**



\*Excl. non-controlling interests

# Major Business Units

(JPY Bn)

	FY2014 Results	FY2015 Results	YoY	vs. Forecast (%)
<b>Japan</b>	<b>480.5</b>	<b>494.7</b>	<b>+14.2</b>	<b>100.7%</b>
<b>Daiichi Sankyo Healthcare</b>	<b>47.8</b>	<b>53.4</b>	<b>+5.5</b>	<b>108.9%</b>
<b>Daiichi Sankyo Inc.</b>	<b>173.0</b>	<b>185.1</b>	<b>+12.1</b>	<b>105.2%</b>
Olmesartan	106.6	111.6	+5.1	110.5%
Welchol	47.4	48.4	+1.0	102.9%
Effient	17.6	20.7	+3.2	-
Savaysa	0.7	0.4	-0.2	22.5%
Movantik	-	2.0	+2.0	-
<b>Luitpold</b>	<b>57.4</b>	<b>91.0</b>	<b>+33.6</b>	<b>105.8%</b>
Venofer	28.6	31.2	+2.6	104.1%
Injectafer	7.6	18.6	+11.0	109.6%
<b>Daiichi Sankyo Europe</b>	<b>83.5</b>	<b>77.8</b>	<b>-5.7</b>	<b>102.3%</b>
Olmesartan	65.2	58.9	-6.3	101.6%
Efient	4.8	5.4	+0.6	-
Lixiana	-	1.5	+1.5	90.9%
<b>Asia, South and Central America (ASCA)</b>	<b>67.5</b>	<b>75.3</b>	<b>+7.8</b>	<b>85.6%</b>

# Major Products in Japan

(JPY Bn)

		FY2014 Results	FY2015 Results	YoY	vs. Forecast (%)
<b>Olmetec</b>	antihypertensive agent	<b>76.3</b>	<b>73.9</b>	<b>-2.5</b>	<b>93.5%</b>
<b>Nexium</b>	ulcer treatment	<b>69.3</b>	<b>82.4</b>	<b>+13.1</b>	<b>107.0%</b>
<b>Memary</b>	Alzheimer's disease treatment	<b>36.8</b>	<b>42.4</b>	<b>+5.6</b>	<b>90.3%</b>
<b>Loxonin</b>	anti-inflammatory analgesic	<b>49.5</b>	<b>48.1</b>	<b>-1.4</b>	<b>109.4%</b>
<b>Cravit</b>	synthetic antibacterial agent	<b>27.8</b>	<b>18.4</b>	<b>-9.5</b>	<b>108.1%</b>
<b>Rezaltas</b>	antihypertensive agent	<b>18.4</b>	<b>18.2</b>	<b>-0.2</b>	<b>95.6%</b>
<b>Artist</b>	treatment for hypertension, angina pectoris and chronic heart failure	<b>18.1</b>	<b>15.1</b>	<b>-3.0</b>	<b>88.6%</b>
<b>Omnipaque</b>	contrast medium	<b>17.2</b>	<b>16.9</b>	<b>-0.3</b>	<b>105.4%</b>
<b>Mevalotin</b>	antihyperlipidemic agent	<b>16.2</b>	<b>13.4</b>	<b>-2.7</b>	<b>96.0%</b>
<b>Ranmark</b>	treatment for bone complications caused by bone metastases from tumors	<b>10.2</b>	<b>12.4</b>	<b>+2.2</b>	<b>95.3%</b>
<b>Inavir</b>	anti-influenza treatment	<b>16.6</b>	<b>14.0</b>	<b>-2.6</b>	<b>116.9%</b>
<b>Urief</b>	treatment for dysuria	<b>11.5</b>	<b>11.8</b>	<b>+0.3</b>	<b>107.6%</b>
<b>Pralia</b>	treatment for osteoporosis	<b>7.3</b>	<b>12.5</b>	<b>+5.1</b>	<b>124.5%</b>
<b>Lixiana</b>	anticoagulant agent	<b>3.6</b>	<b>13.0</b>	<b>+9.4</b>	<b>118.0%</b>
<b>Efient</b>	antiplatelet agent	<b>0.7</b>	<b>4.9</b>	<b>+4.2</b>	<b>98.0%</b>
<b>Teneria</b>	type 2 diabetes mellitus inhibitor	<b>7.6</b>	<b>16.5</b>	<b>+9.0</b>	<b>-</b>

# **FY2016 Consolidated Forecast, Shareholder Returns**

A decorative graphic consisting of many thin, parallel, wavy lines in shades of yellow and green, flowing from the bottom left towards the right side of the slide.

# FY2016 Consolidated Forecast

(JPY Bn)

	FY2015 Results	FY2016 Forecast	YoY
<b>Revenue</b>	<b>986.4</b>	<b>920.0</b>	<small>-6.7%</small> <b>-66.4</b>
<b>Cost of Sales</b>	<b>318.6</b>	<b>320.0</b>	<b>+1.4</b>
<b>SG&amp;A Expenses</b>	<b>328.8</b>	<b>310.0</b>	<b>-18.8</b>
<b>R&amp;D Expenses</b>	<b>208.7</b>	<b>190.0</b>	<b>-18.7</b>
<b>Operating Profit</b>	<b>130.4</b>	<b>100.0</b>	<small>-23.3%</small> <b>-30.4</b>
<b>Profit before Tax</b>	<b>122.4</b>	<b>100.0</b>	<b>-22.4</b>
<b>Profit attributable to owners of the Company</b>	<b>82.3</b>	<b>65.0</b>	<small>-21.0%</small> <b>-17.3</b>

## Major factors

See next page

Incl. approx. 20.0 Bn\* Yen relating to restructuring costs etc.

\*Expenses of special items:  
18.5 Bn Yen in FY2015



See slide 7

Currency Rate	USD/JPY	<b>120.14</b>	<b>110.00</b>
	EUR/JPY	<b>132.57</b>	<b>125.00</b>

# Major Business Units FY2016 Forecast

(JPY Bn)

	FY2015 Results	FY2016 Forecast	YoY
<b>Japan</b>	<b>494.7</b>	<b>496.0</b>	<b>+1.3</b>
<b>Daiichi Sankyo Healthcare</b>	<b>53.4</b>	<b>60.0</b>	<b>+6.6</b>
<b>Daiichi Sankyo Inc.</b>	<b>185.1</b>	<b>123.0</b>	<b>-62.1</b>
Olmesartan	111.6	58.0	-53.6
Welchol	48.4	37.0	-11.4
Effient	20.7	-	-
Savaysa	0.4	2.0	+1.6
Movantik	2.0	-	-
<b>Luitpold</b>	<b>91.0</b>	<b>92.0</b>	<b>+1.0</b>
Venofer	31.2	25.0	-6.2
Injectafer	18.6	27.0	+8.4
<b>Daiichi Sankyo Europe</b>	<b>77.8</b>	<b>74.0</b>	<b>-3.8</b>
Olmesartan	58.9	46.0	-12.9
Efient	5.4	-	-
Lixiana	1.5	9.0	+7.5
<b>Asia, South and Central America (ASCA)</b>	<b>75.3</b>	<b>71.0</b>	<b>-4.3</b>

# Major Business Units FY2016 Forecast

(Local Currency)

	FY2015 Results	FY2016 Forecast	YoY
<b>Daiichi Sankyo Inc.</b> (USD Mn)	<b>1,540</b>	<b>1,118</b>	<b>-422</b>
Olmesartan	929	527	-402
Welchol	403	336	-66
Effient	173	-	-
Savaysa	4	18	+14
Movantik	17	-	-
<b>Luitpold</b> (USD Mn)	<b>758</b>	<b>836</b>	<b>+79</b>
Venofer	260	227	-33
Injectafer	155	245	+90
<b>Daiichi Sankyo Europe</b> (EUR Mn)	<b>587</b>	<b>592</b>	<b>+5</b>
Olmesartan	444	368	-76
Efient	41	-	-
Lixiana	12	72	+60

# Major Products in Japan FY2016 Forecast (JPY Bn)

		FY2015 Results	FY2016 Forecast	YoY
<b>Nexium</b>	ulcer treatment	82.4	80.0	-2.4
<b>Olmetec</b>	antihypertensive agent	73.9	68.0	-5.9
<b>Memary</b>	Alzheimer's disease treatment	42.4	51.0	+8.6
<b>Loxonin</b>	anti-inflammatory analgesic	48.1	37.0	-11.1
<b>Teneria</b>	type 2 diabetes mellitus inhibitor	16.5	28.0	+11.5
<b>Lixiana</b>	anticoagulant agent	13.0	25.0	+12.0
<b>Rezaltas</b>	antihypertensive agent	18.2	19.0	+0.8
<b>Pralia</b>	treatment for osteoporosis	12.5	16.0	+3.5
<b>Ranmark</b>	treatment for bone complications caused by bone metastases from tumors	12.4	13.0	+0.6
<b>Cravit</b>	synthetic antibacterial agent	18.4	13.0	-5.4
<b>Inavir</b>	anti-influenza treatment	14.0	13.0	-1.0
<b>Omnipaque</b>	contrast medium	16.9	12.0	-4.9
<b>Artist</b>	treatment for hypertension, angina pectoris and chronic heart failure	15.1	11.0	-4.1
<b>Urief</b>	treatment for dysuria	11.8	11.0	-0.8
<b>Mevalotin</b>	antihyperlipidemic agent	13.4	10.0	-3.4
<b>Efient</b>	antiplatelet agent	4.9	8.0	+3.1



**Annual ordinary dividend will be increased from 60 yen/share to 70 yen/share.**

(Yen)

		Second quarter	Fiscal year-end	Total
<b>FY2016 (Plan)</b>	ordinary dividend	<b>35</b>	<b>35</b>	<b>70</b>
<b>FY2015 (Results)</b>	ordinary dividend	30	30	60
	commemorative dividend	10	-	10

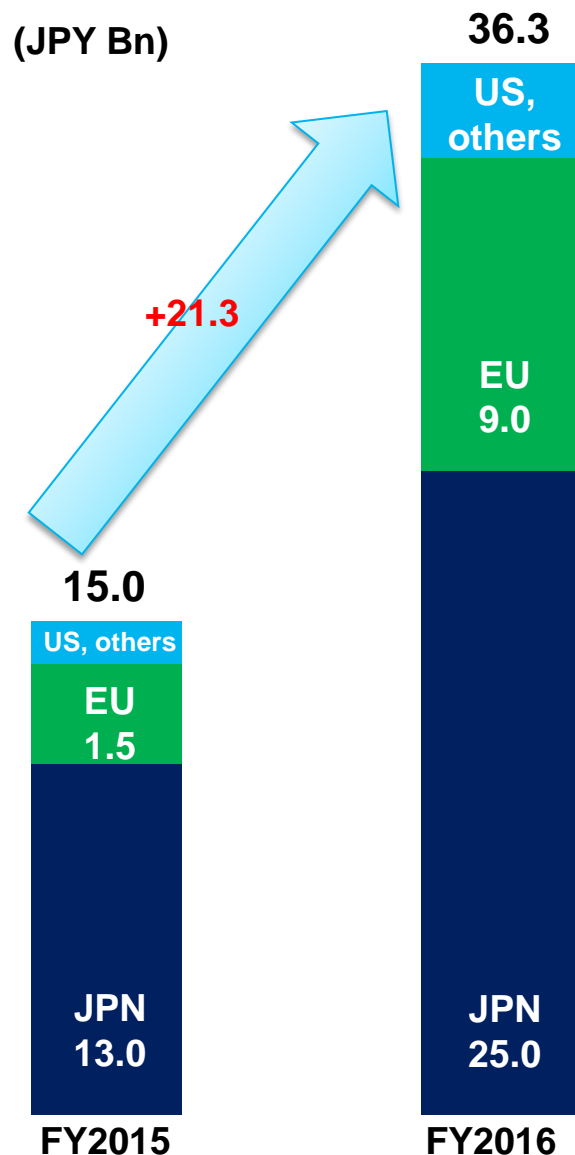
## ◆ Shareholder returns policy during 5YBP

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

# Major Management Topics

- **Edoxaban**
- **Daiichi Sankyo, Inc. (DSI)**
- **R&D Topics**

# Edoxaban : FY2016 Global Sales Forecast



**Realize rapid market penetration in Japan and Europe by highlighting unique product profile**

## ◆ Japan

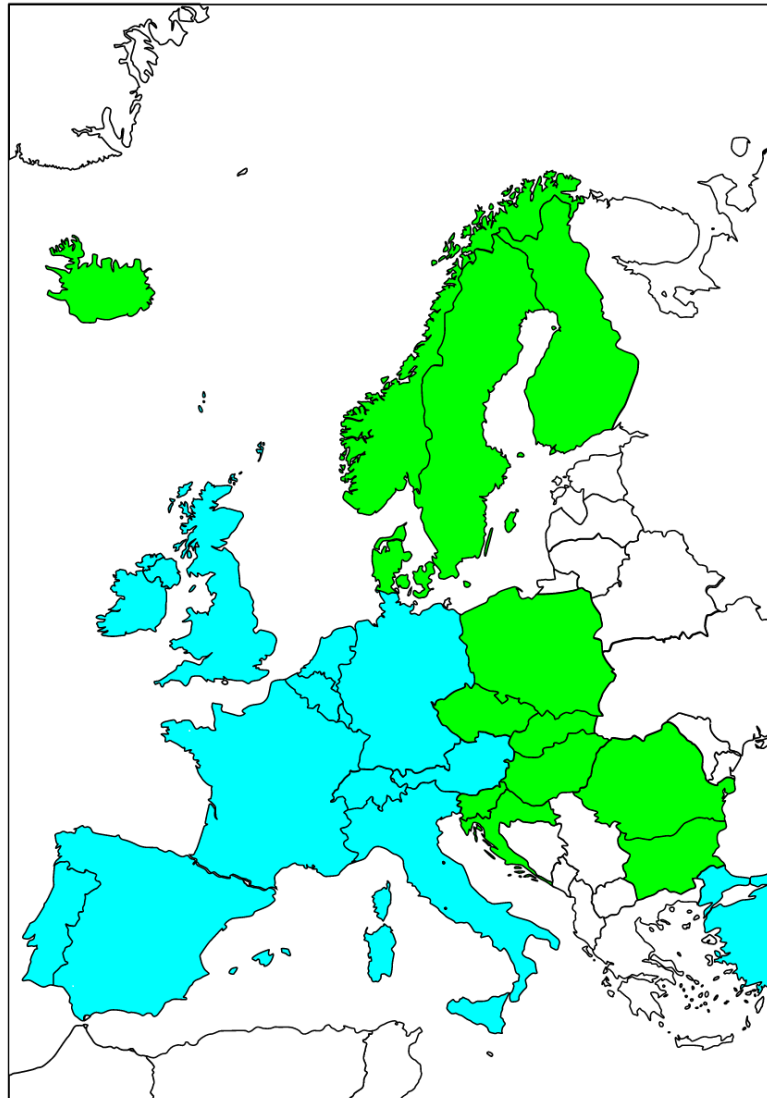
- The only Japan origin DOAC\* with 3 indications
- Sales capabilities with high quality/credibility

## ◆ Europe

- Steady launch in major countries
- Further promote access models in line with market needs in each country

\*DOAC : Direct Oral Anticoagulant Same meaning as NOAC (novel oral anticoagulant)


# Edoxaban : Marketing Structure in Europe



 DSE

 MSD

**Maximize sales by partnering  
in countries with no DS sales  
subsidiary**

 DSE promotes Lixiana in 18 countries and books sales.

Germany, UK, Ireland, France, Spain, Portugal, Italy, Netherlands, Belgium, Luxembourg, Austria, Switzerland, Turkey etc.

 MSD promotes Lixiana in 13 countries and books sales.

Denmark, Finland, Norway, Sweden, Iceland, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Slovakia, Slovenia

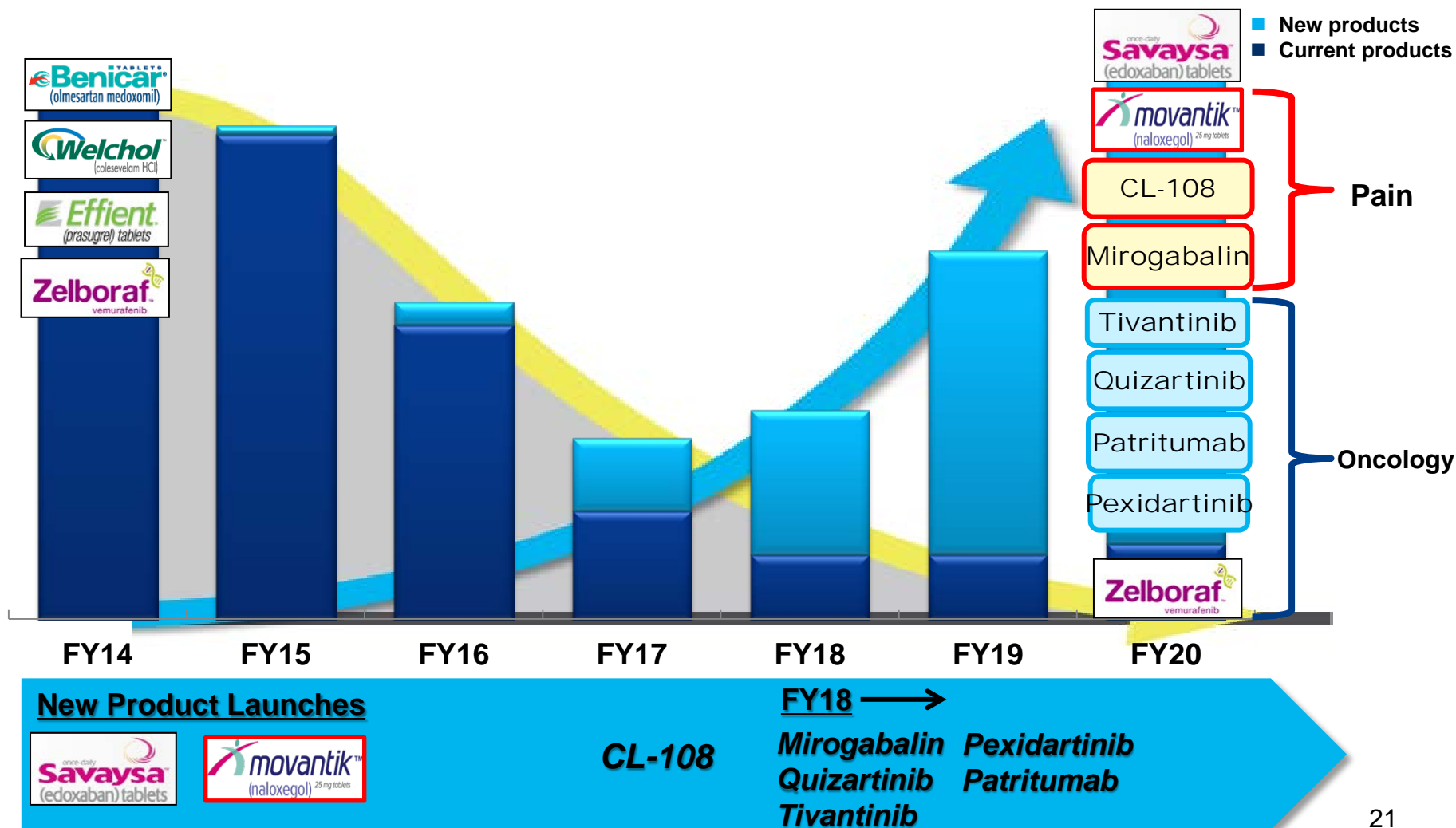
\*MSD: Merck Sharp and Dohme Europe Subsidiary of Merck & Co., Inc.

# Major Management Topics

- Edoxaban
- **Daiichi Sankyo, Inc. (DSI)**
- R&D Topics

# DSI: Shift in product portfolio

**With the LOE of key products DSI will transition from a mature primary care company to one with a differentiated specialty portfolio centered on Pain and Oncology**



# DSI Commercial: Focus Shifts from PCP to New Specialty Product Portfolio

	Before Restructuring 2015/10	After Restructuring 2016/4
<b>Sales Force Areas—US Commercial</b>	<ul style="list-style-type: none"> <li>• Management</li> <li>• Specialty/Hospital</li> <li>• Primary care</li> </ul>	<ul style="list-style-type: none"> <li>• Management</li> <li>• Specialty/Hospital</li> </ul>
<b>Sales Force Positions—US Commercial</b>	<b>1,500*</b>	<b>750*</b>

**DSI US Commercial Home Office Positions Also Reduced  
To Reflect Emerging Product Portfolio**

**DSI US Headquarters Office Co-Location  
Unite Commercial and Development Divisions**

**Expected Annual Savings: Total >\$250\*\* mn**

\*Numbers are approximate

\*\*Savings estimates are approximate (Restructuring costs in US: 15.2 Bn Yen in FY2015)



# Major Management Topics

- Edoxaban
- Daiichi Sankyo, Inc. (DSI)
- **R&D Topics**



## ◆ Progress of late-phase development pipeline


## ◆ Progress of oncology pipeline

- Four major late-phase development pipeline
- Four major early-phase development pipeline
  - ✓ DS-6051
- New phase 1 product
  - ✓ PLX73086/AC708
  - ✓ PLX51107

## ◆ Innovative technology: diving into cell therapy

- Research for new stem cells (CapSCs)
- In-licensed cell therapeutics: Heartcel

# Progress in late-phase pipeline to NDA

- ◆ **CL-108: Novel, opioid-containing formulation to treat moderate to severe pain while preventing or reducing opioid-induced nausea and vomiting (OINV)**
  - Charleston Laboratories, Inc. submitted NDA to U.S. Food and Drug Administration  March 2016
  - Targeted for launch in FY2017
  - Full results from pivotal phase 3 study of patients with moderate to severe pain following bunionectomy will be presented at the American Pain Society Scientific Meeting  in May 2016
- ◆ **Denosumab (anti-RANKL antibody): Treatment of rheumatoid arthritis**
  - In DESIRABLE study conducted in Japan, which is a randomized, double-blind, placebo-controlled Phase 3 clinical trial in patients with rheumatoid arthritis treating with disease-modifying anti-rheumatic drugs (DMARDs), a major objective of the study was achieved in March 2016.
  - An application for partial changes in approved items in preparation, targeted for launch in FY2017
- ◆ **Hydromorphone\*: Narcotic analgesic**
  - Oral administration formulation:  
Applied for manufacturing/marketing authorization in Japan on March 2016
  - Injectable formulation: Phase 3 study on-going

\*: Hydromorphone was publicly offered for development by the Review Committee on Unapproved Drugs and Indications with High Medical Needs organized by MHLW. Daiichi Sankyo decided to develop this drug to give patients an treatment option which is a standard of care for pain associated with cancer.

# Four major late-phase development pipeline

## Update during Q4 FY2015 written in red

TLR : anticipated Top Line Result

### Quizartinib

Acute myeloid leukemia (AML)  
2<sup>nd</sup> line (P3)  
**TLR: 1H CY2017**  
-----  
1<sup>st</sup> line (P3)

- Orphan Drug Designation by the FDA and EMA
- Fast Track Status by the FDA
- Anticipating effectiveness to patients with FLT3-ITD patients to whom midostaurin doesn't show efficacy
- **Is being launched. Estimated Primary Completion Date: Q4 FY2019**

### Tivantinib

Hepatocellular carcinoma (HCC)(P3)  
**TLR: 1H CY2017**

- Orphan Drug Designation by the FDA and EMA
- Refractory HCC
- Anticipating high effectiveness by stratification of patients
- **the independent data monitoring committee (DMC) of the METIV-HCC study conducted the planned interim assessment and it was determined the trial will continue to its final analysis (Mar 2016)**

### Pexidartinib

Tenosynovial giant cell tumor (TGCT)(P3)  
**TLR: 1H CY2018**  
-----  
Solid tumor(P1/2a)  
**TLR: 2H CY2019**

- Orphan Drug Designation by the FDA and EMA
- Breakthrough Therapy designation by FDA
- **On track**
- Combination therapy with Merck's anti-PD-1 antibody
- **On track**

### Patritumab

Non-small cell lung cancer (P2/3)  
**TLR: 2H CY2018**  
-----  
Head and Neck cancer (P2)

- Anticipating high effectiveness in specific group of patients selected by biomarker
- **Promising data for a single-arm phase 1 study in combination with cetuximab and a platinum containing therapy for patients with recurrent and metastatic head and neck cancer**
- **Data to be published at ASCO in June 2016**

# Four major early-phase development pipeline

## Update during Q4 FY2015 written in red

<b>DS-8201 (HER2-ADC)</b>	<b>Solid tumor (P1)</b>	<ul style="list-style-type: none"> <li>Anticipating effectiveness to patients resistant to treatment by Herceptin or Kadcyla</li> <li>Applied DS proprietary ADC* technology</li> <li>Target: obtaining of phase 1 results in FY2017</li> <li><b>On track</b></li> </ul> <p>*:Antibody Drug Conjugate</p>
<b>DS-3201 (EZH1/2)</b>	<b>Non-Hodgkin's lymphoma (incl. adult T-cell leukemia) (P1)</b>	<ul style="list-style-type: none"> <li>Targeted epigenetics**</li> <li>Aiming at permanent cure of hematological cancer by eradication of "cancer stem cell"</li> <li>FIC as an EZH 1/2 dual inhibitor</li> <li>Anticipating More potent as compared to EZH2 inhibitor</li> <li><b>Started phase1 clinical study (Mar 2016)</b></li> <li><b>Target: completion of phase 1 study in FY2018</b></li> </ul> <p>**:.chemical modification of DNA or histone leading to acquired change in gene expression without modification of DNA sequence</p>
<b>DS-3032 (MDM2)</b>	<b>Solid tumor Hematologic tumor(P1)</b>	<ul style="list-style-type: none"> <li>Anticipating high effectiveness to cancer with MDM2 gene amplification/Wt p53</li> <li>FIC</li> <li>Based on the phase 1 study in the US suggesting effectiveness in patients with liposarcoma (LPS), LPS is selected as a potential indication for further development, which is under consideration</li> <li><b>On track</b></li> </ul>
<b>DS-6051 (NTRK/ROS1)</b>	<b>Solid Tumor (Lung cancer)</b>	<ul style="list-style-type: none"> <li>ROS1 fusion is one of the major driver mutations observed in lung cancer etc.</li> <li>Phase 1 study is planned to complete in FY2017 (US/JP)</li> <li>Partial response is observed in a patient in US phase1 study.</li> <li><b>Interim analysis of efficacy and safety was presented at AACR in April 2016.</b></li> <li><b>Utilizing SCRUM-Japan*** for patient selection in Japan</b></li> </ul>

\*\*\*SCRUM-Japan: National project led by National Cancer Center Japan to screen oncogenic abnormality of cancer patients in order to provide the best-fit medicines to them

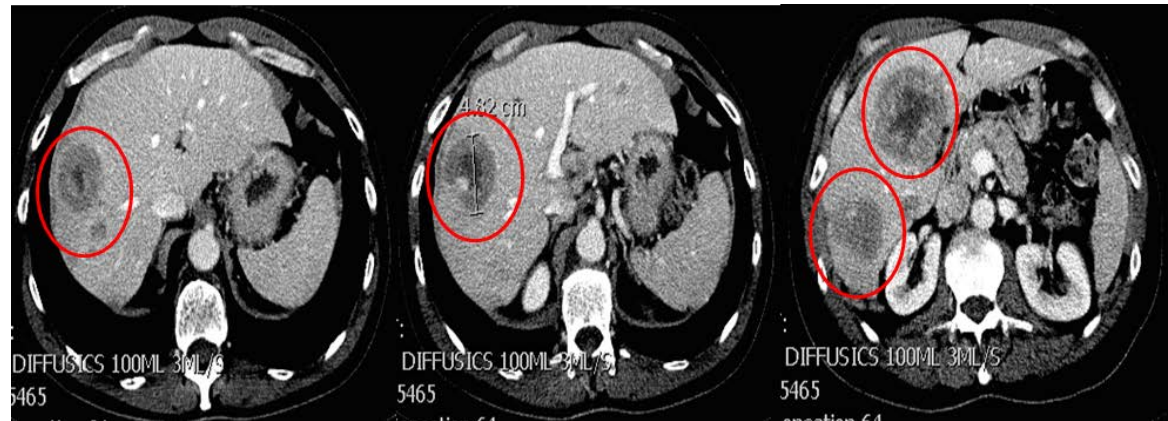
- ◆ **Partial response in a patient who had prior crizotinib and ceritinib therapies with metastatic NSCLC ROS1+ w/ liver metastases was confirmed in Phase 1 study in US\***
  - First report for Ros1 inhibitor which is effective to a tumor patient who is resistant to crizotinib
  - Currently on treatment in Cycle 13 (from July 2015)
  
- ◆ **Started phase 1 study in Japan (Q4 FY2015)**
  - Initiated in February 2016 in collaboration with SCRUM-Japan\*\*
  - Oral once-daily (QD) continuous dosing, 21-day cycle

\*Presented at American Association for Cancer Research (AACR) annual meeting Apr 16-20 2016

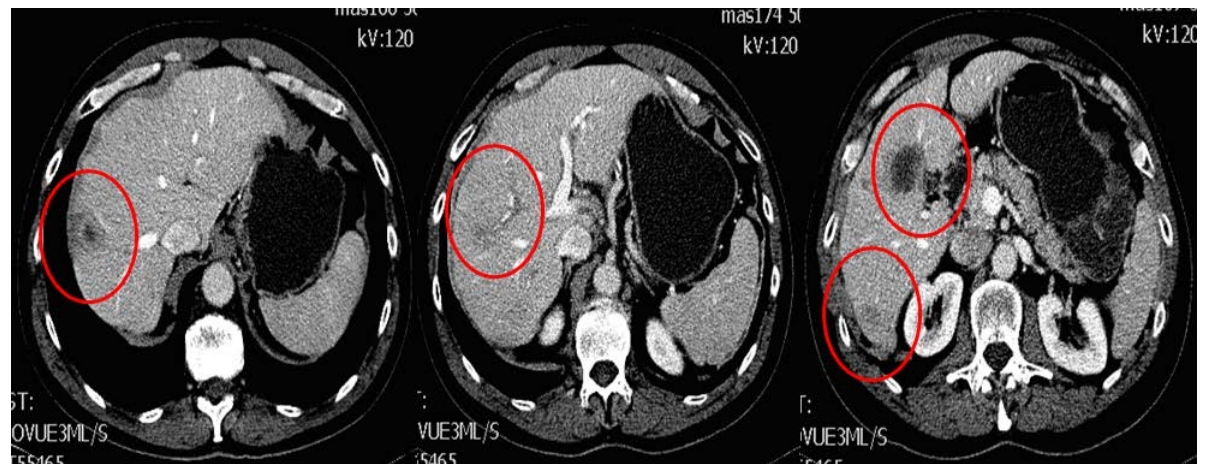
\*\* Cancer Genome Screening Project for Individualized Medicine in Japan

## Diagnostic image of patient with Partial Response Observed anti-tumor effect

Baseline  
(July 2015)



After 9 weeks on  
therapy  
(September 2015)



## ◆ **PLX73086/AC708: CSF-1R inhibitor**

- Fast follow-on to Pexidartinib, potential best-in-class
- Improved selectivity relative to Pexidartinib
- Target indication: Tenosynovial Giant Cell Tumor (TGCT)
- Summary of the phase 1 study
  - ✓ Study objectives
    - Primary: safety, PK&PD
    - Secondary: efficacy (ORR)
  - ✓ Part1: Open-label, dose escalation in solid tumors subjects
  - ✓ Part2: Extension cohort at the recommended phase 2 dose (RP2D) in subjects with histologically confirmed, unresectable, locally advanced or refractory TGCT
  - ✓ Estimated Primary Completion: Q4 FY2018



## ◆ PLX51107: BRD4 inhibitor

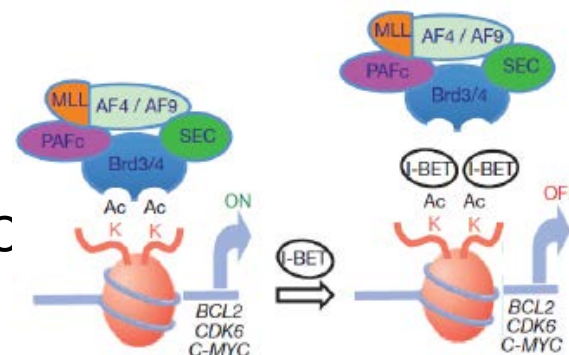
### ➤ BRD4

- ✓ A member of BET (Bromodomain and Extra-Terminal domain) protein family
- ✓ Recruit regulatory complexes to influence gene expression, especially oncogenes, such as c-MYC
- ✓ Epigenetic target potential

### ➤ PLX51107 inhibits the interaction between BRD4 and acetylated lysines of histones to down-regulate expressions of oncogenes

### ➤ Summary of the phase 1 study

- ✓ Study objectives
  - Primary: safety, PK and MTD/RP2D
  - Secondary: ORR, DOR, PFS
  - Exploratory: gene expression (e.g. c-MYC in tumor cells and tumor biopsies)
- ✓ Estimated study completion: Q4 FY2017





# Innovative technology: Diving into cell therapy

## ◆ Cell therapy business environment

- A revolutionary therapeutic technology with full potential still to be defined
- Autologous vs. Allogeneic
  - ✓ Autologous: Advanced technology with challenges about business potential to be defined
  - ✓ Allogeneic: many technical hurdles to be defined
- Cell therapy related regulations have been enacted in Japan, but it is unclear how to make such technology into a sustainable business
  - ✓ We will have to partner with regulators regarding clinical study, pharmaceutical affairs, manufacturing etc.

## ◆ Our strategy

- Capitalize licensing and partnering with many companies and academies to mitigate enterprise risk and accelerate business development
  - ✓ Create synergy by bringing each company/academia's strength
  - ✓ Catch up with top group together and establish a business foundation and business model



**Innovative therapy which changing SOC  
for patients**

# Innovative technology:

New technology for cell therapeutics

## ◆ In-licensed Heartcel™ technology from Cell Therapy Ltd, CTL, based in the UK

### CTL technology

- CTL has developed a novel and proprietary platform, based on the stem cell discoveries of Professor Sir Martin Evans, Nobel prize winner, which can discover tissue- and disease-specific progenitor cells from healthy donor blood
- CTL is developing a range of allogeneic therapies for different indications by selecting a cell appropriate for target disease
- Heartcel is designed to avoid rejection, and has immuno-modulatory and regenerative properties



Heart-specific immuno-modulatory cells ⇒ *Heartcel*

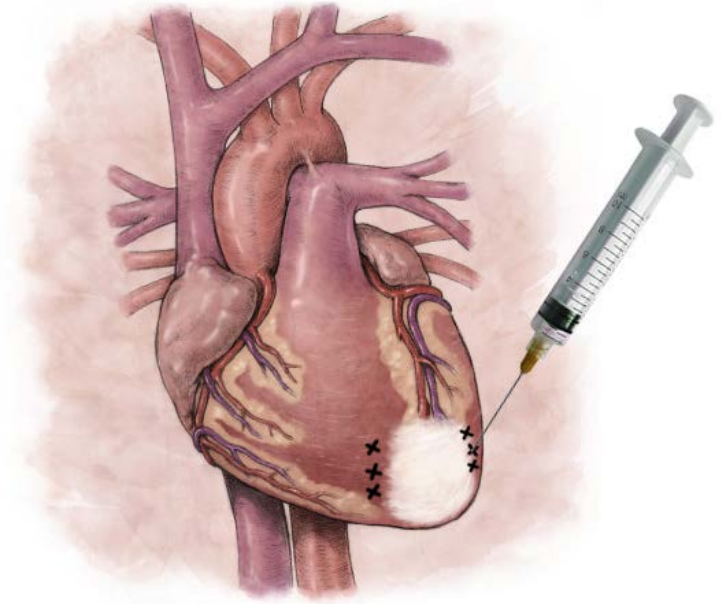
# Innovative technology:

## New technology for cell therapeutics

### Heartcel: Route of administration

**Intra-myocardial injection with CABG\***

**Regeneration of ischemic scar tissue is expected by administration to the infarcted site of the heart**



Modified from 'Understanding What Went Wrong'  
by Laura E. Smith

### ◆ A part of the licensing conditions

- Expected as a treatment for severe ischemic heart failure
- Development stage : in preparation for Phase 3 study in EU,  
in preparation for Phase 1 study in Japan
- Territory : Japan
- Role: Daiichi Sankyo: Development & sales  
CTL: Manufacturing of investigational drug and commercial drug

\* Coronary Artery Bypass Graft

# Innovative technology:

## Research for new stem cell

- ◆ **Started an collaborative research to develop new cell therapy on new stem cells with Asahikawa Medical University in April 2016**
- Therapeutic use of capillary stem cell (CapSCs) for various kinds of diseases in addition to a practical use of the CapSCs stem cells as a source of therapy will be investigated.

### What are CapSCs:

- New somatic stem cells isolated and identified by the joint research of Prof. Kawabe in Asahikawa Medical University and Asubio Pharma Co., Ltd, a member of Daiichi Sankyo group
- Have potential to be differentiated into various kinds of tissues, such as blood vessel, nerve and skeletal muscle
- Has potential as a regenerative medicine treatment for wide range of diseases like lower leg ischemia, ischemic heart disease, sarcopenia, nerve-related disease and so on.

# Innovative technology:

## Research for new stem cell

Example of therapeutic effect of CapSCs transplantation experiment with model mice of sever lower leg ischemia. CapSC treatment dramatically inhibited necrosis of lower leg caused by ischemia

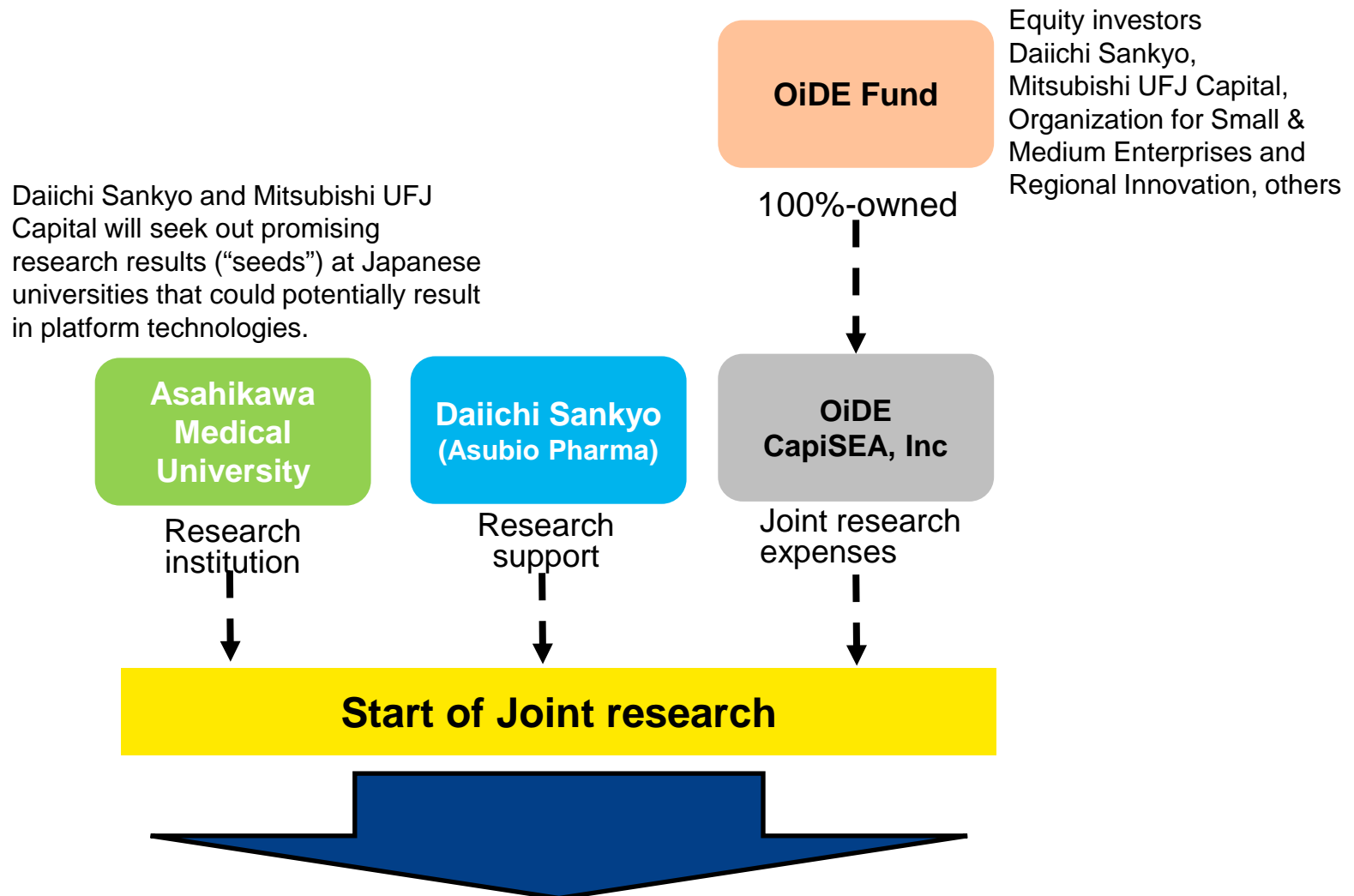
Control group



CapSCs group



# Open innovation research scheme utilizing OiDE Fund



In case of meeting success factors  
DS will acquire all stocks from OiDE CapiSEA  
and the research program will shift to the R&D project of DS

# Major R&D milestone events

## <Milestones towards NDA submission>

Project	Indication/Study	Event	Target
<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*	H1 FY2016
<b>DS-8500</b>	Type 2 Diabetes phase 2b study (JP)	TLR	Q4 FY2016

TLR\*: Top Line Result

## <Publication of results of major clinical studies in academic conference>

project	Study
<b>DS-8500</b>	<b>Type 2 Diabetes phase 2a study (JP)</b> Elected as the topic for the late breaking session of the American Diabetes Association (ADA) 76 <sup>th</sup> scientific sessions June 10-16, 2016

# Major R&D Pipeline

As of May 2016

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

Red: Major changes after the FY2015 Q3 financial announcement on January 29, 2016



# Introducing Daiichi Sankyo Cancer Enterprise: Creating a transformation

Executive VP & Global Head R&D Oncology  
Antoine Yver, MD MSc



- ◆ **Former Pediatrician Oncologist, academic faculty Paris, France**
- ◆ **Former Head, Oncology Global Medicines Development at AstraZeneca (2009-2016)**
- ◆ **26 years pharma experience in global R&D, including early & late phase development and licensing**
- ◆ **Global clinical leader for 12 marketing applications in oncology, 4 new drugs**
- ◆ **In addition, in 2015: olaparib (PARPi), osimertinib (3<sup>rd</sup>-G mut-EGFRi T790M)+**
- ◆ **Multinational line management experience for development functions, including Japan R&D and China R&D**

- ◆ **Rigorous science, pursuing unique patient needs**
- ◆ **Simplicity, decentralized decision-making allowing autonomy and accountability**
- ◆ **Do the hard, right thing**
- ◆ **Take seriously what we do, don't take ourselves seriously**
- ◆ **Be passionate and competitive externally**
- ◆ **Focus and prioritize**
- ◆ **Relentless pursuit of perfection**
- ◆ **Be courageous, creative, collaborative, candid**

## Needs

- ◆ In 2012, 8.2 million cancer-related deaths worldwide
- ◆ New cancer cases are expected to rise from 14 to 22 million within the next two decades
- ◆ World population is aging, and cancer rates increase with age

## Opportunity

- ◆ Six new US/Japan INDs for oncology agents in FY2015
- ◆ Market continuously reshaping; medical needs far from being fully addressed
  - Immuno-oncology is yet to mature: with today's science, only a fraction of cancer patients can hope to benefit
  - Many opportunities to be either first- or best-in-class

**SCIENCE-DRIVEN, COMPETITIVE,  
FOCUSED, WITH EXCELLENCE**

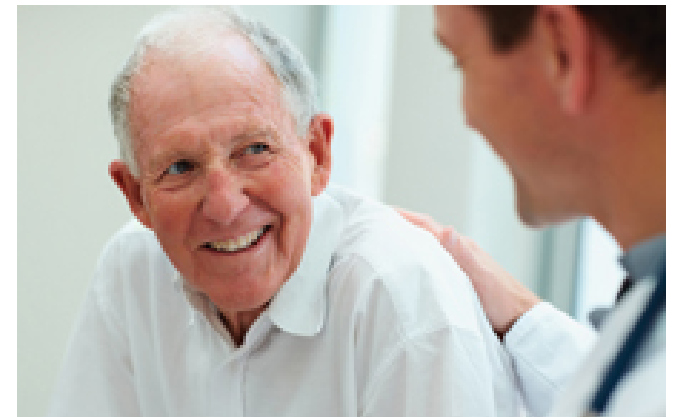
**DS Cancer Enterprise:**  
**To lead in science and transform**  
**evidence into value**  
**for cancer patients in need**

# Enterprise: what do we mean?

“A professional firm seeking to achieve ultimate solutions for patients with cancer”

“A dedicated group pursuing entrepreneurial behavior together, driven by each member’s initiatives, expertise and passion”

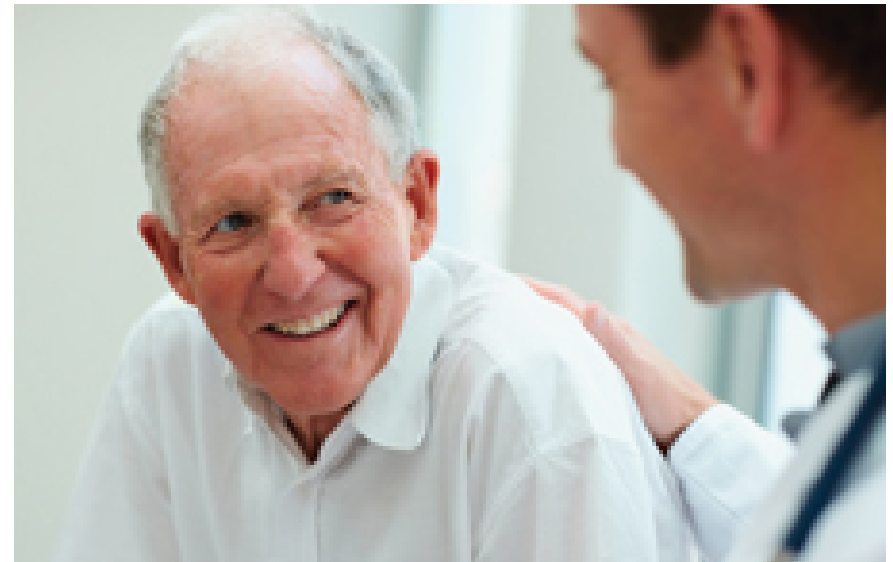
- ◆ Come together and work together beyond boundaries and titles
- ◆ Desire to go beyond limits, i.e., beyond boundaries, limitations, breaking points
- ◆ All this for a noble cause



# My Vision for DS Cancer Enterprise:

Be perfect in 3 areas

- ◆ **Select** with discipline the right molecules & technologies in which to invest
- ◆ **Design** efficient, effective & differentiated strategies and products based upon data, facts, observations and patient/customer/expert insights
- ◆ **Deliver** on our strategy and thereby delight DS in its transformation



## Cancer Enterprise

Grow and  
enrich **talent**  
base and ways  
of working

Select the  
most valuable  
& promising  
**assets** to  
ensure we  
compete at our  
best, and  
secure/  
accelerate  
delivery plans

Refresh the  
2014-2015  
Oncology R&D  
portfolio  
**strategy**

Create the  
right **support**  
for the teams



Contact address regarding this material

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