

# Top Management Presentation

Financial Results for FY2016 (April 1, 2016 – March 31, 2017)

DAIICHI SANKYO CO., LTD

George Nakayama  
Chairman and CEO

Sunao Manabe  
President and COO

May 11, 2017

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- ◆ **FY2016 Financial Results**
- ◆ **FY2017 Consolidated Forecast**
- ◆ **Progress of 5-Year Business Plan**

# FY2016 Financial Results

# Overview of FY2016 Results

(Bn JPY)

	FY2015 Results	FY2016 Results	YoY
Revenue	986.4	955.1	<div>-3.2%</div> -31.3
Cost of Sales	318.6	349.4	+30.8
SG&A Expenses	328.8	302.5	-26.3
R&D Expenses	208.7	214.3	+5.7
Operating Profit	130.4	88.9	<div>-31.8%</div> -41.5
Profit before Tax	122.4	87.8	-34.6
Profit attributable to owners of the Company	82.3	53.5	<div>-35.0%</div> -28.8

Currency Rate	USD/JPY	120.14	108.42	-11.72
	EUR/JPY	132.57	118.84	-13.73

- ◆ **Impairment test was needed by the delay of the progress for some pipeline projects centered on Measles-Mumps-Rubella vaccine**
- ◆ **According to impairment test, KDSV booked an impairment loss of 21.9 Bn JPY on tangible fixed assets and intangible assets  
Its liabilities exceed its assets by approx. 23.0 Bn JPY (net debt)**

Reference: Profit before Tax of KDSV

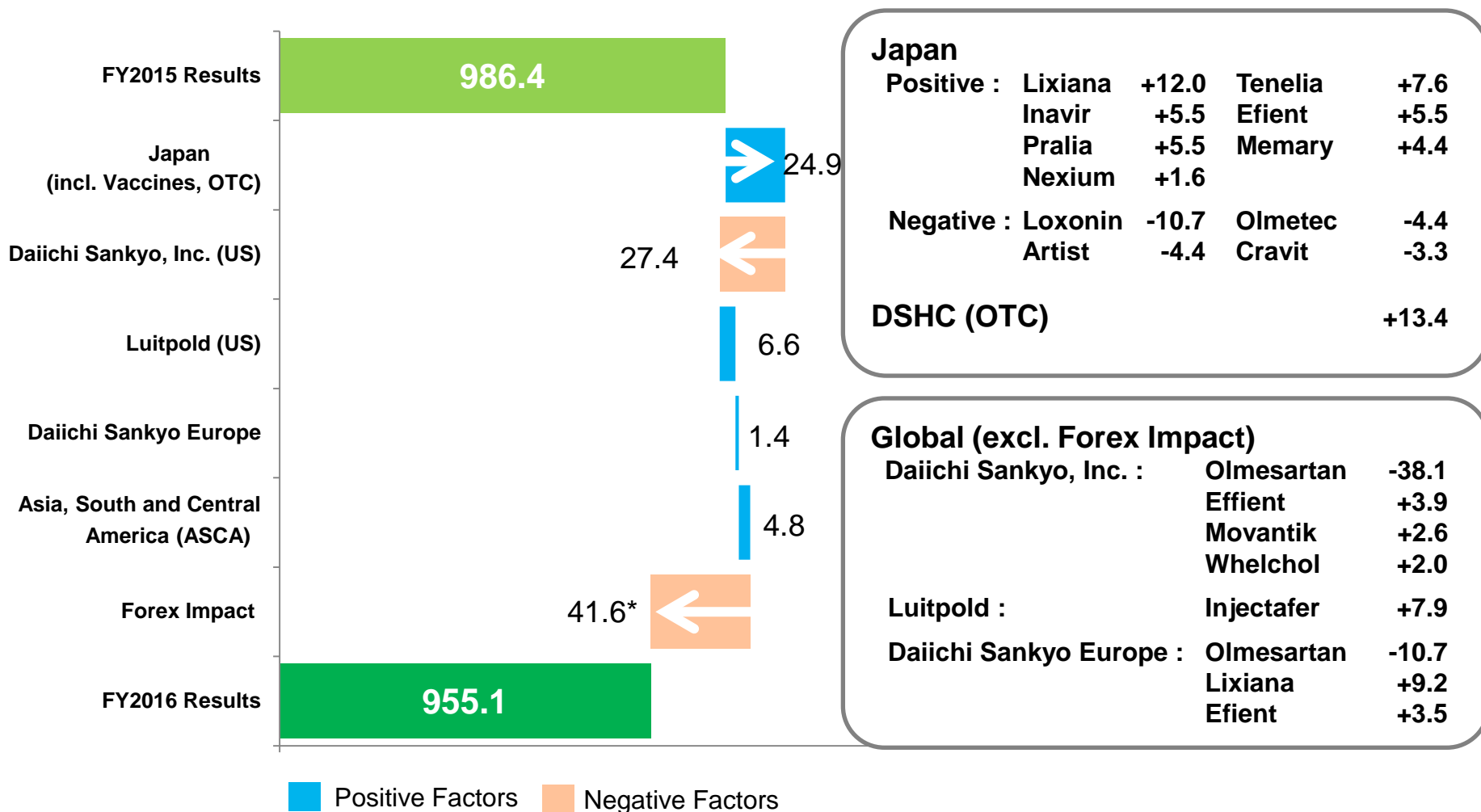
	FY2015 Results	FY2016 Results
Profit before Tax	-7.9	-29.8

- ◆ **An additional capital increase of approx. 40.0 Bn JPY will be made by DS's investment mid-June 2017**
  - To eliminate net debt and strengthen the financial basis
  - To become early profitable by cost reductions and streamlining
  - To improve its long-term profitability by developing and launching new products

# Revenue

Decreased by 31.3 Bn JPY (Increased by 10.3 Bn JPY excl. forex impact)

(Bn JPY)

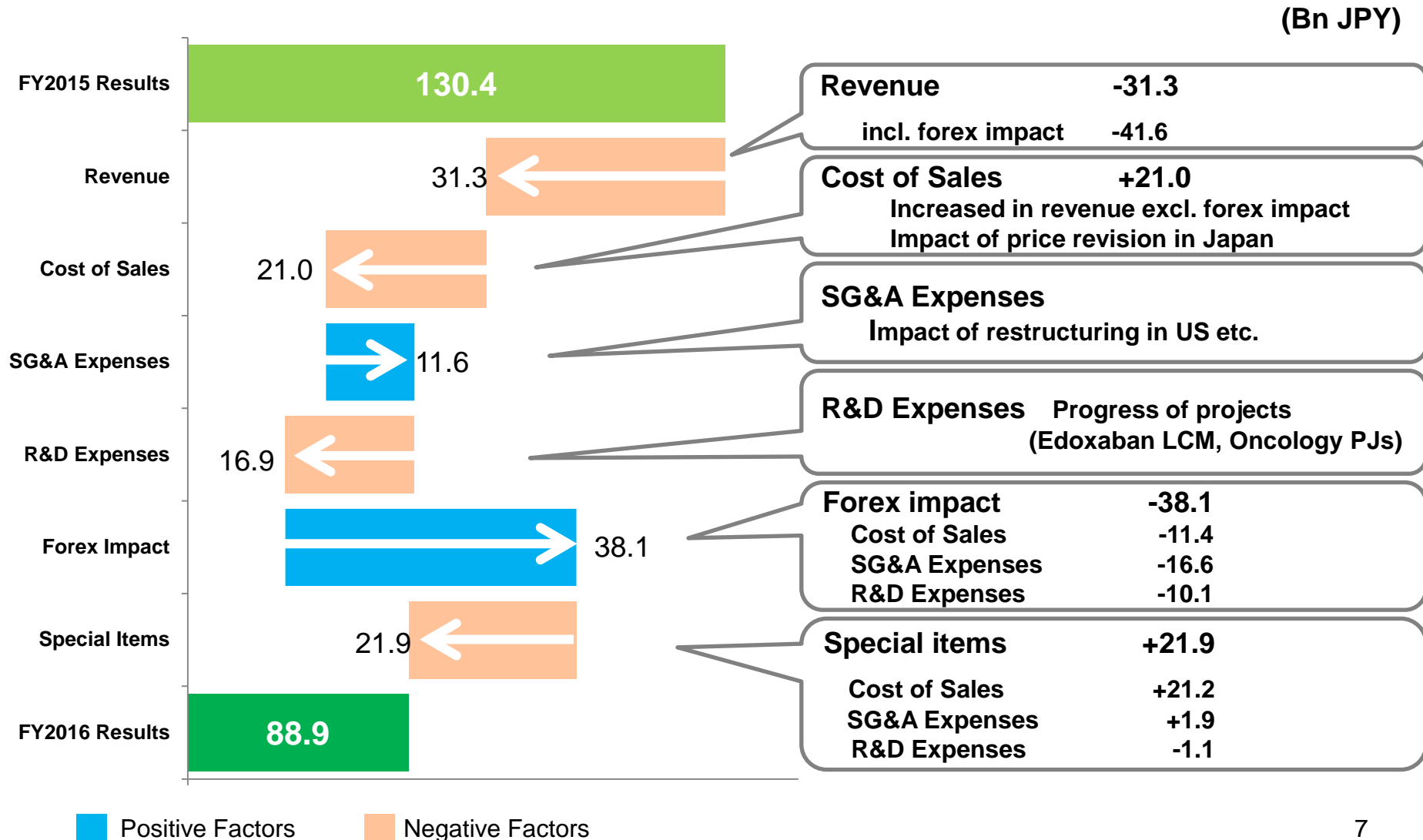


\* Forex impact USD: -25.4, EUR: -8.3, ASCA: -8.0

# Operating Profit

Decreased by 41.5 Bn JPY

(Decreased by 16.1 Bn JPY excl. forex impact and special items)





# Special Items

(Bn JPY)

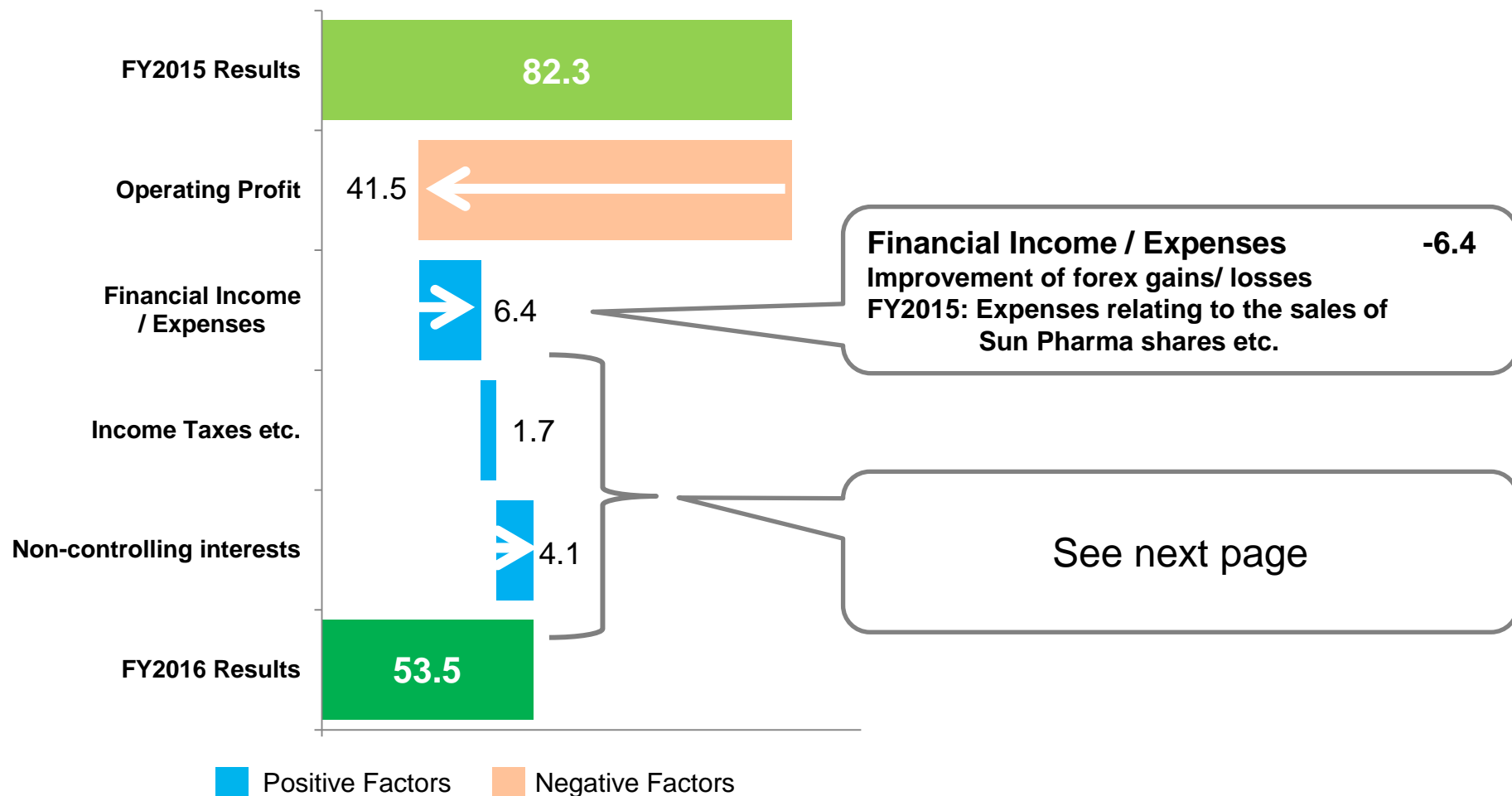
	FY2015 Results		FY2016 Results		YoY
<b>Cost of Sales</b>	Gain on sales of subsidiary	-2.4			
	Gain on sales of fixed assets	-1.1	Restructuring costs in SC	3.6	
	Impairment loss (Intangible)	1.9	Impairment loss (Vaccine)	20.6	+21.2
	Restructuring costs in SC	4.6			
<b>SG&amp;A Expenses</b>	Restructuring costs in US	15.2	Restructuring costs in EU	10.6	
	Restructuring costs in EU	2.9	Impairment loss (Vaccine)	1.0	+1.9
	Gain on sales of fixed assets	-8.2			
<b>R&amp;D Expenses</b>			Restructuring costs in R&D	2.5	
	Restructuring costs in R&D	5.6	Impairment loss (Vaccine)	0.2	-1.1
			Impairment loss (Intangible)	1.8	
<b>Total</b>		18.5		40.4	+21.9

- : Cost decrease items

# Profit Attributable to Owners of the Company

Decreased by 28.8 Bn JPY

(Bn JPY)



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

# Income Taxes, Non-Controlling Interests

(Bn JPY)

	FY2015 Results	FY2016 Results	YoY
Profit before Tax	122.4	87.8	-28.3%
Income taxes etc.	42.0	40.3	-1.7
(Tax rate)	(34.3%)	(45.9%)	(+11.6%)
Profit for the year	80.4	47.5	-40.9%
Non-controlling interests	-1.9	-6.0	-4.1
Profit attributable to owners of the Company	82.3	53.5	+35.0%

KDSV\* with Net Operating Loss from the previous term has been not applicable to tax effect accounting on its loss

The loss of KDSV was increased drastically in FY2016  
→ With the KDSV's negative impact on DS Consolidated, tax rate in FY2016 was deteriorated

Loss attributable to Kitasato Institute (20%)

\*KDSV: Kitasato Daiichi Sankyo Vaccine

# Revenue: Major Business Units

(Bn JPY)

	FY2015 Results	FY2016 Results	YoY	vs. Forecast (%)
<b>Japan</b>	<b>494.7</b>	<b>506.6</b>	<b>+11.9</b>	<b>100.3%</b>
<b>Daiichi Sankyo Healthcare</b>	<b>53.4</b>	<b>66.7</b>	<b>+13.4</b>	<b>101.1%</b>
<b>Daiichi Sankyo Inc.</b>	<b>185.1</b>	<b>142.3</b>	<b>-42.8</b>	<b>98.8%</b>
Olmesartan	111.6	66.4	-45.3	92.2%
Welchol	48.4	45.5	-2.9	111.0%
Effient	20.7	22.2	+1.5	-
Savaysa	0.4	1.9	+1.4	93.8%
Movantik	2.0	4.2	+2.1	-
<b>Luitpold</b>	<b>91.0</b>	<b>88.1</b>	<b>-2.9</b>	<b>100.1%</b>
Venofer	31.2	28.5	-2.8	101.7%
Injectafer	18.6	24.0	+5.3	99.9%
<b>Daiichi Sankyo Europe</b>	<b>77.8</b>	<b>71.0</b>	<b>-6.8</b>	<b>101.4%</b>
Olmesartan	58.9	43.2	-15.7	102.8%
Efient	5.4	7.9	+2.6	-
Lixiana	1.5	9.7	+8.1	107.5%
<b>Asia, South and Central America (ASCA)</b>	<b>75.3</b>	<b>72.1</b>	<b>-3.2</b>	<b>101.6%</b>

Currency	USD/JPY	120.14	108.42	-11.72
Rate	EUR/JPY	132.57	118.84	-13.73

\*Incl. Forex impact

# Revenue: Major Products in Japan

(Bn JPY)

		FY2015 Results	FY2016 Results	YoY	vs. Forecast (%)
<b>Nexium</b>	ulcer treatment	82.4	84.0	+1.6	101.2%
<b>Olmetec</b>	antihypertensive agent	73.9	69.4	-4.4	100.6%
<b>Memary</b>	Alzheimer's disease treatment	42.4	46.9	+4.4	95.6%
<b>Loxonin</b>	anti-inflammatory analgesic	48.1	37.4	-10.7	101.1%
<b>Tenelia</b>	type 2 diabetes mellitus inhibitor	16.5	24.2	+7.6	93.0%
<b>Lixiana</b>	anticoagulant agent	13.0	25.0	+12.0	100.0%
<b>Rezaltas</b>	antihypertensive agent	18.2	17.5	-0.6	97.4%
<b>Pralia</b>	treatment for osteoporosis	12.5	18.0	+5.5	105.6%
<b>Ranmark</b>	treatment for bone complications caused by bone metastases from tumors	12.4	13.9	+1.5	107.1%
<b>Inavir</b>	anti-influenza treatment	14.0	19.6	+5.5	139.7%
<b>Cravit</b>	synthetic antibacterial agent	18.4	15.1	-3.3	107.9%
<b>Omnipaque</b>	contrast medium	16.9	14.2	-2.7	109.2%
<b>Urief</b>	treatment for dysuria	11.8	11.4	-0.4	103.9%
<b>Artist</b>	treatment for hypertension, angina pectoris and chronic heart failure	15.1	10.6	-4.4	96.8%
<b>Mevalotin</b>	antihyperlipidemic agent	13.4	10.4	-3.0	104.5%
<b>Efient</b>	antiplatelet agent	4.9	10.4	+5.5	94.7%

# FY2017 Consolidated Forecast

# FY2017 Consolidated Forecast

(Bn JPY)

	FY2016 Results	FY2017 Forecast	YoY
Revenue	955.1	930.0	-2.6% -25.1
Cost of Sales	349.4	340.0	-9.4
SG&A Expenses	302.5	300.0	-2.5
R&D Expenses	214.3	190.0	-24.3
Operating Profit	88.9	100.0	+12.4% +11.1
Profit before Tax	87.8	100.0	+12.2
Profit attributable to owners of the Company	53.5	66.0	+23.4% +12.5

Currency Rate	USD/JPY	108.42	110.00
	EUR/JPY	118.84	120.00

# FY2017 Consolidated Forecast

(Bn JPY)

	FY2016 Results (excl. special items)	FY2017 Forecast	YoY
<b>Revenue</b>	<b>955.1</b>	<b>930.0</b>	<b>-2.6%</b> <b>-25.1</b>
<b>Cost of Sales</b>	<b>34.0%</b> <b>325.2</b>	<b>36.6%</b> <b>340.0</b>	<b>+14.8</b>
<b>SG&amp;A Expenses</b>	<b>290.8</b>	<b>300.0</b>	<b>+9.2</b>
<b>R&amp;D Expenses</b>	<b>209.8</b>	<b>190.0</b>	<b>-19.8</b>
<b>Operating Profit</b>	<b>129.3</b>	<b>100.0</b>	<b>-22.7%</b> <b>-29.3</b>

See next page

Product mix  
(Impact of olmesartan  
LOE)

- Increase of co-promotion expenses (Japan・China)
- Cost reduction/ Cost efficiency

- Mirogabalin study completed
- Cost reduction/ Cost efficiency

Currency Rate	USD/JPY	108.42	110.00
	EUR/JPY	118.84	120.00

Operating Profit in FY2017 will be decreased by 29.3 Bn JPY compared to FY2016 excluding special items (40.4 Bn JPY)



# Revenue: Major Business Units

(Bn JPY)

	FY2016 Results	FY2017 Forecast	YoY
Japan	506.6	536.0	+29.4
Daiichi Sankyo Healthcare	66.7	69.0	+2.3
Daiichi Sankyo Inc.	142.3	62.0	-80.3
Luitpold	88.1	103.0	+14.9
Daiichi Sankyo Europe	71.0	66.0	-5.0
Asia, South and Central America (ASCA)	72.1	84.0	+11.9

# Revenue: Global Products

(Bn JPY)

	FY2016 Results	FY2017 Forecast	YoY
<b>Olmesartan</b>	<b>218.0</b>	<b>134.0</b>	<b>-84.0</b>
Olmetec, Rezaltas (JPN)	87.0	63.0	-24.0
Benicar/Benicar HCT etc. (US)	66.4	14.0	-52.4
Olmetec/Olmetec Plus etc. (EU)	43.2	26.0	-17.2
Other subsidiaries, export, etc.	21.5	31.0	+9.5
<b>Edoxaban</b>	<b>37.3</b>	<b>65.0</b>	<b>+27.7</b>
Lixiana (JPN)	25.0	39.0	+14.0
Savaysa (US)	1.9	2.0	+0.1
Lixiana (EU)	9.7	22.0	+12.3
Other subsidiaries	0.8	2.0	+1.2

# Progress of 5-Year Business Plan

## Global Pharma Innovator with Competitive Advantage in Oncology

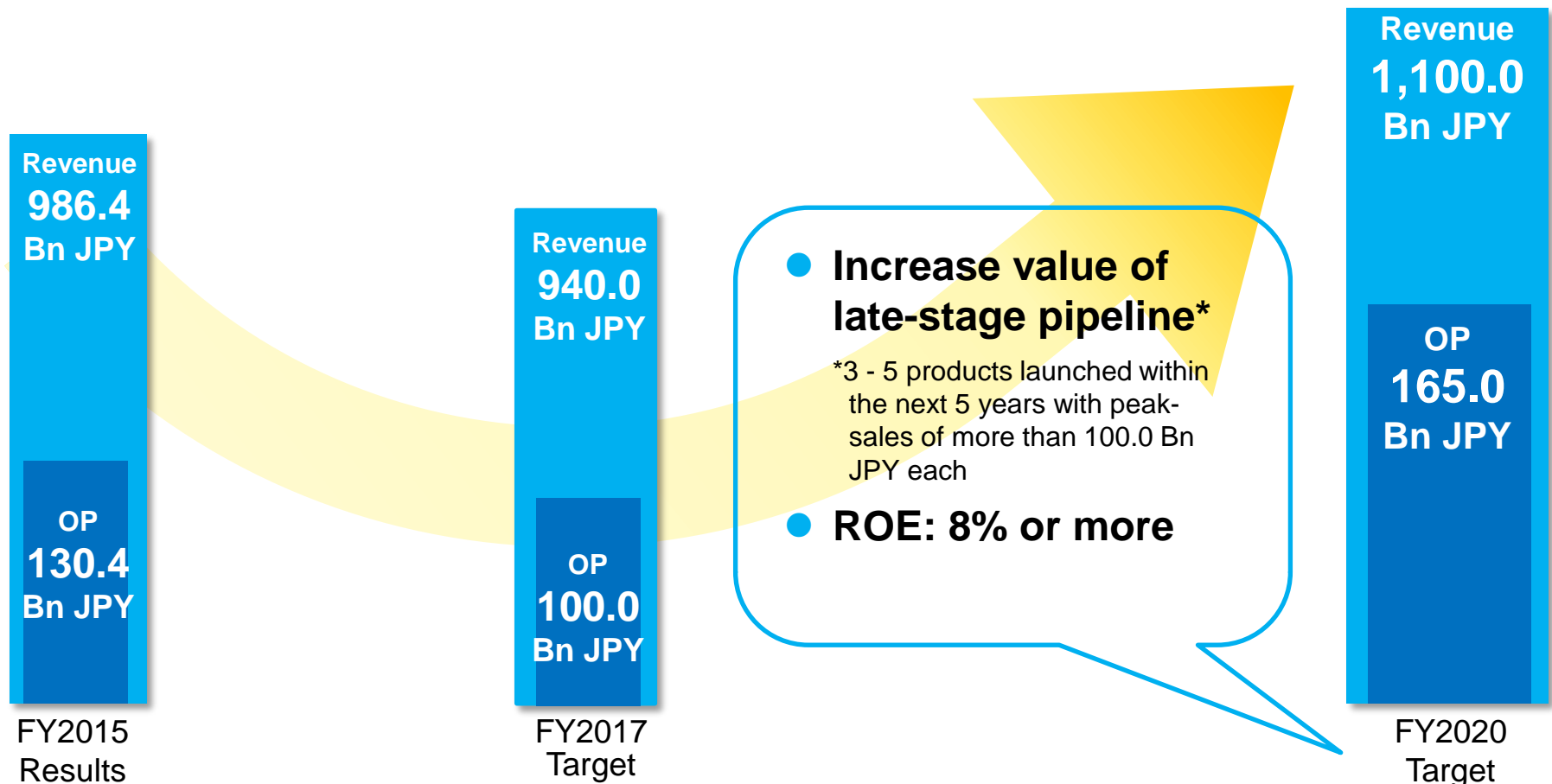
- *Build a specialty area\* centered on oncology as the core business*
- *Enrich regional value aligned with market needs*
- *Create innovative products*
  - *change SOC (Standard of Care)*
- *Realize shareholder value through highly efficient management*

\*specialty area: Drugs mainly prescribed at hospital and/or by specialty practitioners

# 5-Year Business Plan (FY2016 - FY2020)

**Challenge 1:**  
**Grow beyond FY2017 LOE**

**Challenge 2:**  
**Establish Foundation of Sustainable Growth**



# Strategic Targets

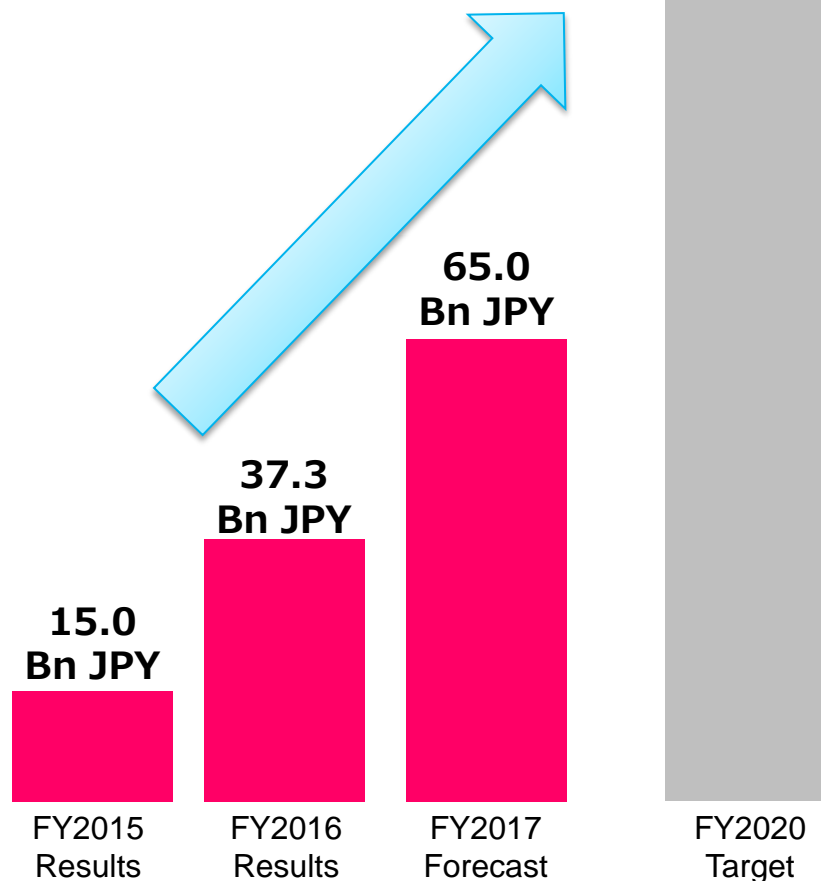
~For establishing foundation of sustainable growth~

## Six Strategic Targets

- ◆ **Grow Edoxaban**
- ◆ **Grow as No.1 company in Japan**
- ◆ **Expand US Businesses**
- ◆ **Establish Oncology Business**
- ◆ **Continuously Generate Innovative Medicine Changing SOC (Standard of Care)**
- ◆ **Enhance Profit Generation Capabilities**

# Grow Edoxaban

**Over 120.0 Bn JPY**  
**(1 Bn USD) in FY2020**



- ◆ Expand launched and approved countries
- ◆ Steady revenue growth in Japan, Germany and South Korea
- ◆ Accelerate new evidence creation



# Expand Launched and Approved Countries

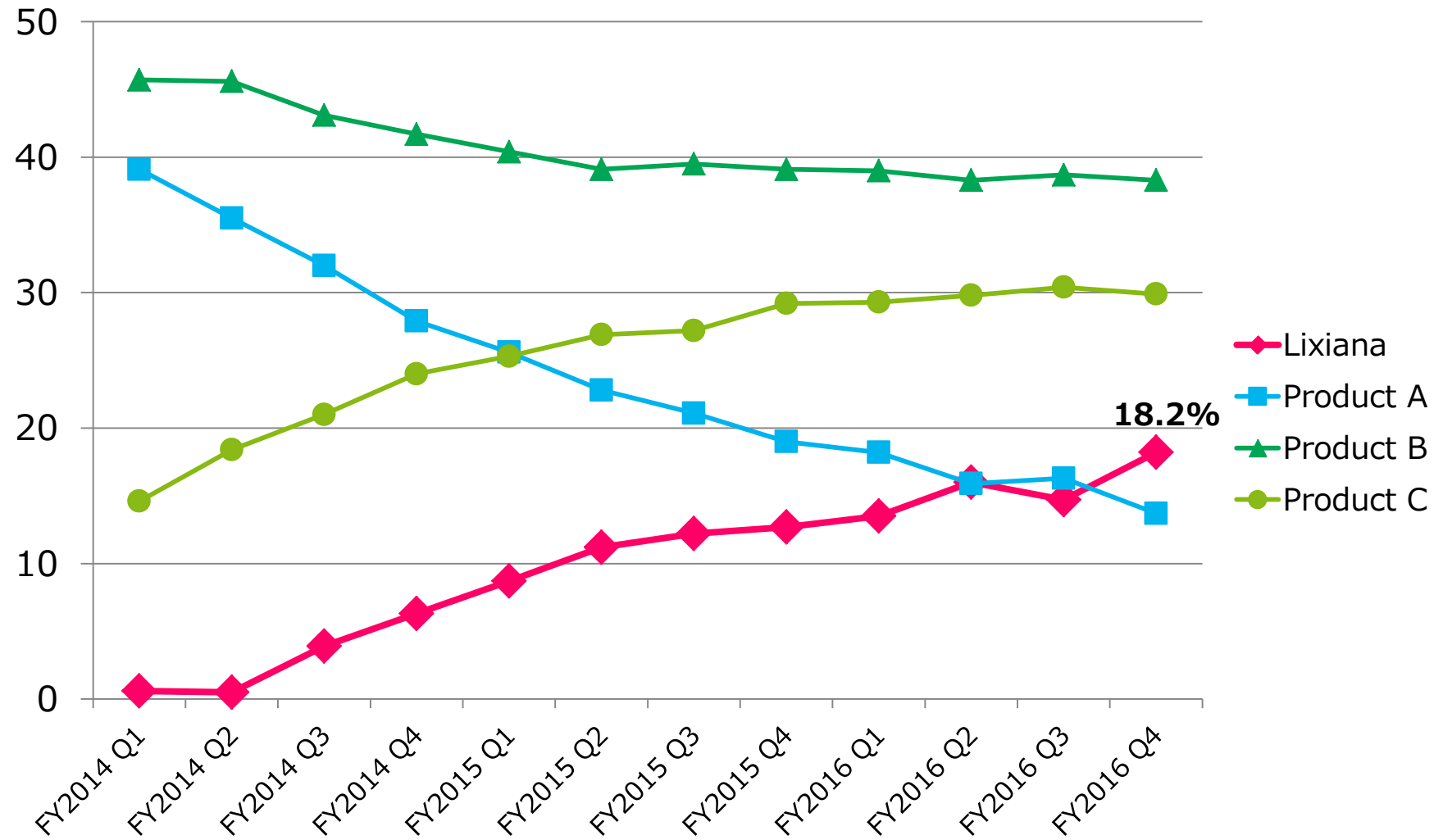
- ◆ Launched and approved in over **20** countries
- ◆ Covered about **95%** of DOAC\* market potential



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

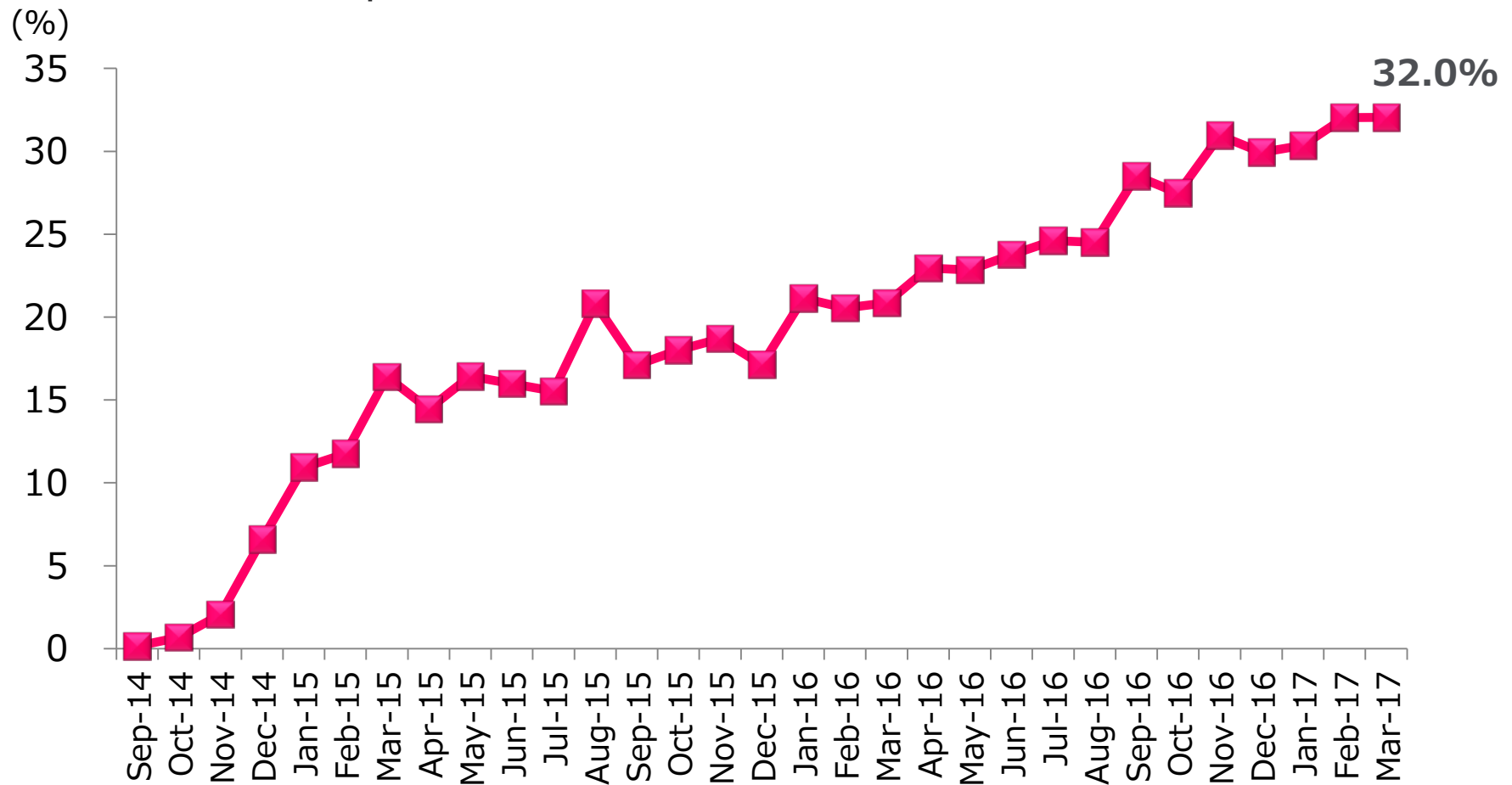
# Growth in Japan

(%) Market share reached **third (18.2%)** out of the four DOACs



# Growth in Japan

Lixiana reached **32.0%** of market share in new patients for AF+VTE

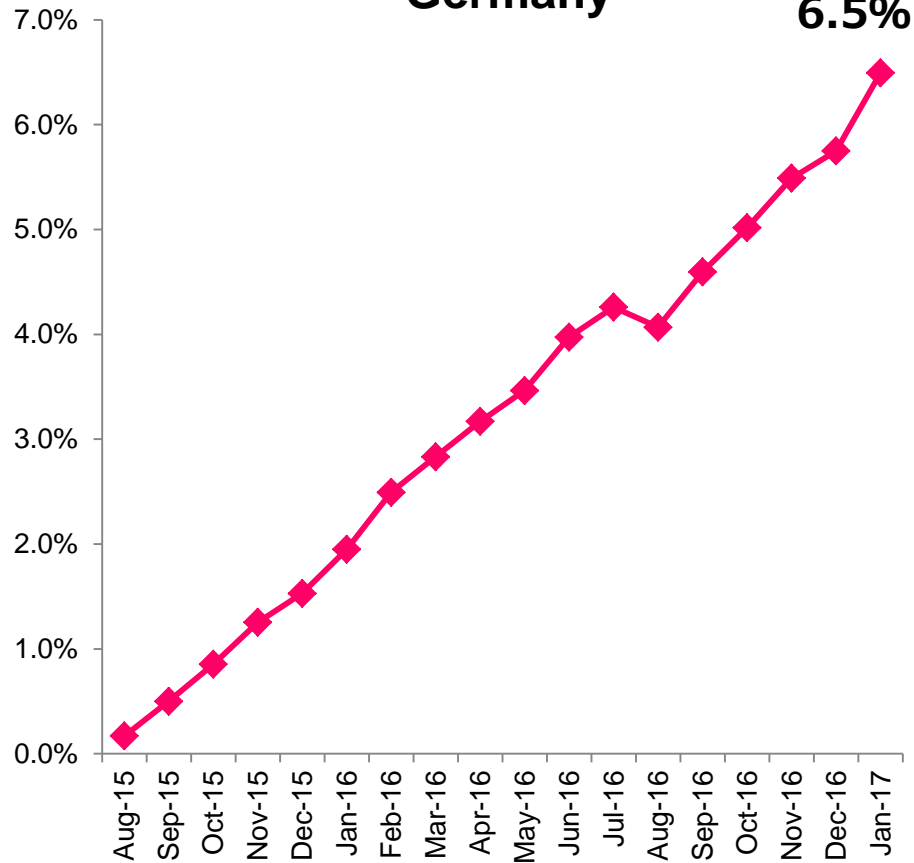


Source : Medi-trend

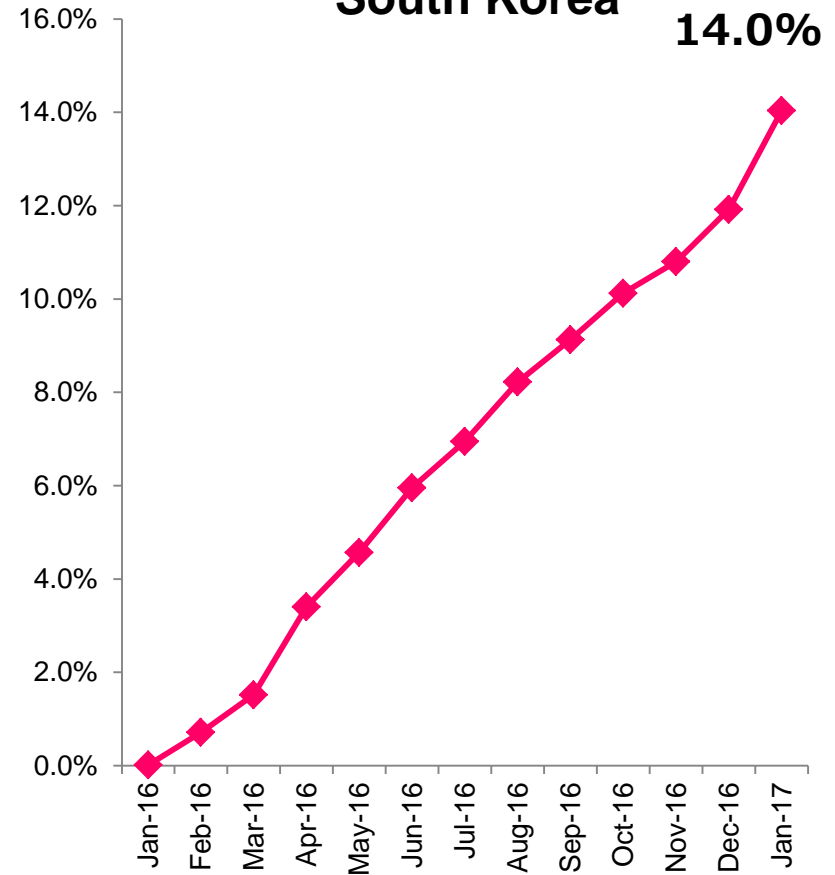
# Growth in Germany and South Korea

Steady uptake of sales share after launch

**Germany**

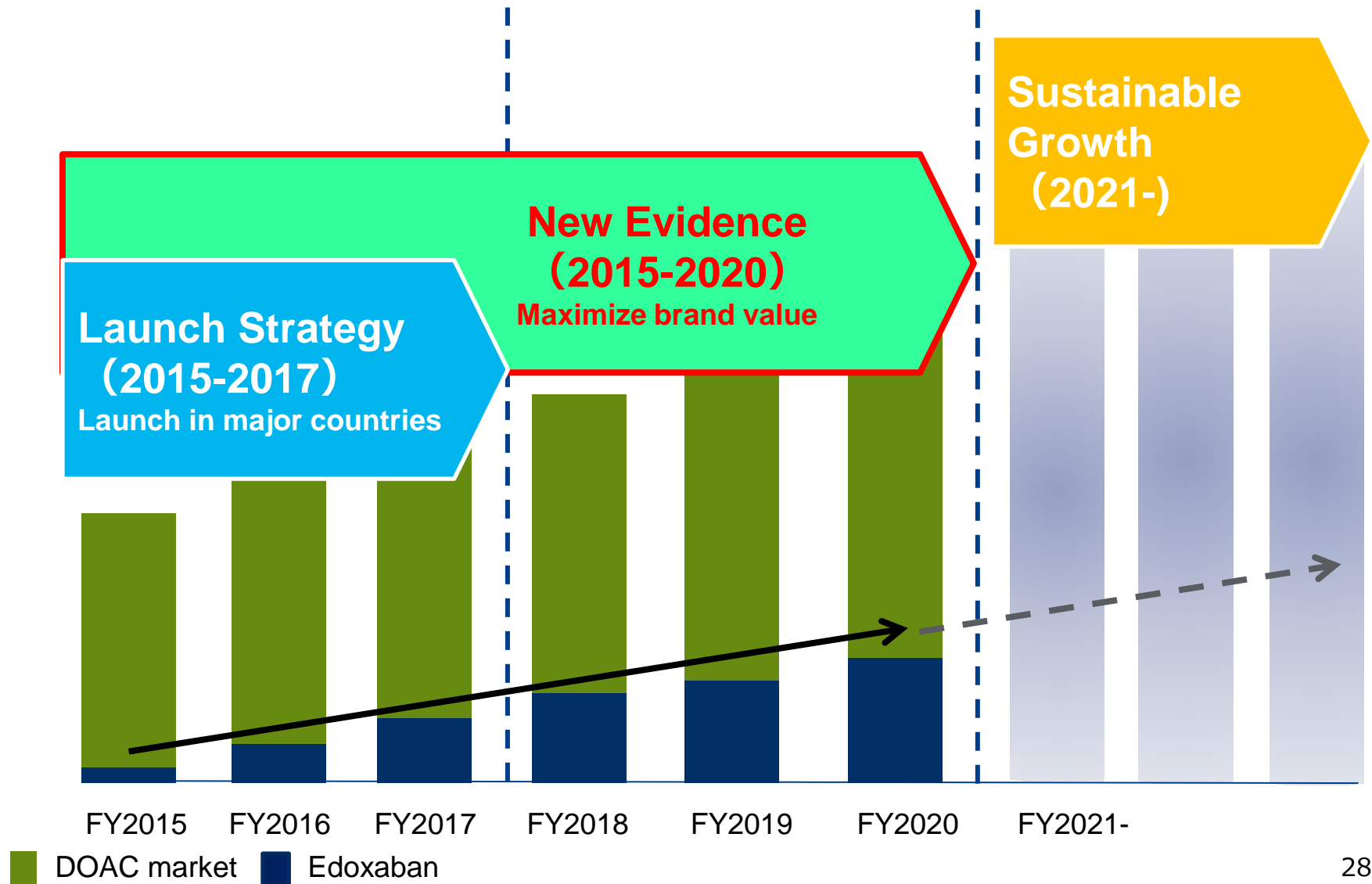


**South Korea**



# Maximize Product Value

Maximize product value by accelerating creation of new evidence









# Accelerate New Evidence Creation

Ongoing randomized controlled trials in various clinical settings



Study started since FY2016







Study Name	Clinical Setting (Comparator)	Primary Completion
 ENSURE-AF	Cardioversion (enoxaparin/ warfarin)	Presented at ESC 2016
 ENTRUST-AF PCI	PCI (VKA)	November 2018
 ELIMINATE-AF	Cardiac ablation (VKA)	December 2018
 ENVISAGE-TAVI AF	Transcatheter aortic valve implantation (VKA)	May 2020
 ELDERCARE-AF	80 years or older who are ineligible for current OAC therapy (placebo)	December 2019
 Hokusai VTE	VTE associated with cancer (dalteparin)	December 2017



Ph3 study for new dosage and administration

# Accelerate New Evidence Creation

Non-interventional studies and registries to generate real-world data with  
>100,000 patients including completed, ongoing and future research

Study Name	Clinical Setting
	Edoxaban Treatment in routine clinical practice in AF
	Edoxaban Treatment in routine clinical practice in VTE
	Edoxaban Management In diagnostic and Therapeutic procedures–AF/VTE
	Prolongation PREFER in AF, European Registry
	All Nippon in AF Elderly registry in Japan
	Multicenter Prospective Registry in Cancer patients in VTE patients in Japan

Study started  
since FY2016

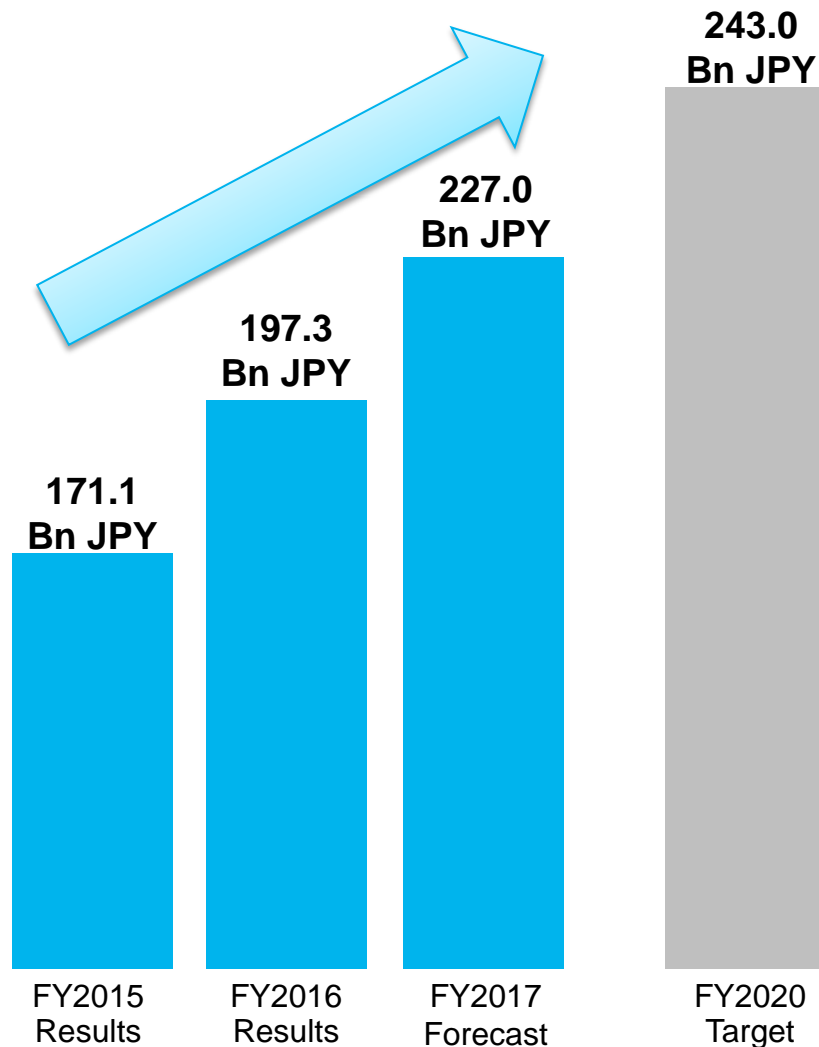
**Grow as No.1 company in Japan**

A decorative graphic consisting of many thin, parallel, wavy lines that create a sense of movement and flow. The lines are colored in a gradient from light yellow to light green, with the yellow being more prominent on the left and the green on the right. The overall shape is a broad, sweeping curve that rises from the bottom left and then levels out towards the right.



# Grow Major Products in Japan

Many of innovative major products reached No. 1 share and continue to expand market share



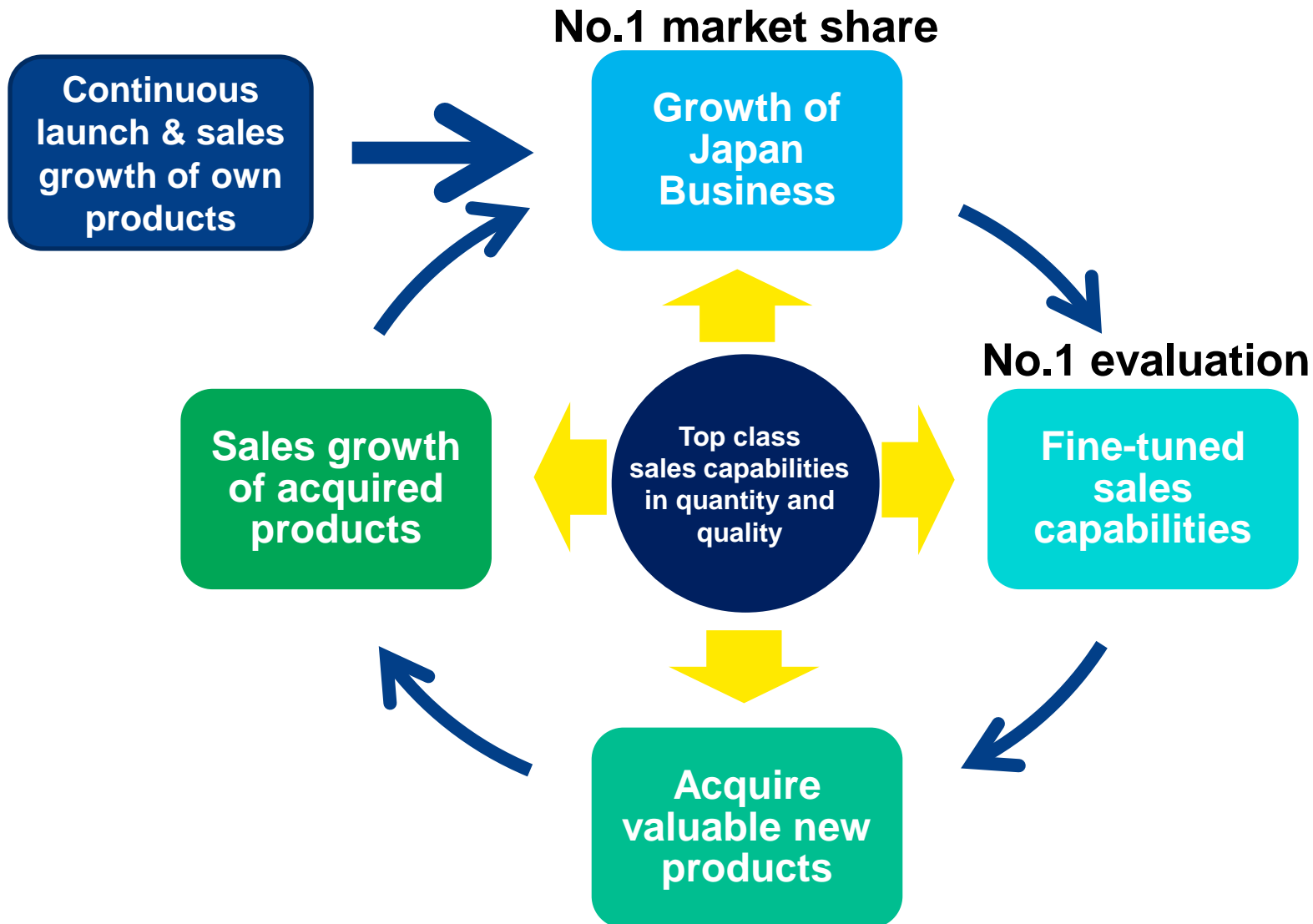
Total of 6 products in right column (excl. Lixiana), Including the impact of mandated price revisions

 <p><b>Share No.1</b></p> <p>Ulcer treatment <b>Nexium</b></p>	 <p><b>Share No.1</b></p> <p>Alzheimer's disease treatment <b>Memary</b></p>
 <p><b>Share No.1*</b></p> <p>Treatment for osteoporosis <b>Pralia</b></p>	 <p><b>Share No.1</b></p> <p>Treatment for bone complication caused by bone metastases from tumors <b>Ranmark</b></p>
 <p><b>Antiplatelet agent Efient</b></p>	 <p><b>Type 2 diabetes mellitus inhibitor Tenelia</b></p>

\*In the market for Bone resorption inhibitors

# Process for Sustainable Growth

Realize sustainable growth by leveraging No.1 sales capabilities of leading company in Japan



# Achievements in FY2016

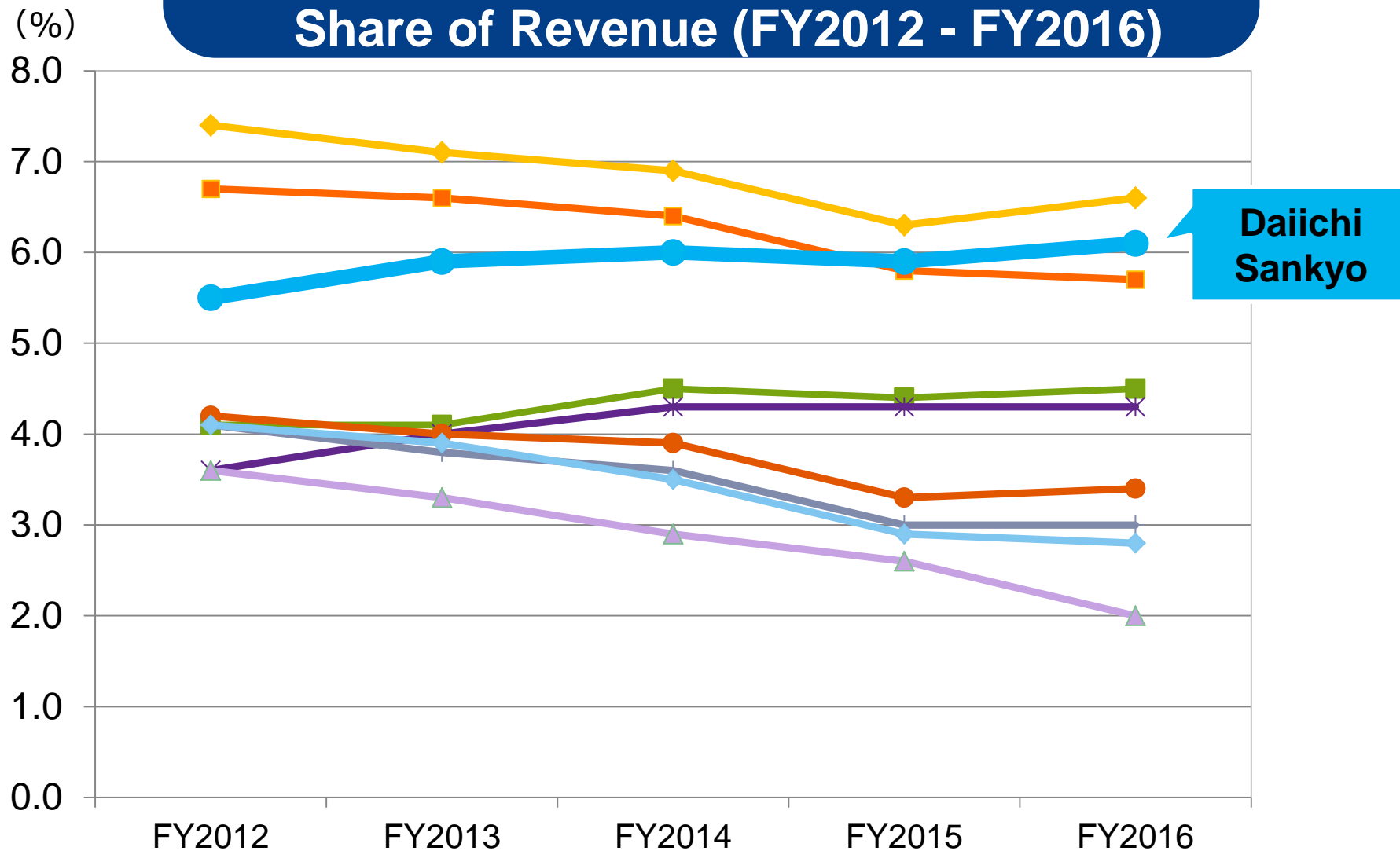
## Acquire valuable new products

- ◆ **Launched anti epilepsy VIMPAT and filed an new indication**
- ◆ **9 biosimilars in-licensed from Amgen**
- ◆ **Expand strategic alliance in the diabetes field with Mitsubishi Tanabe Pharma**
  - Entered into a marketing alliance agreement for MT-2412, a combination drug consisting of TENELIA and CANAGLU in March 2017
- ◆ **Strengthen authorized generic (AG) business through Daiichi Sankyo Espha**
  - Obtained approval for manufacturing and marketing for multiple AG products including olmesartan (own product), telmisartan, rosuvastatin etc. in Feb. 2017

## Fine-tuned sales capabilities

- ◆ **Ranked No. 1 on MR activities by external survey**
  - ANTERIO Inc. : All physicians, HP, GP (4 consecutive years)
  - SSRI Co., Ltd. : Visit situation by MR, Trusted manufacturer
  - Mix survey : Excellent MR

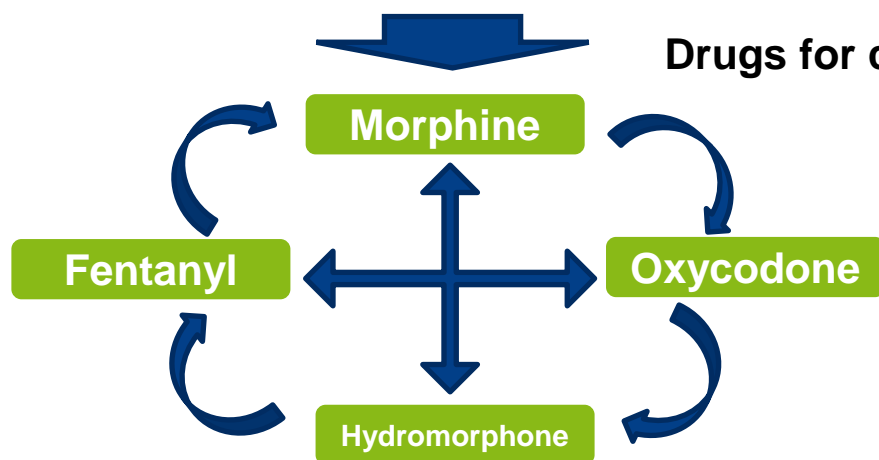
## Japanese Pharmaceutical Companies Share of Revenue (FY2012 - FY2016)



# “Opioid Switching” is now Available in Japan

“Opioid switching”, a global standard way for use of opioids is now available in Japan with the approval of hydromorphone in Japan

	Hydromorphone	Oxycodone	Morphine	Fentanyl	Remifentanyl
IR	Narurapid Manufacture and Sales Approval (March 2017)	Launch preparation	Launched	—	—
ER	Narusus Manufacture and Sales Approval (March 2017)	Oxycodone Extended Release Tablets "Daiichi Sankyo" launch (March 2017)	—	—	—
IV	NDA	Study on going	Launched	Launched	Analgesic for General Anaesthesia Remifentanyl Intravenous Injection “Daiichi Sankyo” launch (Dec. 2016)



Drugs for cancer pain

## Opioid Switching

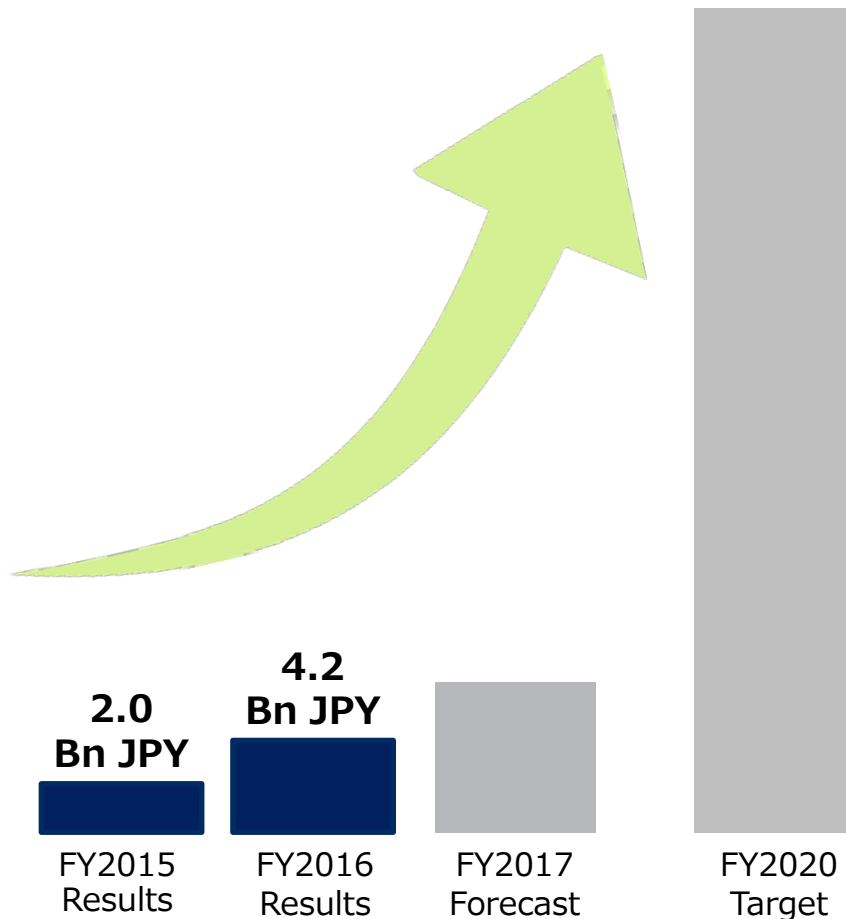
Switching to another opioids is a global standard way for use of opioids recommended by WHO guidelines etc.

Red: Update or new

Global standard (WHO guidelines etc.)

# Expand US Businesses

**> 100 Bn JPY** business  
in FY2020



◆ **Movantik (Opioid-Induced Constipation: OIC)**

- Raise awareness of burden of OIC



◆ **Licensed two abuse-deterrent opioids**

- **Plan to launch MorphaBond ER in 2017**

**MORPHABOND<sup>TM</sup> ER**  
(morphine sulfate) extended-release tablets   
15 mg • 30 mg • 60 mg • 100 mg

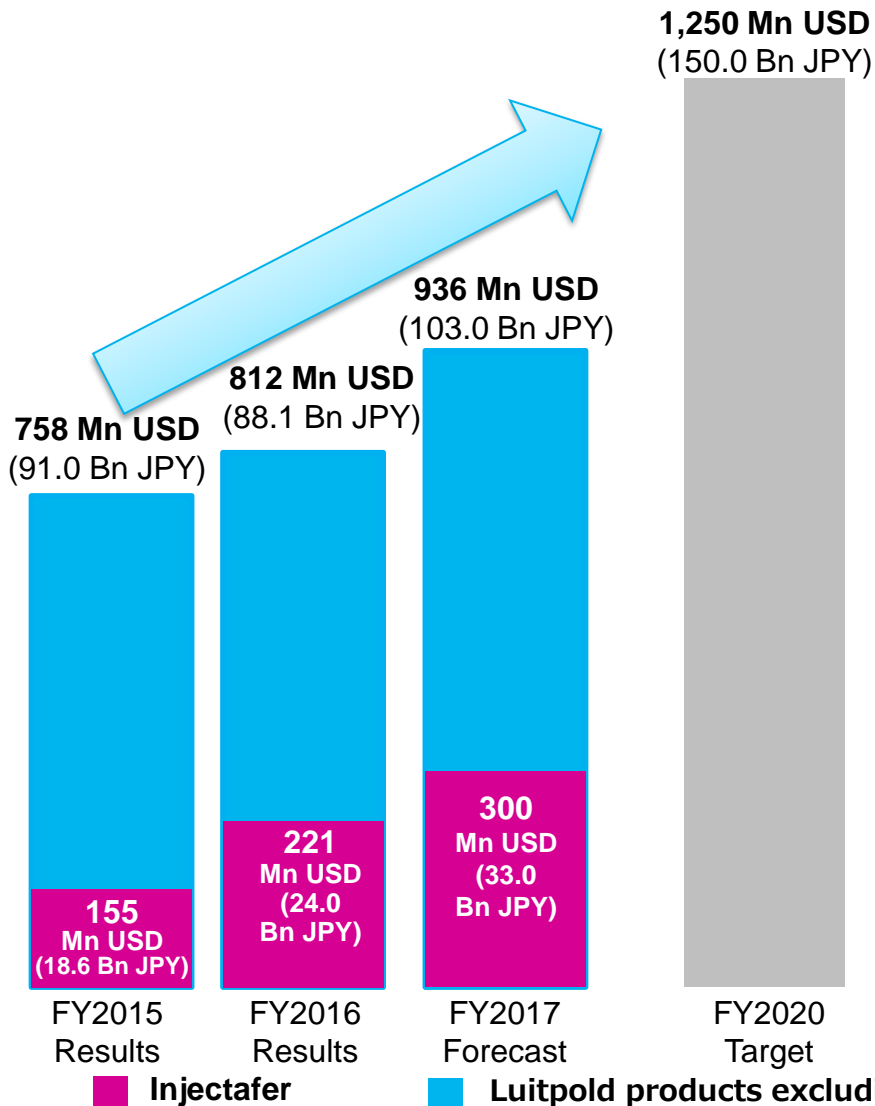
◆ **CL-108 (Opioid-Induced Nausea & Vomiting: OINV)**

- Received complete response letter from FDA
- Intend to work closely with the FDA to address points raised in this letter

◆ **Mirogabalin (Fibromyalgia)**

- TLR: CY2017 H1

Realize rapid and sustainable growth with  
Iron Franchise and Generic injectable franchise



## ◆ Iron Franchise

Accelerate the growth of Injectafer by enhanced promotion by DSI



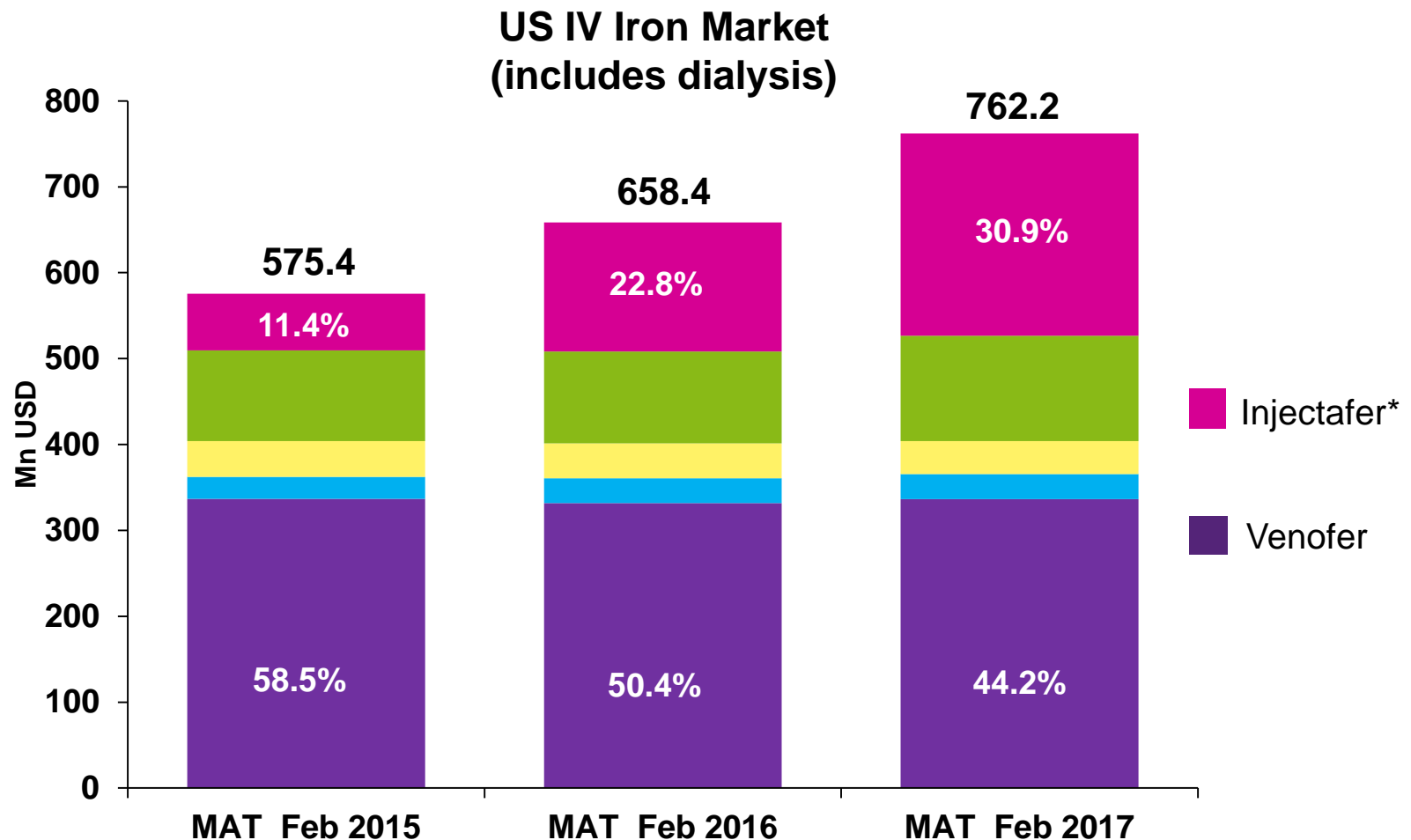
## ◆ Generic Injectable Franchise

Launch new products steadily with increasing focus on expanding and prioritizing portfolio to increase revenue



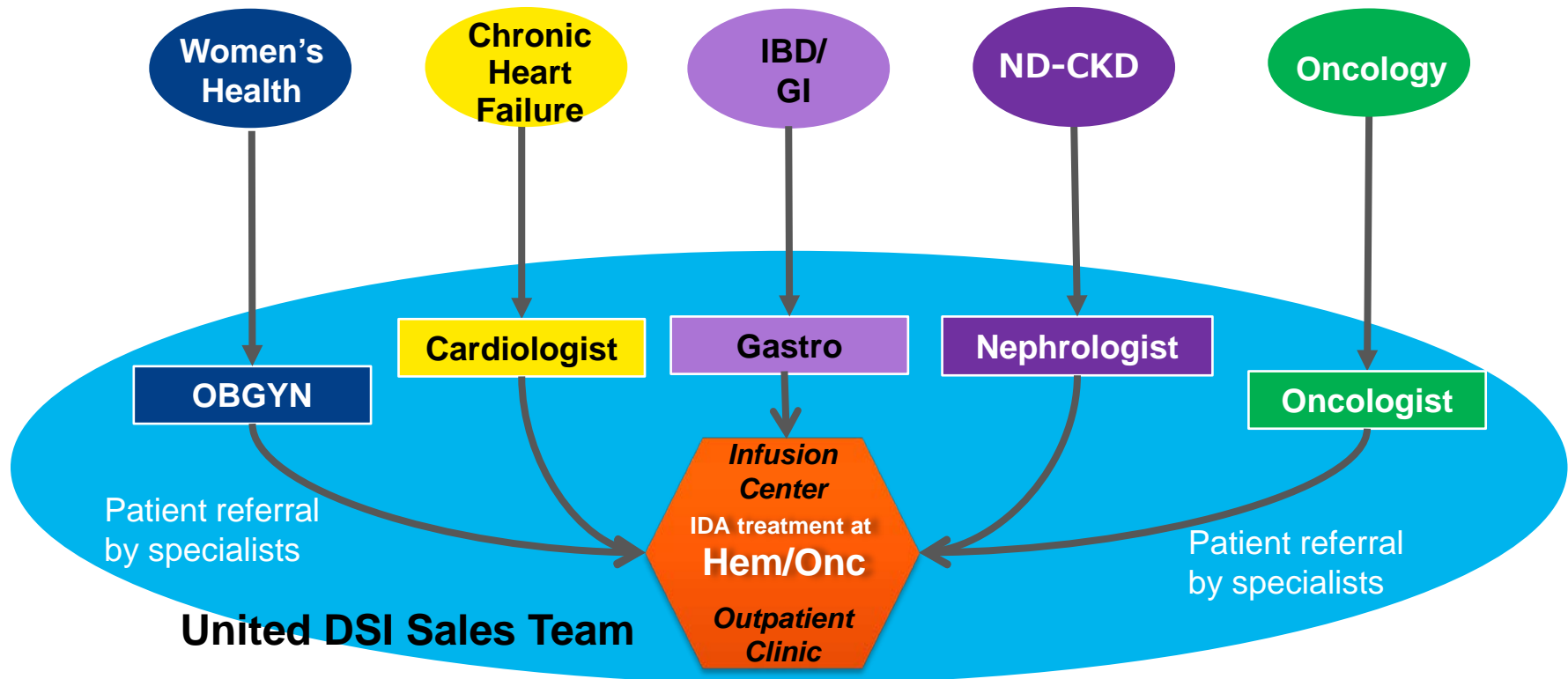
# The U.S. IV Iron Market

Injectafer and Venofer keep over **70% market share** in the U.S. IV iron market



# New Sales Team for Injectafer

From Jan. 2017, LPI sales team for Injectafer has become DSI employees. With the LPI team, DSI formed a united sales team for Injectafer .



The sales are going well with the new sales team.

The highest monthly Net Sales (25.7 Mn USD) were recorded in March 2017.

The Net Sales forecast for FY2017 is 300 Mn USD (33.0 Bn JPY).

Heart failure prevalence is 6.5 million in the U.S.\* Iron deficiency is a common comorbidity that affects up to 50% (up to 3.25 million) of heart failure patients.\*\* Approximately 10 million people are iron deficient in the U.S.\*\*\*

Started in Mar. 2017: Phase 3 study for heart failure patients with iron deficiency

- ◆ Study name : HEART-FID
- ◆ Study design : randomized, double-blind, placebo-controlled study
- ◆ Patient : heart failure with iron deficiency
- ◆ Estimated enrollment : more than 3,000 adult patients across North America
- ◆ Primary outcome measure
  - the 12-month rate of death
  - the 12-month number of hospitalizations for worsening heart failure
  - the 6-month change in 6-minute walk test (6MWT)
- ◆ Estimated study completion date : June 2022

\* Benjamin, Emelia J., et al. "Heart disease and stroke statistics—2017 update: a report from the American Heart Association." *Circulation* 135.10 (2017): e146-e603.

\*\* McDonagh, Theresa, and Iain C. Macdougall. "Iron therapy for the treatment of iron deficiency in chronic heart failure: intravenous or oral?" *European journal of heart failure*. 2015; 17(3):248-262.

\*\*\* Miller, Jeffrey. *Iron Deficiency Anemia: A Common and Curable Disease*. Cold Spring Harb Perspect Med 2013;3

# Generic Injectable Franchise

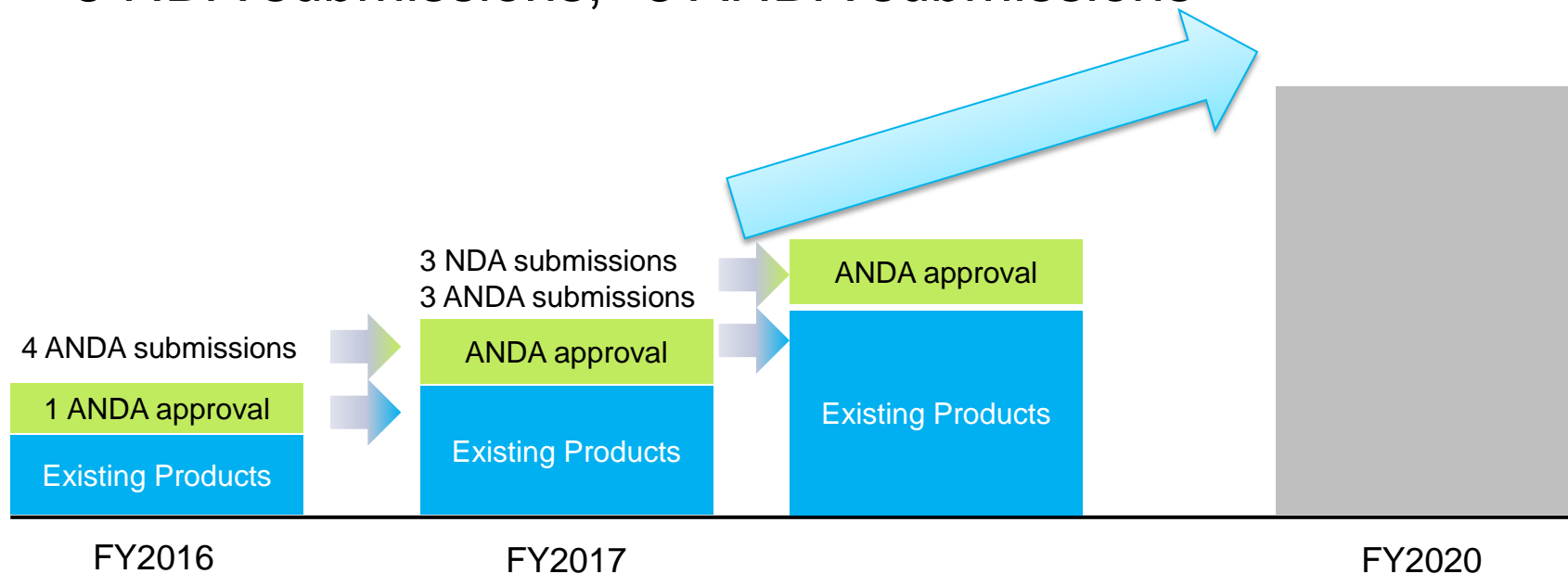
The only way to deliver sustainable consistent growth is to continuously launch new products

## ◆ FY2016 Results

4 ANDA submissions, 1 ANDA approval

## ◆ FY2017 Targets

3 NDA submissions, 3 ANDA submissions



# **Establish Oncology Business**

# Establish Oncology Business

**Daiichi Sankyo's  
2 New Cancer Franchises**

**Antibody-Drug  
Conjugate(ADC)**

Develop and expand  
DS' proprietary technology

**Acute Myeloid  
Leukemia (AML)**

Multiple exciting assets



Daiichi-Sankyo  
**cancer**enterprise

**2 Organization  
restructuring**

**Established  
Biologics Unit**

Seamless technological transition

**Established Global  
Oncology Marketing**

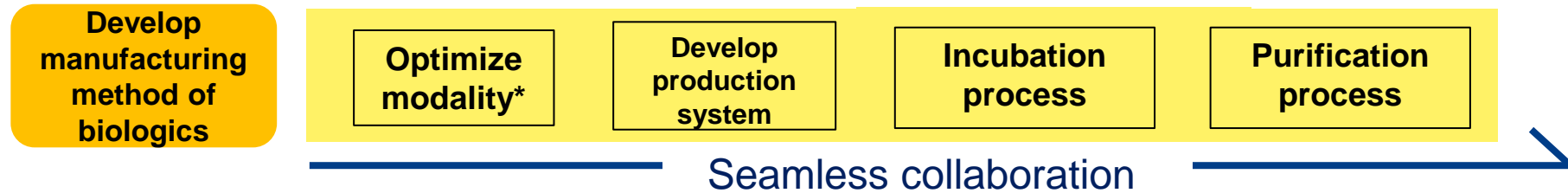
Successful launch and  
global access

**Capital investment for  
enhancing oncology business**

**15.0 Bn JPY investment to enhance  
ADC manufacturing capabilities**

More than triple capacities by 2021

# Established Biologics Unit (Apr 2017)



**Establish seamless collaboration**



**Accelerate development of biologics, such as DS-8201**

**Biologics Unit**

Consolidate research and development as well as Pharmaceutical technology and scale up of biologics (especially ADC).

**Biologics Planning Department (New)**

**Biologics Technology Research Lab**  
(Transferred from PT Unit)

**Modality Research Lab**  
(Transferred from RD Unit)

**Cell Therapy Research Lab**  
(Transferred from RD Unit)

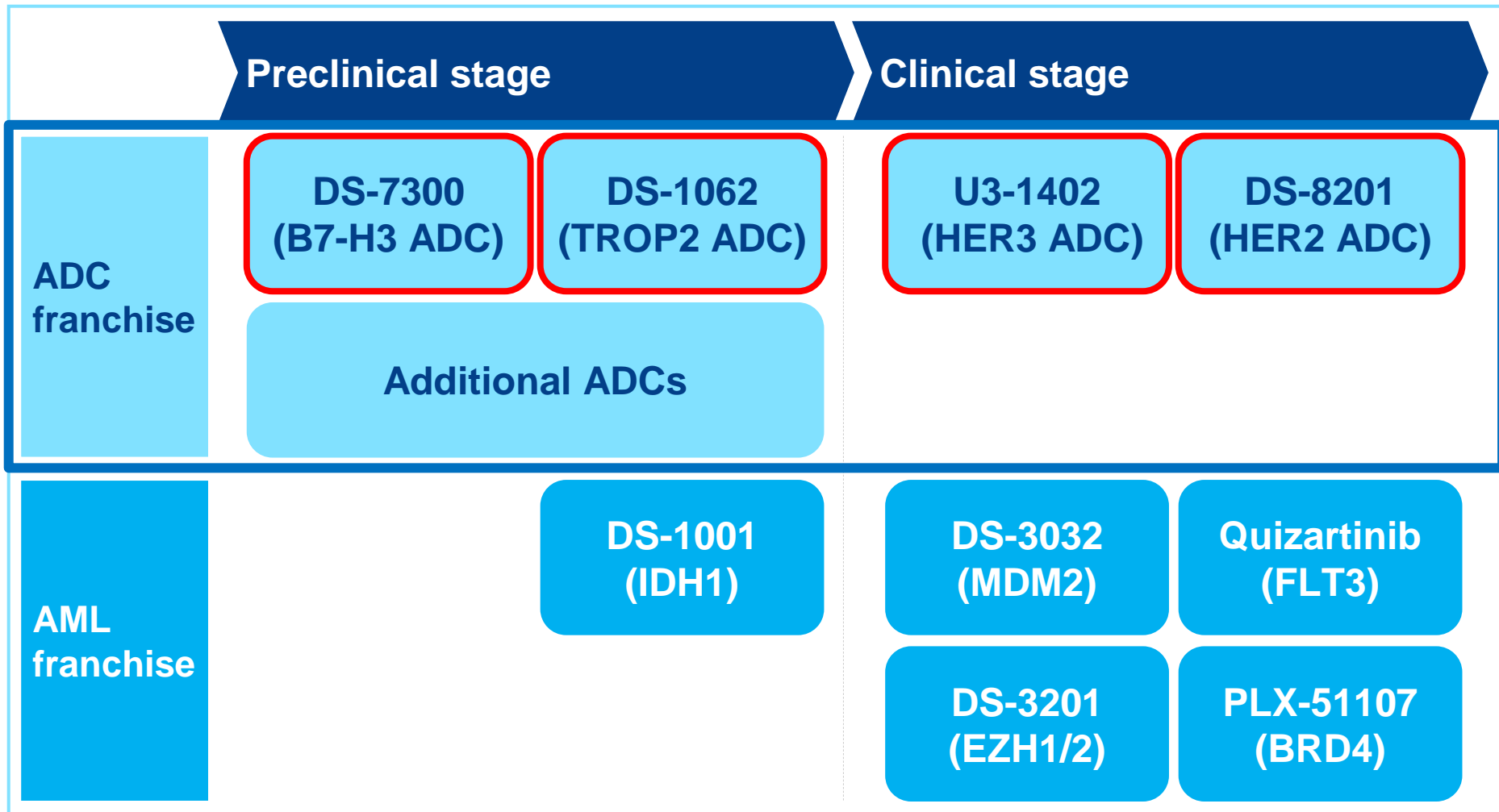
\*Fundamental technology

- ◆ Hired an experienced leader as Head of Global Oncology Marketing  
⇒ **Thierry Gruson, DVM, MBA**

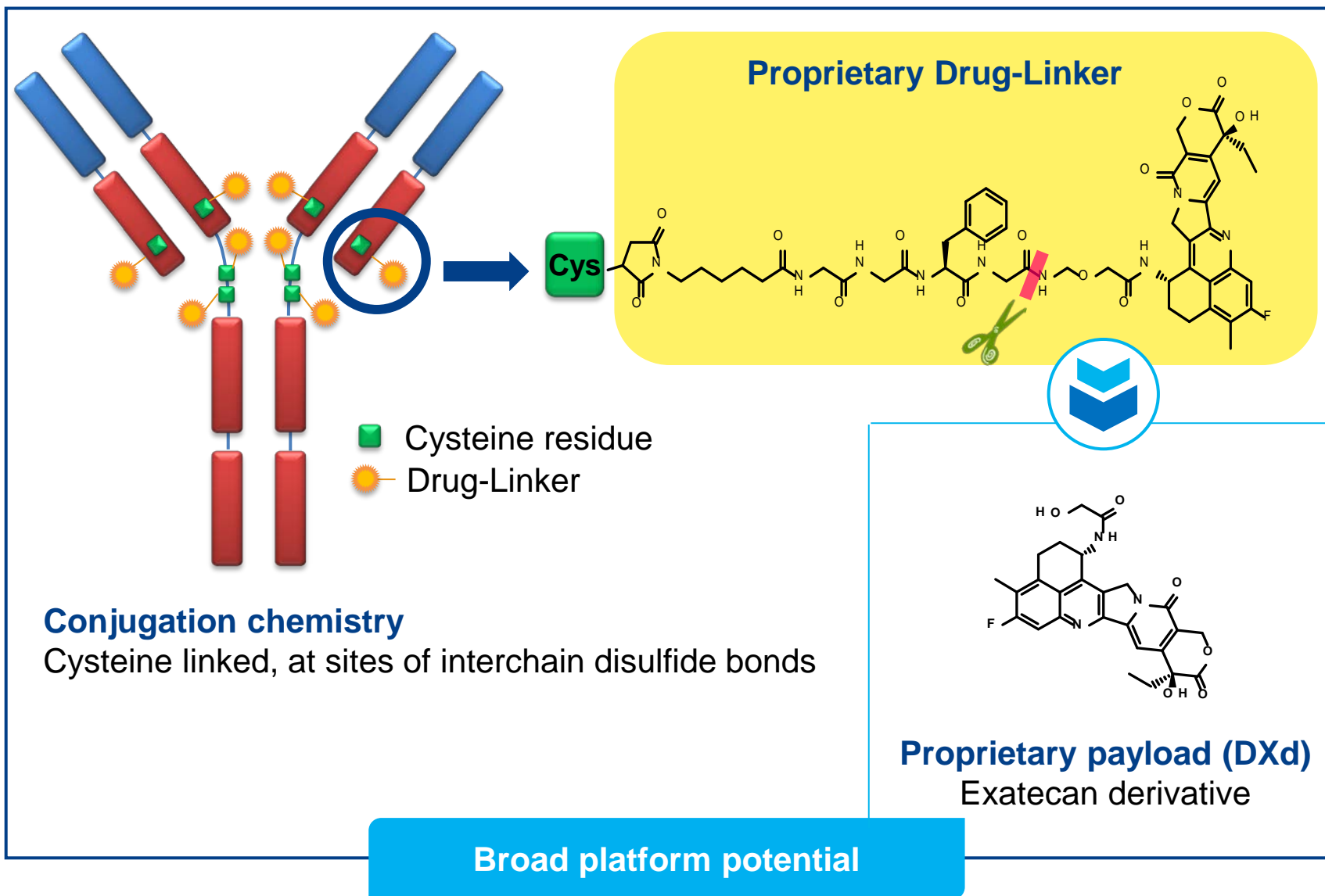


- 27 yrs of oncology commercial experience
- Former worldwide commercial lead position at BMS in immuno-oncology
- Launch experience in EU and life cycle management for EU, US and Asia.



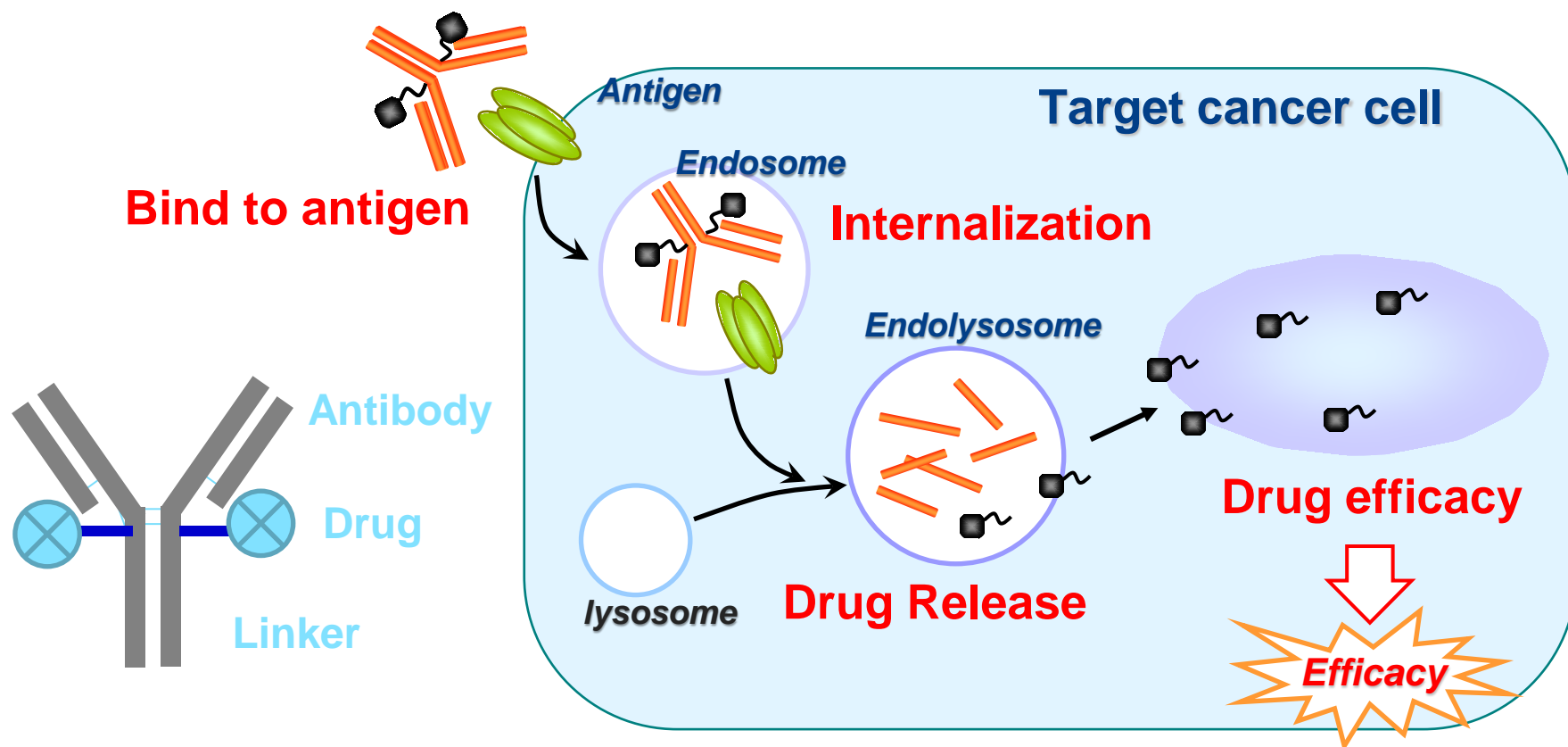


# DS's Proprietary ADC technology



# ADC technology: Mode of Action (MOA)

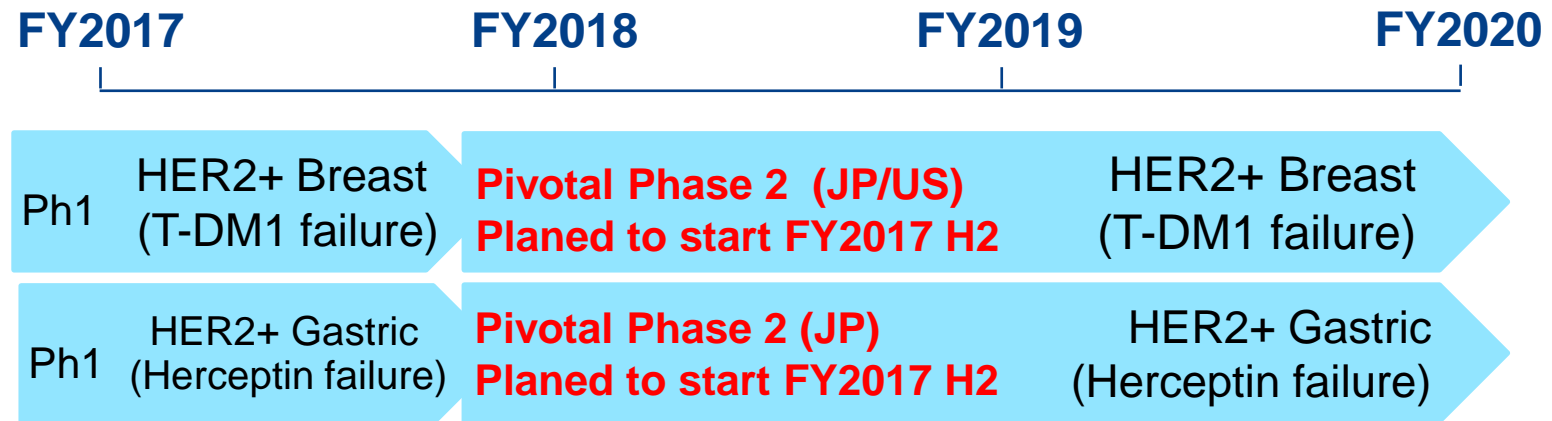
- ◆ ADC technology has broad application across multiple types of cancer
- ◆ Designed to deliver enhanced cancer cell destruction with less systemic exposure to chemotherapy



# ADC Franchise: DS pipeline

Antigen & General Cancer Types		Own ADC	Major Competitors
<b>HER2</b>	Breast cancer Gastric cancer	<b>DS-8201</b> Phase 1	Kadcyla: Roche (launched) SYD985: Synthron (Ph1) MEDI4276: AZ (Ph1)
<b>HER3</b>	Breast cancer Lung cancer	<b>U3-1402</b> Phase 1	MP-HER3-ADC: Mediapharma (pre-clinical)
<b>TROP2</b>	Breast cancer Lung cancer Esophagus cancer Pancreatic cancer Bile duct cancer Cervical cancer	<b>DS-1062</b> Pre-clinical	IMMU-132: Immunomedics (Ph3)
<b>B7-H3</b>	Esophagus cancer Lung cancer Endometrium cancer Prostate cancer	<b>DS-7300</b> Pre-clinical	MGC018: MACROGENICS's ADC (pre-clinical)

## ◆ Progress of clinical trials



## ◆ Obtained regulatory support for accelerated registration trials

- FDA: HER2-positive metastatic breast cancer
  - ✓ Fast Track Designation (Nov. 2016)

## ◆ Key reports at scientific conferences

- AACR (Apr. 2017), poster presentations
  - ✓ Presented estimated phase 2 dose by population pharmacokinetics and exposure-response relationship.
- ASCO (Jun. 2017), oral and poster presentations are planned

## ◆ Progress of phase 1 study

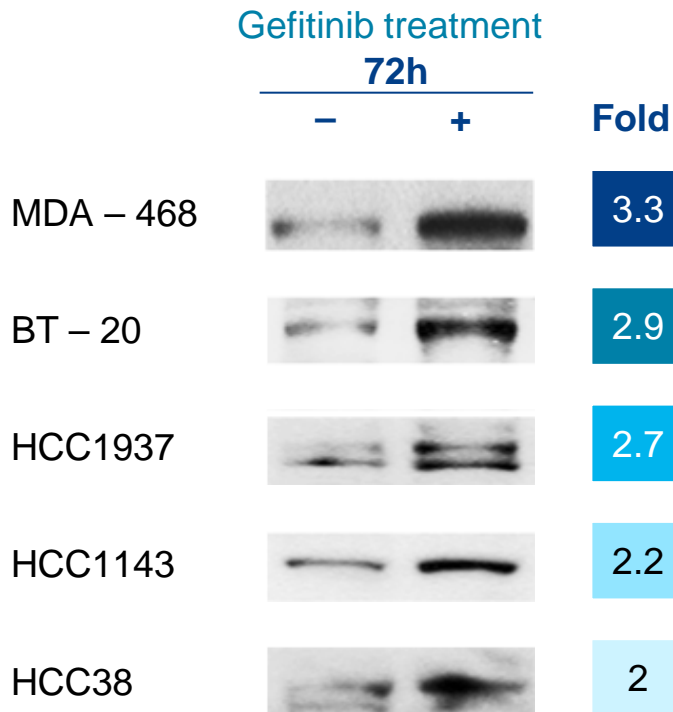
- HER3 positive refractory/metastatic breast cancer (Dec. 2016)
  - ✓ TLR: FY2018 Q4
- EGFRm NSCLC
  - ✓ Expected to start from FY2017 **Q3**

## ◆ Key reports at scientific conference

- AACR (Apr. 2017), poster presentation of pre-clinical result
- ASCO (Jun. 2017), poster presentation is planned

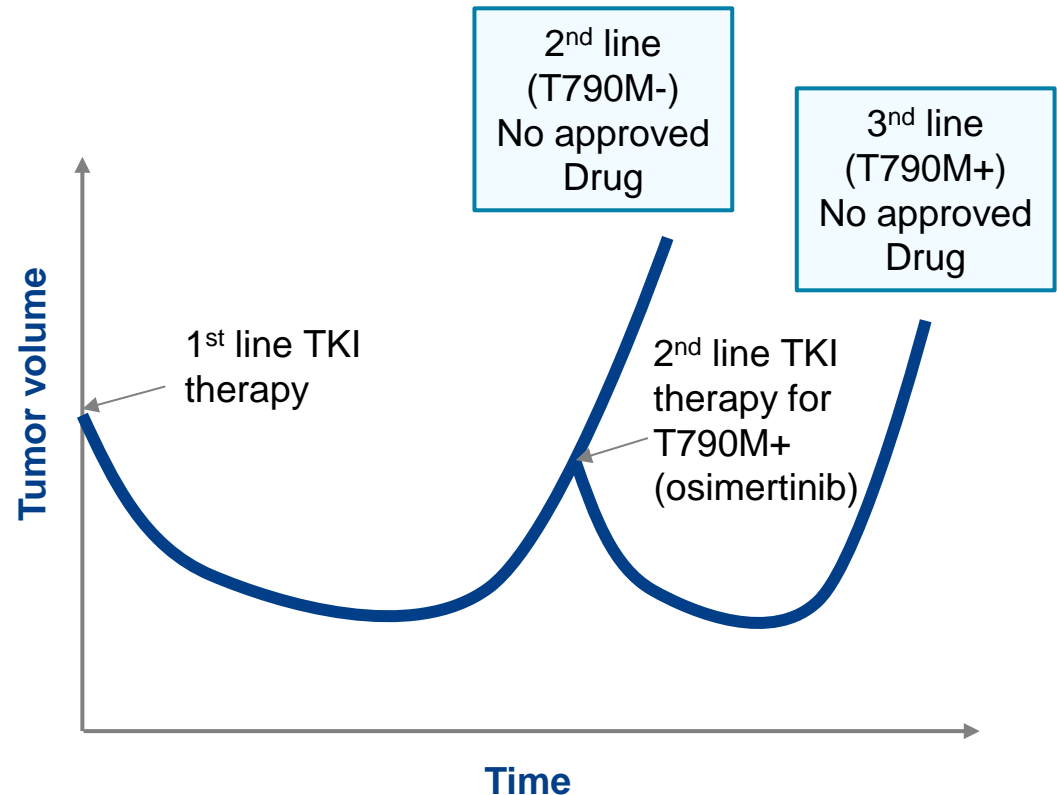
## ◆ Potential in EGFRm NSCLC

### HER3 expression after EGFR TKI treatment (in-vitro cell lines)



HER3 is upregulated by EGFR TKI therapy

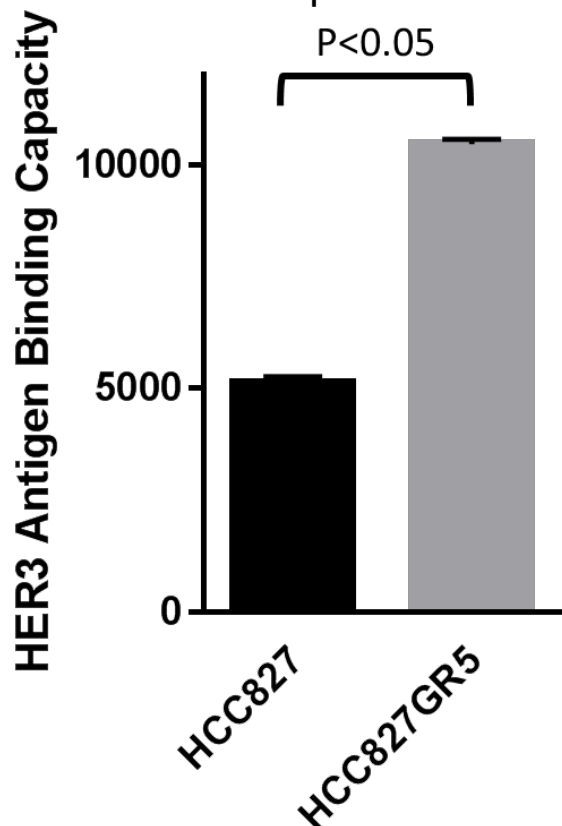
### EGFRm NSCLC patient journey



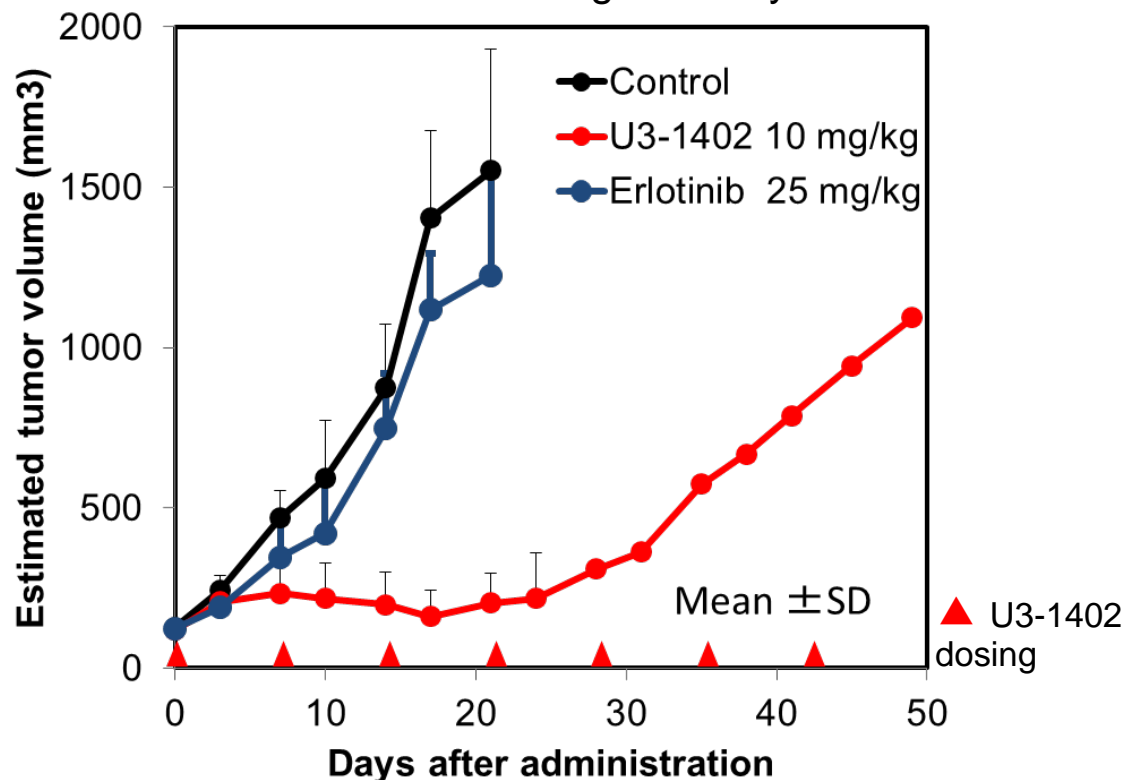
HER3-ADC has potential to address unmet need of patients who progress on current therapies

## U3-1402 was shown to have anti tumor activity on EGFR-TKI resistant NSCLC in xenograft study

HER3 cell-surface protein level



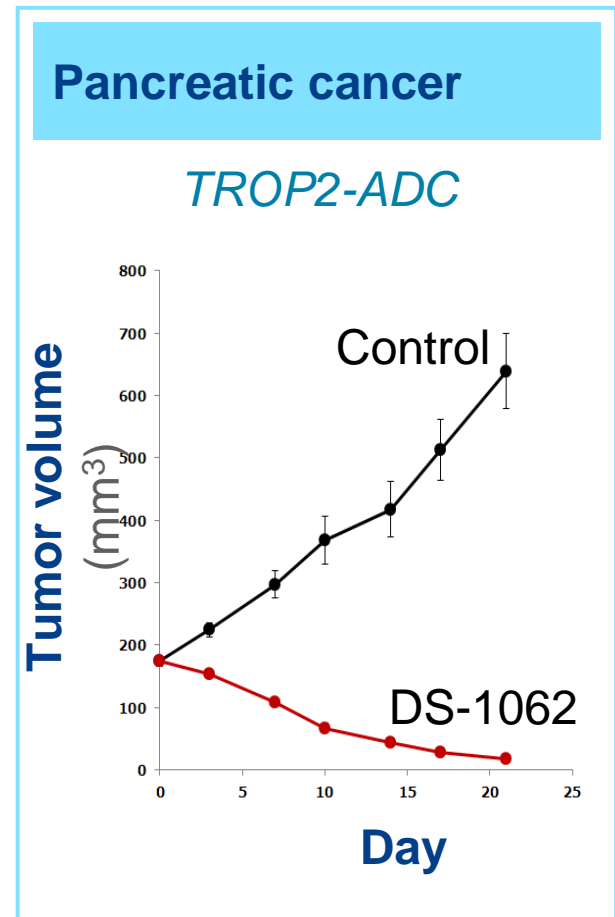
HCC827GR5 Xenograft study



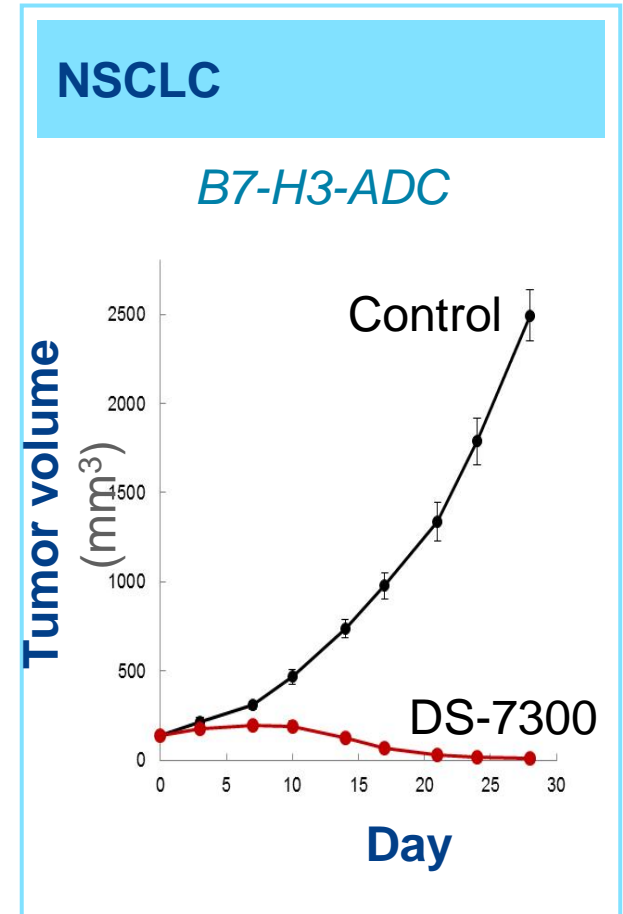
1. Upregulation of HER3 is observed in EGFR-TKI resistant NSCLC cell (HCC827GR5).
2. Anti tumor activity is observed on HCC827GR5 xenograft model.



- ◆ TROP2 is highly expressing in a variety of tumors (e.g., breast cancer, lung cancer, esophagus cancer) and effectively internalizes with binding antibody.
- ◆ DS-1062 is being investigated against TROP2 expressed solid tumors.
- ◆ Possible target tumor type is TROP2 positive solid tumors with high unmet medical needs (e.g., pancreatic, bile duct and cervical cancers).



- ◆ B7-H3 is overexpressed at a high frequency in wide range of solid tumors, including esophageal, lung, endometrial, prostate cancer and also sarcoma, but low expression in normal tissues.
- ◆ DS-7300 shows anti-tumor activity against B7-H3-expressing tumors in xenograft models.



## Preclinical stage

## Clinical stage

ADC  
franchise

**DS-7300**  
(B7-H3 ADC)

**DS-1062**  
(TROP2 ADC)

**U3-1402**  
(HER3 ADC)

**DS-8201**  
(HER2 ADC)

**Additional ADCs**

AML  
franchise

**DS-1001**  
(IDH1)

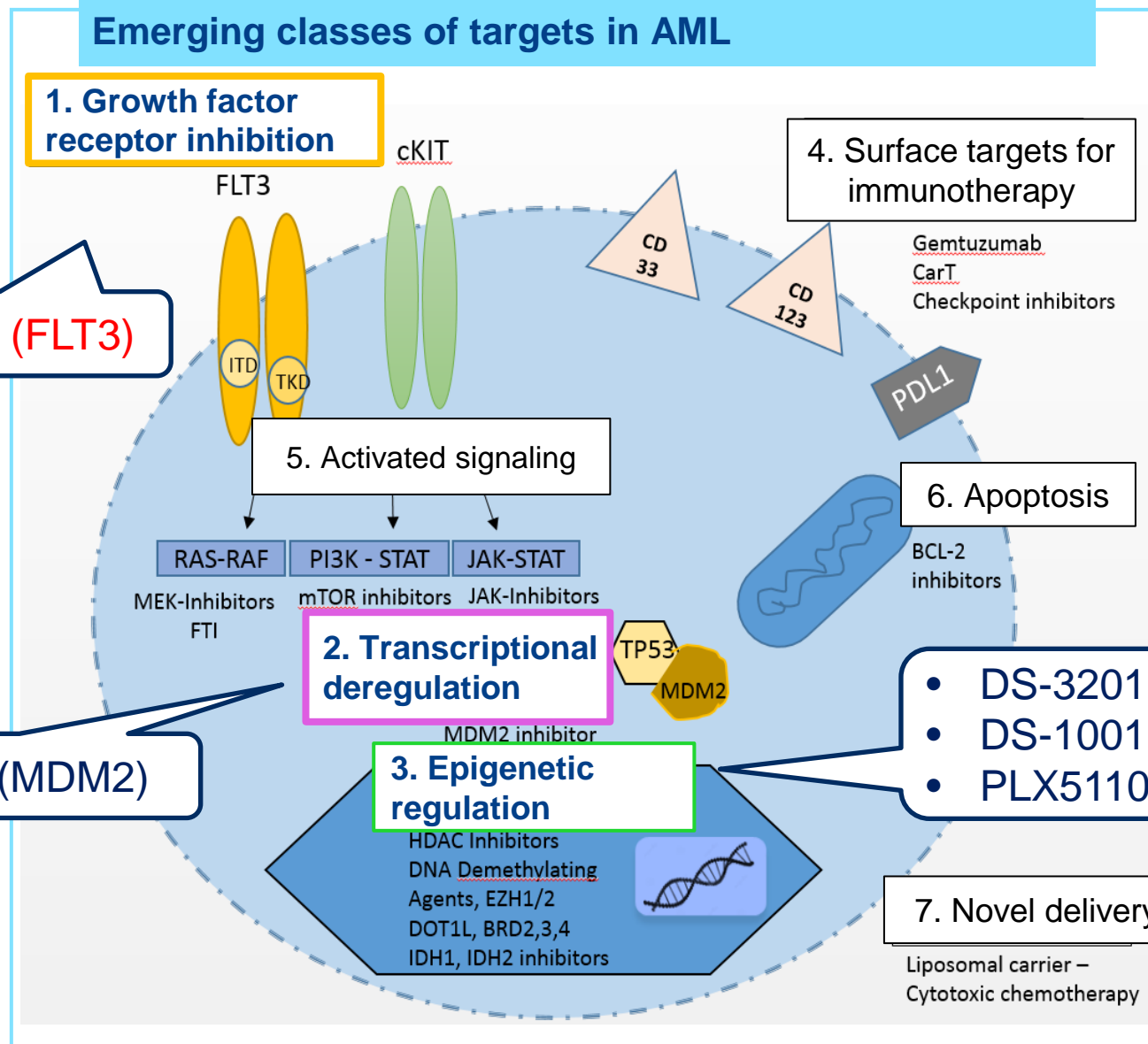
**DS-3032**  
(MDM2)

**Quizartinib**  
(FLT3)

**DS-3201**  
(EZH1/2)

**PLX-51107**  
(BRD4)

# AML Franchise: Developing 3 of 7 Emerging Classes of Targets



## Induction

## Consolidation

## Maintenance

## Relapsed / Refractory



- Phase 3 study
- Combination with SOC chemotherapy\*
- First patient dosed Oct. 2016



- Phase 3 study
- Monotherapy
- Overall Survival
- Interim analysis was conducted by independent data monitoring committee
  - Recommended to continue the study
- TLR: FY2018 H1

\*Induction (Cytarabine + Anthracycline + Quizartinib for 1-2 cycles)  
Consolidation (High dose Cytarabine + Quizartinib up to 4 cycles and/or HSCT)  
Maintenance (Quizartinib or Placebo up to 12 cycles)

# **Continuously Generate Innovative Medicine Changing SOC (Standard of Care)**



Primary  
Focused  
Area

**Oncology (incl. Immuno-Oncology)**

New  
Horizon  
Area

**Pain**

**CNS  
disease**

**Heart-  
kidney  
disease**

**Rare  
disease**

**Continuously Generate Innovative Medicine  
Changing SOC (Standard of Care)**

## Implementing and partnering innovative technology for accelerating research and development

### Oncolytic virus

- **G47Δ: DS-1647**  
Co-development with Dr. Todo, a professor at the Institute of Medical Science, the University of Tokyo

### Bi-specific antibody

- Cross-licensing and collaboration agreement with Zymeworks

### Immuno-Oncology

- Research Collaboration with AgonOx
- **Open innovation research with The National Institutes of Biomedical Innovation, Health and Nutrition, and Mitsubishi UFJ Capital**



### Cellular therapy

- Strategic partnership with Kite Pharma  
(KTE-C19: cancer CAR-T therapy)

### Biomarker

- **Partnership with Astellas/Takeda and Sysmex/Astellas**

### Others

- Collaboration with Dana-Farber Cancer Institute
- **Partnership with DarwinHealth**



## Implementing and partnering innovative technology for accelerating research and development

### Pain

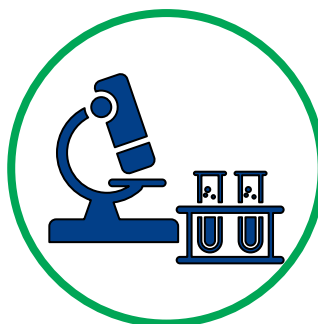
- Partnering with Heptares for newly low-molecule drug

### CNS disease

- Generate drugs for neurodegenerative disease through collaborative research with UCSF

### Heart-kidney disease

- In-license Heartcel Tm from Celixir (former Cell Therapy) (DS-8100)



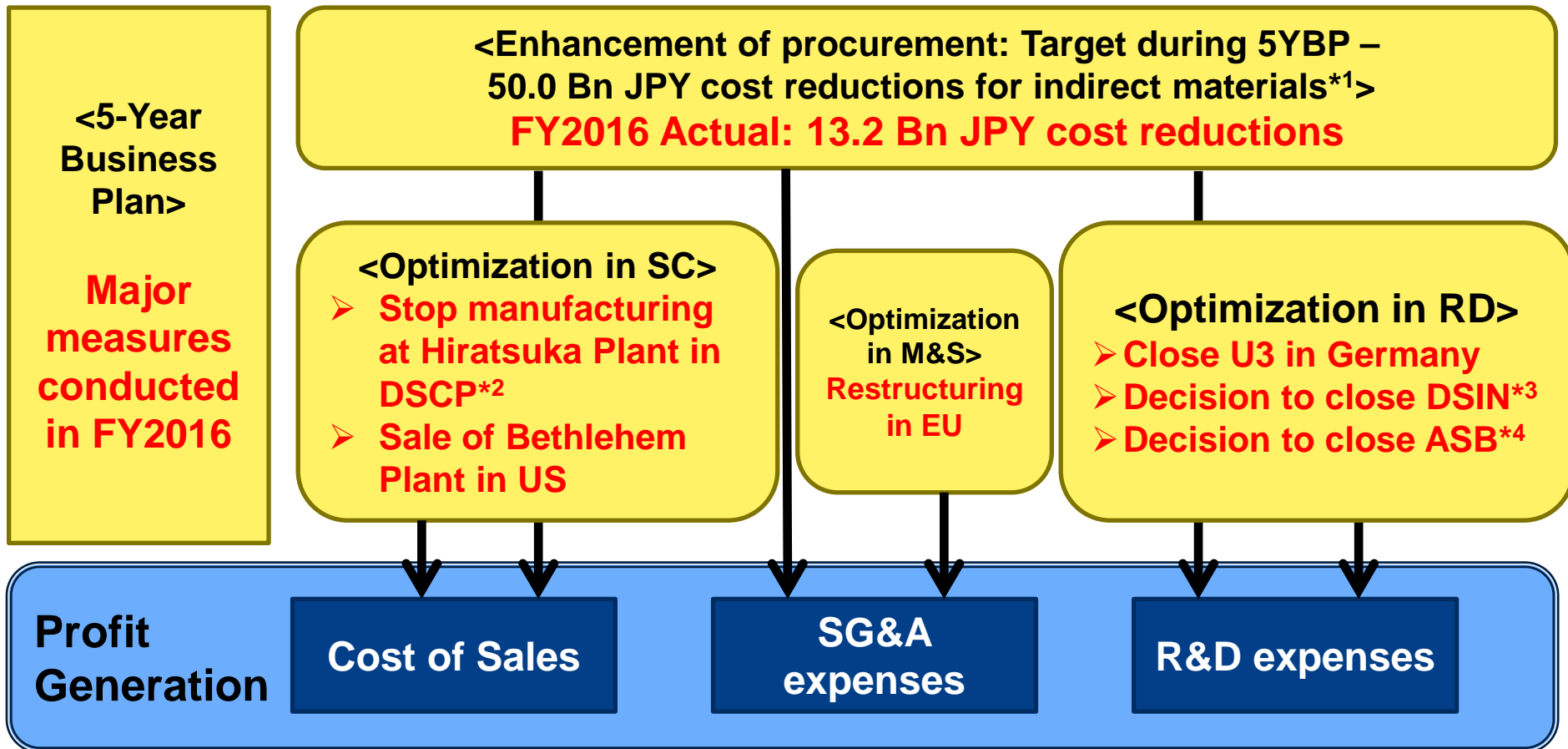
### Rare disease

- Starting Ph1/2 study for Duchenne Muscular Dystrophy Treatment (DS-5141)  
**SAKIGAKE designation by PMDA**

# Enhance Profit Generation Capabilities

# Enhance Profit Generation Capabilities

**Realize “Process Excellence”: Further cost reductions and streamlining**



\*1 indirect materials: materials excluding direct materials (raw materials, packaging materials and finished products)

\*2 DSCP: Daiichi Sankyo Chemical Pharma in Japan

\*3 DSIN: Daiichi Sankyo India Pharma Private Limited

\*4 ASB: Asubio Pharma Co., Ltd in Japan

## ◆ **Optimize capital expenditures**

To make an initial 15 Bn JPY investment to optimize and enhance its manufacturing capabilities to support its growing ADC pipeline,  
and optimize totally for pursuing the efficiency

## ◆ **Reduce Cross-Shareholding shares**

Reduce to the appropriate level from the point of view of capital efficiency

Progress in FY2016

➤ To sell 17.3 Bn JPY for 14 stocks

## ◆ Low cost funding

### ➤ Issuance of unsecured straight bonds

**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**

- ✓ Total amount of issue: 100.0 Bn JPY  
(75.0 Bn JPY: 20 years, 25.0 Bn 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

## ◆ Efficient operation for DS Group cash management

### ➤ Introduction of “Global Cash Management System”

- ✓ Enhancement of efficiency of funds operations
- ✓ Enhancement of forex risk management
- ✓ Cost reductions in forex fee and remittance charge
- ✓ Simplification in operation process

# Shareholder Returns

## 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)

		FY2015 Results	FY2016 Results	FY2017 Plan	(Target during 5YBP)
Total return ratio		118.9%	180.7%		100% or more
Dividend	Ordinary dividend	60 JPY	70 JPY	70 JPY	more than 70 JPY
	Anniversary dividend	10 JPY	-	-	-
Acquisition of own shares		50.0 Bn JPY	50.0 Bn JPY	flexible	flexible

**Back-up**



# FY2017 Major R&D Milestone Events

Project	Indication/Study	Q1	Q2	Q3	Q4	FY18-Q1
Denosumab	Rheumatoid arthritis (JP)	Under review				
CL-108	Pain/Opioid-induced nausea and vomiting (US)			Re-submission		
CHS-0214 (etanercept BS)	Rheumatoid arthritis (JP)					submission
Mirogabalin	Fibromyalgia Phase 3 study (US/EU)	TLR				
	DPNP/PHN Phase 3 studies (JP/Asia)	TLR				
Pexidartinib	Tenosynovial giant cell tumor Phase 3 study (US/EU)		TLR			submission
Quizartinib	QuANTUM-R AML 2nd line treatment Phase 3 study (US/EU/Asia)	Interim Analysis				
Esaxerenone (CS-3150)	Hypertension Phase 3 study (JP)		TLR		Submission	
	Diabetic nephropathy Phase 3 study (JP)			Study initiation		
DS-8201	HER2-positive Breast Cancer (T-DM1 failure) Phase 2 study (pivotal) (JP/US)			Study initiation		
	HER2-positive Gastric Cancer (Herceptin failure) Phase 2 study (pivotal) (JP)			Study initiation		
U3-1402	EGFRm NSCLC Phase 1 study			Study initiation		
DS-5141	Duchenne Muscular Dystrophy Phase 1/2 study (JP)	SAKIGA KE			TLR	

# Major R&D Pipeline

As of May 2017

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>■ DS-3201 (JP/US) (EZH1/2 inhibitor)</li> <li>■ PLX73086 (US) (CSF-1R inhibitor)</li> <li>■ PLX51107 (US) (BRD4 inhibitor)</li> <li>■ DS-8273 (US) (Anti-DR5 antibody)</li> <li>■ DS-8201 (JP/US) (anti-HER2 ADC)</li> <li>■ DS-1123 (JP) (Anti-FGFR2 antibody)</li> <li>■ U3-1402 (JP) (Anti-HER3 ADC)</li> <li>■ <u>DS-1001 (JP)</u> (<u>IDH1m inhibitor</u>)</li> </ul>	<ul style="list-style-type: none"> <li>■ Patritumab (EU) (U3-1287 / Anti-HER3 antibody)</li> <li>■ Pexidartinib (US) (PLX3397 / Glioblastoma / CSF-1R/KIT/FLT3-ITD inhibitor)</li> <li>■ DS-1647 (JP) (Glioblastoma / <b>G47Δ virus</b>)</li> <li>■ <u>Quizartinib (JP)</u> (<u>AC220 / AML-2<sup>nd</sup> / FLT3-ITD inhibitor</u>)</li> </ul>	<ul style="list-style-type: none"> <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>■ Quizartinib (US/EU/Asia) (AC220 / AML-1<sup>st</sup> / FLT3-ITD inhibitor)</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 / TAF1a inhibitor)</li> <li>■ DS-2330 (Hyperphosphatemia)</li> <li>■ DS-9231/TS23 (Thrombosis / <b>α2-PI</b> inactivating antibody)</li> </ul>	<ul style="list-style-type: none"> <li>■ Esaxerenone (JP) (CS-3150 / DM nephropathy / MR antagonist)</li> </ul>	<ul style="list-style-type: none"> <li>■ Edoxaban (JP) (DU-176b / AF / FXa inhibitor)</li> <li>■ Prasugrel (JP) (CS-747 / Ischemic stroke / Anti-platelet agent)</li> <li>■ Esaxerenone (JP) (CS-3150 / Hypertension / MR antagonist)</li> </ul>	<ul style="list-style-type: none"> <li>■ Edoxaban (ASCA etc.) (DU-176b / AF / FXa inhibitor)</li> <li>■ Edoxaban (ASCA etc.) (DU-176b / VTE / FXa inhibitor)</li> </ul>
Others	<ul style="list-style-type: none"> <li>■ DS-1971 (Chronic pain)</li> <li>■ DS-1501 (US) (Osteoporosis / Anti-Siglec-15 antibody)</li> <li>■ DS-7080 (US) (AMD / Angiogenesis inhibitor)</li> <li>■ DS-2969 (US) (<i>Clostridium difficile</i> infection / GyrB inhibitor)</li> <li>■ DS-5141 (JP) (DMD / ENA oligonucleotide)</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-<b>5565</b> / <b>Fibromyalgia</b> / <b>α2δ ligand</b>)</li> <li>■ Mirogabalin (JP/Asia) (DS-<b>5565</b> / <b>DPNP</b> / <b>α2δ ligand</b>)</li> <li>■ Mirogabalin (JP/Asia) (DS-<b>5565</b> / <b>PHN</b> / <b>α2δ ligand</b>)</li> <li>■ CHS-0214 (JP) (Etanercept BS / Rheumatoid arthritis / TNFα inhibitor)</li> <li>■ VN-0105 (JP) (DPT-IPV / Hib vaccine)</li> <li>■ Laninamivir (JP) (CS-8958 / Anti-influenza / nebulizer)</li> </ul>	<ul style="list-style-type: none"> <li>■ <u>Hydromorphone (JP)</u> (<u>DS-7113 / Cancer pain / Opioid μ-receptor agonist</u> &lt;Injection&gt;)</li> <li>■ CL-108 (US) (Acute pain / Opioid μ-receptor agonist)</li> <li>■ Intradermal Seasonal Influenza Vaccine (JP) (VN-100 / prefilled i.d. vaccine for seasonal flu)</li> <li>■ VN-0107/MEDI3250 (JP) (Nasal spray flu vaccine)</li> <li>■ Denosumab (JP) (AMG 162 / Rheumatoid arthritis / Anti-RANKL antibody)</li> </ul>

Red: Major changes after the FY2016 Q3 financial announcement on January 31, 2017

Contact address regarding this material

Daiichi Sankyo Co., Ltd.

**Corporate Communications Department**

**TEL: +81-3-6225-1126**

**Email: [DaiichiSankyoIR@daiichisankyo.co.jp](mailto:DaiichiSankyoIR@daiichisankyo.co.jp)**