Passion for Innovation. Compassion for Patients.™



# Top Management Presentation Financial Results for FY2017 (April 1, 2017 - March 31, 2018)

## DAIICHI SANKYO CO., LTD

Sunao Manabe President and COO

April 27, 2018

# Forward-Looking Statements



Management strategies and plans, financial forecasts, future projections and policies, and R&D information that Daiichi Sankyo discloses in this material are all classified as Daiichi Sankyo's future prospects. These forward looking statements were determined by Daiichi Sankyo based on information obtained as of today with certain assumptions, premises and future forecasts, and thus, there are various inherent risks as well as uncertainties involved. As such, please note that actual results of Daiichi Sankyo may diverge materially from Daiichi Sankyo's outlook or the content of this material. Furthermore, there is no assurance that any forward-looking statements in this material will be realized. Regardless of the actual results or facts, Daiichi Sankyo is not obliged and does not have in its policy the duty to update the content of this material from the date of this material onward.

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# Agenda



FY2017 Financial Results

Progress of 5-Year Business Plan

FY2018 Consolidated Forecast



## **FY2017 Financial Results**

# Overview of FY2017 Results



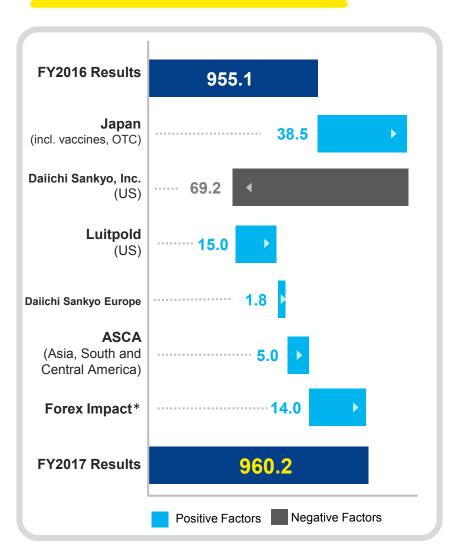
(Bn JPY)

	FY2016 Results	FY2017 Results	YoY
Revenue	955.1	960.2	+5.1
Cost of Sales	349.4	346.0	-3.4
SG&A Expenses	302.5	301.8	-0.6
R&D Expenses	214.3	236.0	+21.7
Operating Profit	88.9	76.3	-12.6
Profit before Tax	87.8	81.0	-6.8
Profit attributable to owners of the Company	53.5	60.3	+12.7% +6.8
Currency USD/JPY	108.42	110.86	+2.44
Rate EUR/JPY	118.84	129.70	+10.86

## Revenue



#### Increased by 5.1 Bn JPY (Decreased by 8.9 Bn JPY excl. forex impact)



	(Bn JPY)
Positive Factors	Negative Factors
Japan Lixiana +20.3 Inavir +5.7 Pralia +5.2	Olmetec
Daiichi Sankyo +26.5 Espha (GE) Telmisartan AG Olmesartan AG Rosuvastatin AG etc.	
Daiichi Sankyo, Inc.	Olmesartan -45.5 Welchol -12.3 Effient -11.8
Luitpold Injectafer +9.6 GE injectables +5.8	
Daiichi Sankyo Europe	
Lixiana+15.1	Olmesartan ····· -12.5

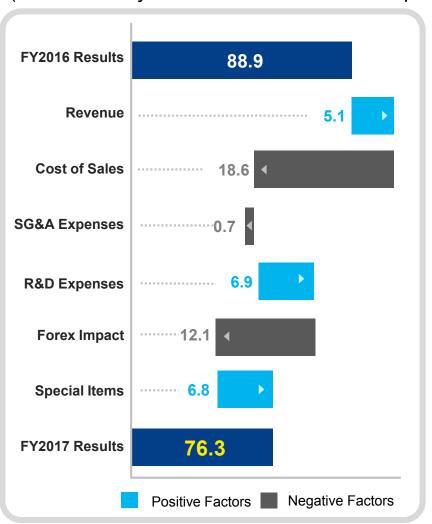
<sup>\*</sup> Forex impact USD: +4.1, EUR: +6.7, ASCA: +3.2

# Operating Profit



#### Decreased by 12.6 Bn JPY

(Decreased by 21.3 Bn JPY excl. forex impact and special items)



(Bn JPY) Revenue +5.1 incl. forex impact of +14.0 Cost of Sales -----++18.6 (Cost increased) Product mix due to impact of olmesartan LOE R&D Expenses --- -6.9 (Cost decreased) Due to completion of Mirogabalin study Forex Impact +12.1 (Cost increased) Cost of Sales +3.3 SG&A Expenses +5.9 R&D Expenses \*See next slide for details

# Special Items



(Bn JPY)

	FY2016 Results	S	FY2017 Results	;	YoY
Cost of Sales	Restructuring costs in SC Impairment loss (Vaccine)	3.6 20.6	Gain on sales of fixed assets Impairment loss (Intangible)	-6.1 5.1	-25.2
SG&A Expenses	Restructuring costs in EU Impairment loss (Vaccine)	10.6 1.0	Restructuring costs in US Litigation fee	2.8 1.7	-7.2
R&D Expenses	Restructuring costs in R&D Impairment loss (Vaccine) Impairment loss (Intangible)	2.5 0.2 1.8	Impairment loss (Intangible)	30.2	+25.7
Total		40.4		33.6	-6.8

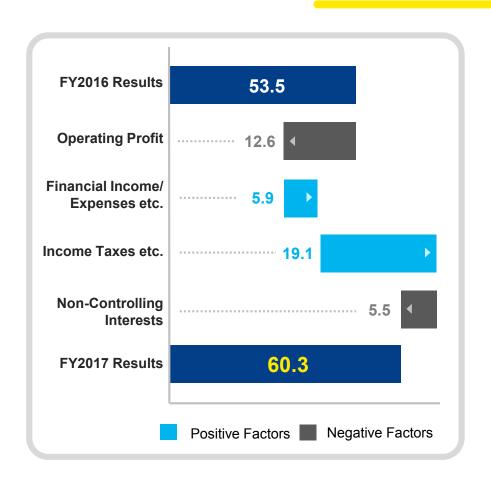
-: Cost decreased items

Booked in Q4

### Profit Attributable to Owners of the Company



#### Increased by 6.8 Bn JPY



(Bn JPY)

Improvement of forex gains/ losses

Income Taxes etc. -19.1 (Cost decreased)

FY2016: Tax rate was deteriorated for not being applicable to tax effect due to impairment loss (vaccines) etc.

FY2017: Impact of the tax rate reduction in US

	FY2016	FY2017	YoY
Profit before Tax	87.8	81.0	-6.8
Income Taxes etc.	40.3	21.2	-19.1
Tax rate	45.9%	26.2%	-19.7%

Non-Controlling 5.5

FY2016: Loss of KDSV\* attributable to Kitasato Institute

\*KDSV: Kitasato Daiichi Sankyo Vaccine

# Revenue: Major Business Units (incl. Forex Impact)



(Bn JPY)

				(511 01 1)
	FY2016 Results	FY2017 Results	YoY	vs. Forecast* (%)
Japan	506.6	540.0	+33.5	100.8%
Daiichi Sankyo Healthcare	66.7	72.9	+6.2	102.7%
Daiichi Sankyo Inc.	142.3	74.8	-67.5	106.8%
Olmesartan	66.4	21.3	-45.0	118.5%
Welchol	45.5	33.9	-11.6	102.8%
Effient	22.2	10.7	-11.5	-
Savaysa	1.9	2.2	+0.3	108.4%
Movantik	4.2	4.7	+0.5	-
Luitpold	88.1	105.4	+17.3	100.4%
Venofer	28.5	31.0	+2.5	99.9%
Injectafer	24.0	34.3	+10.4	98.1%
GE injectables	30.5	37.1	+6.6	-
Daiichi Sankyo Europe	71.0	79.4	+8.5	101.9%
Olmesartan	43.2	33.5	-9.7	104.7%
Efient	7.9	8.0	+0.1	100.2%
Lixiana	9.7	27.0	+17.3	103.8%
ASCA (Asia, South and Central America)	72.1	80.4	+8.2	101.8%

Currency	USD/JPY	108.42	110.86	+2.44
Rate	FUR/JPY	118 84	129 70	+10.86

\* Calculated based on forecast updated in Jan. 2018

# Revenue: Major Products in Japan



(Bn JPY)

		FY2016 Results	FY2017 Results	YoY	vs. Forecast* (%)
Nexium	ulcer treatment	84.0	86.5	+2.6	104.3%
Memary	Alzheimer's disease treatment	46.9	48.6	+1.7	97.1%
Olmetec	antihypertensive agent	69.4	44.6	-24.8	94.9%
Lixiana	anticoagulant	25.0	45.3	+20.3	100.8%
Loxonin	anti-inflammatory analgesic	37.4	36.5	-1.0	101.3%
Tenelia	type 2 diabetes mellitus treatment	24.2	26.3	+2.1	101.1%
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	18.0	23.2	+5.2	100.8%
Rezaltas	antihypertensive agent	17.5	16.8	-0.8	104.7%
Ranmark	treatment for bone complications caused by bone metastases from tumors	13.9	15.4	+1.5	102.7%
Efient	antiplatelet agent	10.4	12.8	+2.4	98.7%
Inavir	anti-influenza treatment	19.6	25.3	+5.7	140.4%
Cravit	synthetic antibacterial agent	15.1	12.7	-2.4	97.5%
Urief	treatment for dysuria	11.4	11.1	-0.3	101.1%
Omnipaque	contrast medium	14.2	14.0	-0.2	107.4%
Mevalotin	antihyperlipidemic agent	10.4	8.6	-1.8	95.7%





- 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
- Shareholder Returns

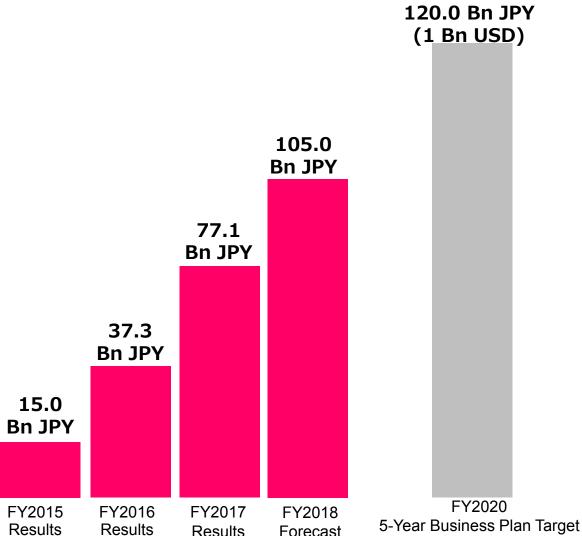


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# Edoxaban: Target and Progress



#### Expanding mainly in Japan, EU and Asia





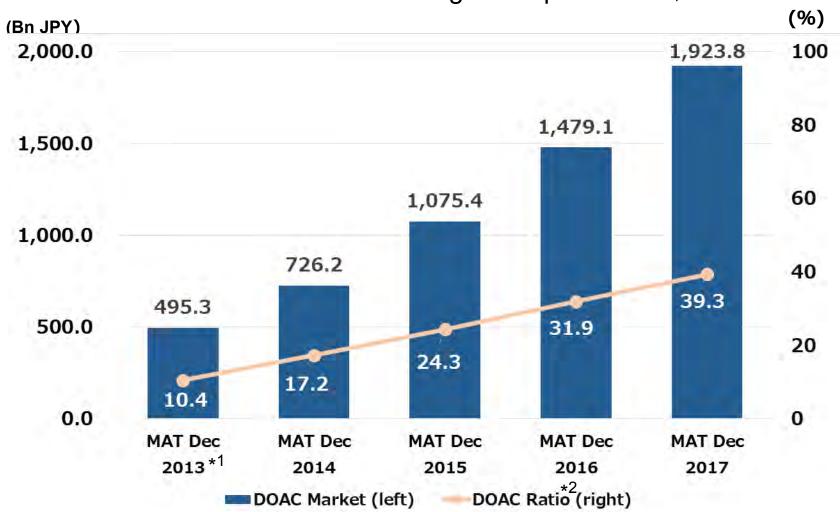


### Global DOAC Market









**Currency Rate USD/JPY: 110** 

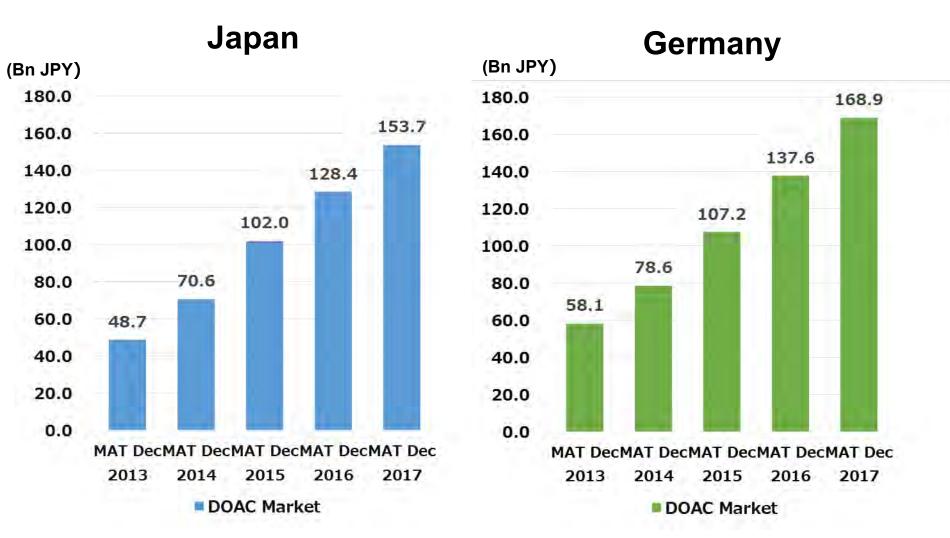
<sup>\*1:</sup> Jan. 2013 - Dec. 2013

<sup>\*2:</sup> Percentage of DOAC Days of Therapy (DOT) counts to total DOT of warfarin and DOAC

## DOAC Market in Japan and Germany







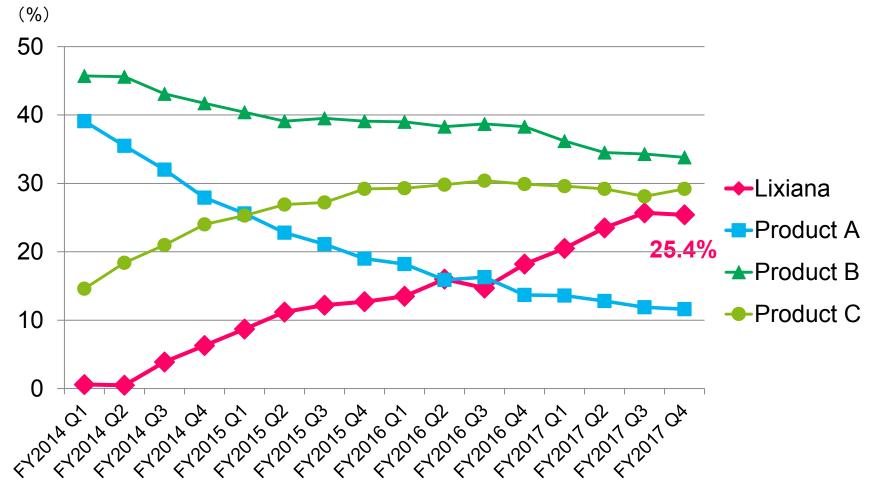
**Currency Rate USD/JPY: 110** 

## Lixiana: Growth in Japan





As of FY2017 Q4, Lixiana increased its sales share to **25.4%**.

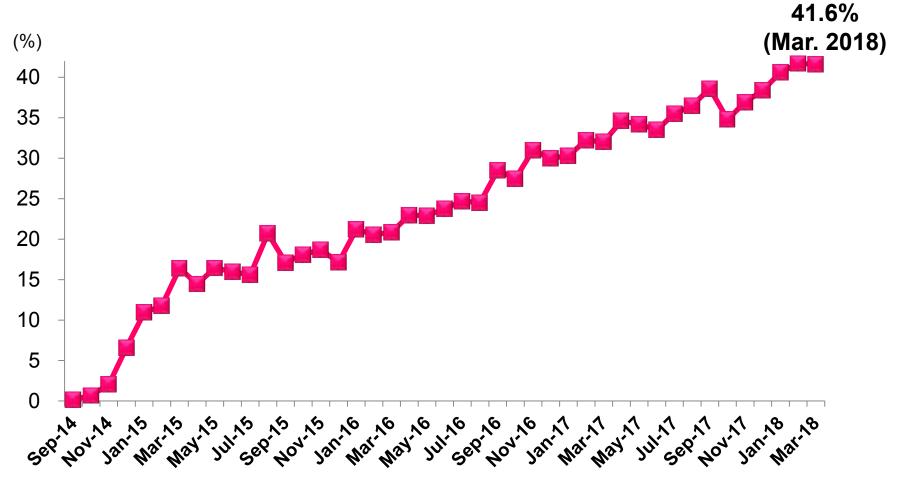


# Lixiana: Growth in Japan





Lixiana has reached top Rxs share since Mar. 2017 in prescription number of new patients for AF+VTE. The share expanded to **41.6%** in Mar 2018.

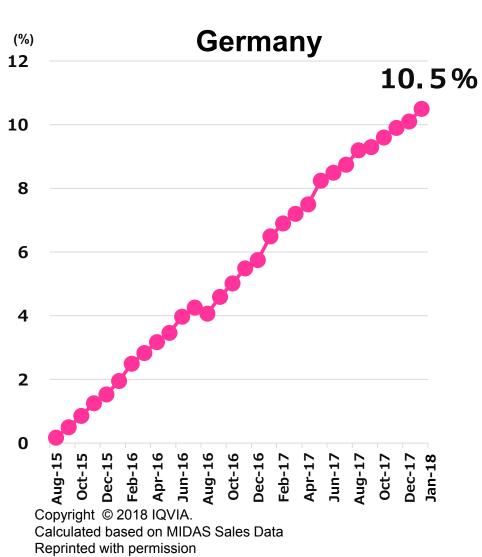


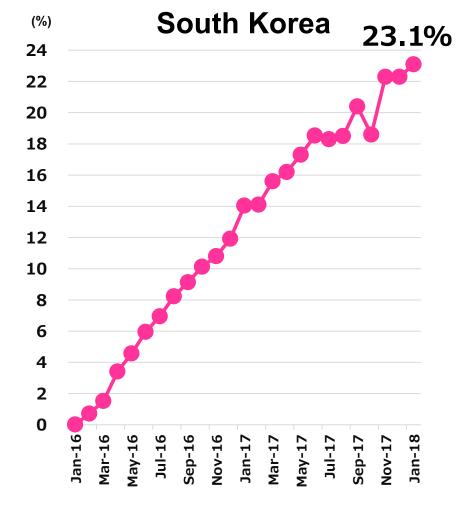
# Lixiana: Growth in Germany and South Korea





- Steady growth since launch
- Reached 3rd share in Germany and South Korea



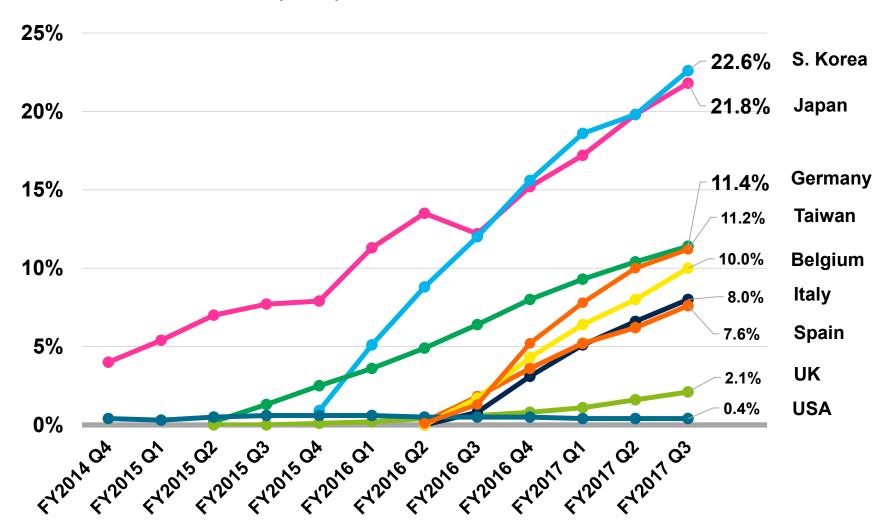


## Growth in Each Country/Region (Summary)





#### Edoxaban volume (DoT) % share of DOAC markets over time



# Image for future growth



#### **Launch Strategy**

Launched and approved in over 20 countries

Covered about 95% of DOAC market potential

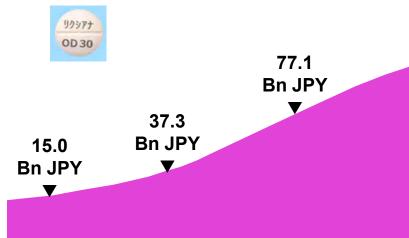
- ◆ Launched: Portugal, Canada, Slovakia, Czech Republic, Turkey, Thailand
- Approved: Brazil, Indonesia, Saudi Arabia
- Submitted: China

#### **Life Cycle Management (LCM)**

Many clinical trials ongoing to maximize product value



Launched anticoagulant Lixiana OD tablets in Japan



Sustainable Growth

Countries launched by FY2016: Japan, US,

Netherlands, S. Korea, Italy, Spain, Taiwan,

Belgium, Hong Kong, Denmark, Hungary,

Switzerland, UK, Germany, Ireland,

Finland, Norway, Austria etc.

FY2015 FY2016 FY2017 FY2018 FY2019 FY2020 FY2021~

Red: Update or new 22

# Edoxaban Life Cycle Management Edoxaban Clinical Research Program







## Edoxaban Life Cycle Management







Ongoing randomized controlled trials in various clinical settings in AF and VTE

	FY2017 Results

Study Name	Clinical Setting (Comparator)	Primary Completion
ENSURE-AF	Cardioversion (enoxaparin/ warfarin)	Presented at ESC 2016
ENTRUST-AFPCI	PCI (VKA)	November 2018
ELIMINATE-AF	Cardiac ablation (VKA)	December 2018
ENVISAGE-TAVI A F	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)	Presented at ASH 2017

- Following the positive opinion of European CHMP for LIXIANA in patients with NVAF undergoing cardioversion, SmPC of LIXIANA was updated
  - Physicians now use LIXIANA for NVAF patients undergoing cardioversion with more confidence than ever.

- Met primary endpoint against the standard of care in US/EU dalteparin (injectable)
  - The 1st DOAC to show non-inferiority against dalteparin
  - Presented in late breaking session at ASH 2017

## Edoxaban Life Cycle Management





Edoxaban Clinical Research Program

Non-interventional studies and registries to generate real-world data including completed, ongoing and future research

	FY2017 Results
Pad: Una	late or new

Study Name	Clinical Setting
ETNA-AF®	Edoxaban Treatment in routine clinical practice in AF
ETNA-VTE®	Edoxaban Treatment in routine clinical practice in VTE
EMIT-AF/VTE	Edoxaban Management In diagnostic and Therapeutic procedures–AF/VTE
PREFER in AF Prolongation	Prolongation PREFER in AF, European Registry
ANAFIE	All Nippon AF In Elderly Registry (in more than 75 years in Japan)
Cancer-VTE Registry Versus Thromboembolism	Multicenter Prospective Registry in VTE patients associated with cancer



- Patient enrollment is ongoing
  - Baseline data will be disclosed in FY2018 (Plan)



Baseline data will be presented at Japanese
 College of cardiology (JCC) in Sep. 2018. (Plan)



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## Major Products in Japan: Target and Progress

243.0

**Bn JPY** 

FY2020

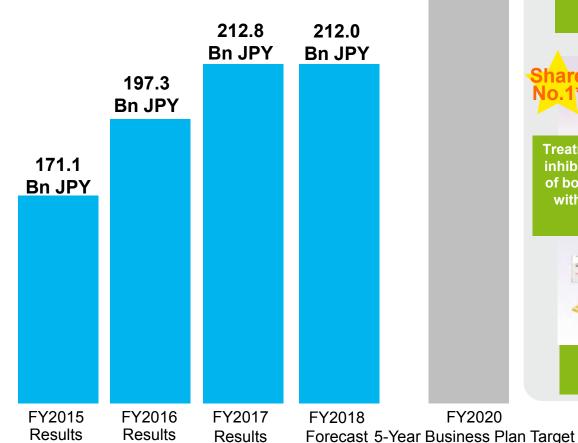


#### Major factors changed from original assumption

Nexium: "Special expansion re-pricing"

Memary: Slow down of growth

Efient: Delay of additional indication for brain area



Alzheimer's disease **Ulcer treatment** treatment **Nexium Memary Treatment for bone** Treatment for osteoporosis/ complication caused inhibitor of the progression of bone erosion associated by bone metastases with rheumatoid arthritis from tumors Ranmark **Pralia** Type 2 diabetes mellitus treatment **Antiplatelet agent Tenelia Efient** 

\*In the market for Bone resorption inhibitors

27

#### Innovative Business: Results in FY2017



#### Sustain growth momentum built in FY2017



Red: Update or new

#### Continuous launch & sales growth of own products

- NDA submissions for Mirogabalin for PNP and Esaxerenone for hypertension
- Approval for PRAI IA for additional indication for RA
- Launch of Narurapid and Narusus for cancer pain treatment

**Growth of** Japan **Business** 



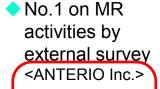
No.1 in Japanese pharmaceutical market (FY2016)



Sales growth of acquired products

Top class sales capabilities in quantity and quality







**No.1** In 6 yrs

**Acquire** valuable new products

- Approval for VIMPAT (UCB Japan) for additional indication for monotherapy in epilepsy patients
- Launch of CANALIA Combination Tablet (Mitsubishi Tanabe Pharma Corporation) for type 2 diabetes mellitus treatment

#### For Continuous launch of Own Products



#### Mirogabalin

- NDA submission in Feb. 2018
- For peripheral neuropathic pain (PNP)
- PNP is caused by damage or functional abnormality of peripheral nerves due to various causes. Typical PNPs are diabetic PNP (DPNP\*) and postherpetic neuralgia (PHN\*).

#### Esaxerenone

- NDA submission in Feb. 2018
- For hypertension
- Hypertensive population estimated to be about 43 million in Japan.

Red: Update or new

<sup>\*</sup>Of the diabetic population estimated to exceed 10 million in Japan, 9-22% of the patients are reported to suffer DPNP.

Of the 500-600 thousand patients who develop herpes zoster annually in Japan, 10-25% patients are reported to be PNH.

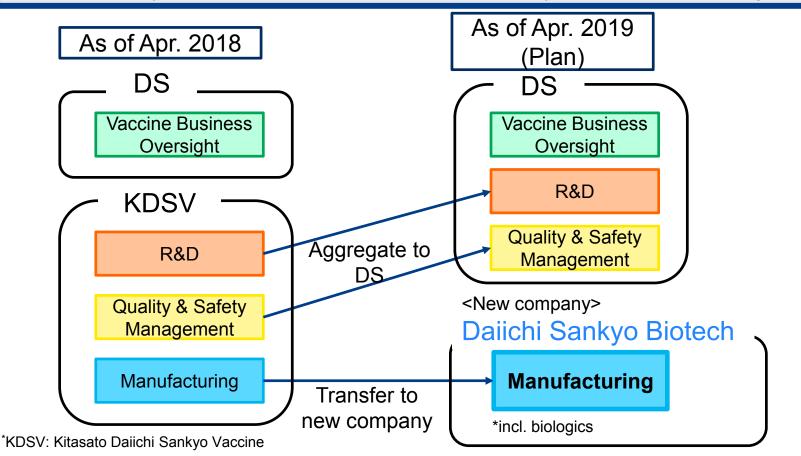
## Reorganization of KDSV



# KDSV's manufacturing will be transferred to newly established Daiichi Sankyo Biotech

Leveraging expertise and technology related to biologics which KDSV has experienced,

Daiichi Sankyo Biotech will manufacture not only vaccine but biologics

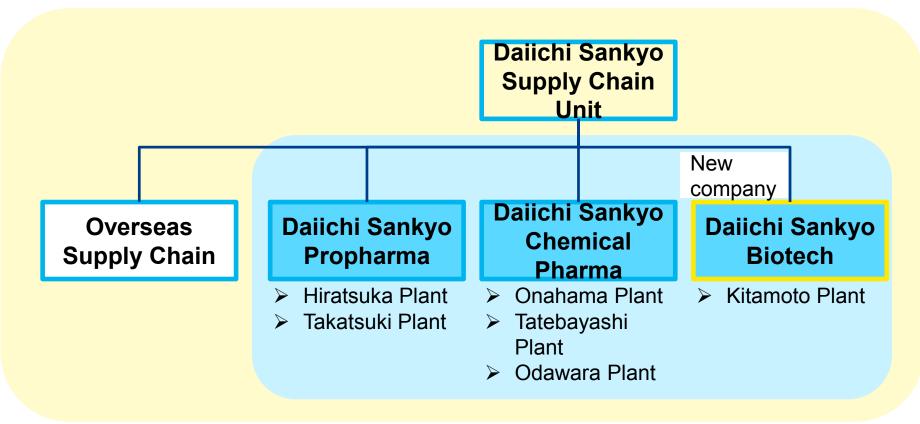


## Position of Daiichi Sankyo Biotech



### **Daiichi Sankyo Biotech:**

Improving stable production and quality level by strengthening GMP system as one of Daiichi Sankyo Supply Chain Unit

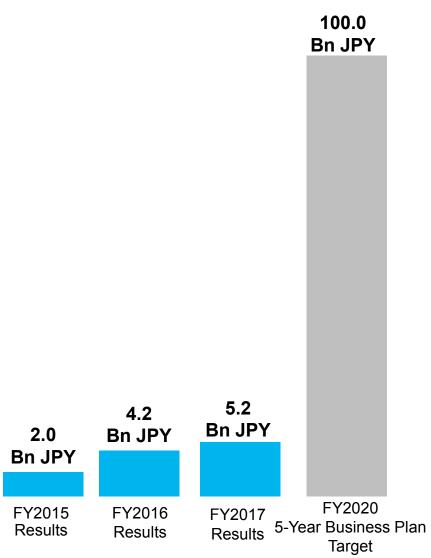




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#### Pain Business of Daiichi Sankyo, Inc.: Target and Progress





#### Major factors happened in FY2017

- Returned development and commercialization right of CL-108 to Charleston Labs, Inc.
- The Ph3 trials of Mirogabalin for fibromyalgia failed

Revisit pain business of Daiichi Sankyo, Inc.

## Revisit pain business of Daiichi Sankyo, Inc.



• We take the complex issues surrounding the US opioid market very seriously. We are committed to marketing our three pain care medicines, Movantik, MorphaBond ER and RoxyBond, in a responsible manner while responding to patient needs.









Launch expected FY2018

 We have established Commitments in Pain Care – a program dedicated to awareness and education around responsible pain management.



For more information, please visit www.CommitmentsinPainCare.com.

## Reorganization of US Commercial Organization



FY2017 Resu
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We reorganized US commercial organization to align with current portfolio and prepare for upcoming oncology pipeline.

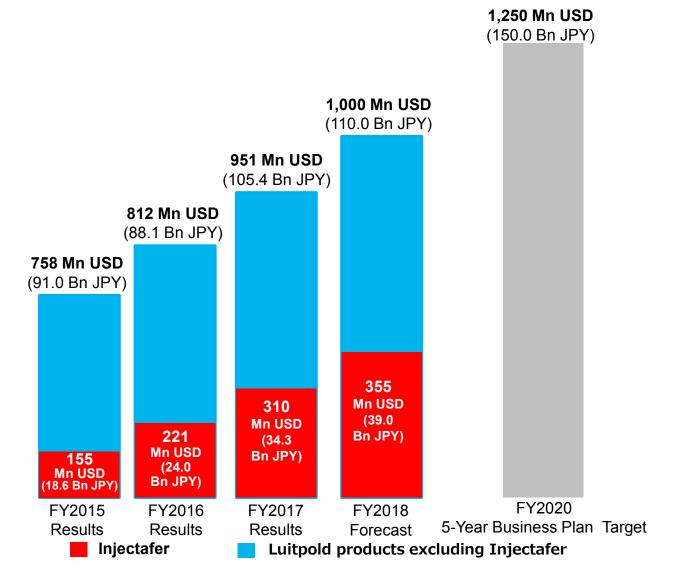
(Reduced headcount by approximately 280 employees, one fourth in U.S. commercial organization including sales force and home office)



# Luitpold Business: Target and Progress



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





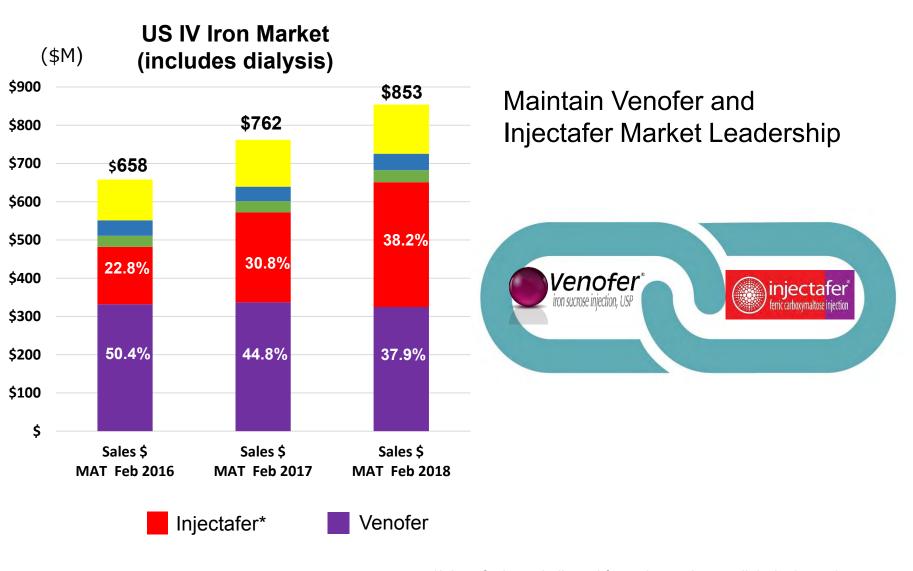






#### Growth of Iron Franchise





## Value Maximization for Injectafer



#### Integrated sales team (Daiichi Sankyo, Inc. and Luitpold)

- Accelerated sales growth (continue double digit growth)
- Sales promotion is expanding into new area

**OBGYN** 

Cardiologist

Gastro

Nephrologist

Oncologist





#### HEART-FID (Ph3 study)\*

- For patients in heart failure from reduced ejection fraction (HFrEF) with iron deficiency (ID)
- Started MAR 2017, expected completion in 2022
- ► HF prevalence 5.8 million\*\* Americans ≥ 20 years of age; 50% of HF patients have ID

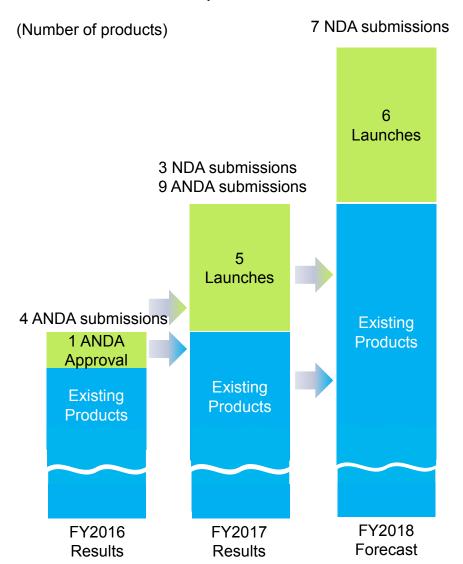
<sup>\*:</sup> Injectafer is not currently approved for heart failure with reduced ejection fraction in patients with iron deficiency.

<sup>\* \*:</sup> https://www.cdc.gov/dhdsp/data\_statistics/fact\_sheets/fs\_heart\_failure.htm

## Growth of Generic Injectable Franchise



## Increase of product by continuous launch of new products



#### **Submission and Launch**

- FY2017 Results
  - 3 NDA submissions, 9 ANDA submissions
  - 5 Launches
- FY2018 Targets
  - 7 NDA submissions
  - 6 Launches

## Progress of 5-Year Business Plan



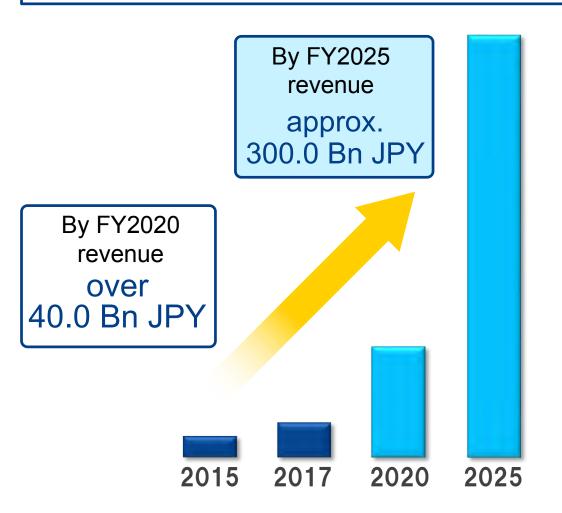
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#### Establish Oncology Business: 5-Year Business Plan



- Steadily drive development of early-stage pipeline
- Accelerate oncology R&D through new R&D organization

Going well





#### Consolidating Internal Structure for Launch



## Restructured organization and hired top oncology talent to accelerate development and launch

## Accelerate Development

Shift resources to achieve "7 in 8" target

## **Strengthen Manufacturing**

15.0 Bn JPY investment to enhance ADC manufacturing capabilities

#### **Global Oncology Marketing**

Positioning assets to meet customers' need through competitive differentiation

#### **Global Medical Affairs**

Delivering innovative solutions to patients, through creation and communication of medical value

#### **Global Market Access & Pricing**

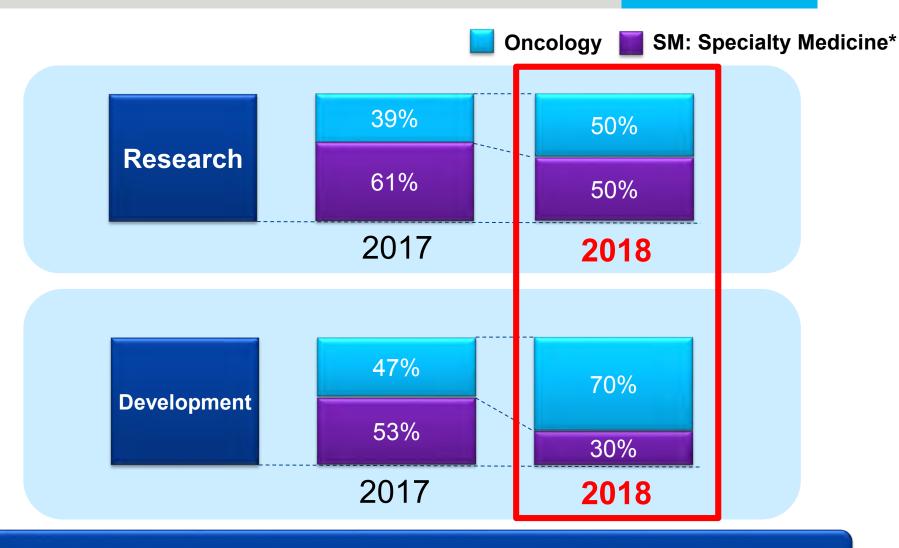
Defining and communicating the "Value" of our assets to stakeholders

Launch Excellence

Cross functional efforts to be prepared for launch

### Shifting Internal Resources to Oncology



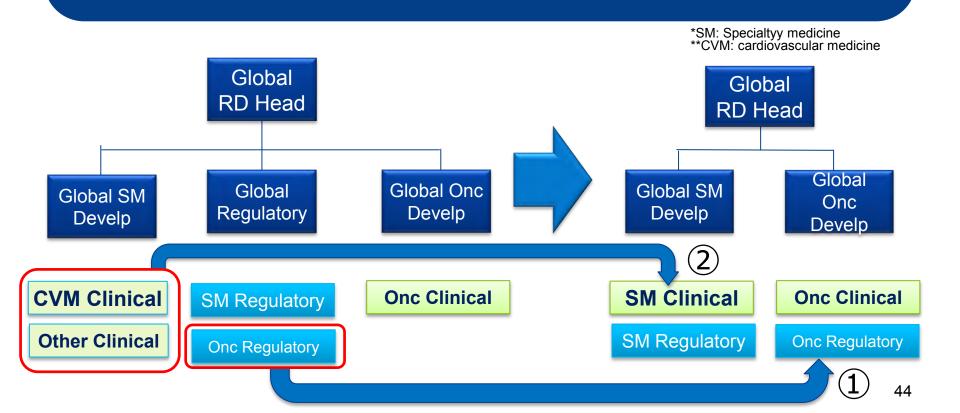


Development budget allocation is done ahead of schedule

## Restructuring to Strengthen Oncology



- Oncology regulatory placed under global oncology development function (SM\* regulatory under SM development)
  - Regulatory focusing only on oncology provides acceleration of oncology development
- 2 Consolidate CVM\*\* and Other Clinical functions to one function
  - A smaller SM function provides more resources for oncology development



## Cancer Enterprise 2025 Vision



- By 2025, Cancer Enterprise will be a leading world-class science organization built on 3 pillars aiming to deliver 7 valuable, distinct NME\*s
- Establish Investigative ADC and AML franchises and Breakthrough Science as 3 pillars
  \*NME: new molecular entity

#### **ADC Franchise**

 Lead in Smart-Treatment with best-in-class & first-in-class ADC

3

#### **AML Franchise**

 Establish a Competitive Hematology Franchise

3

## Breakthrough Science

Lead with Breakthrough Science

1

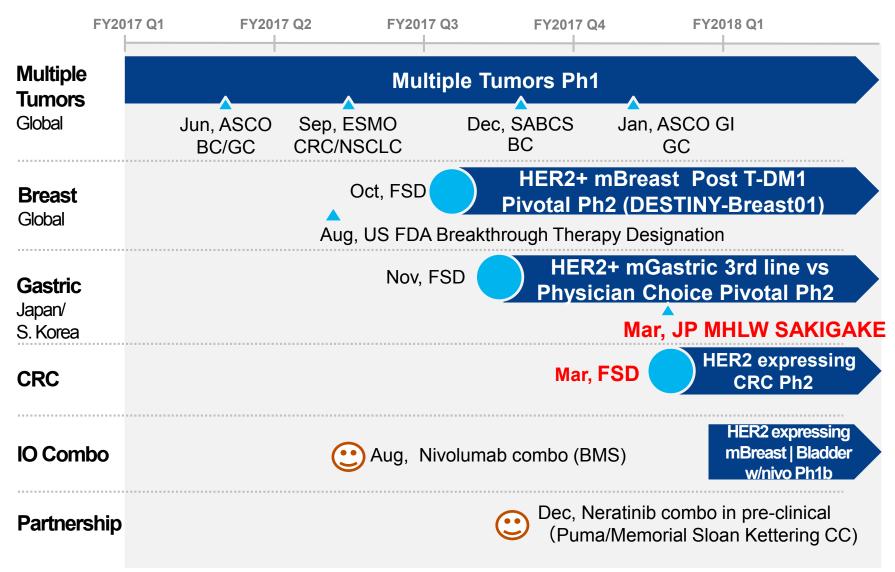
#### 7 NMEs in 8 years



## DS-8201: FY2017 Progress



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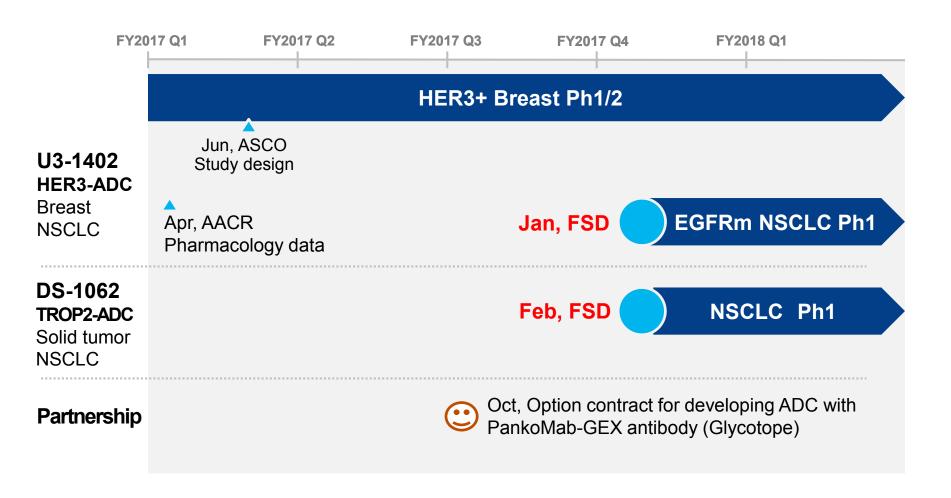
FSD: First subject dosed As of Apr 2018

Red: New or update



## ADC Franchise: FY2017 Progress





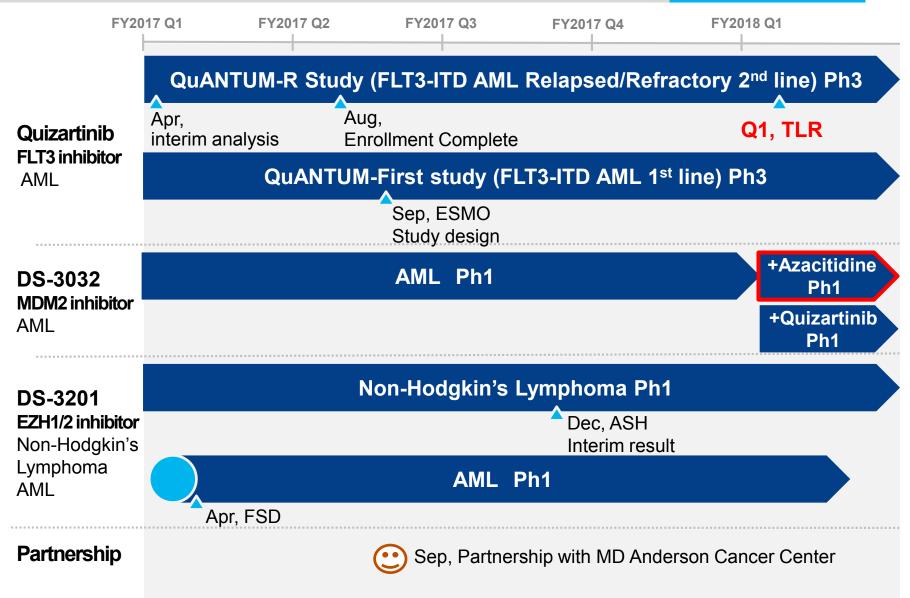
FSD: First subject dosed Red: New or update

47



## AML Franchise: FY2017 Progress





As of Apr 2018

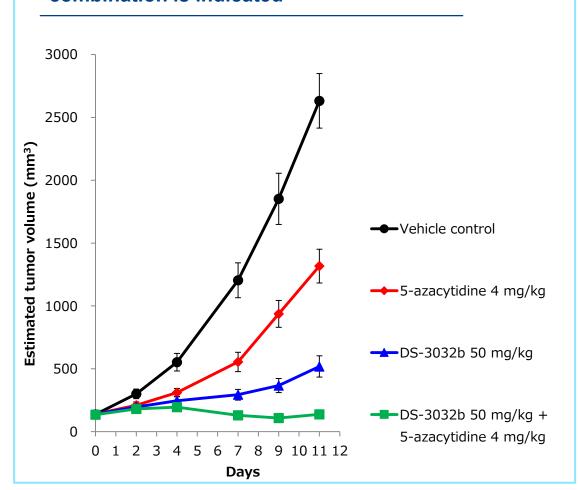


### DS-3032 + Azacitidine Combo Study



#### Non-clinical Study Result DS-3032 + Azacitidine

human AML Xenograft model 50 mg/kg DS-3032b + 4 mg/kg Azacitidine Enhancement of additive efficacy by the combination is indicated



#### **Hypothesis: Combination of drugs** with broad activity spectrum will improve efficacy

- Target heterogeneity and complexity of AML including multiple mechanisms of resistant
- Cytotoxic effects with different mechanisms

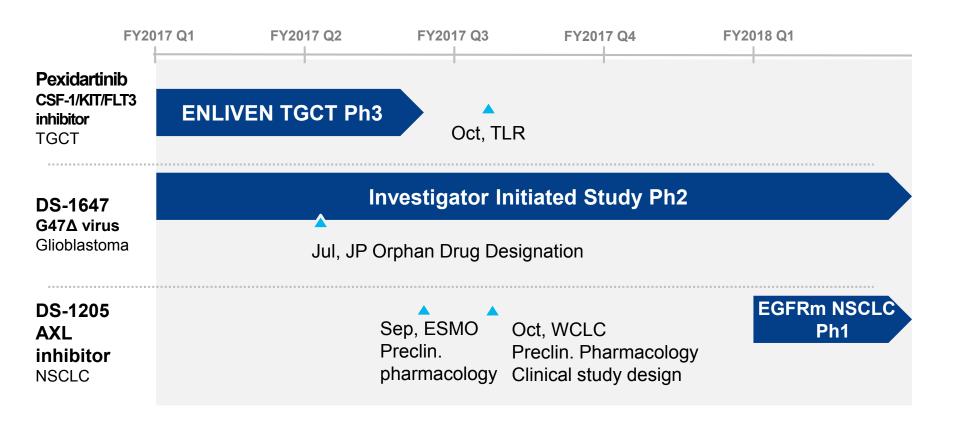
p53 activation by DS-3032 Inhibition of protein synthesis and DNA methylation by azacitidine

- DS-3032: Activity and early safety profile in AML patients have been confirmed
- Azacitidine: Approved for MDS, many clinical trials in AML are ongoing



## Breakthrough Science: FY2017 Progress

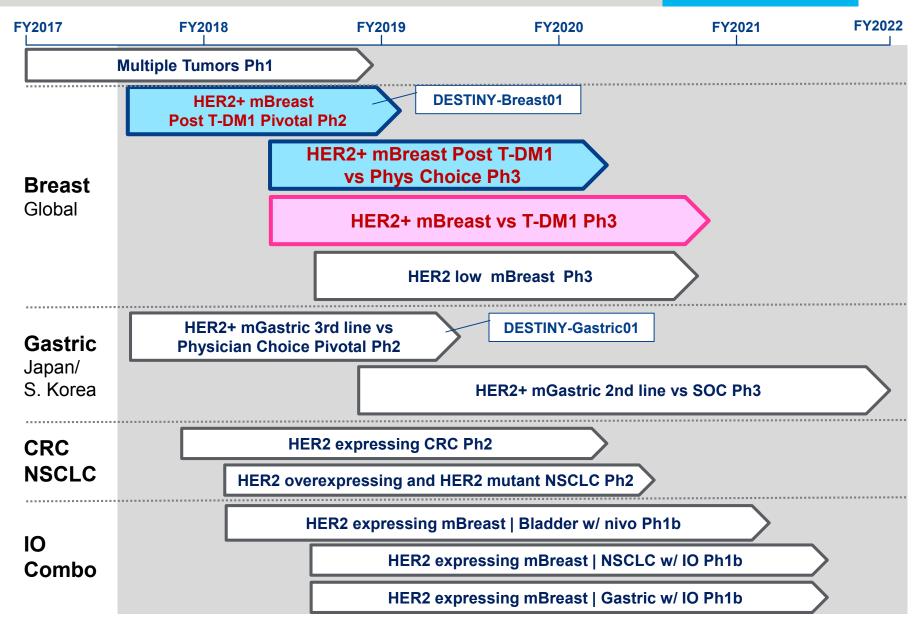






## Oncology Project Update

## DS-8201: Clinical Program



## DS-8201: Expand in mBC





Ph2

#### **DESTINY-Breast01**

HER2+ mBreast Post T-DM1 Pivotal Ph2 **Endpoint: ORR** 

BLA/MAA filing with results for Accelerated/Conditional approval

**Ongoing** 

Ph3 HER2+ mBreast Post T-DM1 vs Phys Choice Ph3 Primary endpoint: PFS Secondary endpoint: OS

**Confirm overall survival** 

Plan to start from FY2018 Q2

HER2+ mBreast vs T-DM1 Ph3 Endpoint: PFS

Ph3

Indication seeking in 2nd line

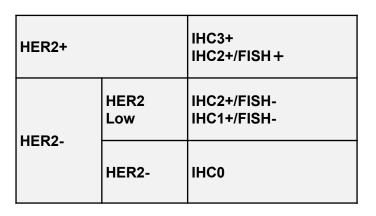
Plan to start from FY2018 Q2

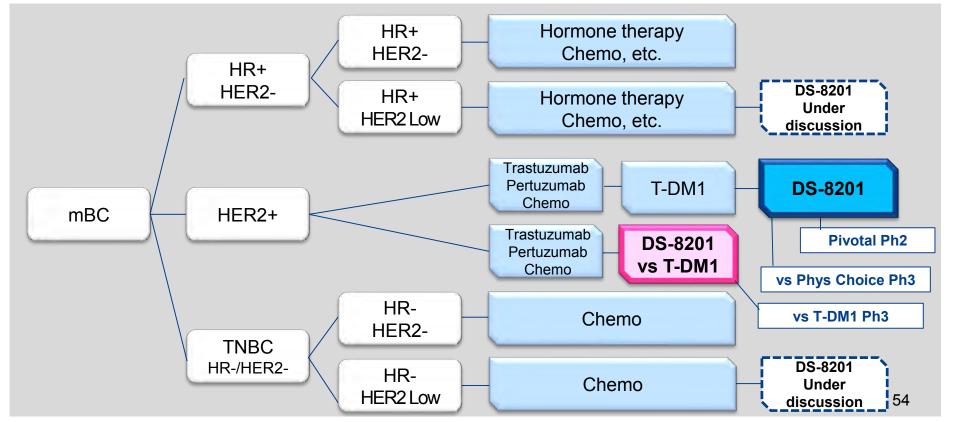


### DS-8201: Target of BC Ph3 Under Preparation



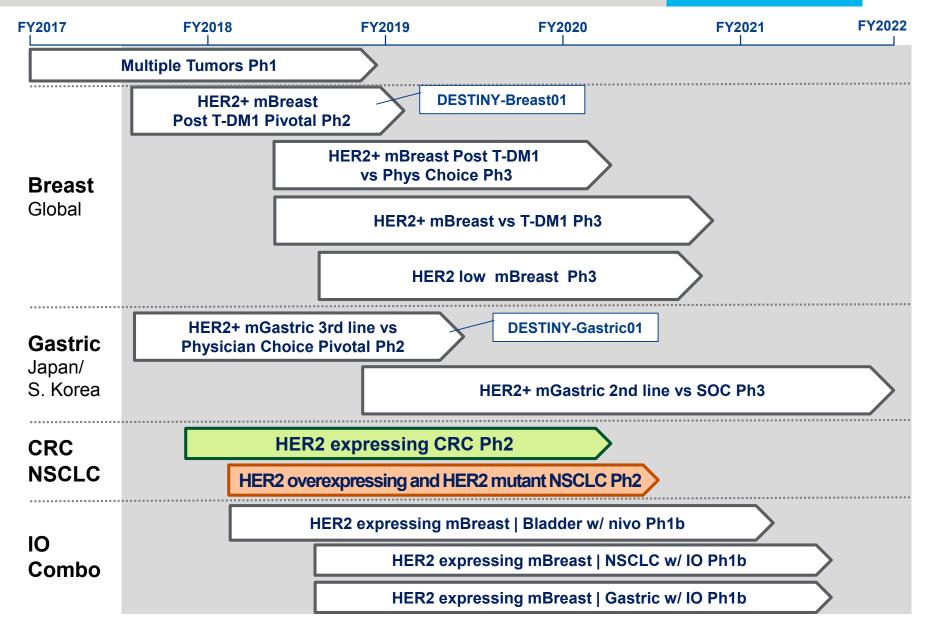
	Cula Tura	HR Re	ПЕВО	
	Sub Type	ER	PR	HER2
ND+/NED3	Luminal A	+	+	-
HR+/HER2-	Luminal B (HER2-)	+/-	weak+ /-	-
LIEDO.	Luminal B (HER2+)	+	+/-	+
HER2+	HER2	-	-	+
TNBC	Triple negative	-	-	-





## DS-8201: Clinical Program



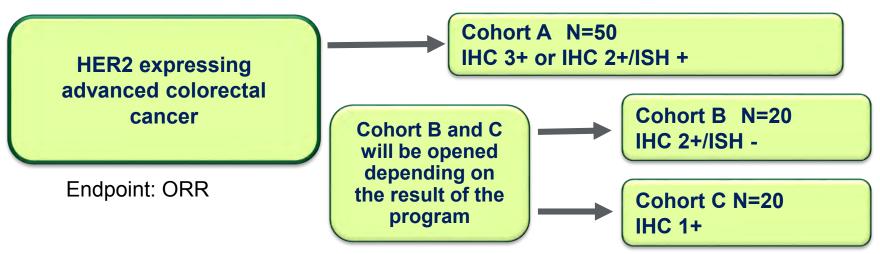




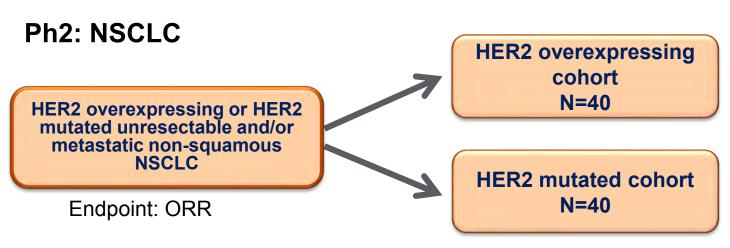
## DS-8201: Expand to New Indications



#### Ph2: CRC



#### Started Mar 2018



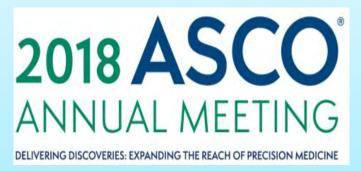
Plan to start FY2018 Q1

#### Oncology Future Data Disclosure



Will hold conference call from ASCO to review details of presentation June 2, 2018, 9:00~10:00am (JST)

June 2018 American Society of Clinical Oncology



Abstracts available on May 16

- ◆ DS-8201
  - June 1, Oral: Update of Ph1 including HER2 low BC
    - ✓ Result of ILD adjudication committee assessment will be presented
- ◆ U3-1402
  - June 4, Poster: preliminary result of BC Ph1/2
- Pexidartinib
  - June 4, Oral: TGCT Ph3 (ENLIVEN) result

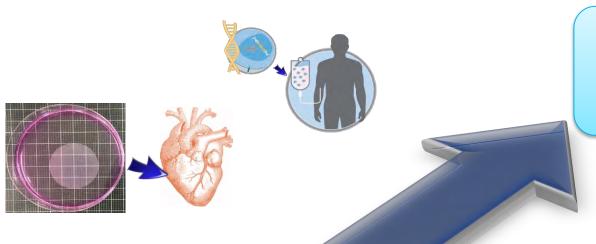
## Progress of 5-Year Business Plan



- 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
- Shareholder Returns

#### DS Advancing in Regenerative Medicine / Cell Therapy





#### 2025 Vision

Fulfill pipeline with innovative projects that change SOC\*

\*SOC: standard of care

#### **Activities in 2016-2017**

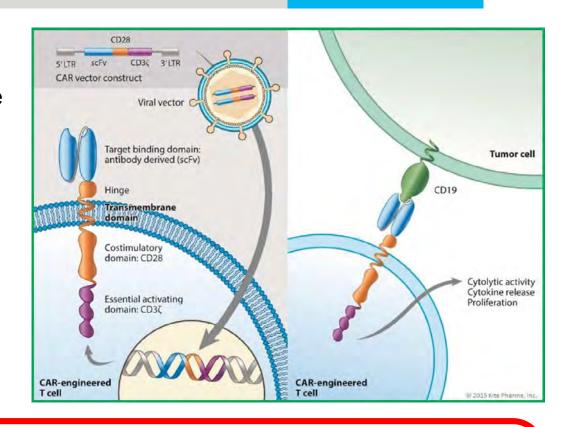
- Strengthen our RD structure (established Cell Therapy Lab.)
- Explore seeds utilizing alliances and move forward to commercialization
  - In-license KTE-C19 (CAR-T)
  - In-license Heartcel for severe ischemic heart failure
  - Open innovation research of capillary stem cells("CapSCs")
  - Research collaboration of iPS-derived Cardiomyocyte Sheet

## KTE-C19: MOA and Japan Ph2 Study



#### MOA

- Engineered T cells express antigen-specific CAR\* on the cell surface.
- When CAR molecules recognize CD19 antigen on tumor cells, they transmit activation signals to T cells.
- Activated T cells release cytokines and show cytolytic activity against tumor cells.
   \*CAR: Chimeric Antigen Receptor



- Japan Ph2 study
  - Target: Refractory or Relapsed Large B Cell Lymphoma
  - Endpoint: ORR
  - JapicCTI-183914

#### KTE-C19: Establishing Manufacturing Process for Launch

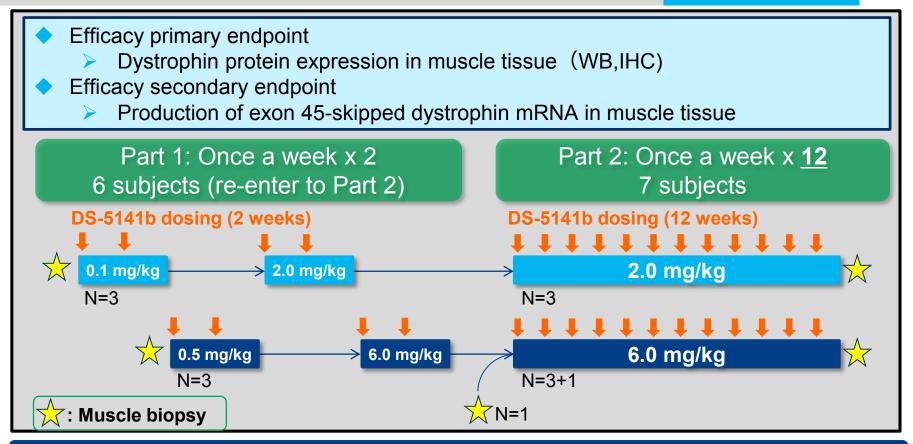


Apheresis	Manufacturing Process			Infusion
Collect patient's white blood cells	Isolate and activate T cells	Engineer T cell	Grow and expand	Infuse patient with engineered T cell
	→ · · · · · · · · · · · · · · · · · · ·			

- PMDA consultation to initiate clinical study in Japan has been completed
- Currently under preparation to construct logistic process in Japan which is traceable and fastest to dosing
- Contract out manufacturing of clinical materials to Hitachi Chemical as part of establishing manufacturing and supply platform in Japan

#### DS-5141: Ph1/2 Design and Summary of Result





#### **Summary of result**

- No safety concerns were observed
- ◆ After 12-week treatment, skipping of exon 45 was clearly confirmed in all patients
- Expression of dystrophin protein was partially identified, but was not be clearly detected as a whole

## Progress of 5-Year Business Plan



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## Enhance Profit Generation Capabilities



#### Realize "Process Excellence": Further cost reductions and streamlining

## Enhancement of procurement

Target during 5YBP – 50.0 Bn JPY cost reductions for indirect materials\*1

Optimization in SC

Optimization in M&S

Optimization in RD

FY2016

13.2 Bn JPY cost reductions

Sale of Bethlehem Plant in US

Restructuring in EU

Close U3 in Germany

FY2017

18.2 Bn JPY cost reductions

Close Hiratsuka Plant in DSCP\*2

Restructuring in US

Close DSIN\*3
Close ASB\*4

<sup>\*1</sup> indirect materias: materials excluding direct materials (raw materials, packaging materials and finished products)

<sup>\*2</sup> DSCP: Daiichi Sankyo Chemical Pharma in Japan

<sup>\*3</sup> DSIN: Daiichi Sankyo India Pharma Private Limited

<sup>\*4</sup> ASB: Asubio Pharma Co., Ltd in Japan

## Enhance Cash Flow Generation Capabilities: Streamlining of Assets



# Reduce Cross-Shareholding shares Reduce to the appropriate level from the point of view of capital efficiency

	FY2016 Results	FY2017 Results	Total
Number of stocks	14 stocks	9 stocks	23 stocks
Sales proceeds	17.3 Bn JPY	14.4 Bn JPY	31.7 Bn JPY
Gain on sales*	9.3 Bn JPY	9.8 Bn JPY	19.1 Bn JPY

<sup>\*</sup> Booked in other comprehensive income

## Progress of 5-Year Business Plan



- Grow Edoxaban
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- Shareholder Returns

#### Shareholder Returns



#### **Shareholder Returns Policy during 5YBP\***

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



	FY2016 Results	FY2017 Results	FY2018 Plan	(Target during 5YBP)
Dividend	70 JPY	70 JPY	70 JPY	more than 70 JPY
Acquisition of own shares	50.0 Bn JPY	50.0 Bn JPY	Flexible	Flexible
Total return	180.7%	159.1%		100%
ratio	169.2%		-	or more



### **FY2018 Consolidated Forecast**

### FY2018 Consolidated Forecast



(Bn JPY)

				( = /	
		FY2017 Results	FY2018 Forecast	YoY	
Revenue		960.2	910.0	-5.2% - <b>50.2</b>	
Cost of Sales		346.0	330.0	-16.0	
SG&A Expenses		301.8	292.0	-9.8	
R&D Expenses		236.0	210.0	-26.0	
Operating Pr	ofit	76.3	78.0	+1.7	
Profit before Tax		ofit before Tax 81.0		-3.0	
Profit attributable to owners of the Company		60.3	55.0	-8.8% <b>-5.3</b>	
Currency	USD/JPY	110.86	110.00	]	
Rate	EUR/JPY	129.70	130.00		

### FY2018 Consolidated Forecast



			(Bn JPY)	
	FY2017 Results (excl. special items)	FY2018 Forecast	YoY	> Impacts of patent cliff
Revenue	960.2	910.0	-50.2	Impact of price revision in Japan
Cost of Sales	36.1%	36.3%	-17.0	Decrease due to revenue decrease
SG&A Expenses	297.4	292.0	-5.4	<ul> <li>Optimization in US sales operation</li> <li>Continuous cost</li> </ul>
R&D Expenses	205.9	210.0	+4.1	reduction  Investments in
Operating Profit	109.9	78.0	-31.9	DS-8201, U3-1402 etc.

Currency Rate	USD/JPY	110.86	110.00
	EUR/JPY	129.70	130.00



#### Current Review of 5-Year Business Plan

#### Current Review of 5-Year Business Plan



- Edoxaban: Growing in momentum beyond the initial target
- Oncology: Accelerating toward 2025 Vison
  - DS-8201, other ADCs and AMLs clinical trials are steadily progressing
- US Pain Business: Difficult to achieve the initial target
- Japan Business: Daunting business environment in the future
- FY2018 Forecast: Below 5YBP target of OP 100.0 Bn JPY

Internal/External changes negatively affect business profitability

Examining initiatives to support business profitability

Upon finalization, new financial targets will be announced



# Appendix

- R&D Milestone Events
- Major R&D Pipeline
- Out-licensing Projects
- DS-8201 summary of conference presentation
- Abbreviations

#### **R&D Milestone Events**

#### As of Apr 2018



Droinet	Indication / Study	FY2017	FY2018			
Project		Q4	Q1	Q2	Q3	Q4
Pexidartinib	Ph3: TGCT (US)				Submission	
Quizartinib	Ph3: QuANTUM-R AML2nd line treatment		TLR			
DS-3032	Ph1: AML with Quizartinib		Study initiation			
D3-3032	Ph1: AML with Azacitidine		Study initiation			
	Ph3: HER2+ Breast Post T-DM1 vs Phys Choice			Study initiation		
	Ph3: HER2+ Breast vs T-DM1			Study initiation		
	Ph3: HER2 low Breast				Study initiation	
DS-8201	Ph2: HER2 expressing CRC	Study initiation				
D3-0201	Ph2: HER2 overexpressing/HER2 mutant NSCLC		Study initiation			
	Ph1b: HER2 expressing Breast/Bladder with nivolumab		Study initiation			
	Ph1b: HER2 expressing Breast/NSCLC with IO				Study initiation	
	Ph1b: HER2 expressing Breast/Gastric with IO				Study initiation	
U3-1402	Ph1/2: HER3+ Breast		P2 part Study initiation			
	Ph1: EGFRm NSCLC	Study initiation				
DS-1062	Ph1: Solid tumor (NSCLC)	Study initiation				
DS-1205	Ph1: EGFRm NSCLC with osimertinib	$\Rightarrow$	Study initiation			
KTE-C19	Ph2: Refractory or Relapsed Large B Cell Lymphoma			Study initiation		
Hydromorphone	Ph3: Cancer pain (injection formulation) (JP)	<u>Approved</u>				
Mirogabalin	Ph3: DPNP/PHN (JP)	Submission				Approval
Esaxerenone	Ph3: Essential hypertension (JP)	Submission				Approval
Laninamivir	Ph3: Anti-influenza (nebulizer formulation) (JP)			Submission		
DS-5141	Ph1/2: Duchenne Muscular Dystrophy (JP)		<u>TLR</u>			

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TLR: Top Line Results

#### As of Apr 2018



	Phase 1	Phase 2	Phase 3	Application
Oncology	Phase 1  DS-3032 (US/JP) (MDM2 inhibitor)  PLX7486 (US) (FMS / TRK inhibitor)  PLX8394 (US) (BRAF inhibitor)  PLX9486 (US) (KIT inhibitor)  DS-3201 (JP/US) (EZH1/2 inhibitor)  PLX73086 (US) (CSF-1R inhibitor)  PLX51107 (US) (BRD4 inhibitor)	Phase 2  Patritumab (EU) (U3-1287 / H&N cancer / Anti-HER3 antibody)  DS-1647 (JP) (Glioblastoma / G47∆ virus)  Quizartinib (JP) (AC220 / AML-2nd / FLT3 inhibitor)  DS-8201 (JP/US/EU) (Breast cancer/anti-HER2 ADC)  DS-8201 (JP/Asia) (Gastric cancer/anti-HER2 ADC)  DS-8201 (JP/US/EU) (CRC/anti-HER2 ADC)  DS-8201 (JP/US/EU) (NSCLC/anti-HER2 ADC)  KTE-C19(JP) (Large B Cell Lymphoma/anti-CD19 CAR T cells)	Denosumab (JP) (AMG 162 / Breast cancer adjuvant/ Anti-RANKL antibody)  Quizartinib (US/EU/Asia) (AC220 / AML-2nd / FLT3 inhibitor)  Quizartinib (US/EU/Asia) (AC220 / AML-1nd / FLT3 inhibitor)  Pexidartinib (US/EU) (PLX3397 / TGCT / CSF-1R/KIT/FLT3 inhibitor)	Application
Specialty Medicine	■ DS-1040 (US/EU/JP) (Acute ischemic stroke, acute pulmonary embolism / TAFla inhibitor) ■ DS-2330 (Hyperphosphatemia) ■ DS-1501 (US) (Osteoporosis / Anti-Siglec-15 antibody) ■ DS-7080 (US) (AMD / Angiogenesis inhibitor) ■ DS-5141 (JP) (DMD / ENA oligonucleotide) ■ DS-1211 (US) (TNAP inhibitor) ■ VN-0102/JVC-001 (JP) (MMR vaccine)		Edoxaban (JP) (DU-176b / AF (very elderly) / FXa inhibitor)  Prasugrel (JP) (CS-747 / Ischemic stroke / Anti-platelet agent)  Esaxerenone (JP) (CS-3150 / DM nephropathy / MR antagonist)  Laninamivir (JP) (CS-8958 / Anti-influenza / nebulizer)  VN-0105 (JP) (DPT-IPV / Hib vaccine)  Intradermal Seasonal Influenza Vaccine (JP) (VN-100 / prefilled i.d. vaccine for seasonal flu)	Edoxaban (ASCA) (DU-176b / AF / FXa inhibitor)  Edoxaban (ASCA) (DU-176b / VTE / FXa inhibitor)  Mirogabalin (JP) (DS-5565 / DPNP/PHN α2δ ligand)  Esaxerenone (JP) (CS-3150/Hypertension/ MR antagonist)  VN-0107/MEDI3250 (JP) (Nasal spray flu vaccine)

Major R&D Pipeline

Red: New or update 75

## Out-licensing Projects

As of Apr 2018



	Pre-clinical	Phase1	Phase 2	Phase 3
Oncology		■ DS-6051 (NTRK/ROS1 inhibitor)		
Specialty Medicine	<ul> <li>■ DS-1515         (Inflammatory disease/PI3Kδ inhibitor)</li> <li>■ DS-1039         (Cystic fibrosis / new MOA (CFTR independent fluid secretion))</li> <li>■ DS-7411         (Hemophilia A and B / antibody)</li> </ul>	■ DS-2969 (Clostridium difficile infection / GyrB inhibitor) ■ DS-1093 (inflammatory bowel disease (IBD)/HIF-PH inhibitor)	■ Laninamivir (CS-8958/Anti-influenza/ Out- licensing with Vaxart Inc)	

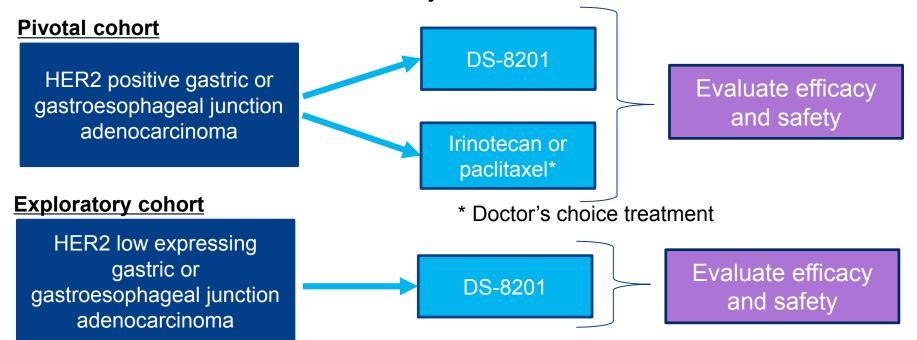
Red: New or update 76



#### DS-8201: HER2+ GC SAKIGAKE Designation



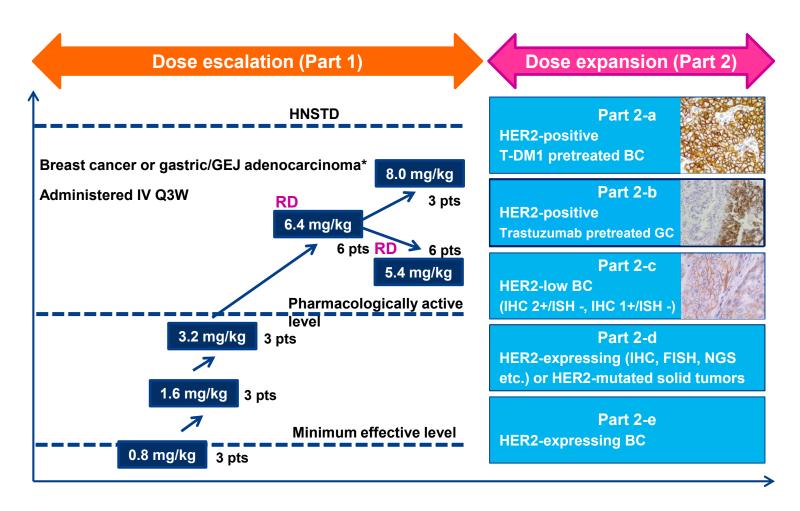
- SAKIGAKE designation in Mar 2018
  - For the treatment of HER2-positive advanced gastric or gastroesophageal junction cancer by the MHLW
  - Gastric cancer treatment in Japan has high unmet medical needs and SAKIGAKE designation will help us accelerate the development
- Following pivotal Ph2 study is on-going (DESTINY-Gastric01 Study)





## DS-8201: Ph1 Study Design





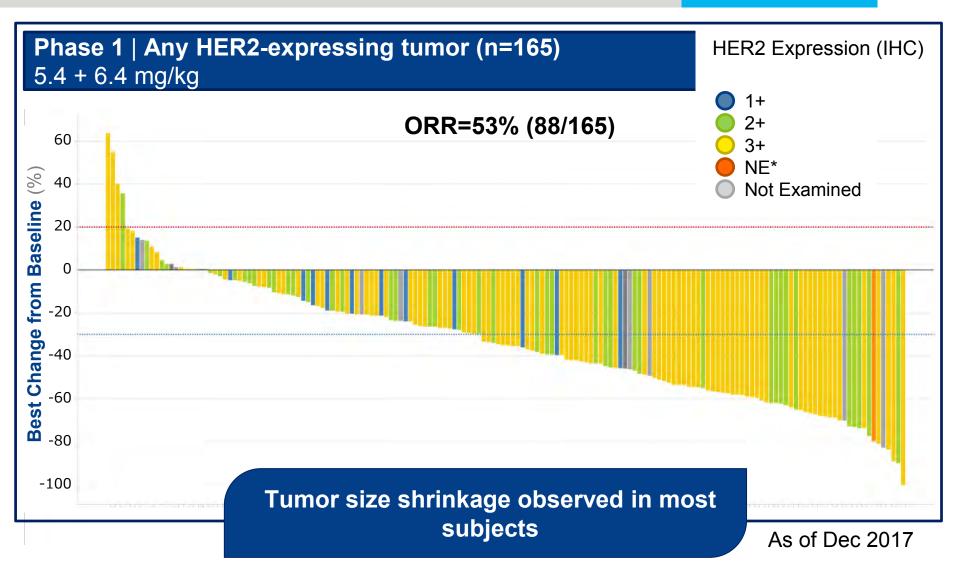
<sup>\*</sup>Subjects in part 1 are not required to have HER2-positive (IHC 3+ or IHC2+/ISH-positive) tumors.

BC, breast cancer; EWOC, escalation with overdose control; FISH, fluorescent in situ hybridization; GC, gastric cancer; GEJ, gastroesophageal junction; HER2, human epidermal growth factor receptor 2; HNSTD, highest non-severely toxic dose; IHC, immunohistochemistry; ISH, in situ hybridization; IV, intravenous; mCRM, modified continuous reassessment method; NGS, next-generation sequencing; Q3W, once every 3 weeks; RD, recommended dose for dose expansion: T-DM1, trastuzumab emtansine.



## DS-8201: Ph1 Efficacy





\*NE: Not Evaluated (Same as Not Examined)



# DS-8201: Ph1 Preliminary Efficacy

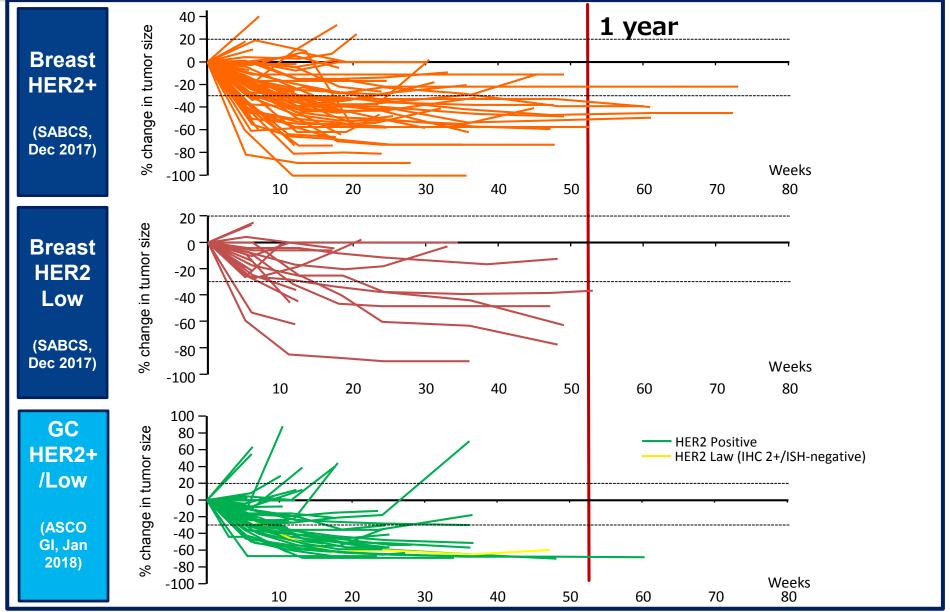


Breast (SABCS, Dec 2017)	ORR	Disease Control Rate	PFS Median (months) - range		
HER2 positive					
All 61% (35/57)		95% (54/57)	10.4 (1.2+, 16.8+)		
HR Positive	56% (22/39)	92% (36/39)	NR (1.2+, 16.8+)		
HR Negative	75% (12/16)	100% (16/16)	10.4 (1.2+, 14.1+)		
Prior pertuzumab	62% (31/50)	94% (47/50)	10.3 (1.2+, 16.8+)		
HER2 Low					
All	32% (6/19)	84% (16/19)	NR (0.5, 12.2+)		
HR Positive	31% (5/16)	88% (14/16)	NR (1.2+, 12.2+)		
HR Negative	0% (0/2)	50% (1/2)	7.6 (0.5, 7.6)		
Gastric (ASCO Gl. Jan 2018)	ORR	Disease Control Rate	PFS Median (months) - range		
HER2 positive	HER2 positive				
All	45.5% (20/44)	81.8% (36/44)	5.8 (3.0+, 8.3+)		
Prior CPT-11 (irinotecan)	43.5% (10/23)	82.6% (19/23)	4.1 (2.5+, 8.3+)		
CRC, NSCLC (ESMO、Sep 2017)	ORR	Disease Control Rate	PFS Median (months) - range		
Colorectal	20% (2/10)	80% (8/10)	_		
NSCLC 20% (1/5)		60% (3/5)			



## DS-8201: Ph1 Efficacy BC&GC







## DS-8201: Ph1 Preliminary Safety



**Treatment-emergent events, any grade (>20%)** All subjects with 5.4 or 6.4 mg/kg (N = 185, as of 15 Oct 2017)

			n (%)		
Preferred Term (MedDRA v18.0.)	Grade 1	Grade 2	Grade 3	Grade 4	Any
Hematologic					
Anaemia	14 (7.6)	22 (11.9)	25 (13.5)	2 (1.1)	63 (34.1)
Platelet count decreased	27 (14.6)	14 (7.6)	13 (7.0)	6 (3.2)	60 (32.4)
Neutrophil count decreased	1 (0.5)	17 (9.2)	23 (12.4)	8 (4.3)	49 (26.5)
White blood cell count decreased	5 (2.7)	17 (9.2)	21 (11.4)	3 (1.6)	46 (24.9)
Gastrointestinal disorders					
Nausea	99 (53.5)	25 (13.5)	7 (3.8)	0 (0.0)	131 (70.8)
Decreased appetite	64 (34.6)	34 (18.4)	9 (4.9)	0 (0.0)	107 (57.8)
Vomiting	51 (27.6)	9 (4.9)	3 (1.6)	0 (0.0)	63 (34.1)
Diarrhea	43 (23.2)	11 (5.9)	3 (1.6)	0 (0.0)	57 (30.8)
Constipation	45 (24.3)	6 (3.2)	1 (0.5)	0 (0.0)	52 (28.1)
Others					
Alopecia	51 (27.6)	10 (5.4)	0 (0.0)	0 (0.0)	61 (33.0)
Malaise	31 (16.8)	12 (6.5)	2 (1.1)	0 (0.0)	45 (24.3)
Fatigue	26 (14.1)	11 (5.9)	1 (0.5)	0 (0.0)	38 (20.5)

Pneumonitis: Two cases from Breast (both grade 5) and two cases in GC (grade 1 and grade 3)

### Abbreviations



Abbreviation	
BTD	Breakthrough therapy designation
CR	Complete response
DCR	Disease control rate
DLT	Dose limiting toxicity
DOR	Duration of response
EGFR	Epidermal growth factor receptor
MTD	Maximum tolerated dose
NSCLC	Non-small-cell lung cancer
ORR	Overall response rate Objective response rate
OS	Overall survival
PD	Progress disease
PFS	Progression-free survival
PR	Partial response

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