

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

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- ◆ **FY2017 Financial Results**
- ◆ **Progress of 5-Year Business Plan**
- ◆ **FY2018 Consolidated Forecast**

FY2017 Financial Results

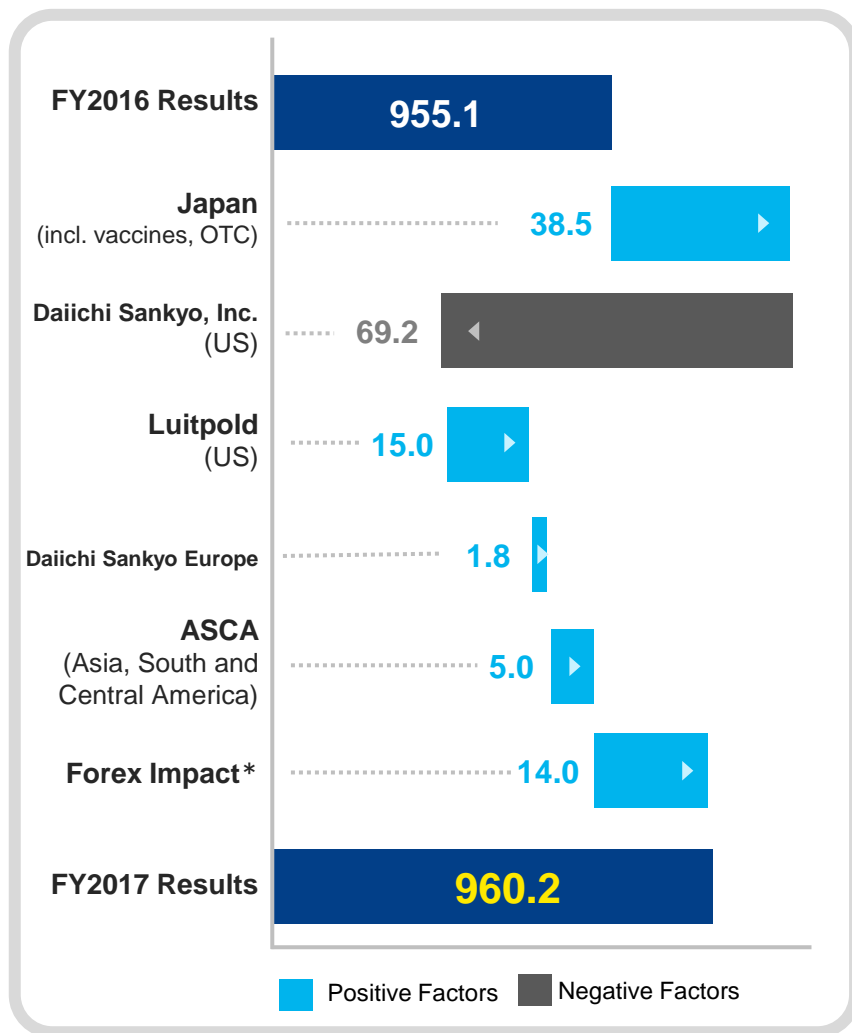
Overview of FY2017 Results

(Bn JPY)

	FY2016 Results	FY2017 Results	YoY	
Revenue	955.1	960.2	+0.5% +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	-14.2% -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 Rate	USD/JPY	108.42	110.86	+2.44
	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	Olmotec	-24.8
Inavir	+5.7		
Pralia	+5.2		

Daiichi Sankyo Espha (GE) +26.5

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

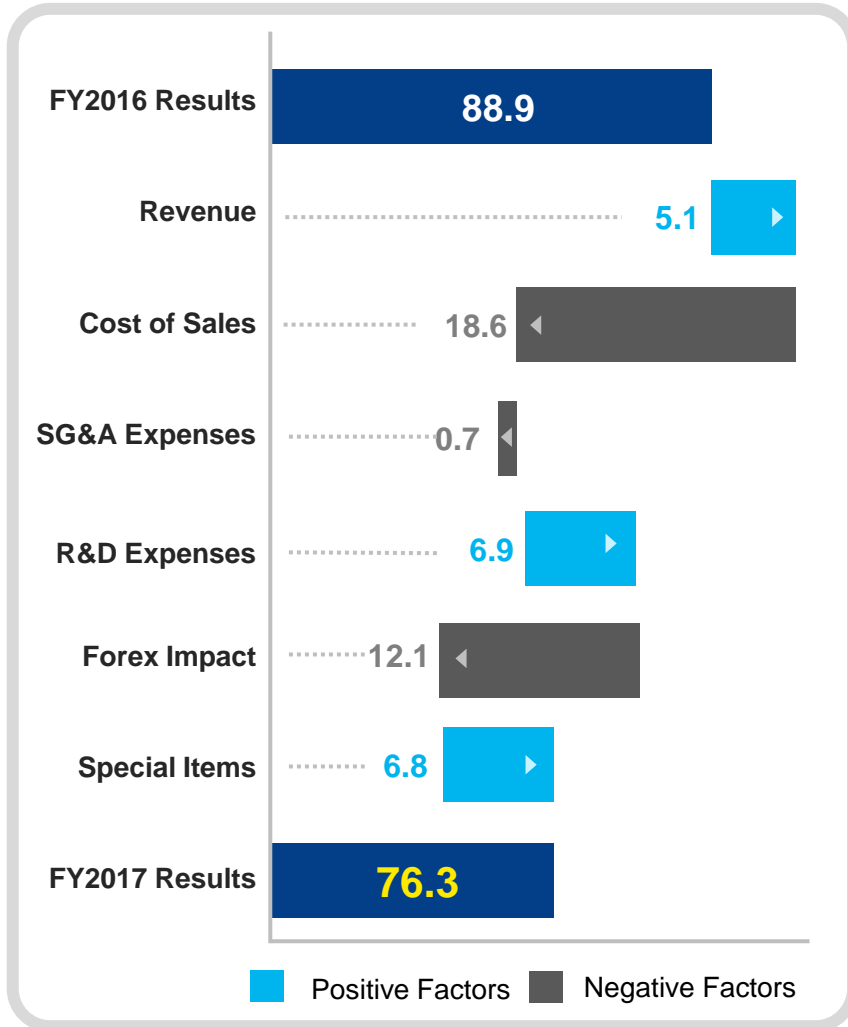
Lixiana	+15.1	Olmesartan	-12.5
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* Forex impact USD: +4.1, EUR : +6.7, ASCA: +3.2

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 **+2.9**

Special Items **-6.8 (Cost decreased)**

*See next slide for details

Special Items

(Bn JPY)

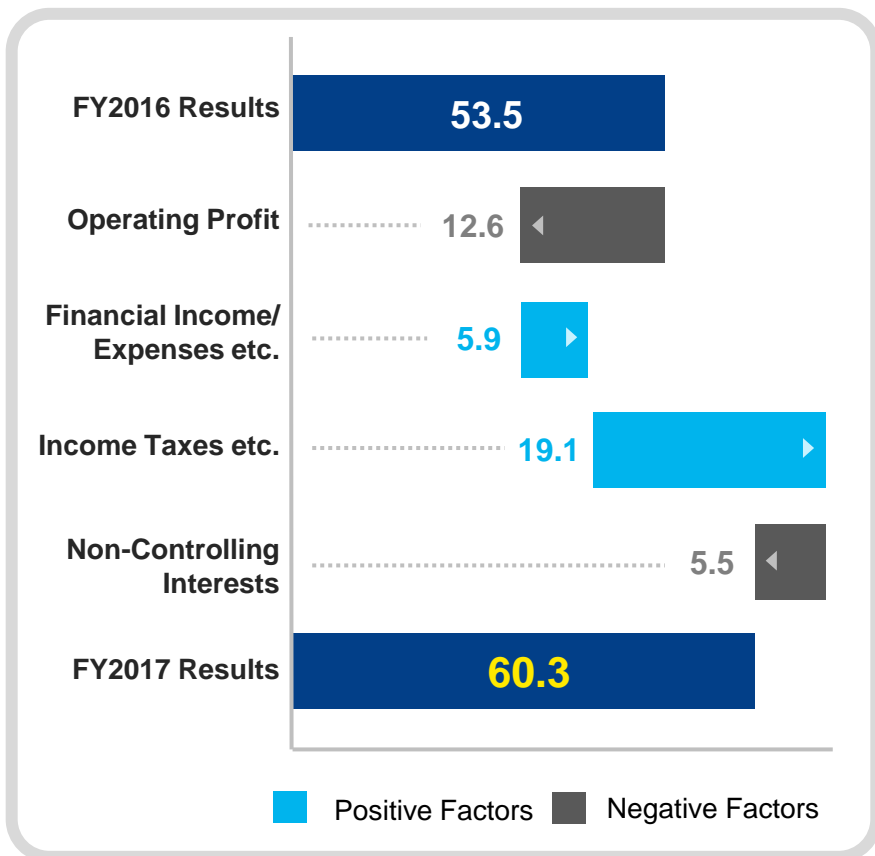
	FY2016 Results		FY2017 Results		YoY
Cost of Sales	Restructuring costs in SC	3.6	Gain on sales of fixed assets	-6.1	-25.2
	Impairment loss (Vaccine)	20.6	Impairment loss (Intangible)	5.1	
SG&A Expenses	Restructuring costs in EU	10.6	Restructuring costs in US	2.8	-7.2
	Impairment loss (Vaccine)	1.0	Litigation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

Financial Income/ Expenses etc. -5.9 (Cost decreased)

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 Interests 5.5

FY2016: Loss of KDSV* attributable to Kitasato Institute
 *KDSV: Kitasato Daiichi Sankyo Vaccine

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	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	EUR/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%
Olmotec	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%

* Calculated based on forecast updated in Jan. 2018

Progress of 5-Year Business Plan

Progress of 5-Year Business Plan

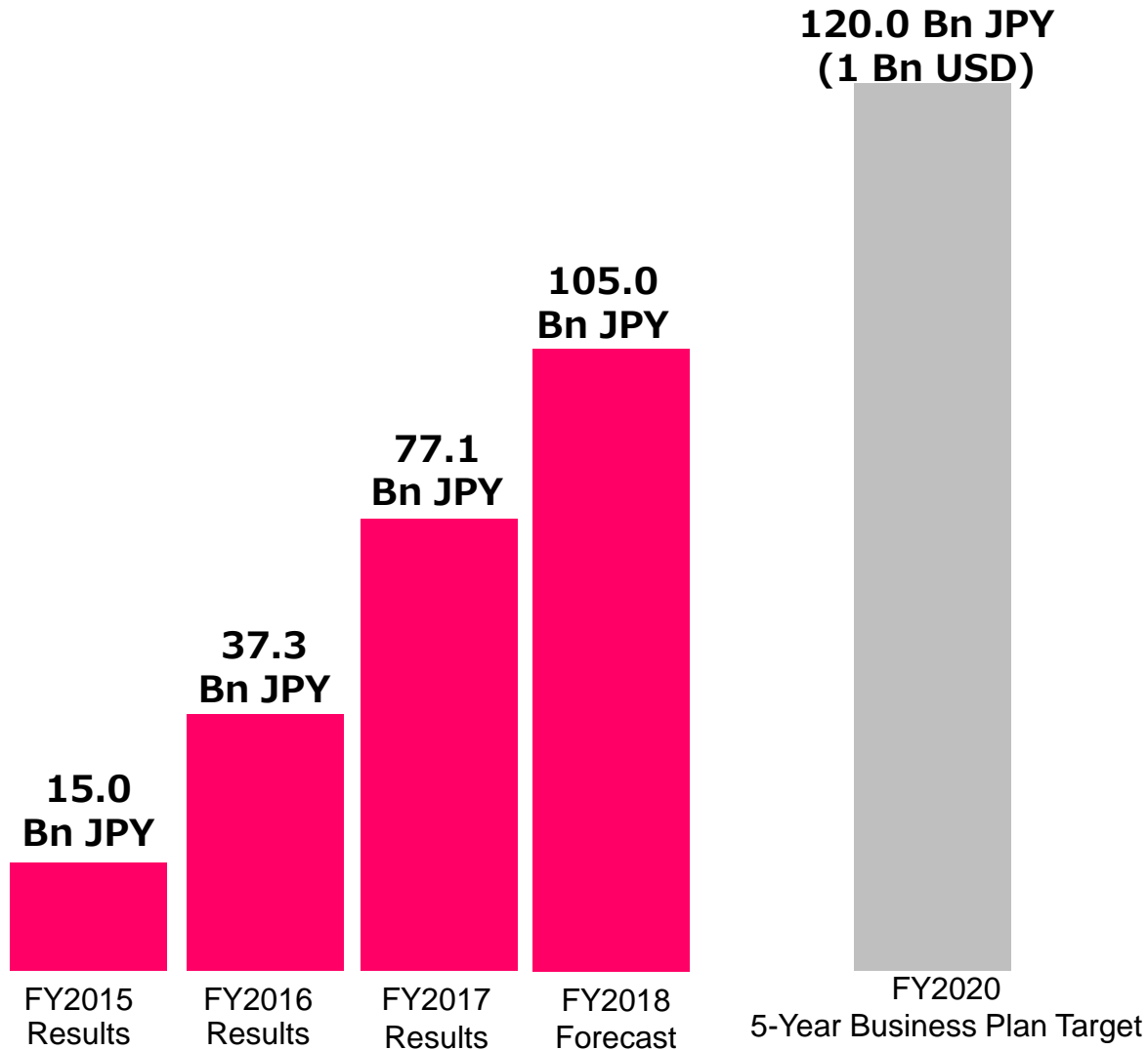
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- ◆ **Grow as No.1 Company in Japan**
- ◆ **Expand US Businesses**
- ◆ **Establish Oncology Business**
- ◆ **Continuously Generate Innovative Medicine Changing SOC (Standard of Care)**
- ◆ **Enhance Profit Generation Capabilities**
- ◆ **Shareholder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

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Edoxaban: Target and Progress

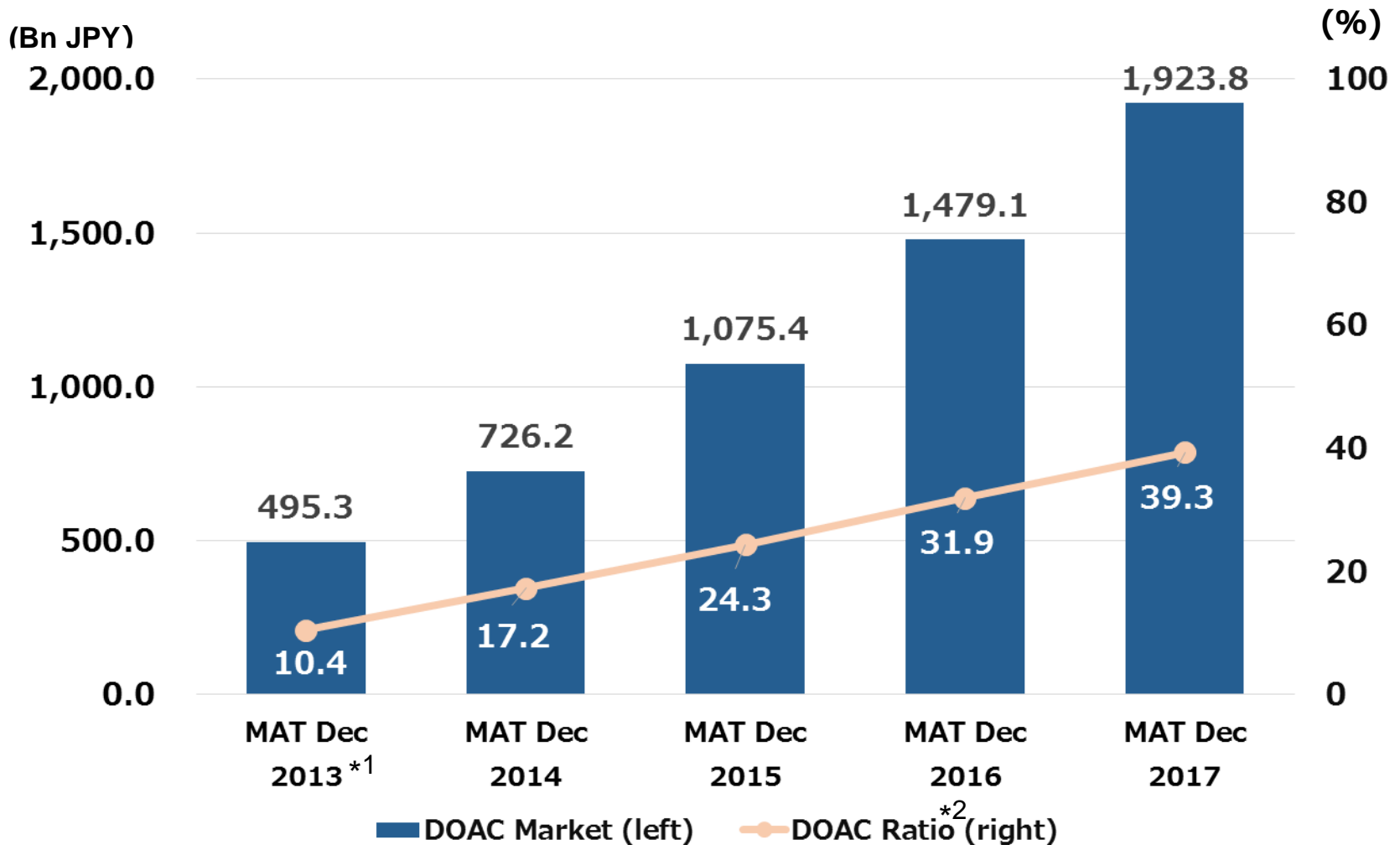
Expanding mainly in Japan, EU and Asia



Global DOAC Market



Global DOAC market value was grown up to about \$20 Bn



Currency Rate USD/JPY : 110

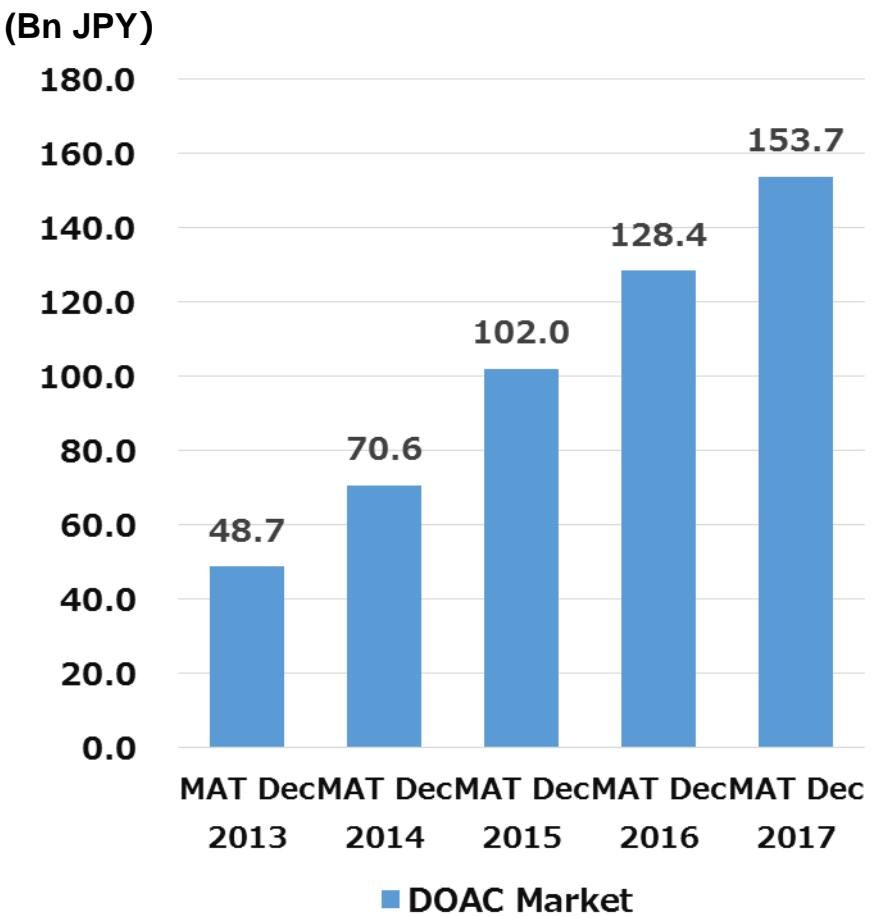
*1: Jan. 2013 – Dec. 2013

*2: Percentage of DOAC Days of Therapy (DOT) counts to total DOT of warfarin and DOAC

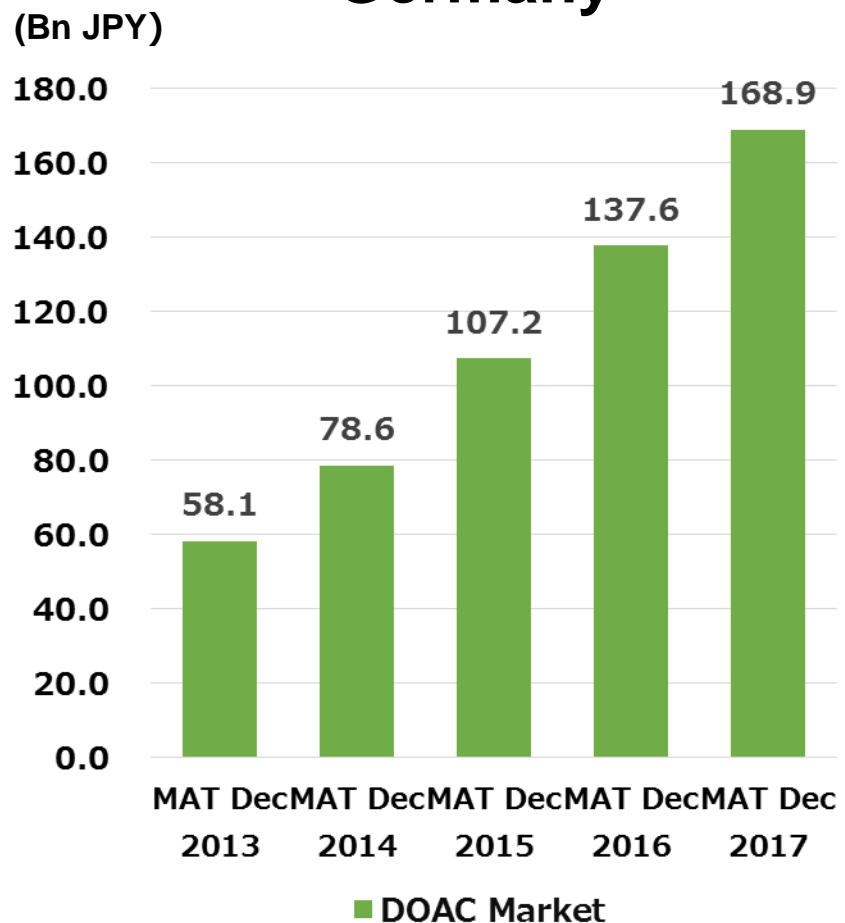
DOAC Market in Japan and Germany



Japan



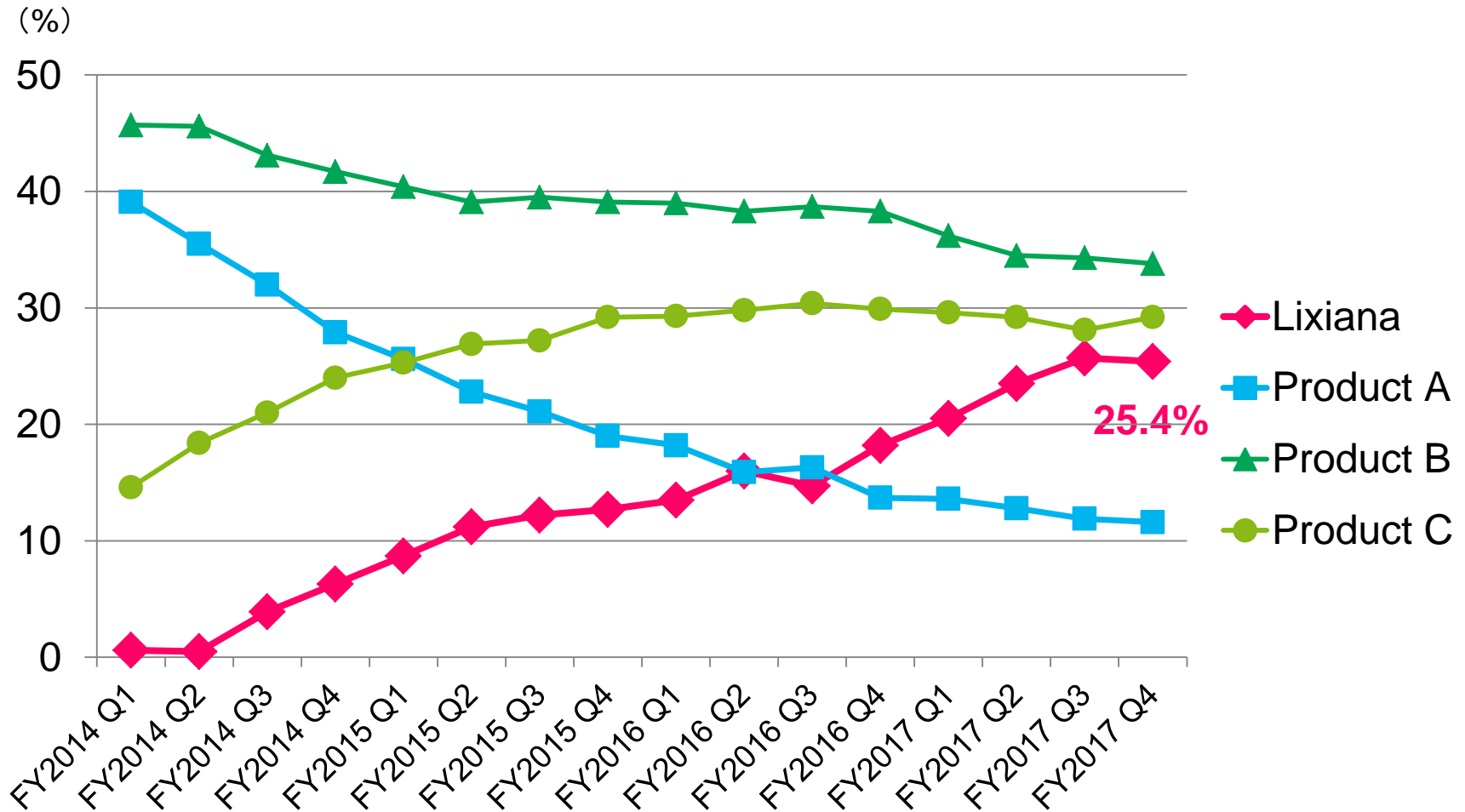
Germany



Currency Rate USD/JPY : 110

Lixiana: Growth in Japan

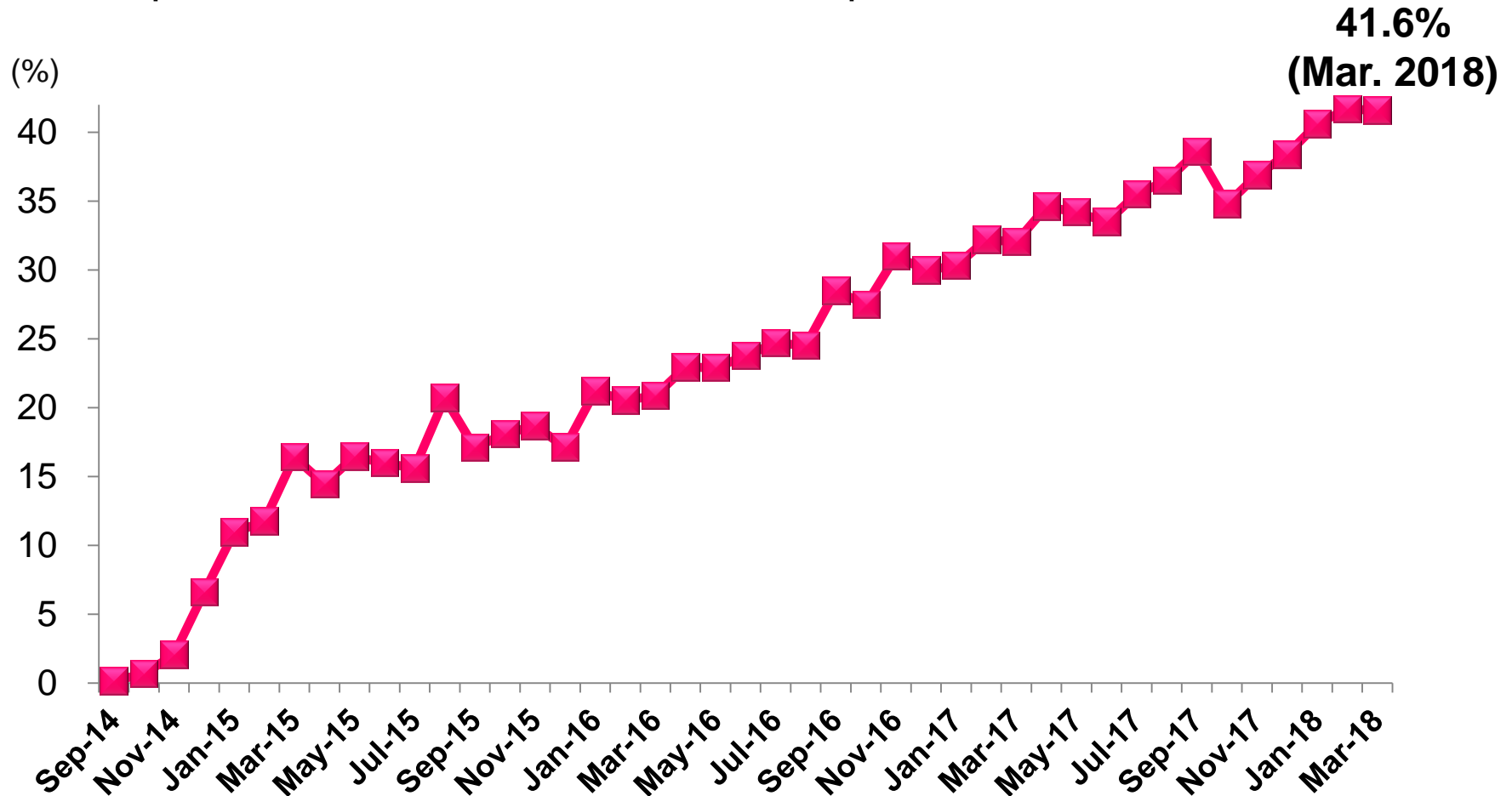
As of FY2017 Q4, Lixiana increased its sales share to **25.4%**.



Lixiana: Growth in Japan



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

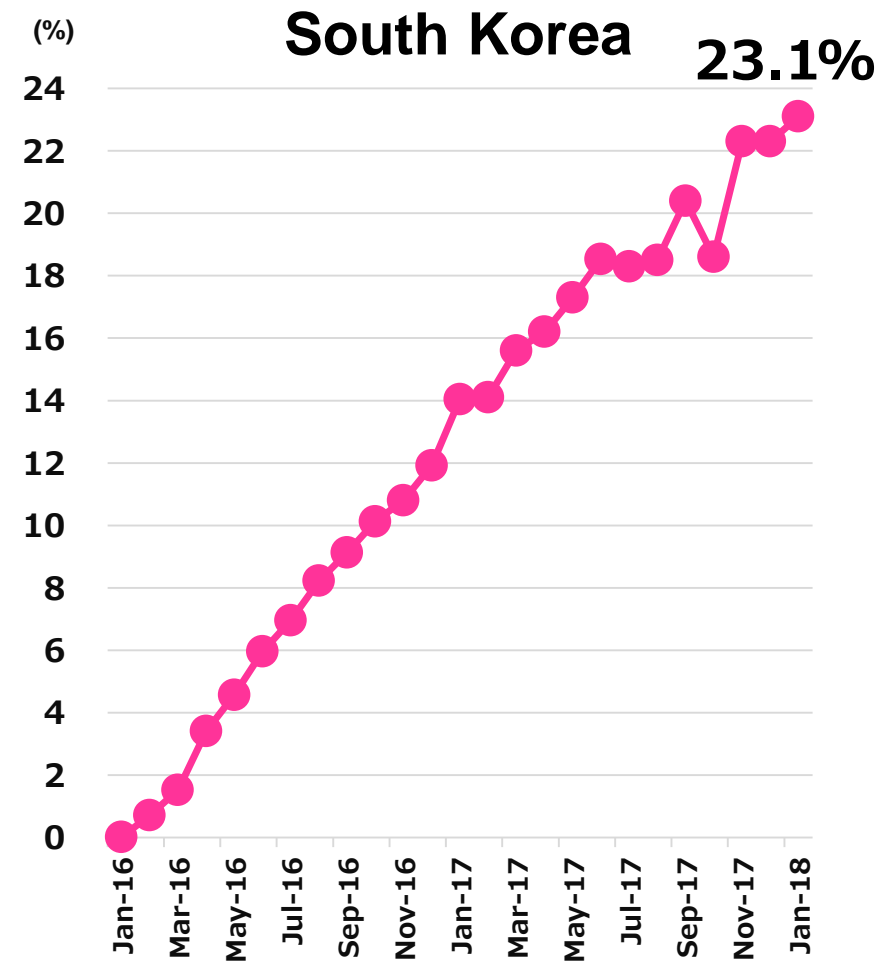
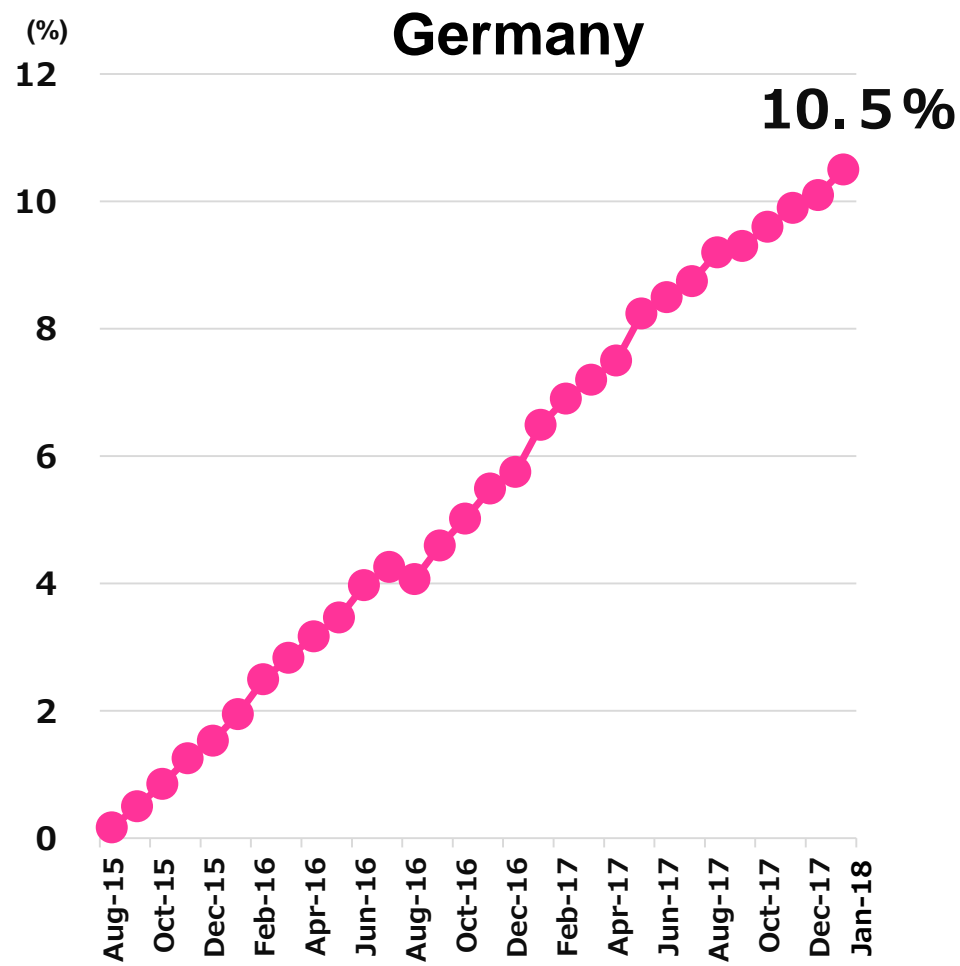


Source : Medi-trend

Lixiana : Growth in Germany and South Korea



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



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Growth in Each Country (Summary)



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

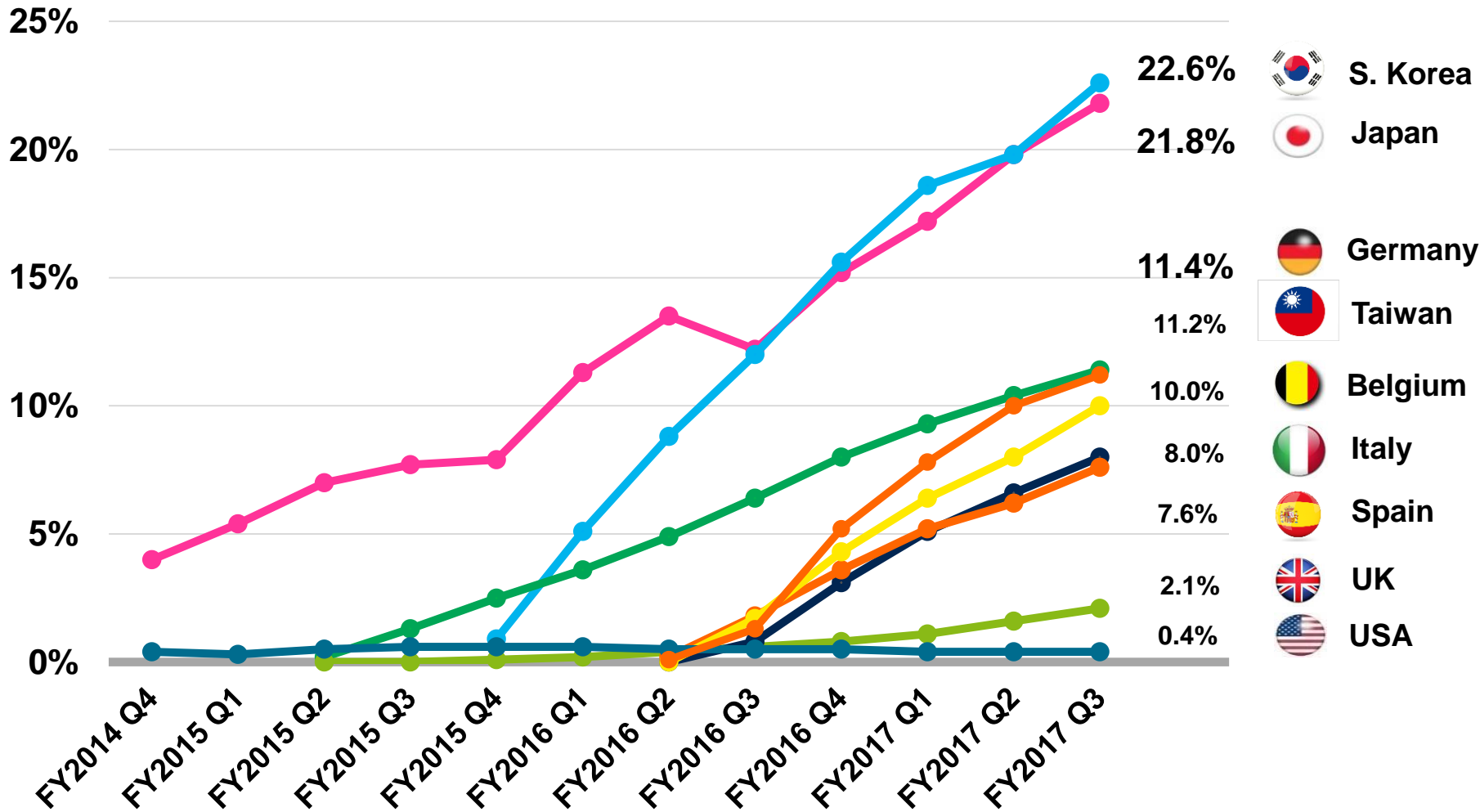


Image for future growth

Launch Strategy

Launched and approved in over 20 countries

Covered about 95% of DOAC market potential

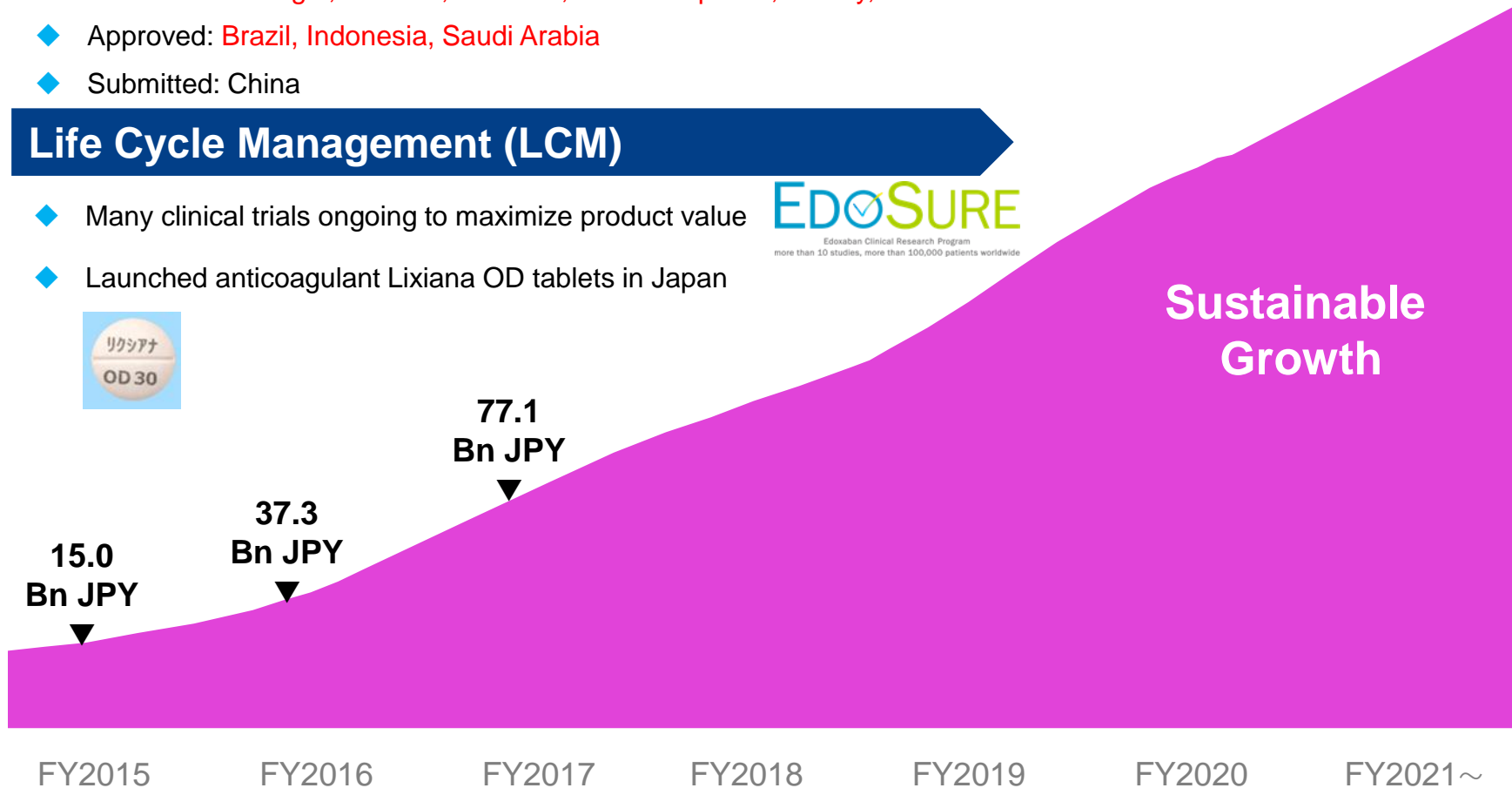
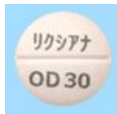
- ◆ Launched: Portugal, Canada, Slovakia, Czech Republic, Turkey, Thailand
- ◆ Approved: Brazil, Indonesia, Saudi Arabia
- ◆ Submitted: China

Countries launched by FY2016: Japan, US, Switzerland, UK, Germany, Ireland, Netherlands, S. Korea, Italy, Spain, Taiwan, Belgium, Hong Kong, Denmark, Hungary, Finland, Norway, Austria etc.

Life Cycle Management (LCM)

- ◆ Many clinical trials ongoing to maximize product value
- ◆ Launched anticoagulant Lixiana OD tablets in Japan

EDOSURE
Edoxaban Clinical Research Program
more than 10 studies, more than 100,000 patients worldwide



Edoxaban Life Cycle Management

Edoxaban Clinical Research Program

EDoSURE

Edoxaban Clinical Research Program
more than 10 studies, more than 100,000 patients worldwide



EDoSURE
Edoxaban Clinical Research Program
more than 10 studies, more than 100,000 patients worldwide

ETNA-VTE[®] Global

EMIT-AF/VTE

ELDERCARE-AF

Hokusai VTE

ENSURE-AF

ENTRUST-AF-PCI

ANAFIE[®]

Cancer-VTE

PREFER in AF

ELIMINATE-AF

ENWISAGE-TAVIAF

ETNA-AF[®] Global

Hokusai VTE

Engage AF
TIMI 48







Daiichi Sankyo expects that more than 100,000 patients will participate in the Edoxaban clinical research program, including completed, ongoing and future research.

Edoxaban Life Cycle Management

Edoxaban Clinical Research Program

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-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 CANCER	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
Red: Update or new

Study Name	Clinical Setting	
	Edoxaban Treatment in routine clinical practice in AF	<ul style="list-style-type: none"> ◆ Patient enrollment is ongoing ➤ Baseline data will be disclosed in FY2018 (Plan)
	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 AF In Elderly Registry (in more than 75 years in Japan)	<ul style="list-style-type: none"> ◆ Patient enrollment is ongoing ➤ Baseline data will be presented at Japanese College of cardiology (JCC) in Sep. 2018. (Plan)
	Multicenter Prospective Registry in VTE patients associated with cancer	

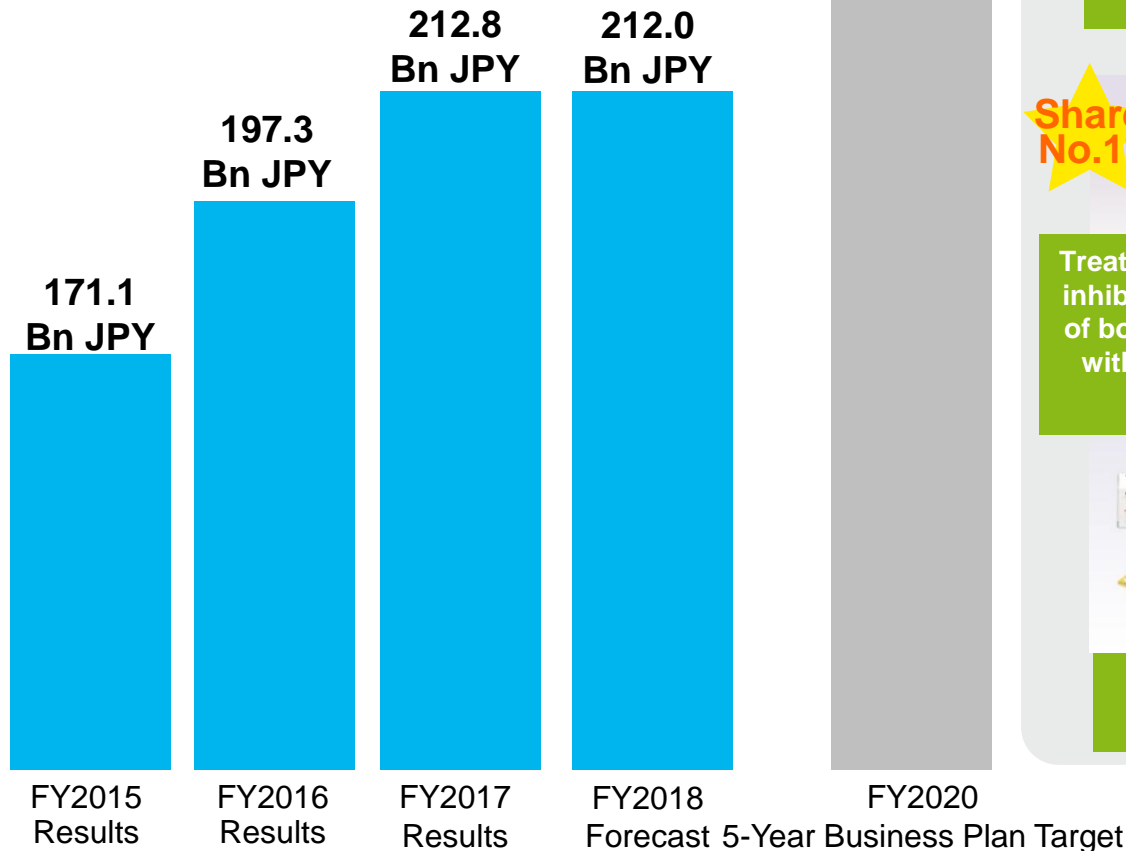
Progress of 5-Year Business Plan

- ◆ 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

Major Products in Japan: Target and Progress

◆ Major factors changed from original assumption

- Nexium: “Special expansion re-pricing”
- Memary: Slow down of growth
- Efient: Delay of additional indication for brain area



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

- Share No.1** Ulcer treatment **Nexium**
- Share No.1** Alzheimer's disease treatment **Memary**
- Share No.1*** Treatment for osteoporosis/inhibitor of the progression of bone erosion associated with rheumatoid arthritis **Pralia**
- Share No.1** Treatment for bone complication caused by bone metastases from tumors **Ranmark**
- Antiplatelet agent **Efient**
- Type 2 diabetes mellitus treatment **Tenelia**

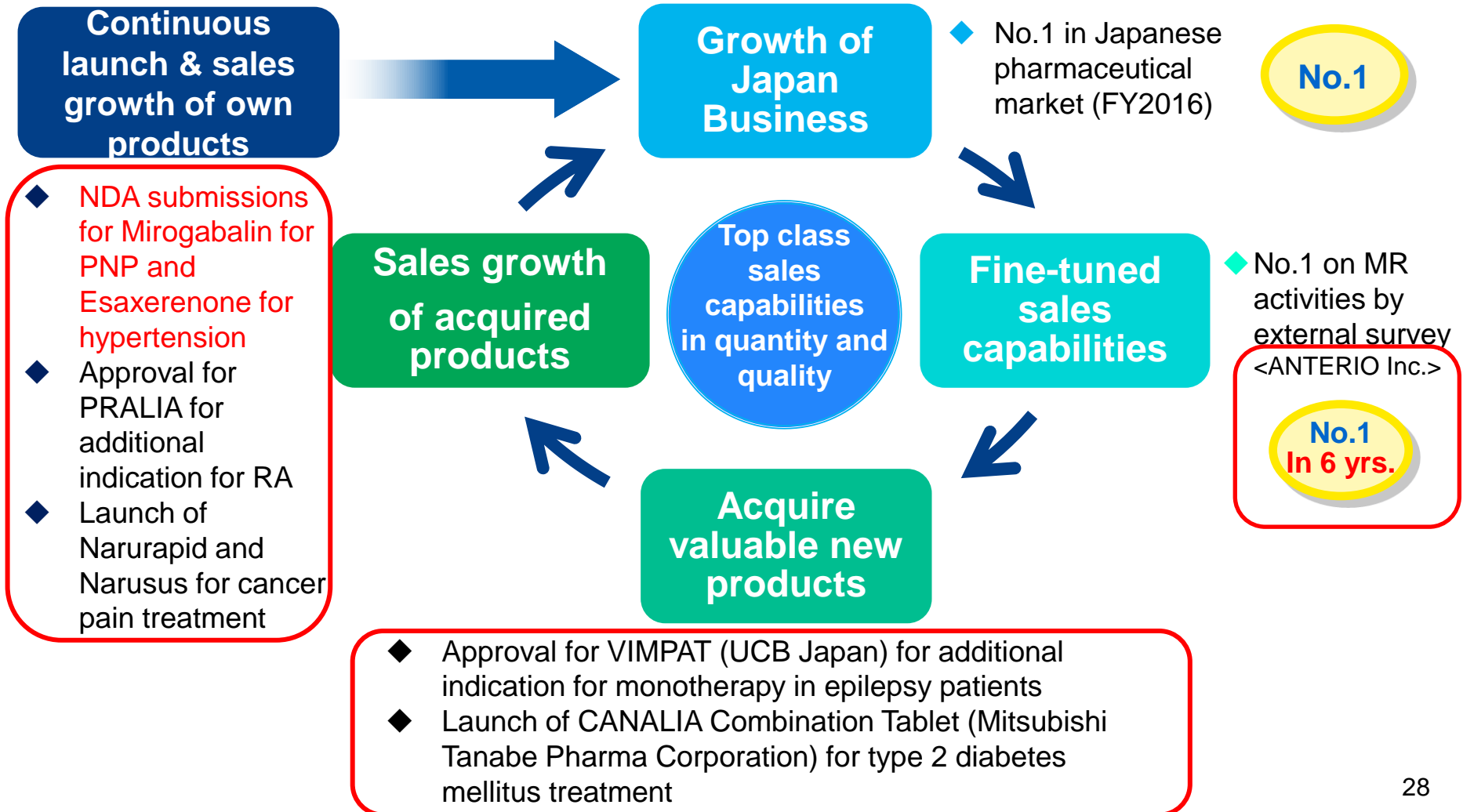
*In the market for Bone resorption inhibitors

Innovative Business : Results in FY2017

Sustain growth momentum built in FY2017

 FY2017 Results

Red: Update or new



◆ 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

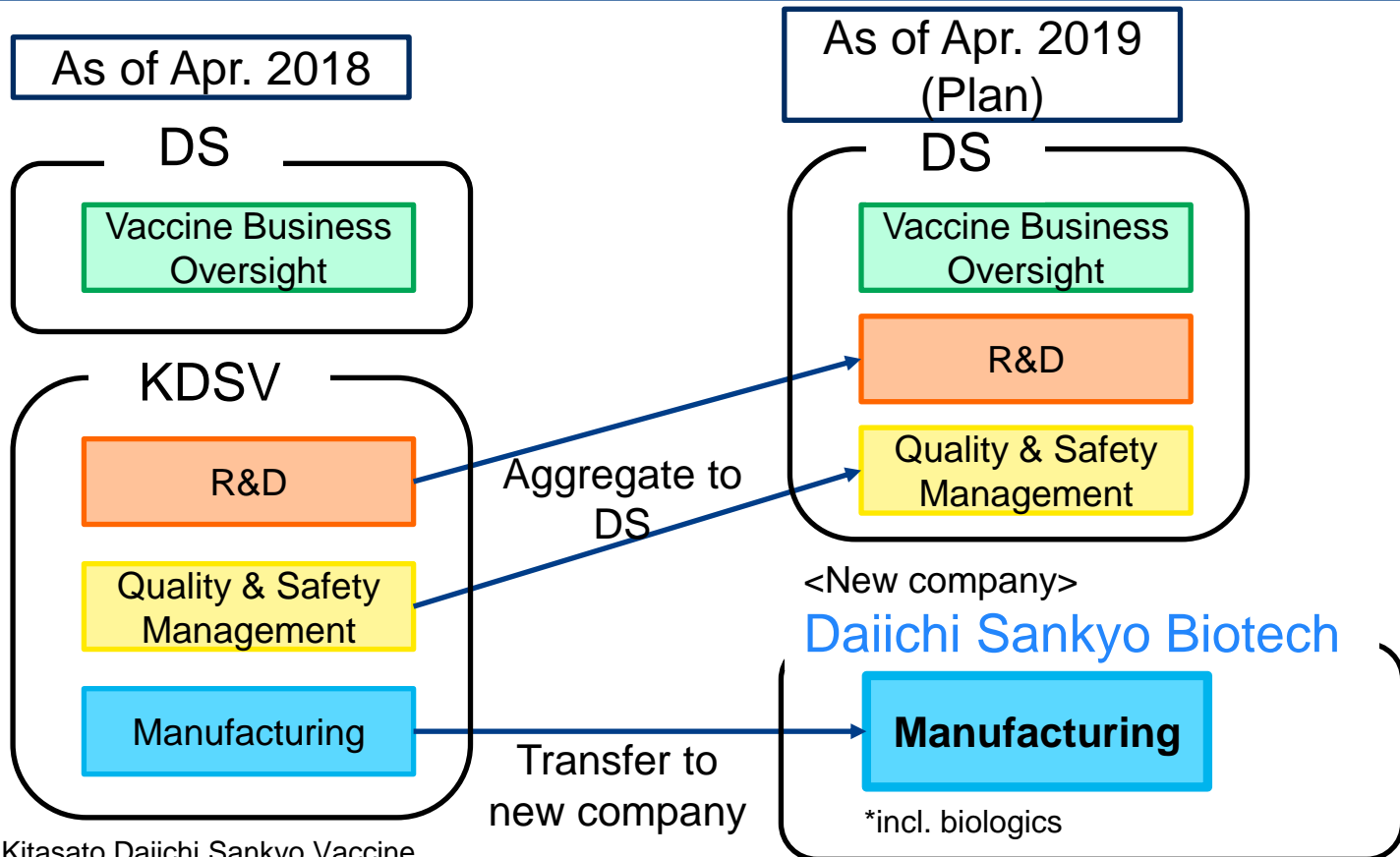
- **NDA submission in Feb. 2018**
- For hypertension
- Hypertensive population estimated to be about 43 million in Japan.

*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 PHN.

Reorganization of KDSV

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

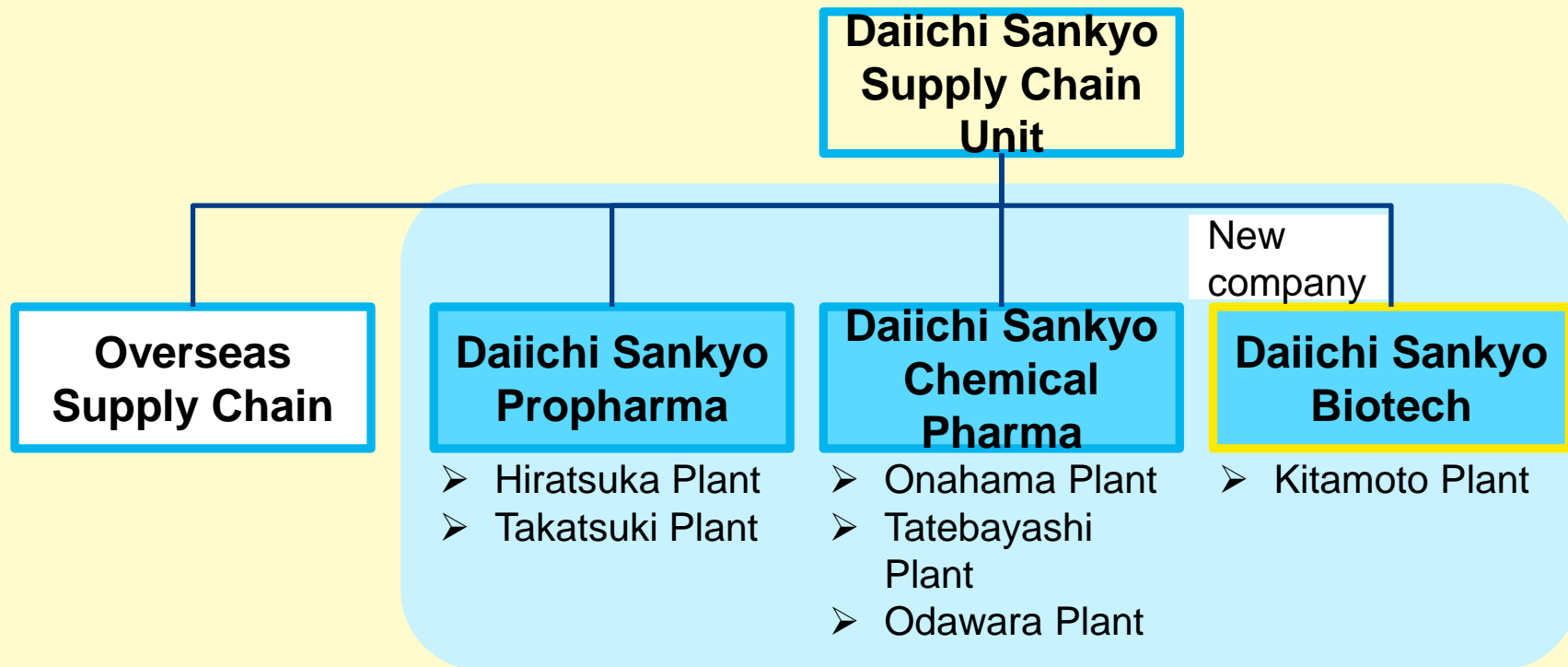
Leveraging expertise and technology related to biologics which KDSV has experienced, Daiichi Sankyo Biotech will manufacture not only vaccine but biologics



*KDSV: Kitasato Daiichi Sankyo Vaccine

Daiichi Sankyo Biotech:

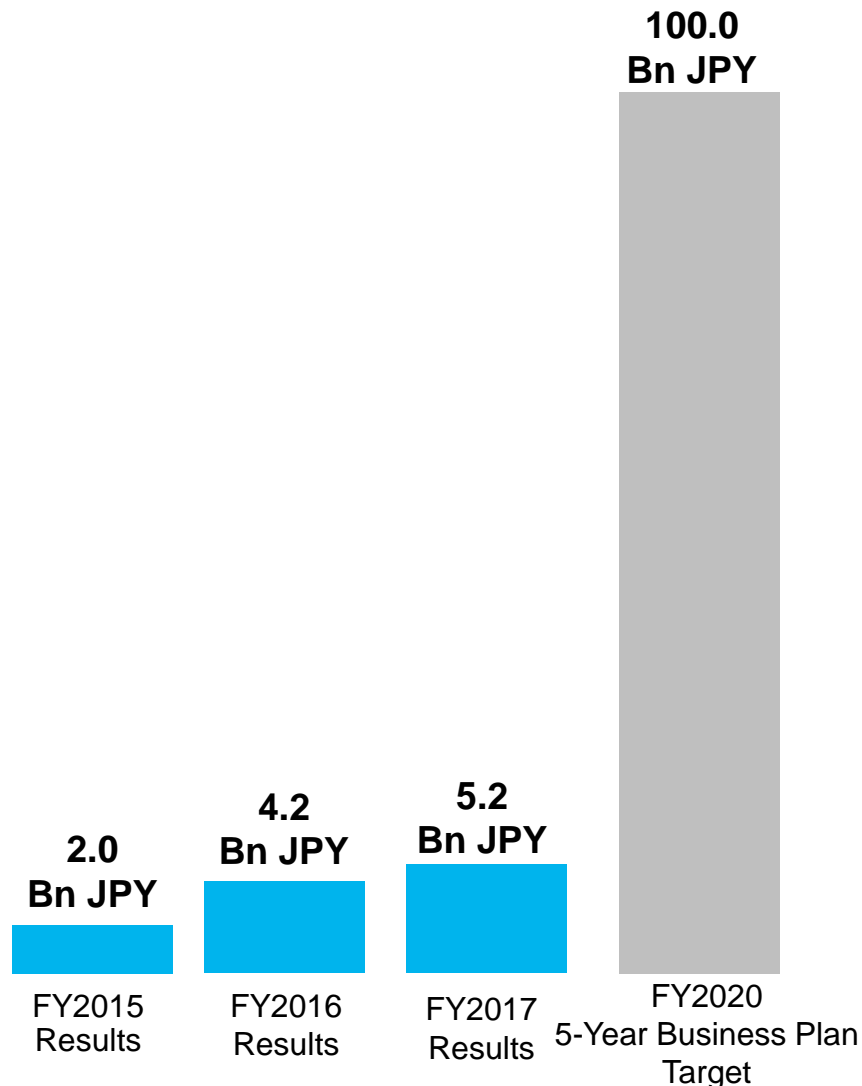
Improving stable production and quality level
by strengthening GMP system
as one of Daiichi Sankyo Supply Chain Unit



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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.



MORPHABOND™ ER
(morphine sulfate) extended-release tablets 
15 mg • 30 mg • 60 mg • 100 mg

➤ **Launched October 2017**

ROXYBOND™
(oxycodone hydrochloride)
immediate release tablets 
5 mg • 15 mg • 30 mg

➤ **Launch expected FY2018**

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



Commitments
IN PAIN CARE

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

Reorganization of US Commercial Organization

FY2017 Results

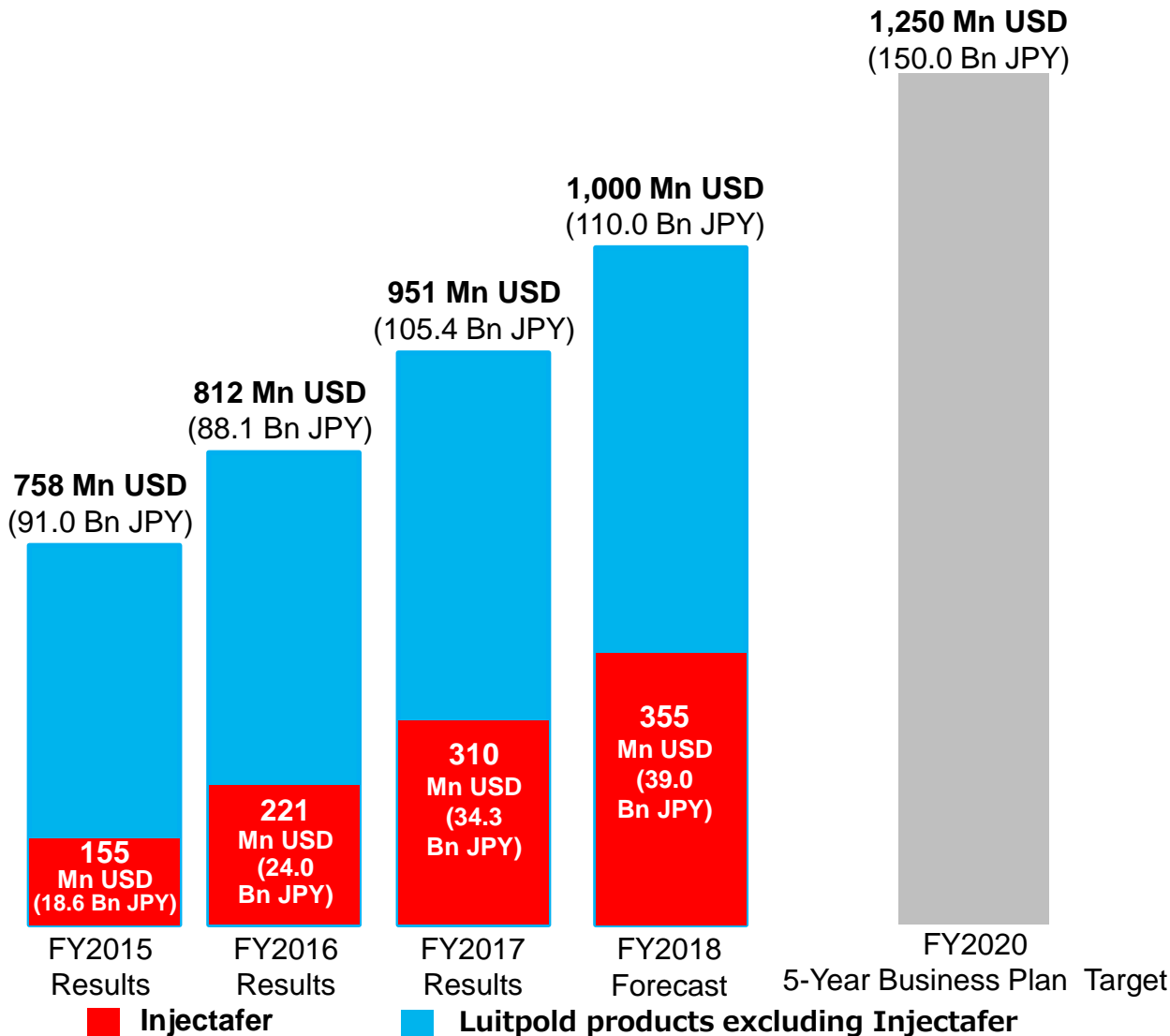
We reorganized US commercial organization to align with current portfolio and prepare for upcoming oncology pipeline.

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

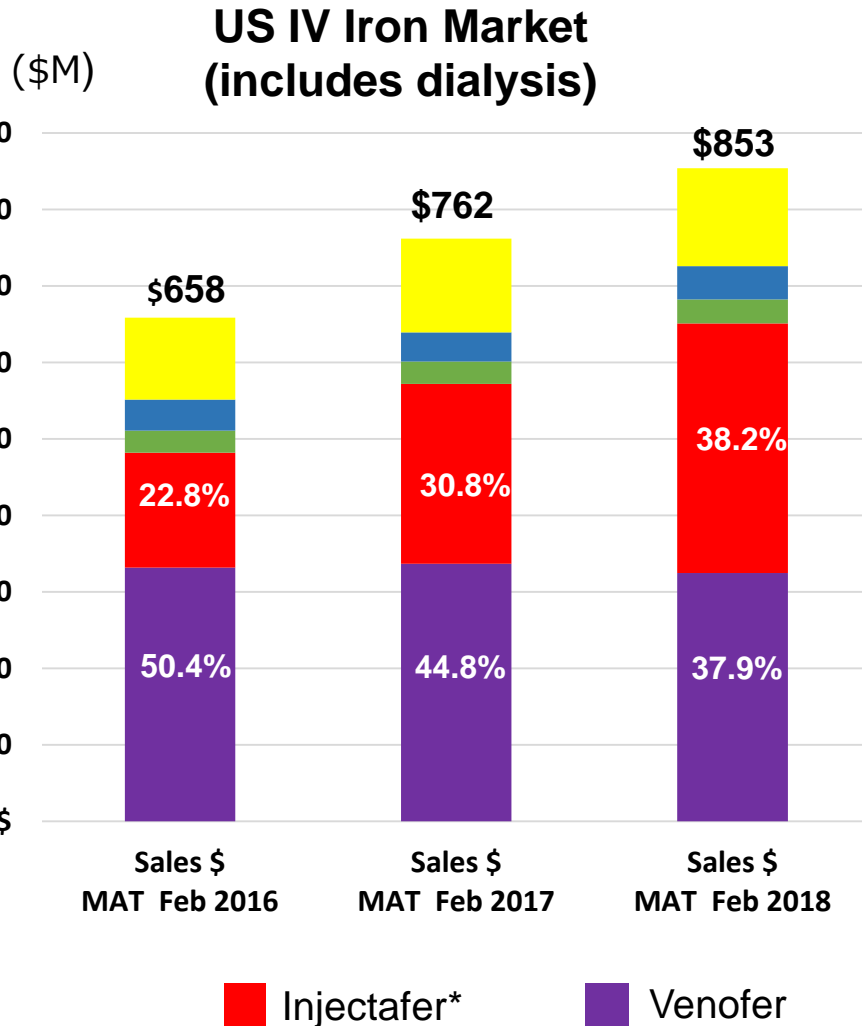


Luitpold Business: Target and Progress

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



Growth of Iron Franchise



Maintain Venofer and Injectafer Market Leadership



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 \geq 20 years of age ; 50% of HF patients have ID

* : Injectafer is not currently approved for heart failure with reduced ejection fraction in patients with iron deficiency.

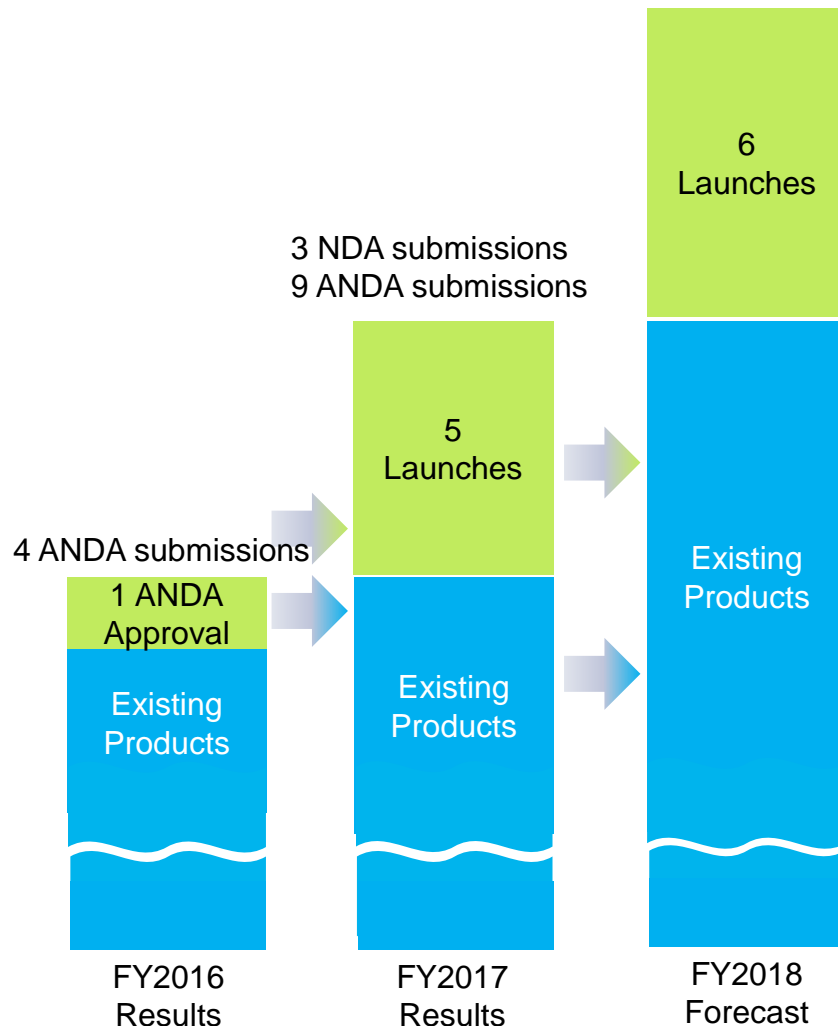
* * : https://www.cdc.gov/dhdspl/data_statistics/fact_sheets/fs_heart_failure.htm

Growth of Generic Injectable Franchise

Increase of product by continuous launch of new products

(Number of products)

7 NDA submissions



Submission and Launch

◆ FY2017 Results

3 NDA submissions, 9 ANDA submissions
5 Launches

◆ FY2018 Targets

7 NDA submissions
6 Launches

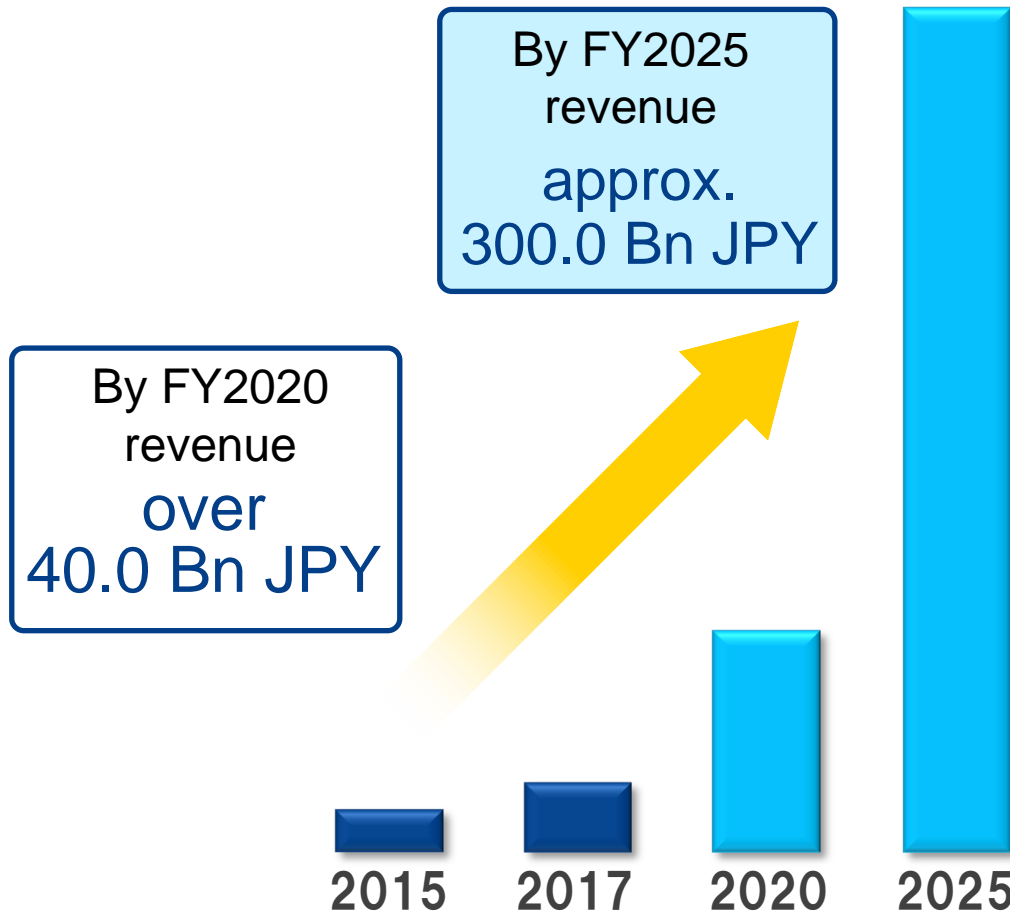
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Establish Oncology Business: 5-Year Business Plan

- ◆ 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

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

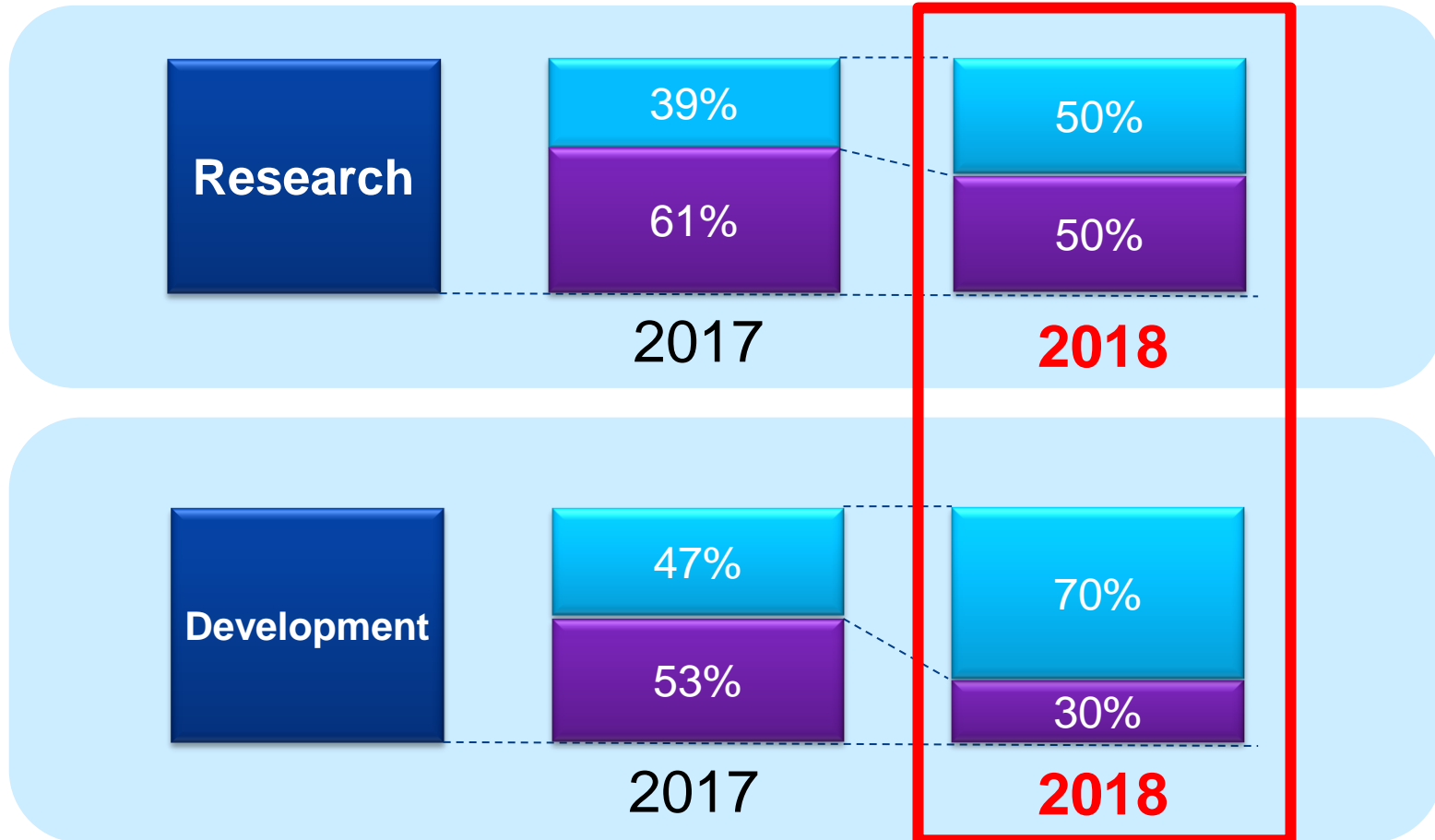
Strengthen Manufacturing

15.0 Bn JPY investment to enhance ADC manufacturing capabilities

Cross functional efforts to be prepared for launch

Shifting Internal Resources to Oncology

■ Oncology ■ SM: Specialty Medicine*



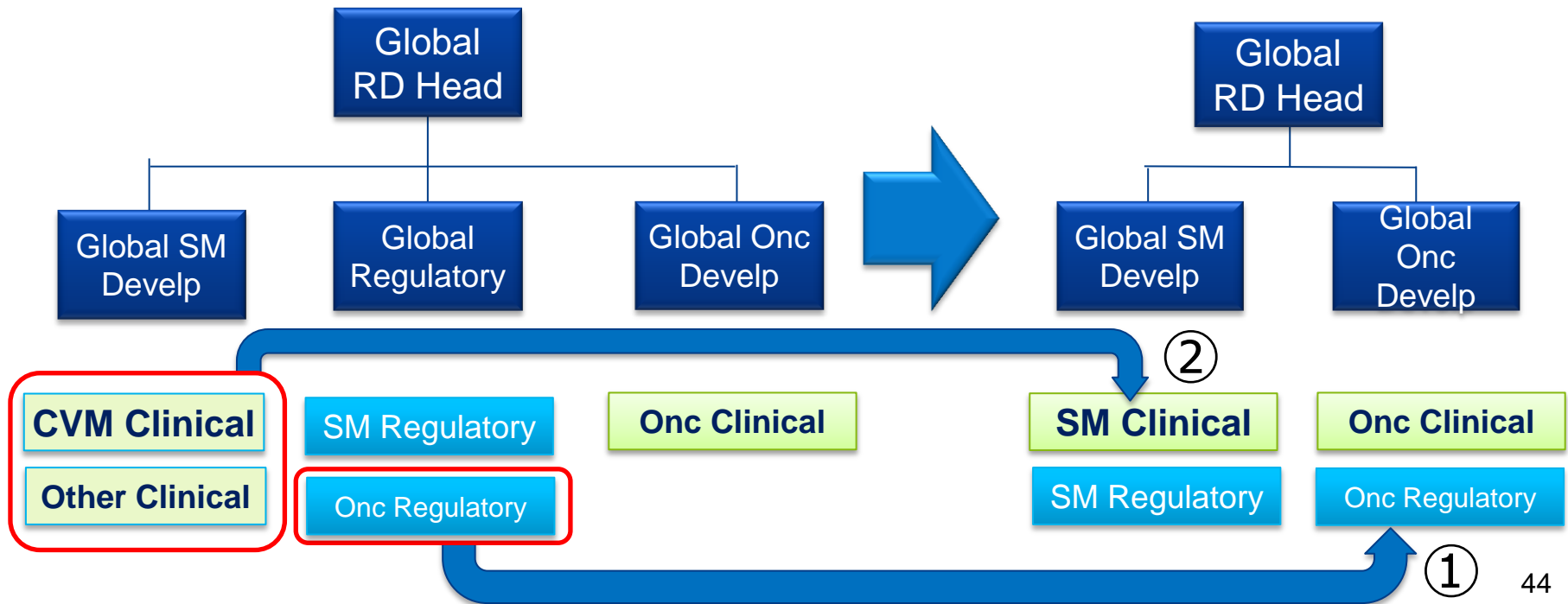
Development budget allocation is done **ahead of schedule**

*Other than oncology. Including CVM, pain, CNS disease, heart-kidney disease, and rare diseases.

Restructuring to Strengthen Oncology

- ① **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**

*SM: Specialty medicine
 **CVM: cardiovascular medicine



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

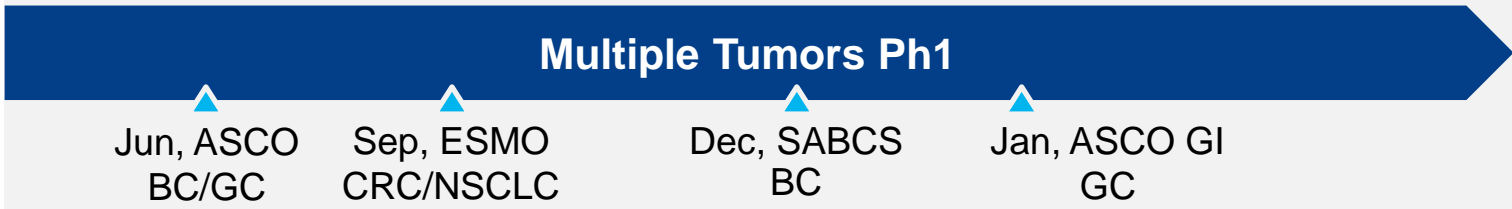


7 NMEs in 8 years

FY2017 Q1 FY2017 Q2 FY2017 Q3 FY2017 Q4 FY2018 Q1

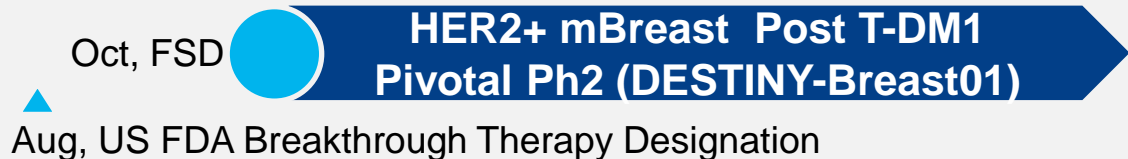
Multiple Tumors

Global



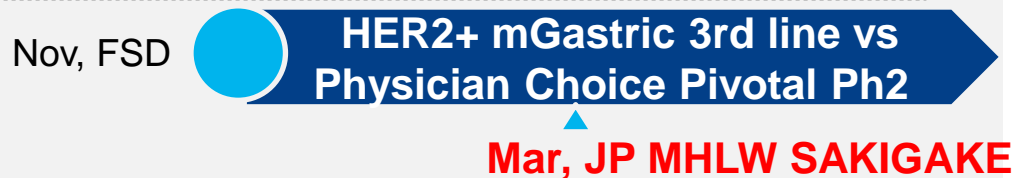
Breast

Global



Gastric

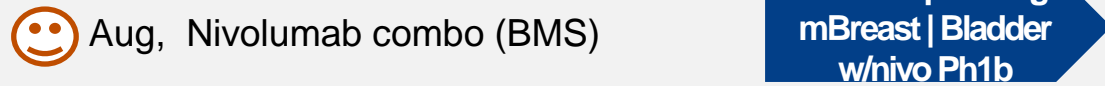
Japan/
S. Korea



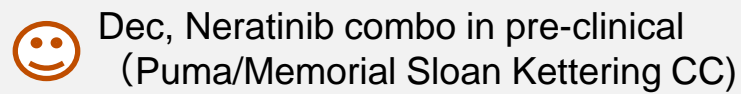
CRC



IO Combo

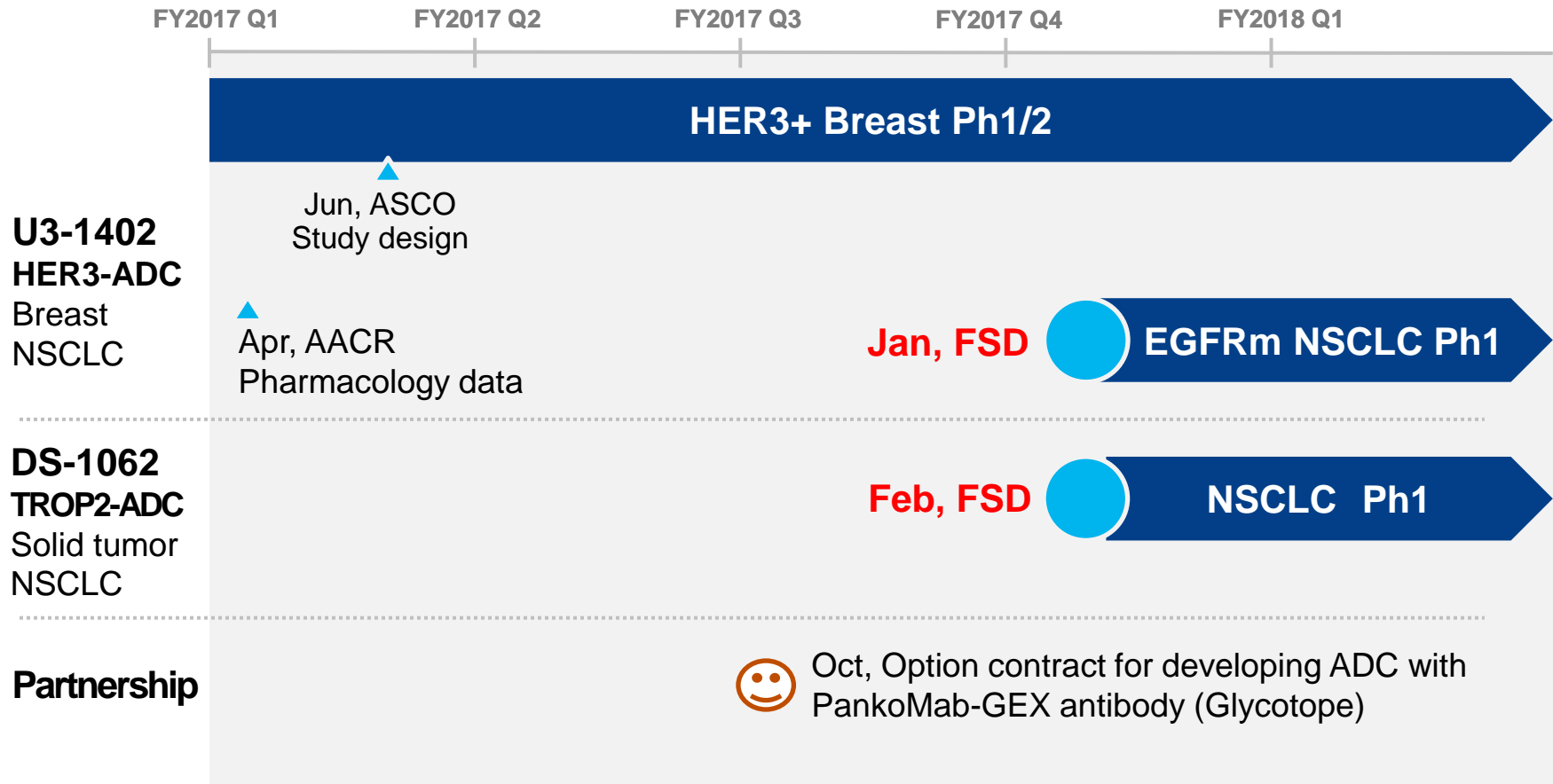


Partnership

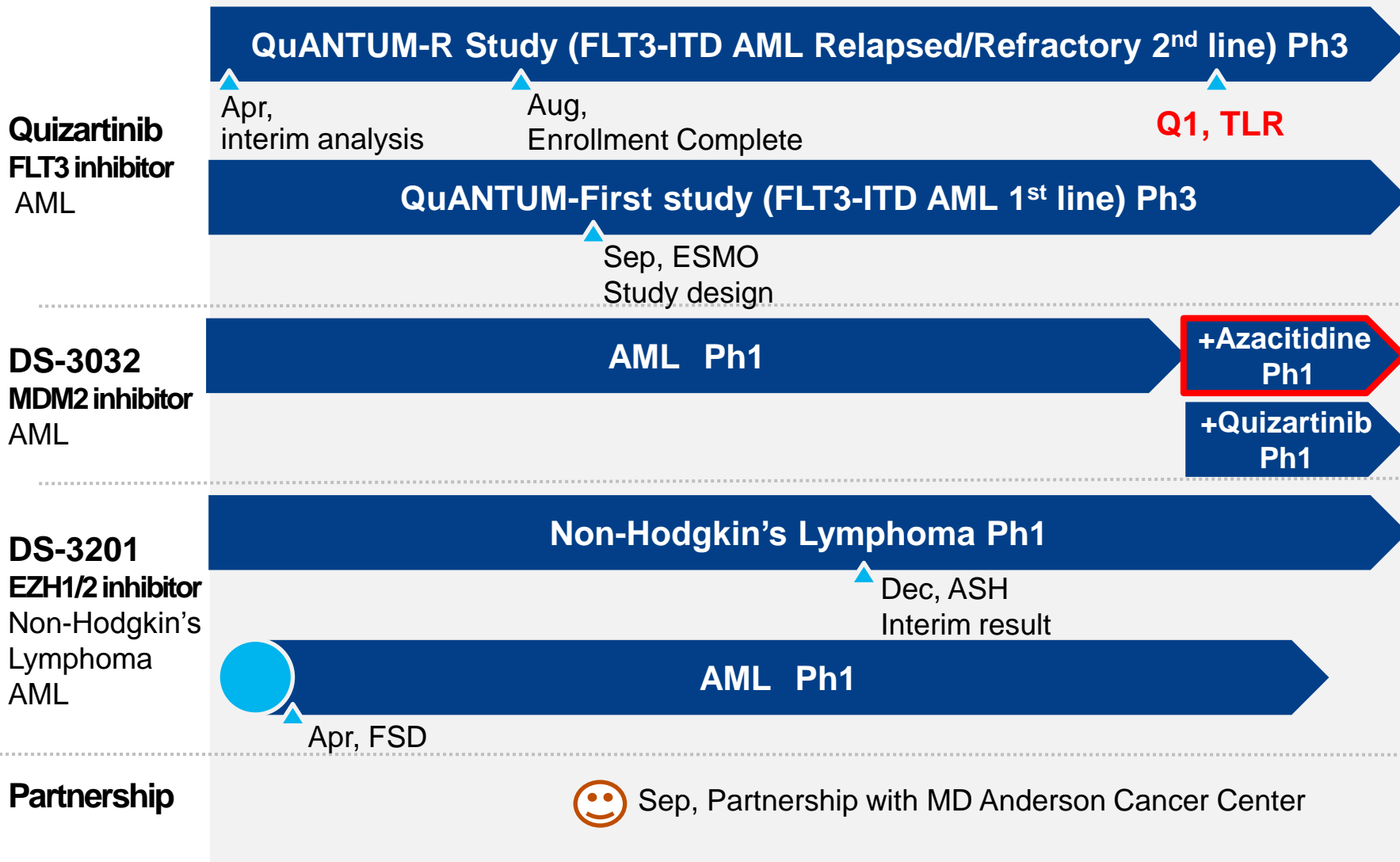


FSD: First subject dosed

As of Apr 2018



FY2017 Q1 FY2017 Q2 FY2017 Q3 FY2017 Q4 FY2018 Q1

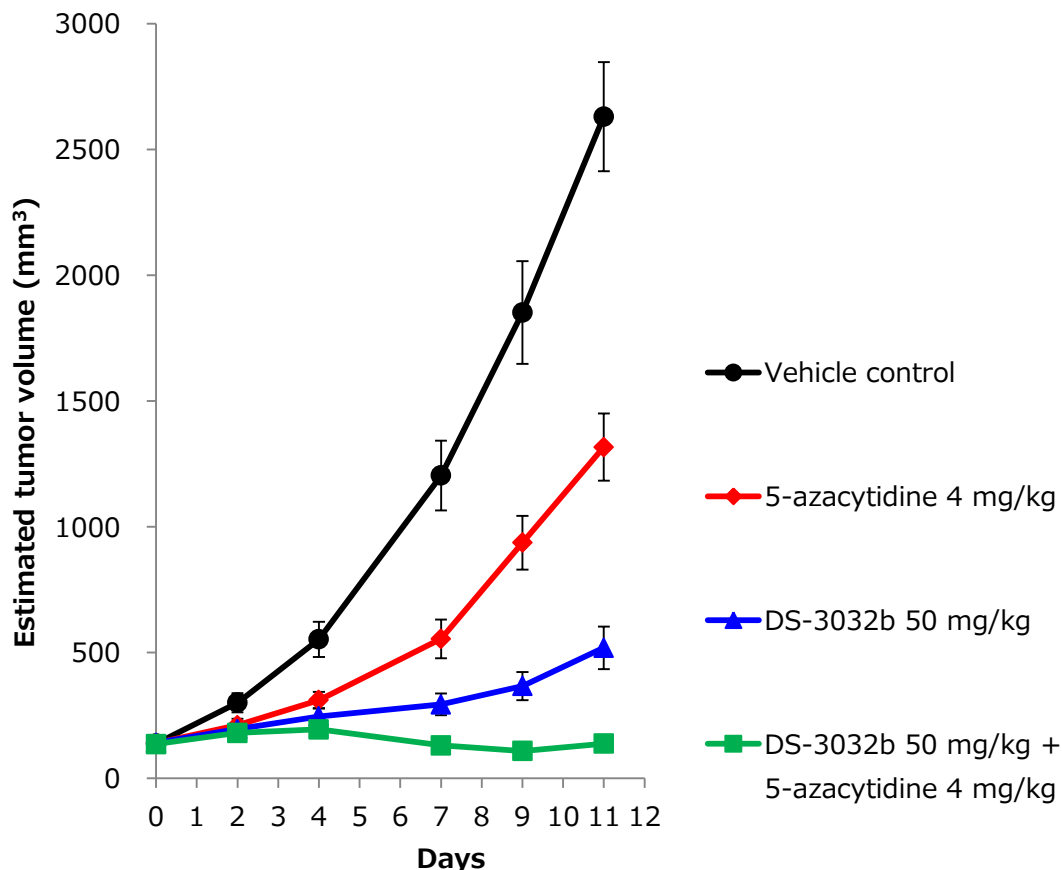


Non-clinical Study Result DS-3032 + Azacitidine

human AML Xenograft model

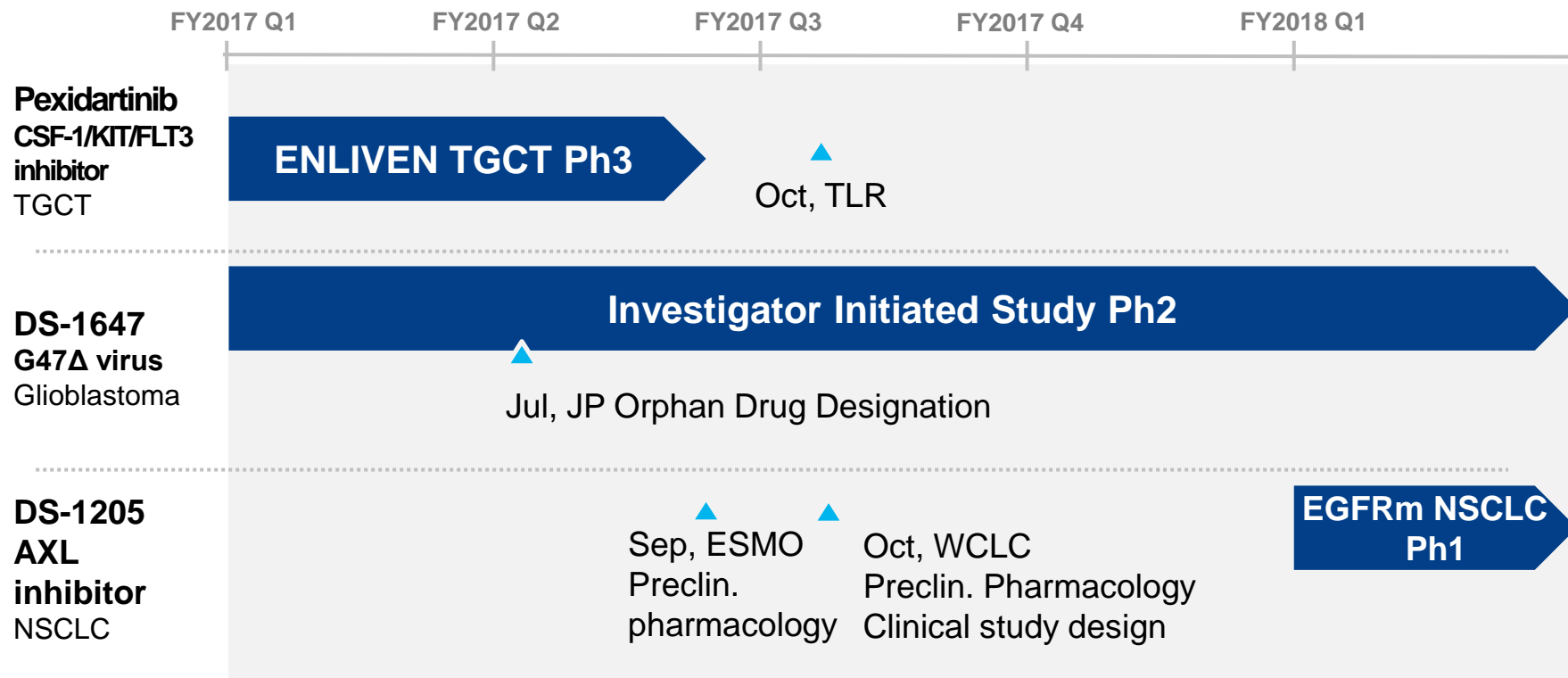
50 mg/kg DS-3032b + 4 mg/kg Azacitidine

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

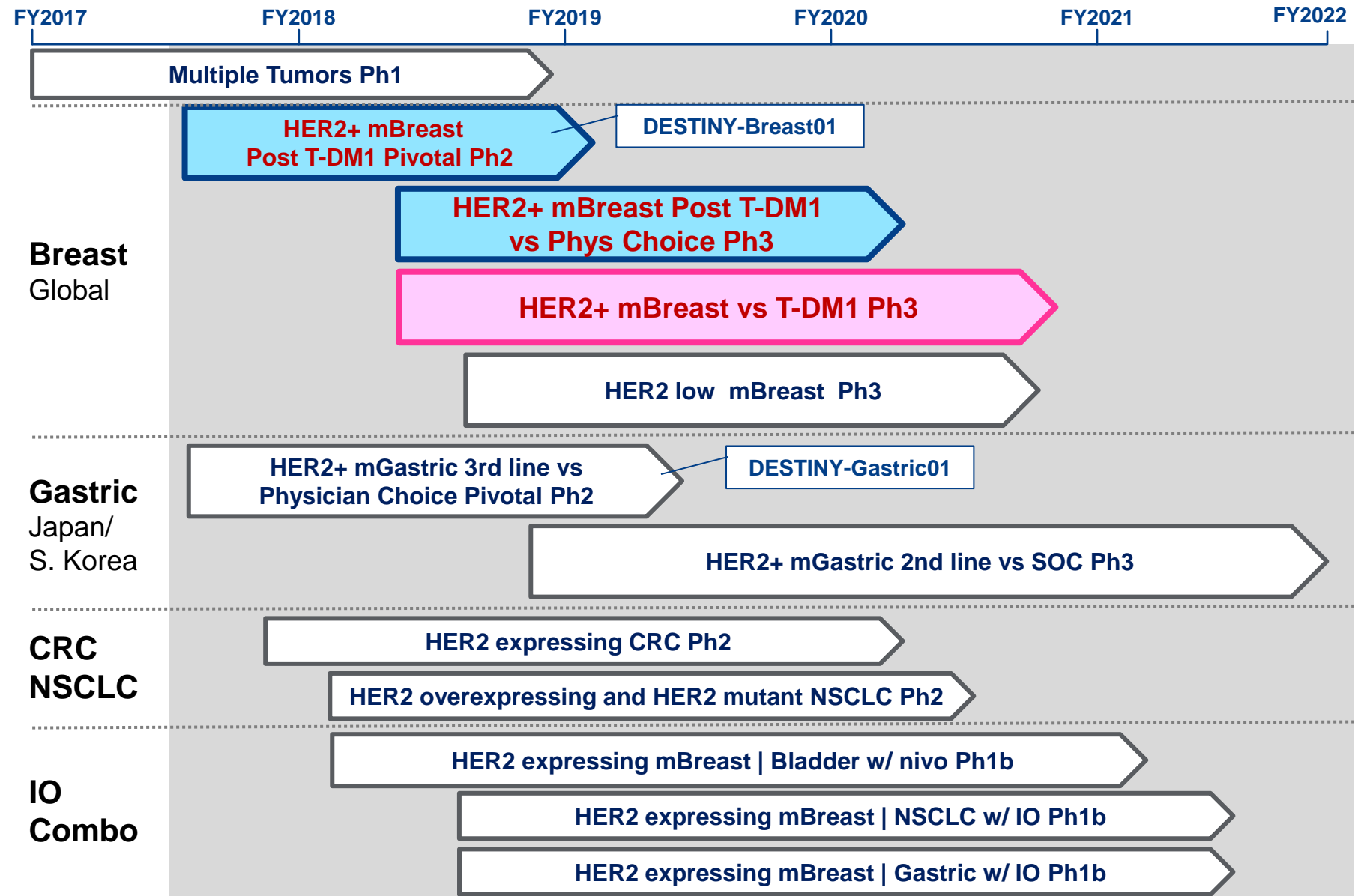



Oncology Project Update



DS-8201: Clinical Program

As of Apr 2018





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

Ph3

HER2+ mBreast vs T-DM1 Ph3
Endpoint: PFS

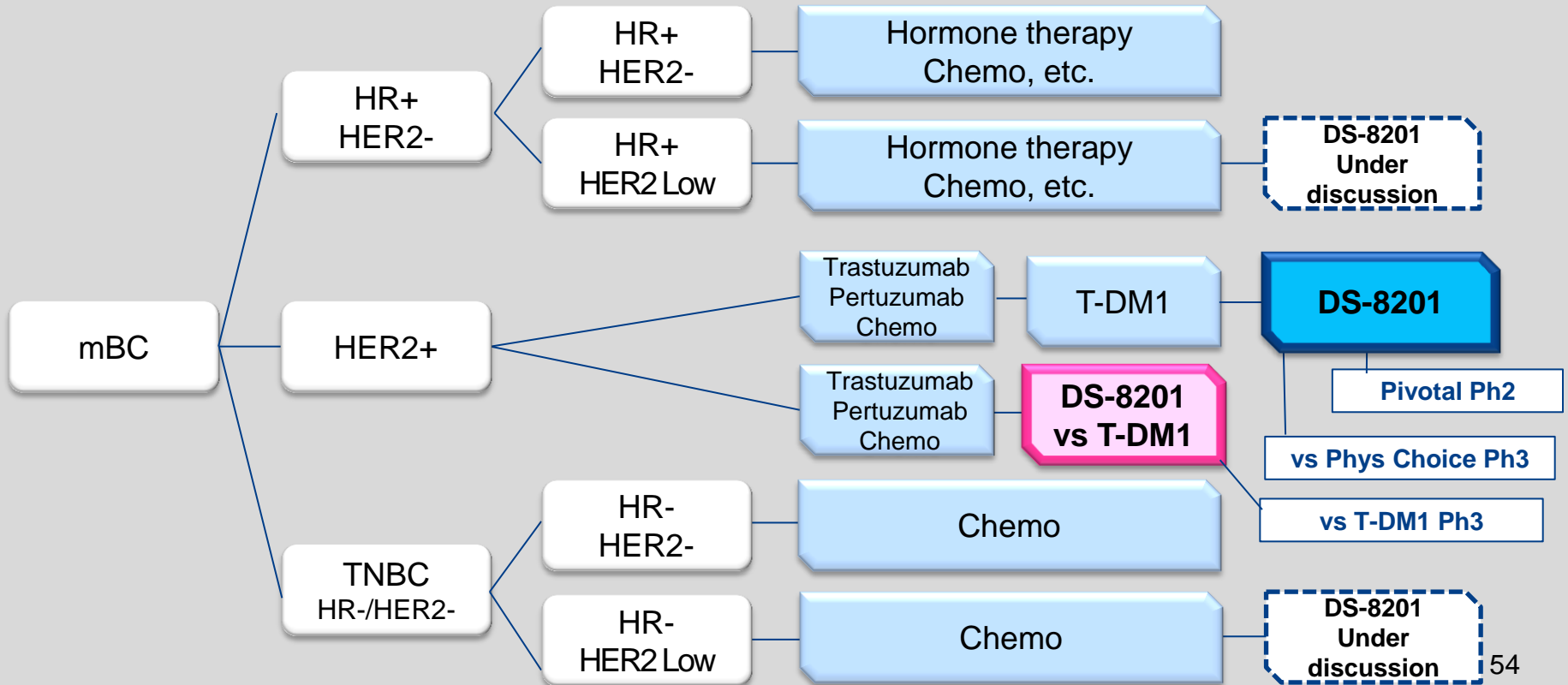
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Indication seeking in 2nd line

Plan to start from FY2018 Q2

	Sub Type	HR Receptor		HER2
		ER	PR	
HR+/HER2-	Luminal A	+	+	-
	Luminal B (HER2-)	+/-	weak+ /-	-
HER2+	Luminal B (HER2+)	+	+/-	+
	HER2	-	-	+
TNBC	Triple negative	-	-	-

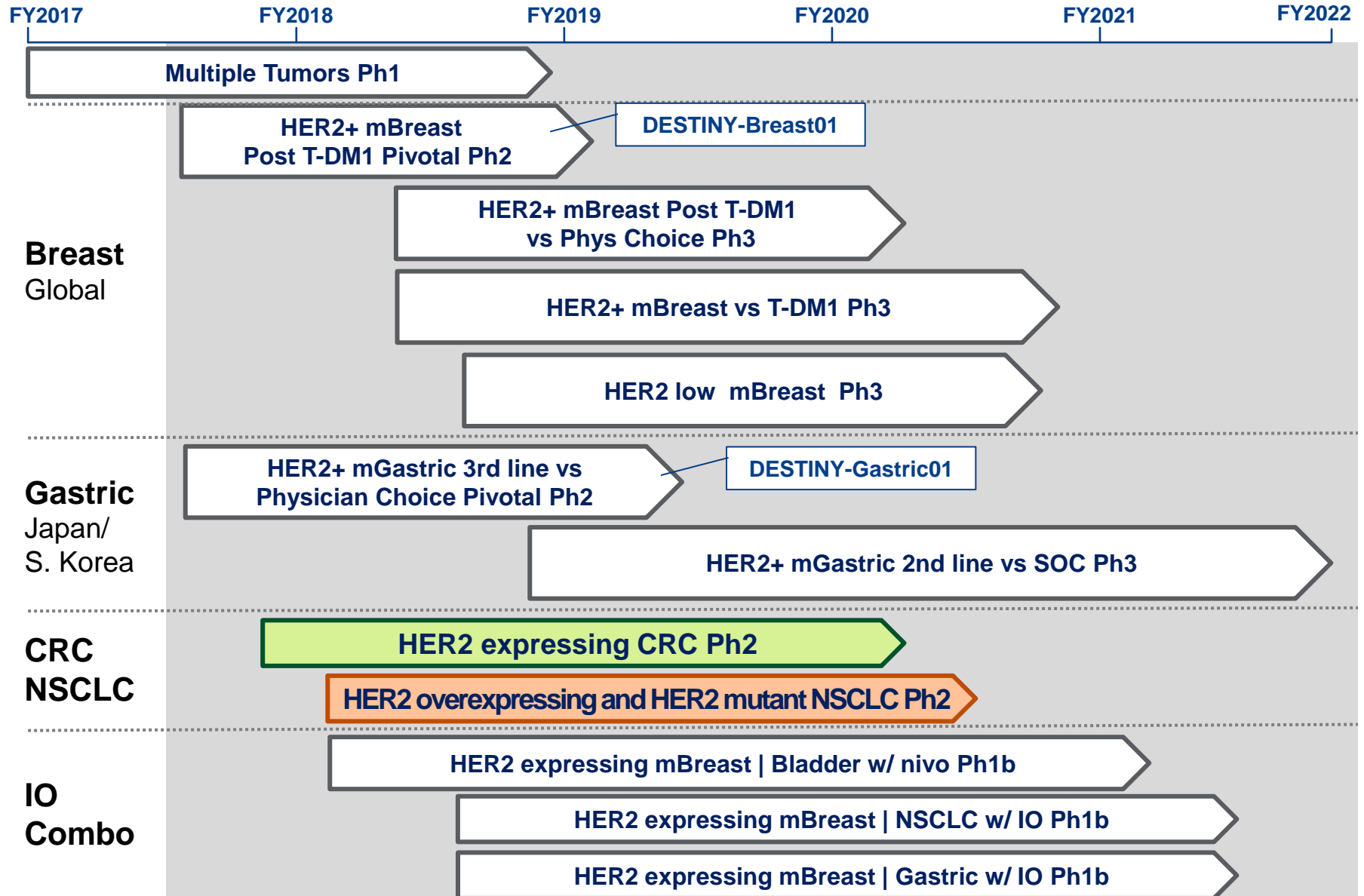
HER2+		IHC3+ IHC2+/FISH+
HER2-	HER2 Low	IHC2+/FISH- IHC1+/FISH-
	HER2-	IHC0



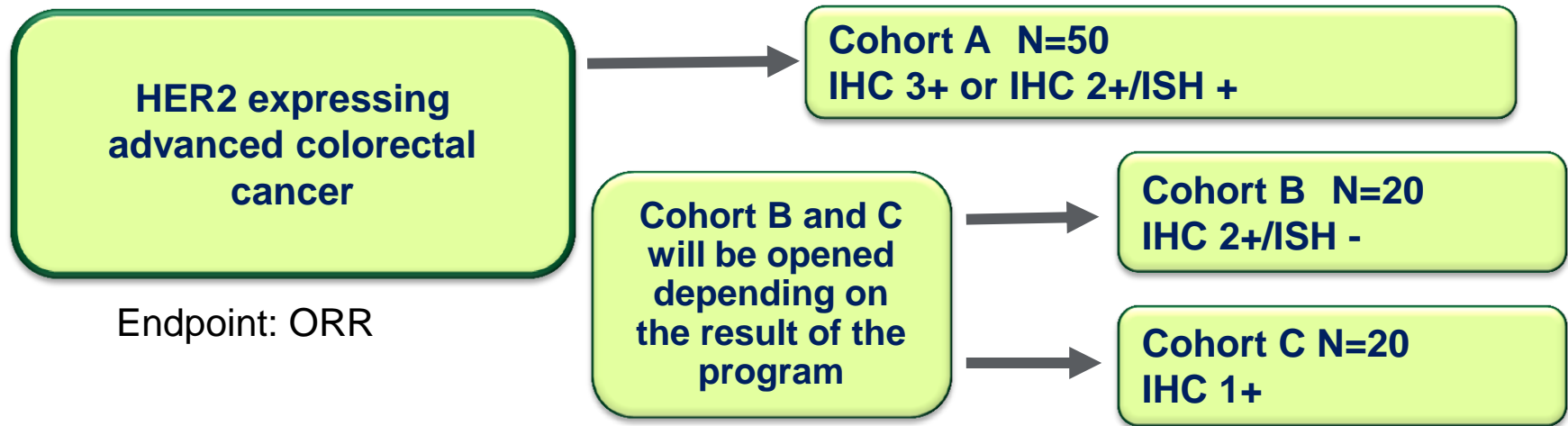


DS-8201: Clinical Program

As of Apr 2018

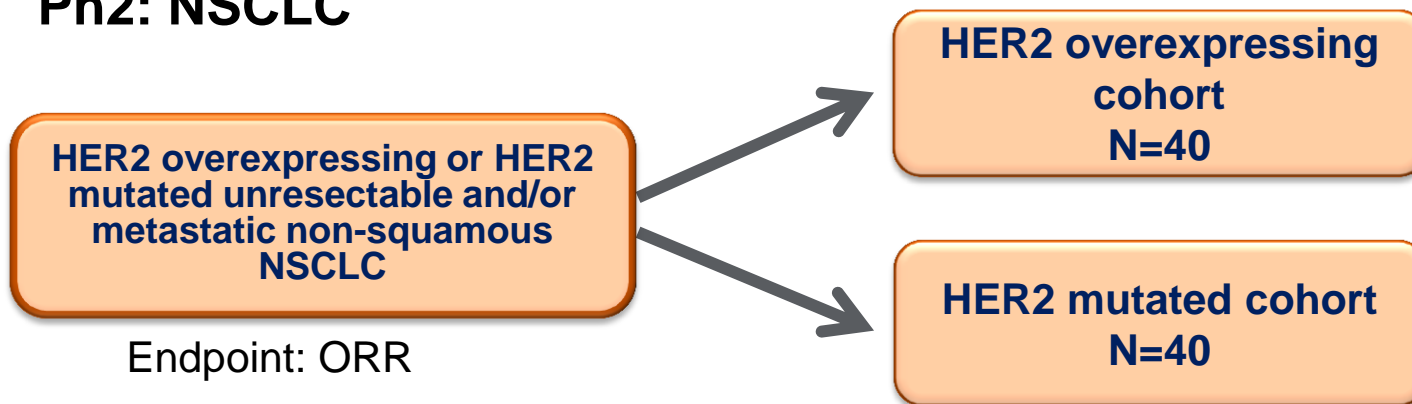


Ph2: CRC



Started Mar 2018

Ph2: NSCLC



Plan to start FY2018 Q1

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

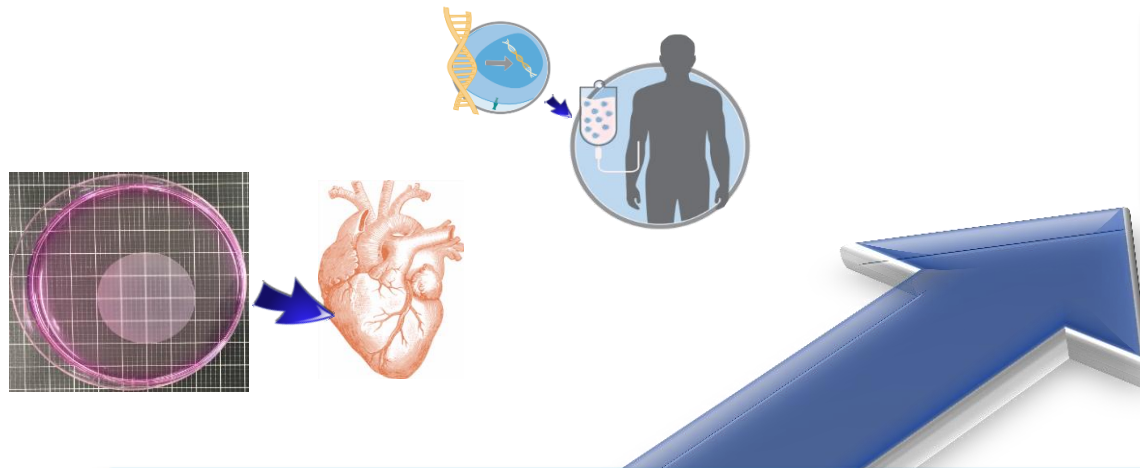


Abstracts available
on May 16

- ◆ 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



2025 Vision
Fulfill pipeline with innovative projects that change SOC*

*SOC: standard of care

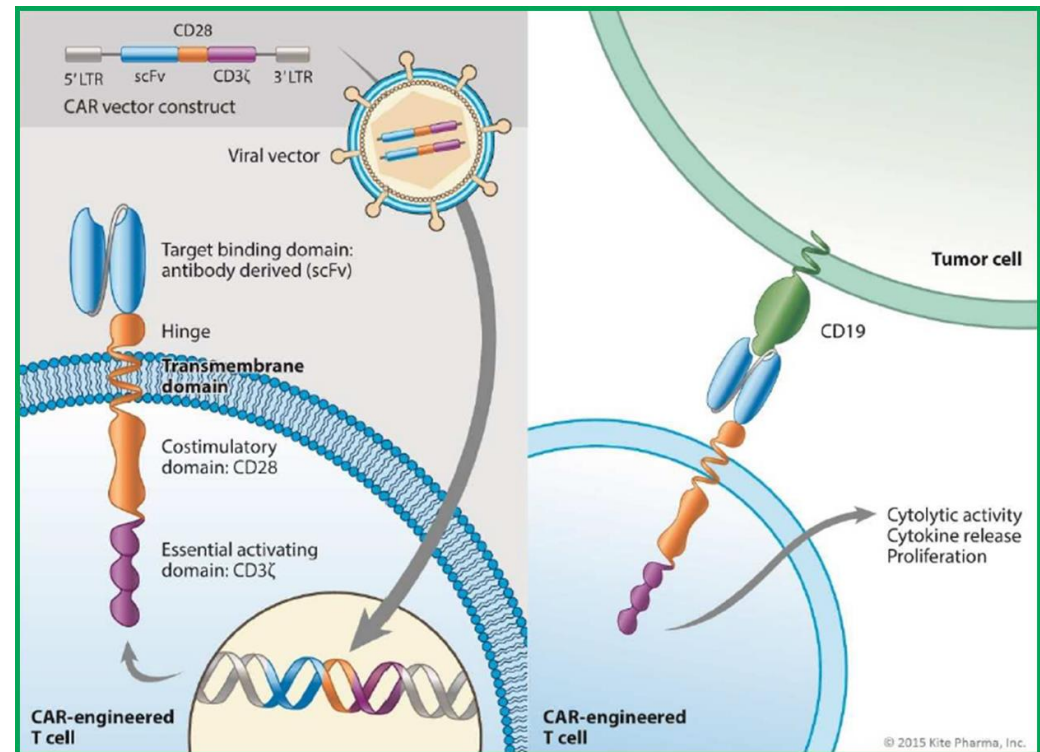
Activities in 2016-2017

- ◆ 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

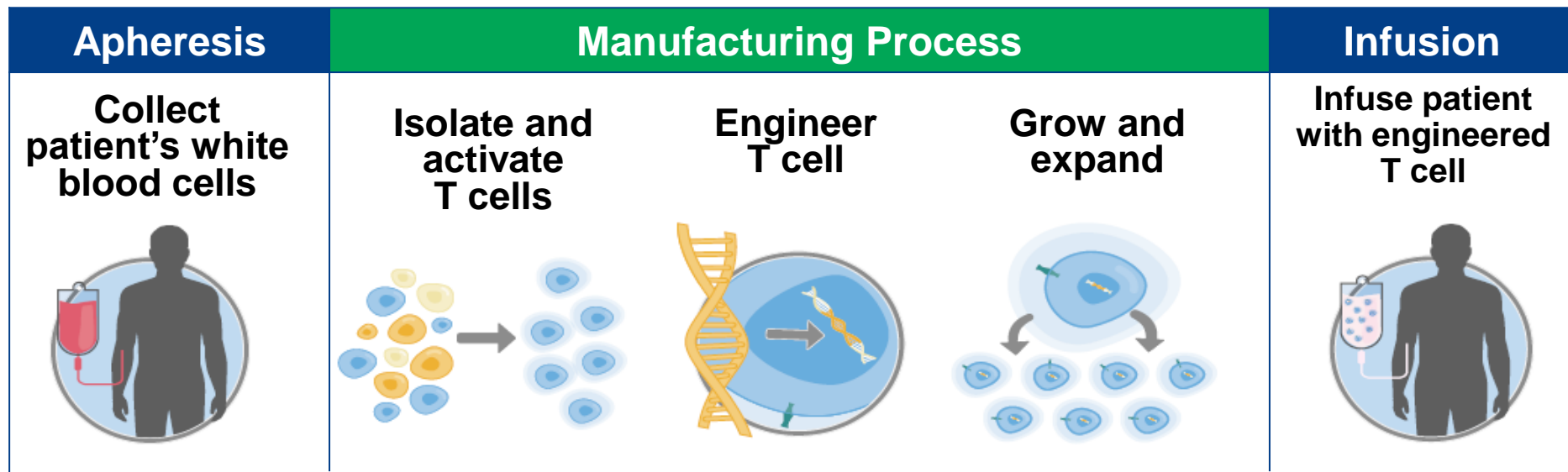
◆ MOA

- 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



- ◆ 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

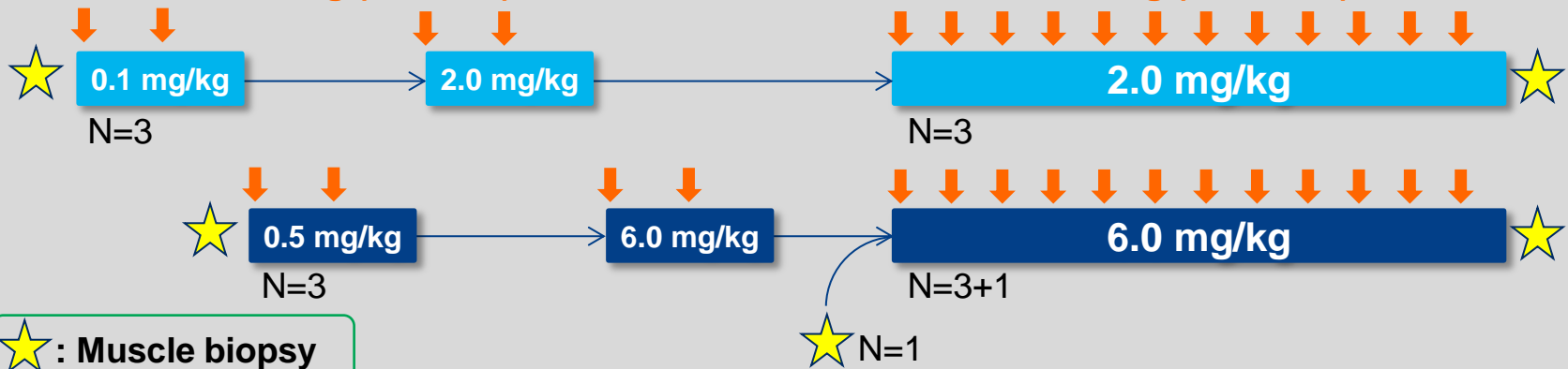
- ◆ Efficacy primary endpoint
 - Dystrophin protein expression in muscle tissue (WB,IHC)
- ◆ Efficacy secondary endpoint
 - Production of exon 45-skipped dystrophin mRNA in muscle tissue

Part 1: Once a week x 2
6 subjects (re-enter to Part 2)

Part 2: Once a week x 12
7 subjects

DS-5141b dosing (2 weeks)

DS-5141b dosing (12 weeks)



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

Ph1/2 extension study will be re-started soon

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

Enhance Profit Generation Capabilities

Realize “Process Excellence”: Further cost reductions and streamlining

	FY2016	FY2017
Enhancement of procurement Target during 5YBP – 50.0 Bn JPY cost reductions for indirect materials*1	13.2 Bn JPY cost reductions	18.2 Bn JPY cost reductions
Optimization in SC	Sale of Bethlehem Plant in US	Close Hiratsuka Plant in DSCP*2
Optimization in M&S	Restructuring in EU	Restructuring in US
Optimization in RD	Close U3 in Germany	Close DSIN*3 Close ASB*4

*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

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

* Booked in other comprehensive income

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**

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 ratio	180.7%	159.1%	-	100% or more
	169.2%			

FY2018 Consolidated Forecast

FY2018 Consolidated Forecast

(Bn JPY)

	FY2017 Results	FY2018 Forecast	YoY
Revenue	960.2	910.0	-5.2% -50.2
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 Profit	76.3	78.0	+2.3% +1.7
Profit before Tax	81.0	78.0	-3.0
Profit attributable to owners of the Company	60.3	55.0	-8.8% -5.3

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

FY2018 Consolidated Forecast

(Bn JPY)

	FY2017 Results (excl. special items)	FY2018 Forecast	YoY
Revenue	960.2	910.0	-5.2% -50.2
Cost of Sales	347.0 36.1%	330.0 36.3%	-17.0
SG&A Expenses	297.4	292.0	-5.4
R&D Expenses	205.9	210.0	+4.1
Operating Profit	109.9	78.0	-29.0% -31.9

- Impacts of patent cliff
- Impact of price revision in Japan

- Decrease due to revenue decrease

- Optimization in US sales operation
- Continuous cost reduction

- Investments in 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 Vision
 - **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



Project	Indication / Study	FY2017	FY2018			
		Q4	Q1	Q2	Q3	Q4
Pexidartinib	Ph3: TGCT (US)				Submission	
Quizartinib	Ph3: QuANTUM-R AML2 nd line treatment		TLR			
DS-3032	Ph1: AML with Quizartinib		Study initiation			
	Ph1: AML with Azacitidine		Study initiation			
DS-8201	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	
	Ph2: HER2 expressing CRC	Study initiation				
	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	
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			Study initiation		
KTE-C19	Ph2 : Refractory or Relapsed Large B Cell Lymphoma				Study initiation	
Hydromorphone	Ph3: Cancer pain (injection formulation) (JP)	Approved				
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)		TLR			

Major R&D Pipeline

As of Apr 2018



	Phase 1	Phase 2	Phase 3	Application	
Oncology	<ul style="list-style-type: none"> ■ 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) 	<ul style="list-style-type: none"> ■ U3-1402 (JP/US) (Anti-HER3 ADC) ■ DS-1001 (JP) (IDH1m inhibitor) ■ DS-1205 (US) (AXL inhibitor) ■ PLX2853 (US) (BRD4 inhibitor) ■ DS-1062 (US/JP) (Anti-TROP2 ADC) 	<ul style="list-style-type: none"> ■ Patritumab (EU) (U3-1287 / H&N cancer / Anti-HER3 antibody) ■ DS-1647 (JP) (Glioblastoma / G47Δ virus) ■ Quizartinib (JP) (AC220 / AML-2nd / FLT3 inhibitor) ■ DS-2853 (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) 	<ul style="list-style-type: none"> ■ 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-1st / FLT3 inhibitor) ■ Pexidartinib (US/EU) (PLX3397 / TGCT / CSF-1R/KIT/FLT3 inhibitor) 	
Specialty Medicine	<ul style="list-style-type: none"> ■ DS-1040 (US/EU/JP) (Acute ischemic stroke, acute pulmonary embolism / TAF1a 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) 		<ul style="list-style-type: none"> ■ 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) 	<ul style="list-style-type: none"> ■ 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) 	

Out-licensing Projects

As of Apr 2018



	Pre-clinical	Phase1	Phase 2	Phase 3
Oncology		<ul style="list-style-type: none"> ■ DS-6051 (NTRK/ROS1 inhibitor) 		
Specialty Medicine	<ul style="list-style-type: none"> ■ DS-1515 (Inflammatory disease/PI3Kδ inhibitor) ■ DS-1039 (Cystic fibrosis / new MOA (CFTR independent fluid secretion)) ■ DS-7411 (Hemophilia A and B / antibody) 	<ul style="list-style-type: none"> ■ DS-2969 (Clostridium difficile infection / GyrB inhibitor) ■ DS-1093 (inflammatory bowel disease (IBD)/ HIF-PH inhibitor) 	<ul style="list-style-type: none"> ■ Laninamivir (CS-8958/Anti-influenza/ Out-licensing with Vaxart Inc) 	

- ◆ 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)

Pivotal cohort

HER2 positive gastric or gastroesophageal junction adenocarcinoma

DS-8201

Irinotecan or paclitaxel*

Evaluate efficacy and safety

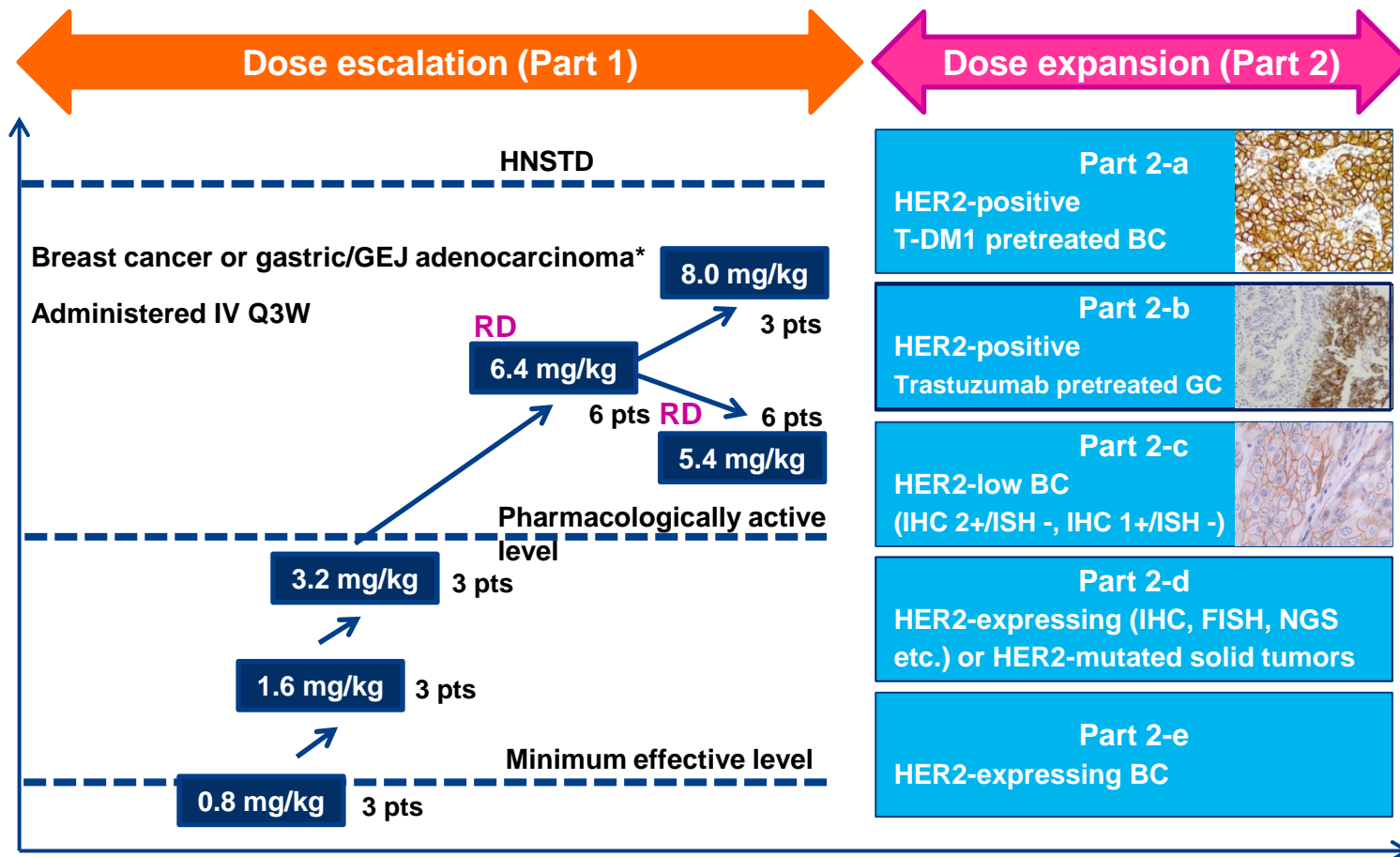
Exploratory cohort

HER2 low expressing gastric or gastroesophageal junction adenocarcinoma

DS-8201

Evaluate efficacy and safety

* Doctor's choice treatment



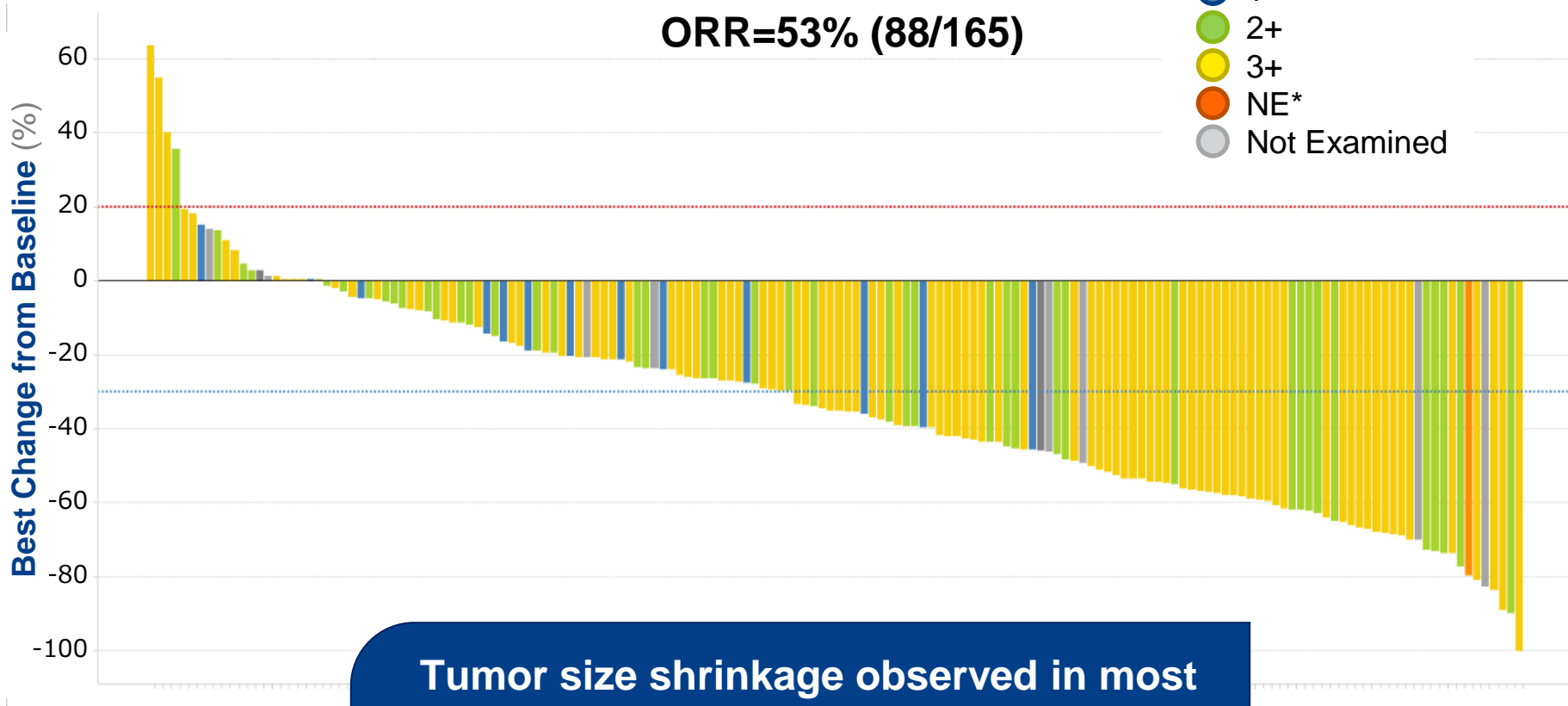
*Subjects in part 1 are not required to have HER2-positive (IHC 3+ or IHC2+/ISH-positive) tumors.
 BC, breast cancer; EWOC, escalation with overdose control; FISH, fluorescent in situ hybridization; GC, gastric cancer; GEJ, gastroesophageal junction; HER2, human epidermal growth factor receptor 2; HNSTD, 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.

Phase 1 | Any HER2-expressing tumor (n=165)
5.4 + 6.4 mg/kg

HER2 Expression (IHC)

- 1+
- 2+
- 3+
- NE*
- Not Examined

ORR=53% (88/165)



Tumor size shrinkage observed in most subjects

As of Dec 2017

*NE: Not Evaluated (Same as Not Examined)



DS-8201: Ph1 Preliminary Efficacy

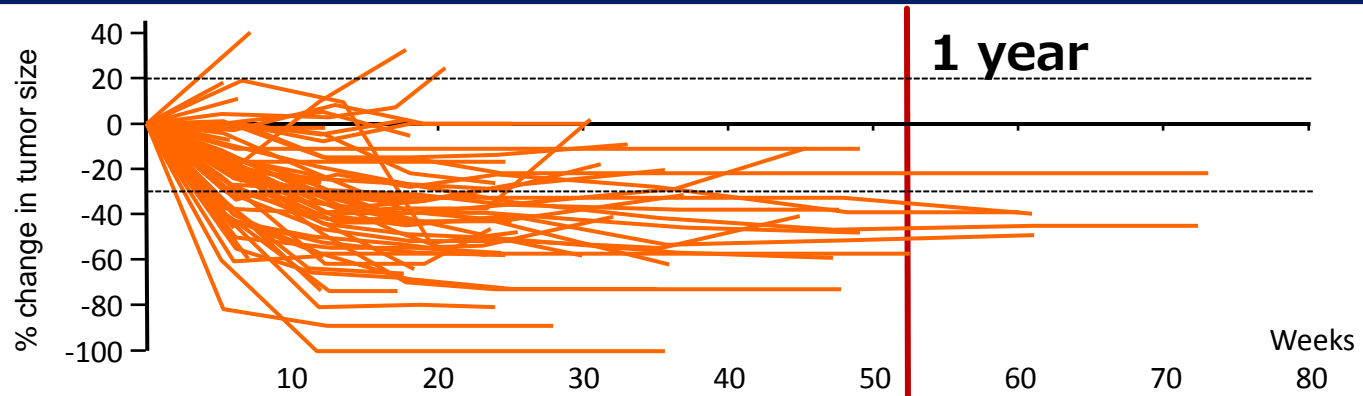


Breast (SABCS, Dec 2017)	ORR	Disease Control Rate	PFS Median (months) - range
HER2 positive			
All	61% (35/57)	95% (54/57)	10.4 (1.2+, 16.8+)
HR Positive	56% (22/39)	92% (36/39)	NR (1.2+, 16.8+)
HR Negative	75% (12/16)	100% (16/16)	10.4 (1.2+, 14.1+)
Prior pertuzumab	62% (31/50)	94% (47/50)	10.3 (1.2+, 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 GI, Jan 2018)	ORR	Disease Control Rate	PFS Median (months) - range
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

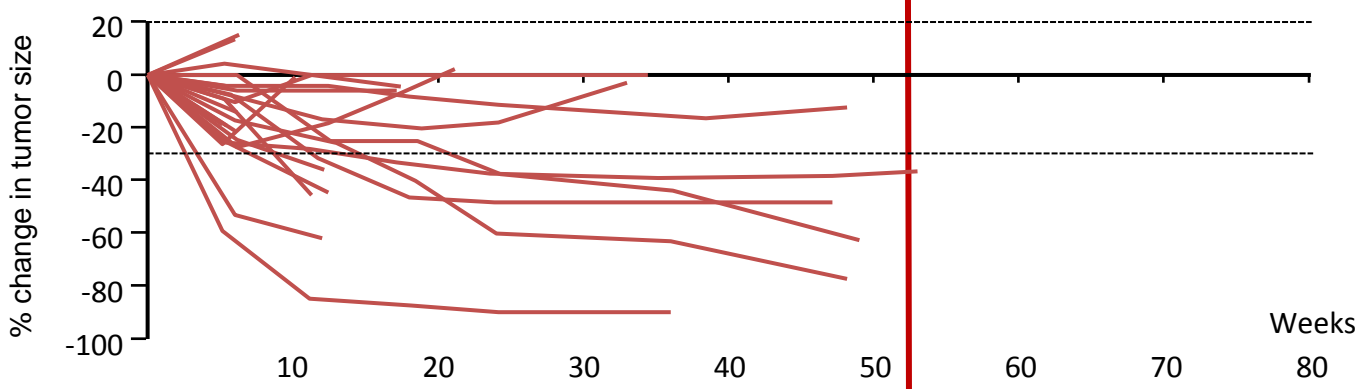
**Breast
HER2+**

(SABCS,
Dec 2017)



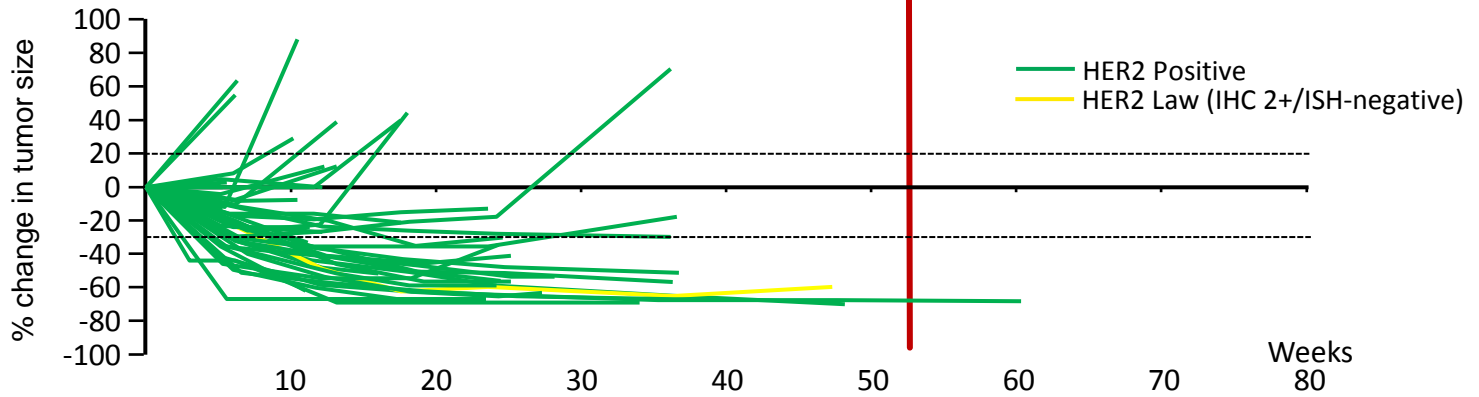
**Breast
HER2
Low**

(SABCS,
Dec 2017)



**GC
HER2+
/Low**

(ASCO
GI, Jan
2018)



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

Preferred Term (MedDRA v18.0.)	n (%)				
	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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