

# Vision, Business Plan and Progress

DAIICHI SANKYO CO., LTD.

Junichi Onuma  
Senior Director, IR Group

November, 15 2018

# Forward-Looking Statements

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- ◆ **About Daiichi Sankyo**
- ◆ **2025 Vision and 5-Year Business Plan (5YBP)**
- ◆ **Revised Target for 5YBP**

## ◆ About Daiichi Sankyo

## A Japanese Pharmaceutical Company

- ◆ Headquarters: Nihonbashi, Tokyo, Japan
  - ◆ Chairman & CEO: Mr. George Nakayama
  - ◆ President & COO: Dr. Sunao Manabe
- 
- ◆ Revenue: US \$8.73 Bn (JPY 960.2 Bn)
  - ◆ Operating profit: US \$694 Mn (JPY 76.3 Bn)\*
  - ◆ Listed on Tokyo Stock Exchange (Ticker code 4568)  
(ADR code DSNKY)
  - ◆ Number of shares issued: 709 Mn
  - ◆ Market cap: around US\$28Bn (@US\$39~40)

# Our History – Road after the Merger

## Sankyo

1899~

**pravastatin**  
(*Mevalotin/Pravachol*)

antihyperlipidemic agent



1989

## Daiichi Sankyo

2005~

**Olmesartan**

(*Olmetec/Benicar*)

antihypertensive agent



## Daiichi

1915~

**levofloxacin**

(*Cravit/Levaquin*)

synthetic antibacterial agent



1993

**Edoxaban**

(*Lixiana/Savaysa*)

anticoagulant agent

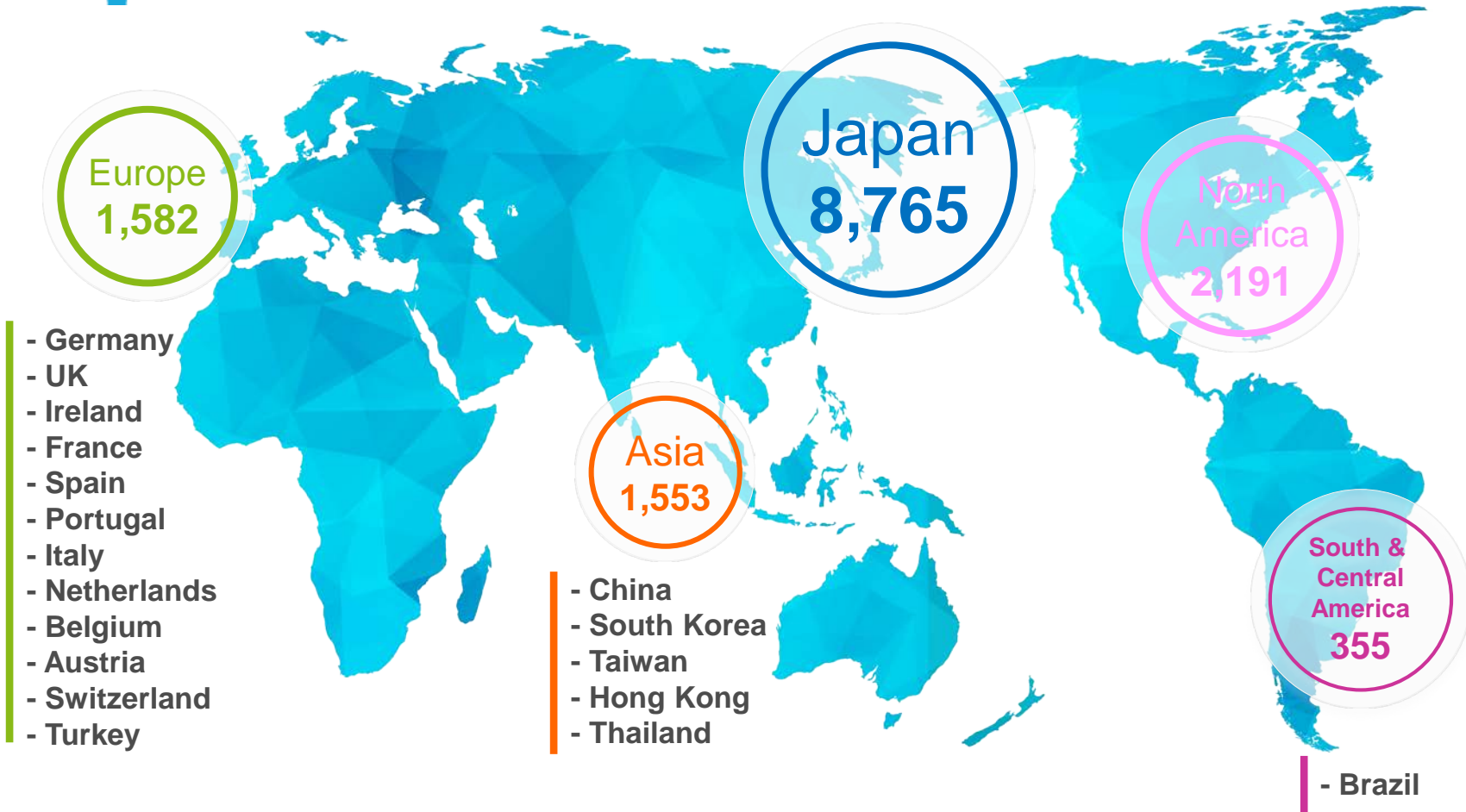


# Employees and Bases

As of Mar. 2018

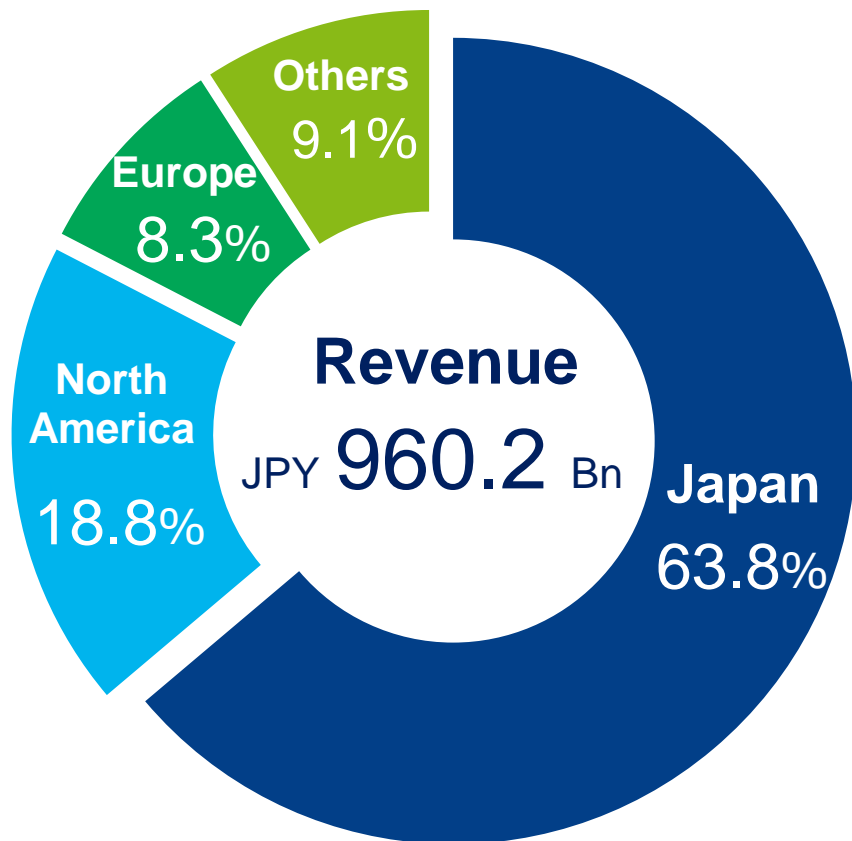


## 14,446 Worldwide Employees



# FY2017 Financial Results

(Bn JPY)



Revenue	960.2	100.0%
Cost of Sales	346.0	36.0%
SG&A Expenses	301.8	31.4%
R&D Expenses	236.0	24.6%
<b>Operating Profit</b>	<b>76.3</b>	<b>7.9%</b>
Profit before Tax	81.0	8.4%
<b>Profit attributable to owners of the Company</b>	<b>60.3</b>	<b>6.3%</b>

Equity attributable to owners of the Company	1,133.0
Total assets	1,897.8
Ratio of equity attributable to owners of the Company to total assets	59.7%
<b>ROE</b>	<b>5.2%</b>



## ◆ 2025 Vision and 5-Year Business Plan (5YBP)

A decorative graphic consisting of numerous thin, parallel lines that form a wavy, ribbon-like shape. The color transitions from a light yellow on the left to a pale green on the right, with a slight dip in the middle. The lines are closely spaced and create a sense of movement and flow.

## 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

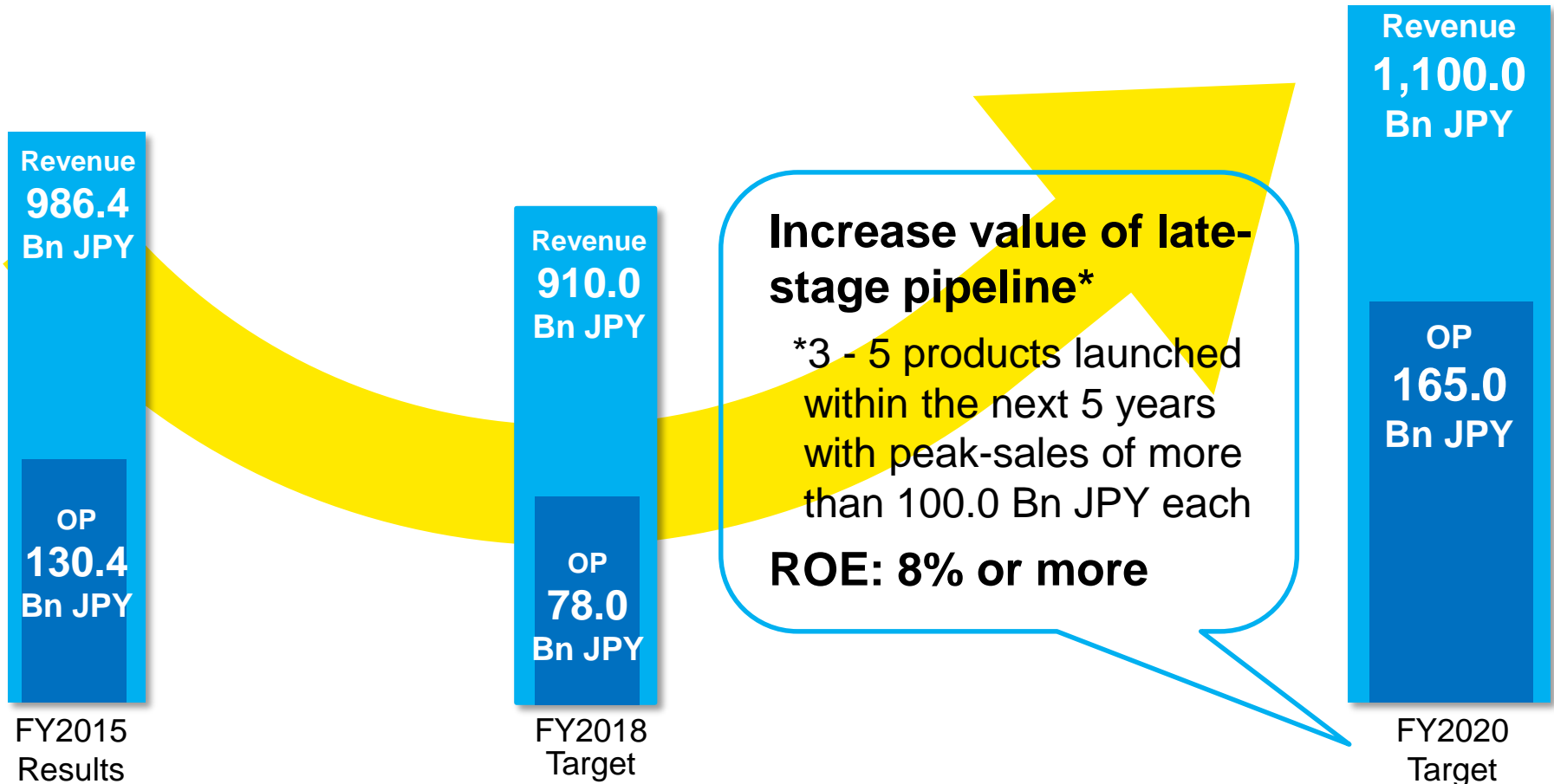
# 5-Year Business Plan (FY2016 - FY2020)

Challenge 1:

**Grow beyond the LOE of *olmesartan***

Challenge 2:

**Establish a foundation of sustainable growth**



# Strategic Targets

-For establishing foundation of sustainable growth~

- ◆ **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**

# Strategic Targets

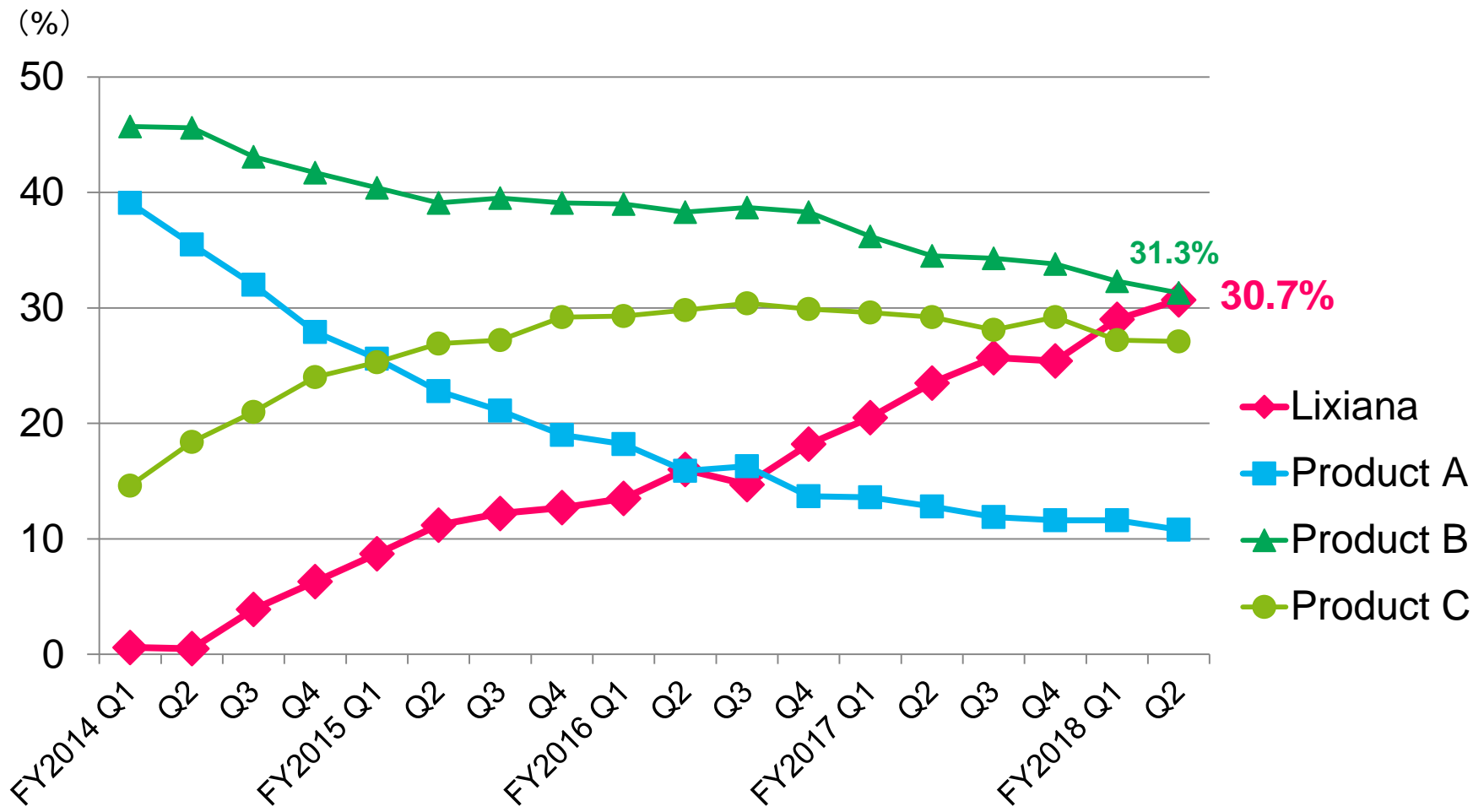
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# Edoxaban: Growth in Japan



◆ As of FY2018 Q2, Edoxaban (brand name in JP: Lixiana) closed in on No.1 sales share

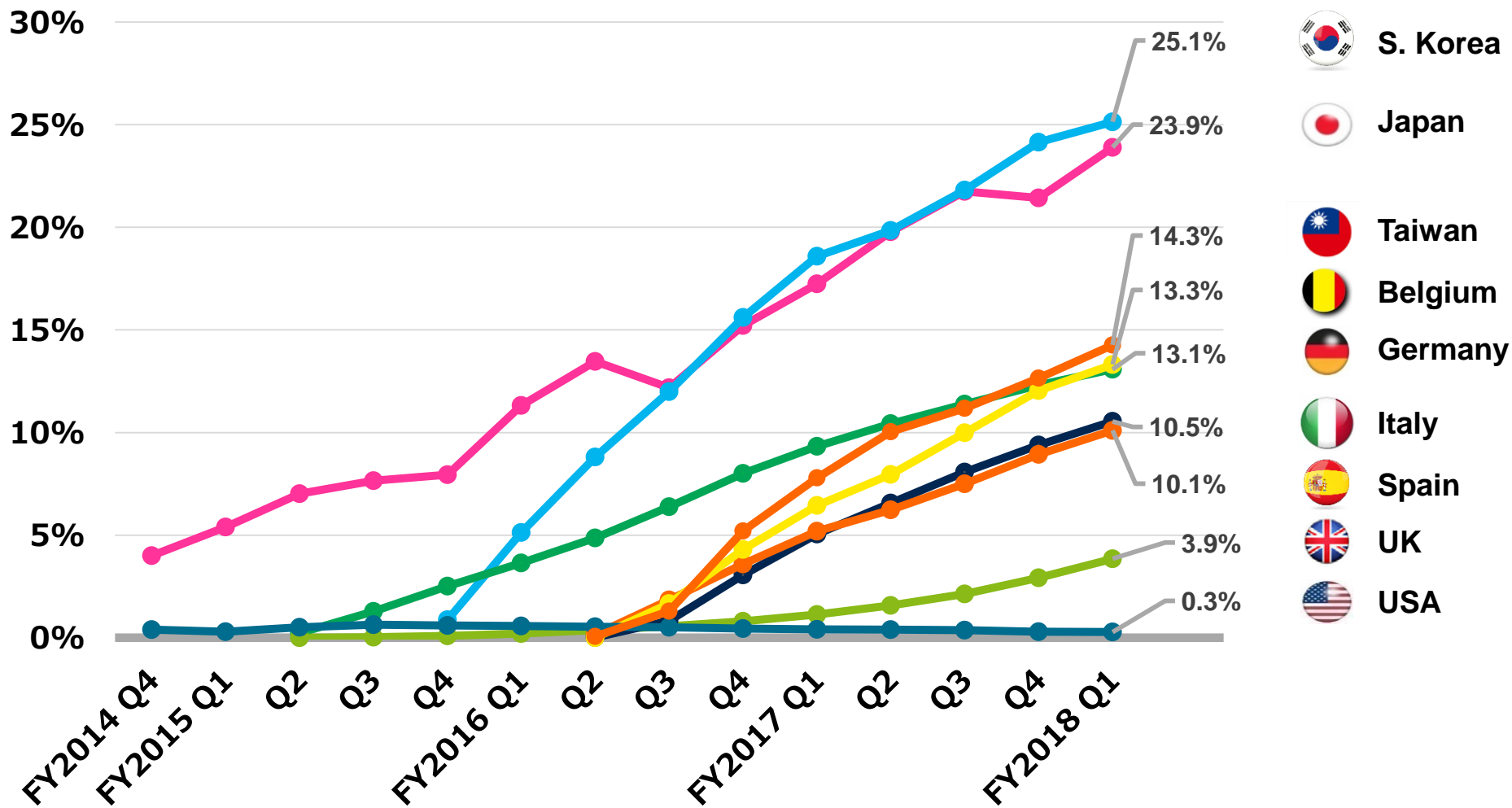


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# Edoxaban: Growth in Each Country



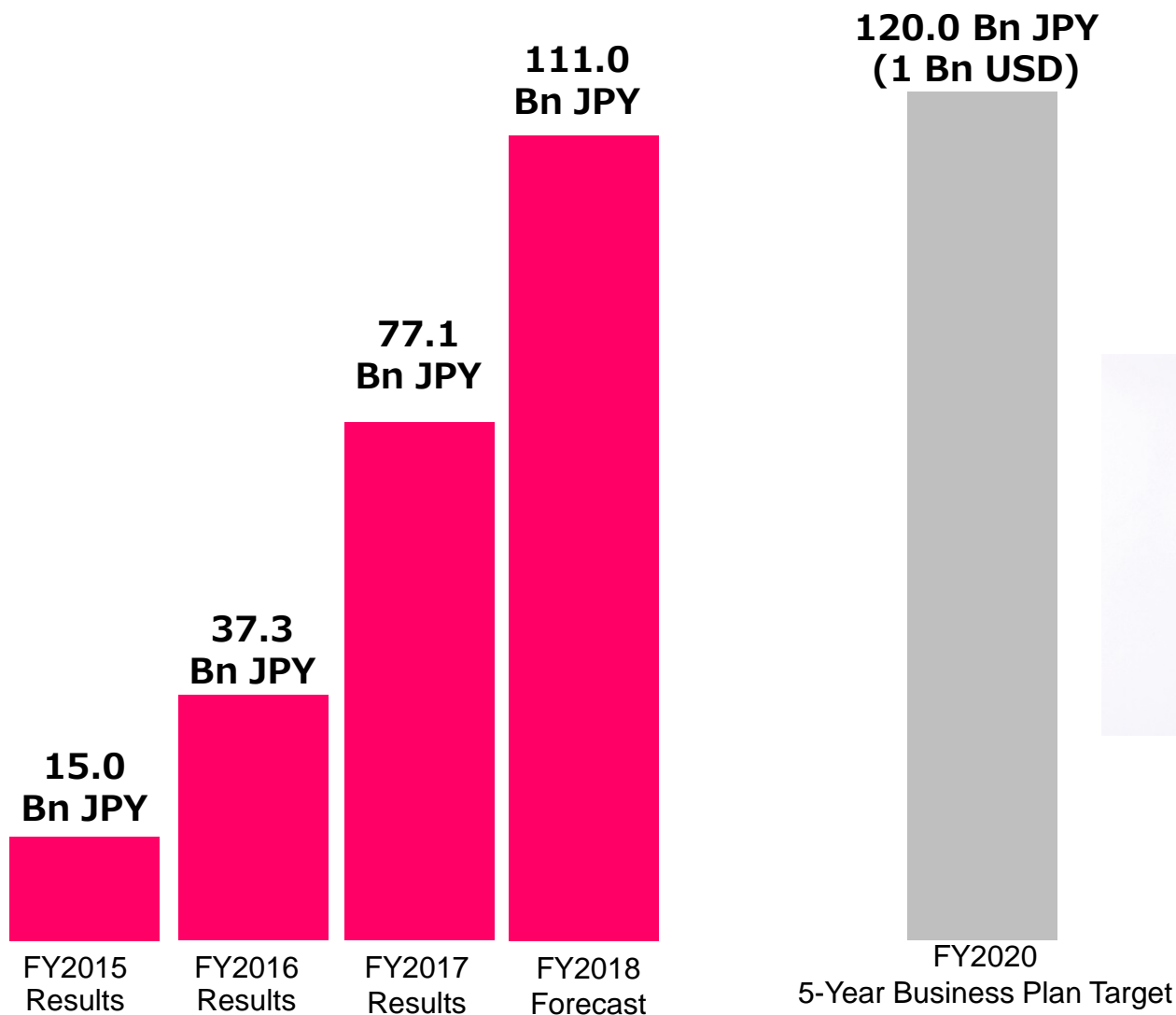
Edoxaban volume (DoT) % share of DOAC markets over time



**Brazil: Launched in Aug. 2018**

# Edoxaban: FY2020 Target

Expanding mainly in Japan, EU and Asia



anticoagulant agent  
**Edoxaban**  
(Lixiana/Savaysa)



Conservative assumption that insurance reimbursement status in United States will remain unchanged



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# Japan Business: 6 Major Products

Share No.1



**Nexium**

ulcer treatment

Share No.1



**Memary**

Alzheimer's disease treatment

Share No.1\*



**Pralia**

treatment for osteoporosis

Share No.1



**Ranmark**

treatment for bone complication caused by bone metastases from tumors



**Efient**

antiplatelet agent



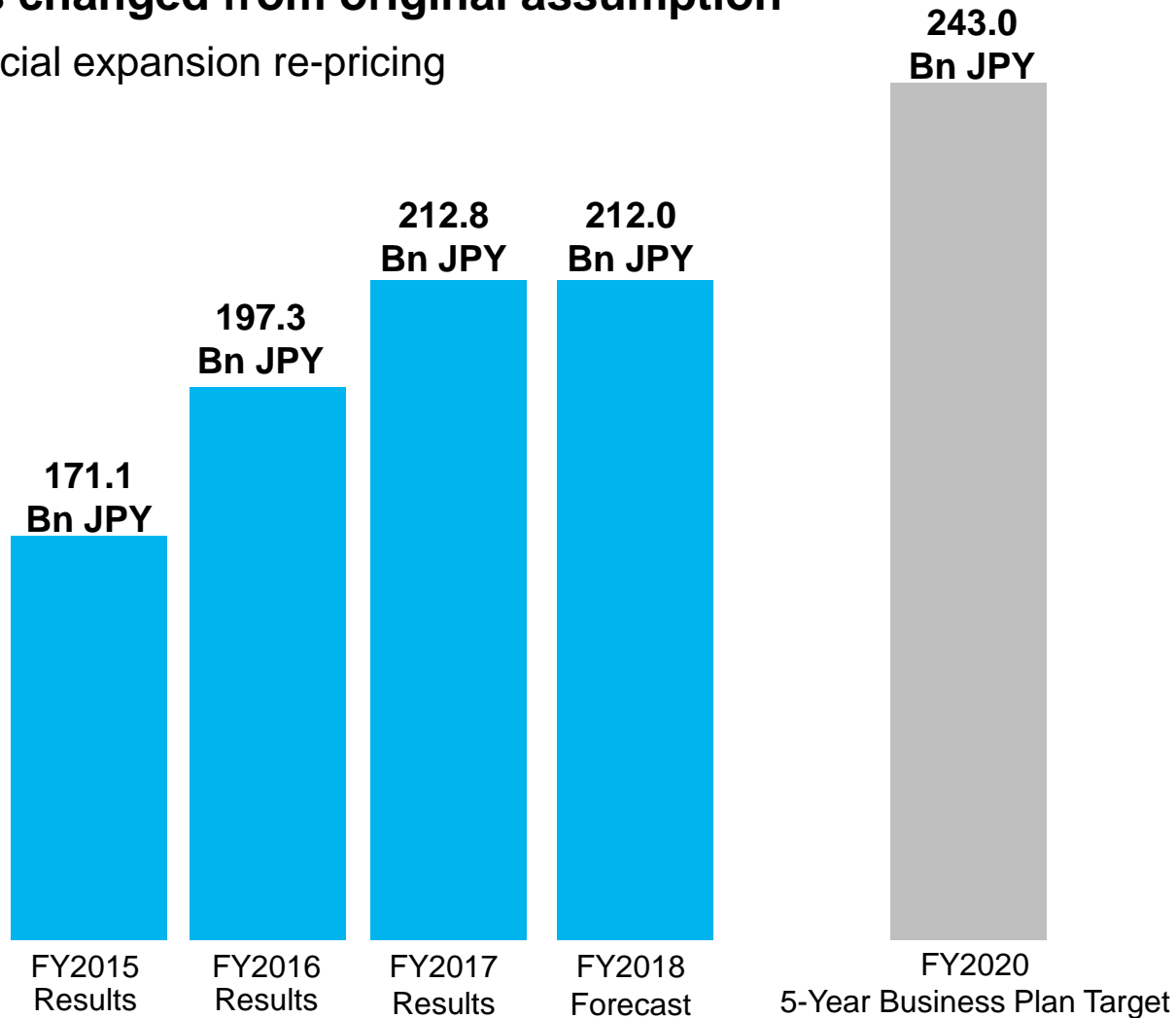
**Tenelia**

type 2 diabetes mellitus inhibitor

- ◆ Introduced Special expansion re-pricing
- ◆ Limited application of Price Maintenance Premium (PMP)
- ◆ Further price pressure on long-listed drugs
- ◆ Price revision may occur every year

## ◆ Major factors changed from original assumption

- Nexium: Special expansion re-pricing



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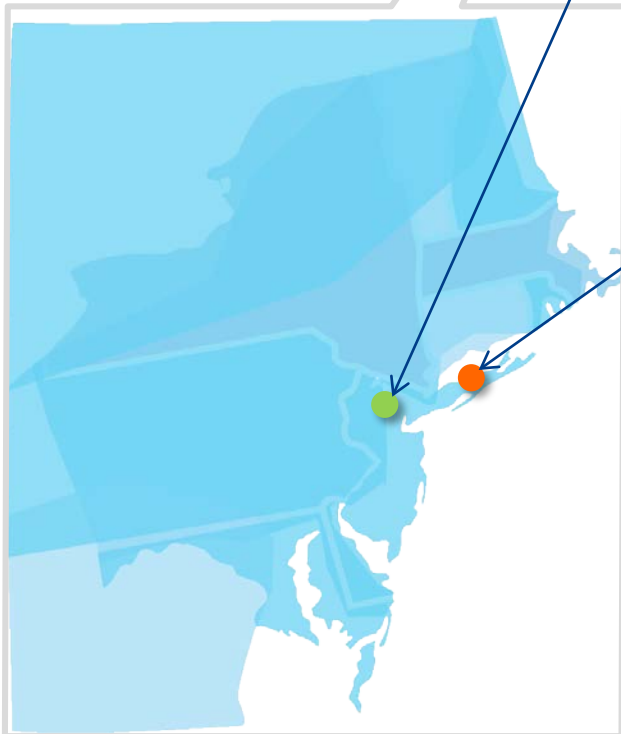
# Two Business Units in US



## **Daiichi Sankyo, Inc. (DSI)** **(Basking Ridge, NJ)**

**FY2018 revenue forecast: US\$ 281 Mn**

With the LOE of key products, Daiichi Sankyo, Inc. will transition from a mature primary care company to one with a differentiated specialty portfolio centered on Pain and Oncology



## **Luitpold Pharmaceuticals, Inc. (LPI)** **(Shirley, NY)**

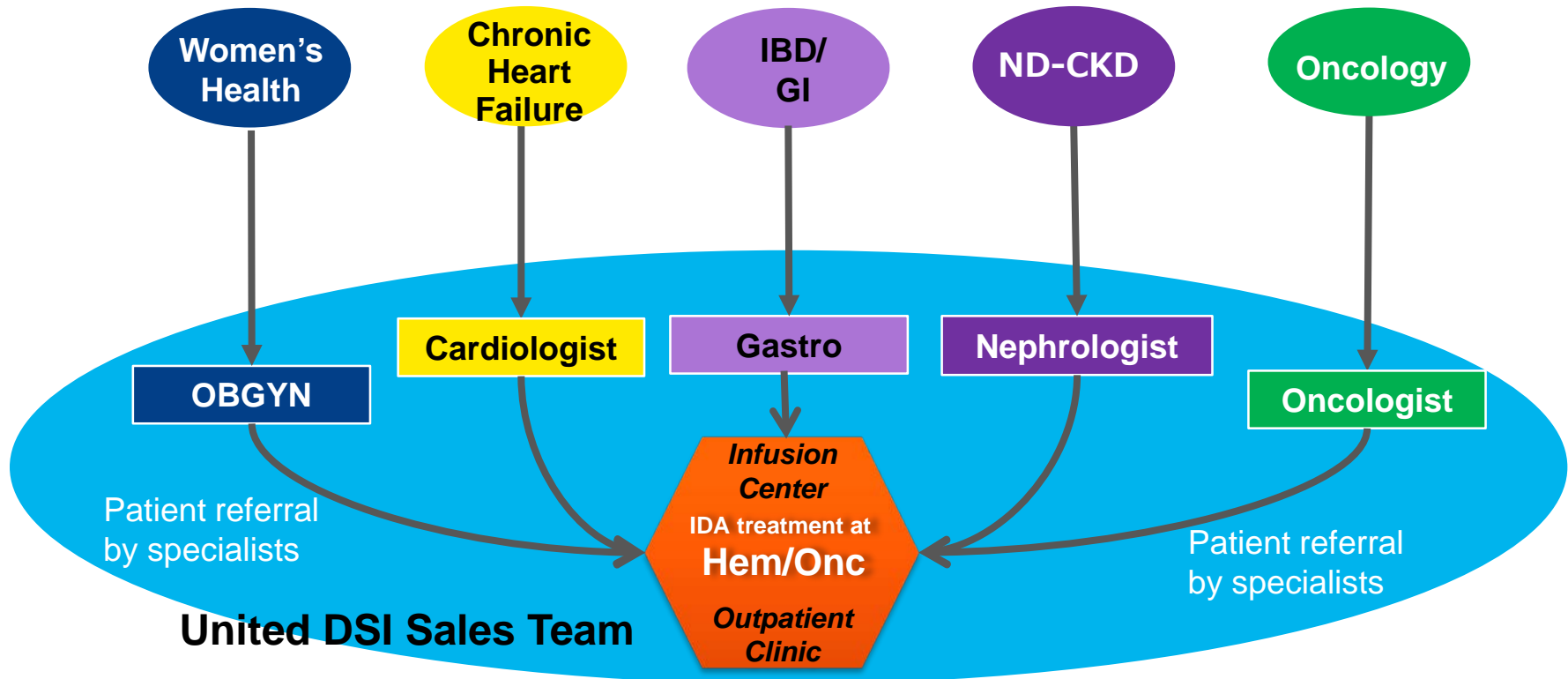
**FY2018 revenue forecast: US\$ 1,026 Mn**

LPI successfully competes in high value specialty branded & generic injectable market segments with following franchises

- Iron Injectable Franchise
- Generic Injectable Franchise

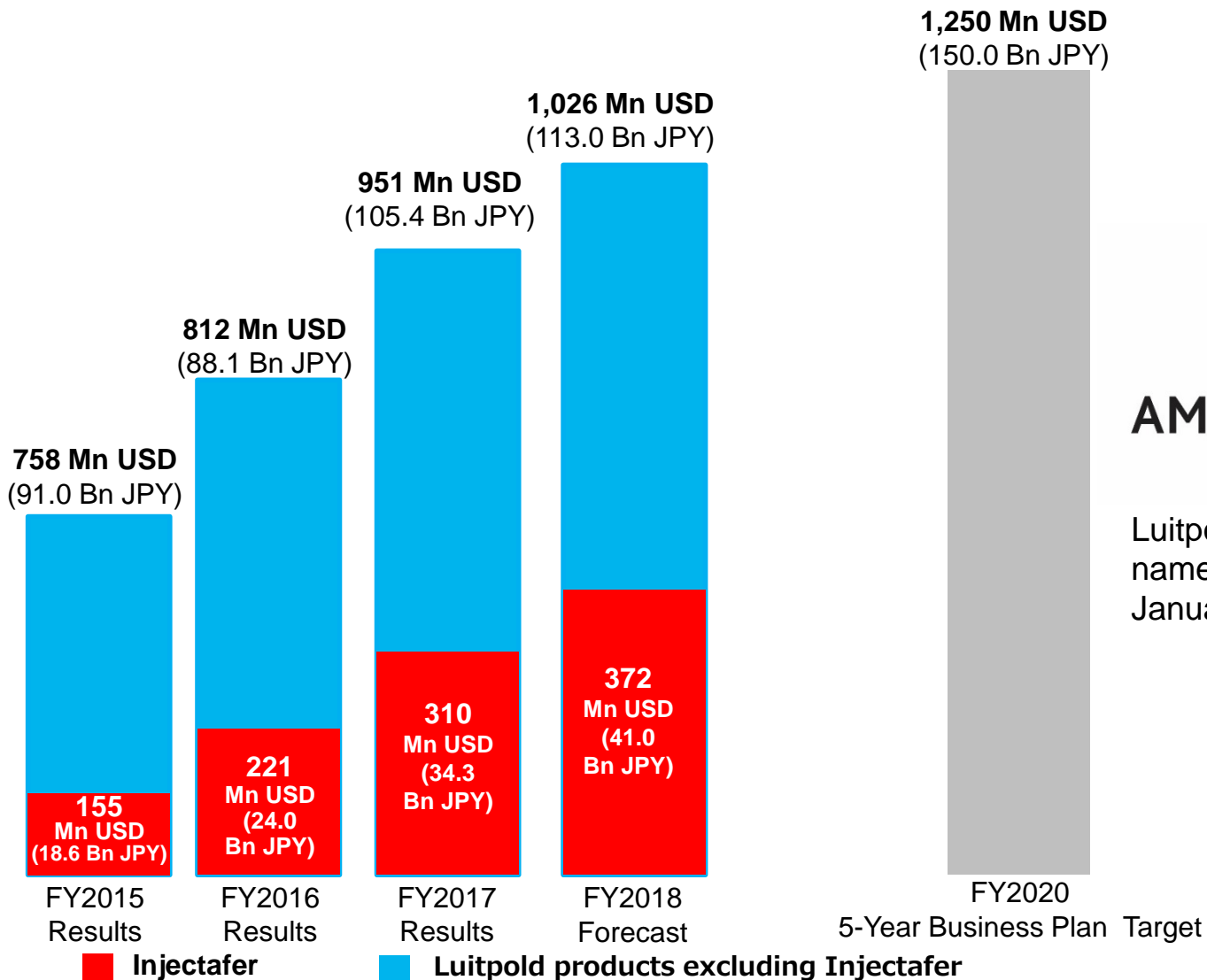
# Injectafer: Sales Team

In Jan. 2017, LPI sales team for Injectafer became DSI employees:  
Now DSI and LPI are a united sales team for Injectafer



# Luitpold Business: FY2020 Target

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



Luitpold will change the company name to “American Regent” in January 2019.

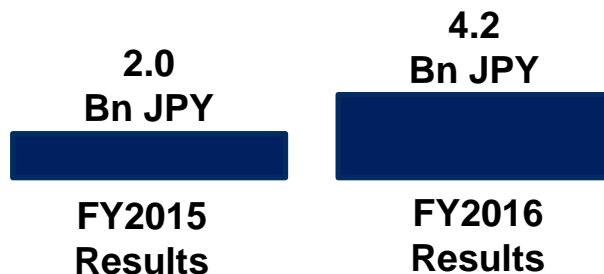


## ◆ CL-108

- Decided to return all of rights regarding CL-108

## ◆ Mirogabalin

- Did not meet the primary efficacy endpoint



> ~~100 Bn JPY~~  
in FY2020



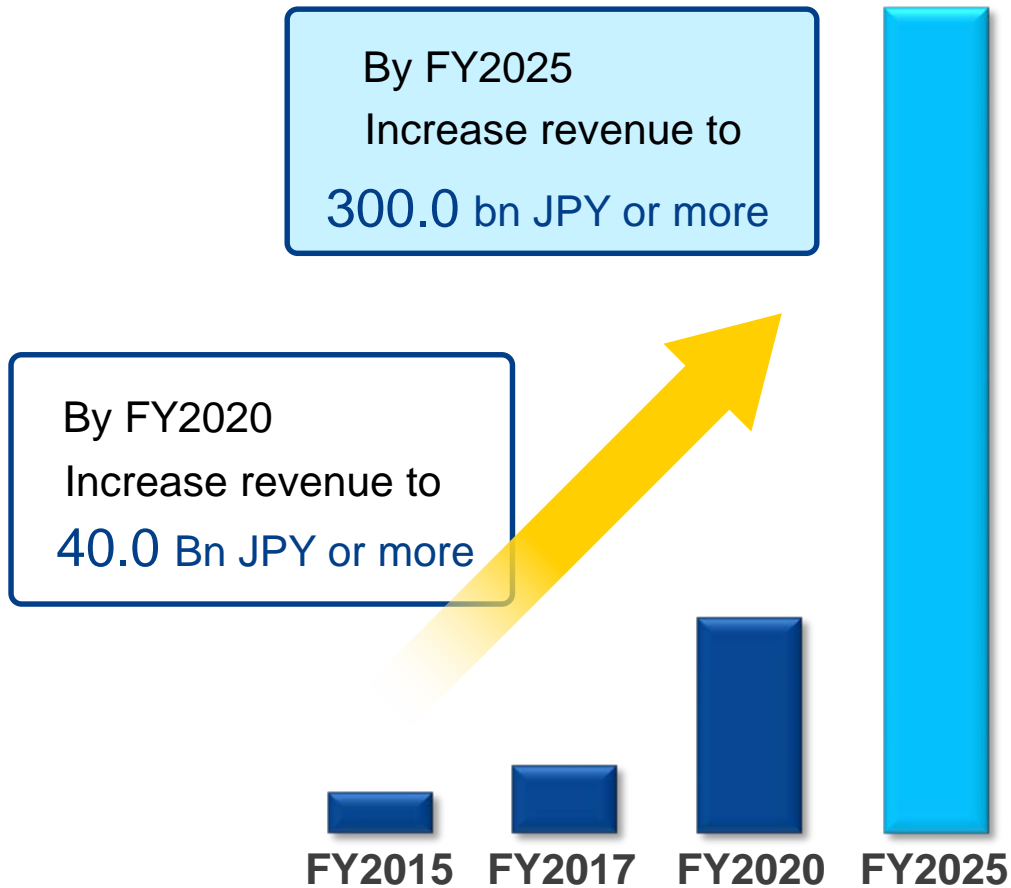
FY2020  
Target

# Strategic Targets

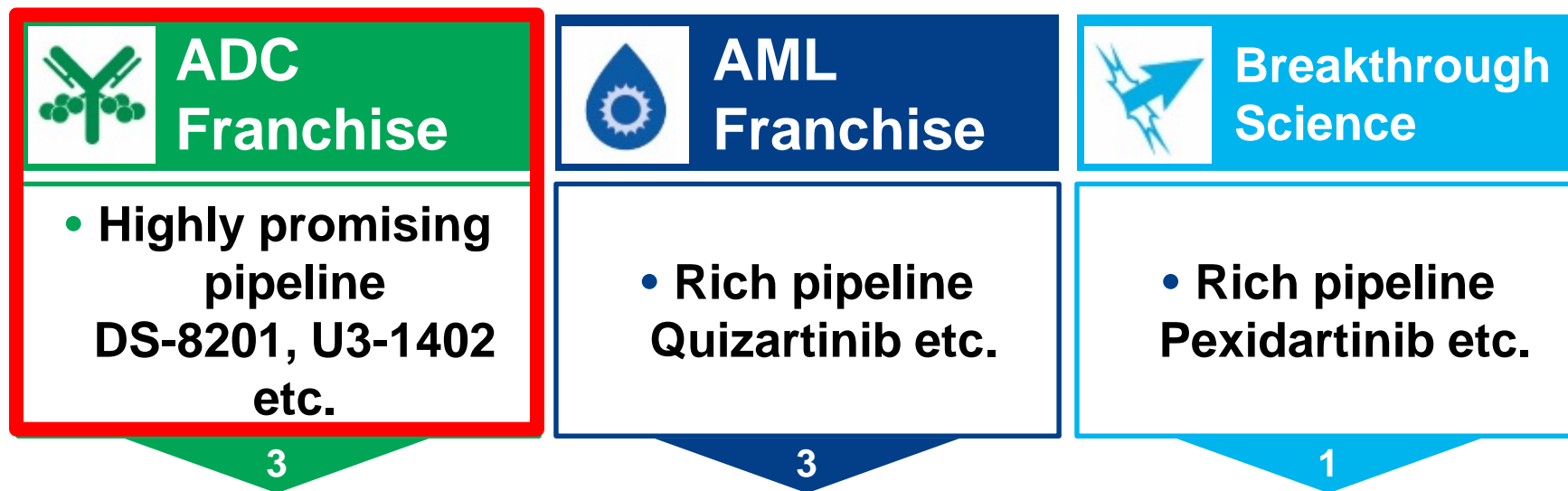
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# Oncology Business: FY2020 Target



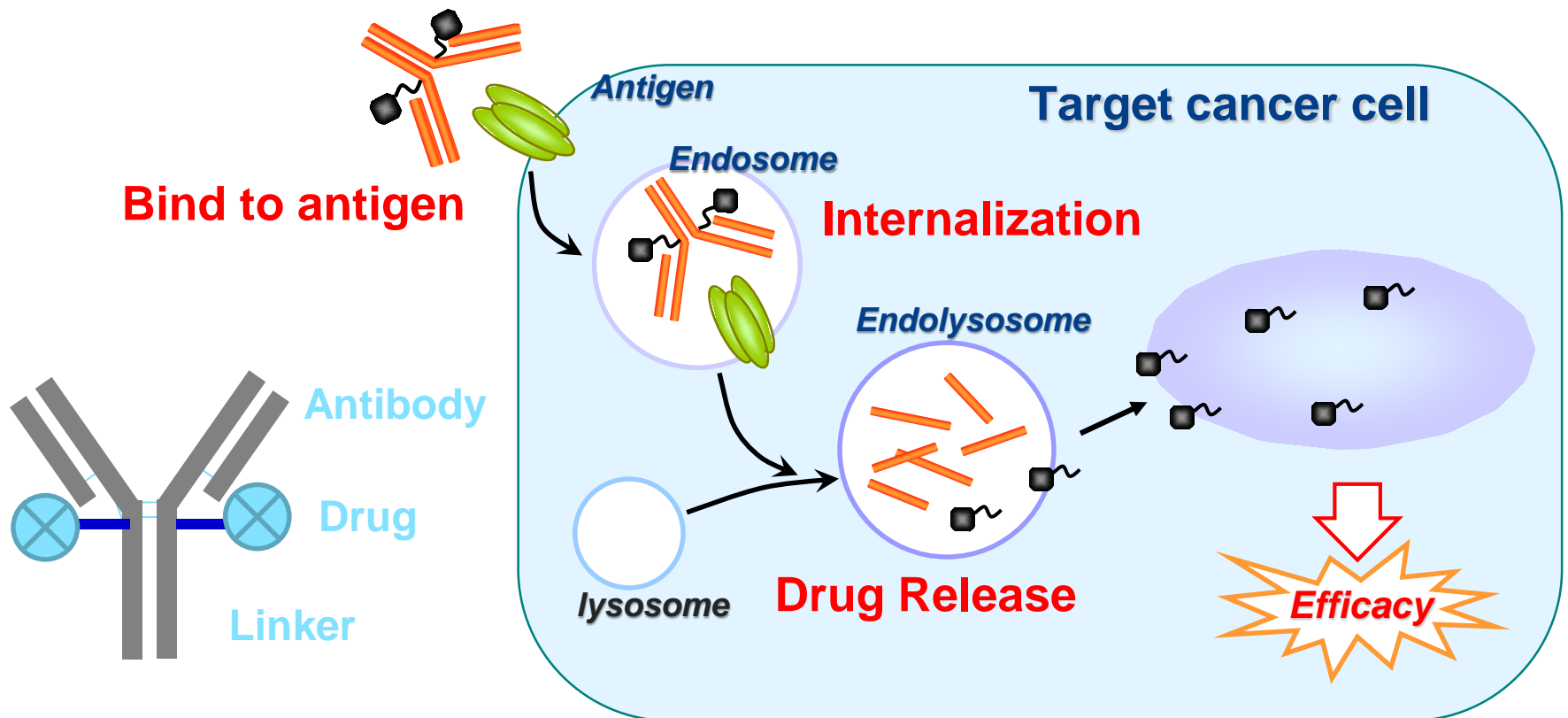
- ◆ Built 3 pillars of oncology business, ADC Franchise, AML Franchise and Breakthrough Science, and focus investments on the pillars

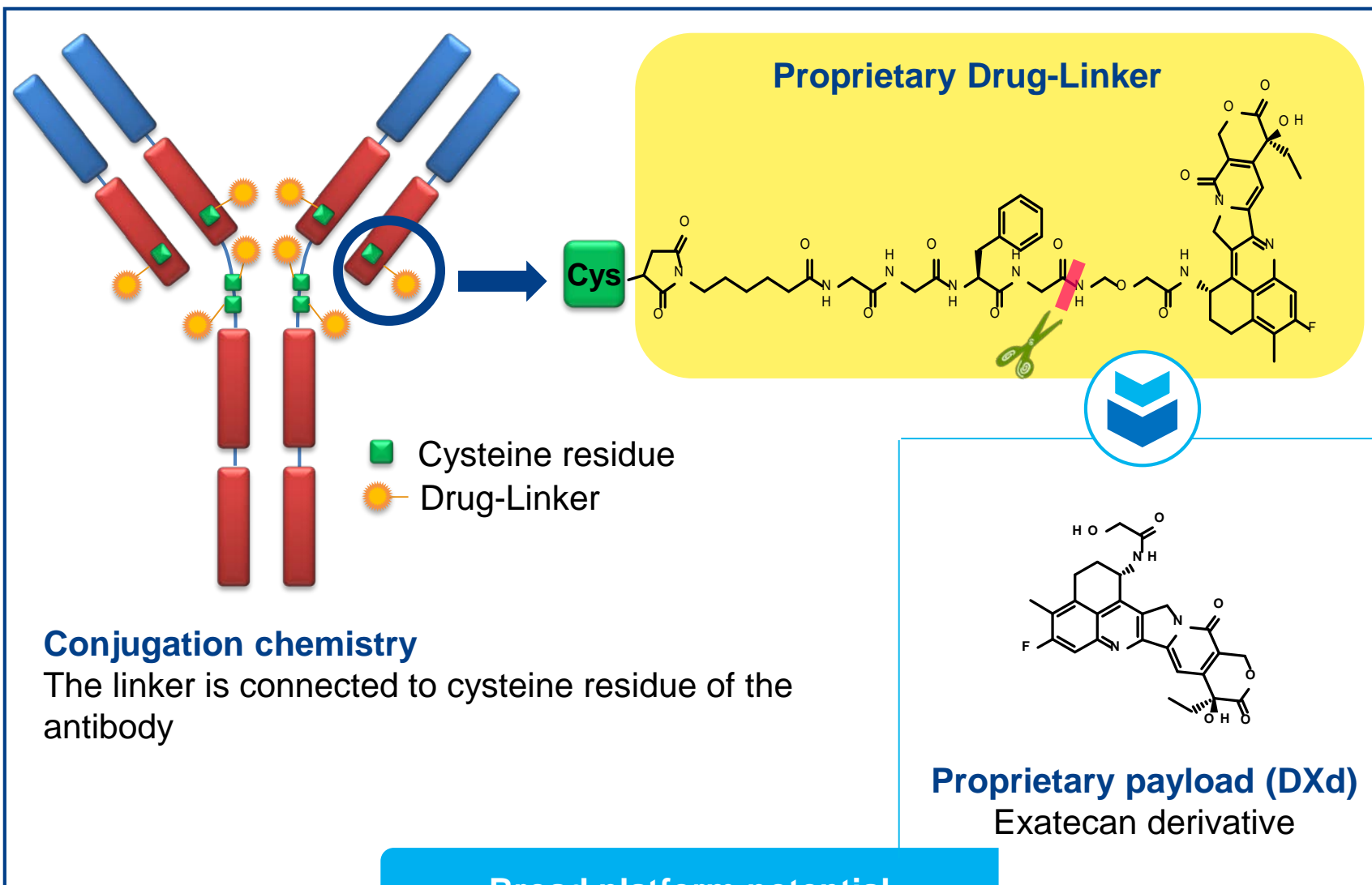


Cancer Enterprise  
2025 Vision

## 7 new molecular entitles by 2025

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





**Broad platform potential**



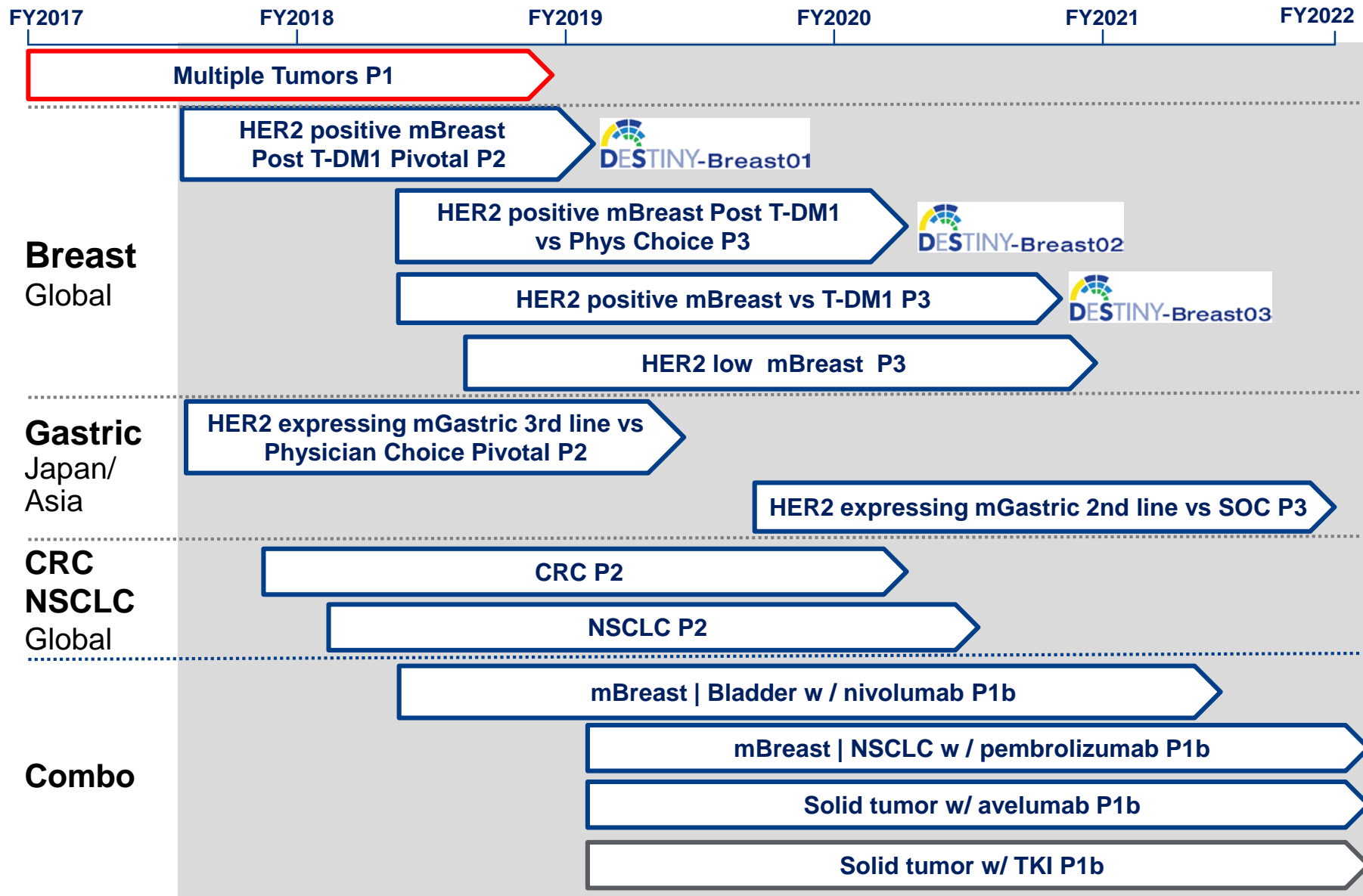
## ADC Franchise

Clinical stage

	Project (Target)	Potential Indication	Discovery	Pre-Clinical	Phase 1	Pivotal
1	DS-8201 (HER2)	Breast, Gastric, CRC, NSCLC				
2	U3-1402 (HER3)	Breast, NSCLC				
3	DS-1062 (TROP2)	NSCLC				
4	DS-7300 (B7-H3)	Solid tumor				
5	DS-6157 (GPR20)	GIST				
6	DS-6000 (undisclosed)	Renal, Ovarian				
7	(TA-MUC1)	Solid tumor				

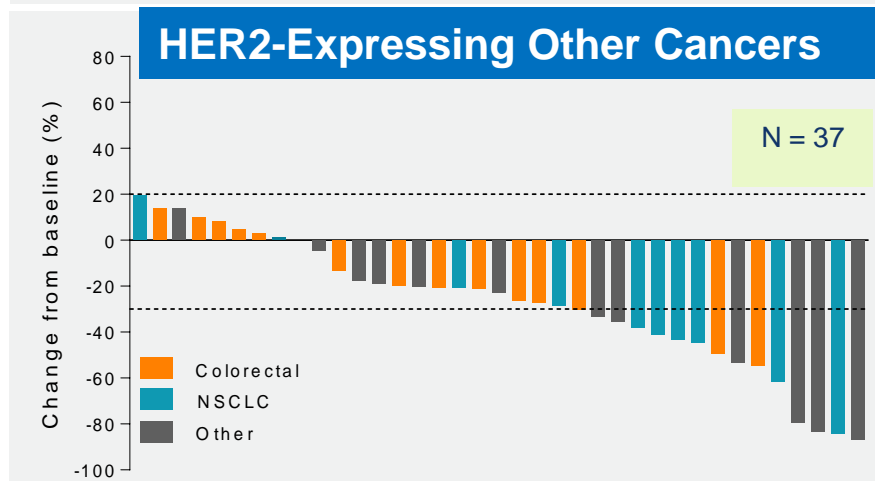
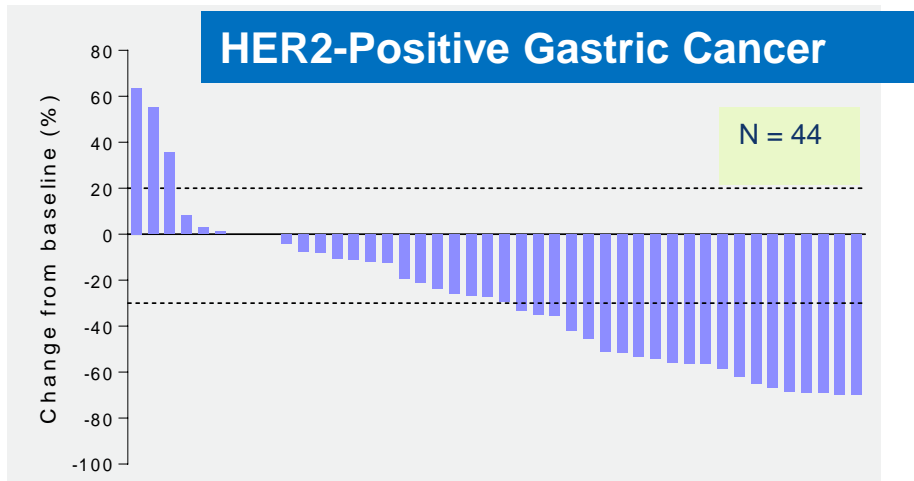
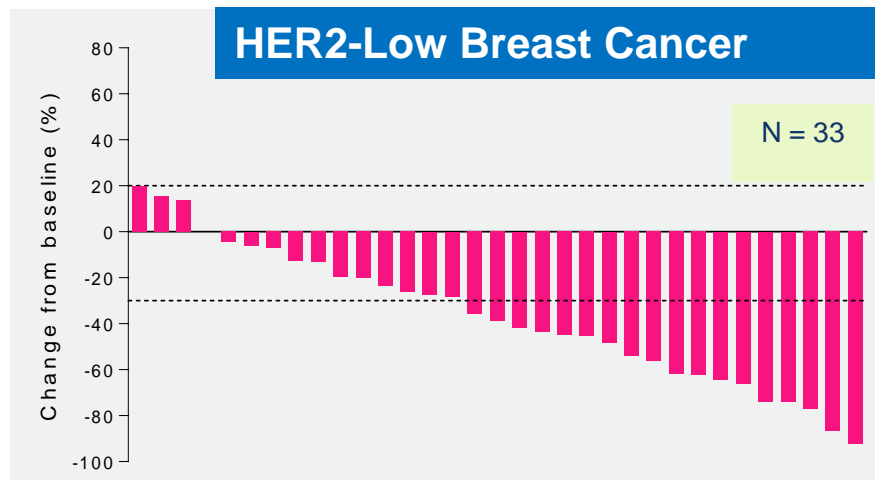
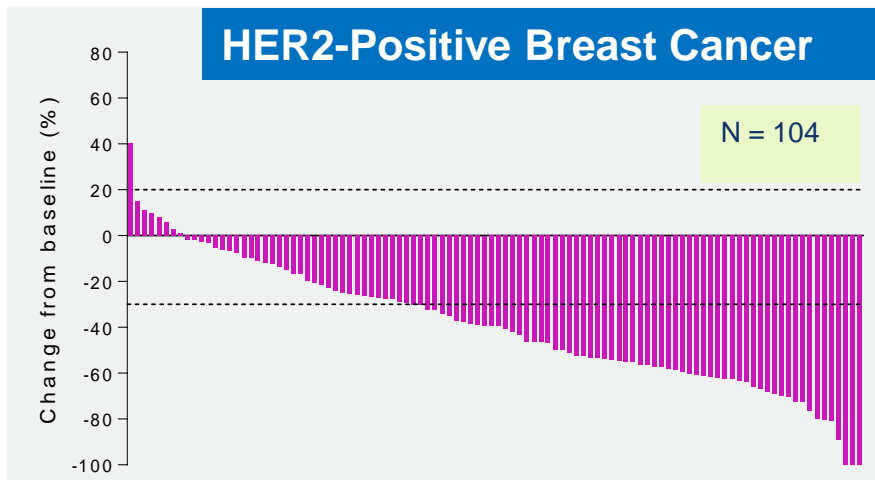
CRC: colorectal cancer, GIST: gastrointestinal stromal tumor, NSCLC: non-small cell lung cancer

# DS-8201: Clinical Program





## Tumor Shrinkage by Tumor Types: (5.4 or 6.4 mg/kg)



Includes subjects who had  $\geq 1$  postbaseline scan. Dotted lines denote 20% increase and 30% reduction in tumor size, respectively.

\*Confirmed response includes subjects who had  $\geq 2$  postbaseline scans, progressive disease, or discontinued treatment for any reason prior to second postbaseline scan.

Data cutoff is April 18, 2018.

## Efficacy Outcomes by Tumor Type (5.4 or 6.4 mg/kg)

	HER2-Positive BC N = 111	HER2-Low BC N = 34	HER2-Positive GC N = 44	HER2-Expressing Other Cancers N = 51
<b>Confirmed ORR* % (n/N)</b>	<b>54.5%</b> (54/99)	<b>50.0%</b> (17/34)	<b>43.2%</b> (19/44)	<b>38.7%</b> (12/31)
DCR % (n/N)	93.9% (93/99)	85.3% (29/34)	79.5% (35/44)	83.9% (26/31)
ORR in modified ITT**, % (n/N)	48.6% (54/111)	50.0% (17/34)	43.2% (19/44)	23.5% (12/51)
<b>DOR</b>				
<b>Median</b> (95% CI), months	NR	11.0 (NA)	7.0 (NA)	12.9 (2.8, 12.9)
<b>PFS</b>				
<b>Median</b> , (95% CI), months	NR	12.9 (NA)	5.6 (3.0, 8.3)	12.1 (2.7, 14.1)
Min, max	1.0, 22.2+	0.5, 19.6+	1.2, 19.6+	0.7, 14.1+

\* Confirmed response includes subjects who had  $\geq 2$  postbaseline scans, had progressive disease, or discontinued treatment for any reason prior to second postbaseline scan.

\*\* Modified ITT population included all subjects who received  $\geq 1$  dose of DS-8201a at either 5.4 or 6.4 mg/kg, including those subjects who were too early to assess, but are ongoing on study.

+ after value indicates censoring.

BC, breast cancer; CI, confidence interval; DCR, disease control rate; DOR, duration of response; GC, gastric/gastroesophageal junction cancer; HER2, human epidermal growth factor receptor 2; ITT, intent-to-treat; NA, not available; NR, not reached; ORR, overall response rate; PFS, progression-free survival.

Data cutoff for this analysis is April 18, 2018.

- ◆ ORR of HER2-Low BC was 50%, similar to HER2-positive BC, 54.5%
- ◆ ORR of GC was 43.2%
- ◆ ORR of other Cancer (NSCLC, CRC, etc.) was 38.7%



# DS-8201: Frequent TEAEs ( $\geq 20\%$ ) (all tumor types from part 1 and part 2)

All tumor types from P1 study part 1 and part 2; 5.4 or 6.4 mg/kg <sup>a</sup> (N = 259)		
	Any Grade, n (%)	Grade $\geq 3$ , n (%)
Nausea	192 (74.1)	9 (3.5)
Decreased appetite	147 (56.8)	12 (4.6)
Vomiting	113 (43.6)	6 (2.3)
Anemia	98 (37.8)	50 (19.3)
Alopecia	97 (37.5)	0
Fatigue	88 (34.0)	6 (2.3)
Diarrhea	87 (33.6)	6 (2.3)
Constipation	85 (32.8)	2 (0.8)
Platelet count decreased	73 (28.2)	27 (10.4)
Neutrophil count decreased	66 (25.5)	40 (15.4)
White blood cell count decreased	66 (25.5)	32 (12.4)
Malaise	58 (22.4)	1 (0.4)
Pyrexia	53 (20.5)	2 (0.8)
Aspartate aminotransferase increased	53 (20.5)	4 (1.5)

Data cutoff, August 10, 2018. A subject was counted once if the same AE was reported more than once.

<sup>a</sup>All subjects from Part 1 and Part 2 receiving  $\geq 1$  dose of [fam-] trastuzumab deruxtecan 5.4 mg/kg or 6.4 mg/kg regardless of tumor type.

AE, adverse event; TEAE, treatment-emergent adverse event.

- ◆ Adverse events were generally of low grade
- ◆ The most frequent AEs Grade  $\geq 3$  were hematologic in nature



# DS-8201: Adverse Events of Special Interest (all tumor types from part 1 and part 2)

All tumor types from P1 study part 1 and part 2; 5.4 or 6.4 mg/kg <sup>a</sup> (N = 259)		
	Any Grade, n (%)	Grade ≥3, n (%)
AST increased	53 (20.5)	4 (1.5)
ALT increased	40 (15.4)	2 (0.8)
Blood bilirubin increased	6 (2.3)	1 (0.4)
Ejection fraction decreased	2 (0.8)	0
Electrocardiogram QT prolonged	13 (5.0)	1 (0.4)
Interstitial lung disease (ILD)	10 (3.9)	2 (0.8)
Pneumonitis	22 (8.5)	6 (2.3)
Infusion-related reactions	4 (1.5)	0

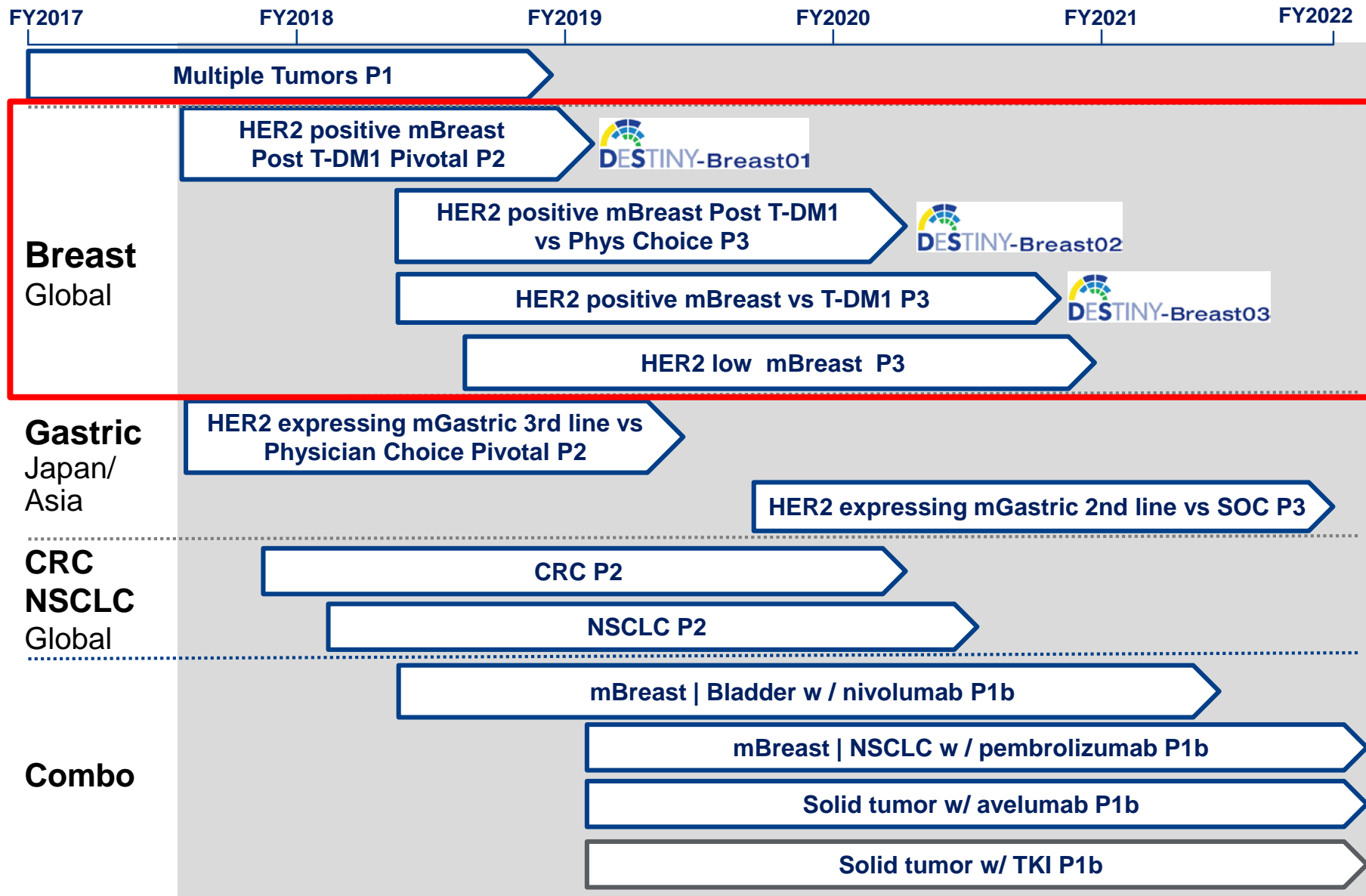
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<sup>a</sup>All subjects from Part 1 and Part 2 receiving ≥1 dose of [fam-] trastuzumab deruxtecan 5.4 mg/kg or 6.4 mg/kg regardless of tumor type.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; ILD, interstitial lung disease; NSCLC, non-small cell lung cancer; QTc, QT interval corrected for heart rate.

- ◆ There were 5 fatal cases of ILD/pneumonitis observed in the overall population
- ◆ There was only one grade 5 pneumonitis case in the NSCLC cohort and this case was determined to be unrelated to study drug by the independent adjudication committee

# DS-8201: Clinical Program





HER2 **positive** metastatic Breast Cancer

**1<sup>st</sup> line**

**Herceptin (Trastuzumab) (+ Perjeta (Pertuzumab))**



**2<sup>nd</sup> line**

**Kadcyla (T-DM1)**

HER2 positive mBreast  
vs T-DM1 P3



**Started**



**3<sup>rd</sup> line**

**Physician's Choice**

HER2 positive mBreast  
Post T-DM1 Pivotal P2



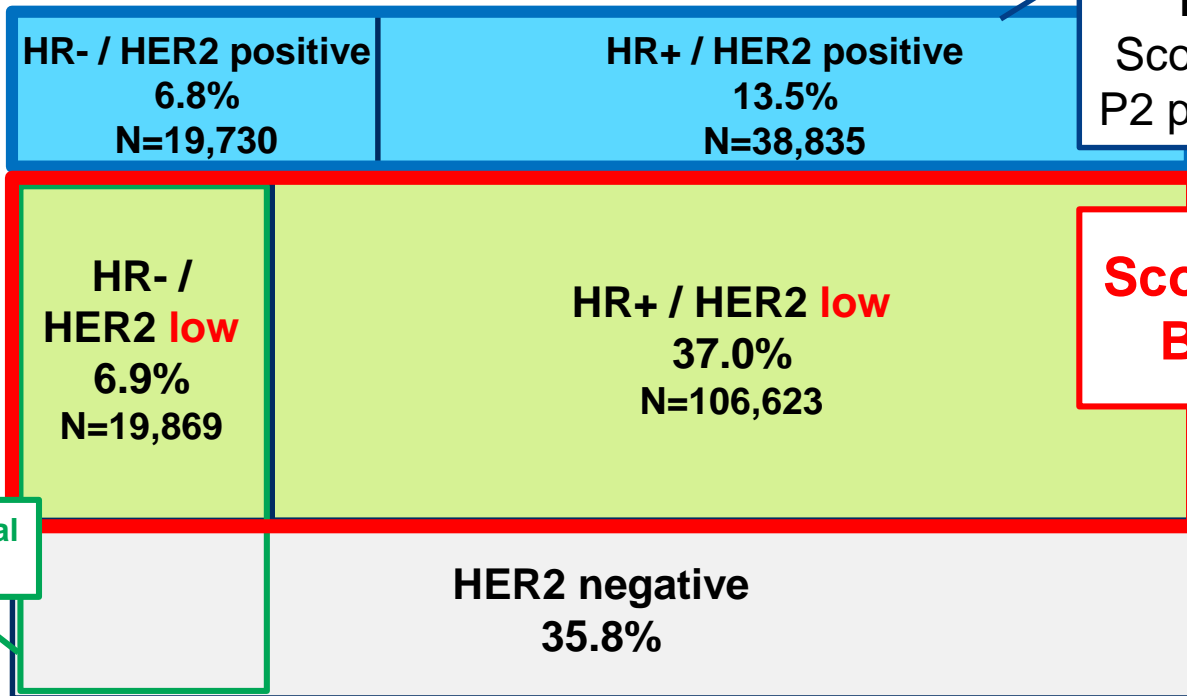
**Enrollment Completed**

HER2 positive mBreast Post T-DM1  
vs Phys Choice P3





**Patients with metastatic Breast Cancer  
N=288,550**



**Herceptin/Perjeta  
Kadcyla (T-DM1)**  
Scope of HER2 positive  
P2 pivotal and P3 studies

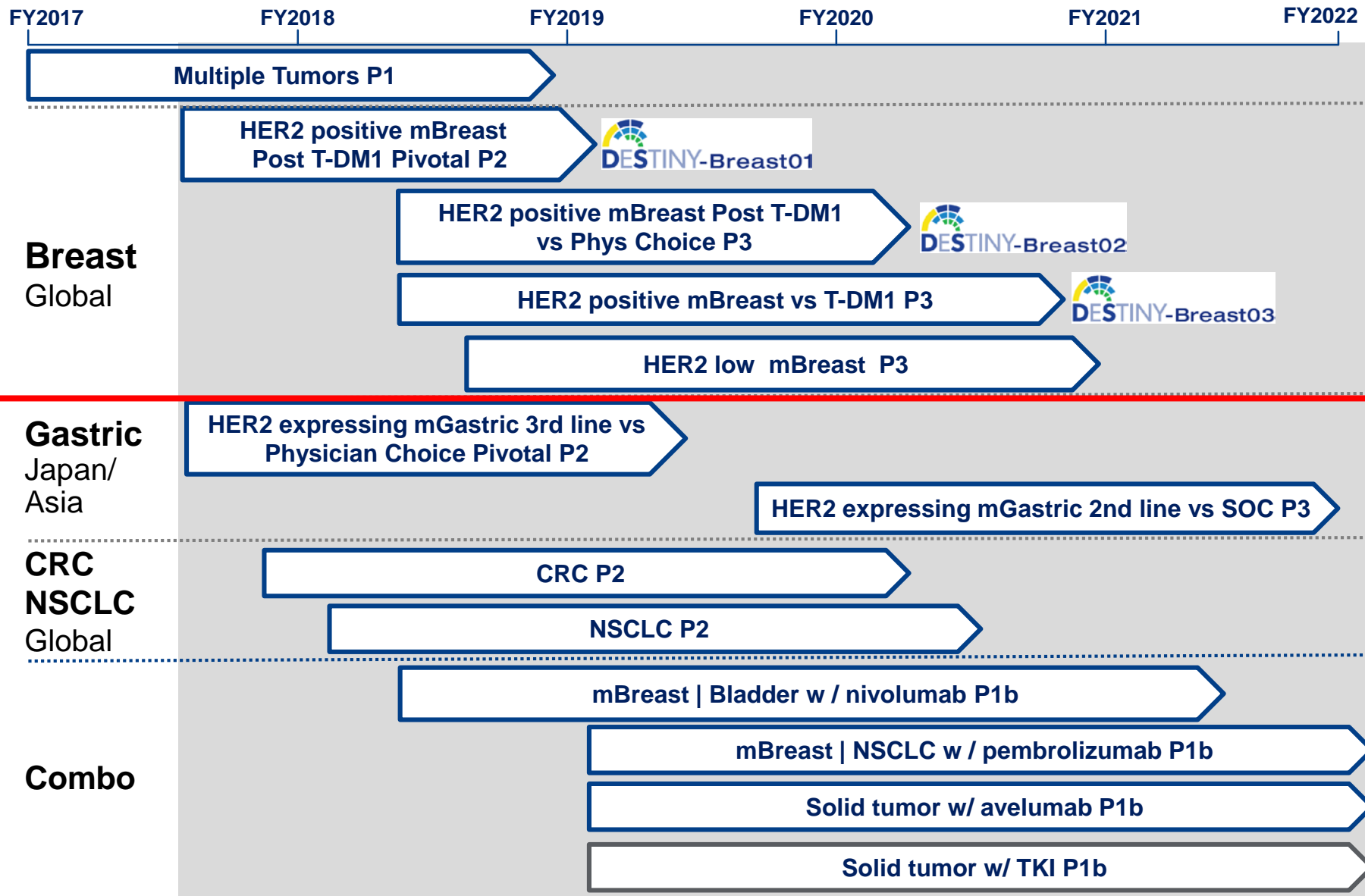
**Scope of HER2 Low  
BC P3 Program**

Conventional  
TNBC

**Treatment Groups**  
HER2 low (IHC2+/ISH- , IHC1+) with

- ◆ HR positive/ no prior CDK
- ◆ HR positive / prior CDK
- ◆ HR negative

HR: hormone receptor; TNBC: triple negative breast cancer  
HR-: estrogen-receptor (ER) and progesterone-receptor (PR) negative







## Gastric

- ◆ Pivotal P2 study is on track
- ◆ P3 study is under preparation

- ◆ CRC: P2 study is on track
- ◆ NSCLC: P2 study is on track

## CRC NSCLC

## IO Combo

- ◆ Started Opdivo (nivolumab) combo study
- ◆ Signed Keytruda (pembrolizumab) combo study alliance
- ◆ Signed Bavencio (avelumab) combo study alliance



## ADC Franchise

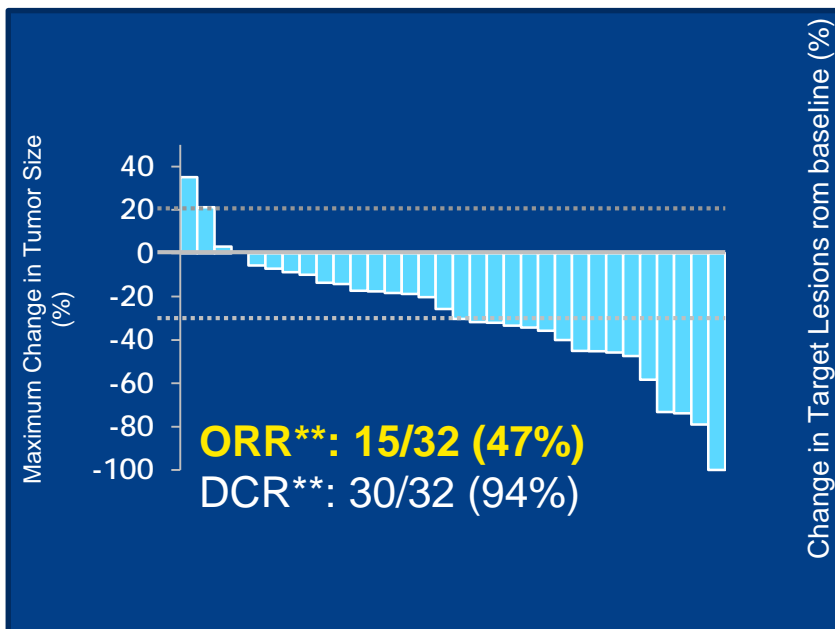
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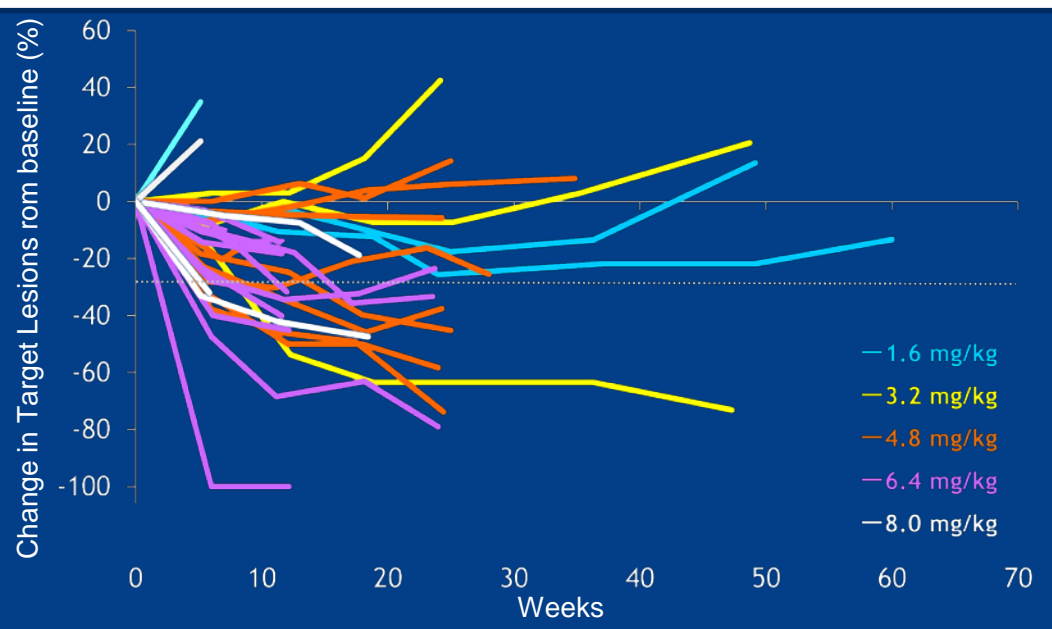
CRC: colorectal cancer, GIST: gastrointestinal stromal tumor, NSCLC: non-small cell lung cancer



## Best Percentage Change in Sum of Diameters From Baseline in Target Lesions\*



## Percentage Change in Sum of Longest Diameters



\*Analysis set: Efficacy evaluable patients with at least one scan. Baseline is defined as the last measurement taken before the first dose of study drug.

\*\*Investigators assessment. For each patient, the best percent change from baseline in the sum of diameters for all target lesions is represented by a vertical bar.

DCR = disease control rate; ORR = objective response rate.

Based on April 27, 2018 data cutoff.

- ◆ U3-1402 data resembles that of early DS-8201 data
  - U3-1402 ASCO 2018 ORR : 15/32 (47%)
  - DS-8201 ESMO 2016 ORR : 7/20 (35%)
- ◆ Validates portability of ADC technology



## Treatment-Emergent Blood and Liver related AE in $\geq 15\%$ Patients, Dose Escalation Phase (Total N = 34)\*

Preferred Term	All Grades (%)	Grade $\geq 3$ (%)
Platelet count decreased/Thrombocytopenia	23 (68)	10 (29)
Neutrophil count decreased/Neutropenia	20 (59)	9 (27)
White blood cell count decreased	18 (53)	6 (18)
Anemia	13 (38)	4 (12)

Preferred Term	All Grades (%)	Grade $\geq 3$ (%)
ALT increased	13 (38)	3 (9)
AST increased	13 (38)	3 (9)
Blood alkaline phosphatase increased	6 (18)	0

\*Analysis set: Patients who received at least one dose of U3-1402. Percentage is calculated using the number of patients in the column heading as the denominator.  
TEAE = treatment-emergent adverse event.  
Based on April 27, 2018 data cutoff.

- ◆ DLTs consisted of the followings:
  - 4.8 mg/kg: one case of Gr.4 platelet count decreased
  - 6.4 mg/kg: one case of Gr.4 platelet count decreased
  - 8.0 mg/kg: one case of Gr.4 platelet count decreased, Gr.3 AST increased, Gr.3 ALT increased  
one case of Gr.3 ALT increased
- ◆ MTD has not been reached
- ◆ Serious AE's noted in 11 (32%) of treated patients
- ◆ Majority of TEAEs were Grades 1 and 2 and toxicities have so far been manageable

## DS-8201

### ◆ Further evaluation in:

- HER2+ mBC who failed Herceptin and/or Kadcylla
- HER2 low mBC where there is no approved HER2 targeted therapy
  - ✓ Patient population is twice of HER 2 positive mBC
- HER2 expressing mGC where Herceptin is only approved HER2 targeted therapy
- HER2 expressing/mutated NSCLC/CRC where there is no approved HER2 targeted therapy

- ◆ Showed similarity to earlier DS-8201 clinical data in P1 Breast study
- ◆ P1 NSCLC study is on track
- ◆ 2nd ADC to show clinical activity: proof of DS ADC technology as validated platform



**U3-1402**



**Other ADC**

- ◆ DS-1062: P1 NSCLC study is on track
- ◆ DS-7300: Will start P1 study in FY2019
- ◆ DS-6157: disclosed target antigen=> GPR20

# Next Data Points and R&D Day



December 1-3, 2018: American Society of Hematology (ASH) @ San Diego

- ◆ AML Franchise: Multiple abstracts submitted (including Quizartinib QuANTUM-R)



December 4-8, 2018: San Antonio Breast Cancer Symposium (SABCS)

- ◆ DS-8201
  - P1 study BC HER2 positive/low update
  - Dose justification for BC P2 and P3 studies
  - **Result of ILD Adjudication Committee**
- ◆ U3-1402
  - BC P1 study update



## R&D Day

December 12, 2018 15:00 – 17:00 (plan) @ Daiichi Sankyo Headquarters

# Revised Target for 5-Year Business Plan



- ◆ **Edoxaban: Growing** in momentum beyond the initial target
- ◆ **Luitpold (US): Maintaining** a high level **growth**
- ◆ **Oncology: Enriching our pipeline value** including DS-8201
  
- ◆ **Pain Business (US):** Difficult to achieve the initial target
- ◆ **Japan Business:** Future business environment getting severe



**Difficult to achieve the FY2020 Target : OP 165.0 Bn JPY**

- ◆ Established ADC technology as a platform technology
  - DS-8201: Accumulated promising clinical data
  - U3-1402: Disclosed promising preliminary clinical data
  - Increasing expectation on other ADCs



## ADC Franchise

TA-MUC1

DS-7300  
B7-H3

U3-1402  
HER3

DS-8201  
HER2

DS-6000

DS-6157  
GPR20

DS-1062  
TROP2

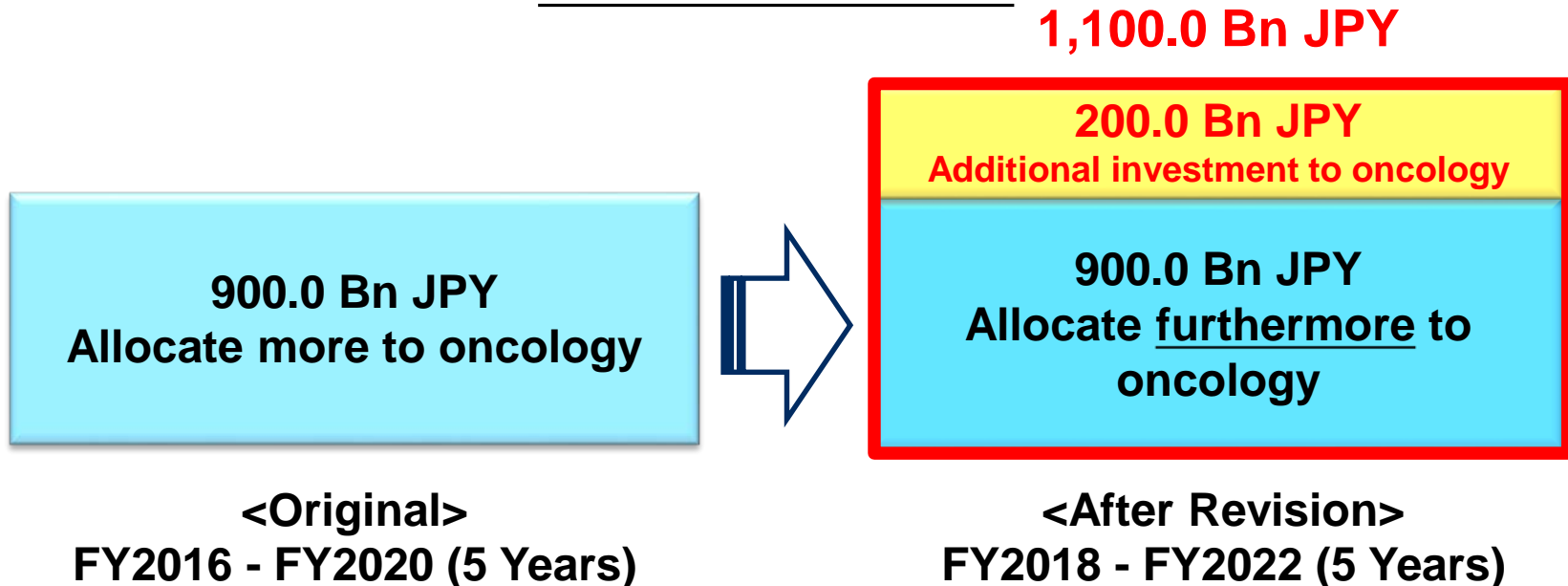
Next-  
Gen  
ADC

# Oncology Business: Increase Investments

FY2018 - FY2022 (5 Years)

- ◆ R&D Investments: 1.1 Tn JPY
  - Prioritize the investments to maximize the potential of ADC franchise
- ◆ Capital Exp. to enhance oncology: 25.0 Bn JPY or more

## R&D Investments



# Oncology Business: Revenue Target

◆ Expand the future oncology revenue by accelerating and enhancing the investments

## <Original>

Oncology Business:  
Revenue

FY2020: 40.0 Bn JPY  
FY2025: 300.0 Bn JPY

Value of late-stage pipeline

FY2020:  
3-5 products  
with peak-sales of more  
than 100.0 Bn JPY each

40.0  
Bn JPY

FY2020

Oncology  
Revenue  
150.0  
Bn JPY

FY2022

Value of late-stage  
pipeline

FY2022:

Total expected  
revenue at peak  
: 500.0 Bn JPY  
or more

Oncology  
Revenue  
500.0  
Bn JPY

FY2025

# 5-Year Business Plan (Original)

- ◆ Grow beyond FY2017 LOE of olmesartan
- ◆ Establish a foundation of sustainable growth

## 2025 Vision

**Global Pharma Innovator  
with Competitive  
Advantage in Oncology**

Revenue  
910.0  
Bn JPY

Revenue  
1,100.0  
Bn JPY

OP  
165.0  
Bn JPY

OP  
78.0  
Bn JPY

FY2018  
Forecast

FY2020  
Target

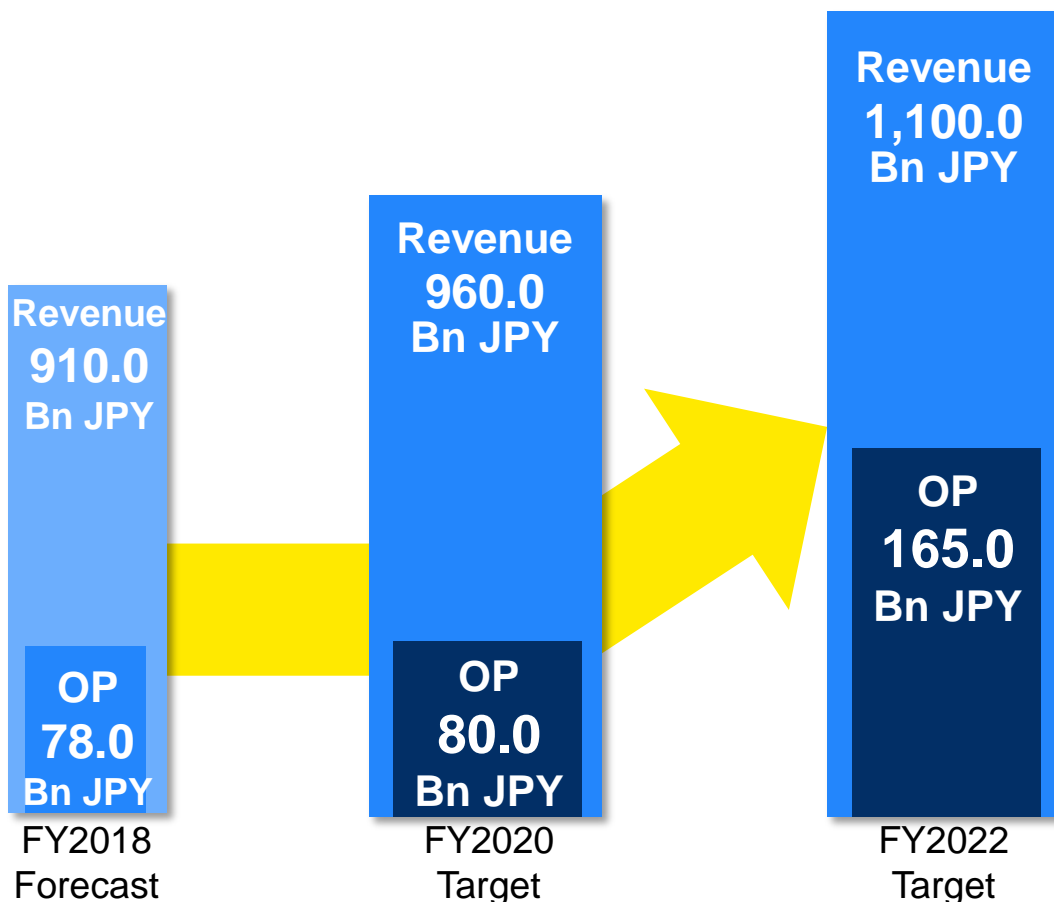
- Increase value of late-stage pipeline  
3-5 products with peak-sales of more than 100.0 Bn JPY each
- ROE: 8% or more
- Shareholder Returns  
(FY2016 - FY2020)
  - Annual ordinary dividends : 70 JPY or more
  - Flexible acquisition of own shares
  - Total return ratio: 100% or more

# Revised Target for 5-Year Business Plan

- ◆ Revised FY2020 Target
- ◆ Achieve original OP target two years behind

## 2025 Vision

**Global Pharma Innovator  
with Competitive  
Advantage in Oncology**



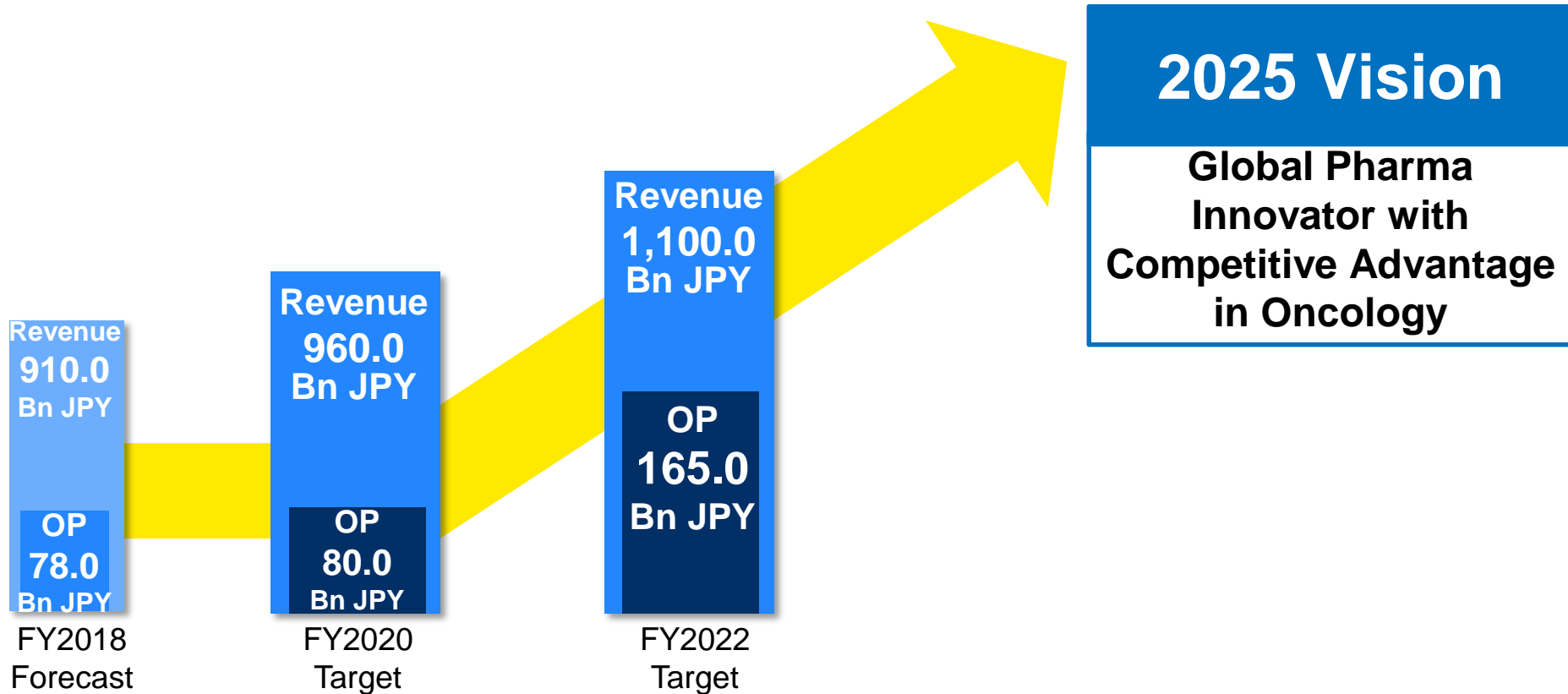
- Increase value of late-stage pipeline  
Total expected revenue at peak  
: **500.0 Bn JPY or more**
- ROE: 8% or more
- Shareholder Returns  
(FY2016 - FY2022)
  - Annual ordinary dividends  
: **70 JPY or more**
  - **Flexible** acquisition of own shares
  - Total return ratio: **100% or more**

## Shareholder Returns Policy: FY2016 - FY2022



- ◆ Annual ordinary dividends: 70 JPY dividend in FY2016 and FY2017
- ◆ Acquisition of own shares: 50.0 Bn JPY in both FY2016 and FY2017
- ◆ Total return ratio : 100% or more (extended to FY2022)

\*Total return ratio = ( Dividends + Total acquisition costs of own shares) / Profit attributable to owners of the company



## ◆ Enhance investments and maximize oncology business

R&D investments: **1.1 Tn JPY**, Oncology revenue: **500 Bn JPY** in FY2025

## ◆ Commitment of FY2022

OP **165 Bn JPY**, ROE **8%** or more, Value of late-stage pipeline\* **500 Bn JPY** or more, Total return ratio **100%** or more

\* Total expected revenue at peak



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