

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

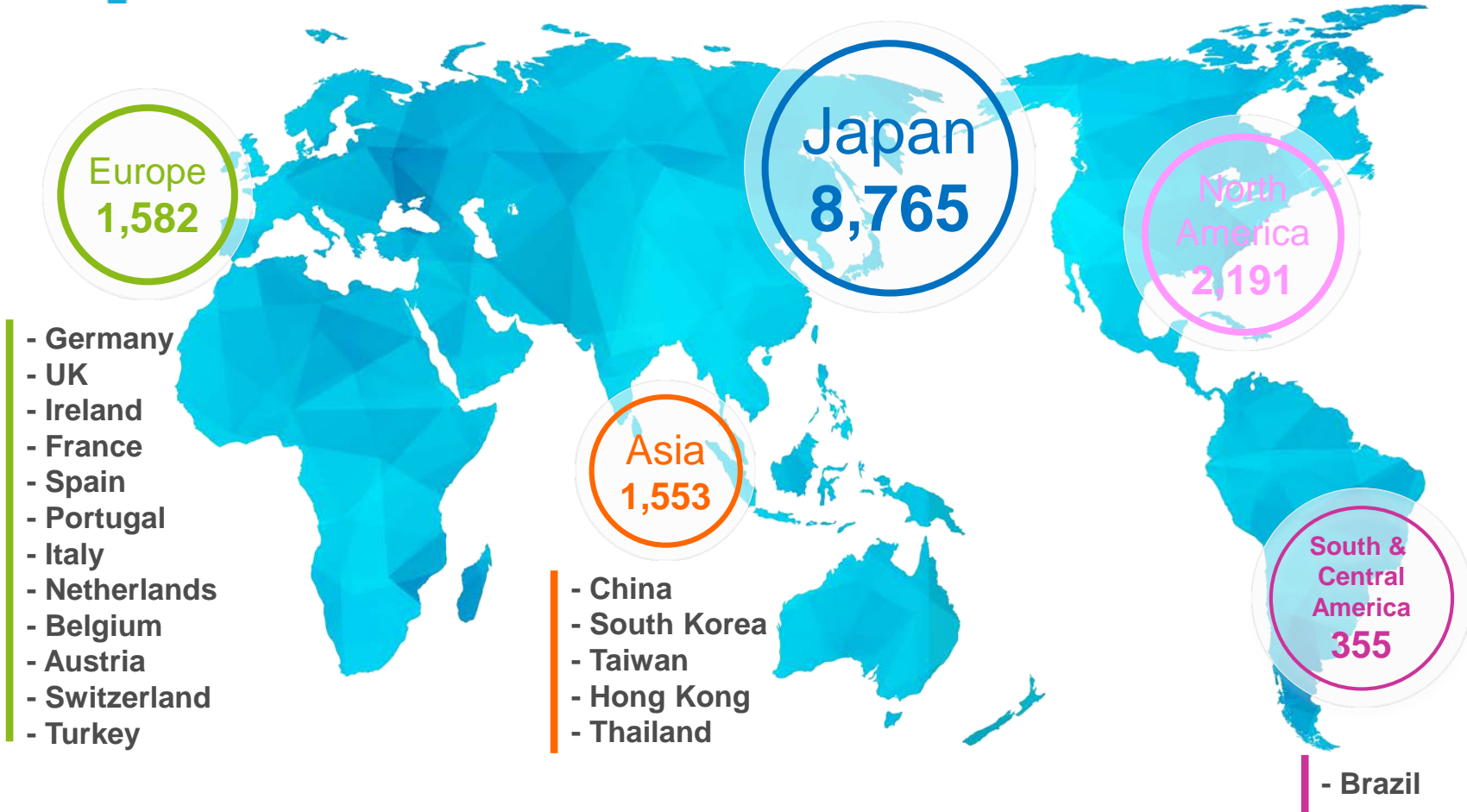


Employees and Bases

As of Mar. 2018

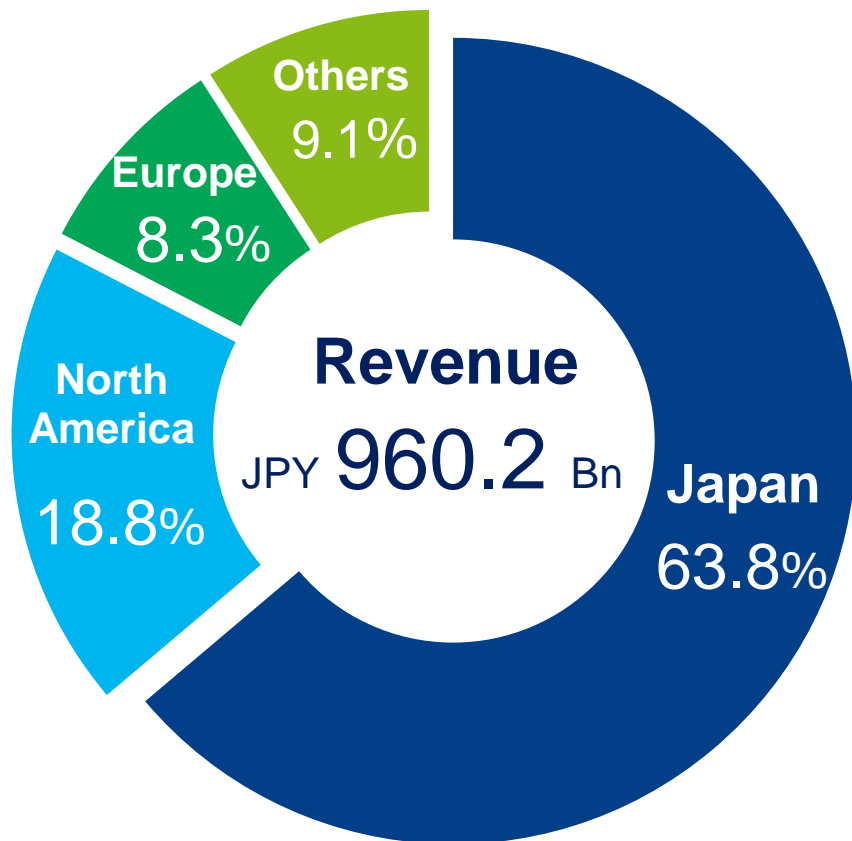


14,446 Worldwide Employees



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%
Operating Profit	76.3	7.9%
Profit before Tax	81.0	8.4%
Profit attributable to owners of the Company	60.3	6.3%

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%
ROE	5.2%

◆ 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 bright yellow on the left to a light green on the right, with a slight dip in the middle.

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*

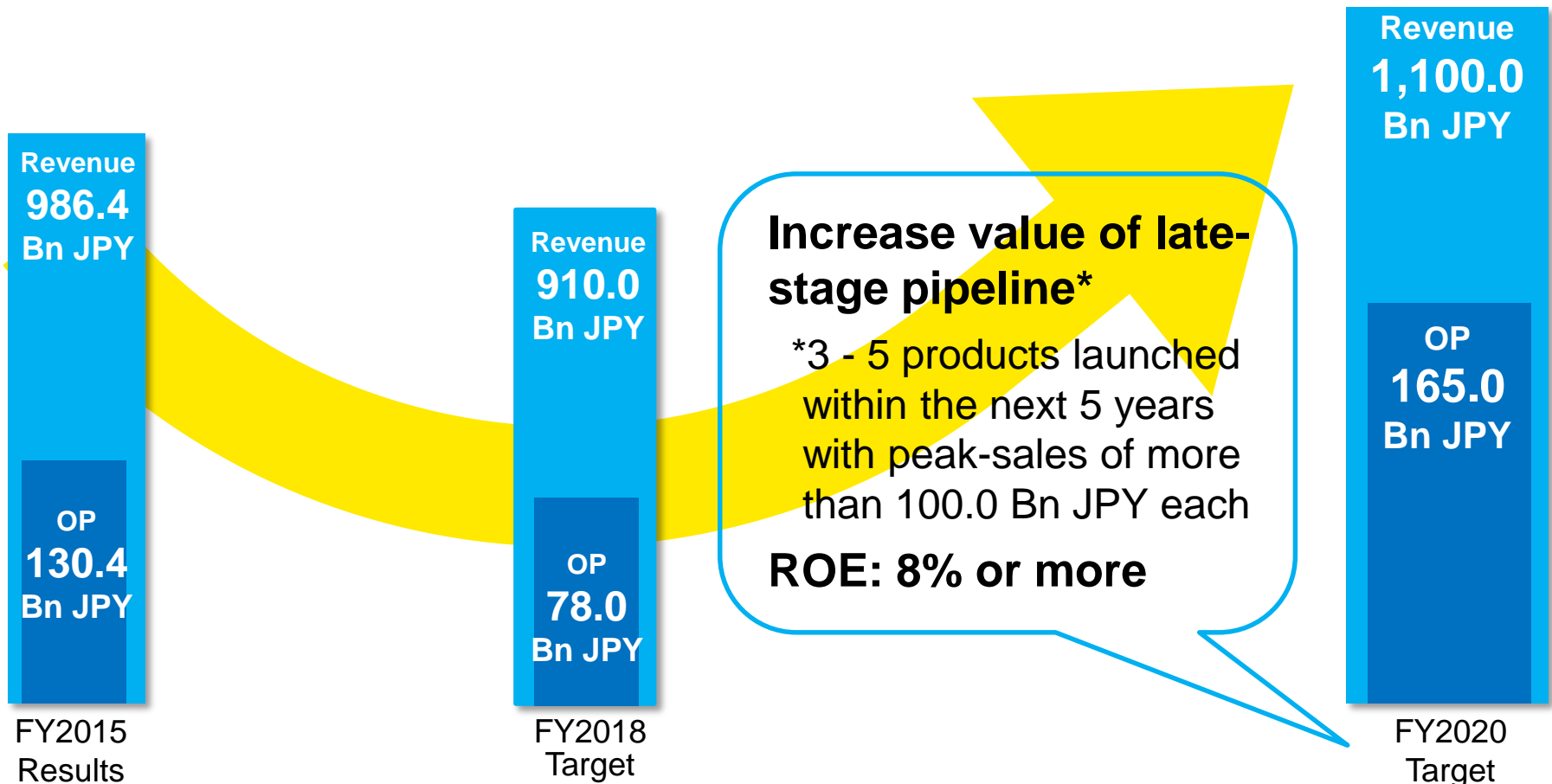
5-Year Business Plan (FY2016 - FY2020)

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

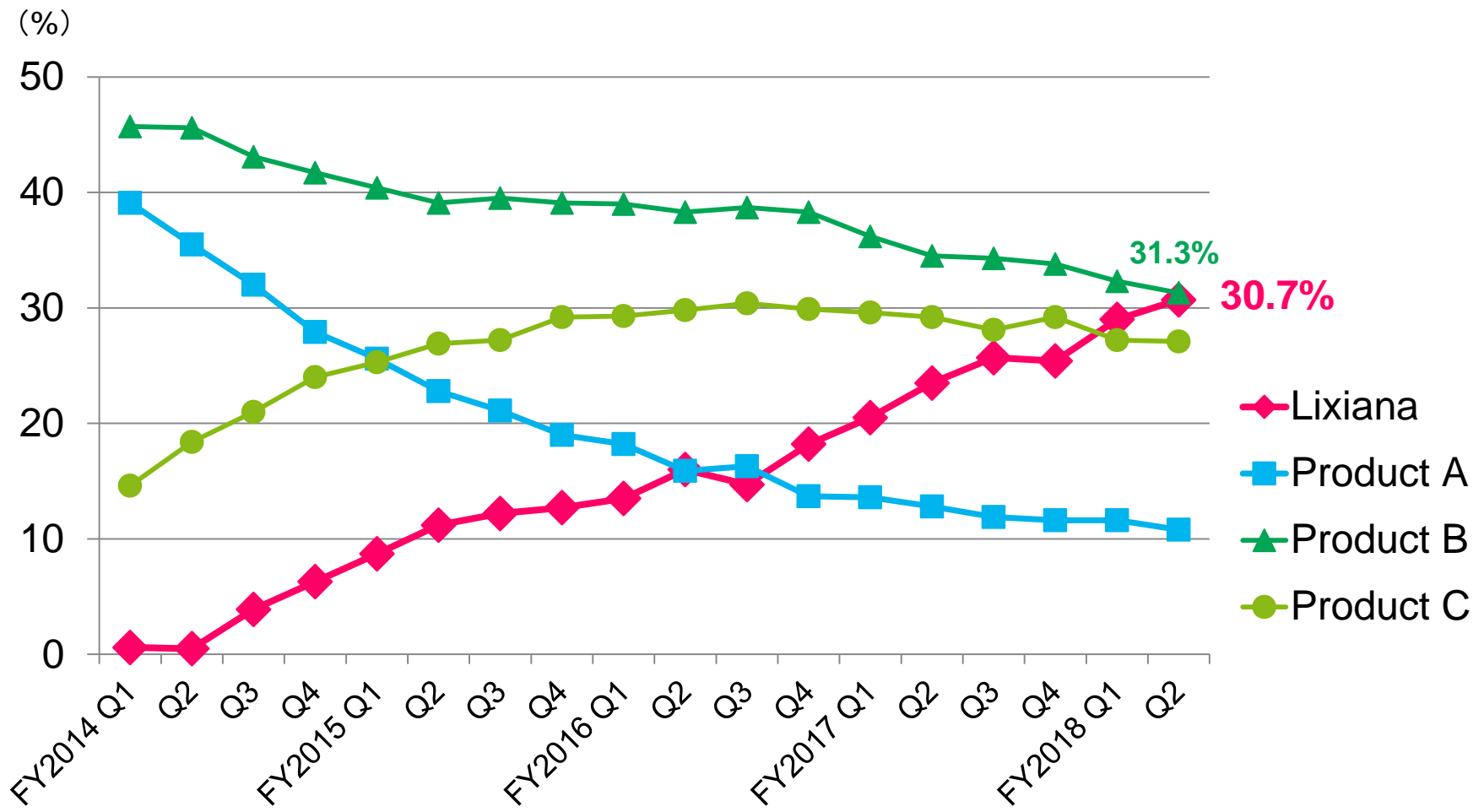
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Edoxaban: Growth in Japan



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

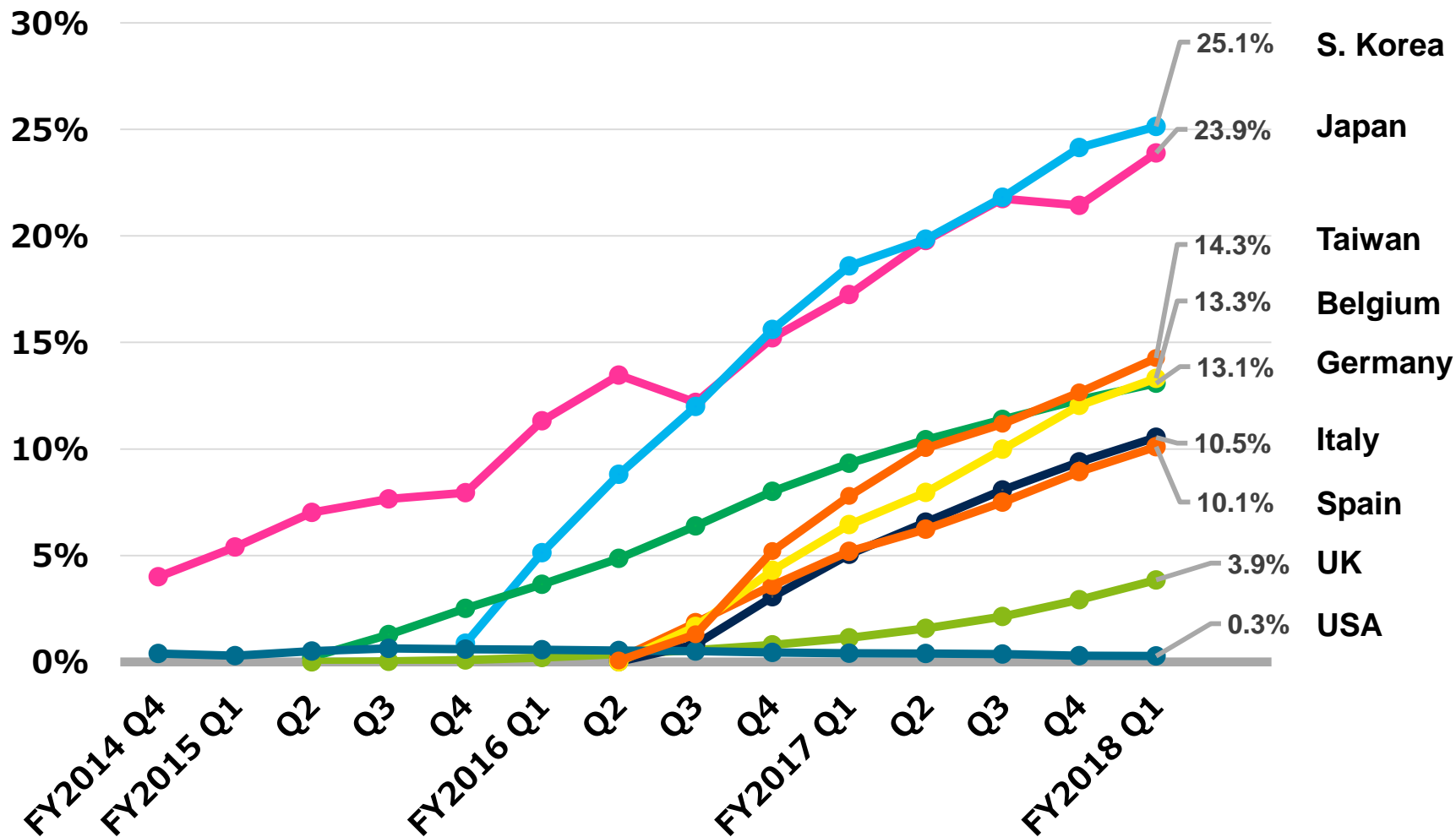


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Edoxaban: Growth in Each Country/**Region**



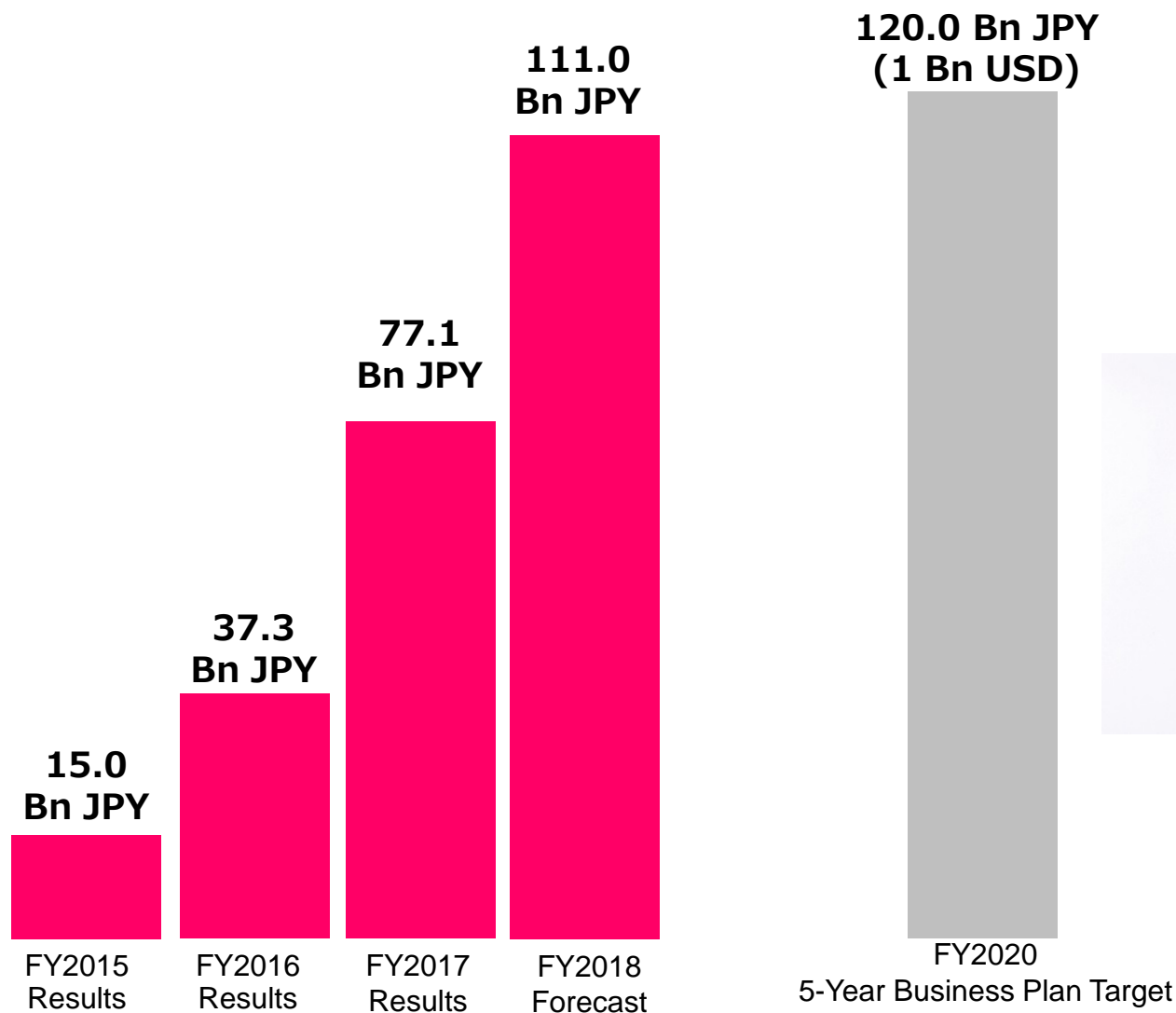
Edoxaban volume (DoT) % share of DOAC markets over time



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

Strategic Targets

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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



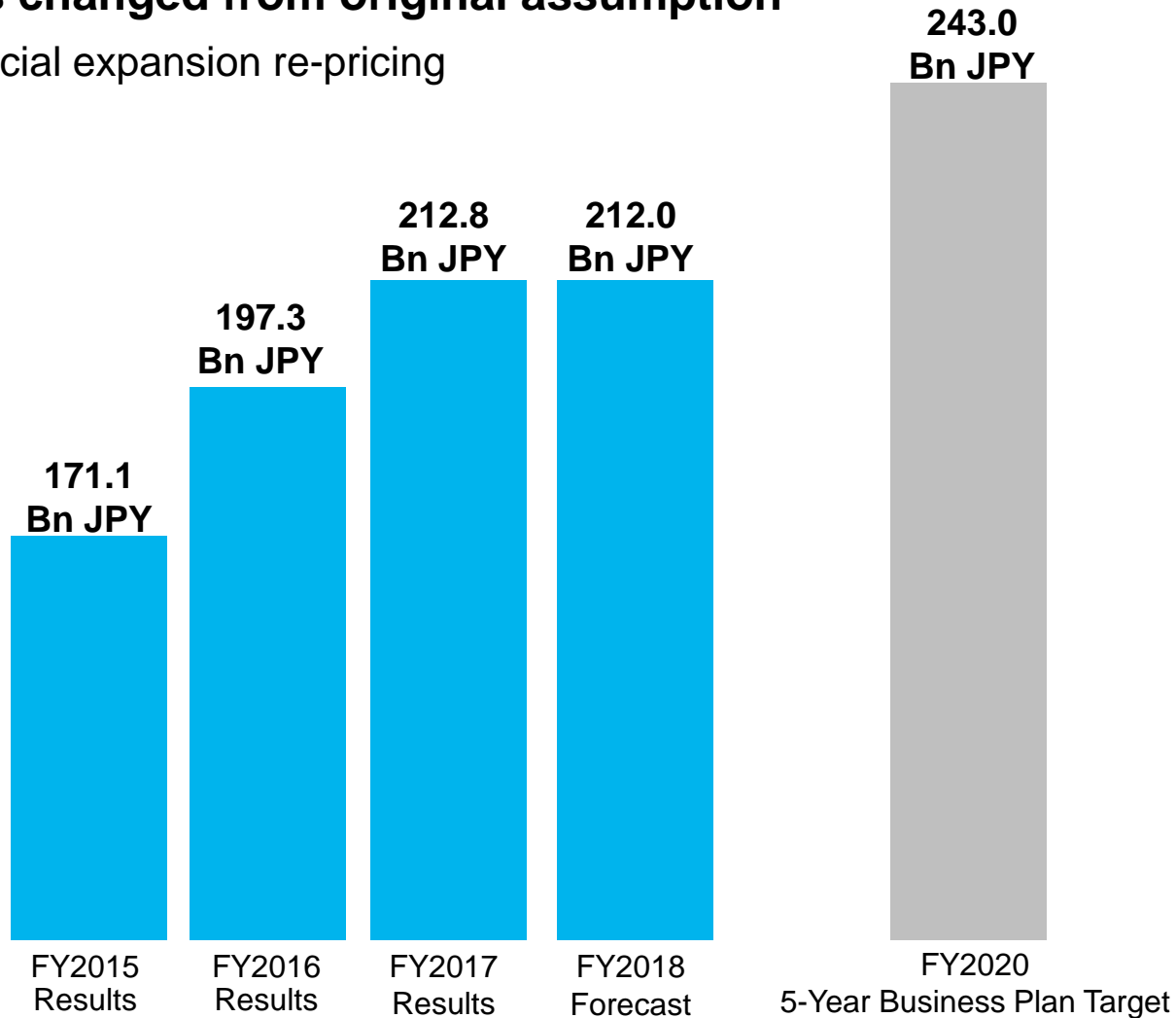
Tenelia

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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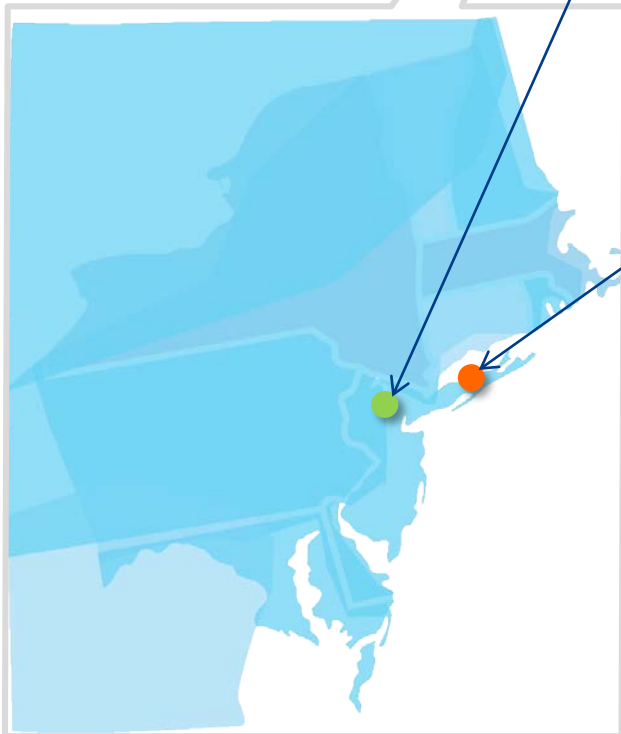
Two Business Units in US



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)

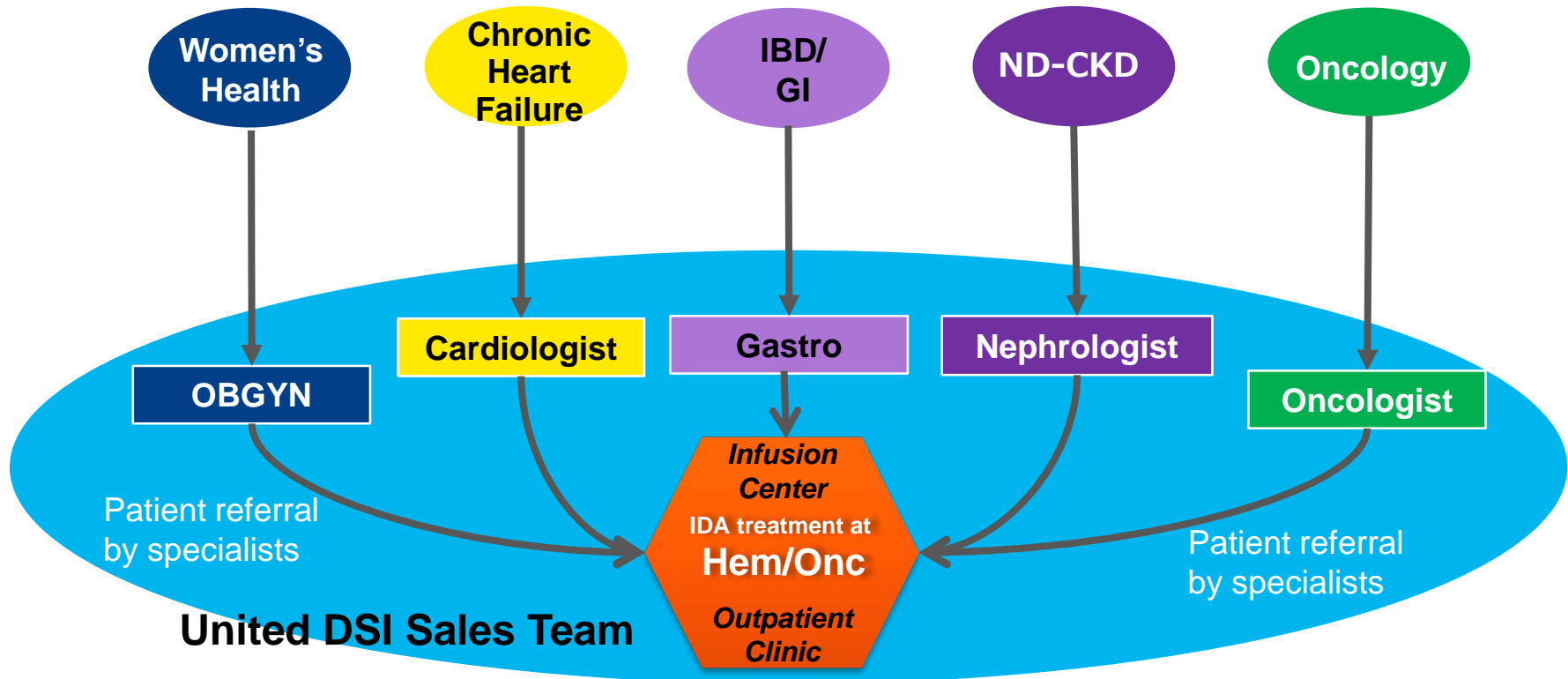
FY2018 revenue forecast: US\$ 1,026 Mn

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

- Iron Injectable Franchise
- Generic Injectable Franchise

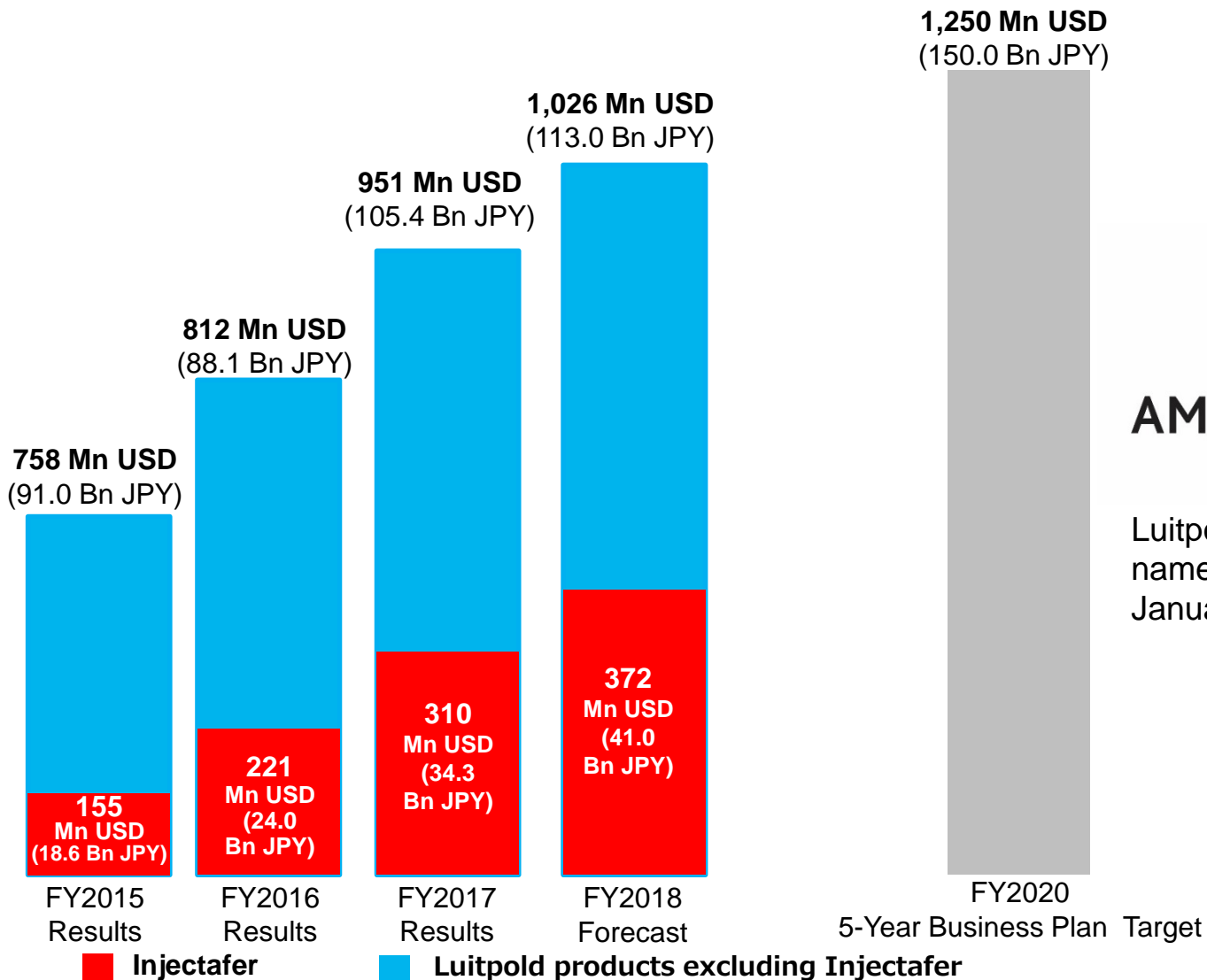
Injectafer: Sales Team

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



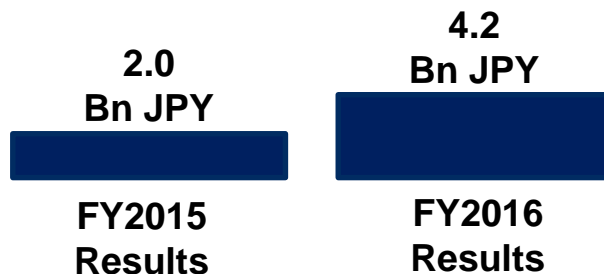
Luitpold will change the company name to “American Regent” in January 2019.

◆ CL-108

- Decided to return all of rights regarding CL-108

◆ Mirogabalin

- Did not meet the primary efficacy endpoint



> ~~100 Bn JPY~~
in FY2020



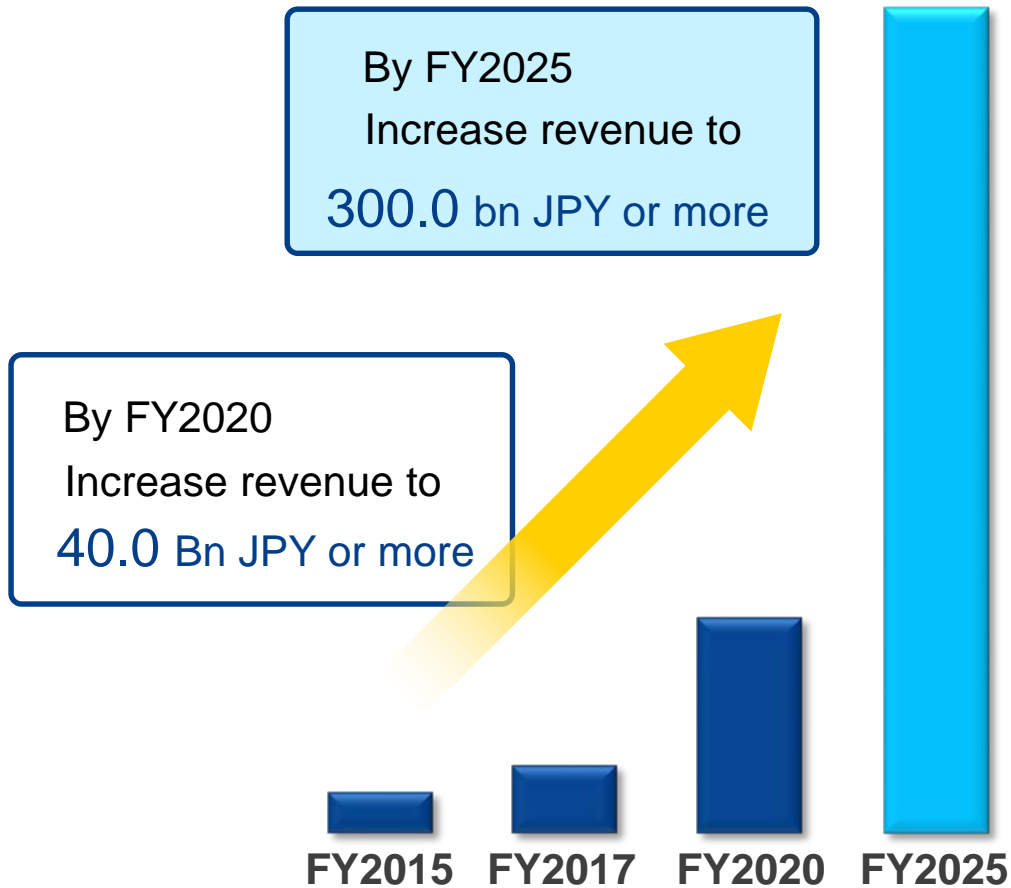
FY2020
Target

Strategic Targets

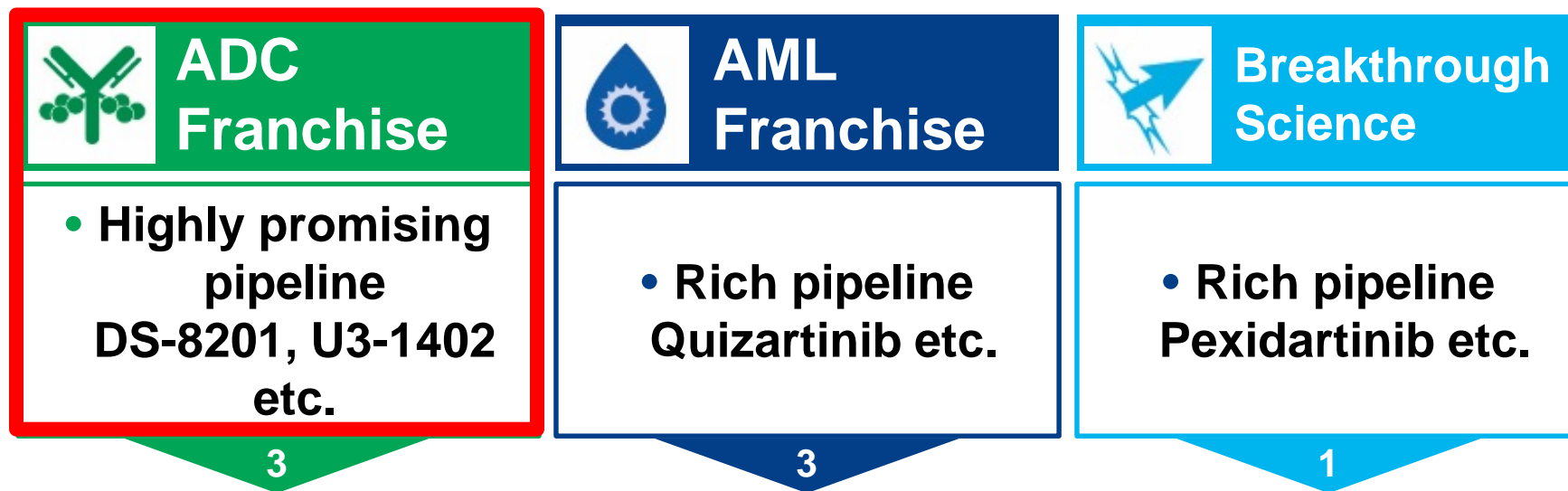
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Oncology Business: FY2020 Target



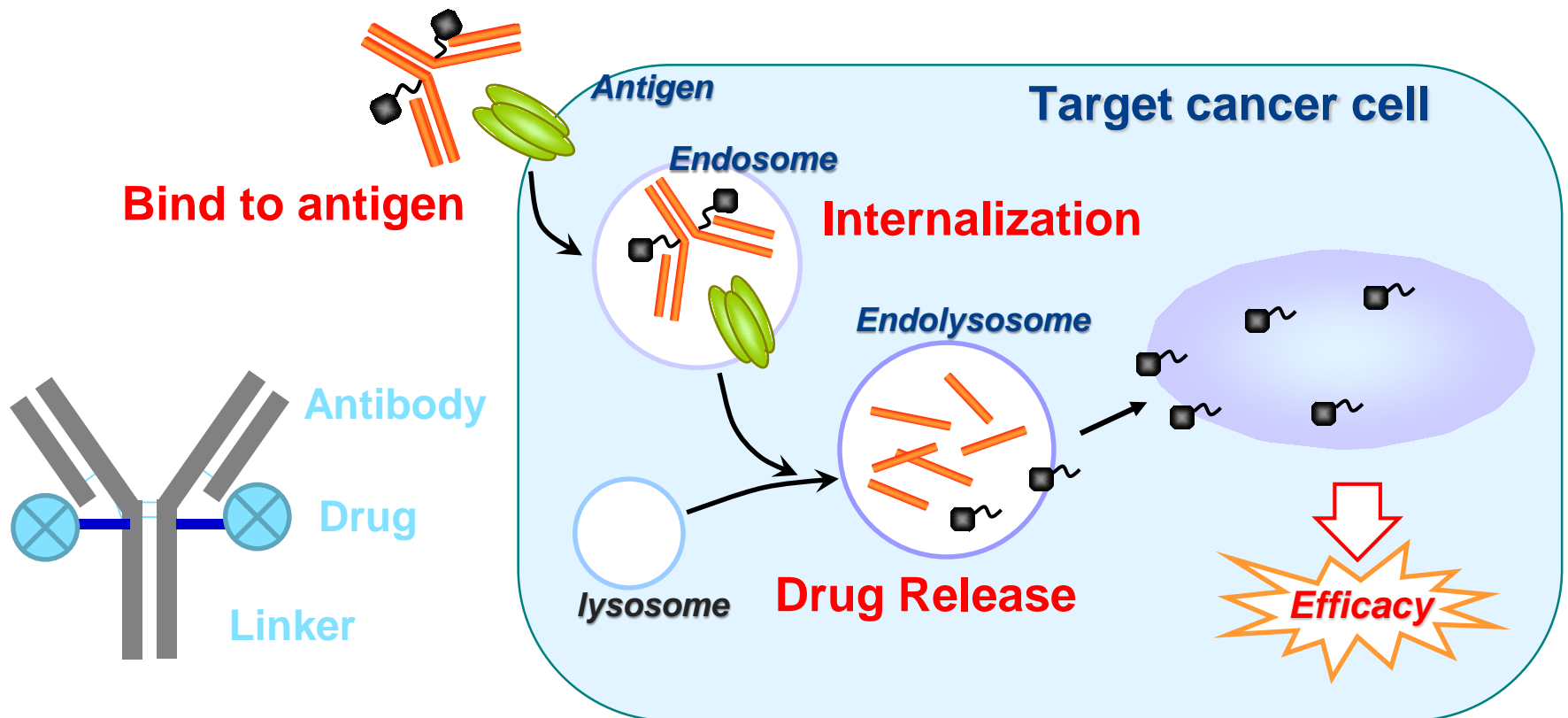
- ◆ Built 3 pillars of oncology business, ADC Franchise, AML Franchise and Breakthrough Science, and focus investments on the pillars

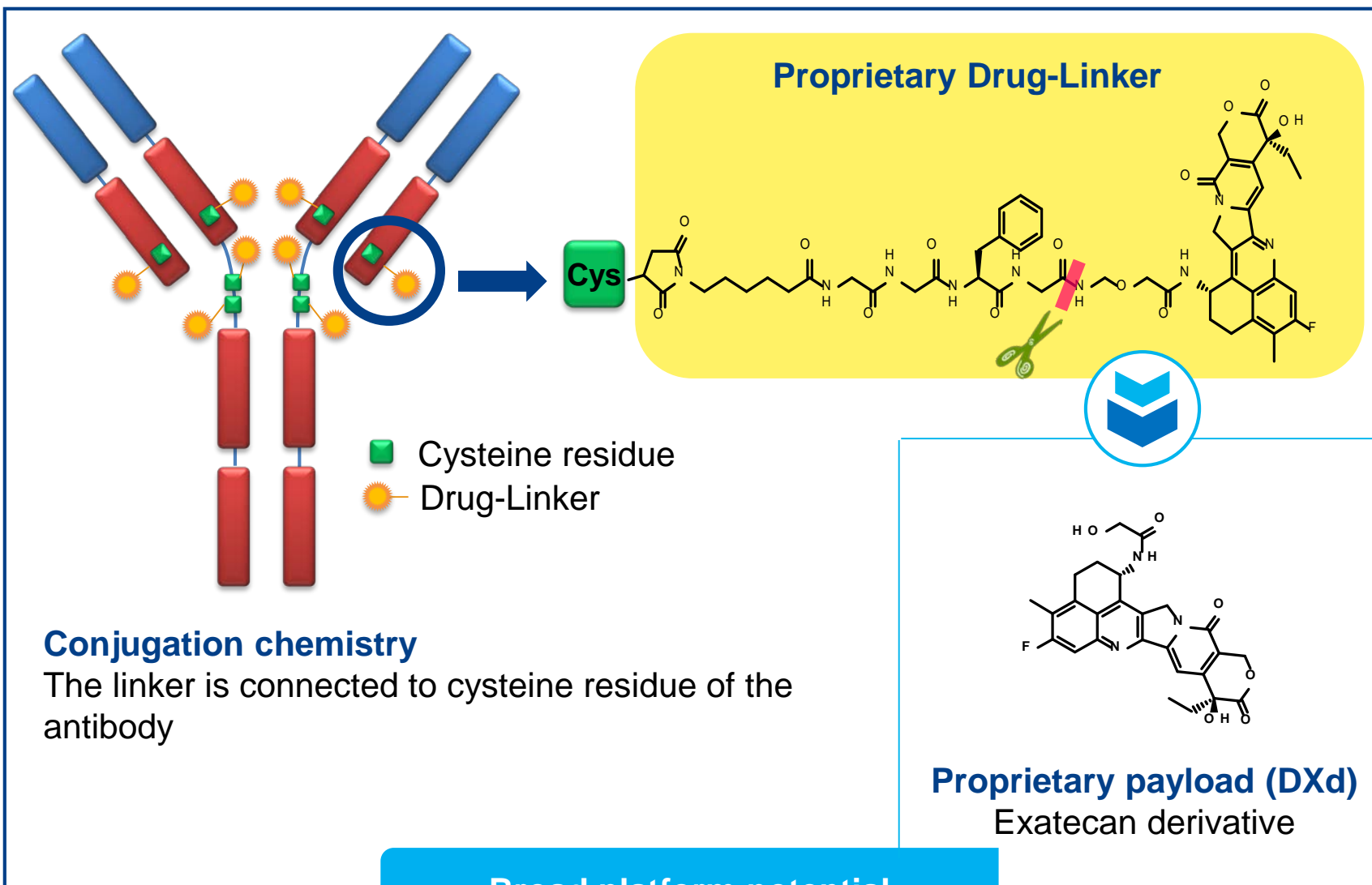


Cancer Enterprise
2025 Vision

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







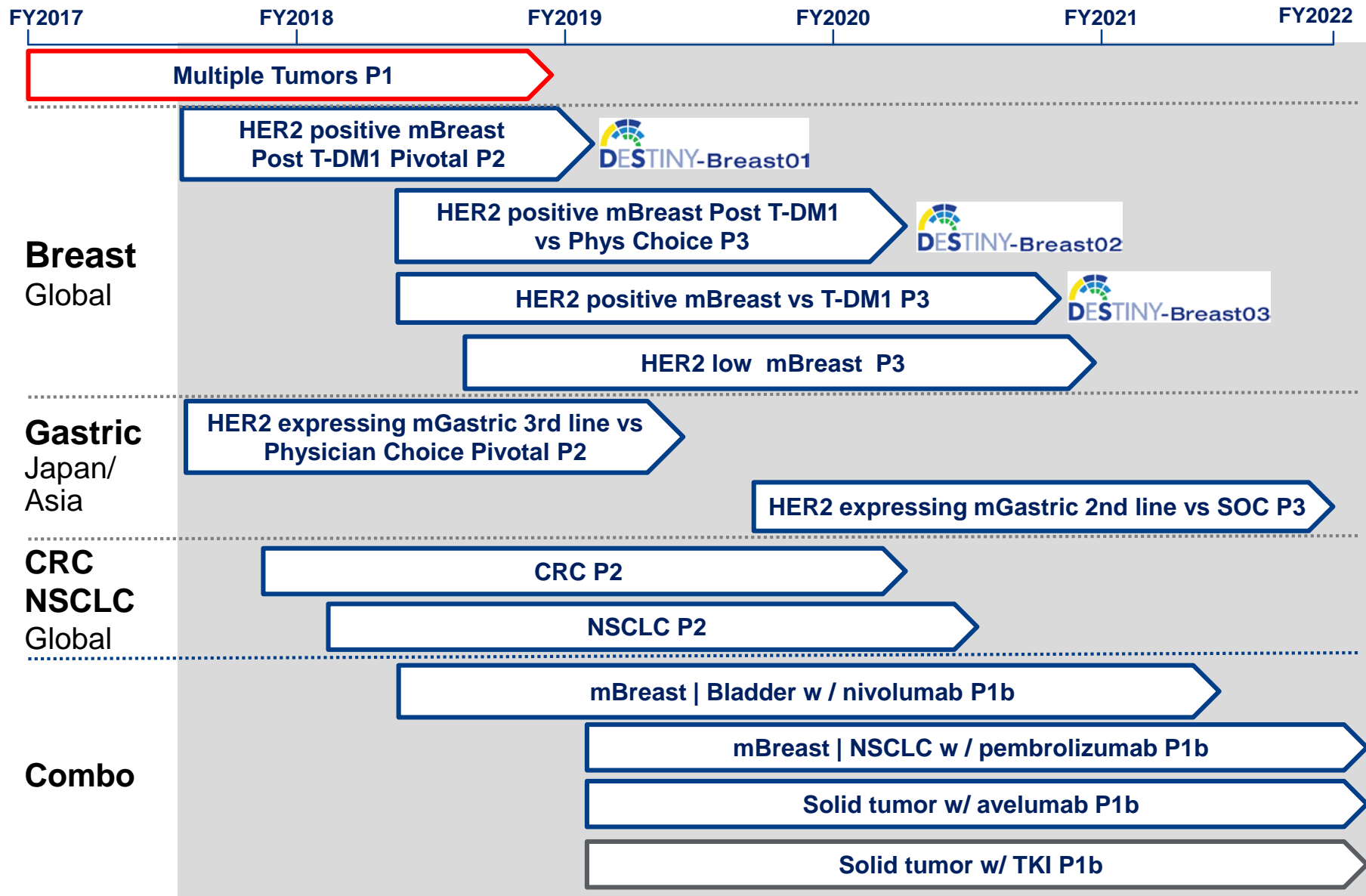
ADC Franchise

Clinical stage

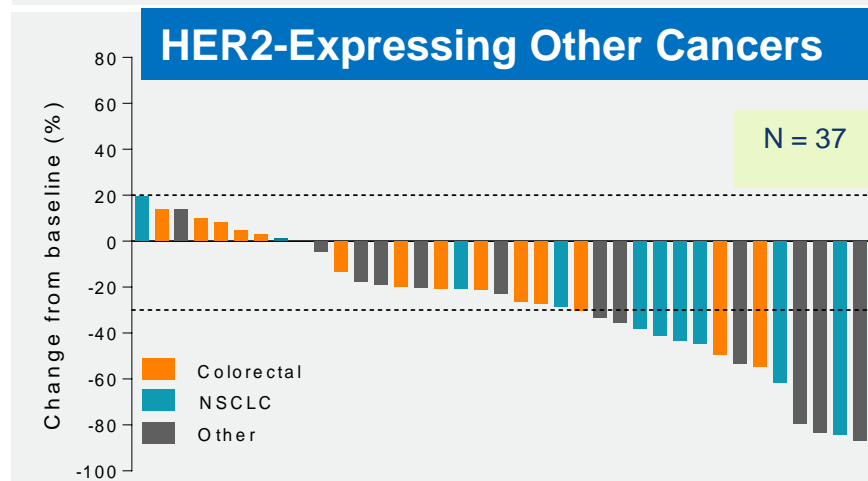
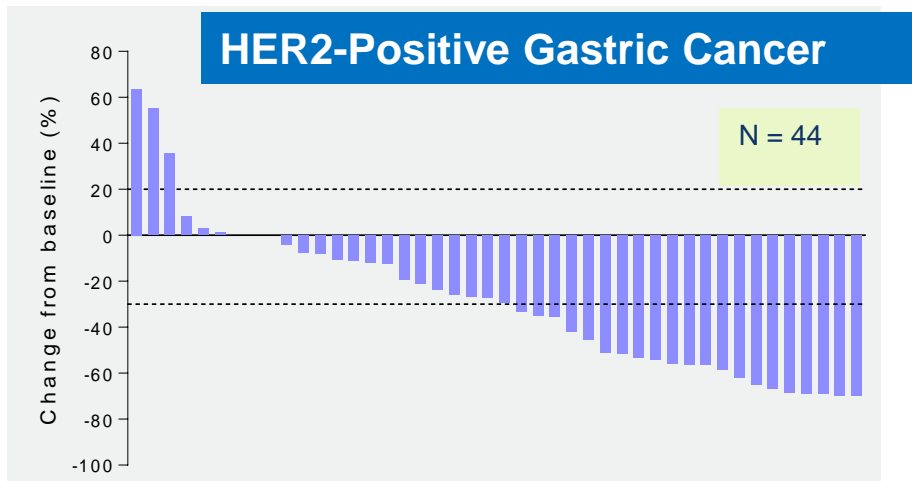
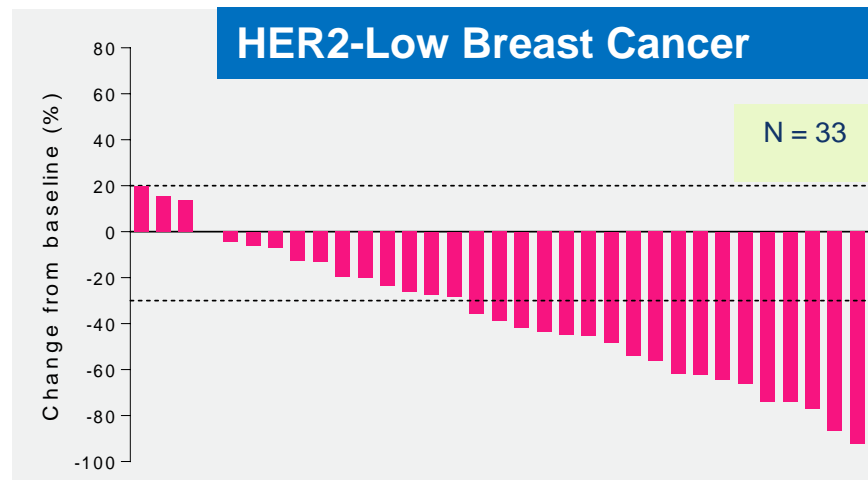
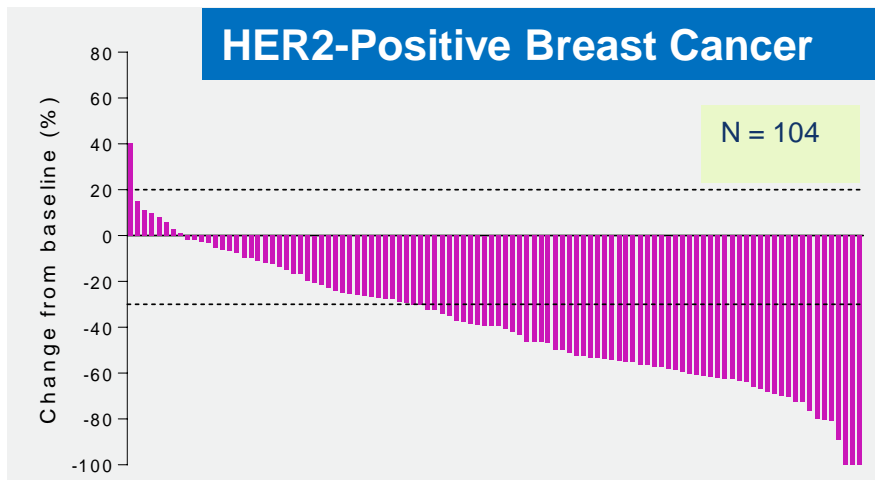
	Project (Target)	Potential Indication	Discovery	Pre-Clinical	Phase 1	Pivotal
1	DS-8201 (HER2)	Breast, Gastric, CRC, NSCLC				
2	U3-1402 (HER3)	Breast, NSCLC				
3	DS-1062 (TROP2)	NSCLC				
4	DS-7300 (B7-H3)	Solid tumor				
5	DS-6157 (GPR20)	GIST				
6	DS-6000 (undisclosed)	Renal, Ovarian				
7	(TA-MUC1)	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 ≥ 1 postbaseline scan. Dotted lines denote 20% increase and 30% reduction in tumor size, respectively.

*Confirmed response includes subjects who had ≥ 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
Confirmed ORR* % (n/N)	54.5% (54/99)	50.0% (17/34)	43.2% (19/44)	38.7% (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)
DOR				
Median (95% CI), months	NR	11.0 (NA)	7.0 (NA)	12.9 (2.8, 12.9)
PFS				
Median , (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 ≥ 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 ≥ 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 ^a (N = 259)		
	Any Grade, n (%)	Grade ≥ 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.

^aAll 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.

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

- ◆ Adverse events were generally of low grade
- ◆ The most frequent AEs Grade ≥ 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 ^a (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

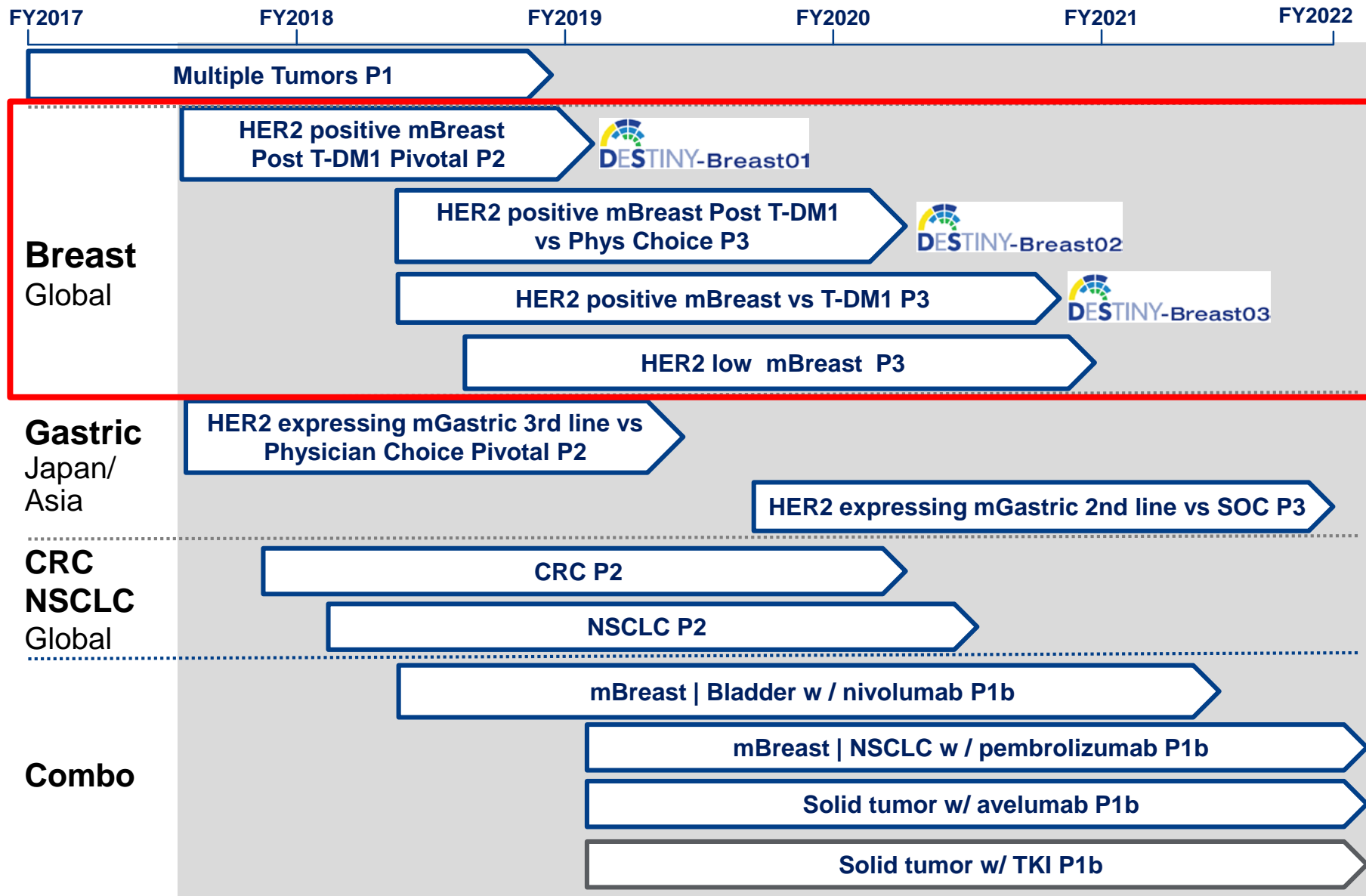
Data cutoff, August 10, 2018.

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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

1st line

Herceptin (Trastuzumab) (+ Perjeta (Pertuzumab))



2nd line

Kadcyla (T-DM1)

HER2 positive mBreast
vs T-DM1 P3



Started



3rd line

Physician's Choice

HER2 positive mBreast
Post T-DM1 Pivotal P2



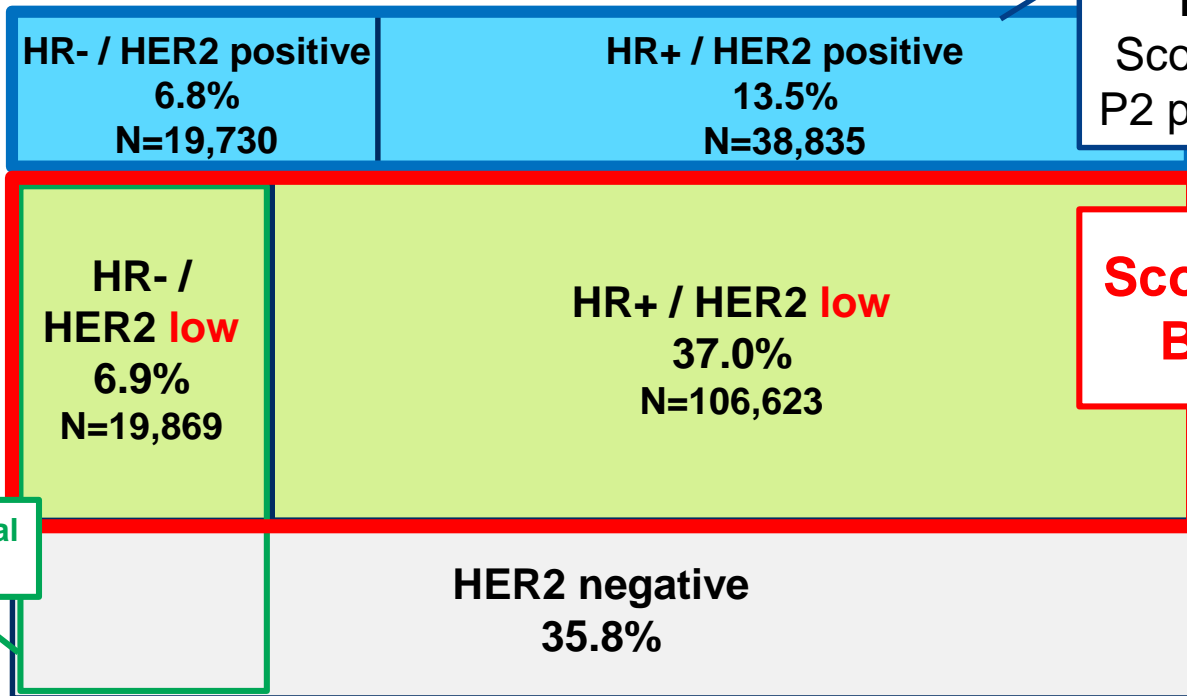
Enrollment Completed

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

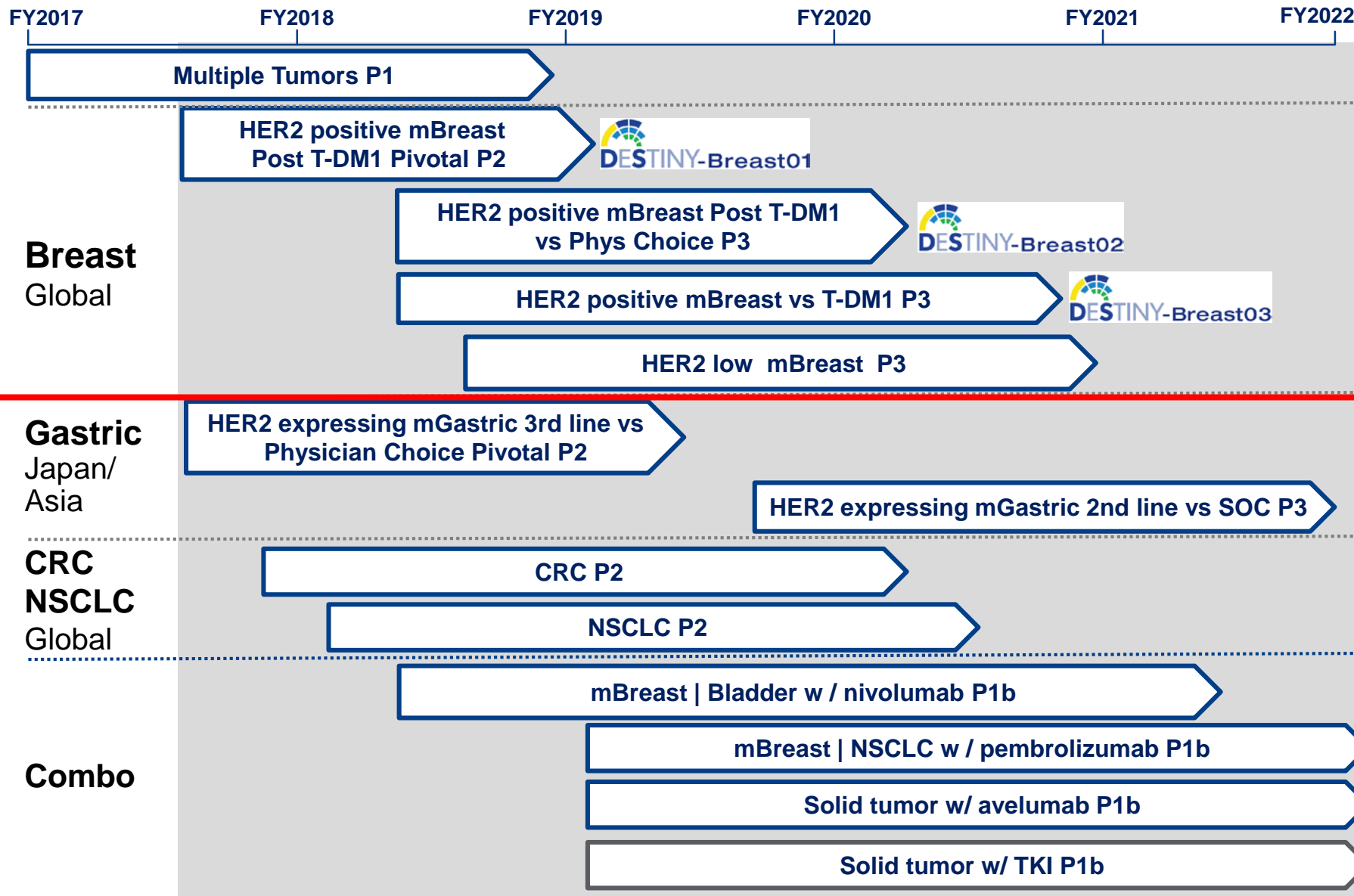
**Scope of HER2 Low
BC P3 Program**

**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

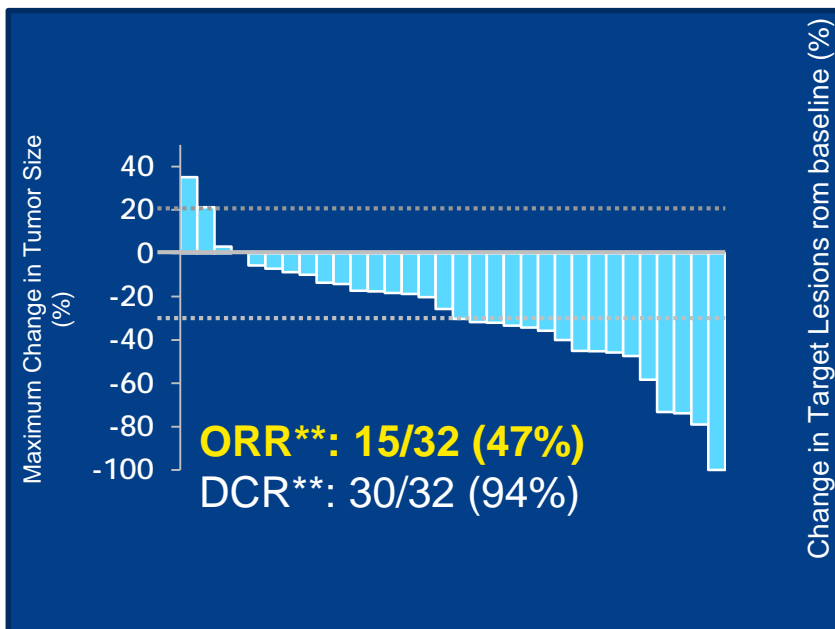
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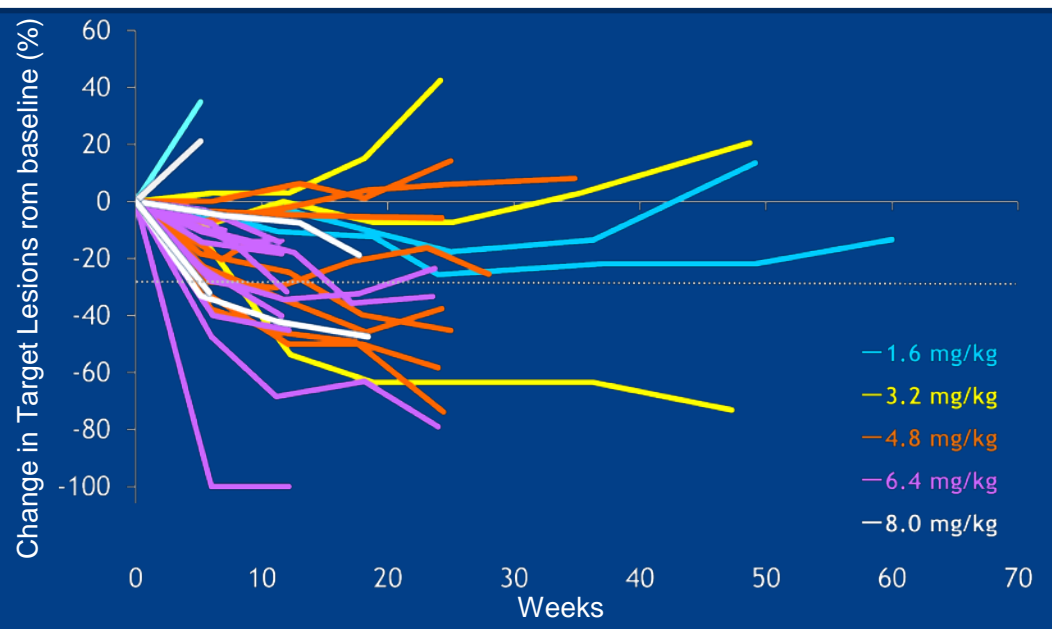
CRC: colorectal cancer, GIST: gastrointestinal stromal tumor, NSCLC: non-small cell lung cancer



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 ≥ 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 ≥ 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

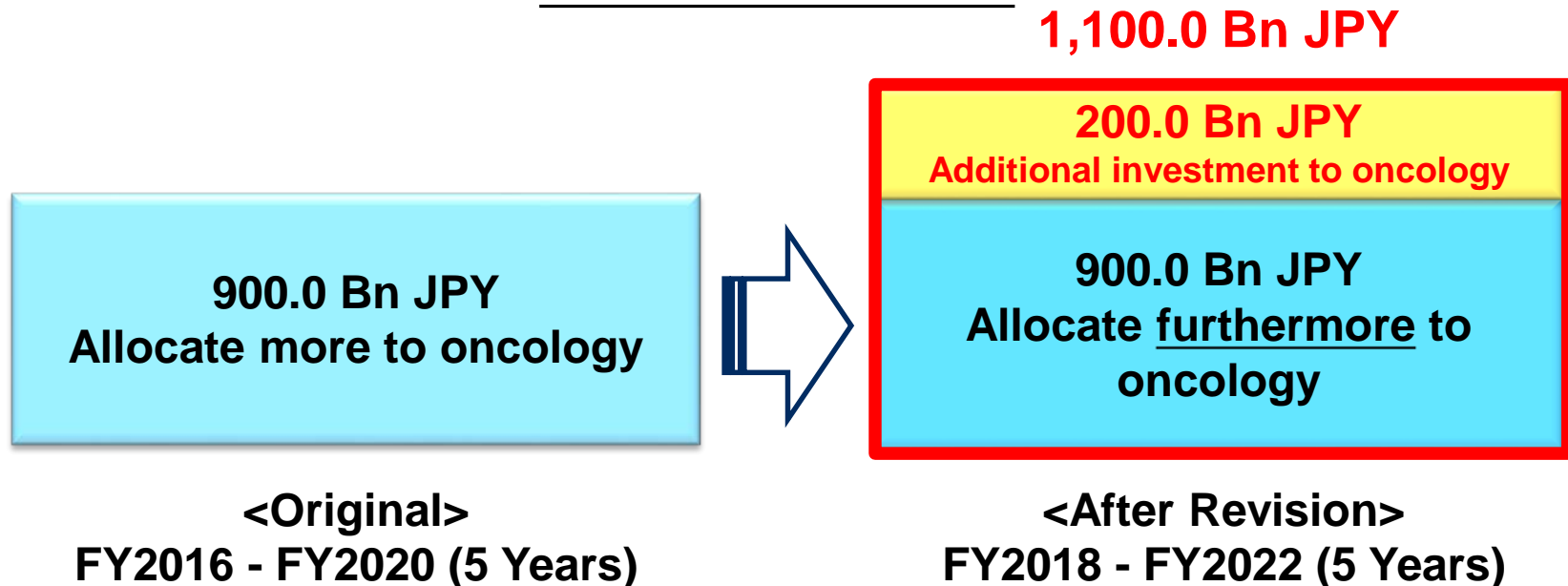
Next-
Gen
ADC

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

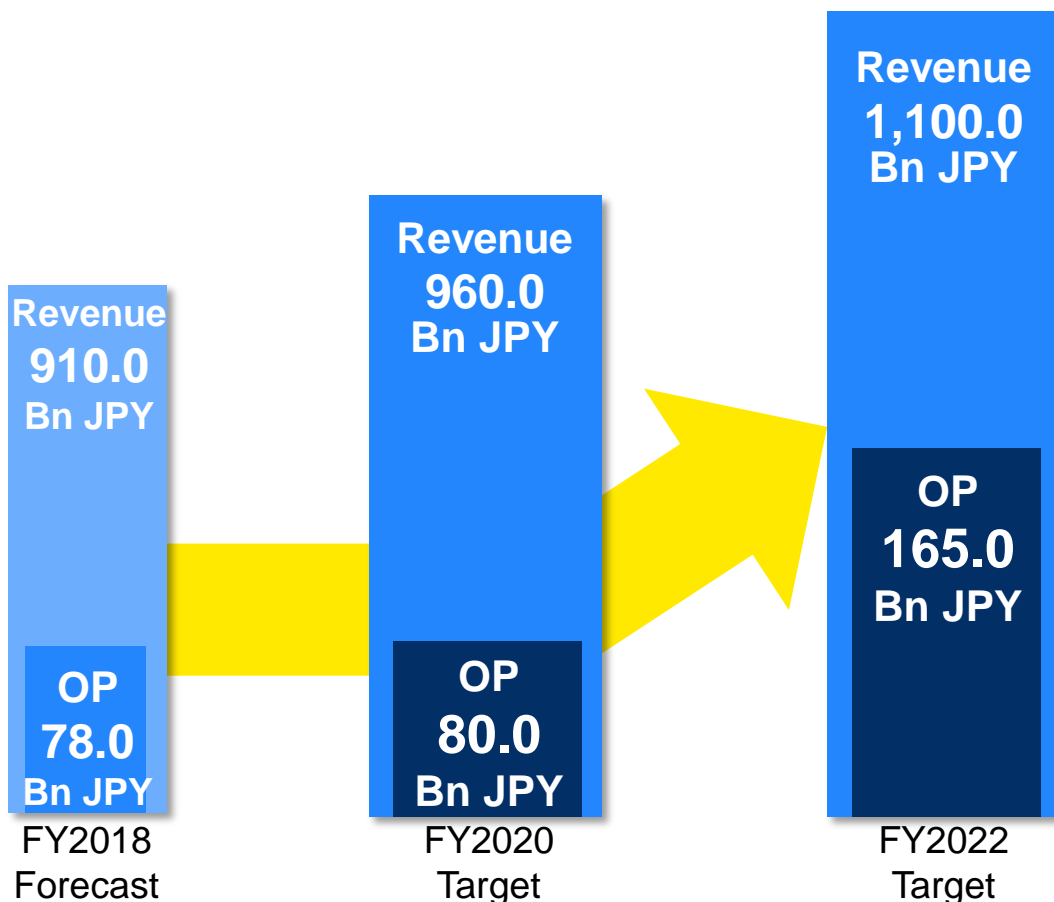
- **Increase value of late-stage pipeline**
3-5 products with peak-sales of more than 100.0 Bn JPY each
- **ROE: 8% or more**
- **Shareholder Returns**
(FY2016 - FY2020)
 - Annual ordinary dividends : 70 JPY or more
 - Flexible acquisition of own shares
 - Total return ratio: 100% or more

Revised Target for 5-Year Business Plan

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

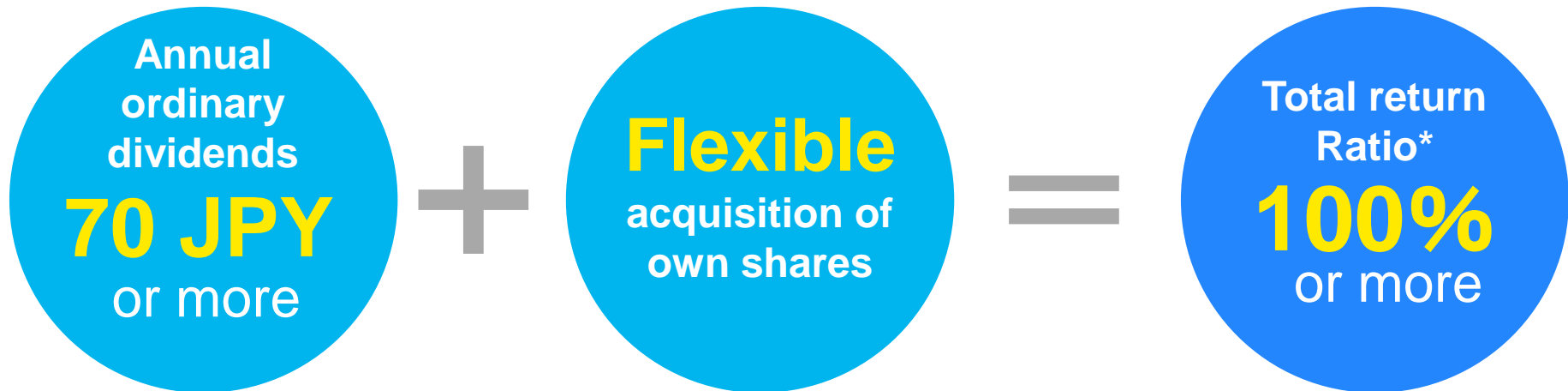
2025 Vision

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



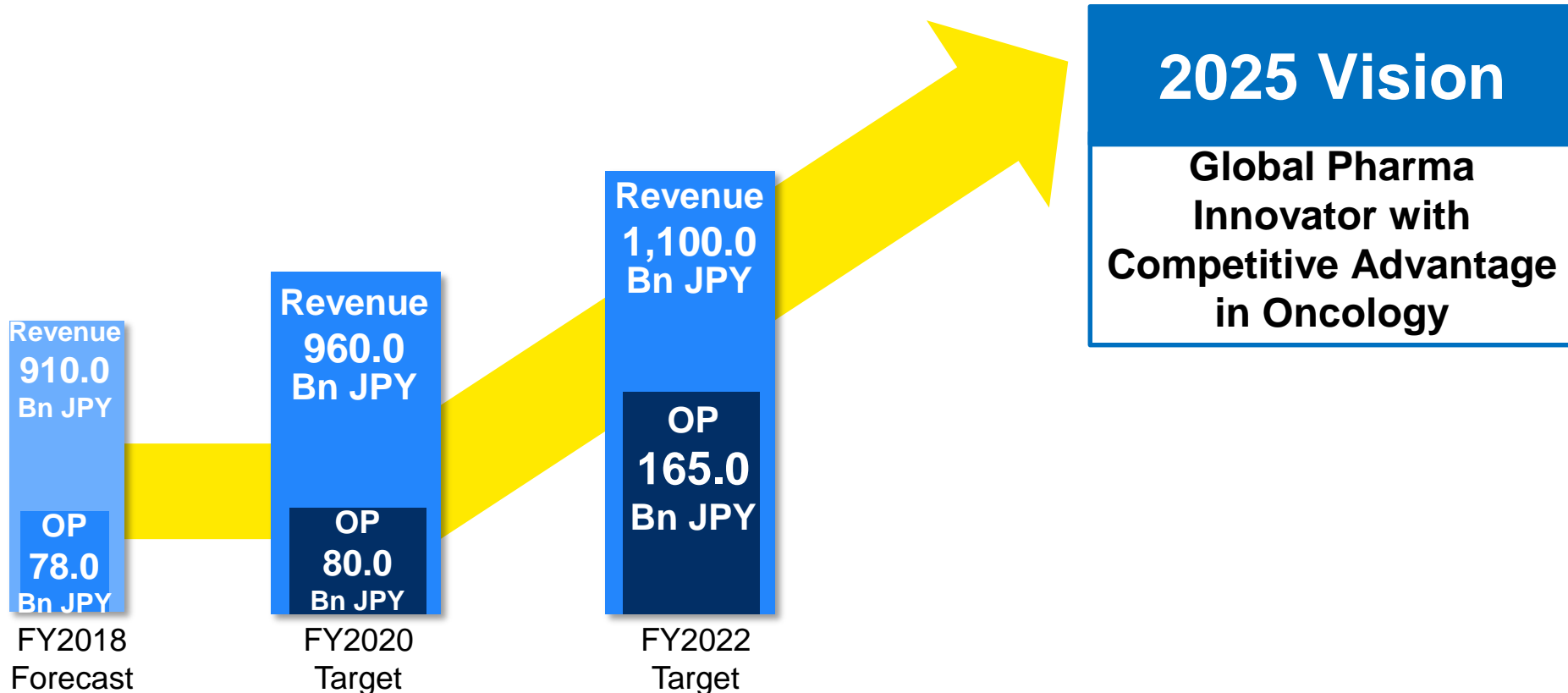
- Increase value of late-stage pipeline
Total expected revenue at peak
: **500.0 Bn JPY or more**
- ROE: 8% or more
- Shareholder Returns
(FY2016 - FY2022)
 - Annual ordinary dividends
: **70 JPY or more**
 - **Flexible** acquisition of own shares
 - Total return ratio: **100% or more**

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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