Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

DAIICHI SANKYO CO., LTD

Global Pharma Innovator with Competitive Advantage in Oncology

George Nakayama, Chairman and CEO

January 7, 2019

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.

Compounds under discussion are investigational agents and are not approved by the FDA or any other regulatory agency worldwide as a treatment for indications under investigation. Efficacy and safety have not been established in areas under investigation. There are no guarantee that these compounds will become commercially available in indications under investigation.

Daiichi Sankyo takes reasonable care to ensure the accuracy of the content of this material, but shall not be obliged to guarantee the absolute accuracy, appropriateness, completeness and feasibility, etc. of the information described in this material. Furthermore, any information regarding companies, organizations or any other matters outside the Daiichi Sankyo Group that is described within this material has been compiled or cited using publicly available information or other information, and Daiichi Sankyo has not performed in-house inspection of the accuracy, appropriateness, completeness and feasibility, etc. of such information, and does not guarantee the accuracy thereof.

The information described in this material may be changed hereafter without notice. Accordingly, this material or the information described herein should be used at your own judgment, together with any other information you may otherwise obtain.

This material does not constitute a solicitation of application to acquire or an offer to sell any security in the United States, Japan or elsewhere.

The material disclosed here is for reference purposes only. Final investment decisions should be made at your own discretion.

Daiichi Sankyo assumes no responsibility for any damages resulting from the use of this material or its content, including without limitation damages related to the use of erroneous information

Highlights

- 2025 Vision
- Growth of Current Core Businesses
- Exciting ADC Pipeline
- Revised Target for 5-Year Business Plan

2025 Vision

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 and 6 Strategic Targets

2025 Vision

5-Year Business Plan

Transformation toward 2025 Vision

Establish a Foundation of Sustainable Growth: Six Strategic Targets

- Grow Edoxaban
- Grow as No.1 Company in Japan
- Expand US Businesses
- Establish Oncology Business
- Continuously Generate Innovative Medicine Changing SOC
- Enhance Profit Generation Capabilities

5-Year Business Plan and 6 Strategic Targets

2025 Vision

5-Year Business

- Grow Edoxaban
- Grow as No.1 Company in Japan
- Expand US Businesses
- Establish Oncology Business

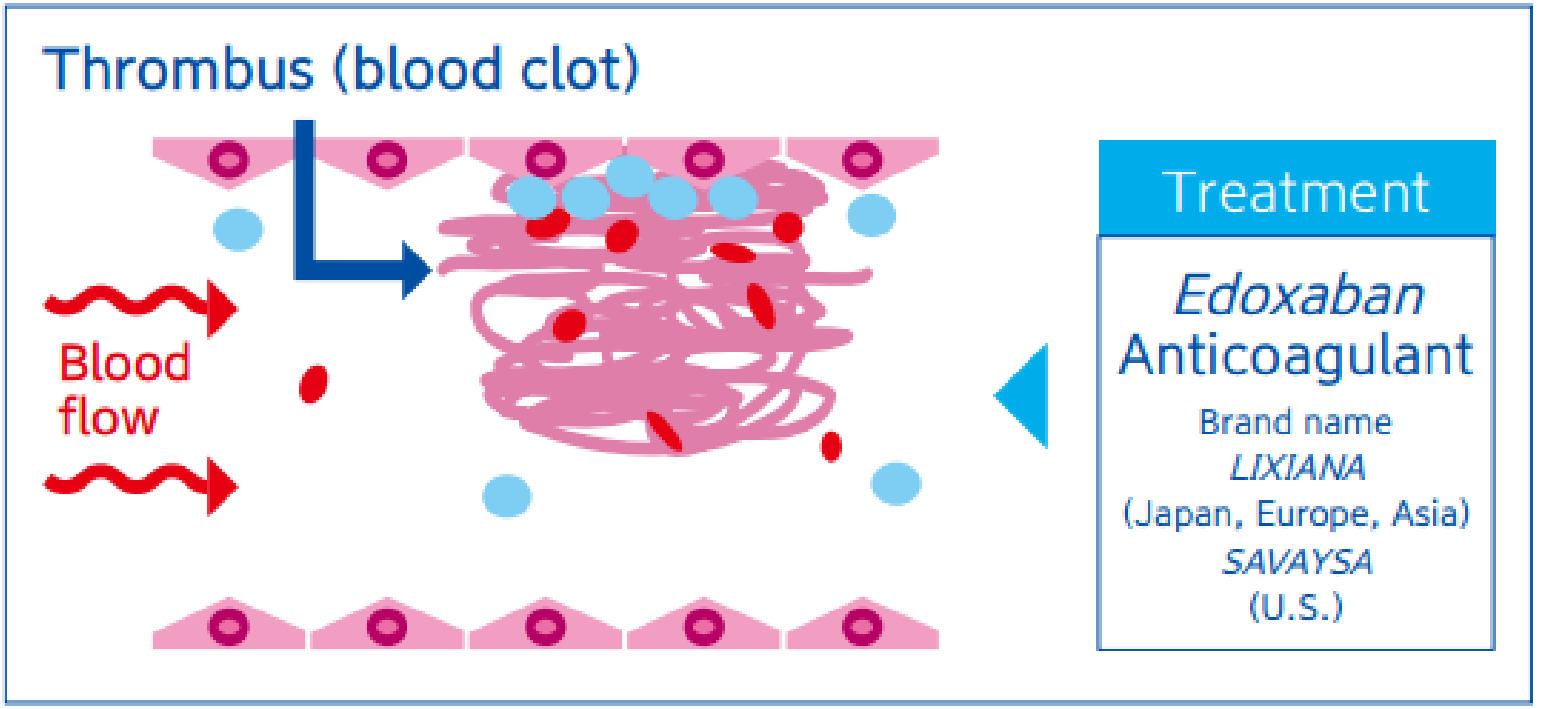
Establish a Foundation of Sustainable Growth: Six Strategic Targets

- Grow Edoxaban
- Grow as No.1 Company in Japan
- Expand US Businesses
- Establish Oncology Business
- Continuously Generate Innovative Medicine Changing SOC
- Enhance Profit Generation Capabilities

Highlights

- **Growth of Current Core Businesses**
  - **Grow Edoxaban**

Thrombosis and Anticoagulants

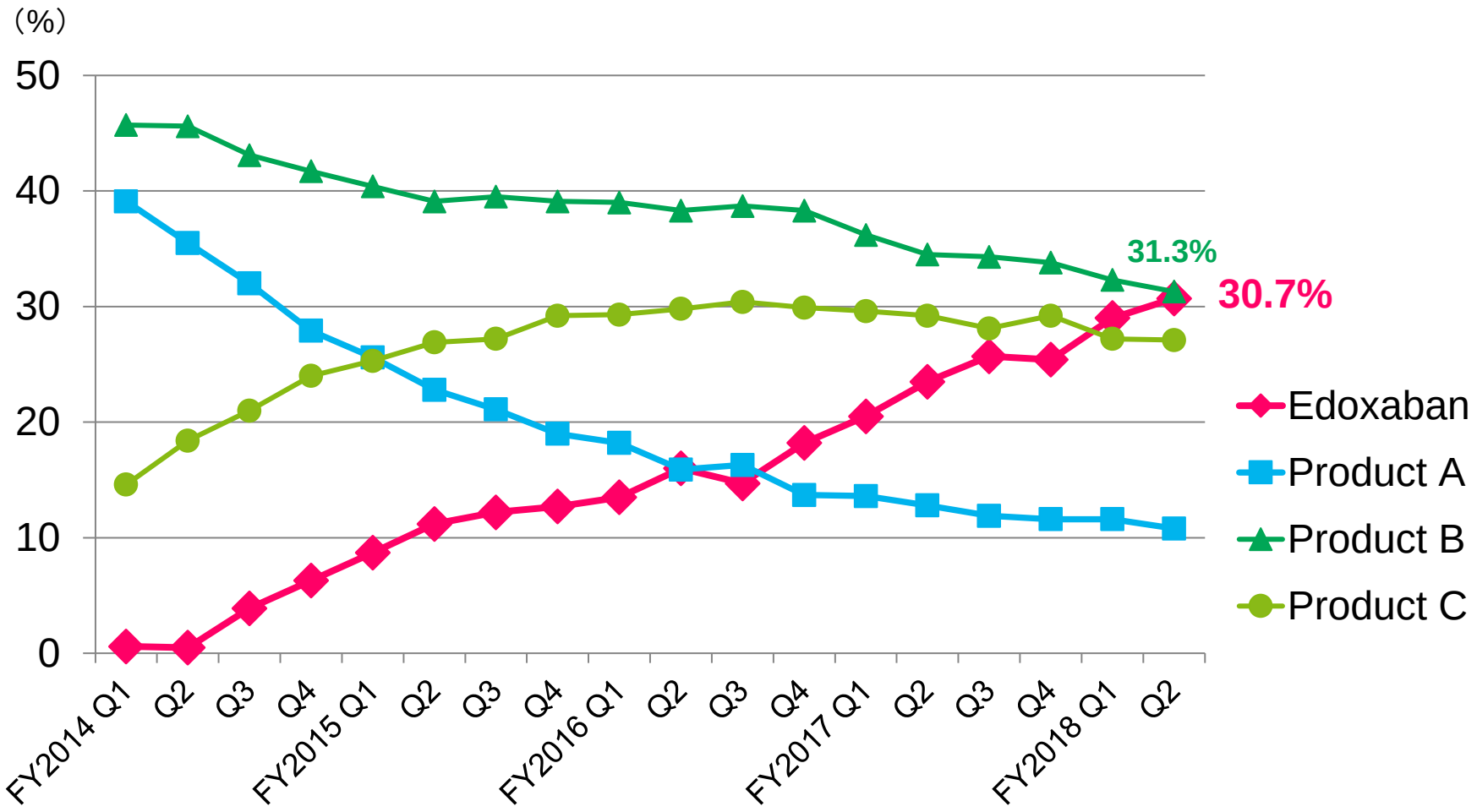


Major Indications treated with Anticoagulants

- Atrial Fibrillation (AF)
- Venous Thromboembolism (VTE)
  - Deep Vein Thrombosis (DVT)
  - Pulmonary Embolism (PE)

Edoxaban: Growth in Japan

◆ As of FY2018 Q2, Edoxaban closed in on No.1 sales share

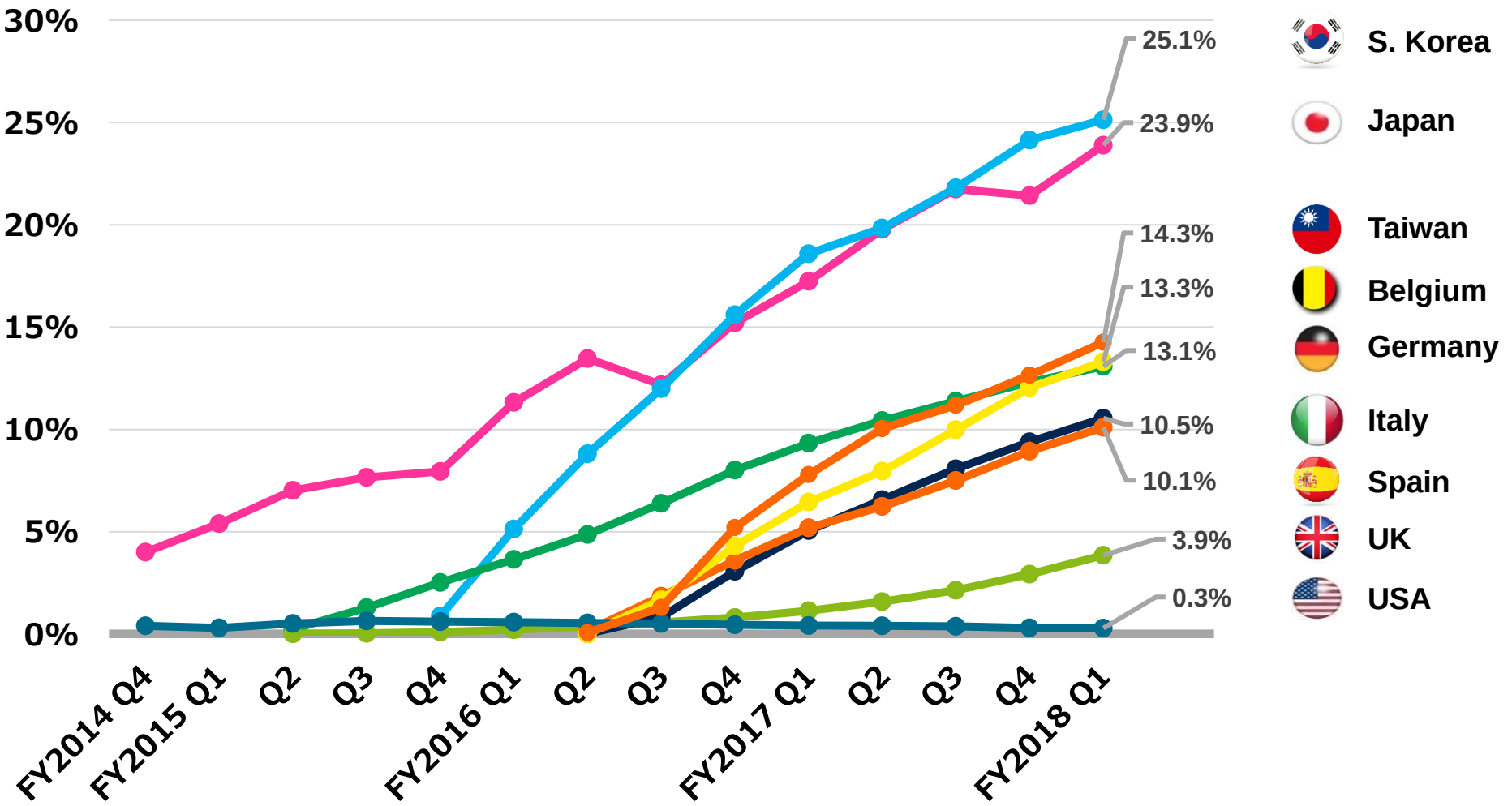


Edoxaban: Growth in Each Country

Volume

Daiichi-Sankyo

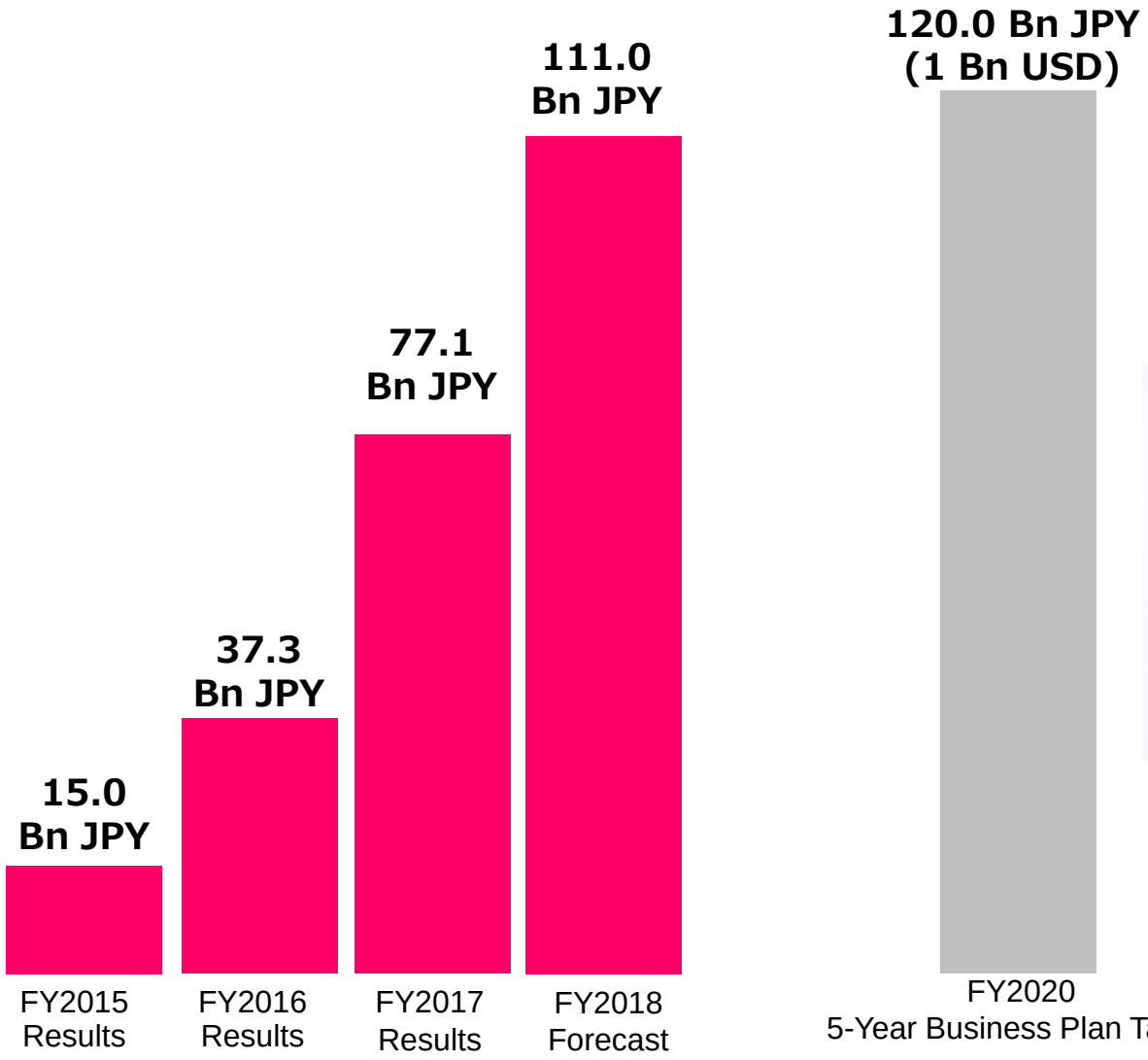
Edoxaban volume (DoT) % share of DOAC markets over time



Brazil: Launched in Aug. 2018

Edoxaban: FY2020 Target

Expanding mainly in Japan, EU and Asia



anticoagulant agent

Edoxaban

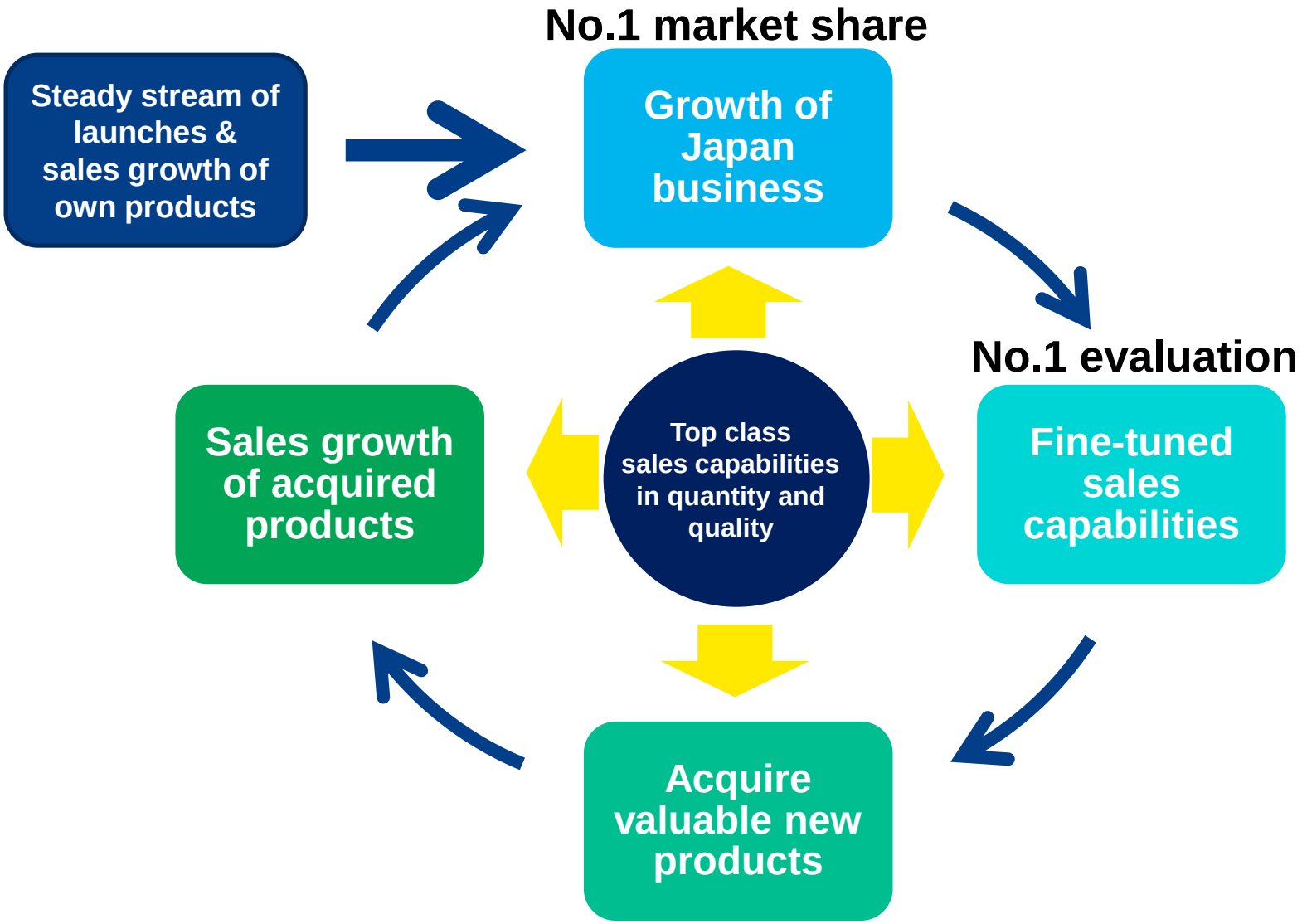
(Lixiana/Savaysa)

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

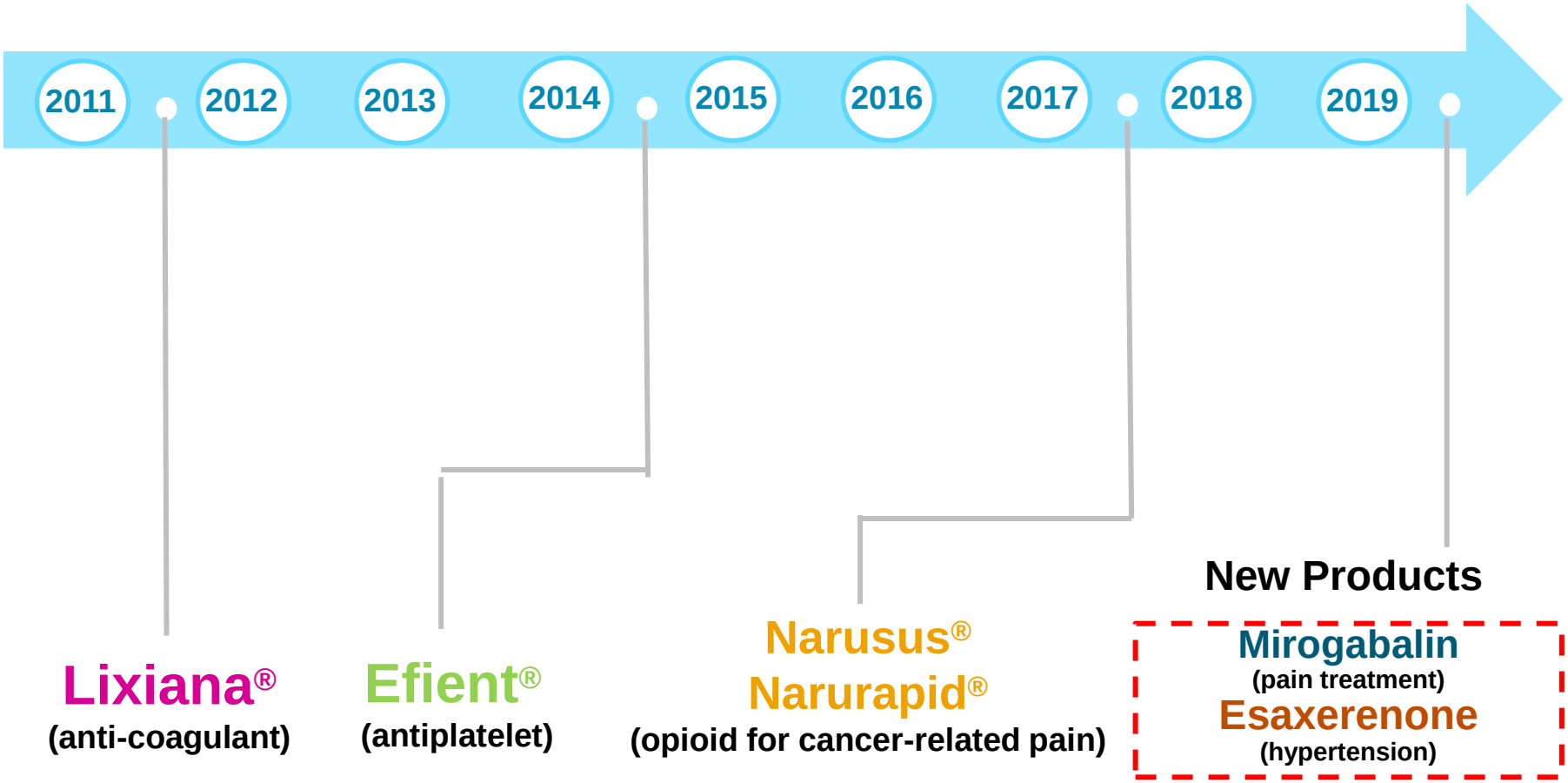
Highlights

- **Growth of Current Core Businesses**
  - Grow as No.1 Company in Japan

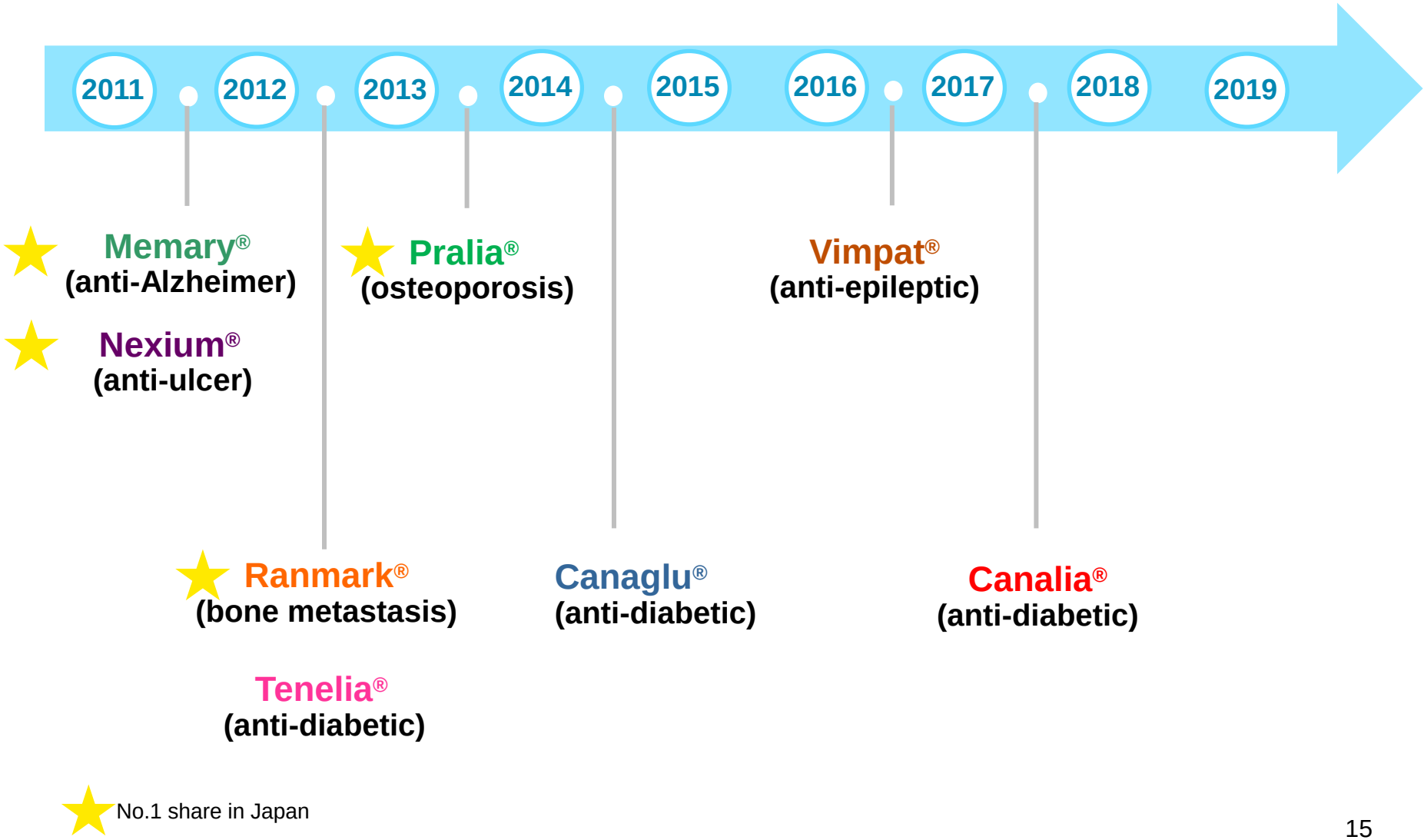
Business Cycle for Sustainable Growth



Own or In-House Products

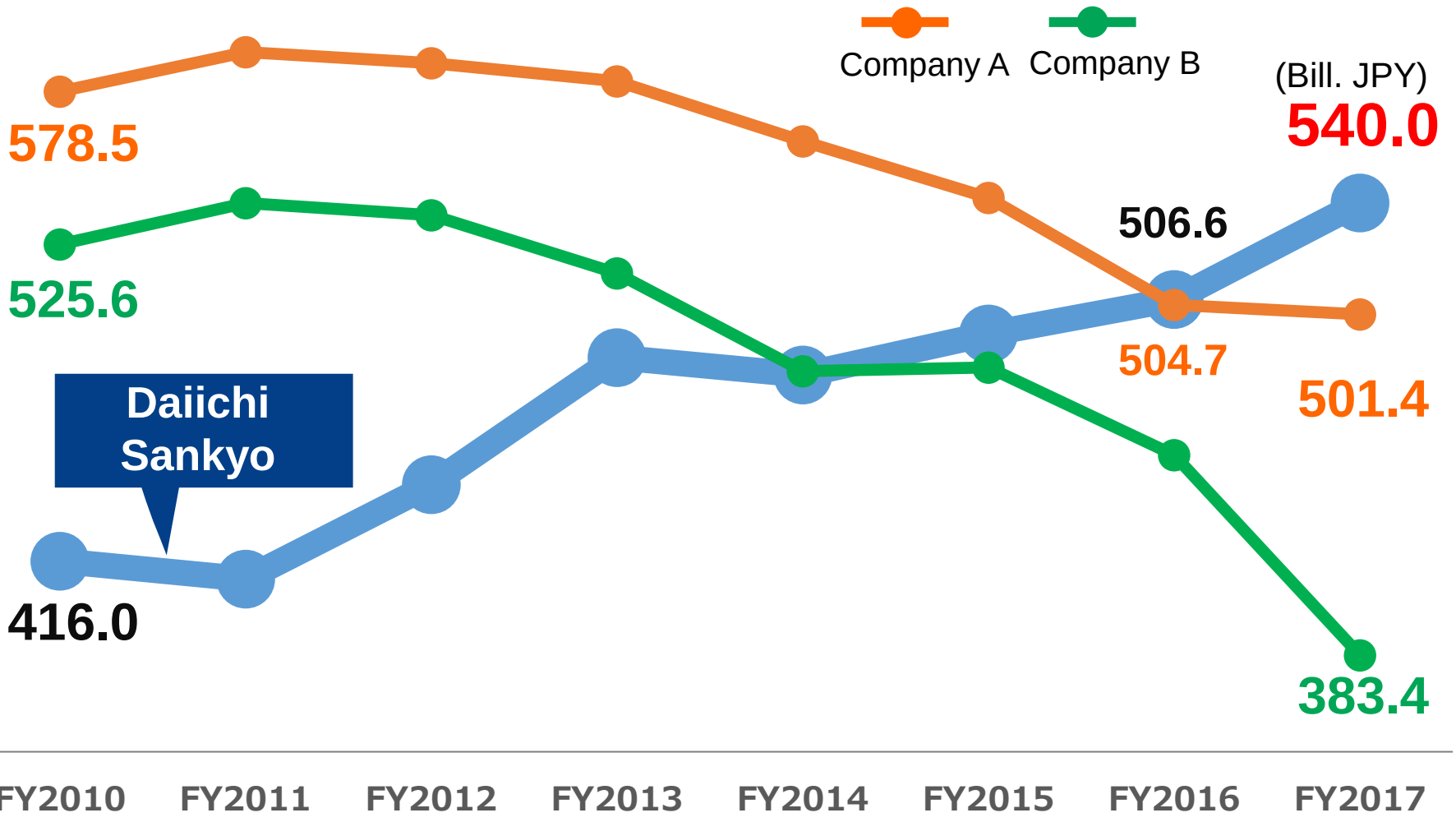


Acquired or In-Licensed Products



Growth of Japan Business

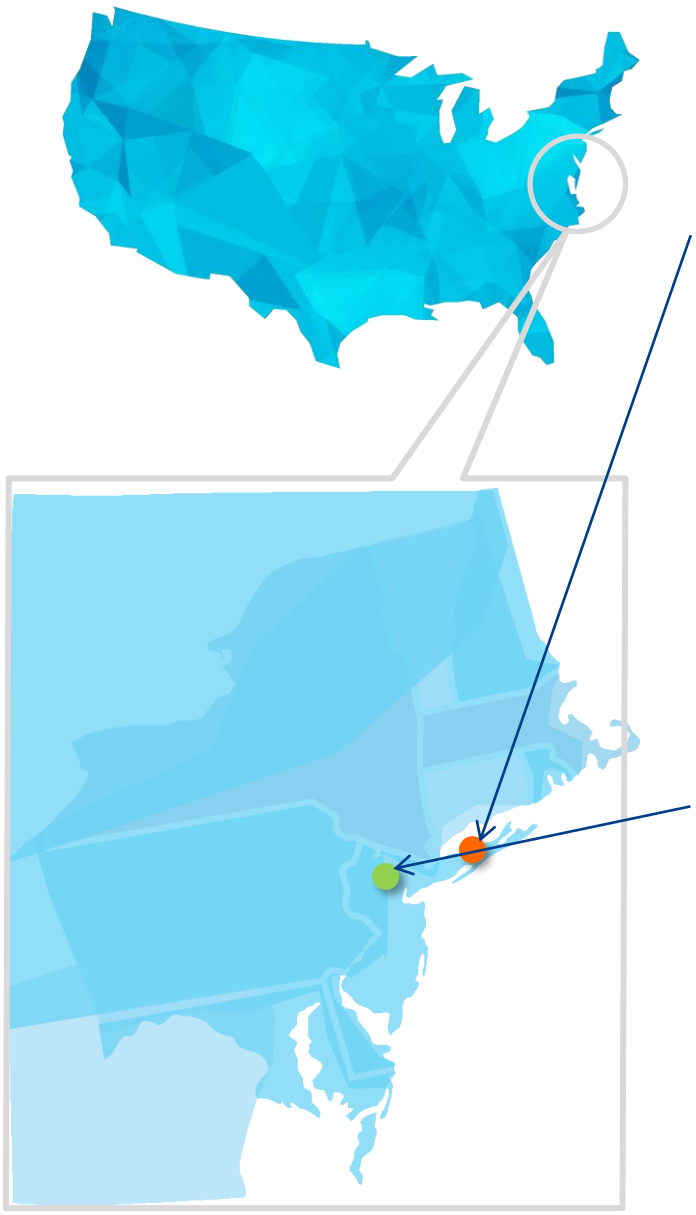
◆ NO.1 in Japan, by prescription drug revenue for 2 consecutive years



Highlights

- **Growth of Current Core Businesses**
  - **Expand US Businesses**

Two Business Units in US



American Regent (formerly LPI) (Shirley, NY)

FY2018 revenue forecast: US$ 1,026 Mn

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

- Iron Injectable Franchise
- Generic Injectable Franchise

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

Injectafer: High-dose IV Iron with Broad Indication

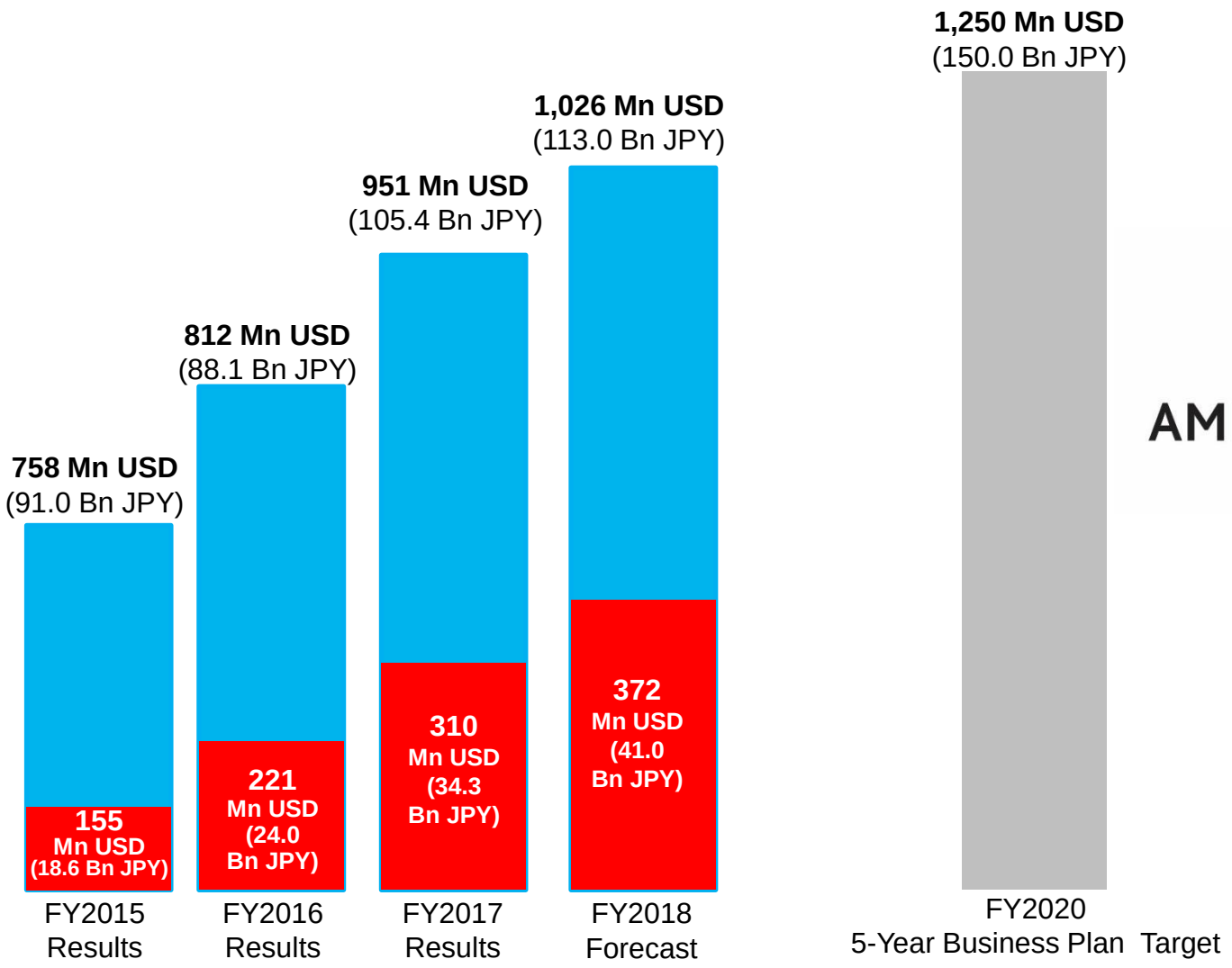
Daiichi-Sankyo

- **Broad indication – Treatment of IDA in adult patients with:**
  - Intolerance or unsatisfactory response to oral iron
  - Non-dialysis chronic kidney disease
- **Convenient dosing & administration**

IV Infusion over at least 15 minutes

Slow IV push over at least 7.5 minutes

American Regent Business: FY2020 Target



Highlights

- **Exciting ADC Pipeline**

Three Pillars

◆ Focus investments 3 pillars of oncology business

ADC Franchise

- **Highly promising pipeline DS-8201, U3-1402 etc.**

3

AML Franchise

- **Rich pipeline Quizartinib etc.**

3

Breakthrough Science

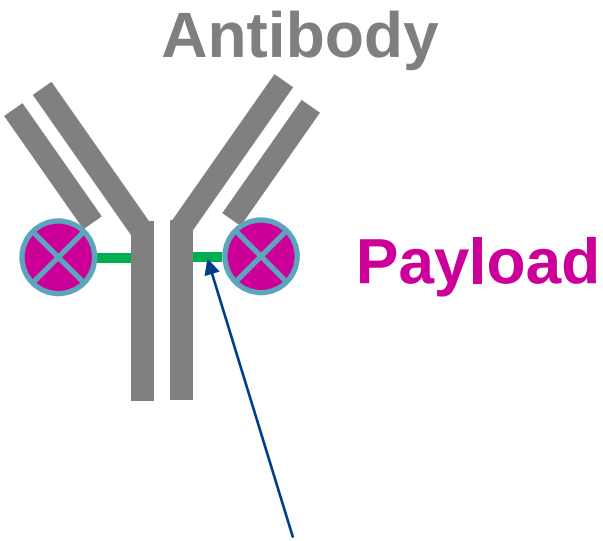
- **Rich pipeline Pexidartinib etc.**

1

Cancer Enterprise 2025 Vision

7 new molecular entities by 2025

ADC Technology



- Novel payload
- High potency
- Bystander effect
- High clearance of the payload

- Stable linker-payload
- Tumor selective cleavable-linker
- High DAR* and homogeneity

*DAR: drug antibody ratio

Daiichi Sankyo ADC Franchise

As of Dec 2018

Daiichi-Sankyo

ADC Franchise

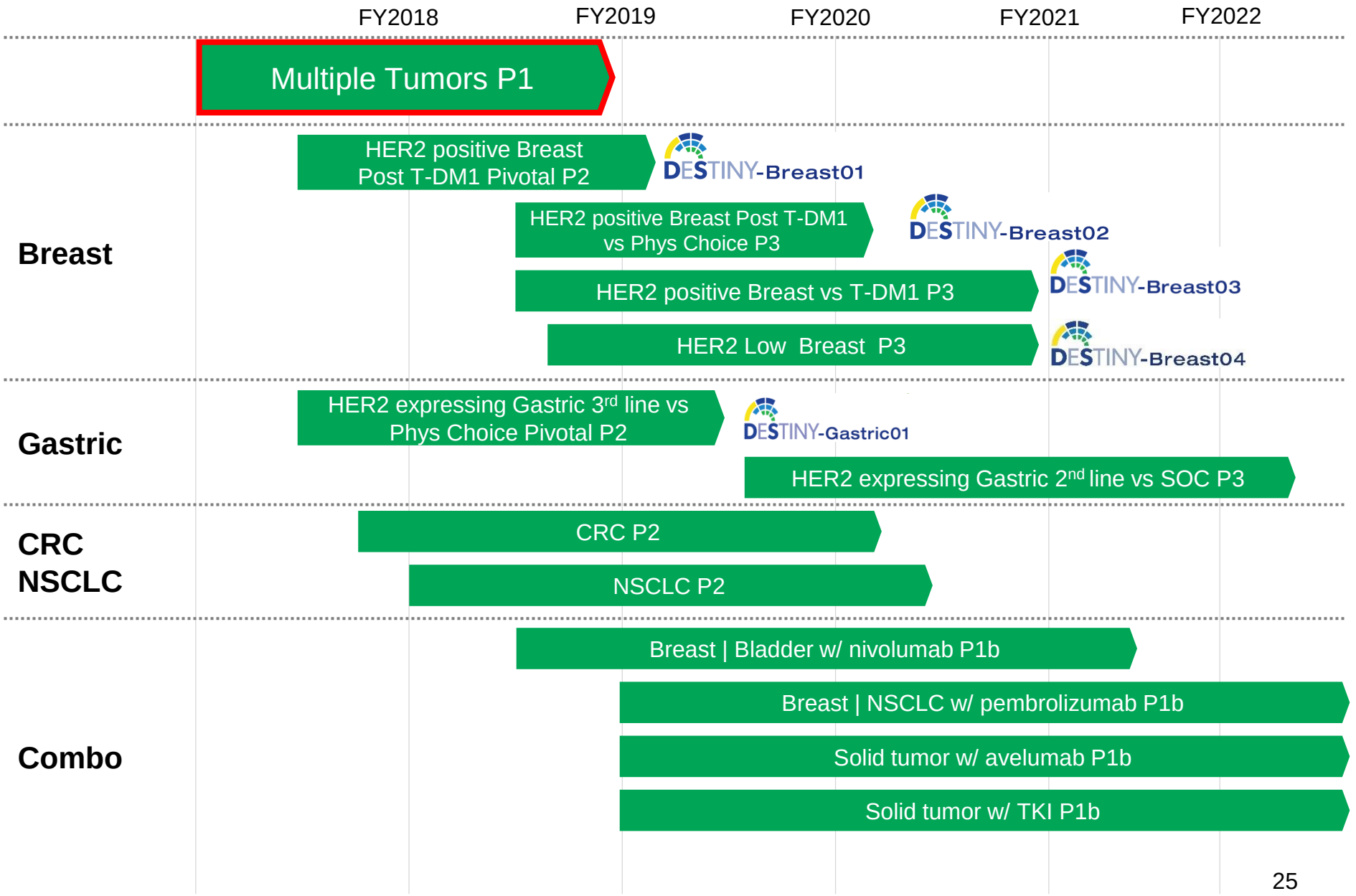
	Project (Target)	Potential Indications	Discovery	Pre-Clinical	Ph 1	Pivotal
1	DS-8201 (HER2)	Breast, Gastric, CRC, NSCLC				
2	U3-1402 (HER3)	Breast, NSCLC				
3	DS-1062 (TROP2)	NSCLC				
4	DS-7300 (B7-H3)	Solid tumors				
5	DS-6157 (GPR20)	GIST				
6	DS-6000 (undisclosed)	Renal, Ovarian				
7	(TA-MUC1)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

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

DS-8201: Clinical Program

As of Dec 2018

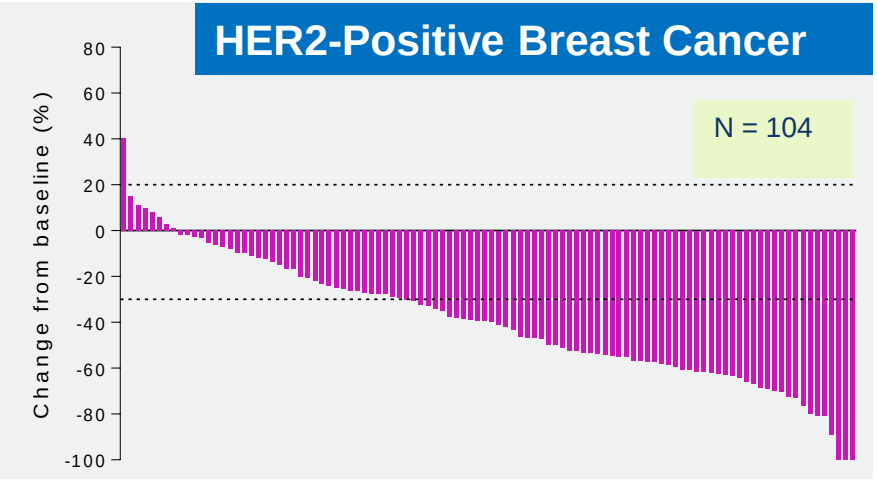
Daiichi-Sankyo

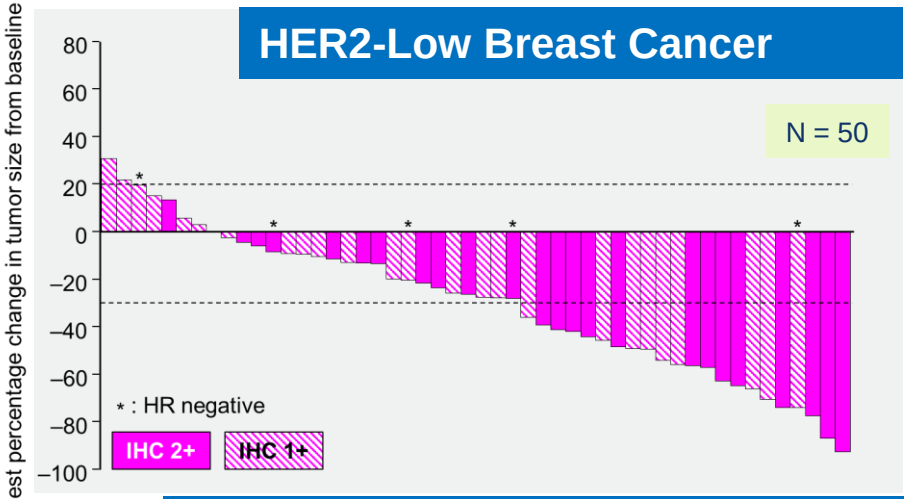


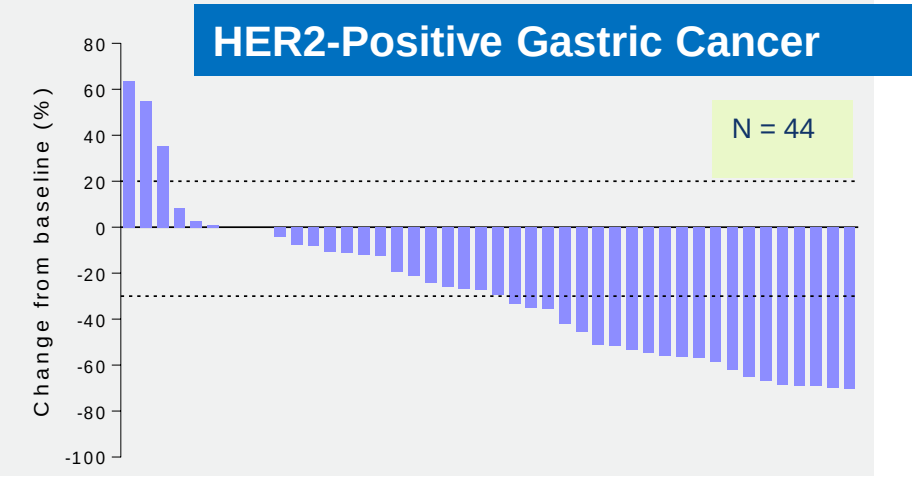
DS-8201: P1 Study Efficacy

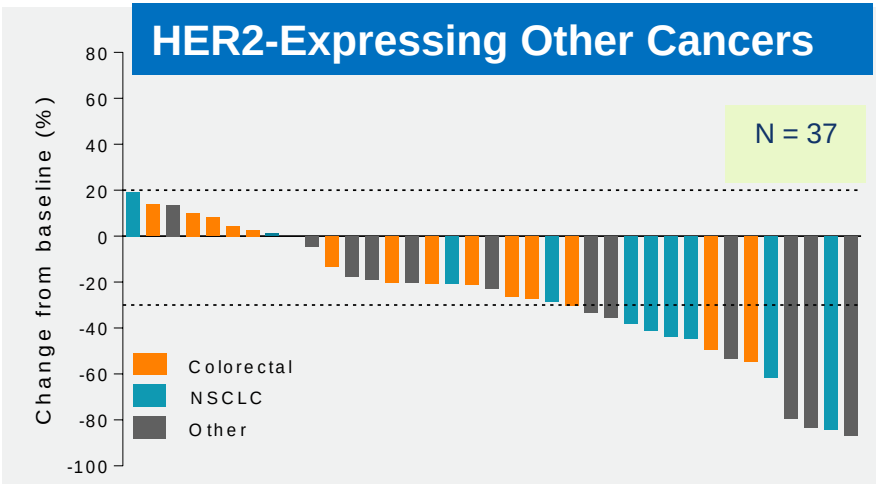
Daiichi-Sankyo

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









HER2-Positive Breast Cancer, Gastric Cancer, HER2-Expressing Other cancers: ASCO 2018 Presentation
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.

HER2-Low Breast Cancer: Modi et al, SABCS, 2018; Poster # P6-17-02, Abstract #486

DS-8201: HER2 Positive BC New Data

Duration of Response > 20 months

Daiichi-Sankyo

Efficacy Outcomes in Subjects with HER2 Positive Breast Cancer in the Ongoing Ph 1 Trial (Aug 10, 2018 data cutoff)[1]

	HER2 Positive (IHC 3+ or IHC 2+/ISH+) Breast Cancer
Confirmed Overall Response Rate (66/111)[a]	59.5% (95% CI 49.7, 68.7)
Median duration of response	**20.7 months** (range 0.0+, 21.8+)

[a]Subjects who received 5.4 or 6.4 mg/kg with ≥2 postbaseline scans, or who had progressive disease or discontinued treatment for any reason before second postbaseline scan.
DCR, disease control rate; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization; ORR, objective response rate.

[1] Daiichi Sankyo Data on File

DS-8201: Safety ILD

Investigator-Reported and Adjudicated Cases of ILD

Population	Adjudication status	Grade					Total
		1	2	3	4	5	
All subjects All doses, N = 665	Investigator reported, n (%)	30 (4.5)	23 (3.5)	6 (0.9)	2 (0.3)	5 (0.8)	66 (9.9)
	Cases adjudicated, n	16	13	4	0	5	38
	Adjudicated as drug-related ILD, n	11	12	3	0	4	30

Data cutoff: October 15, 2018

- Median duration of treatment 108 days
- 29.5% subjects on treatment for ≥180 days
  - Median time to onset of ILD 149 days

- **Feb-March 2018: ILD recognized as DS-8201 risk: key actions implemented**:
  - Proactive awareness of subjects thru consent, to report signs or symptoms of possible ILD
  - Active training of investigational sites on monitoring for, evaluation and treatment of suspected ILD cases

Powell et al, SABCS, 2018; Poster # P6-17-06, Abstract #979

DS-8201: ILD experience BC at Recommended Dose

- Based on safety, efficacy and exposure data, 5.4 mg/kg was selected as the dose for pivotal development in breast cancer
- At 5.4mg/kg in breast cancer, ILD appears as a well characterized risk

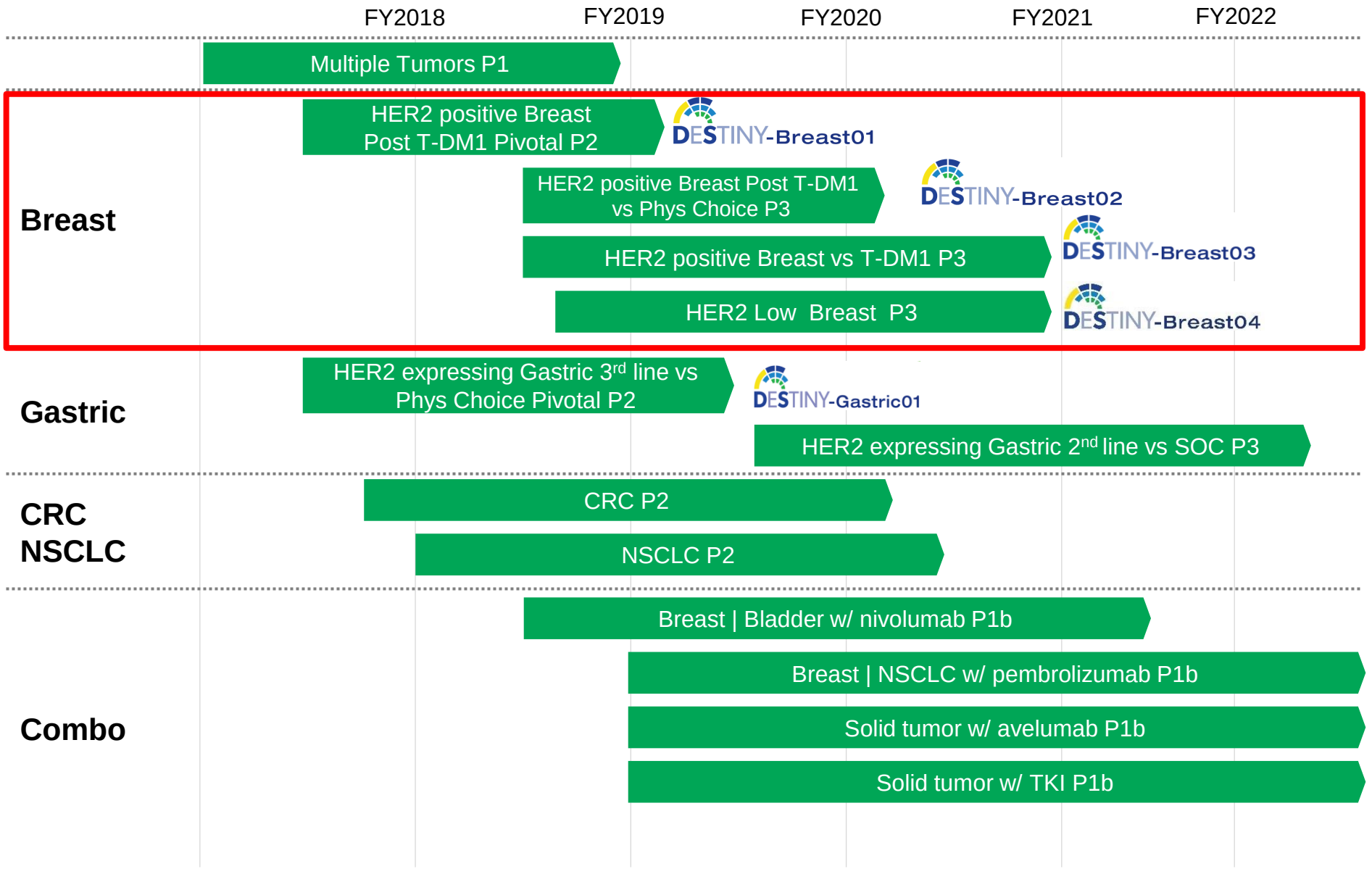
Population	Adjudication status	ILD experience in breast cancer at 5.4 mg/kg					
		ILD Severity Grade					
		1	2	3	4	5	Total
Breast Cancer 5.4 mg/kg N = 269	**Investigator reported, n (%)**	**8 (3.0)**	**4 (1.5)**	**2 (0.7)**	**0**	**1 (0.4)**	**15 (5.6)**
	Cases adjudicated, n	3	3	0	0	1	7
	Adjudicated as drug-related ILD, n	2	2	0	0	1	5

Powell et al, SABCS, 2018; Poster # P6-17-06, Abstract #979

DS-8201: Clinical Program

As of Dec 2018

Daiichi-Sankyo



DS-8201: HER2 Positive Metastatic BC Target Population

Daiichi-Sankyo

HER2 Positive Metastatic Breast Cancer

1st Line
Herceptin® (trastuzumab) + Perjeta® (pertuzumab) + docetaxel

2nd Line
Kadcyla® (T-DM1)

vs T-DM1
Phase 3

DESTINY-Breast03

Started

3rd Line
Physician's Choice

Pivotal Phase 2

DESTINY-Breast01

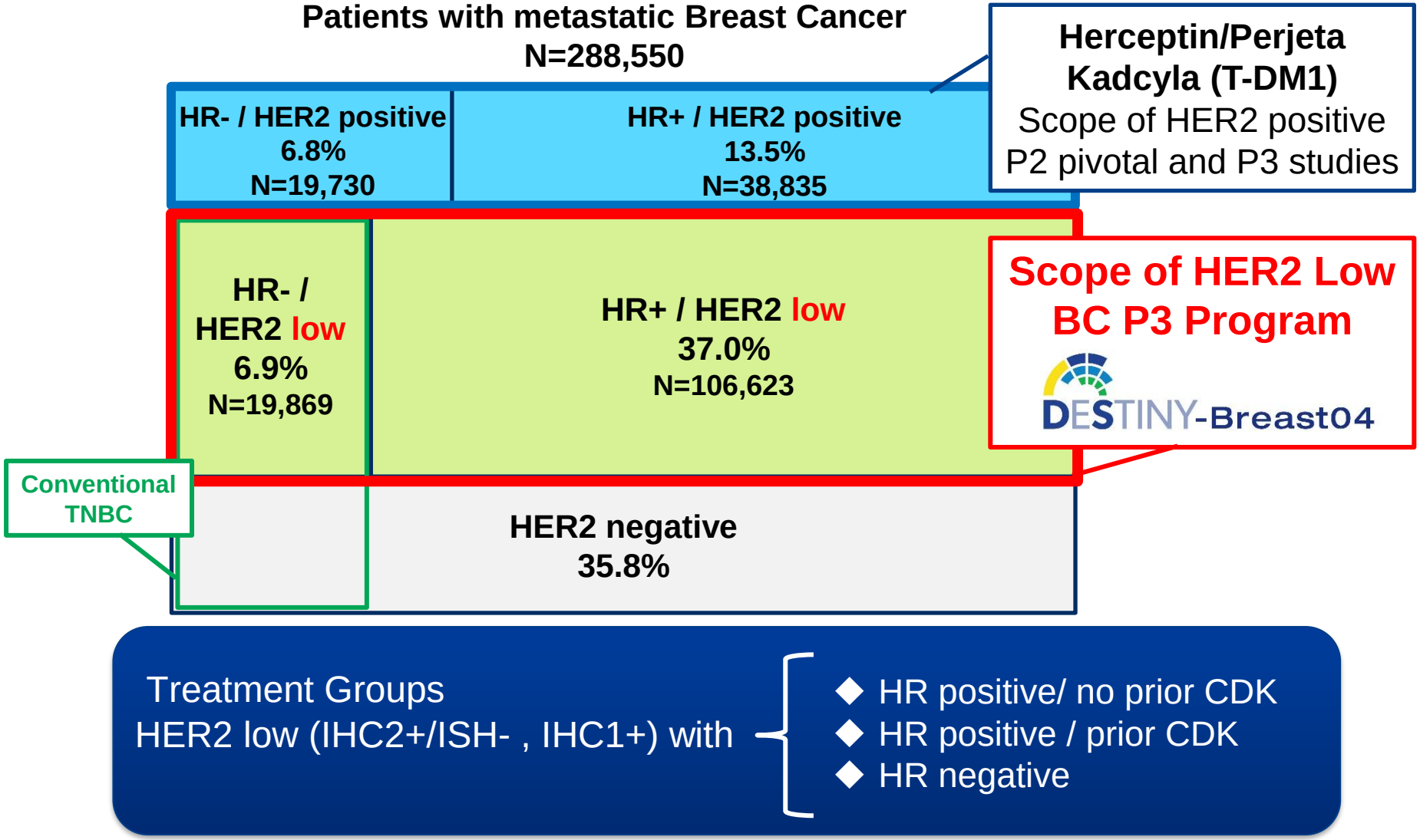
Enrollment Complete

vs Physician Choice
Phase 3

DESTINY-Breast02

Started

DS-8201: HER2 Low BC P3 Target Population

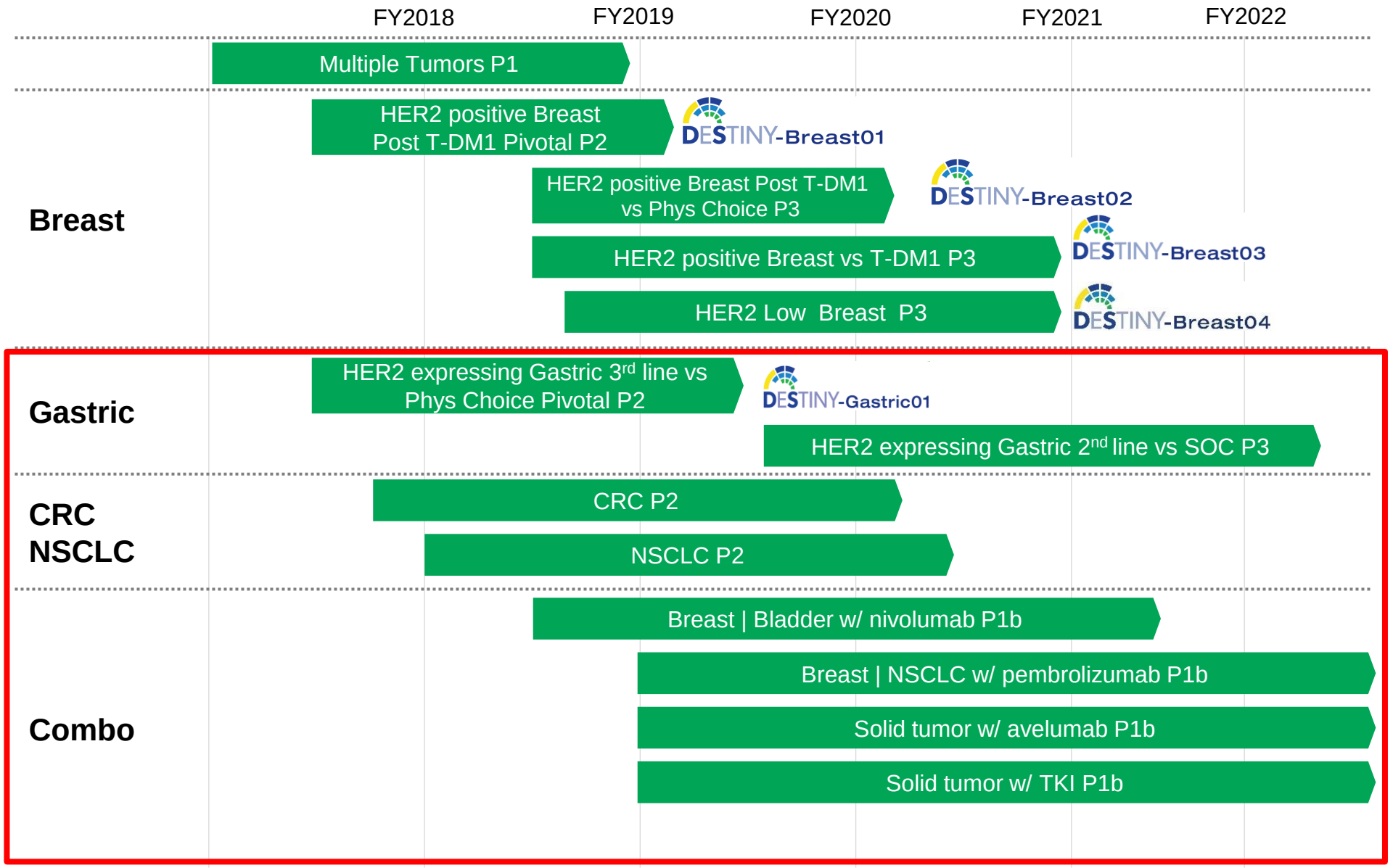


HR: hormone receptor; TNBC: triple negative breast cancer
HR-: estrogen-receptor (ER) and progesterone-receptor (PR) negative

DS-8201: Clinical Program

As of Dec 2018

Daiichi-Sankyo



DS-8201: Beyond Breast Cancer

Gastric

- Pivotal P2 study on track
- P3 study under preparation

DESTINY-Gastric01

CRC NSCLC

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

IO Combo

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

DS-8201: New Plan

As of Dec 2018

Daiichi-Sankyo

Current/future trials for further data-gated development

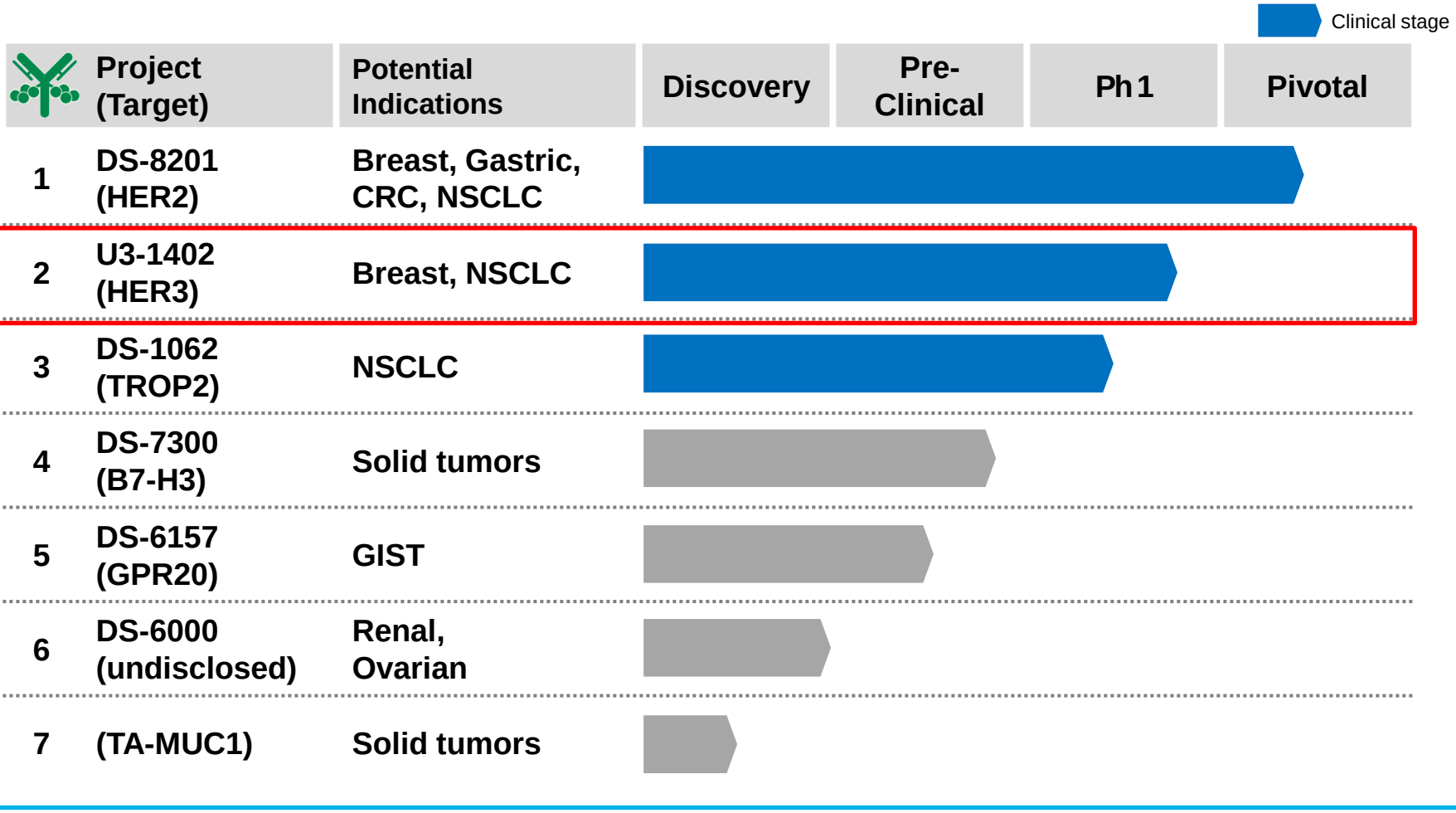
New plans

		Directions (Ph 1-3)
Breast	Move to 1st Line Metastatic Early Breast Cancer	• Neo-adjuvant • Adjuvant • Ph 3 in 1st Line HER2 positive • IO combinations • Hormonal therapy combinations • CDK4/6i combinations • PARPi combinations • Dual anti-HER2 combinations
Gastric	West HER2 expressing Gastric 2nd Line P2	• VEGFi combinations • Chemo combinations • IO combinations • HER2 Low • Early disease Gastric cancer
CRC **NSCLC**	CRC P2 NSCLC P2	• VEGFi combinations • Chemo combinations • IO combinations • HER2 Low
Other Combo	Other Tumor Types P2	• HER2 gene amplified basket • HER2 mutant basket • Ovarian • Uterine • Salivary • Bladder • Novel IO combos

Daiichi Sankyo ADC Franchise

As of Dec 2018

ADC Franchise

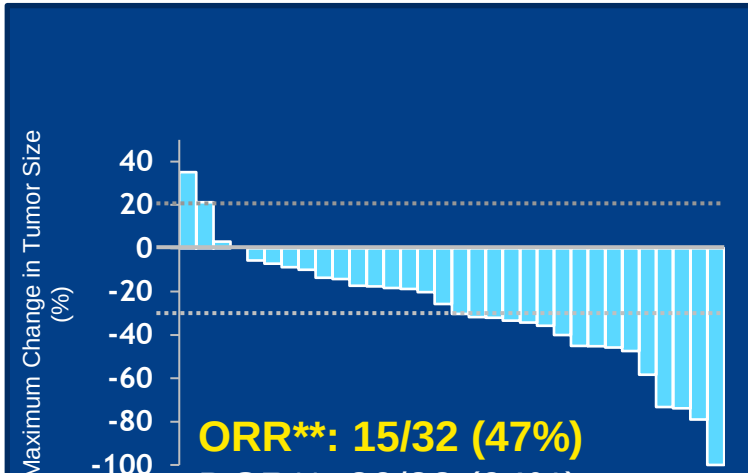


CRC: colorectal cancer, NSCLC: non-small cell lung cancer, GIST: gastrointestinal stromal tumor

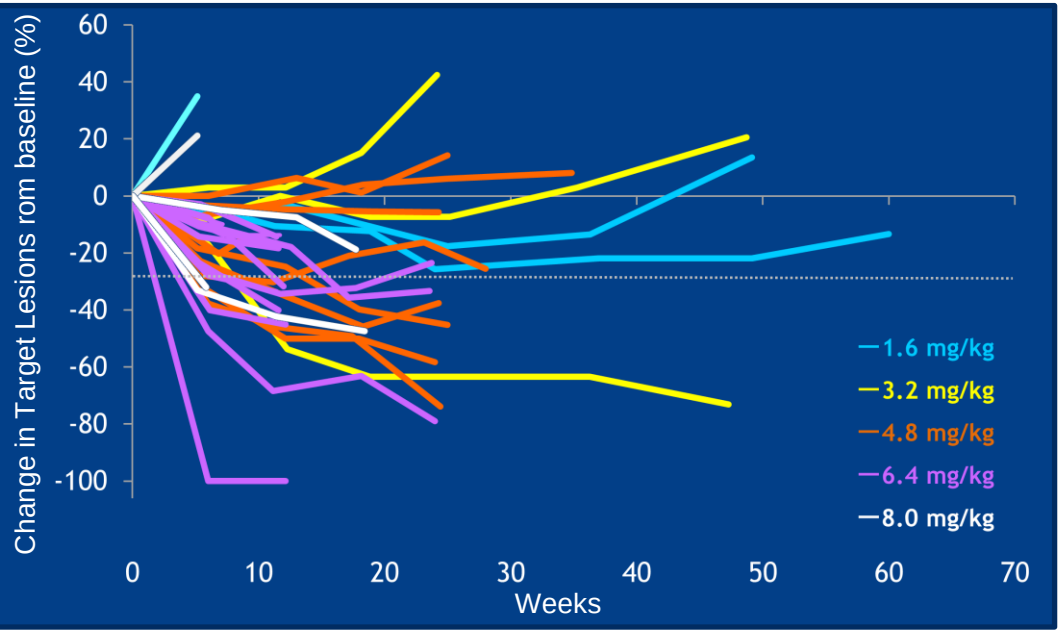
U3-1402: BC P1/2 Study Efficacy

Daiichi-Sankyo

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

Summary of ADC Pipelines

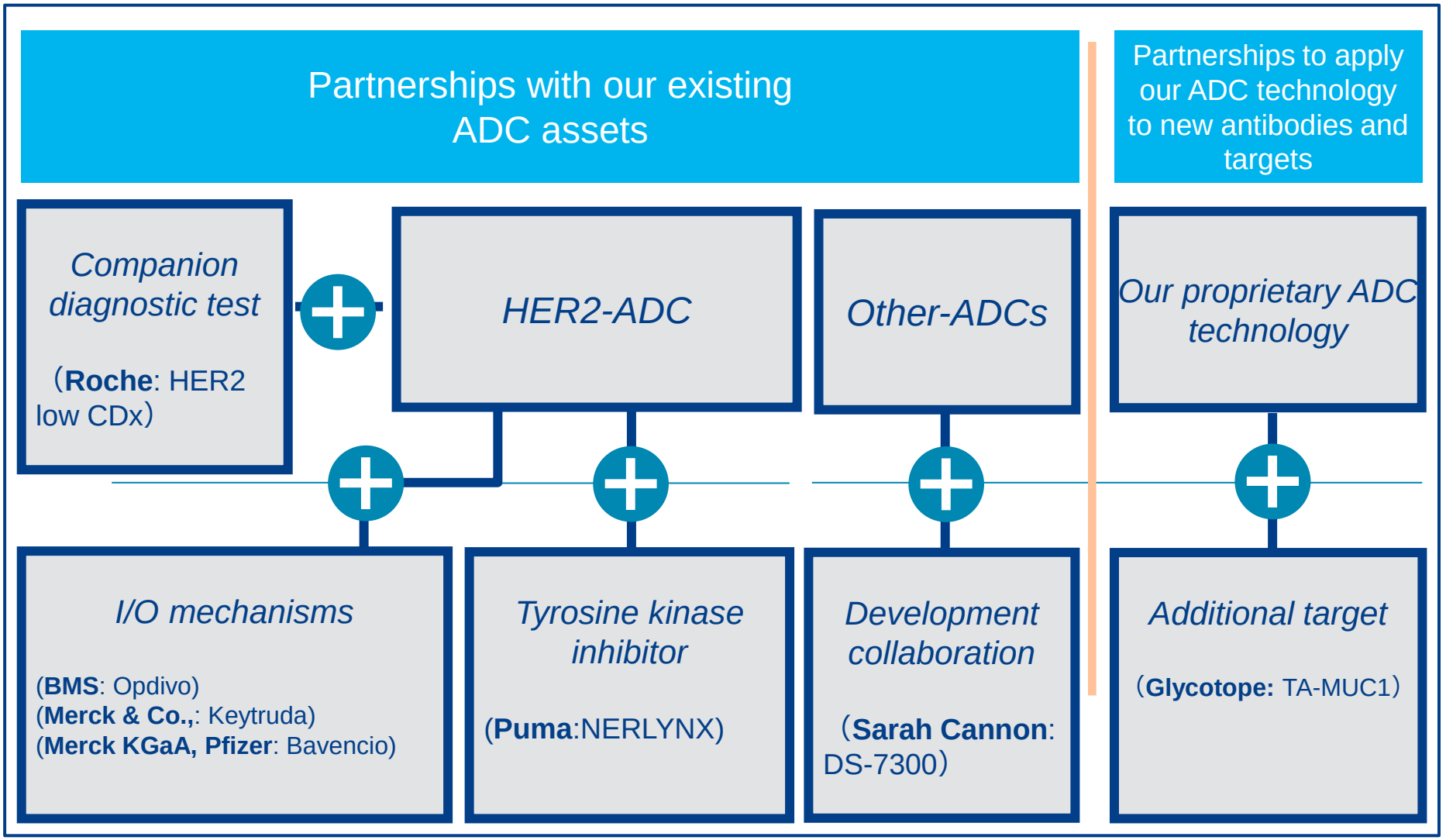
DS-8201

- Further evaluation in:
  - HER2+ mBC who failed Herceptin and/or Kadcyla
  - HER2 low mBC where there is no approved HER2 targeted therapy
  - HER2 expressing mGC where Herceptin is only approved HER2 targeted therapy
  - HER2 expressing/mutated NSCLC/CRC where there is no approved HER2 targeted therapy

U3-1402

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

ADC Collaborations with Partners

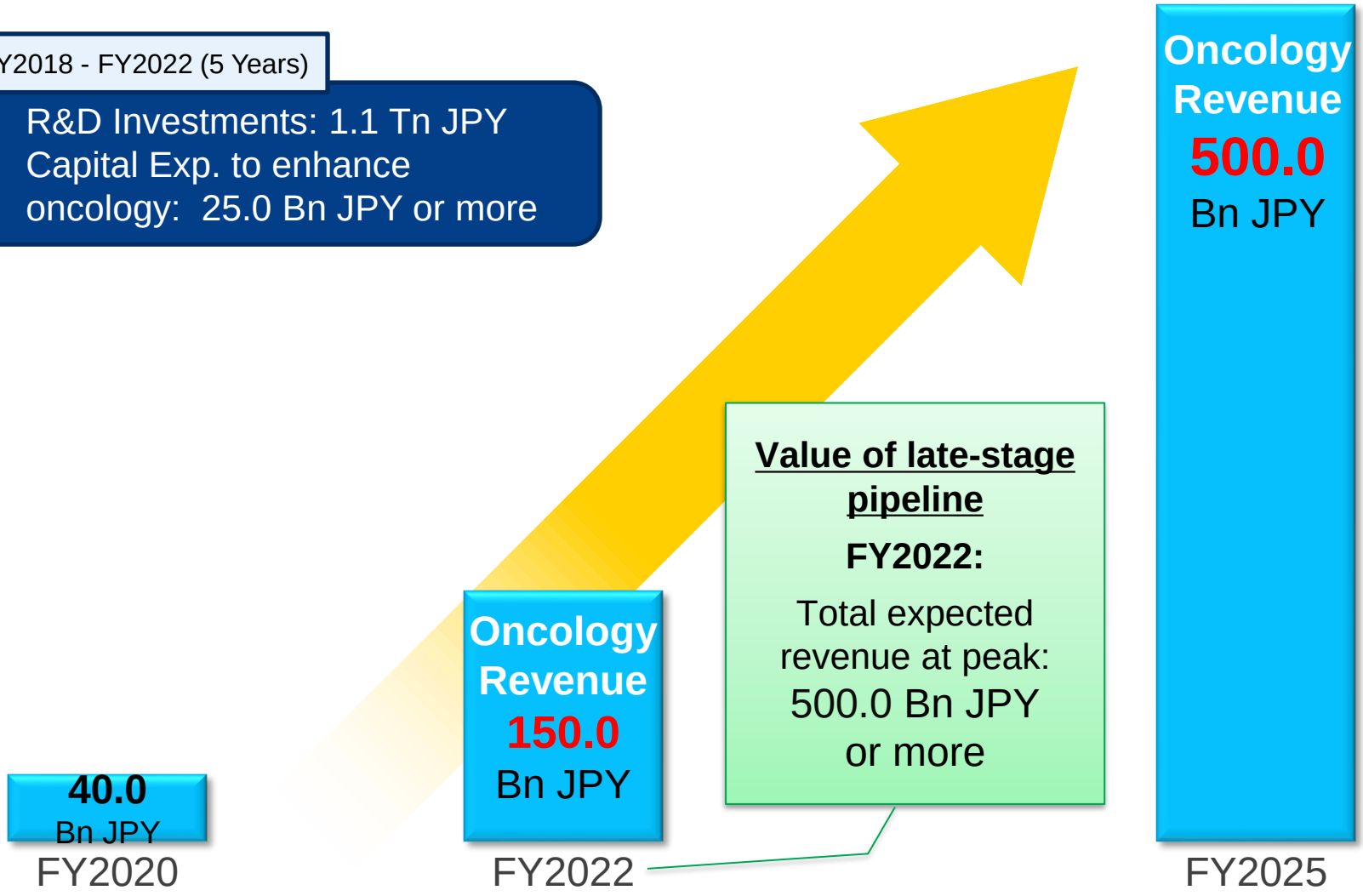


Oncology Business: Revenue Target

- Expand future oncology revenue by accelerating and increasing investments to fast-track growth

FY2018 - FY2022 (5 Years)

- R&D Investments: 1.1 Tn JPY
- Capital Exp. to enhance oncology: 25.0 Bn JPY or more



Highlights

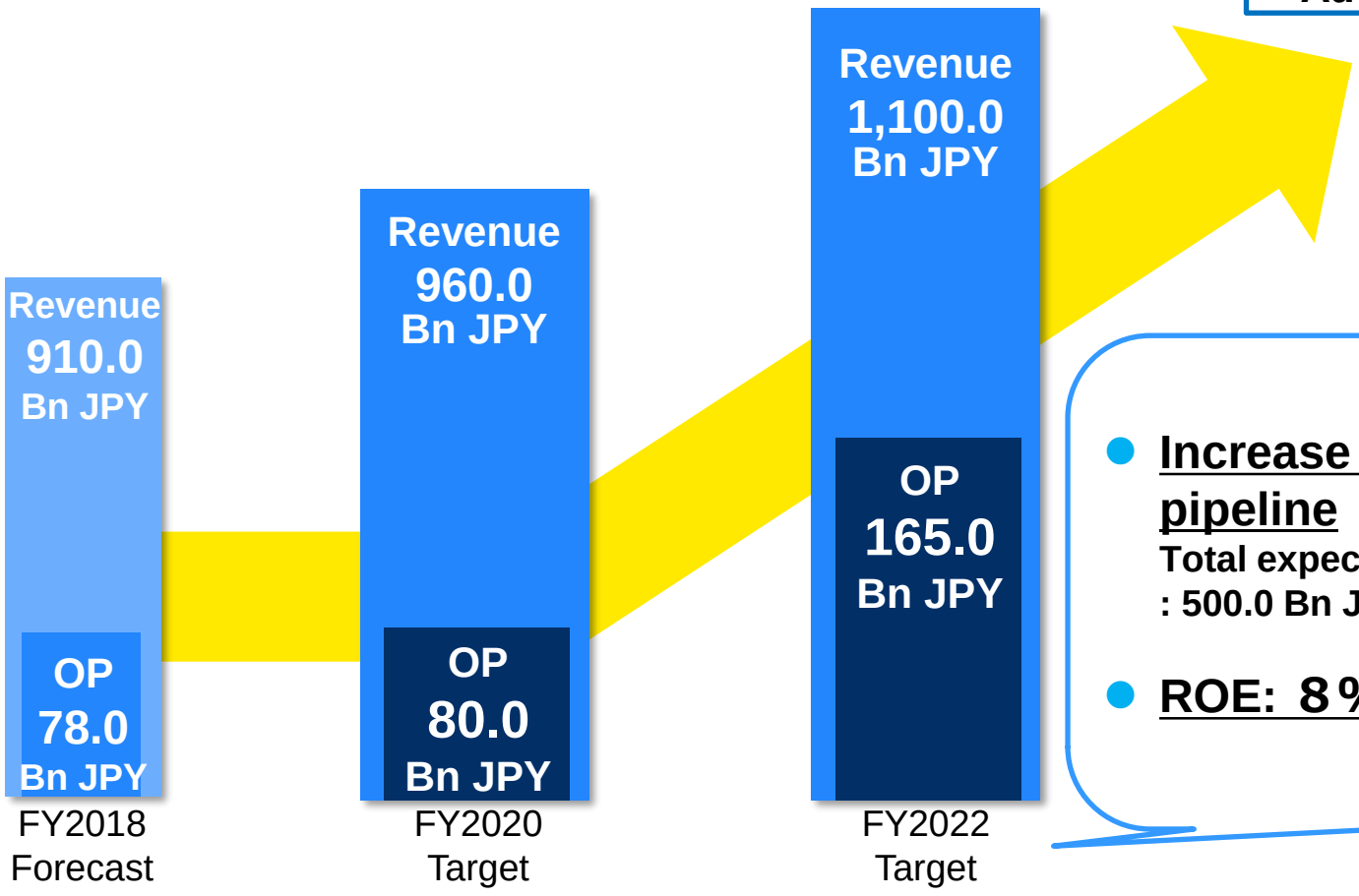
- **Revised Target for 5-Year Business Plan**

Revised Target for 5-Year Business Plan

Daiichi-Sankyo

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**

* The targets excludes the impact of gain on sales of fixed assets, transformation business portfolio and partnering

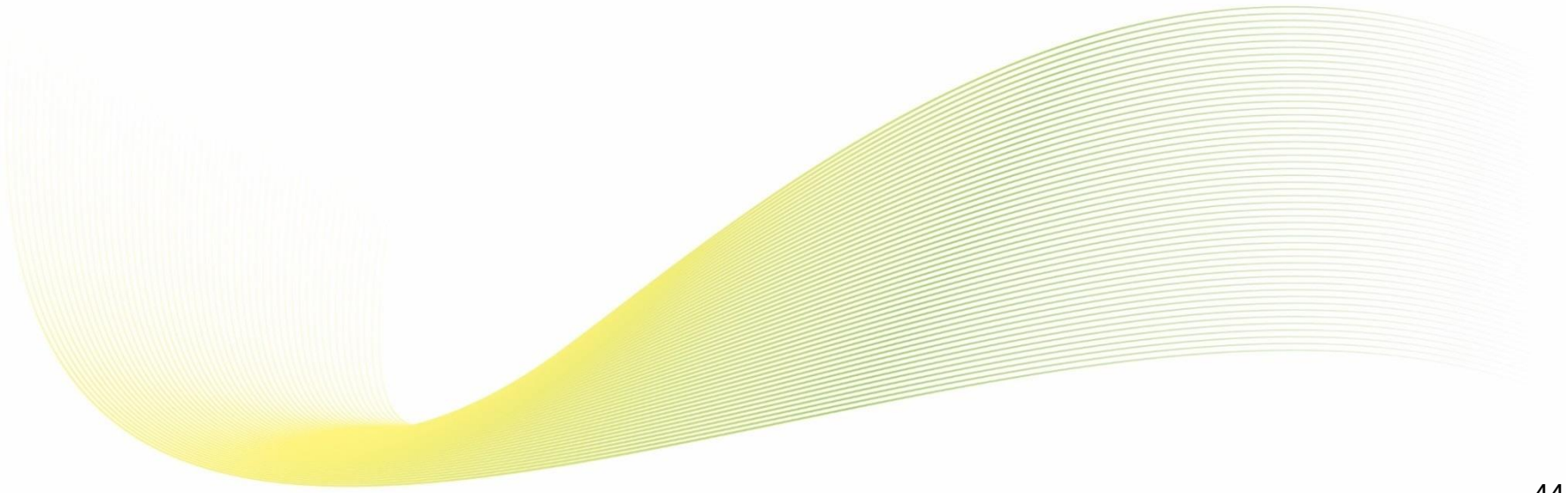
Shareholder Returns

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 in 7 yrs. FY2016-FY2022

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

Wrap up



Key Takeaways

- **Edoxaban, Japan business and American Regent business are on track**
- **Exciting ADC pipeline**
- **We will increase R&D investment to accelerate our transformation towards “2025 Vision”**

Contact address regarding this material

Daiichi Sankyo Co., Ltd.
Corporate Communications Department

TEL: +81-3-6225-1126