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

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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

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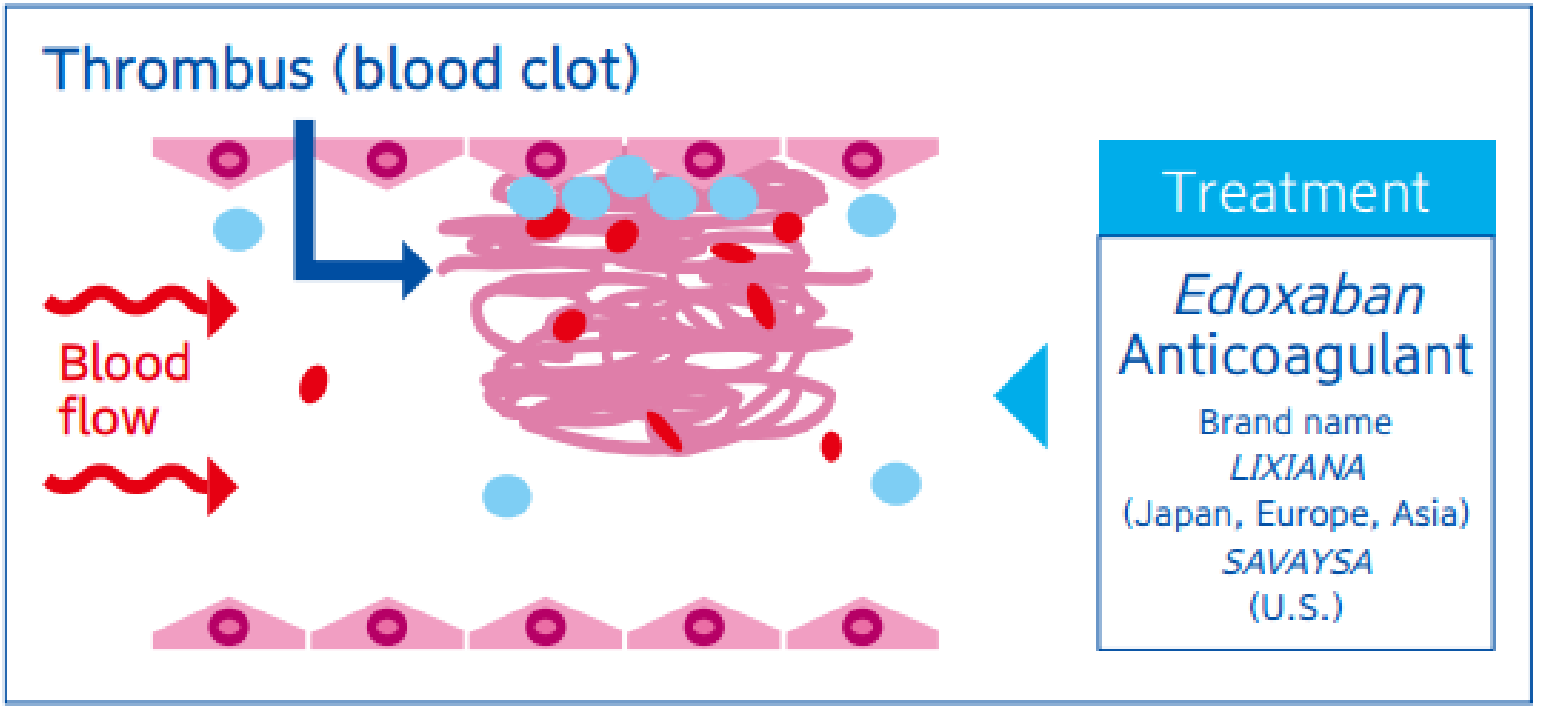
Highlights

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

Thrombosis and Anticoagulants

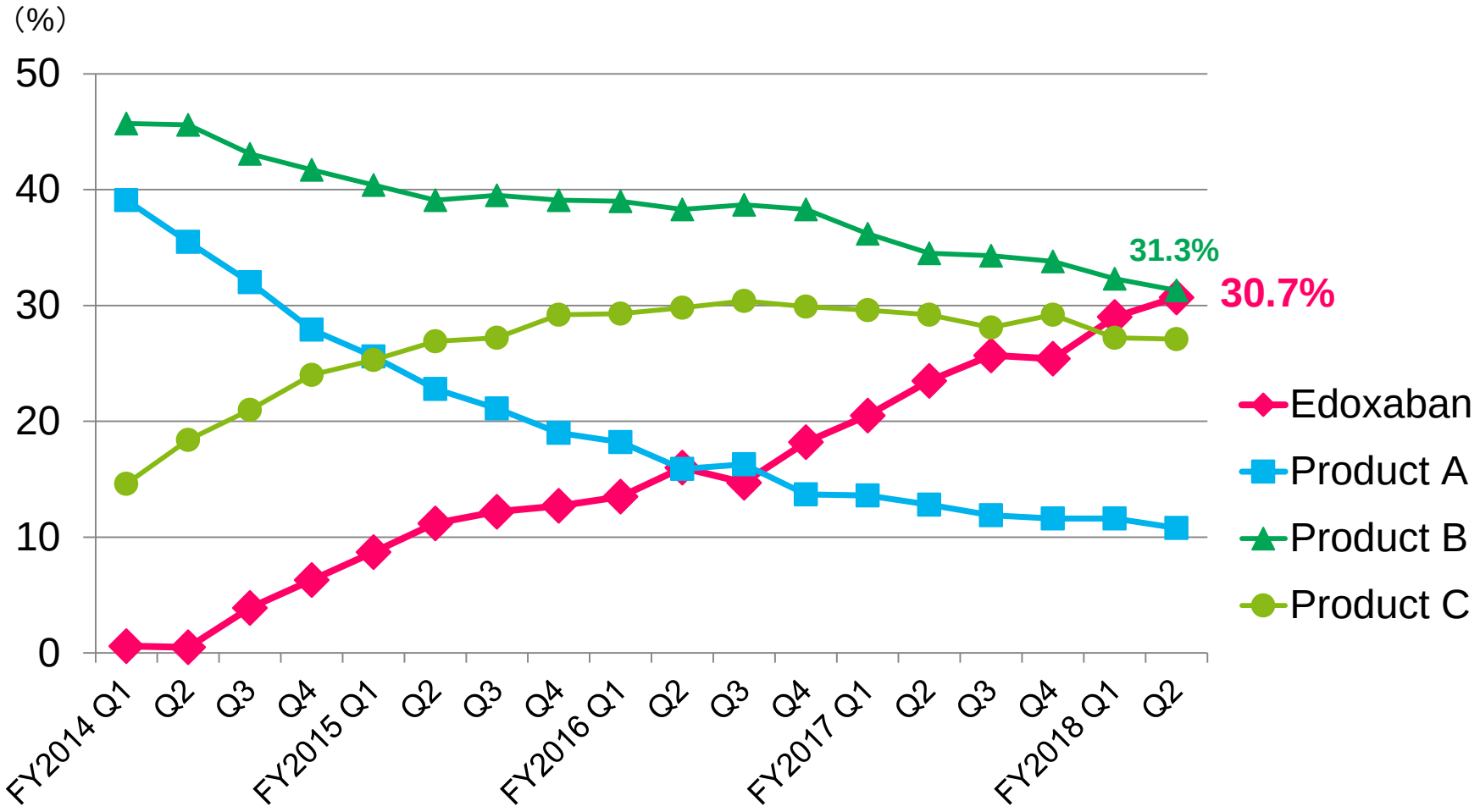


Major Indications treated with Anticoagulants

- 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

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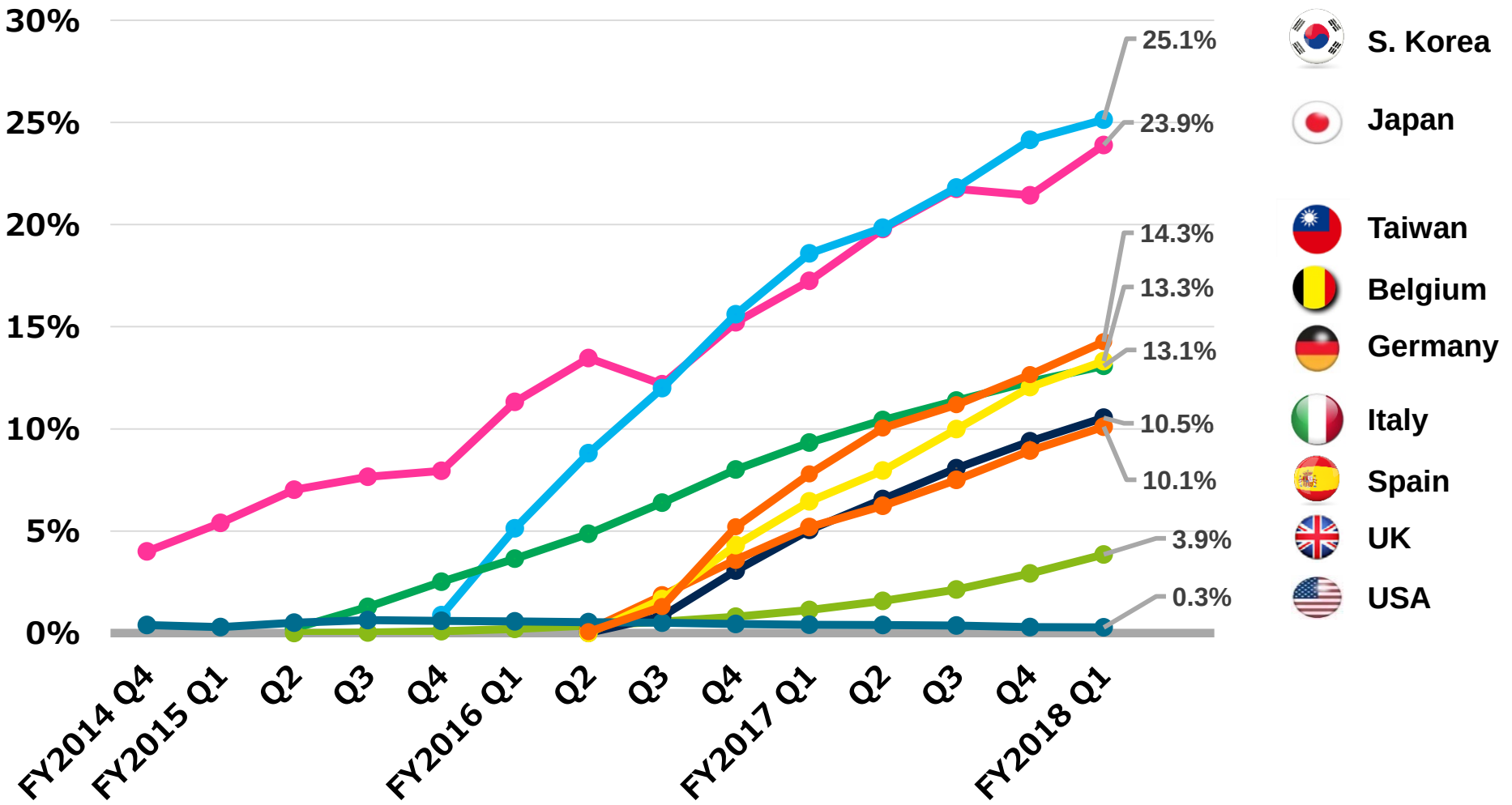
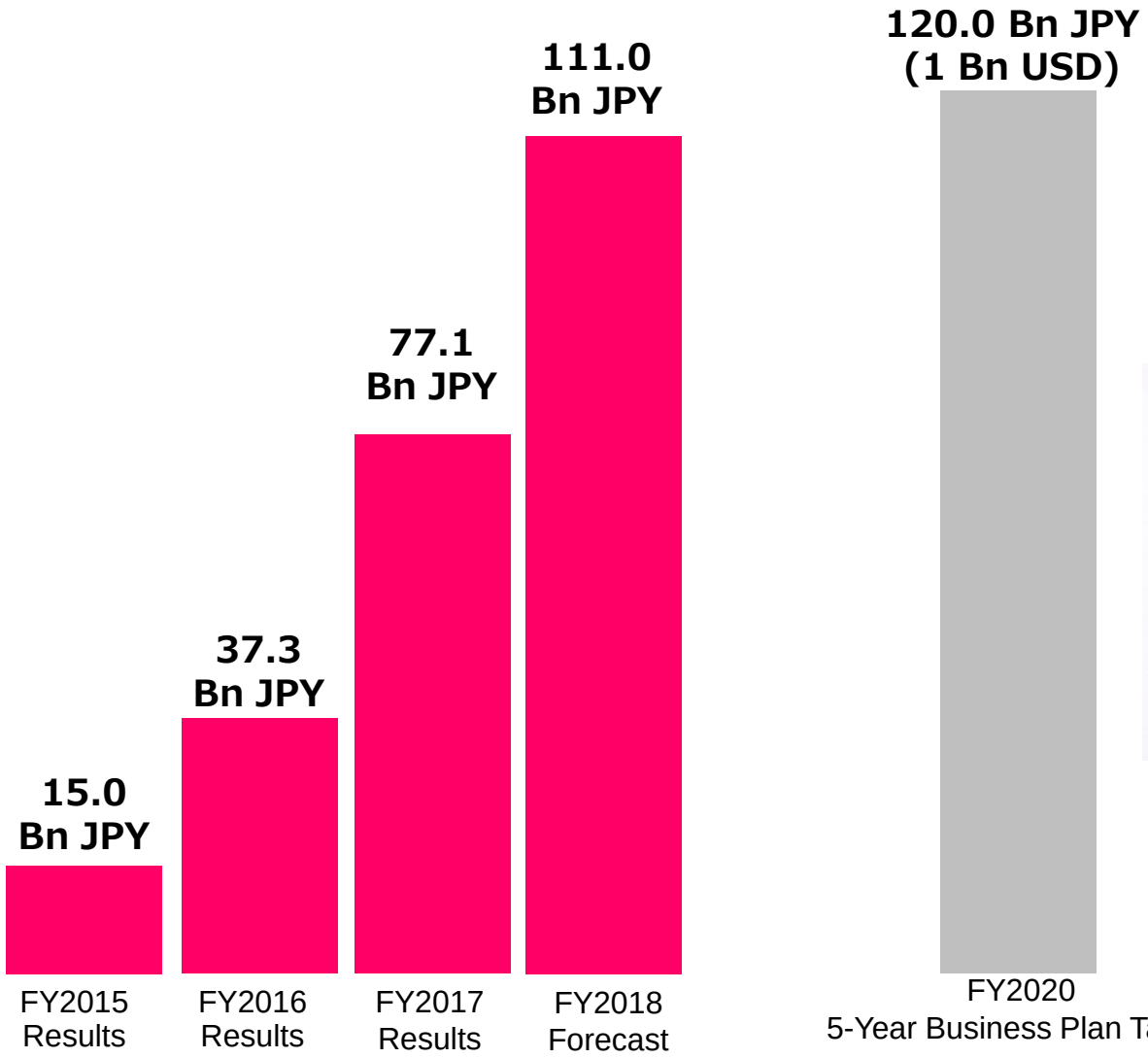
Edoxaban volume (DoT) % share of DOAC markets over time



Brazil: Launched in Aug. 2018

Edoxaban: FY2020 Target

Expanding mainly in Japan, EU and Asia



anticoagulant agent

Edoxaban

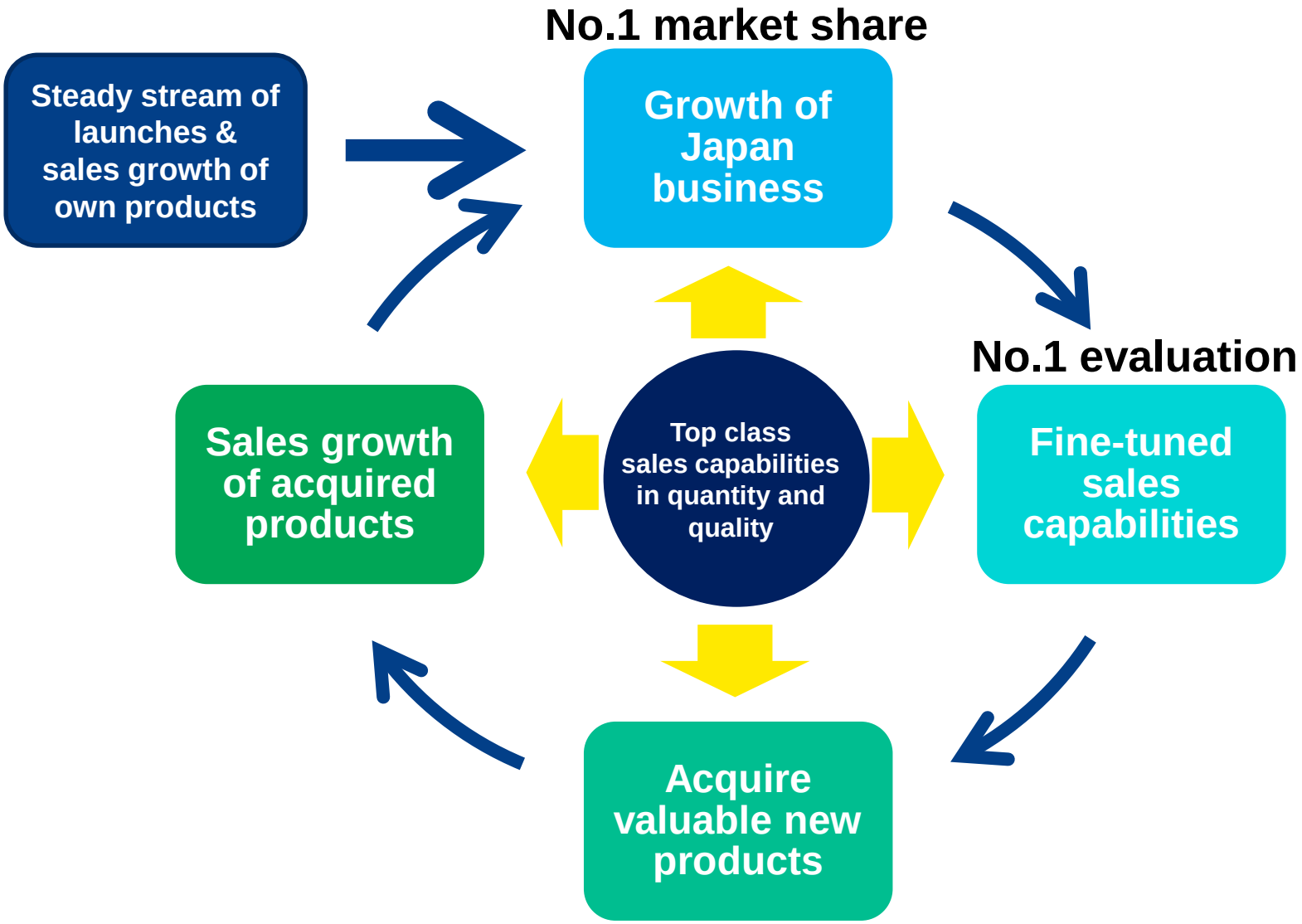
(Lixiana/Savaysa)

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

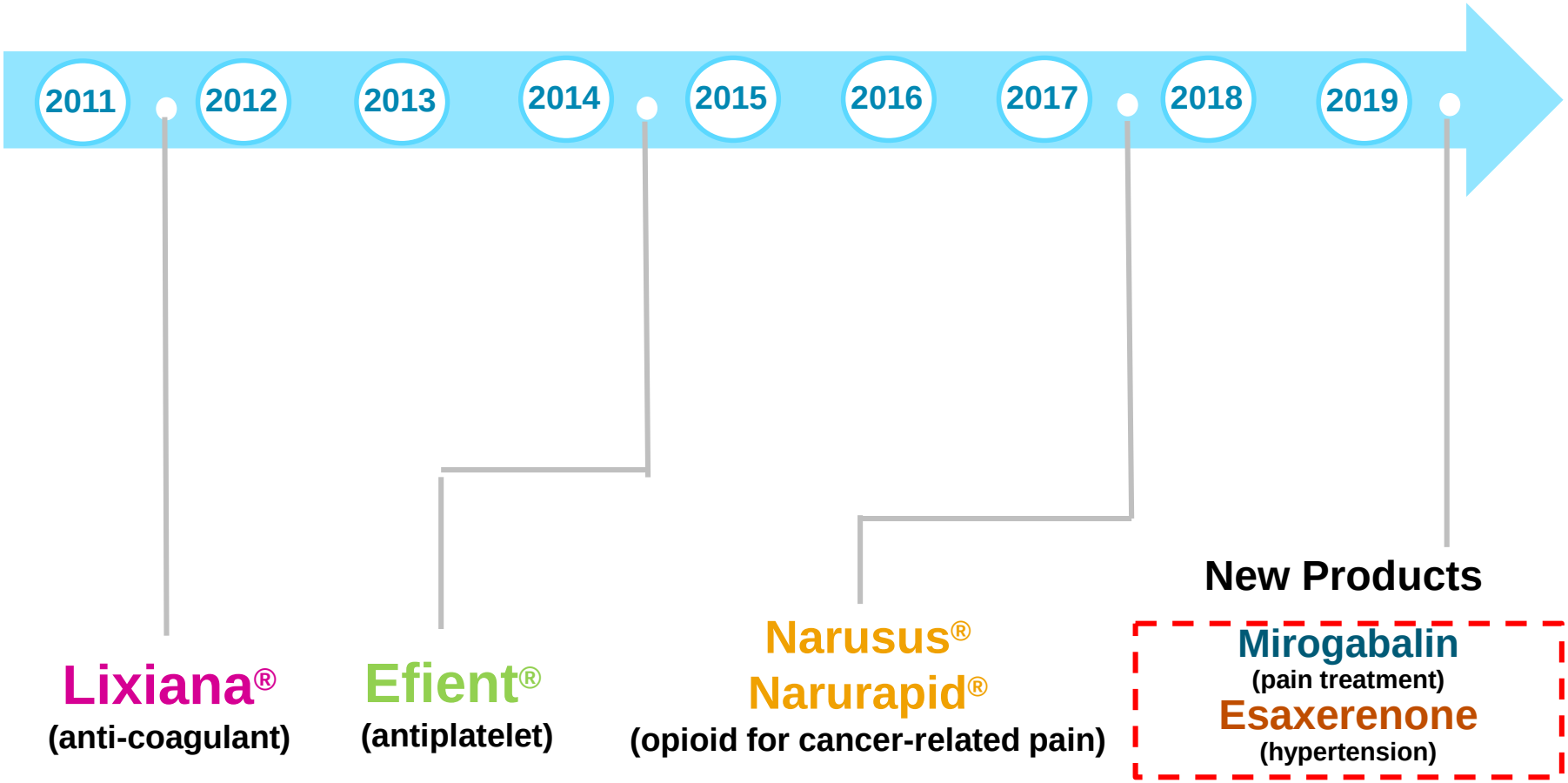
Highlights

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

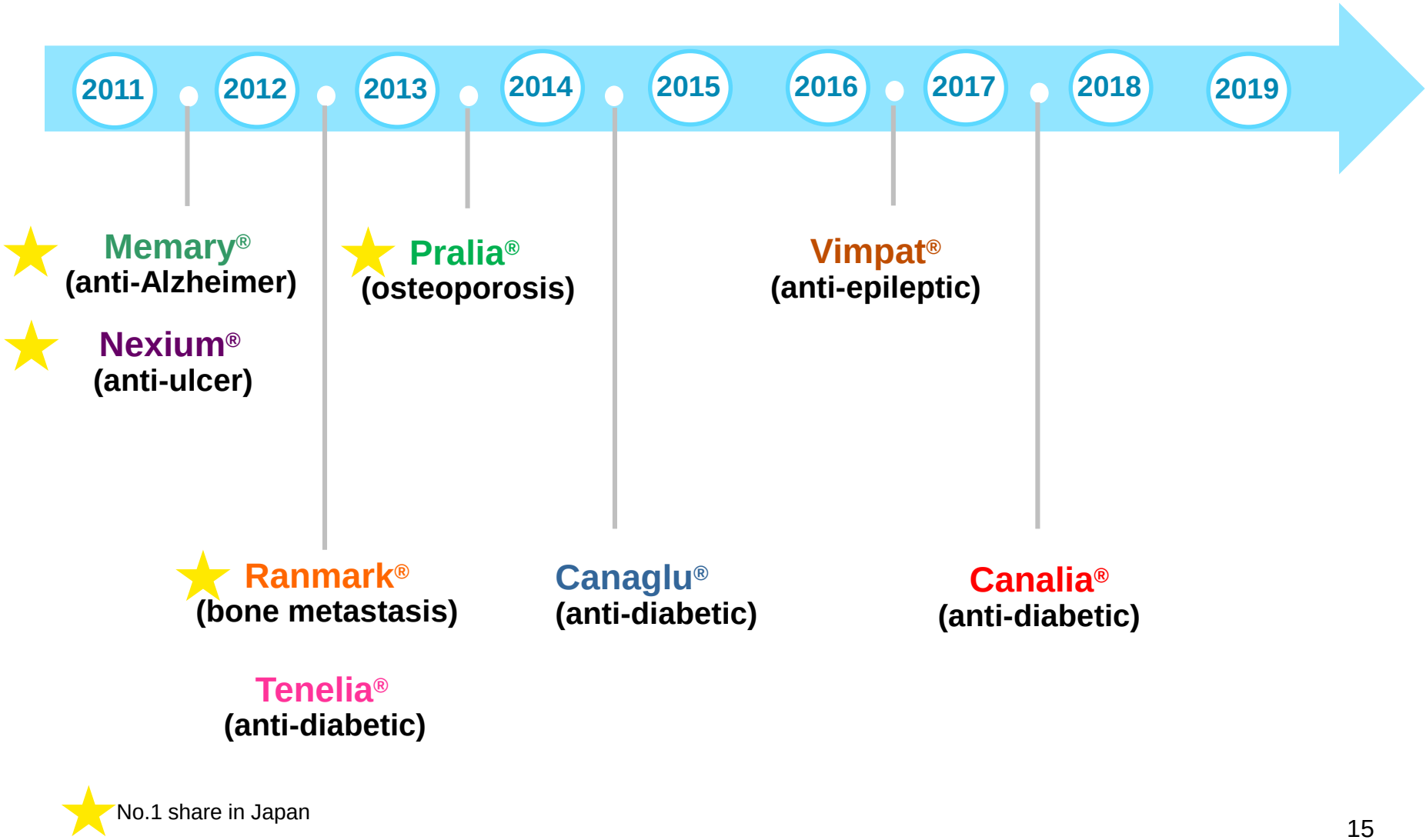
Business Cycle for Sustainable Growth



Own or In-House Products

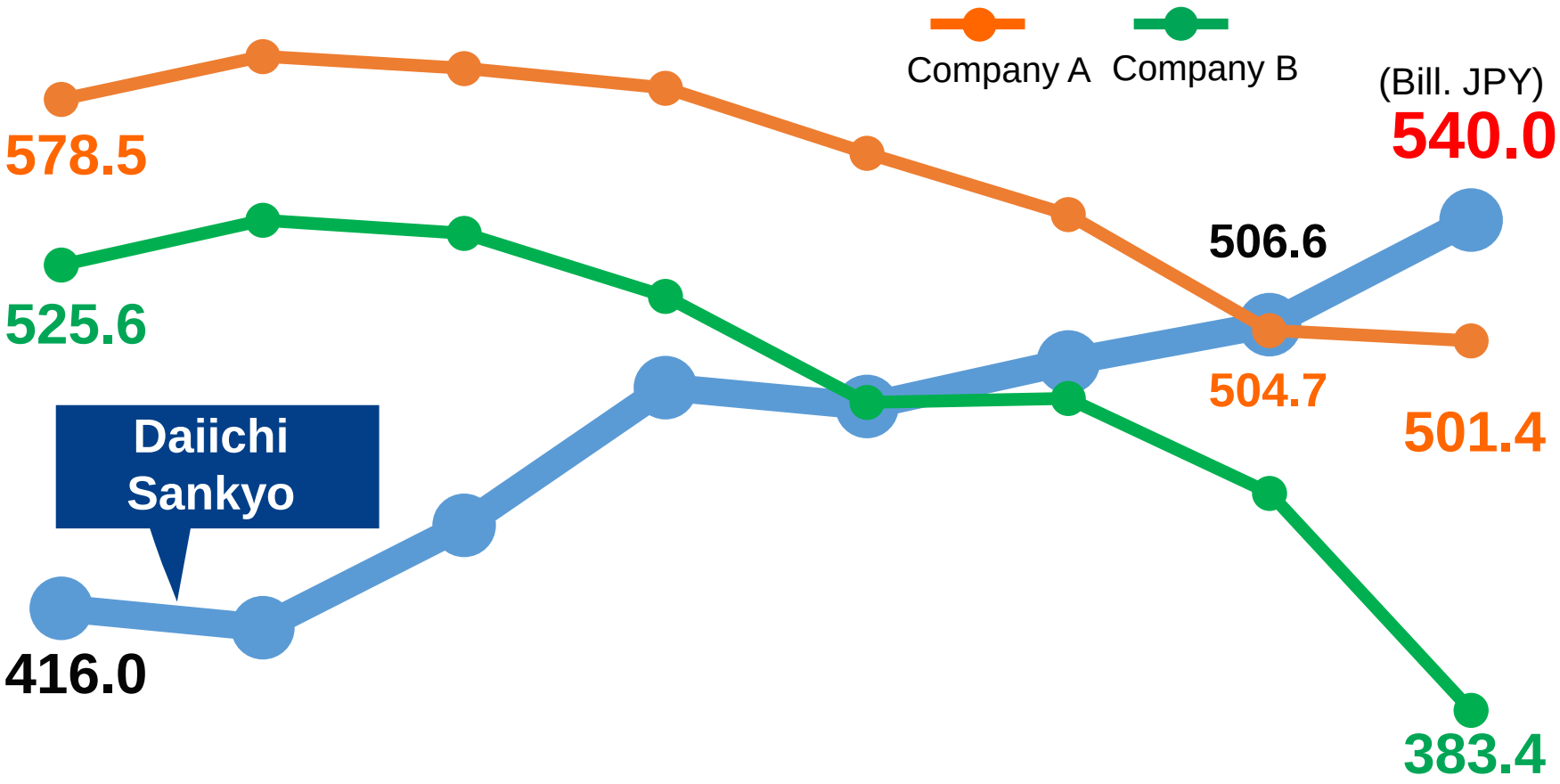


Acquired or In-Licensed Products



Growth of Japan Business

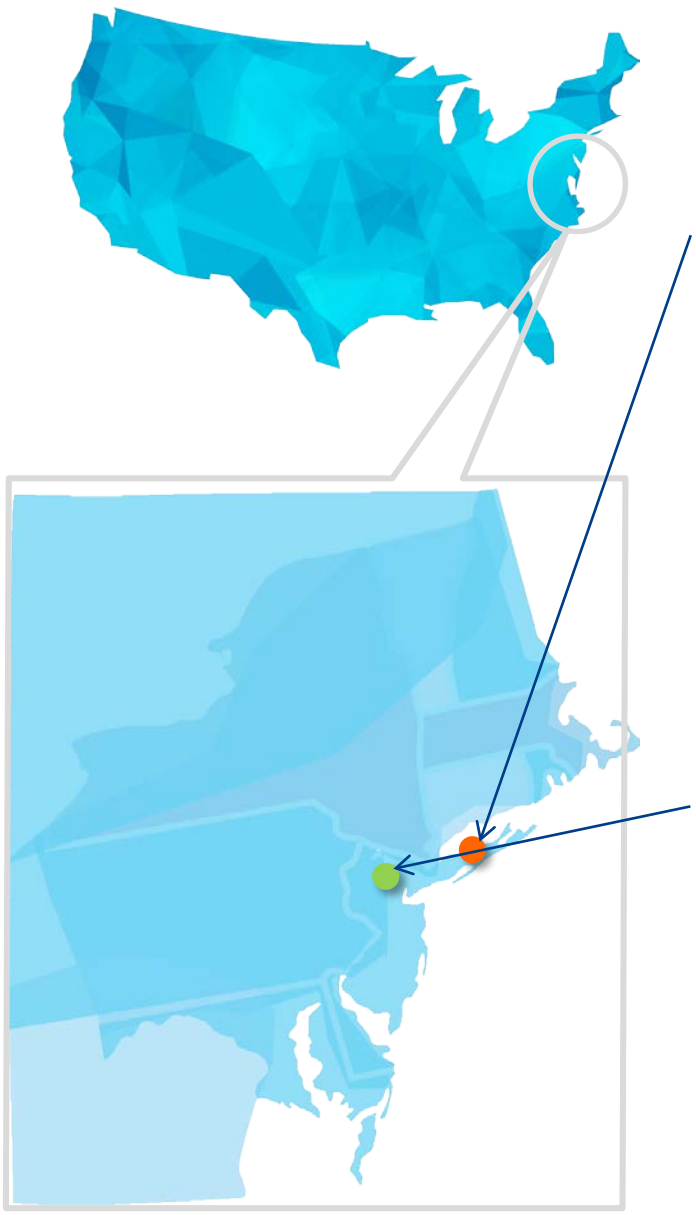
◆ **NO.1 in Japan, by prescription drug revenue for 2 consecutive years**



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

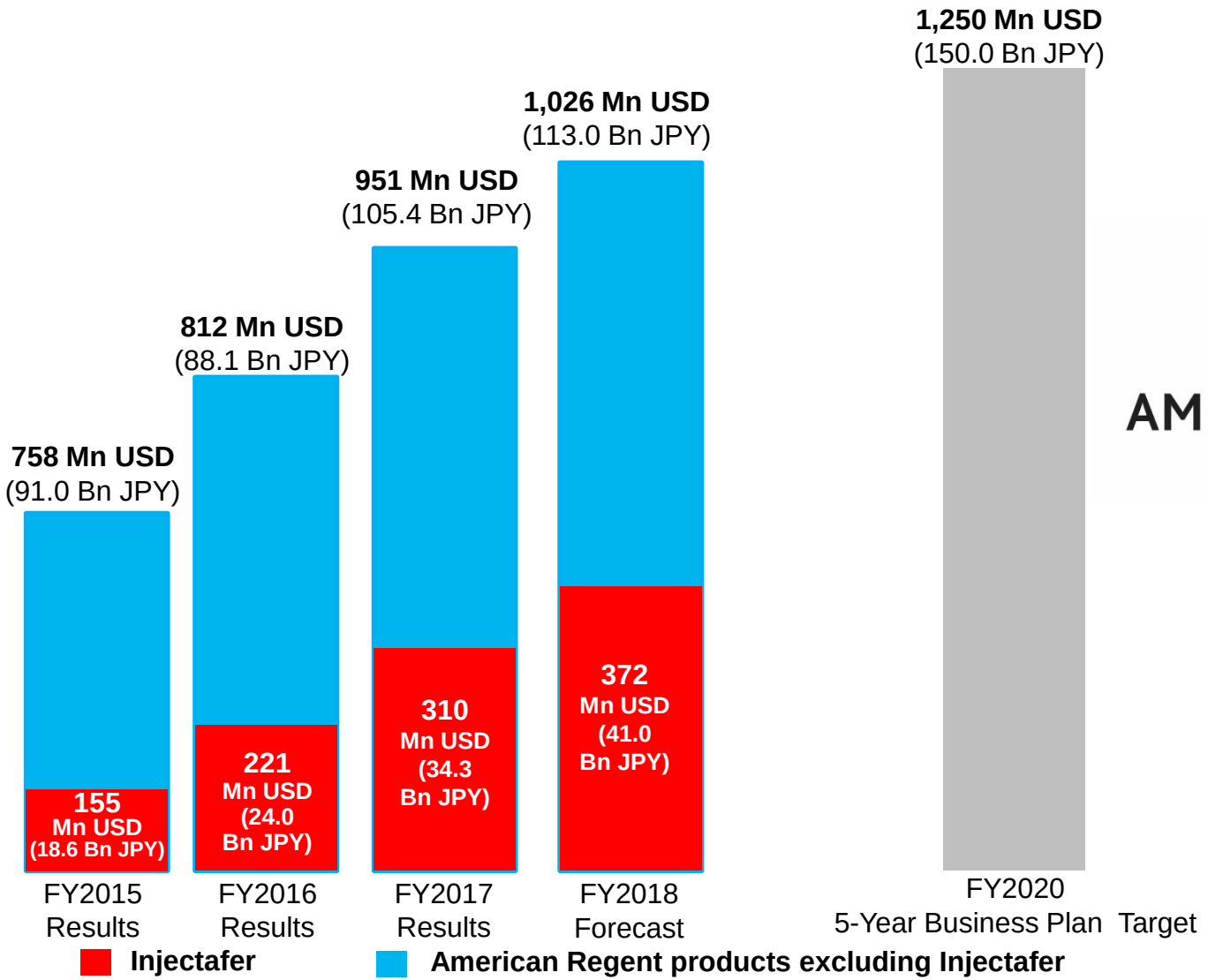
Injectafer: High-dose IV Iron with Broad Indication

- **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

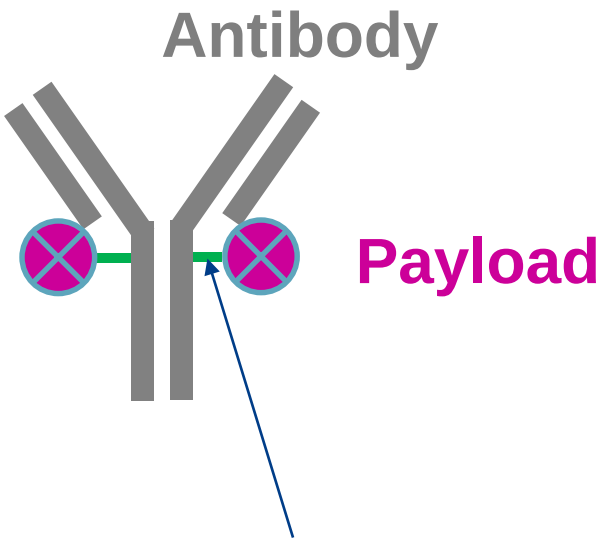
- **Rich pipeline Pexidartinib etc.**

1

Cancer Enterprise 2025 Vision

7 new molecular entities by 2025

ADC Technology



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

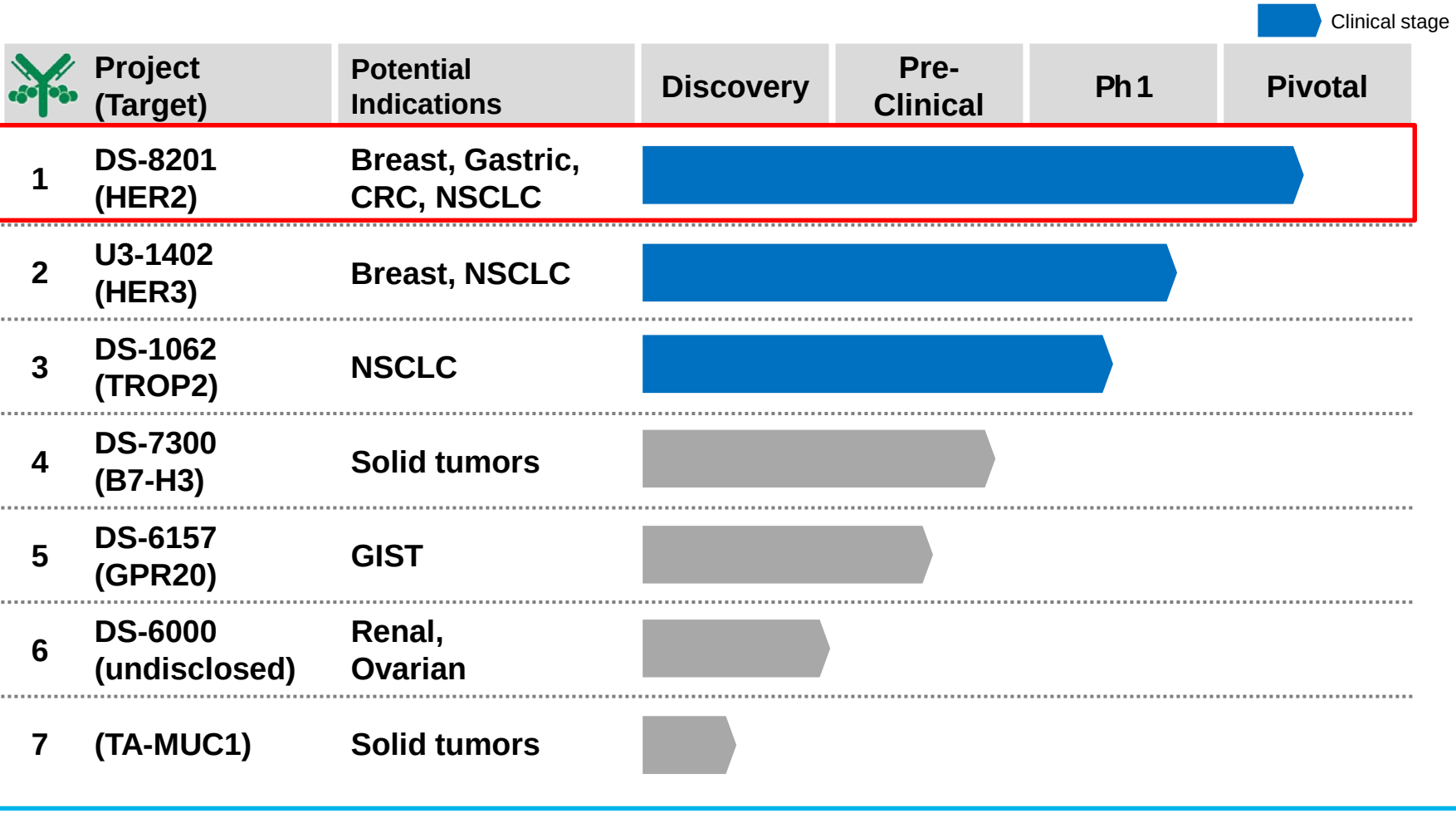
- Stable linker-payload
- Tumor selective cleavable-linker
- High DAR* and homogeneity

*DAR: drug antibody ratio

Daiichi Sankyo ADC Franchise

As of Dec 2018

ADC Franchise



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

DS-8201: Clinical Program

As of Dec 2018

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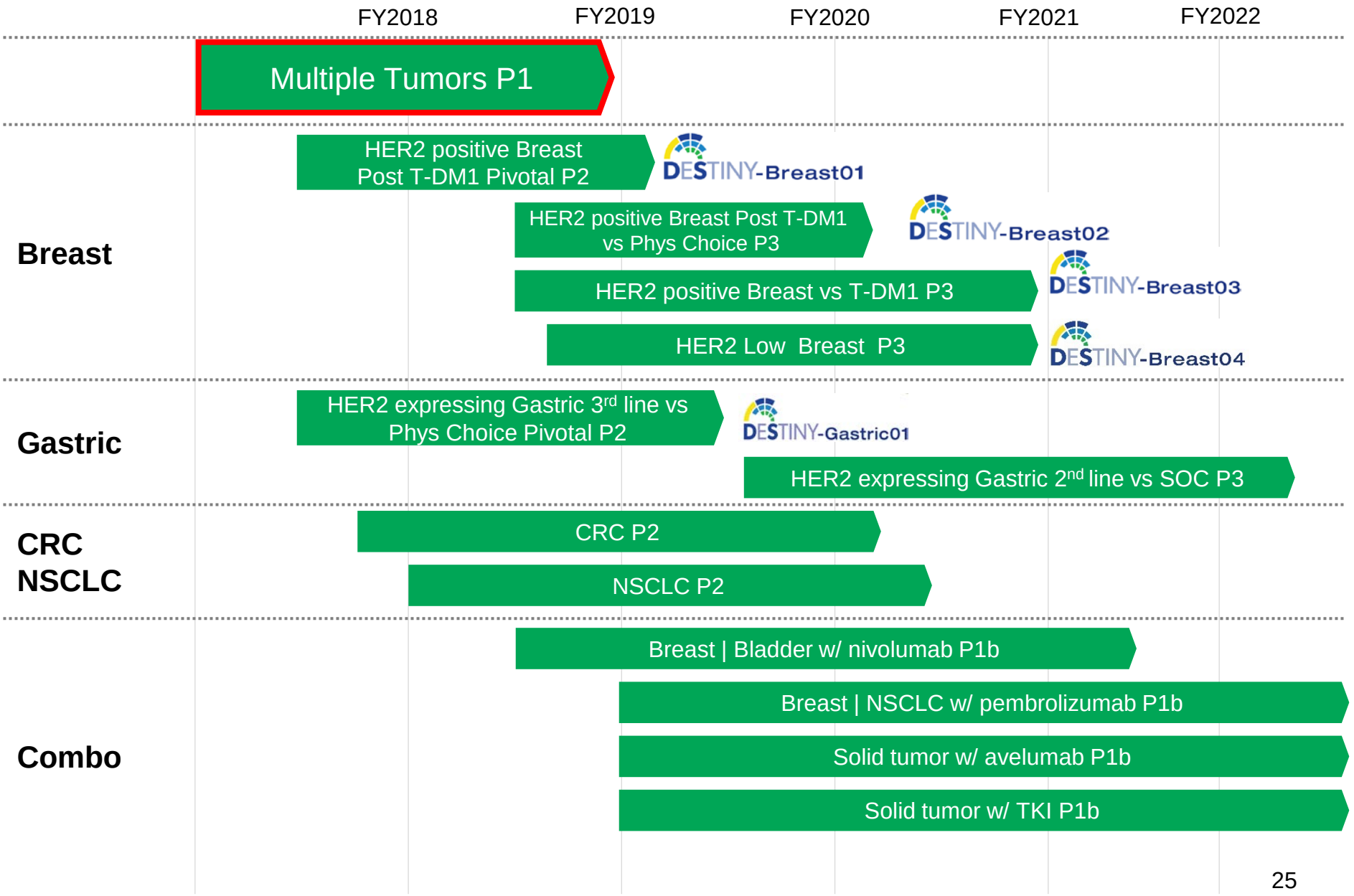
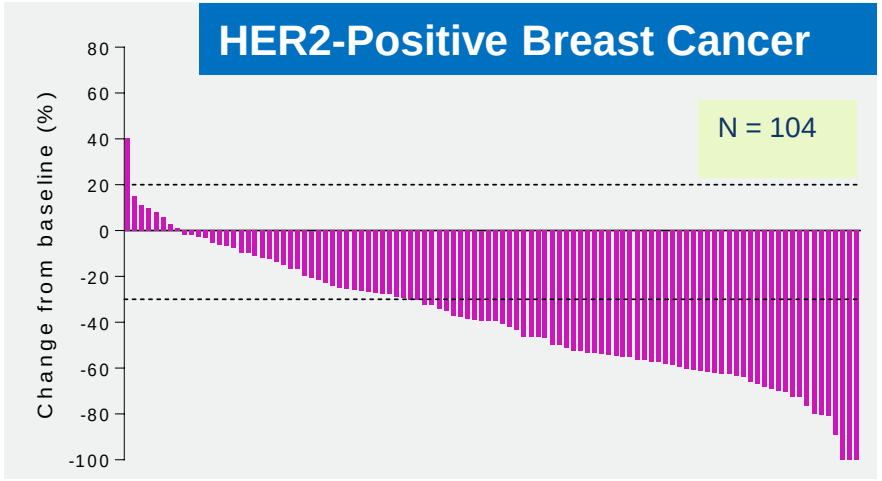
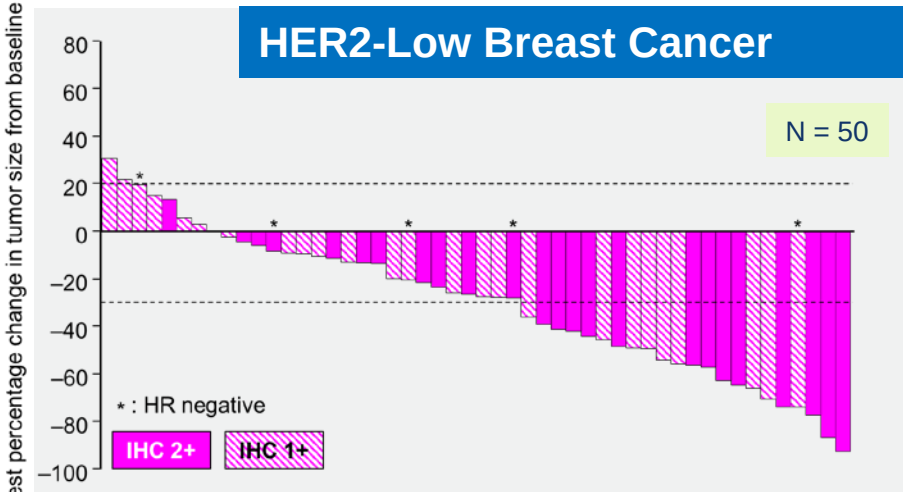
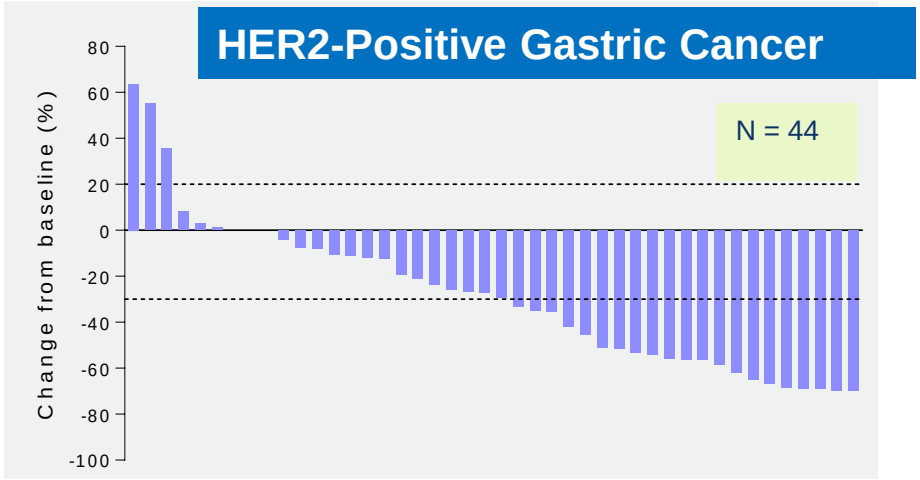


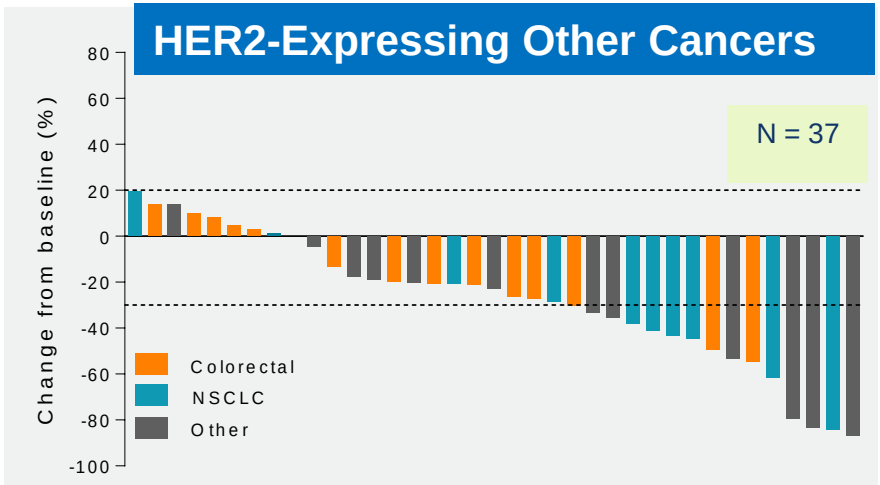
DS-8201: P1 Study Efficacy

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

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

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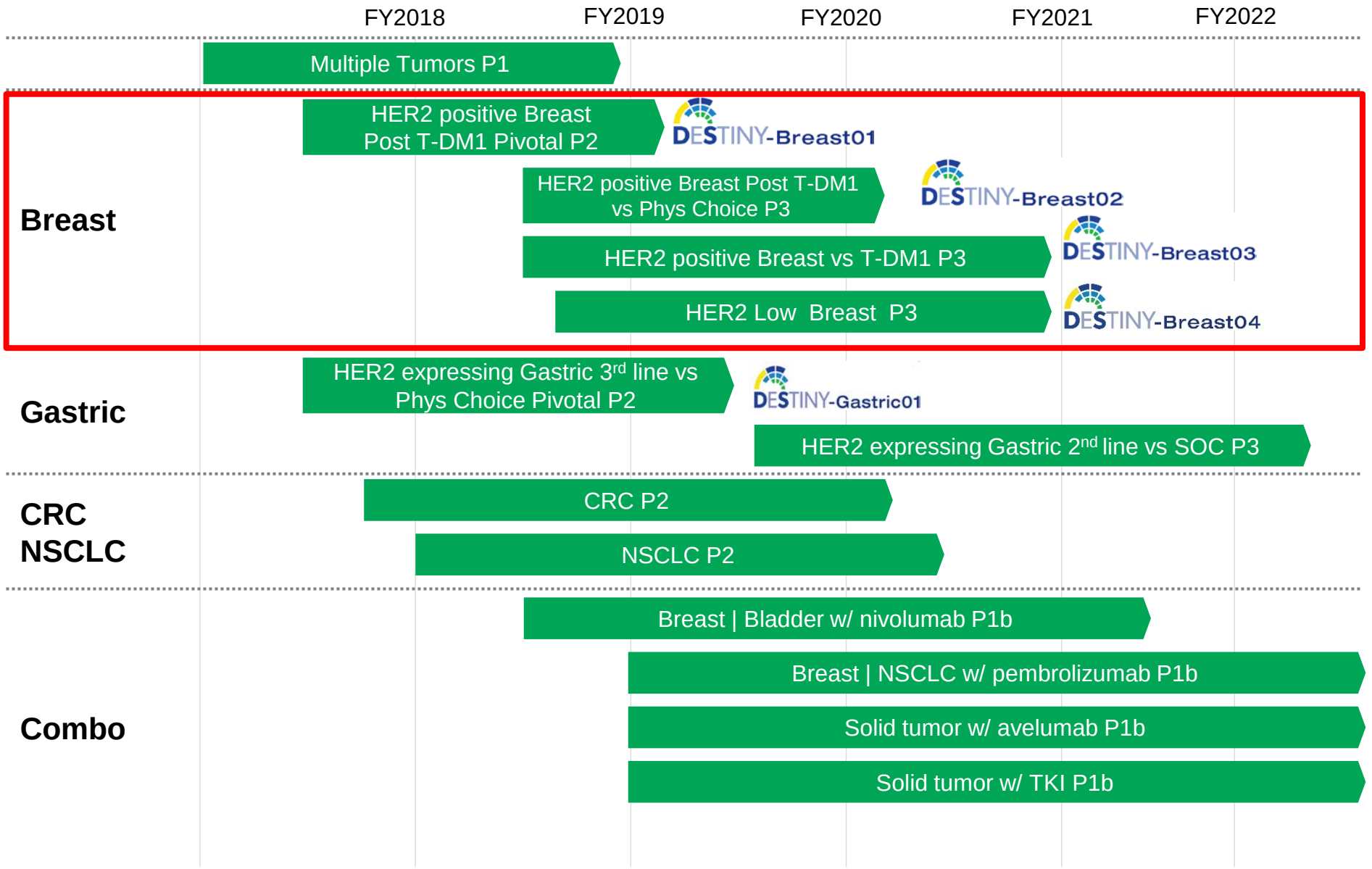


DS-8201: HER2 Positive Metastatic BC Target Population

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

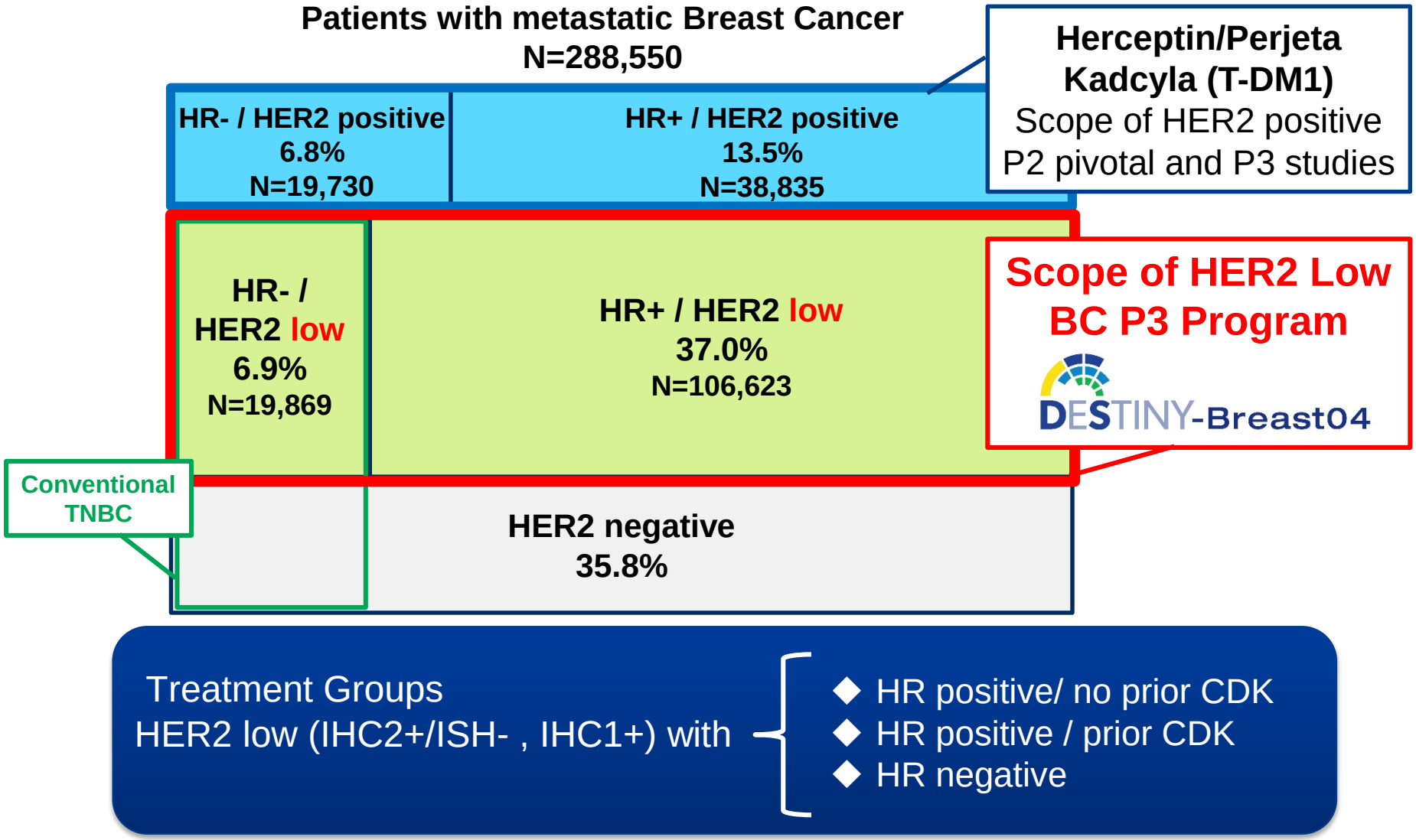
Enrollment Complete

vs Physician Choice
Phase 3

DESTINY-Breast02

Started

DS-8201: HER2 Low BC P3 Target Population

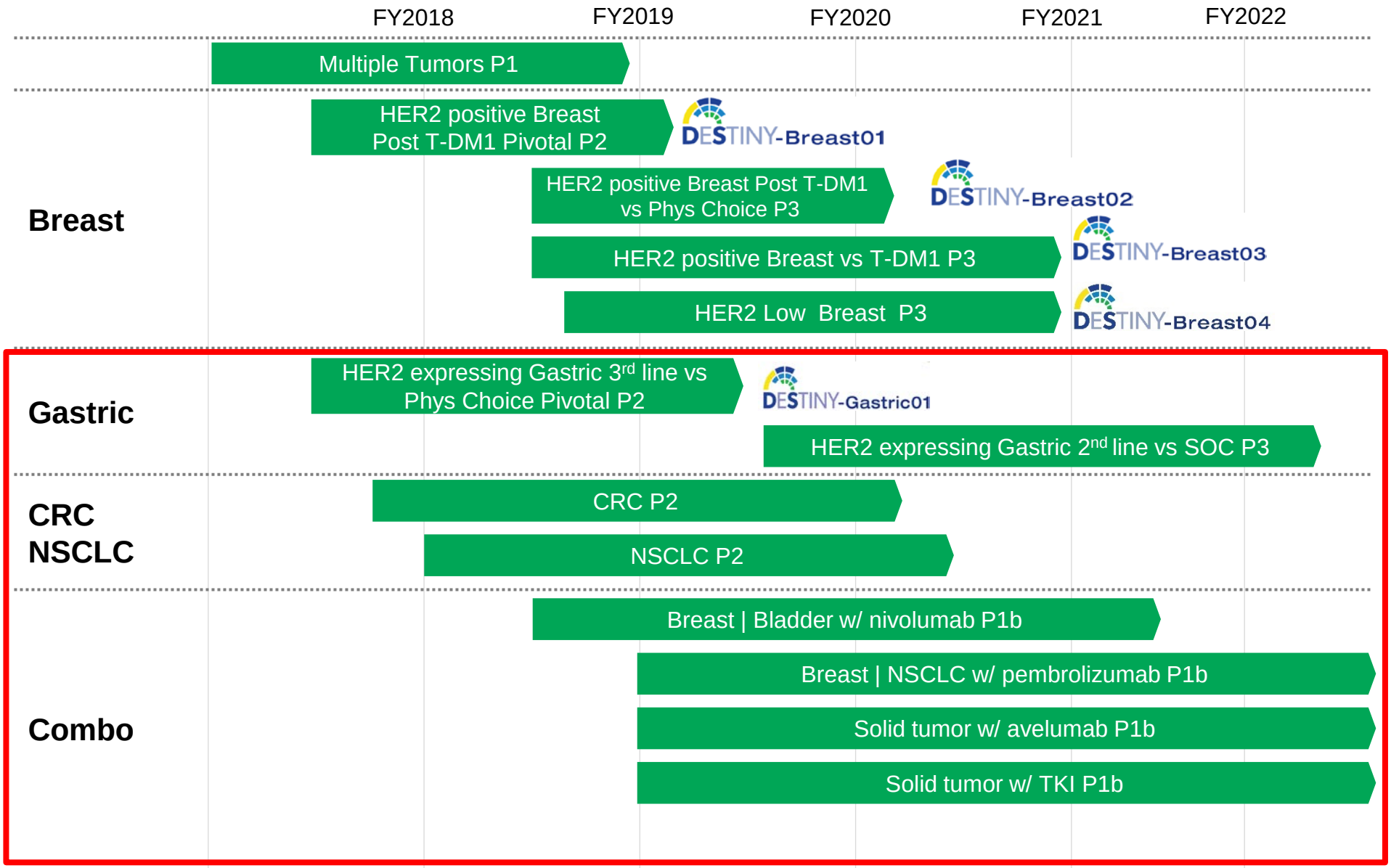


HR: hormone receptor; TNBC: triple negative breast cancer
HR-: estrogen-receptor (ER) and progesterone-receptor (PR) negative

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

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Current/future trials for further data-gated development

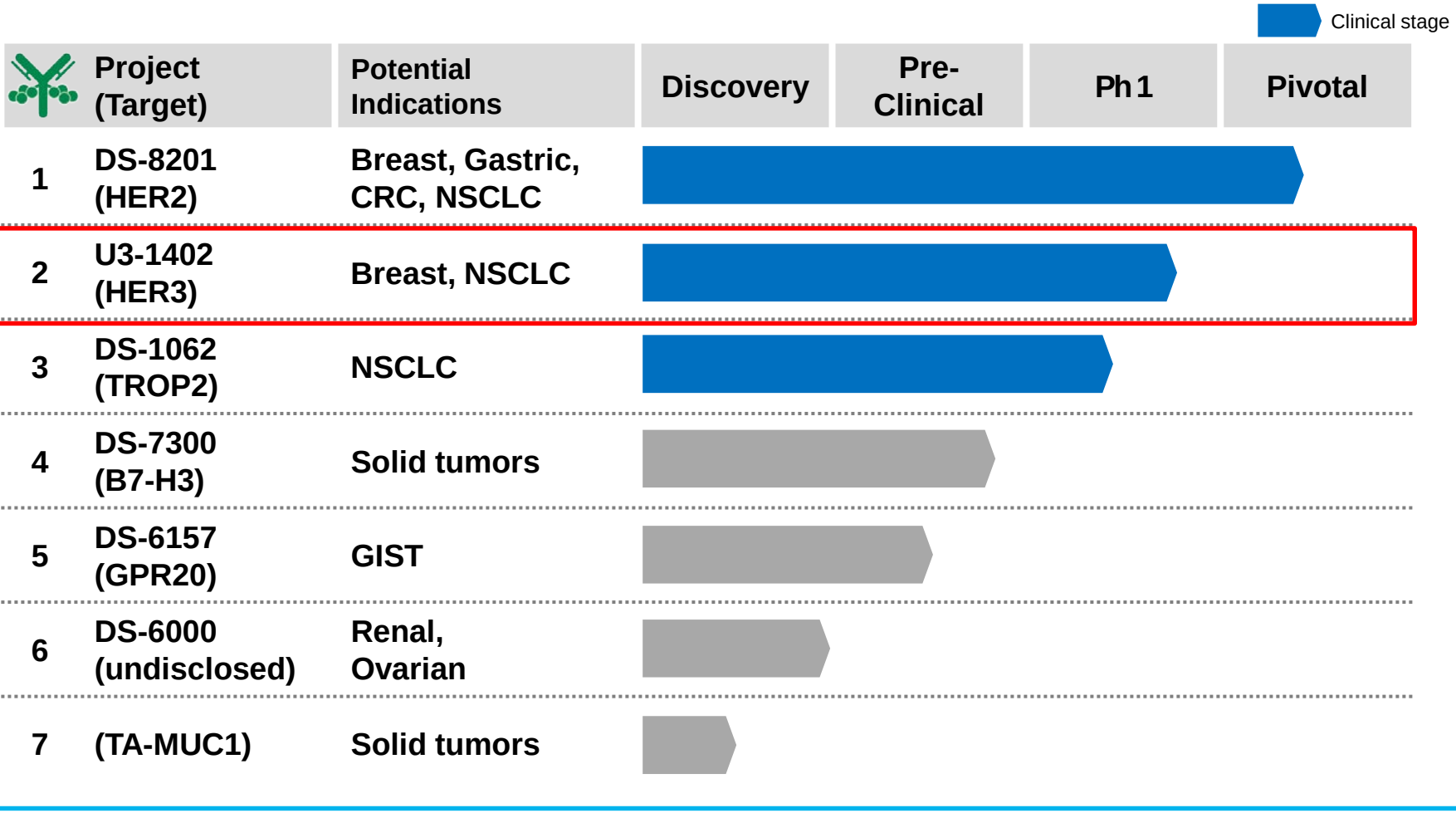
New plans

		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

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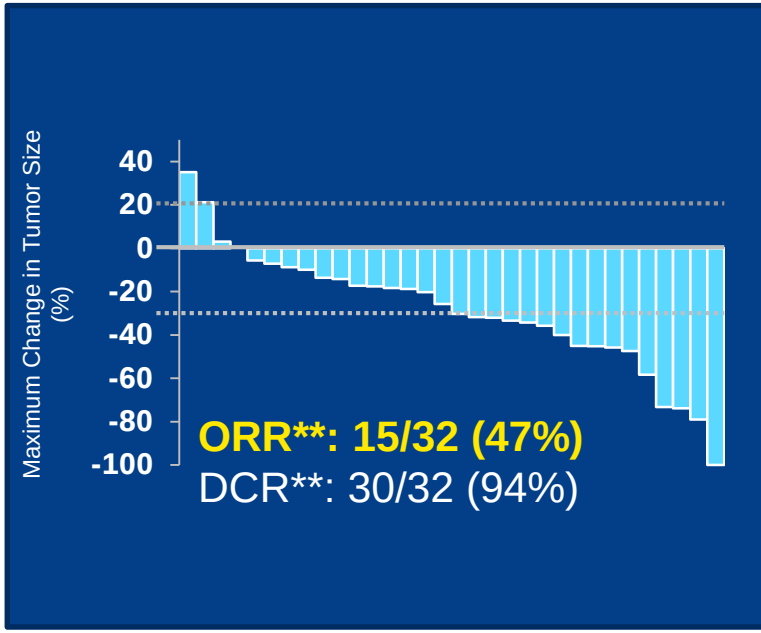
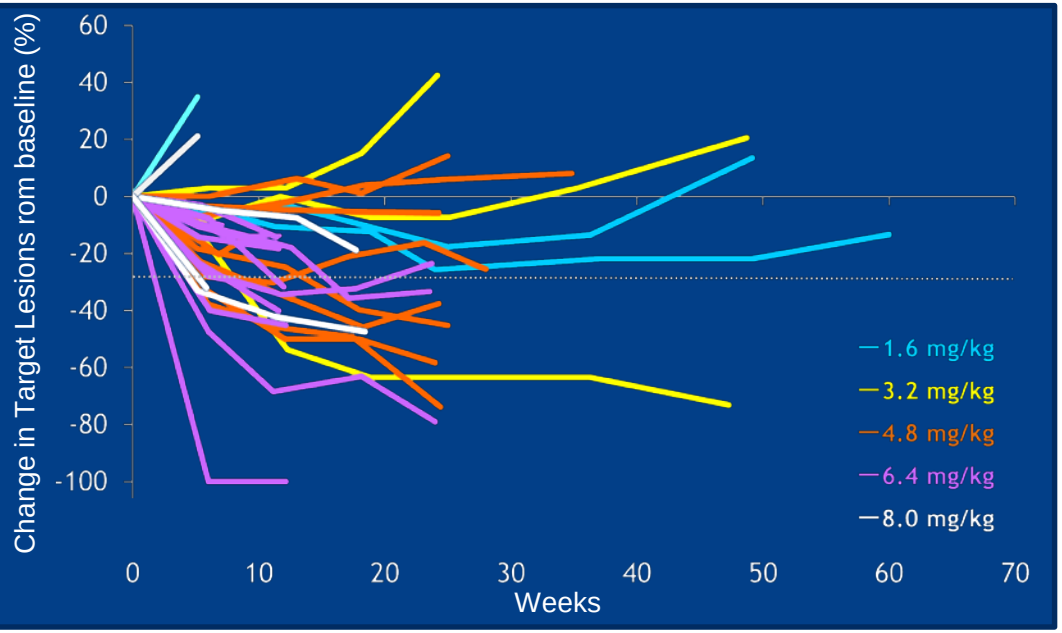
Best Percentage Change in Sum of Diameters From Baseline in Target Lesions*



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

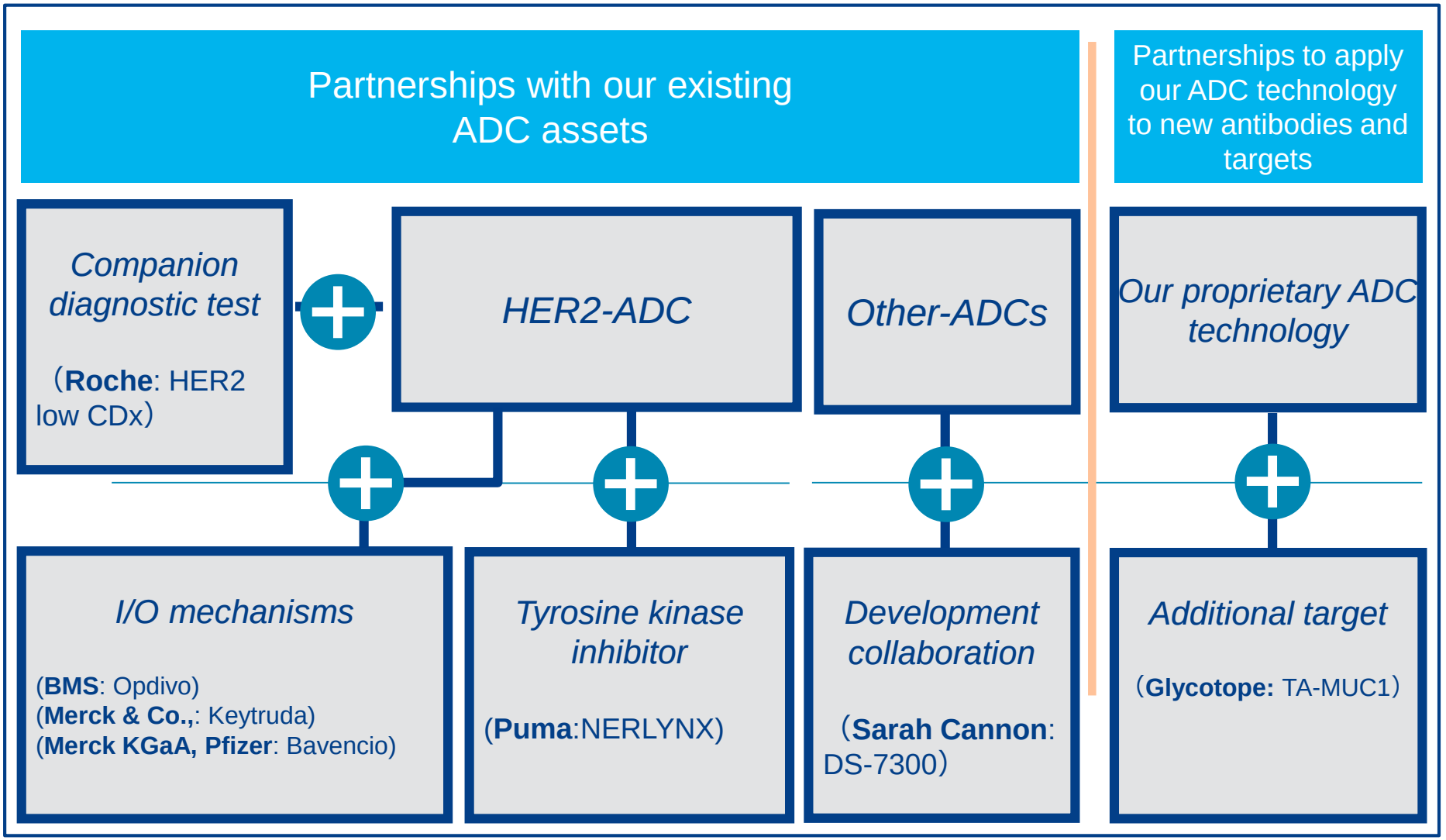
DS-8201

- 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

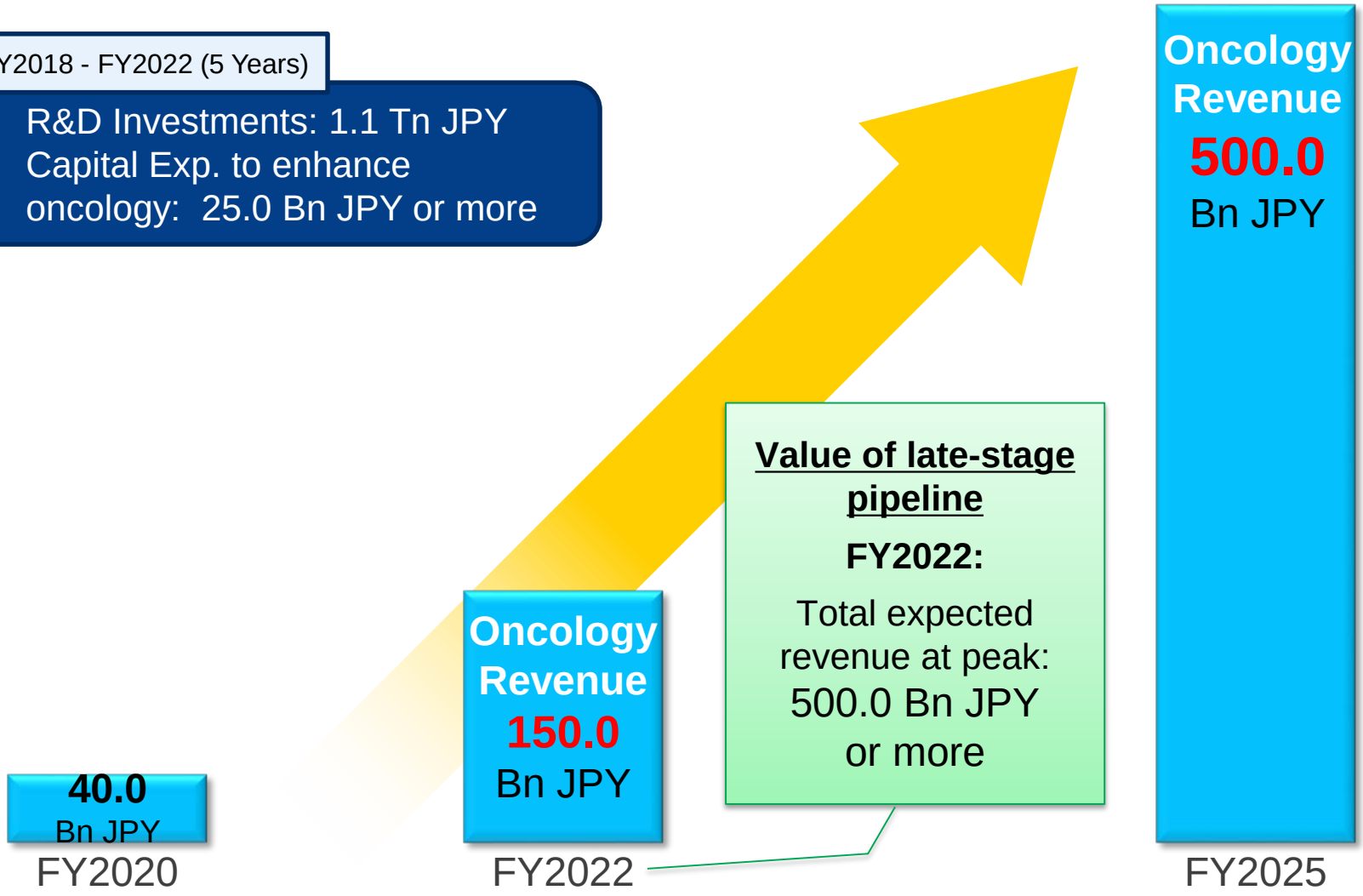


Oncology Business: Revenue Target

- 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



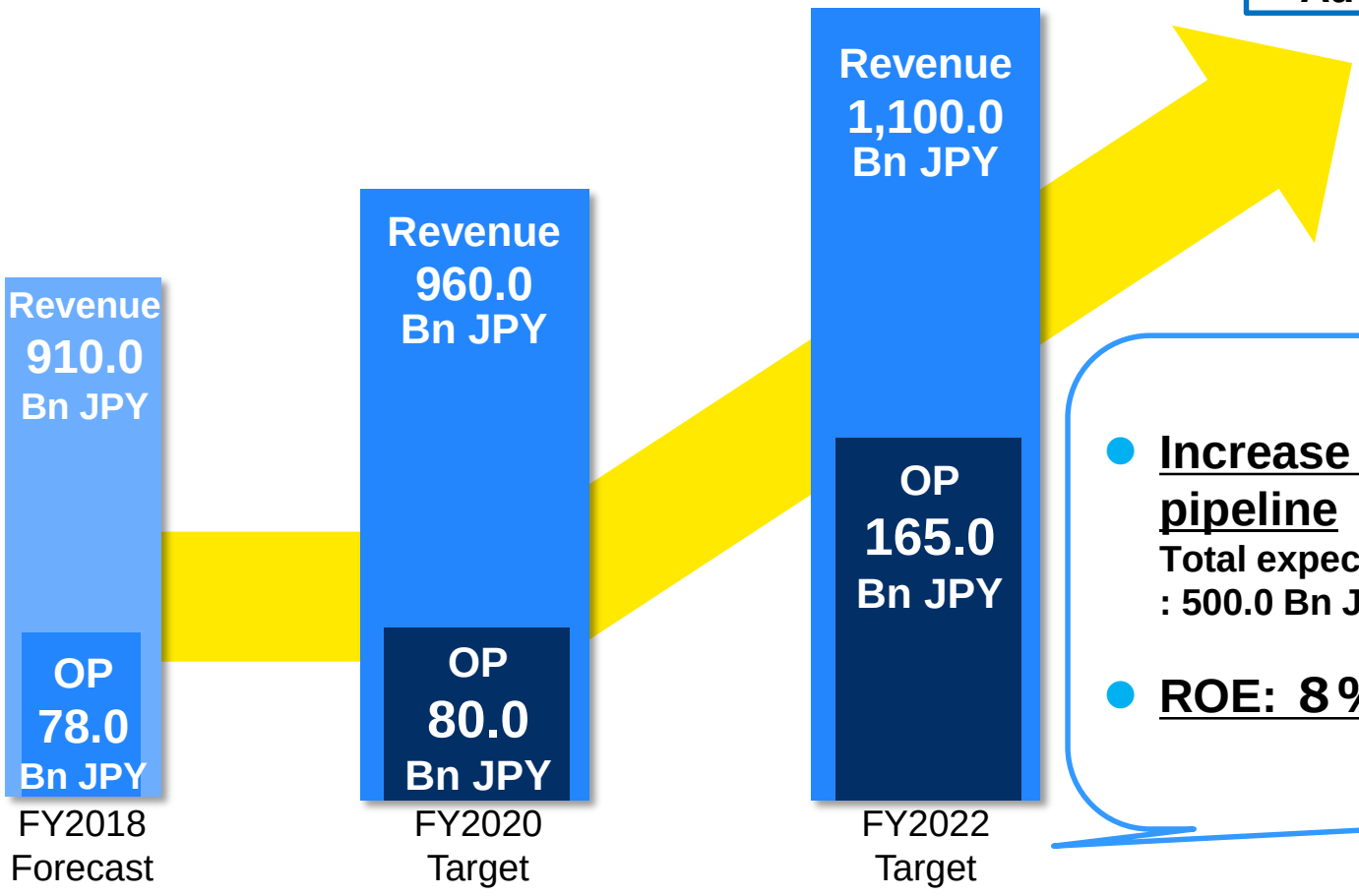
Highlights

Revised Target for 5-Year Business Plan

Revised Target for 5-Year Business Plan

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

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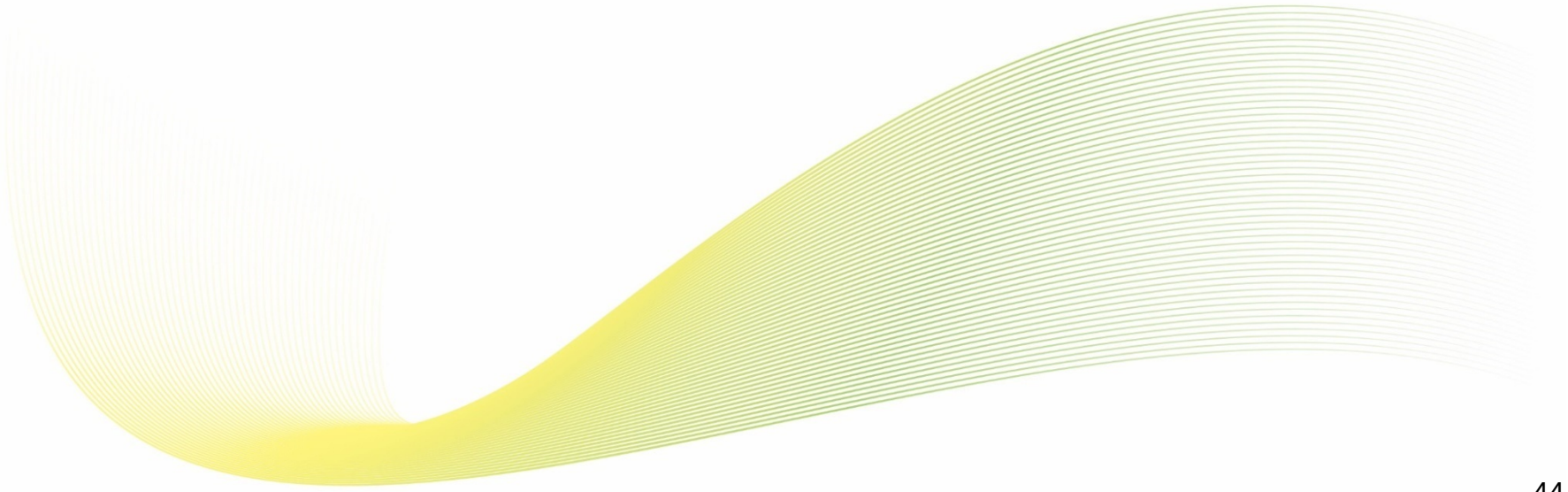
Shareholder Returns Policy: FY2016 - FY2022

- 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

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