

Passion for Innovation.  
Compassion for Patients.™



Daiichi Sankyo Vision:

To Be a Global Pharma Innovator with  
a Competitive Advantage in Oncology

**George Nakayama**

President and CEO, Daiichi Sankyo Co., LTD.  
JP Morgan Healthcare Conference 2017

# 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.

This 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

- ◆ 2025 Vision and 5-Year Business Plan (5YBP)
- ◆ Progress of 5-Year Business Plan
- ◆ Oncology R&D

- ◆ **2025 Vision and 5-Year Business Plan (5YBP)**
- ◆ Progress of 5-Year Business Plan
- ◆ Oncology R&D

## Global Pharma Innovator with a 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 the standard of care***
- ◆ **Realize shareholder value through highly efficient management**

## Global Pharma Innovator with a Competitive Advantage in Oncology

### 2016 - 2020 5-Year Business Plan

Transformation  
toward 2025 Vision

## 2025 Vision

Until 2015

- CVM area
- PCP focus
- Global products
- In-house
- Sales volume

- Oncology area
- Specialty area
- Regional value
- Alliance
- Sustainable profit growth

# To Achieve Our 5-Year Business Plan, We Must...

- 1) Grow beyond FY2017 LOE
- 2) Establish Foundation of Sustainable Growth

# Key Targets

	FY2015 (Forecast)	FY2017 (Target)	FY2020 (Target)
Revenue (Bn JPY)	980.0	940.0	1,100.0
Operating Profit (Bn JPY)	130.0	<u>100.0</u>	165.0

- ◆ ROE: 8% or more (FY2020)
- ◆ Increase value of late-stage pipeline  
3 - 5 products launched within the next 5 years with peak-sales of more than 100.0 Bn JPY each
- ◆ Total return ratio: 100% or more (during 5YBP)
- ◆ Annual ordinary dividends: more than 70 JPY (during 5YBP)
- ◆ Flexible acquisition of own shares

Assumption: Exchange rate of 1USD=120JPY, 1EUR=130JPY



# 6 Strategic Targets

- 1) Grow Edoxaban
- 2) Grow as No.1 Company in Japan
- 3) Expand US Business
- 4) Continuously Generate Innovative Medicine:  
Change Standard of Care (SOC)
- 5) Establish Oncology Business
- 6) Enhance Profit Generation Capabilities

- ◆ 2025 Vision and 5-Year Business Plan (5YBP)
- ◆ **Progress of 5-Year Business Plan**
- ◆ Oncology R&D

## 1) **Grow Edoxaban**

2) Grow as No.1 Company in Japan

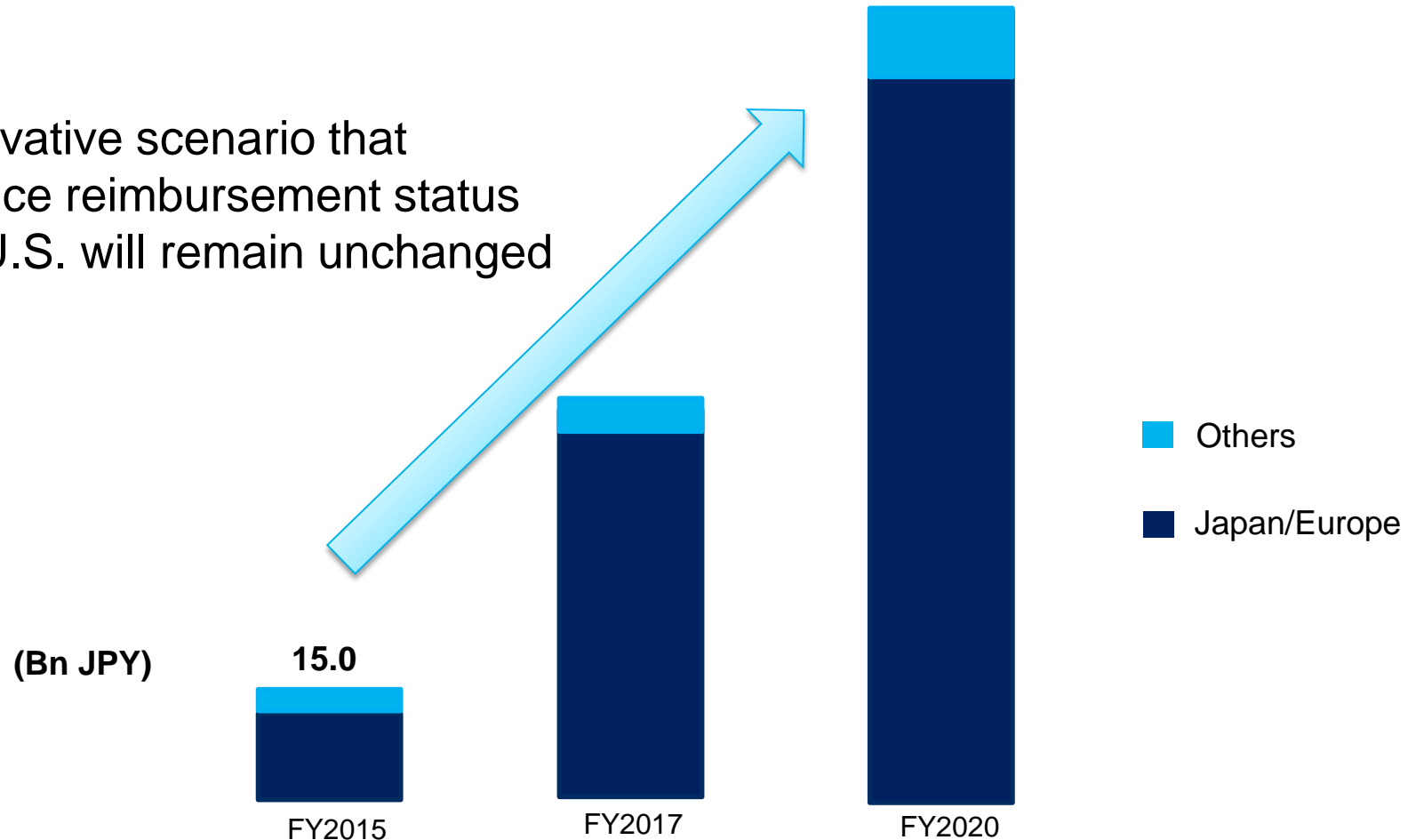
3) Expand US Business

4) Continuously Generate Innovative Medicine:  
Change Standard of Care (SOC)

# Global Target for Edoxaban

**Over 120.0 Bn JPY**  
**(1 Bn USD) in FY2020**

Conservative scenario that insurance reimbursement status in the U.S. will remain unchanged



Assumption: Exchange rate of 1USD=120JPY, 1EUR=130JPY

## ◆ Product launches & alliances as of FY2015

Japan, the U.S, Switzerland, the U.K, Germany, Ireland,  
the Netherlands, South Korea

Partner with MSD\* in EU

## ◆ New market launches

Italy, Spain, Taiwan (Sep. 2016)

Belgium, Hong Kong (Oct. 2016)

## ◆ New alliances

Partner with Servier Canada inc.\*\*

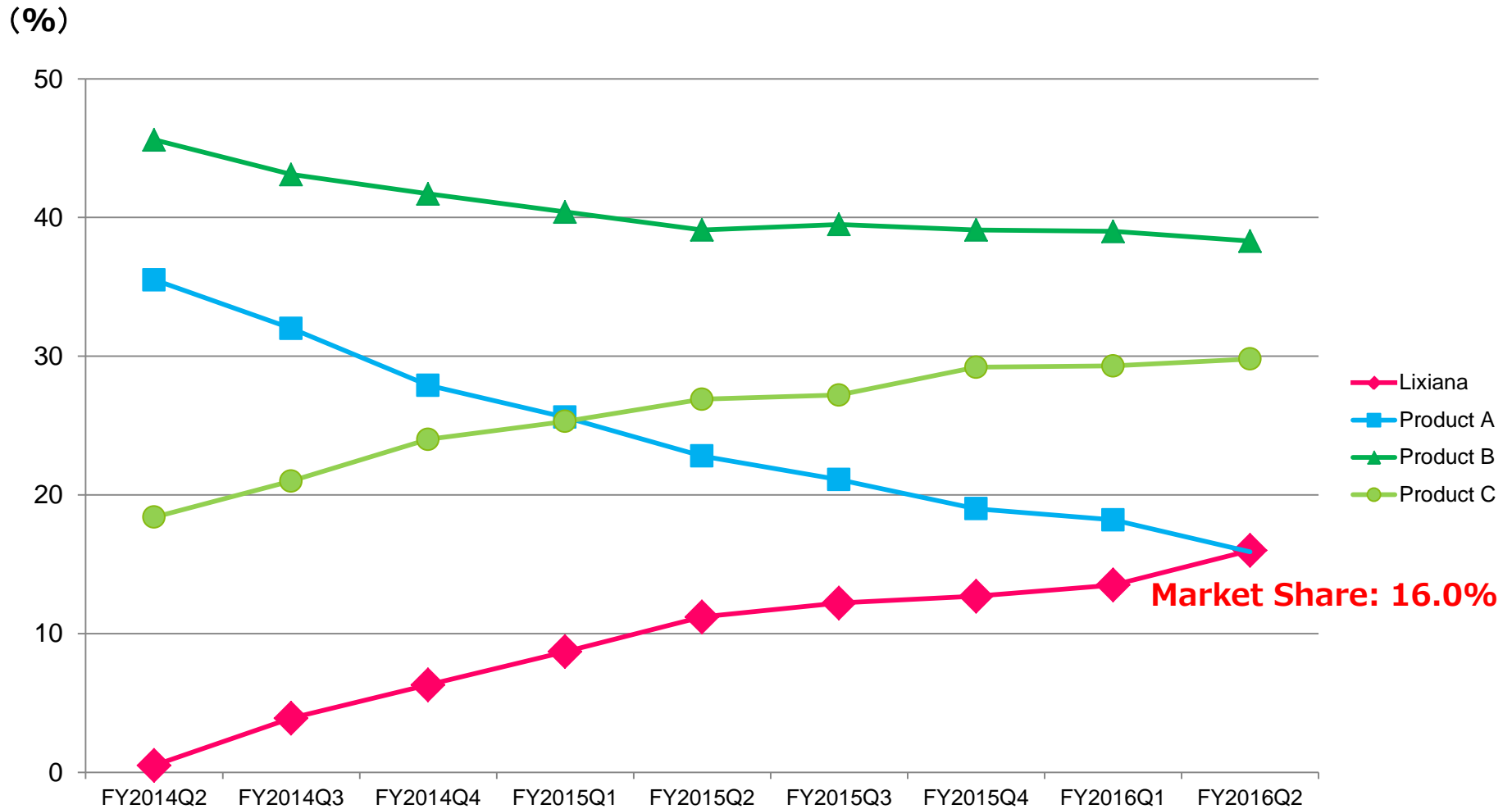
in Canada (Jun. 2016)

\*MSD: Merck Sharp and Dohme European Subsidiary of Merck & Co., Inc.

\*\*Canadian Subsidiary of LES LABORATOIRES SERVIER

# Growth in Japan







Latest market share reached: 16.0% (Jul. 2016 - Sep. 2016)



Copyright © 2016 QuintilesIMS  
Calculated based on JPM 2014. Jul.-2016. Sep.  
Reprinted with permission

# Edoxaban Clinical Research Program (1)

## Ongoing randomized controlled trials in various clinical settings

	Clinical Setting (Comparator)	Primary Outcome	Primary Completion
	Cardioversion (enoxaparin/warfarin)	<ul style="list-style-type: none"> <li>Stroke, SEE, MI, CV mortality</li> <li>Major and CRNM bleeding</li> </ul>	Presented at ESC 2016
	PCI (VKA)	<ul style="list-style-type: none"> <li>Major and CRNM bleeding</li> </ul>	Nov. 2018
	Cardiac ablation (VKA)	<ul style="list-style-type: none"> <li>Composite of All cause mortality, Stroke and Major bleeding</li> <li>Major bleeding</li> </ul>	Dec. 2018
	Transcatheter aortic valve implantation (VKA)	<ul style="list-style-type: none"> <li>Net adverse clinical events</li> <li>Major bleeding</li> </ul>	May 2020
	80 years or older who are ineligible for current OAC therapy (placebo)	<ul style="list-style-type: none"> <li>Stroke, SEE</li> </ul>	Dec. 2019
	VTE associated with cancer (dalteparin)	<ul style="list-style-type: none"> <li>Recurrent VTE</li> <li>Clinically relevant bleeding</li> </ul>	Dec. 2017

## Ongoing non-interventional studies to generate real-world data with more than 60,000 patients



Edoxaban Treatment in routine clinical practice in Patients with non valvular Atrial Fibrillation



Prolongation PREFER in AF PREvention of thromboembolic events-European Registry in Atrial Fibrillation



Edoxaban Treatment in routine clinical practice in Patients with Venous Thromboembolism



All Nippon AF In Elderly registry in Japan to study NVAF in elderly patients aged 75 years and older



Edoxaban Management in diagnostic and Therapeutic procedures—AF/VTE



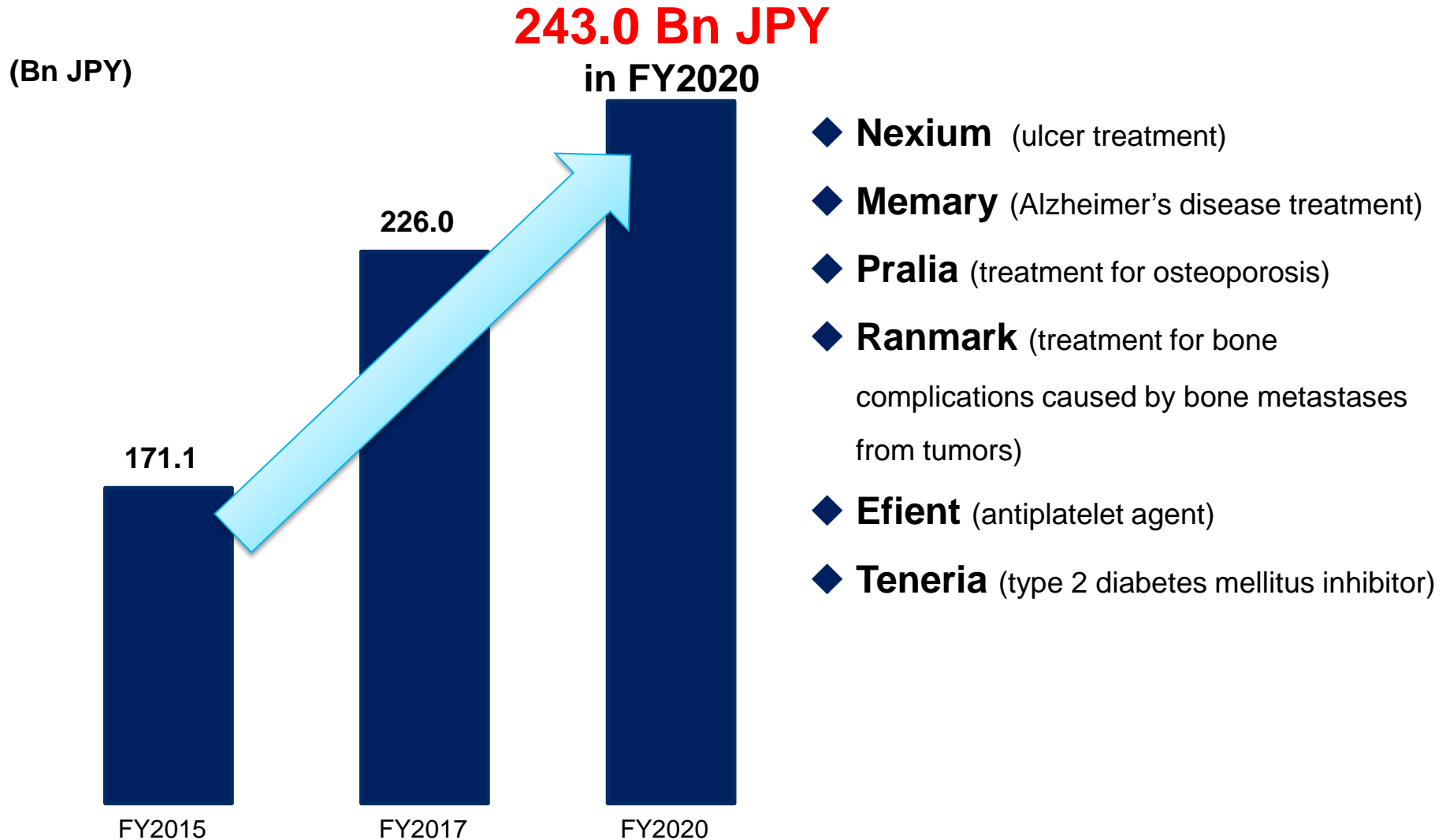
1) Grow Edoxaban

**2) Grow as No.1 Company in Japan**

3) Expand US Business

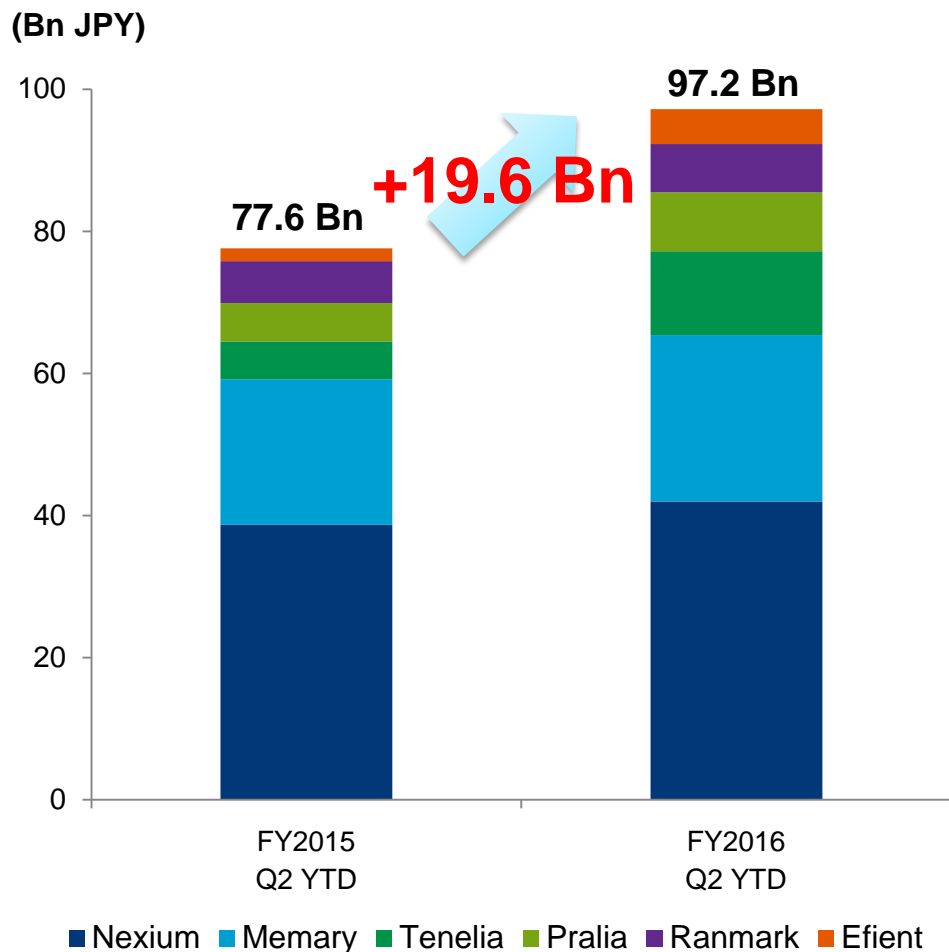
4) Continuously Generate Innovative Medicine:  
Change Standard of Care (SOC)

# Target for Major 6 Products



# Growth of Major Products

Many of innovative major products reached No. 1 share and continue to expand market share



## ◆ Nexium

Reached No. 1 share in Jan. 2014 with rapid expansion and continue to expand market share

## ◆ Memary

Reached No. 1 share in Jan. 2016 catching up with Aricept

## ◆ Pralia

In highly competitive market, reached No. 1 share in Feb. 2016 and continue to expand market share

## ◆ Ranmark

Reached No. 1 share in May 2014 and continue to expand market share promoting appropriate use

- 1) Grow Edoxaban
- 2) Grow as No.1 Company in Japan
- 3) Expand US Business**
- 4) Continuously Generate Innovative Medicine:  
Change Standard of Care (SOC)



## Daiichi Sankyo, Inc. (DSI) (Parsippany, NJ)

FY2016 revenue target  
**US\$ 1.2 Billion**

**Core business: Pain and Oncology**

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

FY2016 revenue target  
**US\$ 808 Million**

**Core business: Iron injectable and  
Generic injectable**



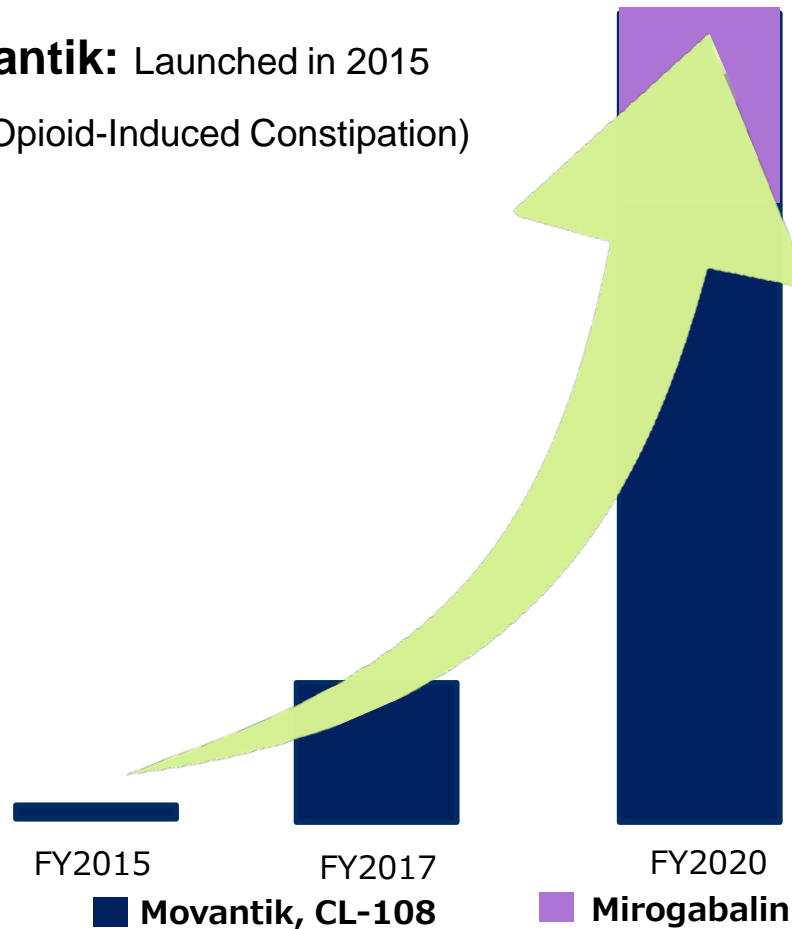
# Target for DSI Pain Franchise

**100 Bn JPY**  
business in FY2020

◆ **Movantik:** Launched in 2015  
(OIC: Opioid-Induced Constipation)

◆ **CL-108:** Targeted launch in FY 2017  
(OINV: Pain & Opioid-Induced Nausea & Vomiting)

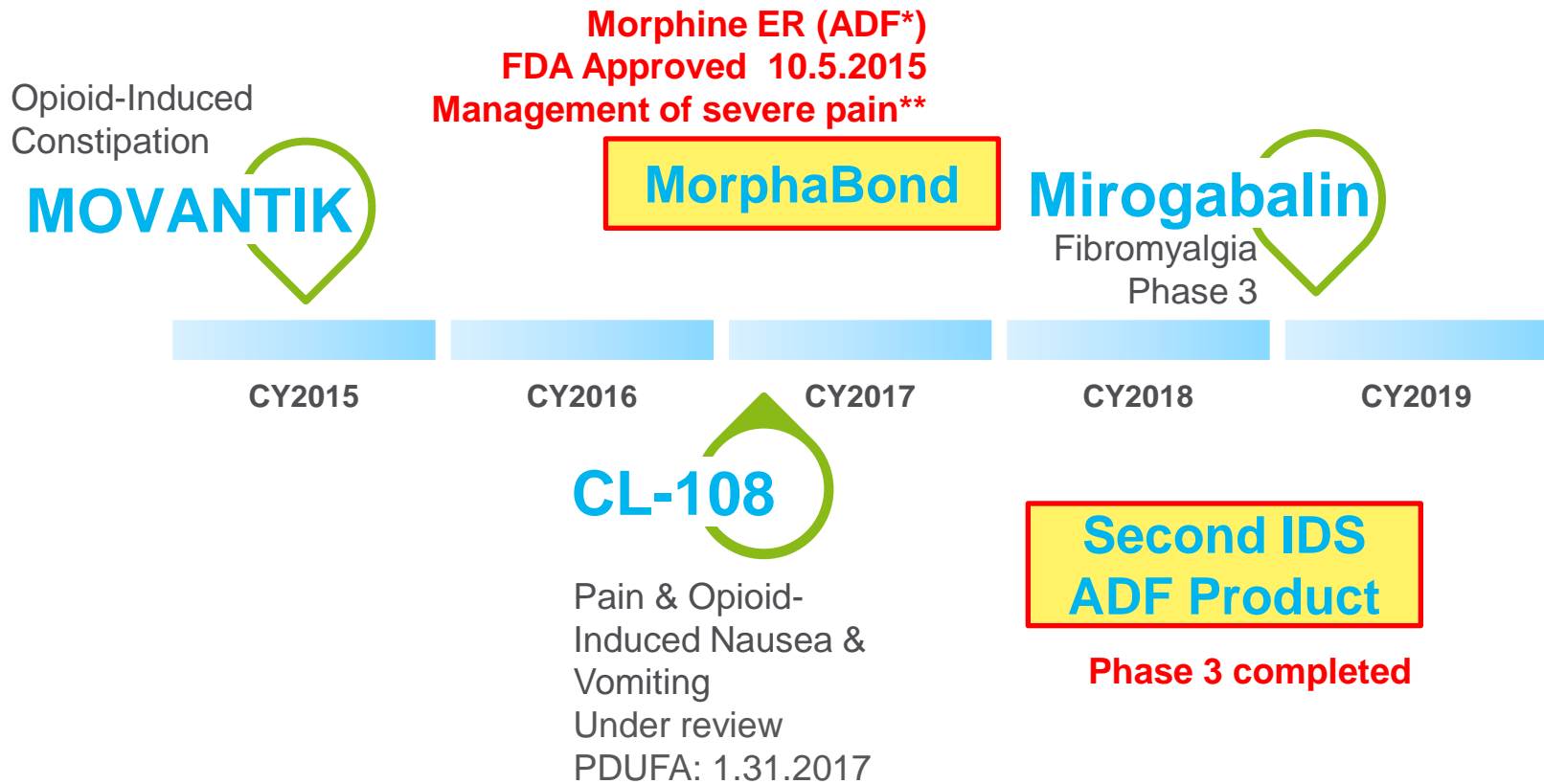
◆ **Mirogabalin** Targeted launch in FY 2019  
(Fibromyalgia)



Assumption: Exchange rate of 1USD=120JPY

# Expand DSI Pain Franchise

**Two ADF products are complementary and require no additional headcount**



\*ADF: Abuse-Deterrent Formulation

\*\*indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate

# DSI Commitments in Pain Care

**Inappropriate usage of opioids (diversion, misuse, abuse, addiction, or overdose) has become an epidemic in the US**

DSI launched [www.CommitmentsinPainCare.com](http://www.CommitmentsinPainCare.com), which hosts an overview of our company's approach to responsible pain management and our dedication to being part of the solution to controlled substance abuse as we prepare to enter the opioid marketplace.



Location F

 **Daiichi-Sankyo**

Passion for Innovation. Compassion for Patients.™

**Daiichi Sankyo, Inc.**

About Us Responsibility Research & Development Products Me

Home > Responsibility > Commitments In Pain Care

## Commitments in Pain Care

Daiichi Sankyo is dedicated to bringing innovative medicines to patients who need relief from their pain. We recognize pain management may require the appropriate use of prescription medicines including controlled substances such as opioids, and that these medicines may be associated with safety concerns such as diversion, misuse, abuse, addiction, or overdose. We are also cognizant of the tragic individual and societal consequences that can result from the improper use of prescription medicines.

We are committed to...

 **Commitments**  
IN PAIN CARE

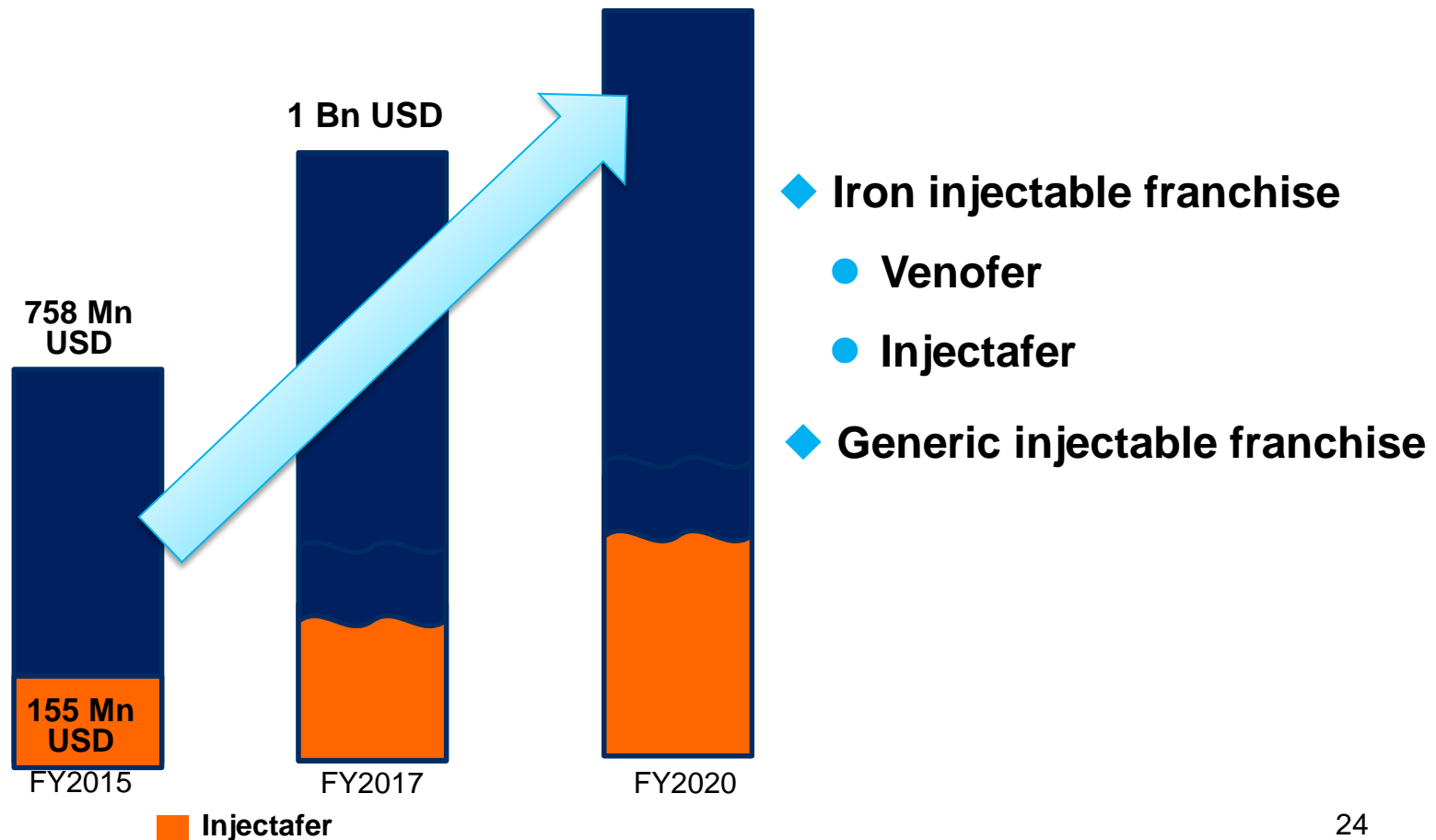
- **The well-being and proper treatment of patients** who suffer from pain and to providing prescription medicines to treat their pain and other related conditions.
- **Educating healthcare providers, patients, families and caregivers** on the appropriate use of pain medicines, and recognizing and preventing their potential for diversion, misuse, abuse, addiction, and overdose.



# Target for Luitpold Business

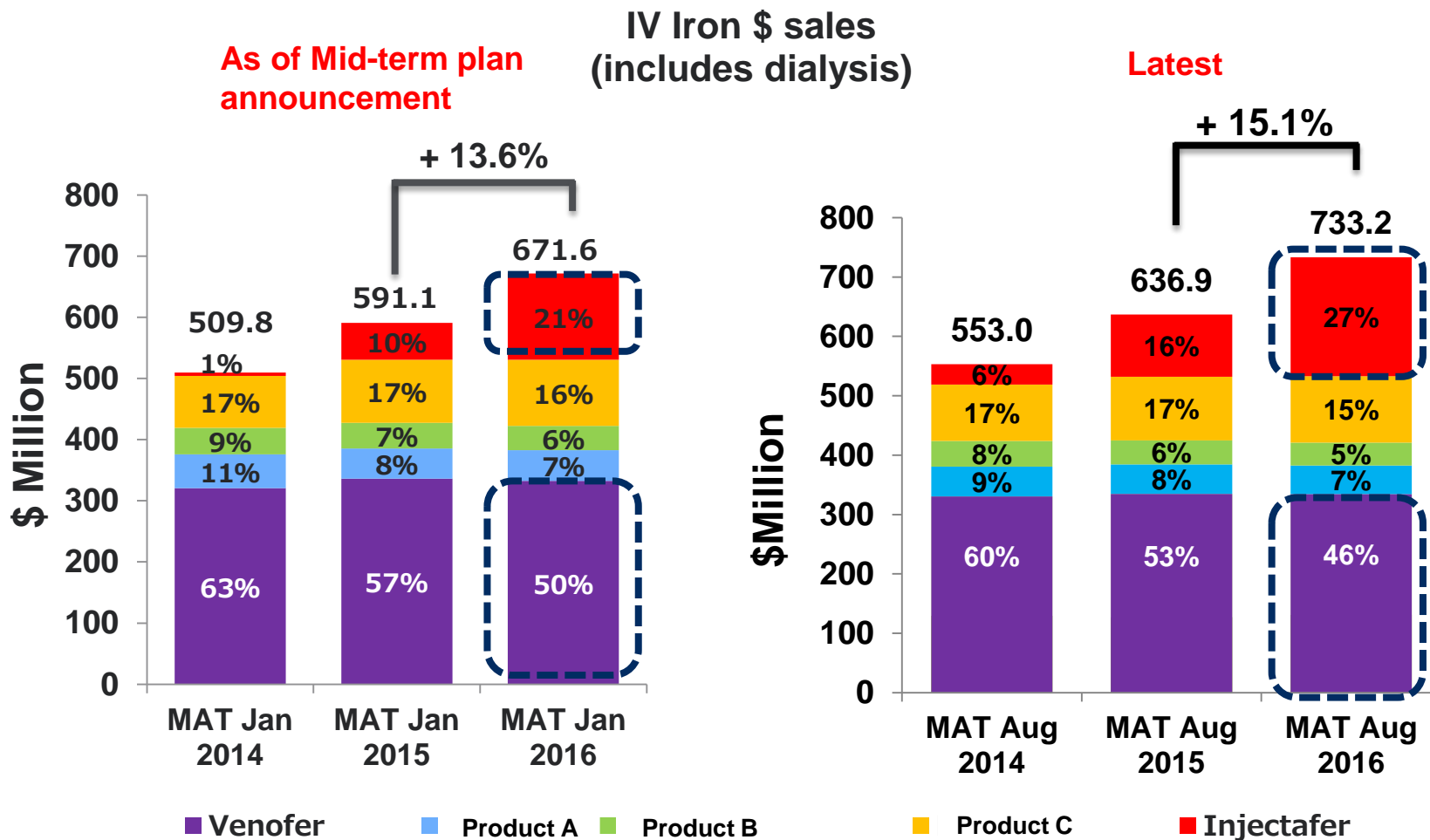
Realize rapid and sustainable growth with iron franchise and generic injectable franchise

**1.25 Bn USD**  
business in FY2020



# Growth of Injectafer

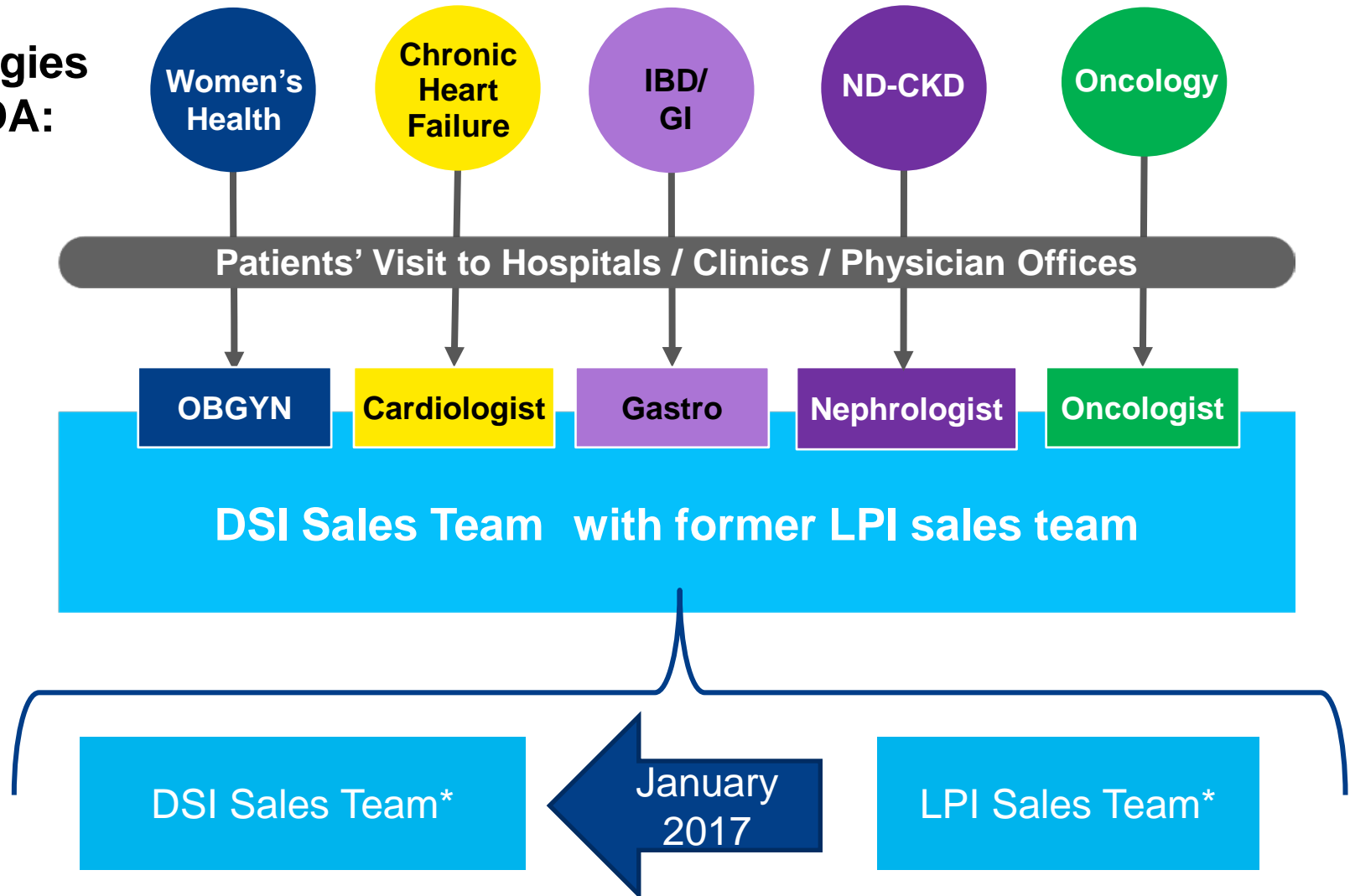
**Injectafer\* drives the growth of US IV Iron Market  
Market share has reached 27% in terms of MAT**



\*Injectafer is not indicated for patients who are dialysis dependent . Copyright © 2016 QuintilesIMS. Reprinted with permission  
Source: IMS National Sales Perspectives Jan 2016, Aug 2016 (includes all US IV Iron sales in all channels including dialysis chains)

# New Promotion for Injectafer

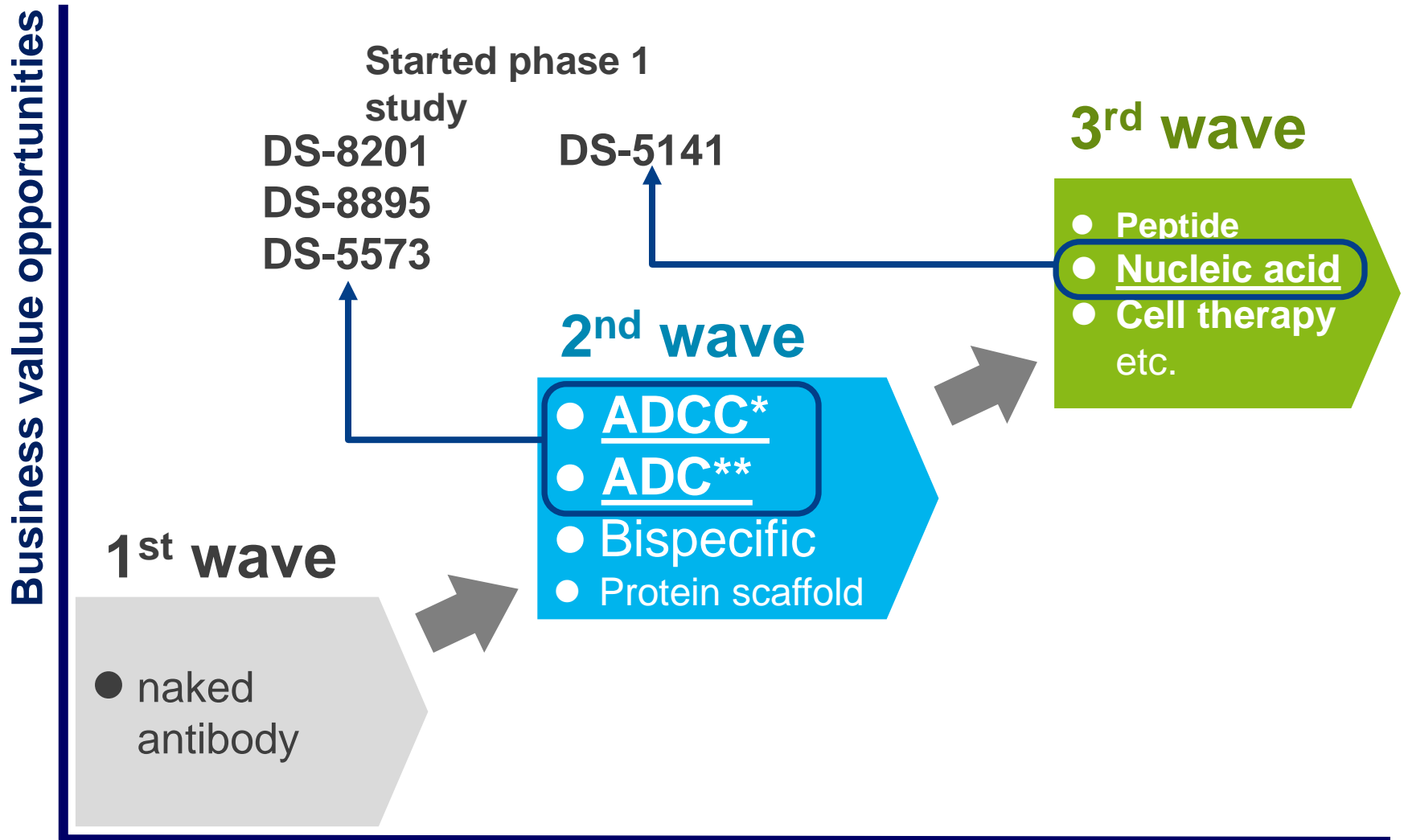
**Etiologies of IDA:**



\*As of January 1, 2017, LPI sales teams has become DSI employees.

- 1) Grow Edoxaban
- 2) Grow as No.1 Company in Japan
- 3) Expand US Business
- 4) Continuously Generate Innovative  
Medicine: Change Standard of Care (SOC)**

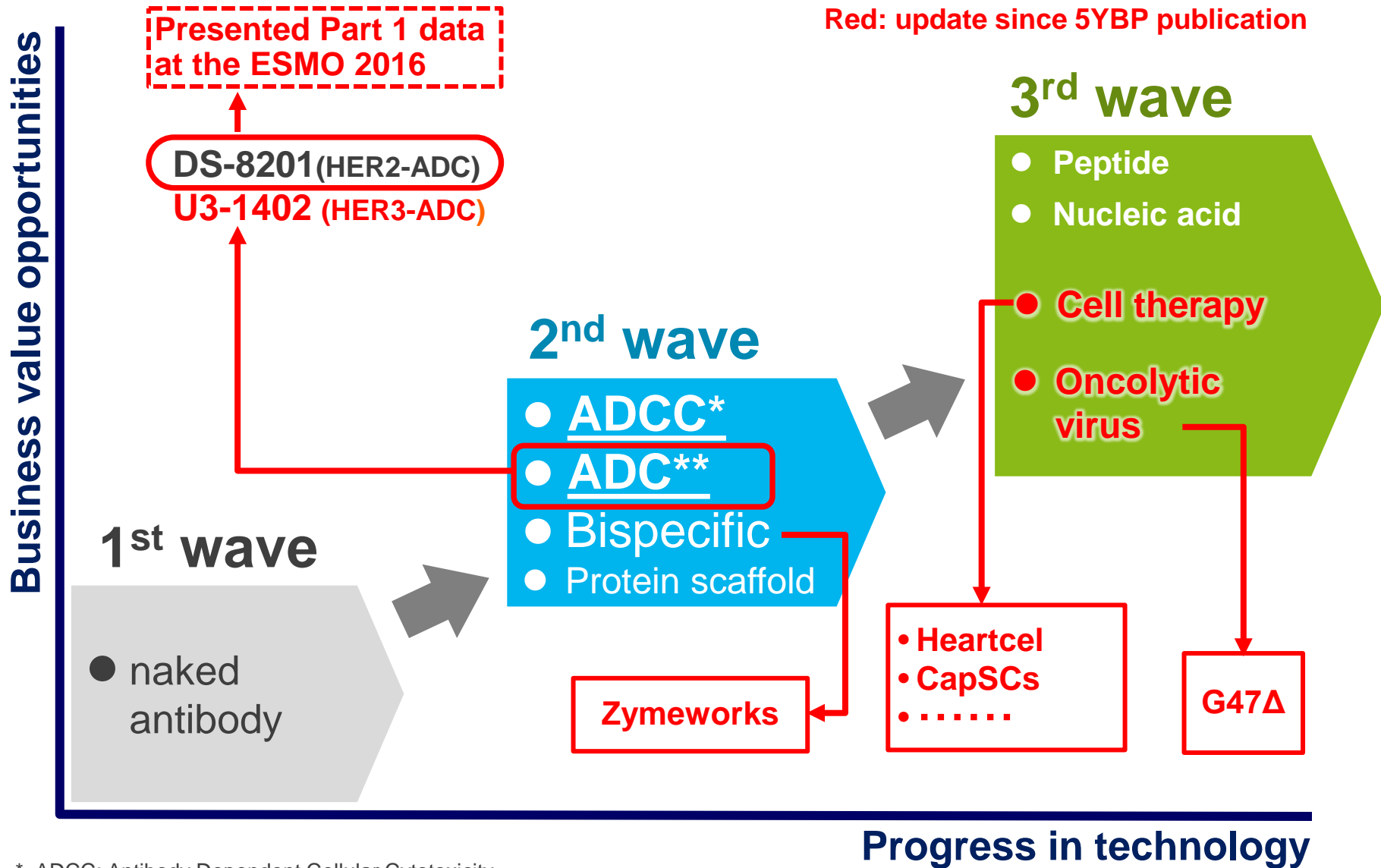
# Scope for Innovative Technology



\* ADCC: Antibody Dependent Cellular Cytotoxicity

\*\*ADC: Antibody Drug Conjugate

# Progress towards Clinical Application



\* ADCC: Antibody Dependent Cellular Cytotoxicity

\*\*ADC: Antibody Drug Conjugate

- ◆ 2025 Vision and 5-Year Business Plan (5YBP)
- ◆ Progress of 5-Year Business Plan
- ◆ **Oncology R&D (Establish Oncology Business)**

## Revenue

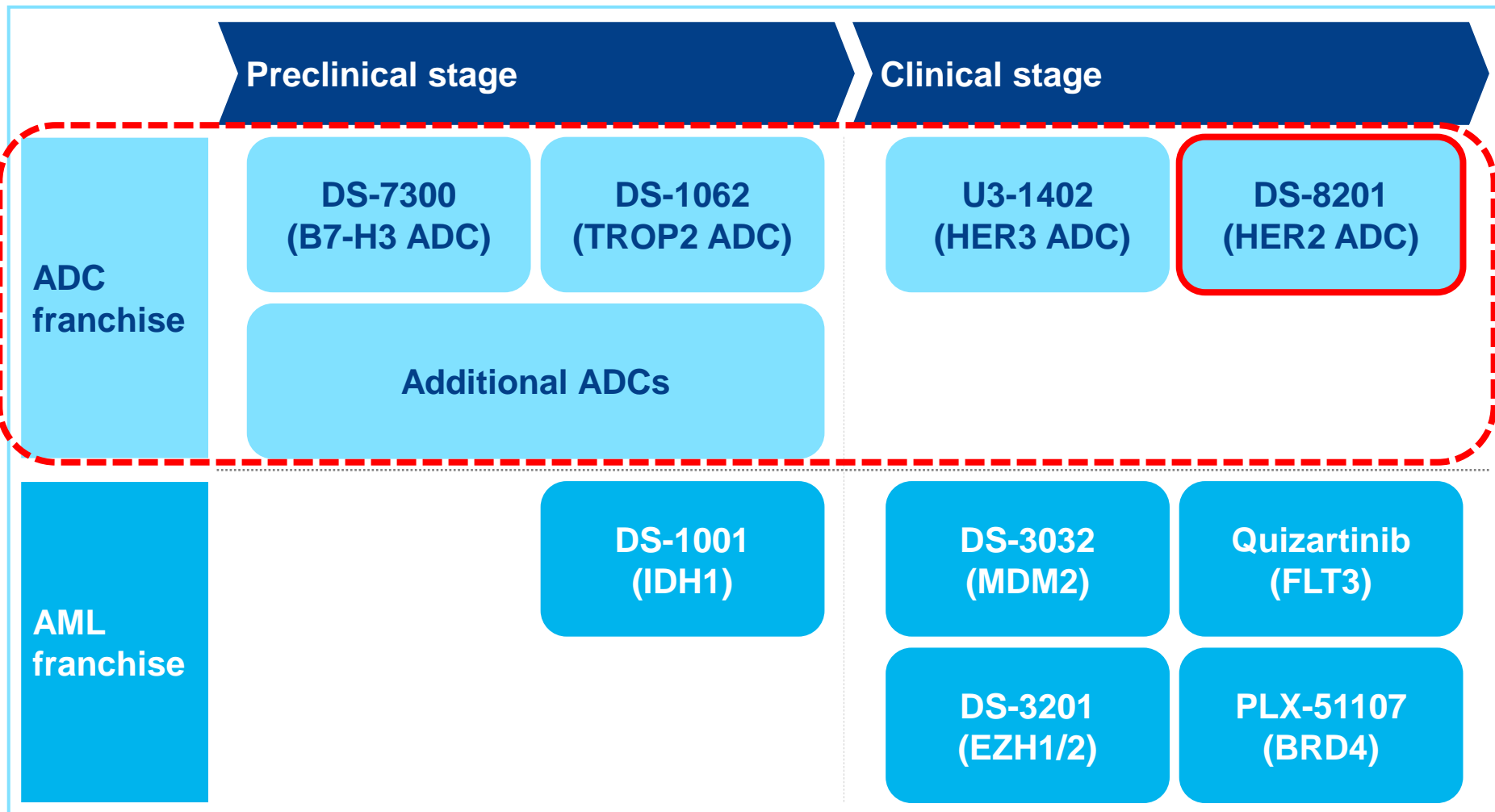
**FY2020: over 40.0 Bn JPY**

**FY2025: approx. 300.0 Bn JPY**

- ◆ Establish oncology business by launching current late-stage pipeline
- ◆ Steadily drive development of early-stage pipeline
- ◆ Enrich pipeline by acquisition of external assets
- ◆ Accelerate oncology R&D through new R&D organization



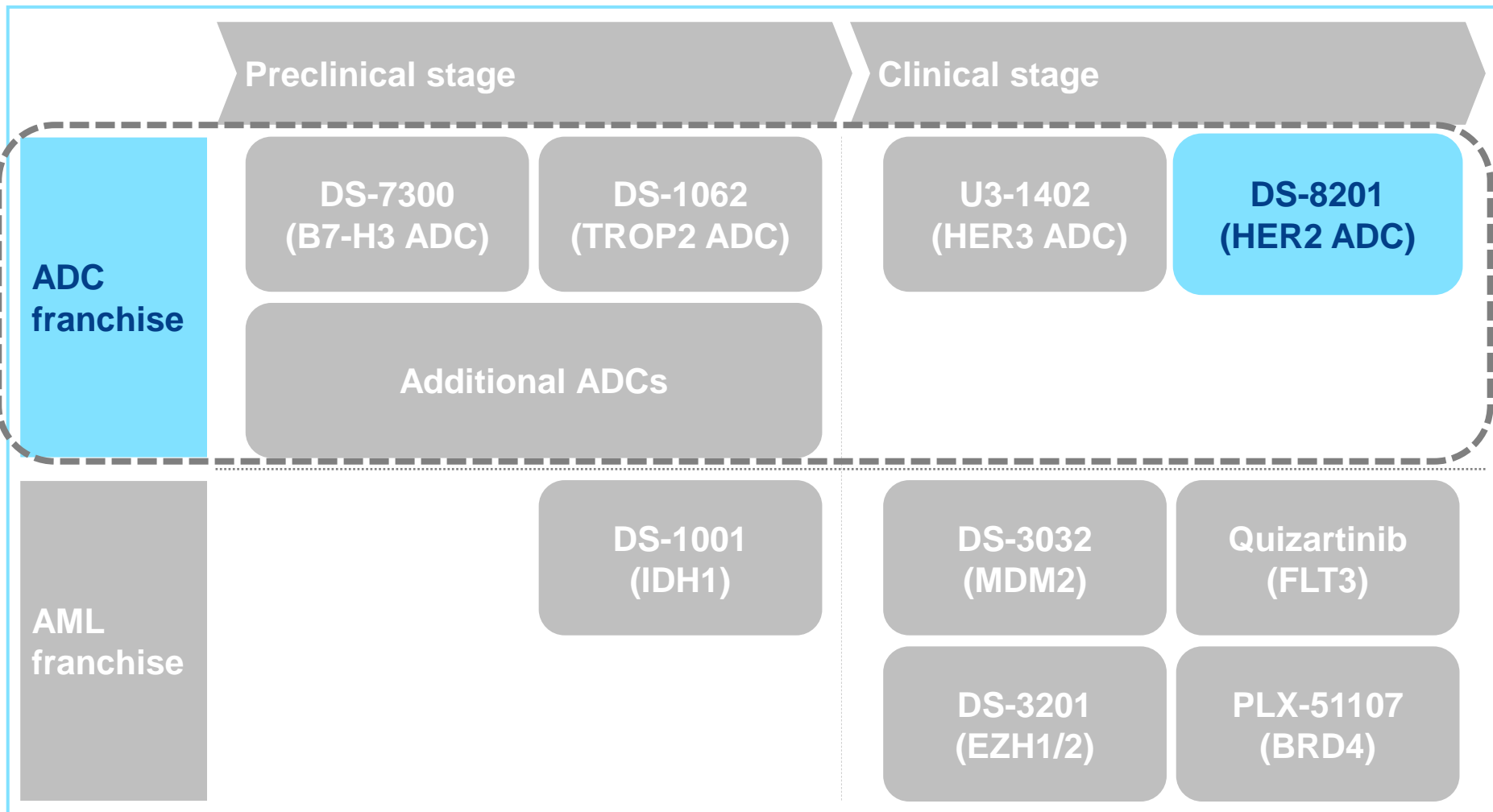
# Two Oncology Franchises



As of December 2016

Note: 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.

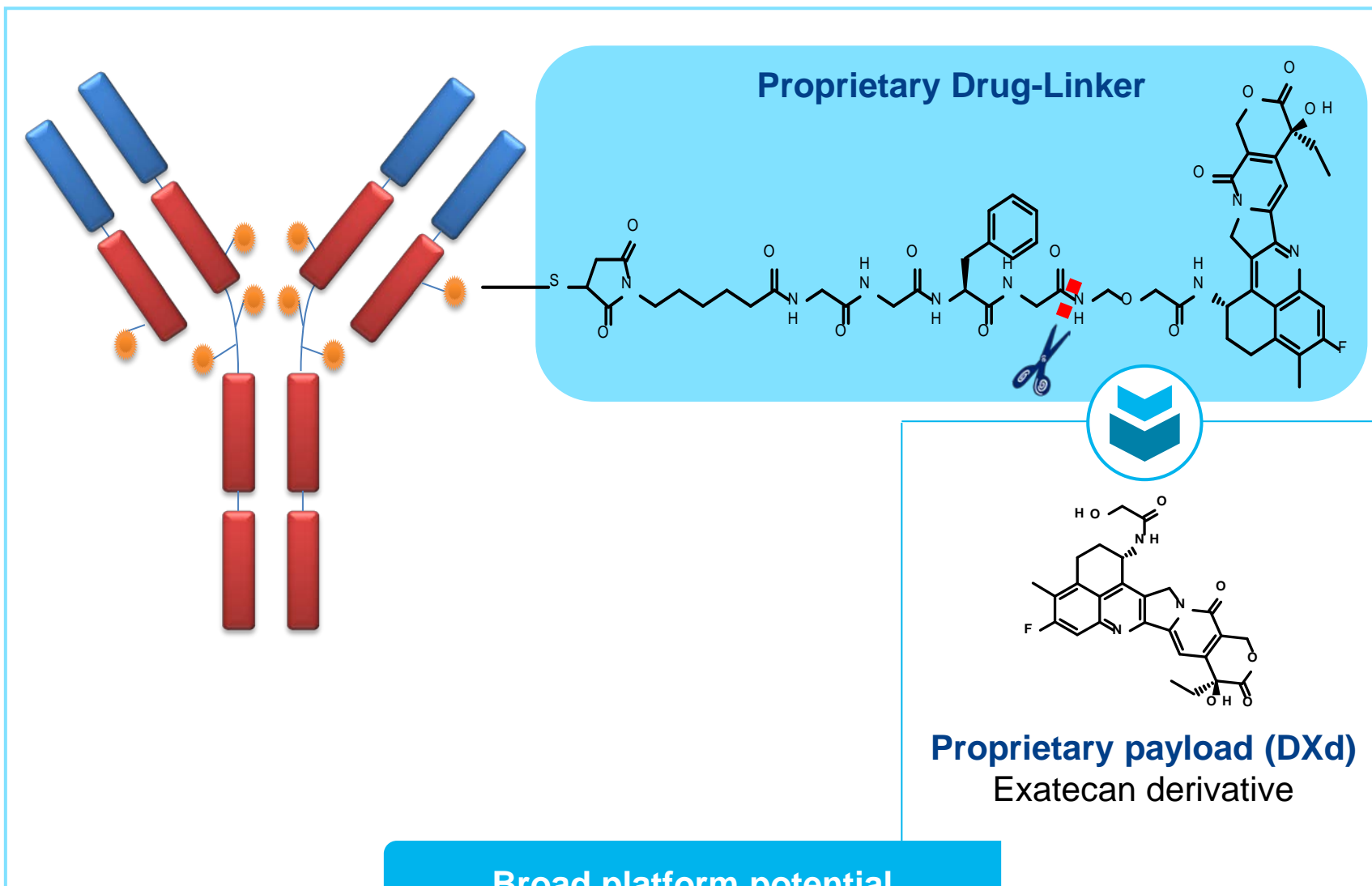
# DS-8201 / ADC Franchise



As of December 2016

Note: 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.

# Unique Antibody-Drug Conjugate (ADC) Technology From our Japan Research Labs



## Prior generation ADCs



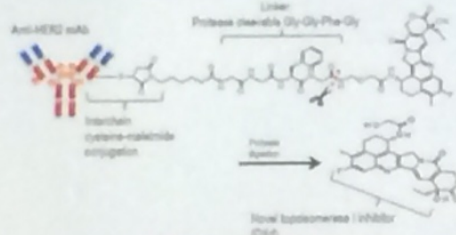
- Limited drug-to-antibody ratio (3.5-4)
- Linker instability and lack of tumoral specificity result in toxicity
- Payload related to typical chemotherapy previously received

## Our ADC technology

- Doubled drug-to-antibody ratio (7-8)
- High linker stability and more cancer-cell selective linker release
- Novel differentiated payload
  - Potent DNA topoisomerase I inhibitor
  - Effective in heterogeneous tumor microenvironment (bystander effect)
  - Very short systemic half-life

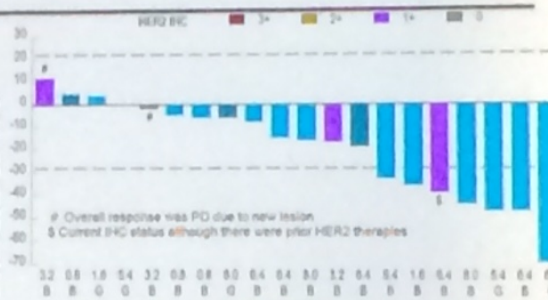
# Single Agent Activity Of Her2 Antibody Drug-Conjugate DS-8201A

## Structure of DS-8201a compared with T-DM1

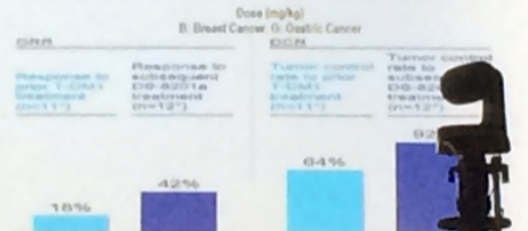


	DS-8201a	T-DM1
Antibody	Anti-HER2 Ab	Trastuzumab
Payload	Topoisomerase I inhibitor (DAI)	Tubulin inhibitor (DM1)
DAR	7.4	3.5

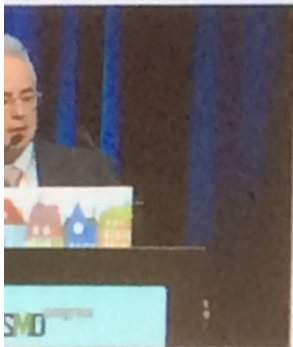
\* DAR: Average drug-to-antibody Ratio



Overall response was PD due to new lesion  
 Current PRG status although there were prior HER2 therapies



Tamura K et al. ESMO 2016 Abstract 17



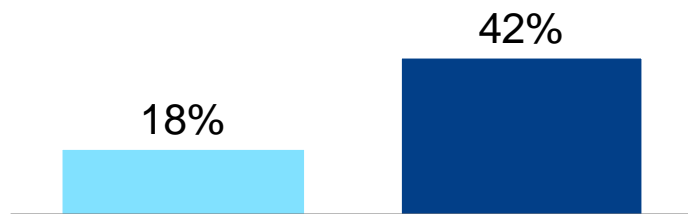
“Highlights of ESMO 2016” session

## Response rate in T-DM1 resistant breast cancer patients (Phase 1)

### ORR<sup>1</sup>

Prior T-DM1  
treatment  
(n=11\*)

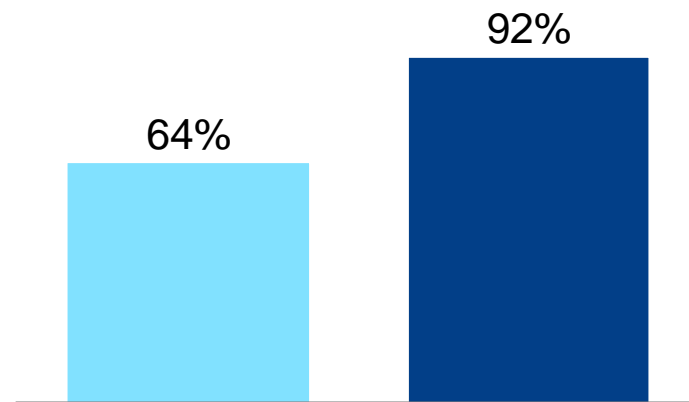
Subsequent DS-  
8201 treatment  
(n=12\*)



### DCR<sup>2</sup>

Prior T-DM1  
treatment  
(n=11\*)

Subsequent DS-  
8201 treatment  
(n=12\*)



\*1/12 subjects with no information of the best response on prior T-DM1 treatment

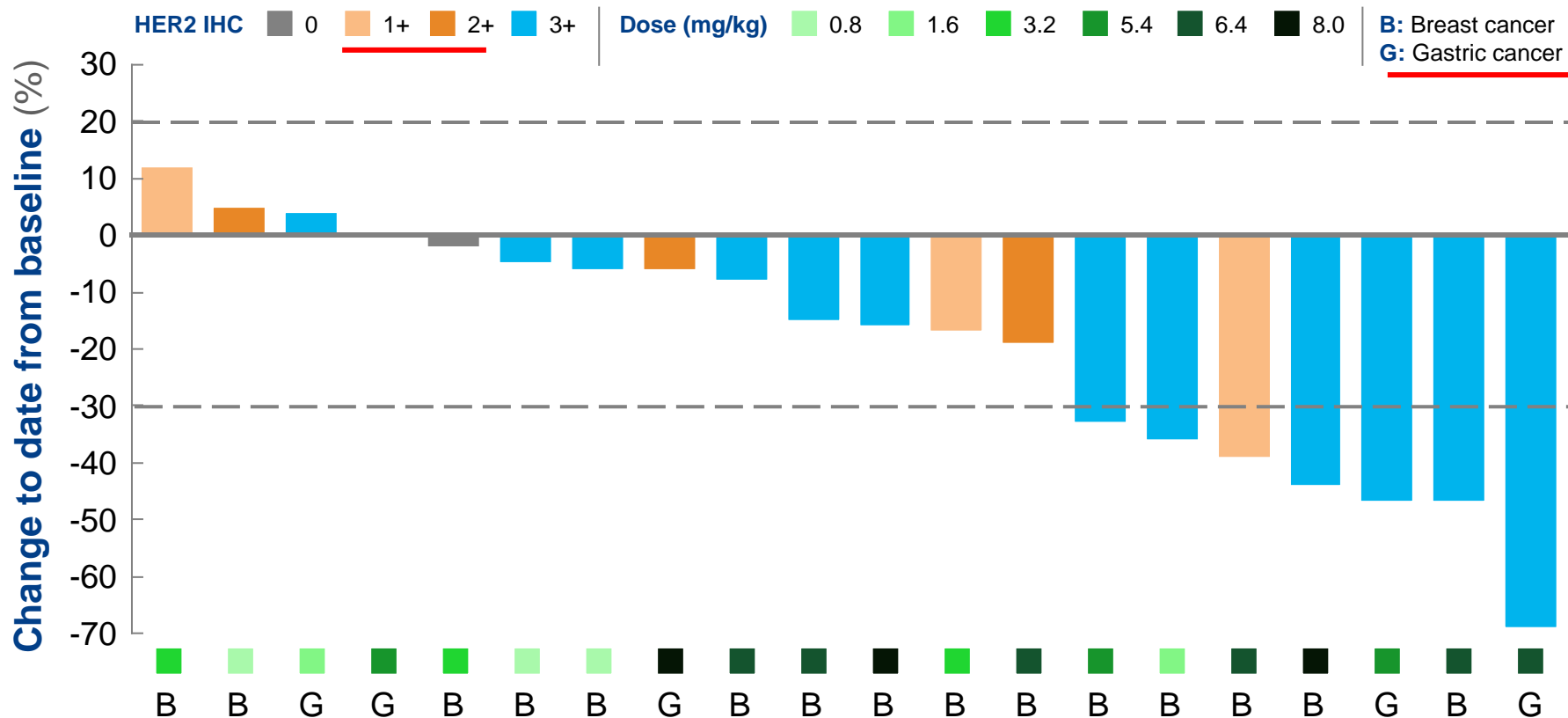
**Strong response in  $\geq 3^{\text{rd}}$  line HER2+ breast cancer**

1 Overall Response Rate = [Complete Response (CR) + Partial response (PR)]

2 Disease Control Rate = [Complete Response (CR) + Partial response (PR) + Stable Disease (SD)]

# DS-8201: ESMO 2016 Data (2/2)

## Best response to DS-8201 therapy, (Phase 1)



Potential across doses, HER2 status, and both breast and gastric cancers

# DS-8201: Promising First-in-Human Trial Data

## Highlights

Presented at ESMO, October 2016

### Well tolerated;

Maximum Tolerated Dose (MTD) not reached

No grade 4 AE

**Robust anti-tumor activity** in T-DM1 pre-treated breast cancer patients, gastric cancer, and HER2 low expression tumors

**Anti-tumor activity at all doses tested**



## Current trial status

Late-stage HER2+ breast, gastric and other cancer, and low HER2 breast

**77** Patients treated

**10** Active sites in US & Japan

**54** More subjects relative to ESMO data

**U.S. FDA Fast Track designation for HER2+ metastatic breast cancer**



# DS-8201: HER2-ADC with Potential to Address Significant Patient Unmet Needs

## Unmet need in HER2+ cancers

**T-DM1 resistant** HER2+  
breast cancer

**No**

approved HER2+  
directed therapy

**Herceptin resistant** HER2+  
gastric cancer

**No**

approved HER2+  
directed therapy

**HER2 low<sup>1</sup>** expressing  
tumors

**No**

approved therapy  
indicated for HER2 low

Insensitivity to **checkpoint  
inhibitors** as monotherapy

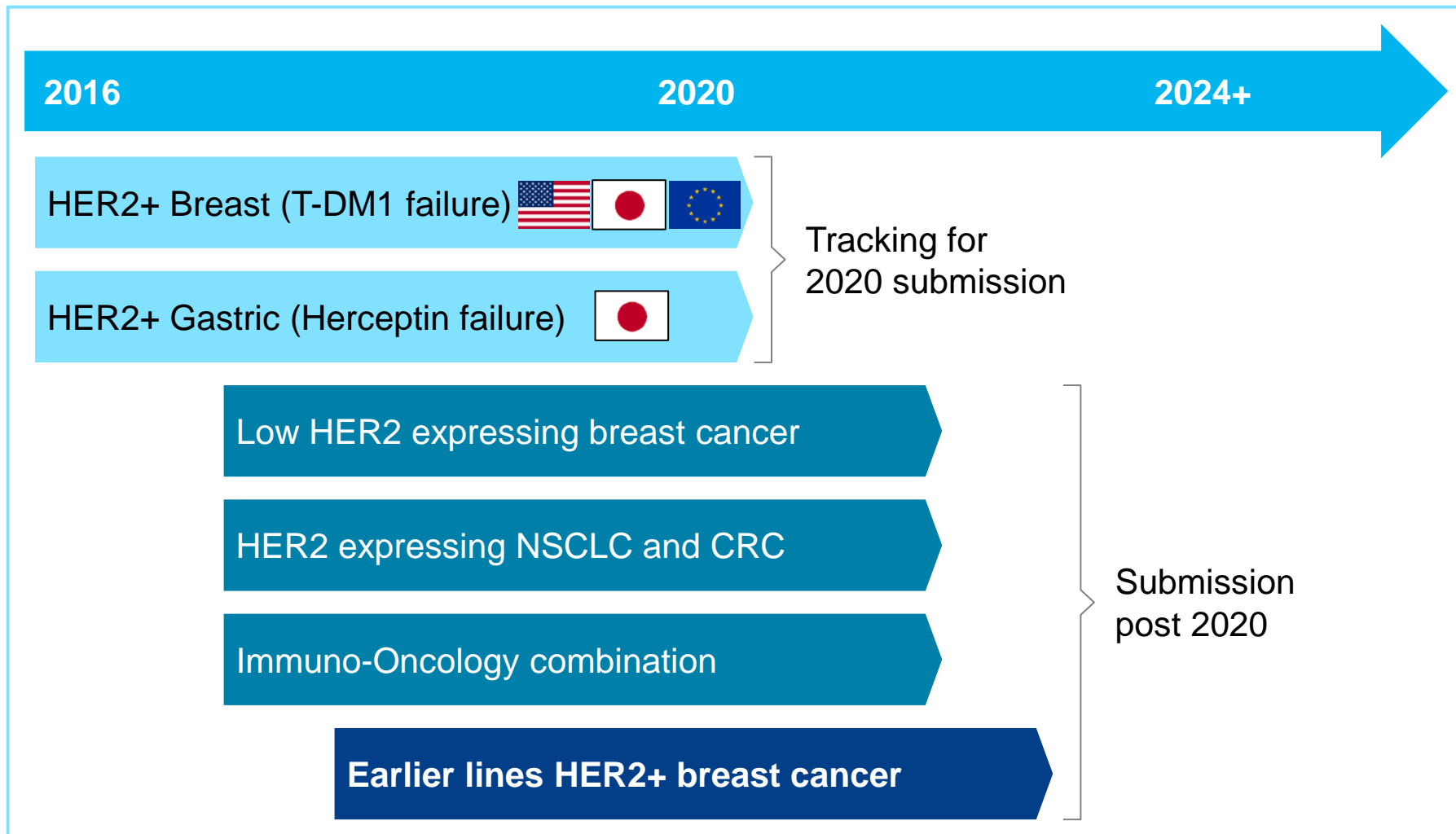
**~20%** response rate



<sup>1</sup> IHC1+ or IHC2+/FISH-

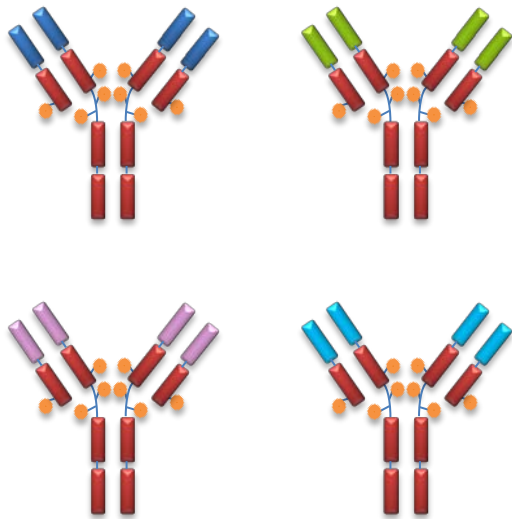
# DS-8201: Development Scope

▶ Current development   ▶ Planned to start 2H 2017   ▶ Planned



# ADC Franchise: Expansion Strategy

## Our pipeline



## Partnerships



# ADC Franchise: Our Pipeline



Clinical stage

Antibody target	Potential indications	Discovery	Preclinical	Phase1	
HER2 (DS-8201)	Breast, Gastric				
HER3 (U3-1402)	Breast, NSCLC				<b>First-in-class</b> and potential to <b>overcome TKI resistance</b> in <b>EGFRm NSCLC</b>
TROP2 (DS-1062)	Solid Tumors				<b>Best-in-class</b>
B7-H3 (DS-7300)	Solid Tumors				<b>First-in-class</b>
Project 5	Solid Tumors				
Project 6	Solid Tumors				

Note: 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.

**Immuno-Oncology**  
partnerships with our existing  
ADC assets

*HER2-  
ADC*

*HER3-  
ADC*

*TROP2-  
ADC*

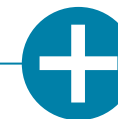
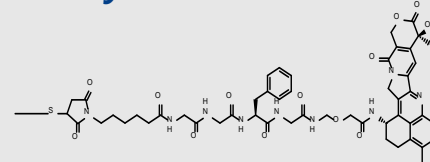
*B7-H3-  
ADC*



*I/O mechanisms  
(e.g., checkpoint inhibitors)*

Partnerships to apply  
our ADC technology to new  
**antibodies and targets**

*Our proprietary linker and novel payload*



*Additional  
targets*



Daiichi-Sankyo

---

**cancer**enterprise

Care. Compassion. Science.  
It's Our Obligation.

Contact address regarding this material

Daiichi Sankyo Co., Ltd.

**Corporate Communications Department**

**TEL: +81-3-6225-1126**

**Email: [DaiichiSankyoIR@daiichisankyo.co.jp](mailto:DaiichiSankyoIR@daiichisankyo.co.jp)**