

Passion for Innovation.  
Compassion for Patients.™



DAIICHI SANKYO CO., LTD

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

**George Nakayama, Chairman and CEO**

January 8, 2018

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- ◆ **2025 Vision and 5-Year Business Plan (5YBP)**
- ◆ **Growth Plans for Current Core Businesses**
- ◆ **Exciting ADC Technology and Pipeline**



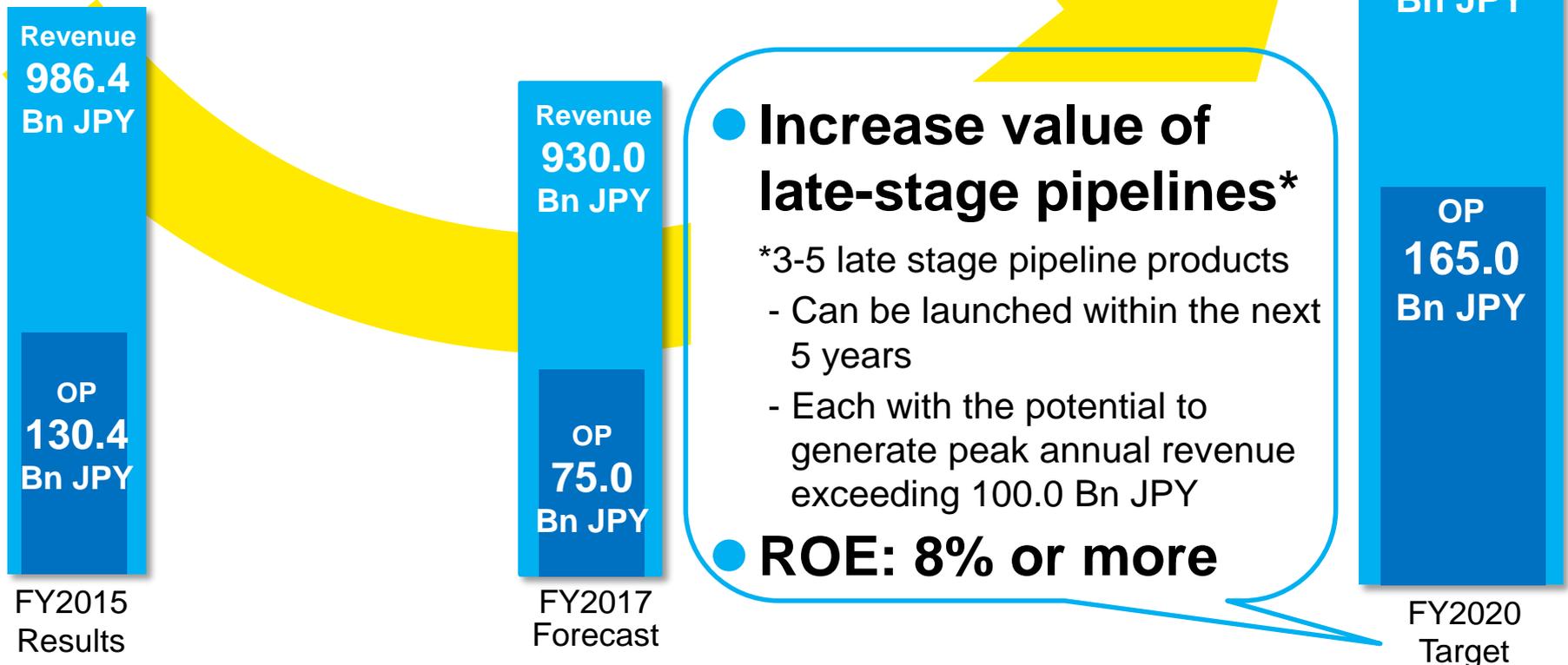
## Global Pharma Innovator with Competitive Advantage in Oncology

- *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 FY2017 LOE**

**Challenge 2:  
Establish Foundation of Sustainable Growth**

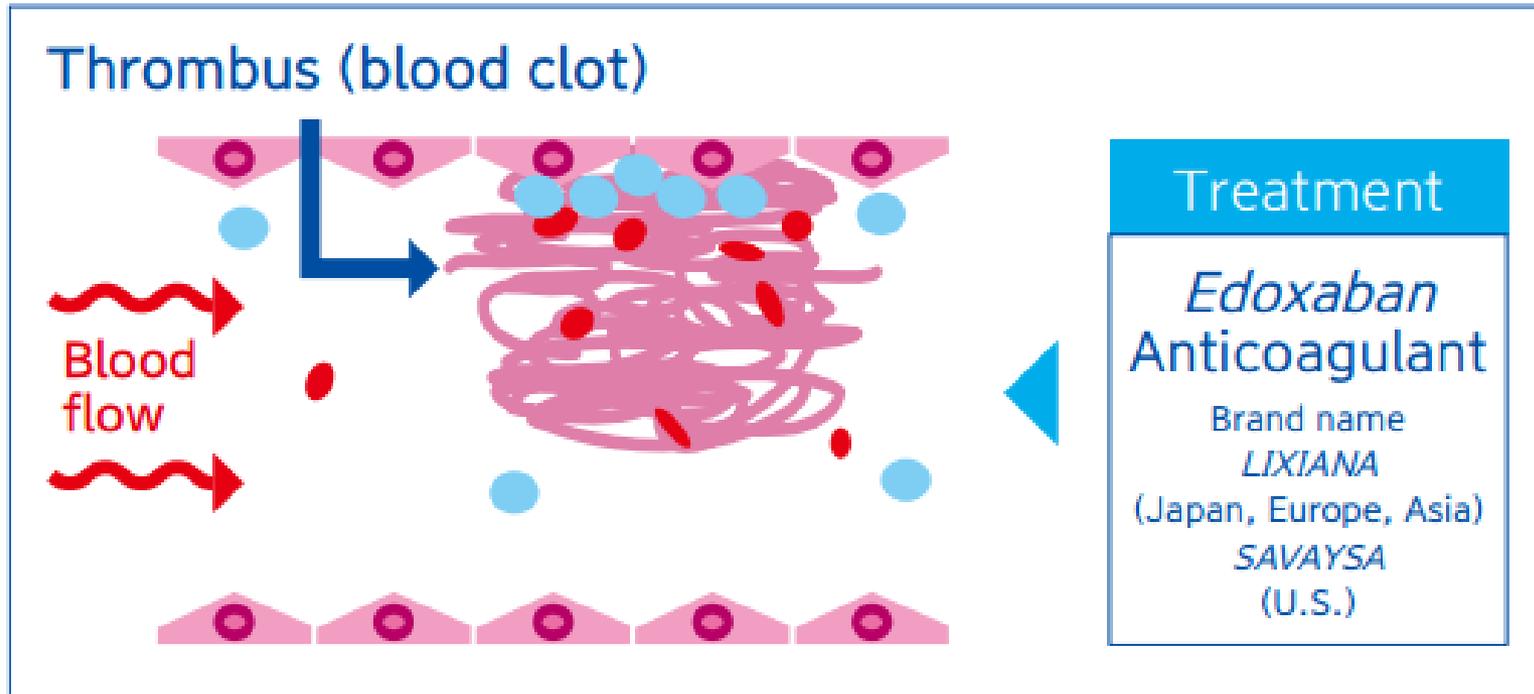


Assumes exchange rate of 1USD=120JPY, 1EUR=130JPY

## Shareholder Returns Policy during 5YBP\*

- ◆ Total return ratio: 100% or more
- ◆ Annual ordinary dividend: more than 70 JPY
- ◆ Flexible acquisition of own shares

## ◆ Growth Plans for Current Core Businesses - Edoxaban

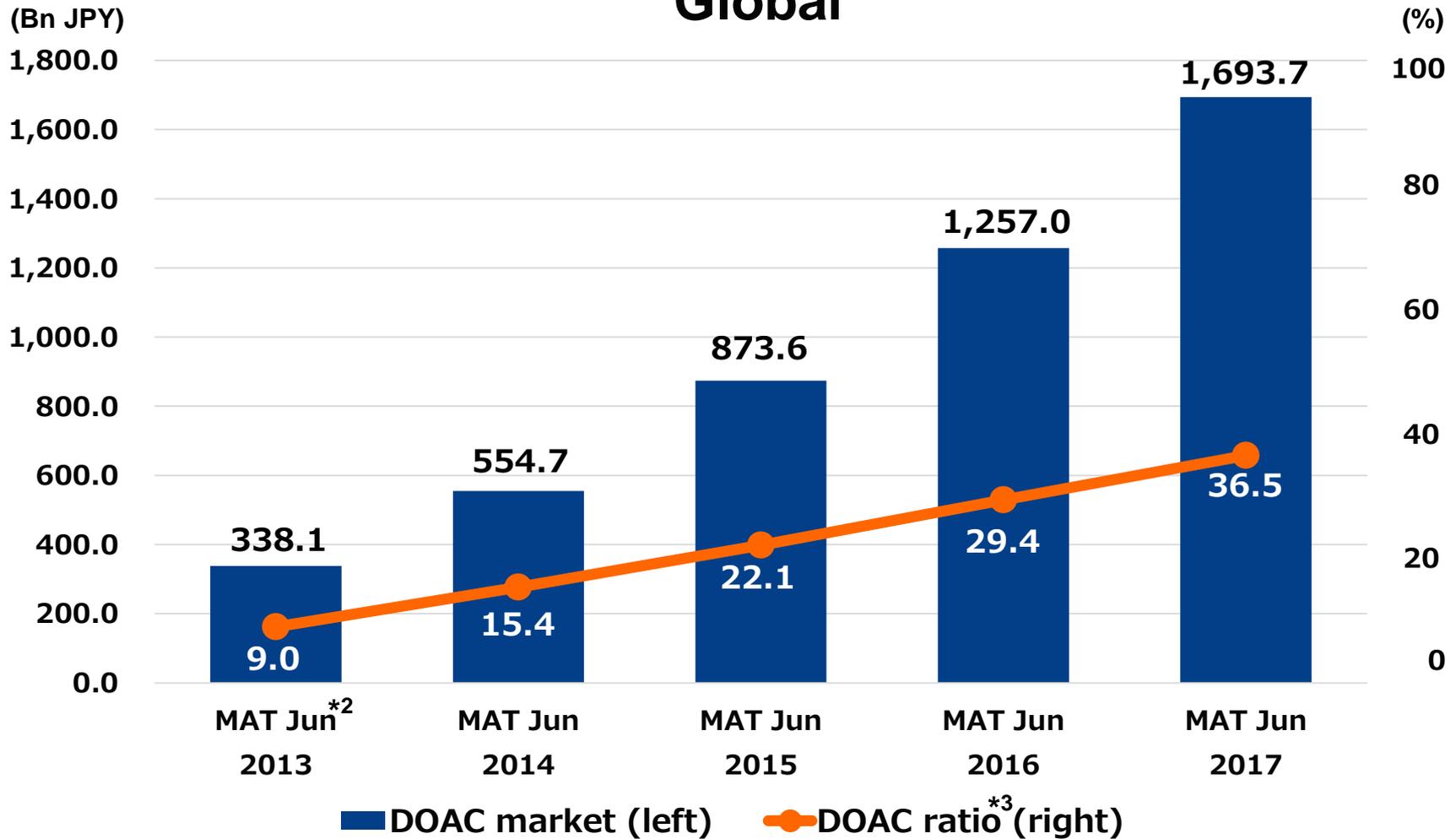


## Major Indications treated with Anticoagulants

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

# Direct Oral Anticoagulant (DOAC\*<sup>1</sup>) Market

## Global



Currency Rate USD/JPY : 110

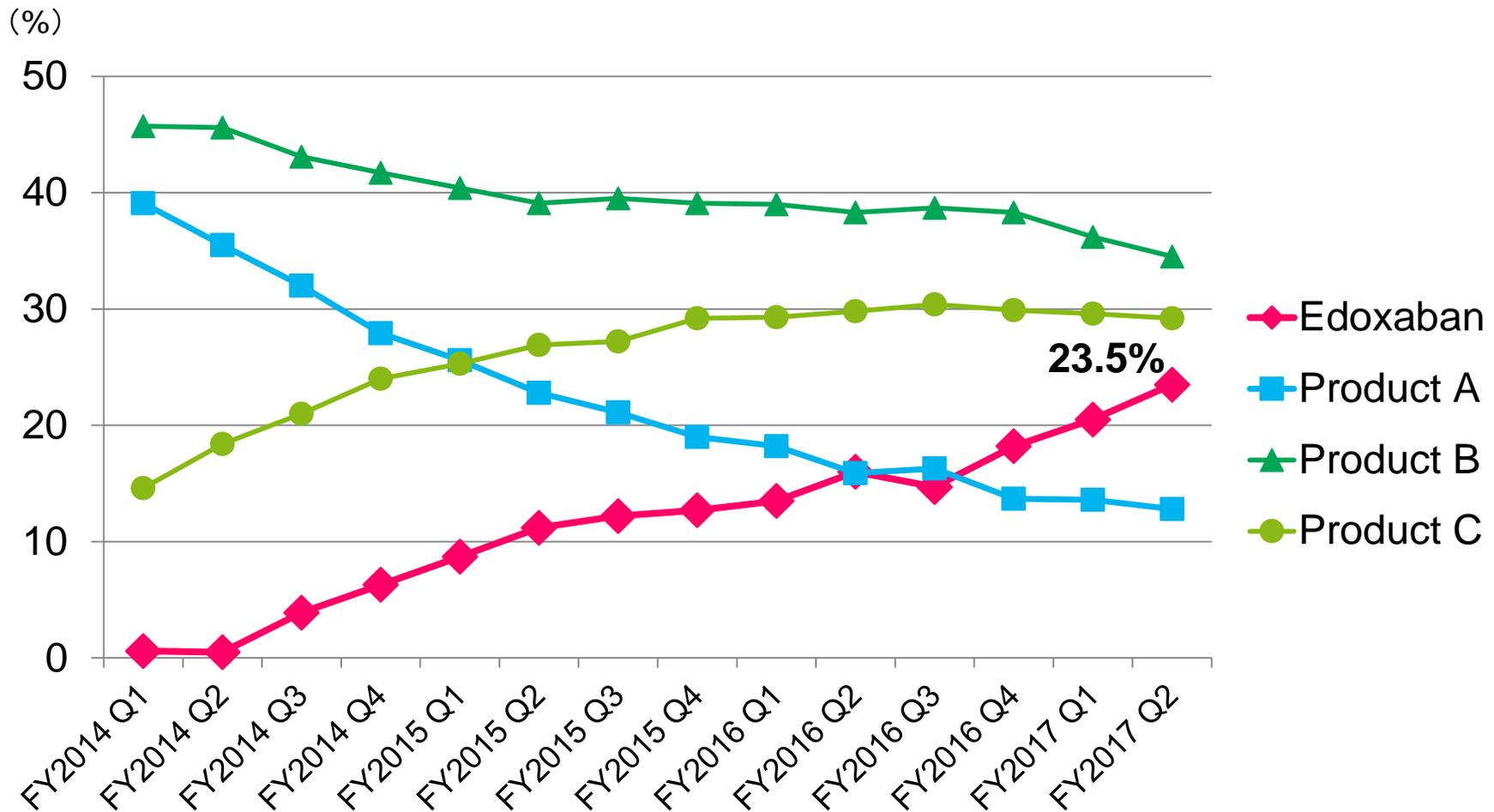
# Edoxaban: Global Rollout

- ◆ Launched and approved in over 20 countries
- ◆ 95% Coverage of Global DOAC market



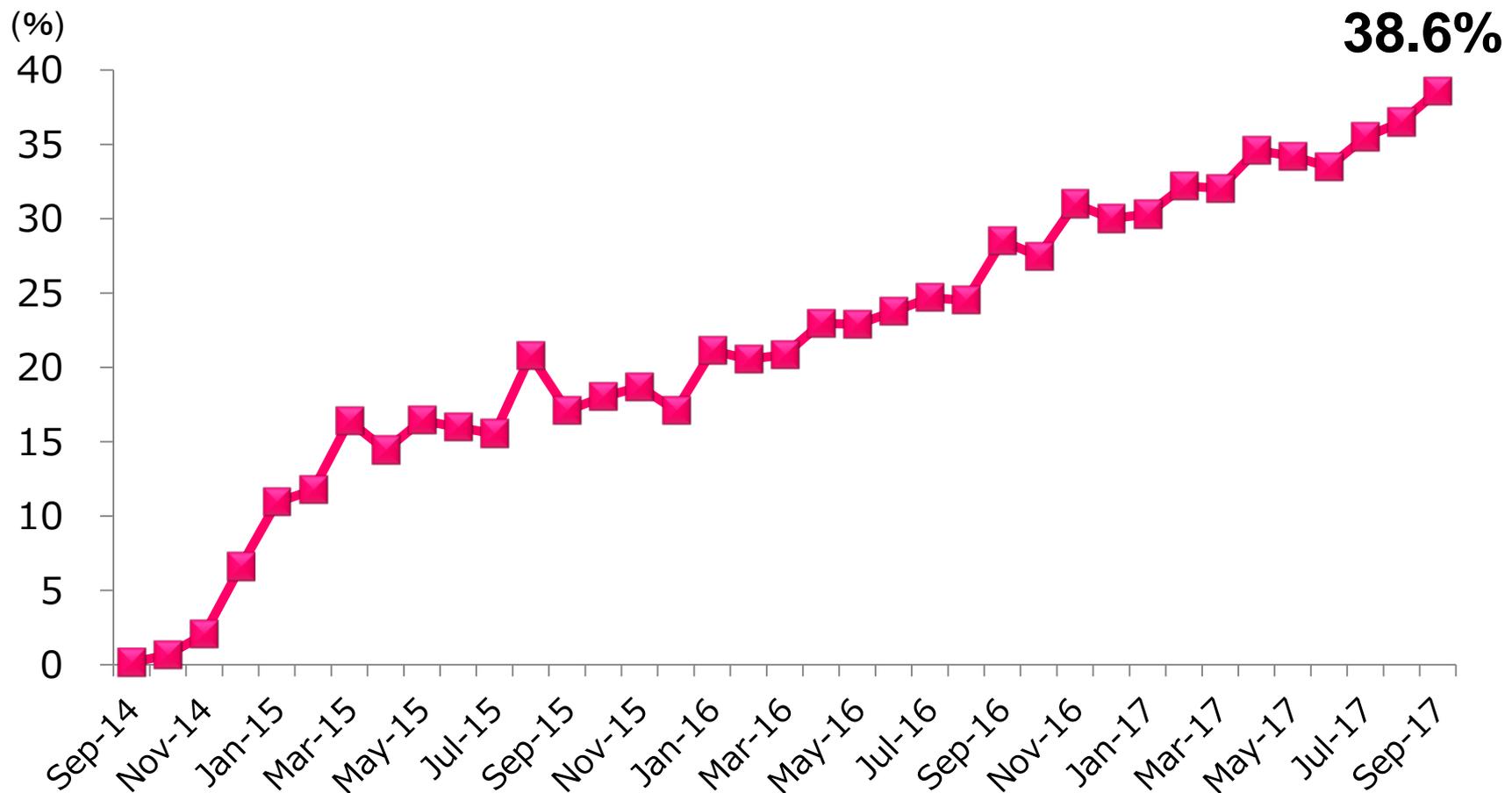
# Edoxaban (Lixiana) : Growth in Japan

◆ As of FY2017 Q2, Lixiana increased share to **23.5%**



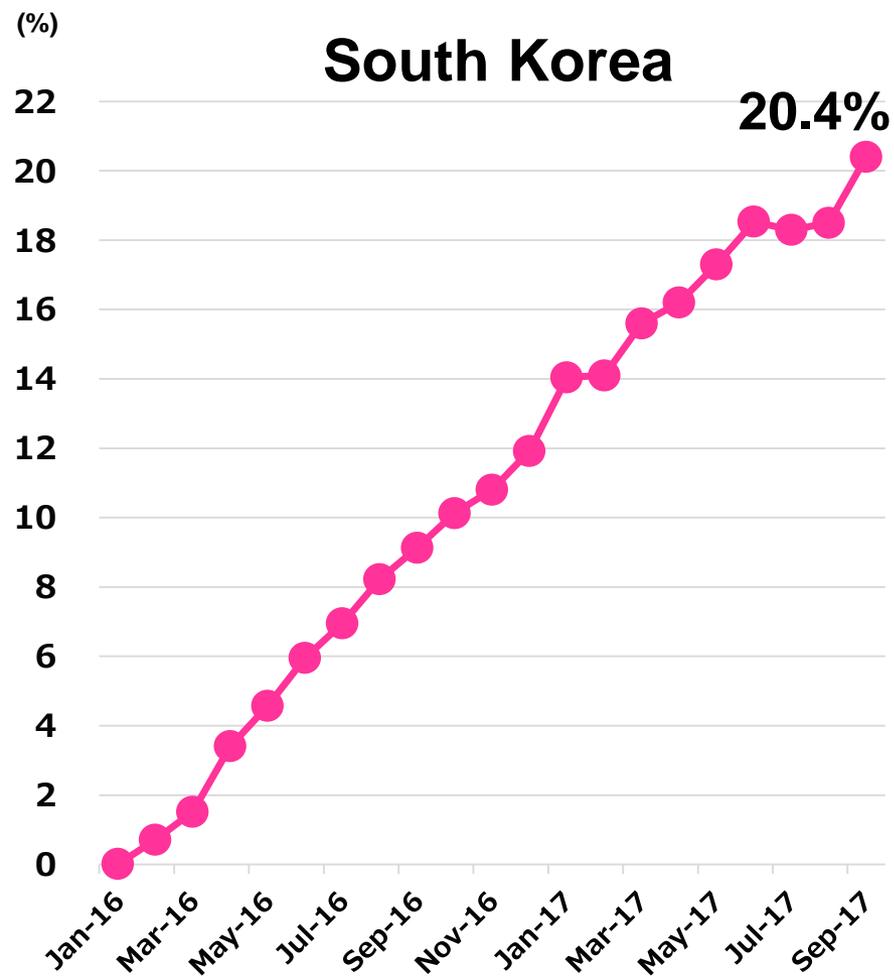
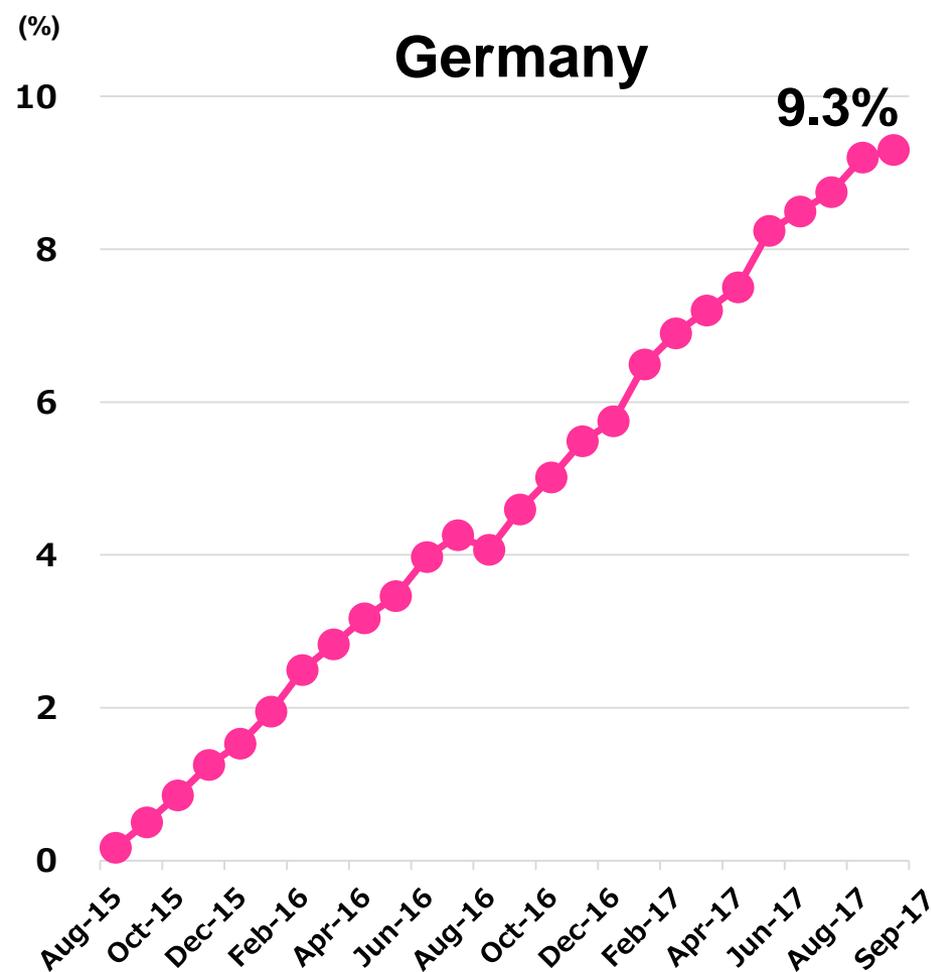
# Edoxaban (Lixiana) : Growth in Japan

- ◆ Reached top Rx share for new patient prescriptions for AF+VTE since Mar. 2017
- ◆ The share expanded to **38.6%** in Sep. 2017



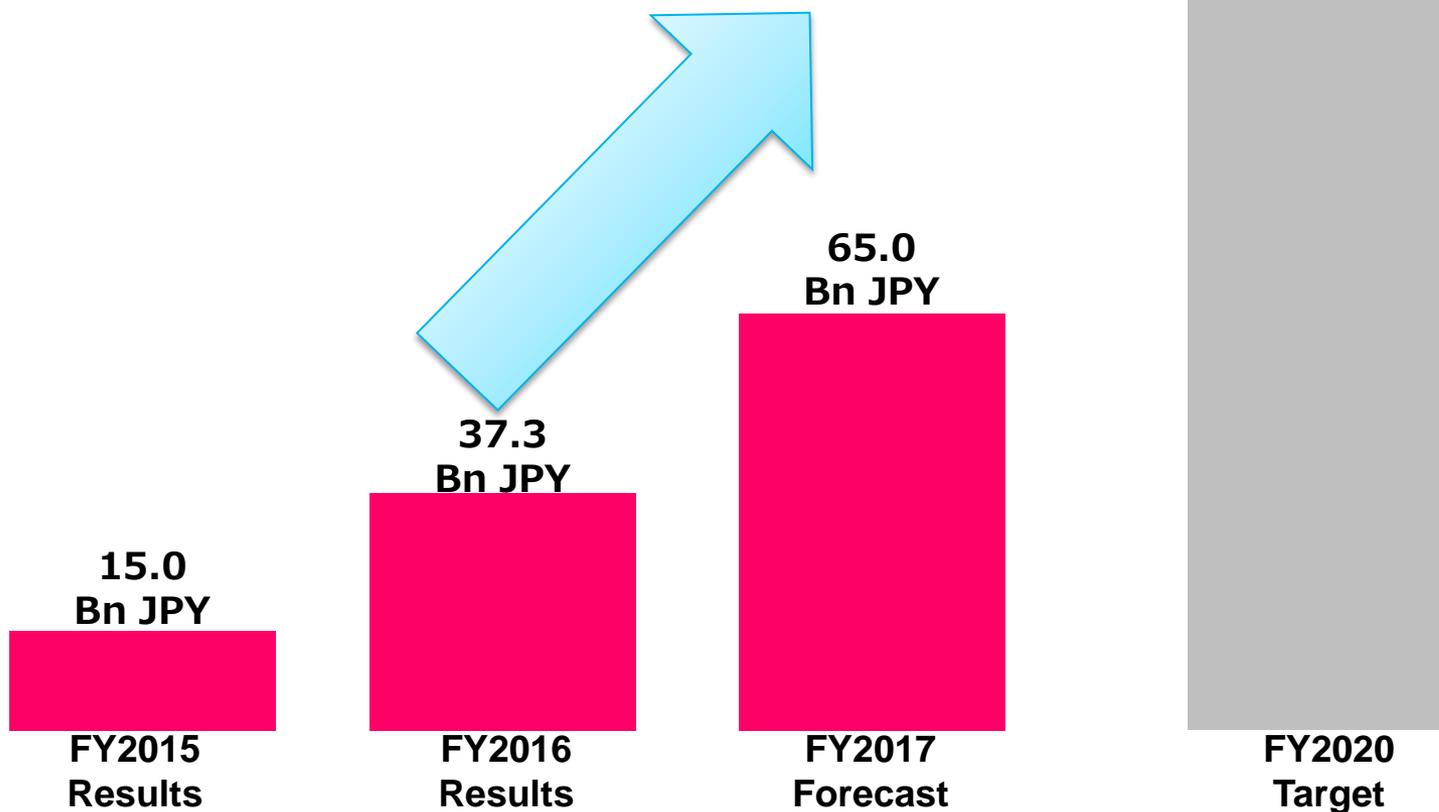
# Edoxaban (Lixiana) : Growth in Germany and South Korea

- ◆ Steady growth since launch
- ◆ Reached 3<sup>rd</sup> share in Germany and South Korea



# Edoxaban: FY2020 Target

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



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

- ◆ **Growth Plans for Current Core Businesses**  
**- No. 1 in Japan**

# Japan: Six Major Products

◆ 4 of 6 major products achieved the No.1 share in their respective markets



**Share No.1**

Ulcer treatment  
**Nexium**



**Share No.1\***

Treatment for osteoporosis  
**Pralia**



Antiplatelet agent  
**Efient**



**Share No.1**

Alzheimer's disease treatment  
**Memary**



**Share No.1**

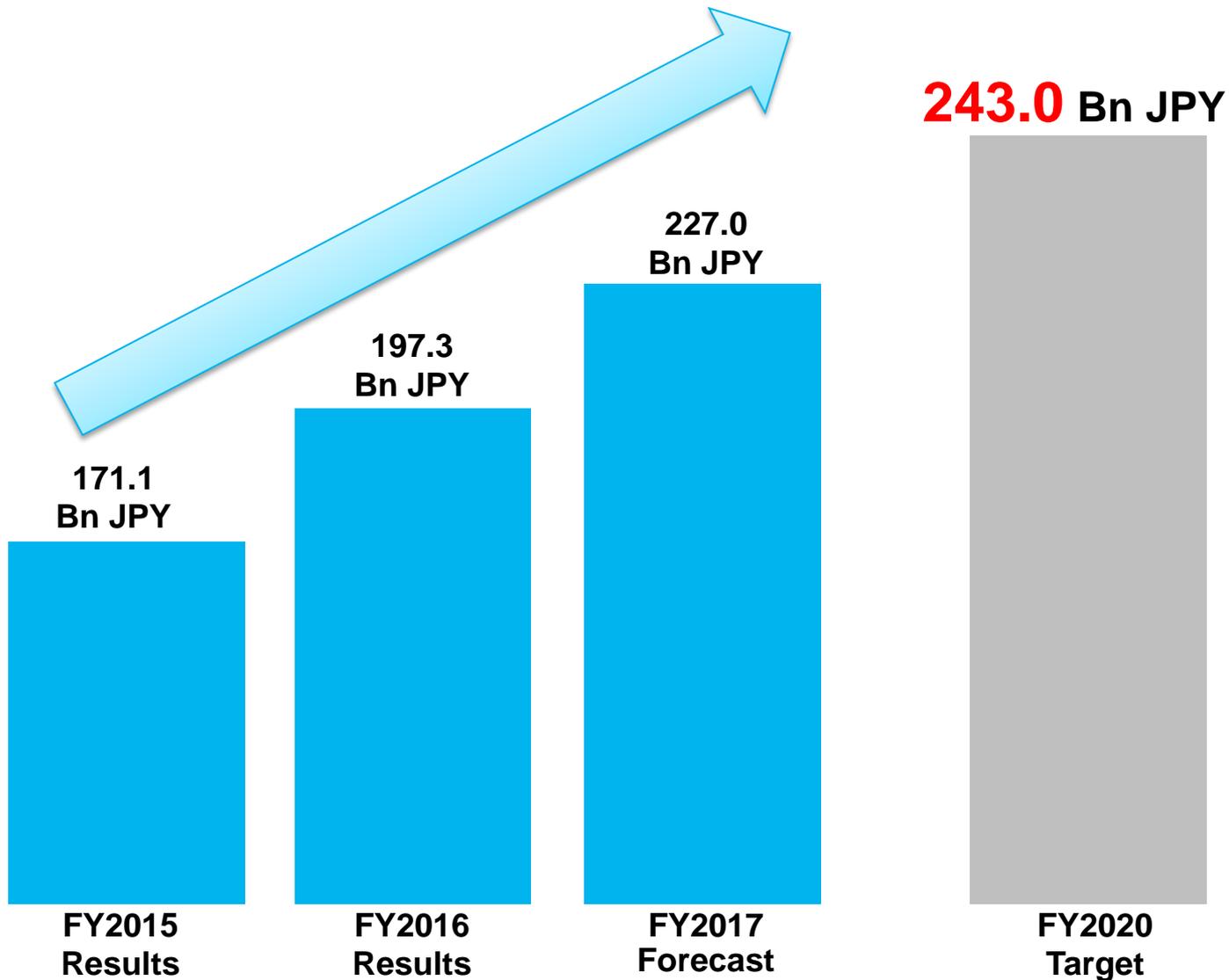
Treatment for bone complication caused by bone metastases from tumors  
**Ranmark**



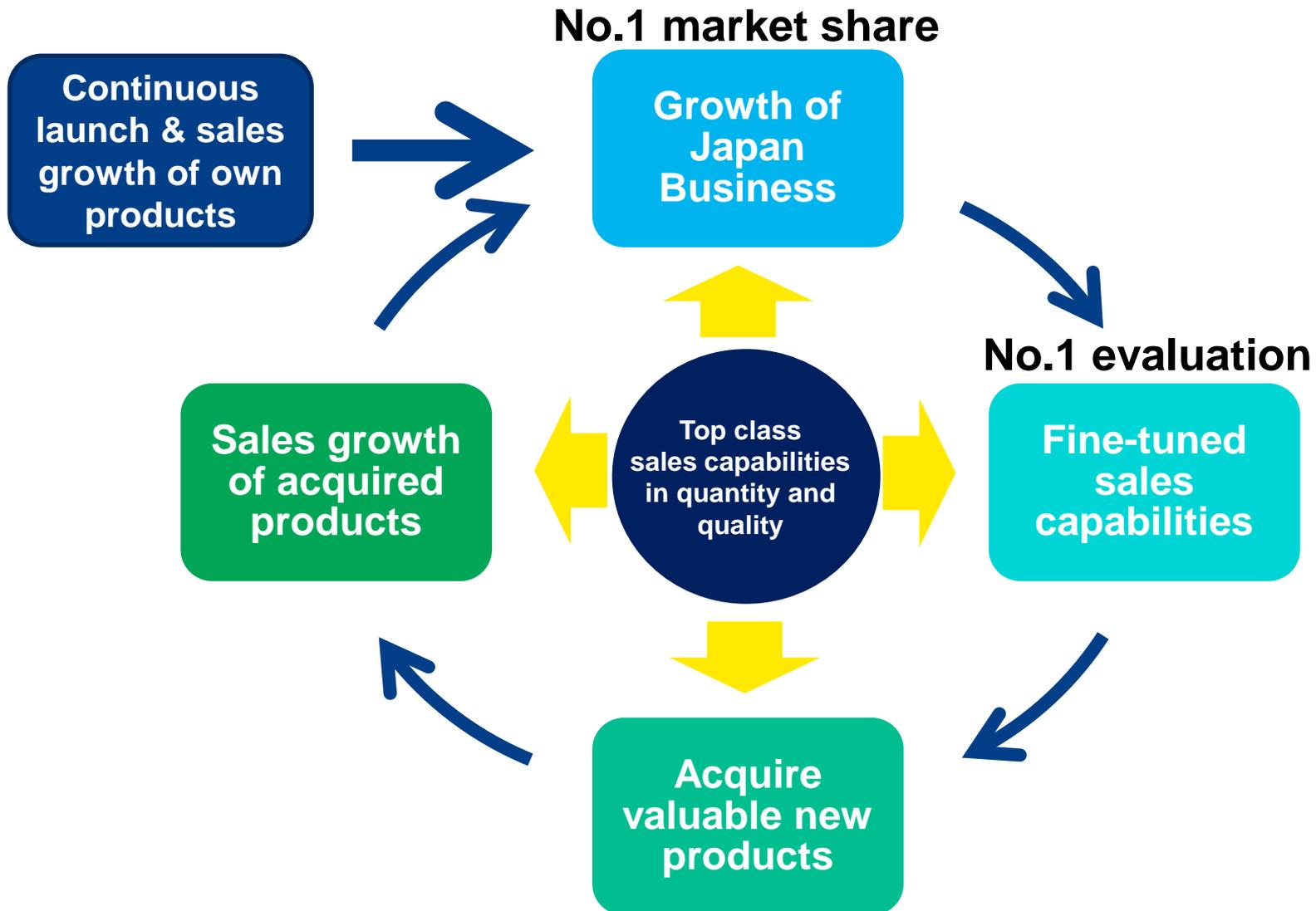
Type 2 diabetes mellitus treatment  
**Tenelia**

\*In the market for Bone resorption inhibitors

# Six Major Products: FY2020 Target



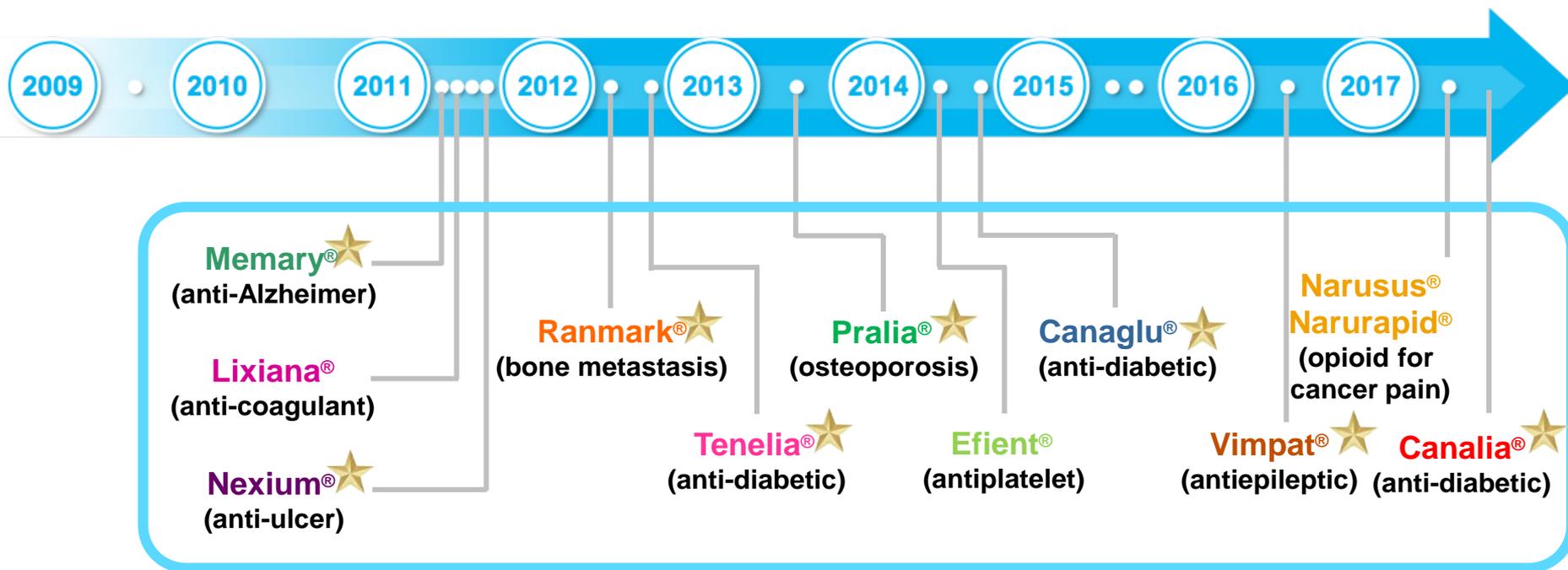
# Business Cycle for Sustainable Growth



## ◆ Ranked No.1 in various external surveys

- Daiichi Sankyo Japan MRs ranked No.1 for five consecutive years in survey of physicians conducted by ANTERIO Inc.
- Highly rated for MR visit activities and as a trustworthy manufacturer in survey conducted by Social Survey Research Information Co., Ltd.
- Judged to have superior MRs in survey by Mix Online

## ◆ Successful Japan launches of acquired or in-licensed products



★ : acquired or in-licensed products

## ◆ Growth Plans for Current Core Businesses - Injectafer

# U.S. Business Units



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

FY2017 revenue target  
**US\$ 564 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)**

FY2017 revenue target  
**US\$ 936 Mn**

**LPI successfully competes in high value specialty branded & generic injectable market segments through the following Franchises**

- ◆ **Iron Injectable Franchise**
  - **Venofer**
  - **Injectafer**
- ◆ **Generic Injectable Franchise**

## ◆ Broad indication – Treatment of IDA in adult patients with:

- Intolerance or unsatisfactory response to oral iron or;
- Non-dialysis chronic kidney disease



## ◆ Convenient dosing & administration



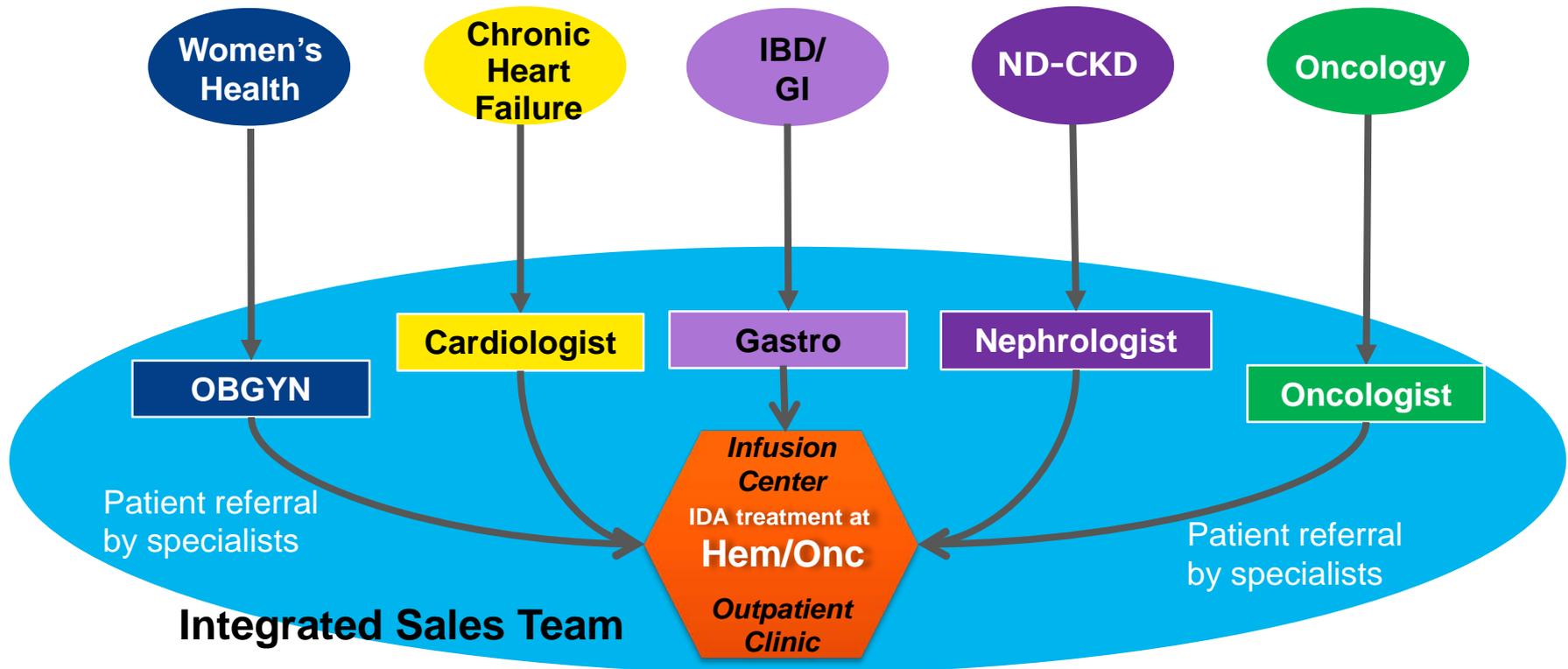
**IV Infusion  
over at least  
15 minutes**



**Slow IV push  
over at least  
7.5 minutes**

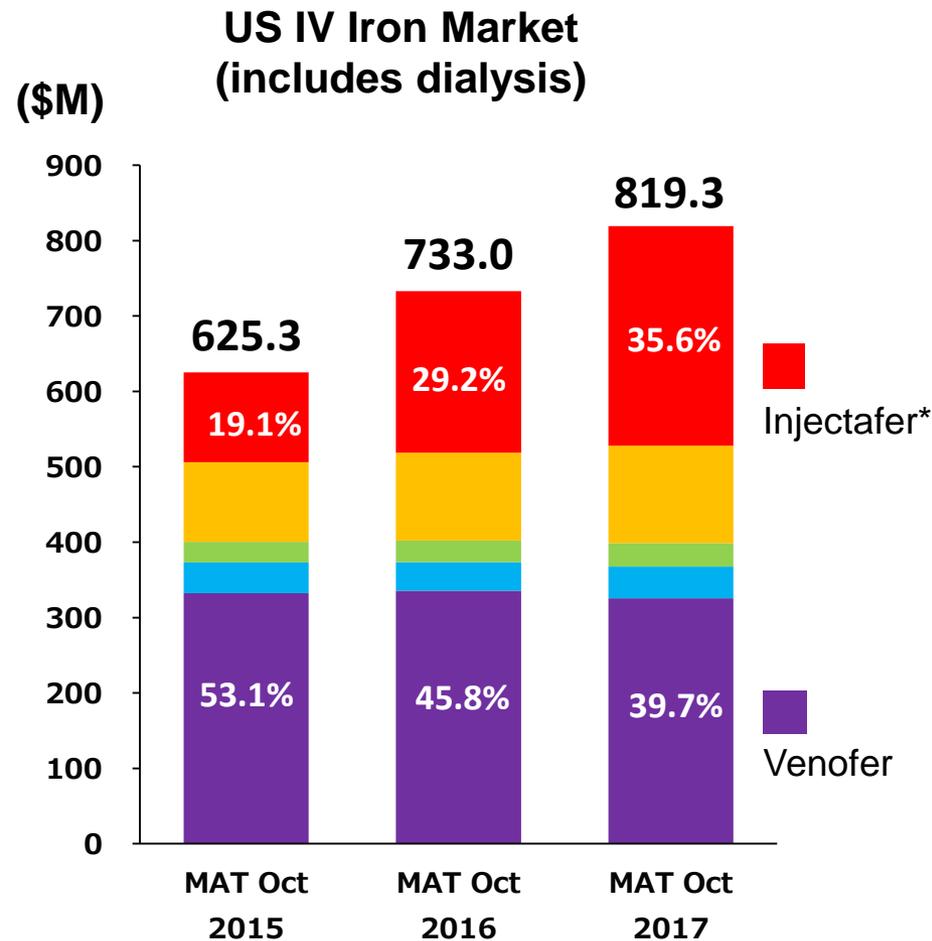
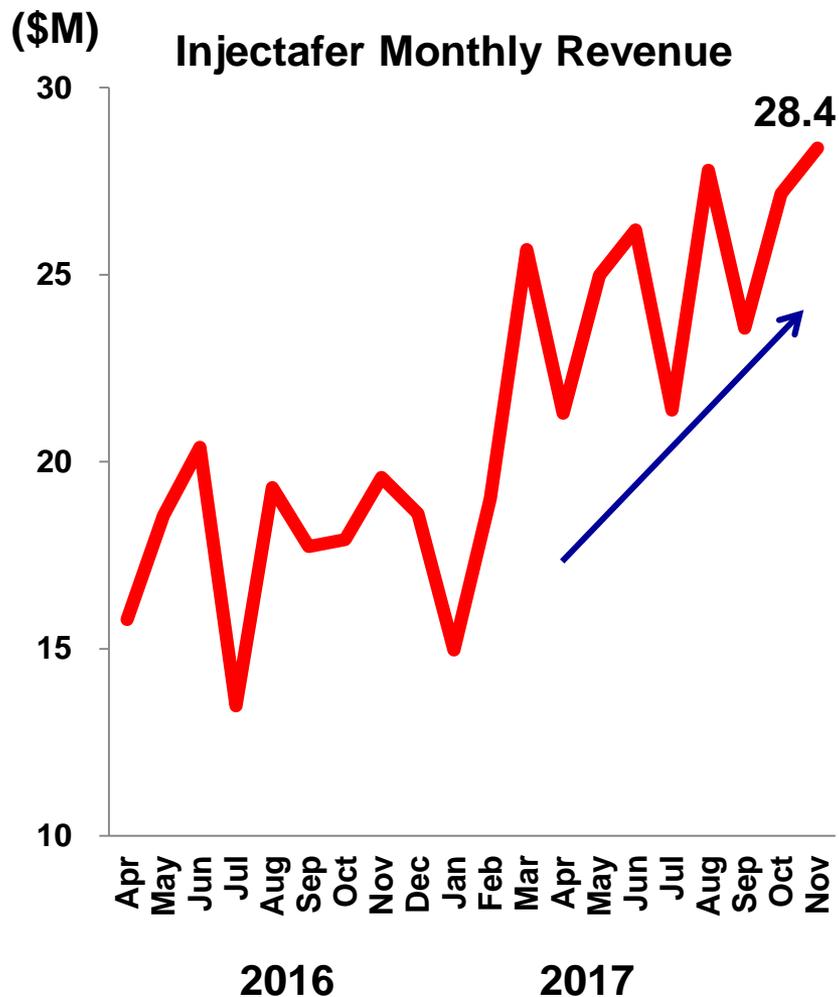
# New Sales Team for Injectafer

From Jan. 2017, the LPI sales team for Injectafer became DSI employees and formed one unified team for Injectafer in the United States.



# Growth of Injectafer

◆ Expanding monthly revenue under the integrated sales team structure launched in Jan 2017



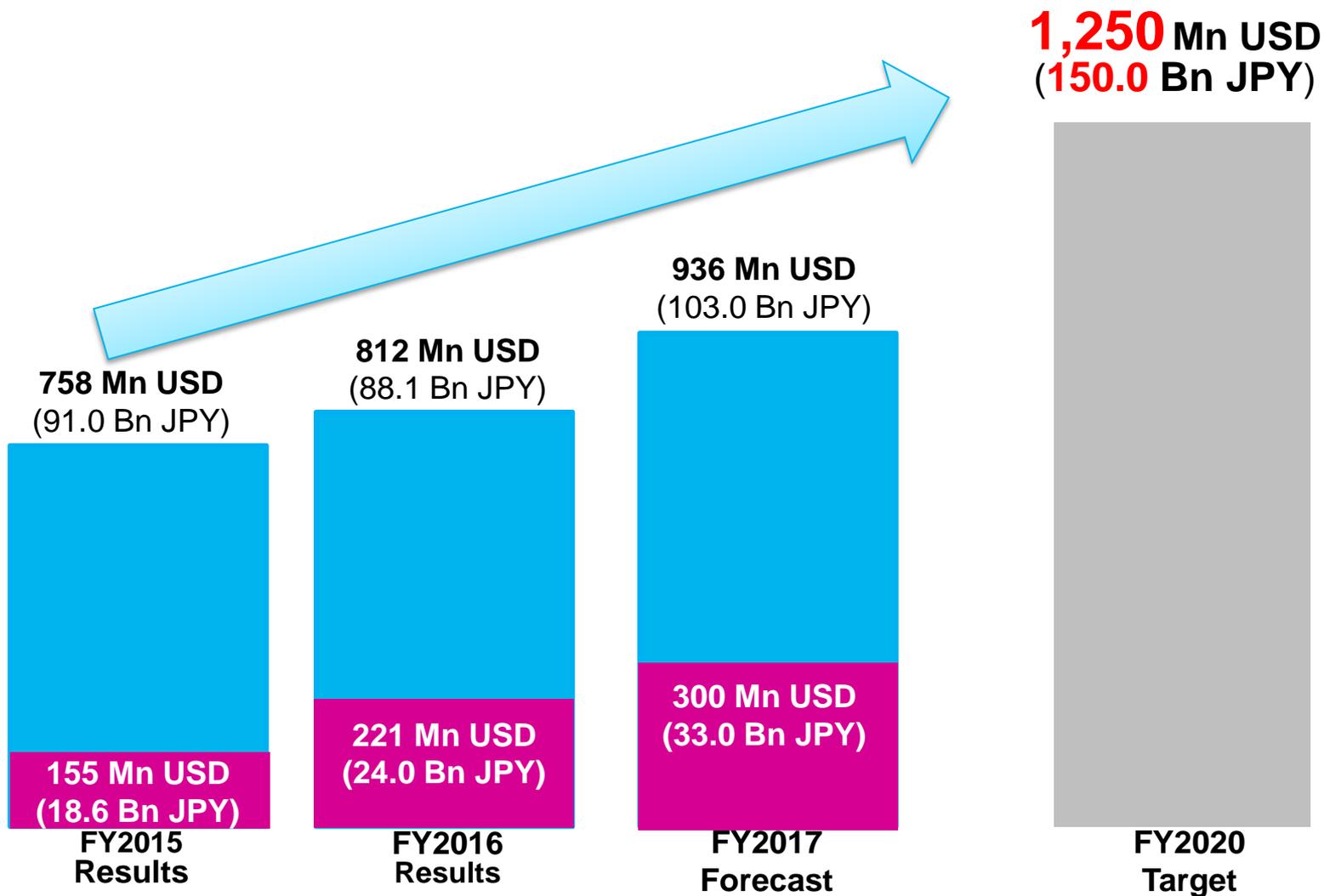
\*Injectafer is not indicated for patients who are dialysis dependent

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Source: IMS National Sales Perspectives Oct 2017

(includes all US IV Iron sales in all channels including dialysis chains)

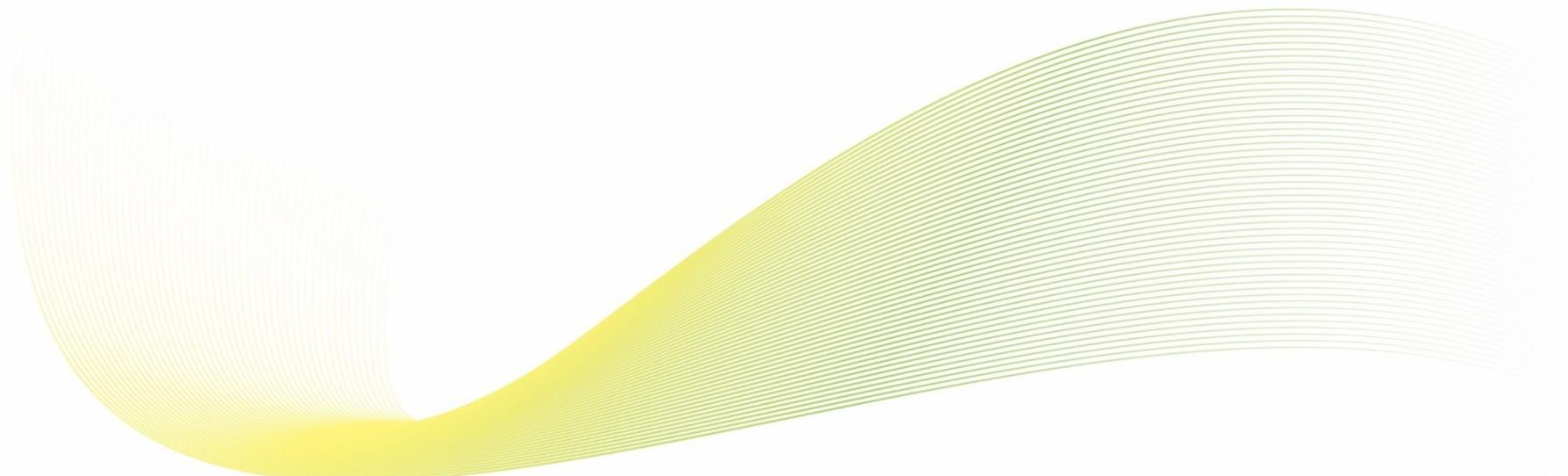
# LPI: FY2020 Target



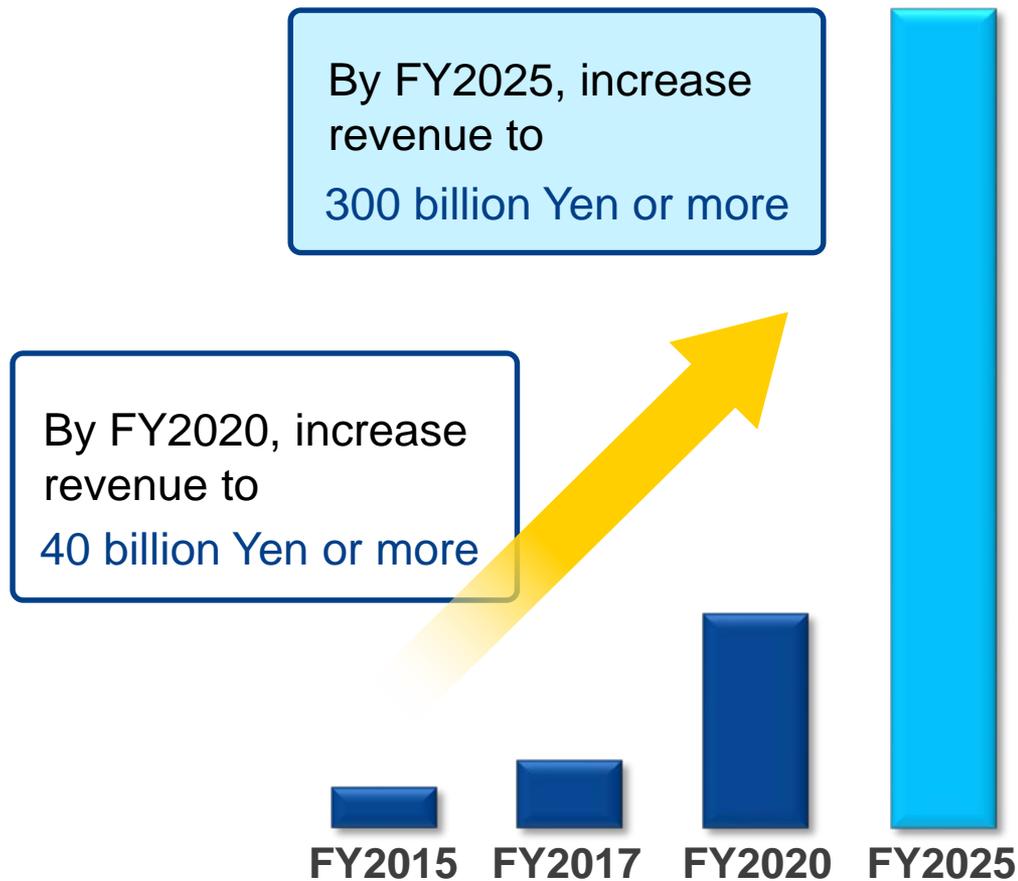
■ Injectafer

■ Luitpold products excluding Injectafer

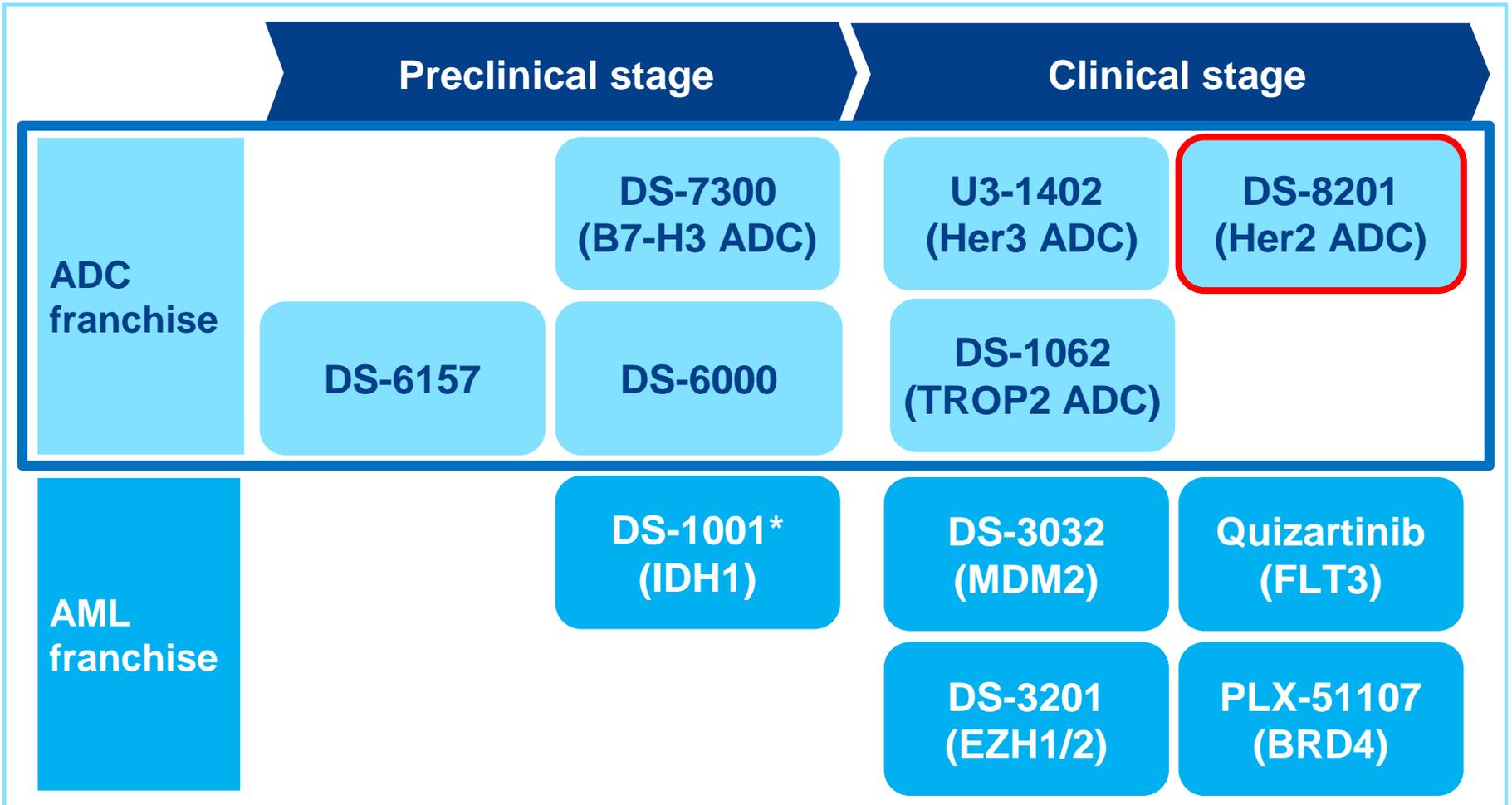
## ◆ Exciting ADC Technology and Pipeline



# Oncology Business: FY2020 Target

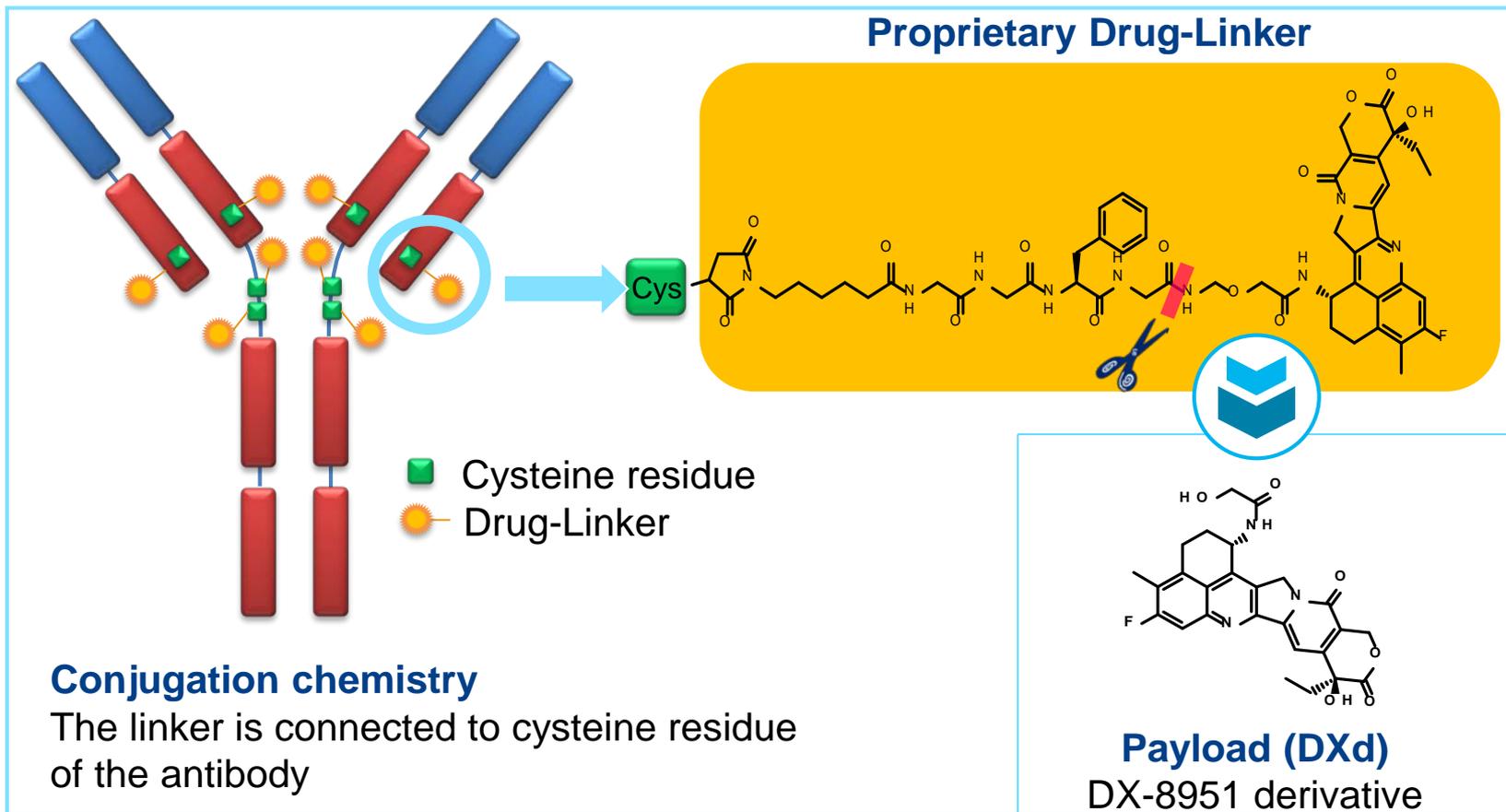


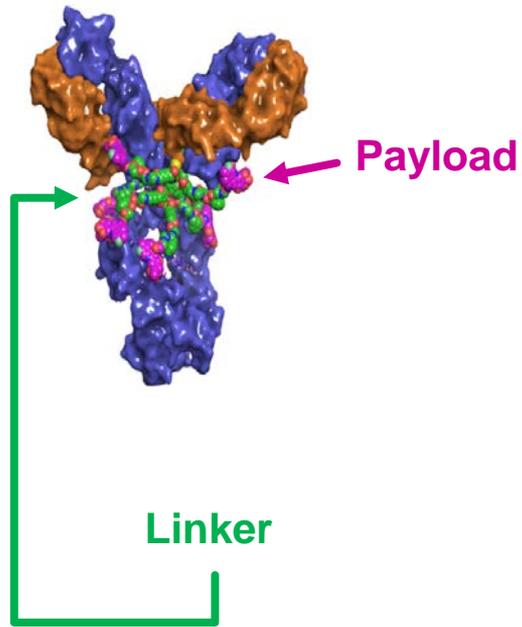
# Two Franchises: ADC and AML



\*: Ph1 in glioma. Preclinical development in AML.

# DS-8201: Flagship Asset

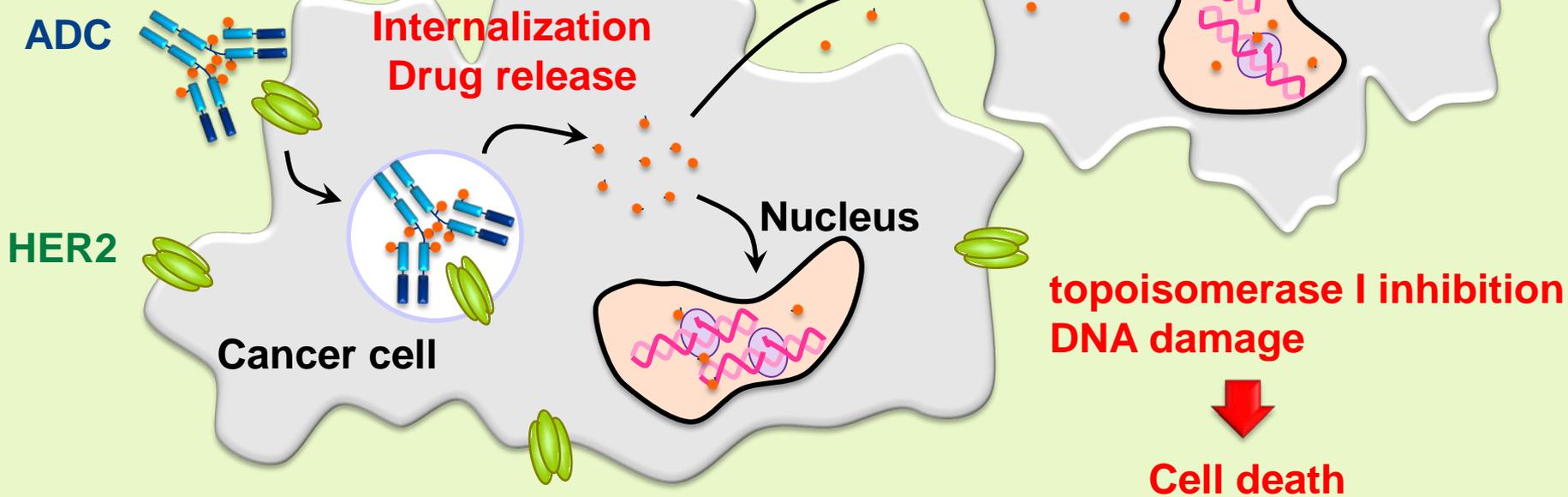




- Novel payload
- High potency
- Bystander effect
- High clearance of the payload

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

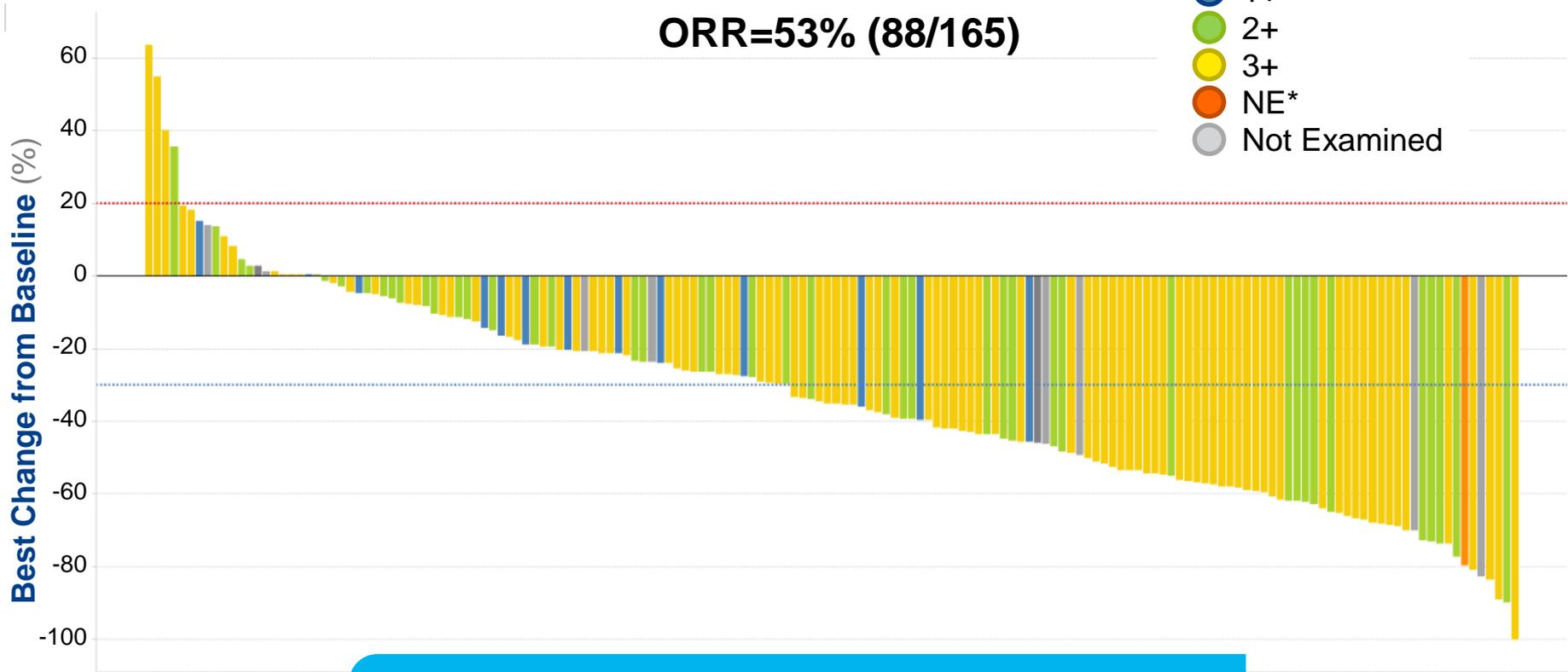
**Free payloads penetrate neighboring tumor cells**



## Phase 1 | Any Her2-expressing tumor (n=165) 5.4 + 6.4 mg/kg

Her2 Expression (IHC)

- 1+
- 2+
- 3+
- NE\*
- Not Examined



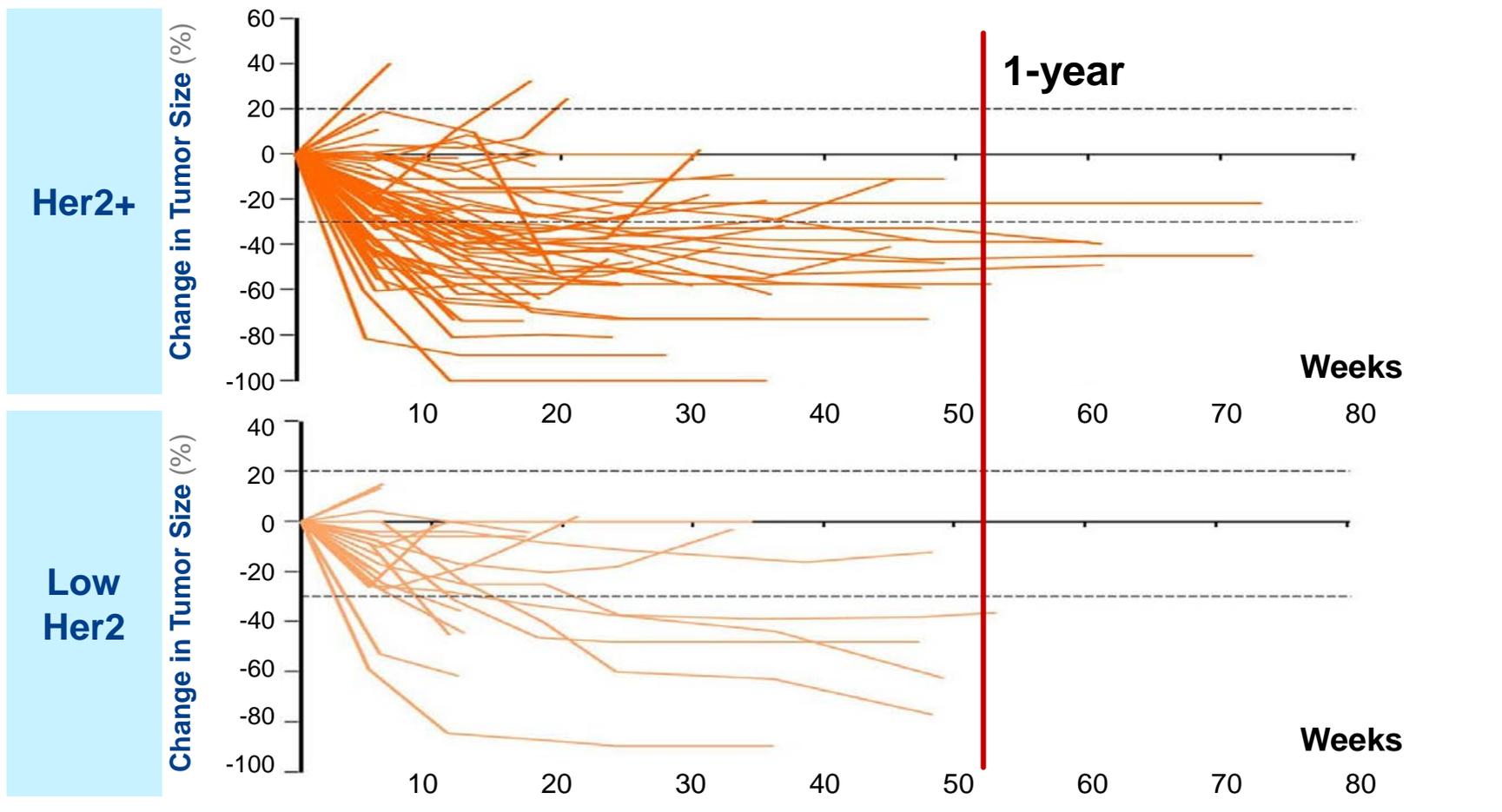
Tumor size shrinkage observed in most subjects

\*NE: Not Evaluated (same as Not Examined)

# DS-8201: Preliminary Activity

## Phase 1 | Her2-expressing breast cancer (n=105)

5.4 + 6.4 mg/kg



## Clinical efficacy

Breast	SABCS 2017		
	ORR	Disease Control Rate	PFS Median (months) - range
<b>Her2 Positive (trastuzumab &amp; T-DM1 failure)</b>			
All	61% (35/57)	95% (54/57)	10.4 (1.2+, 16.8+)
HR Positive	56% (22/39)	92% (36/39)	NR (1.2+, 16.8+)
HR Negative	75% (12/16)	100% (16/16)	10.4 (1.2+, 14.1+)
Prior pertuzumab	62% (31/50)	94% (47/50)	10.3 (1.2+, 16.8+)
<b>Her2 Low</b>			
All	32% (6/19)	84% (16/19)	NR (0.5, 12.2+)
HR Positive	31% (5/16)	88% (14/16)	NR (1.2+, 12.2+)
HR Negative	0% (0/2)	50% (1/2)	7.6 (0.5, 7.6)

## ASCO 2017, to be updated at ASCO GI Jan. 2018

Gastric	ORR	Disease Control Rate
	<b>Her2 Positive</b>	
All	44% (16/36)	89% (32/36)
Prior CPT 11	44% (8/18)	94% (17/18)

Sources: Doi T, *et al.* ASCO, 2017. Modi S, *et al.* SABCS, 2017.

N/R – Not Recorded

# DS-8201: Treatment-Emergent Events

## Treatment-emergent events, any grade (>20%)

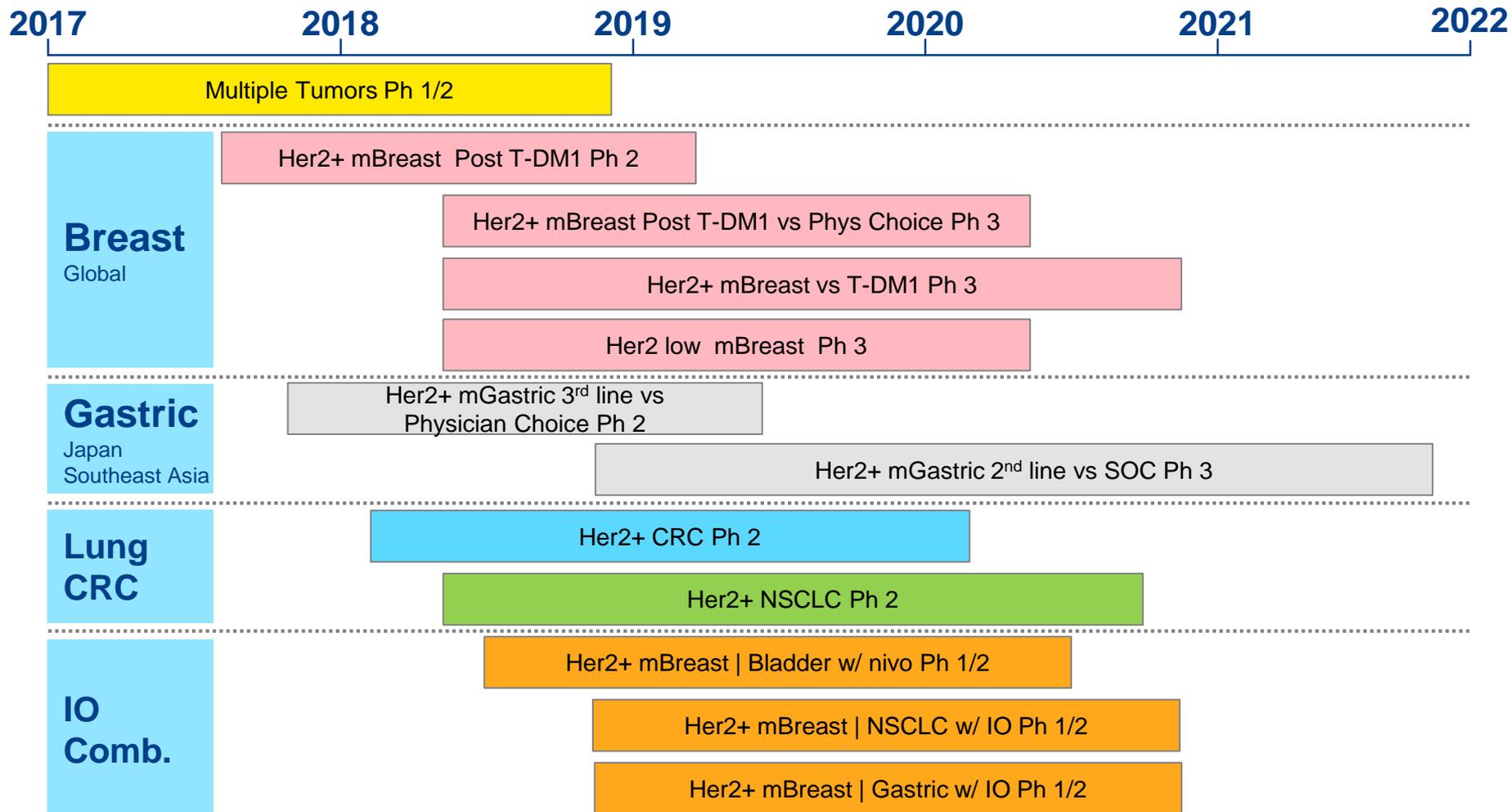
All subjects with 5.4 or 6.4 mg/kg (N = 185, as of 15 Oct 2017)

Preferred Term (MedDRA v18.0.)	n (%)				
	Grade 1	Grade 2	Grade 3	Grade 4	Any
<b>Hematologic</b>					
Anaemia	14 (7.6)	22 (11.9)	25 (13.5)	2 (1.1)	63 (34.1)
Platelet count decreased	27 (14.6)	14 (7.6)	13 (7.0)	6 (3.2)	60 (32.4)
Neutrophil count decreased	1 (0.5)	17 (9.2)	23 (12.4)	8 (4.3)	49 (26.5)
White blood cell count decreased	5 (2.7)	17 (9.2)	21 (11.4)	3 (1.6)	46 (24.9)
<b>Gastrointestinal disorders</b>					
Nausea	99 (53.5)	25 (13.5)	7 (3.8)	0 (0.0)	131 (70.8)
Decreased appetite	64 (34.6)	34 (18.4)	9 (4.9)	0 (0.0)	107 (57.8)
Vomiting	51 (27.6)	9 (4.9)	3 (1.6)	0 (0.0)	63 (34.1)
Diarrhea	43 (23.2)	11 (5.9)	3 (1.6)	0 (0.0)	57 (30.8)
Constipation	45 (24.3)	6 (3.2)	1 (0.5)	0 (0.0)	52 (28.1)
<b>Others</b>					
Alopecia	51 (27.6)	10 (5.4)	0 (0.0)	0 (0.0)	61 (33.0)
Malaise	31 (16.8)	12 (6.5)	2 (1.1)	0 (0.0)	45 (24.3)
Fatigue	26 (14.1)	11 (5.9)	1 (0.5)	0 (0.0)	38 (20.5)

Two cases of potential Grade 5 pneumonitis have been reported and will be assessed by an interstitial lung disease (ILD) adjudication committee

# DS-8201: Broad and Bold Program

## Estimated development timelines



# ADC franchise pipeline

## U3-1402 (Her3-ADC)

### Our ADC Technology

DAR8



### patritumab

Clinically validated mAb

Acceptable safety & tolerability in >300 subjects

- Breast Cancer (U101 study): Data at ASCO 2018
- NSCLC: Starts Q3 FY2017

## DS-1062 (TROP2-ADC)

### Our ADC Technology

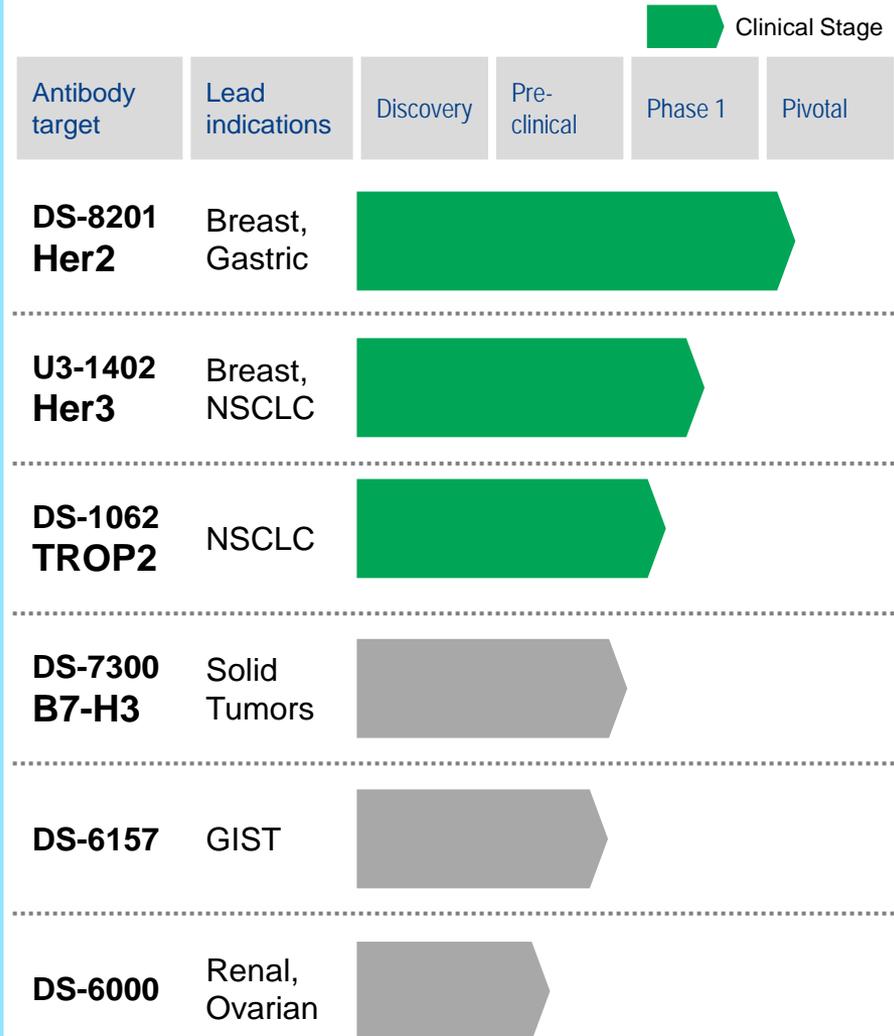
DAR4



humanized anti-TROP2 monoclonal antibody (hlgG1)

- FIH Study: NSCLC  $\geq$  3rd line, Planned to start Q4 FY2017

## ADC Franchise



# ADC: Collaborations with Partners

Partnerships with our existing  
ADC assets

*Her2-ADC*

*Other-ADCs*



*I/O mechanisms*  
(**BMS**: Opdivo)

*Tyrosine kinase  
inhibitor*  
(**Puma**:NERLYNX)

Partnerships to apply  
our ADC technology to new antibodies  
and targets

*Our proprietary ADC technology*



*Additional target*  
(**Glycotope**: TA-MUC1)



Daiichi-Sankyo  
cancerenterprise

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

## Key collaborations completed to date in 2017



**KTE-C19 CAR T-cell**  
JPN Development  
Jan 2017



Bristol-Myers Squibb  
**Combination Study**  
**DS-8201 + nivolumab**  
Aug 2017



**Progress re**  
**Bi-specific Antibody**  
**Collaboration**  
July 2017



THE UNIVERSITY OF TEXAS  
**Broad AML**  
**Collaboration,**  
**multiple pipeline assets**  
Sep 2017



**Target discovery**  
July 2017



**ADC Collaboration**  
Oct 2017



**G47Δ (DS-1647)**  
**Oncolytic Virus Orphan**  
**Drug Designation in JP**  
July 2017



**Research**  
**Collaboration**  
Dec 2017



**DS-5010 (RETi)**  
**out- licensed to focus**  
**on our pipeline**  
Aug 2017



**Combination**  
**DS-8201 + neratinib**  
Dec 2017



**Research**  
**Collaboration**  
Dec 2017

# Wrap up

- ◆ **Edoxaban on track to become billion-dollar Blockbuster**
- ◆ **Daiichi Sankyo is No. 1 in Japan by pharma sales**
- ◆ **Strong growth of Injectafer in the U.S. ;  
LPI on track to become a billion-dollar company**
- ◆ **Exciting ADC technology and pipeline**

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