

Passion for Innovation.  
Compassion for Patients.™



# Global Pharma Innovator with Competitive Advantage in Oncology

**DAIICHI SANKYO CO., LTD.**

**Sunao Manabe**  
President and CEO

January 13, 2021

# 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.

Some of the 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.

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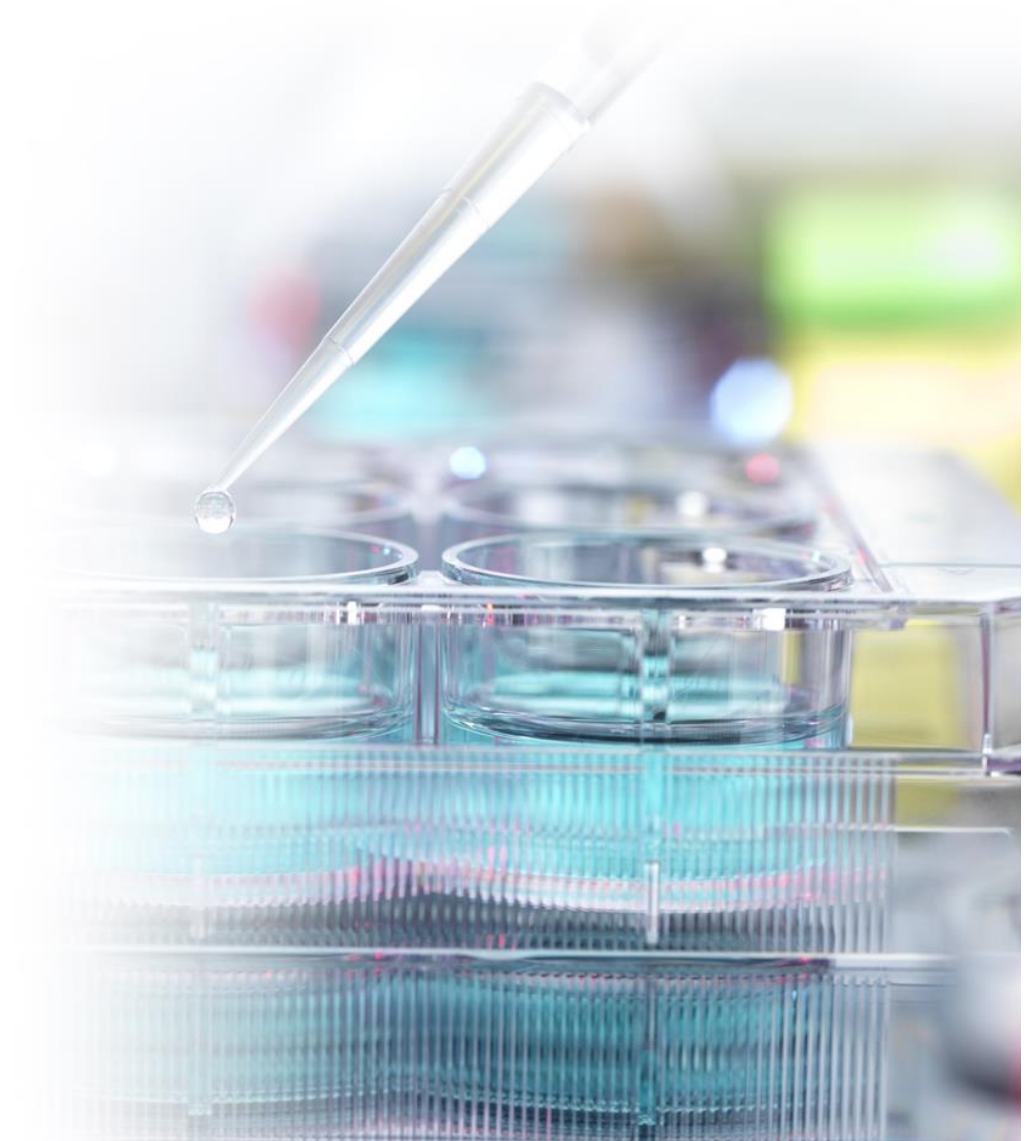
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**① Overview of Daiichi Sankyo**

**② Growth Strategy**

**③ Maximizing Shareholder Value**

**④ Appendix**

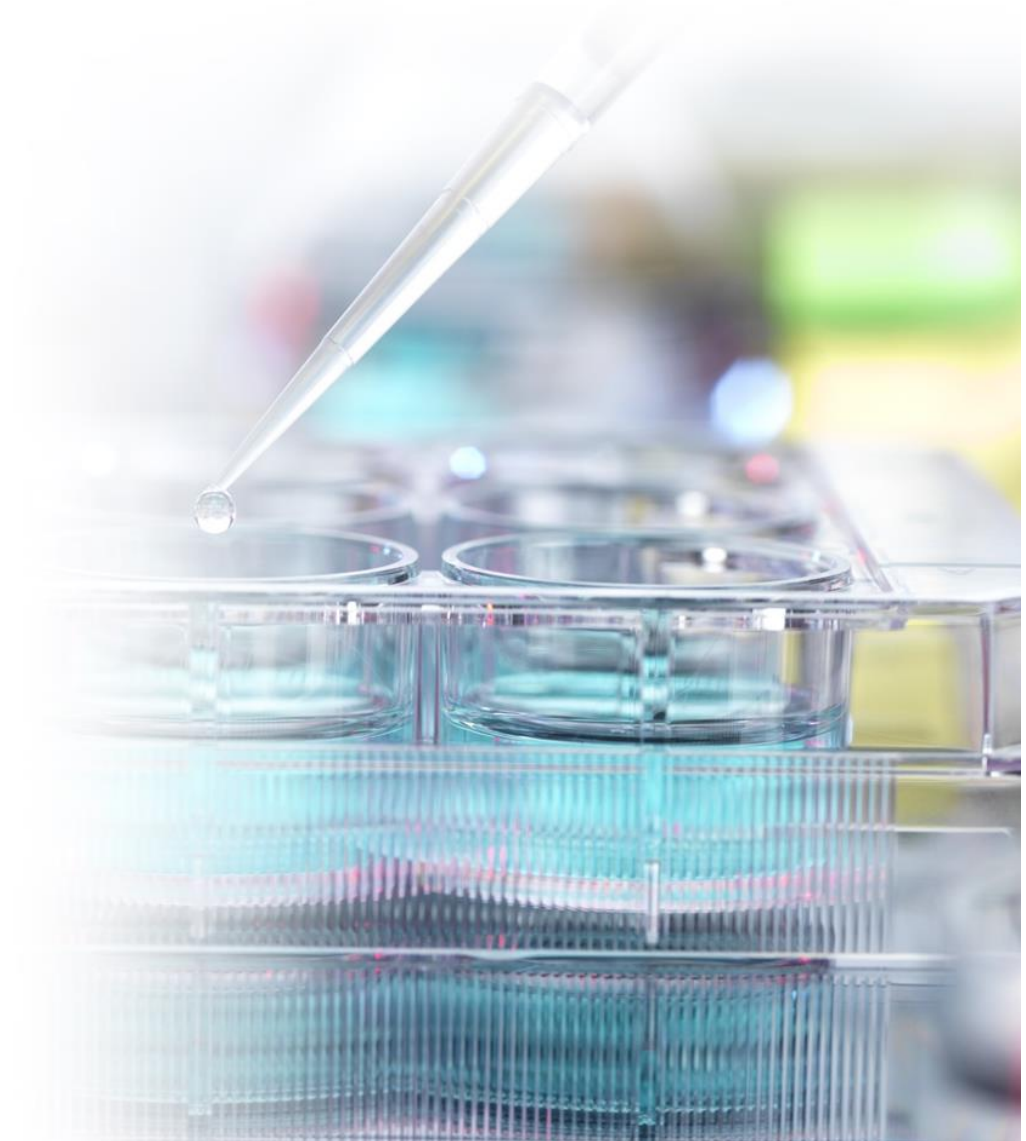


## ① Overview of Daiichi Sankyo

## ② Growth Strategy

## ③ Maximizing Shareholder Value

## ④ Appendix

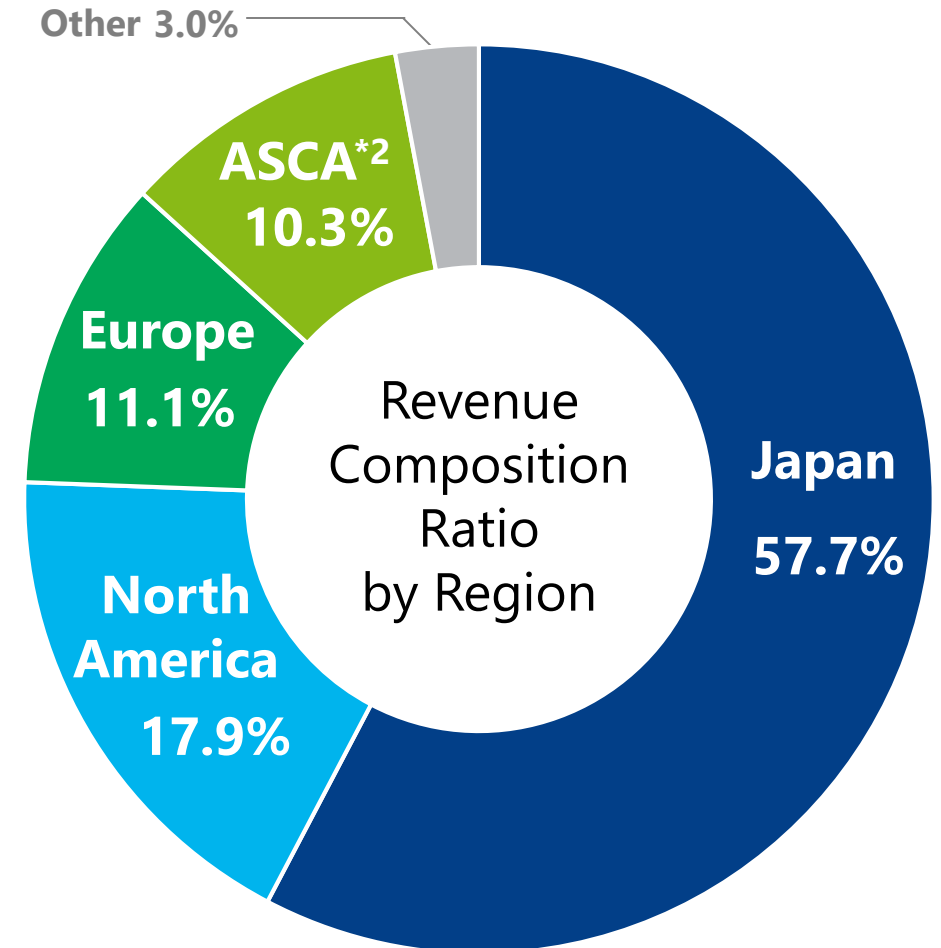


# Financial Summary

## Overview of FY2020 consolidated P&L

(Bn JPY)

	FY2020 Forecast <sup>*1</sup>	
		to revenue
<b>Revenue</b>	<b>960.0</b>	<b>100.0%</b>
<b>Cost of sales</b>	<b>340.0</b>	<b>35.4%</b>
<b>SG&amp;A expenses</b>	<b>317.0</b>	<b>33.0%</b>
<b>R&amp;D expenses</b>	<b>243.0</b>	<b>25.3%</b>
<b>Operating profit</b>	<b>60.0</b>	<b>6.3%</b>
<b>Profit attributable to owners of the Company</b>	<b>53.0</b>	<b>5.5%</b>



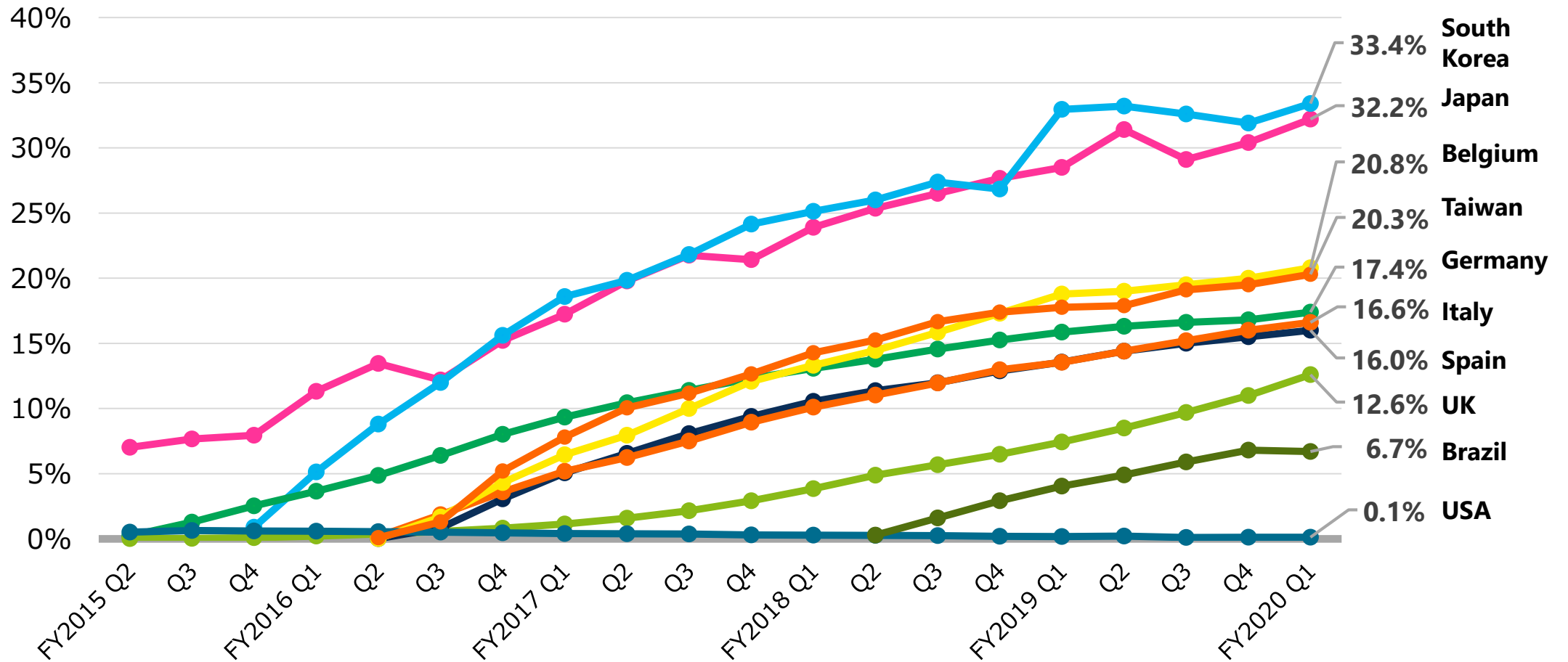
\*1 Forecast as of Oct. 30, 2020

\*2 Asia, South & Central America

# Edoxaban Global Growth

◆ **Steady growth across markets**  
 ◆ **Global revenue (FY2020 forecast\*): 160.9 Bn JPY**

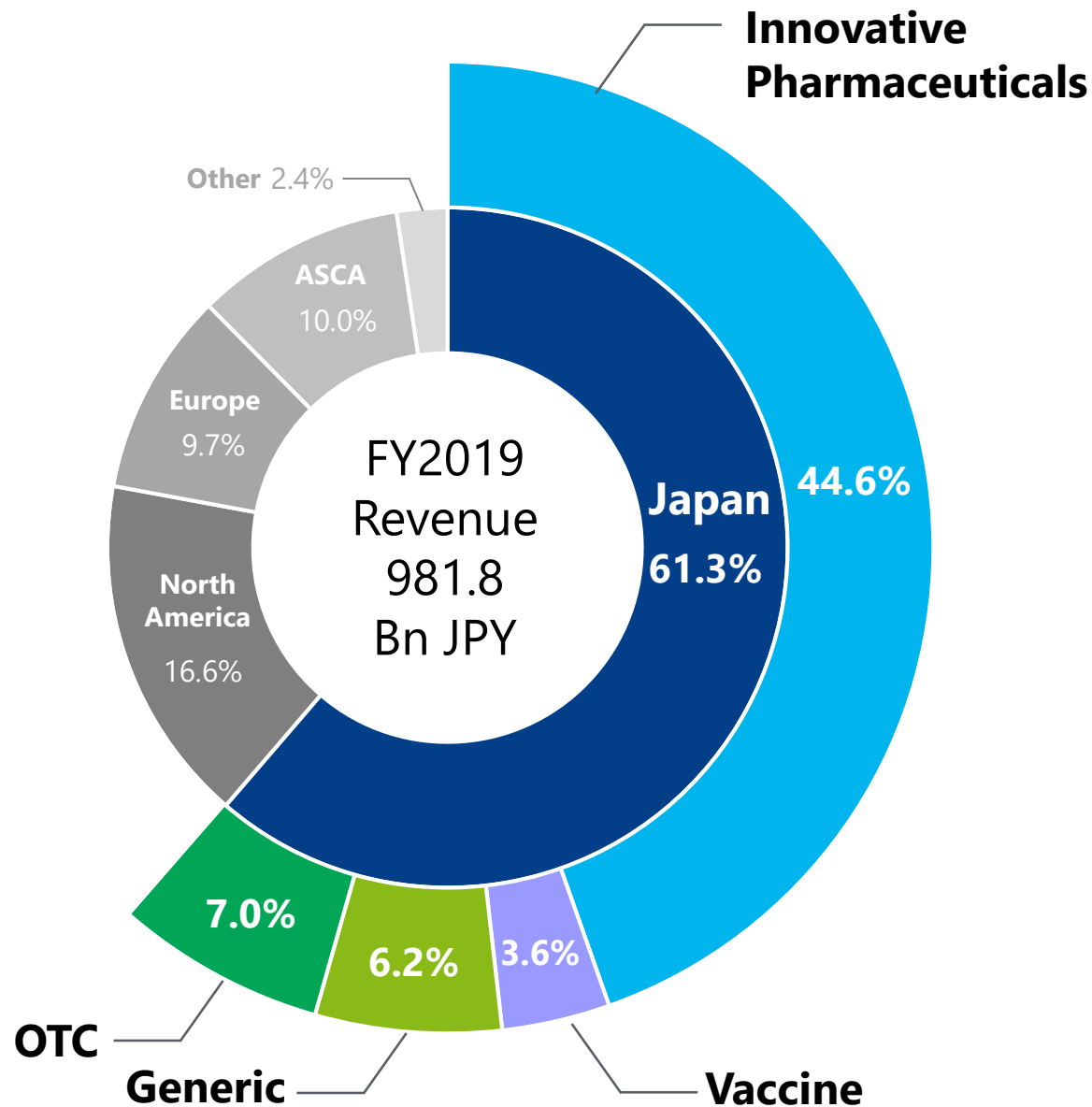
Volume-based Share



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 Calculated based on IQVIA MIDAS Data: FY2015 Q2 -FY2020 Q1 Reprinted with permission

\*Forecast as of Oct. 30, 2020

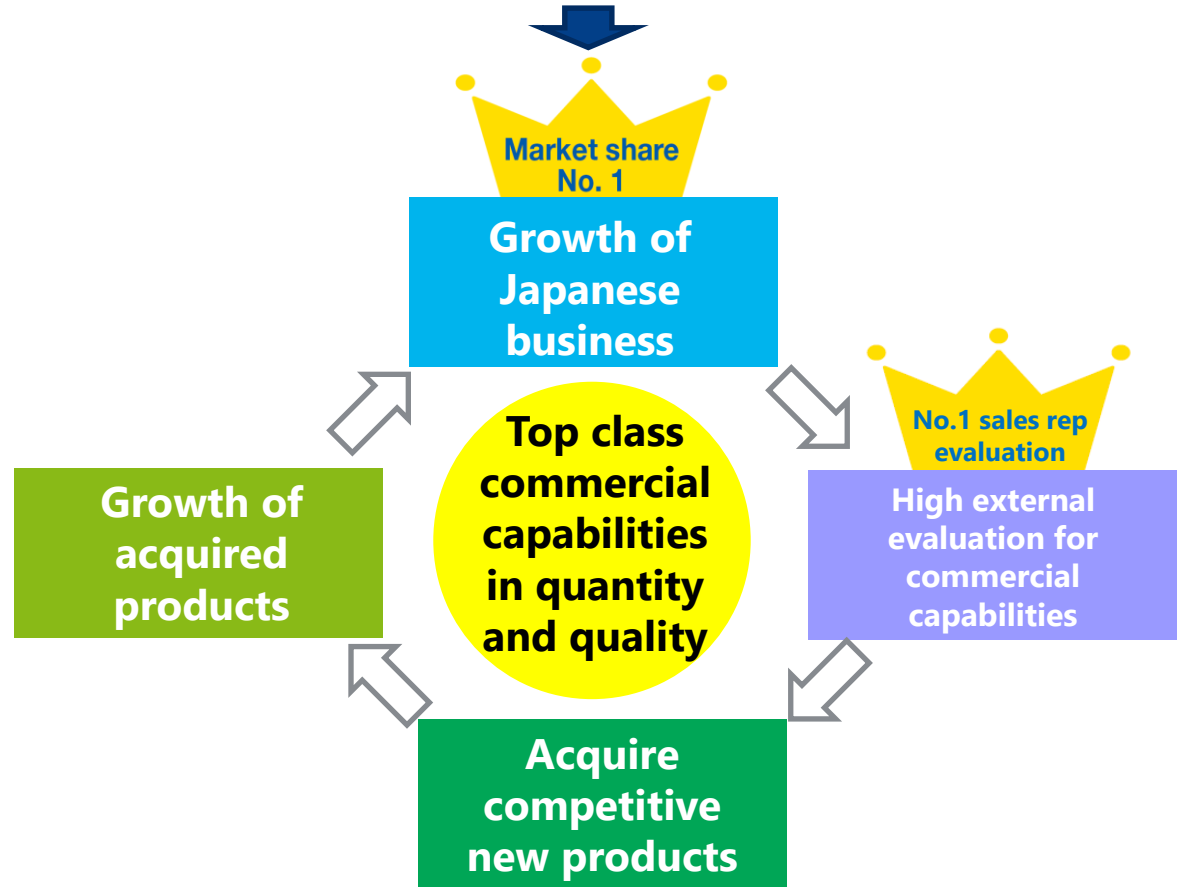
# Japan Business: No.1 market share (FY2016-FY2019)



## Business Model for Sustainable Growth

**Continuous launch & growth of DS original products**

Lixiana<sup>®</sup>, Tarlige<sup>®</sup>, ENHERTU<sup>®</sup>, etc.



PRALIA<sup>®</sup>/Ranmark<sup>®\*</sup>, VIMPAT<sup>®</sup>, etc.

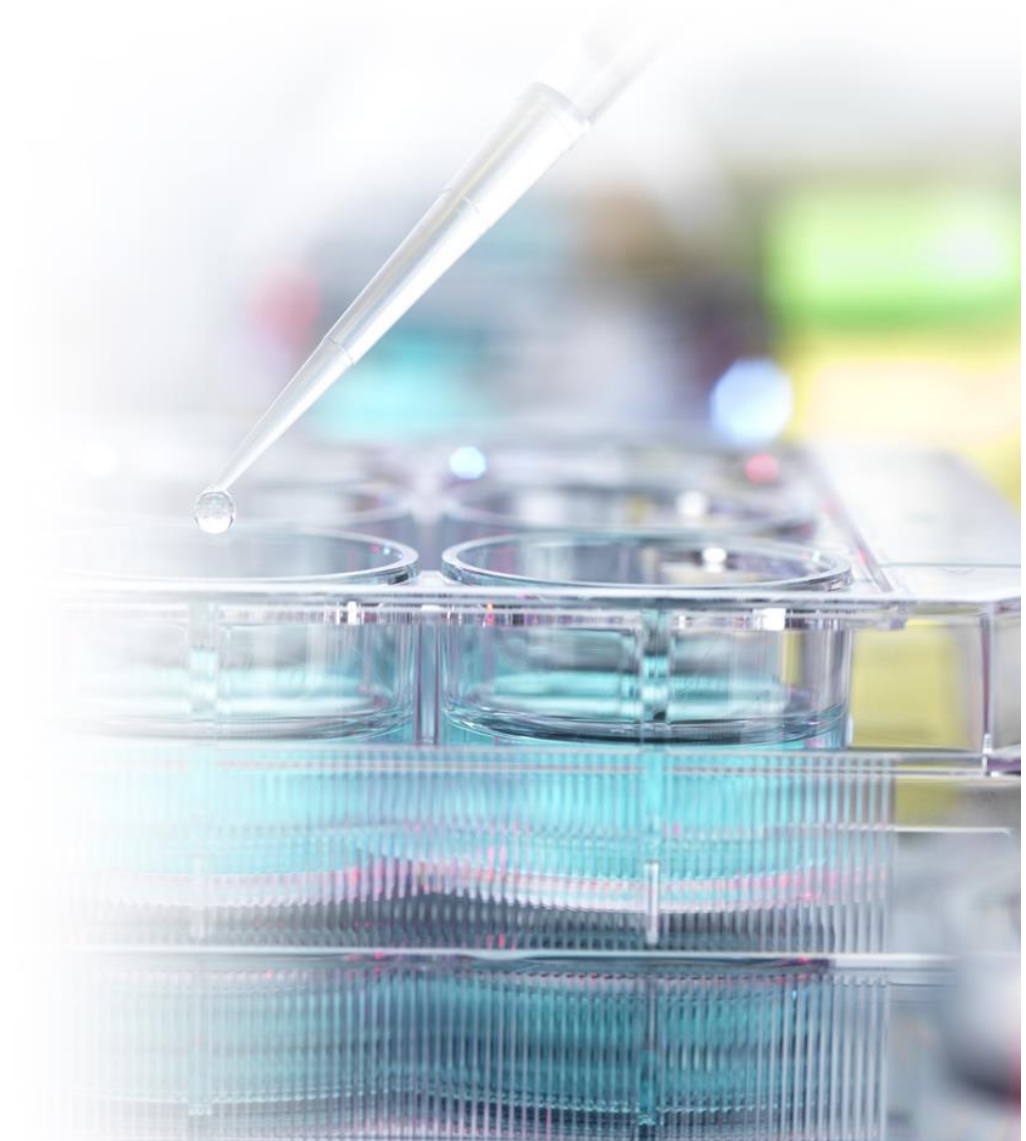
\*US product name: Prolia<sup>®</sup>/XGEVA<sup>®</sup>

**1 Overview of Daiichi Sankyo**

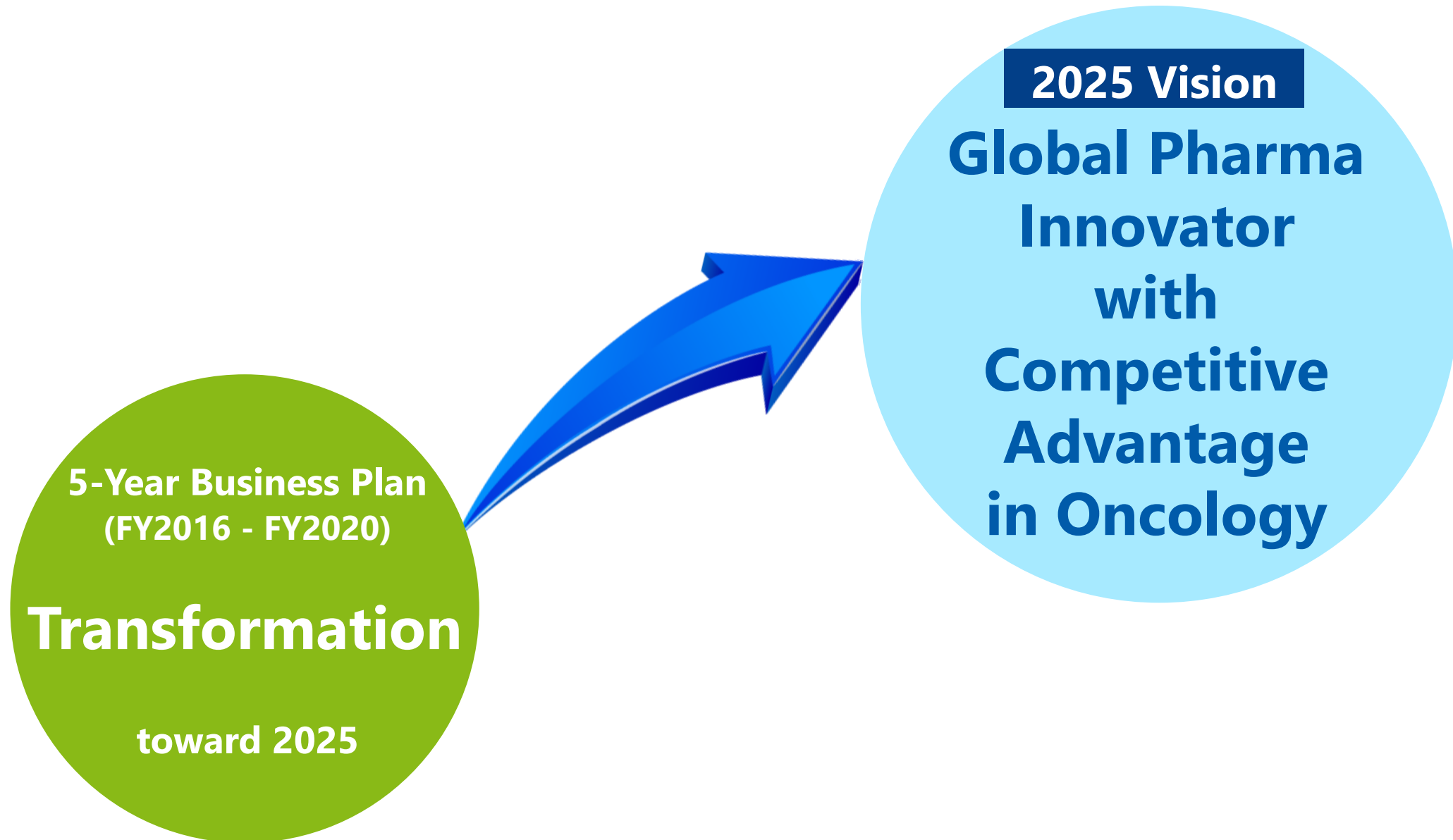
**2 Growth Strategy**

**3 Maximizing Shareholder Value**

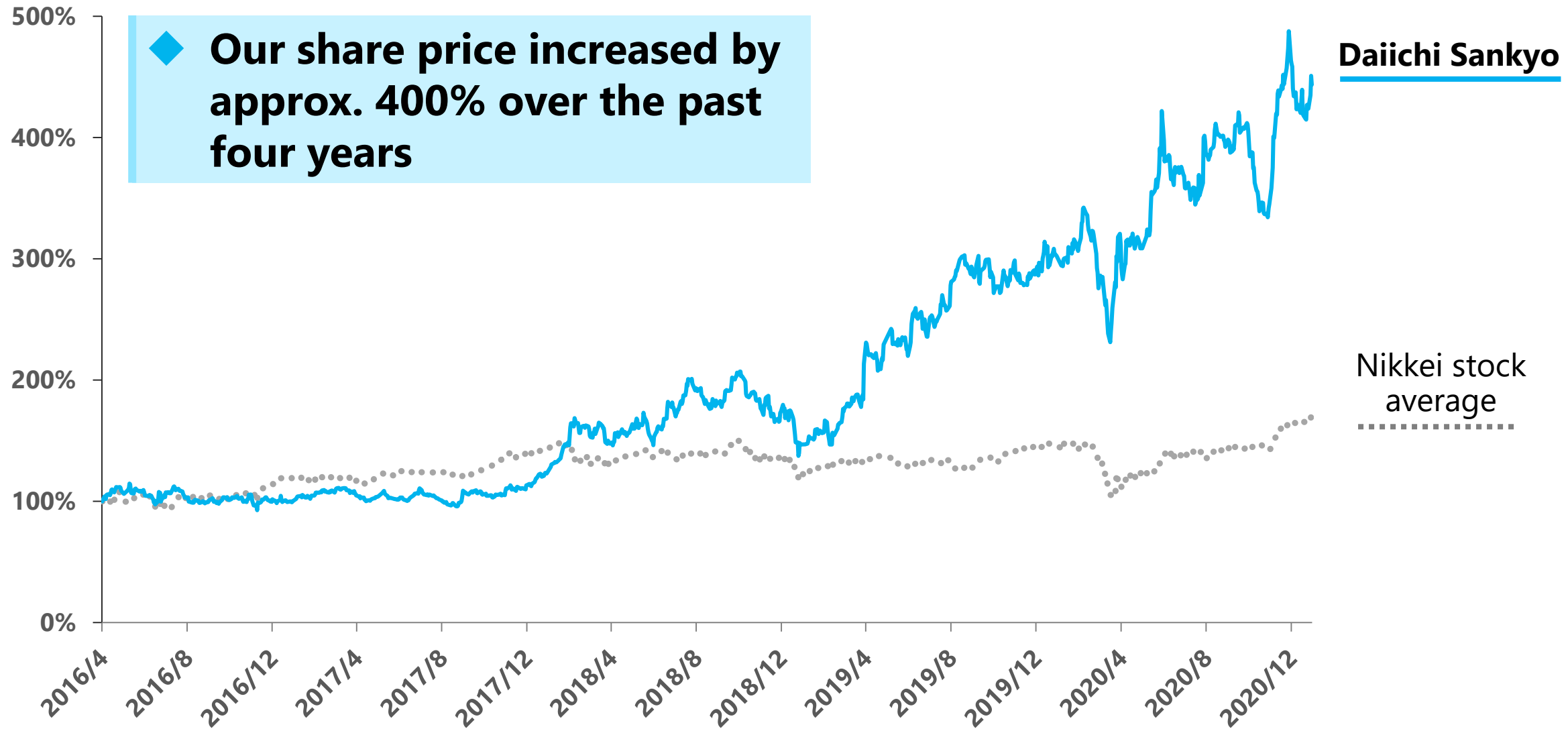
**4 Appendix**







# Share Price During the Current 5-Year Business Plan

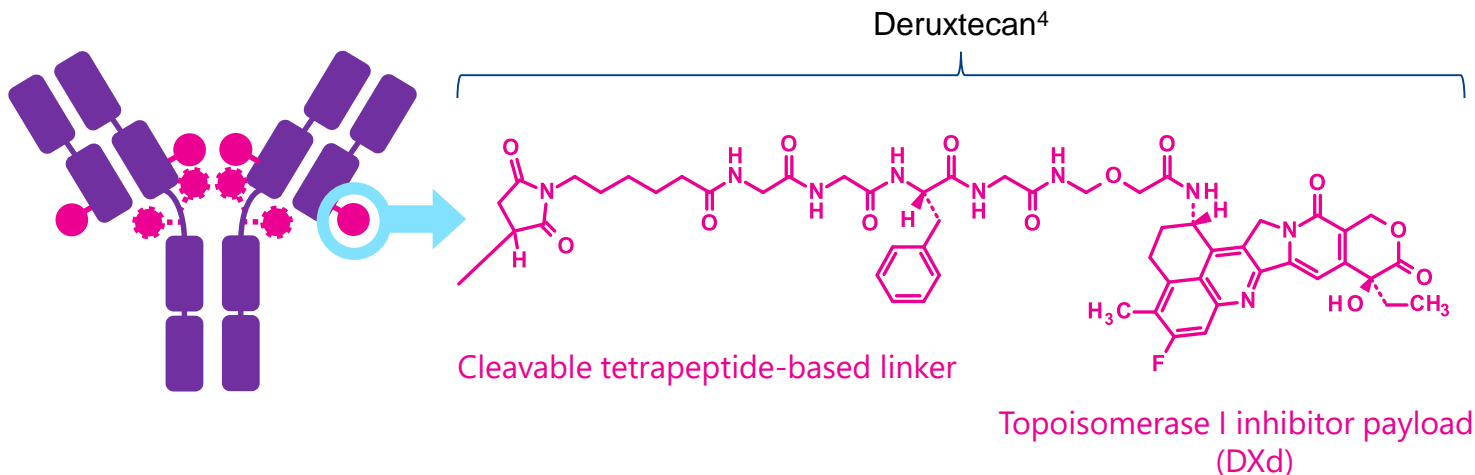


# Our Proprietary Antibody Drug Conjugates (ADC)

## DXd ADCs are composed of 3 components<sup>1,2</sup>:

- A monoclonal antibody attached to:
- A topoisomerase I inhibitor payload, an exatecan derivative, via
- A tetrapeptide-based cleavable linker

## DXd ADC Technology<sup>b</sup>



Payload mechanism of action:  
topoisomerase I inhibitor <sup>a,1-5</sup>

High potency of payload <sup>a,2-5</sup>

Optimized drug to antibody  
ratio <sup>a,c,1-4</sup>

Payload with short systemic  
half-life <sup>a,c,2,3</sup>

Stable linker-payload <sup>a,2,3,5</sup>

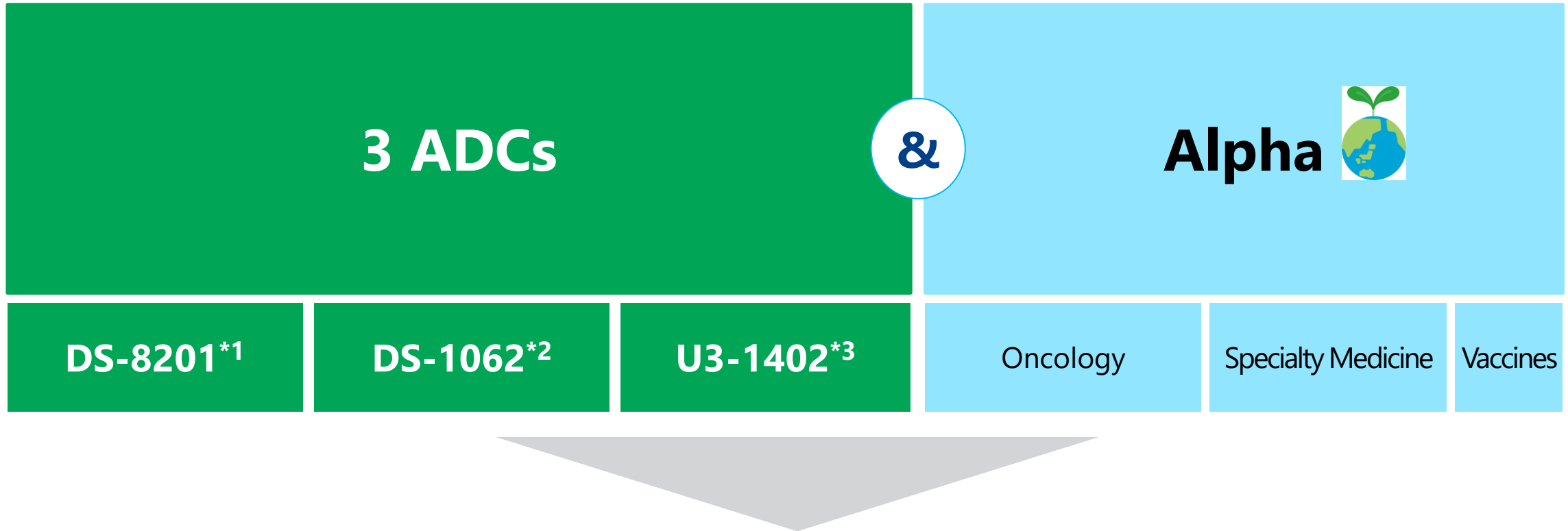
Tumor-selective cleavable  
linker <sup>a,2-6</sup>

Bystander antitumor effect <sup>a,2,7</sup>

<sup>1</sup> Okajima D, et al. Poster presented at: AACR-NCI-EORTC International Conference; October 26-30, 2019; Boston, MA [abstract C026].; <sup>2</sup> Nakada T, et al. Chem Pharm Bull (Tokyo). 2019;67(3):173-185.; <sup>3</sup> Ogitani Y, et al. Clin Cancer Res. 2016;22(20):5097-5108.; <sup>4</sup> Hashimoto Y, et al. Clin Cancer Res. 2019;25:7151-7161.; <sup>5</sup> Koganemaru S, et al. Mol Cancer Ther. 2019;18:2043-2050.; <sup>6</sup> Haratani K, et al. J Clin Invest. 2020;130(1):374-388.; <sup>7</sup> Ogitani Y, et al. Cancer Sci. 2016;107(7):1039-1046.

<sup>a</sup> The clinical relevance of these features is under investigation.; <sup>b</sup> Image is for illustrative purposes only; actual drug to antibody ratio and drug positions may vary.; <sup>c</sup> Based on animal data.

# Our R&D strategy: 3 and Alpha

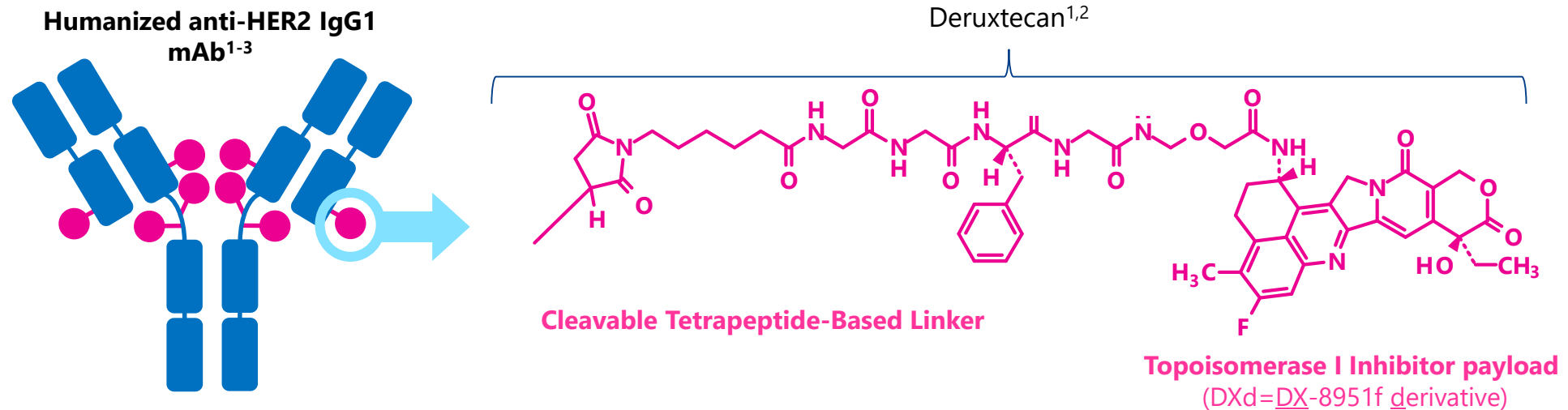


## ◆ 3 and Alpha strategy

- Allocate financial/human resources with priority to **maximize the 3 ADCs**
- Focus on activities with potential to change the current Standards of Care for Alpha

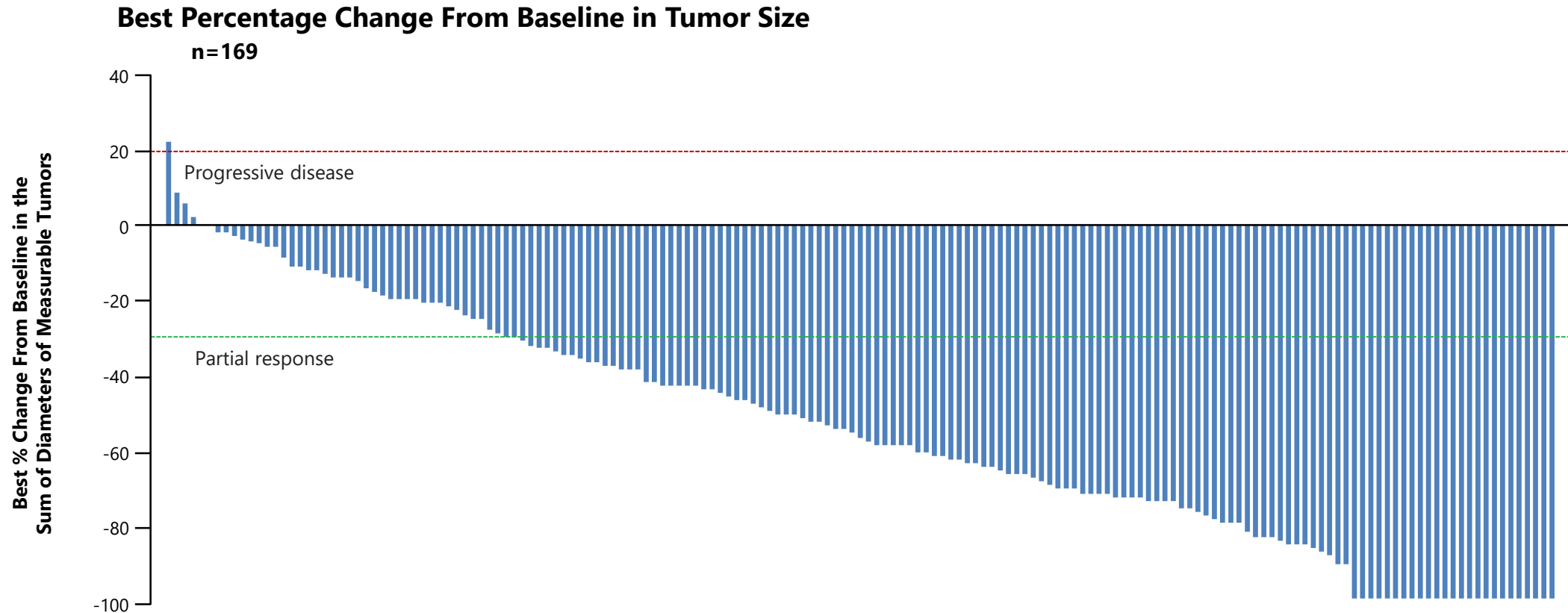
## DS-8201 is an ADC composed of 3 components<sup>1,2</sup>:

- A humanized anti-HER2 IgG1 mAb with the same amino acid sequence as trastuzumab, covalently linked to:
- A topoisomerase I inhibitor payload, an exatecan derivative, via
- A tetrapeptide-based cleavable linker



# DS-8201: Efficacy - Breast Cancer (DESTINY-Breast01)

◆ **Confirmed ORR: 61.4%** (95% CI, 54.0%–68.5%)

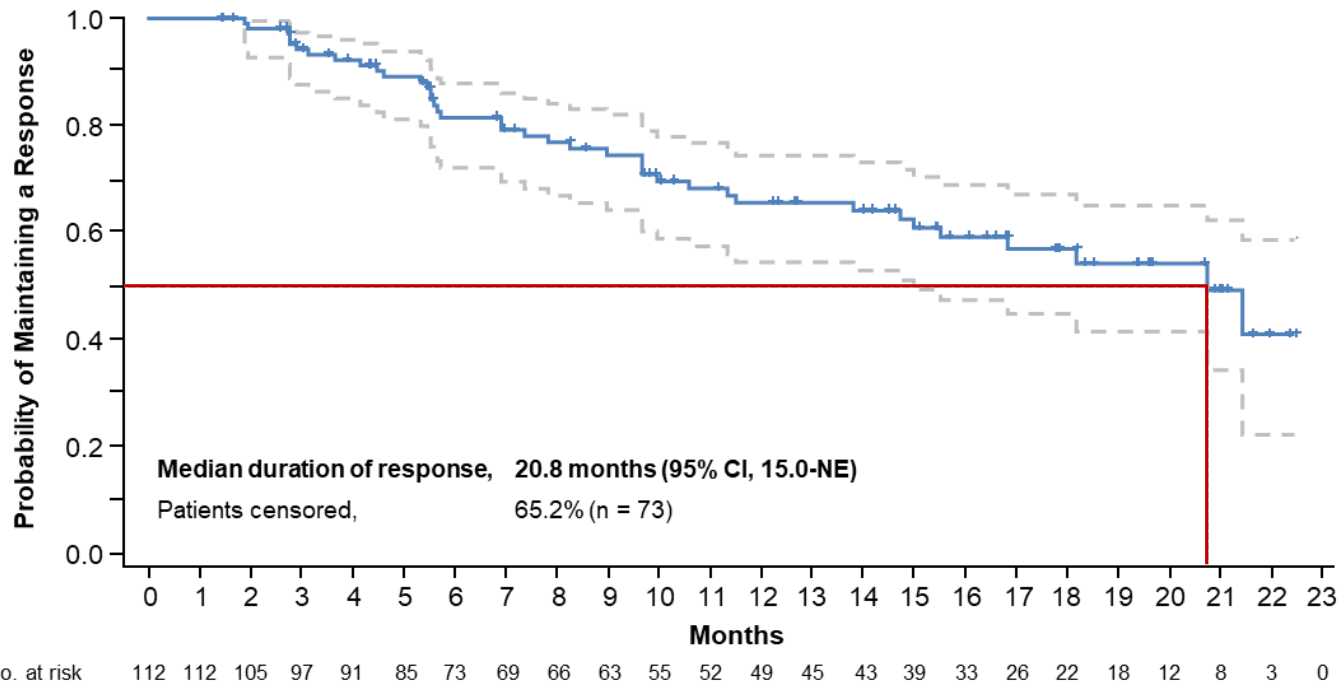


Source: S. Modi et al., Abstract #1190; PD3-06, SABCS 2020

ENHERTU® is approved in US with a Boxed WARNING for Interstitial Lung Disease (ILD)/pneumonitis and Embryo-Fetal Toxicity.

ORR: overall response rate

## ◆ Duration of Response: 20.8 months (median)



**Standard of care in first-line mBC:  
the CLEOPATRA Study in 1<sup>st</sup> line mBC  
THP (trastuzumab, pertuzumab and docetaxel)**  
Duration of response = **20.2 months** (95% CI, 16.0 to 24.0)  
S Swain J Baselga et al NEJM2015

### Intent-to-treat analysis

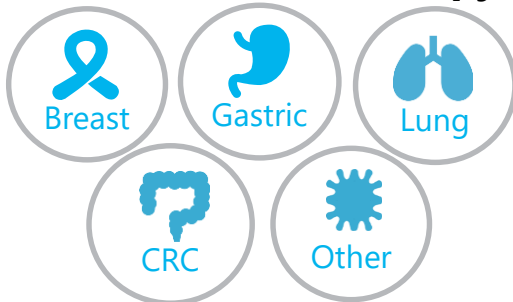
	<b>June 2020 data cutoff DS-8201 5.4 mg/kg (N = 184)</b>
Duration of follow-up, median (range)	20.5 months (0.7-31.4)
Patients remaining on treatment	20.1% (n = 37)
<b>Confirmed ORR by ICR</b>	<b>61.4% (n = 113)</b> (95% CI, 54.0%-68.5%)

- ◆ **Co-development and co-commercialization with AstraZeneca (entered in Mar. 2019)**
  - Maximize the value of DS-8201 by accelerating development & commercialization
  - Accelerate building in-house global oncology infrastructure
  - Expand resource allocation for other ADC assets



## Development

- ◆ **Co-develop** as **mono-therapy** and **combination therapy**



## Commercial

- ◆ **Global (excluding Japan)**  
The companies will **co-promote** and **share profits**
- ◆ **Japan**  
**Daiichi Sankyo** will **solely commercialize** and **pay royalty** to AstraZeneca

## Financial Consideration

- ◆ Up to **US\$ 6.9 Bn (759.0 Bn JPY\*)** in total  
Including upfront payment, regulatory / sales-related milestones and other contingencies  
\* US\$1 = 110 JPY



- ◆ Launched in 2020 (US/JP) – Breast cancer 3<sup>rd</sup> line therapy
- ◆ Expansion in region and indication is progressing steadily



## HER2 Positive Breast Cancer 3L

- January 2020  
**Launched in US\*<sup>1</sup>**
- May 2020  
**Launched in JP\*<sup>2</sup>**
- July 2020  
**MAA accepted in EU**  
✓ **Recommended for approval by CHMP in Dec. 2020**  
**(Approval anticipated in FY2020 Q4)**



## HER2 Positive Gastric Cancer 3L

- September 2020  
**Indication expanded in JP\*<sup>3</sup>**
- October 2020  
**sBLA accepted in US**  
**(PDUFA Date: Feb. 28, 2021)**

\*1 Treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting

\*2 Treatment of patients with HER2 positive unresectable or recurrent breast cancer after prior chemotherapy (limit the use to patients who are refractory or intolerant to standard treatments)

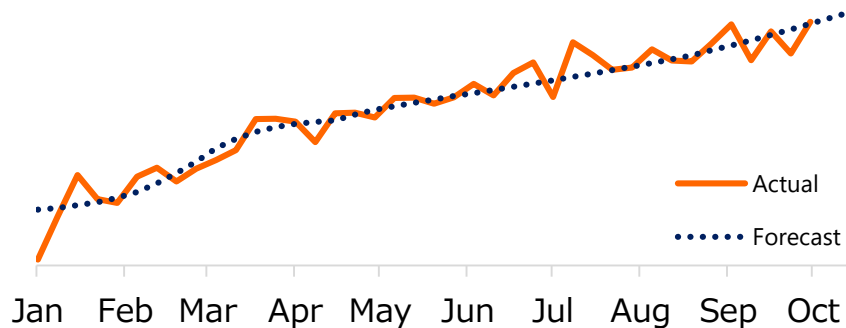
\*3 Treatment of patients with HER2 positive unresectable advanced or recurrent gastric cancer that has progressed after chemotherapy

# ENHERTU®: Performance in US and Japan

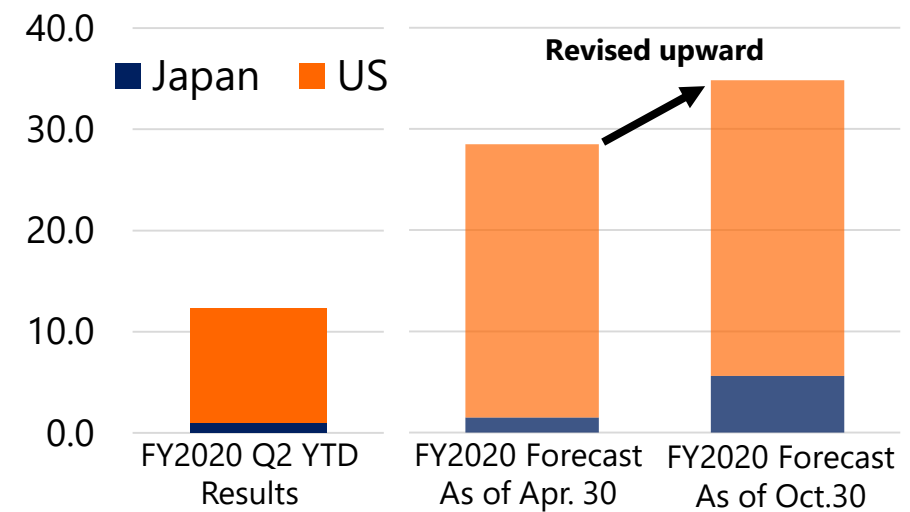
- ◆ Strong market penetration
- ◆ Product sales FY2020 forecast\*: **34.9 Bn JPY (+6.4 Bn JPY vs initial plan)**

## US

- Total number of unique outlets purchasing ENHERTU® since launch is approximately 1,600, and number of repeat outlets is approximately 1,300
- Encouraging increase in demand
  - ✓ ENHERTU® units shipped to account in Oct. increased more than 60% from Mar.



Revenue (Bn JPY)



## Japan

- Providing product information with the highest priority on safety
- ENHERTU® delivered only to medical institutions that meet doctor and facility requirements

\*Forecast as of Oct. 30, 2020

# DS-8201: Development to Maximize Value

◆ Accelerating development to expand indications for **early treatment lines of HER2 positive breast cancer and HER2 low expressing breast cancer**

As of December 2020		~FY2019	FY2020	FY2021	Under Discussion		
<b>HER2 Positive</b>	<b>Metastatic 3L</b>	DESTINY-Breast01 monotherapy				Ph 1 ongoing	
		DESTINY-Breast02 monotherapy					Ph 2 ongoing
	<b>Metastatic 2L</b>	DESTINY-Breast03 monotherapy					Ph 3 ongoing
				DESTINY-Breast07 combination (2L/1L) Ph1			Completed
	<b>Metastatic 1L</b>			DESTINY-Breast09 combo Ph3			New
	<b>Post-neoadjuvant</b>			DESTINY-Breast05 monotherapy vs. T-DM1			
	<b>Neoadjuvant</b>					Phase 3	
<b>Adjuvant</b>					Phase 3		
<b>HER2 Low</b>	<b>HR+/ HR-</b>	DESTINY-Breast04 monotherapy					
				DESTINY-Breast08 combination Ph1			
	<b>Post-neoadjuvant</b>					Phase 3	
	<b>HR+</b>	<b>Metastatic Chemo Naive</b>		DESTINY-Breast06 monotherapy			
		<b>Metastatic Endocrine Therapy</b>					Phase 3
	<b>HR-</b>	<b>Metastatic 1L</b>		BEGONIA (durvalumab combination)			
<b>Neoadjuvant</b>						Phase 3	

# DS-8201: Development to Maximize Value

◆ Accelerating development to expand indications for **early treatment lines of HER2 positive gastric cancer** and treatment of **lung cancer**

As of December 2020		~FY2019	FY2020	FY2021	Under Discussion	
Gastric	HER2 Positive	Advanced/ Metastatic 3L~	DESTINY-Gastric01 monotherapy (HER2 low in exploratory cohort)			
		Advanced/ Metastatic 2L	DESTINY-Gastric02 monotherapy (2L) - West			
			DESTINY-Gastric03 combination (2L/1L)			
			DESTINY-Gastric04 monotherapy Ph3			
						Phase 3
Advanced/ Metastatic 1L				Phase 3		
Lung	HER2 Expressing	Advanced/ Metastatic 2L~	DESTINY-Lung01 monotherapy			
			HUDSON (durvalumab combination)			
		Advanced/ Metastatic 2L				Phase 3 monotherapy
		Advanced/ Metastatic 1L	DESTINY-Lung03 combination Ph1			Phase 3 combination
	HER2 Mutated	Advanced/ Metastatic 2L~	DESTINY-Lung01 monotherapy			
			DESTINY-Lung02 monotherapy Ph2			
	Expressing/ Mutated	Advanced/ Metastatic 1L				Phase 3
			Early disease			

- Ph 1 ongoing
- Ph 2 ongoing
- Ph 3 ongoing
- Completed
- New

Study initiation points for FY2020 H2 are all shown as beginning of H2. Study initiation points for FY2021 are all shown as beginning of FY2021.

# DS-8201: Development to Maximize Value

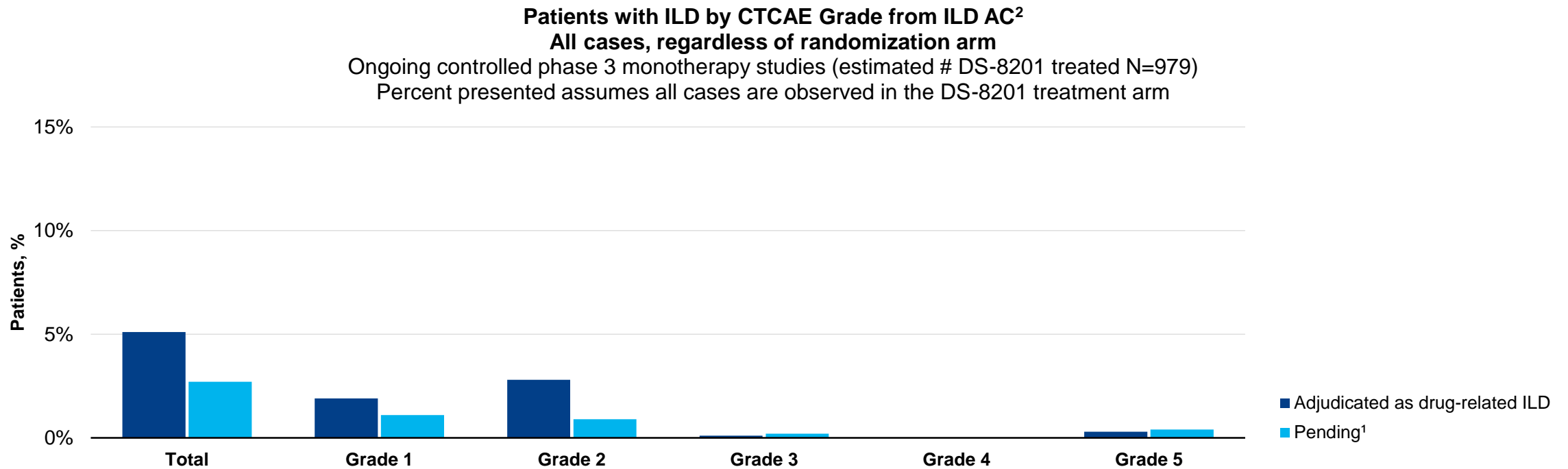
◆ Accelerating development to expand indications for **colorectal cancer** and **other tumors** and **I/O combination therapy**

As of December 2020		~FY2019	FY2020	FY2021	Under Discussion		
CRC	HER2 Expressing	Metastatic 3L	DESTINY-CRC01 monotherapy (HER2 Low in exploratory cohort)	DESTINY-CRC02 monotherapy Ph2		Ph 1 ongoing	
		Metastatic 2L				Phase 3 combination	Ph 2 ongoing
		Metastatic 1L				Phase 3 combination	Ph 3 ongoing
Other Tumors	HER2 Expressing	Metastatic 2L	Nivolumab combination (breast, bladder)			Completed	
			Pembrolizumab combination (breast, NSCLC)				
			DESTINY-PanTumor02			New	
	Ovarian				Phase 2 combination		
	HER2 Mutated	Metastatic 2L		DESTINY-PanTumor01 Ph2			

Study initiation points for FY2020 H2 are all shown as beginning of H2. Study initiation points for FY2021 are all shown as beginning of FY2021.

## ◆ Conducting clinical studies through investigator safe use campaign to detect and manage ILD

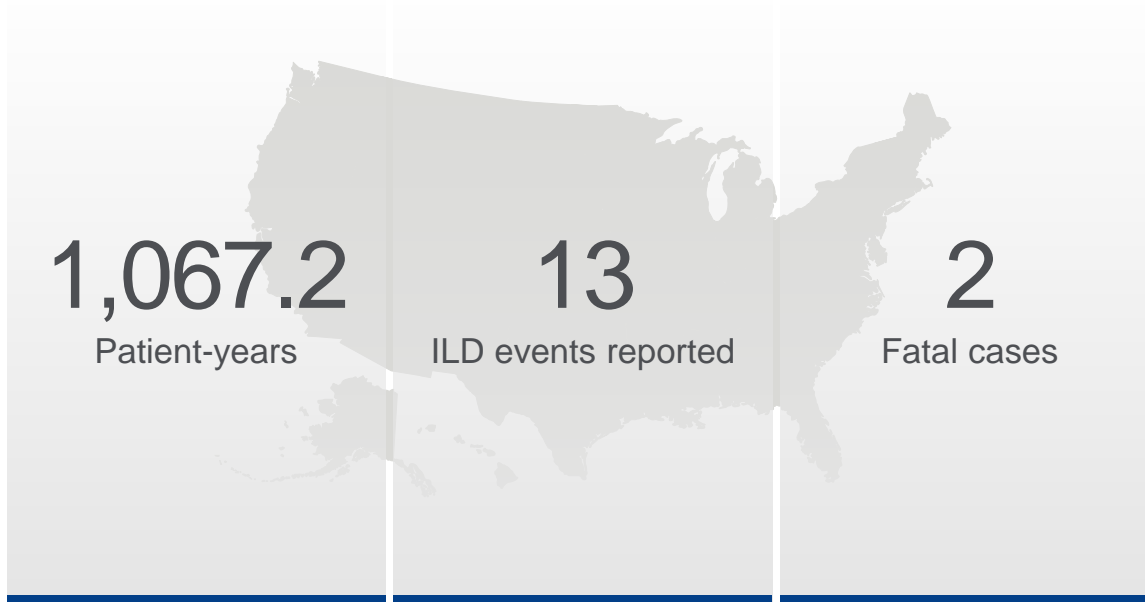
Cumulative ILD data, all phase 3 monotherapy studies as of Nov.15, 2020, preliminary data



<sup>1</sup> Investigator reported grades.

# DS-8201: Post-Marketing Cumulative ILD Reported Data

## US (as of November 15, 2020)



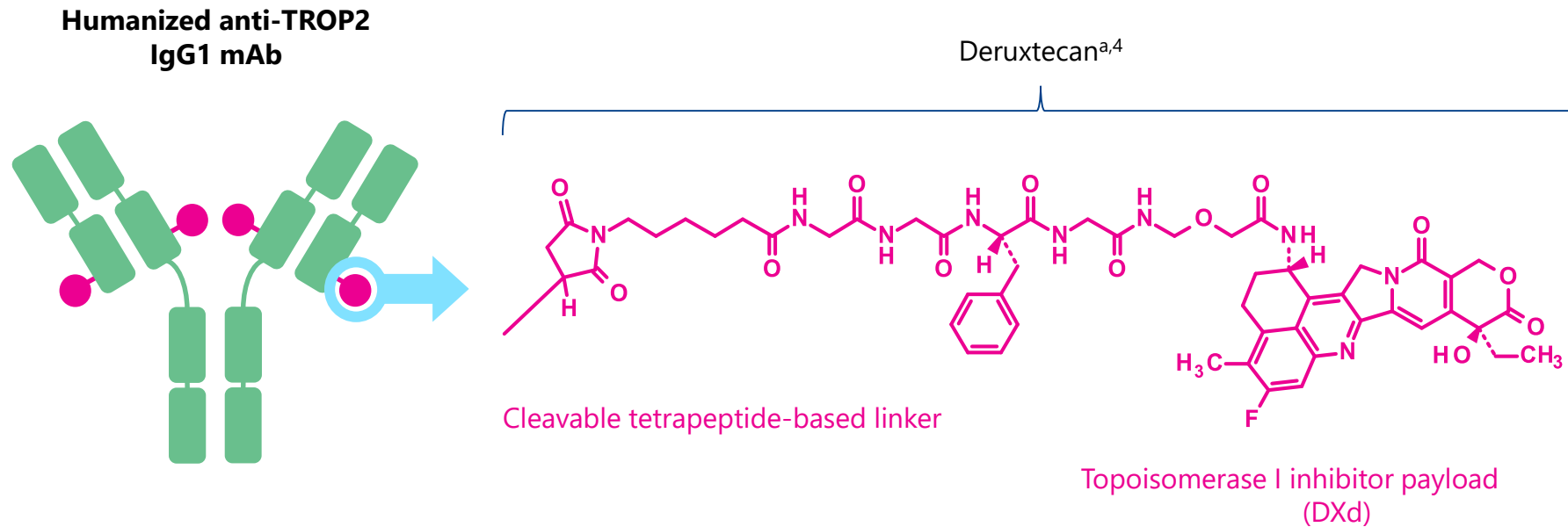
## Japan (as of November 15, 2020)



# DS-1062: TROP2 Directed ADC

## DS-1062 is an ADC composed of 3 components<sup>1,2</sup>:

- A humanized anti-TROP2 IgG<sup>13</sup> monoclonal antibody attached to:
- A topoisomerase I inhibitor payload, an exatecan derivative, via
- A tetrapeptide-based cleavable linker



<sup>1</sup> Okajima D, et al. Poster presented at: AACR-NCI-EORTC International Conference; October 26-30, 2019; Boston, MA [abstract C026]; <sup>2</sup> Nakada T, et al. *Chem Pharm Bull.* 2019;67(3):173-185.; <sup>3</sup> Daiichi Sankyo Co. Ltd. DS-1062. Daiichi Sankyo.com. Accessed October 6, 2020. [https://www.daiichisankyo.com/media\\_investors/investor\\_relations/ir\\_calendar/files/005438/DS-1062%20Seminar%20Slides\\_EN.pdf](https://www.daiichisankyo.com/media_investors/investor_relations/ir_calendar/files/005438/DS-1062%20Seminar%20Slides_EN.pdf); <sup>4</sup> Krop I, et al. Oral presentation at: SABCS Symposium; December 10-14, 2019; San Antonio, TX [abstract GS1-03].

<sup>a</sup> Image is for illustrative purposes only; actual drug positions may vary.



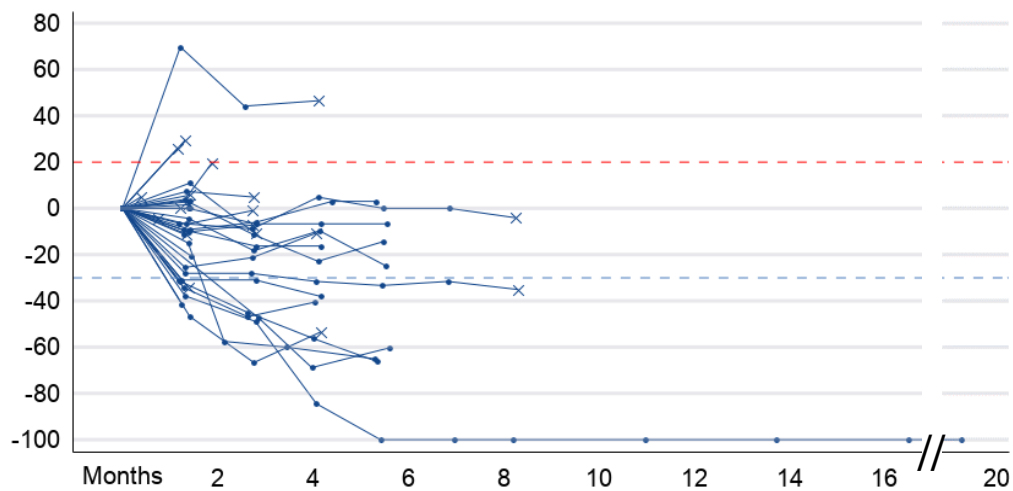


# DS-1062: Efficacy - NSCLC Phase 1 study

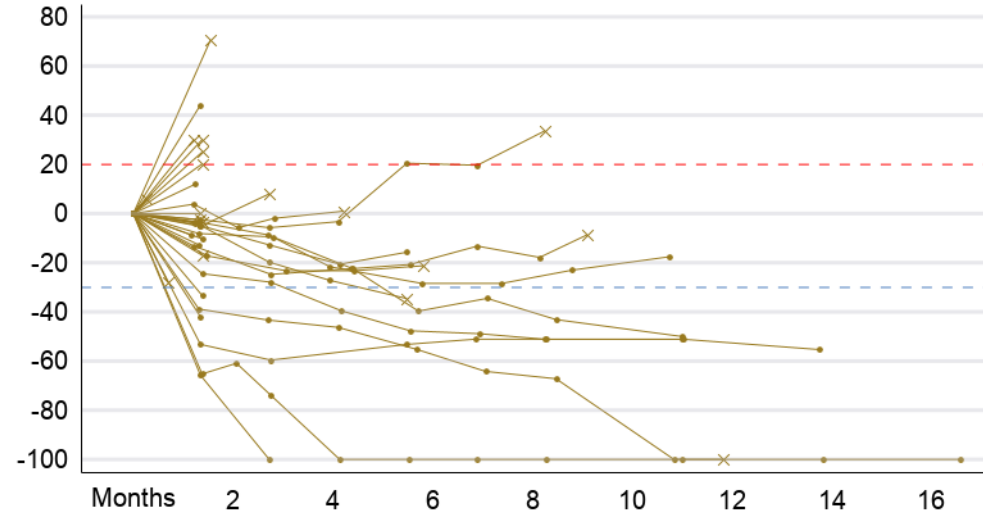
◆ Preliminary data indicates potential for similar durability as DS-8201

Spider plots of target lesions, based on BICR by dose

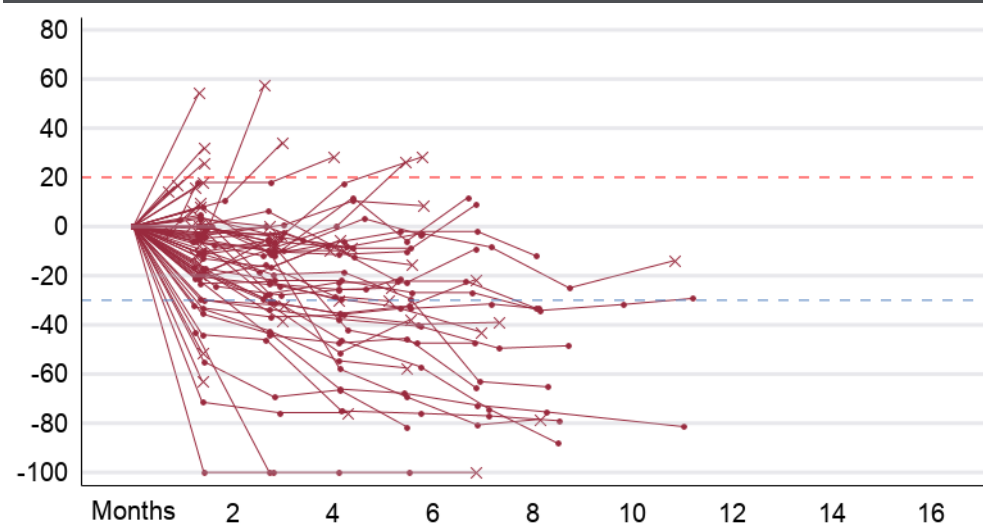
4 mg/kg



6 mg/kg



8 mg/kg



# DS-1062: Strategic Collaboration

- ◆ **Co-development and co-commercialization with AstraZeneca (entered in July 2020)**
  - Maximize the value of DS-1062 by accelerating and expanding development
  - Allocate resources rapidly with flexibility to DXd-ADC / Alpha portfolio



Development	Commercial	Financial Consideration
<ul style="list-style-type: none"><li>◆ <b>Co-develop</b> as <b>mono-therapy</b> and <b>combination therapy</b></li></ul> <div data-bbox="242 1092 840 1278"><p>Lung</p><p>Breast</p><p>Other Cancers</p></div>	<ul style="list-style-type: none"><li>◆ <b>Global (excluding Japan)</b> The companies will <b>co-promote</b> and <b>share profits</b></li><li>◆ <b>Japan</b> <b>Daiichi Sankyo</b> will <b>solely commercialize</b> and <b>pay royalty</b> to AstraZeneca</li></ul>	<ul style="list-style-type: none"><li>◆ Up to <b>US\$ 6.0 Bn (660.0 Bn JPY*)</b> in total</li></ul> <p>Including upfront payment, regulatory and sales-related milestones</p> <p>* US\$1 = 110 JPY</p>

## ◆ Development with utmost focus in lung and breast cancer is underway

### NSCLC

- **Pivotal Phase3 study in post IO/chemo started in December 2020**
  - ✓ TROPION-Lung01: NSCLC without actionable mutations
- **Phase1 studies in IO combination are underway**
  - ✓ TROPION-Lung02: Combination with pembrolizumab
  - ✓ TROPION-Lung04: Combination with durvalumab
- **Phase2 study in post platinum-based chemotherapy/EGFR TKI started in December 2020**
  - ✓ TROPION-Lung05: NSCLC with actionable mutations



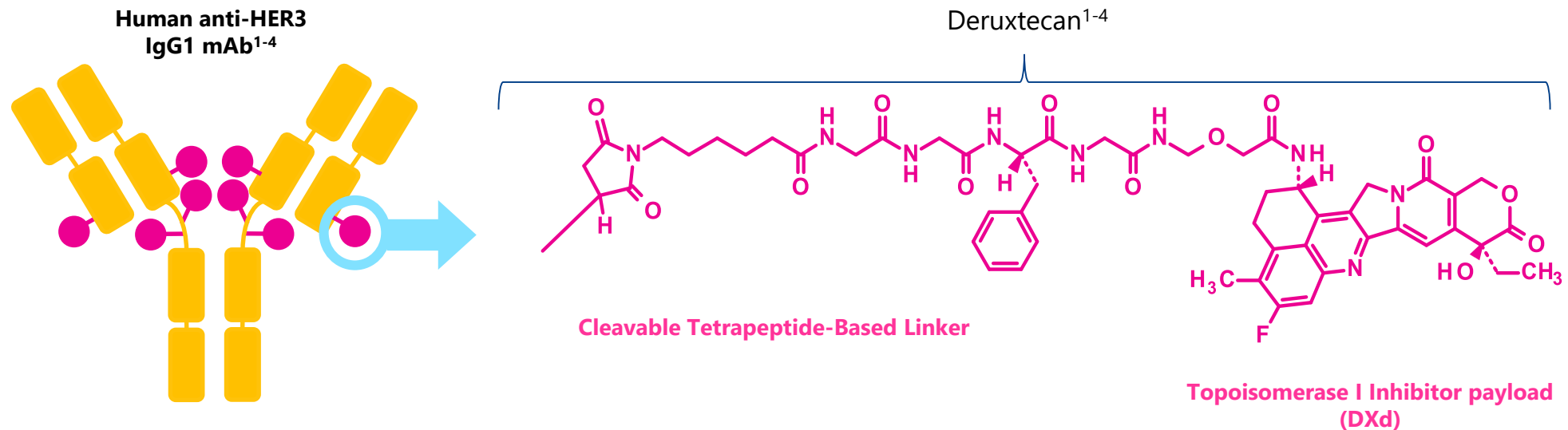
TROPION

### Breast Cancer, Other Cancers

- **TNBC cohort was added to ongoing Phase1 study in July 2020**
- **Other tumor cohorts planned**

## U3-1402 is an ADC composed of 3 components<sup>1-4</sup>:

- A fully human anti-HER3 IgG1 mAb (patritumab), covalently linked to:
- A topoisomerase I inhibitor payload, an exatecan derivative, via
- A tetrapeptide-based cleavable linker

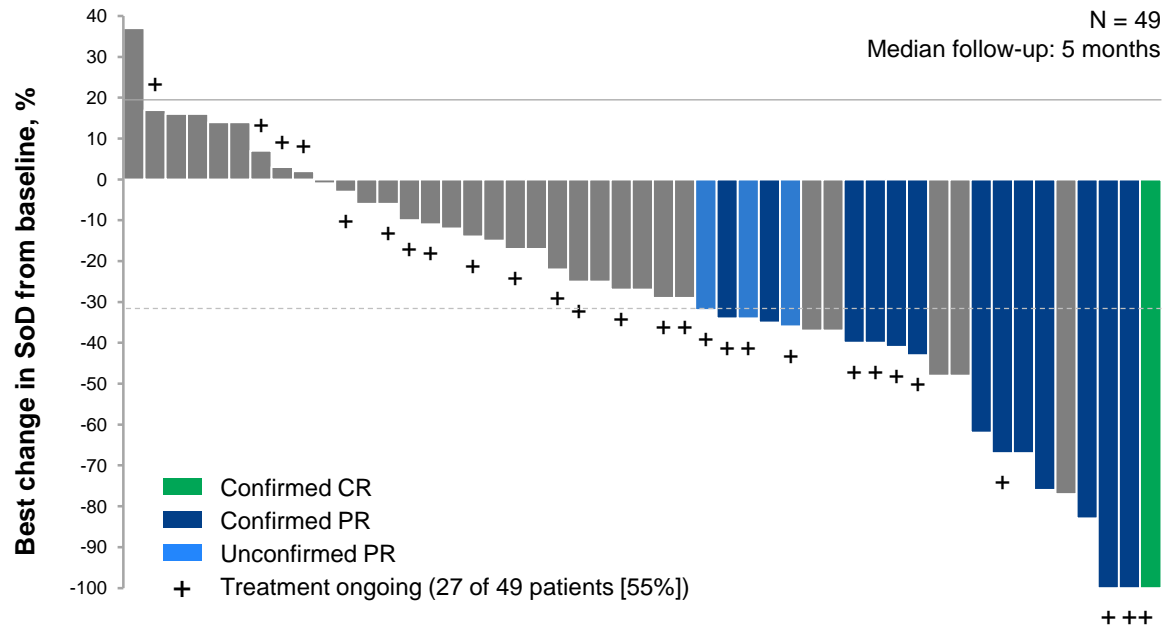


<sup>1</sup> Hashimoto Y, et al. Clin Cancer Res. 2019;25:7151-7161.; <sup>2</sup> Nakada T, et al. Chem Pharm Bull (Tokyo). 2019;67(3):173-185.; <sup>3</sup> Ogitani Y, et al. Clin Cancer Res. 2016;22(20):5097-5108.; <sup>4</sup> Koganemaru S, et al. Mol Cancer Ther. 2019;18:2043-2050.

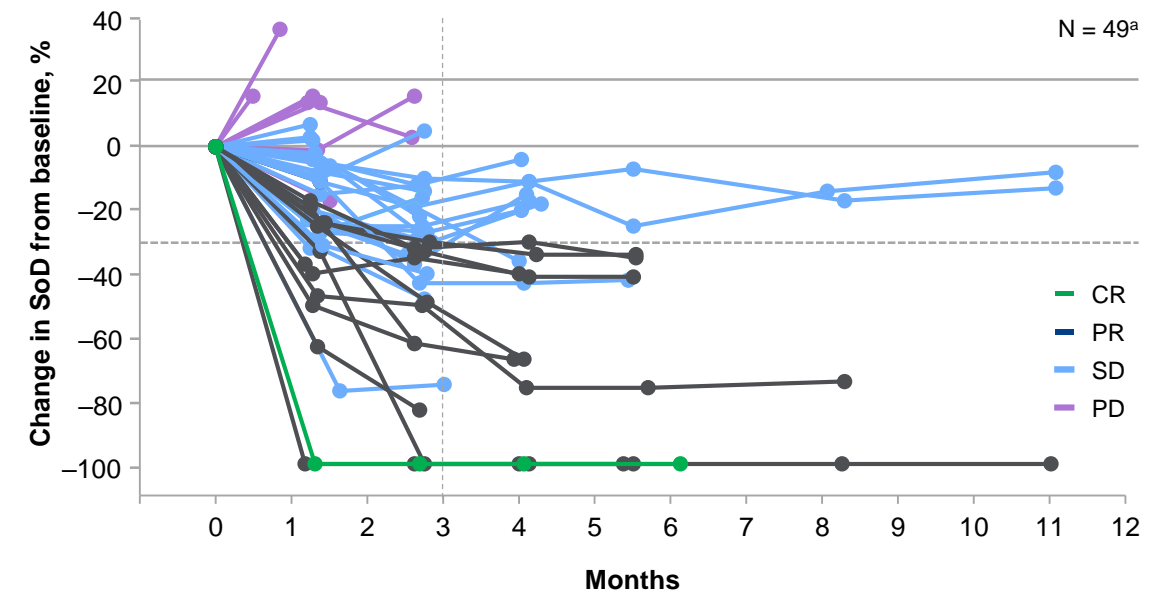
# U3-1402: Efficacy - EGFR-mutated NSCLC Phase1 study

- ◆ Phase1 study is progressing smoothly
- ◆ Interim data presented at ESMO 2020

EGFR-mutated NSCLC post TKI and platinum-based chemotherapy



Spider plot



Source: Yu et al., ESMO 2020. U31402-U102 (NCT03260491)

## ◆ Accelerating development for fast-to-market in EGFRm NSCLC

### EGFR Mutant NSCLC

➤ **Pivotal Phase2 study planned to start in January 2021**

✓ HERTHENA-Lung01:  
Post platinum-based chemotherapy/EGFR TKI



HERTHENA

➤ **Phase1 osimertinib combination study planned to start in January 2021**

### Colorectal Cancer

➤ **Phase2 study started in September 2020**

### Breast Cancer

➤ **Phase1/2 study is progressing smoothly**

➤ **Interim data presented at SABCS 2020**

## Seven ADC Assets

Project (Target)	Potential indications	Discovery	Pre-clinical	Clinical	Pivotal/ approved
DS-8201 (HER2)	Breast, Gastric NSCLC, CRC, etc.	[Green bar spanning Discovery, Pre-clinical, and Clinical phases]			
DS-1062 (TROP2)	NSCLC, Breast	[Green bar spanning Discovery, Pre-clinical, and Clinical phases]			
U3-1402 (HER3)	NSCLC, CRC, Breast	[Green bar spanning Discovery, Pre-clinical, and Clinical phases]			
DS-7300 (B7-H3)	SCCHN, NSCLC, Esophageal, etc.	[Light blue bar spanning Discovery and Pre-clinical phases]			
DS-6157 (GPR20)	GIST	[Light blue bar spanning Discovery and Pre-clinical phases]			
DS-6000 (CDH6)	Renal, Ovarian	[Grey bar spanning Discovery and Pre-clinical phases]			
DS-3939 (TA-MUC1)	Solid tumors	[Grey bar spanning Discovery and Pre-clinical phases]			

NSCLC: non-small cell lung cancer, CRC: Colorectal cancer, SCCHN: squamous cell carcinoma of the head and neck, Gastrointestinal Stromal Tumor



# Creating “Beyond ADC” Assets to Achieve Sustainable Growth

- ◆ Advancing drug discovery research by using wide variety of modalities to create innovative therapies



Next Generation ADC



ENA<sup>®</sup> Nucleotide



Gene Therapy



Bispecific Antibody

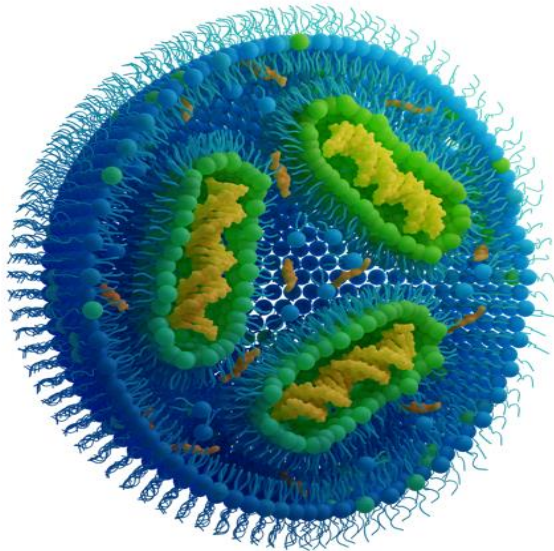


Cell Therapy



LNP/mRNA

- ◆ Developing mRNA vaccine leveraging our modality research
- ◆ Encouraging data obtained from non-clinical pharmacology studies: Clinical study is planned to start in Mar. 2021



## DS-5670: LNP-mRNA

- ◆ DS original cationic lipid
- ◆ Efficient encapsulation of mRNA in nanoparticles, and efficient delivery of mRNA to cells
- ◆ Applying to pandemic and other vaccines

① Overview of Daiichi Sankyo

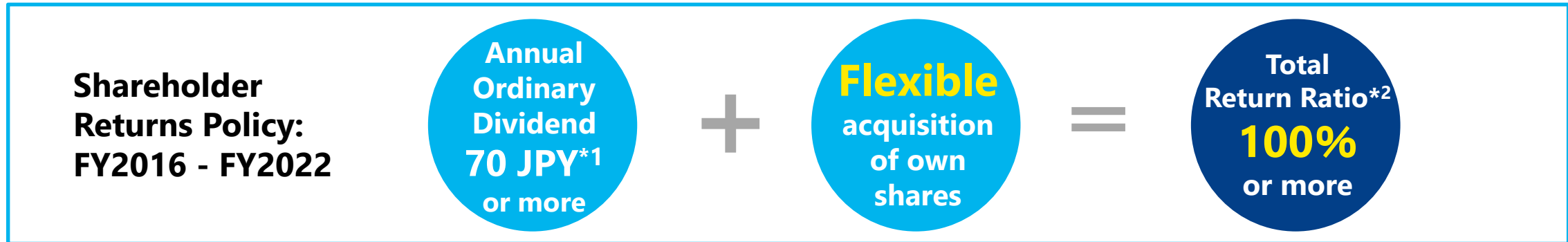
② Growth Strategy

③ Maximizing Shareholder Value

④ Appendix



## ◆ Decided dividend increase, acquisition and cancellation of own shares in FY2020 to enrich shareholder returns



### Dividend increase

- Annual dividend forecast for FY2020
  - ✓ Increased by 11 JPY per share (70 JPY → 81 JPY\*1)

### Acquisition of own shares

- Total amount of acquisition cost
  - ✓ 100.0 Bn JPY (max.)
- Total number of shares
  - ✓ 60 Mn shares (max.)
- Acquisition period
  - ✓ From Nov. 2020 to Mar. 2021

### Cancellation of own shares

- Number of shares
  - ✓ 180 Mn shares
  - ✓ Cancel except for the shares to be used for stock option and restricted share-based remuneration
- Cancellation date
  - ✓ Apr. 15, 2021

\*1 Pre-split base; Share split, three-for-one (effective date: Oct. 1, 2020)

\*2 Total return ratio = (Dividends + Total acquisition costs of own shares) / Profit attributable to owners of the company

**Investment  
for Future  
Growth**

R&D investment  
Capital investment

**Maximize  
Profitability  
as well as  
Shareholder  
Value**

**Sustainable  
Growth**

◆ **Maximize future shareholder value through aggressive investment in our pipeline**

**Maximize the value of 3 lead ADCs**

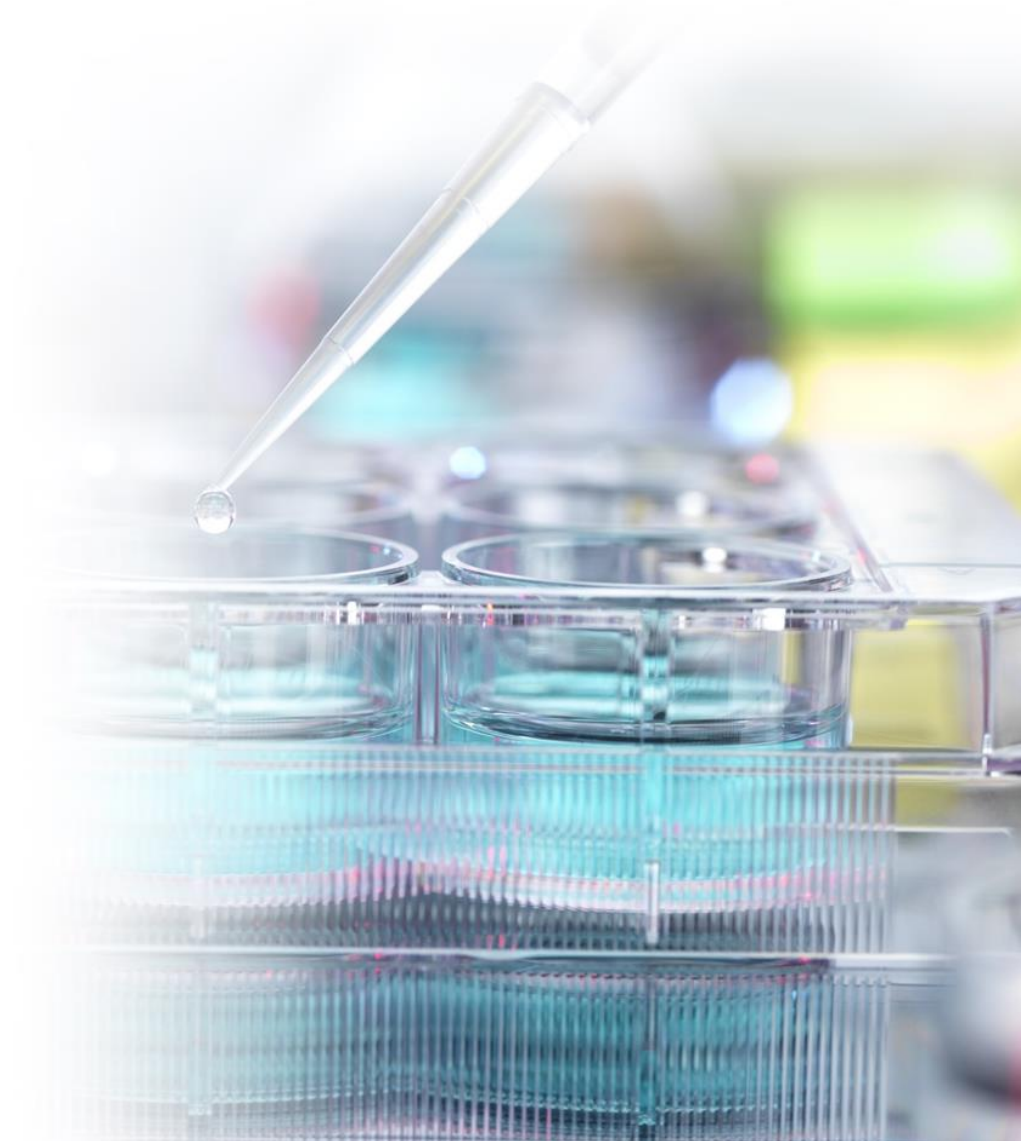
**Strive for sustainable growth**

**1 Overview of Daiichi Sankyo**

**2 Growth Strategy**

**3 Maximizing Shareholder Value**

**4 Appendix**



## January – March 2021

### **DS-8201:**

DESTINY-Lung01  
HER2 expressing cohort  
(Late-Breaker)

### **DS-1062:**

Phase 1 NSCLC update

### **U3-1402:**

Phase 1 NSCLC update

## April – June 2021

### **DS-8201:**

DESTINY-Gastric01,  
biomarker analysis

### **U3-1402:**

Phase 1 NSCLC update

## Upcoming Catalysts

### **DS-8201:**

EU DESTINY-Breast01 approval  
US DESTINY-Gastric01 approval

DESTINY-Breast02 data  
DESTINY-Breast03 data  
DESTINY-Breast04 data

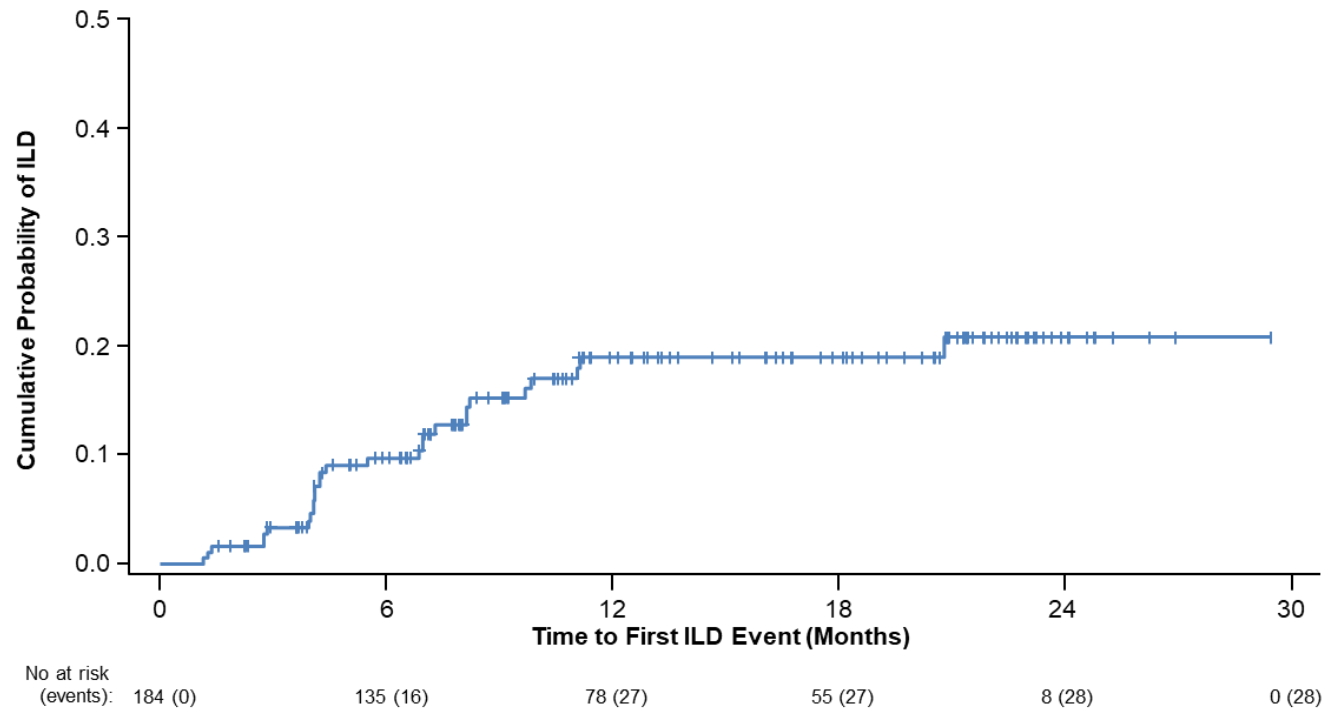
EU DESTINY-Gastric01 submission



# DS-8201: ILD & safety update (DESTINY-Breast01)

ILD risk appears to flatten after 12 months

## Cumulative Probability of Adjudicated Drug-related Interstitial Lung Disease (ILD)



n (%)	August 2019 data cutoff DS-8201 5.4 mg/kg (N = 184)	June 2020 data cutoff DS-8201 5.4 mg/kg (N = 184)
Any TEAE	183 (99.5)	183 (99.5)
Drug-related	183 (99.5)	183 (99.5)
TEAE grade $\geq 3$	105 (57.1)	113 (61.4)
Drug-related	89 (48.4)	97 (52.7)
TEAE associated with discontinuation	28 (15.2)	34 (18.5)
Drug-related	27 (14.7)	33 (17.9)

# DS-1062: Safety (Ph1 study in advanced NSCLC)

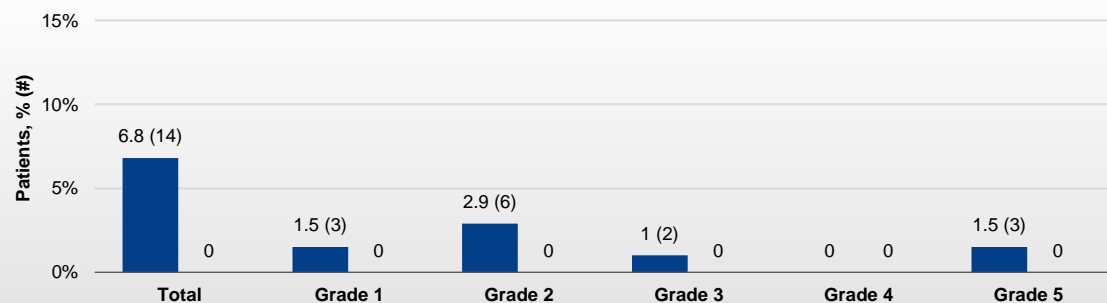
- ◆ MTD: 8 mg/kg  
(2 DLTs at 10 mg/kg: 1 mucosal inflammation [grade 3], 1 stomatitis [grade 3])
- ◆ TEAEs led to DS-1062 withdrawal in 7 patients (5%)
- ◆ SAE in 20 patients (15%)
- ◆ 8 ILD events (5.8%) adjudicated as treatment related  
(1 grade 1, 4 grade 2, 1 grade 3, 2 grade 5 i.e., 1.45%, onset at cycle 2 and 3)

Patients treated with DS-1062 (N = 138)		
TEAE in ≥ 15% subjects	All grades, n (%)	Grade ≥3, n (%)
Any TEAE	129 (94)	62 (45)
TEAEs in ≥15% of patients, by preferred term		
Nausea	60 (44)	0
Fatigue	56 (41)	4 (3)
Stomatitis	47 (34)	4 (3)
Alopecia	46 (33)	0
Vomiting	37 (27)	0
Decreased appetite	31 (23)	0
Infusion-related reaction	29 (21)	0
Anemia	26 (19)	4 (3)
Constipation	26 (19)	1 (1)
Cough	26 (19)	1 (1)
Mucosal inflammation	25 (18)	4 (3)
Rash	25 (18)	0
Dyspnea	23 (17)	6 (4)
Diarrhea	20 (15)	0
TEAE, treatment-emergent adverse event.		

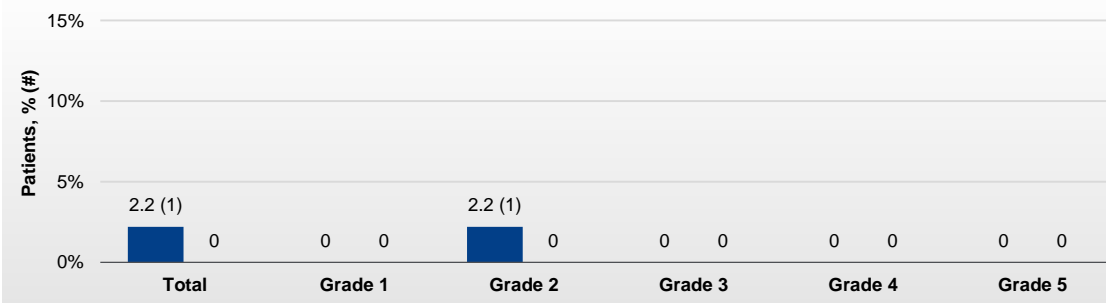
# DS-1062: NSCLC cumulative ILD, by dose As of September 4, 2020

■ Adjudicated as drug-related ILD  
■ Pending<sup>1</sup>

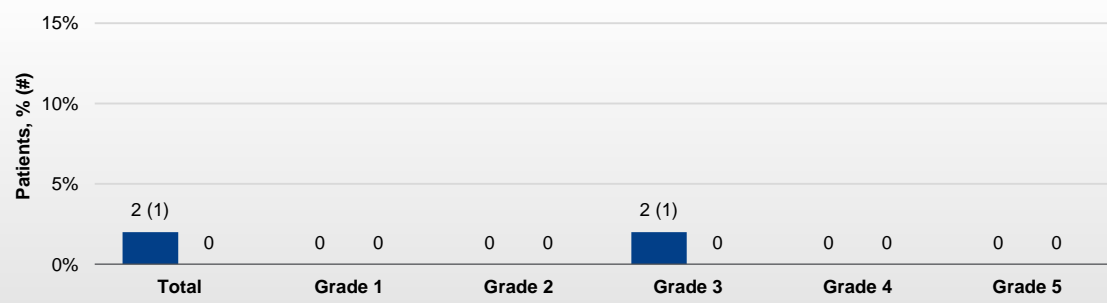
All doses, NSCLC, % (N) (total N=205)



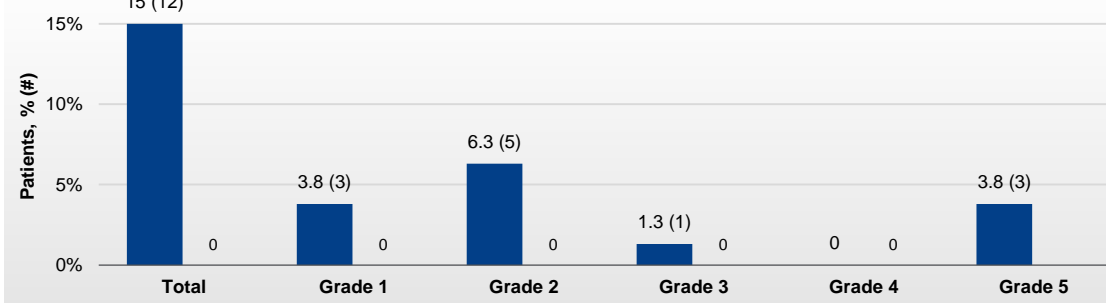
6.0 mg/kg, NSCLC (N=45)



4.0 mg/kg, NSCLC (N=50)



8.0 mg/kg, NSCLC (N=80)



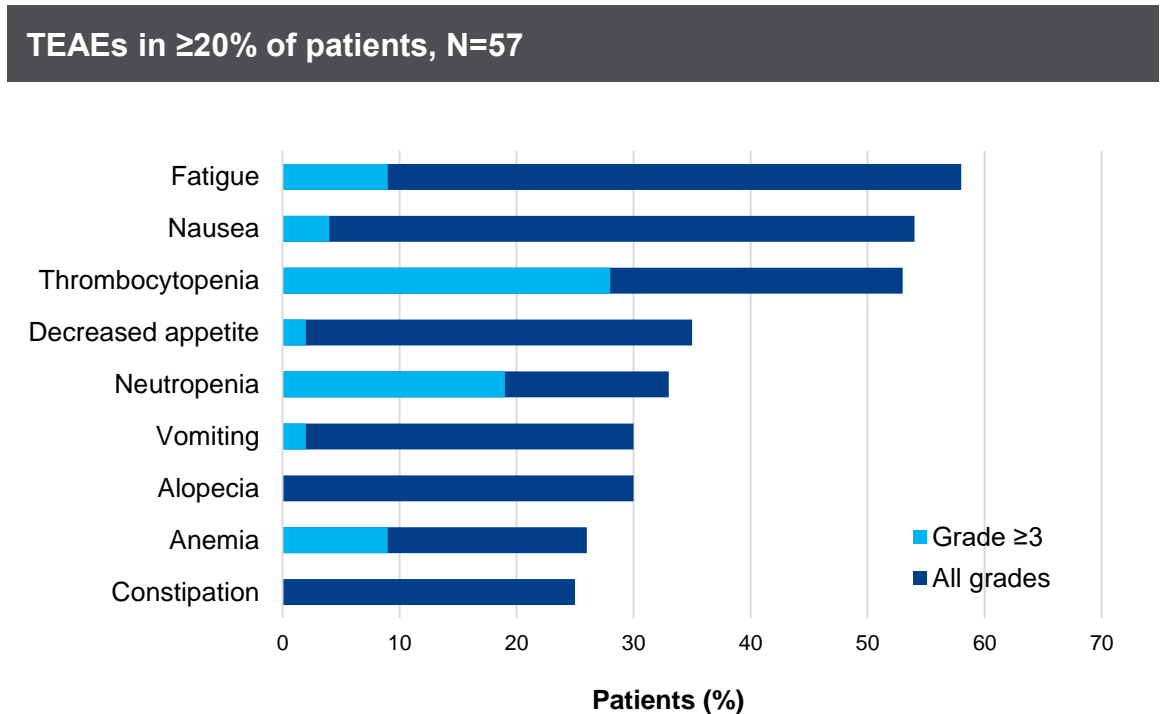
<sup>1</sup> Investigator reported grades.

# U3-1402: Safety (Ph1 study in advanced EGFRm NSCLC)

5.6 mg/kg, Q3W

TEAEs n (%)	N = 57
<b>TEAEs</b>	57 (100)
Grade ≥3	38 (67)
Associated with discontinuation	5 (9)
Associated with dose reduction	10 (18)
Associated with dose interruption	17 (30)
Associated with death	3 (5)
<b>Treatment-emergent SAEs</b>	21 (37)
Grade ≥3	18 (32)
Treatment related	11 (19)

Three (5.3%) ILD events were adjudicated by an independent central review committee as U3-1402 related

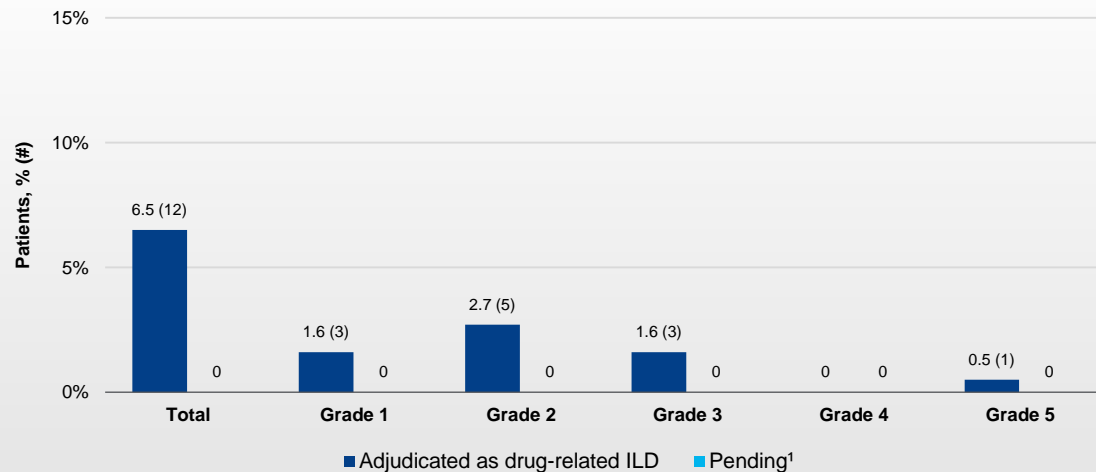


# U3-1402: Cumulative ILD data by tumor type

## As of November 15, 2020

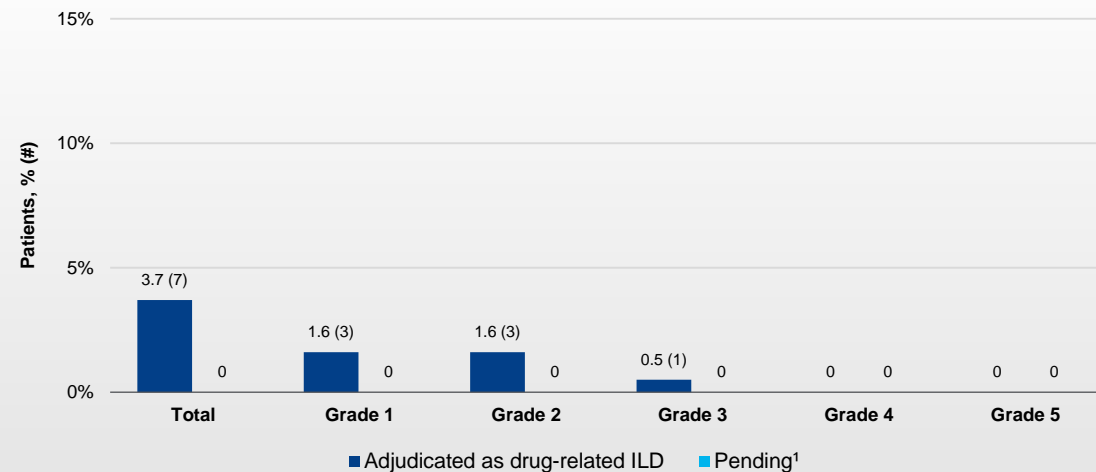
### Patients with CTCAE grade from ILD AC

#### Breast Cancer phase 1 (N=184)



### Patients with CTCAE grade from ILD AC

#### NSCLC phase 1 (N=187)



¹ Investigator reported grades

# Early ADC programs



Asset	Target	Potential indications	Status
<b>DS-7300</b>	B7-H3 (DAR ≈ 4)	Solid tumors (SCCHN, NSCLC, Esophageal, etc.)	FIH: October 2019 Delivery model: collaboration with Sarah Cannon, unselected subjects Current status (Phase 1): completed dose level 6 (8 mg/kg); no DLT. Early Clinical Signal with confirmed responses
<b>DS-6157</b>	GPR20 (DAR ≈ 8)	GIST	FIH: May 2020 Delivery model: collaboration with Sarah Cannon; led by Dana Farber Current status (Phase 1): 4 <sup>th</sup> dose level. No DLT.
<b>DS-6000</b>	CDH6* (DAR ≈ 8)	RCC, Ovarian	FIH: FY2020 Q4 (estimated) Delivery model: collaboration with Sarah Cannon
<b>DS-3939</b>	TA-MUC1	Solid tumors	FIH: FY2022 (estimated)




\*CDH6: cadherin 6

# Major R&D Pipeline: 3 ADCs

As of January 2021



Phase 1		Phase 2		Phase 3		Submitted	
(JP/US) NSCLC, TNBC TROPION-PanTumor01	(TBD) HER2+ BC 2L~/1L DESTINY-Breast07	(JP/US/EU/Asia) NSCLC (w actionable mutation) TROPION-Lung05	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia)HER2+ BC 3L DESTINY-Breast02	(EU)HER2+BC 3L DESTINY-Breast01		
(JP/US) NSCLC (w/o actionable mutation, pembrolizumab combo) TROPION-Lung02	(TBD) HER2 low BC chemo naïve/ post chemo DESTINY-Breast08	(JP/US) EGFRm NSCLC HERTHENA-Lung01	(US/EU) HER2+ GC 2L DESTINY-Gastric02	(JP/US/EU/Asia) HER2+ BC 2L DESTINY-Breast03	(US)HER2+GC 3L DESTINY-Gastric01	 	
(JP/US) NSCLC (w/o (actionable mutation, durvalumab combo) TROPION-Lung04	(US/EU/Asia) HER2+ GC combo, 2L ~/1L DESTINY-Gastric03	(JP/US/EU) HER3+ CRC	(JP/US/EU)HER2+/mutated NSCLC DESTINY-Lung01	(JP/US/EU/Asia) HER2 low BC 3L~ DESTINY-Breast04			
(JP/US/EU/Asia) NSCLC	(EU/Asia)HER2+ NSCLC (durvalumab combo) DESTINY-Lung03		(JP/US/EU)HER2+/mutated NSCLC DESTINY-Lung02	(JP/US/EU/Asia) HER2+ BC post neoadjuvant DESTINY-Breast05			
(JP/US)EGFRm NSCLC (osimertinib combo)	(US/EU) BC, bladder (nivolumab combo)		(US/EU/Asia) NSCLC(durvalumab combo) HUDSON	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06			
(JP/US) HER3+ BC	(US/EU) BC, NSCLC (pembrolizumab combo)		(JP/US/EU) HER2+ CRC DESTINY-CRC01	(JP/US/EU/Asia) NSCLC(w/o actionable mutation) TROPION-Lung01			
			(US/EU/Asia) HER2 mutated tumor DESTINY-PanTumor01				
			(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02				

-  DS-8201 HER2-directed ADC
-  DS-1062 TROP2-directed ADC
-  U3-1402 HER3-directed ADC

BC: breast cancer, CRC: colorectal cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, TNBC: triple negative breast cancer

: Breakthrough Designation (US) : Orphan drug designation (JP/US/EU)

# Major R&D Pipeline: Alpha

As of January 2021



Phase 1		Phase 2	Phase 3	Submitted
<b>DS-7300</b> (JP/US) B7-H3-directed ADC Solid tumors	<b>DS-3201</b> (JP/US) EZH1/2 inhibitor Non-Hodgkin's lymphomas (PTCL)	<b>DS-3201</b> (JP) EZH1/2 inhibitor ATL/L	<b>Quizartinib</b> (JP/US/EU/Asia) FLT3 inhibitor 1L AML QuANTUM-First	<b>Axicabtagene ciloleucel Axi-Cel™</b> (JP) Anti CD19 CAR-T cells R/R B-cell lymphoma
<b>DS-6157</b> (JP/US) 抗GPR20 ADC GIST	<b>DS-3201</b> (US) EZH1/2 inhibitor AML, ALL	<b>DS-1001</b> (JP) Mutant IDH1 inhibitor Glioma	<b>Pexidartinib</b> (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	<b>DS-1647 (G47Δ)</b> (JP) Oncolytic HSV-1 Malignant glioma IIS
<b>DS-1055</b> (JP/US) Anti-GARP antibody Solid tumors	<b>PLX2853</b> (US) BET inhibitor AML	<b>DS-5141</b> (JP) ENA oligonucleotide DMD	<b>Mirogabalin</b> (JP/Asia) α <sub>2</sub> δ Ligands Central neuropathic pain	<b>Edoxaban</b> (JP) FXa inhibitor AF in the very elderly
<b>DS-2741</b> (JP) Anti-Orai1 antibody Atopic dermatitis	<b>PLX2853</b> (US) BET inhibitor Solid tumor	<b>DS-1211</b> (US) TNAP inhibitor Pseudoxanthoma elasticum	<b>Esaxerenone</b> (JP) MR blocker Diabetic nephropathy	<b>Prasugrel</b> (JP) ADP receptor inhibitor Ischemic stroke
	<b>PLX2853</b> (US) BET inhibitor Gynecologic neoplasms, ovarian cancer		<b>VN-0102/JVC-001</b> (JP) Measles mumps rubella combined vaccine	<b>VN-0107/MEDI3250</b> (JP) Live attenuated influenza vaccine nasal spray
	<b>PLX2853</b> (US) BET inhibitor Prostate cancer			

- Oncology
- Specialty medicine
- Vaccine

AF: atrial fibrillation, ALL: acute lymphocytic leukemia, AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, DMD: Duchenne muscular dystrophy, GIST: gastrointestinal stromal tumor, IIS: investigator-initiated study, NSCLC: non-small cell lung cancer, PTCL: peripheral T-cell lymphoma

□: project in oncology that is planned to be submitted for approval based on the results of phase 2 trials

🏆: SAKIGAKE Designation (JP) 🌟: Orphan drug designation (JP/US/EU)



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