Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2020 Q2
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Sunao Manabe
President and CEO

October 30, 2020

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.

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.

1 **Actions Against COVID-19**

2 FY2020 Q2 Financial Results

3 FY2020 Forecast

4 Business Update

5 R&D Update

6 Appendix

Update on Actions Against COVID-19

Development of Genetic (mRNA) vaccination: DS-5670

- Participating in fundamental research supported by AMED[*1] and pursuing the development of genetic (mRNA) vaccine using Daiichi Sankyo's original novel nucleic acid delivery technology[*2]

- **Selected to be a provider for the MHLW's "Emergent Initiative to Build Production Capacity for COVID-19 Vaccines[*3] (First Round)"** – Aug. 7, 2020

  - ✓ Subsidy 6.0 Bn JPY (Utilized to develop production and storage facilities for COVID-19 vaccine)
  - ✓ Develop production capacity at Daiichi Sankyo Biotech
  - ✓ Aim to build production platform technology in Japan that can accommodate not only COVID-19 , but also emerging and re-emerging infectious disease vaccines in the future

- **Selected to be a company for the AMED's drug discovery support program "Development of a Vaccine for COVID-19 Vaccines[*4] (Second Round)"** – Aug. 31, 2020

- Clinical studies planned to be initiated around Mar. 2021

*1 "Fundamental Research on the Control of a Novel Coronavirus (2019-nCoV), which is an initiative supported by the Japan Agency for Medical Research and Development (AMED). (Principal investigator: Prof. Yoshiro Kawaoka, Institute of Medical Sciences, The University of Tokyo)
*2 Technology focusing on forming lipid nanoparticle structures, stabilizing pharmaceutical active ingredients and delivering nucleic acids into immune cells. Compared to conventional vaccine technology, it has been demonstrated to induce a more optimal immune response
*3 The project aims to swiftly develop an actual (large-scale) production system for biologics, including vaccines, in order to ensure that the vaccines necessary for the prevention of the spread and severity of unexpected epidemics, including COVID-19, are produced as soon as possible, and that their supply is secured for the Japanese people.
*4 The project aims to support the development of a vaccine against COVID-19, for which R&D is already underway, and aims to ensure the early commercialization of safe and effective vaccines.

1 Actions Against COVID-19

2 **FY2020 Q2 Financial Results**

3 FY2020 Forecast

4 Business Update

5 R&D Update

6 Appendix

Overview of FY2020 Q2 Results

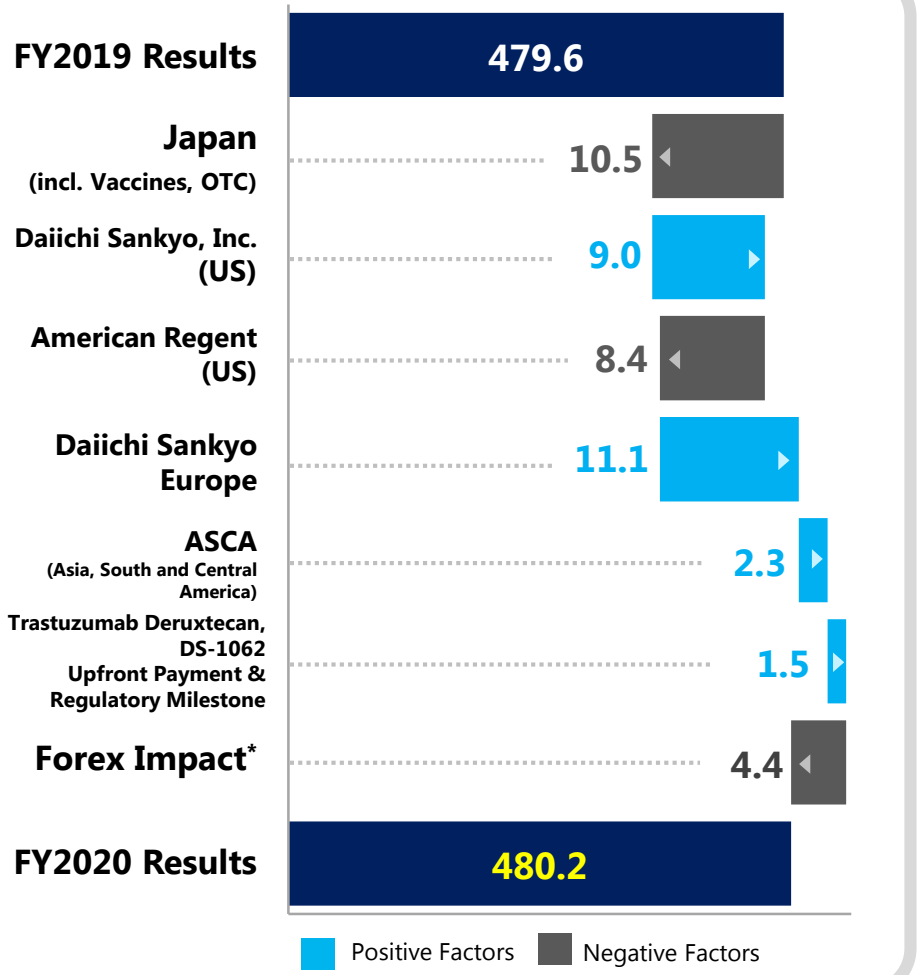
(Bn JPY)

	FY2019 Q2 YTD Results	FY2020 Q2 YTD Results	YoY	
Revenue	**479.6**	**480.2**	+0.1%	**0.6**
Cost of sales	177.1	168.6		-8.5
SG&A expenses	130.5	148.6		18.2
R&D expenses	85.9	104.5		18.7
Operating Profit	**86.2**	**58.5**	-32.1%	**-27.7**
Profit before tax	**87.0**	**67.0**		**-20.1**
Profit attributable to owners of the Company	**64.4**	**51.7**	-19.8%	**-12.8**

Currency Rate	USD/JPY	108.63	106.92	-1.71
	EUR/JPY	121.41	121.29	-0.12

Revenue

Increased by 0.6 Bn JPY (Increased by 5.0 Bn JPY excl. forex impact)



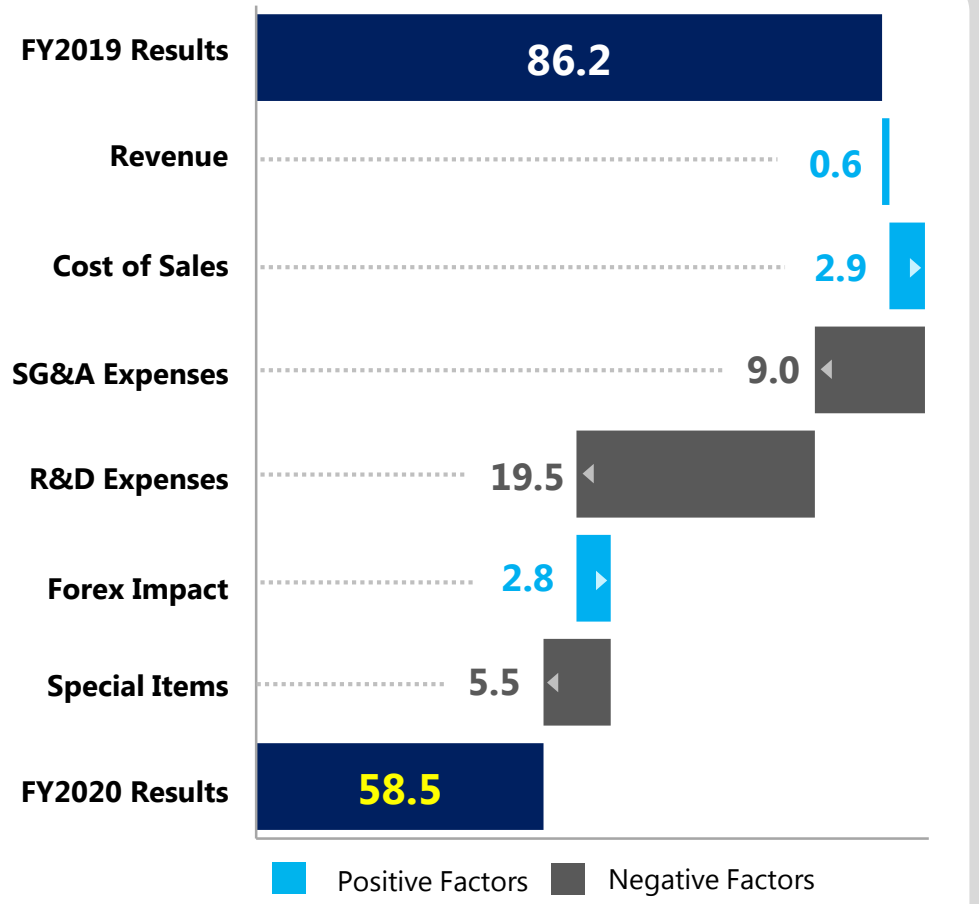
(Bn JPY)

Positive Factors		Negative Factors	
Japan			
Tarlige	+5.8	Memary	-10.8
		Lixiana	-3.5
Daiichi Sankyo Espha Memantine AG, Ezetimibe AG etc.	+2.9	Vaccines business ActHIB	-5.1
		Daiichi Sankyo Healthcare Lulu	-1.0
Daiichi Sankyo, Inc. (US)			
Enhertu	+11.3	Welchol	-2.6
American Regent (US)			
		Injectafer	-4.7
		Venofer	-1.5
		GE injectables	-2.3
Daiichi Sankyo Europe			
Lixiana	+7.6		
Gain on sales of transferring long-listed products	+4.4		
Trastuzumab Deruxtecan, DS-1062 Upfront Payment & Regulatory Milestone			
DS-1062 upfront payment	+1.0		

* Forex impact USD: -1.4, EUR : -0.1, ASCA: -2.9

Operating Profit

Decreased by 27.7 Bn JPY (Decreased by 20.6 Bn JPY excl. forex impact and special items)



(Bn JPY)

Revenue +0.6
incl. forex impact of -4.4

Cost of Sales -2.9 **(Profit increased)**
Improvement in cost of sales ratio by product mix

SG&A Expenses +9.0 **(Profit decreased)**
Increase in Enhertu related expenses
(including sales promotion expenses and profit share with AstraZeneca)

R&D Expenses +19.5 **(Profit decreased)**
- Increase in 3 ADCs R&D investments
- Increase due to oncology development structure enhancement

Forex Impact -2.8 **(Profit increased)**
Cost of Sales -0.5
SG&A Expenses -1.5
R&D Expenses -0.8

Special Items +5.5 **(Profit decreased)**
See next slide for details

Special Items

(Bn JPY)

	FY2019 Q2 YTD Results		FY2020 Q2 YTD Results	YoY
Cost of sales	Restructuring costs in SC	1.3	-	-5.1
	Impairment loss (intangible assets)*1	3.8		
SG&A expenses	Gain on sales of fixed assets*2	-10.6	-	10.6
R&D expenses		-	-	-
Total		-5.5	-	5.5

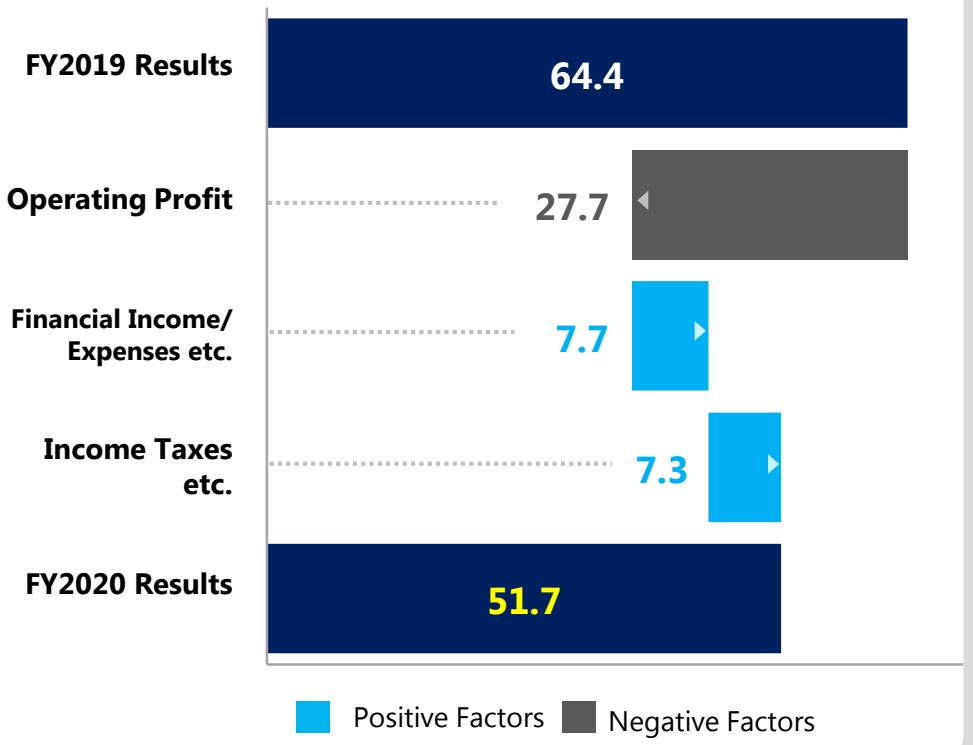
- : Cost decreased items

*1 Morphabond, Roxybond
*2 Nihonbashi Building

Special items :
Items having a transitory and material impact on operating profit are defined as "Special items".
Specifically, gains and losses related to: sale of fixed assets, restructuring, impairment, litigation, etc. amounting to 1 billion JPY or more are defined as "Special items".

Profit Attributable to Owners of the Company

Decreased by 12.8 Bn JPY



(Bn JPY)

Financial Income/ Expenses etc. ..... **-7.7 (Profit increased)**

- Recognition of financial income due to decrease in contingent consideration of quizartinib acquisition ..... -4.8
- Improvement in forex gains/losses ..... -3.5

Income Taxes etc. ..... **-7.3 (Profit increased)**

	FY2019 Q2 YTD Results	FY2020 Q2 YTD Results	YoY
Profit before Tax	87.0	67.0	-20.1
Income Taxes etc.	22.7	15.4	-7.3
Tax rate	26.0%	23.0%	-3.1%

Reference: Tax rate improved due to the increase in tax credit for R&D expenses

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2019 Q2 YTD Results	FY2020 Q2 YTD Results	YoY
Japan	261.0	250.1	-10.9
Daiichi Sankyo Healthcare	34.1	33.0	-1.0
Daiichi Sankyo, Inc.	14.9	23.5	+8.6
Enhertu	-	11.3	+11.3
Olmesartan	5.5	5.5	-0.1
Welchol	4.8	2.2	-2.6
American Regent, Inc.	68.3	58.9	-9.4
Injectafer	26.0	21.0	-5.0
Venofer	16.4	14.6	-1.8
GE injectables	22.4	19.8	-2.6
Daiichi Sankyo Europe	43.2	54.3	+11.1
Lixiana	27.5	35.0	+7.5
Olmesartan	11.2	11.0	-0.2
Efient	1.4	0.8	-0.6
ASCA (Asia, South and Central America)	49.0	48.4	-0.6

Currency Rate	USD/JPY	108.63	106.92	-1.71
	EUR/JPY	121.41	121.29	-0.12

Revenue: Major Products in Japan

(Bn JPY)

		FY2019 Q2 YTD Results	FY2020 Q2 YTD Results	YoY
Nexium	ulcer treatment	**40.2**	**39.0**	**-1.3**
Lixiana	anticoagulant	**41.8**	**38.3**	**-3.5**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion	**15.4**	**17.0**	**+1.5**
Memary	Alzheimer's disease treatment	**25.7**	**14.9**	**-10.8**
Tenelia	type 2 diabetes mellitus treatment	**12.8**	**12.4**	**-0.3**
Loxonin	anti-inflammatory analgesic	**14.8**	**12.3**	**-2.5**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**9.2**	**9.7**	**+0.5**
Inavir	anti-influenza agent	**1.0**	**1.3**	**+0.3**
Tarlige	pain treatment	**3.3**	**9.1**	**+5.8**
Canalia	type 2 diabetes mellitus treatment	**6.1**	**7.7**	**+1.5**
Vimpat	anti-epileptic agent	**5.2**	**7.1**	**+1.9**
Efient	antiplatelet agent	**7.1**	**7.2**	**+0.1**
Rezaltas	antihypertensive agent	**7.5**	**6.8**	**-0.8**
Olmetec	antihypertensive agent	**6.2**	**4.9**	**-1.3**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**-**	**1.0**	**+1.0**

1 Actions Against COVID-19

2 FY2020 Q2 Financial Results

3 **FY2020 Forecast**

4 Business Update

5 R&D Update

6 Appendix

Revision to the forecast

(Bn JPY)

	FY2020 Forecast (as of Apr.)	FY2020 Forecast (as of Oct.)	vs. Forecast as of Apr. (%)
Revenue	**970.0**	**960.0**	**-10.0**
Cost of sales	337.0	340.0	+3.0
SG&A expenses	325.0	317.0	-8.0
R&D expenses	228.0	243.0	+15.0
Operating Profit	**80.0**	**60.0**	**-20.0**
Profit before tax	**80.0**	**69.0**	**-11.0**
Profit attributable to owners of the Company	**56.0**	**53.0**	**-3.0**

Currency Rate	USD/円	110.00	108.46	-1.54
	EUR/円	120.00	120.65	+0.65

Assumption of currency rate for Q3 and Q4 : USD/JPY 110, EUR/JPY 120

Revenue

Increase factors
- Sales expansion of main products (Enhertu, Tarlige, influenza vaccine etc.)
- DS-1062 (Upfront payment)
- Gain on sales of transferring Daiichi Sankyo Europe's long-listed products

Decrease factors
- COVID-19 impact (Injectafer, Inavir, Daiichi Sankyo Healthcare products etc.)

Cost of sales
- Loss on disposal/valuation of inventory and others

SG&A expenses

Increase factors
- Personnel expenses in US (Increase in share-based remuneration due to increase in stock price)

Decrease factors
- Reduction of expenditures due to COVID-19 expansion

R&D expenses
- Increase in 3 ADCs R&D investments
- Personnel expenses in US (Increase in share-based remuneration due to increase in stock price)

Profit before tax
- Net financial income/expenses for FY2020 Q2 YTD (forex gains/losses and others)

Impact of COVID-19 and others
- Reflected the impact of COVID-19 and the strong R&D progress exceeding the original plan etc. in the forecast
- The impact will be examined separately in case the infection status becomes worse

Trastuzumab Deruxtecan (DS-8201) / DS-1062: Revenue

(Bn JPY)

		FY2020 Q2 YTD Results	FY2020 Forecast (As of October)	vs. Forecast (as of April)	<Reference> Total Consideration (Received/ Receivable)
Trastuzumab Deruxtecan (DS-8201)	Product sales	12.3	34.9	+6.4	-
	Japan	1.0	5.6	+4.1	-
	US	11.3	29.2	+2.2	-
	Upfront payment	4.9 *1	9.8 *1	-	149.0
	Regulatory milestone payment	0.5 *1	2.4 *1	+1.5 *1,2	13.7
	Total	17.7	47.1	+7.9	162.7
DS-1062	Upfront payment	1.0 *1	3.9 *1	+3.9 *1	105.5 *3

*1 Revenue recognized in each period
*2 Approval in Europe (HER2+ BC 3L) and additional indication in US (HER2+ GC 3L) are assumed
*3 Received through three separate payments; 1) upon contract execution, 2) 12 months after execution, 3) 24 months after execution. Currency conversion amount based on FOREX at the first payment date.

1 Actions Against COVID-19

2 FY2020 Q2 Financial Results

3 FY2020 Forecast

4 **Business Update**

5 R&D Update

6 Appendix

ENHERTU

Edoxaban

Japan Business

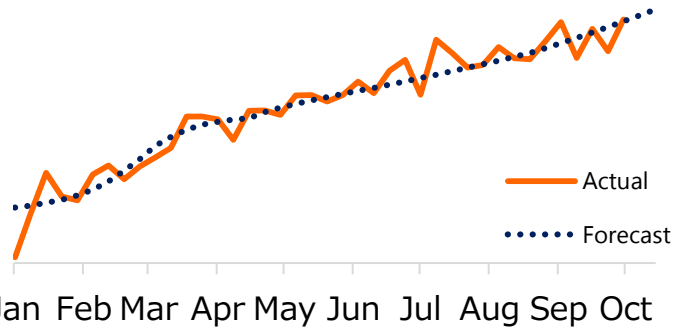
Shareholder Returns

ENHERTU: Performance in US and Japan

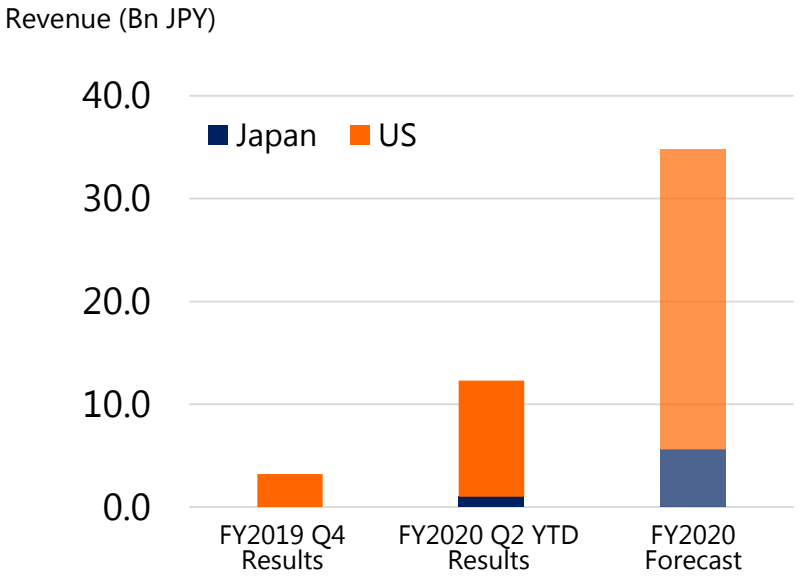
- **Strong market penetration**
- **Product sales FY2020 Q2 YTD Results: 12.3 Bn JPY** <US 11.3 Bn JPY, Japan 1.0 Bn JPY>
  FY2020 Forecast: Revised upward to 34.9 Bn JPY (+6.4 Bn JPY)
  <US 29.2 Bn JPY (+2.2 Bn JPY), Japan: 5.6 Bn JPY (+4.1 Bn JPY)>

US

- Launched in Jan. 2020 (HER2+ BC 3L)
- Total number of unique outlets purchasing ENHERTU since launch is approx. 1,600, and number of repeat outlets is approx. 1,300
- Encouraging increase in demand
  - ✓ ENHERTU units shipped to account in Oct. increased more than 60% from Mar.



- **sBLA accepted for HER2+ GC 3L in Oct. 2020**
  - ✓ **Priority Review granted**
  - ✓ **PDUFA Date: Feb. 28, 2021**
  - ✓ Breakthrough Therapy Designation and Orphan Drug Designation granted



Japan

- Launched in May 2020 (HER2+ BC 3L)
- **Indication expanded in Sep. 2020 (HER2+ GC 3L)**
- Providing product information with the highest priority on safety
- ENHERTU delivered only to medical institutions that meet doctor and facility requirements

ENHERTU

Edoxaban

Japan Business

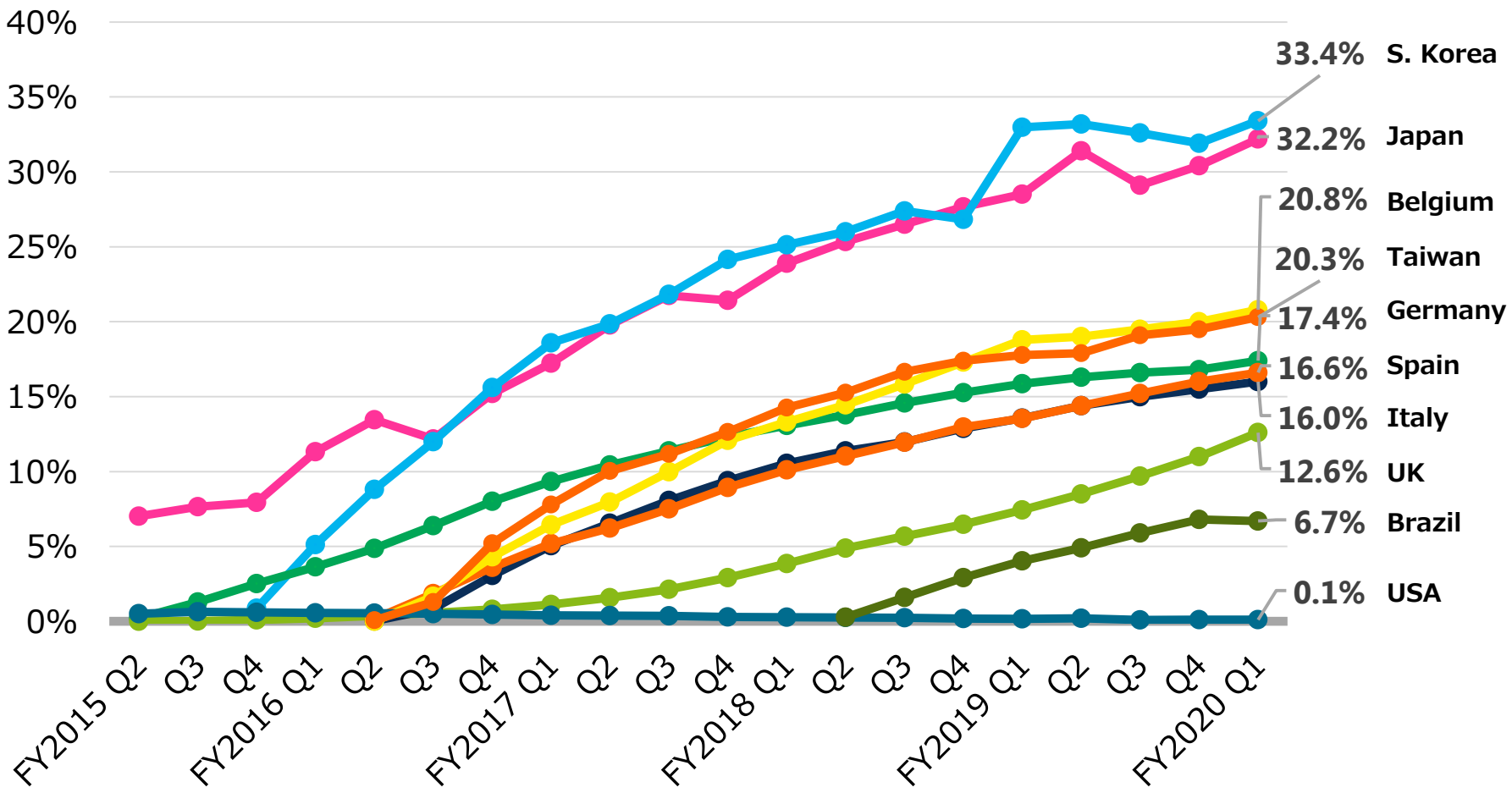
Shareholder Returns

Edoxaban: Growth in Each Country/Region

Volume

Daiichi-Sankyo

- **Steady growth in each country/region**
- **Global revenue results: FY2020 Q2 YTD**
  79.1 Bn JPY (YoY +5.4 Bn JPY)

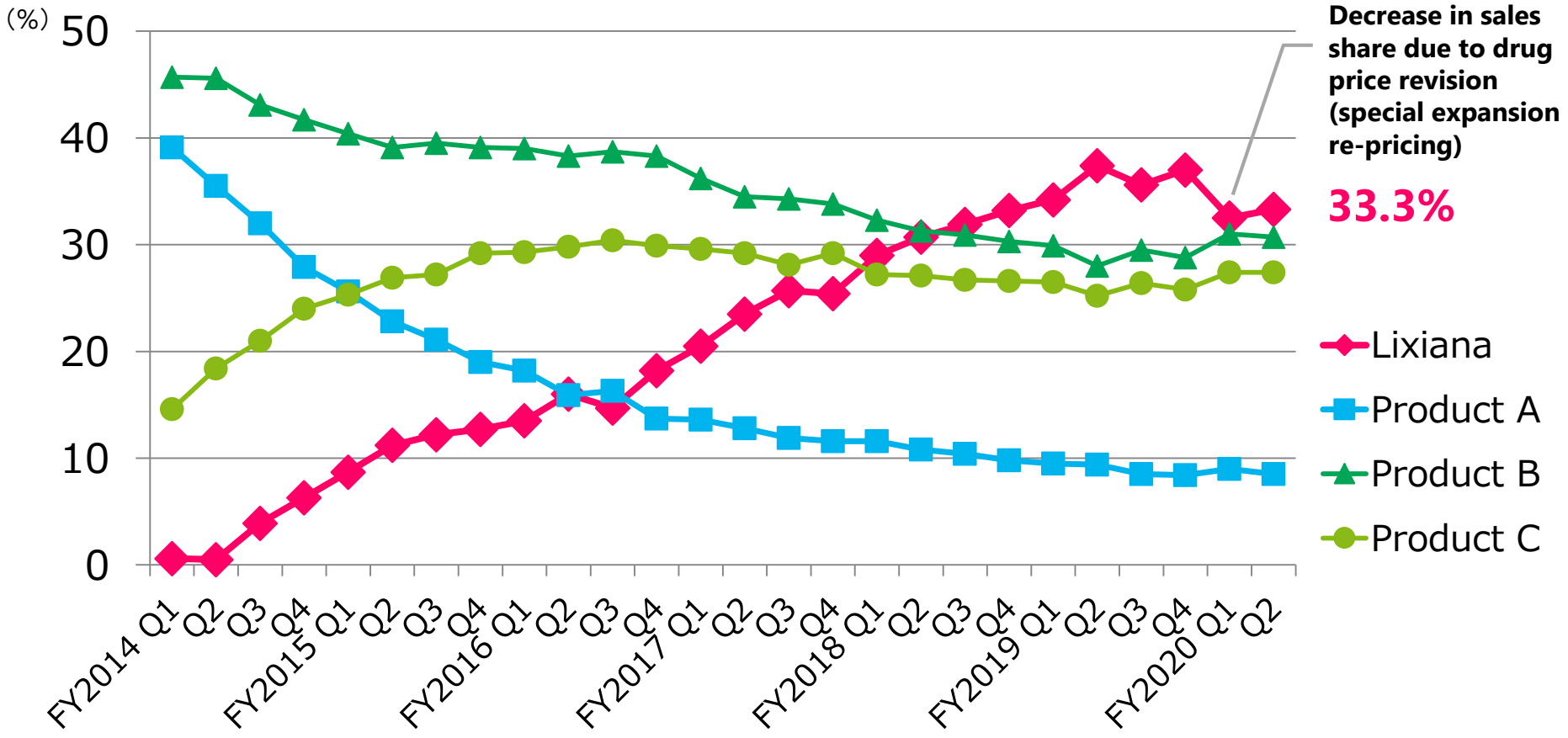


Lixiana: Growth in Japan

Sales

Daiichi-Sankyo

- No.1 sales share (FY2020 Q2: 33.3%)
- Revenue results: FY2020 Q2 YTD 38.3 Bn JPY (YoY -3.5 Bn JPY*)
  * Previous drug price base YoY +9.2 Bn JPY

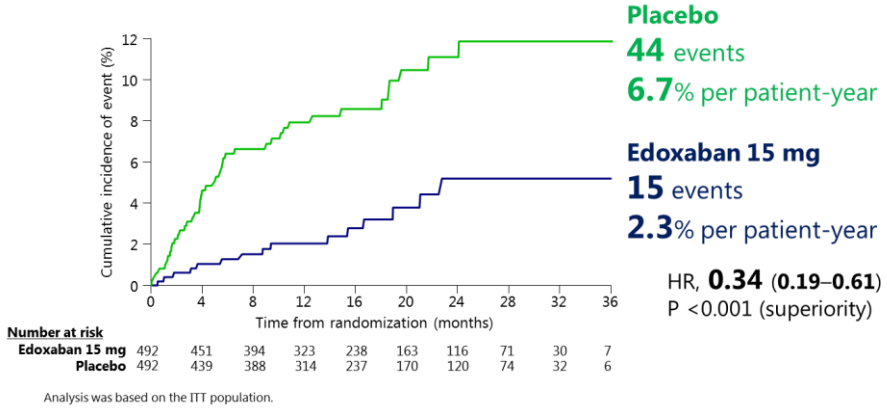


Edoxaban: Results of ELDERCARE-AF

ELDERCARE-AF

A study comparing efficacy and safety of edoxaban 15 mg/day with placebo in Japanese non-valvular AF patients who are very elderly (80 years or older) at high risk of bleeding

Efficacy



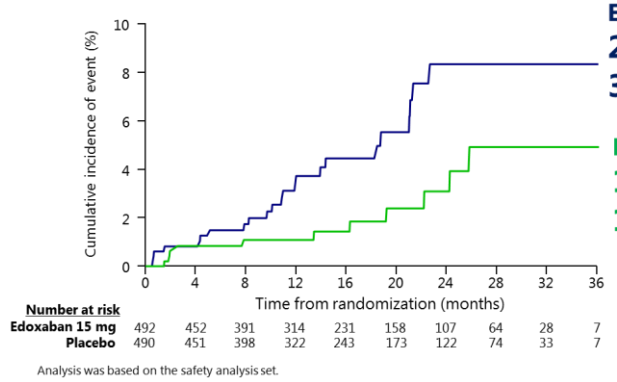
Placebo
44 events
6.7% per patient-year

Edoxaban 15 mg
15 events
2.3% per patient-year

HR, **0.34** (**0.19–0.61**)
P <0.001 (superiority)

- Edoxaban significantly reduced the annual incidence of stroke / systemic embolus compared to placebo

Safety



Edoxaban 15 mg
20 events
3.3% per patient-year

Placebo
11 events
1.8% per patient-year

HR, **1.87** (**0.90–3.89**)
P = 0.09

- Annual incidence of major bleeding is higher with edoxaban compared to placebo
- There is no clear difference between the two groups in the incidence of clinically relevant bleeding (death or intracranial hemorrhage)

- **JP sNDA submitted in Sep. 2020 and approval anticipated in FY2021 Q2**
- **More than 10,000 elderly patients in Japan are estimated to have non-valvular AF with high risk of bleeding**

ESC 2020

ENHERTU

Edoxaban

Japan Business

Shareholder Returns

Japan: Commercialization Collaboration of Migraine Prevention Drug

Daiichi-Sankyo

◆ **Agreement with Eli Lilly Japan to co-promote a first-in-class migraine prevention drug galcanezumab-gnlm (US product name: Emgality) in Japan**

Product overview

- Generic name: **galcanezumab-gnlm**
- MOA: **anti-CGRP Antibody**
  - A monoclonal antibody with a novel MOA designed to specifically bind to calcitonin gene-related peptide (CGRP) which is regarded to be associated with migraine, thereby inhibits binding of CGRP to its receptor
- Target indication: **Suppression of migraine attacks**
- Administration: **subcutaneous injection (once a month)**
- Development status: **NDA submitted in Japan**
  (submitted in Jan. 2020)

Agreement overview

- Co-promotion
  - Daiichi Sankyo
    Responsible for **distribution** and **sales** under **co-promotion with Eli Lilly Japan (Booking sales)**
  - Eli Lilly Japan
    Responsible for **development**, **manufacturing** and **promotion**

Value of this deal

- Contribute to improve QOL of patients with migraine by new treatment option
- Enhance product portfolio toward sustainable growth of Japan businesses

ENHERTU

Edoxaban

Japan Business

Shareholder Returns

Shareholder Returns

◆ Decided acquisition and cancellation of own shares

Acquisition

- Acquisition period: **From Nov. 2, 2020 to Mar. 23, 2021**
- Aggregate amount of acquisition cost: **100.0 Bn JPY** (maximum)
- Total number of shares to be acquired: **60 Mn shares** (maximum)

Cancellation

- Cancellation date: **Apr. 15, 2021**
- Number of shares to be cancelled: **180 Mn shares**
  (Cancel except for the number of shares to be used for stock option and restricted share-based remuneration)

Shareholder Returns Policy: FY2016 - FY2022

Annual Ordinary Dividend **70 JPY*1 or more** + **Flexible acquisition of own shares** = **Total Return Ratio*2 100% or more**

Reference: Total return ratio based on FY2020 forecast profit attributable for owners of the Company

	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results	FY2020 Plan
Dividend per share*1	**70 JPY**	**70 JPY**	**70 JPY**	**70 JPY**	**81 JPY**
Acquisition of own shares	**50.0 Bn JPY**	**50.0 Bn JPY**	**-**	**-**	**100.0 Bn JPY**
Total return ratio*2	**180.7%**	**159.1%**	**48.5%**	**35.1%**	**286.9%*3**
	111.8%*3				

*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
*3 Estimation assuming that own shares will be acquired at the average of closing stock price from Oct. 2 to Oct. 23, 2020

1 Actions Against COVID-19

2 FY2020 Q2 Financial Results

3 FY2020 Forecast

4 Business Update

5 **R&D Update**

6 Appendix

3 ADC Update

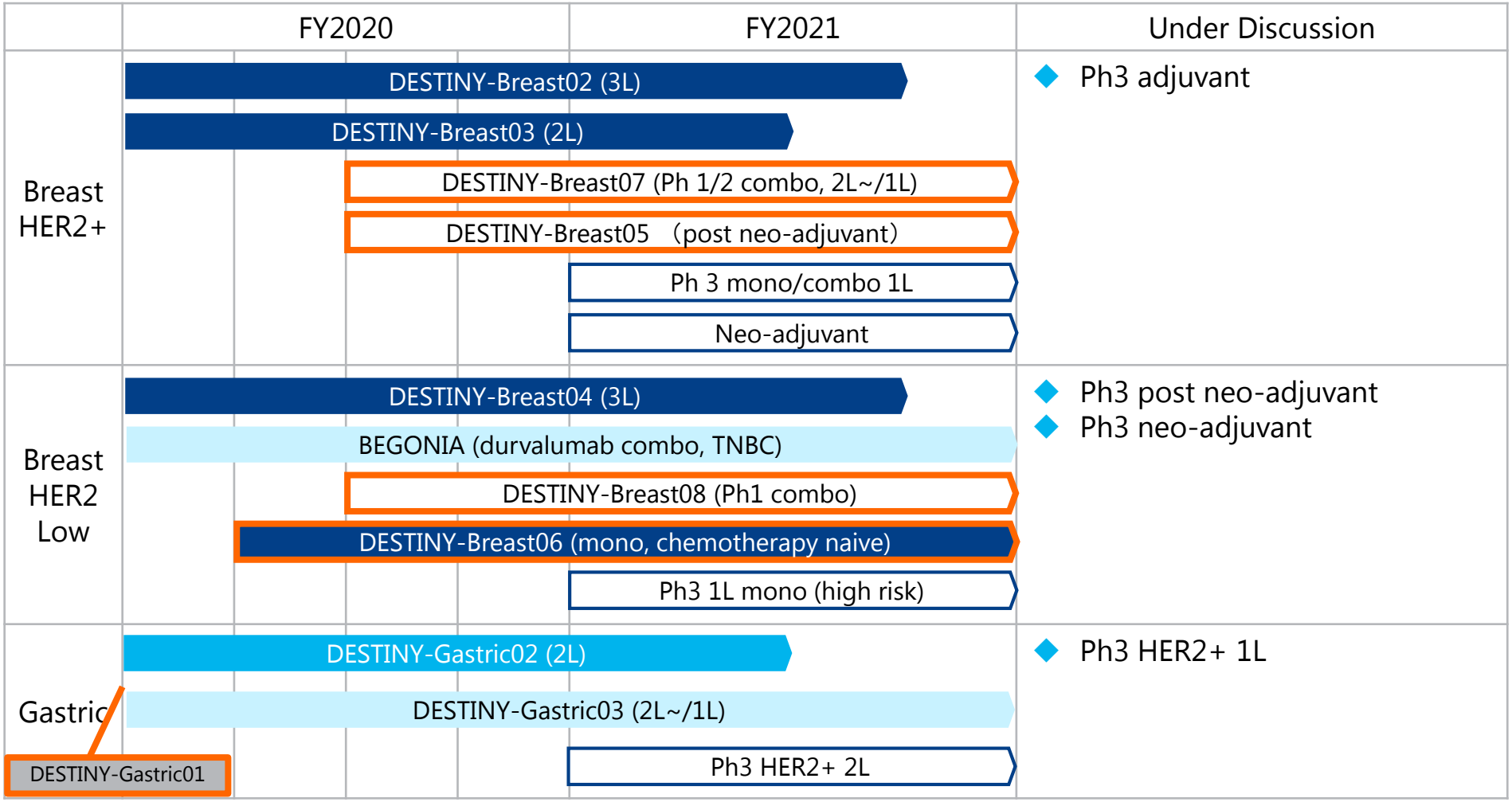
Alpha Update

News flow

DS-8201: Clinical Development Plan

As of October 2020

Daiichi-Sankyo



Study initiation points for FY2020 H1 are shown on quarterly basis
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

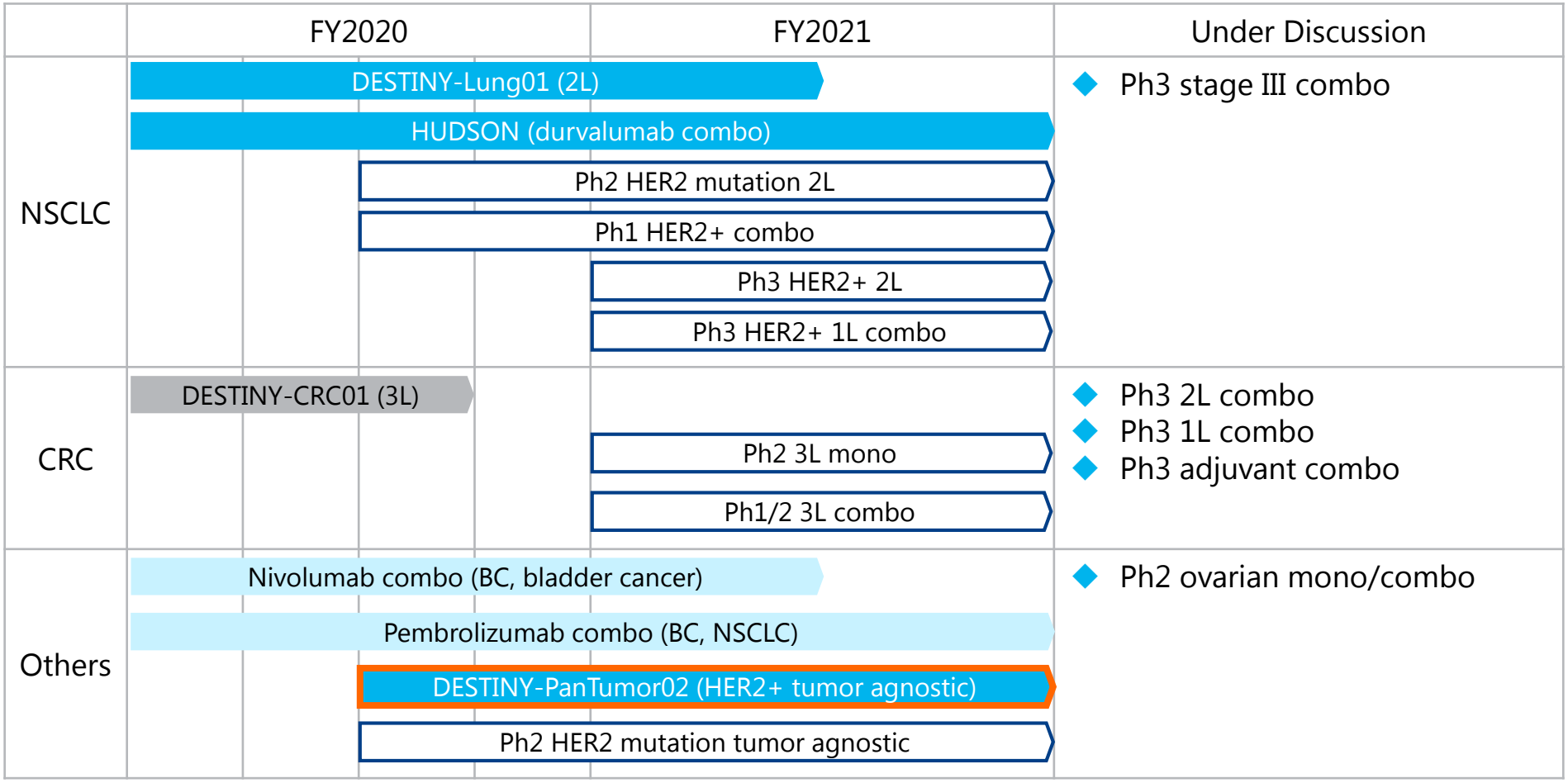
Will be presented today

Ph 3 ongoing | Ph 2 ongoing | Ph 1 ongoing | New | Completed

DS-8201: Clinical Development Plan

As of October 2020

Daiichi-Sankyo

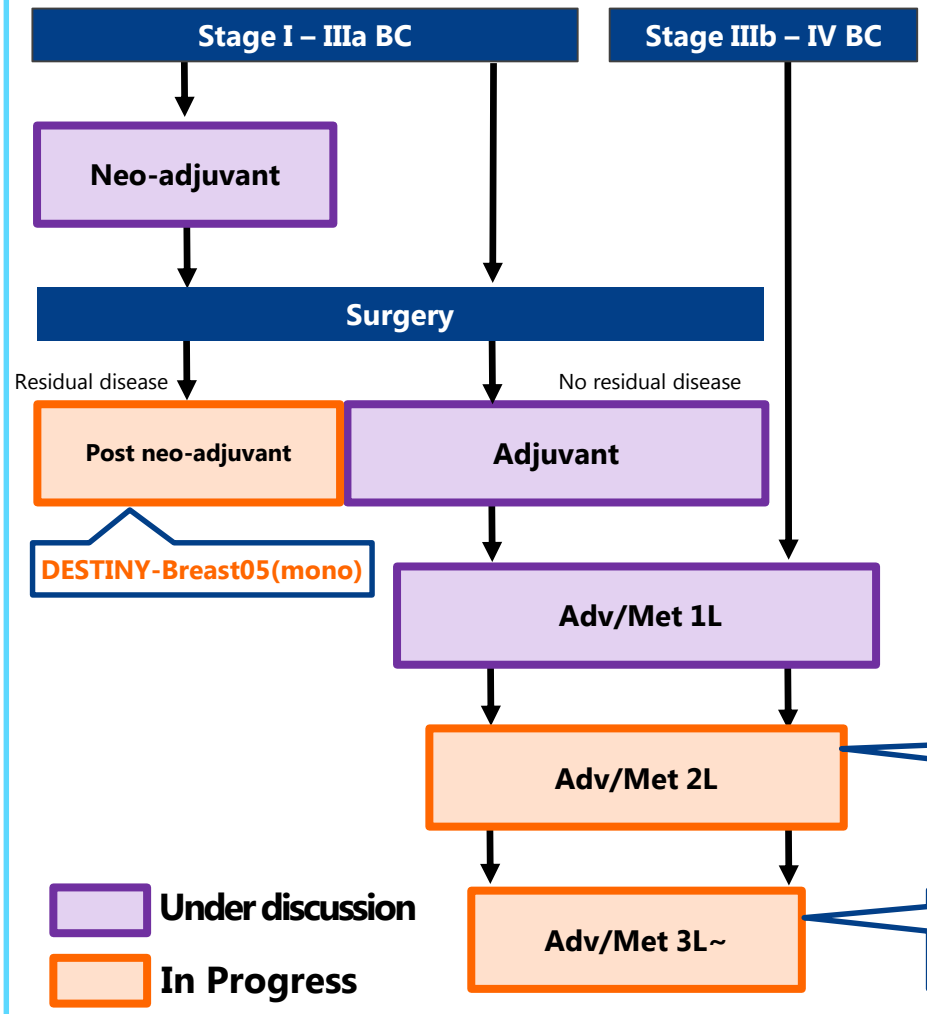


Study initiation points for FY2020 H2 are all shown as beginning of H2
Study initiation points for FY2021 are all shown as beginning of FY2021

Will be presented today

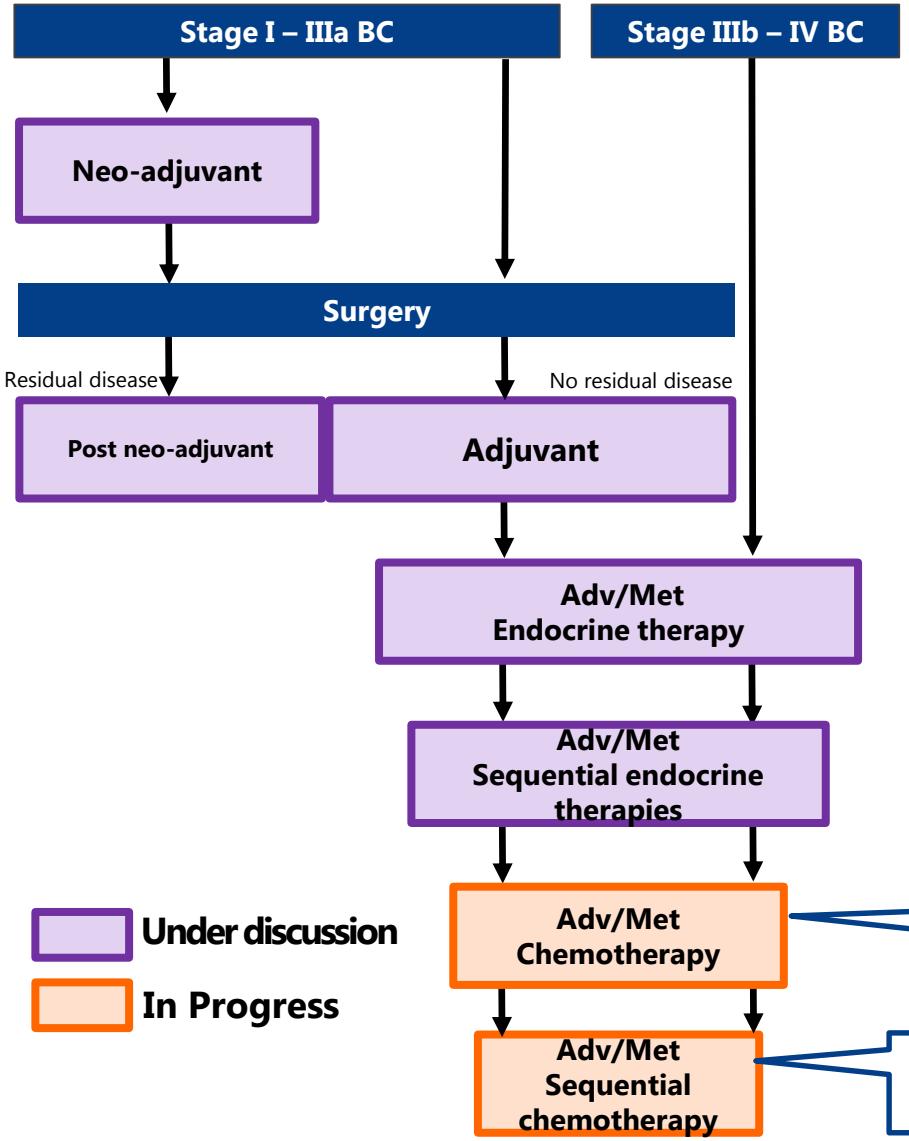
Ph 3 ongoing | Ph 2 ongoing | Ph 1 ongoing | New | Completed

DS-8201: Purpose of New Studies (HER2+ BC)



- **DESTINY-Breast05** (Ph3)
  - DS-8201 vs. T-DM1 in patients with high-risk recurrence of HER2 positive breast cancer who have residual invasive disease following neoadjuvant therapy
- **DESTINY-Breast07** (Ph1b/2)
  - Fundamental studies for development in earlier line HER2 positive breast cancer

DS-8201: Purpose of New Studies (HER2 Low/HR+ BC)



- **DESTINY-Breast06** (Ph3)
  - DS-8201 vs. physican's choice of therapy in patients with HER2 low/HR positive breast cancer who have progressed after endocrine therapy and have not been treated with chemotherapy
  - **Started in Aug. 2020**

- **DESTINY-Breast08** (Ph1/2)
  - Fundamental studies for development in earlier line HER2 low breast cancer

DESTINY-Breast06(mono)

DESTINY-Breast04(mono, incl. HR(-))
DESTINY-Breast08(combo, incl. HR(-))

DS-8201: DESTINY-Gastric01 Study (HER2 Low GC)

Daiichi-Sankyo

Efficacy

	Primary Cohort[1]		Exploratory Cohorts	
	DS-8201 (n = 119)	PC Overall (n = 56)	Cohort 1 IHC 2+/ISH− (n = 19)	Cohort 2 IHC 1+ (n = 21)
ORR by ICR (CR + PR)	**51.3% (n = 61)** 95% CI, 41.9-60.5; *P* < .0001[a]	**14.3% (n = 8)** 95% CI, 6.4-26.2	**36.8% (n = 7)** 95% CI, 16.3%-61.6%	**19.0% (n = 4)** 95% CI, 5.4%-41.9%
Confirmed ORR by ICR (CR + PR)	**42.9% (n = 51)** 95% CI, 33.8-52.3	**12.5% (n = 7)** 95% CI, 5.2-24.1	**26.3% (n = 5)** 95% CI, 9.1%-51.2%	**9.5% (n = 2)** 95% CI, 1.2%-30.4%
CR	8.4% (n = 10)	0	0	0
PR	34.5% (n = 41)	12.5% (n = 7)	26.3% (n = 5)	9.5% (n = 2)
SD	42.9% (n = 51)	50.0% (n = 28)	63.2% (n = 12)	61.9% (n = 13)
PD	11.8% (n = 14)	30.4% (n = 17)	10.5% (n = 2)	28.6% (n = 6)
NE	2.5% (n = 3)	7.1% (n = 4)	0	0
Confirmed DCR (CR + PR + SD)	85.7% (n = 102) 95% CI, 78.1-91.5	62.5% (n = 35) 95% CI, 48.5-75.1	89.5% (n = 17) 95% CI, 66.9%-98.7%	71.4% (n = 15) 95% CI, 47.8%-88.7%
Median confirmed DOR	11.3 months 95% CI, 5.6 months-NE	3.9 months 95% CI, 3.0-4.9 months	7.6 months 95% CI, 4.1 months-NE	12.5 months 95% CI, NE-NE

Includes data for the response-evaluable set: all randomized (for primary cohort) patients who received ≥ 1 dose of study drug and had measurable tumors based on independent central review at baseline.
[a]Comparison between T-DXd and PC overall using Cochran-Mantel-Haenszel test stratified by region.

1. Shitara K, et al. *N Engl J Med*. 2020;382:2419-2430.

- **Presented results of exploratory cohorts (HER2 low GC) at ESMO 2020**
- **Tumor reduction seen in HER2 low GC where no HER2 directed therapies are approved**

GC: gastric cancer, PC: Physician's choice

DS-8201: DESTINY-Gastric01 Study (HER2 Low GC)

Daiichi-Sankyo

Safety

Adverse Events (≥ 20% in either cohort)	Cohort 1 IHC 2+/ISH− (n = 20)		Cohort 2 IHC 1+ (n = 24)	
Preferred Term, n (%)	Any Grade	Grade ≥ 3	Any Grade	Grade ≥ 3
Decreased appetite	65	20	75	21
Nausea	55	5	79	4
Anemia	50	30	42	29
Neutrophil count decrease	45	25	50	29
Diarrhea	30	0	33	4
Constipation	25	0	21	0
Fatigue	25	10	25	8
Malaise	20	0	38	0
White-cell count decrease	20	0	33	13
Vomiting	20	0	29	0
Weight decrease	20	0	29	8
Peripheral edema	20	0	4	0
Dysgeusia	20	0	4	0
Pyrexia	15	0	25	0
Platelet count decrease	15	0	29	13
Hypoalbuminemia	10	0	21	8

All hematologic terms are grouped terms. Febrile neutropenia occurred in 1 patient (cohort 1, grade 3).

TEAEs Associated With:	Cohort 1 IHC 2+/ISH− (n = 20)	Cohort 2 IHC 1+ (n = 24)
Drug discontinuation, %	10	4
Dose reduction, %	30	33
Dose interruption, %	40	42

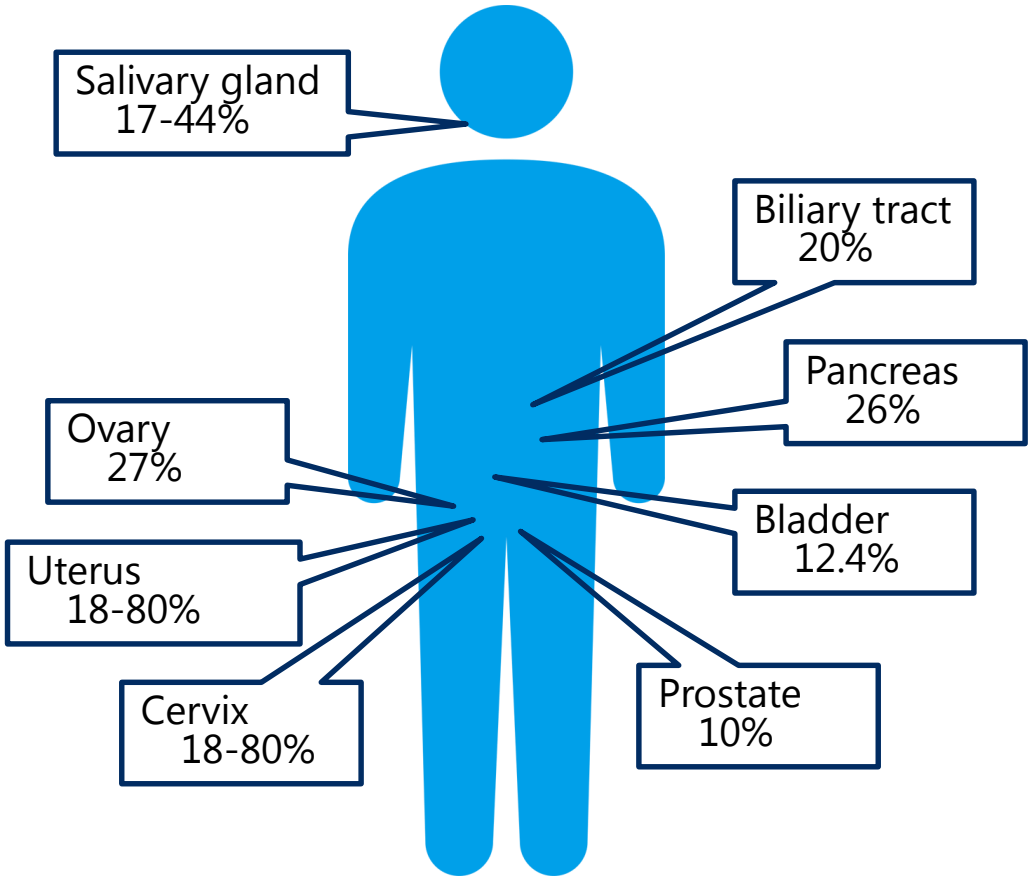
- There were no drug-related deaths in either cohort
- Median treatment duration was 4.2 months (range, 1.3-10.5 months) in cohort 1 and 2.8 months (range, 0.7-14.9 months) in cohort 2
- One patient in each cohort had DS-8201–related ILD/pneumonitis (cohort 1, grade 1; cohort 2, grade 2) as determined by an independent adjudication committee
  - Time to onset was 248 days in cohort 1 and 171 days in cohort 2
  - At data cutoff, the case in cohort 2 was resolving and the case in cohort 1 had not resolved

No significant difference in safety compared to previously reported DS-8201 safety information

GC: gastric cancer

DS-8201: Purpose of New Studies (Other Tumors)

HER2 positive rate



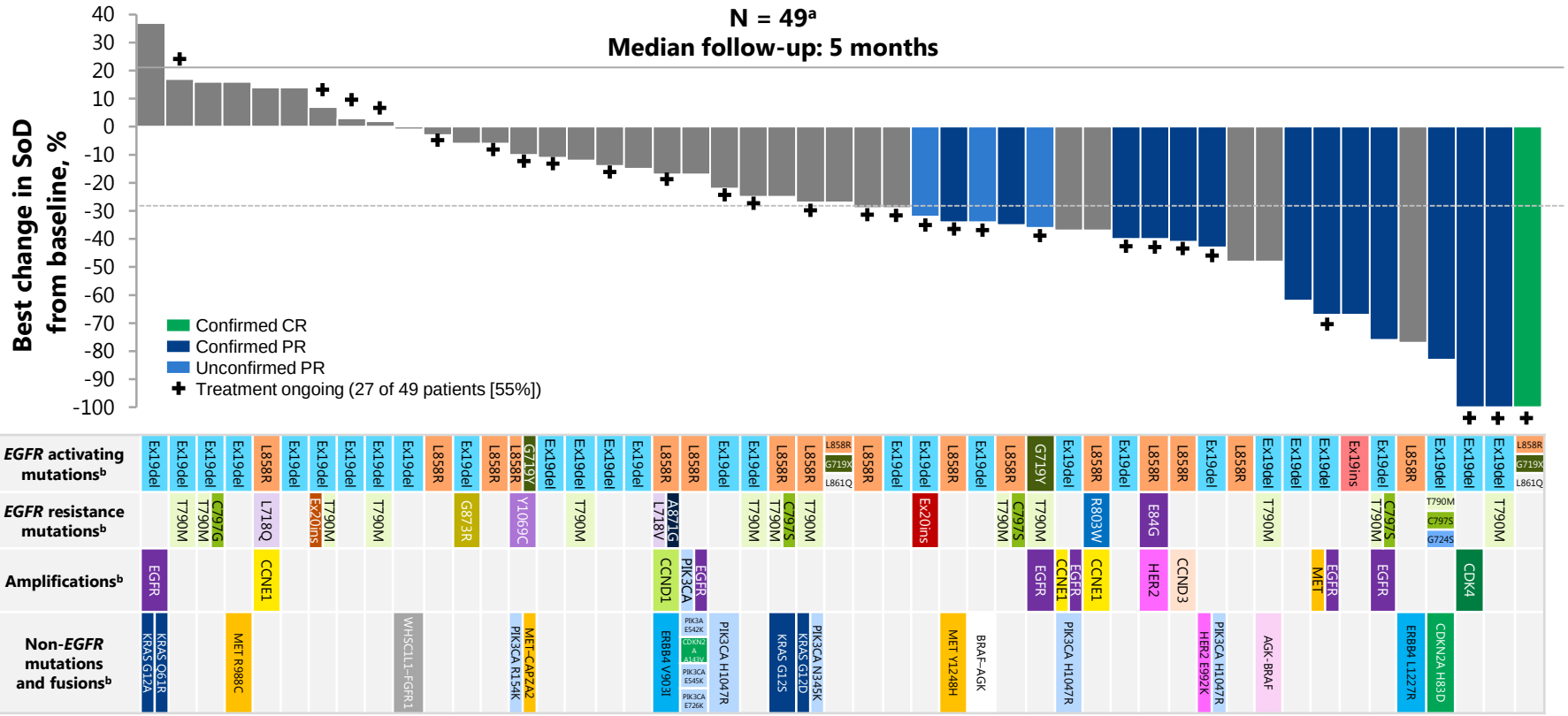
Oh and Bang Nature Oncology Reviews 2017

DESTINY-PanTumor02 (Ph2)

- Study to evaluate efficacy and safety in HER2 expressing tumors (bladder cancer, biliary tract cancer, cervical cancer, endometrial cancer, ovarian cancer, pancreatic cancer, and rare tumors)
- **Started in Oct. 2020**

U3-1402: EGFRm NSCLC Phase 1 Study

Efficacy



A phase 1 study of patritumab deruxtecan in NSCLC (NCT03260491). Safety and activity in patients with *EGFR*-mutated NSCLC treated with 5.6 mg/kg patritumab deruxtecan. Data cutoff April 30, 2020.

[a]This analysis does not include 7 patients without post-baseline tumor assessments by the data cutoff date.

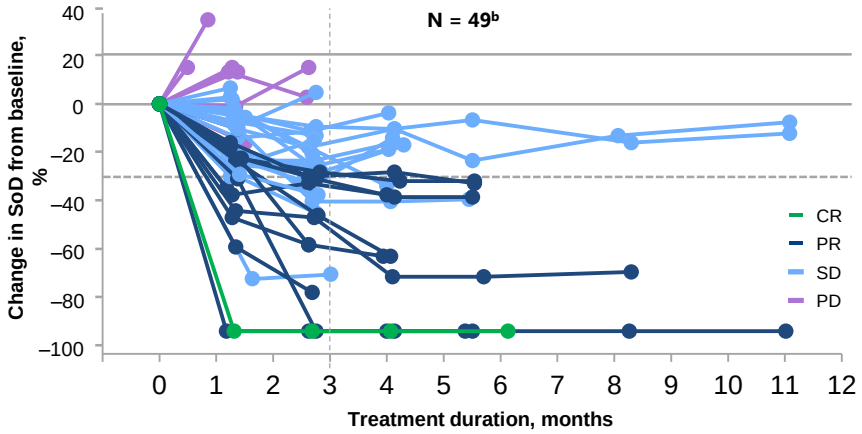
[b]Performed centrally using Oncomine™ Comprehensive Assay v3 from pretreatment tumor tissue. Results from local testing are included for patients where tissue was unavailable for central analysis. Additional mutations detected from cfDNA in blood collected prior to treatment with U3-1402 using GuardantOMNI™ assay are included. For cfDNA analysis, a minor allelic frequency of 1% was used as a threshold for detection of mutations. The copy number data from cfDNA are not shown.

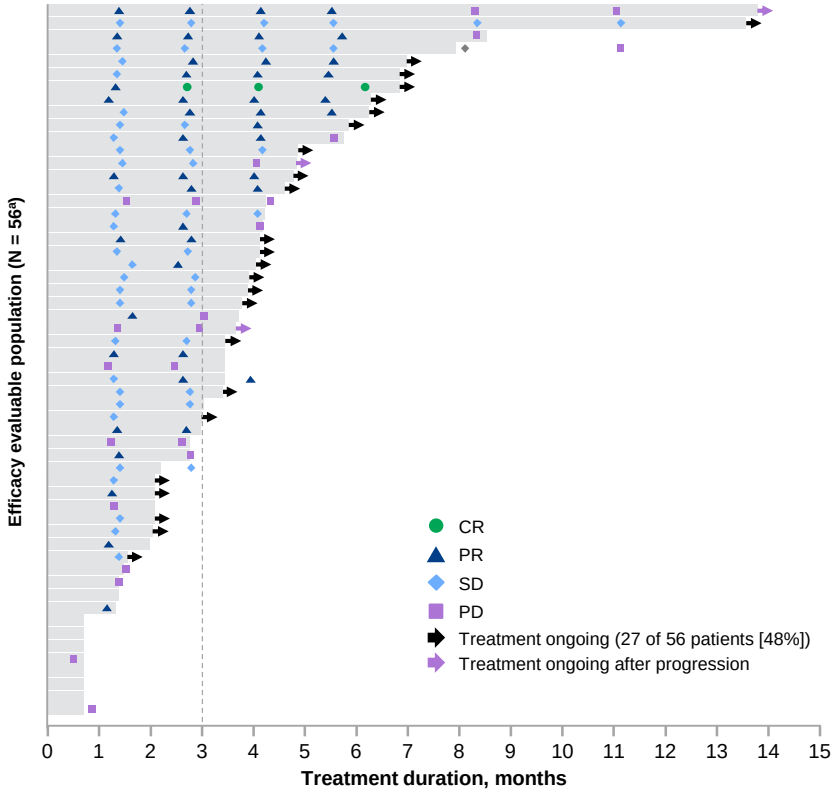
- **Presented data for patients at 5.6mg/kg with a median follow-up time of 5 months**
- **Anti-tumor activity was observed in patients without and with diverse mechanisms of TKI resistance**

U3-1402: EGFRm NSCLC Phase 1 Study

Efficacy

Activity according to BICR evaluation (efficacy-evaluable population) N = 56[a]	
Confirmed BOR, n/N (%)	
CR	1/56 (2%)
PR	13/56 (23%)
SD	25/56 (45%)
PD	9/56 (16%)
NE	8/56 (14%)
Confirmed ORR, % (n/N; 95% CI)	25% (14/56; 14.4-38.4)
DCR, % (n/N; 95% CI)	70% (39/56; 55.9-81.2)
Median TTR, months (range)	2.0 (1.2-2.8)
Median DoR, months (range)	6.9 (3.0-7.0)





A phase 1 study of patritumab deruxtecan in NSCLC (NCT03260491). Safety and activity in patients with *EGFR*-mutated NSCLC treated with 5.6 mg/kg patritumab deruxtecan. Data cutoff April 30, 2020.

[a]Of 56 patients, 22 (39%) had best percentage decrease in sum of tumor diameters ≥ 30%. [b]This analysis does not include 7 patients without post-baseline tumor assessments by the data cutoff date.

- **Early anti-tumor activity was observed and ORR was 25.0%**
- **28 patients are ongoing treatment, 3 PRs are not yet confirmed, 6 patients had only 1 tumor evaluation**

U3-1402: EGFRm NSCLC Phase 1 Study

Safety

- Patritumab deruxtecan continued to demonstrate a manageable safety profile
  - The most common grade ≥3 TEAEs were thrombocytopenia (16 patients [28%]) and neutropenia (11 patients [19%])
  - TEAEs associated with discontinuation (9%) included fatigue (n = 2), decreased appetite (n = 1), ILD (n = 1), pneumonitis (n = 1), and URTI (n = 1)
    - There were no discontinuations due to thrombocytopenia or neutropenia
  - Three (5.3%) ILD events were adjudicated by an independent central review committee as being related to treatment
  - There were no treatment-related TEAEs associated with death

TEAEs (regardless of causality), n (%)	N = 57
TEAEs	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)
Treatment-emergent SAEs	21 (37)
Grade ≥3	18 (32)
Treatment related	11 (19)

TEAEs in ≥20% of patients, n (%)	N = 57	
	All grades	Grade ≥3
Fatigue	33 (58)	5 (9)
Nausea	31 (54)	2 (4)
Thrombocytopenia[a]	30 (53)	16 (28)
Decreased appetite	20 (35)	1 (2)
Neutropenia[b]	19 (33)	11 (19)
Vomiting	17 (30)	1 (2)
Alopecia	17 (30)	NA
Anemia[c]	15 (26)	5 (9)
Constipation	14 (25)	0

A phase 1 study of patritumab deruxtecan in NSCLC (NCT03260491). Safety and activity in patients with *EGFR*-mutated NSCLC treated with 5.6 mg/kg patritumab deruxtecan. Data cutoff April 30, 2020.

[a]Thrombocytopenia includes decreased platelet count and thrombocytopenia. [b]Neutropenia includes decreased neutrophil count and neutropenia. [c]Anemia includes decreased hemoglobin, decreased red blood cell count, anemia, and decreased hematocrit.

Continued to demonstrated a manageable safety profile

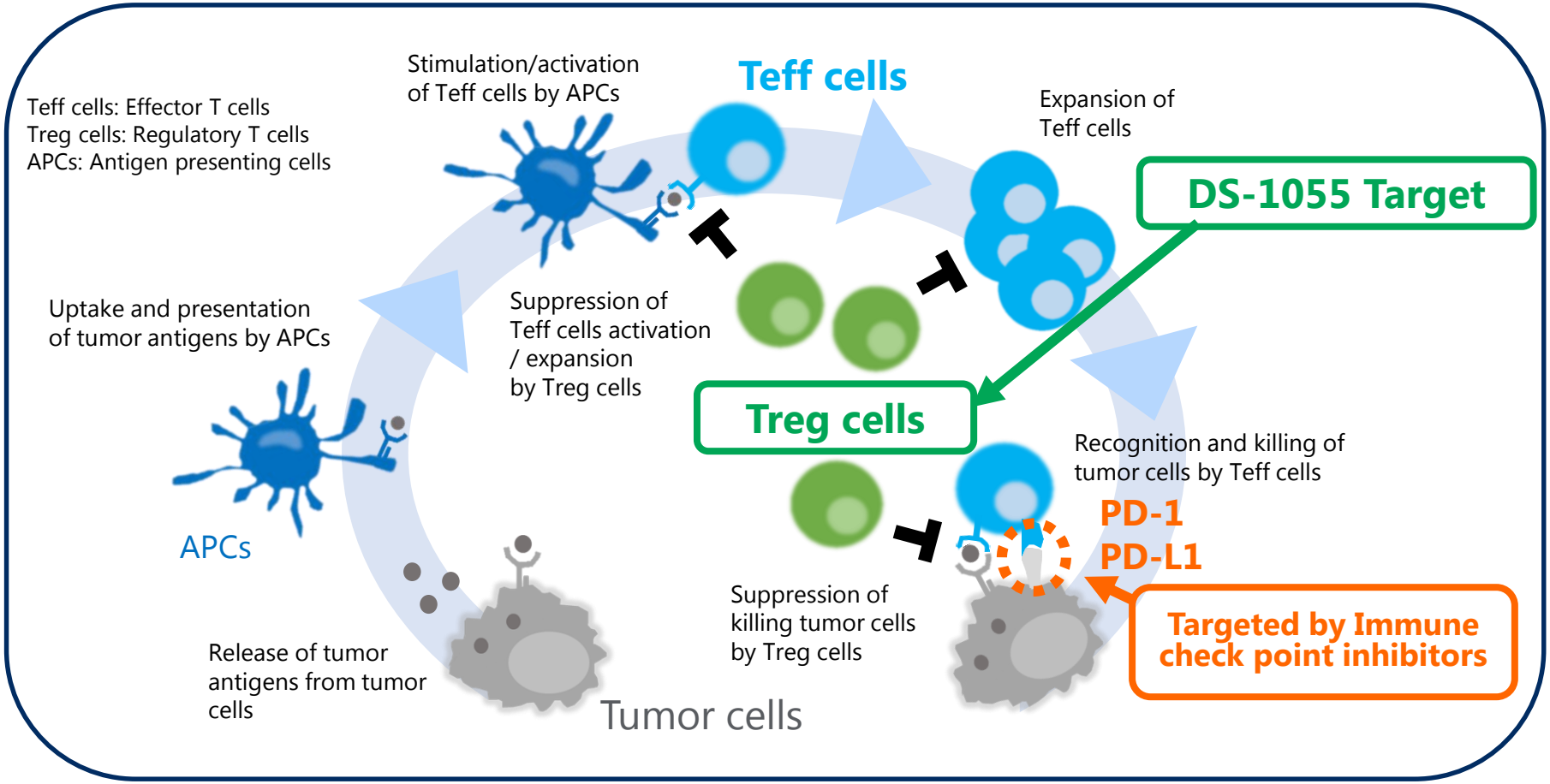
3 ADC Update

Alpha Update

News flow

DS-1055 Target: Regulatory T Cells

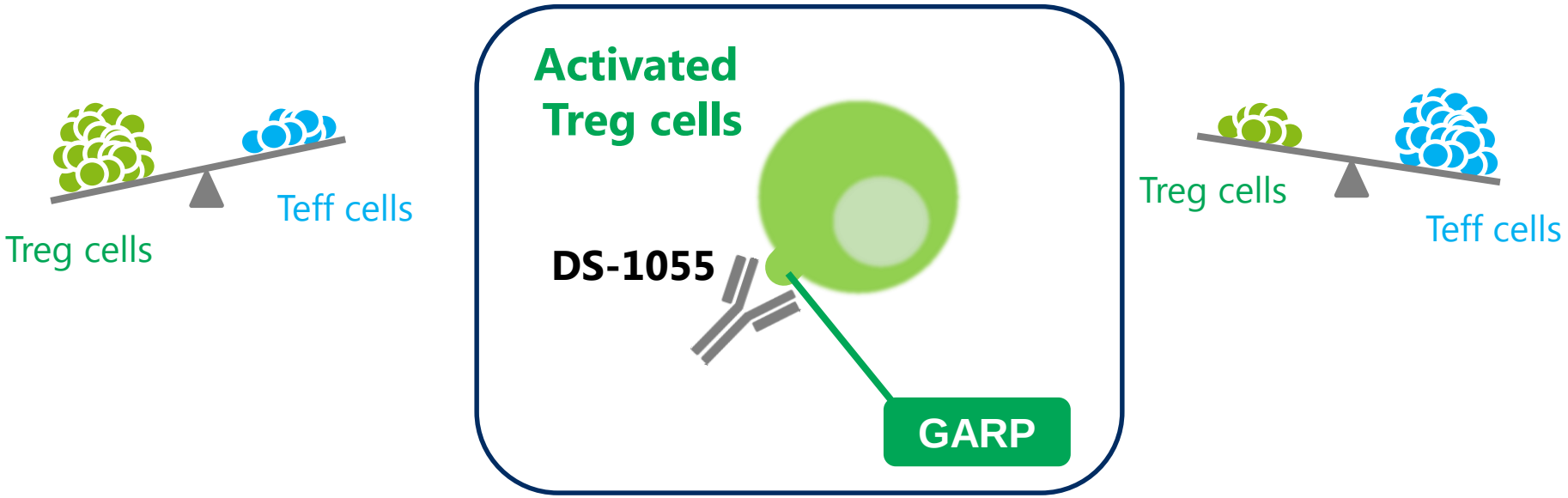
- **DS-1055 is anti-GARP antibody with different MOA from that of anti-PD-1 / PD-L1 antibody**
- **Activates anti-tumor immunity by targeting regulatory T cells (Treg cells) involved in immune escape of cancer cells**



GARP：Glycoprotein A repetitions predominant

DS-1055: MOA of Anti-GARP Antibody

Treg cells > Teff cells	Treg cells < Teff cells
Immune escape of tumor by suppression of Treg cells	Elimination of tumor by activated Teff cells

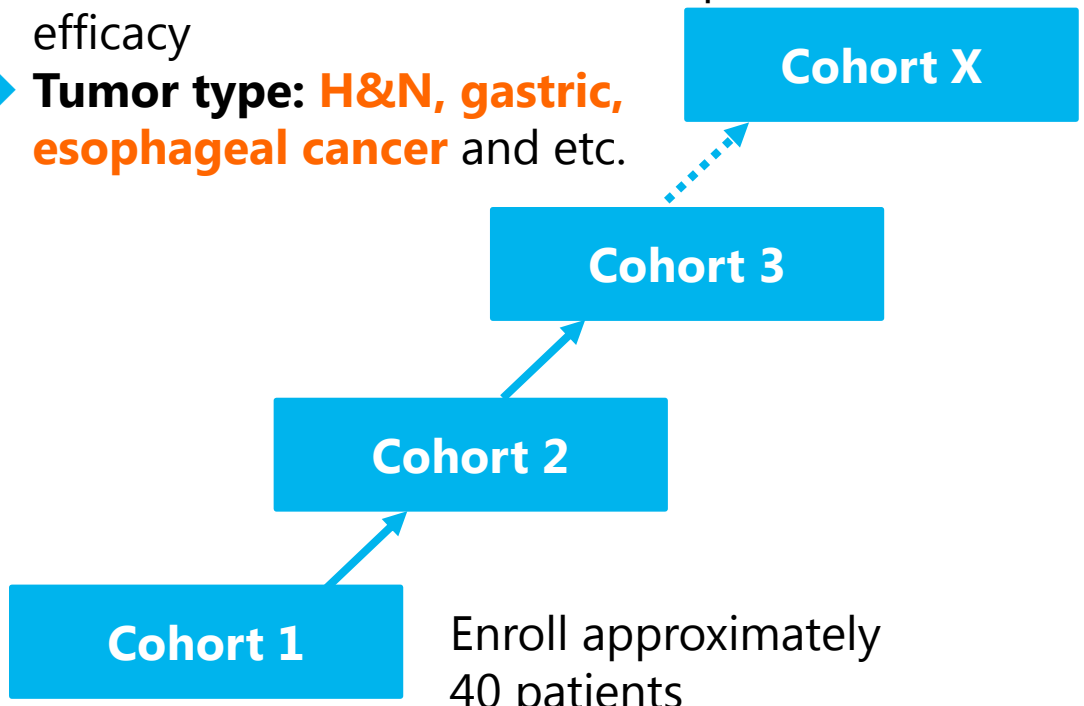


- **By recognizing GARP specifically expressed on activated Treg cells and depleting activated Treg cells, Teff cells can work as its original nature (anti-tumor activity)**

DS-1055: FIH Phase 1 Study Design

Dose Escalation

- **Purpose:** Safety and tolerability, determine the recommended dose for dose expansion, initial efficacy
- **Tumor type:** **H&N, gastric, esophageal cancer** and etc.



Enroll approximately 40 patients

Dose Expansion

Choose recommended dose from appropriate cancer type from dose escalation part

- **Study started in Oct. 2020**
- **Combination with immune checkpoint inhibitor is under discussion**

JapicCTI-205292, NCT04419532

3 ADC Update

Alpha Update

News flow

News Flow

As of October 2020

Daiichi-Sankyo

Trastuzumab deruxtecan (DS-8201)	Phase 2 pivotal DESTINY-Breast01: HER2 positive BC, 3L • **Updated data planned for SABCS in Dec. 2020** • EU: Approval anticipated in FY2020 Q4 Phase 2 pivotal DESTINY-Gastric01: HER2 positive GC, 3L • JP: **Approved in Sep. 2020** • US: **Submission accepted in Oct. 2020 (PDUFA Date: Feb. 28, 2021)**
DS-1062	Phase 1: NSCLC • Updated data planned for WCLC in Jan. 2021 Phase 1 TROPION-Lung02: NSCLC (without actionable mutation, pembrolizumab combo) • **Started study in Oct. 2020** **Phase 2 TROPION-Lung05: NSCLC (with actionable mutation)** • **Planned to start in FY2020 Q3**
Patritumab deruxtecan (U3-1402)	**Phase 2: EGFRm NSCLC** • **Planned to start in FY2020 H2** Phase 1: EGFRm NSCLC (osimertinib combo) • Planned to start in FY2020 H2 Phase 1/2: HER3 positive BC • Updated data planned for SABCS in Dec. 2020 Phase 2: CRC • **Started study in Sep. 2020**
Axicabtagene ciloleucel/ Axi-Cel™	Phase 2: R/R B-Cell Lymphoma • **Oct. 2020: presented JP phase 2 data at Japanese Society of Hematology** • JP: Approval anticipated in FY2020 Q3
DS-1647 (G47Δ)	Phase 2: Malignant glioma • JP: **NDA planned in FY2020 H2**

Underlined: New or Updated from FY2020 Q1

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

FY2020 R&D Day (Virtual Meeting)

Date and time	• Tuesday, Dec. 15th, 7:00-9:00pm (JST)
Presenters (Planned)	• Sunao Manabe, President and CEO • Antoine Yver, Global Head of Oncology R&D
Contents	• Data planned to be presented at SABCS 2020 (DS-8201, U3-1402) • ADC clinical development plan

1 Actions Against COVID-19

2 FY2020 Q2 Financial Results

3 FY2020 Forecast

4 Business Update

5 R&D Update

6 **Appendix**

Major R&D Milestones in FY2020 (3 ADCs)

As of October 2020

Daiichi-Sankyo

	Project	Target Indications and Studies	FY2020			
			Q1	Q2	Q3	Q4
3 ADC	DS-8201	P2 pivotal DESTINY-Breast01: HER2+ BC, 3L (JP/US/EU/Asia)	EU submitted			EU approval anticipated
		P2 pivotal DESTINY-Gastric01: HER2+ GC, 3L (JP/Asia)	JP submitted	JP approved	US sBLA accepted	US approval anticipated
		P2 HUDSON: NSCLC (durvalumab combo) (US/EU/Asia)	Study started			
		P1b/2 BEGONIA: TNBC (durvalumab combo) (US/EU/Asia)	Study started			
		P1: BC, NSCLC (pembrolizumab combo) (US/EU)	Study started			
		P1b/2 DESTINY-Gastric03: HER2+ GC, 2L~/1L (US/EU/Asia)	Study started			
		P3 DESTINY-Breast05: HER2+ BC, post neo-adjuvant (JP/US/EU/Asia)			Study start planned	
		P3 DESTINY-Breast06：HER2 low BC, chemotherapy naïve (JP/US/EU/Asia)		Study started		
		P1/2 DESTINY-Breast07: HER2+ BC combo, 3L~			Study start planned	
		P1 DESTINY-Breast08：HER2 low BC combo, 3L			Study start planned	
		P2 DESTINY-PanTumor02: HER2 expressing tumors (US/EU/Asia)		Study started		
	DS-1062	P1 TROPION-Lung02: NSCLC (without actionable mutation, pembrolizumab combo) (JP/US)			Study started	
		P2 TROPION-Lung05: NSCLC (with actionable mutation) (JP/US/EU/Asia)			Study start planned	
	U3-1402	P1: EGFRm NSCLC (osimertinib combo)			Study start planned	
		P2: EGFRm NSCLC			Study start planned	
		P2: CRC (JP/US/EU)		Study started		

Red underlined: new or updated from FY2020 Q1

BC: breast cancer, CRC: colorectal cancer, GC: gastric cancer, GIST: gastrointestinal stromal tumors, IIS: investigator-initiated study, NSCLC: non-small-cell lung cancer

Major R&D Milestones in FY2020 (Alpha)

As of October 2020

Daiichi-Sankyo

	Project	Target Indications and Studies	FY2020 Q1	FY2020 Q2	FY2020 Q3	FY2020 Q4
Alpha	**Pexidartinib**	P3 ENLIVEN: tenosynovial giant cell tumor (EU)	CHMP negative opinion			
	DS-1647	IIS: malignant glioma (JP)			→ **JP submission planned**	
	Axi-Cel™	P2 pivotal: R/R B-cell lymphoma (JP)			Approval anticipated	
	DS-6157	P1: GIST (JP/US)	Study started			
	DS-1055	**P1: Solid tumors (JP/US)**			**Study started**	
	Edoxaban	P3: atrial fibrillation in the very elderly (JP)	Obtained TLR	**JP Submitted**		
	Prasugrel	P3: ischemic stroke (JP)	Obtained TLR			JP Submission planned
	Mirogabalin	**P3: Central neuropathic pain (JP/Asia)**				**Data anticipated**
	DS-5141	P1/2: Duchenne type muscular dystrophy (JP)			Data anticipated	
	DS-5670	Clinical study: COVID-19 vaccine (JP)				Study start planned
	DS-2319	Clinical study: COVID-19 (JP)				Study start planned

Red underlined: new or updated from FY2020 Q1

BC: breast cancer, CRC: colorectal cancer, GC: gastric cancer, GIST: gastrointestinal stromal tumors, IIS: investigator-initiated study, NSCLC: non-small-cell lung cancer

Major R&D Pipeline: 3 ADCs

As of October 2020

Daiichi-Sankyo

Phase 1		Phase 2	Phase 3	Submitted
U3-1402 (JP/US) HER3+BC	**DS-8201** (US/EU) BC, bladder cancer (nivolumab combo)	**DS-8201** (JP/US/EU) HER2+/m NSCLC DESTINY-Lung01	**DS-8201** (JP/US/EU/Asia) HER2+BC, 3L DESTINY-Breast02	**DS-8201** (US) HER2+GC, 3L DESTINY-Gastric01
U3-1402 (JP/US/EU/Asia) NSCLC	**DS-8201** (US/EU) BC, NSCLC (pembrolizumab combo)	**DS-8201** (JP/US/EU) HER2+ CRC DESTINY-CRC01	**DS-8201** (JP/US/EU/Asia) HER2+BC, 2L DESTINY-Breast03	**DS-8201** (EU) HER2+BC, 3L DESTINY-Breast01
DS-1062 (JP/US) NSCLC, TNBC	**DS-8201** (US/EU/Asia) HER2+ GC combo, 2L~/1L DESTINY-Gastric03	**DS-8201** (US/EU) HER2+GC, 2L DESTINY-Gastric02	**DS-8201** (JP/US/EU/Asia) HER2 low BC, Post Chemo DESTINY-Breast04	
DS-1062 (JP/US) NSCLC (without actionable mutation, pembrolizumab combo) TROPION-Lung02		**DS-8201** (US/EU/Asia) NSCLC (durvalumab combo) HUDSON	**DS-8201** (JP/US/EU/Asia) HER2 low BC, chemo naive DESTINY-Breast06	
		DS-8201 (US/EU/Asia) TNBC (durvalumab combo) BEGONIA		
		DS-8201 (US/Asia) HER2 expressing tumors DESTINY-PanTumor02		
		U3-1402 (JP/US/EU) HER3+ CRC		

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

Major R&D Pipeline: Alpha

As of October 2020

Daiichi-Sankyo

Phase 1	Phase 2	Phase 3	Submitted
DS-7300 (JP/US) B7-H3-directed ADC Solid tumors	**DS-3201** (JP/US) EZH1/2 inhibitor Non-Hodgkin's Lymphomas (PTCL)	**DS-1647 (G47Δ)** (JP) Oncolytic HSV-1 Malignant glioma IIS	**Quizartinib** (JP/US/EU/Asia) FLT3 inhibitor AML, 1L	**Axicabtagene ciloleucel Axi-Cel™** (JP) Anti CD19 CAR-T cells R/R B-cell lymphoma
DS-6157 (JP/US) GPR20-directed ADC GIST	**DS-3201** (US) EZH1/2 inhibitor AML, ALL	**DS-3201** (JP) EZH1/2 inhibitor ATL/L	**Prasugrel** (JP) ADP receptor inhibitor Ischemic stroke	**VN-0107/MEDI3250** (JP) live attenuated influenza vaccine nasal spray
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	**PLX2853** (US) BET inhibitor AML	**DS-1001** (JP) Mutant IDH1 inhibitor Glioma	**Mirogabalin** (JP/Asia) $\alpha_2\delta$ Ligands Central neuropathic pain	**Edoxaban** (JP) FXa inhibitor AF in the very elderly
DS-2741 (JP) Anti-Orai1 antibody Atopic dermatitis	**PLX2853** (US) BET inhibitor Solid tumors	**DS-5141** (JP) ENA oligonucleotide DMD	**Esaxerenone** (JP) MR blocker Diabetic nephropathy	
	DS-1211 (US) TNAP inhibitor Pseudoxanthoma elasticum		**VN-0102/JVC-001** (JP) Measles mumps rubella combined vaccine	

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)

Projects for Out-Licensing

As of October 2020

Daiichi-Sankyo

Preclinical	Phase 1
DS-2087 Exon 20 insertion mutant EGFR/HER2 inhibitor NSCLC with EGFR/HER2 exon 20 insertion mutation **Global**	**DS-2969** GyrB inhibitor *Clostridium difficile* infection **Global**

Oncology Specialty medicine

- Out-licensed projects
  - DS-1205: to AnHeart Therapeutics
  - DS-1001: to AnHeart Therapeutics (regions other than Japan)
  - DS-3032: to Rain Therapeutics

NSCLC: non-small cell lung cancer

Abbreviations

Abbreviations	English	Implications
AE	Adverse event	Undesirable experience associated with the use of a medical product in a patient
BTD	Breakthrough therapy designation	Designation granted by US FDA that expedites drug development
CR	Complete response	Complete response (complete resolution of cancer)
DCR	Disease control rate	Disease control rate (percentage of patients with controlled disease status)
DLT	Dose limiting toxicity	Dose-limiting toxicities (toxicities that may explain the inability to escalate doses)
DOR	Duration of response	Length of time that a tumor responds to treatment
EGFR	Epidermal growth factor receptor	Epidermal growth factor receptor
ILD	Interstitial lung disease	Interstitial lung disease
MTD	Maximum tolerated dose	The highest dose of a drug or treatment that does not cause unacceptable side effects
ORR	Overall response rate Objective response rate	Overall response rate (expressed as the proportion of patients who responded to treatment and the sum of CR and PR)
OS	Overall survival	Overall survival (time from start of treatment to death)
PD	Progressive disease	Disease progression (worsening disease despite treatment)
PFS	Progression-free survival	Progression-free survival (without cancer progression)
PR	Partial response	Partial response (a reduction in the size of the cancer by 30% or more that lasts for 4 weeks)
SD	Stable disease	The size of the cancer is almost unchanged before and after treatment
TEAE	Treatment emergent adverse event	Any event not present prior to the initiation of the treatments or any event already present that worsens in either intensity or frequency following exposure to the treatments

Contact information regarding this material

Daiichi Sankyo Co., Ltd.
Corporate Communications Department
TEL: +81-3-6225-1126
Email: DaiichiSankyoIR@daiichisankyo.co.jp