

FY2020 Q2 Financial Results Presentation

DAIICHI SANKYO CO., LTD.

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President and CEO

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◆ 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.

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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	USD/JPY	108.63	106.92	-1.71
Rate	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)

FY2019 Results

479.6

Japan

(incl. Vaccines, OTC)

10.5

Daiichi Sankyo, Inc.
(US)

9.0

American Regent
(US)

8.4

Daiichi Sankyo
Europe

11.1

ASCA

(Asia, South and Central
America)

2.3

Trastuzumab Deruxtecan,
DS-1062

Upfront Payment &
Regulatory Milestone

1.5

Forex Impact*

4.4

FY2020 Results

480.2

Positive Factors Negative Factors

Positive Factors

Negative Factors

Japan

Tarlige +5.8

Memary -10.8

Lixiana -3.5

Daiichi Sankyo Espha +2.9
Memantine AG, Ezetimibe AG etc.

Vaccines business -5.1
ActHIB

Daiichi Sankyo Healthcare ... -1.0
Lulu

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

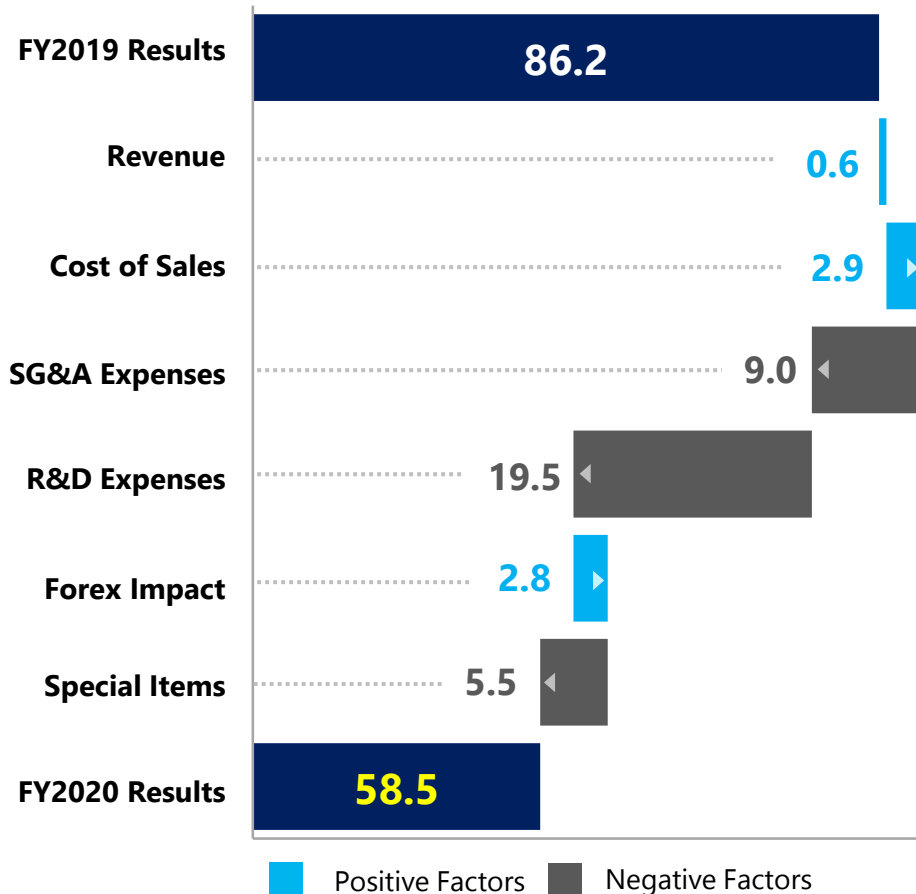
Trastuzumab Deruxtecan, DS-1062 Upfront Payment & Regulatory Milestone

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 Impairment loss (intangible assets) ^{*1} 3.8	-	-5.1
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 Morhabond, Roxybond

*2 Nihonbashi Building

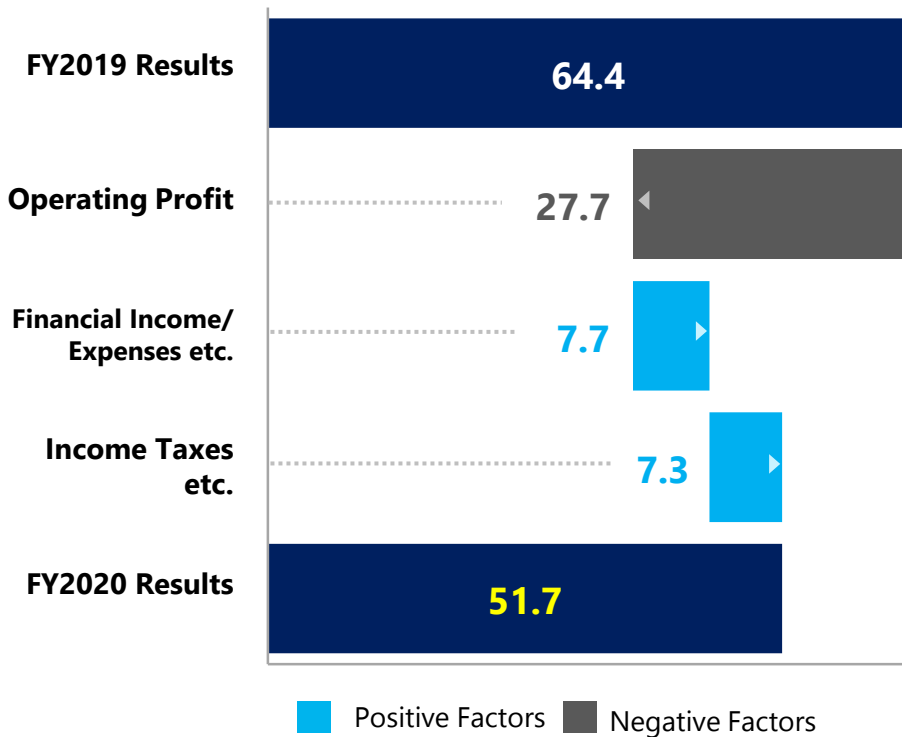
Special items :

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	USD/JPY	108.63	106.92	-1.71
Rate	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

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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	USD/円	110.00	108.46	-1.54
Rate	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)		<Reference> Total Consideration (Received/ Receivable)
				vs. Forecast (as of April)	
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.

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ENHERTU

Edoxaban

Japan Business

Shareholder Returns

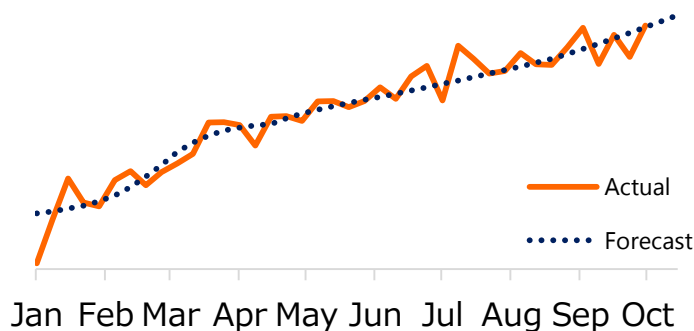
ENHERTU: Performance in US and Japan

◆ 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)>

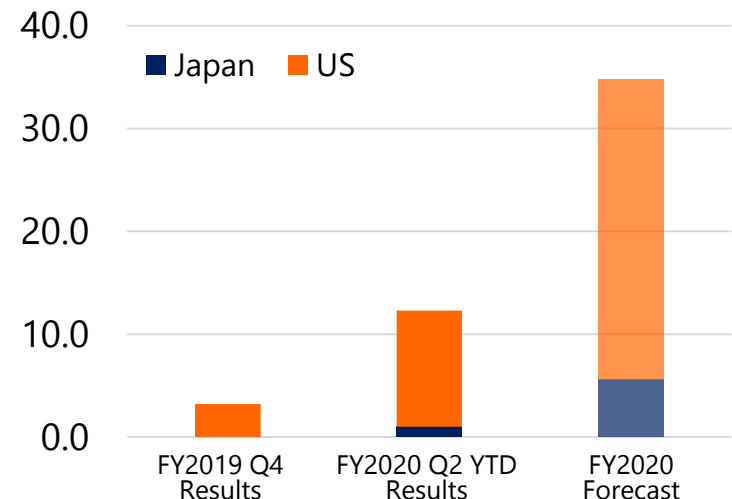
US

- 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

Revenue (Bn JPY)



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

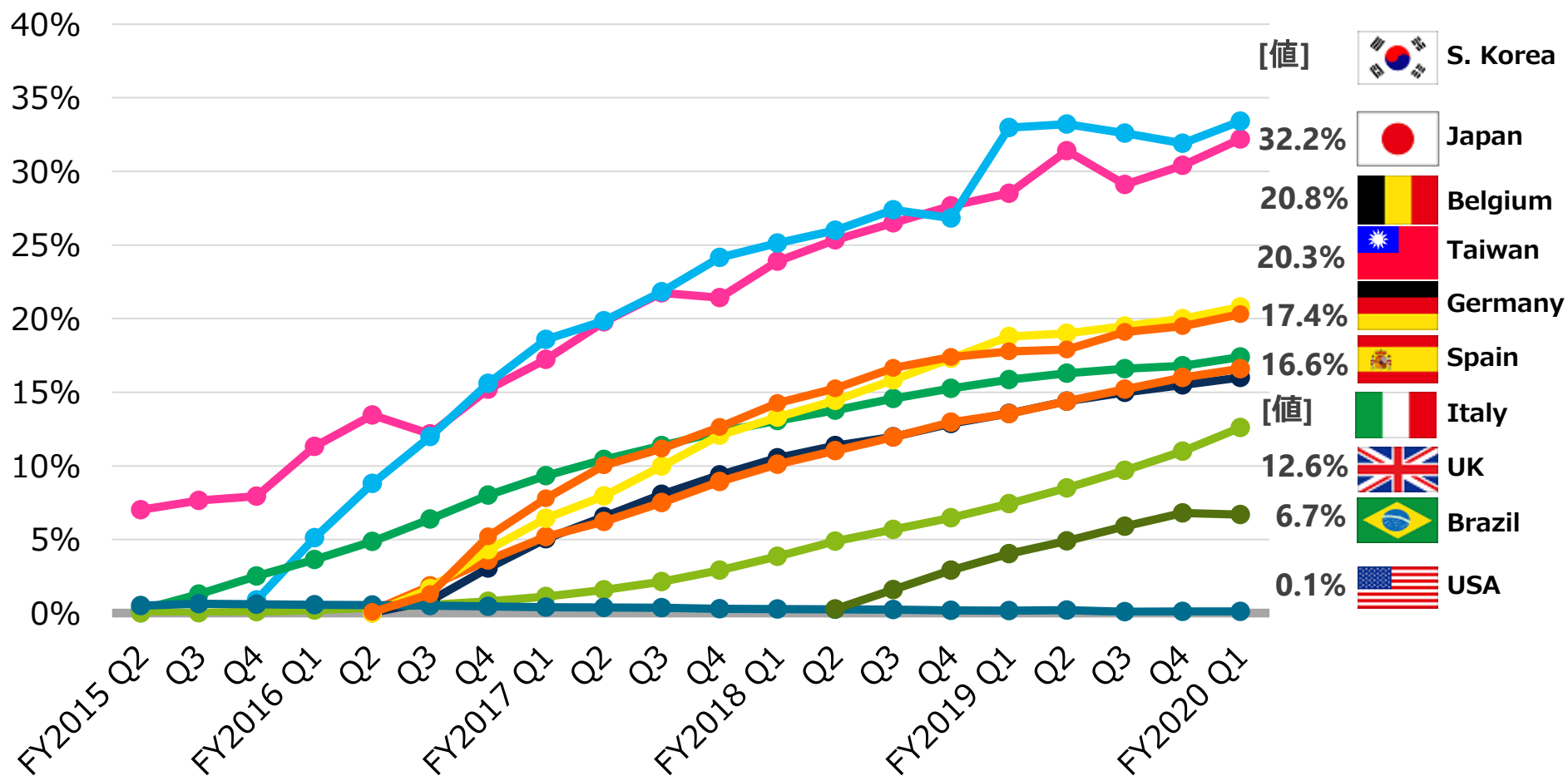
Shareholder Returns

Edoxaban: Growth in Each Country

Volume



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

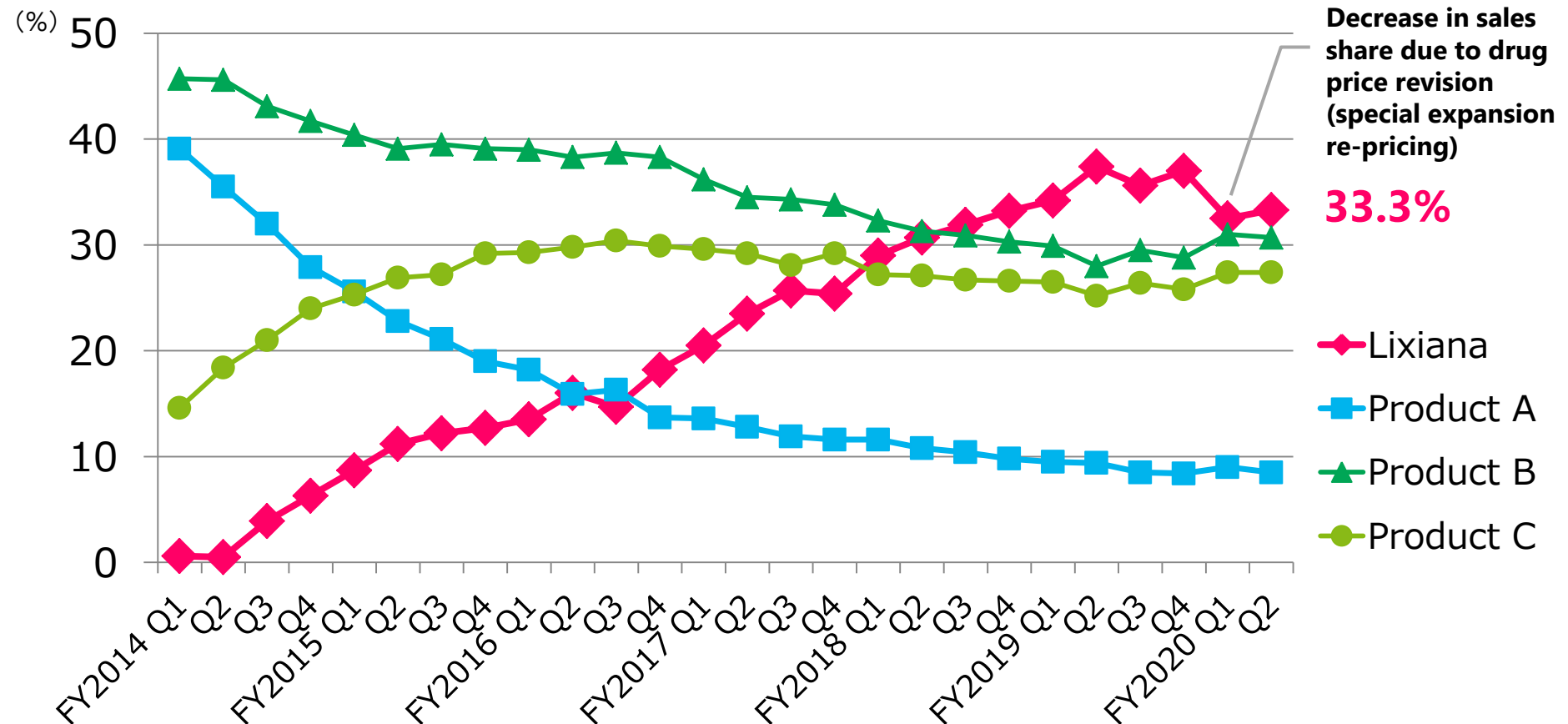


Lixiana: Growth in Japan

Sales



- ◆ 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**

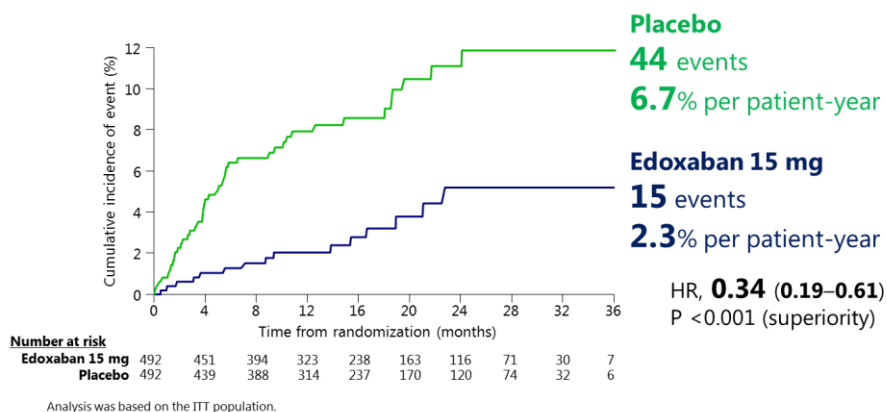


Edoxaban: Results of ELDERCARE-AF

ELDERCARE-AF

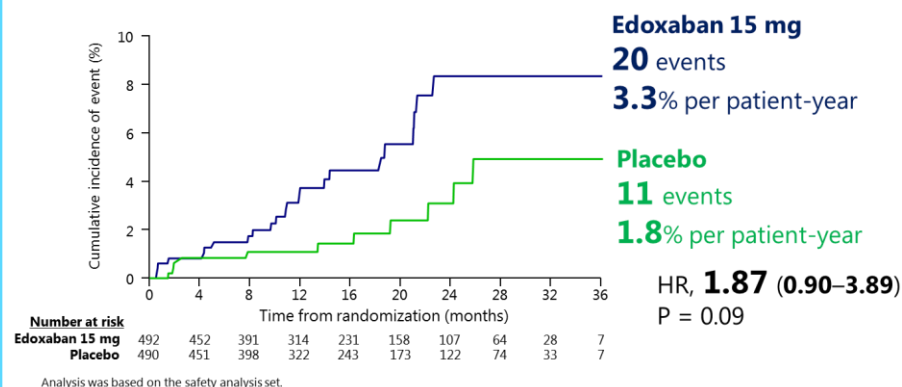
A study comparing efficacy and safety of edoxaban 15 mg/day with placebo in Japanese non-valvular AF patients who are very elderly (80 years or older) at high risk of bleeding

◆ Efficacy



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

◆ Safety



- ◆ 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

ENHERTU

Edoxaban

Japan Business

Shareholder Returns

- ◆ **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

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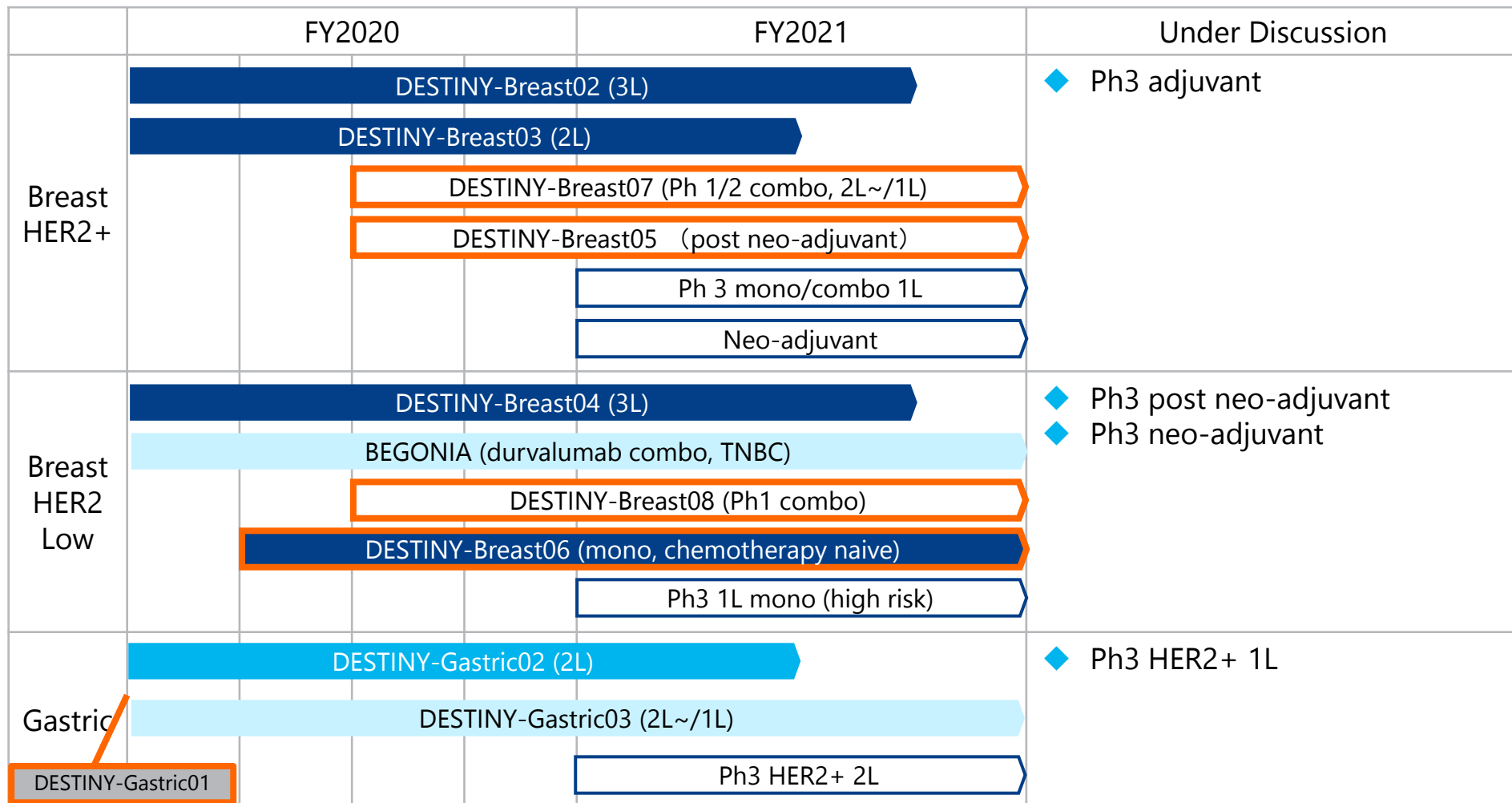
3 ADC Update

Alpha Update

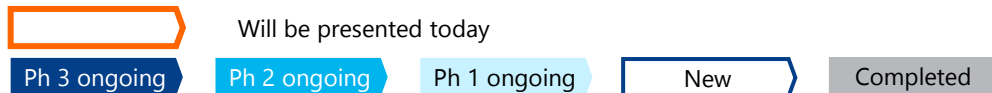
News flow

DS-8201: Clinical Development Plan

As of October 2020



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



DS-8201: Clinical Development Plan

As of October 2020



	FY2020	FY2021	Under Discussion
NSCLC	DESTINY-Lung01 (2L)		◆ Ph3 stage III combo
	HUDSON (durvalumab combo)		
	Ph2 HER2 mutation 2L		
	Ph1 HER2+ combo		
	Ph3 HER2+ 2L		
	Ph3 HER2+ 1L combo		
CRC	DESTINY-CRC01 (3L)		◆ Ph3 2L combo ◆ Ph3 1L combo ◆ Ph3 adjuvant combo
	Ph2 3L mono		
	Ph1/2 3L combo		
Others	Nivolumab combo (BC, bladder cancer)		◆ Ph2 ovarian mono/combo
	Pembrolizumab combo (BC, NSCLC)		
	DESTINY-PanTumor02 (HER2+ tumor agnostic)		
	Ph2 HER2 mutation tumor agnostic		

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

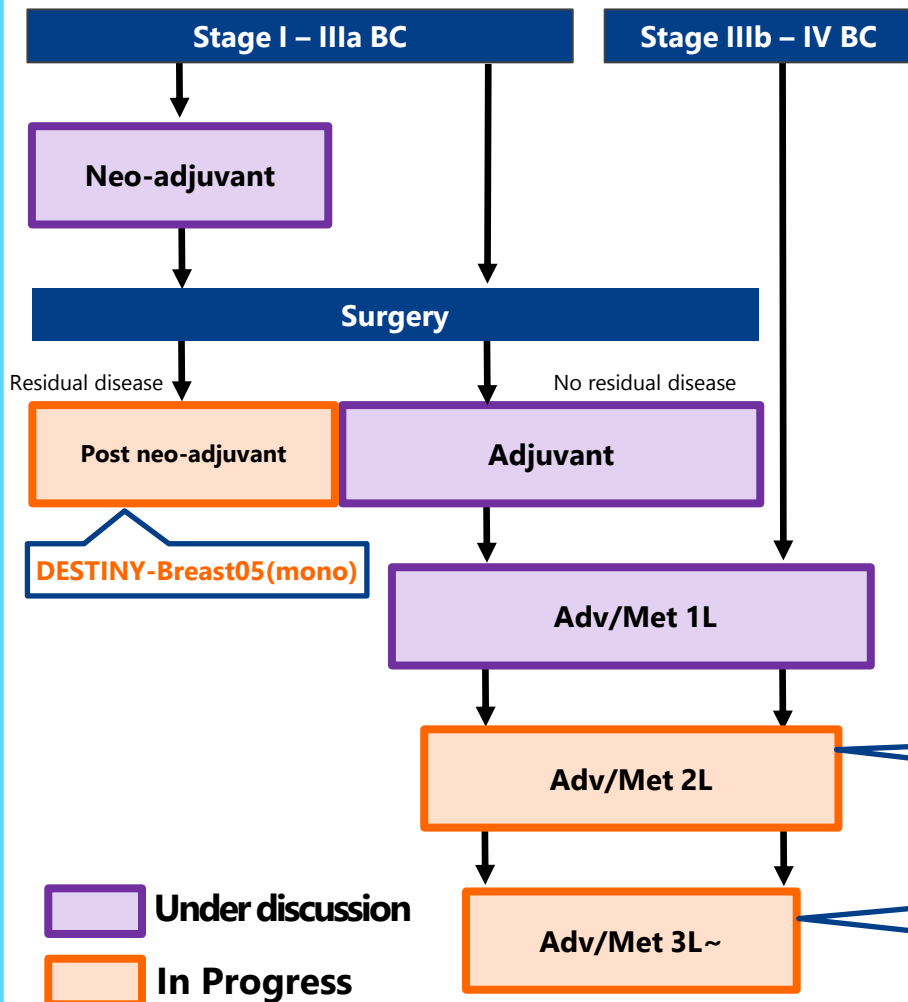
Ph 2 ongoing

Ph 1 ongoing

New

Completed

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



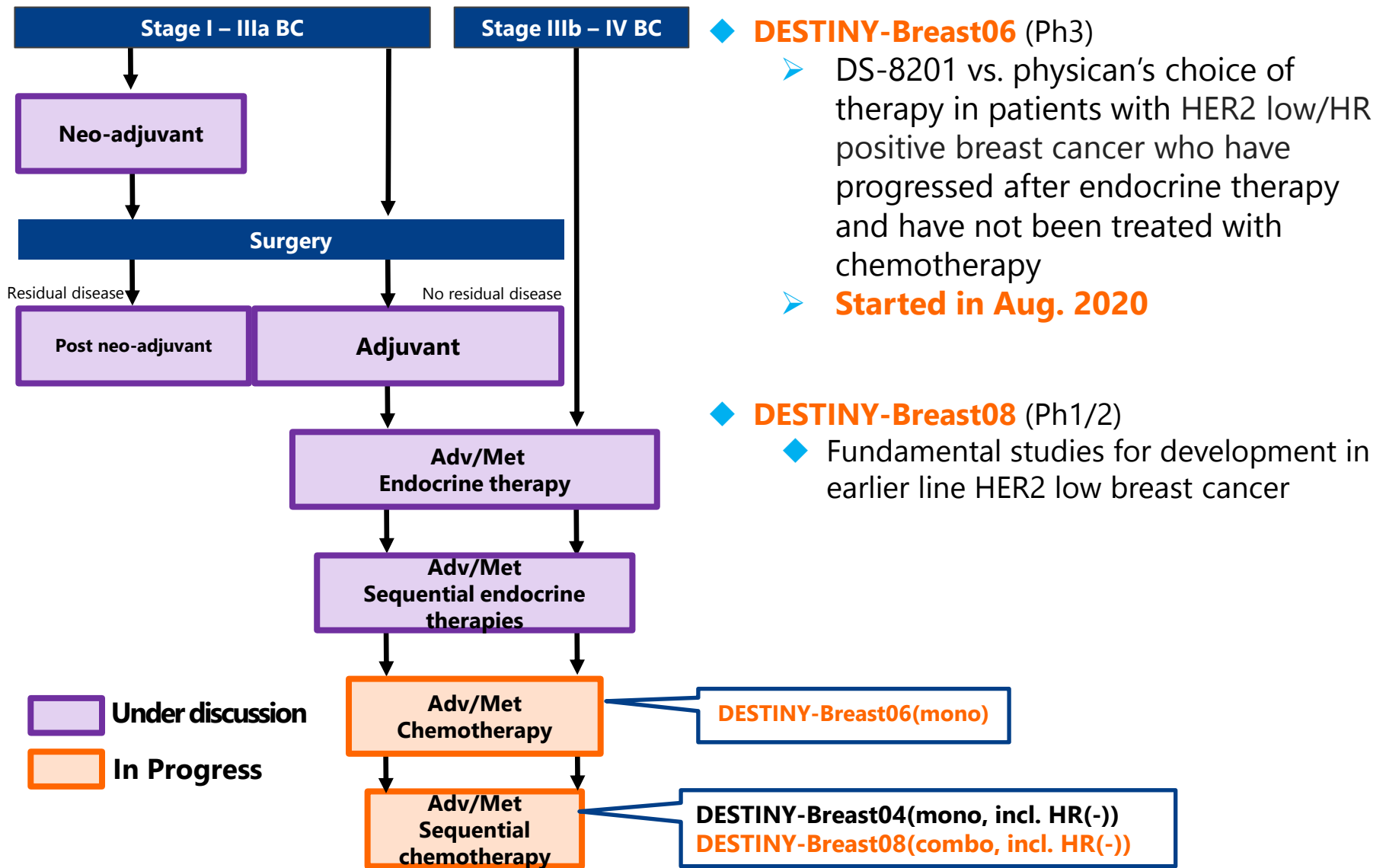
◆ DESTINY-Breast05 (Ph3)

- 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)



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

◆ 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; <i>P</i> < .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.

^aComparison 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

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

◆ Safety

Adverse Events (≥ 20% in either cohort)

Preferred Term, n (%)	Cohort 1 IHC 2+/ISH- (n = 20)		Cohort 2 IHC 1+ (n = 24)	
	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:

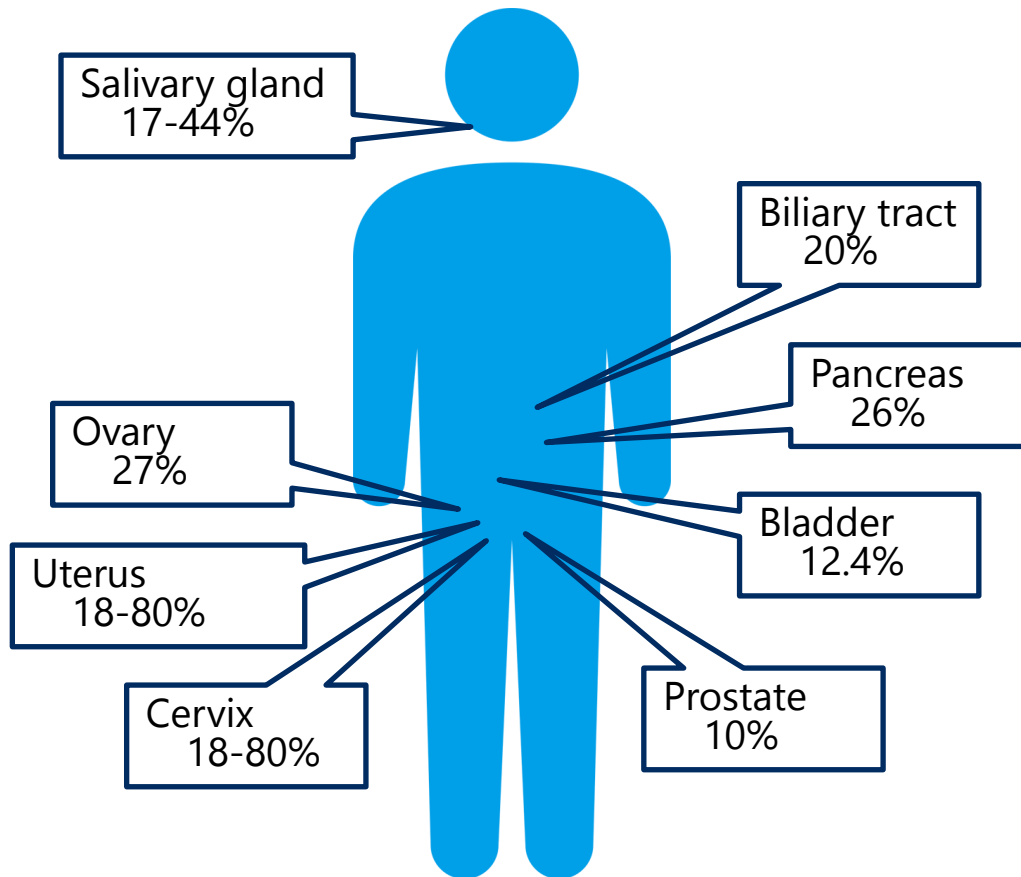
	Cohort 1 IHC 2+/ISH- (n = 20)	Cohort 2 IHC 1+ (n = 24)
Drug discontinuation, %	10	4
Dose reduction, %	30	33
Dose interruption, %	40	42

- 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

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**

N = 49^a
Median follow-up: 5 months

Best change in SoD from baseline, %

- Confirmed CR
- Confirmed PR
- Unconfirmed PR
- + Treatment ongoing (27 of 49 patients [55%])

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.

⁴Performed centrally using OncoPrint™ 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.

- ESMO 2020

U3-1402: EGFRm NSCLC Phase 1 Study

◆ Efficacy

Activity according to BICR evaluation (efficacy-evaluable population) N = 56^a

Confirmed BOR, n/N (%)

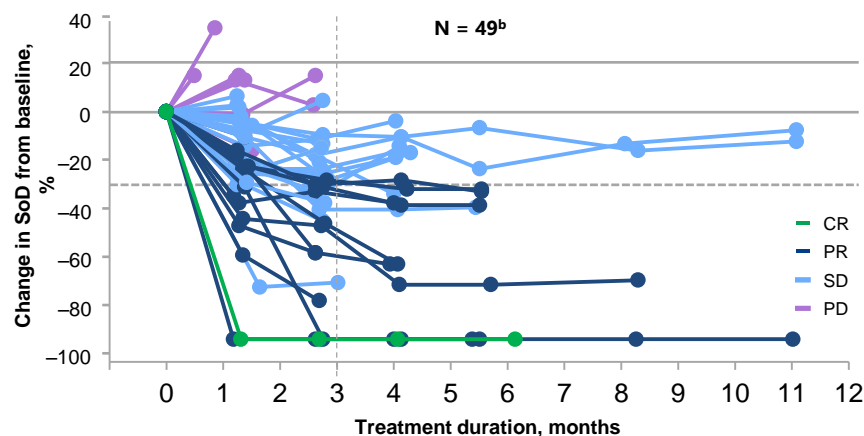
CR	1/56 (2%)
PR	13/56 (23%)
SD	25/56 (45%)
PD	9/56 (16%)
NE	8/56 (14%)

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)

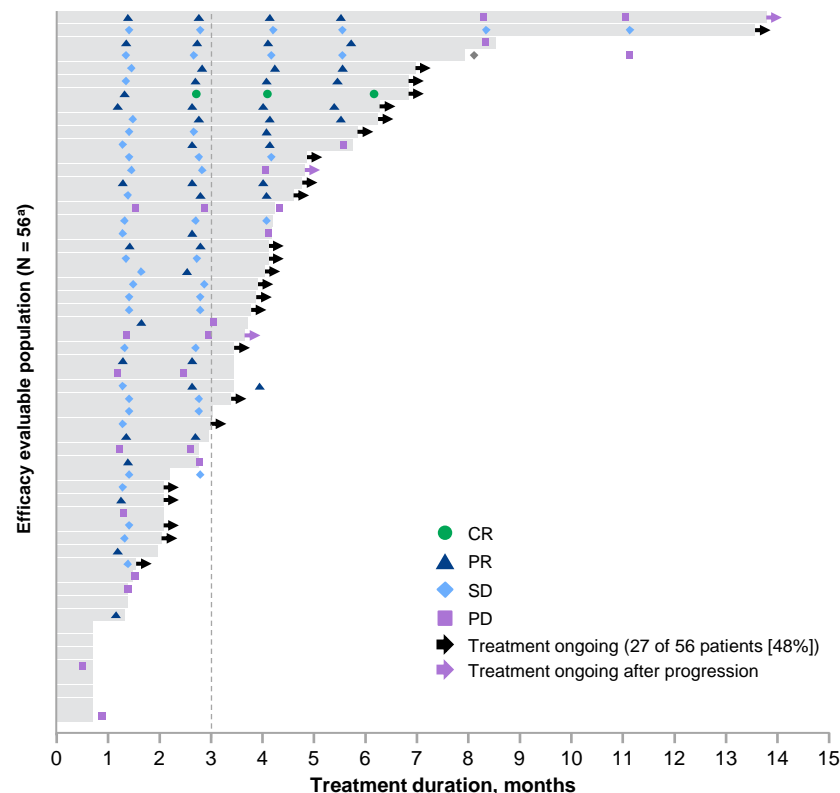
Median TTR, months (range) 2.0 (1.2-2.8)

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.

^aOf 56 patients, 22 (39%) had best percentage decrease in sum of tumor diameters $\geq 30\%$. ^bThis 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 in $\geq 20\%$ of patients, n (%)	N = 57	
			All grades	Grade ≥ 3
TEAEs	57 (100)	Fatigue	33 (58)	5 (9)
Grade ≥ 3	38 (67)	Nausea	31 (54)	2 (4)
Associated with discontinuation	5 (9)	Thrombocytopenia^a	30 (53)	16 (28)
Associated with dose reduction	10 (18)	Decreased appetite	20 (35)	1 (2)
Associated with dose interruption	17 (30)	Neutropenia^b	19 (33)	11 (19)
Associated with death	3 (5)	Vomiting	17 (30)	1 (2)
Treatment-emergent SAEs	21 (37)	Alopecia	17 (30)	NA
Grade ≥ 3	18 (32)	Anemia^c	15 (26)	5 (9)
Treatment related	11 (19)	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.

^aThrombocytopenia includes decreased platelet count and thrombocytopenia. ^bNeutropenia includes decreased neutrophil count and neutropenia. ^cAnemia includes decreased hemoglobin, decreased red blood cell count, anemia, and decreased hematocrit.

◆ Continued to demonstrated a manageable safety profile

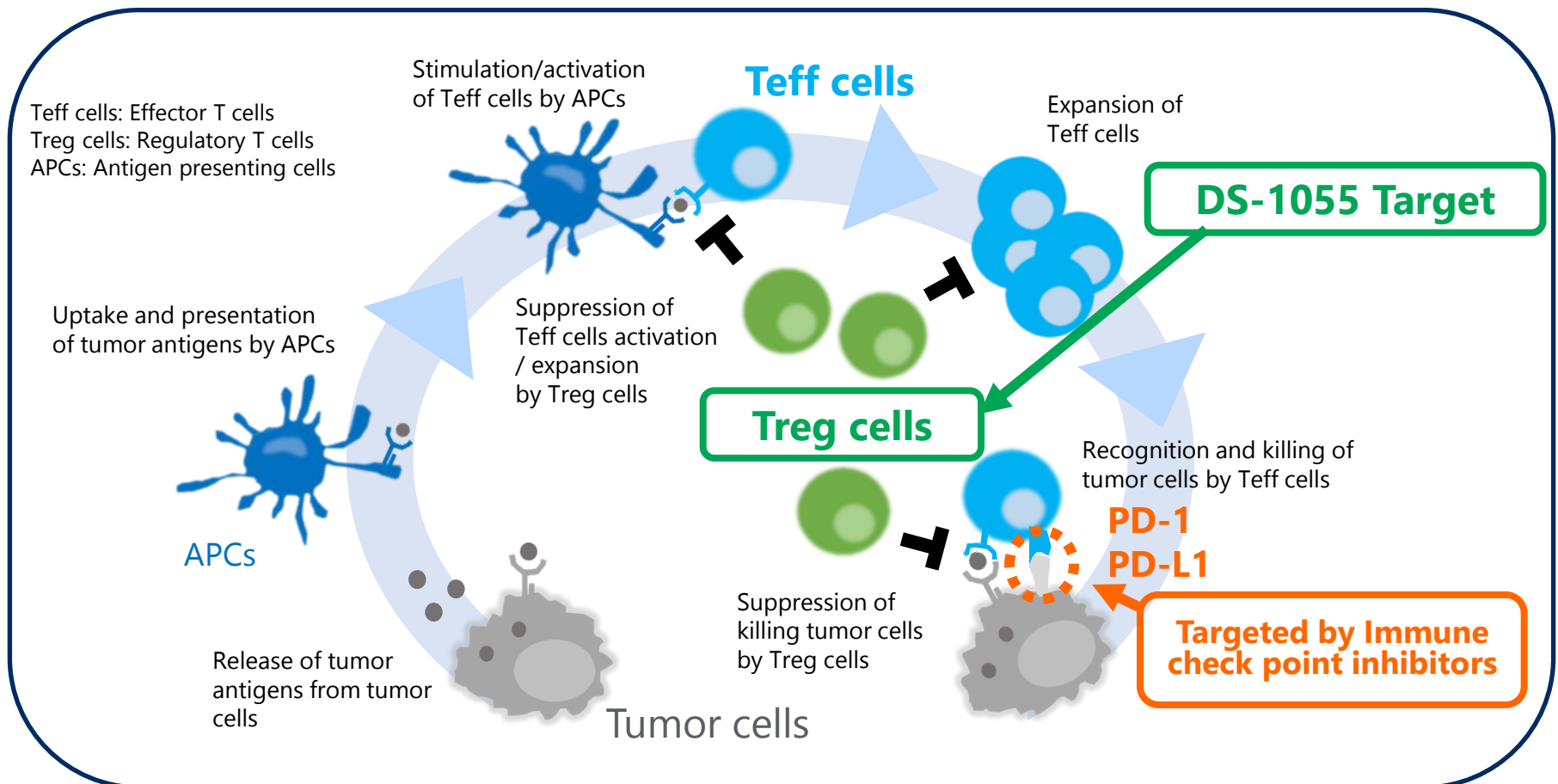
3 ADC Update

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



DS-1055: MOA of Anti-GARP Antibody

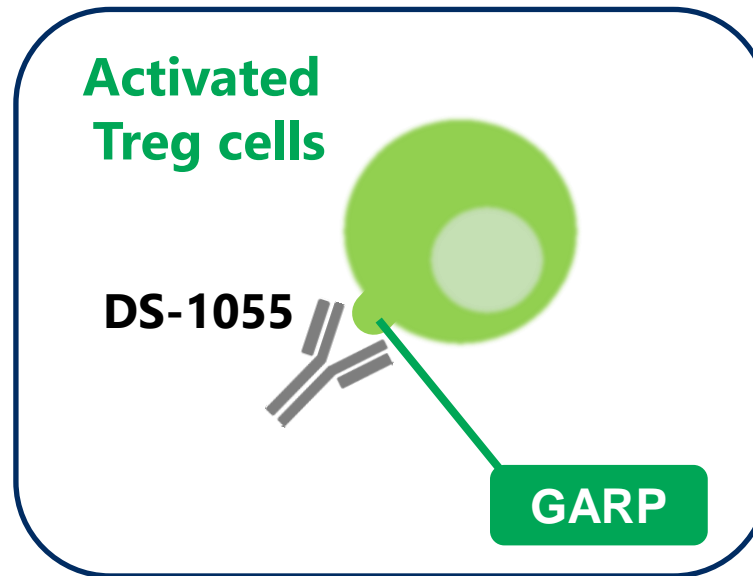
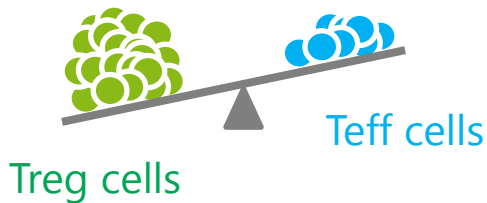
Treg cells > Teff cells

Immune escape of tumor
by suppression of Treg cells



Treg cells < Teff 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.

Cohort X

Cohort 3

Cohort 2

Cohort 1

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**

3 ADC Update

Alpha Update

News flow

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


	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	<u>JP approved</u>	<u>US sBLA accepted</u>	<u>US approval anticipated</u>
		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	
		<u>P3 DESTINY-Breast06 : HER2 low BC, chemotherapy naïve (JP/US/EU/Asia)</u>		<u>Study started</u>		
		<u>P1/2 DESTINY-Breast07: HER2+ BC combo, 3L~</u>			<u>Study start planned</u>	
		<u>P1 DESTINY-Breast08 : HER2 low BC combo, 3L</u>			<u>Study start planned</u>	
		<u>P2 DESTINY-PanTumor02: HER2 expressing tumors (US/EU/Asia)</u>		<u>Study started</u>		
	DS-1062	P1 TROPION-Lung02: NSCLC (without actionable mutation, pembrolizumab combo) (JP/US)			<u>Study started</u>	
		<u>P2 TROPION-Lung05: NSCLC (with actionable mutation) (JP/US/EU/Asia)</u>			<u>Study start planned</u>	
3 ADC	U3-1402	P1: EGFRm NSCLC (osimertinib combo)			Study start planned	
		<u>P2: EGFRm NSCLC</u>			<u>Study start planned</u>	
		P2: CRC (JP/US/EU)		<u>Study started</u>		

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

	Project	Target Indications and Studies	FY2020			
			Q1	Q2	Q3	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	<u>P1: Solid tumors (JP/US)</u>			<u>Study started</u>	
	Edoxaban	P3: atrial fibrillation in the very elderly (JP)	Obtained TLR	<u>JP Submitted</u>		
	Prasugrel	P3: ischemic stroke (JP)	Obtained TLR			JP Submission planned
	Mirogabalin	<u>P3: Central neuropathic pain (JP/Asia)</u>				<u>Data anticipated</u>
	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

Phase 1

U3-1402 (JP/US)
HER3+BC

U3-1402 (JP/US/EU/Asia)
NSCLC

DS-1062 (JP/US)
NSCLC, TNBC


DS-1062 (JP/US)
NSCLC (without actionable
mutation, pembrolizumab
combo)
TROPION-Lung02

DS-8201 (US/EU)
BC, bladder cancer
(nivolumab combo)

DS-8201 (US/EU)
BC, NSCLC (pembrolizumab
combo)

DS-8201 (US/EU/Asia)
HER2+ GC combo, 2L~1L
DESTINY-Gastric03

Phase 2

DS-8201 (JP/US/EU)
HER2+/m NSCLC
DESTINY-Lung01 

DS-8201 (JP/US/EU)
HER2+ CRC
DESTINY-CRC01

DS-8201 (US/EU)
HER2+GC, 2L
DESTINY-Gastric02

DS-8201 (US/EU/Asia)
NSCLC (durvalumab combo)
HUDSON

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

Phase 3



DS-8201 (JP/US/EU/Asia)
HER2+BC, 3L
DESTINY-Breast02

DS-8201 (JP/US/EU/Asia)
HER2+BC, 2L
DESTINY-Breast03


DS-8201 (JP/US/EU/Asia)
HER2 low BC, Post Chemo
DESTINY-Breast04


DS-8201 (JP/US/EU/Asia)
HER2 low BC, chemo naive
DESTINY-Breast06


Submitted

DS-8201 (US)
HER2+GC, 3L
DESTINY-Gastric01  



DS-8201 (EU)
HER2+BC, 3L
DESTINY-Breast01

 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

Phase 1

DS-7300 (JP/US)
B7-H3-directed ADC
Solid tumors

DS-6157 (JP/US)
GPR20-directed ADC
GIST

DS-1055 (JP/US)
Anti-GARP antibody
Solid tumors

DS-2741 (JP)
Anti-Orai1 antibody
Atopic dermatitis

DS-3201 (JP/US)
EZH1/2 inhibitor
Non-Hodgkin's
Lymphomas (PTCL)

DS-3201 (US)
EZH1/2 inhibitor
AML, ALL

PLX2853 (US)
BET inhibitor
AML

PLX2853 (US)
BET inhibitor
Solid tumors

DS-1211 (US)
TNAP inhibitor
Pseudoxanthoma elasticum

Phase 2

DS-1647 (G47Δ) (JP)
Oncolytic HSV-1
Malignant glioma
IIS

DS-3201 (JP)
EZH1/2 inhibitor
ATL/L

DS-1001 (JP)
Mutant IDH1 inhibitor
Glioma

DS-5141 (JP)
ENA oligonucleotide
DMD

Phase 3

Quizartinib (JP/US/EU/Asia)
FLT3 inhibitor
AML, 1L

Prasugrel (JP)
ADP receptor inhibitor
Ischemic stroke

Mirogabalin (JP/Asia)
 $\alpha_2\delta$ Ligands
Central neuropathic pain

Esaxerenone (JP)
MR blocker
Diabetic nephropathy

VN-0102/JVC-001 (JP)
Measles mumps rubella
combined vaccine

Submitted

Axicabtagene ciloleucel
Axi-Cel™ (JP)
Anti CD19 CAR-T cells
R/R B-cell lymphoma

VN-0107/MEDI3250 (JP)
live attenuated influenza
vaccine nasal spray

Edoxaban (JP)
FXa inhibitor
AF in the very elderly

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)

Preclinical

DS-2087

Exon 20 insertion mutant
EGFR/HER2 inhibitor
NSCLC with EGFR/HER2 exon 20
insertion mutation

Global

Phase 1

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

Abbreviations

Abbreviations	English	Implications
AE	Adverse event	Undesirable experience associated with the use of a medical product in a patient
BTB	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

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