Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2020 Q1
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Toshiaki Sai
Executive Vice President and CFO

July 31, 2020

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Agenda

1. **Actions Against COVID-19**
2. DS-1062 Strategic Collaboration
3. FY2020 Q1 Financial Results
4. FY2020 Forecast
5. Business Update
6. R&D Update
7. Appendix

Update on Actions Against COVID-19

Manufacturing, Supply of COVID-19 Vaccines

◆ Vaccine being developed by AstraZeneca and Oxford University

- Entered the agreement to proceed with discussions for supply in Japan
- Daiichi Sankyo Biotech plans to receive undiluted solution from AstraZeneca and carry out formulation procedures (vial filling, packaging, and storage)

Development of COVID-19 Vaccines and Therapeutics

◆ Genetic (mRNA) vaccination (DS-5670)

- Participating in fundamental research supported by AMED[*1] and taking part in development of genetic (mRNA) vaccine using Daiichi Sankyo's original novel nucleic acid delivery technology[*2]
- Confirmed an increase in antibody titers in animal experiments
- Clinical studies planned to be initiated around March 2021

◆ Nafamostat[*3] inhalation formulation (DS-2319)

- Collaborative R&D with the University of Tokyo, RIKEN, Nichi-Iko Pharmaceutical Co., Ltd for the treatment of COVID-19
- Daiichi Sankyo plans to carry out formulation research, non-clinical studies and clinical development using technology gained through the development of Inavir
- Formulation research and non-clinical studies initiated; plan to proceed to clinical studies by March 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 A treatment for acute pancreatitis and disseminated intravascular coagulation (injectable)

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DS-1062 Strategic Collaboration

Daiichi-Sankyo

- **Co-development and co-commercialization of DS-1062 with AstraZeneca**
  - **Maximize the value of DS-1062 by accelerating and expanding development**
  - Allocate resource rapidly with flexibility to DXd-ADC/Alpha portfolio

Development

- **Co-development** as monotherapy and combination therapy

- **Equally share development costs**
- Combination studies with other companies' products possible

Commercial

- **Commercial activities**
  - **Global (excluding Japan)**
    The companies will **co-promote** and **share profits**
  - **Japan**
    Daiichi Sankyo will **solely commercialize** and **pay royalty** to AstraZeneca
- **Sales booking**
  - **Daiichi Sankyo**
    Japan, US, certain countries in Europe and other markets with subsidiaries
  - **AstraZeneca**
    All other markets including China, Australia, Canada and Russia

Financial Terms

- Up to **US$ 6.0 Bn (660.0 Bn JPY*) in total**
  - Upfront payment
    US$ 1.0 Bn (110.0 Bn JPY*)
  - Regulatory milestones (max.)
    US$ 1.0 Bn (110.0 Bn JPY*)
  - Sales-related milestones (max.)
    US$ 4.0 Bn (440.0 Bn JPY*)
- **Revenue booking**
  - **Upfront payment, Regulatory milestones**
    Deferred and will be **booked considering the exclusivity period**
  - **Sales-related milestones booked in the year of achievement**

Manufacturing

- Daiichi Sankyo will manufacture DS-1062

* US$1= 110 JPY

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Overview of FY2020 Q1 Results

(Bn JPY)

	FY2019 Q1 Results	FY2020 Q1 Results	YoY	
Revenue	249.2	236.9	-4.9%	-12.3
Cost of sales	87.9	82.2		-5.7
SG&A expenses	63.2	71.8		8.6
R&D expenses	41.2	48.8		7.6
Operating Profit	57.0	34.1	-40.1%	-22.9
Profit before tax	57.1	41.4		-15.7
Profit attributable to owners of the Company	43.3	31.9	-26.5%	-11.5

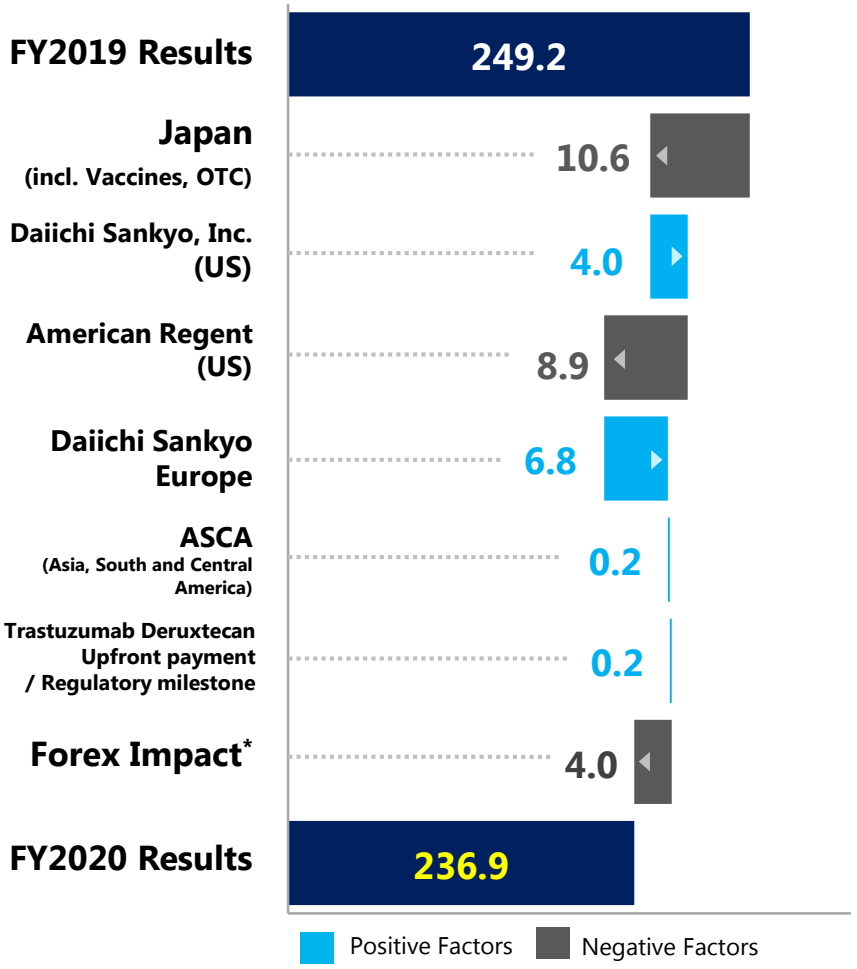
Currency Rate	USD/JPY	109.90	107.62	-2.28
	EUR/JPY	123.49	118.47	-5.02

Impact of COVID-19

- Decrease in sales of American Regent's injectable iron products and Daiichi Sankyo Healthcare products
- Decrease in expenses due to restrictions on sales promotion activities

Revenue

Decreased by 12.3 Bn JPY (Decreased by 8.3 Bn JPY excl. forex impact)



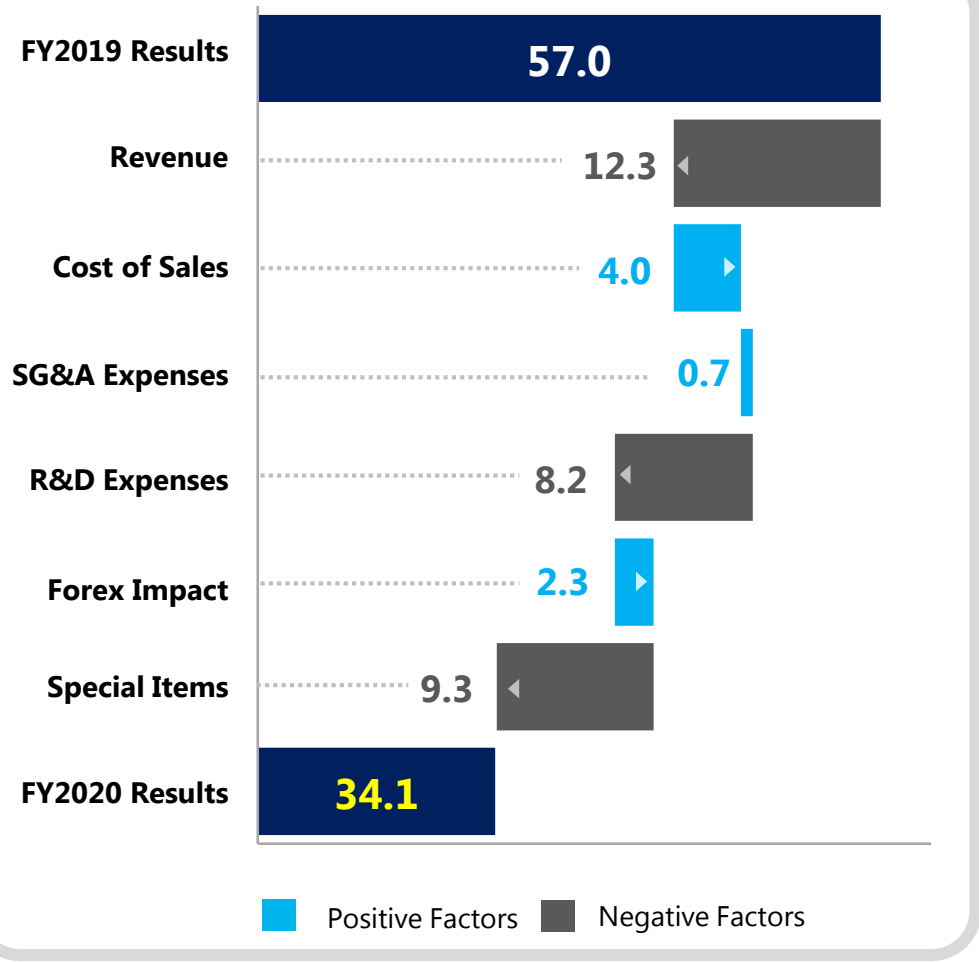
(Bn JPY)

Positive Factors		Negative Factors	
Japan			
Tarlige	+2.3	Nexium	-2.0
		Lixiana	-1.8
		Memary	-1.0
		Vaccines business ActHIB	-4.6
		Daiichi Sankyo Healthcare Lulu	-1.1
Daiichi Sankyo, Inc. (US)			
Enhertu	+5.0		
American Regent, Inc. (US)			
		Injectafer	-4.1
		Venofer	-2.2
		GE injectables	-2,4
Daiichi Sankyo Europe			
Lixiana	+3.6		
Gain on sales of transferring long-listed products	+4.3		

* Forex impact USD: -0.8, EUR : -1.2, ASCA: -2.0

Operating Profit

Decreased by 22.9 Bn JPY (Decreased by 12.0 Bn JPY excl. forex impact and special items)



(Bn JPY)

Revenue ····· **-12.3**
incl. forex impact of -40.0

Cost of Sales ····· **-4.0** **(Profit increased)**
Decrease by revenue decrease

SG&A Expenses ····· **-0.7** **(Profit increased)**
- Increase in Enhertu related expenses (sales promotion expenses and profit share with AstraZeneca)
- Decrease due to restrictions on sales promotion activities associated with COVID-19

R&D Expenses ····· **+8.2** **(Profit decreased)**
- Increase in 3 ADCs R&D investments
- Increase due to oncology development structure enhancement
- Decrease due to increase in trastuzumab deruxtecan cost share with AstraZeneca

Forex Impact ····· **-2.3** **(Profit increased)**
Cost of Sales ····· **-0.4**
SG&A Expenses ····· **-1.3**
R&D Expenses ····· **-0.6**

Special Items ····· **+9.3** **(Profit decreased)**
See next slide for details

Special Items

(Bn JPY)

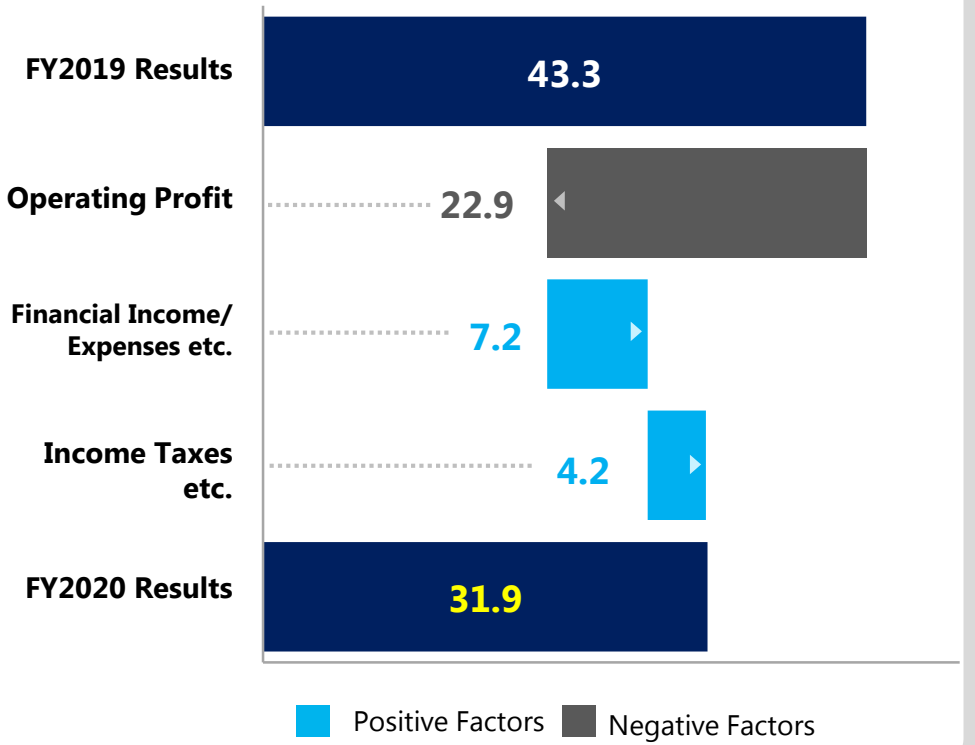
	FY2019 Q1 Results		FY2020 Q1 Results	YoY
Cost of sales	Restructuring costs in SC	1.3	-	-1.3
SG&A expenses	Gain on sales of fixed assets*	-10.6	-	10.6
R&D expenses		-	-	-
Total		-9.3	-	9.3

- : Cost decreased items　　* 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 11.5 Bn JPY



(Bn JPY)

Financial Income/ Expenses etc. ..... **-7.2 (Profit increased)**

- Recognition of financial income due to decrease in contingent consideration of quizartinib acquisition ..... -4.7
- Improvement in forex gains/losses ..... -3.2

Income Taxes etc. ..... **-4.2 (Profit increased)**

	FY2019 Q1 Results	FY2020 Q1 Results	YoY
Profit before Tax	57.1	41.4	-15.7
Income Taxes etc.	13.7	9.6	-4.2
Tax rate	24.1%	23.1%	-1.0%

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2019 Q1 Results	FY2020 Q1 Results	YoY
Japan	139.0	130.2	-8.8
Daiichi Sankyo Healthcare	15.4	14.3	-1.1
Daiichi Sankyo, Inc.	7.8	11.6	+3.7
Enhertu	-	5.0	+5.0
Olmesartan	3.1	3.7	+0.6
Welchol	2.6	0.6	-2.0
American Regent, Inc.	36.0	26.5	-9.5
Injectafer	13.7	9.4	-4.3
Venofer	9.3	6.9	-2.4
GE injectables	11.1	8.5	-2.6
Daiichi Sankyo Europe	22.1	27.7	+5.6
Lixiana	13.5	16.4	+2.9
Olmesartan	6.4	5.2	-1.1
Efient	0.8	0.3	-0.5
ASCA (Asia, South and Central America)	24.3	22.5	-1.8

Currency Rate	USD/JPY	109.90	107.62	-2.28
	EUR/JPY	123.49	118.47	-5.02

Revenue: Major Products in Japan

(Bn JPY)

		FY2019 Q1 Results	FY2020 Q1 Results	YoY
Nexium	ulcer treatment	**21.9**	**19.9**	**-2.0**
Lixiana	anticoagulant	**21.6**	**19.8**	**-1.8**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone	**8.2**	**8.7**	**+0.5**
Memary	Alzheimer's disease treatment	**13.7**	**12.8**	**-1.0**
Tenelia	type 2 diabetes mellitus treatment	**6.9**	**6.6**	**-0.3**
Loxonin	anti-inflammatory analgesic	**7.8**	**6.2**	**-1.6**
Ranmark	treatment for bone complications caused by bone metastases from	**4.7**	**5.0**	**+0.3**
Inavir	anti-influenza agent	**0.0**	**0.6**	**+0.6**
Tarlige	pain treatment	**2.0**	**4.3**	**+2.3**
Canalia	type 2 diabetes mellitus treatment	**3.2**	**3.9**	**+0.8**
Vimpat	anti-epileptic agent	**2.7**	**3.8**	**+1.1**
Efient	antiplatelet agent	**3.8**	**3.8**	**-0.0**
Rezaltas	antihypertensive agent	**4.2**	**3.6**	**-0.5**
Olmetec	antihypertensive agent	**3.5**	**2.7**	**-0.8**
Enhertu	anti-cancer agent (anti-HER2 antibody drug conjugate)	**-**	**0.2**	**+0.2**

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FY2020 Consolidated Forecast Update

Daiichi-Sankyo

- **No revision to the forecast announced in April 2020**
  - **No significant change on COVID-19 impact compared to the expectations announced in April**
  - **Impact of DS-1062 strategic collaboration is anticipated to be limited**

(Bn JPY)

	FY2020 Forecast
Revenue	**970.0**
Cost of sales	337.0
SG&A expenses	325.0
R&D expenses	228.0
Operating Profit	**80.0**

Impact of COVID-19

- The impact is not reflected in the forecast as it is difficult to forecast precisely at this point
- Assuming that global activity restrictions continue until the fourth quarter, the expectations are as follows
  - Negative impact on sales revenue of 2-4% (approx. 20.0-40.0 Bn JPY)
  - Expenses expected to be restrained due to an impact on business activities
  - Minor impact on operating income

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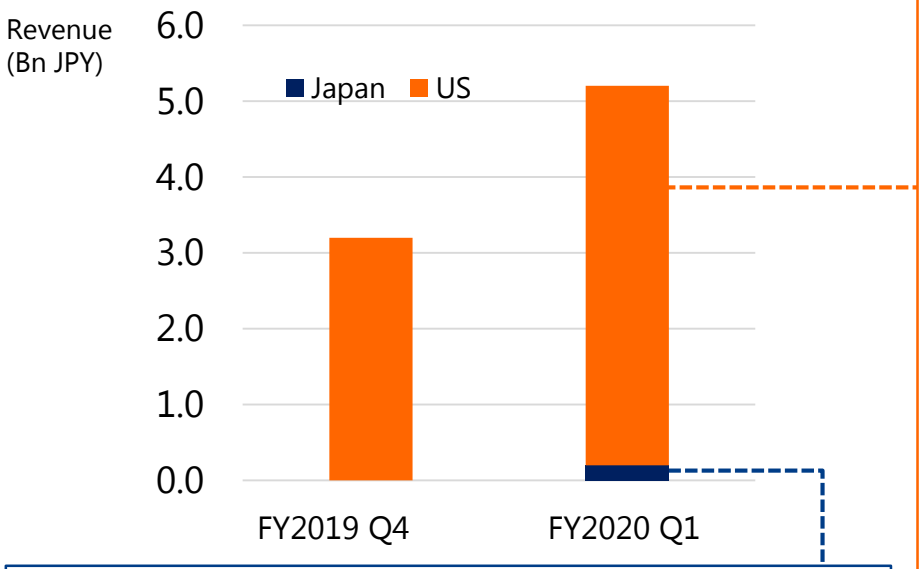
ENHERTU: Performance in US and Japan

Strong market penetration

- **FY2020 Q1 revenue results**

US: 5.0 Bn JPY (FY2019 Q4 revenue was 3.2 Bn JPY) **Japan: 0.2 Bn JPY**

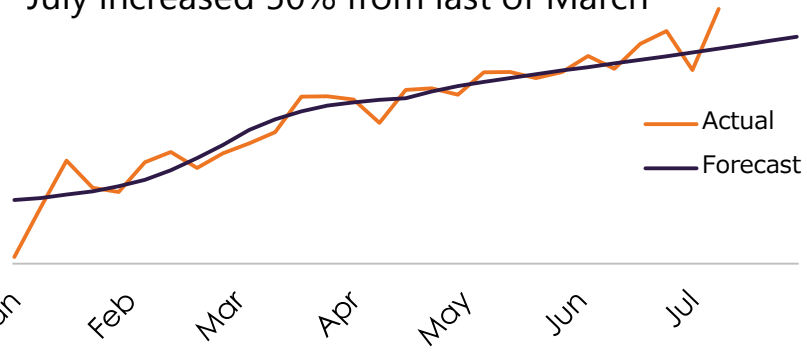


Japan

- Launched in May 2020
- Providing product information with the highest priority on safety
- ENHERTU delivered only to medical institutions that meet doctor and facility requirements

US

- Total number of unique outlets purchasing ENHERTU since launch is approx. 1,300, and number of repeat outlets is approx. 1,000
- Encouraging increase for demand units
  - ✓ ENHERTU demand units shipped to account in July increased 50% from last of March



- Increasing new patient share
  - ✓ Around 40% share for new patients in HER2+ breast cancer 3L setting (FY2020 Q1)

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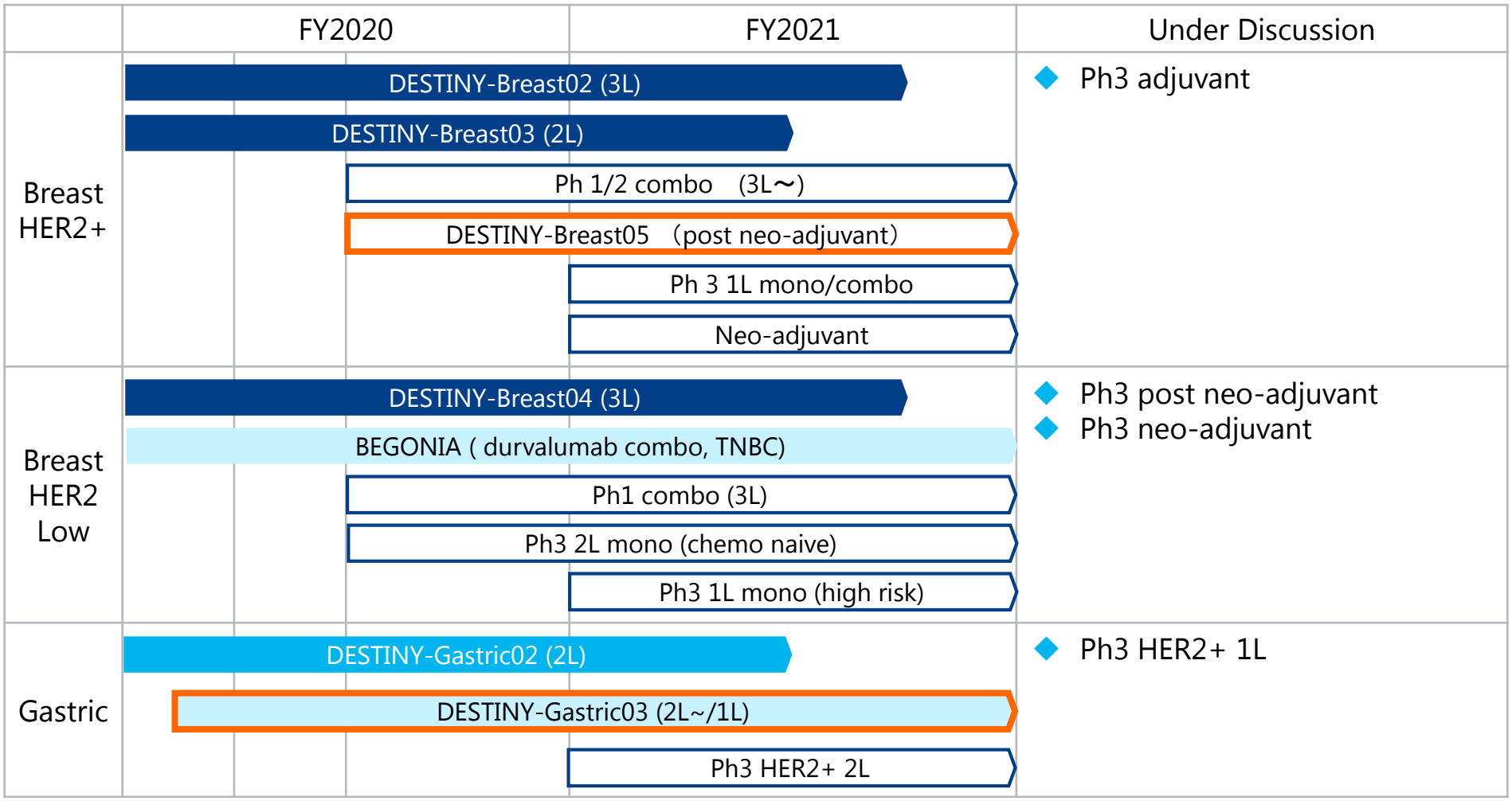
News flow

DS-8201: Clinical Development Plan

As of July 2020

Daiichi-Sankyo



Study initiation points for FY2020 H1 are shown on quarterly basis.
Study initiation points for FY2020 H2are all shown as beginning of H2
Study initiation points for FY2021 are all shown as beginning of FY2021.

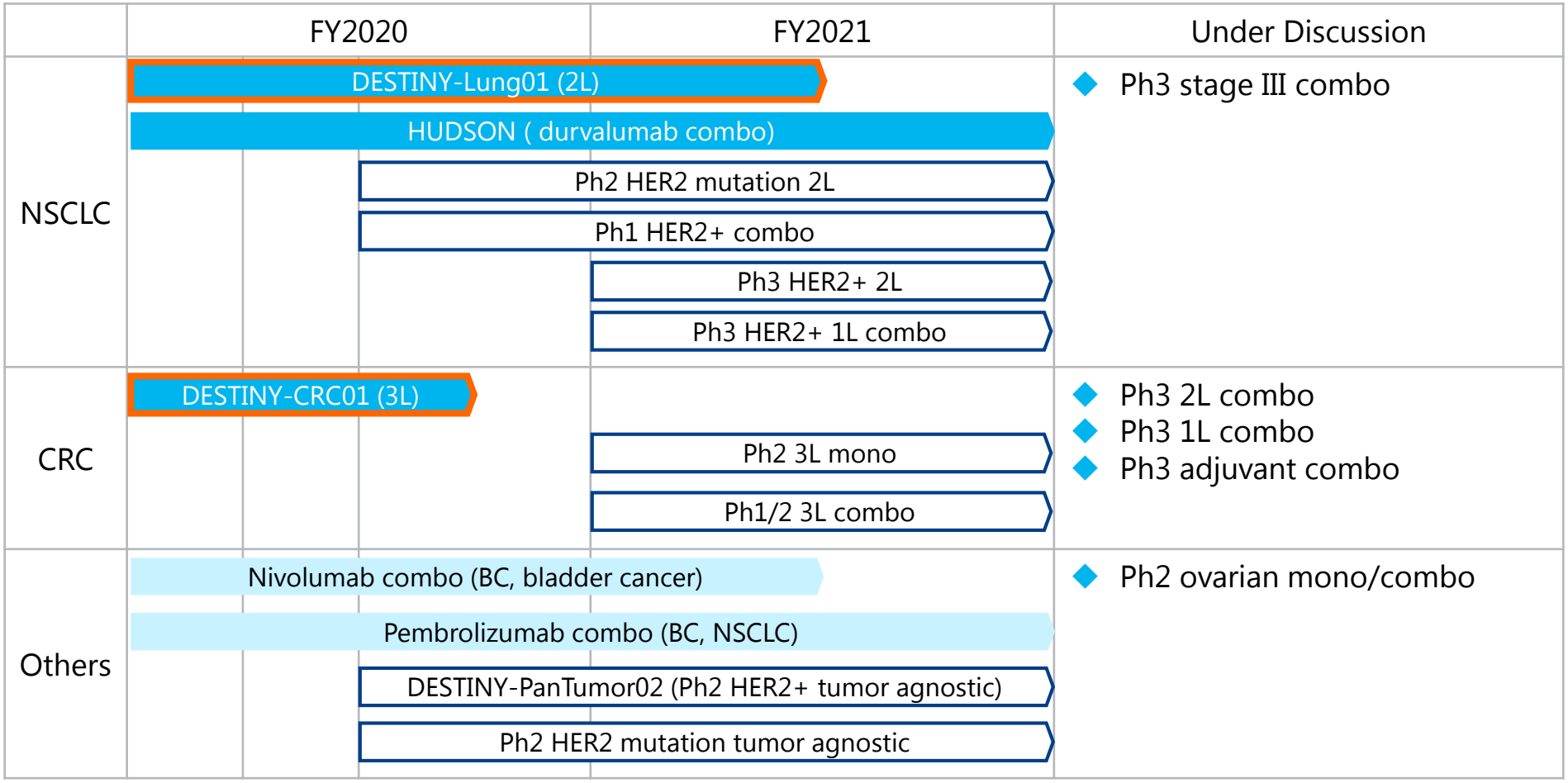
Will be mentioned today

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

DS-8201: Clinical Development Plan

As of July 2020

Daiichi-Sankyo



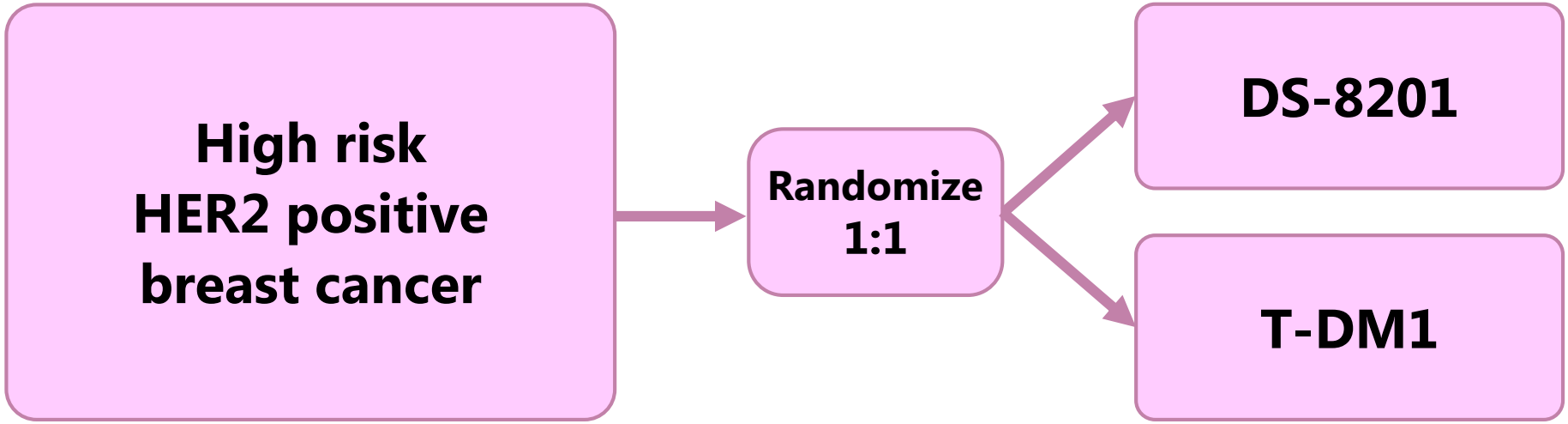
Study initiation points for FY2020 H2 are all shown as beginning of H2
Study initiation points for FY2021 are all shown as beginning of FY2021.

Will be mentioned today

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

DS-8201: DESTINY-Breast05 Study

- **DS-8201 vs. T-DM1 in patients with high-risk recurrence of HER2 positive breast cancer who have residual invasive disease following neoadjuvant therapy**



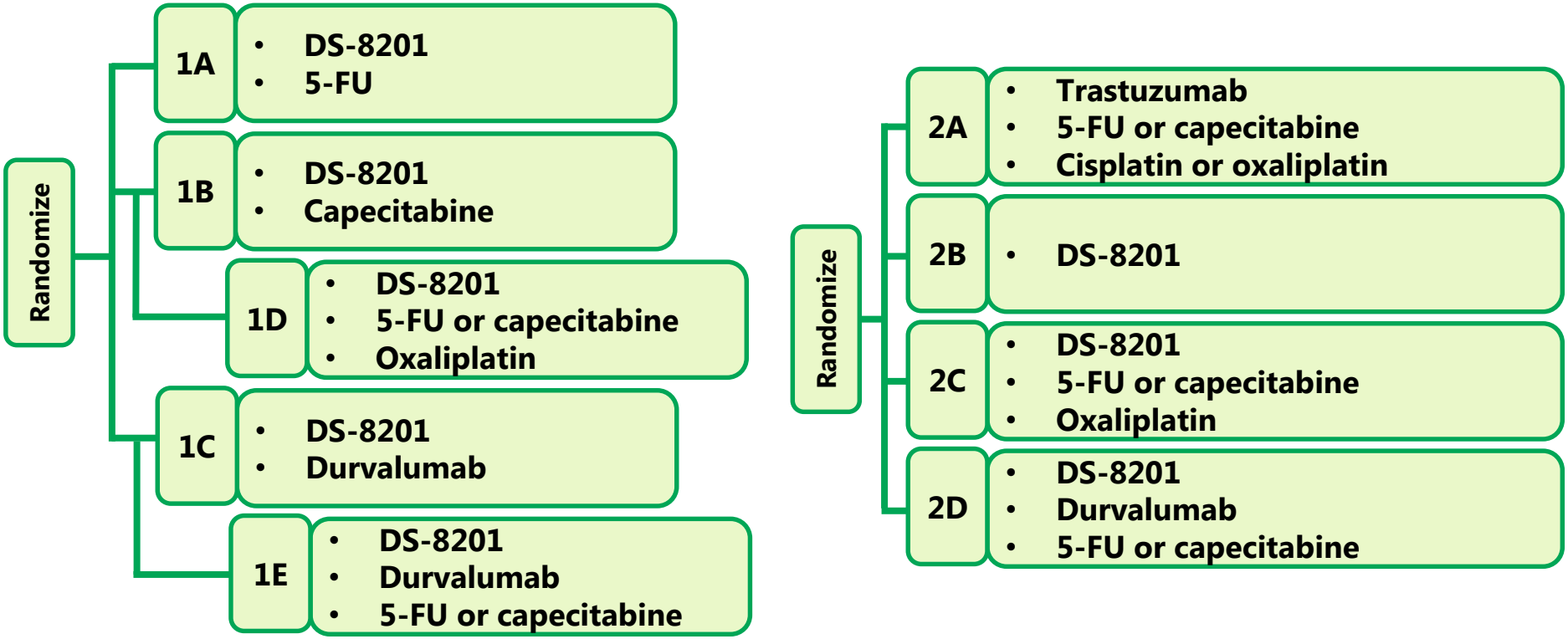
- Endpoints: IDFS as well as other endpoints
- Study start: FY2020 H2 planned

IDFS: invasive disease-free survival

DS-8201: DESTINY-Gastric03 Study

HER2 positive gastric cancer, 2L or later / 1L phase 1/2 study

Part 1: dose escalation, HER2+ GC 2L or later **Part 2: dose expansion, HER2+ GC 1L**



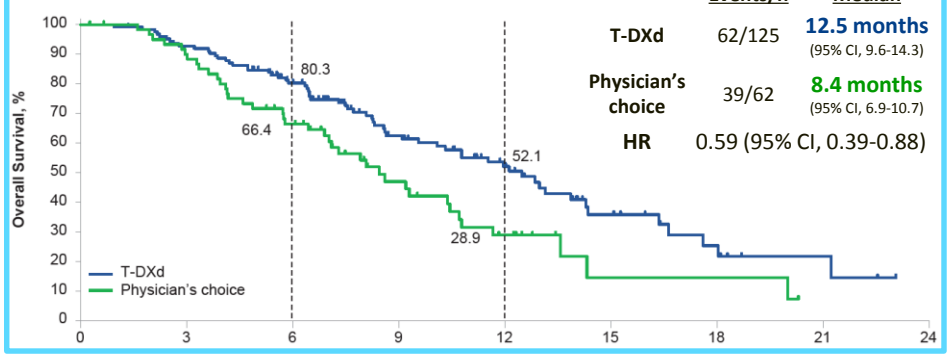
- Primary endpoint: ORR, safety
- Study started in June 2020

ClinicalTrials.gov Identifier: NCT04379596

DS-8201: Gastric (DESTINY-Gastric01 Study)

Efficacy

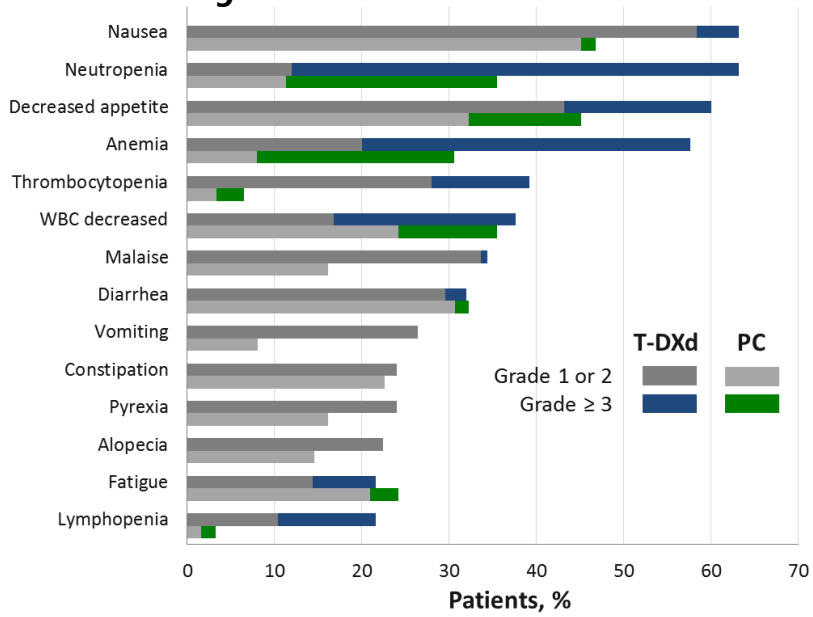
	T-DXd (n = 119)	PC (n = 56)
ORR by ICR (CR + PR)	51.3% (n = 61) 95% CI, 41.9-60.5; *P* < .0001	14.3% (n = 8) 95% CI, 6.4-26.2
Confirmed ORR by ICR (CR + PR)	**42.9% (n = 51)** **95% CI, 33.8-52.3**	**12.5% (n = 7)** **95% CI, 5.2-24.1**
CR	**8.4% (n = 10)**	0
PR	34.5% (n = 41)	12.5% (n = 7)
SD	42.9% (n = 51)	50.0% (n = 28)
PD	11.8% (n = 14)	30.4% (n = 17)
Not evaluable	2.5% (n = 3)	7.1% (n = 4)
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
Median confirmed DOR	**11.3 months** 95% CI, 5.6-NE	**3.9 months** 95% CI, 3.0-4.9



	Events/n	Median
T-DXd	62/125	12.5 months (95% CI, 9.6-14.3)
Physician's choice	39/62	8.4 months (95% CI, 6.9-10.7)
HR	0.59 (95% CI, 0.39-0.88)	

Safety

Treatment-Emergent Adverse Events in >20% of Patients



Interstitial lung disease (ILD) in DS-8201 Arm, n=125

Gr1	Gr2	Gr3	Gr4	Gr5	Total
3 (2.4)	6 (4.8)	2 (2.4)	1 (0.8)	0	12(9.6)

- **Results presented at ASCO 2020 and published in NEJM**
- **JP: Submitted in April 2020 and approval anticipated in FY2020 Q3 (SAKIGAKE)**
- **US: BTD/ODD in May 2020, discussion ongoing with FDA for submission**

PC: Physician's choice

DS-8201: NSCLC (DESTINY-Lung01 Study)

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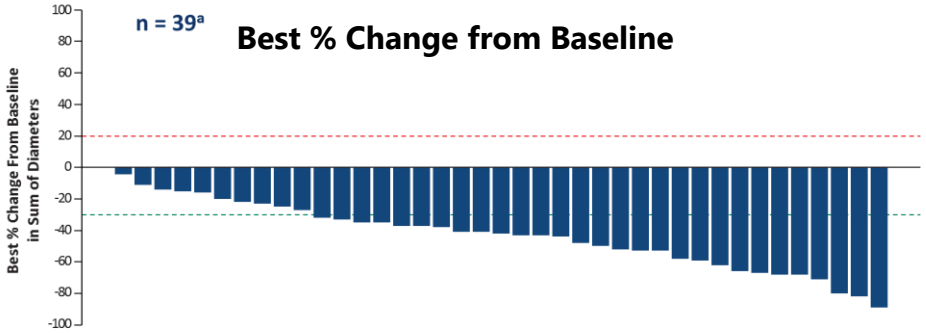
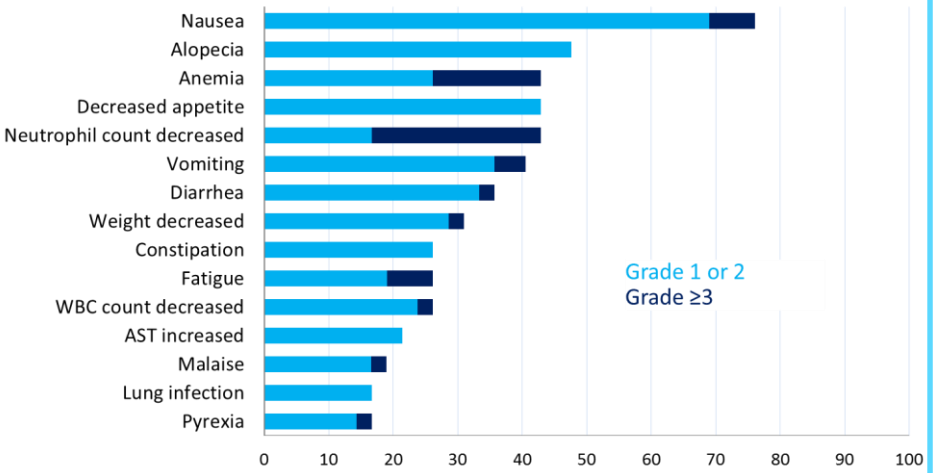
Efficacy



	Patients (N = 42)
Confirmed ORR by ICR	**61.9% (n = 26)** (95% CI, 45.6%-76.4%)
CR	**2.4%** (n = 1)
PR	59.5% (n = 25)
SD	28.6% (n = 12)
PD	4.8% (n = 2)
Not evaluable	4.8% (n = 2)
Disease control rate	90.5% (95% CI, 77.4%-97.3%)
Duration of response, median	**Not reached** (95% CI, 5.3 months-NE)
PFS, median	**14.0 mo** (95% CI, 6.4-14.0 months)

Safety

Treatment-Emergent Adverse Events in >15% of Patients



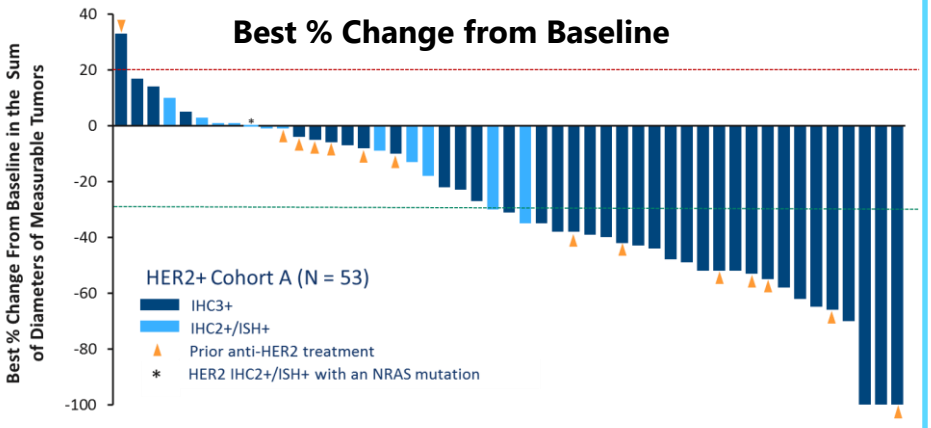
Interstitial lung disease (ILD), n=42

Gr1	Gr2	Gr3	Gr4	Gr5	Total
0	5 (11.9)	0	0	0	5 (11.9)

- **Interim analysis of HER2 mutant NSCLC cohort presented at ASCO 2020**
- **US: BTD in May 2020 (HER2 mutant NSCLC)**

DS-8201: CRC (DESTINY-CRC01 Study)

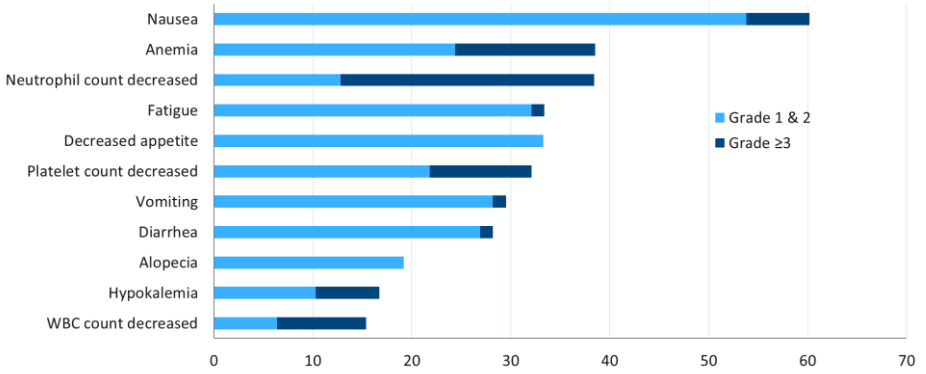
Efficacy



	HER2+ Cohort A (N = 53)
Confirmed ORR by ICR	**45.3% (n = 24)** (95% CI, 31.6%-59.6%)
CR	**1.9%** (n = 1)
PR	43.4% (n = 23)
SD	37.7% (n = 20)
PD	9.4% (n = 5)
Not evaluable	7.5% (n = 4)[a]
Disease control rate	83.0% (95% CI, 70.2%-91.9%)
Duration of response, median	**Not reached** (95% CI, 4.2 months-NE)

Safety

Treatment-Emergent Adverse Events in >15% of Patients



Interstitial lung disease (ILD), n=78

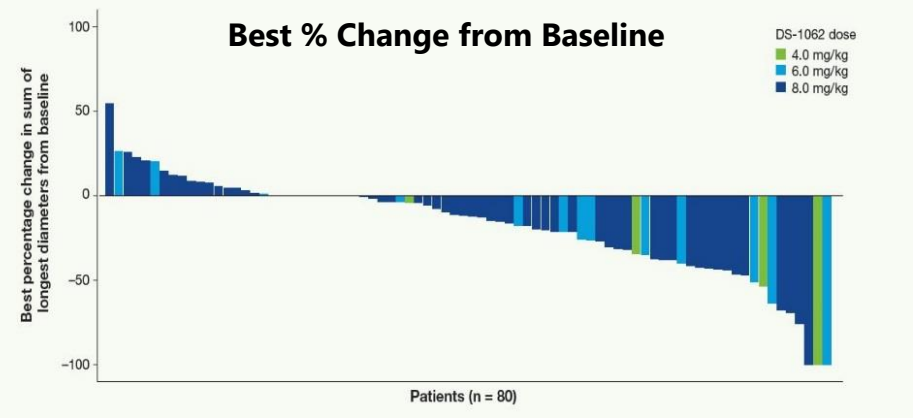
Gr1	Gr2	Gr3	Gr4	Gr5	Total
0	2 (2.6)	1 (1.3)	0	2 (2.6)	5 (6.4)

*One additional grade 5 ILD case in Cohort B was reported after the data cutoff.

Primary analysis of HER2 positive primary cohort presented at ASCO 2020

DS-1062: NSCLC (Phase 1 Study)

Efficacy



DS-1062 dose, mg/kg	Evaluable patients[a]	Confirmed CR/PR	CR/PR (too early to be confirmed)	ORR % (n/N) (95% CI)
4	6	3	0	50% (3/6) (12-88)
6	19	4	1	26% (5/19) (9-51)
8	60	13	2	25% (15/60) (15-38)
Total	**85**	**20**	**3**	**27%** (23/85) **(18-38)**

[a]Includes patients with ≥1 posttreatment scan or who discontinued treatment.

Safety

Treatment-Emergent Adverse Events in >15% of Patients

TEAE in ≥ 15% subjects	Patients treated with DS-1062 (N = 138) 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.

Interstitial lung disease (ILD), n=138

Gr1	Gr2	Gr3	Gr4	Gr5	Total
1 (0.7)	4 (2.9)	1 (0.7)	0	2 (1.4)	8 (5.8)

- **Interim analysis was presented at ASCO 2020**
- **Announced clinical research collaboration to evaluate DS-1062 in combination with pembrolizumab**
- **Future updated clinical development plan will be discussed with AstraZeneca**

News flow

News Flow

As of July 2020

Daiichi-Sankyo

Trastuzumab deruxtecan (DS-8201)	DESTINY-Breast01: Pivotal phase 2 HER2 positive mBC study • EU: **Submission validated with accelerated assessment in Jun. 2020, approval anticipated in FY2020 Q4** DESTINY-Gastric01: Pivotal phase 2 HER2 positive mGC study • JP: **Submitted in Apr. 2020, approval anticipated in FY2020 Q3 (SAKIGAKE)** • Discussions underway with additional global health authorities
DS-1062	Phase 1 Study: NSCLC • **Updated data planned for WCLC in Jan. 2021** **Phase 1 I/O combination studies: Planned start in FY2020 H2**
Patritumab deruxtecan (U3-1402)	Phase 1 study: EGFRm NSCLC • **Updated data planned for ESMO in Sep. 2020** Phase 1 EGFR TKI combination study EGFRm NSCLC: Planned start in FY2020 H2 Phase 1/2 study: HER3 positive mBC • **Updated data planned for SABCS in Dec. 2020** **Phase 2 study mCRC: Planned start in FY2020 H2**
Axicabtagene ciloleucel/ Axi-Cel™	Phase 2 study: R/R B-Cell Lymphoma • JP: Approval anticipated in FY2020 Q3
DS-1647 (G47Δ)	Phase 2: Malignant glioma • JP: NDA planned in FY2020 H1

Underlined: New or Updated from FY2019 Q4

mBC: metastatic breast cancer, mCRC: metastatic colorectal cancer, mGC: metastatic gastric cancer, NSCLC: non-small cell lung cancer

1 Actions Against COVID-19

2 DS-1062 Strategic Collaboration

3 FY2020 Q1 Financial Results

4 FY2020 Forecast

5 Business Update

6 R&D Update

7 **Appendix**

Major R&D Milestones in FY2020

As of July 2020

Daiichi-Sankyo

	Project	Target Indications and Studies	FY2020 Q1	Q2	Q3	Q4
3 ADC	DS-8201	P2 pivotal DESTINY-Breast01: HER2+ 3L BC (JP/US/EU/Asia)	EU submitted			EU approval anticipated
		P2 pivotal DESTINY-Gastric01: HER2 + 3L GC (JP/Asia)	JP submitted		JP approval anticipated	
		P2: HUDSON : NSCLC (with durvalumab) (US/EU/Asia)	Study started			
		P1b/2: BEGONIA: TNBC (with durvalumab) (US/EU/Asia)	Study started			
		P1: BC, NSCLC (with pembrolizumab) (US/EU)	Study started			
		P1b/2 DESTINY-Gastric03: HER2+ GC 2L~/1L (US/EU/Asia)	Study started			
		P3 DESTINY-Breast05: HER2+ post neo-adjuvant			Study start planned	
	DS-1062	P1: NSCLC (with pembrolizumab)			Study start planned	
	U3-1402	P1: EGFRm NSCLC (with TKI)			Study start planned	
		P2: CRC			Study start planned	
Alpha	Pexidartinib	P3 ENLIVEN: tenosynovial giant cell tumor (EU)	CHMP negative opinion			
	DS-1647	IIS: malignant glioma (JP)	JP submission		Approval anticipated	
	Axicabtagene ciloleucel/ Axi-Cel™	P2 pivotal: R/R B-cell lymphoma (JP)			Approval anticipated	
	DS-6157	P1: GIST (JP/US)	Study started			
	Edoxaban	P3: atrial fibrillation in the very elderly (JP)	Obtained TLR		Submission planned	
	Prasugrel	P3: ischemic stroke (JP)	Obtained TLR			Submission planned
	DS-5141	P1/2: Duchenne type muscular dystrophy (JP)			Data anticipated	
	DS-5670	Clinical study: COVID-19 vaccine				Study start planned
	DS-2319	Clinical study: COVID-19				Study start planned

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

Red underlined: new or updated from FY2019 Q4

Major R&D Pipeline: 3 ADCs

As of July 2020

Daiichi-Sankyo

Phase 1		Phase 2	Phase 3	Submitted
U3-1402 (JP/US) Anti HER3-ADC BC	**DS-8201** (US/EU) Anti HER2-ADC BC, bladder cancer (with nivolumab)	**DS-8201** (JP/US/EU) Anti HER2-ADC NSCLC DESTINY-Lung01	**DS-8201** (JP/US/EU/Asia) Anti HER2-ADC 3L BC DESTINY-Breast02	**DS-8201** (JP) Anti HER2-ADC 3L GC DESTINY-Gastric01
U3-1402 (JP/US/Asia) Anti HER3-ADC EGFRm NSCLC	**DS-8201** (US/EU) Anti HER2-ADC BC, NSCLC (with pembrolizumab)	**DS-8201** (JP/US/EU) Anti HER2-ADC CRC DESTINY-CRC01	**DS-8201** (JP/US/EU/Asia) Anti HER2-ADC 2L BC DESTINY-Breast03	**DS-8201** (EU) Anti HER2-ADC 3L BC DESTINY-Breast01
DS-1062 (JP/US) Anti TROP2-ADC NSCLC, TNBC	**DS-8201** (US/EU/Asia) Anti HER2-ADC 2L~/1L GC DESTINY-Gastric03	**DS-8201** (US/EU) Anti HER2-ADC 2L GC DESTINY-Gastric02	**DS-8201** (JP/US/EU/Asia) Anti HER2-ADC HER2 low BC DESTINY-Breast04	
		DS-8201 (US/EU/Asia) Anti HER2-ADC NSCLC (with durvalumab) HUDSON		
		DS-8201 (US/EU/Asia) Anti HER2-ADC TNBC (with durvalumab) BEGONIA		
		DS-8201 (US/Asia) prep Anti HER2-ADC HER2 expressing tumors DESTINY-PanTumor02		

DS-8201 U3-1402 DS-1062

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

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

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

Major R&D Pipeline: Alpha

As of July 2020

Daiichi-Sankyo

Phase 1		Phase 2	Phase 3	Submitted
DS-1205 (JP) AXL inhibitor EGFRm NSCLC (with gefitinib)	**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 1L AML	**Axicabtagene ciloleucel Axi-Cel™** (JP) Anti CD19 CAR-T cells R/R B-cell lymphoma
DS-1205 (Asia) AXL inhibitor EGFRm NSCLC (with osimertinib)	**DS-3201** (US) EZH1/2 inhibitor AML, ALL	**DS-3201** (JP) EZH1/2 inhibitor ATL/L	**Edoxaban** (JP) FXa inhibitor Atrial fibrillation in the very elderly	**VN-0107/MEDI3250** (JP) live attenuated influenza vaccine nasal spray
DS-7300 (JP/US) Anti B7-H3-ADC Solid tumors	**DS-3032** (JP/US) MDM2 inhibitor Solid tumors (liposarcoma)	**DS-1001** (JP) Prep Mutant IDH1 inhibitor Glioma	**Prasugrel** (JP) ADP receptor inhibitor Ischemic stroke	
DS-6157 (JP/US) Anti GPR20-ADC GIST	**DS-3032** (JP/US) MDM2 inhibitor AML	**DS-5141** (JP) ENA oligonucleotide DMD	**Mirogabalin** (JP/Asia) $\alpha_2\delta$ Ligands Central neuropathic pain	
DS-2741 (JP) Anti-Orai1 antibody Atopic dermatitis	**PLX2853** (US) BET inhibitor AML		**Esaxerenone** (JP) MR blocker Diabetic nephropathy	
	PLX2853 (US) BET inhibitor Solid tumor		**VN-0102/JVC-001** (JP) Measles mumps rubella combined vaccine	
	DS-1211 (US) TNAP inhibitor Pseudoxanthoma elasticum			

Oncology Specialty medicine Vaccine

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 July 2020

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Discovery	Preclinical	Phase 1	Phase 2/3
Tryptophanase inhibitor Uremia/late stage chronic kidney disease **Global**	**DS-2087** Exon 20 insertion mutant EGFR/HER2 inhibitor NSCLC with EGFR/HER2 exon 20 insertion mutation **Global**	**DS-1205** AXL inhibitor EGFRm NSCLC **Global**	**DS-1001** Mutant IDH1 inhibitor Glioma **Regions other than Japan**
Long Acting ANP: long-acting GC-A activator Resistant hypertension/chronic heart failure **Global**		**DS-3032** MDM2 inhibitor AML, MDS, solid tumor **Global**	
		DS-2969 GyrB inhibitor *Clostridium difficile* infection **Global**	

Oncology Specialty medicine

AML: acute myeloid leukemia, MDS: myelodysplastic syndromes

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)
CRL	Complete response letter	Letter issued by the FDA after completion of its review and determined the application cannot be approved based on the current submission
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
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