Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2020 Q3
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Toshiaki Sai
Executive Vice President and CFO

January 29, 2021

Forward-Looking Statements

Management strategies and plans, financial forecasts, future projections and policies, and R&D information that Daiichi Sankyo discloses in this material are all classified as Daiichi Sankyo's future prospects. These forward looking statements were determined by Daiichi Sankyo based on information obtained as of today with certain assumptions, premises and future forecasts, and thus, there are various inherent risks as well as uncertainties involved. As such, please note that actual results of Daiichi Sankyo may diverge materially from Daiichi Sankyo's outlook or the content of this material. Furthermore, there is no assurance that any forward-looking statements in this material will be realized. Regardless of the actual results or facts, Daiichi Sankyo is not obliged and does not have in its policy the duty to update the content of this material from the date of this material onward.

Some of the compounds under discussion are investigational agents and are not approved by the FDA or any other regulatory agency worldwide as a treatment for indications under investigation. Efficacy and safety have not been established in areas under investigation. There are no guarantee that these compounds will become commercially available in indications under investigation.

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.

Agenda

1. **FY2020 Q3 Financial Results**
2. Business Update
3. R&D Update
4. Appendix

Overview of FY2020 Q3 Results

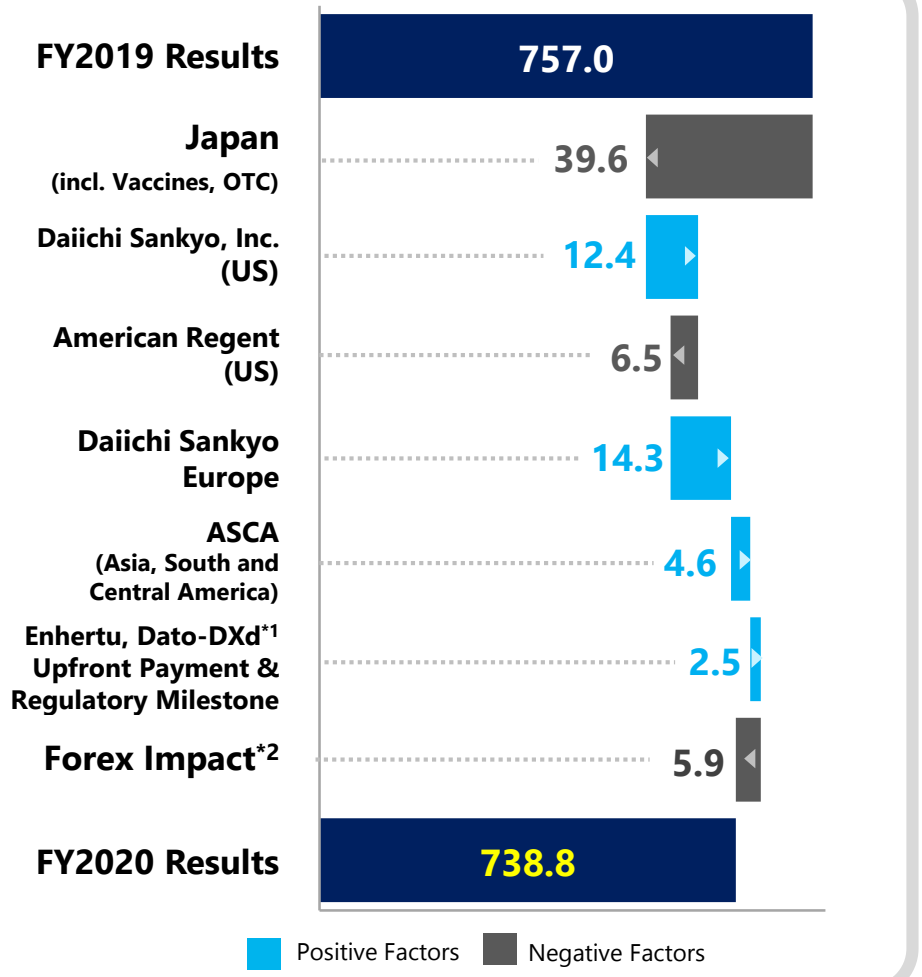
(Bn JPY)

	FY2019 Q3 YTD Results	FY2020 Q3 YTD Results	YoY	
Revenue	**757.0**	**738.8**	-2.4%	**-18.2**
Cost of sales	256.3	256.4		0.1
SG&A expenses	208.2	229.3		21.0
R&D expenses	136.9	163.6		26.7
Operating Profit	**155.6**	**89.5**	-42.5%	**-66.1**
Profit before tax	**160.0**	**99.6**		**-60.4**
Profit attributable to owners of the Company	**134.3**	**75.8**	-43.5%	**-58.5**

Currency Rate	USD/JPY	108.67	106.11	-2.56
	EUR/JPY	121.05	122.37	+1.32

Revenue

Decreased by 18.2 Bn JPY (Decreased by 12.3 Bn JPY excl. forex impact)



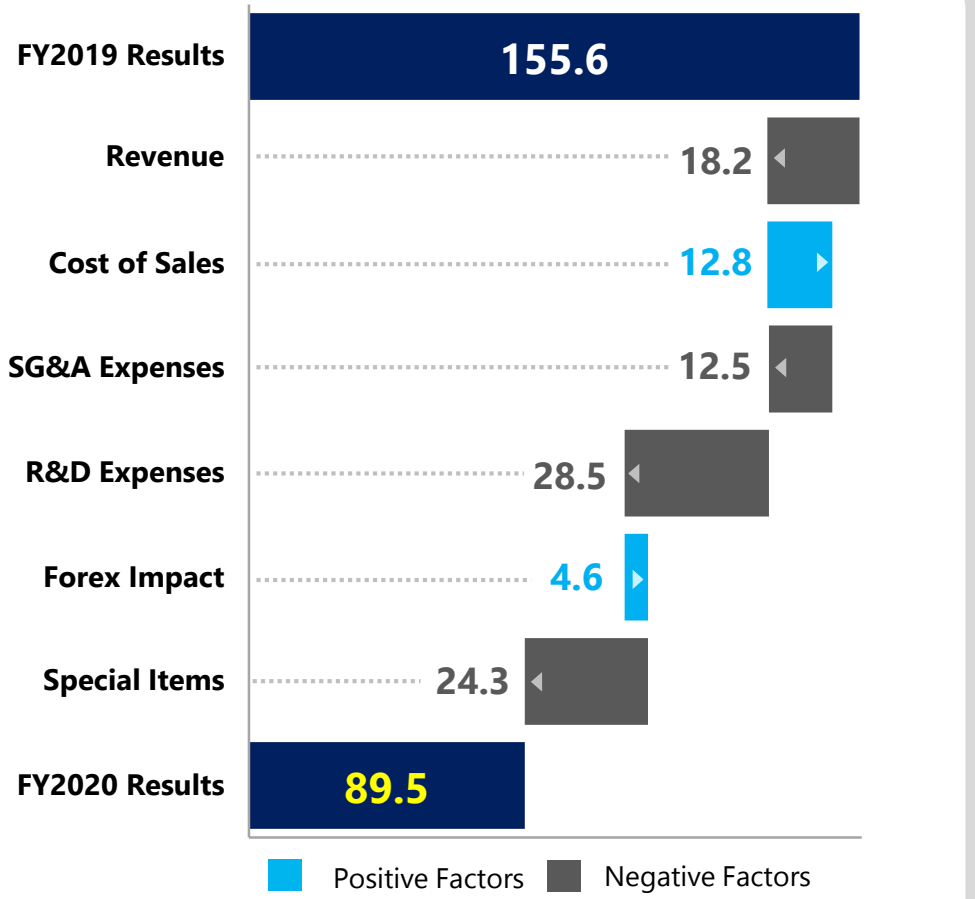
(Bn JPY)

Positive Factors		Negative Factors	
Japan			
Tarlige	+9.9	Memary	-23.3
		Inavir	-9.3
		Lixiana	-5.8
Daiichi Sankyo Espha Memantine AG, Ezetimibe AG etc.	+7,3	Vaccines business ActHIB	-14.5
		Daiichi Sankyo Healthcare Lulu	-1.4
Daiichi Sankyo, Inc. (US)			
Enhertu	+18.5	Welchol	-4.6
American Regent (US)			
		Injectafer	-6.3
Daiichi Sankyo Europe			
Lixiana	+11.6		
Gain on sales of transferring long-listed products	+4.5		
Enhertu, Dato-DXd*1 Upfront Payment & Regulatory Milestone			
Dato-DXd upfront payment	+2.5		

*1 Dato-DXd: Datopotamab deruxtecan (DS-1062)
*2 Forex impact USD: -3.2, EUR : +0.9, ASCA: -3.6

Operating Profit

Decreased by 66.1 Bn JPY (Decreased by 40.4 Bn JPY excl. forex impact and special items)



(Bn JPY)

Revenue ····· -18.2
incl. forex impact of -5.9

Cost of Sales ····· -12.8 **(Profit increased)**
- Decrease by revenue decrease
- Improvement in cost of sales ratio by change in product mix

SG&A Expenses ····· +12.5 **(Profit decreased)**
Increase in Enhertu related expenses
(including sales promotion expenses and profit share with AstraZeneca)

R&D Expenses ····· +28.5 **(Profit decreased)**
- Increase in 3 ADCs* R&D investments
- Increase due to oncology development structure enhancement

Forex Impact ····· -4.6 **(Profit increased)**
Cost of Sales ····· -0.7
SG&A Expenses ····· -2.1
R&D Expenses ····· -1.8

Special Items ····· +24.3 **(Profit decreased)**
See next slide for details

* 3 ADCs: 1) Enhertu, Trastuzumab deruxtecan (T-DXd, DS-8201), 2) Datopotamab deruxtecan (Dato-DXd, DS-1062) and 3) Patritumab deruxtecan (HER3-DXd, U3-1402)

Special Items

(Bn JPY)

	FY2019 Q3 YTD Results		FY2020 Q3 YTD Results	YoY
Cost of sales	Restructuring costs in SC	1.3	-	13.7
	Impairment loss (intangible assets)*1	3.8		
	Gain on sales of subsidiary*2	-18.8		
SG&A expenses	Gain on sales of fixed assets*3	-10.6	-	10.6
R&D expenses		-	-	-
Total		-24.3	-	24.3

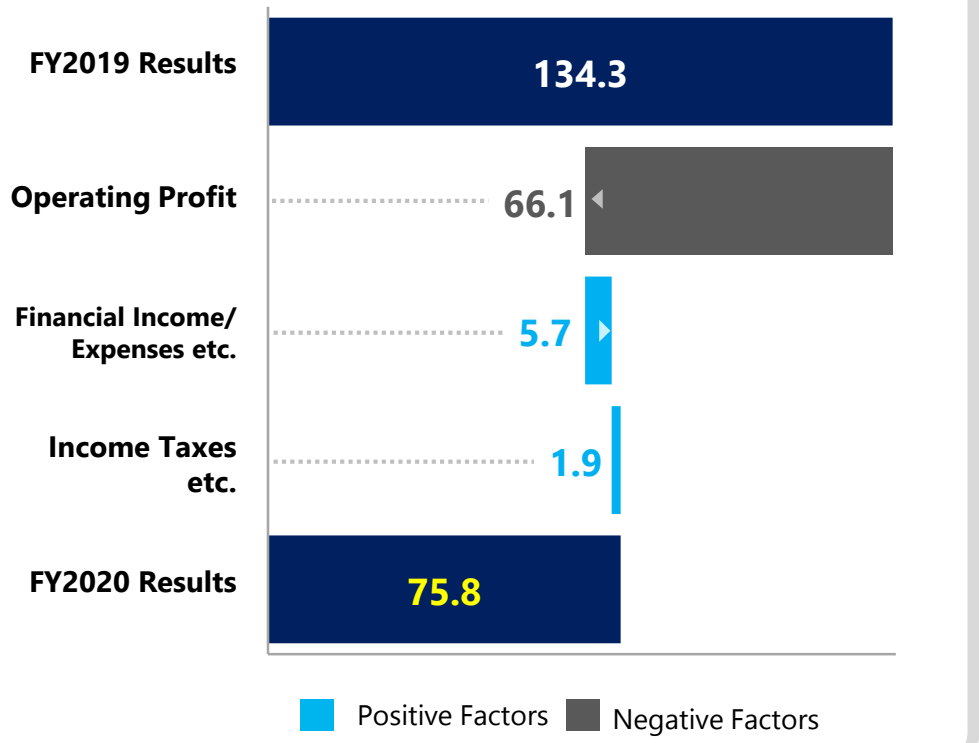
- : Cost decreased items

*1 Morphabond, Roxybond
*2 Takatsuki plant
*3 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 58.5 Bn JPY



(Bn JPY)

Financial Income/ Expenses etc. ..... **-5.7 (Profit increased)**

- Recognition of financial income due to decrease in contingent consideration of quizartinib acquisition ..... -4.8
- Improvement in forex gains/losses ..... -2.3

Income Taxes etc. ..... **-1.9 (Profit increased)**

	FY2019 Q3 YTD Results	FY2020 Q3 YTD Results	YoY
Profit before Tax	160.0	99.6	-60.4
Income Taxes etc.	25.8	23.9	-1.9
Tax rate	16.1%	24.0%	7.9%

Reference:
Tax rate increased compared to FY2019 Q3 YTD since the tax rate for FY2019 Q3 YTD was low due to impact of introduction of consolidated taxation system

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2019 Q3 YTD Results	FY2020 Q3 YTD Results	YoY
Japan	422.3	386.4	-35.9
Daiichi Sankyo Healthcare	52.9	51.5	-1.4
Daiichi Sankyo, Inc.	23.8	35.4	+11.6
Enhertu	0.0	18.0	+18.0
Olmesartan	7.8	7.2	-0.6
Welchol	8.6	3.9	-4.7
American Regent, Inc.	99.7	91.0	-8.7
Injectafer	39.3	32.2	-7.1
Venofer	23.3	22.2	-1.2
GE injectables	32.1	31.3	-0.7
Daiichi Sankyo Europe	67.7	82.9	+15.2
Lixiana	43.9	56.0	+12.2
Olmesartan	16.9	16.2	-0.7
Efient	1.9	1.2	-0.8
ASCA (Asia, South and Central America)	73.5	74.5	+1.0

Currency Rate	USD/JPY	108.67	106.11	-2.56
	EUR/JPY	121.05	122.37	+1.32

Revenue: Major Products in Japan

(Bn JPY)

		FY2019 Q3 YTD Results	FY2020 Q3 YTD Results	YoY
Nexium	ulcer treatment	**62.3**	**60.8**	**-1.5**
Lixiana	anticoagulant	**65.6**	**59.8**	**-5.8**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**24.3**	**26.4**	**+2.1**
Memary	Alzheimer's disease treatment	**40.2**	**16.9**	**-23.3**
Tenelia	type 2 diabetes mellitus treatment	**19.7**	**19.2**	**-0.5**
Loxonin	anti-inflammatory analgesic	**22.7**	**19.1**	**-3.6**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**14.0**	**14.9**	**+0.9**
Inavir	anti-influenza agent	**11.5**	**2.3**	**-9.3**
Tarlige	pain treatment	**5.4**	**15.3**	**+9.9**
Canalia	type 2 diabetes mellitus treatment	**9.8**	**11.9**	**+2.1**
Vimpat	anti-epileptic agent	**8.5**	**11.2**	**+2.7**
Efient	antiplatelet agent	**11.1**	**11.0**	**-0.1**
Rezaltas	antihypertensive agent	**11.6**	**10.4**	**-1.2**
Olmetec	antihypertensive agent	**9.4**	**7.4**	**-2.0**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**-**	**2.7**	**+2.7**

1 FY2020 Q3 Financial Results

2 **Business Update**

3 R&D Update

4 Appendix

ENHERTU® : Initiatives to Maximize Value

- **Product sales FY2020 Q3 YTD Results: 20.7 Bn JPY** <US 18.0 Bn JPY, JP 2.7 Bn JPY>
- **Steady expansion in market and indication**

HER2+ Breast Cancer
3rd Line

- **US**
  Launched in January 2020*1
- **JP**
  Launched in May 2020*2
- **EU**
  Approved in January 2021*3

HER2+ Gastric Cancer
3rd Line

- **JP**
  Indication expanded in September 2020*4

HER2+ Gastric Cancer
2nd Line

- **US**
  Indication expanded in January 2021*5

Red underlined: Updated from FY2020 Q2

*1 Treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti HER2 based regimens in the metastatic setting
*2 Treatment of patients with HER2 positive unresectable or recurrent breast cancer after prior chemotherapy (limit the use to patients who are refractory or intolerant to standard treatments)
*3 Treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti-HER2 based regimens
*4 Treatment of patients with HER2 positive unresectable advanced or recurrent gastric cancer that has progressed after chemotherapy
*5 Treatment of adult patients with locally advanced or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen

ENHERTU® : Revenue

(Bn JPY)

	FY2020 Q3 YTD Results	FY2020 Forecast		<Reference> Total Consideration (Received/ Receivable)
			vs. Forecast (as of Oct.)	
Product Sales	20.7	34.9	-	-
Japan	2.7	5.6	-	-
US	18.0	29.2	-	-
Upfront payment	7.4 *1	9.8 *1	-	149.0
Regulatory milestone payment	0.7 *1	3.7 *1	+1.2	34.6
US HER2+ Breast Cancer 3L	0.7	0.9	-	13.7
EU HER2+ Breast Cancer 3L	-	1.1 *2	-	8.3 *2
US HER2+ Gastric Cancer 2L+3L	-	1.7 *2	+1.2	12.7 *2
Total	28.8	48.3	+1.2	183.6

*1 Revenue recognized in each period
*2 US$1=JPY110

Initiatives for Business Growth in Each Region

◆ Initiatives to strengthen the product portfolio and maximize product value are progressing steadily

Japan

- Prophylaxis of migraine attacks
  EMGALITY®
  Jan. 2021
  Approved
- Treatment for large B-cell lymphoma
  YESCARTA®
  Jan. 2021
  Approved
- Anti-epileptic agent
  VIMPAT®
  Dec. 2020
  Indication expanded*1

*1 Combination therapy for tonic-clonic seizure in patients with epilepsy

Europe

- Cholesterol-lowering treatment
  NILEMDO® and NUSTENDI®
  Nov. 2020
  Launched in Germany

ASCA*2

- Anticoagulant **LIXIANA（里先安®）**
  Dec. 2020
  Listed in National Reimbursement Drug List (NRDL) in China
  (Scheduled to be applied from Mar. 2021)

*2 Asia, South & Central America

Europe: New Products Launch

- **Launched cholesterol-lowering treatment in-licensed from Esperion, NILEMDO® and NUSTENDI® in Germany in Nov. 2021**
  (Further launches planned in European markets)

NILEMDO® (bempedoic acid)

- Bempedoic acid
- First-in-class oral ACL* inhibitor
- Provides additional LDL-C lowering of up to 28% on top of other lipid-lowering therapies

NUSTENDI® (bempedoic acid and ezetimibe)

- Fixed dose combination tablet of bempedoic acid and ezetimibe
- Combines two complementary ways of reducing cholesterol
  - bempedoic acid: inhibits cholesterol production
  - ezetimibe: reduces absorption of dietary cholesterol in the gut
- Reduces LDL-C by 38% compared to placebo in high-risk patients already taking maximum-tolerated statin therapy

Indication: for use in adults with hypercholesterolaemia or dyslipidaemia

- **Improve European regional value through synergistic effect with anticoagulant Lixiana**

*ACL: adenosine triphosphate citrate lyase, an enzyme which is involved in the production of cholesterol in the liver

1 FY2020 Q3 Financial Results

2 Business Update

3 **R&D Update**

4 Appendix

3 ADC Update

Alpha Update

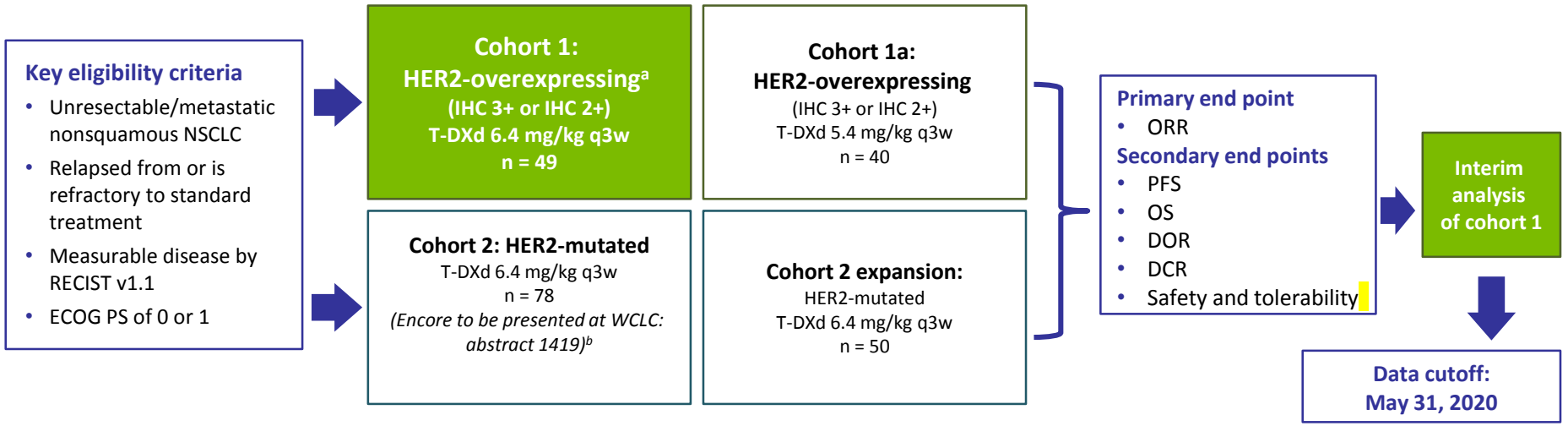
News Flow

IR material will use following terms

- DS-8201/trastuzumab deruxtecan
  =>**ENHERTU®/T-DXd**
- DS-1062/datopotamab deruxtecan
  =>**Dato-DXd**
- U3-1402/patritumab deruxtecan
  =>**HER3-DXd**

ENHERTU®: DESTINY-Lung01 Study Design

Phase 2 study of T-DXd, a novel antibody-drug conjugate, in patients with HER2-overexpressing or HER2-mutated metastatic NSCLC (NCT03505710)



- In cohort 1, 11 patients remained on treatment, and 38 patients had discontinued treatment primarily because of PD (n = 22) or AEs (n = 9)[c]
- Median treatment duration was 18.0 weeks (range, 3.0-57.1 weeks)

AE, adverse event; DCR, disease control rate; OS, overall survival; PD, progressive disease; q3w, every 3 weeks.
[a]HER2 overexpression (without known HER2 mutation) was assessed by local assessment of archival tissue and centrally confirmed. [b]Smit EF et al. Presented at: 2020 World Conference on Lung Cancer Singapore, Virtual Meeting; January 28-31, 2021. [c]Other reasons for discontinuation included death (n = 2; unrelated to study treatment), withdrawal of consent (n = 2), investigator decision (n = 2), and other (n = 1).

DESTINY-Lung01 (HER2+): Patient Background

Demographics and Baseline Characteristics	Patients (N = 49)
Age, median (range), years	63.0 (37-85)
<65 years, n (%) | ≥75 years, n (%)	27 (55.1%) | 2 (4.1%)
Female, n (%)	19 (38.8%)
Region, n (%)	
Asia	12 (24.5%)
North America	19 (38.8%)
Europe	18 (36.7%)
HER2 IHC status, n (%)	
IHC 3+	10 (20.4%)
IHC 2+	39 (79.6%)
IHC 1+ | IHC 0 | missing	0 | 0 | 0

Demographics and Baseline Characteristics	Patients (N = 49)
Other gene abnormality status, n (%)	
EGFR/ALK/ROS1/BRAF	3 (6.1%)
No EGFR/ALK/ROS1/BRAF	14 (28.6%)
Not reported	32 (65.3%)
ECOG performance status, n (%) 0 | 1	14 (28.6%) | 35 (71.4%)
Presence of CNS metastases, n (%)	17 (34.7%)
Prior therapies, n (%)	49 (100.0%)
Platinum-based Anti–PD-1/PD-L1 Docetaxel	45 (91.8%) 36 (73.5%) 12 (24.5%)
Median number of prior lines of therapies (range)	3 (1-8)

CNS, central nervous system; ECOG, Eastern Cooperative Oncology Group; PD-1, programmed death 1; PD-L1, programmed death ligand 1.
Full analysis set data are shown.

DESTINY-Lung01 (HER2+): Efficacy

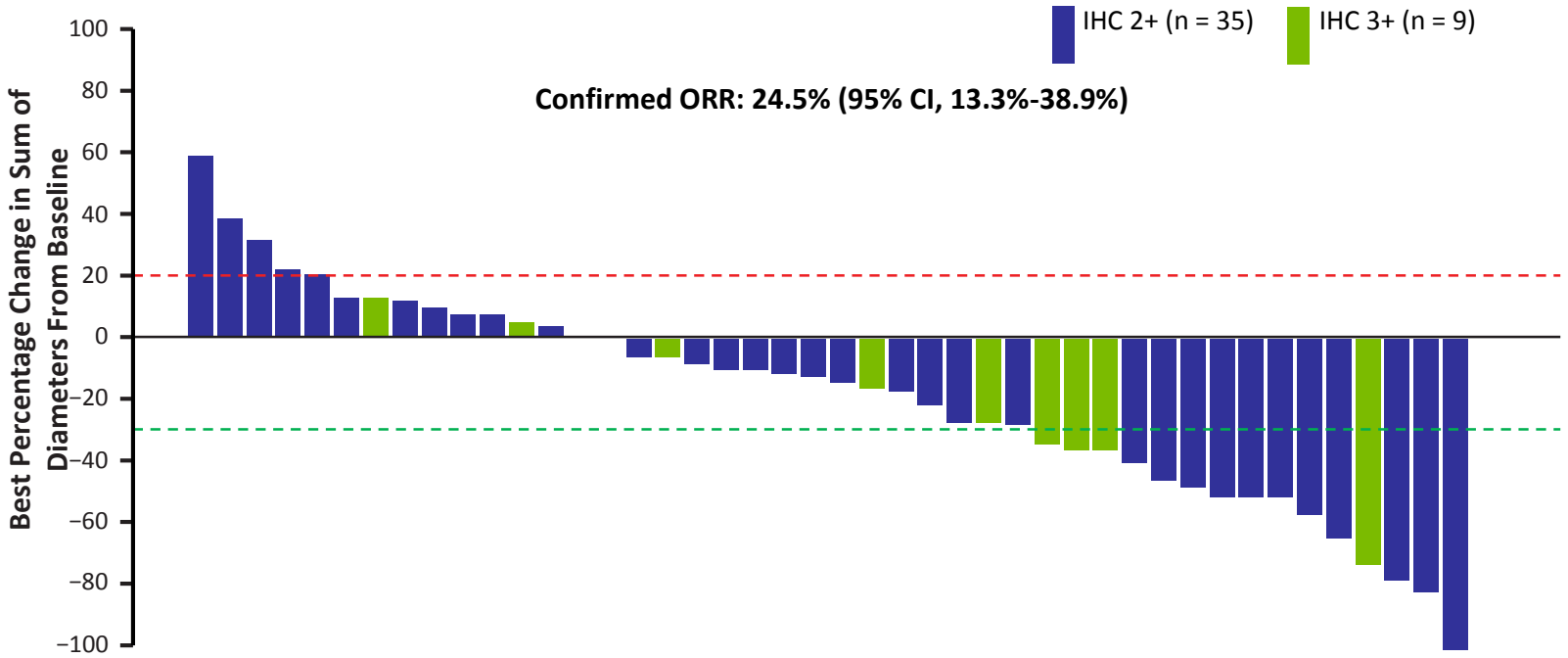
Response Assessment by ICR	IHC 3+ (n = 10)	IHC 2+ (n = 39)	Overall (N = 49)
Confirmed ORR, n (95% CI)	**20.0%** 2 (2.5-55.6)	**25.6%%** 10 (13.0-42.1)	**24.5%** 12 (13.3-38.9)
CR, n (%)	0	1 (2.6%)	1 (2.0%)
PR, n (%)	2 (20.0%)	9 (23.1%)	11 (22.4%)
SD, n (%)	6 (60.0%)	16 (41.0%)	22 (44.9%)
PD, n (%)	1 (10.0%)	10 (25.6%)	11 (22.4%)
Not evaluable, n (%)	1 (10.0%)	3 (7.7%)	4 (8.2%)
DCR, n (95% CI)	**80.0%** 8 (44.4-97.5)	**66.7%** 26 (49.8-80.9)	**69.4%** 34 (54.6-81.8)
Median DOR, months (95% CI)	**6.0 (NE-NE)**	**5.8 (3.2-NE)**	**6.0 (3.2-NE)**

CR, complete response; PR, partial response; SD, stable disease.
Full analysis set data are shown.

◆ **Overall response was 24.5%**

DESTINY-Lung01 (HER2+): Efficacy

Best Percentage Change in Tumor Size[a] With T-DXd



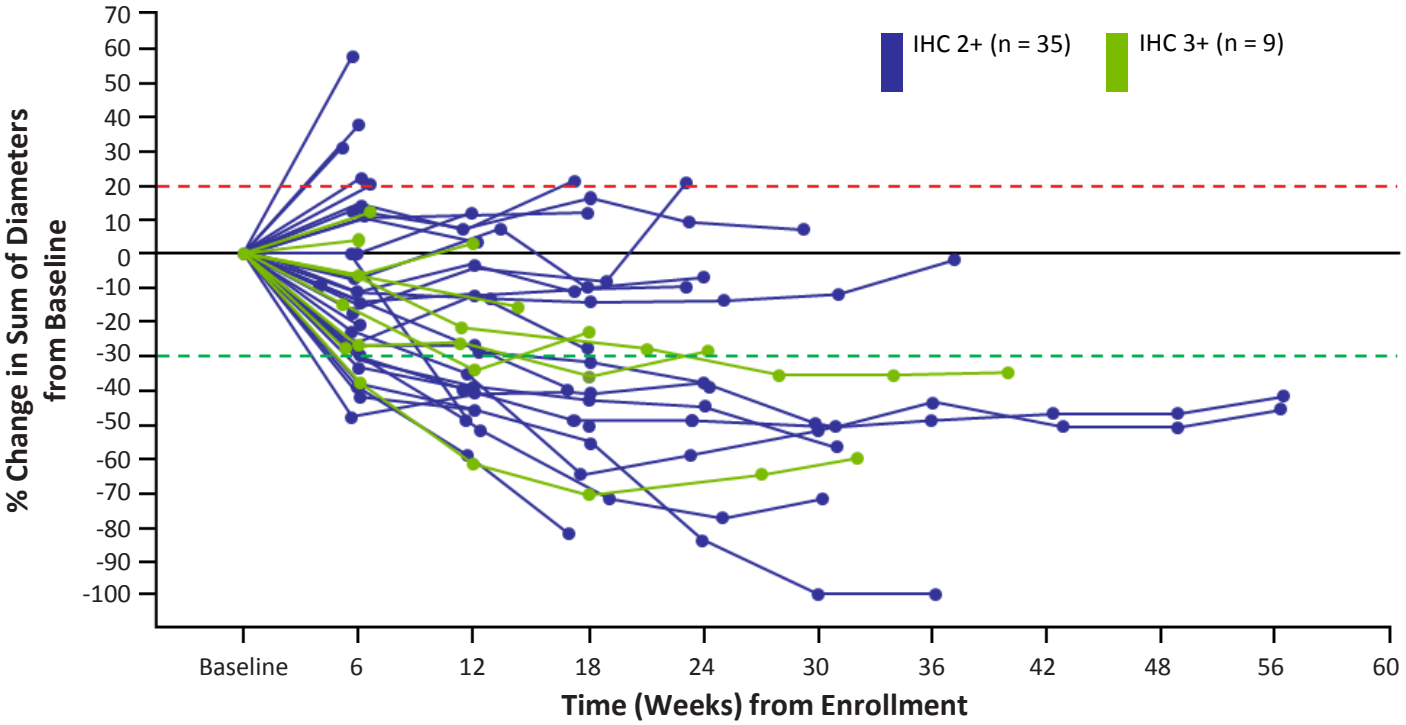
[a]Best (minimum) percentage change from baseline in the sum of diameters for all target lesions, based on ICR. Baseline was last measurement taken before enrollment. Red line at 20% indicates PD, and green line at −30% indicates PR (when considering only target lesions). Full analysis set data are shown.

◆ **Efficacy was confirmed in both IHC3+ and IHC2+ cohorts**

WCLC 2021

DESTINY-Lung01 (HER2+): Efficacy

Change in Tumor Size Over Time



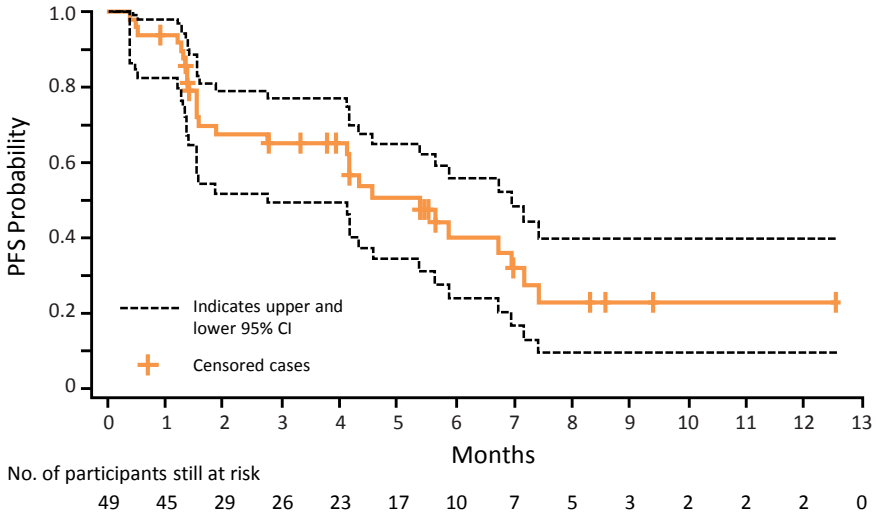
Baseline is defined as the last measurement taken before enrollment. Data beyond first determination of progressive disease or start of new antineoplastic therapy are not displayed. Red line at 20% indicates PD, and green line at −30% indicates PR (when considering only target lesions). Plot is based on ICR and in the full analysis set.

◆ **Durable responses were observed**

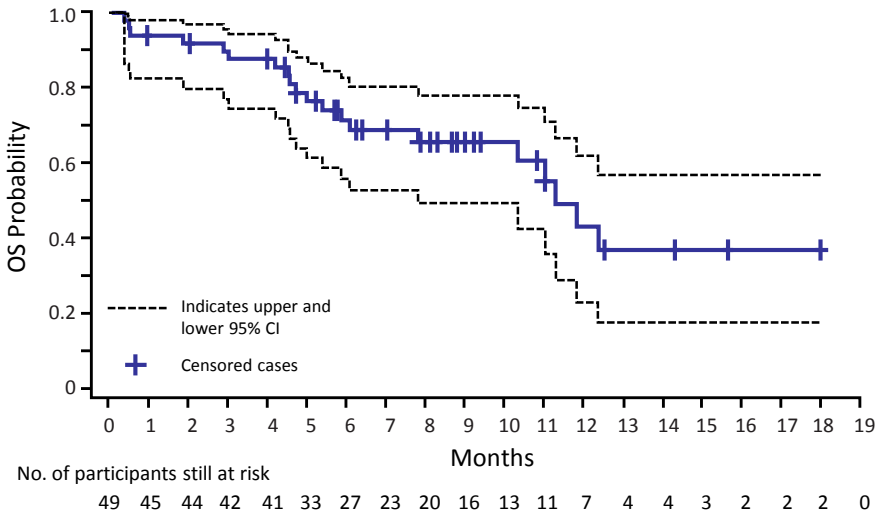
DESTINY-Lung01 (HER2+): Efficacy

PFS and OS

PFS (N = 49)
Median: 5.4 months (95% CI, 2.8-7.0 months)



OS (N = 49)
Median: 11.3 months (95% CI, 7.8-NE)



Progressive disease was assessed by ICR using Response Evaluation Criteria in Solid Tumors, version 1.1 (RECIST v1.1). The median was based on Kaplan-Meier estimate; 95% CI for the median was computed using the Brookmeyer-Crowley method.
Median follow-up was 6.1 months (range, 0.4-18.0 months). Full analysis set data are shown.

◆ **Median PFS was 5.4 months and median OS was 11.3 months**

DESTINY-Lung01 (HER2+): Safety

Type of Adverse Event[a]	Patients, n (%) N = 49
Any TEAE	49 (100.0%)
Drug related	44 (89.8%)
TEAE grade ≥3	36 (73.5%)
Drug related	27 (55.1%)
Serious TEAE	22 (44.9%)
Drug related	8 (16.3%)
TEAE associated with dose discontinuation	11 (22.4%)
Drug related	6 (12.2%)
TEAE associated with dose reduction	17 (34.7%)
Drug related	16 (32.7%)
TEAE associated with dose interruption	26 (53.1%)
Drug related	17 (34.7%)

Type of Adverse Event[a]	Patients, n (%) N = 49
TEAE grade ≥3 (>15%)	
Decreased neutrophil count	10 (20.4%)
TEAE associated with dose discontinuation[b]	
Pneumonitis	5 (10.2%)
TEAEs associated with dose reduction[b]	
Decreased neutrophil count	5 (10.2%)
Fatigue	4 (8.2%)
Nausea	3 (6.1%)
TEAEs associated with dose interruption[b]	
Decreased neutrophil count	5 (10.2%)
Nausea	3 (6.1%)
TEAE grade 5[c] | Drug related	7 (14.3%) | 1 (2.0%)

- Median treatment duration was 18 weeks (range, 3.0-57.1 weeks)

TEAE, treatment-related adverse event.
[a]Relationship to study drug was determined by the treating investigator. [b]Most common occurring in more than 2 patients. [c]The grade 5 TEAEs included disease progression (n = 4), hydrocephalus, pneumonitis, and bronchospasm (n = 1 each).
Safety analysis set data are shown.

◆ Safety profile was generally consistent with other ENHERTU trials

DESTINY-Lung01 (HER2+): Safety

AEs of Special Interest: ILD

All Patients (N = 49)						
n (%)	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**	**Any Grade/Total**
Adjudicated drug-related ILD[a]	2 (4.1%)	3 (6.1%)	0	0	3 (6.1%)	8 (16.3%)

Adjudicated drug-related ILDs[b]

- Median time to onset was 64.5 days (range, 2-126 days)
- All patients had drug withdrawn
- Steroid treatment was used in patients who had grade 2 (n = 3) and those who had grade 5 ILDs (n = 3)
- 3 patients recovered (grade 1 [n = 1] and grade 2 [n = 2]) and 2 patients had not recovered by data cutoff (grade 1 [n = 1] and grade 2 [n = 1])
- 4 of 8 patients had immune checkpoint inhibitors included in their prior lines of therapy

Grade 5 ILD[c] events

- Medical history of the 3 patients included
  1. Pulmonary embolism, productive cough, dyspnea, pleural effusion, and lobectomy; 4 prior lines of therapy
  2. Cough, dyspnea, pleural effusion, and pulmonary embolism; 5 prior lines of therapy
  3. Dyspnea, SLE without lung involvement, and TTP; 1 prior line of therapy
- Steroid treatment was initiated within 5 days after the event was reported by the investigator[d]
- All had previously received immune checkpoint inhibitors
- Primary cause of death was PD in 2 patients and pneumonitis in 1 patient

ILD, interstitial lung disease; SLE, systemic lupus erythematosus; TTP, thrombotic thrombocytopenic purpura.
[a]Drug-related ILD was determined by an independent ILD adjudication committee based on 44 preferred terms. [b]All potential cases of ILD that occurred before the data cutoff were adjudicated. [c]The 3 cases of grade 5 ILD were initially reported by the investigator as grade 4 pneumonitis and grade 4 respiratory failure (n = 1), grade 4 respiratory failure (n = 1), and grade 5 pneumonitis (n = 1). [d]Steroid treatment was initiated 2 days later for case 1, 5 days later for case 2, and on the same day for case 3. Safety analysis set data are shown

◆ ILD requires careful monitoring and prompt intervention

DESTINY-Lung01 (HER2+): Summary

T-DXd Showed Preliminary Evidence of Antitumor Activity in Patients With HER2-Overexpressing NSCLC

Efficacy Results

- In extensively pretreated patients who had previously received a median of 3 lines of therapies (range, 1-8), T-DXd 6.4 mg/kg demonstrated
  - A confirmed ORR of 24.5%, with no apparent difference in ORR by HER2 expression (IHC 3+ vs 2+)
  - A DCR of 69.4% and median OS of 11.3 months

Safety Results

- The safety profile was generally consistent with previous trials[1-5]
- In this interim analysis of 49 patients, drug-related ILD occurred in 16.3% of patients with fatal outcomes observed in 6.1% of patients; ILD continues to be closely monitored and proactively managed, with further investigation as more follow-up data become available

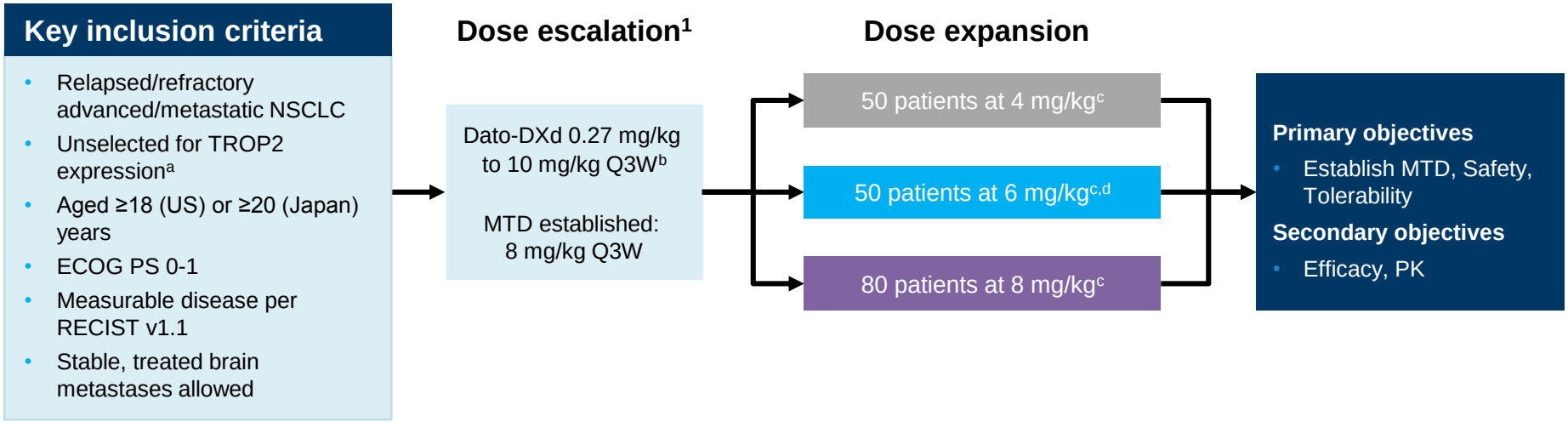
Future Studies

- These encouraging early efficacy results support the continued exploration of T-DXd in patients with HER2-overexpressing NSCLC

1. Tsurutani J et al. *Cancer Discov*. 2020;10(5):688-701. 2. Tamura K et al. *Lancet Oncol*. 2019;20(6):816-826. 3. Modi S et al. *N Engl J Med*. 2020;382(7):610-621. 4. Modi S et al. *J Clin Oncol*. 2020;38(17):1887-1896. 5. Shitara K et al. *Lancet Oncol*. 2019;20(6):827-836.

Dato-DXd: TROPION-PanTumor01 Study Design

Phase 1 Dose Escalation and Expansion Study



- NSCLC enrollment complete[d]
- TNBC cohort 6 mg/kg Q3W is enrolling; cohorts in other tumor types may be added
- Here we report updated results for the NSCLC dose expansion cohort (175 patients treated at 4, 6, or 8 mg/kg of Dato-DXd)

[a]Pretreatment tumor tissue was required for retrospective analysis of TROP2 expression. [b]The 4, 6, and 8 mg/kg dose levels are being further evaluated for safety and efficacy. A TNBC cohort is currently open for enrollment at 6 mg/kg, although no TNBC patients are included in this analysis. [c]Inclusive of patients treated in dose escalation and dose expansion. [d]The current analysis includes 45 patients treated at the 6 mg/kg dose (data cutoff: 4 September 2020).
ECOG PS, Eastern Cooperative Oncology Group performance status; FIH, first-in-human; MTD, maximum tolerated dose; NSCLC, non–small cell lung cancer; PK, pharmacokinetics; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; TNBC, triple-negative breast cancer; TROP2, trophoblast cell surface antigen 2; Q3W, once every 3 weeks; US, United States.

1. Lisberg AE, et al. Presented at: ASCO Annual Meeting; May 29-June 2, 2020; virtual meeting. Abstract 9619.

TROPION-PanTumor01: Patient Background

Characteristic	Dato-DXd dose		
	4 mg/kg (n = 50)	6 mg/kg (n = 45)	8 mg/kg (n = 80)
Male, n (%)	27 (54)	26 (58)	41 (51)
Median age (range), y	61 (35-82)	62 (45-76)	64 (31-84)
United States, n (%); Japan, n (%)	29 (58); 21 (42)	36 (80); 9 (20)	63 (79); 17 (21)
ECOG PS 0, n (%)	21 (42)	8 (18)	16 (20)
Nonsquamous histology, n (%)	41 (82)	40 (89)	70 (88)
≥3 prior lines of therapy, n (%)	25 (50)	26 (58)	51 (64)
Previous systemic treatment, n (%)			
Immunotherapy	42 (84)	35 (78)	70 (88)
Platinum-based chemotherapy	44 (88)	43 (96)	78 (98)
Tyrosine kinase inhibitor	10 (20)	6 (13)	14 (18)
History of brain metastases, n (%)	19 (38)	15 (33)	32 (40)
EGFR mutations,[a] n (%)	8 (16)	3 (7)	15 (19)

Data cutoff: 4 September 2020.

[a]*Alk* fusions were found in 1 patient treated with 4 mg/kg and 1 patient treated with 6 mg/kg.

AE, adverse event; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor.

TROPION-PanTumor01: Treatment Status

- Median follow-up of 7.4 months (range, 0.10-21.7 months)
  - Follow-up was shorter for patients treated with 4 mg/kg and 6 mg/kg than with 8 mg/kg of Dato-DXd
- Patients receiving 8 mg/kg discontinued treatment due to AEs more frequently and had a lower median relative dose intensity than patients receiving 4 mg/kg or 6 mg/kg

	Dato-DXd dose		
	4 mg/kg (n = 50)	6 mg/kg (n = 45)	8 mg/kg (n = 80)
Treatment status, n (%)			
Ongoing on study treatment	27 (54)	22 (49)	19 (24)
Discontinued from study treatment[a]	23 (46)	23 (51)	61 (76)
Progression[b]	17 (34)	18 (40)	38 (48)
Adverse events	2 (4)	3 (7)	12 (15)
Median relative dose intensity,[c] %	99.7	98.6	93.9

Data cutoff: 4 September 2020.

[a]Other reasons for discontinuation include withdrawal by patient, death, physician decision, and other.

[b]Progression includes progressive disease per RECIST v1.1 and clinical progression.

[c]Relative dose intensity (%) is calculated as 100 × actual total intensity/planned dose intensity, where planned dose intensity is the assigned dose level.

AE, adverse event; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1.

TROPION-PanTumor01: Safety

- Dato-DXd demonstrated a manageable safety profile
  - More grade ≥3 TEAEs and serious TEAEs were observed with 8 mg/kg than with 4 mg/kg and 6 mg/kg

	Dato-DXd dose		
	4 mg/kg (n = 50) n (%)	6 mg/kg (n = 45) n (%)	8 mg/kg (n = 80) n (%)
TEAE	48 (96)	41 (91)	79 (99)
Grade ≥3	11 (22)	17 (38)	45 (56)
Treatment-related TEAE	43 (86)	35 (78)	76 (95)
Grade ≥3	5 (10)	7 (16)	27 (34)
Serious TEAE[a]	9 (18)	16 (36)	38 (48)
Treatment related	4 (8)	4 (9)	16 (20)
TEAEs associated with death[b]	4 (8)	1 (2)	7 (9)
Treatment related[c]	1 (2)	0	2 (3)

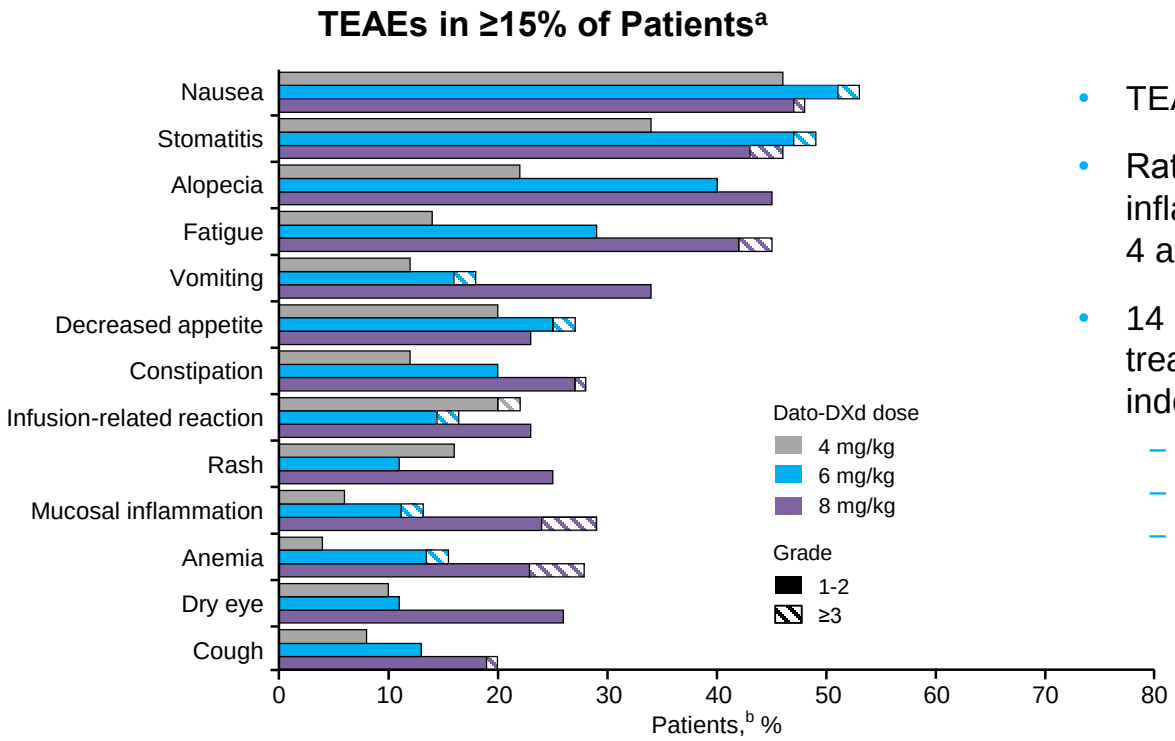
Data cutoff: 4 September 2020.

[a]A serious TEAE is any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is an important medical event. [b]Most frequent (in ≥3 patients): respiratory failure/acute respiratory failure (n = 4): 2 at 4 mg/kg, 1 at 6 mg/kg, 1 at 8 mg/kg.
[c]Respiratory failure: 1 at 4 mg/kg; pneumonitis: 2 at 8 mg/kg (with one patient having additional event of dyspnea).
TEAE, treatment-emergent adverse event.

◆ Safety profile was generally consistent with past results

TROPION-PanTumor01: Safety

Treatment-Emergent Adverse Events



- TEAEs were predominantly nonhematologic
- Rates of grade ≥3 stomatitis and mucosal inflammation were higher with 8 mg/kg vs 4 and 6 mg/kg[c]
- 14 out of 175 patients (8%) had treatment-related ILD as adjudicated by an independent committee[d]
  - 4 mg/kg: 1 patient (grade 3)
  - 6 mg/kg: 1 patient (grade 2)
  - 8 mg/kg: 12 patients (8 patients grade 1-2; 1 patient grade 3; 3 patients grade 5)

Data cutoff: 4 September 2020.

Median duration of Dato-DXd exposure (months): 2.09 (0.7-20.0) for 4 mg/kg, 2.07 (0.7-19.7) for 6 mg/kg, 3.33 (0.7-13.5) for 8 mg/kg.

[a]Out of 175 patients. [b]Out of 50, 45, and 80 patients treated with 4, 6, or 8 mg/kg, respectively.

[c]Grade ≥3 stomatitis: 4 mg/kg, 0%; 6 mg/kg, 2%; 8 mg/kg, 3%. Grade ≥3 mucosal inflammation: 4 mg/kg, 0%; 6 mg/kg, 2%; 8 mg/kg, 5%.

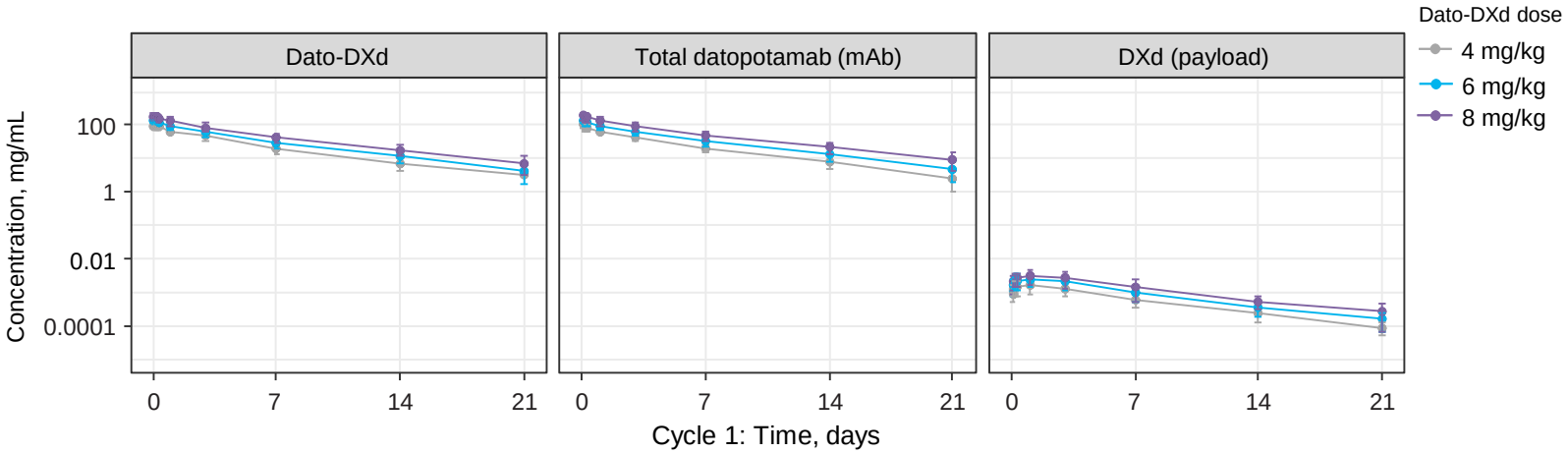
[d]Potential ILD occurred on or before data cutoff. Adjudication could have occurred after data cutoff.

ILD, interstitial lung disease; TEAE, treatment-emergent adverse event.

◆ Safety profile was generally consistent with previous results

TROPION-PanTumor01: Pharmacokinetics

- The PK profile of Dato-DXd remained consistent throughout 3 cycles of treatment, regardless of dose



- Half-life of Dato-DXd was 4.6 days for 6 mg/kg, supporting the Q3W dosing regimen
- Exposure of all analytes increased proportionally with dose
- Systemic exposure of DXd (payload) was low (mean <0.01 μg/mL) throughout treatment at all doses
- PK profile of total datopotamab mAb was similar to that of the ADC, suggesting high linker stability

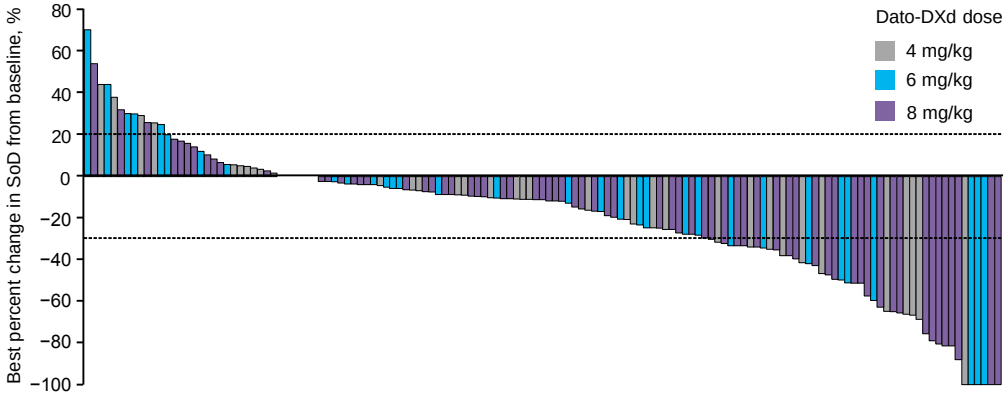
Data cutoff: 4 September 2020.
ADC, antibody drug conjugate; mAb, monoclonal antibody; PK, pharmacokinetics; Q3W, once every 3 weeks.

Systemic exposure of payload was low and confirmed stability of Dato-DXd in blood stream

TROPION-PanTumor01: Efficacy

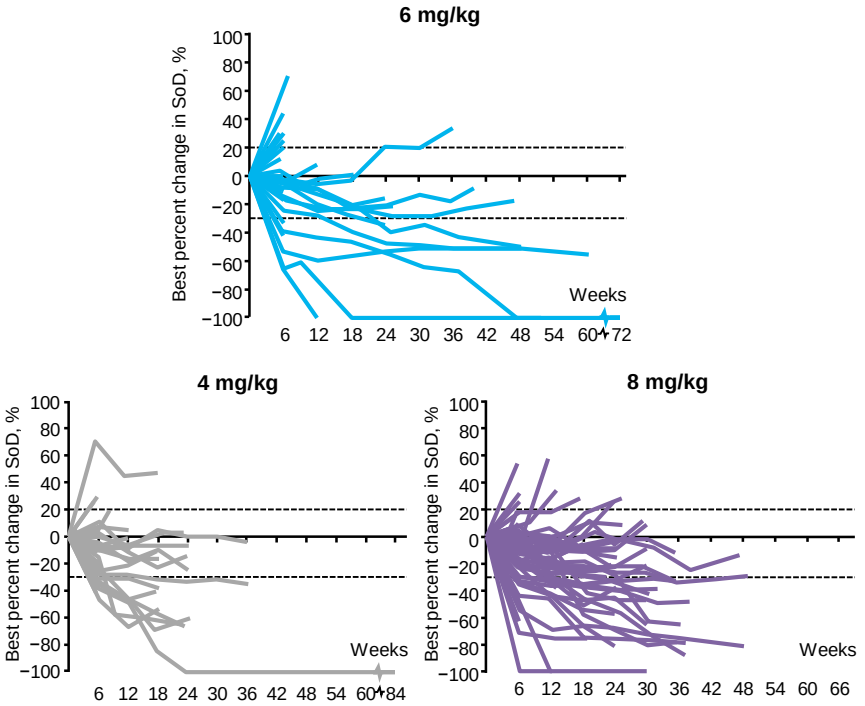
Daiichi-Sankyo

Best Change in Sum of Diameters and Overall Response (BICR)



Dato-DXd dose	Response-evaluable patients,[a] n	Confirmed CR/PR,[b] n	CR/PR (too early to be confirmed),[b] n	ORR,[b] % (n)	DCR, % (n)	PD, % (n)
4 mg/kg	40	7	2	23 (9)	73 (29)	15 (6)
6 mg/kg	39	6	2	21 (8)	67 (26)	21 (8)
8 mg/kg	80	19	1	25 (20)	80 (64)	9 (7)

Change in Sum of Diameters for Target Lesions (BICR)



Preliminary Progression-free Survival (BICR)[c]

- Median PFS (95% CI)
  - 4 mg/kg: 4.3 months (2.0-NE), 6 mg/kg: 8.2 months (1.5-11.8), 8 mg/kg: 5.4 months (4.1-7.1)

Data cutoff: 4 September 2020.

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

[b]Responses are confirmed (CRs/PRs; n = 32) plus those CRs/PRs too early to be confirmed (n = 5).

[c]Preliminary PFS limited by earlier censoring by data cutoff due to immature duration of follow-up for 4 and 6 mg/kg dose cohorts.

AE, adverse event; BICR, blinded independent central review; CI, confidence interval; CR, complete response; DCR, disease control rate; NE, not evaluable; ORR, overall response rate; PFS, progression-free survival; PD, progressive disease; PR, partial response; SoD, sum of diameter.

◆ Similar response and durability were confirmed among 4,6,8mg/kg

TROPION-PanTumor01: Summary

- In the ongoing TROPION-PanTumor01 phase 1 study, datopotamab deruxtecan (Dato-DXd; DS-1062) demonstrated highly encouraging antitumor activity and a manageable safety profile in heavily pretreated NSCLC patients
  - 84% received prior immunotherapy, and 94% received prior platinum-based chemotherapy
  - 4 mg/kg and 6 mg/kg doses were better tolerated than 8 mg/kg
  - ORR by BICR was 21%-25%, and a high DCR was achieved (67%-80%) across the 4, 6, and 8 mg/kg dose cohorts

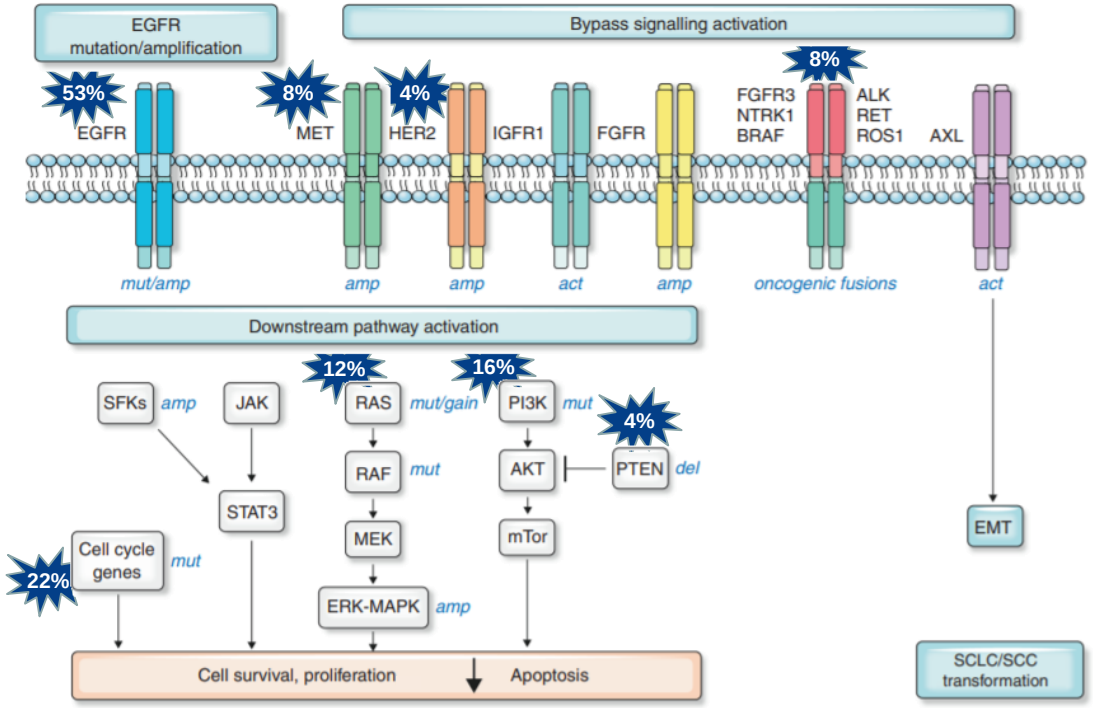
Based on promising efficacy and safety, 6 mg/kg of Dato-DXd has been selected for the phase 3 TROPION-Lung01 (NCT04656652) study in advanced or metastatic NSCLC previously treated with immunotherapy and platinum-based chemotherapy

Data cutoff: 4 September 2020.
BICR, blinded independent central review; DCR, disease control rate; NSCLC, non–small cell lung cancer; ORR, overall response rate.

◆ **6 mg/kg has been selected for the recommended dose for phase 3 study**

HER3-DXd: Genomic Alterations Observed in NSCLC P1 Study

Observed Mechanisms of EGFR TKI Resistance in Pretreatment Tumor Tissue and ctDNA (Percentages Shown for U31402-A-U102 Study Specimens)



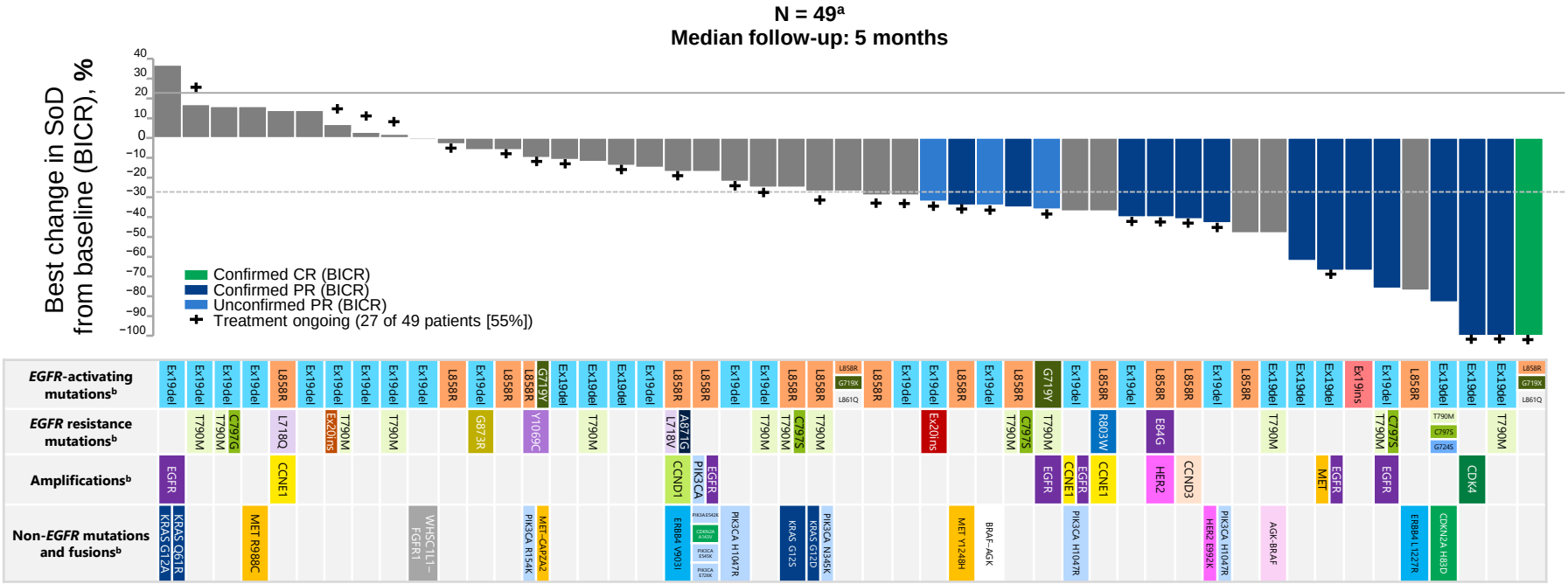
Other	
HER3 mut	2%
HER4 mut	8%
CDKN2A mut	6%
NTRK2 mut	2%

Schematic representation of the known mechanisms of resistance to EGFR TKIs. Adapted from Leonetti A, Sharma S, Minari R, Perego P, Giovannetti E, Tiseo M. Resistance mechanisms to osimertinib in EGFR-mutated non-small cell lung cancer. *Br J Cancer.* 2019;121(9):725-737. This work is licensed under a Creative Commons Attribution 4.0 International (CC BY 4.0) License. https://creativecommons.org/licenses/by/4.0/.[15] Percentages in blue highlight the mechanisms observed in the U31402-A-U102 study specimens (n = 49). *EGFR* mutations were retrieved from case report forms, Oncomine™ Comprehensive Assay v3, GuardantOMNI™, and Biodesix. Mutations in the other genes were retrieved from Oncomine™ Comprehensive Assay v3 and GuardantOMNI™. Detection cutoff was set at 0.1% for both GuardantOMNI™ and Biodesix.
Act, activation; amp, amplification; ctDNA, circulating tumor DNA; del, deletion; EGFR, epidermal growth factor receptor; EMT, epithelial–mesenchymal transition; HER, human epidermal growth factor receptor; mut, mutation; SCC, squamous cell carcinoma; SCLC, small cell lung cancer; TKI, tyrosine kinase inhibitor.

- **Patients with NSCLC harboring various genomic alterations after EGFR TKI treatment were enrolled into this study**

HER3-DXd: Efficacy in Various Genomic Alterations

Antitumor Activity of HER3-DXd 5.6 mg/kg Q3W in *EGFR*-Mutated NSCLC With Diverse TKI Resistance Mechanisms



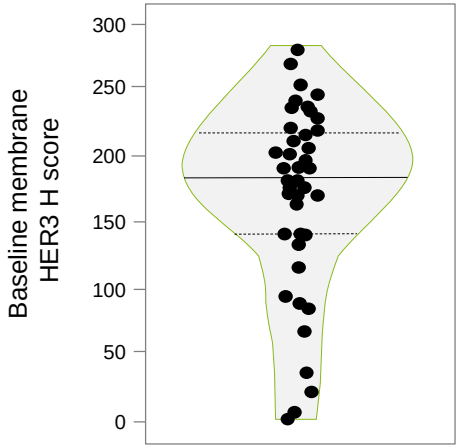
[a]This analysis does not include 7 patients (out of 56) without postbaseline tumor assessments by the data cutoff date. [b]Performed centrally using Oncomine™ Comprehensive Assay v3 from pretreatment tumor tissue. Results from local testing are included for patients when tissue was unavailable for central analysis. Additional mutations detected using GuardantOMNI™ assay from cfDNA in blood collected prior to treatment with HER3-DXd are included. For cfDNA analysis, a minor allelic frequency of 0.5% was used as a threshold for inclusion of mutations. The copy number data from cfDNA are not shown.

BICR, blinded independent central review; cfDNA, circulating free DNA; CR, confirmed response; EGFR, epidermal growth factor receptor; NSCLC, non–small cell lung cancer; PR, partial response; Q3W, every 3 weeks; SoD, sum of diameters; TKI, tyrosine kinase inhibitor.

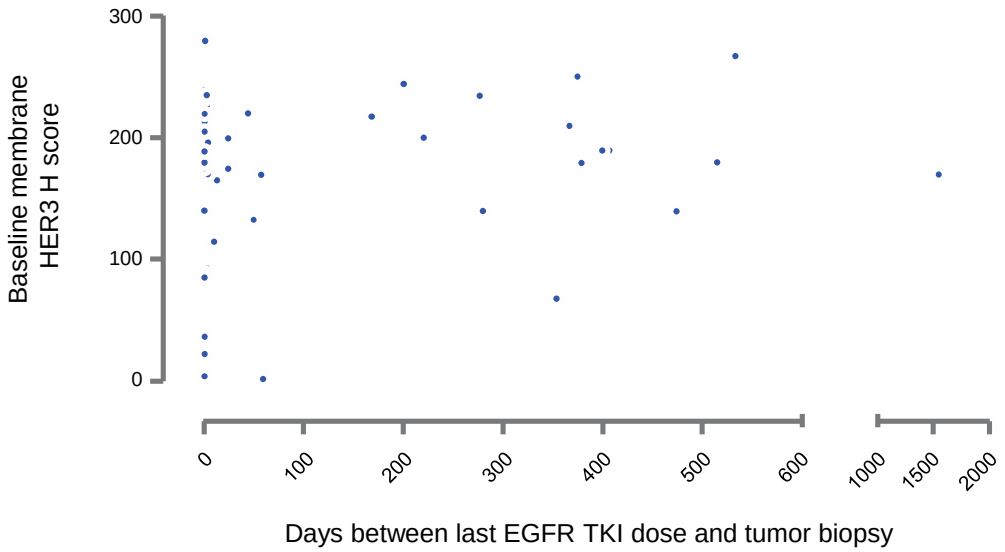
- **Antitumor activity of HER3-DXd was seen in NSCLC with various genomic alterations**

HER3-DXd: HER3 Expression in NSCLC Tumors

Baseline Membrane HER3 Expression and Association With Time Since Most Recent EGFR TKI Therapy[a,b]



	All patients
Evaluable patients, n	43
Median membrane HER3 H score (range)	180 (2-280)

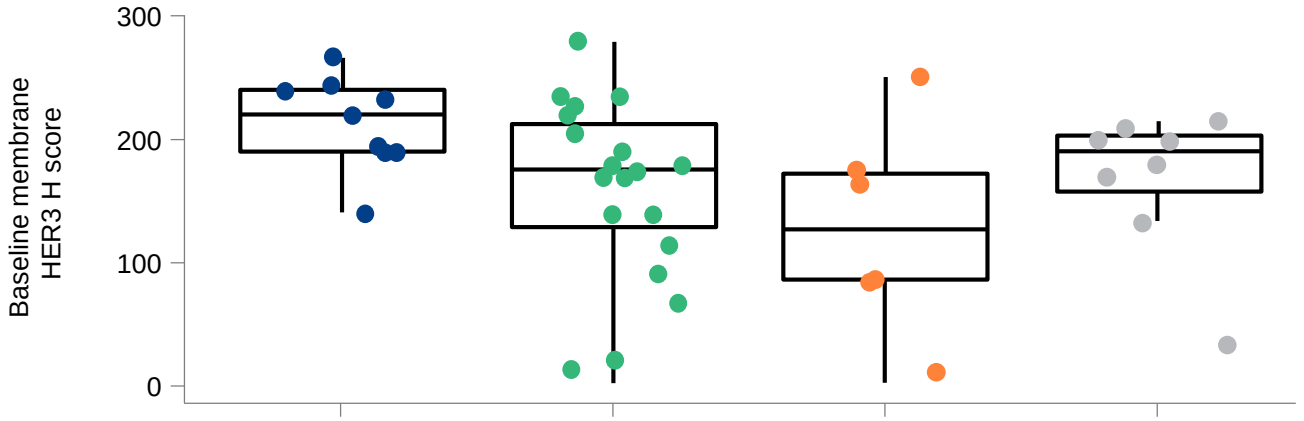


[a]One patient without evaluable postbaseline tumor assessments was included. [b]Solid horizontal bars in figure 3A denote medians; dotted horizontal lines are 25th and 75th percentiles.
EGFR, epidermal growth factor receptor; HER3, human epidermal growth factor receptor 3; TKI, tyrosine kinase inhibitor.

- **HER3 was expressed in nearly all tumors from unselected NSCLC patients enrolled to the study**

HER3-DXd: Association of HER3 Expression and Response

HER3 Membrane H Score and Association With Confirmed Clinical Response by BICR



cBOR (BICR)	CR/PR	SD	PD	NE
Evaluable patients, n	9	19	6	8
Median membrane HER3 H score (range)	220 (140-268)	175 (4-280)	126.5 (2-251)	190 (36-215)

BICR, blinded independent central review; cBOR, confirmed best overall response; CR, complete response; HER3, human epidermal growth factor receptor 3; NE, not evaluable; PD, progressive disease; PR, partial response; SD, stable disease.

- **Preliminary trend of an association between HER3 expression and clinical response was observed***

*From partial data obtained from ongoing phase 1 study

3 ADC Update

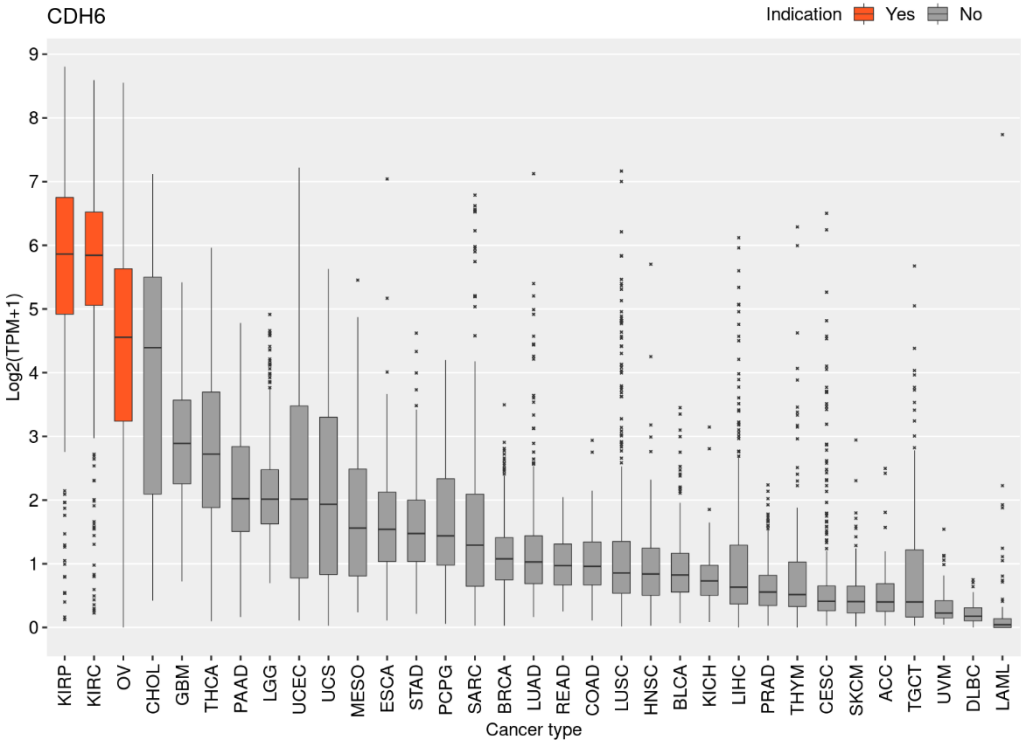
Alpha Update

News Flow

DS-6000: Target CDH6

CDH6 (cadherin 6)

- Member of CDH family. The function of CDH6 is still to be fully elucidated. It is said to be related to cell-cell adhesion, epithelial to mesenchymal transition (EMT) and metastasis
- In developmental stage, CDH6 is expressed in kidney, endometrium, placenta and CNS, and **minimal expression in adult normal tissues**
- **Highly expressed in renal cell carcinoma (RCC) and ovarian cancer (OVC)**



ACC, Adrenocortical Carcinoma; **BLCA**, Bladder Urothelial Carcinoma; **BRCA**, Breast Invasive Carcinoma; **CESC**, Cervical Squamous Cell Carcinoma and Endocervical Adenocarcinoma; **CHOL**, Cholangiocarcinoma; **COAD**, Colon Adenocarcinoma; **DLBC**, Lymphoid Neoplasm Diffuse Large B-cell Lymphoma; **ESCA**, Esophageal Carcinoma; **GBM**, Glioblastoma Multiforme; **HNSC**, Head and Neck Squamous Cell Carcinoma; **KICH**, Kidney Chromophobe; **KIRC, Kidney Renal Clear Cell Carcinoma**; **KIRP, Kidney Renal Papillary Cell Carcinoma**; **LAML**, Acute Myeloid Leukemia; **LGG**, Brain Lower Grade Glioma; **LIHC**, Liver Hepatocellular Carcinoma; **LUAD**, Lung Adenocarcinoma; **LUSC**, Lung Squamous Cell Carcinoma; **MESO**, Mesothelioma; **OV, Ovarian Serous Cystadenocarcinoma**; **PAAD**, Pancreatic Adenocarcinoma; **PCPG**, Pheochromocytoma and Paraganglioma; **PRAD**, Prostate Adenocarcinoma; **READ**, Rectum Adenocarcinoma; **SARC**, Sarcoma; **SKCM**, Skin Cutaneous Melanoma; **STAD**, Stomach Adenocarcinoma; **TGCT**, Testicular Germ Cell Tumors; **THCA**, Thyroid Carcinoma; **THYM**, Thymoma; **UCEC**, Uterine Corpus Endometrial Carcinoma; **UCS**, Uterine Carcinosarcoma; **UVM**, Uveal Melanoma

The data is a result of analysis used TCGA (The Cancer Genome Atlas) dataset

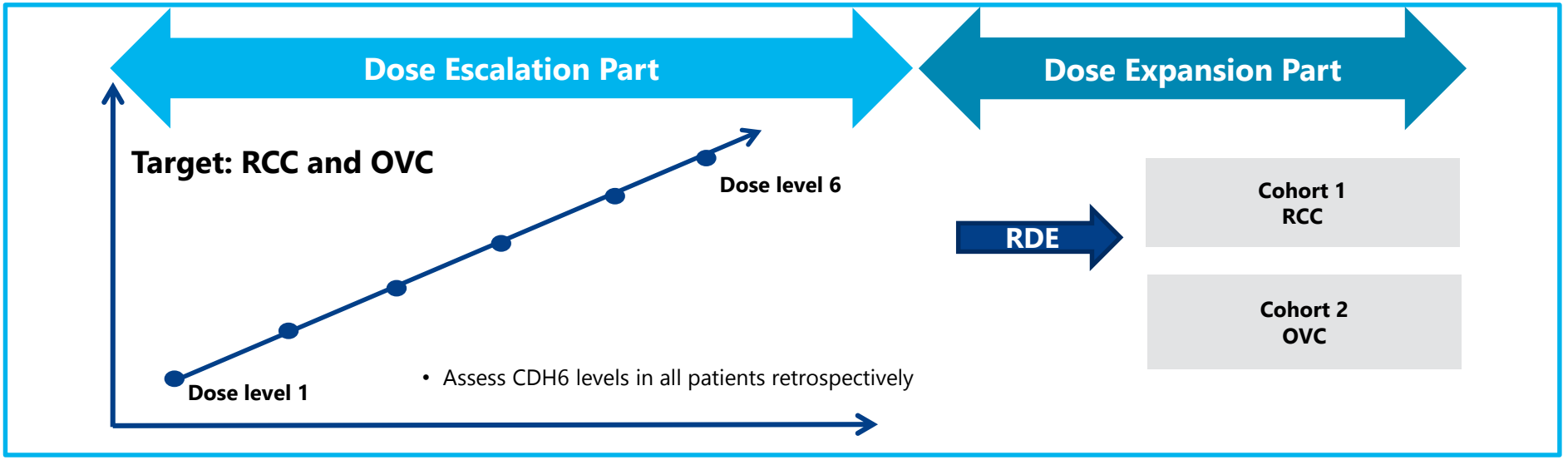
DS-6000: Target Indication and Phase 1 Study Design

Renal cell carcinoma

- **Disease:** Cancer of renal parenchymal cells, which accounts for about 90% of kidney cancers
- **SOC:** 1L; I/O + I/O or I/O + TKI, 2L~: cabozantinib, VEGFR TKI, and etc.
- **Incidence:** 166,000 (JP/US/EU5)*

Ovarian Cancer

- **Disease:** 70% of OVC cases are diagnosed at an advanced stage and this has a significant impact on 5-year survival
- **SOC :** Chemotherapy, chemotherapy + bevacizumab, chemotherapy +PARP inhibitors
- **Incidence:** 63,000 (JP/US/EU5)*



*Source: CancerMPact®, Kantar Health/Synix inc.（Strict diversion of confidential information）
TKI: Tyrosine kinase inhibitor, VEGFR: Vascular endothelial growth factor receptor

DS-1647 (G47Δ): Malignant Glioma

Dec. 2020: Submitted in Japan

Malignant glioma

- **Disease:** Glioma accounts for about 1/4 of brain tumors and is classified into 4 stages according to malignancy. Those with high malignancy (grades 3 and 4) are called malignant gliomas
- **SOC:** Radiation therapy + temozolomide after removal of the tumor by surgery
  No treatment option available for recurrent glioma
- **Incidence:** Malignant gliomas are estimated to be about 2,800 pts/year (JP)[*1]

Study results[*2]

- **Primary endpoint:** 1 year survival rate 92.3%（12/13）
- **Secondary endpoint:** Median PFS 8.6M
- **Safety:** Manageable safety profile

Next step

- **Approval: Anticipated in FY2021 H1** (SAKIGAKE Designation)
- **Global Development:** to be determined

*1 The Committee of Brain Tumor Registry of Japan. Report of Brain Tumor Registry of Japan (2005-2008) 14th Edition. Neurol Med Chir (Tokyo). 2017;57(Supplement 1):9-102
*2 Phase 2 IIS for glioblastoma conducted by Prof. Tomoki Todo of the institute of medical science, the university of Tokyo

Efient® : Ischemic Stroke

Dec. 2020: sNDA submitted for ischemic stroke in Japan

Ischemic Stroke (non-cardioembolic ischemic stroke)

- **Disease:** Non-cardioembolic ischemic stroke represented by atherothrombotic and lacunar stroke is caused mainly by thrombosis in the artery and has a high risk of recurrence. **There is high unmet medical need for the prevention of recurrence of non-cardioembolic ischemic stroke**
- **Incidence:** 1.4 million patients with atherothrombotic and lacunar stroke (JP)*

Background

- Non-inferiority was not verified in a previous confirmatory study with ischemic stroke using clopidogrel as a control, but a decrease in the occurrence of cerebrocardiovascular events was confirmed in the atherothrombotic/lacunar stroke subgroup analysis
- Additional **phase 3 study** was conducted with **atherothrombotic/lacunar stroke**
- Since **primary endpoint was achieved** in this study, sNDA was submitted together with the previous study results

Next step

- **Conference:** Results of additional P3 study will be presented at Japan Stroke Society in March 2021
- **Approval: Anticipated in FY2021 Q3**

*DS estimation

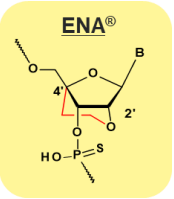
DS-5141: Duchenne Muscular Dystrophy

Daiichi-Sankyo

◆ Dec. 2020: TLR obtained from phase 1/2 study（12 and 48-week study)

Duchenne Muscular Dystrophy (amenable to Exon 45 skipping)

- **Disease:** Hereditary muscle disorder caused by abnormalities in the dystrophin gene resulting in the absence of dystrophin protein production. Muscle weakness progresses with age, and many patients die of respiratory or cardiac failure in their 20s or 30s
- **SOC: No Exon 45 skipping drug is available**
- **Incidence:** About 450 patients who are amenable to Exon 45 skipping (JP)*



Study results

- **Safety:** No safety concerns
- **Efficacy:** Production of messenger RNA with exon 45 skipping of the dystrophin gene was found in all patients, and the expression of dystrophin protein showed a clear increase in several patients. Analysis of the further trial results is currently ongoing

Next step

- **Conference:** Study results will be presented in FY2021
- **NDA: Plan to consult with the regulatory authority based on the detailed analysis results**

*Jikken-igaku (Japanese), 2016; 34(19): 3151-8.
Takeshima Y, Yagi M, Okizuka Y, et al. Mutation spectrum of the dystrophin gene in 442 Duchenne/Becker muscular dystrophy cases from one Japanese referral center. J Hum Genet. 2010;55(6):379-88.

Tarlige® : Central Neuropathic Pain

◆ Dec. 2020: TLR obtained from phase 3 study

Central Neuropathic Pain

- **Disease:** Pain caused by central nervous system damage or associated dysfunction, accompanied by various sensory abnormalities (e.g. central post-stroke pain, central neuropathic pain after spinal cord injury)
- **SOC:** $\alpha_2\delta$ ligand, opioid
- **Incidence:** About 210,000 patients are treated with $\alpha_2\delta$ ligand (JP)*

Study results

- **Safety:** No additional safety concerns were observed
- **Efficacy:** Change in the average daily pain score, from baseline to Week 14 with placebo, show superiority of mirogabalin over the placebo, achieving the primary objective

Next step

- **Conference:** Study results will be presented in FY2022
- **sNDA: Planned in FY2021 Q1**

*DS estimation

3 ADC Update

Alpha Update

News Flow

News Flow

As of January 2021

Daiichi-Sankyo

ENHERTU®	**Phase 3 DESTINY-Breast02: HER2 positive BC, 3L** • **TLR anticipated in FY2021 Q2** **Phase 3 DESTINY-Breast03: HER2 positive BC, 2L** • **TLR anticipated in FY2021 Q2** **Phase 3 DESTINY-Breast04: HER2 low BC, post chemo** • **TLR anticipated in FY2021 Q2** **Phase 2 DESTINY-Lung01: HER2 positive/mutated NSCLC** • **TLR anticipated in FY2021 H1**
Dato-DXd	**Phase 1 TROPION-Lung04: NSCLC (w/o actionable mutation, durvalumab combo)** • **Planned to start in FY2020 Q4**
HER3-DXd	Phase 2 HERTHERNA-Lung01: EGFRm NSCLC • Planned to start in FY2020 Q4
G47Δ	Malignant glioma • JP: **Approval anticipated in FY2021 H1**
DS-3201	**Phase 2 pivotal: Peripheral T-cell lymphoma** • **Planned to start in FY2021 Q1**
DS-6000	**FIH Phase 1: Renal cell carcinoma, ovarian cancer** • **Planned to start in FY2020 Q4**
Lixiana®	**Atrial fibrillation in the very elderly** • **JP: Approval anticipated in FY2021 H1**
Tarlige®	**Central neuropathic pain** • **JP: Submission planned in FY2021 Q1**

Underlined: New or updated from FY2020 Q2

BC: breast cancer, FIH: first-in-human, NSCLC: non-small cell lung cancer

1 FY2020 Q3 Financial Results

2 Business Update

3 R&D Update

4 **Appendix**

Major R&D Milestones in FY2020 (3 ADCs)

As of January 2021

Daiichi-Sankyo

Project		Target Indications [phase, study name]	FY2020 Q1	FY2020 Q2	FY2020 Q3	FY2020 Q4	FY2021 H1
Enhertu	BC	HER2+, 3L [P2 pivotal, DESTINY-Breast01]	EU submitted		CHMP positive opinion	EU approved	
		HER2+, 3L [P3, DESTINY-Breast02]					TLR anticipated
		HER2+, 2L [P3, DESTINY-Breast03]					TLR anticipated
		HER2 low, post chemo [P3, DESTINY-Breast04]					TLR anticipated
		HER2+, post-neoadjuvant [P3, DESTINY-Breast05]			Study started		
		HER2 low, chemo naive [P3, DESTINY-Breast06]		Study started			
		HER2+, 3L~ combo [P1/2, DESTINY-Breast07]				Study started	
		HER2 low, 3L combo [P1, DESTINY-Breast08]				Study started	
		TNBC, dulvalmab combo [P1b/2, BEGONIA]	Study started				
	GC	HER2+, 3L [P2 pivotal, DESTINY-Gastric01]	JP submitted	JP approved	US sBLA accepted	US approved (2L)	
		HER2+, 2L～/1L [P1b/2, DESTINY-Gastric03]	Study started				
		HER2+, 2L [P3, DESTINY-Gastric04]					Study start planned
	NSCLC	Dulvalmab combo [P2, HUDSON]	Study started				
		HER2 mutant [P2, DESTINY-Lung02]				Study start planned	
		HER2+, 1L [P1b, DESTINY-Lung03]				Study start planned	
	Others	BC/NSCLC, pembrolizmab combo [P1]	Study started				
		HER2 mutant [P2, DESTINY-PanTumor01]				Study started	
		HER2 expressing tumors [P2, DESTINY-PanTumor02]		Study started			
Dato-DXd		NSCLC, w/o actionable mutation [P3, TROPION-Lung01]				Study start planned	
		NSCLC, w/o actionable mutation, pembrolizmab combo [P1, TROPION-Lung02]			Study started		
		NSCLC, w/o actionable mutation, dulvalmab combo [P1, TROPION-Lung04]				Study start planned	
		NSCLC, with actionable mutation [P2, TROPION-Lung05]				Study start planned	
HER3-DXd		EGFRm NSCLC [P2 pivotal, HERTHENA-Lung01]				Study start planned	
		EGFRm NSCLC, osimertinib combo [P1]				Study start planned	
		CRC [P2]		Study started			

Red underlined: new or updated from FY2020 Q1

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

Major R&D Milestones in FY2020 (Alpha)

As of January 2021

Daiichi-Sankyo

Project	Target Indications [phase, study name, region]	FY2020 Q1	FY2020 Q2	FY2020 Q3	FY2020 Q4	FY2021 H1
Pexidartinib	Tenosynovial giant cell tumor [P3, ENLIVEN,EU]	CHMP negative opinion				
	Tenosynovial giant cell tumor [P2, JP]				**Study start planned**	
G47Δ	Malignant glioma [IIS, JP]			**Submitted**		**Approval anticipated**
Yescarta	R/R B-cell lymphoma [P2 pivotal, JP]				**Approved**	
DS-3201	PTCL [P2 pivotal, JP/US/Asia]					**Study start planned**
DS-6157	GIST [P1, JP/US]	Study started				
DS-1055	Solid tumors [P1, JP/US]			Study started		
DS-6000	Renal cell calcinoma, ovarian cancer [P1, US]				**Study start planned**	
Lixiana	AF in the very elderly [P3, ELDERCARE-AF, JP]	TLR obtained	Submitted			**Approval anticipated**
Efient	Ischemic stroke [P3, PRASTRO III, JP]	TLR obtained		**Submitted**		
Tarlige	Central neuropathic pain [P3, JP]			**TLR obtained**		**Submission planned**
DS-5141	Duchenne type muscular dystrophy [P1/2, JP]			**TLR obtained**		
DS-5670	COVID-19 vaccine [JP]				Study start planned	
DS-2319	COVID-19 [JP]				Study start planned	

Red underlined: new or updated from FY2020 Q2

AF: atrial fibrillation, GIST: gastrointestinal stromal tumor, IIS: investigator-initiated study, PTCL: peripheral T-cell lymphoma, TLR: top line results

Major R&D Pipeline: 3 ADCs

As of January 2021

Daiichi-Sankyo

Phase 1		Phase 2	Phase 3	Submitted
(JP/US) NSCLC, TNBC TROPION-PanTumor01	(US/EU/Asia) HER2+ BC 2L~/1L DESTINY-Breast07	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia)HER2+ BC 3L DESTINY-Breast02	
(JP/US) NSCLC (w/o actionable mutation, pembrolizumab combo) TROPION-Lung02	(US/EU/Asia) HER2 low BC chemo naïve/ post chemo DESTINY-Breast08	(US/EU) HER2+ GC 2L DESTINY-Gastric02	(JP/US/EU/Asia) HER2+ BC 2L DESTINY-Breast03	
(JP/US) NSCLC (w/o (actionable mutation, durvalumab combo) TROPION-Lung04	(US/EU/Asia) HER2+ GC combo, 2L～/1L DESTINY-Gastric03	(JP/US/EU)HER2+/mutated NSCLC DESTINY-Lung01	(JP/US/EU/Asia) HER2 low BC post chemo DESTINY-Breast04	
(JP/US/EU/Asia) NSCLC	(EU/Asia)HER2+ NSCLC (durvalumab combo) DESTINY-Lung03	(JP/US/EU)HER2+/mutated NSCLC DESTINY-Lung02	(JP/US/EU/Asia) HER2+ BC post neoadjuvant DESTINY-Breast05	
(JP/US)EGFRm NSCLC (osimertinib combo)	(US/EU) BC, bladder (nivolumab combo)	(US/EU/Asia) NSCLC(durvalumab combo) HUDSON	(JP/US/EU/Asia) HER2 low BC chemo naive DESTINY-Breast06	
(JP/US) HER3+ BC	(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU) HER2+ CRC DESTINY-CRC01	(JP/US/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	
		(US/EU/Asia) HER2 mutated tumor DESTINY-PanTumor01	(JP/US/EU/Asia) NSCLC(w/o actionable mutation) TROPION-Lung01	
		(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02		
		(JP/US/EU/Asia) NSCLC (w actionable mutation) TROPION-Lung05		
		(JP/US) EGFRm NSCLC HERTHENA-Lung01		
		(JP/US/EU) HER3+ CRC		

Enhertu® HER2-directed ADC

Dato-DXd TROP2-directed ADC

HER3-DXd 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)

Major R&D Pipeline: Alpha

As of January 2021

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	**DS-3201** (JP) EZH1/2 inhibitor ATL/L	**Quizartinib** (JP/US/EU/Asia) FLT3 inhibitor 1L AML QuANTUM-First	**DS-1647 (G47Δ)** (JP) Oncolytic HSV-1 Malignant glioma IIS
DS-6157 (JP/US) GPR20-directed ADC GIST	**DS-3201** (US) EZH1/2 inhibitor AML, ALL	**DS-3201** (JP/US/EU/Asia) EZH1/2 inhibitor PTCL	**Pexidartinib** (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	**Lixiana** (JP) FXa inhibitor AF in the very elderly
DS-6000 (US) CDH6-directed ADC Renal cell calcinoma, ovarian cancer	**PLX2853** (US) BET inhibitor AML	**DS-1001** (JP) Mutant IDH1 inhibitor Glioma	**Tarlige** (JP/Asia) $\alpha_2\delta$ Ligands Central neuropathic pain	**Efient** (JP) ADP receptor inhibitor Ischemic stroke
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	**PLX2853** (US) BET inhibitor Solid tumor	**DS-5141** (JP) ENA oligonucleotide DMD	**Minnebro** (JP) MR blocker Diabetic nephropathy	**VN-0107/MEDI3250** (JP) Live attenuated influenza vaccine nasal spray
DS-2741 (JP) Anti-Orai1 antibody Atopic dermatitis	**PLX2853** (US) BET inhibitor Gynecologic neoplasms, ovarian cancer	**DS-1211** (US) TNAP inhibitor Pseudoxanthoma elasticum	**VN-0102/JVC-001** (JP) Measles mumps rubella combined vaccine	
	PLX2853 (US) BET inhibitor Prostate cancer			

Oncology

Specialty medicine

Vaccine

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

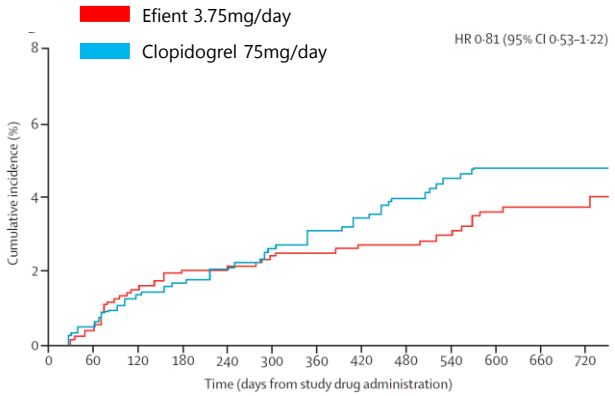
□: project in oncology that is planned to be submitted for approval based on the results of phase 2 trials

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

Efient® : Ischemic Stroke

PRASTRO-I

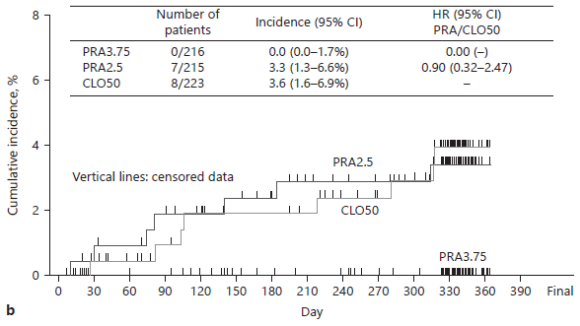
- Ischemic stroke patients: N=3,747
- 19% risk reduction in atherothrombotic/lacunar stroke patients (N=2,275)
- No increase in significant bleeding



Lancer Neurol 2019; 18: 238-47

PRASTRO-II

- Ischemic stroke patients (elderly/underweight): N=654
- No cerebrocardiovascular events were seen in Efient 3.75mg cohort (0.0%)
- No increase in significant bleeding



Cerebrovasc Dis 2020;49:152–159

PRASTRO-III

- Atherothrombotic/lacunar stroke patients: N=234
- Incidence of cerebrocardiovascular event was lower in Efient 3.75 mg cohort compared to clopidogrel cohort
- No new safety concern

（Detail to be presented at future conference)

sNDA

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: +81-3-6225-1125
Email: DaiichiSankyoIR@daiichisankyo.co.jp