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Daiichi-Sankyo

FY2021 Q1
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

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July 30, 2021

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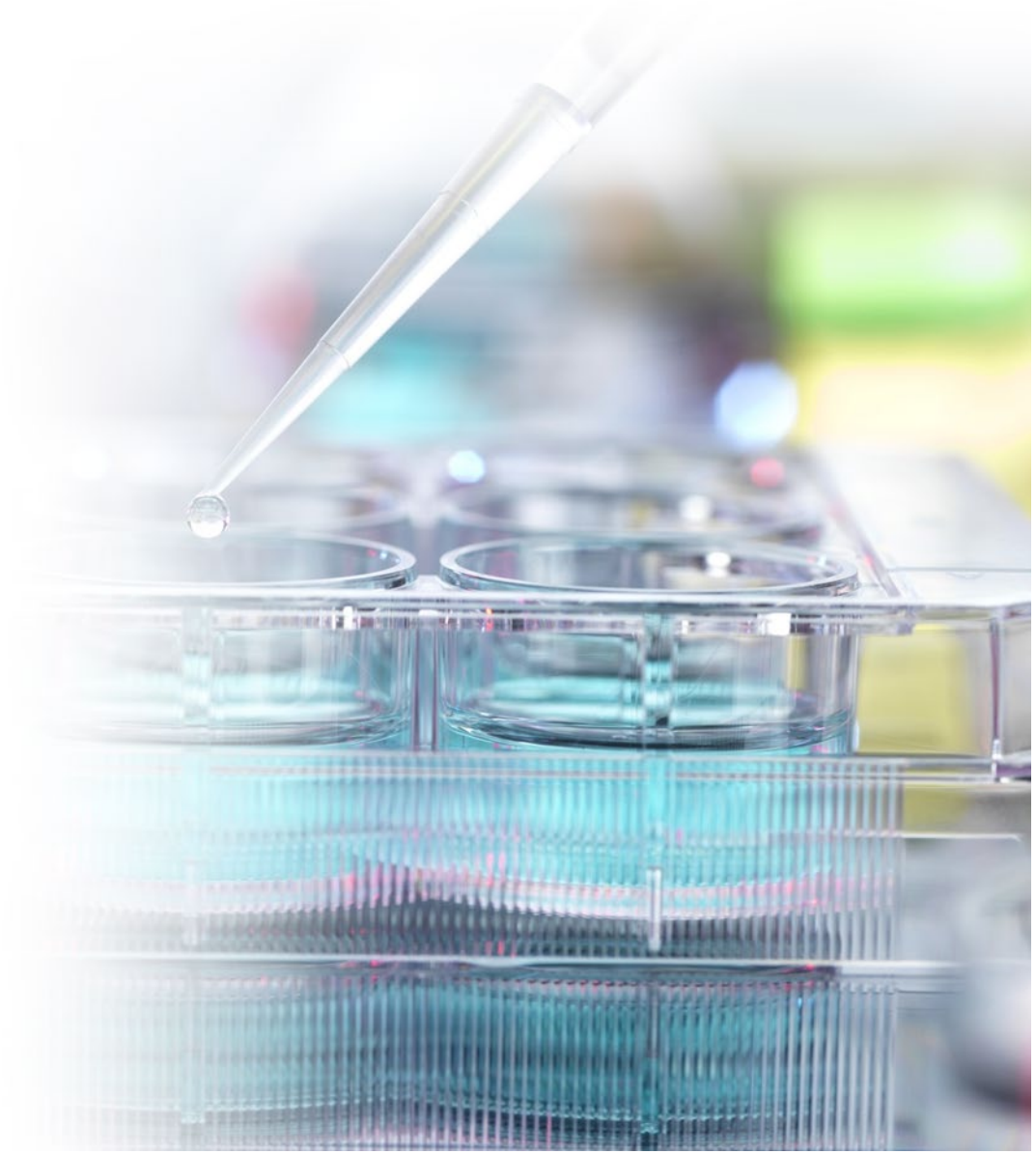
Agenda

1. **FY2021 Q1 Financial Results**
2. Business Update
3. R&D Update
4. Appendix



Overview of FY2021 Q1 Results

(Bn JPY)

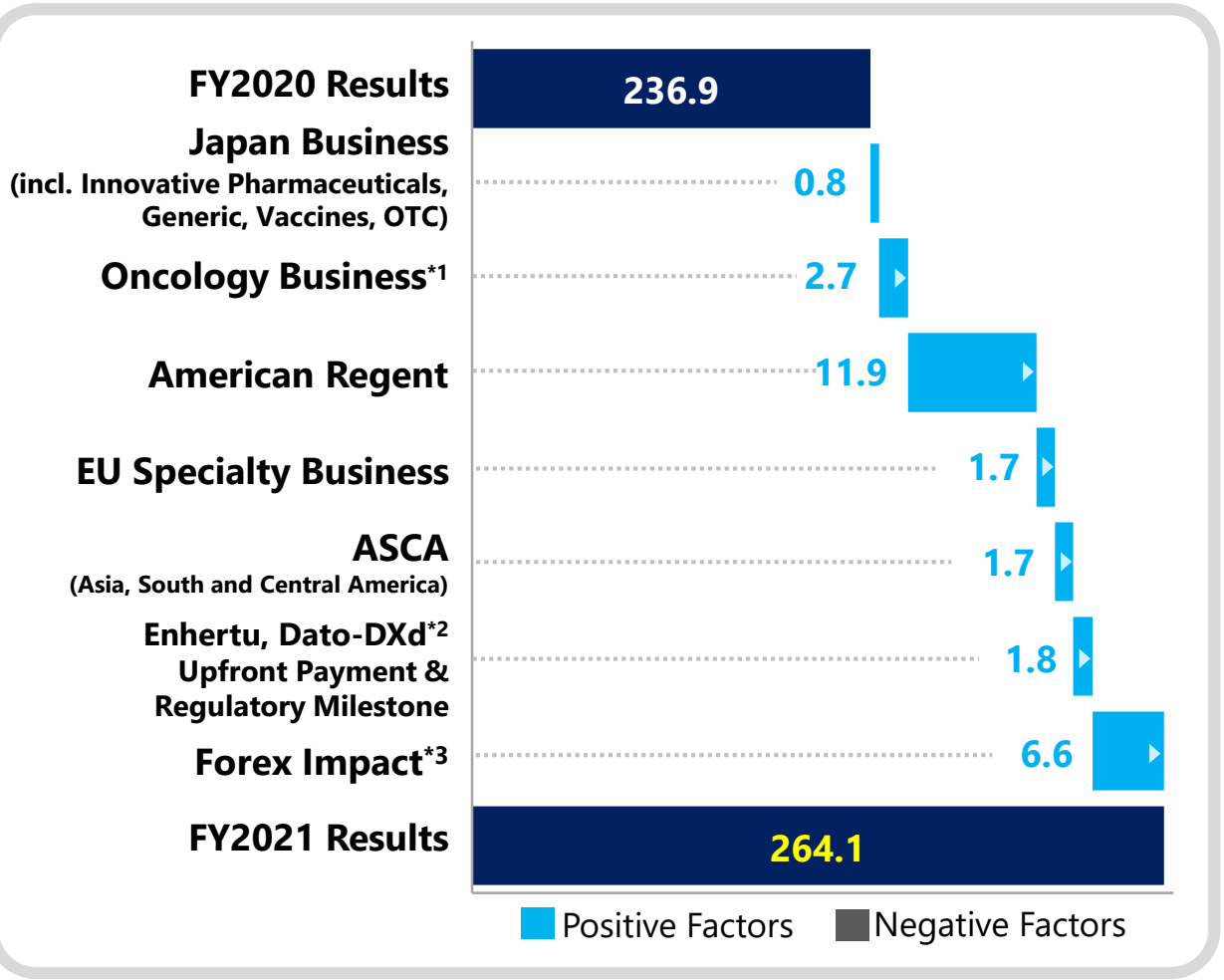
	FY2020 Q1 Results	FY2021 Q1 Results	YoY	
Revenue	**236.9**	**264.1**	**+11.4%**	**27.1**
Cost of sales	82.2	85.2		2.9
SG&A expenses	71.8	81.2		9.4
R&D expenses	48.9	54.0		5.2
Core operating profit	**34.1**	**43.7**	**+28.2%**	**9.6**
Other revenue	0.1	2.1		2.0
Other expenses	0.0	0.0		-0.0
Operating profit	**34.1**	**45.8**	**+34.1%**	**11.6**
Profit before tax	**41.4**	**47.1**		**5.7**
Profit attributable to owners of the Company	**31.9**	**35.2**	**+10.6%**	**3.4**

Currency Rate	USD/JPY	107.62	109.49	+1.87
	EUR/JPY	118.47	131.95	+13.48

As an indicator of ordinary profitability, "core operating profit" which excludes temporary gains and losses (other revenue and other expenses) from operating income is disclosed.
Gains and losses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, reconciliation, and other non-temporary and material gains and losses are included in the "temporary gains and losses".
Temporary gains and losses are excluded from results and forecast for cost of sales, SG&A expenses and R&D expenses shown in the list above.

Revenue

Increased by 27.1 Bn JPY (Increased by 20.5 Bn JPY excl. forex impact)



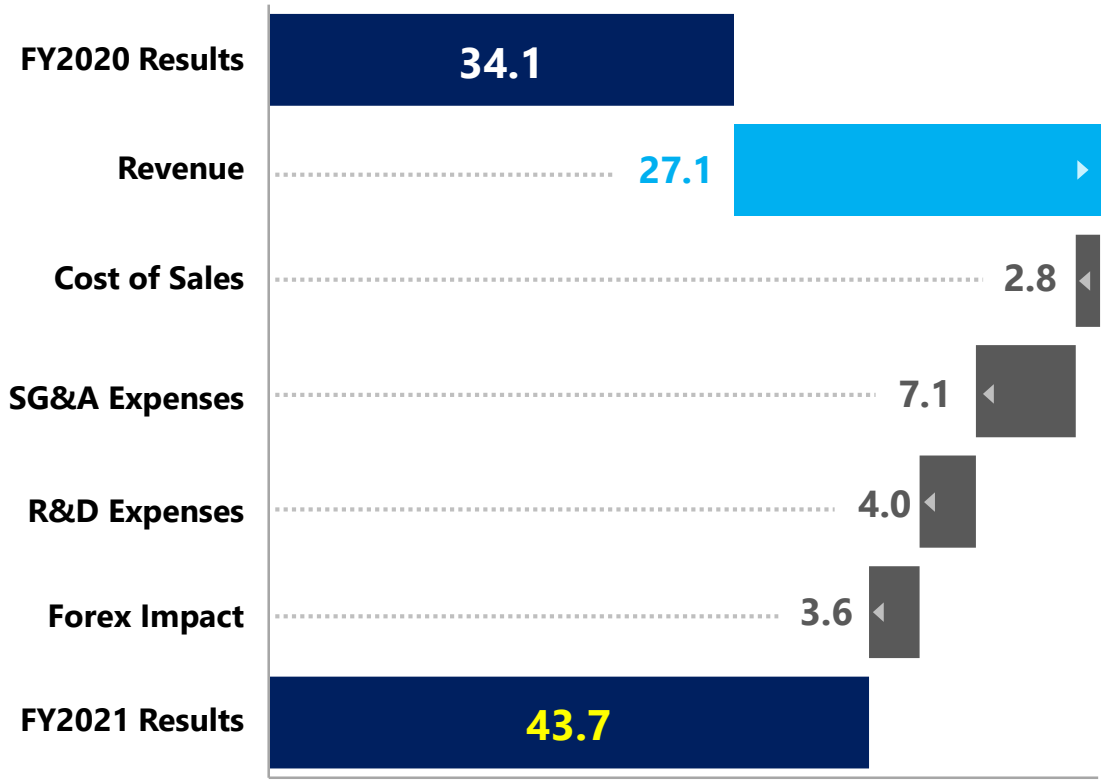
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+3.1	Memary	-10.7
Tarlige	+2.8		
Enhertu	+2.0		
Daiichi Sankyo Espha	+2.5	Vaccines business	-1.5
Ezetimibe AG, Memantine AG etc.		Rotarix	
Daiichi Sankyo Healthcare	+1.1		
Roxionin			
Oncology Business*1 Unit			
Enhertu	+5.6	Olmesartan	-2.2
American Regent Unit			
Injectafer	+5.2		
GE injectables	+5.1		
EU Specialty Business Unit			
Lixiana	+4.6	Gain on sales of transferring long-listed products	-3.2
Enhertu, Dato-DXd*2 Upfront Payment & Regulatory Milestone			
Dato-DXd upfront payment	+1.5		

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Dato-DXd: Datopotamab deruxtecan (DS-1062)
*3 Forex impact USD: +0.9, EUR : +3.5, ASCA: +2.2

Core Operating Profit

Increased by 9.6 Bn JPY (Increased by 6.6 Bn JPY excl. forex impact)



(Bn JPY)

Revenue ..... +27.1
incl. forex impact of +6.6

Cost of Sales ..... +2.8 (Profit decreased)
Improvement in cost of sales ratio by change in product mix

SG&A Expenses ..... +7.1 (Profit decreased)
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

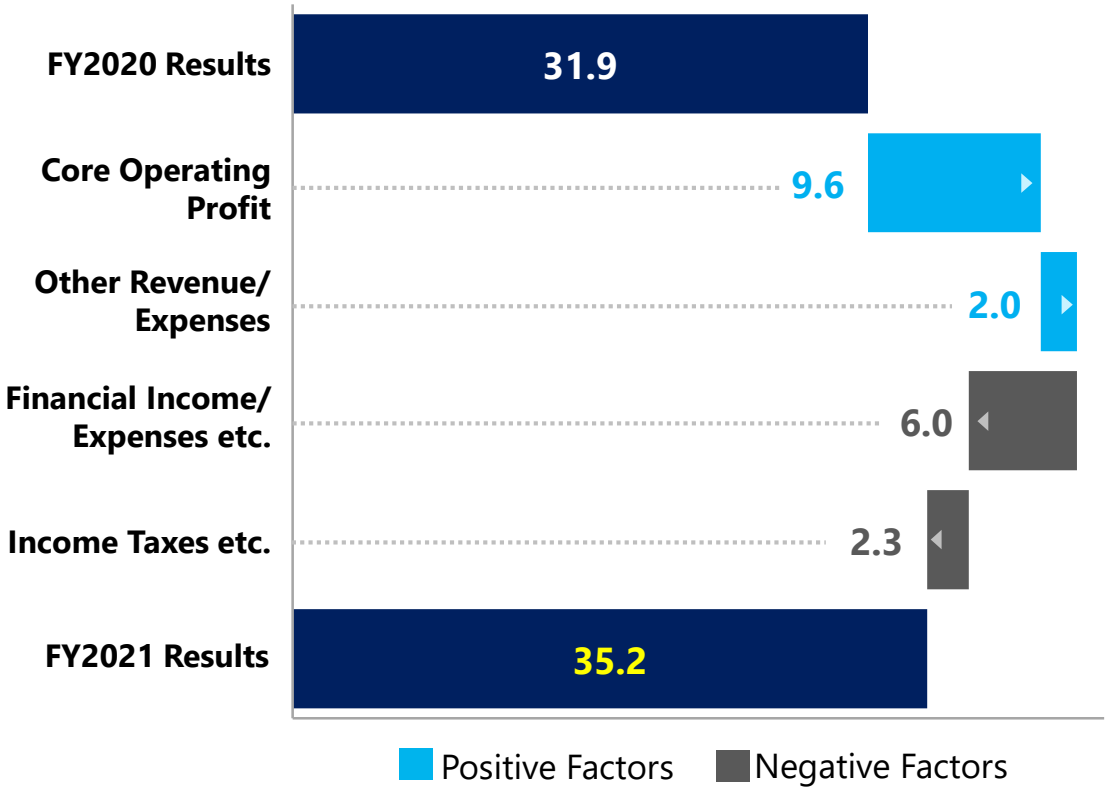
R&D Expenses ..... +4.0 (Profit decreased)
Increase in 3ADCs* R&D investments

Forex Impact ..... +3.6 (Profit decreased)
Cost of Sales ..... +0.1
SG&A Expenses ..... +2.3
R&D Expenses ..... +1.2

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

Profit Attributable to Owners of the Company

Increased by 3.4 Bn JPY



(Bn JPY)

Other Revenue/Expenses ····· **-2.0 (Profit increased)**

FY2021: Gains related to sale of Osaka logistics center ····· -2.1

Financial Income/Expenses etc. ····· +6.0（Profit Decreased）

- FY2020: Financial income due to decrease in contingent consideration of Ambit/quizartinib acquisition ····· +4.7
- Deterioration in forex gains/losses ····· +0.6

Income Taxes etc. ····· +2.3（Profit Decreased）

	FY2020 Q1	FY2021 Q1	YoY
Profit before Tax	41.4	47.1	+5.7
Income Taxes etc.	9.6	11.8	+2.3
Tax rate	23.1%	25.2%	+2.1%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2020 Q1 Results	FY2021 Q1 Results	YoY
Japan Business	130.2	129.1	-1.1
Daiichi Sankyo Healthcare	14.3	15.4	+1.1
Oncolgy Business	11.6	14.5	+2.9
Enhertu	5.0	10.8	+5.8
Turalio	0.3	0.6	+0.3
American Regent	26.5	39.1	+12.6
Injectafer	9.4	14.9	+5.4
Venofer	6.9	7.9	+1.0
GE injectables	8.5	13.8	+5.3
EU Speciality Business	27.7	32.7	+5.0
Lixiana	16.4	23.4	+7.0
Nilemdo/Nustendi	-	0.7	+0.7
Olmesartan	5.2	5.6	+0.4
ASCA (Asia, South and Central America)	22.5	26.5	+3.9

Currency Rate	USD/JPY	107.62	109.49	+1.87
	EUR/JPY	118.47	131.95	+13.48

Revenue: Major Products in Japan

(Bn JPY)

		FY2020 Q1 Results	FY2021 Q1 Results	YoY
Lixiana	anticoagulant	**19.8**	**22.9**	**+3.1**
Nexium	ulcer treatment	**19.9**	**19.7**	**-0.2**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**8.7**	**9.2**	**+0.5**
Tarlige	pain treatment	**4.3**	**7.1**	**+2.8**
Tenelia	type 2 diabetes mellitus treatment	**6.6**	**6.4**	**-0.2**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**5.0**	**5.1**	**+0.2**
Loxonin	anti-inflammatory analgesic	**6.2**	**5.8**	**-0.4**
Vimpat	anti-epileptic agent	**3.8**	**4.5**	**+0.7**
Canalia	type 2 diabetes mellitus treatment	**3.9**	**4.3**	**+0.4**
Efient	antiplatelet agent	**3.8**	**4.1**	**+0.3**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**0.2**	**2.2**	**+2.0**
Rezaltas	antihypertensive agent	**3.6**	**3.3**	**-0.3**
Inavir	anti-influenza agent	**0.6**	**0.3**	**-0.3**

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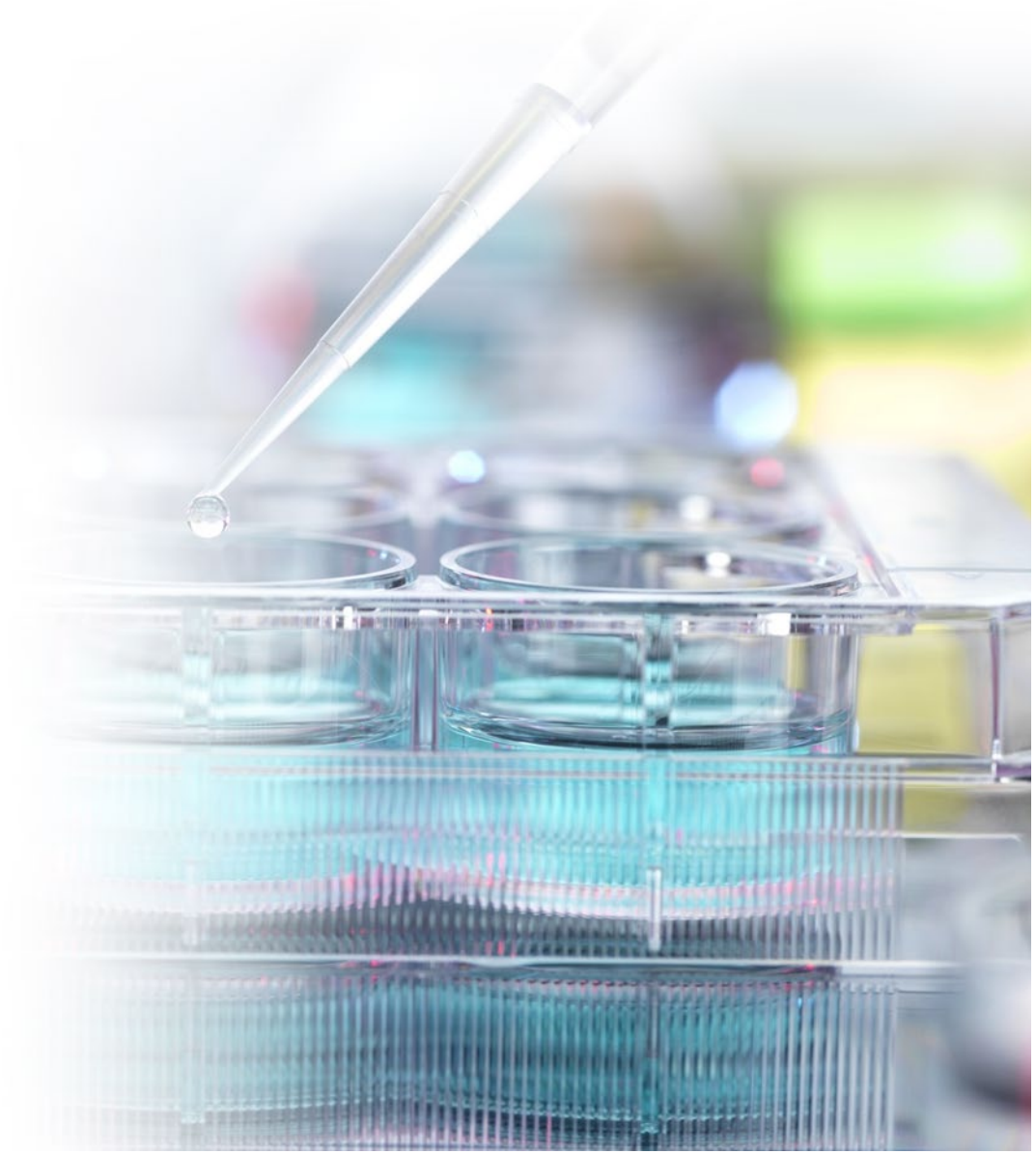


ENHERTU®: Revenue

(Bn JPY)

	FY2021 Q1 Results	YoY	FY2021 Forecast (as of Jul.)	vs. as of Apr.	<Reference> Total Consideration
Product Sales	13.0	7.7	61.0	-8.4	-
Japan	2.2	2.0	13.4	-	-
US	9.6	4.6	42.4	-8.0	-
Europe	1.2	1.2	5.1	-0.4	-
ASCA	-	-	0.2	-	-
Upfront payment	2.5 *1	-	9.8 *1	-	149.0
Regulatory milestone payment	0.6 *1	0.3	2.2 *1	-2.6	33.7
US HER2+ Breast Cancer 3L	0.2	-	0.9	-	13.7
EU HER2+ Breast Cancer 3L	0.1	0.1	0.5	-	7.9
US HER2+ Gastric Cancer 2L + 3L	0.2	0.2	0.8	-	12.1
US HER2+ or HER2 Mutant NSCLC 2L	-	-	-	-2.6 *2	-
Total	16.0	8.1	73.1	-11.0	182.7

*1 Revenue recognized in each period
*2 Revenue based on the assumption that milestone will be achieved in FY2021; Expected consideration converted with forex rate of 105 JPY to 1 USD : 13.1 billion yen

ENHERTU®: Performance in Each Region

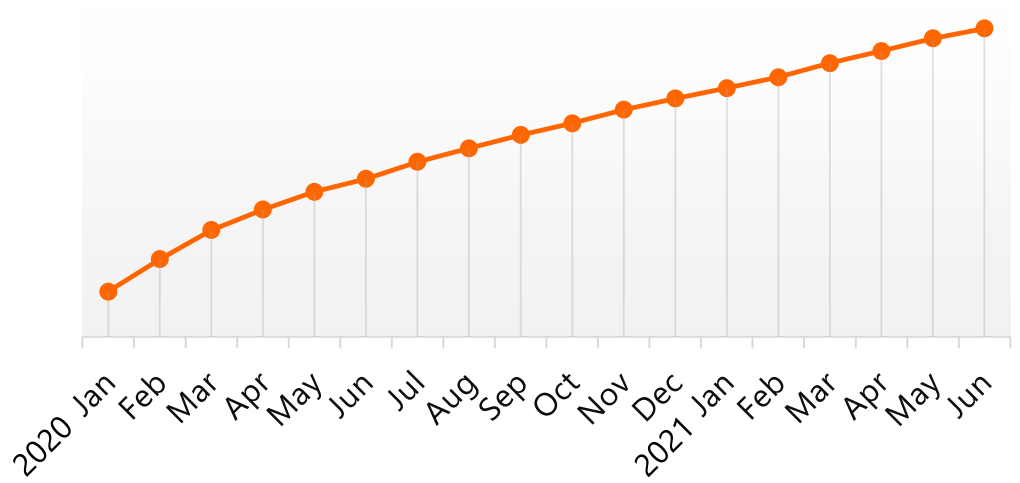
- **Steady increase in product sales due to market penetration in launched countries and expansion in market**
- **Product sales: FY2021 Q1 Results 13.0 Bn JPY (YoY +7.7 Bn JPY)**
  FY2021 Forecast 58.6 Bn JPY (YoY +28.5 Bn JPY)

ENHERTU® trastuzumab deruxtecan

US (HER2+ Breast Cancer 3L, HER2+ Gastric Cancer 2L)

- **Steady growth in the market**
  - New patient share as planned
  - Outlets purchasing as planned

Accumulated total of outlets purchasing



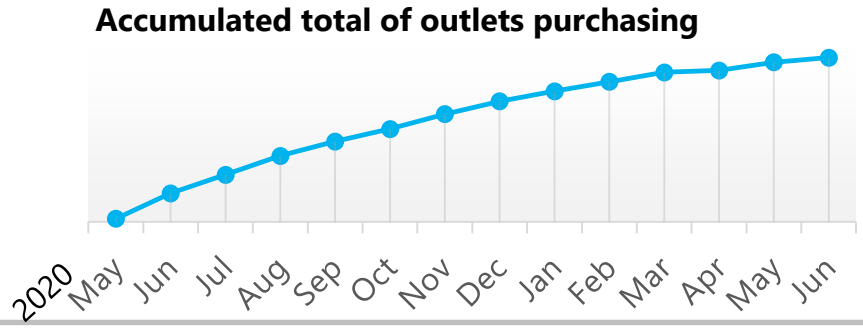
Europe (HER2+ Breast Cancer 3L)

- **Steady expansion in the market**
  - EU: Launched in FY2020 Q4
  - **UK: Launched in FY2021 Q1**

Japan (HER2+ Breast Cancer 3L, HER2+ Gastric Cancer 3L)

- **Steady growth in the market**
  - New patient share as planned
  - Outlets purchasing as planned

Accumulated total of outlets purchasing



Japan: New Product Approval

- **Oncolytic virus G47Δ* (product name: DELYTACT®) was approved in June 2021, which was co-developed with Dr. Todo of the Institute of Medical Science, The University of Tokyo**
- **The first oncolytic virus in the world to target malignant glioma**

- Generic name: **teserpaturev**
- Indication: **malignant glioma**
  - Grade III and grade IV among glioma which originates in glial cells in brain tissue
  - Estimated number of new patients in Japan: **around 2,800 patients annually**
- Overview of the approval
  - The approval is primarily based on the results of Japan Ph2 study (investigator initiated study) in patients with residual or recurrent glioblastoma conducted by Dr. Todo of the Institute of Medical Science, The University of Tokyo
  - **Received conditional and time-limited approval which requires verification of clinical benefit and safety within 7 years for all patients treated with DELYTACT®**

***G47Δ**

The third generation oncolytic herpes simplex virus type 1 created by Dr. Todo and his colleagues at the Institute of Medical Science, The University of Tokyo. DELYTACT® has triple mutation within the viral genome and is designed to replicate selectively in cancer cells.

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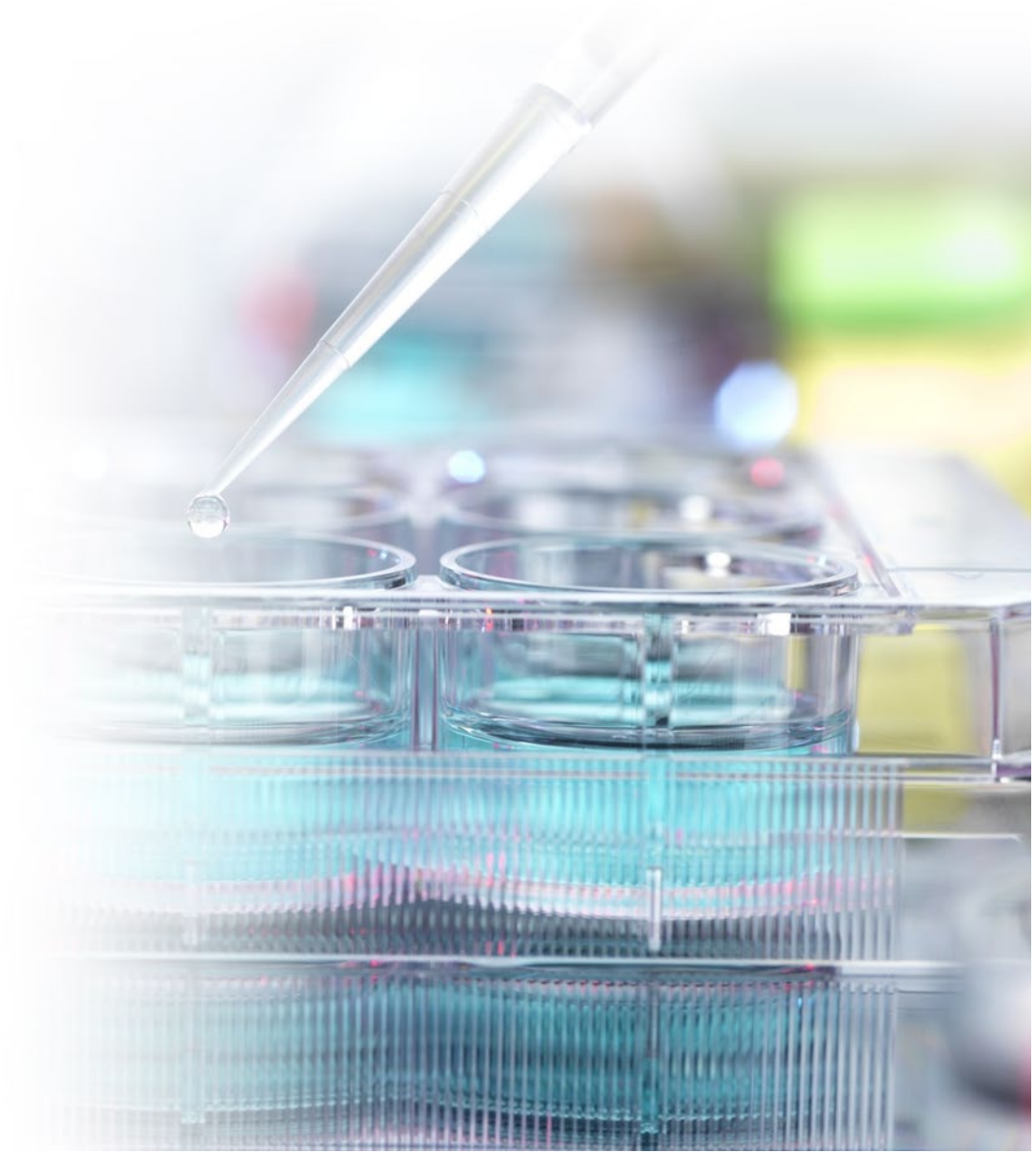


3ADCs update

Alpha update

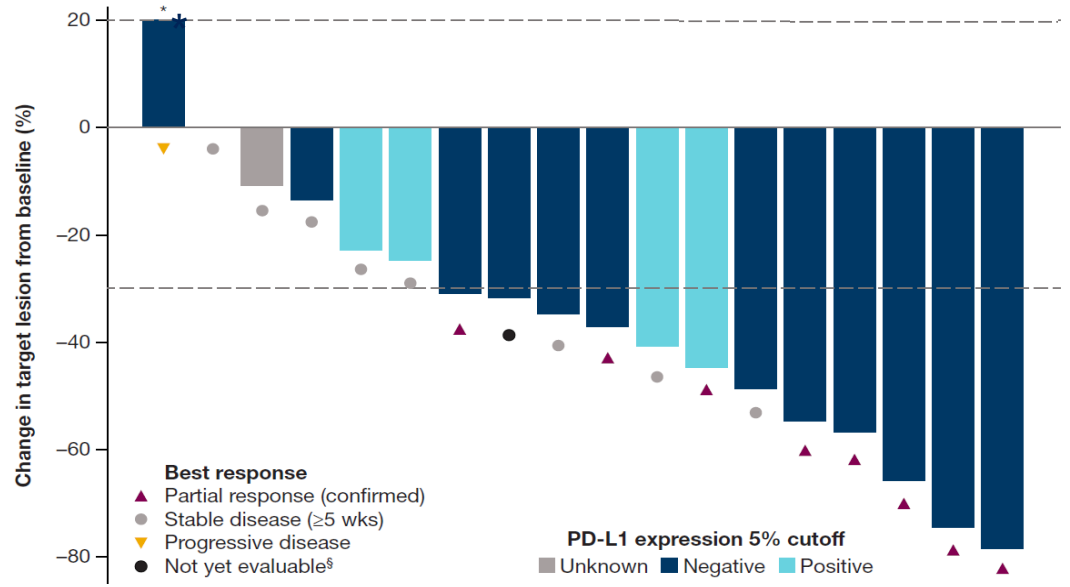
WCLC/ESMO 2021

News Flow

ENHERTU®: Breast cancer

- **DESTINY-Breast03 study (HER2+, 2L, Ph3): TLR of interim analysis anticipated in FY2021 Q2 as originally planned**
- **DESTINY-Breast09 study (HER2+, 1L, Ph3): First patient dosed in June**
- **Presented interim results of BEGONIA study and subgroup analysis data of DESTINY-Breast01 study in patients with brain metastasis at ASCO 2021**

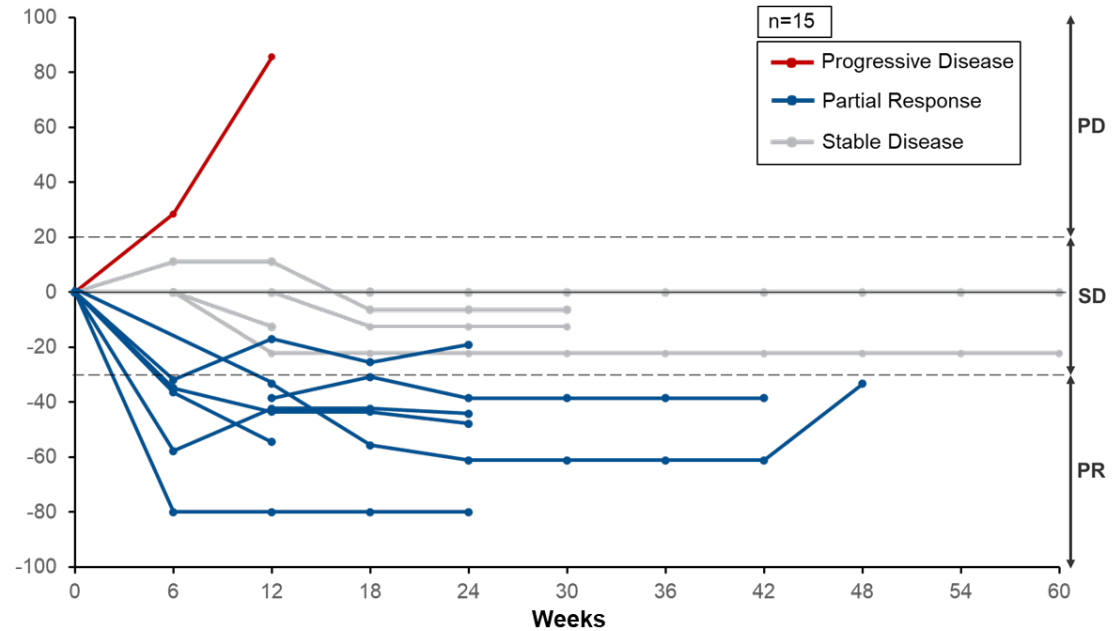
BEGONIA interim results (durvalumab combo)



* If the best percentage change from baseline of target lesions cannot be calculated due to progression, withdrawal or death, the value is imputed at +20% ‡ Number of subjects that had the opportunity to complete at least two on-treatment disease assessments or have PD or death

The confirmed ORR was 66.7% in Arm 6 (HER2 low/ER-/PR-BC, ENHERTU® +durvalumab) of BEGONIA study.

DESTINY-Breast01 brain met subgroup analysis



3 patients with reported baseline measurements had no change over time.
2 patients with brain metastases at baseline did not have sufficient data to evaluate response in the brain and are not shown.

Durable responses were observed in patients with stable, treated brain metastases.

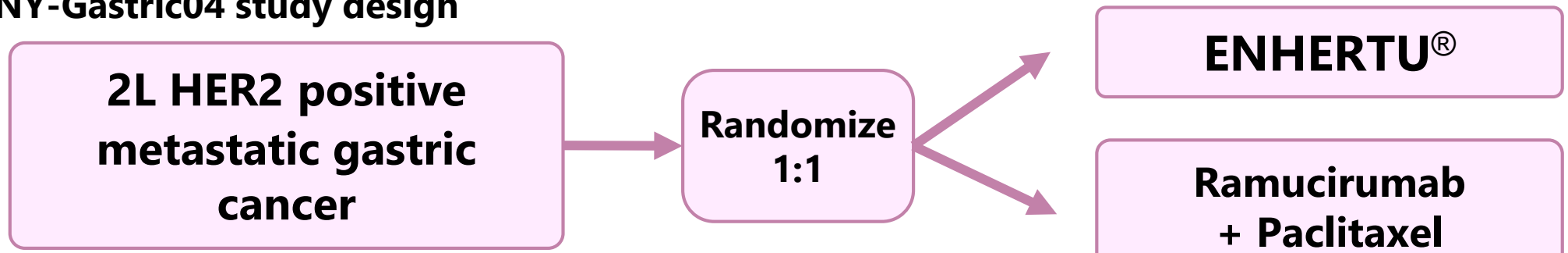
BC: breast cancer, ER: estrogen receptor, ORR: objective response rate, PR: progesterone receptor, TLR: top line results

ENHERTU®: Gastric cancer

- **DESTINY-Gastric02 study (HER2+, 2L, Ph2, US/Europe): TLR obtained in June**
  - Filing strategy currently under discussion with European health authority in FY2021 2H.
- **DESTINY-Gastric04 study (HER2+, 2L, Ph3, global): First patient dosed in June**
  - Ph3 study with overall survival as primary endpoint in patients with 2nd line metastatic gastric cancer
  - The study data is required for filing in Japan

DESTINY-Gastric02 study design

DESTINY-Gastric04 study design

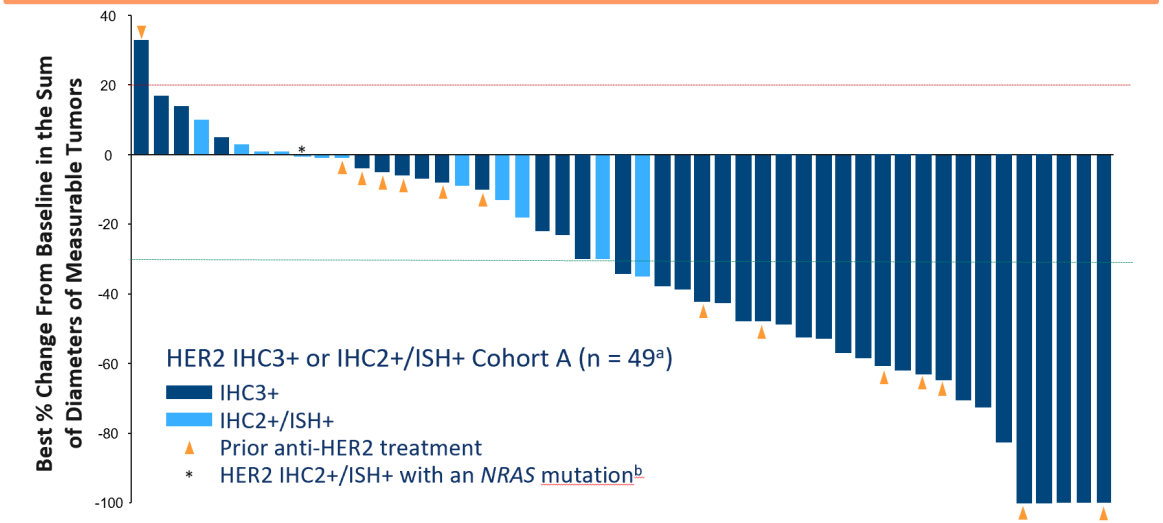


ORR: objective response rate, OS: overall survival, TLR: top line results

ENHERTU®: NSCLC, CRC

- **DESTINY-Lung01 study (HER2 mutated/overexpressing, 2L+, Ph2): TLR obtained in June**
  - HER2 mutated: Granted breakthrough therapy designation in US, filing strategy to be discussed with health authorities
  - HER2 overexpressing: Development strategy under discussion based on the data
- **Presented DESTINY-CRC01 study (HER2 expressing, 3L+, Ph2) final results at ASCO 2021**

DESTINY-CRC01 efficacy



[a]4 patients from the full analysis set were excluded since 1 patient had no measurable target lesion and 3 patients had no postbaseline data. [b]By local assessment.

Promising efficacy profile, ORR 45.3%, mDOR 7 months, mPFS 6.9 months, mOS 15.5 months, were observed in HER2 positive cohort (Cohort A)

DESTINY-CRC01 safety

Adverse Events in ≥20% of Patients

	HER2 IHC3+ or IHC2+/ISH+ Cohort A (n = 53)	HER2 IHC2+/ISH– Cohort B (n = 15)	HER2 IHC1+ Cohort C (n = 18)	Overall (N = 86)	
n (%)	Any Grade	Any Grade	Any Grade	Any Grade	Grade ≥3
Patients with any TEAE	**53 (100)**	**15 (100)**	**18 (100)**	**86 (100)**	**56 (65.1)**
Nausea	37 (69.8)	9 (60.0)	7 (38.9)	53 (61.6)	5 (5.8)
Anemia	21 (39.6)	4 (26.7)	6 (33.3)	31 (36.0)	12 (14.0)
Fatigue	21 (39.6)	7 (46.7)	3 (16.7)	31 (36.0)	1 (1.2)
Decreased appetite	18 (34.0)	5 (33.3)	7 (38.9)	30 (34.9)	0
Platelet count decreased	17 (32.1)	4 (26.7)	7 (38.9)	28 (32.6)	8 (9.3)
Vomiting	23 (43.4)	3 (20.0)	1 (5.6)	27 (31.4)	1 (1.2)
Neutrophil count decreased	20 (37.7)	2 (13.3)	4 (22.2)	26 (30.2)	19 (22.1)
Diarrhea	19 (35.8)	0	4 (22.2)	23 (26.7)	1 (1.2)

Interstitial Lung Disease（ILD）

All Patients (N=86)	n (%)
Grade 1	0
Grade 2	4 (4.7)
Grade 3	1 (1.2)
Grade 4	0
Grade 5	3 (3.5)[a]
Any Grade/Total	8 (9.3)[b,c]

- Safety profile is consistent with the known safety profile
- Careful monitoring and prompt intervention for ILD are required

AE, adverse events; ILD, interstitial lung disease [a]2 patients were from cohort A, 1 from cohort B. [b]4 patients were from cohort A, 3 from cohort B and 1 from cohort C. [c]ILD grades are the highest/most severe grade recorded in a patient.

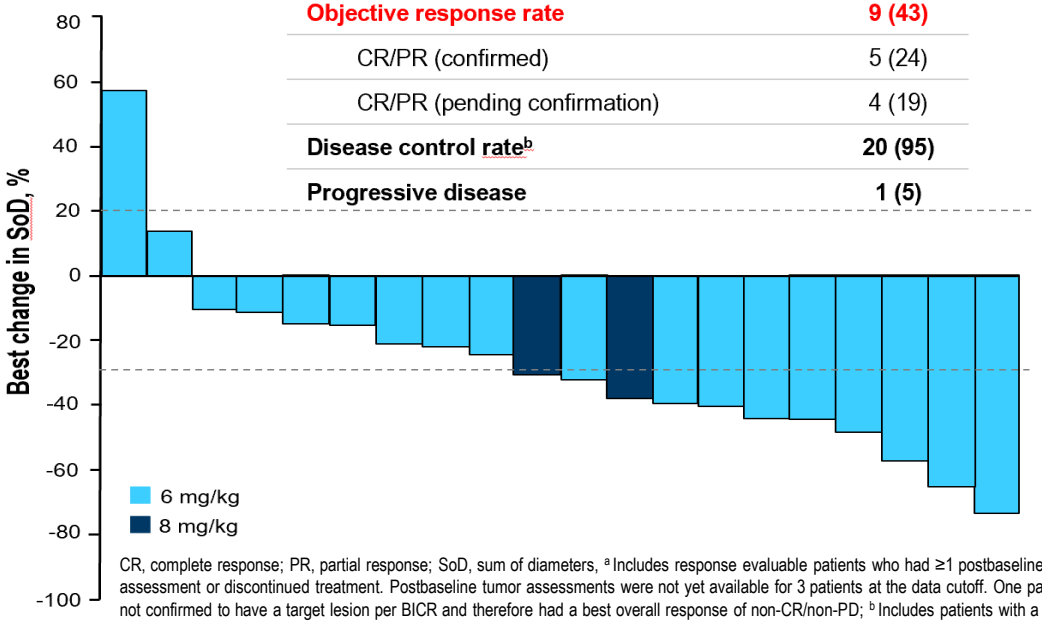
CRC: colorectal cancer, DOR: duration of response, ORR: objective response rate, OS: overall survival, PFS: progression free survival, TLR: top line results

Dato-DXd: Breast cancer, NSCLC

- Presented interim results of TROPION-PanTumor01 study TNBC cohort at ESMO BC 2021
- Presented interim results of TROPION-PanTumor01 study NSCLC cohort at ASCO 2021

TNBC cohort interim results

Patients, n (%)[a]	N=21
Objective response rate	9 (43)
CR/PR (confirmed)	5 (24)
CR/PR (pending confirmation)	4 (19)
Disease control rate[b]	20 (95)
Progressive disease	1 (5)



CR, complete response; PR, partial response; SoD, sum of diameters, [a] Includes response evaluable patients who had ≥1 postbaseline tumor assessment or discontinued treatment. Postbaseline tumor assessments were not yet available for 3 patients at the data cutoff. One patient was not confirmed to have a target lesion per BICR and therefore had a best overall response of non-CR/non-PD; [b] Includes patients with a best overall response of CR, PR, stable disease, or non-CR/non-PD.

Demonstrated promising efficacy and manageable safety profile in heavily treated patients with metastatic TNBC

NSCLC cohort interim results

Best Overall Response (BICR)

Patients[a]	Dato-DXd Dose 4 mg/kg (n=50)	6 mg/kg (n=50)	8 mg/kg (n=80)
ORR, n (%)	12 (24)	13 (26)	19 (24)
CR/PR	10 (20)	11 (22)	19 (24)
CR/PR (too early to be confirmed)	2 (4)	2 (4)	0
DCR, n (%)	38 (76)	35 (70)	64 (80)
PD, n (%)	7 (14)	10 (20)	7 (9)
DOR, median (95% CI), mo	NE (2.8-NE)	10.5 (4.1-NE)	9.0 (5.8-NE)
PFS, median (95% CI), mo[b]	4.3 (3.5-8.4)	6.9 (2.7-8.8)	5.2 (4.1-7.1)

BICR, blinded independent central review; CR, complete response; DCR, disease control rate; DOR, duration of response; NE, not evaluable; ORR, objective response rate; PD, progressive disease; PFS, progression-free survival; PR, partial response.
[a] Includes response evaluable patients who had ≥1 postbaseline tumor assessment or discontinued treatment. [b] Median PFS was limited by immature duration of follow-up in the 4- and 6-mg/kg dosing cohorts.

- Demonstrated promising efficacy and manageable safety profile in patients with advanced or metastatic NSCLC
- The study data and analysis support 6mg/kg as the dose for the pivotal trial

NSCLC: non small cell lung cancer, TNBC: triple negative breast cancer

HER3-DXd: NSCLC

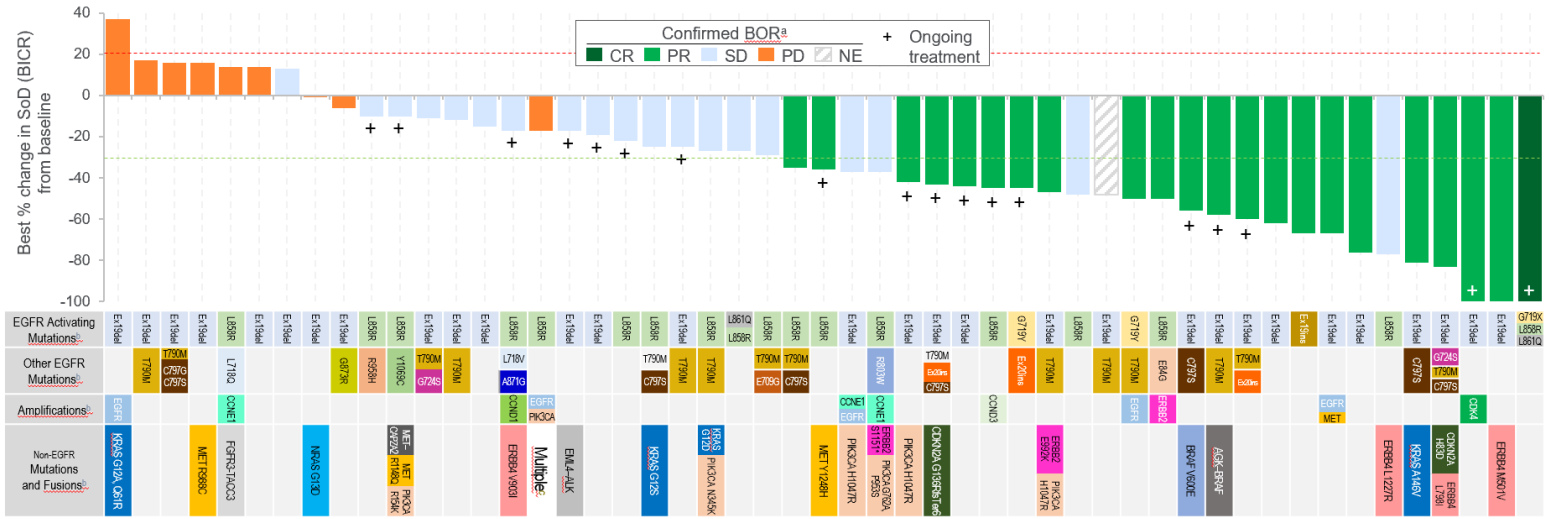
- **EGFR mutated NSCLC Ph1 study (combination with osimertinib): First patient dosed in June**
- **Presented interim results of Ph1 monotherapy EGFR mutated NSCLC cohort at ASCO 2021**

Ph1 efficacy

Confirmed ORR 39%

Median Duration of Response 6.9 months

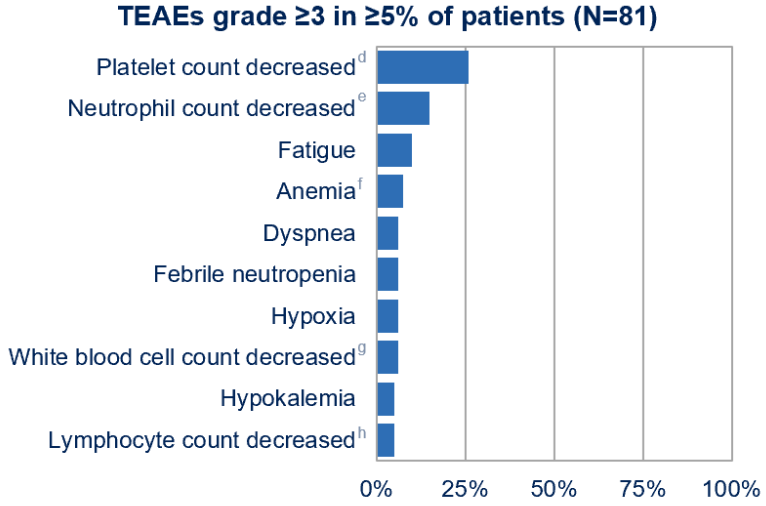
Median PFS 8.2 months



BICR, blinded independent central review; BOR, best overall response; CR, complete response; NE, not evaluable; PD, progressive disease; PR, partial response; SD stable disease; SoD, sum of diameters. Data cutoff: September 24, 2020. [a] Six patients had BORs of NE due to no adequate post-baseline tumor assessment and are not shown; 1 had BOR of NE due to SD too early (< 5 weeks) and is shown with hatched markings [b] Genomic alterations known to be associated with EGFR TKI resistance identified in assays of tumor tissue/ctDNA in blood, collected prior to treatment with HER3-DXd. [c] CDKN2A A143V; PIK3CA E542K, E545K, E726K; ERBB2 K200N; ERBB3 Q847*, Q849*.

Demonstrated promising efficacy in patients with diverse mechanisms of EGFR TKI resistance

Ph1 safety



Data cutoff: September 24, 2020.
[d] Includes thrombocytopenia. [e] Includes neutropenia. [f] Includes hemoglobin decreased. [g] Includes leukopenia. [h] Includes lymphopenia.

Demonstrated manageable safety profile and low rate of discontinuations due to adverse events

NSCLC: non small cell lung cancer, TKI: tyrosine kinase inhibitor

3ADCs update

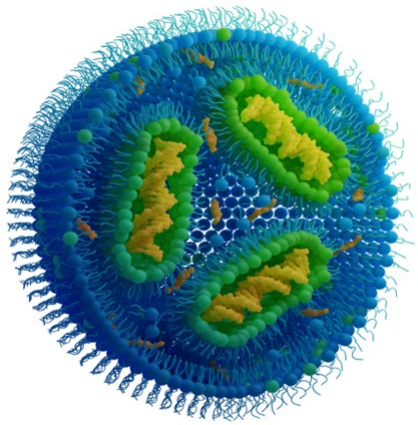
Alpha update

WCLC/ESMO 2021

News Flow

DS-5670 （COVID-19 mRNA vaccine）

Characteristics of DS-5670



Lipid nanoparticle(LNP)-mRNA

- **DS original cationic lipid** is applied
  - Most optimized lipid and lipid composition ratio are selected based on efficacy & safety perspectives
- It is **expected to be effective against variants** as well by targeting **Receptor Binding Domain (RBD)** instead of full spike protein of SARS-Cov-2

- Participating in “Fundamental Research on the Control of a Novel Corona Virus (2019-nCoV)”, an initiative supported by the Japan Agency for Medical Research and Development (AMED).
- **Initiated Ph1/2 study in March 2021** and completed subject enrollment. Currently evaluating the safety, immunogenicity and recommended dose.
- **Planning to initiate active-controlled, non-inferiority confirmatory study this year**, enrolling several thousand subjects. **Submission for approval and commercialization within CY2022** in the case when all regulatory requirements are satisfied.

DS-3201 (EZH1/2 inhibitor): Presented interim results of NHL Ph1 study at EHA

DS3201-A-J101; NCT02732275

Patients with R/R NHL

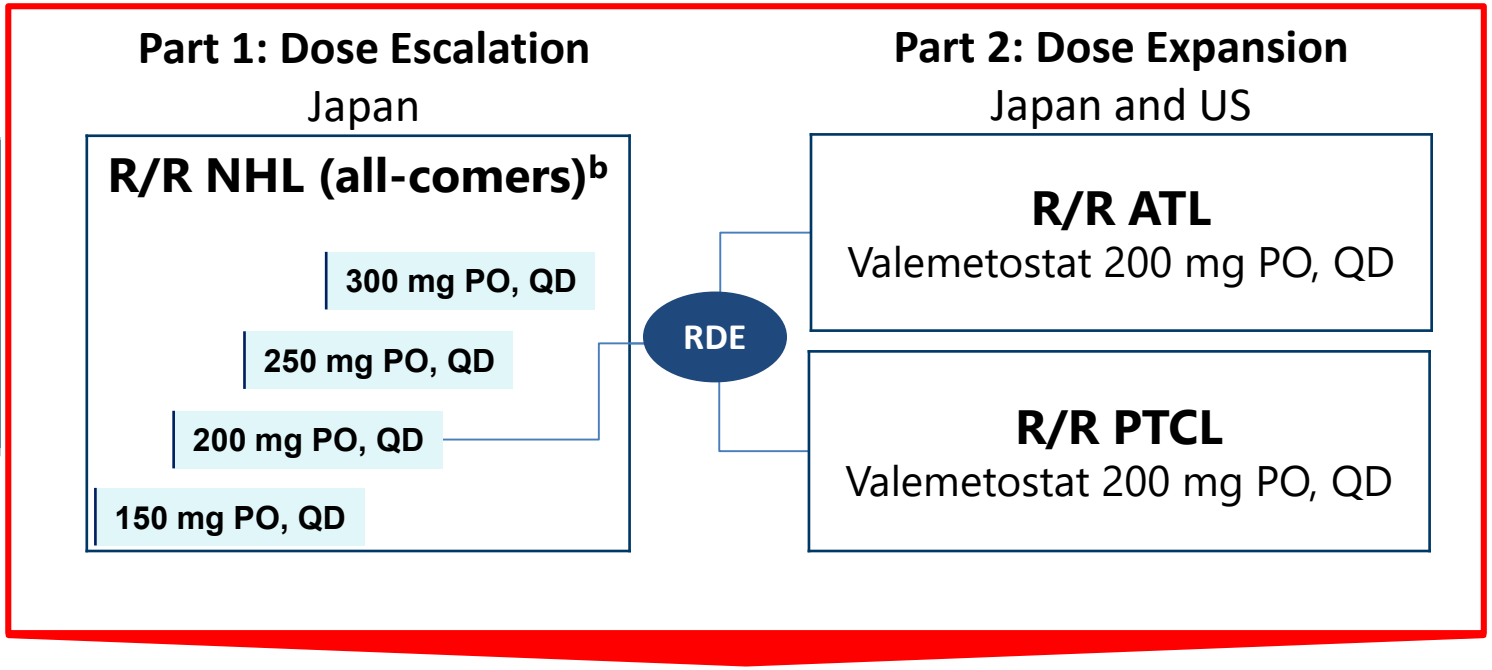
- Age ≥20 (Japan) or ≥18 (US) years
- ECOG PS 0 or 1
- Patients with ATL: positive test result for HTLV-1

Primary endpoints

- Safety (including DLTs, TEAEs)
- Recommended phase 2 dose
- Pharmacokinetics

Secondary endpoints

- Safety
- Antitumor effect[a]



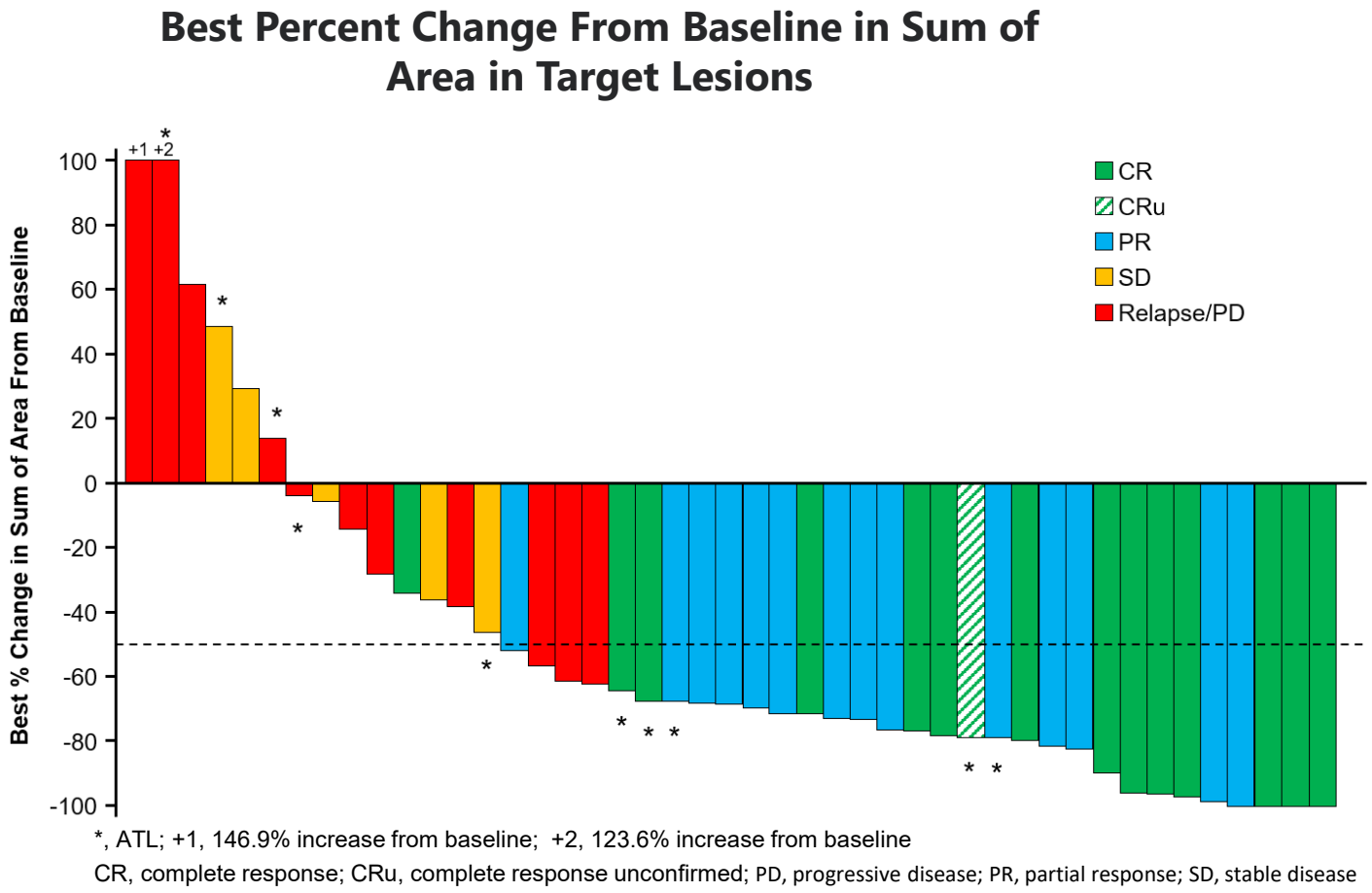
- Safety analysis: all NHL (N=77)
- Safety and efficacy analyses: T-cell NHL (n=58)
  - PTCL (n=44)
  - ATL (n=14)

[a] According to the 2007 revised International Working Group Criteria for Malignant Lymphoma or "Definition, prognostic factors, treatment, and response criteria of adult T-cell leukemia-lymphoma: a proposal from an international consensus meeting." [b] Each dosage was tested with 3 patients.

ATL: adult T-cell leukemia/lymphoma, EHA: European Hematology Association, NHL: non Hodgkin's lymphoma, PTCL: peripheral T-cell lymphoma, R/R: relapsed/refractory

DS-3201 Ph1: Efficacy results

Parameter	All PTCL[a] (N=44)	ATL [a,c] (N=14)
Best response, n (%)		
CR	12 (27.3)	4 (28.6)
PR	12 (27.3)	4 (28.6)
SD	5 (11.4)	2 (14.3)
PD	8 (18.2)	3 (21.4)
NE	1 (2.3)	0 (0)
Not done	6 (13.6)	1 (1.7)
ORR, n (%)	24 (54.5)	8 (57.1)
95% CI	38.8-69.6	28.9-82.3
DOR, median, weeks	56.0	–
(95% CI)	(44.43, –)	(6.14, –)
TTR, median, weeks	8.14	8.14
(range)	(4.1-24.1)	(7.3-84.1)
PFS, median, weeks	52	–
(95% CI)	(16.14, –)	(8.14, –)



*, ATL; +1, 146.9% increase from baseline; +2, 123.6% increase from baseline

CR, complete response; CRu, complete response unconfirmed; PD, progressive disease; PR, partial response; SD, stable disease

Data cutoff: 2 November 2020. Median follow-up times: PTCL , 19.93 (range, 3.1-68.1) weeks; ATL, 23.07 (range, 3.3-125) weeks.

CR, complete response; DOR, duration of response; ORR, overall response rate; PD, progressive disease; PFS, progression-free survival; PR, partial response; SD, stable disease; TCL, T-cell lymphoma; TTR, time to first response.

[a] For PTCL, 42 patients were treated with 200 mg, and 2 were treated with 150 mg. For ATL, 12 patients were treated with 200 mg, and 2 were treated with 150 mg. [c] Consists of 7 patients with acute and 7 patients with lymphomatous subtypes.

Demonstrated ≥50% ORR and trend for durability of response
in relapsed/refractory PTCL and ATL patients who have limited treatment options

DS-3201 Ph1: Most Common TEAEs

Most Common TEAEs (occurring in ≥20% of patients with TCL)[b]	All Histologies[c] (N=77)		PTCL (N=44)		ATL (N=14)	
	All grades	Grade ≥3	All grades	Grade ≥3	All grades	Grade ≥3
Platelet count decreased[d]	47 (61.0)	13 (16.9)	21 (47.7)	5 (11.4)	9 (64.3)	3 (21.4)
Dysgeusia	40 (51.9)	0	20 (45.5)	0	8 (57.1)	0
Anemia	31 (40.3)	9 (11.7)	15 (34.1)	6 (13.6)	5 (35.7)	1 (7.1)
Neutrophil count decreased	27 (35.1)	18 (23.4)	13 (29.5)	8 (18.2)	6 (42.9)	5 (35.7)
Alopecia	26 (33.8)	0	12 (27.3)	0	6 (42.9)	0
WBC count decreased	23 (29.9)	12 (15.6)	10 (22.7)	6 (13.6)	4 (28.6)	3 (21.4)
Diarrhea	22 (28.6)	1 (1.3)	13 (29.5)	0	3 (21.4)	0
Lymphocyte count decreased	22 (28.6)	17 (22.1)	7 (15.9)	6 (13.6)	2 (14.3)	2 (14.3)
ALT increased	16 (20.8)	1 (1.3)	7 (15.9)	0	3 (21.4)	1 (7.1)
Nausea	16 (20.8)	0	11 (25.0)	0	3 (21.4)	0

ALT alanine aminotransferase; BCL, B-cell lymphoma; CTCAE, Common Terminology Criteria for Adverse Events; TEAE, treatment emergent adverse events; WBC, white blood cell.
[a] Study sites could choose to enter thrombocytopenia or platelet count decreased as a term. [b] In order of frequency reported for patients with TCL (n=58). [c] Including 19 patients with BCLs. [d] Grade 3 platelet count decreased, CTCAE 5.0 definition: <50,000-25,000/mm^3; <50.0-25.0 × 10^9/L.

- Demonstrated acceptable safety profile by appropriate monitoring and management of adverse events
  - Grade ≥3 platelet count decrease[a], and thrombocytopenia occurred in 13 patients (16.9%) and 2 patients (2.6%), respectively
  - The median time to platelet count reduction to ≤50x10^9/L from the first dose was 15 days, and the median time to platelet count recovery to ≥50x10^9/L was 12 days
  - 6 patients (9.8%) experienced dose interruption or reduction due to platelet count decrease/thrombocytopenia, but no patients discontinued treatment due to platelet count decrease/thrombocytopenia

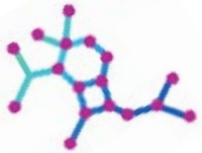
DS-3201 ATL/PTCL development plan

Clinical studies for ATL/PTCL	Region	Status
NHL Ph1 study • ATL, PTCL and others (NCT02732275/JapicCTI-163173)	US/JP	◆ Presented interim data at EHA 2021
R/R ATL **Registrational Ph2 study** (NCT04102150/JapicCTI-194964)	JP	◆ Obtained TLR in July ➢ Preparation underway for filing in Japan in FY2021 2H
R/R PTCL **Registrational Ph2 study** VALENTINE-PTCL01 (NCT04703192/jRCT2071200095)	Global	◆ First patient dosed in June ◆ SAKIGAKE designation in Japan

ATL: adult T-cell leukemia/lymphoma, EHA: European Hematology Association, NHL: non Hodgkin's lymphoma, PTCL: peripheral T-cell lymphoma, R/R: relapsed/refractory, TLR: top line results

Other Alpha update

Oncology

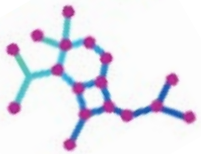


◆DS-1594

（Menin-MLL binding inhibitor）

AML/ALL

Ph1 initiation in US（April）



◆Pexidartinib

（CSF-1/KIT/FLT3 inhibitor）

Tenosynovial giant cell tumor

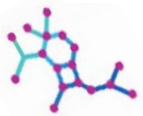
Ph2 initiation in JP（April）

Specialty Medicine

◆ **DS-6016（anti-ALK2 antibody）**

Fibrodysplasia ossificans progressiva

Ph1 initiation in JP（April）

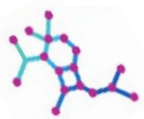


◆ **Tarlige®（α2δ ligand）**

Central neuropathic pain, JP submission (May)

◆ **VN-0200（Vaccine）**

RS virus, Ph1 initiation in JP (June)



◆ **DS-2319（Nafamostat inhalation）**

COVID-19, development discontinued（June）

◆ **DS-2741（anti-Orai1 antibody）**

atopic dermatitis, development discontinued（June）

3ADCs update

Alpha update

WCLC/ESMO 2021

News Flow

Planned Presentation at WCLC/ESMO 2021

WCLC 2021: 9/8-14（Virtual）

Dato-DXd	**TROPION-PanTumor01** (Ph1), NSCLC cohort data update ◆ **Mini oral presentation**

ESMO 2021: 9/16-21 （Virtual）

Enhertu®	**DESTINY-Lung01** (HER2 mutated/overexpressing, 2L+, Ph2), HER2 mutated cohort data ◆ **Late breaking session*** **DESTINY-Breast01** (HER2 positive, 3L, Ph2), updated OS data ◆ **Poster presentation**
Dato-DXd	**TROPION-PanTumor01** (Ph1 NSCLC cohort), sub-analysis of patients with actionable mutations ◆ **Late breaking session***
DS-7300	**Solid tumor Ph1/2**, Ph1 dose escalation data ◆ **Oral presentation**

NSCLC: non small cell lung cancer, OS: overall survival
* Final decision for the acceptance of late breaking abstract will be made after Aug 17

WCLC/ESMO IR event is planned on Sep 22 morning in JP time featuring Ken Takeshita Global R&D Head

3ADCs update

Alpha update

WCLC/ESMO 2021

News Flow

FY2021 News Flow

As of July 2021

Planned publications

WCLC (Sep 8-14)	
Dato-DXd	TROPION-PanTumor01: Ph1 NSCLC cohort • Updated data
ESMO (Sep 16-21)	
Enhertu®	DESTINY-Lung01: HER2mutated/overexpressing NSCLC, 2L, Ph2 • HER2 mutated cohort data* **DESTINY-Breast01: HER2 positive BC, 3L, Ph2** • **Updated OS data**
Dato-DXd	**TROPION-PanTumor01: Ph1 NSCLC cohort** • **Sub-analysis of patients with actionable mutations***
DS-7300	Solid tumor Ph1/2 • Ph1 dose escalation data

* Final decision for the acceptance of late breaking abstract will be made after Aug 17

Regulatory decisions

Lixiana®	Atrial fibrillation in the very elderly • Japan: FY2021 Q2
Efient®	Ischemic stroke • Japan: FY2021 Q3

Planned regulatory submissions

Enhertu®	**DESTINY-Gastric01/02: HER2 positive GC, 2/3L, Ph2** • **Europe: FY2021 2H**
DS-3201	Registrational Ph2: ATL/L • Japan: FY2021 2H

Key data readouts

Enhertu®	DESTINY-Breast03: HER2 positive BC, 2L, Ph3 • FY2021 Q2 DESTINY-Breast04: HER2 low BC, post chemo, Ph3 • FY2021 Q4
Quizartinib	QuANTUM-First: AML, 1L, Ph3 • FY2021 Q3

Underlined: New or updated from ASCO Highlight

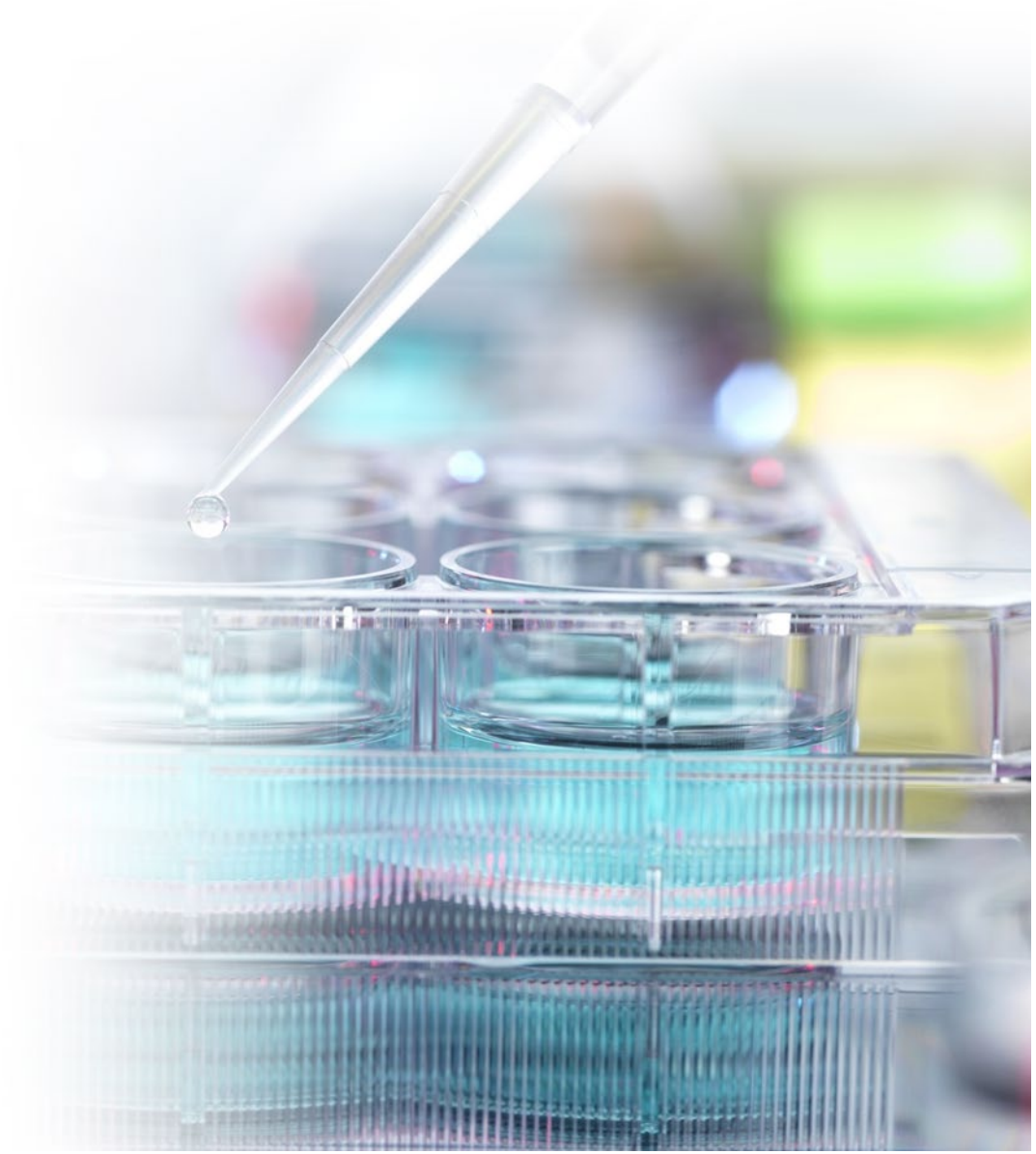
AML: acute myeloid leukemia, ATL: adult T-cell leukemia/lymphoma, BC: breast cancer, NSCLC: non small cell lung cancer, OS: overall survival

1 FY2021 Q1 Financial Results

2 Business Update

3 R&D Update

4 **Appendix**



Major R&D Milestones in FY2021 (3ADCs)

As of July 2021

Project		Target Indications [phase, study name]	FY2021 Q1	Q2	Q3	Q4
ENHERTU®	BC	HER2+, 2L [P3, DESTINY-Breast03]		TLR anticipated		
		HER2 low, post chemo [P3, DESTINY-Breast04]				TLR anticipated
		HER2+, 1L [P3, DESTINY-Breast09]	Study started			
	GC	HER2+, 2L [P2, DESTINY-Gastric02]	TLR obtained		Submission anticipated (Europe)	
		HER2+, 2L [P3, DESTINY-Gastric04]	Study started			
	NSCLC	HER2+/mutant [P2, DESTINY-Lung01]	TLR obtained			
		HER2+, combination [P1b, DESTINY-Lung03]		Study start planned		
Dato-DXd		TNBC, durvalumab combo [P1b/2, BEGONIA]	Study started			
HER3-DXd		EGFR mutated NSCLC, osimertinib combo [P1]	Study started			

Red underlined: new or updated from FY2020 Q4

BC: breast cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, TLR: Top Line Results, TNBC: triple negative breast cancer

Major R&D Milestones in FY2021 (Alpha)

As of July 2021

Project	Target Indications [phase, study name, region]	FY2021 Q1	Q2	Q3	Q4
Quizartinib	AML, 1L [P3, JP/US/EU/Asia]			TLR anticipated	
Pexidartinib	Tenosynovial giant cell tumor [P2, JP]	Study started			
Teserpaturev/G47Δ	Malignant glioma [IIS, JP]	**Approved**			
DS-3201	ATL/lymphoma [P2 registration, JP]		**TLR obtained**	Submission anticipated (Japan)	
	PTCL [P2 registration, JP/US/EU/Asia]	**Study started**			
DS-1594	AML, ALL [P1/2, US]	Study started			
Lixiana®	AF in the very elderly [P3, ELDERCARE-AF, JP]		Approval anticipated		
Efient®	Ischemic stroke [P3, PRASTRO III, JP]			Approval anticipated	
Tarlige®	Central neuropathic pain [P3, JP]	**Submitted**			
DS-6016	Fibrodysplasia Ossificans Progressiva [P1, JP]	Study started			
VN-0200	**RS virus vaccine [P1, JP]**	**Study started**			

Red underlined: new or updated from FY2020 Q4

AF: atrial fibrillation, ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, ATL: adult T-cell leukemia, IIS: investigator-initiated study, PTCL: peripheral T-cell lymphoma, TLR: Top Line Results

Major R&D Pipeline: 3ADCs

As of July 2021

Phase 1		Phase 2	Phase 3	Submitted
(JP/US) NSCLC, TNBC, HR+ BC 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/EU/Asia) 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/EU/Asia) 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 2L~ DESTINY-Lung01	(JP/US/EU/Asia) HER2 low BC post chemo DESTINY-Breast04	
(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(EU/Asia)HER2+ NSCLC (durvalumab combo) 1L DESTINY-Lung03	(JP/US/EU/Asia) HER2 mutated NSCLC 2L~ DESTINY-Lung02	(JP/US/EU/Asia) HER2+ BC post neoadjuvant DESTINY-Breast05	
(JP/US/EU/Asia) NSCLC	(US/EU) BC, bladder (nivolumab combo)	(US/EU/Asia) NSCLC (durvalumab combo) 2L~ HUDSON	(JP/US/EU/Asia) HER2 low BC chemo naive DESTINY-Breast06	
(JP/US)EGFR mutated NSCLC (osimertinib combo)	(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU) HER2+ CRC 3L DESTINY-CRC01	(US)HER2+ BC 1L DESTINY-Breast09	
(JP/US) BC		(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/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/EU/Asia) EGFR mutated NSCLC HERTHENA-Lung01		
		(JP/US/EU) CRC 3L		

ENHERTU®

Dato-DXd

HER3-DXd

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)

Major R&D Pipeline: Alpha

As of July 2021

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	**Tarlige** (JP) $\alpha_2\delta$ Ligands Central neuropathic pain
DS-6157 (JP/US) GPR20-directed ADC GIST	**PLX2853** (US) BET inhibitor AML	**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 carcinoma, ovarian cancer	**PLX2853** (US) BET inhibitor Solid tumor	**DS-1001** (JP) Mutant IDH1 inhibitor Glioma	**Minnebro** (JP) MR blocker Diabetic nephropathy	**Efient** (JP) ADP receptor inhibitor Ischemic stroke
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	**PLX2853** (US) BET inhibitor Gynecologic neoplasms, ovarian cancer	**DS-5141** (JP) ENA oligonucleotide DMD	**VN-0102/JVC-001** (JP) Measles mumps rubella combined vaccine	**VN-0107/MEDI3250** (JP) Live attenuated influenza vaccine nasal spray
DS-1211 (US) TNAP inhibitor Pseudoxanthoma elasticum	**PLX2853** (US) BET inhibitor Prostate cancer			
DS-6016 (JP) Anti-ALK2 antibody Fibrodysplasia Ossificans Progressiva	**DS-1594** (US) Menin-MLL binding inhibitor AML, ALL			
DS-5670 (JP) mRNA vaccine COVID-19	**VN-0200** (JP) RS virus vaccine RS virus			

Oncology
Specialty medicine
Vaccine

AF: atrial fibrillation, ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, DMD: Duchenne muscular dystrophy, GIST: gastrointestinal stromal tumor, 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/Europe)

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