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Compassion for Patients.™

Daiichi-Sankyo

FY2021 Q3
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

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January 31, 2022

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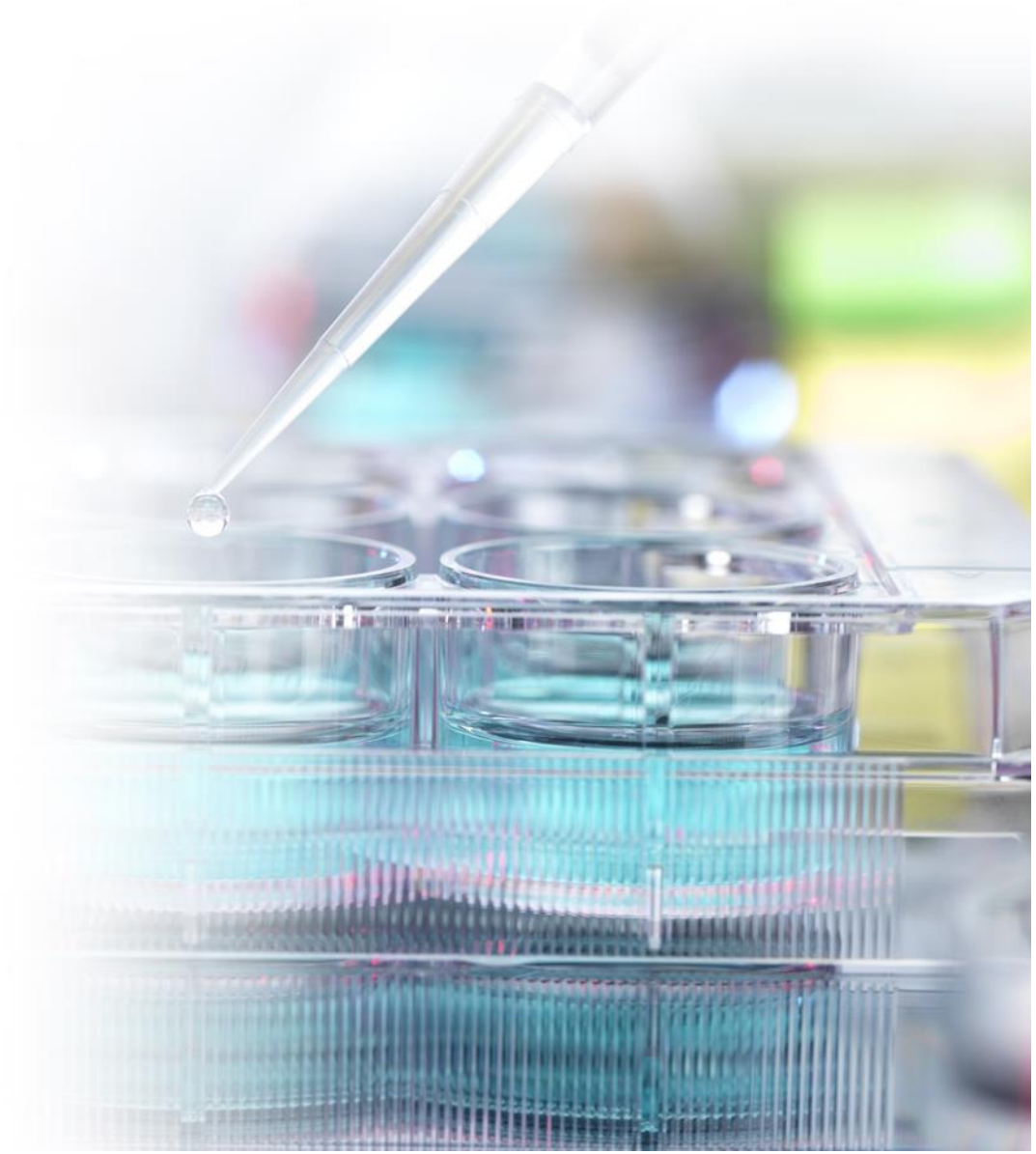
Agenda

1. **FY2021 Q3 Financial Results**
2. Business Update
3. R&D Update
4. Appendix



Overview of FY2021 Q3 Results

(Bn JPY)

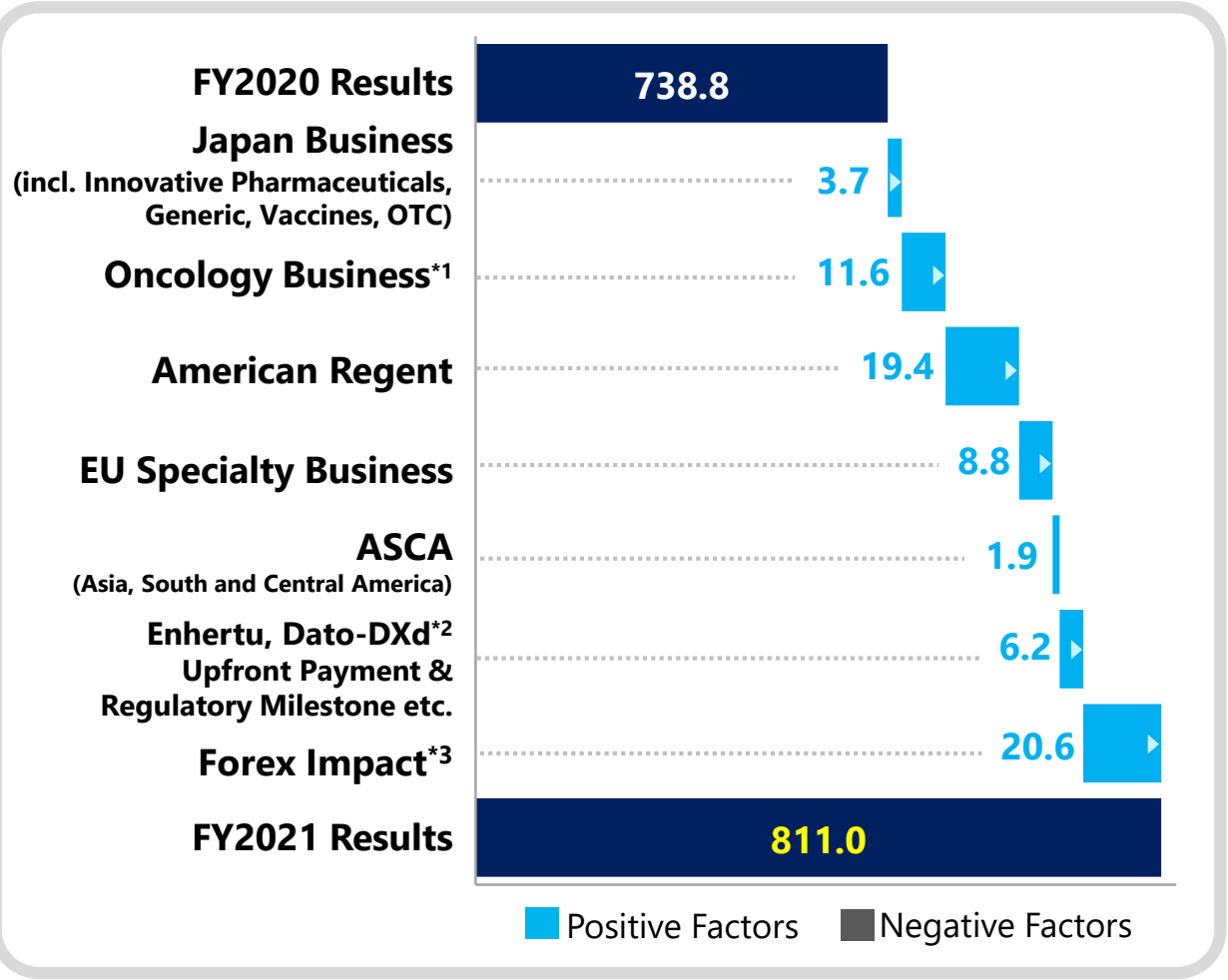
	FY2020 Q3 YTD Results	FY2021 Q3 YTD Results	YoY	
Revenue	**738.8**	**811.0**	+9.8%	**72.2**
Cost of sales *	256.4	263.2		6.8
SG&A expenses *	229.3	255.7		26.4
R&D expenses *	163.7	169.1		5.3
Core operating profit *	**89.4**	**123.0**	+37.6%	**33.6**
Temporary income *	0.1	2.1		2.0
Temporary expenses *	0.0	1.3		1.3
Operating profit	**89.5**	**123.8**	+38.3%	**34.3**
Profit before tax	**99.6**	**125.9**		**26.3**
Profit attributable to owners of the Company	**75.8**	**94.3**	+24.4%	**18.5**

Currency Rate	USD/JPY	106.11	111.10	+4.99
	EUR/JPY	122.37	130.62	+8.25

* As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed.
Income and expenses 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 income and expenses".
Temporary income and expenses are excluded from results and forecast for cost of sales, SG&A expenses and R&D expenses shown in the list above.
The adjustment table from operating profit to core operating profit is stated in the reference data

Revenue

Increased by 72.2 Bn JPY (Increased by 51.6 Bn JPY excl. forex impact)



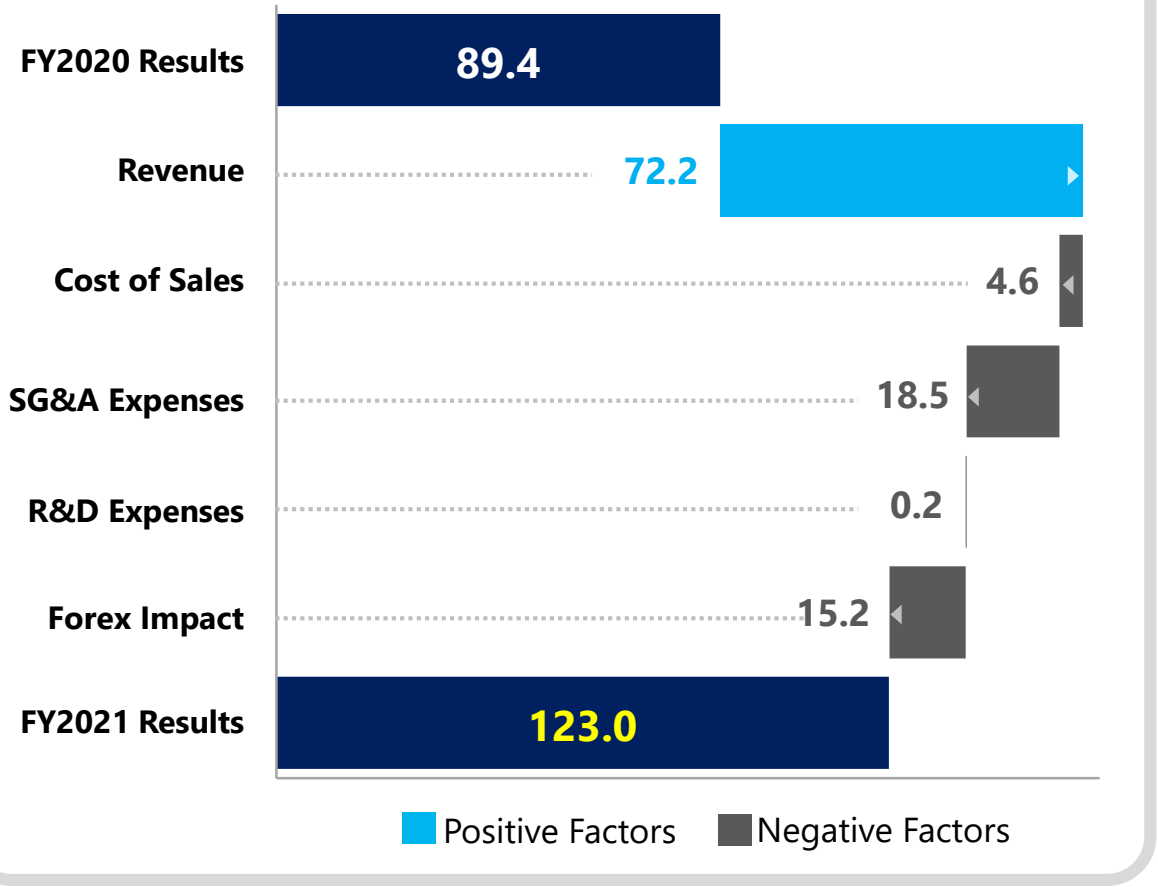
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+10.7	Nexium	-21.2
Tarlige	+7.5	Memary	-11.0
Enhertu	+4.3		
Emgality	+3.4		
Daiichi Sankyo Espha Ezetimibe AG	+8.9		
Oncology Business*1 Unit			
Enhertu	+16.9	Olmesartan	-3.0
American Regent Unit			
Injectafer	+8.2		
GE injectables	+8.5		
EU Specialty Business Unit			
Lixiana	+13.6	Gain on sales of transferring long-listed products	-3.1
		Olmesartan	-2.2
Enhertu, Dato-DXd*2 Upfront Payment & Regulatory Milestone etc.			
Enhertu quid related payment	+3.1		
Dato-DXd upfront payment	+2.1		

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Dato-DXd: Datopotamab deruxtecan (DS-1062)
*3 Forex impact USD: +7.5, EUR : +6.5, ASCA: +6.5

Core Operating Profit

Increased by 33.6 Bn JPY (Increased by 28.3 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +72.2
incl. forex impact of +20.6

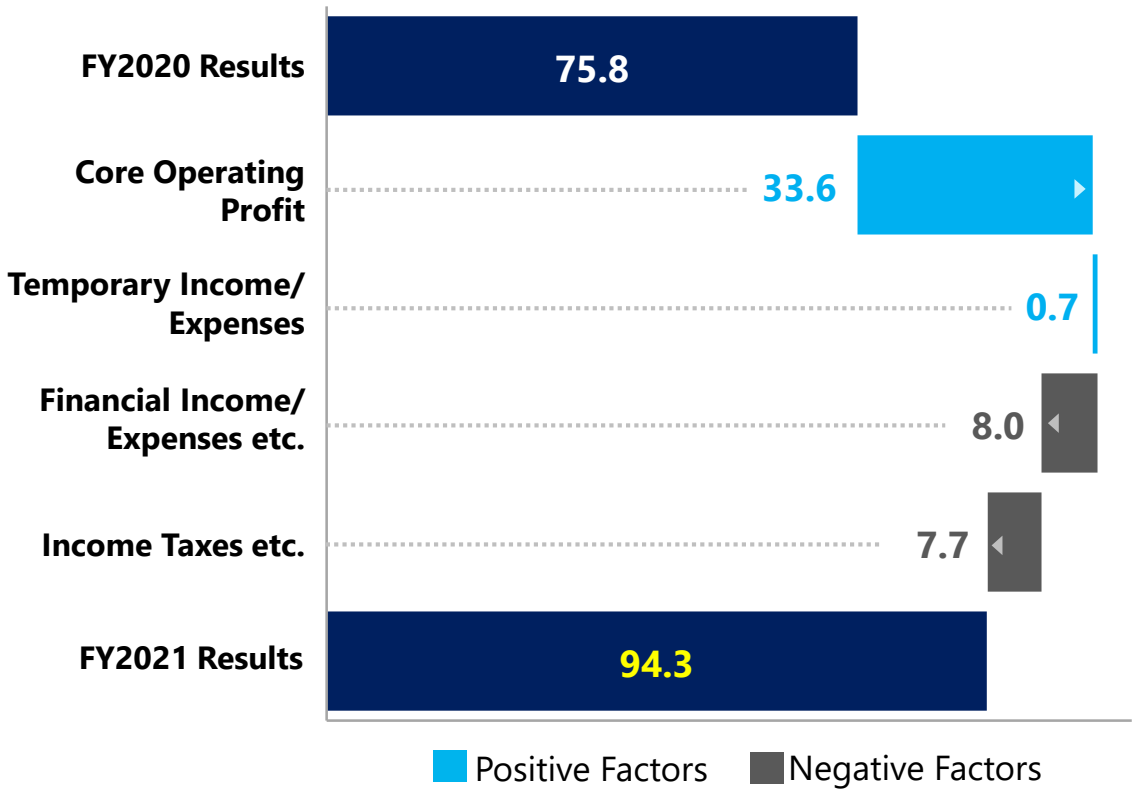
Cost of Sales +4.6 (Profit decreased)
Improvement in cost of sales ratio by change in product mix

SG&A Expenses +18.5 (Profit decreased)
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

Forex Impact +15.2 (Profit decreased)
Cost of Sales +2.2
SG&A Expenses +7.9
R&D Expenses +5.1

Profit Attributable to Owners of the Company

Increased by 18.5 Bn JPY



(Bn JPY)

Temporary Income/Expenses ····· **-0.7 (Profit increased)**

FY2021: Gains related to sale of fixed assets (Osaka logistics center and others) ····· -2.1

Impairment loss (Intangible asset related to Turalio and others) ····· +1.3

Financial Income/Expenses etc. ····· **+8.0 (Profit decreased)**

FY2020: Financial income due to decrease in contingent consideration of Ambit/quizartinib acquisition ····· +4.7

Deterioration in forex gains/losses ····· +1.5

Income Taxes etc. ····· **+7.7 (Profit decreased)**

	FY2020 Q3YTD	FY2021 Q3YTD	YoY
Profit before Tax	99.6	125.9	+26.3
Income Taxes etc.	23.9	31.6	+7.7
Tax rate	24.0%	25.1%	+1.1%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2020 Q3 YTD Results	FY2021 Q3 YTD Results	YoY
Japan Business	386.4	393.7	+7.3
Daiichi Sankyo Healthcare	51.5	49.7	-1.8
Oncolgy Business	35.4	49.2	+13.8
Enhertu	18.0	36.6	+18.5
Turalio	1.3	2.0	+0.7
American Regent	91.0	115.6	+24.6
Injectafer	32.2	42.3	+10.1
Venofer	22.2	25.2	+3.1
GE injectables	31.3	41.7	+10.4
EU Speciality Business	82.9	97.9	+15.0
Lixiana	56.0	74.3	+18.3
Nilemdo/Nustendi	0.1	2.2	+2.1
Olmesartan	16.2	14.9	-1.3
ASCA (Asia, South and Central America)	74.5	82.9	+8.4

Currency Rate	USD/JPY	106.11	111.10	+4.99
	EUR/JPY	122.37	130.62	+8.25

Revenue: Major Products in Japan

(Bn JPY)

		FY2020 Q3 YTD Results	FY2021 Q3 YTD Results	YoY
Lixiana	anticoagulant	**59.8**	**70.5**	**+10.7**
Nexium	ulcer treatment	**60.8**	**39.6**	**-21.2**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**26.4**	**28.7**	**+2.3**
Tarlige	pain treatment	**15.3**	**22.8**	**+7.5**
Tenelia	type 2 diabetes mellitus treatment	**19.2**	**18.6**	**-0.6**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**14.9**	**15.6**	**+0.7**
Loxonin	anti-inflammatory analgesic	**19.1**	**17.6**	**-1.5**
Vimpat	anti-epileptic agent	**11.2**	**13.9**	**+2.7**
Canalia	type 2 diabetes mellitus treatment	**11.9**	**13.0**	**+1.1**
Efient	antiplatelet agent	**11.0**	**12.7**	**+1.7**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**2.7**	**6.9**	**+4.3**
Rezaltas	antihypertensive agent	**10.4**	**9.6**	**-0.8**
Inavir	anti-influenza agent	**2.3**	**1.1**	**-1.2**

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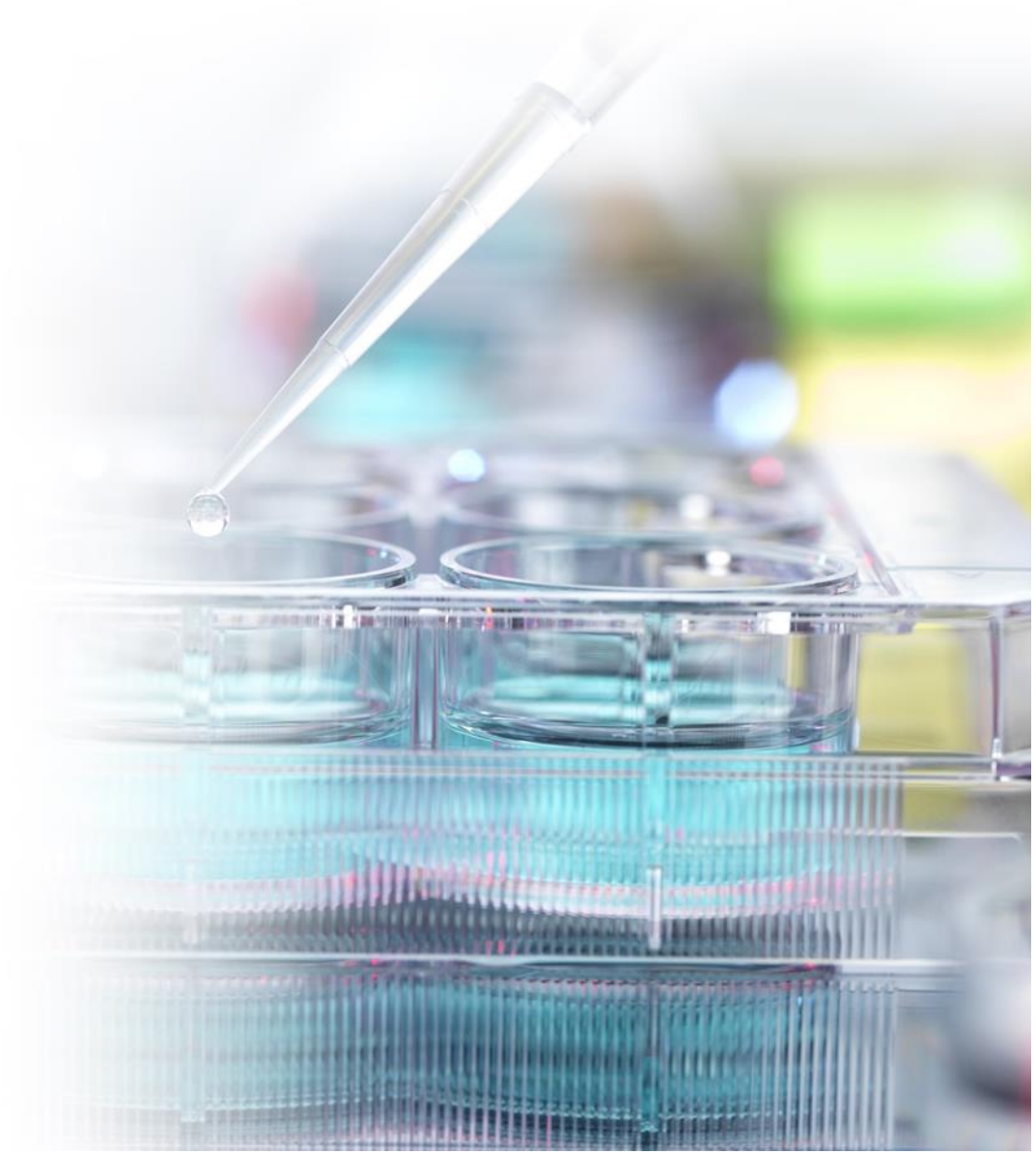

ENHERTU®: Revenue

(Bn JPY)

	FY2021 Q3 YTD Results	YoY	FY2021 Forecast (as of Jan.)	vs. as of Oct.	<Reference> Total Consideration
Product Sales	43.5	22.8	61.2	-1.6	-
Japan	6.9	4.3	10.0	-3.4	-
US	31.6	13.6	43.9	0.9	-
Europe	4.9	4.9	7.1	0.9	-
ASCA	-	-	0.2	-	-
Upfront payment	7.4*	-	9.8*	-	149.0
Regulatory milestone payment	1.7*	1.0	2.2*	-	33.7
US HER2+ Breast Cancer 3L	0.7	-	0.9	-	13.7
EU HER2+ Breast Cancer 3L	0.4	0.4	0.5	-	7.9
US HER2+ Gastric Cancer 2L + 3L	0.6	0.6	0.8	-	12.1
Quid related payment	3.1*	3.1	3.4*	3.4	17.2
Total	55.7	26.9	76.6	1.8	200.0

* Revenue recognized in each period

ENHERTU®: Performance in Each Region

- **Steady increase in product sales due to market penetration in launched countries**
- **Product sales: FY2021 Q3 YTD results 43.5 Bn JPY (YoY +22.8 Bn JPY)**
  FY2021 forecast 61.2 Bn JPY (YoY +31.1 Bn JPY)

ENHERTU® trastuzumab deruxtecan

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

- **Product sales: FY2021 Q3 YTD results 31.6 Bn JPY (285Mn USD)**
  FY2021 forecast 43.9 Bn JPY (400Mn USD)
- **Steady growth in the market**
  - New patient shares increasing
    - HER2+ BC 3L: Maintaining No.1 share
    - HER2+ GC 2L: Good progress
- Nov. 2021: **Classified as a category 1 preferred regimen for HER2+ BC 2L treatment in NCCN[*1] guidelines** based on DESTINY-Breast03 data
- Jan. 2022: **HER2+ BC 2L approval application accepted**

Europe (HER2+ Breast Cancer 3L)

- **Product sales: FY2021 Q3 YTD results 4.9 Bn JPY (44Mn USD)**
  FY2021 forecast 7.1 Bn JPY (65Mn USD)
- **Steady growth in the launched countries**
  - New patient shares increasing (Maintaining No.1 share in France and UK)
- Oct. 2021: **ESMO Clinical Practice Guideline supported ENHERTU® as the new standard of care for HER2+ BC 2L[*2] treatment**
- Nov. 2021: **HER2+ GC 2L approval application accepted**
- Dec. 2021: **HER2+ BC 2L approval application accepted**

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

- **Product sales: FY2021 Q3 YTD results 6.9 Bn JPY**
  FY2021 forecast 10.0 Bn JPY
- **Steady growth in the market**
  - New patient shares increasing (Maintaining No.1 share in HER2+ BC 3L / GC 3L)
- Dec. 2021: **HER2+ BC 2L approval application accepted**

*1 NCCN: National Comprehensive Cancer Network *2 HER2 positive metastatic breast cancer with no, unknown, or stable brain metastasis

Japan Business: Enhance product portfolio

Efient®
(prasugrel hydrochloride)

Obtained approval for additional indication of antiplatelet agent "Efient" which has been on the market since 2014

* Indications: The following ischemic heart diseases that require percutaneous coronary intervention (PCI): Acute coronary syndromes (ACS; unstable angina [UA], non-ST-segment elevation myocardial infarction [NSTEMI], or ST-segment elevation myocardial infarction [STEMI]), Stable angina, old myocardial infarction

- Additional Indications: **Prevention of recurrence of ischemic cerebrovascular disease following the former appearance of ischemic cerebrovascular disease (associated with large-artery atherosclerosis or small-vessel occlusion) (restricted to cases with a high risk of ischemic stroke)**
- Date of Approval: **December 24, 2021**
- Dosage and Administration: 3.75 mg once daily oral dose

Reyvow®
(lasmiditan succinate)

Eli Lilly Japan obtained marketing approval for "Reyvow", a migraine treatment which the company and Daiichi Sankyo signed an agreement on reverse co-promotion* in August 2021

* Eli Lilly Japan is responsible for clinical development and manufacturing.
Daiichi Sankyo is in charge of distribution and sales, and the companies will co-promote the product.

- Indication: **Migraine**
- Date of Approval: **January 20, 2022**
- Dosage and Administration: 100 mg taken orally once, for the migraine attack (50 mg or 200 mg can be taken orally once)

- **Expanding contribution to patients by providing new treatment options**
- **Enhancing product portfolio toward sustainable growth of Japan business**

US: Divested Products

Concluded an asset sale agreement in January 2022 to promote transformation into a profit structure focused on patented drugs

- Divested Products

Brand Name	Generic Name	Therapeutic Category	Launched	Revenue FY2021 Forecast
Benicar (olmesartan medoxomil) / Benicar HCT (olmesartan medoxomil・hydrochlorothiazide) / AZOR amlodipine and olmesartan medoxomil / TRIBENZOR (olmesartan medoxomil, amlodipine, hydrochlorothiazide) tablets	olmesartan medoxomil and its fixed dose combinations	Antihypertensive agent	2002 ～ 2010	9.9 Bn JPY
Welchol (colesevelam HCl)	colesevelam HCL tablets and oral suspension	Hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	2000	
Effient (prasugrel) tablets	prasugrel hydrochloride	Antiplatelet agent	2009	
Evoxac (cevimeline HCl)	cevimeline hydrochloride hydrate	Dry mouth in people with Sjogren's Syndrome	2000	

- New Owner **Cosette Pharmaceuticals, Inc.**

- Schedule **By July 1, 2022** **Commercialization start by Cosette**
  Until June 2024 **Manufacture and supply to Cosette**
  (up to 30 months after signing the contract)

Reorganization of R&D Structure

Decided to winddown business of R&D subsidiary, Plexxikon Inc.

Overview of Plexxikon Inc.

- **Major R&D area**
  - **Oncology and neurology**
- **Launched Products from Plexxikon pipeline**
  - Tenosynovial Giant Cell Tumor (TGCT) treatment
    Turalio® (pexidartinib)
    - Launched in US, under development in JP and ASCA region
  - Melanoma treatment*
    Zelboraf® (vemurafenib)
    - Marketed by Roche group
- **Major R&D project**
  - BET inhibitor PLX2853

Outline of Reorganization

- **Some R&D projects to be transferred to Daiichi Sankyo**
- **Employment will be terminated**
  (Number of employees as of January 2022: approx. 60 employees)
- **Majority of business will end by March 2022**
- **Reorganization expenses expected to be recognized in FY2021 Q4**

**BRAF* V600 mutation-positive advanced or inoperable melanoma treatment

Enhance R&D capabilities for sustainable growth by optimizing resource allocation

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3. **R&D Update**
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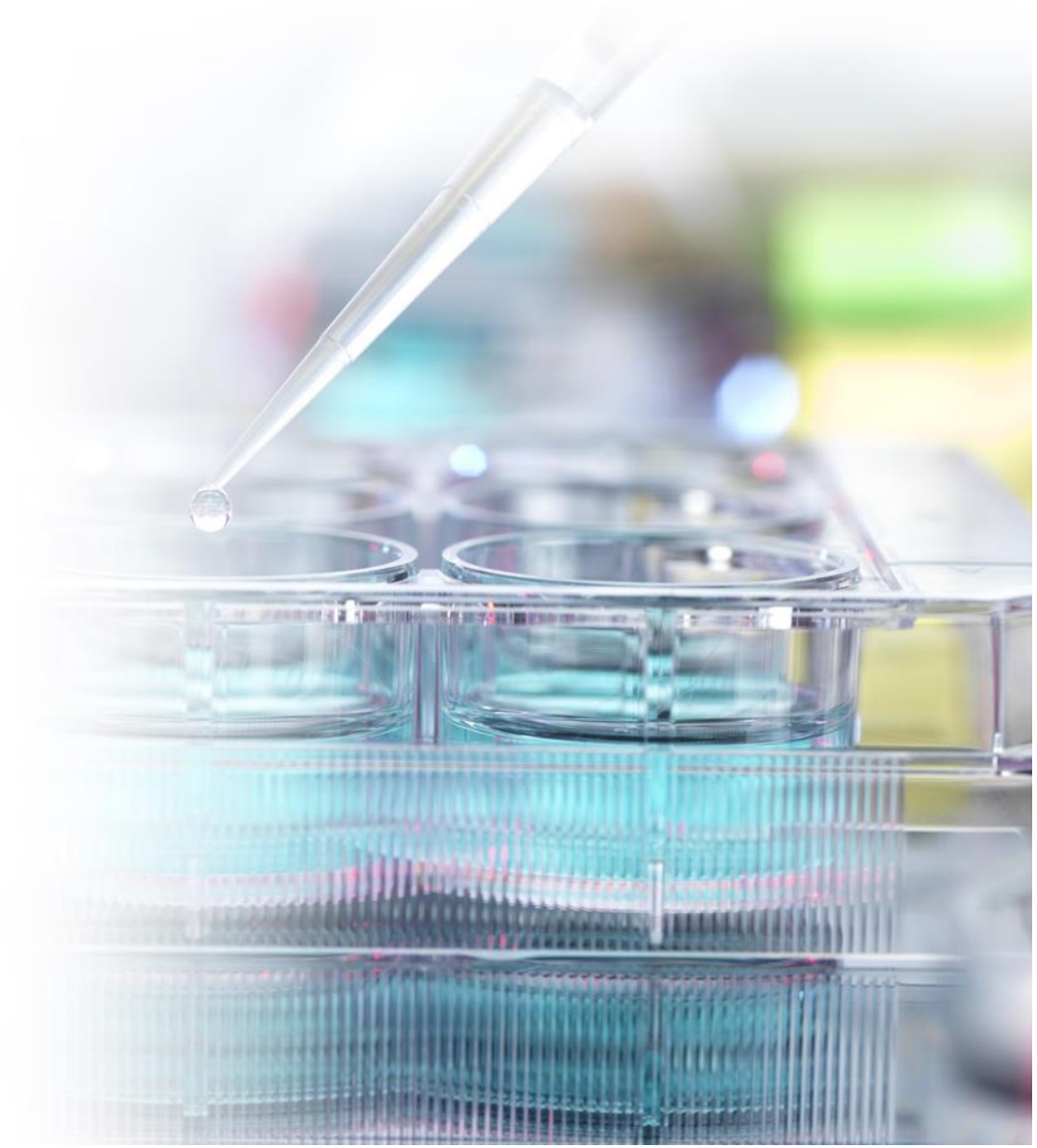


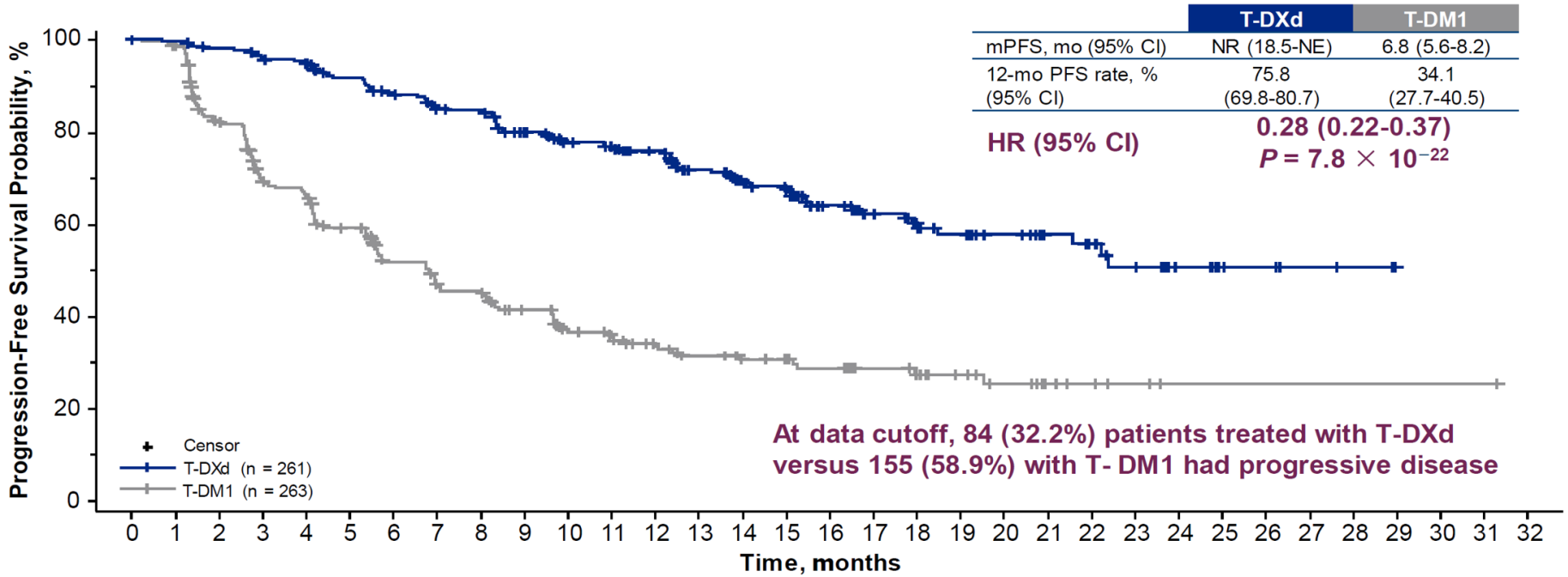
3ADC Update

Alpha Update

News Flow

ENHERTU®: DESTINY-Breast03 efficacy data

Progression-Free Survival (blinded independent central review)



	T-DXd	T-DM1
mPFS, mo (95% CI)	NR (18.5-NE)	6.8 (5.6-8.2)
12-mo PFS rate, % (95% CI)	75.8 (69.8-80.7)	34.1 (27.7-40.5)
HR (95% CI)	0.28 (0.22-0.37)	
	$P = 7.8 \times 10^{-22}$	

BICR, blinded independent central review; HR, hazard ratio; mPFS, median progression-free survival; NE, not estimable; NR, not reached; PFS, progression-free survival; T-DM1, trastuzumab emtansine; T-DXd, trastuzumab deruxtecan.
Median PFS follow-up for T-DXd was 15.5 months (range, 15.1-16.6) and was 13.9 months (range, 11.8-15.1) for T-DM1.
Cortés et al. *Ann Oncol*. 2021; 32(suppl_5):S1283-S1346. 10.1016/annonc/annonc741

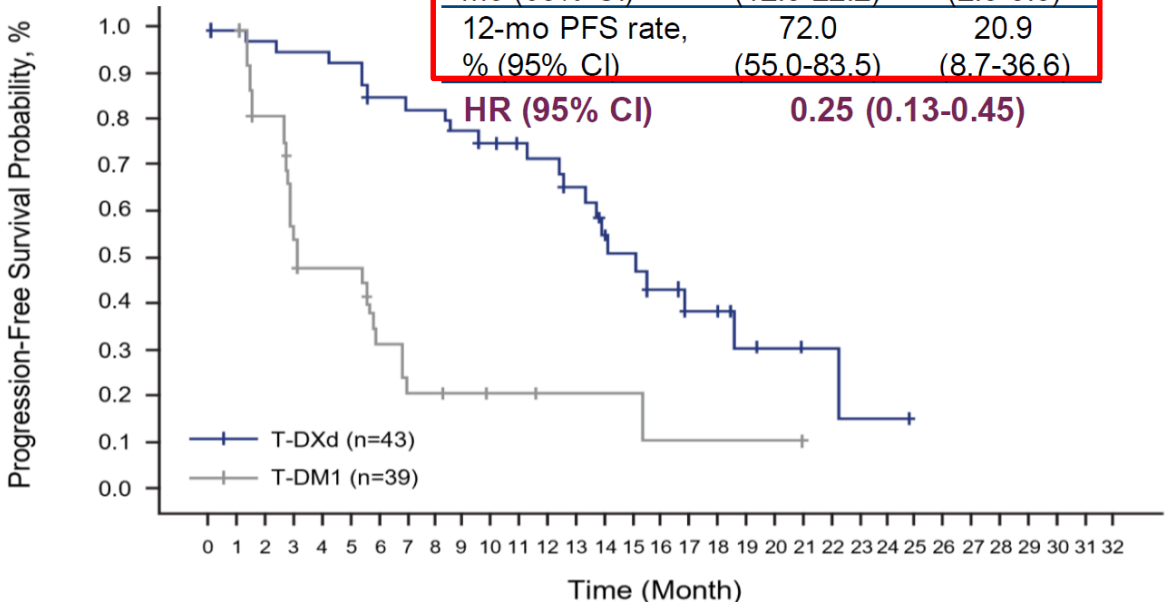
ENHERTU® demonstrated unparalleled improvement in PFS compared to T-DM1 in patients with HER2 positive metastatic breast cancer

ENHERTU®: SABCS 2021 highlights

DESTINY-Breast03 sub-analysis data of patients with stable brain metastases

Progression-Free Survival

	T-DXd	T-DM1
mPFS, mo (95% CI)	15.0 (12.5-22.2)	3.0 (2.8-5.8)
12-mo PFS rate, % (95% CI)	72.0 (55.0-83.5)	20.9 (8.7-36.6)
HR (95% CI)	0.25 (0.13-0.45)	



HR: hazard ratio, mPFS, median progression-free survival

Intracranial Response

(BICR、RECIST 1.1)

	T-DXd (n = 36)	T-DM1 (n = 36)
Best Overall Response, n (%)[a]		
CR	10 (27.8)	1 (2.8)
PR	13 (36.1)	11 (30.6)
Non-CR/Non-PD	6 (16.7)	7 (19.4)
SD	4 (11.1)	7 (19.4)
PD	1 (2.8)	8 (22.2)
Not Evaluable	0	1 (2.8)
Missing	2 (5.6)	1 (2.8)
Subjects with Objective Response of CR or PR, n	23	12

BICR: blinded independent central review, CR: complete response, PD: progressive disease, PR: partial response, SD: stable disease

[a]Denominator for percentages is the number of subjects in the full analysis set with brain metastases tumor assessment

- As for patients with HER2 positive breast cancer with **stable brain metastases,** ENHERTU® showed **greater efficacy** compared to T-DM1
- As for **anti-tumor responses in brain metastases lesion**、ENHERTU® showed **greater intracranial response** compared to T-DM1

ENHERTU®: Other updates

HER2 positive breast cancer

◆ Metastatic 2nd line

Based on **DESTINY-Breast03** (Ph3) data:

- **Dec 2021:** Filing accepted in Japan & Europe
- **Jan 2022:** Filing accepted in US and granted Priority Review (PDUFA date: May 17)
- Simultaneous filings are ongoing in multiple countries under Project Orbis

◆ Neoadjuvant

- **Nov 2021:** Initiated **DESTINY-Breast11** (Ph3) study for patients with early breast cancer

HER2 positive gastric cancer

◆ Metastatic 2nd line

- **Nov 2021:** Filing accepted in Europe based on the data of **DESTINY-Gastric01** (3L, Ph2, JP/KR)、**DESTINY-Gastric02** (2L, Ph2, US/EU) studies

HER2 mutated NSCLC

◆ Metastatic 1st line

- **Dec 2021:** Initiated **DESTINY-Lung04** (Ph3) study

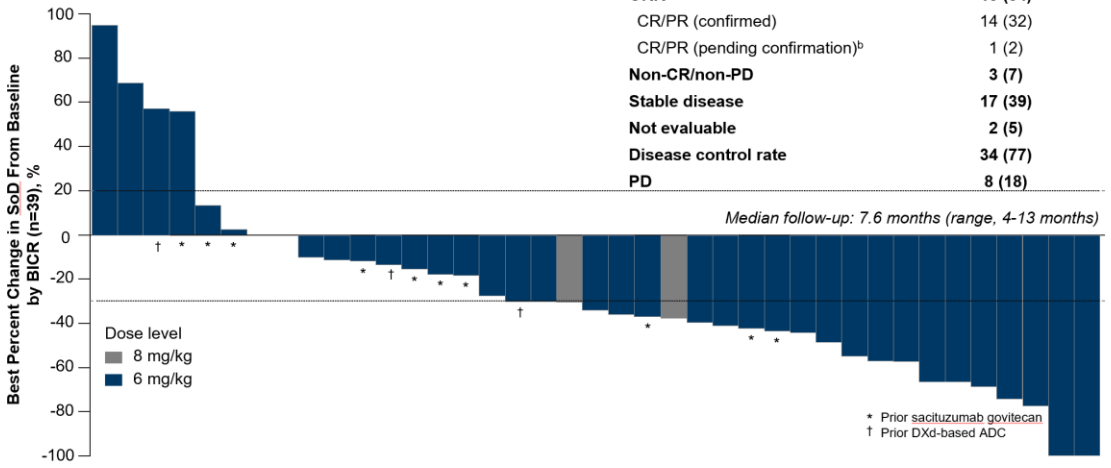
Regulatory filings and new clinical studies in multiple tumor types

Dato-DXd: Breast cancer update

SABCS 2021: TROPION-PanTumor01 triple negative breast cancer (TNBC) cohort data

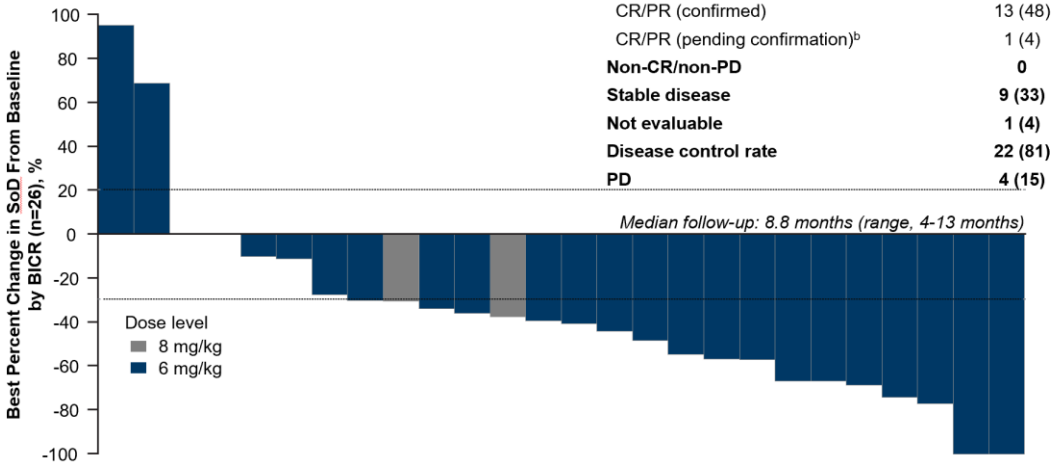
Anti-tumor responses (Blinded Independent Central Review)

All patients with TNBC



Patients, n (%)[a]	All Patients (n=44)
ORR	**15 (34)**
CR/PR (confirmed)	14 (32)
CR/PR (pending confirmation)[b]	1 (2)
Non-CR/non-PD	**3 (7)**
Stable disease	**17 (39)**
Not evaluable	**2 (5)**
Disease control rate	**34 (77)**
PD	**8 (18)**

Patients with TNBC without prior Topo I inhibitor-based ADC



Patients, n (%)[a]	SG/DXd Naïve Patients with Measurable Disease at BL (n=27)
ORR	**14 (52)**
CR/PR (confirmed)	13 (48)
CR/PR (pending confirmation)[b]	1 (4)
Non-CR/non-PD	**0**
Stable disease	**9 (33)**
Not evaluable	**1 (4)**
Disease control rate	**22 (81)**
PD	**4 (15)**

BICR, blinded independent central review; SoD, sum of diameters.

In Ph1 with **heavily pretreated patients with TNBC**, Dato-DXd showed **encouraging efficacy** with ORR at 34% in all patients (n=44) and 52% in patients without prior Topo I inhibitor-based ADC (n=27)

As a potentially best in class TROP2 directed ADC, development in breast cancer is ongoing:

- Planning **Ph3 study** for patients with **TNBC**
- **Nov 2021:** Initiated **TROPION-Breast01** (2/3L, Ph3) study for patients with **HR+/HER2- breast cancer**

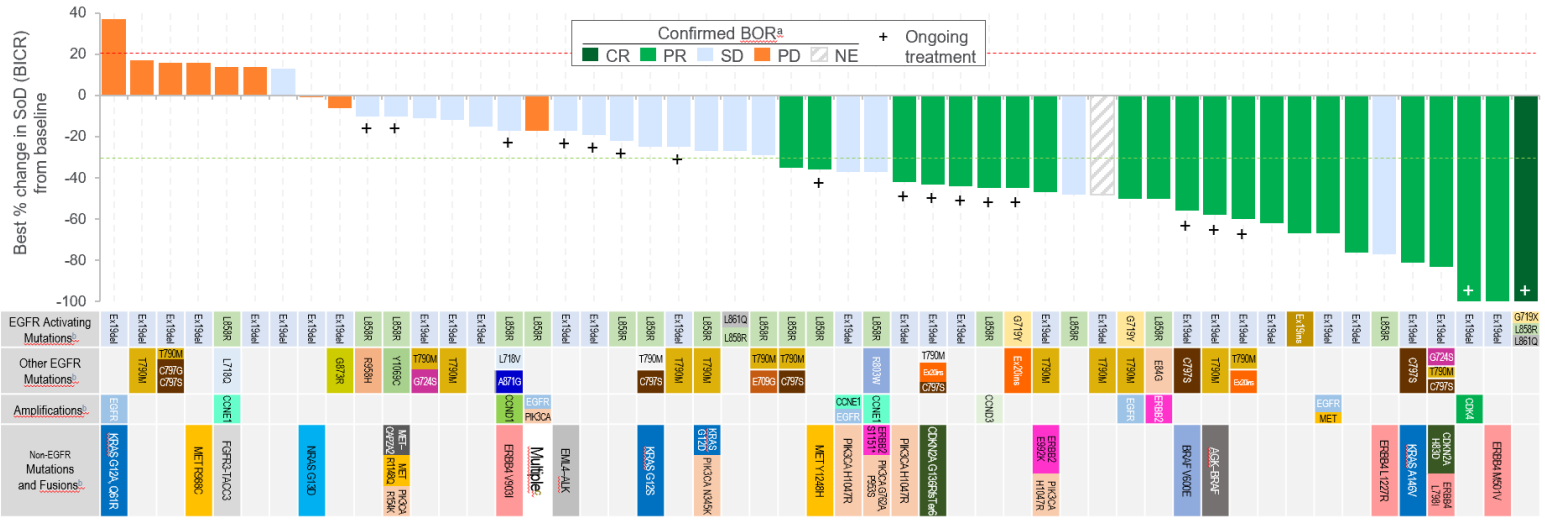
HER3-DXd: Lung cancer update

Dec 2021:
FDA granted **breakthrough therapy designation**

- For the treatment of patients with metastatic EGFR mutated NSCLC with disease progression on or after treatment with a 3rd generation EGFR TKI and platinum based therapies
- Based on Ph1 data presented at ASCO 2021
- First breakthrough therapy designation for HER3-DXd

ASCO 2021: Ph1 efficacy data

Confirmed ORR	Median Duration of Response	Median PFS
39%	6.9 months	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 **tumor response** across **multiple EGFR TKI resistance mechanisms**

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

Initiated HERTHENA-Lung01 (registrational Ph2) study in Feb 2021, registration plan to be determined by close communication with FDA

3ADC Update

Alpha Update

News Flow

DS-5670: Change in development plan

Top priority is development of booster vaccination

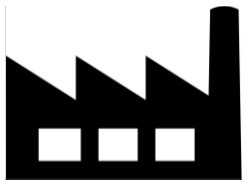
- **Taking into consideration the current situation, development of booster vaccination in Japan will be the top priority and commercialization is expected within CY2022**
  - **Initiated Ph1/2/3 study in Jan 2022**
- **Ph3 study plan for naïve subjects will be continuously discussed with PMDA towards initiation of the study in FY2022 H1.**
  - Initiated Ph2 for dose setting in Nov 2021
  - Ph3 study was planned to start in overseas (Africa, etc.) in FY2021 , however, the study was postponed due to global spread of omicron variant
  - Planning to discuss Ph3 study design, countries, study timing, etc. with PMDA

FY2021		FY2022	
1H	2H	1H	2H

Ph1/2/3 booster vaccination (JP)

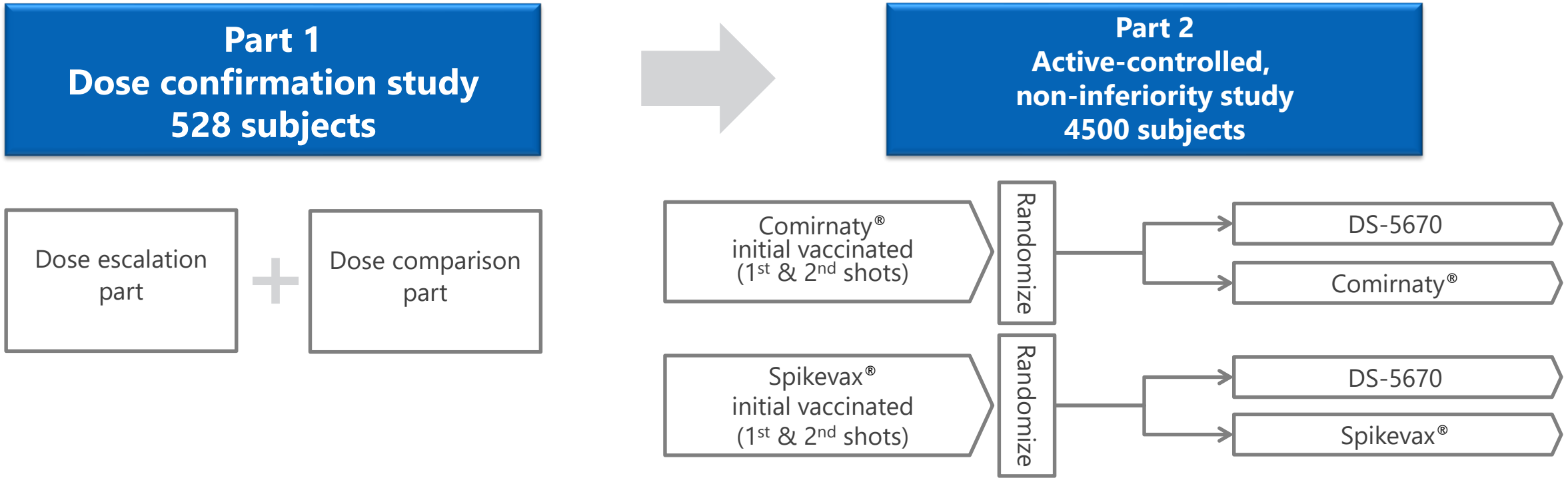
Ph1/2 study → **Dose setting Ph2** → **Ph3 study plan under consideration**

Establishment of manufacturing system at DS Biotech



DS-5670: Study design of booster vaccination

- **Study:** Randomized, active-controlled, evaluator-blinded Ph1/2/3 study to evaluate the booster effect in subjects who completed the initial vaccination (1st & 2nd shots) of approved SARS-CoV-2 vaccine (dose confirmation, non-inferiority confirmatory study)
- **Eligible subjects:** Adult and elderly subjects who completed the initial vaccination (1st & 2nd shots) of approved SARS-CoV-2 vaccine and have elapsed 6 months after the second shot
- **Primary endpoint:** Geometric mean fold rise (GMFR) of SARS-CoV-2 neutralizing activity in blood 4 weeks after administration



Valemetostat: Adult T cell leukemia/lymphoma (ATL/L) update

American Society of Hematology 2021: ATL/L registrational Ph2 data

Population	N	ORR, n (%)	CR, n (%)	CRu, n (%)	PR, n (%)	SD, n (%)	RD/PD, n (%)
All patients	25	12 (48.0)	5 (20.0)	0	7 (28.0)	10 (40.0)	3 (12.0)
ATL subtype							
Acute	16	10 (62.5)	5 (31.3)	0	5 (31.3)	4 (25.0)	2 (12.5)
Lymphoma	6	1 (16.7)	0	0	1 (16.7)	5 (83.3)	0
Unfavorable chronic	3	1 (33.3)	0	0	1 (33.3)	1 (33.3)	1 (33.3)
Disease site							
Nodal or extranodal lesions	20	10 (50.0)	6 (30.0)	2 (10.0)	2 (10.0)	7 (35.0)	3 (15.0)
Skin lesions[a]	7	3 (42.9)	1 (14.3)	NE	2 (28.6)	3 (42.9)	1 (14.3)
Peripheral blood	9	8 (88.9)	2 (22.2)	NE	6 (66.7)	1 (11.1)	0
Disease status							
Relapsed	8	3 (37.5)	1 (12.5)	0	2 (25.0)	4 (50.0)	1 (12.5)
Recurrent	6	4 (66.7)	1 (16.7)	0	3 (50.0)	2 (33.3)	0
Refractory[b]	11	5 (45.5)	3 (27.3)	0	2 (18.2)	4 (36.4)	2 (18.2)

[a] One patient was not evaluated for skin lesions after baseline assessment. [b] Refractory: received ≥1 prior chemotherapy, achieved SD and required a treatment switch, or received ≥1 prior chemotherapy and experienced PD.

- Showed **encouraging efficacy** in registrational Ph2 study targeting **relapsed/refractory ATL/L**
- Based on the study data, the following events occurred in Japan
  - **Nov 2021:** Granted orphan drug designation
  - **Dec 2021:** **Regulatory filing**

Alpha: Other updates

quizartinib

◆ FLT3-ITD positive AML

- **Nov 2021:** Obtained TLR of **QuANTUM-First** (1L, Ph3) study, meeting the primary endpoint for overall survival
- **FY2022: Regulatory filing** and data presentation at scientific conference planned

QuANTUM-FIRST STUDY

DS-7011

◆ Systemic lupus erythematosus

- **Mechanism of action:** Anti-TLR7 antibody
- **Collaboration:** CiCLE program (AMED)
- **Status: Ph1 study planned** in FY2021 Q4

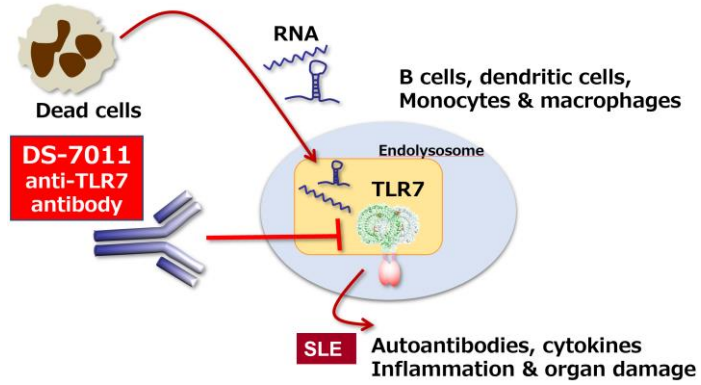


Diagram created & provided by Prof. Miyake of the Institute of Medical Science, The University of Tokyo

AML: acute myeloid leukemia, TLR: Top Line Results

Obtained Ph3 data of quizartinib and Ph1 study of DS-7011 will start soon

3ADC Update

Alpha Update

News Flow

FY2021 News Flow

As of Jan 2022

Planned publications

ASCO Genitourinary Cancers Symposium (Feb 17-19, 2022)	
ENHERTU®	**Ph1b nivolumab combination** • **Urothelial carcinoma cohort data**
DS-7300	**Solid tumor Ph1/2** • **CRPC subanalysis data**

Key data readouts

ENHERTU®	DESTINY-Breast04: HER2 low BC, post chemo, Ph3 • FY2021 Q4

Planned pivotal study initiation

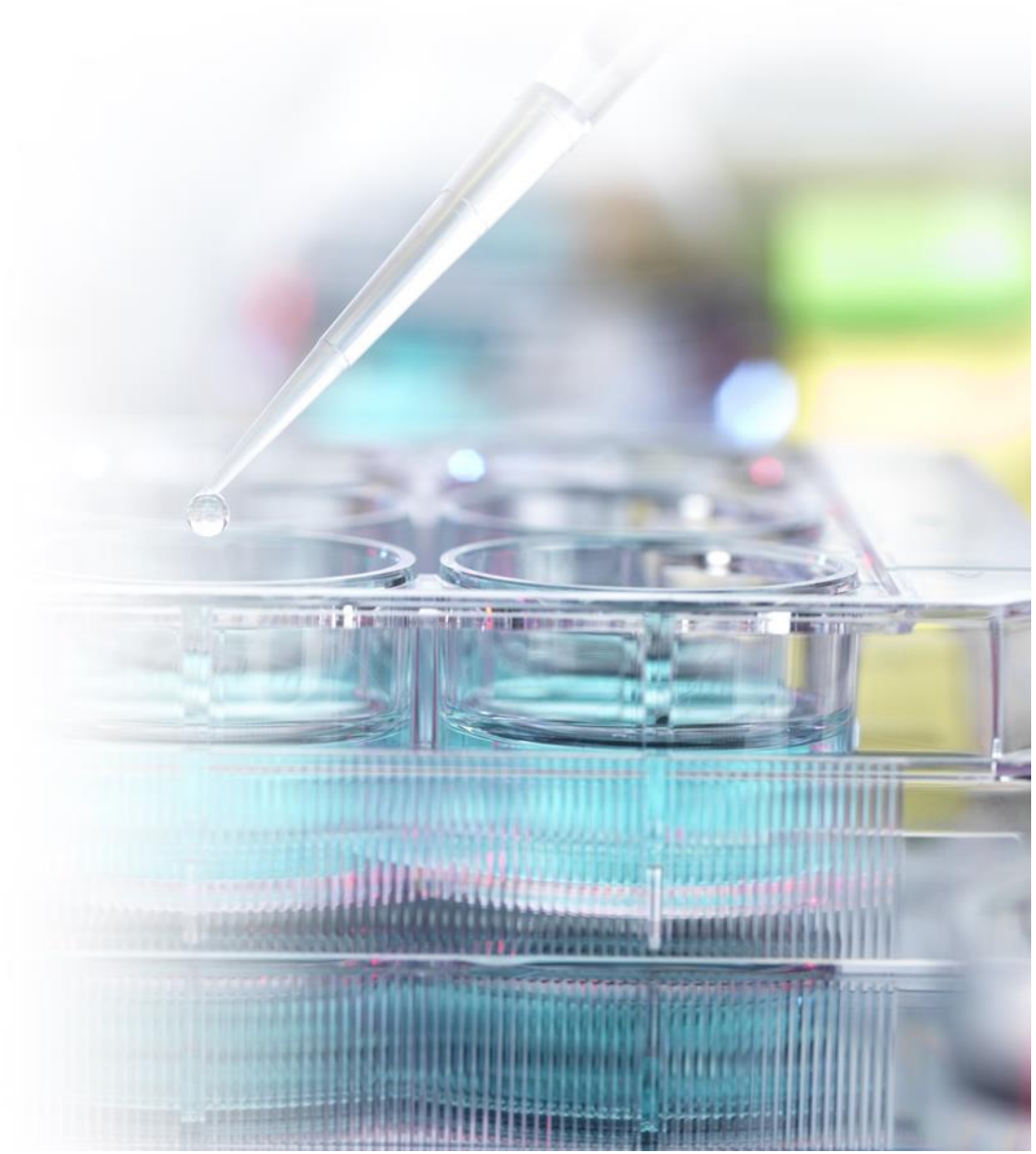
Dato-DXd	TROPION-Lung08: NSCLC w/o AGAs, 1L, Ph3 • FY2021 Q4

Underlined: New or updated from FY2021 Q2

CRPC: castric resistant prostate cancer, NSCLC: non small cell lung cancer

Agenda

1. FY2021 Q3 Financial Results
2. Business Update
3. R&D Update
4. **Appendix**



Major R&D Milestones in FY2021 (3ADCs)

As of Jan 2022

Project		Target Indications [phase, study name]	FY2021 Q1	Q2	Q3	Q4
ENHERTU®	BC	HER2+, 2L [P3, DESTINY-Breast03]		TLR obtained	Filed	
		HER2 low, post chemo [P3, DESTINY-Breast04]				TLR anticipated
		HER2+, 1L [P3, DESTINY-Breast09]	Study started			
		HER2+, neoadjuvant [P3, DESTINY-Breast11]			Study started	
	GC	HER2+, 2L [P2, DESTINY-Gastric02]	TLR obtained		Filed (EU)	
		HER2+, 2L [P3, DESTINY-Gastric04]	Study started			
		HER2+, 3L [P2, DESTINY-Gastric06]		Study started		
	NSCLC	HER2+, combination [P1b, DESTINY-Lung03]			Study started	
		HER2 mutated, 1L [P3, DESTINY-Lung04]			Study started	
Dato-DXd		TNBC, durvalumab combo [P1b/2, BEGONIA]	Study started			
		HR+ BC, 2/3L [P3, TROPION-Breast01]			Study started	
		NSCLC w/o AGAs, 1L, pembrolizumab combo [P3, TROPION-Lung08]				Study start planned
HER3-DXd		EGFR mutated NSCLC, osimertinib combo [P1]	Study started			

Red underlined: new or updated from FY2021 Q2

AGA: actionable genomic alterations, 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 Jan 2022

Project	Target Indications [phase, study name, region]	FY2021 Q1	Q2	Q3	Q4
Quizartinib	AML, 1L [P3, JP/US/EU/Asia]			**TLR obtained**	
Pexidartinib	Tenosynovial giant cell tumor [P2, JP]	Study started			
Teserpaturev/G47Δ	Malignant glioma [IIS, JP]	Approved			
Valemetostat (DS-3201)	ATL/lymphoma [P2 registration, JP]		TLR obtained	**Filed**	
	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]		Approved		
Efient®	Ischemic stroke [P3, PRASTRO III, JP]			**Approved**	
Tarlige®	Central neuropathic pain [P3, JP]	Filed			
DS-6016	Fibrodysplasia ossificans progressiva [P1, JP]	Study started			
DS-7011	**Systemic lupus erythematosus [P1, US]**				**Study start planned**
VN-0200	RS virus vaccine [P1, JP]	Study started			
DS-5670	COVID-19 mRNA vaccine [P2, JP]			**Study started**	
	COVID-19 mRNA vaccine, booster [P1/2/3, JP]				**Study started**

Red underlined: new or updated from FY2021 Q2

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, TBD: to be determined, TLR: Top Line Results

Major R&D Pipeline: 3ADCs

As of Jan 2022

Phase 1		Phase 2	Phase 3	Submitted
(JP/US) NSCLC, TNBC, HR+ BC, SCLC, urothelial, GC, esophageal 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) HER2+ BC 2L DESTINY-Breast03
(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	(China) HER2+ GC 3L DESTINY-Gastric06	(JP/US/EU/Asia) HER2 low BC post chemo DESTINY-Breast04	(EU) HER2+ GC 2L DESTINY-Gastric02
(JP/US/EU) 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+ BC post neoadjuvant DESTINY-Breast05	
(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 low BC chemo naive DESTINY-Breast06	
(JP/US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(US/EU) BC, bladder (nivolumab combo)	(US/EU/Asia) NSCLC (durvalumab combo) 2L~ HUDSON	(US)HER2+ BC 1L DESTINY-Breast09	
(JP/US/EU/Asia) NSCLC	(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU) HER2+ CRC 3L DESTINY-CRC01	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	
(JP/US)EGFR mutated NSCLC (osimertinib combo)	(JP/US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	
(JP/US) HER3+ BC		(US/EU/Asia) HER2 mutated tumor DESTINY-PanTumor01	(US/EU/Asia) NSCLC 1L (w/ exon 19 or exon 20 mutation) DESTINY-Lung04	
		(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02	(JP/US/EU/Asia) NSCLC (w/o actionable mutation) TROPION-Lung01	
		(JP/US/EU/Asia) NSCLC (w/ actionable mutation) TROPION-Lung05	(JP/US/EU/Asia) HR+ BC 2/3L TROPION-Breast01	
		(JP/US/EU/Asia) EGFR mutated NSCLC HERTHENA-Lung01		

ENHERTU®

Dato-DXd

HER3-DXd

BC: breast cancer, CRC: colorectal cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, SCLC: 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 Jan 2022

Phase 1		Phase 2	Phase 3	Submitted
DS-7300 (JP/US) B7-H3-directed ADC ESCC, CRPC, SCLC, etc.	**PLX2853** (US) BET inhibitor AML	**Valemetostat (DS-3201)** (JP/US/EU/Asia) EZH1/2 inhibitor PTCL	**Quizartinib** (JP/US/EU/Asia) FLT3 inhibitor 1L AML	**Tarlige** (JP) $\alpha_2\delta$ Ligands Central neuropathic pain
DS-6000 (US) CDH6-directed ADC Renal cell carcinoma, ovarian cancer	**PLX2853** (US) BET inhibitor Solid tumor	**Valemetostat (DS-3201)** (EU) EZH1/2 inhibitor BCL	**Pexidartinib** (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	**Valemetostat (DS-3201)** (JP) EZH1/2 inhibitor ATL/L
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	**PLX2853** (US) BET inhibitor Gynecologic neoplasms, ovarian cancer	**DS-1001** (JP) Mutant IDH1 inhibitor Glioma	**Minnebro** (JP) MR blocker Diabetic nephropathy	**VN-0107/MEDI3250** (JP) Live attenuated influenza vaccine nasal spray
DS-1211 (US) TNAP inhibitor Pseudoxanthoma elasticum	**PLX2853** (US) BET inhibitor Prostate cancer	**DS-5141** (JP) ENA oligonucleotide DMD	**VN-0102/JVC-001** (JP) Measles mumps rubella combined vaccine	
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	**DS-5670** (JP) mRNA vaccine (Booster) COVID-19	
DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus	**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, BCL: B cell lymphoma, CRPC: castration-resistant prostate cancer, DMD: Duchenne muscular dystrophy, ESCC: esophageal squamous cell carcinoma, GIST: gastrointestinal stromal tumor, SCLC: 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/Europe)

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