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# **FY2021 Q3 Financial Results Presentation**

**DAIICHI SANKYO CO., LTD.**

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# Agenda

① **FY2021 Q3 Financial Results**

② Business Update

③ R&D Update

④ Appendix



# Overview of FY2021 Q3 Results

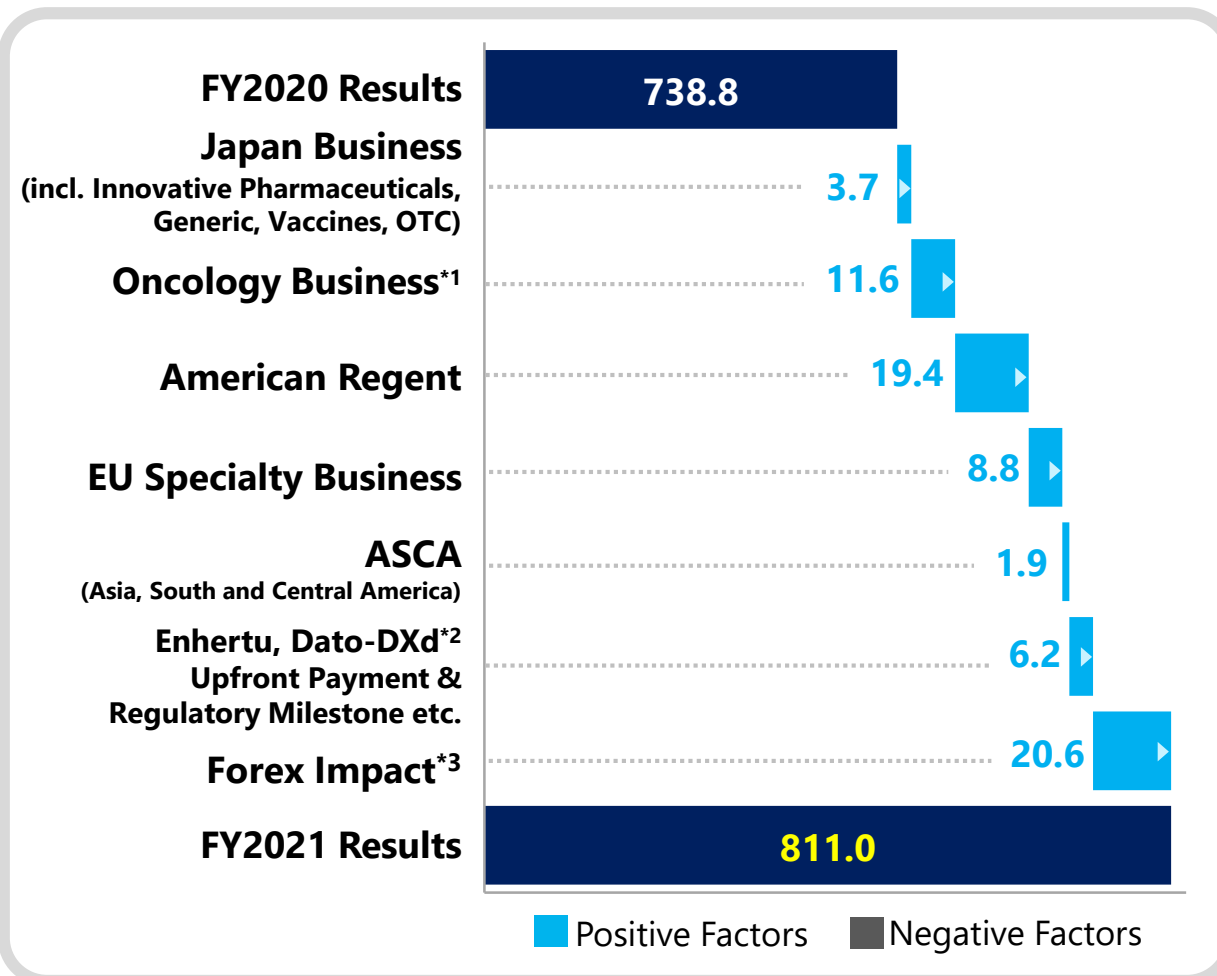
(Bn JPY)

	FY2020 Q3 YTD Results	FY2021 Q3 YTD Results	YoY	
<b>Revenue</b>	<b>738.8</b>	<b>811.0</b>	<b>+9.8%</b>	
<b>Cost of sales*</b>	<b>256.4</b>	<b>263.2</b>	<b>6.8</b>	
<b>SG&amp;A expenses*</b>	<b>229.3</b>	<b>255.7</b>	<b>26.4</b>	
<b>R&amp;D expenses*</b>	<b>163.7</b>	<b>169.1</b>	<b>5.3</b>	
<b>Core operating profit*</b>	<b>89.4</b>	<b>123.0</b>	<b>+37.6%</b>	
<b>Temporary income*</b>	<b>0.1</b>	<b>2.1</b>	<b>2.0</b>	
<b>Temporary expenses*</b>	<b>0.0</b>	<b>1.3</b>	<b>1.3</b>	
<b>Operating profit</b>	<b>89.5</b>	<b>123.8</b>	<b>+38.3%</b>	
<b>Profit before tax</b>	<b>99.6</b>	<b>125.9</b>	<b>26.3</b>	
<b>Profit attributable to owners of the Company</b>	<b>75.8</b>	<b>94.3</b>	<b>+24.4%</b>	
<b>Currency</b>	<b>USD/JPY</b>	<b>106.11</b>	<b>111.10</b>	<b>+4.99</b>
<b>Rate</b>	<b>EUR/JPY</b>	<b>122.37</b>	<b>130.62</b>	<b>+8.25</b>

\* 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

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

(Bn JPY)



Positive Factors		Negative Factors	
<b>Japan Business Unit</b>			
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		
<b>Oncology Business*1 Unit</b>			
Enhertu	+16.9	Olmesartan	-3.0
<b>American Regent Unit</b>			
Injectafer	+8.2		
GE injectables	+8.5		
<b>EU Specialty Business Unit</b>			
Lixiana	+13.6	Gain on sales of transferring long-listed products	-3.1
		Olmesartan	-2.2
<b>Enhertu, Dato-DXd*2 Upfront Payment &amp; Regulatory Milestone etc.</b>			
Enhertu quid related payment	+3.1		
Dato-DXd upfront payment	+2.1		

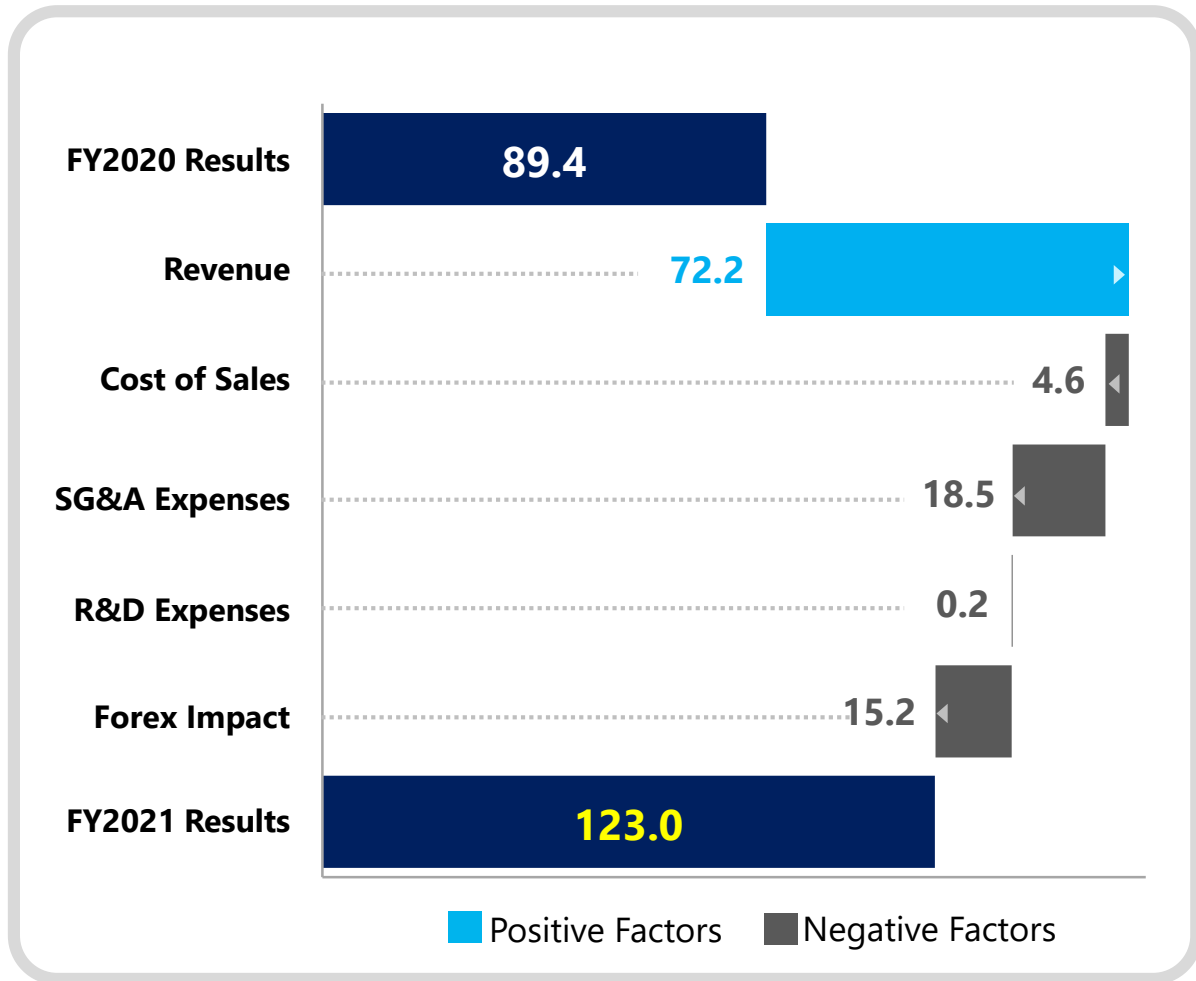
\*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products

\*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)

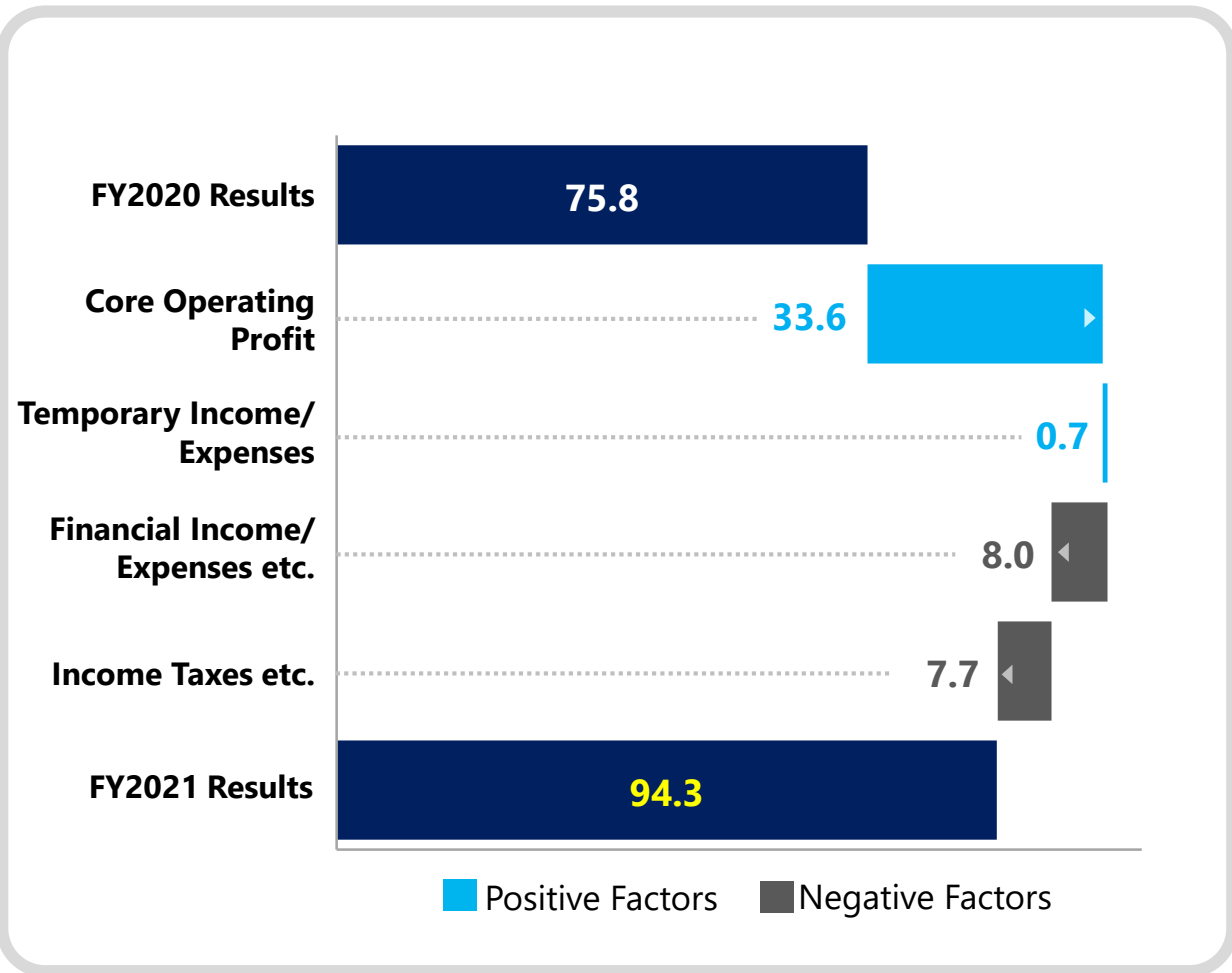
Cost of Sales ..... +2.2

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)

<b>Temporary Income/Expenses</b>	<b>-0.7 (Profit increased)</b>
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

<b>Financial Income/Expenses etc.</b>	<b>+8.0 (Profit decreased)</b>
FY2020: Financial income due to decrease in contingent consideration of Ambit/quizartinib acquisition	+4.7
Deterioration in forex gains/losses	+1.5

<b>Income Taxes etc.</b>	<b>+7.7 (Profit decreased)</b>		
	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
Oncology 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
Olmесartan	16.2	14.9	-1.3
ASCA (Asia, South and Central America)	74.5	82.9	+8.4

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



# Revenue: Major Products in Japan

(Bn JPY)

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

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# ENHERTU®: Revenue

(Bn JPY)

	FY2021 Q3 YTD Results		FY2021 Forecast		<Reference> Total Consideration
		YoY	(as of Jan.)	vs. as of Oct.	
<b>Product Sales</b>	<b>43.5</b>	<b>22.8</b>	<b>61.2</b>	<b>-1.6</b>	-
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	-	-
<b>Upfront payment</b>	<b>7.4<sup>*</sup></b>	<b>-</b>	<b>9.8<sup>*</sup></b>	<b>-</b>	<b>149.0</b>
<b>Regulatory milestone payment</b>	<b>1.7<sup>*</sup></b>	<b>1.0</b>	<b>2.2<sup>*</sup></b>	<b>-</b>	<b>33.7</b>
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
<b>Quid related payment</b>	<b>3.1<sup>*</sup></b>	<b>3.1</b>	<b>3.4<sup>*</sup></b>	<b>3.4</b>	<b>17.2</b>
<b>Total</b>	<b>55.7</b>	<b>26.9</b>	<b>76.6</b>	<b>1.8</b>	<b>200.0</b>

\* 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)**



## 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**

## **Efient<sup>®</sup>** (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<sup>®</sup>** (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
 	olmesartan medoxomil and its fixed dose combinations	Antihypertensive agent	2002 ~ 2010	9.9 Bn JPY
	colesevelam HCL tablets and oral suspension	Hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	2000	
	prasugrel hydrochloride	Antiplatelet agent	2009	
	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**<sup>®</sup> (pexidartinib)
    - Launched in US, under development in JP and ASCA region
  - Melanoma treatment\*  
**Zelboraf**<sup>®</sup> (vemurafenib)
    - Marketed by Roche group
- ◆ **Major R&D project**
  - BET inhibitor PLX2853

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

### 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**

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



# Agenda

① FY2021 Q3 Financial Results

② Business Update

**③ R&D Update**

④ Appendix





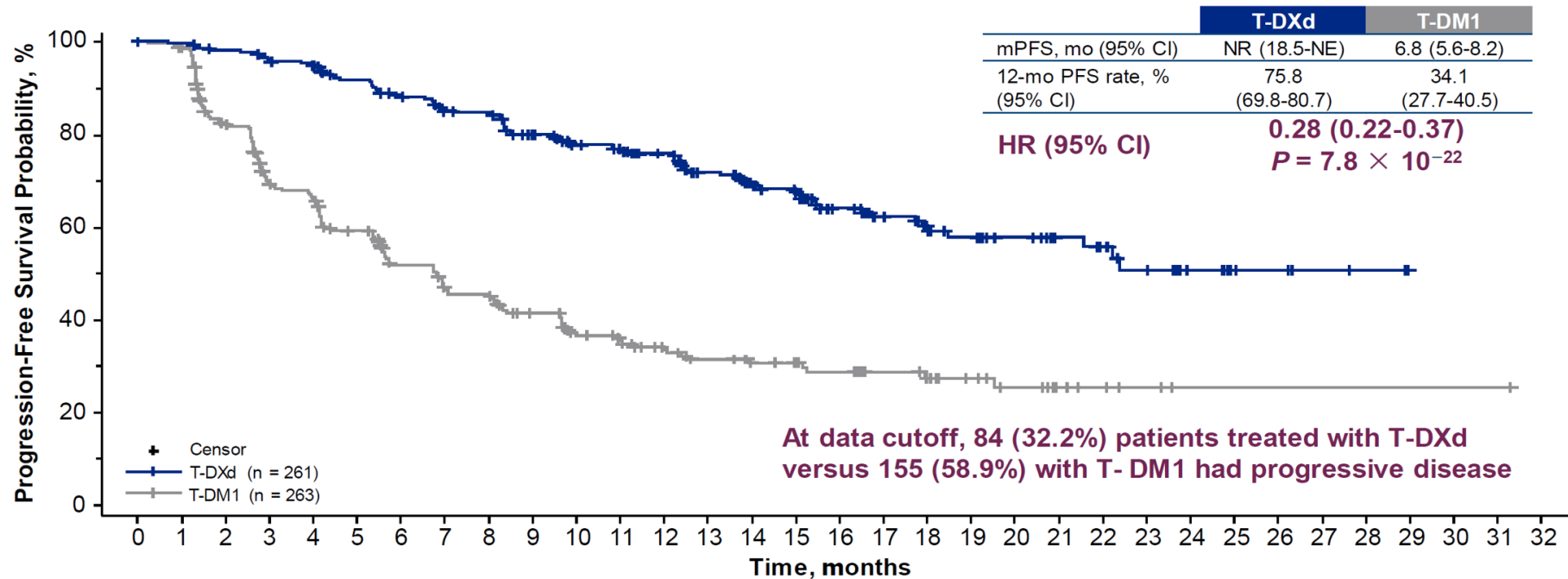
**3ADC Update**

Alpha Update

News Flow

# ENHERTU<sup>®</sup>: DESTINY-Breast03 efficacy data

## Progression-Free Survival (blinded independent central review)



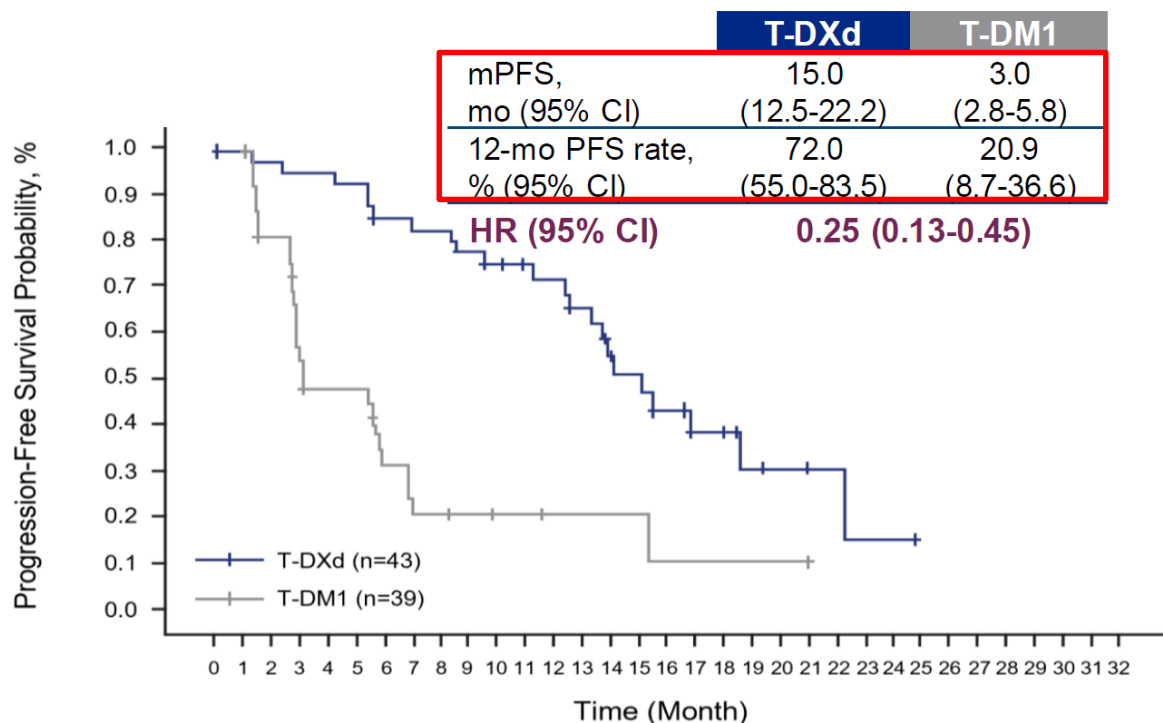
BICR, blinded independent central review; HR, hazard ratio; mPFS, median progression-free survival; NE, not estimable; NR, not reached; PFS, progression-free survival; T-DM1, trastuzumab emtansine; T-DXd, trastuzumab deruxtecan. Median PFS follow-up for T-DXd was 15.5 months (range, 15.1-16.6) and was 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<sup>®</sup> demonstrated unparalleled improvement in PFS compared to T-DM1 in patients with HER2 positive metastatic breast cancer**

# ENHERTU<sup>®</sup>: SABCS 2021 highlights

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

## Progression-Free Survival



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

## Intracranial Response

(BICR, RECIST 1.1)

	T-DXd (n = 36)	T-DM1 (n = 36)
<b>Best Overall Response, n (%)<sup>a</sup></b>		
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

<sup>a</sup>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<sup>®</sup> showed **greater efficacy** compared to T-DM1
- ◆ As for **anti-tumor responses in brain metastases lesion**, ENHERTU<sup>®</sup> showed **greater intracranial response** compared to T-DM1

## HER2 positive breast cancer

### ◆ Metastatic 2<sup>nd</sup> 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 2<sup>nd</sup> 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 1<sup>st</sup> line

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

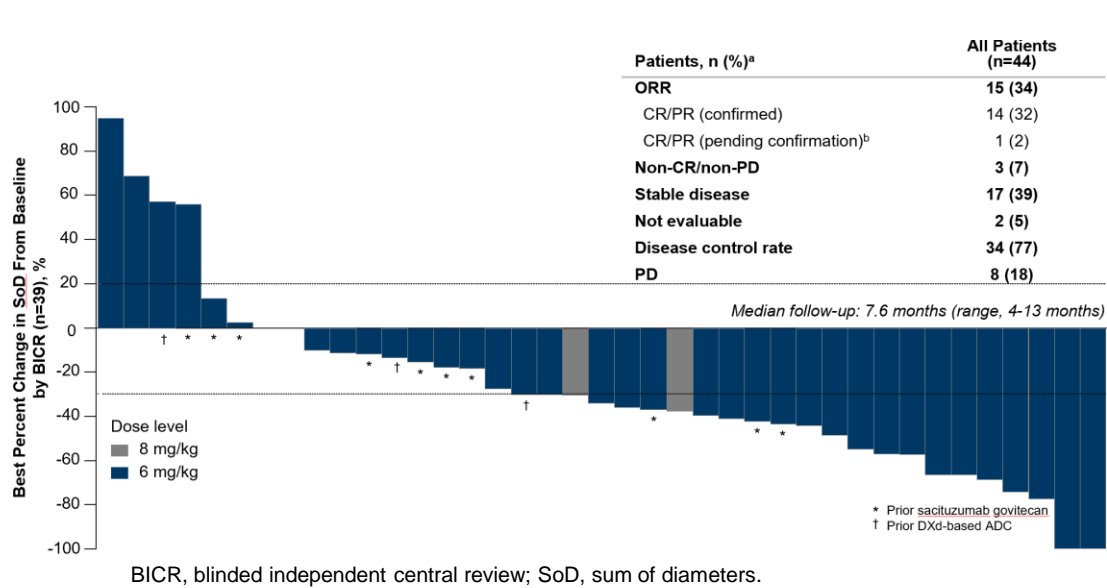
**Regulatory filings and new clinical studies in multiple tumor types**

# Dato-DXd: Breast cancer update

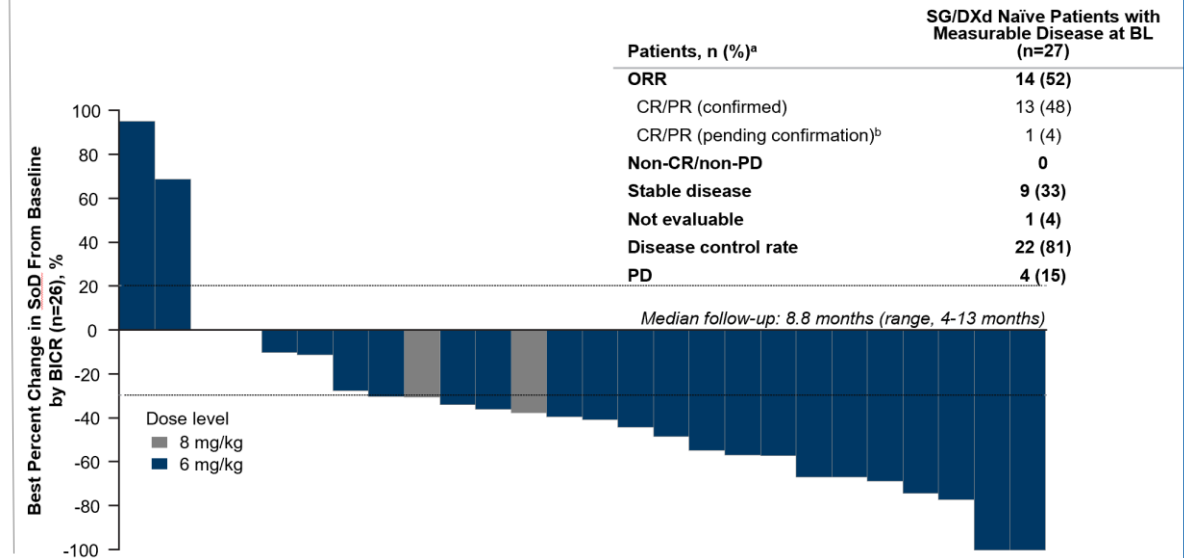
SABCS 2021: TROPION-PanTumor01 triple negative breast cancer (TNBC) cohort data

## Anti-tumor responses (Blinded Independent Central Review)

### All patients with TNBC



### Patients with TNBC without prior Topo I inhibitor-based ADC



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**



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**

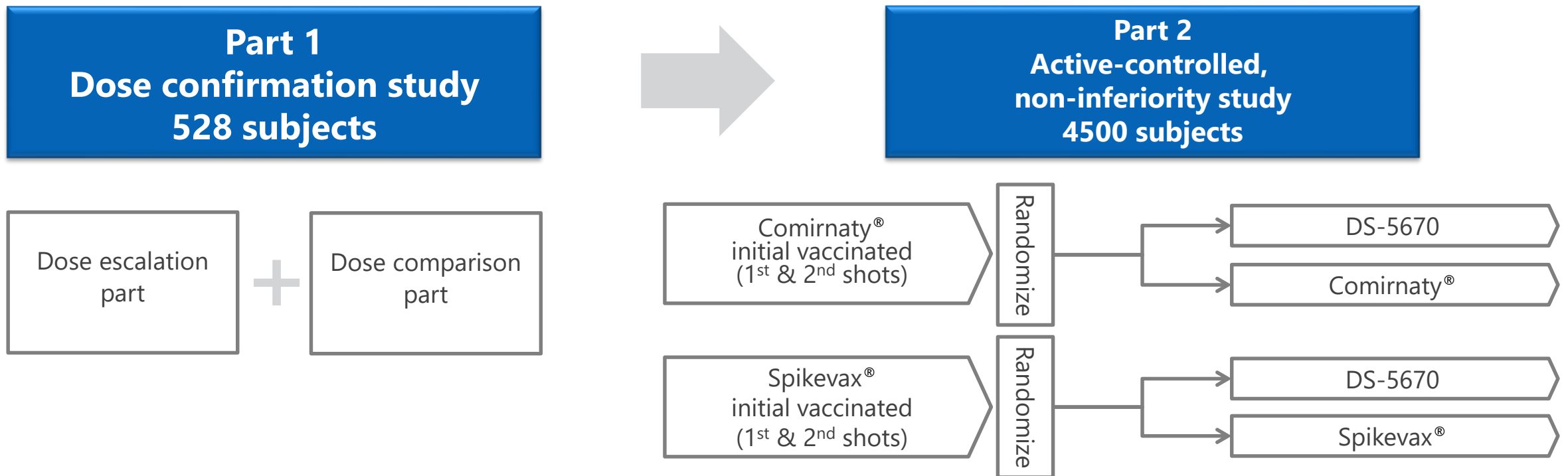
**Establishment of manufacturing system at DS Biotech**





# 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 (1<sup>st</sup> & 2<sup>nd</sup> shots) of approved SARS-CoV-2 vaccine (dose confirmation, non-inferiority confirmatory study)
- ◆ **Eligible subjects:** Adult and elderly subjects who completed the initial vaccination (1<sup>st</sup> & 2<sup>nd</sup> 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 <sup>a</sup>	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 <sup>b</sup>	11	5 (45.5)	3 (27.3)	0	2 (18.2)	4 (36.4)	2 (18.2)

<sup>a</sup> One patient was not evaluated for skin lesions after baseline assessment. <sup>b</sup> 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



AML: acute myeloid leukemia, TLR: Top Line Results

## DS-7011

### ◆ Systemic lupus erythematosus

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

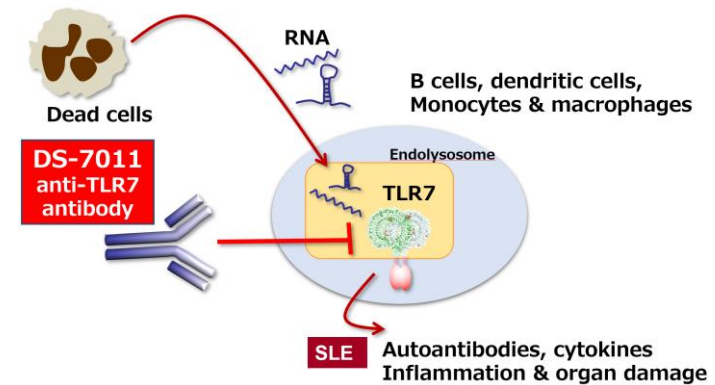


Diagram created & provided by Prof. Miyake of the Institute of Medical Science, The University of Tokyo

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

3ADC Update

Alpha Update

**News Flow**

## Planned publications

ASCO Genitourinary Cancers Symposium (Feb 17-19, 2022)	
ENHERTU®	<u>Ph1b nivolumab combination</u> <ul style="list-style-type: none"><li><u>Urothelial carcinoma cohort data</u></li></ul>
DS-7300	<u>Solid tumor Ph1/2</u> <ul style="list-style-type: none"><li><u>CRPC subanalysis data</u></li></ul>

## Key data readouts

ENHERTU®	DESTINY-Breast04: HER2 low BC, post chemo, Ph3 <ul style="list-style-type: none"><li>FY2021 Q4</li></ul>
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## Planned pivotal study initiation

Dato-DXd	TROPION-Lung08: NSCLC w/o AGAs, 1L, Ph3 <ul style="list-style-type: none"><li>FY2021 Q4</li></ul>
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**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)

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

Project	Target Indications [phase, study name, region]	FY2021			
		Q1	Q2	Q3	Q4
<b>Quizartinib</b>	AML, 1L [P3, JP/US/EU/Asia]			<u>TLR obtained</u>	
<b>Pexidartinib</b>	Tenosynovial giant cell tumor [P2, JP]	Study started			
<b>Teserpaturev/G47Δ</b>	Malignant glioma [IIS, JP]	Approved			
<b>Valemetostat (DS-3201)</b>	ATL/lymphoma [P2 registration, JP]		TLR obtained	<u>Filed</u>	
	PTCL [P2 registration, JP/US/EU/Asia]	Study started			
<b>DS-1594</b>	AML, ALL [P1/2, US]	Study started			
<b>Lixiana<sup>®</sup></b>	AF in the very elderly [P3, ELDERCARE-AF, JP]		Approved		
<b>Efient<sup>®</sup></b>	Ischemic stroke [P3, PRASTRO III, JP]			<u>Approved</u>	
<b>Tarlige<sup>®</sup></b>	Central neuropathic pain [P3, JP]	Filed			
<b>DS-6016</b>	Fibrodysplasia ossificans progressiva [P1, JP]	Study started			
<b>DS-7011</b>	<u>Systemic lupus erythematosus [P1, US]</u>				<u>Study start planned</u>
<b>VN-0200</b>	RS virus vaccine [P1, JP]	Study started			
<b>DS-5670</b>	COVID-19 mRNA vaccine [P2, JP]			<u>Study started</u>	
	<u>COVID-19 mRNA vaccine, booster [P1/2/3, JP]</u>				<u>Study started</u>

**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 naïve 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	
<b>DS-7300</b> (JP/US) B7-H3-directed ADC ESCC, CRPC, SCLC, etc.	<b>PLX2853</b> (US) BET inhibitor AML	<b>Valemetostat (DS-3201)</b> (JP/US/EU/Asia) EZH1/2 inhibitor PTCL	 	<b>Quizartinib</b> (JP/US/EU/Asia) FLT3 inhibitor 1L AML		<b>Tarlige</b> (JP) $\alpha\delta$ Ligands Central neuropathic pain	
<b>DS-6000</b> (US) CDH6-directed ADC Renal cell carcinoma, ovarian cancer	<b>PLX2853</b> (US) BET inhibitor Solid tumor	<b>Valemetostat (DS-3201)</b> (EU) EZH1/2 inhibitor BCL		<b>Pexidartinib</b> (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor		<b>Valemetostat (DS-3201)</b> (JP) EZH1/2 inhibitor ATL/L	
<b>DS-1055</b> (JP/US) Anti-GARP antibody Solid tumors	<b>PLX2853</b> (US) BET inhibitor Gynecologic neoplasms, ovarian cancer	<b>DS-1001</b> (JP) Mutant IDH1 inhibitor Glioma		<b>Minnebro</b> (JP) MR blocker Diabetic nephropathy		<b>VN-0107/MEDI3250</b> (JP) Live attenuated influenza vaccine nasal spray	
<b>DS-1211</b> (US) TNAP inhibitor Pseudoxanthoma elasticum	 <b>PLX2853</b> (US) BET inhibitor Prostate cancer	<b>DS-5141</b> (JP) ENA oligonucleotide DMD		<b>VN-0102/JVC-001</b> (JP) Measles mumps rubella combined vaccine			
<b>DS-6016</b> (JP) Anti-ALK2 antibody Fibrodysplasia ossificans progressiva	<b>DS-1594</b> (US) Menin-MLL binding inhibitor AML, ALL	<b>DS-5670</b> (JP) mRNA vaccine COVID-19		<b>DS-5670</b> (JP) mRNA vaccine (Booster) COVID-19			
<b>DS-7011</b> (US) Anti-TLR7 antibody Systemic lupus erythematosus	<b>VN-0200</b> (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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