

Passion for Innovation.
Compassion for Patients.™



FY2021 Q2 Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Sunao Manabe
President and CEO

October 29, 2021

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Overview of FY2021 Q2 Results

(Bn JPY)

	FY2020 Q2 YTD Results	FY2021 Q2 YTD Results	YoY	
Revenue	480.2	530.0	+10.4%	
Cost of sales*	168.6	172.6	4.0	
SG&A expenses*	148.6	165.7	17.1	
R&D expenses*	104.6	109.0	4.4	
Core operating profit*	58.4	82.7	+41.7%	
Temporary income*	0.1	2.1	2.0	
Temporary expenses*	0.0	0.1	0.0	
Operating profit	58.5	84.7	+44.9%	
Profit before tax	67.0	86.0	19.0	
Profit attributable to owners of the Company	51.7	62.5	+20.9%	
Currency	USD/JPY	106.92	109.80	+2.88
Rate	EUR/JPY	121.29	130.89	+9.60

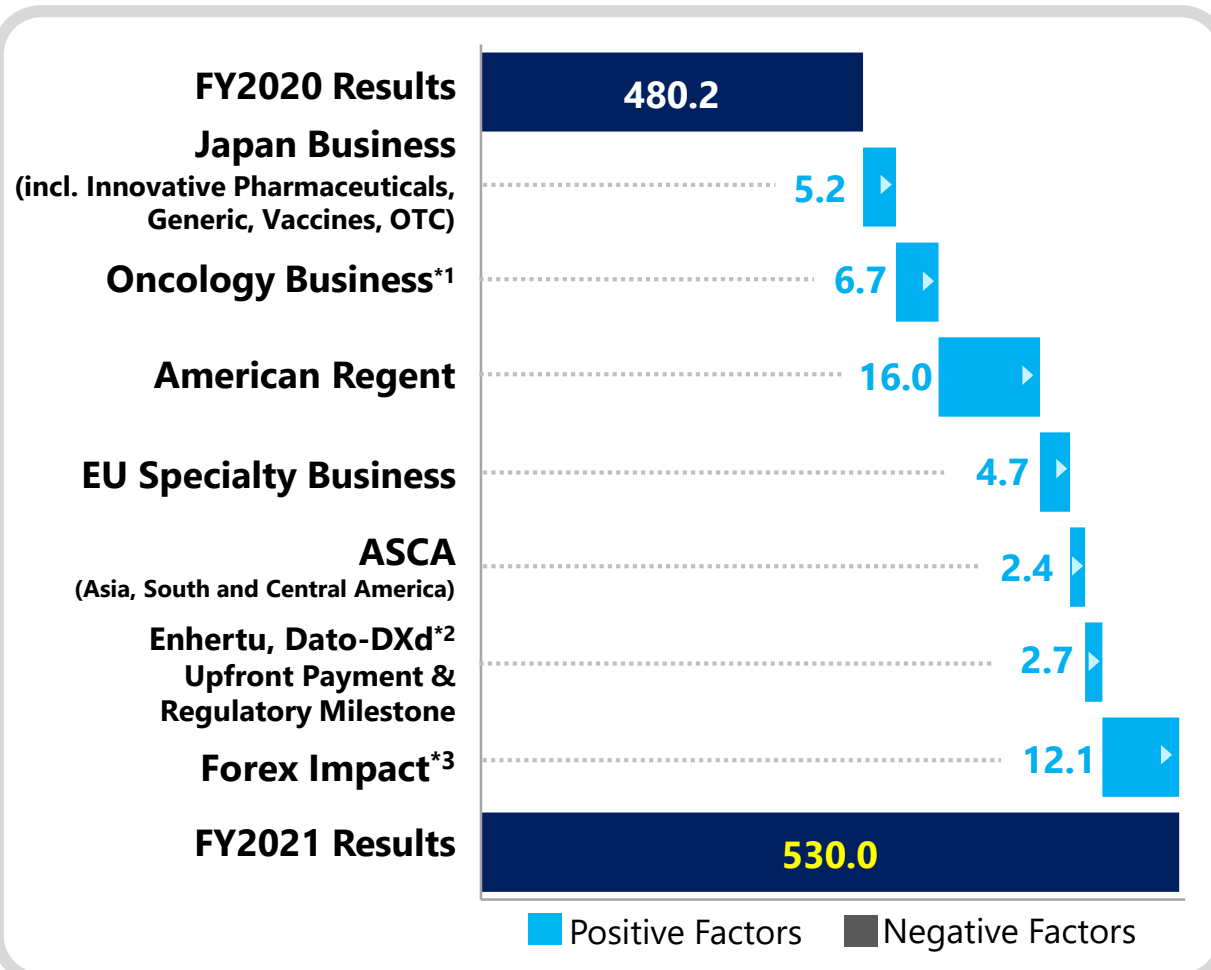
* As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, 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 49.8 Bn JPY (Increased by 37.7 Bn JPY excl. forex impact)

(Bn JPY)



Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+6.6	Memary	-11.0
Tarlige	+5.0		
Enhertu	+3.4		
Daiichi Sankyo Espha (Ezetimibe AG, Memantine AG etc.)	+5.6	Vaccines business (Influenza Vaccine)	-5.3
Daiichi Sankyo Healthcare (Roxionin)	+0.8		
Oncology Business*1 Unit			
Enhertu	+10.4	Olmesartan	-2.7
American Regent Unit			
Injectafer	+7.2		
GE injectables	+6.0		
EU Specialty Business Unit			
Lixiana	+8.6	Gain on sales of transferring long-listed products	-3.3
Enhertu, Dato-DXd*2 Upfront Payment & Regulatory Milestone			
Dato-DXd upfront payment	+2.0		

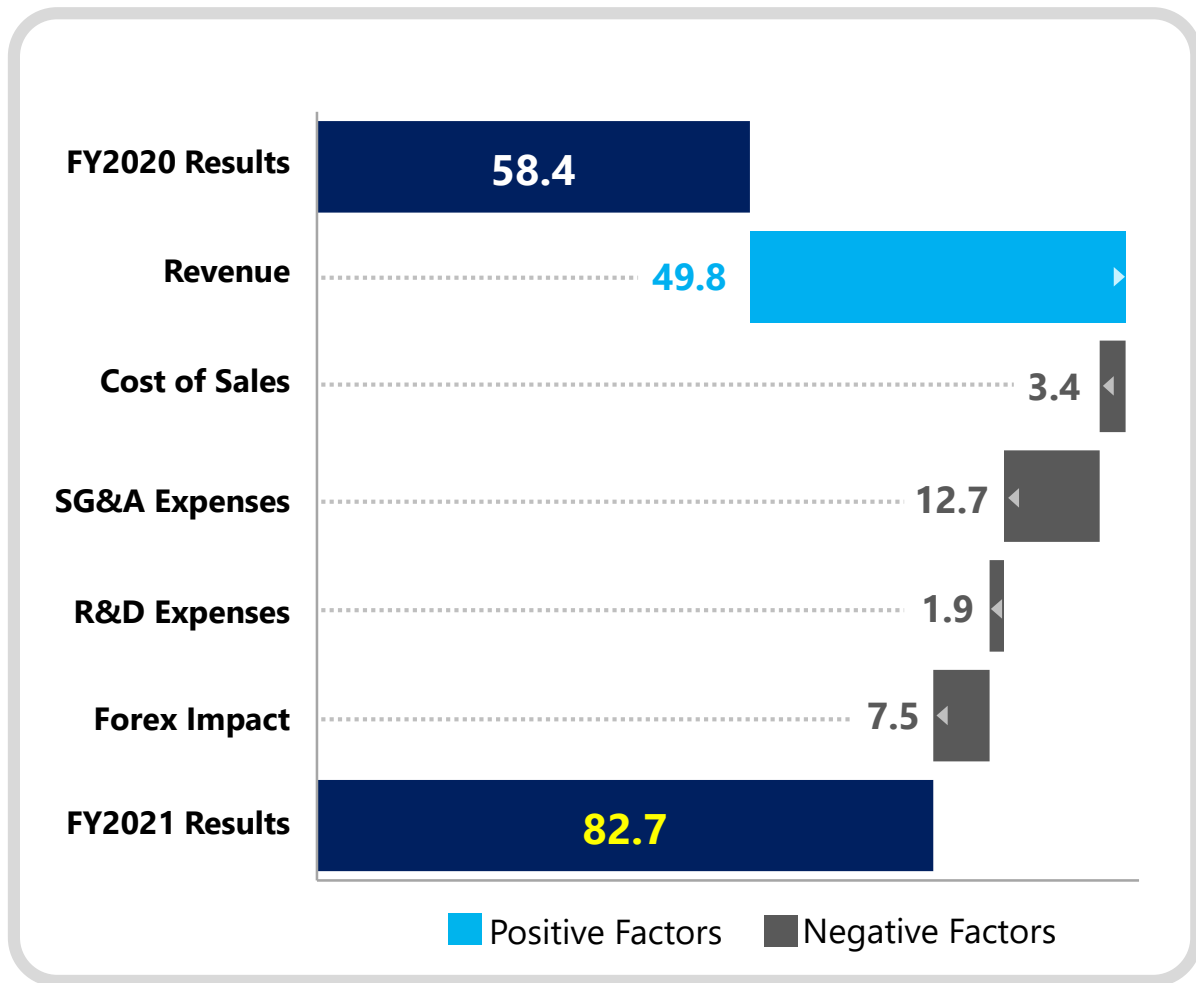
*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products

*2 Dato-DXd: Datopotamab deruxtecan (DS-1062)

*3 Forex impact USD: +2.9, EUR: +4.9, ASCA: +4.3

Core Operating Profit

Increased by 24.3 Bn JPY (Increased by 19.7 Bn JPY excl. forex impact)



(Bn JPY)

Revenue **+49.8**

incl. forex impact of +12.1

Cost of Sales **+3.4 (Profit decreased)**

Improvement in cost of sales ratio by change in product mix

SG&A Expenses **+12.7 (Profit decreased)**

Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses **+1.9 (Profit decreased)**

Increase in 3ADCs* R&D investments

Forex Impact **+7.5 (Profit decreased)**

Cost of Sales **+0.6**

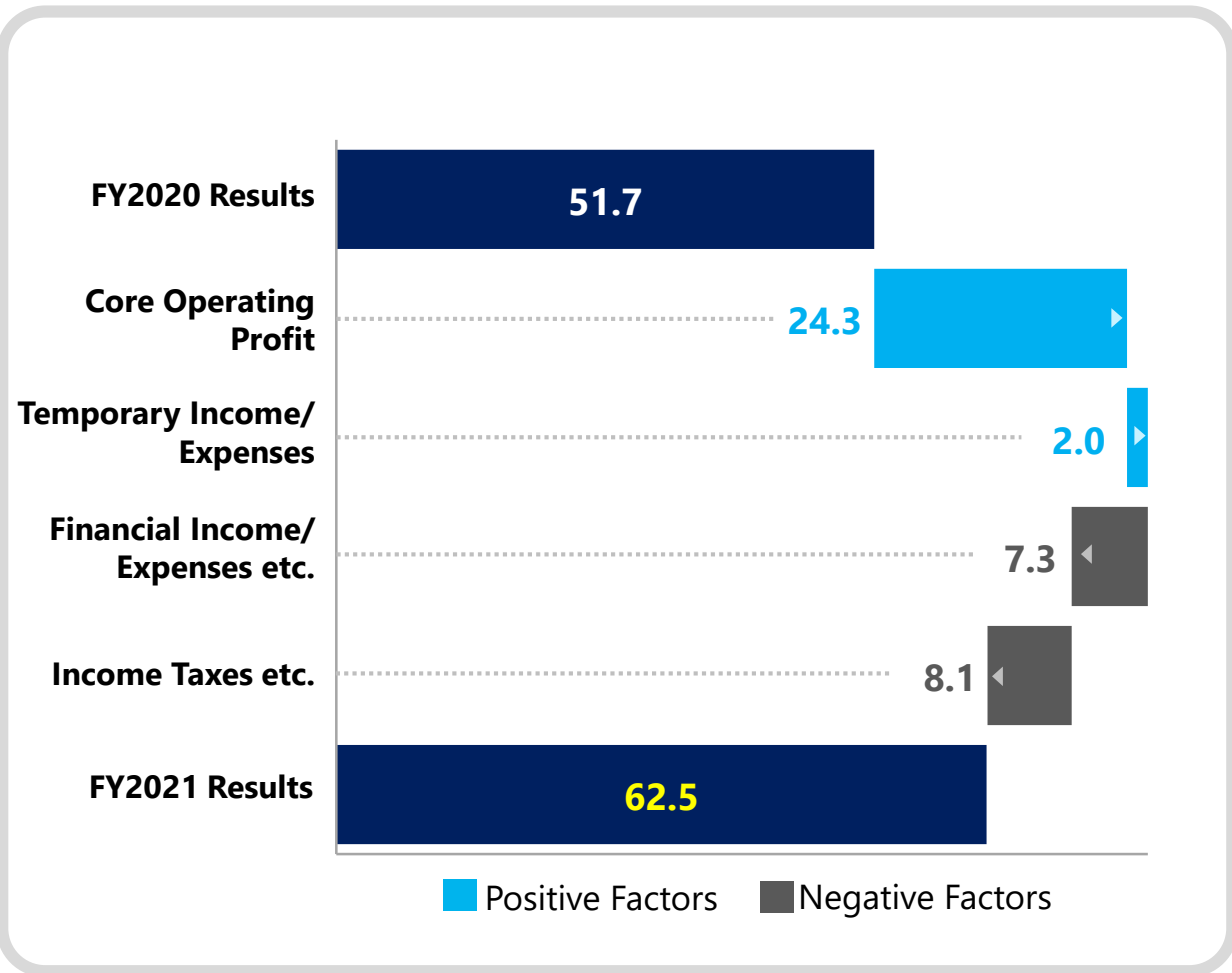
SG&A Expenses **+4.4**

R&D Expenses **+2.5**

* 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 10.8 Bn JPY



(Bn JPY)

Temporary Income/Expenses -2.0 (Profit increased)
 FY2021: Gains related to sale of Osaka logistics center -2.1

Financial Income/Expenses etc. +7.3 (Profit decreased)

- FY2020: Financial income due to decrease in contingent consideration of Ambit/quizartinib acquisition +4.7
- Deterioration in forex gains/losses +1.1

Income Taxes etc. +8.1 (Profit decreased)

	FY2020 Q2YTD	FY2021 Q2YTD	YoY
Profit before Tax	67.0	86.0	+19.0
Income Taxes etc.	15.4	23.5	+8.1
Tax rate	23.0%	27.3%	+4.4%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2020 Q2 YTD Results	FY2021 Q2 YTD Results	YoY	
Japan Business	250.1	255.6	+5.5	
Daiichi Sankyo Healthcare	33.0	33.8	+0.8	
Oncolgy Business	23.5	31.0	+7.5	
Enhertu	11.3	22.4	+11.0	
Turalio	0.8	1.3	+0.5	
American Regent	58.9	77.0	+18.0	
Injectafer	21.0	28.9	+8.0	
Venofer	14.6	16.5	+1.9	
GE injectables	19.8	26.5	+6.7	
EU Speciality Business	54.3	63.7	+9.3	
Lixiana	35.0	47.1	+12.1	
Nilemdo/Nustendi	-	1.6	+1.6	
Olmesartan	11.0	10.3	-0.7	
ASCA (Asia, South and Central America)	48.4	55.1	+6.7	
Currency	USD/JPY	106.92	109.80	+2.88
Rate	EUR/JPY	121.29	130.89	+9.60

Revenue: Major Products in Japan

(Bn JPY)

		FY2020 Q2 YTD Results	FY2021 Q2 YTD Results	YoY
Lixiana	anticoagulant	38.3	44.8	+6.6
Nexium	ulcer treatment	39.0	39.6	+0.7
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	17.0	18.4	+1.5
Tarlige	pain treatment	9.1	14.2	+5.0
Tenelia	type 2 diabetes mellitus treatment	12.4	12.1	-0.4
Ranmark	treatment for bone complications caused by bone metastases from tumors	9.7	10.1	+0.4
Loxonin	anti-inflammatory analgesic	12.3	11.3	-1.0
Vimpat	anti-epileptic agent	7.1	8.9	+1.7
Canalia	type 2 diabetes mellitus treatment	7.7	8.4	+0.7
Efient	antiplatelet agent	7.2	8.0	+0.9
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	1.0	4.4	+3.4
Rezaltas	antihypertensive agent	6.8	6.2	-0.5
Inavir	anti-influenza agent	1.3	0.9	-0.5

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Revision to the forecast

(Bn JPY)

	FY2021 Forecast (as of Apr.)	FY2021 Forecast (as of Oct.)	vs. Forecast as of Apr.
Revenue	990.0	1,030.0	+40.0
Cost of sales*	320.0	330.0	+10.0
SG&A expenses*	334.0	348.0	+14.0
R&D expenses*	266.0	262.0	-4.0
Core operating profit*	70.0	90.0	+200.0
Temporary income*	-	2.0	+2.0
Temporary expenses*	-	-	-
Operating profit	70.0	92.0	+22.0
Profit before tax	70.0	92.0	+22.0
Profit attributable to owners of the Company	50.0	64.0	+14.0

Currency	USD/JPY	105.00	107.40	+2.40
Rate	EUR/JPY	120.00	125.45	+5.45

Assumption of currency rate for Q3 and Q4 : USD/JPY 105, EUR/JPY 120

Revenue

- Increase factors

Sales expansion of main products (Lixiana, Injectafer, etc.), increase by forex impact

- Decrease factors

Enhertu (Update of assumptions on vials per infusion and treatment period per patient), decrease in demand of Inavir

Cost of sales

- Increase by revenue increase

SG&A Expenses

- Increase in sales promotion expenses due to revenue increase, increase by forex impact

Temporary expenses

- FY2021: Gains related to sale of Osaka logistics center

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ENHERTU®: Performance in Each Region

- ◆ Steady increase in product sales due to market penetration in launched countries
- ◆ Product sales: FY2021 Q2 YTD results **26.7 Bn JPY** (YoY +14.4 Bn JPY)
FY2021 forecast **62.7 Bn JPY** (YoY +32.6 Bn JPY)



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

- ◆ Product sales: FY2021 Q2 YTD results **19.7 Bn JPY (180 Mn USD)**
FY2021 forecast **43.0 Bn JPY (400 Mn USD)**

Assumptions on vials per infusion and treatment period per patient have not changed from the forecast announced in July 2021

- ◆ **Steady growth in the market**

- Treated patients continued to increase steadily in Q2
- New patient shares increasing
 - HER2+ BC 3L: Maintaining No.1 share
 - HER2+ GC 2L: Increasing steadily
- Outlets purchasing as planned

- ◆ **Preparations in place for HER2+ Breast Cancer 2L approval**

Europe (HER2+ Breast Cancer 3L)

- ◆ Product sales: FY2021 Q2 YTD results **2.6 Bn JPY (24 Mn USD)**
FY2021 forecast **6.2 Bn JPY (58 Mn USD)**

- ◆ **Steady growth in the launched countries**

- Treated patients continued to increase steadily in Q2
- New patient shares increasing (No.1 in France and UK)

- ◆ **Preparations in place for HER2+ GC 2L approval**

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

- ◆ Product sales: FY2021 Q2 YTD results **4.4 Bn JPY**
FY2021 forecast **13.4 Bn JPY**

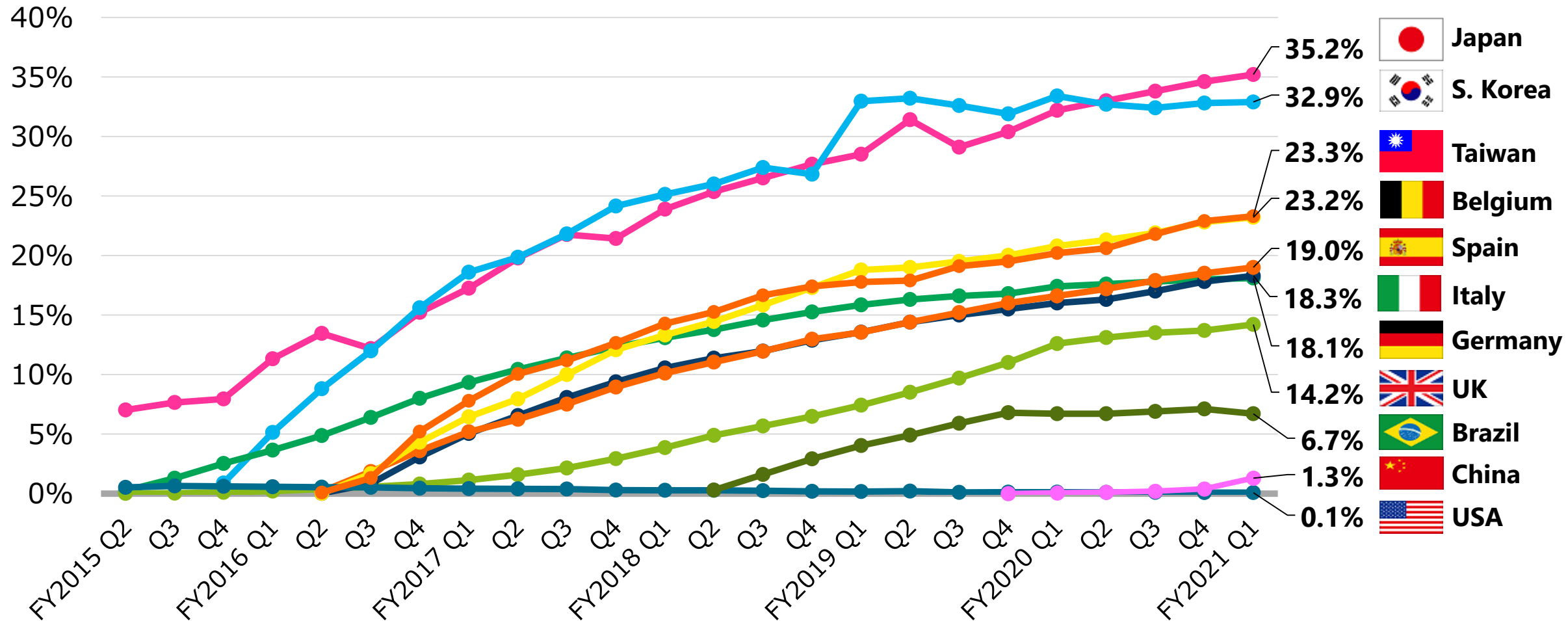
- ◆ **Steady growth in the market**

- Treated patients continued to increase steadily in Q2
- New patient shares increasing (No.1 in HER2+ BC 3L / GC 3L)
- Outlets purchasing as planned

LIXIANA[®]: Growth in Each Country



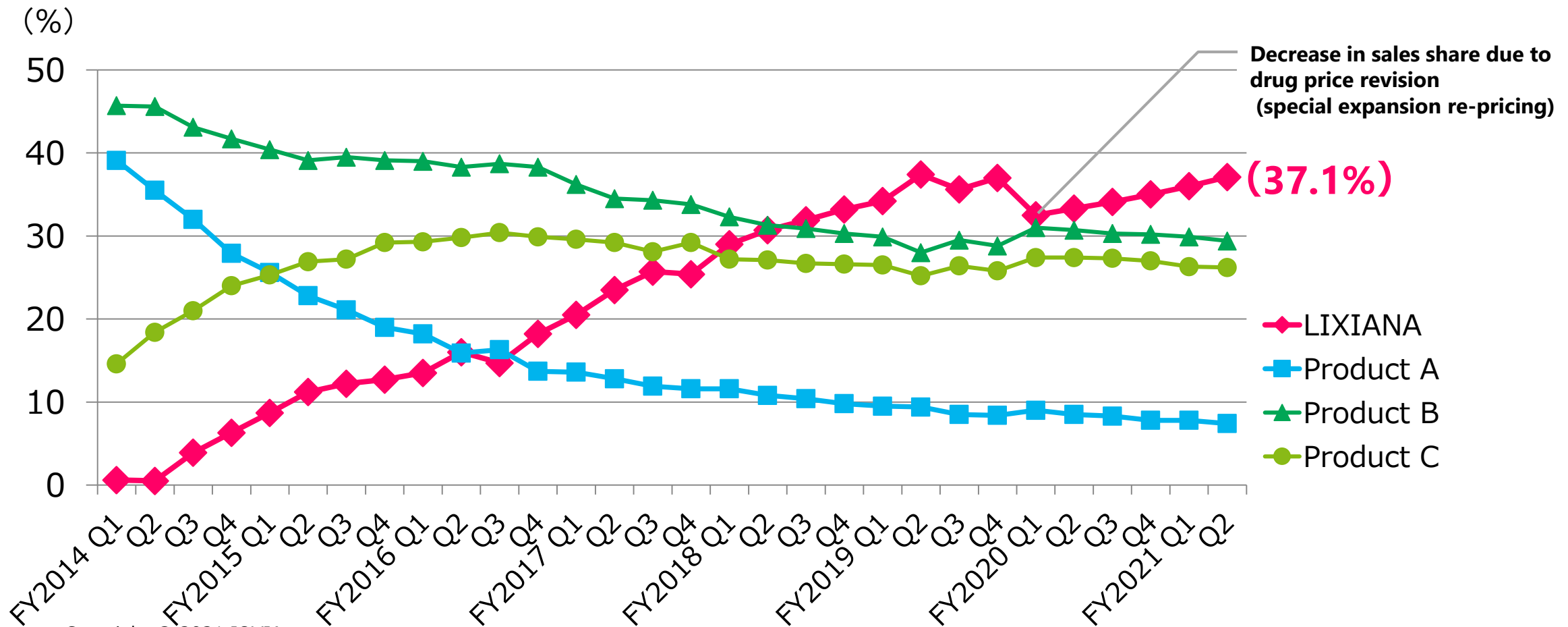
Global revenue FY2021 Q2 YTD results: 99.2 Bn JPY (YoY +20.1 Bn JPY)
FY2021 forecast: 196.7 Bn JPY (YoY +30.7 Bn JPY)



LIXIANA®: Growth in Japan



- ◆ No.1 sales share (FY2021 Q2: **37.1%**)
- ◆ Revenue FY2021 Q2 YTD results: **44.8 Bn JPY** (YoY +6.6 Bn JPY), FY2021 forecast: **93.0 Bn JPY** (YoY +15.6 Bn JPY)
- ◆ In **August 2021**, obtained **approval in Japan** for **additional dosage and administration** of "prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation" in **elderly patients with high risk of bleeding**



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Japan: Commercialization Collaboration of Migraine Treatment Drug

- ◆ In August 2021, signed an agreement on commercialization collaboration with Eli Lilly Japan for migraine treatment drug lasmiditan succinate (US product name: REYVOW®) in Japan

Product overview

- ◆ Generic name: **lasmiditan succinate**
- ◆ MOA: **5-HT_{1F} receptor agonist**
 - Selectively binds to serotonin (5-HT)_{1F} receptors, which are distributed centrally and expressed on central and peripheral trigeminal nerve cells. By acting on 5-HT_{1F} receptors, lasmiditan succinate suppresses pain transmission in the central nervous system, overactivity in the trigeminal nerve system, and the release of the neurotransmitters involved in migraines from the trigeminal nerve.
- Target indication: **migraines**
- ◆ Administration: **oral administration**
- ◆ Development status: **NDA submitted in Japan**

Agreement Overview

- ◆ Co-promotion
 - Daiichi Sankyo
Responsible for **distribution** and **sales** under **co-promotion with Eli Lilly Japan (Booking sales)**
 - Eli Lilly Japan
Responsible for **development, manufacturing** and **promotion**

Value of this deal

- ◆ Contribute to **improve QOL for many more patients with migraine by providing total care support through Emgality®,** a prophylaxis of migraine attacks which is already co-promoted by both companies **and lasmiditan succinate**
- ◆ **Enhance product portfolio toward sustainable growth of Japan businesses**

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ESMO 2021 Highlights

3ADC Update

Alpha Update

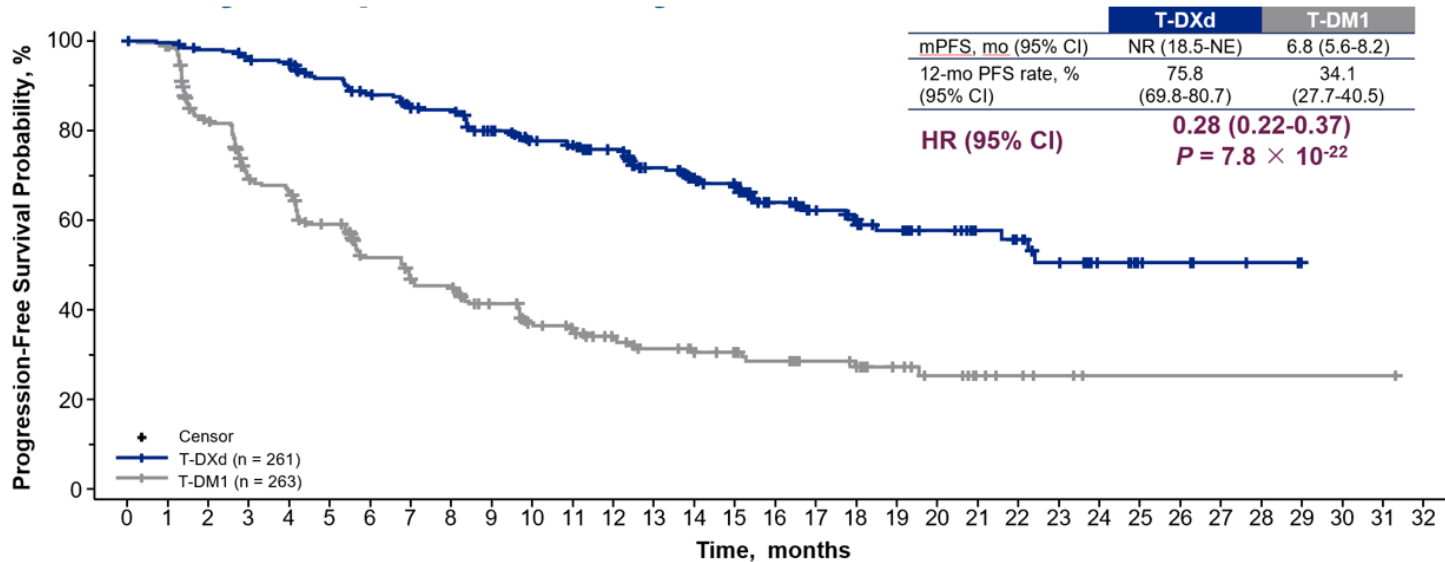
R&D Day

News Flow

- ◆ At this year's ESMO, we reported **unprecedented data** that can change the treatment of breast cancer patients and further demonstrated the **strength of our ADC technology** across multiple cancers
 - 4 late breaking presentations for Enhertu® and Dato-DXd
 - 1st time to present the clinical data of DS-7300, the 4th DXd-ADC

DESTINY-Breast03 Efficacy

Primary end point: PFS by BICR



Median PFS follow-up for T-DXd was 15.5 months (range, 15.1-16.6) and for T-DM1 was 13.9 months (range, 11.8-15.1)
 HR, hazard ratio; INV, investigator; mo, month; NE, not estimable; NR, not reached; PFS, progression free survival

DESTINY-Breast03 Safety

Adjudicated as drug-related ILD/pneumonitis^a

Adjudicated as drug-related ILD/pneumonitis ^a , n (%)			
n (%)	Grade 1	Grade 2	Grade 3
T-DXd (n = 257)	7 (2.7)	18 (7.0)	2 (0.8)
T-DM1 (n = 261)	4 (1.5)	1 (0.4)	0

Grade 4	Grade 5	Any Grade
0	0	27 (10.5)
0	0	5 (1.9)

^aPatients with prior history of ILD/pneumonitis requiring steroids were excluded
 ILD, interstitial lung disease

- ◆ Demonstrated unprecedented, highly statistically significant and clinically meaningful improvement in PFS compared with T-DM1 in HER2 positive breast cancer patients.
- ◆ No grade 4 or 5 ILD/pneumonitis and demonstrated manageable safety profile

◆ Demonstrated transformative potential of Enhertu® across multiple HER2 targetable cancers such as NSCLC and gastric cancer as well as breast cancer

DESTINY-Lung01 HER2 mutated NSCLC, 2L, global Ph2

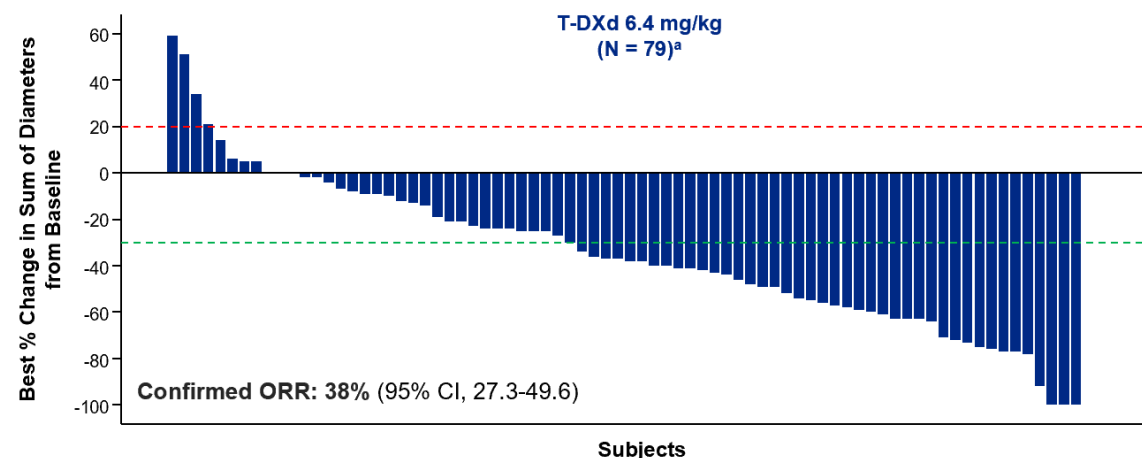
	Patients (N = 91)
Confirmed ORR ^a , n (%)	50 (54.9) (95% CI, 44.2-65.4)
Best overall response, n (%)	
CR	1 (1.1)
PR	49 (53.8)
SD	34 (37.4)
PD	3 (3.3)
Not evaluable	4 (4.4)
DCR, n (%)	84 (92.3) (95% CI, 84.8-96.9)
Median DoR, months	9.3 (95% CI, 5.7-14.7)
Median follow up, months	13.1 (range, 0.7-29.1)

^aPrimary endpoint

CR, complete response; DoR, duration of response; NSCLC, non small cell lung cancer; PD, progressive disease; PR, partial response; SD, stable disease.

Showed the potential that HER2 directed ADC may demonstrate robust and durable tumor response in patients with HER2 mutated NSCLC, where currently no drugs are approved specifically for this patient population.

DESTINY-Gastric02 HER2 positive GC, 2L, Western Ph2



^a3 patients were missing baseline or post-baseline target lesion assessment.

Red line at 20% indicates progressive disease; green line at -30% indicates partial response. Analysis conducted in the full analysis set.

1st trial involving Western patients which showed durable tumor response in patients with 2nd line HER2 positive gastric cancer patients.

ESMO 2021 Highlights

3ADC Update

Alpha Update

R&D Day

News Flow

Enhertu[®] : HER2 positive BC

◆ DESTINY-Breast03 (HER2+, 2L, Ph3)

- Aug 2021: Data obtained
Granted for Real Time Oncology Review* (RTOR) by FDA
- Sep 2021: Data presented at ESMO
Granted Breakthrough Therapy Designation by FDA
- FY2021 Q3: Filing planned to the Health Authorities

◆ **Significantly increasing confidence for all Enhertu[®] studies in HER2 positive BC given the data from DESTINY-Breast03 study.**

← Early treatment

Neoadjuvant	Post-neoadjuvant	Advanced/ Metastatic 1L	Advanced/ Metastatic 2L	Advanced/ Metastatic 3L
DESTINY-BreastXX Ph3 Planning	DESTINY-Breast05 Ph3 Started in Dec 2020	DESTINY-Breast09 Ph3 Started in Jun 2021	DESTINY-Breast03 Ph3 Filing planned FY2021 Q3	DESTINY-Breast01 Ph2 Launched

BC: breast cancer

*RTOR aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible. RTOR allows the FDA to review much of the data earlier, before the applicant formally submits the complete application.

Enhertu[®]: GC, NSCLC, and others

HER2 positive GC



- ◆ **DESTINY-Gastric01** (3L, Ph2, JP & KR),
DESTINY-Gastric02 (2L, Ph2, West)
Filing planned in FY2021 Q3 in Europe



- ◆ **DESTINY-Gastric06** (3L, Ph2, China)
First patient dosed in Sep 2021

Enhertu[®] development in China

- ◆ Development in China is currently underway in breast and gastric cancers, and AstraZeneca's outstanding strength in China is being fully leveraged.
- ◆ Since clinical data for Chinese patients are basically required for filing in China, Chinese patients are being enrolled in the following clinical trials.
 - BC: DESTINY-Breast03, 04, 05, 06
 - GC: DESTINY-Gastric03, 04, 06

HER2 mutated NSCLC

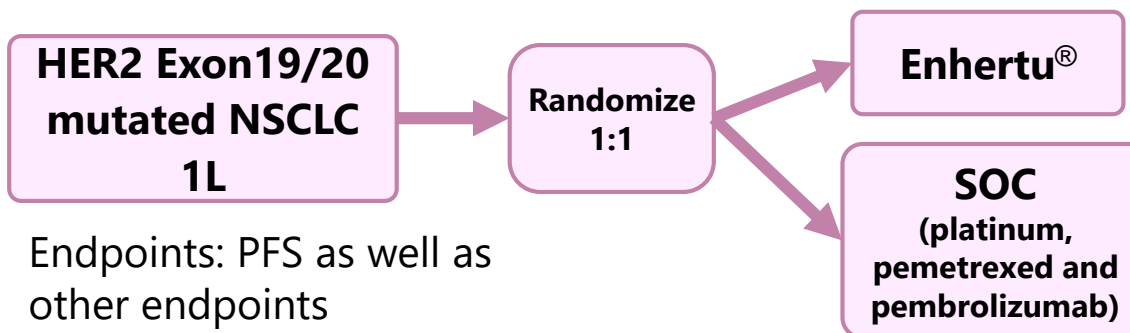
◆ Advanced/Metastatic 2L+

- BTD granted by FDA
- **DESTINY-Lung01** (2L, Ph2) data presented at ESMO 2021
- Filing strategy is under discussion with the Health Authorities

◆ Advanced/Metastatic 1L

- **DESTINY-Lung04** (1L, Ph3) study start planned in FY2021 Q3

DESTINY-Lung04 study design



Dato-DXd: NSCLC

- ◆ **Clinical trial collaboration for TROPION-Lung08 study has been entered with Merck in Sep 2021.**
 - 1st line NSCLC patients without actionable genomic alterations and high PD-L1 expression will be enrolled in the study.
 - Current SOC for this patient population is immunotherapy with or without platinum-based chemotherapy while approximately 40~60% of the patients experience disease progression, underscoring the need for new innovative treatment approaches.

NSCLC without actionable genomic alterations

Advanced/Metastatic 1L	Advanced/Metastatic 2L	Advanced/Metastatic 3L
	TROPION-Lung01 Ph3, Dato-DXd vs docetaxel	
	TROPION-Lung02 Ph1b, Dato-DXd + pembrolizumab ± platinum chemotherapy	
	TROPION-Lung04 Ph1b, Dato-DXd + durvalumab ± platinum chemotherapy	
TROPION-Lung08 Ph3, Dato-DXd + pembrolizumab vs pembrolizumab		

ESMO 2021 Highlights










3ADC Update


Alpha Update

R&D Day

News Flow

Daiichi Sankyo DXd-ADC Franchise

 Project (Target)	Target indications	Discovery	Pre-Clinical	Ph1	Ph2	Ph3	Filed	Launched
1 Enhertu [®] (HER2)	Breast, Gastric, NSCLC, CRC, etc.							
2 Dato-DXd (TROP2)	NSCLC, Breast, etc.							
3 HER3-DXd (HER3)	NSCLC, CRC, Breast							
4 DS-7300 (B7-H3)	ESCC, CRPC, SCLC, etc.							
5 DS-6157 (GPR20)	GIST							
6 DS-6000 (CDH6)	Renal, Ovarian							
7 DS-3939 (TA-MUC1)	Solid tumors							
8 DS-XXXX (Not disclosed)	Not disclosed							

 Timeline indicates the most advanced stage of each project

DS-6157 : GPR20 Directed ADC

Target antigen: GPR20

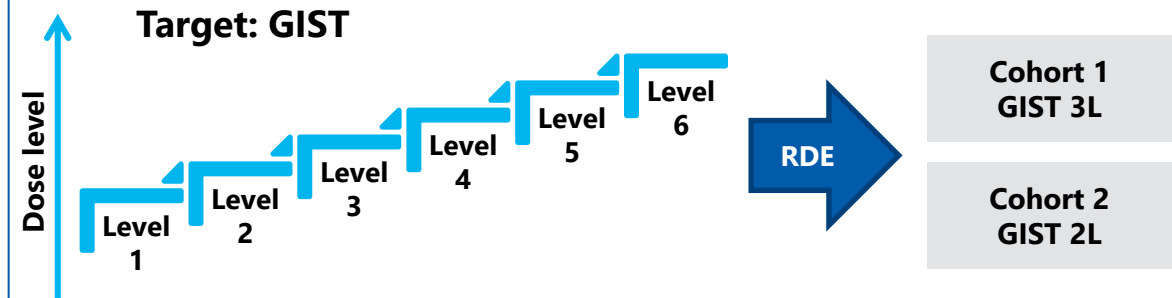
- ◆ Orphan G Protein-Coupled Receptor (GPCR)
- ◆ Highly expressed specifically in GIST
- ◆ Interstitial cells of Cajal, the cell origin of GIST, are the only GPR20+ cells
- ◆ Function in GIST is unknown

GIST

- ◆ Mesenchymal tumor of GI tract, rare disease
- ◆ Stomach: 60%, Small intestine 35%
- ◆ Oncogenic mutation in KIT (~80%) or PDGFRA gene (~5%)
- ◆ Multiple TKIs approved

Ph1 study

Ph1 study design



- ◆ Six dose levels starting from 1.6 mg/kg up to 12.8 mg/kg were evaluated for safety in dose escalation

- ◆ **No clear responses in GIST patients at any dose level in Ph1 dose escalation**
- ◆ **Company decision was made to terminate DS-6157 development without proceeding to dose expansion**
- ◆ **Further investigation is ongoing to explore possible mechanisms of the non-responsiveness, Ph1 data to be presented at scientific conference in FY2022**

Characteristics of DS-5670 (COVID-19 mRNA vaccine): antigen design

DS-5670 targets **Receptor Binding Domain (RBD)** instead of full spike protein of SARS-CoV-2

Full length of spike protein (S-Full)



- ◆ **Length of mRNA**
 - 4.1 kb
- ◆ **Proposed advantages**
 - May contain additional neutralization epitopes and T cell epitopes other than those present in RBD, which makes it possible to induce antigen specific immune responses of various epitopes

epitope: part of an antigen recognized by antibodies, B cell, T cell, etc.

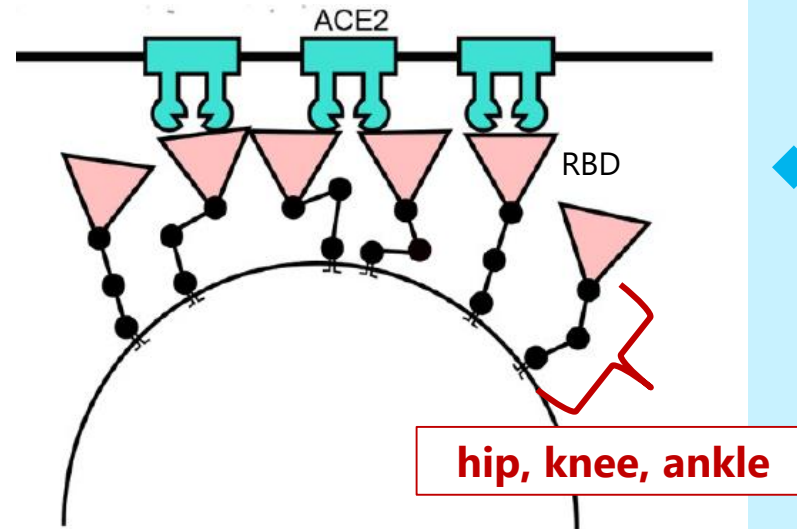
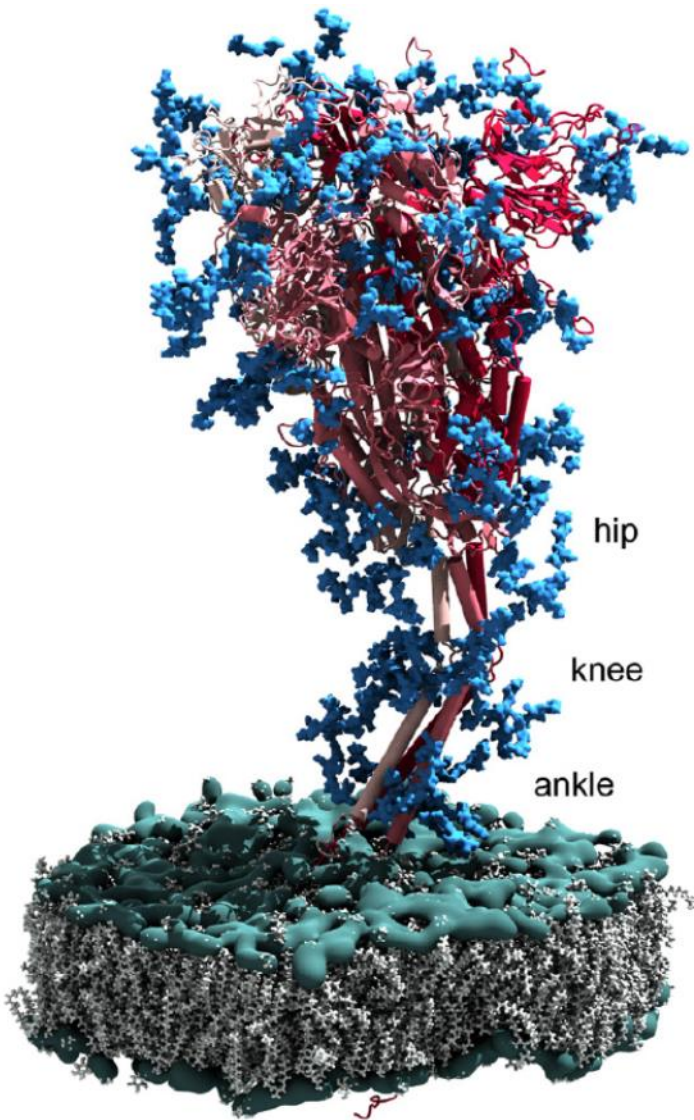
Receptor binding domain (RBD)



- ◆ **Length of mRNA**
 - 1.0 kb
- ◆ **Proposed advantages**
 - Efficient and stable encapsulation of mRNA into LNP because RBD is shorter than S-Full
 - Lower risk of enhanced disease because potentially pathogenic epitopes are less as compared with S-Full

(CELL 12060 <https://doi.org/10.1016/j.cell.2021.05.032>PNAS 117:8218 2020, Vaccine 25:2832 2007)

Superiority of RBD antigen to S-Full antigen



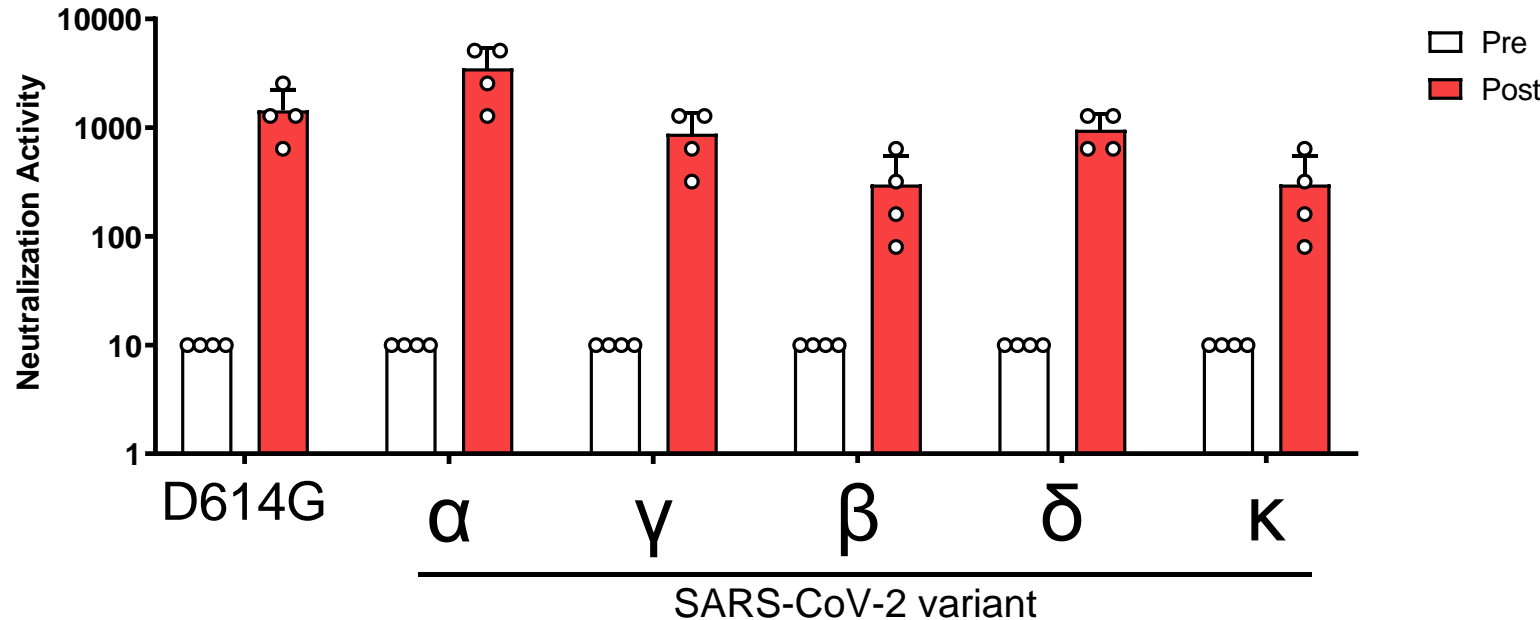
(B. Turoňová et al., Science
10.1126/science.abd5223 (2020).)

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- ◆ **Binding of RBD to ACE2 is cis-regulated by domains other than RBD, so-called 'hip', 'knee', and 'ankle'**
- ◆ **When using the S-Full of variants as vaccine antigen:**
 - Mutations in 'hip', 'knee', and 'ankle' may affect the immunogenicity of RBD (may be evolutionally less immunogenic, enabling viral escape from host immune responses)
- ◆ **When using RBD of variants as vaccine antigen:**
 - Will be more simply designed and predictable

DS-5670: Cross-neutralizing activity against recently emerged variants

- Cynomolgus monkey
- 50 µg/body of DS-5670 by mRNA conversion
- Dosed in brachial deltoid muscle q2w, total 3 times (4 monkeys/group)
- Measured neutralizing activity using plasma collected 2 weeks after the third dose (AMED Kawaoka group)

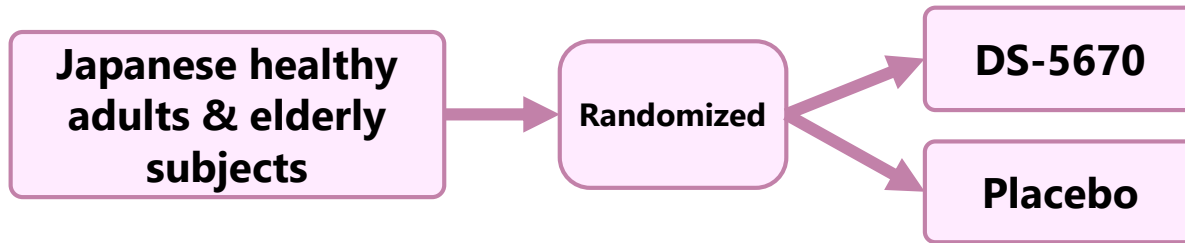


Variant	Mutation in RBD
α	N501Y
γ	K417T/E484K/N501Y
β	K417N/E484K/N501Y
δ	L452R/T478K
κ	L452R/E484Q

Monkey ID	SARS-CoV-2 variant					
	D614G	α	γ	β	δ	κ
#1	640	2560	640	160	1280	160
#2	2560	5120	1280	640	640	640
#3	1280	5120	1280	320	1280	320
#4	1280	1280	320	80	640	80

*This data was acquired in the AMED's drug discovery support program "Development of a Vaccine for COVID-19 Vaccines".

Ph1/2 study design



- ◆ **Objective:** assess the safety and immunogenicity of DS-5670 & determine the recommended dose
- ◆ **Estimated number of enrollment:** 152 subjects
- ◆ **Dosing method:** total 2 intramuscular injections, 4 week intervals
- ◆ **Primary endpoint:** safety, titer of neutralizing antibody
- ◆ **Secondary endpoint:** titer of IgG antibody, PK

Ph1/2 study results

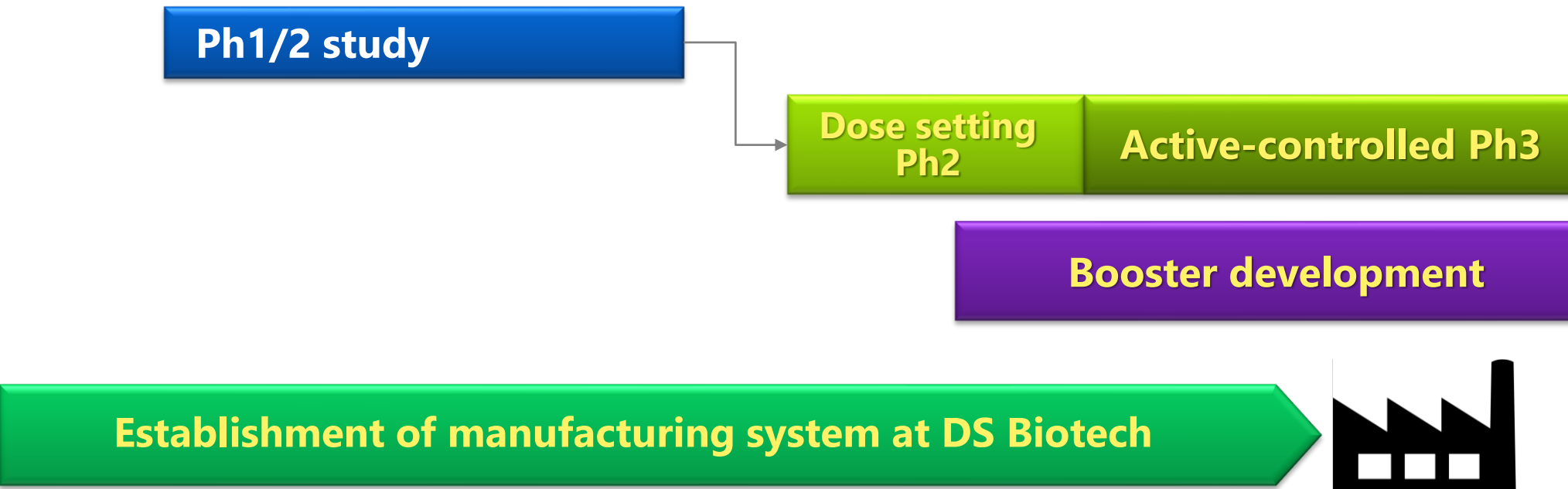
- ◆ **Initiated the study in March 2021 and obtained TLR in October 2021**
 - For the 142 subjects who completed two injections, no critical safety issues were observed within 4 weeks after the second injection
 - Increase of neutralizing antibody titer and IgG antibody titer were confirmed
 - Detailed analysis of the data is currently underway

Ph1/2 study results suggest the potential of DS-5670 as COVID-19 vaccine

DS-5670 : Future development plan

- ◆ **Planning to initiate Ph2 study in November this year to determine the dose**
 - ✓ The objective of the study is to confirm safety and determine the dose for Ph3 study using the clinical trial material which manufacturing process was optimized to ensure stable quality
- ◆ **Planning to initiate active-controlled Ph3 study in FY2021. The details of the study design is under discussion with the Health Authority.**
- ◆ **Commercialization is expected within CY2022**

FY2020		FY2021		FY2022	
2H	1H	2H	1H	2H	



ESMO 2021 Highlights

3ADC Update

Alpha Update

R&D Day

News Flow

Sunao Manabe
President and CEO



Ken Takeshita
Global R&D Head



Date and time

The event will be held once on the following date
➤ Dec 14 (Tue) 17:30-19:00 EST, Dec 15 (Wed) 7:30-9:00 JST

Meeting style

Virtual, teleconference

ESMO 2021 Highlights

3ADC Update

Alpha Update

R&D Day

News Flow

Planned publications

SABCS (Dec 7-10)	
Dato-DXd	<u>TROPION-PanTumor01 TNBC cohort data</u>
ASH (Dec 11-14)	
DS-3201	<u>ATL/L Ph2 data</u>

Regulatory decisions

Efient®	Ischemic stroke <ul style="list-style-type: none"> Japan: FY2021 Q3
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Planned regulatory submissions

Enhertu®	<u>DESTINY-Breast03: HER2 positive BC, 2L, Ph3</u> <ul style="list-style-type: none"> <u>FY2021 Q3</u> <u>DESTINY-Gastric01/02: HER2 positive GC, 2/3L, Ph2</u> <ul style="list-style-type: none"> <u>Europe: FY2021 Q3</u>
DS-3201	Registrational Ph2: ATL/L <ul style="list-style-type: none"> Japan: FY2021 2H

Key data readouts

Enhertu®	DESTINY-Breast04: HER2 low BC, post chemo, Ph3 <ul style="list-style-type: none"> FY2021 Q4
Quizartinib	QuANTUM-First: AML, 1L, Ph3 <ul style="list-style-type: none"> FY2021 Q3

Planned pivotal study initiation

Enhertu®	<u>DESTINY-Lung04: HER2 mutated NSCLC, 1L, Ph3</u> <ul style="list-style-type: none"> <u>FY2021 Q3</u>
Dato-DXd	<u>TROPION-Lung08: NSCLC w/o AGAs, 1L, Ph3</u> <ul style="list-style-type: none"> <u>FY2021 Q4</u>
DS-5670	<u>Ph3: COVID-19 mRNA vaccine</u> <ul style="list-style-type: none"> <u>FY2021 Q4</u>

Underlined: New or updated from FY2021 Q1

AGA: actionable genomic alterations, AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, BC: breast cancer, GC: gastric cancer, NSCLC: non small cell lung cancer

Agenda

① FY2021 Q2 Financial Results

② FY2021 Forecast

③ Business Update

④ R&D Update

⑤ **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]		<u>TLR obtained</u>	<u>Submission anticipated</u>	
		HER2 low, post chemo [P3, DESTINY-Breast04]				TLR anticipated
		HER2+, 1L [P3, DESTINY-Breast09]	Study started			
	GC	HER2+, 2L [P2, DESTINY-Gastric02]	TLR obtained		<u>Submission anticipated (Europe)</u>	
		HER2+, 2L [P3, DESTINY-Gastric04]	Study started			
		<u>HER2+, 3L [P2, DESTINY-Gastric06]</u>		<u>Study started</u>		
	NSCLC	HER2+/mutated [P2, DESTINY-Lung01]	TLR obtained			
		HER2+, combination [P1b, DESTINY-Lung03]			<u>Study start planned</u>	
		<u>HER2 mutated, 1L [P3, DESTINY-Lung04]</u>			<u>Study start planned</u>	
Dato-DXd	TNBC, durvalumab combo [P1b/2, BEGONIA]	Study started				
	<u>NSCLC w/o AGAs, 1L, pembrolizumab combo [P3, TROPION-Lung08]</u>				<u>Study start planned</u>	
HER3-DXd	EGFR mutated NSCLC, osimertinib combo [P1]	Study started				

Red underlined: new or updated from FY2021 Q1

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
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]		<u>Approved</u>		
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			
DS-5670	COVID-19 mRNA vaccine [P2, JP]			<u>Study start planned</u>	
	COVID-19 mRNA vaccine [P3, TBD]				<u>Study start planned</u>

Red underlined: new or updated from FY2021 Q1

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 Oct 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	(China) HER2+ GC 3L DESTINY-Gastric06	(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)HER2+/mutated NSCLC 2L~ DESTINY-Lung01	(JP/US/EU/Asia) HER2+ BC post neoadjuvant DESTINY-Breast05	
(JP/US/EU/Asia) NSCLC	(US/EU) BC, bladder (nivolumab combo)	(JP/US/EU/Asia) HER2 mutated NSCLC 2L~ DESTINY-Lung02	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06	
(JP/US)EGFR mutated NSCLC (osimertinib combo)	(US/EU) BC, NSCLC (pembrolizumab combo)	(US/EU/Asia) NSCLC (durvalumab combo) 2L~ HUDSON	(US)HER2+ BC 1L DESTINY-Breast09	
(JP/US) BC		(JP/US/EU) HER2+ CRC 3L DESTINY-CRC01	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	
		(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(US/EU/Asia) NSCLC 1L (w/ exon 19 or exon 20 mutation) DESTINY-Lung04	
		(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 Oct 2021

Phase 1		Phase 2		Phase 3		Submitted	
DS-7300 (JP/US) B7-H3-directed ADC ESCC, CRPC, SCLC, etc.	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) α2δ Ligands Central neuropathic pain	
DS-6000 (US) CDH6-directed ADC Renal cell carcinoma, ovarian cancer	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		Efient (JP) ADP receptor inhibitor Ischemic stroke	
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	PLX2853 (US) BET inhibitor Solid tumor	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 Gynecologic neoplasms, ovarian 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	PLX2853 (US) BET inhibitor Prostate cancer						
DS-5670 (JP) mRNA vaccine COVID-19	DS-1594 (US) Menin-MLL binding inhibitor AML, ALL						
	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, 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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