Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2021 Q2
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Sunao Manabe

President and CEO

October 29, 2021

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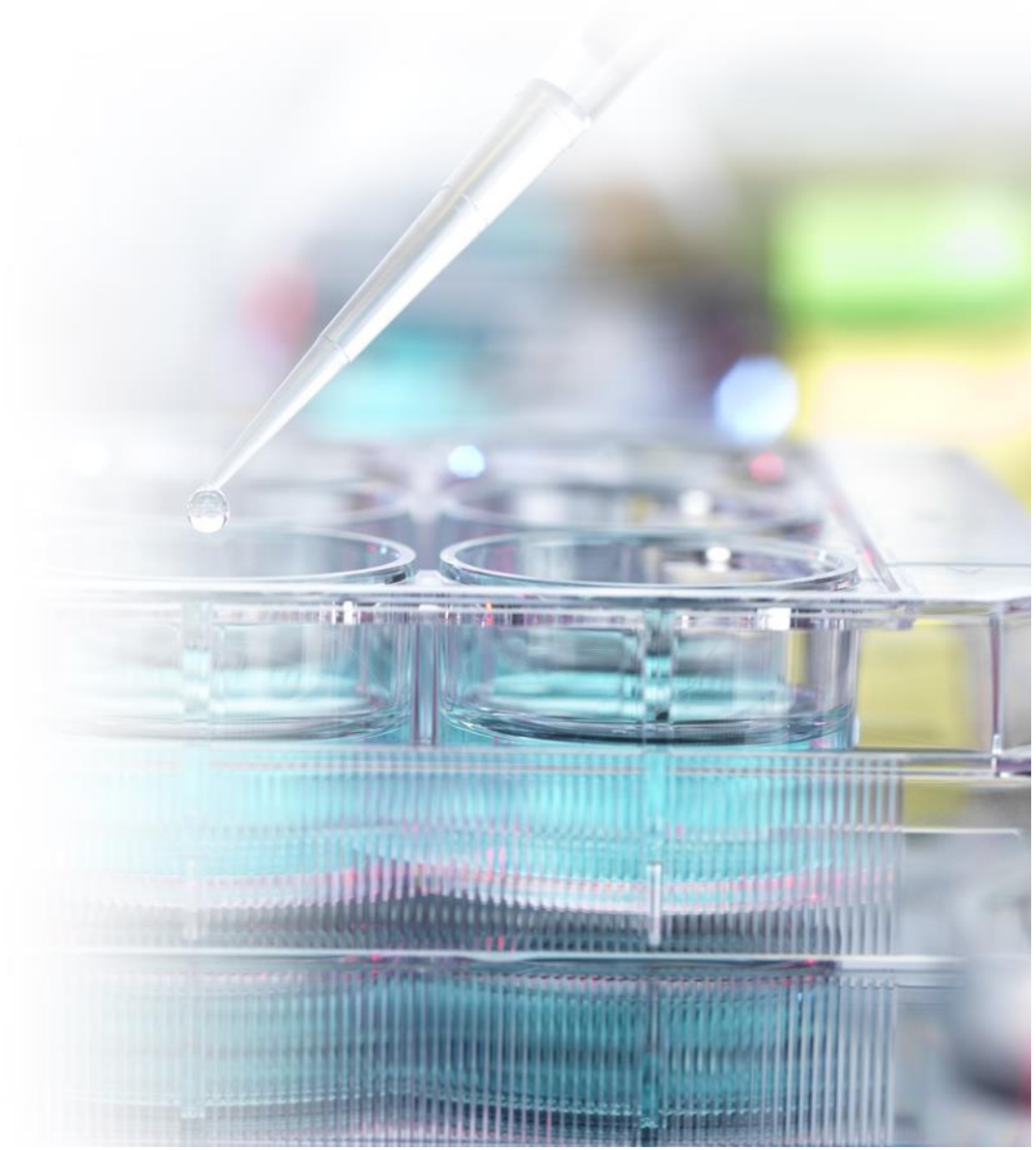
Agenda

1. **FY2021 Q2 Financial Results**
2. FY2021 Forecast
3. Business Update
4. R&D Update
5. Appendix



Overview of FY2021 Q2 Results

(Bn JPY)

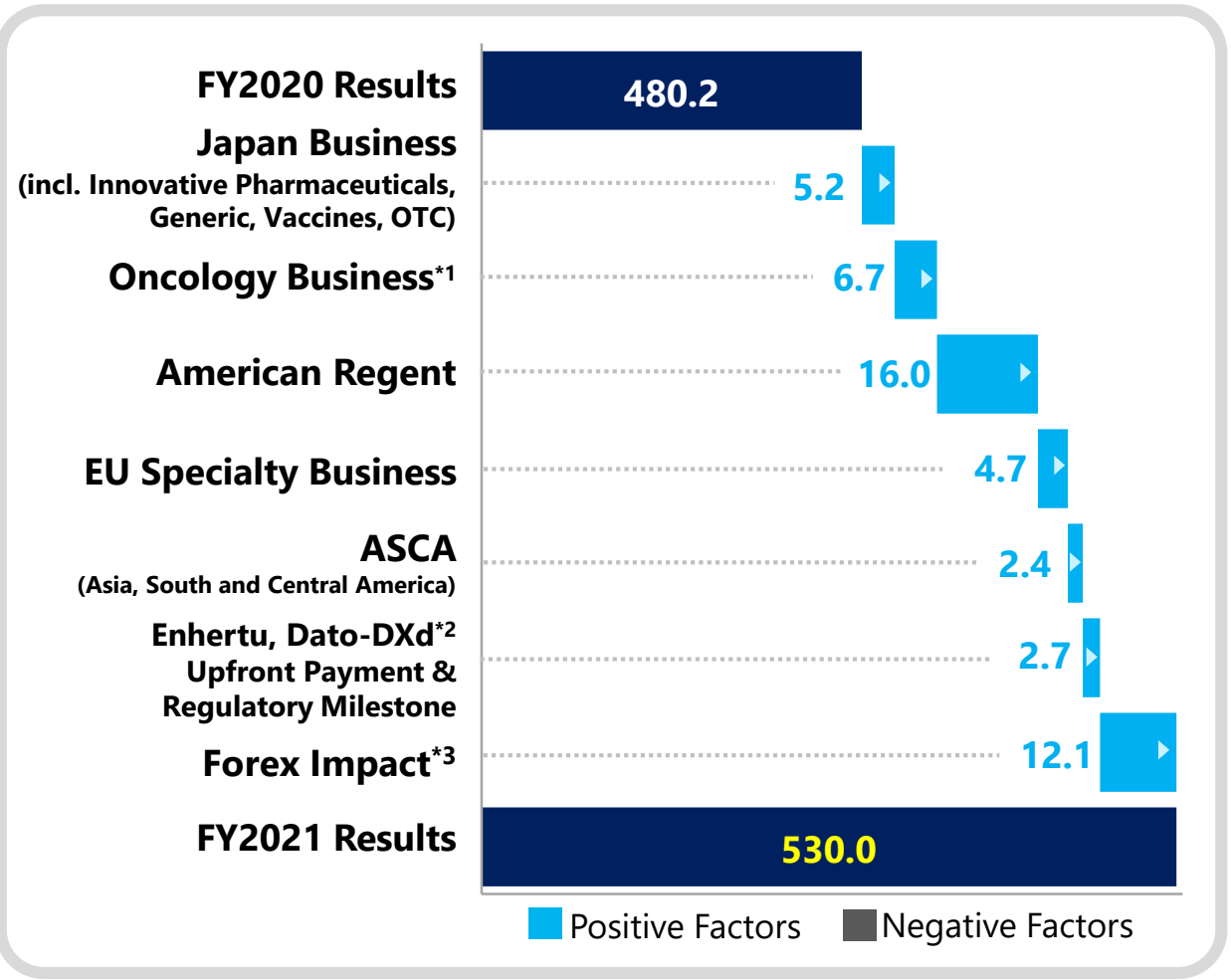
	FY2020 Q2 YTD Results	FY2021 Q2 YTD Results	YoY	
Revenue	**480.2**	**530.0**	+10.4%	**49.8**
Cost of sales*	168.6	172.6		4.0
SG&A expenses*	148.6	165.7		17.1
R&D expenses*	104.6	109.0		4.4
Core operating profit*	**58.4**	**82.7**	+41.7%	**24.3**
Temporary income*	0.1	2.1		2.0
Temporary expenses*	0.0	0.1		0.0
Operating profit	**58.5**	**84.7**	+44.9%	**26.3**
Profit before tax	**67.0**	**86.0**		**19.0**
Profit attributable to owners of the Company	**51.7**	**62.5**	+20.9%	**10.8**

Currency Rate	USD/JPY	106.92	109.80	+2.88
	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

Revenue

Increased by 49.8 Bn JPY (Increased by 37.7 Bn JPY excl. forex impact)



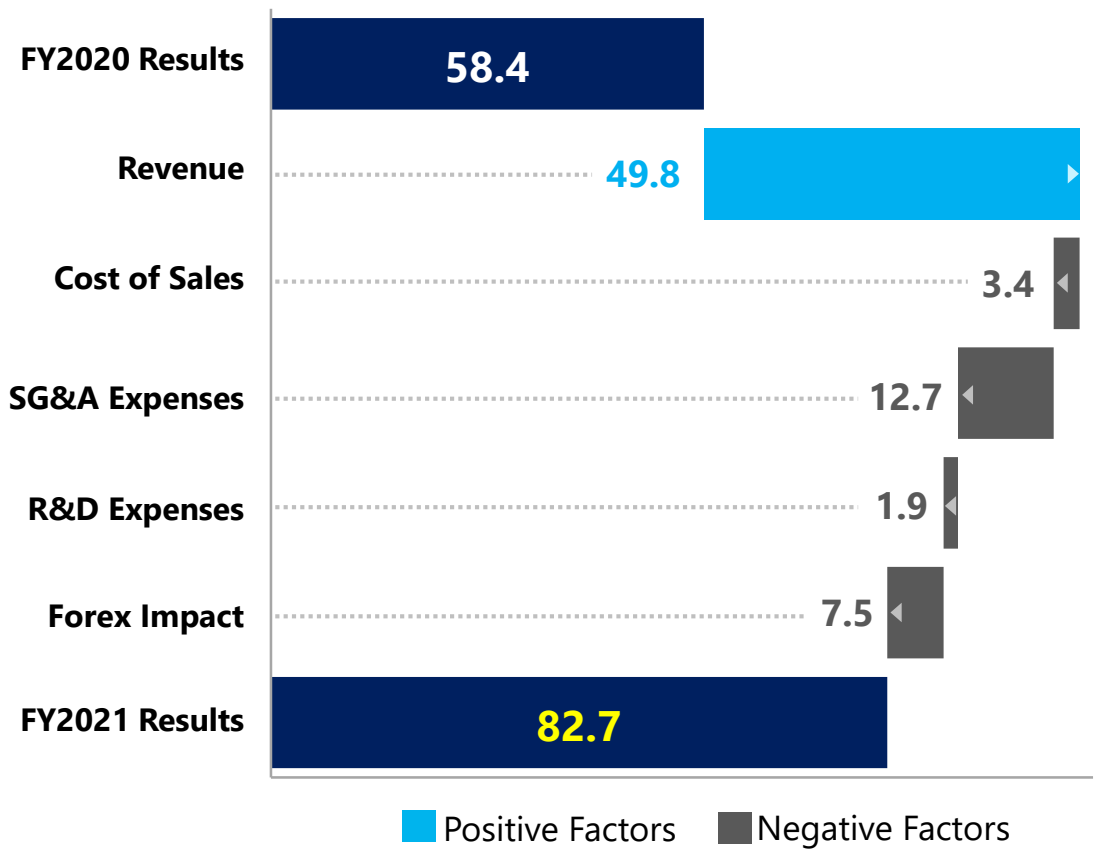
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+6.6	Memary	-11.0
Tarlige	+5.0		
Enhertu	+3.4		
Daiichi Sankyo Espha	+5.6	Vaccines business	-5.3
Ezetimibe AG, Memantine AG etc.		Influenza Vaccine	
Daiichi Sankyo Healthcare	+0.8		
Roxionin			
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

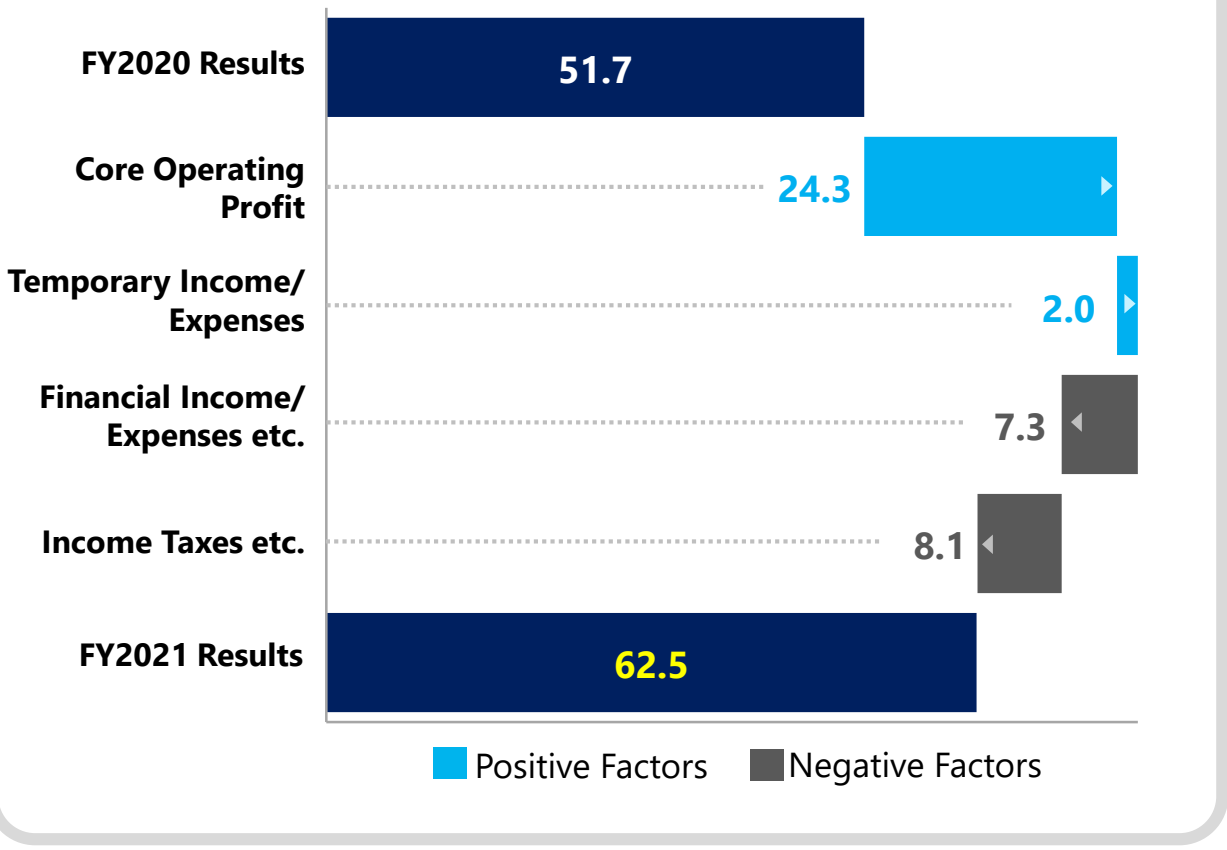
R&D Expenses ..... +1.9 (Profit decreased)
Increase in 3ADCs* R&D investments

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 Rate	USD/JPY	106.92	109.80	+2.88
	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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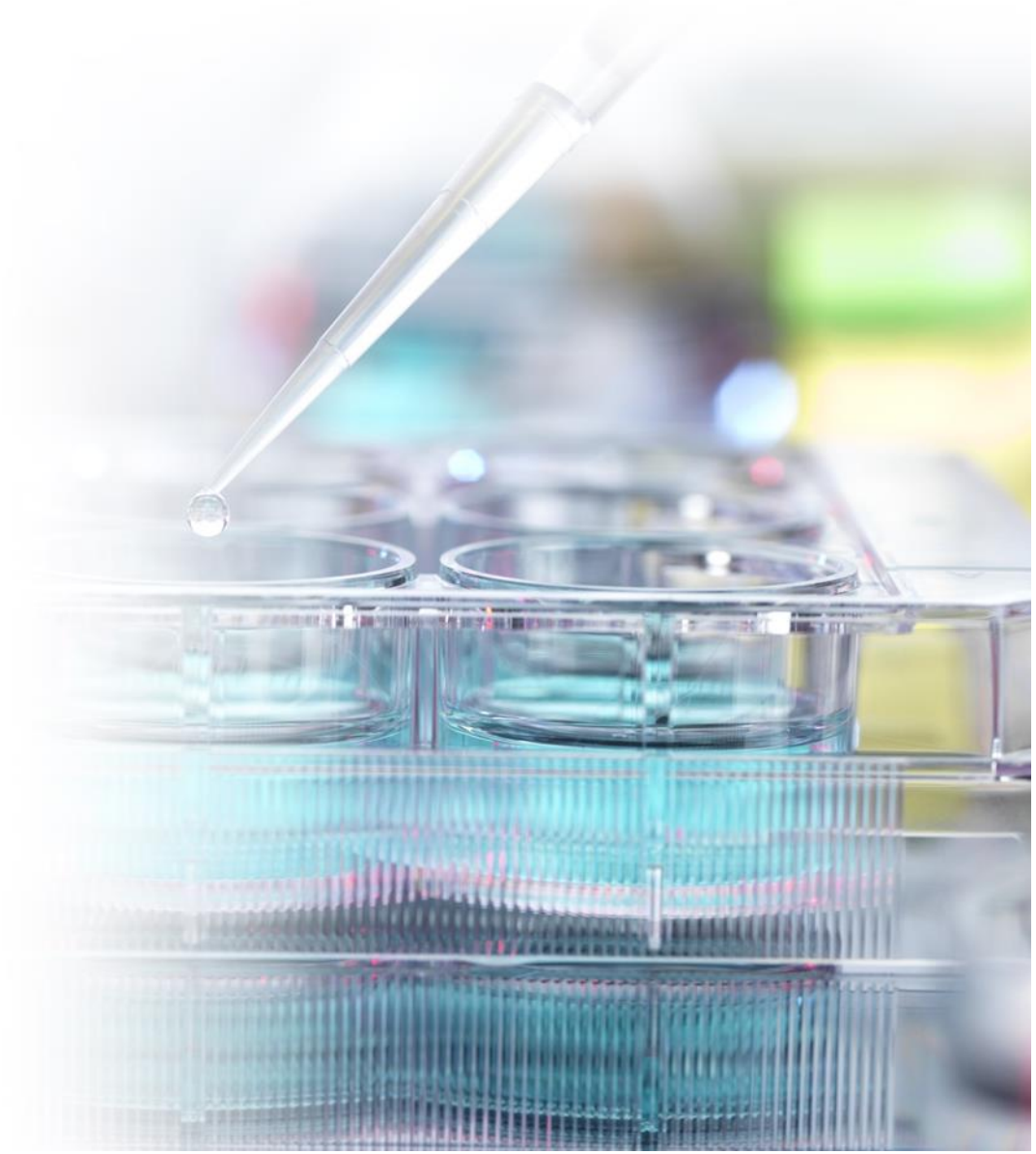

Revision to the forecast

(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**	**+20.0**
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 Rate	USD/JPY	105.00	107.40	+2.40
	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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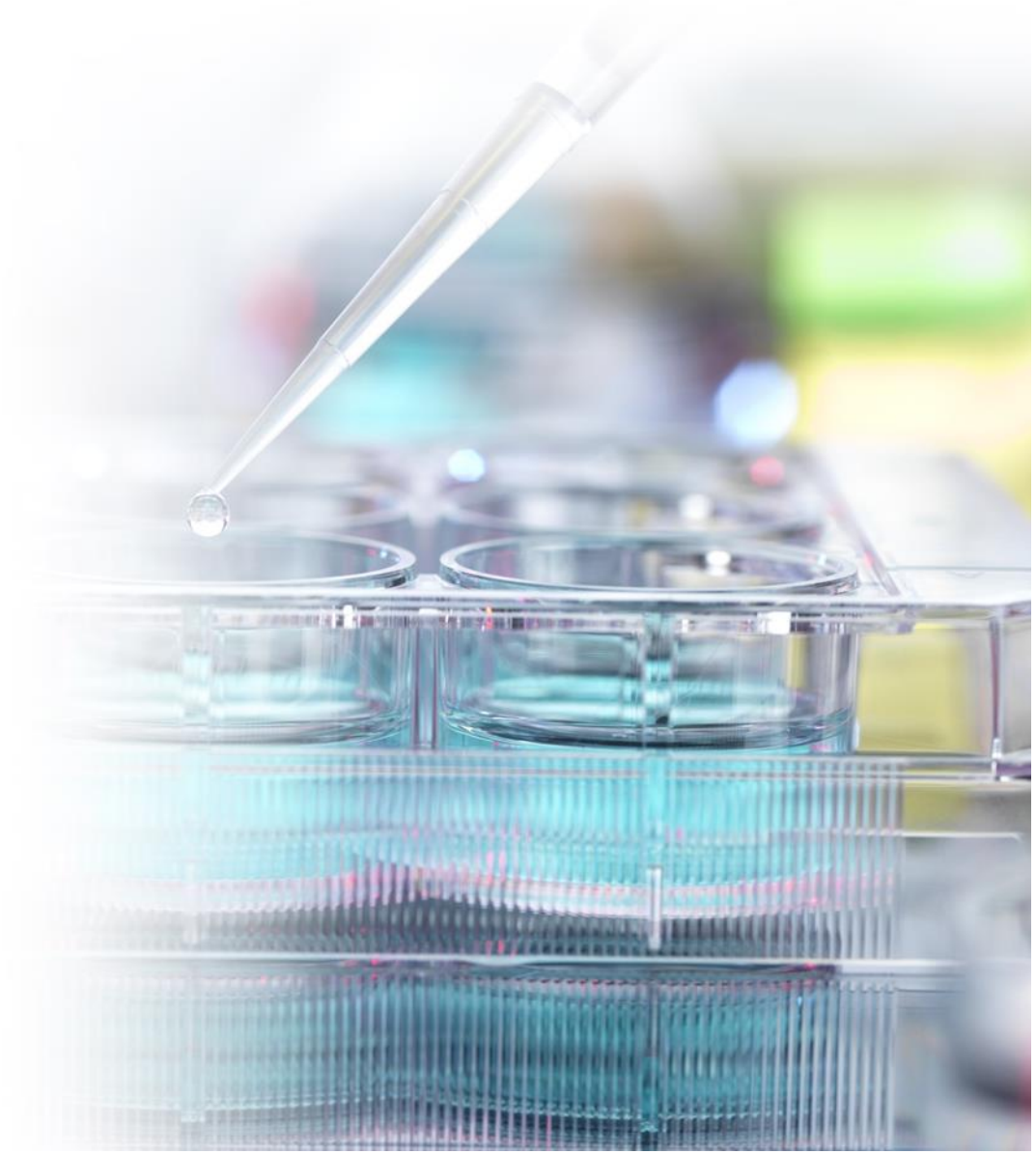


ENHERTU®: Performance in Each Region

- **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)

ENHERTU® trastuzumab deruxtecan

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)

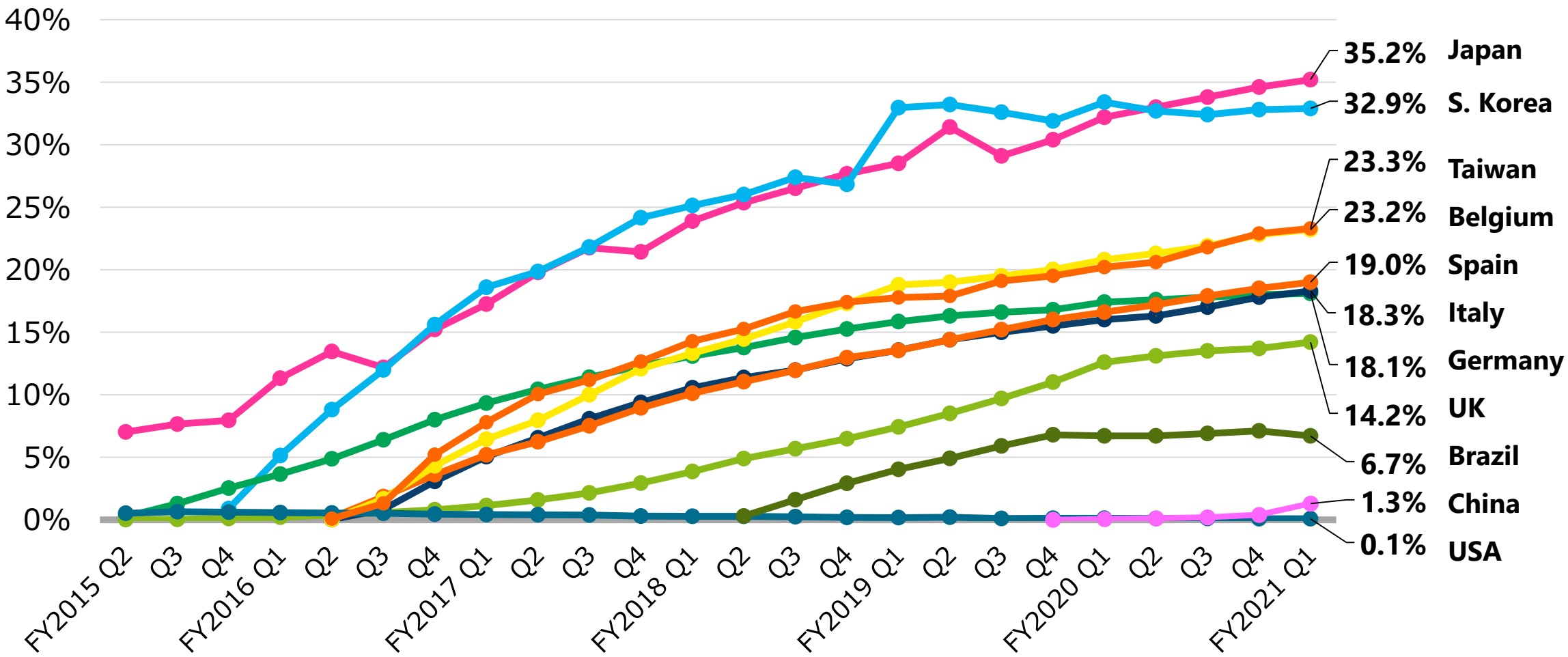
- **Product sales: FY2021 Q2 YTD results 4.4 Bn JPY**
  FY2021 forecast 13.4 Bn JPY
- **Steady growth in the market**
  - Treated patients continued to increase steadily in Q2
  - New patient shares increasing (No.1 in HER2+ BC 3L / GC 3L)
  - Outlets purchasing as planned

LIXIANA®: Growth in Each Country/Region

Volume

Daiichi-Sankyo

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)

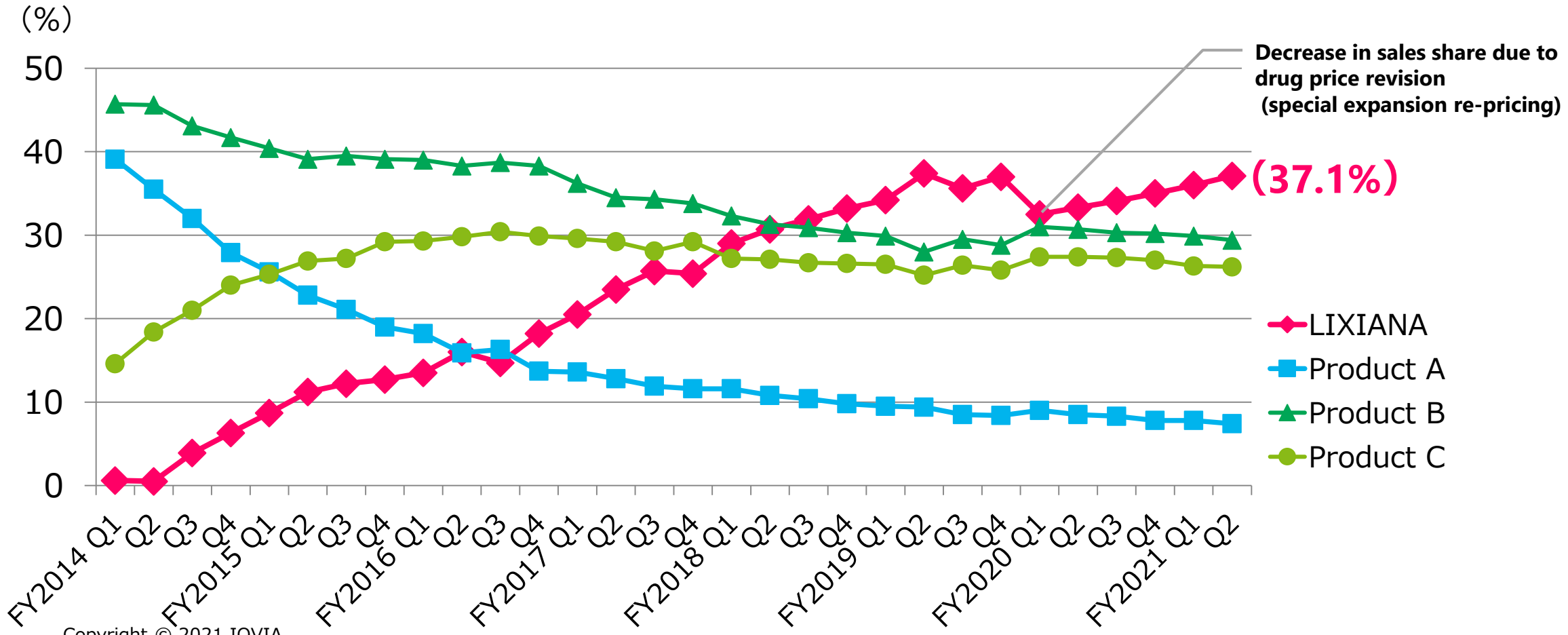


LIXIANA®: Growth in Japan

Sales

Daiichi-Sankyo

- 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



Japan: Commercialization Collaboration of Migraine Treatment Drug

Daiichi-Sankyo

- **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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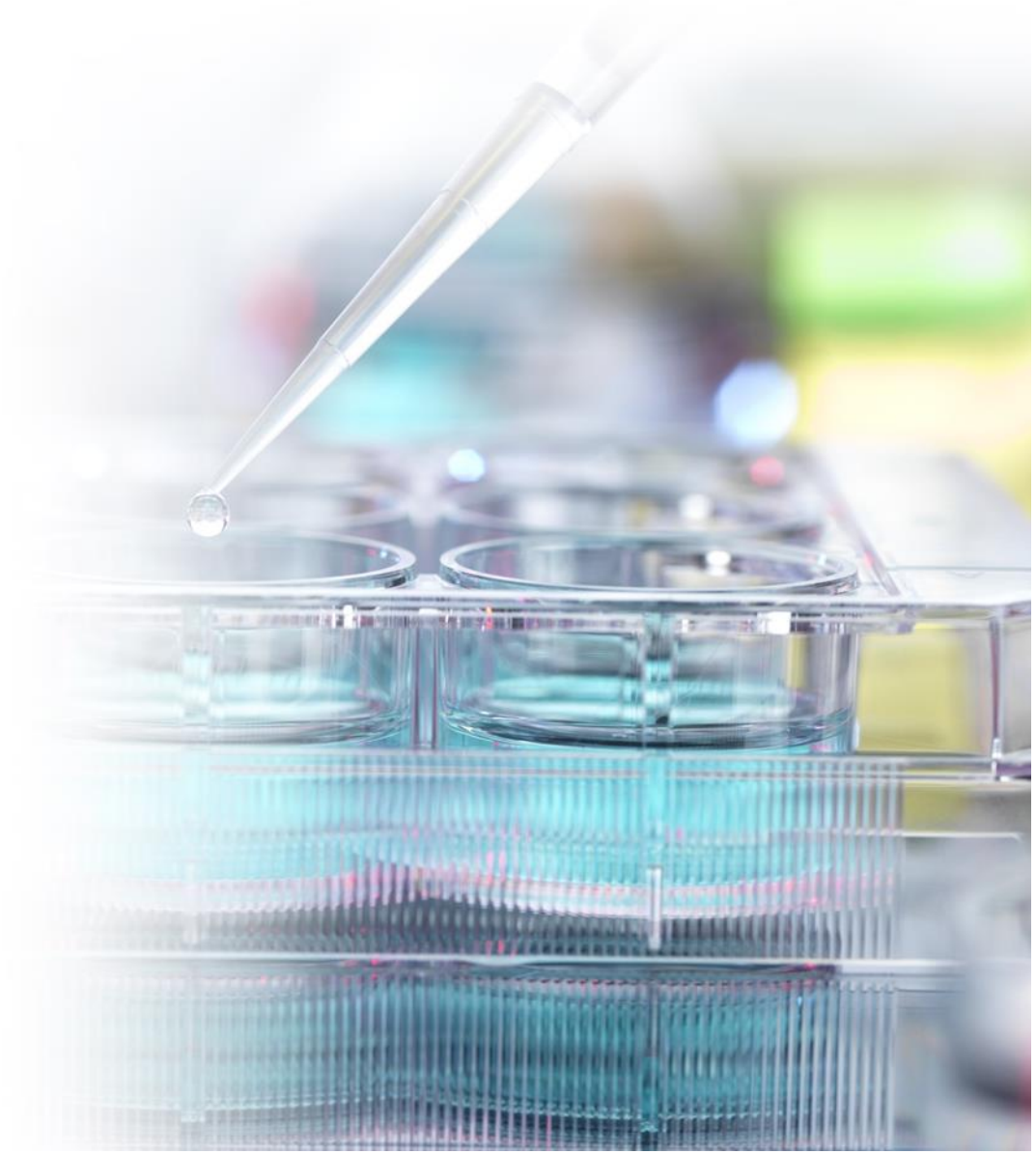


ESMO 2021 Highlights

3ADC Update

Alpha Update

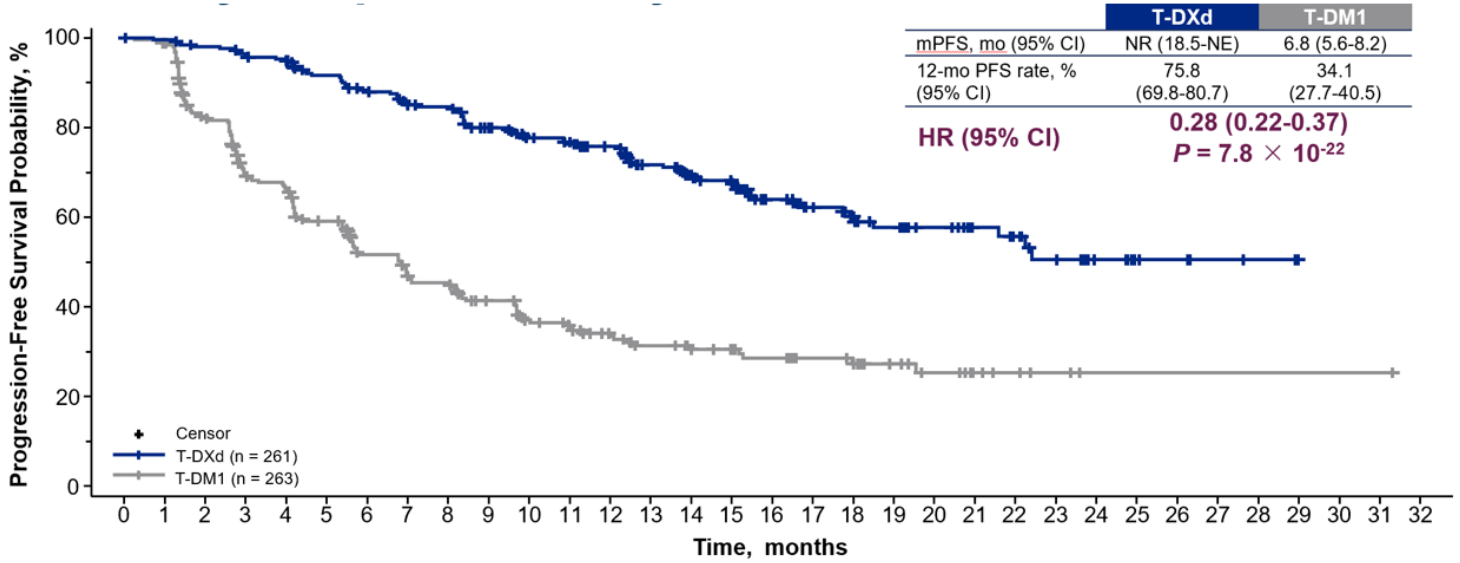
R&D Day

News Flow

ESMO 2021 Highlights: Enhertu®

- **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



	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)	
	$P = 7.8 \times 10^{-22}$	

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)

[a]Patients 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

ESMO 2021 Highlights: Enhertu®

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

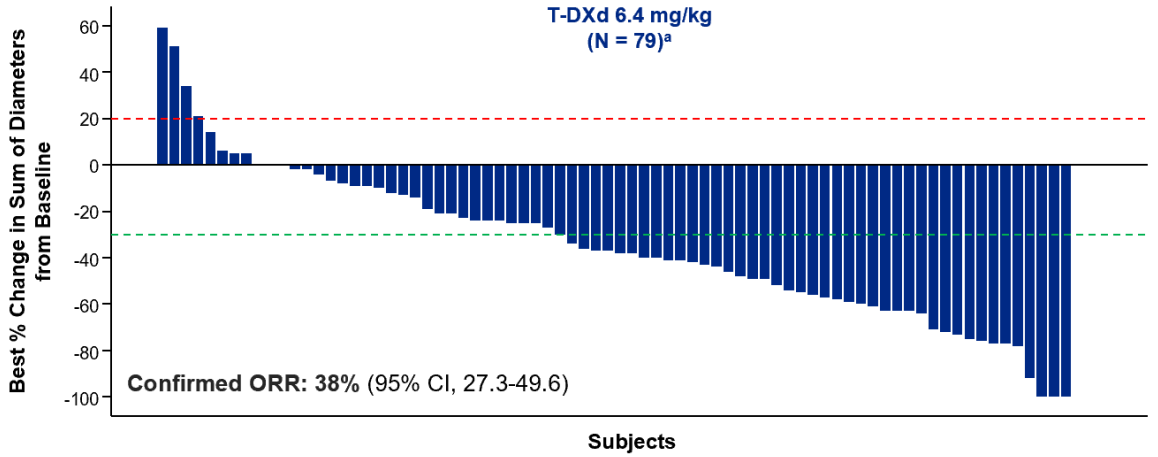
DESTINY-Lung01
HER2 mutated NSCLC、2L、global Ph2

	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)

[a]Primary 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



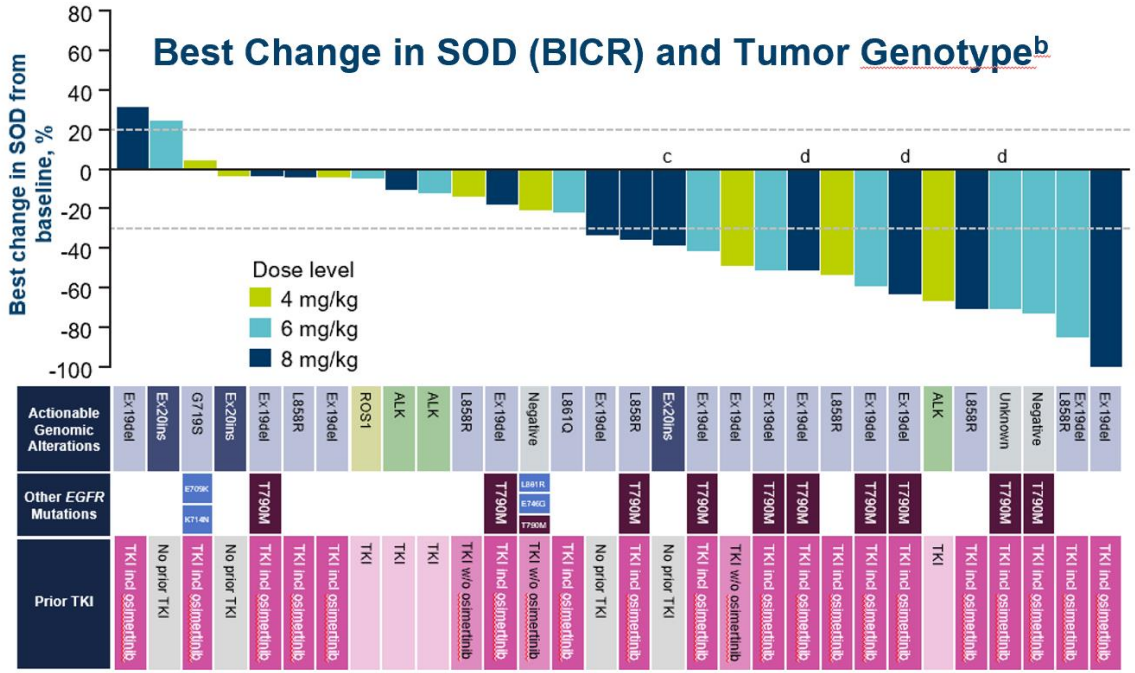
[a]3 patients were missing baseline or post-baseline target lesion assessment.
Red line at 20% indicates progressive disease; green line at -30% indicates partial response.
Analysis conducted in the full analysis set.

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

GC: gastric cancer, NSCLC: non-small cell lung cancer

ESMO 2021 Highlights: Dato-DXd, DS-7300

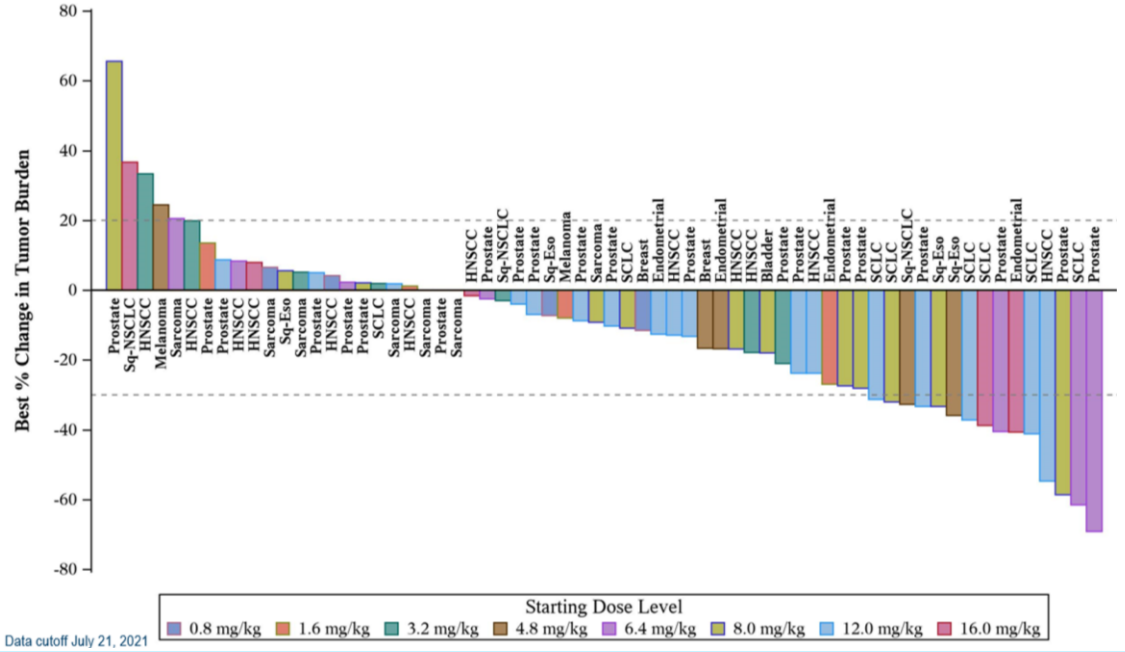
Dato-DXd TROPION-PanTumor01
Subgroup analysis of NSCLC with AGAs



Data cutoff: April 6, 2021.
[b] 4 patients were not included in the waterfall plot: 2 who did not have a target lesion per BICR and 2 who did not have on-study treatment images. [c] Patient NE. [d] Patients with unconfirmed PR.

Demonstrated ORR 35% in NSCLC patients with AGAs, which deepened confidence in the development for this patient population.

DS-7300 solid tumor Ph1/2
Ph1 dose escalation interim analysis



- DS-7300 showed promising early clinical activity in heavily pre-treated patients with several types of advanced solid tumors as well as tolerable safety with no DLTs observed.
- This provides preliminary evidence that targeting B7-H3 with DS-7300 may become a new treatment strategy across several types of cancer where current therapeutic options are limited.

AGA: actionable genomic alterations, DLT: dose limiting toxicities, NSCLC: non-small cell lung cancer, ORR: objective response rate

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

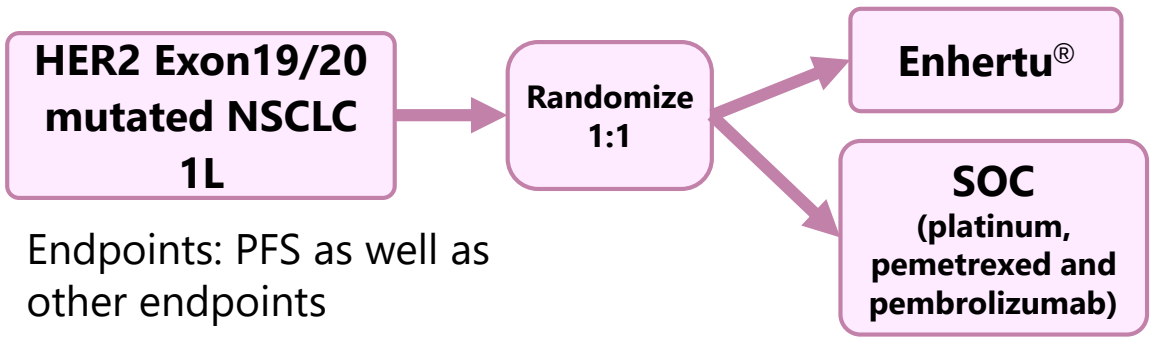
Enhertu® development in China

- 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



Endpoints: PFS as well as other endpoints

BC: breast cancer, BTD: breakthrough therapy designation, GC: gastric cancer, JP: Japan, KR: Korea, NSCLC: non small cell lung cancer, PFS: progression free survival, SOC: standard of care

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		

NSCLC: non small cell lung cancer, SOC: standard of care

ESMO 2021 Highlights

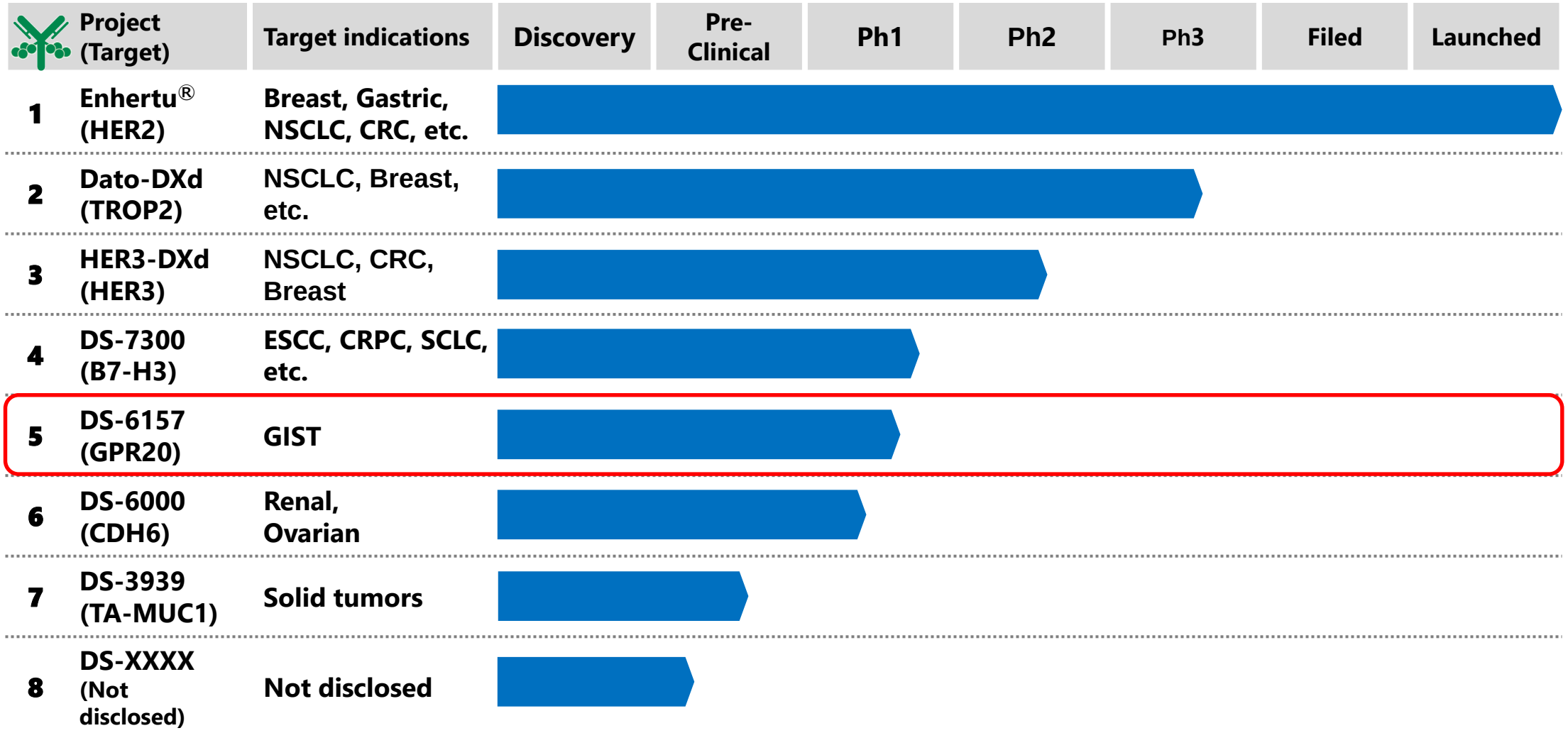
3ADC Update

Alpha Update

R&D Day

News Flow

Daiichi Sankyo DXd-ADC Franchise



CRC: colorectal cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, GIST: gastrointestinal stromal tumor, NSCLC: non small cell lung cancer,. SCLC: small cell lung cancer

DS-6157 : GPR20 Directed ADC

Target antigen: GPR20

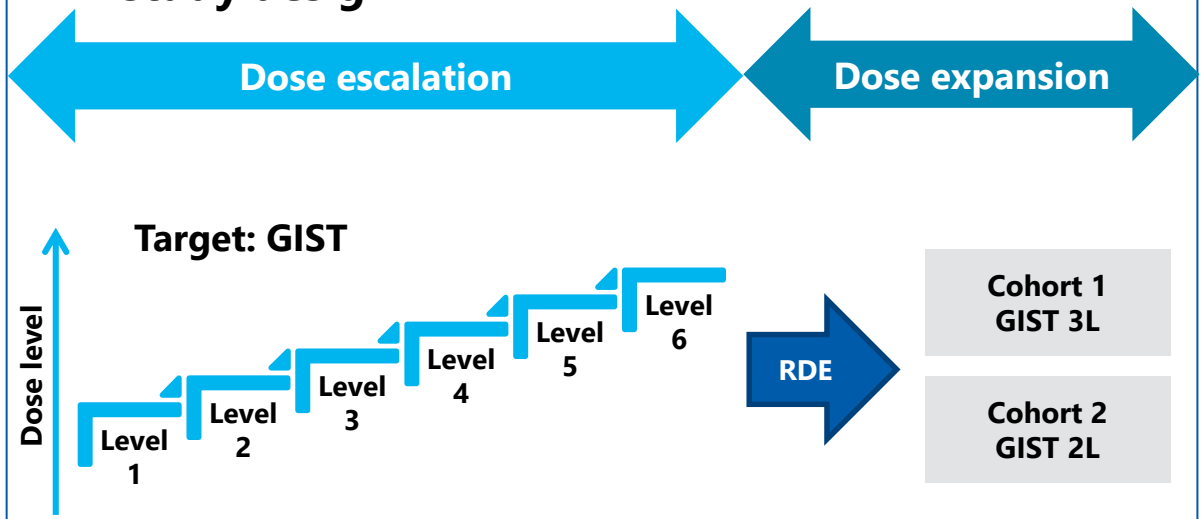
- Orphan G Protein-Coupled Receptor (GPCR)
- Highly expressed specifically in GIST
- Interstitial cells of Cajal, the cell origin of GIST, are the only GPR20+ cells
- Function in GIST is unknown

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**

GIST: gastrointestinal stromal tumor, RDE: recommended dose for expansion, TKI: tyrosine kinase inhibitor

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

Daiichi-Sankyo

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

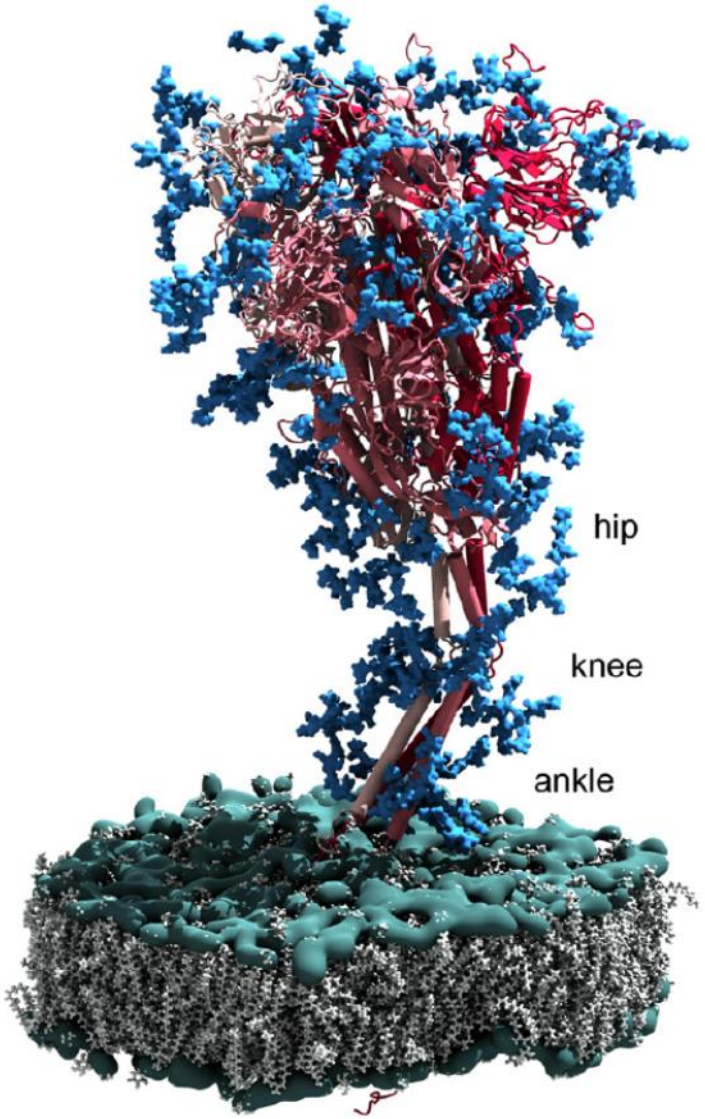
epitope: part of an antigen recognized by antibodies, B cell, T cell, etc.

Receptor binding domain (RBD)

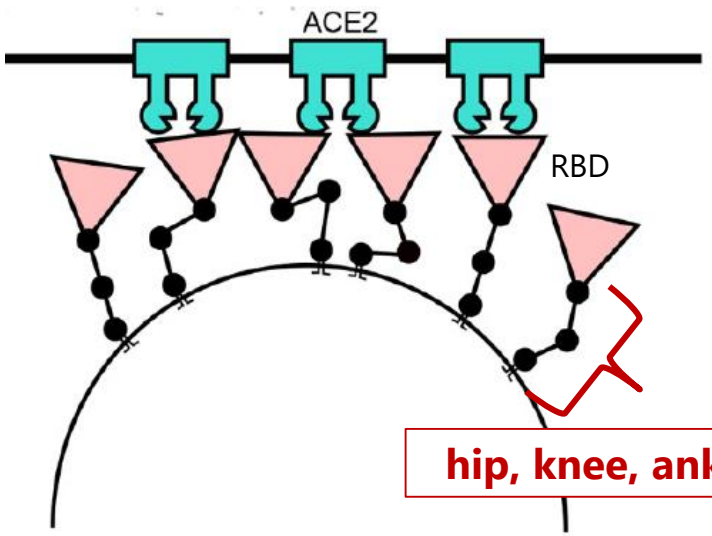
- **Length of mRNA**
  - 1.0 kb
- **Proposed advantages**
  - Efficient and stable encapsulation of mRNA into LNP because RBD is shorter than S-Full
  - Lower risk of enhanced disease because potentially pathogenic epitopes are less as compared with S-Full

(CELL 12060 https://doi.org/10.1016/j.cell.2021.05.032PNAS 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).)

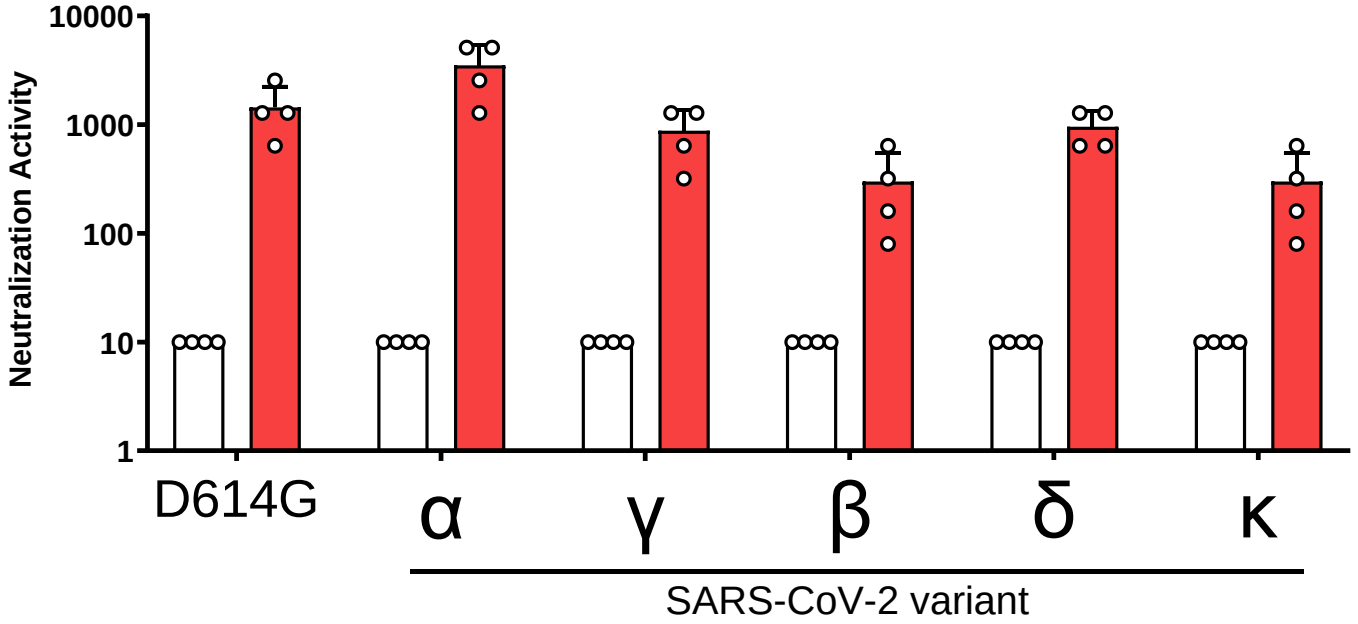


(B. Turoňová et al., Science 10.1126/science.abd5223 (2020).)

- **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)



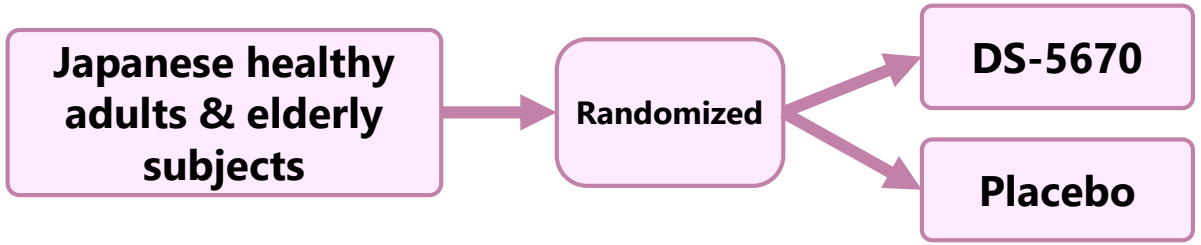
Variant	Mutation in RBD
α	N501Y
γ	K417T/E484K/N501Y
β	K417N/E484K/N501Y
δ	L452R/T478K
κ	L452R/E484Q

	SARS-CoV-2 variant					
Monkey ID	**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".

DS-5670 : Ph1/2 study

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

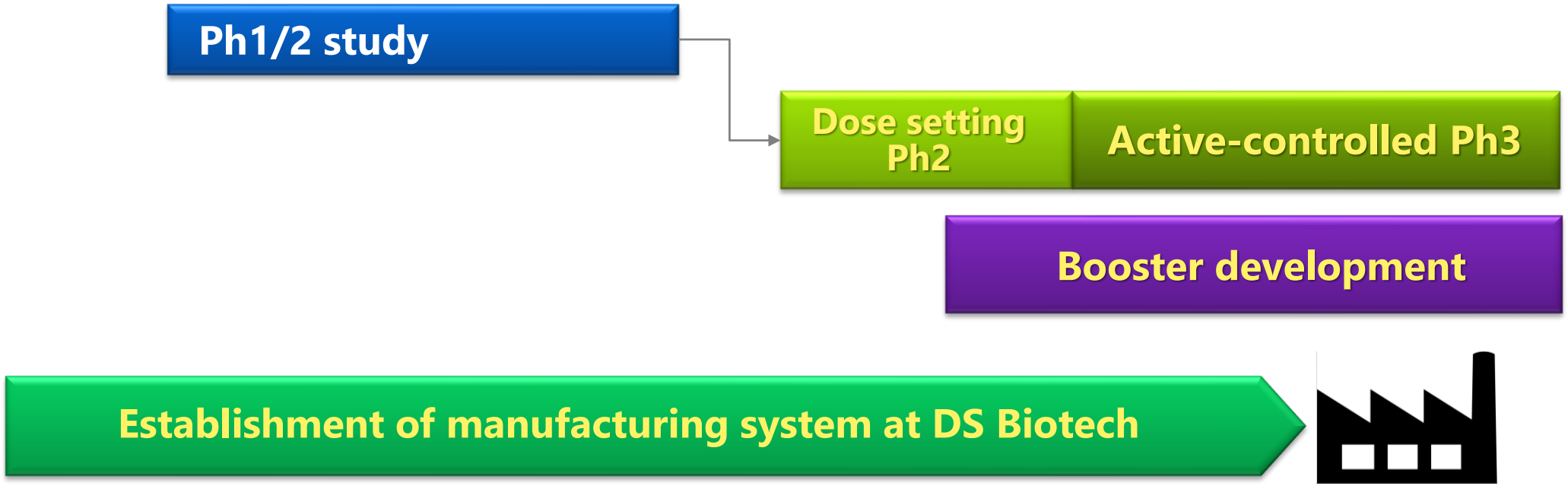
Ph1/2 study results suggest the potential of DS-5670 as COVID-19 vaccine

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

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

R&D Day 2021

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

FY2021 News Flow

As of Oct 2021

Planned publications

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

Regulatory decisions

Efient®	Ischemic stroke • Japan: FY2021 Q3

Planned regulatory submissions

Enhertu®	DESTINY-Breast03: HER2 positive BC, 2L, Ph3 • FY2021 Q3 DESTINY-Gastric01/02: HER2 positive GC, 2/3L, Ph2 • Europe: FY2021 Q3
DS-3201	Registrational Ph2: ATL/L • Japan: FY2021 2H

Key data readouts

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

Planned pivotal study initiation

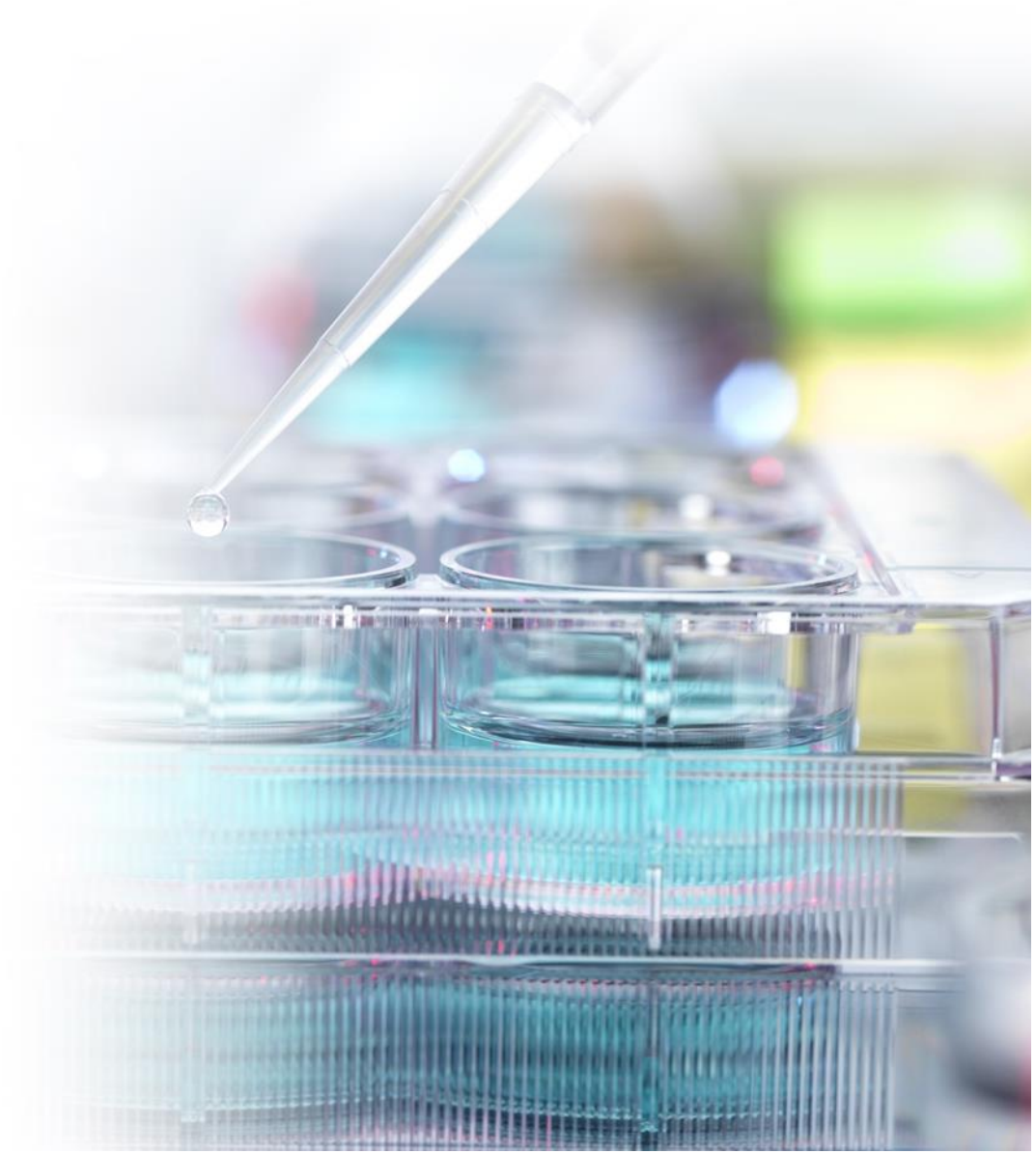
Enhertu®	DESTINY-Lung04: HER2 mutated NSCLC, 1L, Ph3 • FY2021 Q3
Dato-DXd	TROPION-Lung08: NSCLC w/o AGAs, 1L, Ph3 • FY2021 Q4
DS-5670	Ph3: COVID-19 mRNA vaccine • FY2021 Q4

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)

As of Oct 2021

Project		Target Indications [phase, study name]	FY2021 Q1	Q2	Q3	Q4
ENHERTU®	BC	HER2+, 2L [P3, DESTINY-Breast03]		TLR obtained	Submission anticipated	
		HER2 low, post chemo [P3, DESTINY-Breast04]				TLR anticipated
		HER2+, 1L [P3, DESTINY-Breast09]	Study started			
	GC	HER2+, 2L [P2, DESTINY-Gastric02]	TLR obtained		Submission anticipated (Europe)	
		HER2+, 2L [P3, DESTINY-Gastric04]	Study started			
		HER2+, 3L [P2, DESTINY-Gastric06]		Study started		
	NSCLC	HER2+/mutated [P2, DESTINY-Lung01]	TLR obtained			
		HER2+, combination [P1b, DESTINY-Lung03]			Study start planned	
		HER2 mutated, 1L [P3, DESTINY-Lung04]			Study start planned	
Dato-DXd		TNBC, durvalumab combo [P1b/2, BEGONIA]	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 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)

As of Oct 2021

Project	Target Indications [phase, study name, region]	FY2021 Q1	Q2	Q3	Q4
Quizartinib	AML, 1L [P3, JP/US/EU/Asia]			TLR anticipated	
Pexidartinib	Tenosynovial giant cell tumor [P2, JP]	Study started			
Teserpaturev/G47Δ	Malignant glioma [IIS, JP]	Approved			
DS-3201	ATL/lymphoma [P2 registration, JP]		TLR obtained	Submission anticipated (Japan)	
	PTCL [P2 registration, JP/US/EU/Asia]	Study started			
DS-1594	AML, ALL [P1/2, US]	Study started			
Lixiana®	AF in the very elderly [P3, ELDERCARE-AF, JP]		**Approved**		
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]			**Study start planned**	
	COVID-19 mRNA vaccine [P3, TBD]				**Study start planned**

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 naive 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) $\alpha_2\delta$ 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)

Contact address regarding this material

Daiichi Sankyo Co., Ltd.
Corporate Communications Department

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