Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2021
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Sunao Manabe

President and CEO

April 27, 2022

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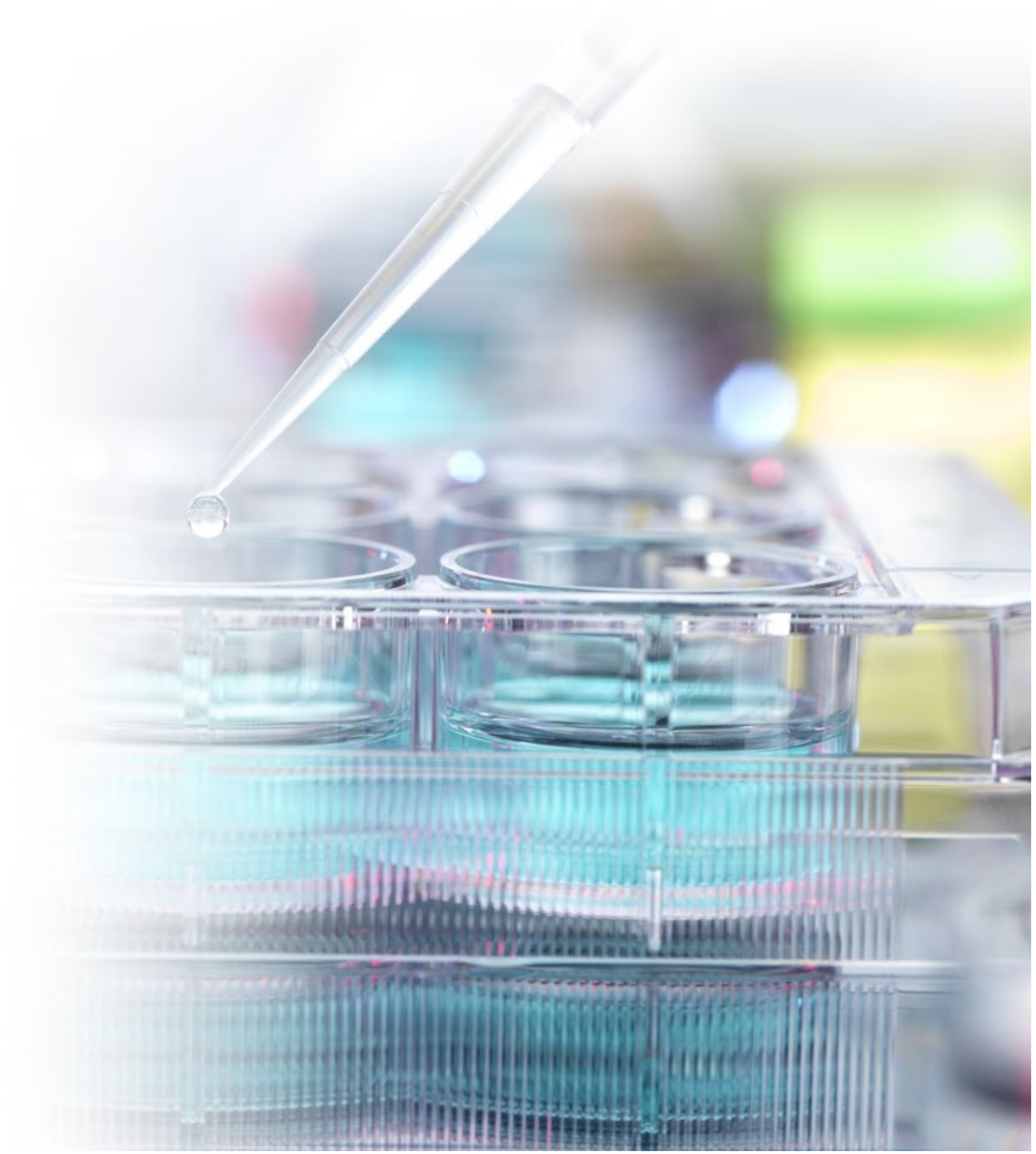
1. **FY2021 Financial Results**
2. FY2022 Forecast
3. Business Update
4. R&D Update
5. 5-Year Business Plan Update
6. Appendix



Overview of FY2021 Results

(Bn JPY)

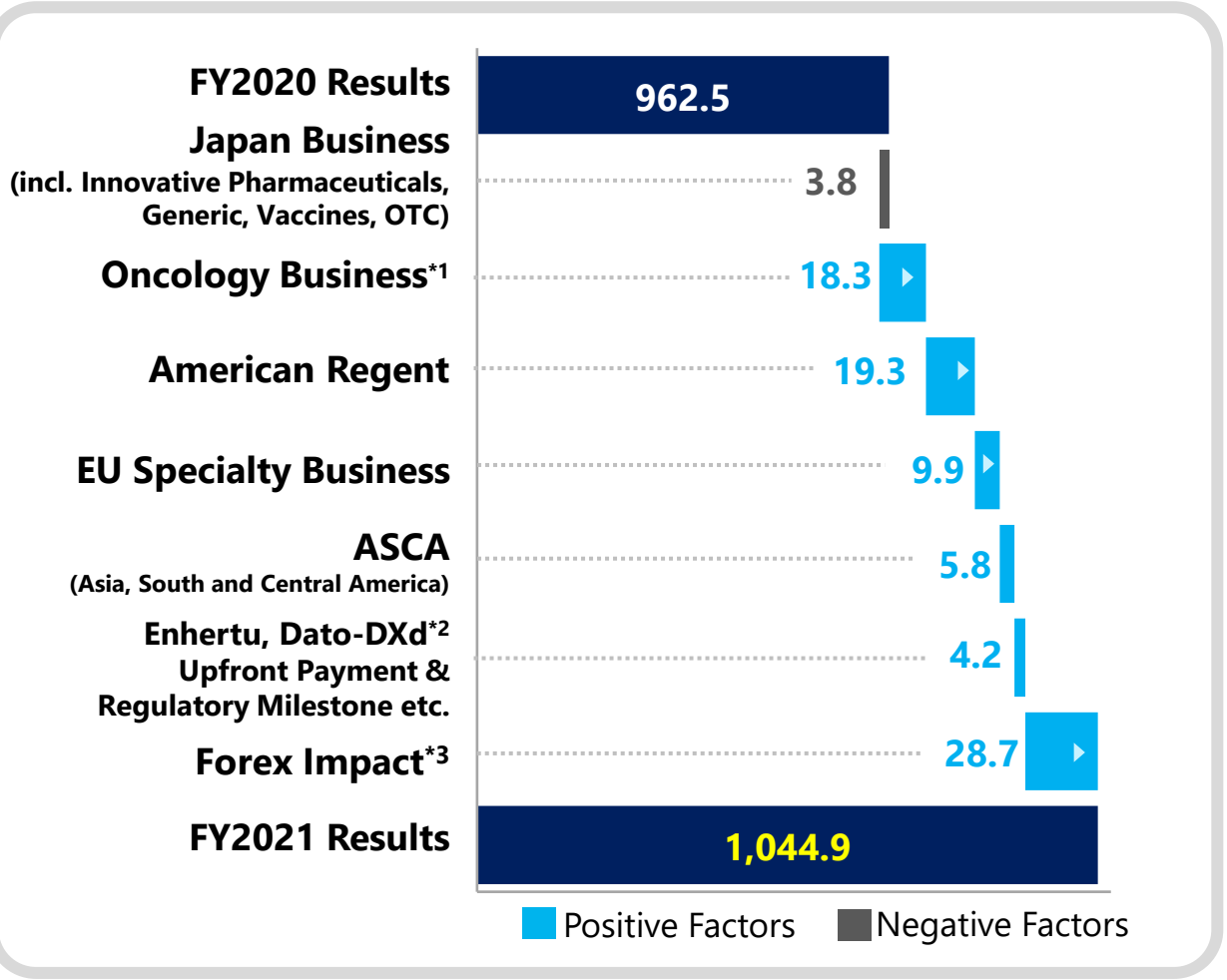
	FY2020 Results	FY2021 Results	YoY	
Revenue	**962.5**	**1,044.9**	**+8.6%**	**82.4**
Cost of sales *	337.8	348.0		10.3
SG&A expenses *	318.5	352.1		33.7
R&D expenses *	227.4	254.1		26.7
Core operating profit*	**78.9**	**90.6**	**+14.9%**	**11.8**
Temporary income *	0.6	3.9		3.4
Temporary expenses *	15.6	21.5		5.9
Operating profit	**63.8**	**73.0**	**+14.5%**	**9.2**
Profit before tax	**74.1**	**73.5**		**-0.6**
Profit attributable to owners of the Company	**76.0**	**67.0**	**-11.8%**	**-9.0**

Currency Rate	USD/JPY	106.06	112.38	+6.32
	EUR/JPY	123.70	130.56	+6.86

* 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 82.4 Bn JPY (Increased by 53.7 Bn JPY excl. forex impact)



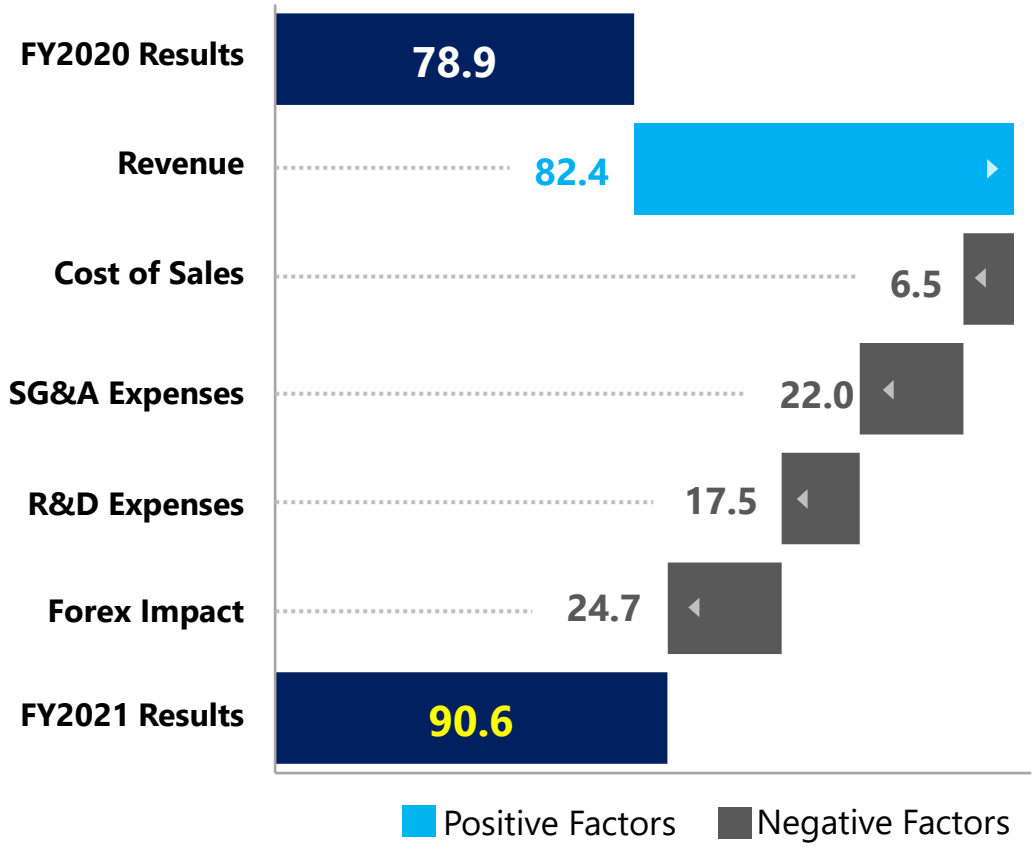
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+15.1	Nexium	-39.6
Tarlige	+9.6	Memary	-11.0
Enhertu	+5.2		
Emgality	+4.6		
Daiichi Sankyo Espha	+11.4		
Ezetimibe AG and others			
Oncology Business*1 Unit			
Enhertu	+25.6	Olmesartan	-3.8
American Regent Unit			
Injectafer	+5.9		
GE injectables	+9.8		
EU Specialty Business Unit			
Lixiana	+15.1	Gain on sales of transferring current products	-3.1
		Olmesartan	-2.3
Enhertu, Dato-DXd*2 Upfront Payment & Regulatory Milestone etc.			
Enhertu quid related payment	+3.4		
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: +12.7, EUR : +7.2, ASCA: +8.7

Core Operating Profit

Increased by 11.8 Bn JPY (Increased by 7.9 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +82.4
incl. forex impact of +28.7

Cost of Sales +6.5
Improvement in cost of sales ratio by change in product mix

SG&A Expenses +22.0
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses +17.5
Increase in 3ADCs* R&D investments

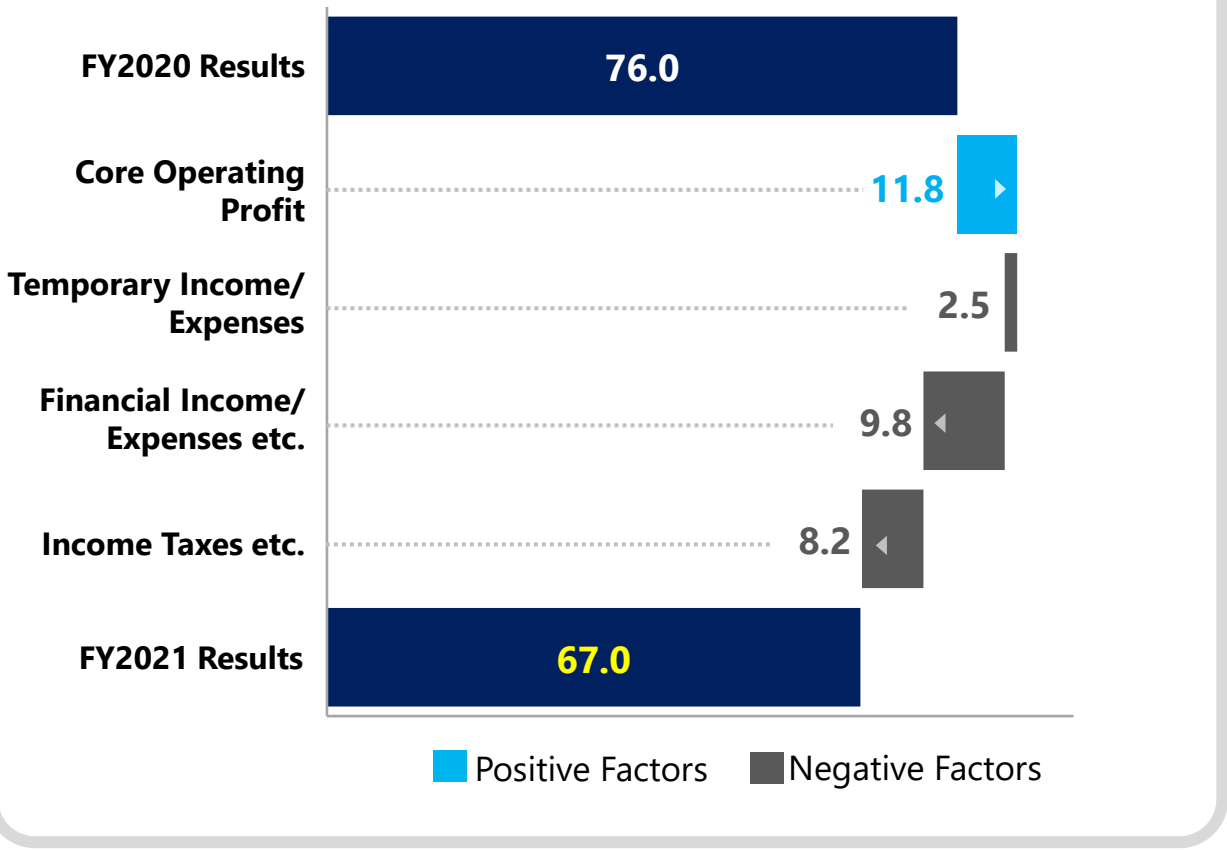
Forex Impact +24.7
Cost of Sales +3.8
SG&A Expenses +11.7
R&D Expenses +9.2

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

Profit Attributable to Owners of the Company

(Bn JPY)

Decreased by 9.0 Bn JPY



Temporary Income/Expenses ····· +2.5 (Profit decreased)

	FY2020	FY2021	YoY
Temporary Income	0.6	3.9*2	+3.4
Temporary Expenses	15.6*1	21.5*3	+5.9

*1 Vaccine business loss compensation (15.0)
*2 Gains related to sale of Osaka logistics center (2.1)
*3 Environmental expenditures related to former Yasugawa plant (9.5)
Losses related to closure of Plexxikon (5.8)

Financial Income/Expenses etc. ····· +9.8 (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. ····· +8.2 (Profit decreased)

	FY2020	FY2021	YoY
Profit before Tax	74.1	73.5	-0.6
Income Taxes etc.	-1.7	6.5	+8.2
Tax rate	-2.3%	8.9%	+11.2%

FY2020: Decrease in Income taxes due to an increase in DTA attributable to future expected taxable income increase of 3ADCs
FY2021: Impact of tax credit for R&D expenses and others

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2020 Results	FY2021 Results	YoY
Japan Business	489.1	489.5	+0.4
Daiichi Sankyo Healthcare	67.2	64.7	-2.5
Oncolgy Business	47.4	69.6	+22.2
Enhertu	25.7	54.4	+28.7
Turalio	1.8	2.8	+1.0
American Regent	121.7	149.5	+27.7
Injectafer	44.1	53.1	+8.9
Venofer	28.8	33.8	+4.9
GE injectables	41.8	54.7	+12.9
EU Speciality Business	111.7	128.2	+16.6
Lixiana	76.7	96.9	+20.2
Nilemdo/Nustendi	0.6	3.1	+2.6
Olmesartan	21.5	20.3	-1.2
ASCA (Asia, South and Central America)	99.7	114.1	+14.5

Currency Rate	USD/JPY	106.06	112.38	+6.32
	EUR/JPY	123.70	130.56	+6.86

Revenue: Major Products in Japan

(Bn JPY)

		FY2020 Results	FY2021 Results	YoY
Lixiana	anticoagulant	**77.4**	**92.5**	**+15.1**
Nexium	ulcer treatment	**77.8**	**39.6**	**-38.2**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**34.6**	**37.9**	**+3.3**
Tarlige	pain treatment	**20.6**	**30.1**	**+9.6**
Tenelia	type 2 diabetes mellitus treatment	**24.2**	**23.7**	**-0.6**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**19.3**	**20.4**	**+1.1**
Loxonin	anti-inflammatory analgesic	**24.2**	**22.2**	**-2.0**
Vimpat	anti-epileptic agent	**14.5**	**18.3**	**+3.7**
Canalia	type 2 diabetes mellitus treatment	**15.4**	**16.8**	**+1.4**
Efient	antiplatelet agent	**14.1**	**16.7**	**+2.7**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**4.4**	**9.6**	**+5.2**
Rezaltas	antihypertensive agent	**13.1**	**12.0**	**-1.1**
Inavir	anti-influenza agent	**3.6**	**1.3**	**-2.3**

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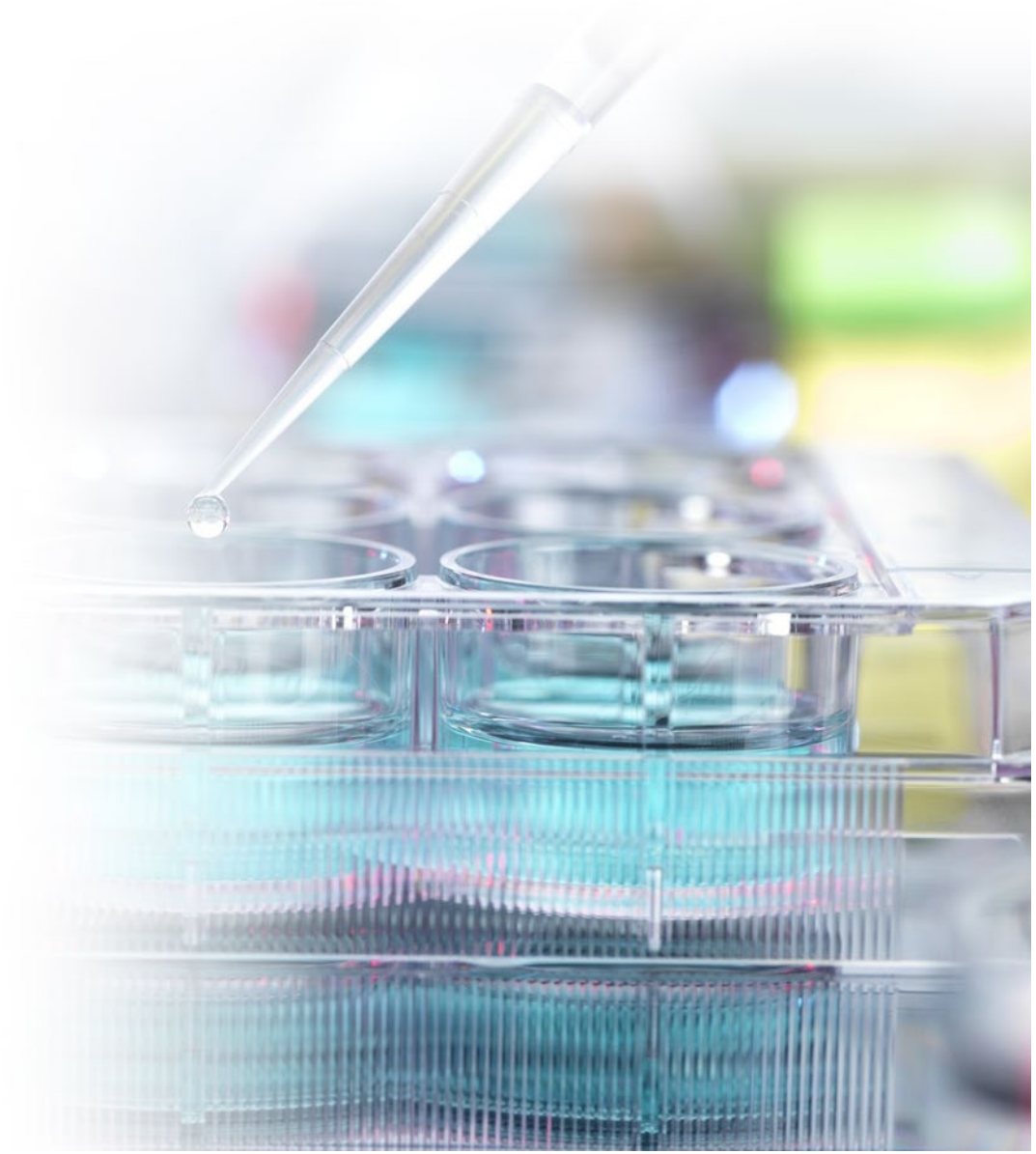

FY2022 Forecast

(Bn JPY)

	FY2021 Results	FY2022 Forecast	vs. Forecast
Revenue	**1,044.9**	**1,150.0**	**105.1**
Cost of sales *	348.0	328.0	-20.0
SG&A expenses *	352,1	410.0	57.9
R&D expenses *	254.1	307.0	52.9
Core operating profit *	**90.6**	**105.0**	**14.4**
Temporary income*	3.9	-	-3.9
Temporary expenses*	21.5	-	-21.5
Operating profit	**73.0**	**105.0**	**32.0**
Profit before tax	**73.5**	**105.0**	**31.5**
Profit attributable to owners of the Company	**67.0**	**83.0**	**16.0**

Currency Rate	USD/JPY	112.38	130.00	17.62
	EUR/JPY	130.56	140.00	9.44

Revenue
Increase factor ↑ Sales expansion of main products (Enhertu, Lixiana, Tarlige, etc.)
Decrease Factor ↓ Drug price revision, Termination of joint sales promotion for Nexium

Cost of sales
Improvement in cost of sales ratio by change in product mix and others

SG&A expenses
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca and others

R&D expenses
Increase in 3ADCs R&D investments and others

Temporary expenses
FY2021: Environmental expenditures related to former Yasugawa plant
Losses related to closure of Plexxikon

Profit attributable to owners of the Company
FY2021: Impact of Tax credit for R&D expenses and others

Forex Impact	**Revenue +55.0 Bn JPY, Core operating profit -6.0 Bn JPY**
COVID-19 Impact	Certain activity restrictions are expected to continue during FY2021, however impact on core operating profit is expected to be minor

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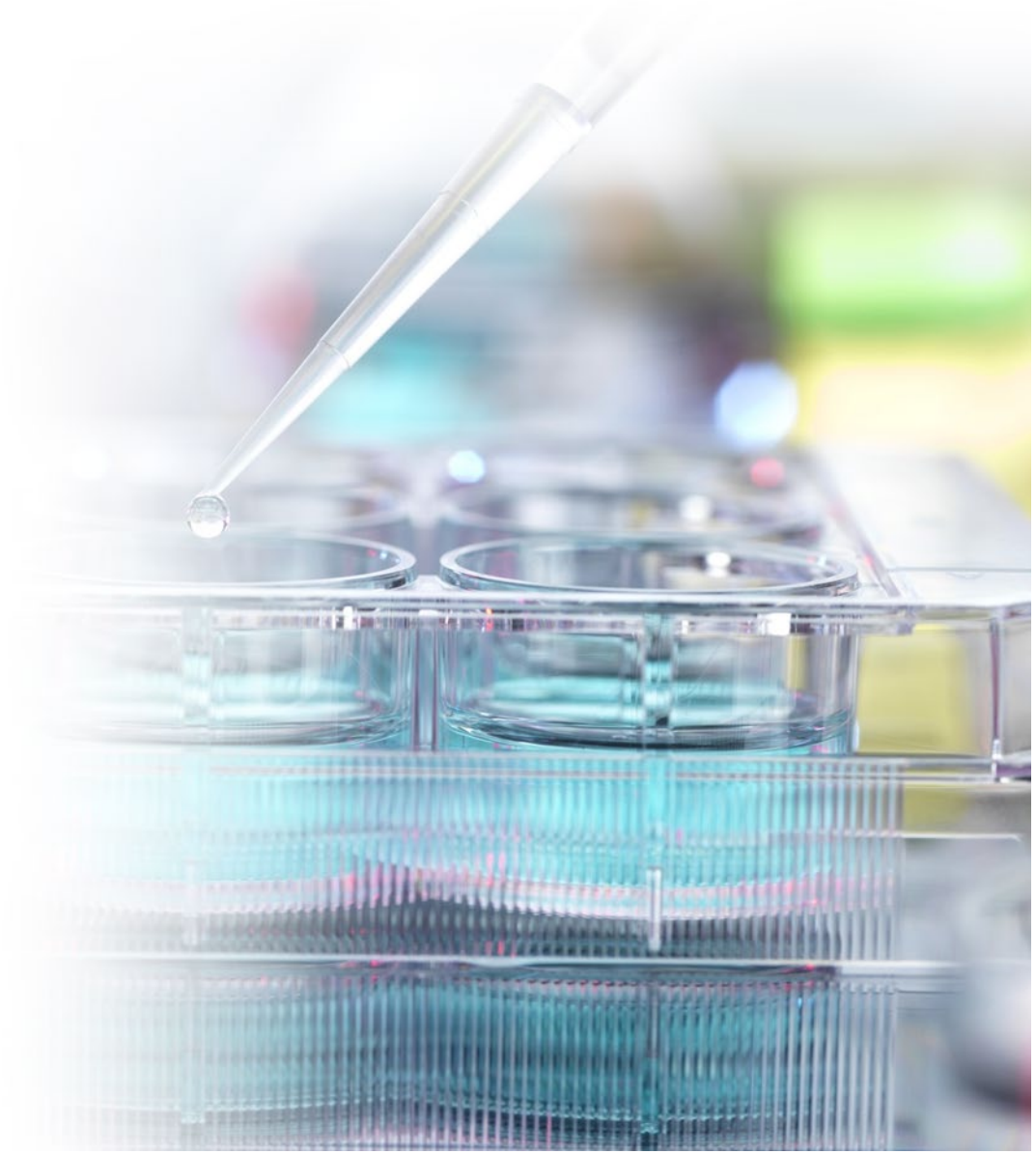


Progress towards “Maximize 3ADCs”

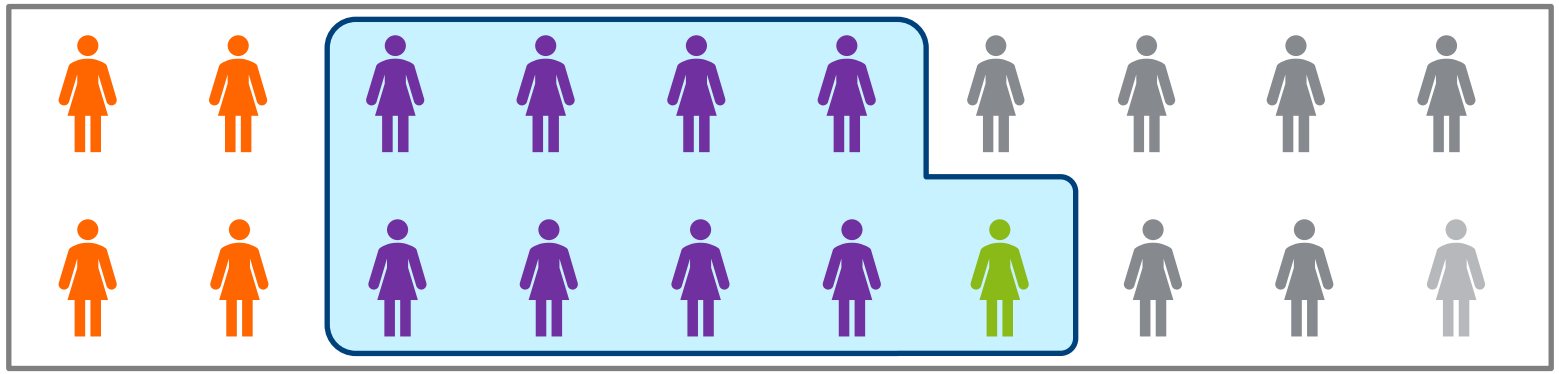
Progress towards “Profit growth for current business and products”

ENHERTU®: Transform Treatment for Breast Cancer Patients

Daiichi-Sankyo

Transform the treatment landscape for previously "un-targetable" HER2 low BC patients
HER2-Low patient totals are approximately 2x HER2 positive BC patients

BC Market Space by HER2 Status



HER2+ (IHC 3+, 2+/ISH+)

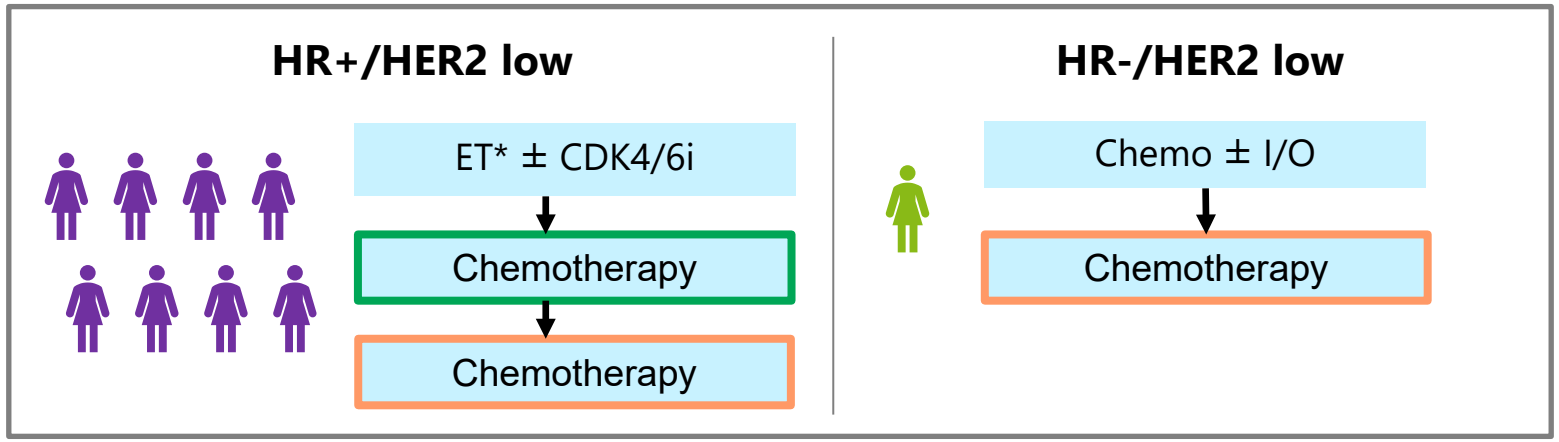
HR+/HER2 low (IHC 1+, 2+/ISH-)

HR-/HER2 low (IHC 1+, 2+/ISH-)

HR+/HER2- (IHC 0)

HR-/HER2- (IHC 0)

Current SOC for Unresectable or Metastatic HER2-low BC Patients



*ET: Endocrine Therapy

ENHERTU® Ph3 Studies

- **DESTINY-Breast04**
  HER2 low BC, post-chemo
  - ✓ **Obtained topline results in Feb. 2022**
  - ✓ **sBLA planned in FY2022 H1**
- **DESTINY-Breast06**
  HER2 low BC, chemo-naïve

ENHERTU®: Revenue

(Bn JPY)

	FY2021 Results	YoY	FY2022 Forecast	YoY	<Reference> Total Consideration
Product Sales	65.4	35.3	128.4	63.0	-
Japan	9.6	5.2	16.0	6.4	-
US	45.4	19.7	83.1	37.7	-
Europe	9.0	9.0	23.0	14.0	-
ASCA	1.4	1.4	6.3	4.9	-
Upfront payment	9.8 *1	-	9.8 *1	-	149.0
Regulatory milestone payment	2.2 *1	-1.3	20.6 *1	18.3	100.2
US HER2+ Breast Cancer 3L	0.9	-	0.9	-	13.7
EU HER2+ Breast Cancer 3L	0.5	-0.5	0.5	-	7.9
US HER2+ Gastric Cancer 2L + 3L	0.8	-0.8	0.8	-	12.1
US HER2+ Breast Cancer 2L	-	-	3.4	3.4	13.0 *2
EU HER2+ Breast Cancer 2L	-	-	2.6	2.6	9.8 *2
US HER2-low Breast Cancer (post-chemo)	-	-	6.9	6.9	26.0 *2
EU HER2+ Gastric Cancer 2L	-	-	1.2	1.2	4.6 *2
US HER2+ or HER2 Mutant NSCLC 2L	-	-	4.3	4.3	13.1 *2
Quid related payment	3.4 *1	3.4	1.1 *1	-2.3	17.2
Total	80.8	37.4	159.9	79.1	266.4

*1 Revenue recognized in each period
*2 Expected consideration based on the assumption of achieving milestones in FY2022

ENHERTU®: Performance in Each Region

- **Steady increase in product sales due to market penetration in launched countries and market expansion**
- **Product sales: FY2021 results 65.4 Bn JPY（YoY +35.3 Bn JPY）**
  FY2022 forecast 128.4 Bn JPY（YoY +63.0 Bn JPY）

ENHERTU® trastuzumab deruxtecan

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

- **Product sales: FY2021 results 45.4 Bn JPY (404 Mn USD)**
  FY2022 forecast 83.1 Bn JPY (639 Mn USD)
- **Steady growth in the market**
  - HER2+ BC 3L: Maintaining No.1 new patient share
  - HER2+ GC 2L: Good progress
- **Other progress**
  - Classified as a category 1 preferred regimen for HER2+ BC 2L treatment in NCCN*1 guidelines (Nov. 2021)

Europe (HER2+ Breast Cancer 3L)

- **Product sales: FY2021 results 9.0 Bn JPY (80 Mn USD)**
  FY2022 forecast 23.0 Bn JPY (177 Mn USD)
- **Steady growth in the market**
  - Market expansion (Launched in UK, France, **Germany (Feb. 2022)**)
  - New patient shares increasing (No.1 share in UK, France, **Germany**)
- **Other progress**
  - ESMO Clinical Practice Guideline supported ENHERTU® as the new standard of care for HER2+ BC 2L*2 treatment (Oct. 2021)

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

- **Product sales: FY2021 results 9.6 Bn JPY (85 Mn USD)**
  FY2022 forecast 16.0 Bn JPY (123 Mn USD)
- **Steady growth in the market**
  - New patient shares increasing (No.1 share in HER2+ BC 3L / GC 3L)

ASCA (HER2+ Breast Cancer 3L)

- **Product sales: FY2021 results 1.4 Bn JPY (12 Mn USD)**
  FY2022 forecast 6.3 Bn JPY (48 Mn USD)
- **New Launch**
  - **Launched in Brazil (Jan. 2022)**

Underlined part: Update from FY2021 Q3

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

Progress towards “Maximize 3ADCs”

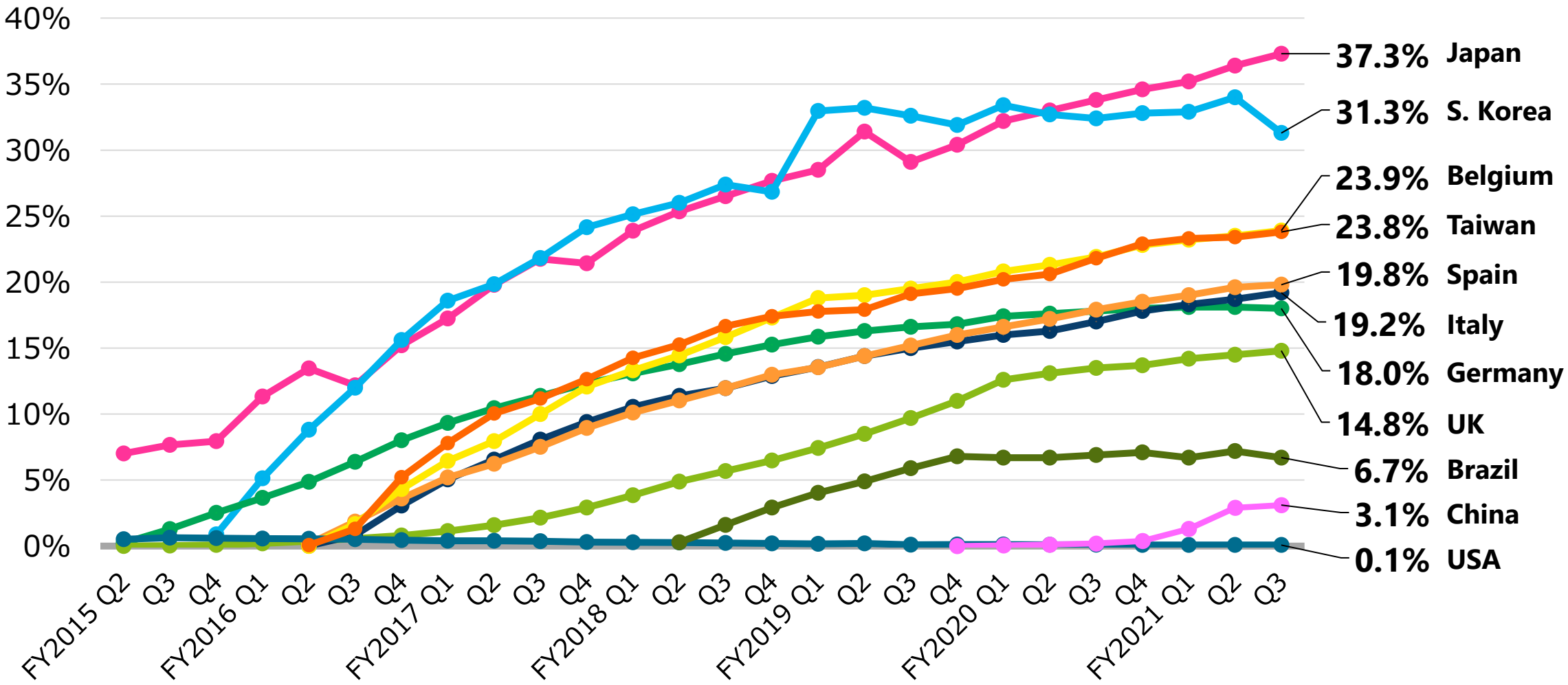
Progress towards “Profit growth for current business and products”

LIXIANA®: Growth in Each Country/Region

Volume

Daiichi-Sankyo

Global revenue **FY2021 results: 205.6 Bn JPY (YoY +39.7 Bn JPY)**
FY2021 forecast: 237.7 Bn JPY (YoY +32.1 Bn JPY)

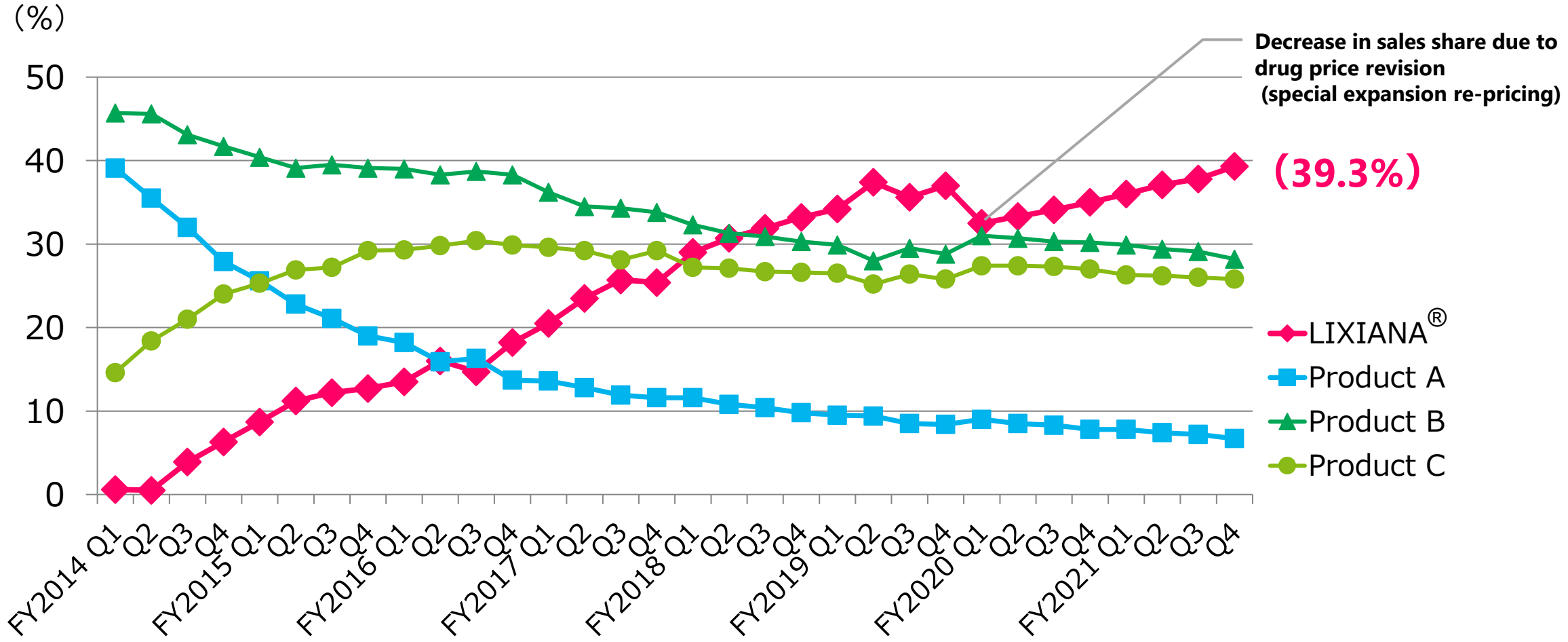


LIXIANA®: Growth in Japan

Sales

Daiichi-Sankyo

- No.1 sales share (FY2021 Q4: 39.3%)
- 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
- Revenue FY2021 results: 92.5 Bn JPY (YoY +15.1 Bn JPY), FY2022 forecast: 104.3 Bn JPY (YoY +11.8 Bn JPY)



Japan Business: Enhance product portfolio

- **EMGALITY®** **Prophylaxis of migraine attacks**
  - **Launched** in Apr. 2021
- **LIXIANA®** **Anticoagulant**
  - **Obtained approval for additional dosage and administration**[*1] in Aug. 2021
- **DELYTACT®** **Oncolytic virus G47Δ**
  - **Launched** in Nov. 2021

*1 For elderly patients with high risk of bleeding, the dose can be reduced to 15 mg once a day depending on the age and condition of the patient.

- **EFIENT®** **Antiplatelet agent**
  - **Obtained approval for additional indication** [*2] in Dec. 2021
- **REYVOW®** **Migraine treatment**
  - **Obtained marketing approval**[*3] in Jan. 2022
- **TARLIGE®** **Pain treatment**
  - **Obtained approval for additional indication** in Mar. 2022

*2 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)

*3 Marketing approval was obtained by Eli Lilly Japan which signed an agreement on reverse co-promotion with Daiichi Sankyo

TARLIGE®: Pain treatment launched in Apr. 2019
Obtained approval to change the indication from "peripheral neuropathic pain" to "neuropathic pain"

- Indication：Neuropathic pain
- Date of Approval ：Mar. 28, 2022

Increase the contribution to patients with neuropathic pain and **maximize the product value of TARLIGE®** by providing a new therapeutic option

Other initiatives in Each Region

Enhance transformation into a profit structure focused on patented drugs

Japan

- **Transferred products in Japan**
  - **Date of Transfer : Nov.-Dec. 2021**
  - **Products : 7 products including antihypertensive agent ACECOL®**
    (FY2020 revenue of 7 products: 2.6 Bn JPY)

US

- **Concluded an asset sale agreement in US**
  - **Date of Agreement : Jan. 2022**
  - **Products : 8 products including antihypertensive agent BENICAR®**
    (FY2021 revenue of 8 products: 8.9 Bn JPY)

Europe

- **Transferred products in Italy**
  - **Date of Transfer : May. , Dec. 2021**
  - **Products : 3 products including antihypertensive agent LOPRESSOR®**
    (FY2020 revenue of 3 products: 0.8 Bn JPY)

ASCA

- **Concluded an asset sale agreement in China**
  - **Date of Agreement : Mar. 2022**
  - **Product : Antibacterial agent Cravit®**
    (FY2021 Revenue ：8.9 Bn JPY)
  - **Subsidiary to be divested：Daiichi Sankyo Pharmaceutical (Beijing) Co., Ltd**

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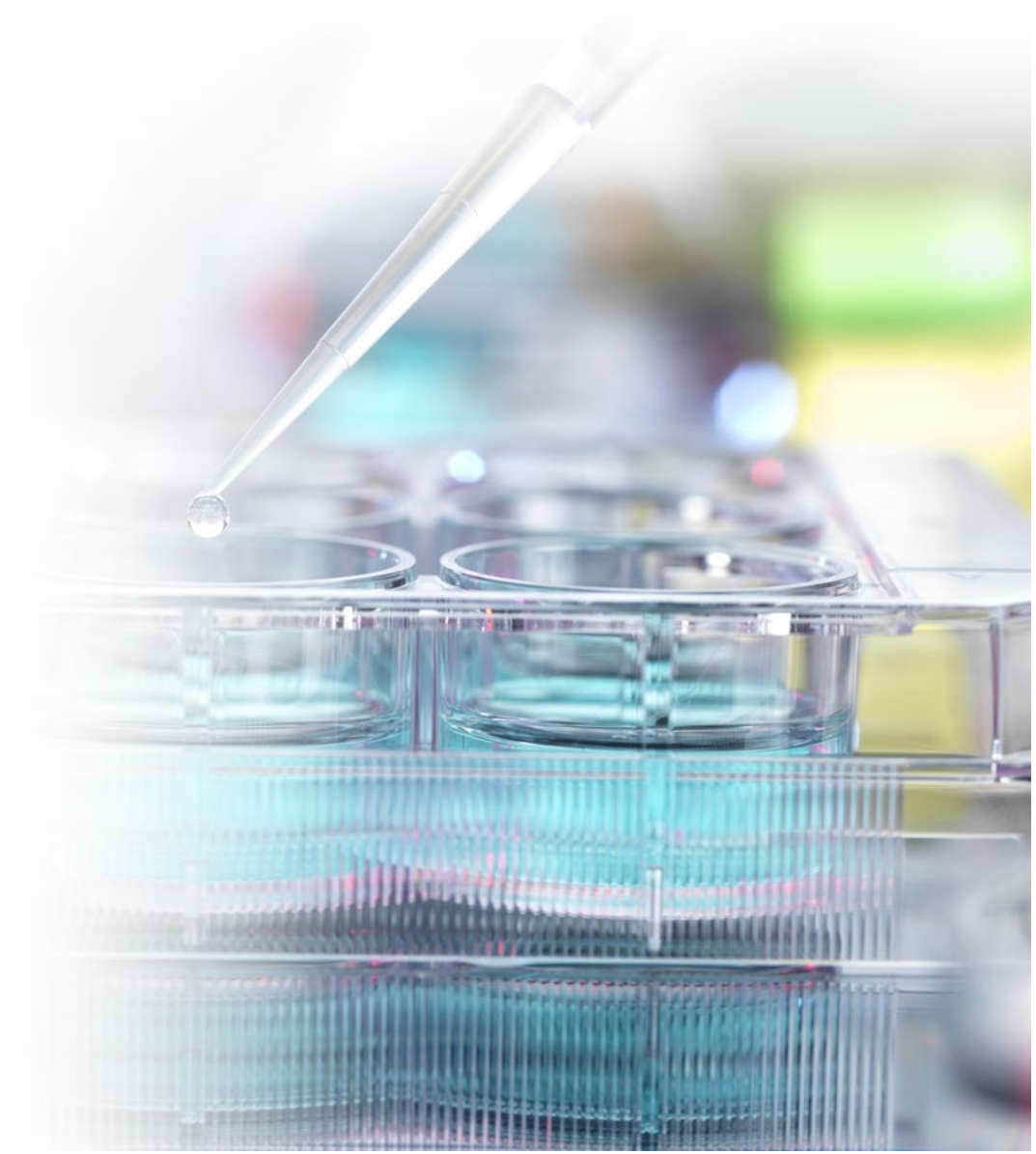


Progress towards “Maximize 3ADCs”

Progress towards “Identify and build pillars for further growth”

ASCO 2022

News Flow

First year of 5-year business plan: Biggest achievement in R&D

ENHERTU®: Achievement of two Ph3 study results with a potential to transform treatment for breast cancer patients

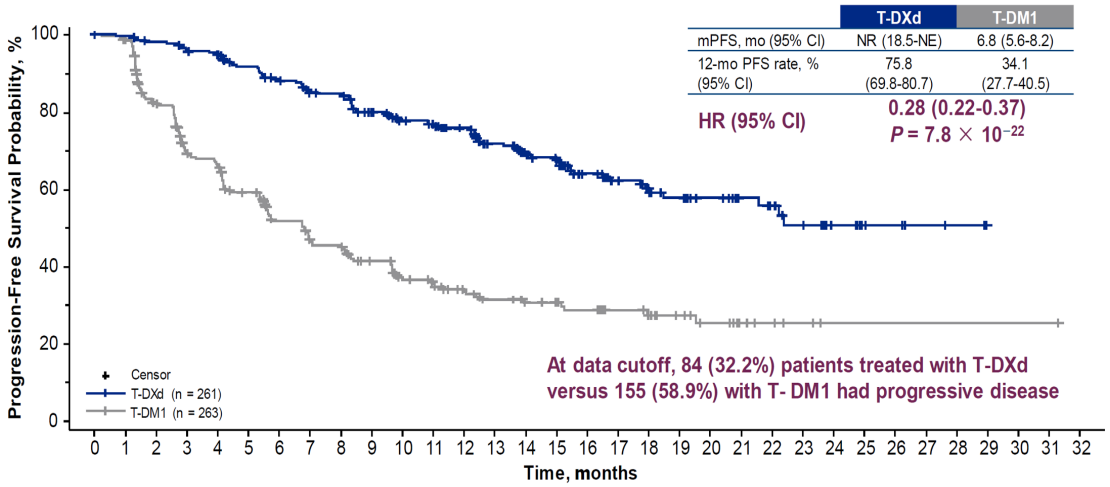
- **DESTINY-Breast03** (HER2 positive breast cancer, 2L)
- **DESTINY-Breast04** (HER2 low breast cancer, post chemotherapy)

FY2021 marked a **major** turning point in Daiichi Sankyo's transformation into a **global leader in oncology**, and got off to a **good start** to achieve the 5-year business plan

ENHERTU®: DESTINY-Breast03 study

Primary endpoint: PFS by BICR

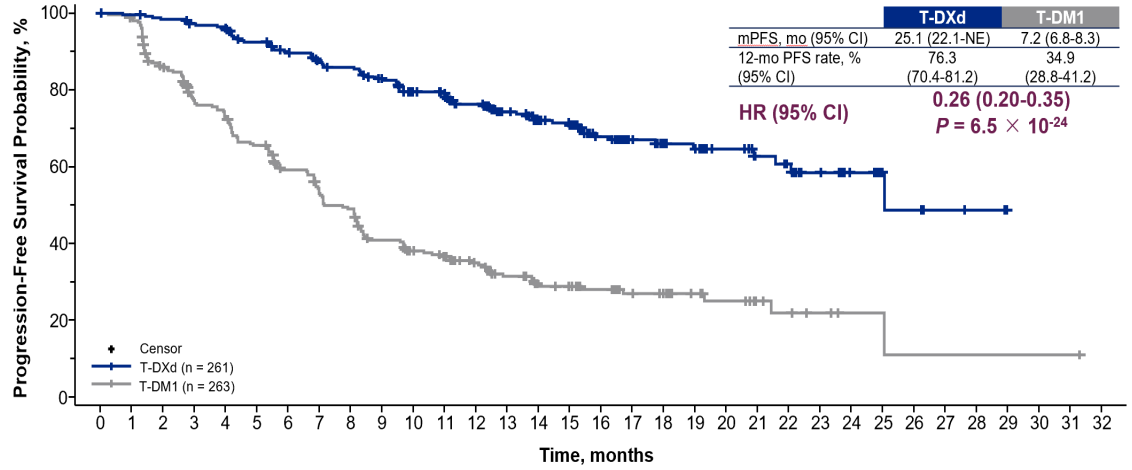
ESMO 2021



- 72% reduction in risk of disease progression or death compared to T-DM1

Secondary endpoint: PFS by investigator assessment

ESMO 2021



- ENHERTU® demonstrated 25.1m median PFS while T-DM1 demonstrated 7.2m median PFS

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. *N Engl J Med*. 2022; 286:1143-54

- ENHERTU® demonstrated **unparalleled** improvement in PFS compared to T-DM1 and no grade 4/5 ILD in patients with HER2+ BC, data published in NEJM
- Regulatory submission accepted in China in Mar 2022, regulatory approval planned in JP/US/EU in FY2022

Transform the course of HER2 positive breast cancer

NEJM: the New England Journal of Medicine

ENHERTU®: DESTINY-Breast04 study

Ph3 study design

Key Eligibility Criteria

- HER2-low (IHC 1+ or IHC 2+/ISH-)
- Unresectable or metastatic breast cancer
- Previously treated with 1 or 2 lines of chemotherapy in the metastatic setting
- If HR-positive, must be refractory to endocrine therapy, no restriction on prior targeted therapy

R 2:1

T-DXd 5.4 mg/kg
n≈360

Investigator's choice
n≈180

(Capecitabine, Eribulin, Gemcitabine, Paclitaxel, or Nab-paclitaxel)

Primary endpoint
- PFS (BICR) in HR+

Key Secondary endpoints
- PFS (BICR) HR+ & HR-
- OS in HR+
- OS in HR+ & HR-

BICR: blinded independent central review, HR: hormone receptor, OS: overall survival, PFS: progression free survival

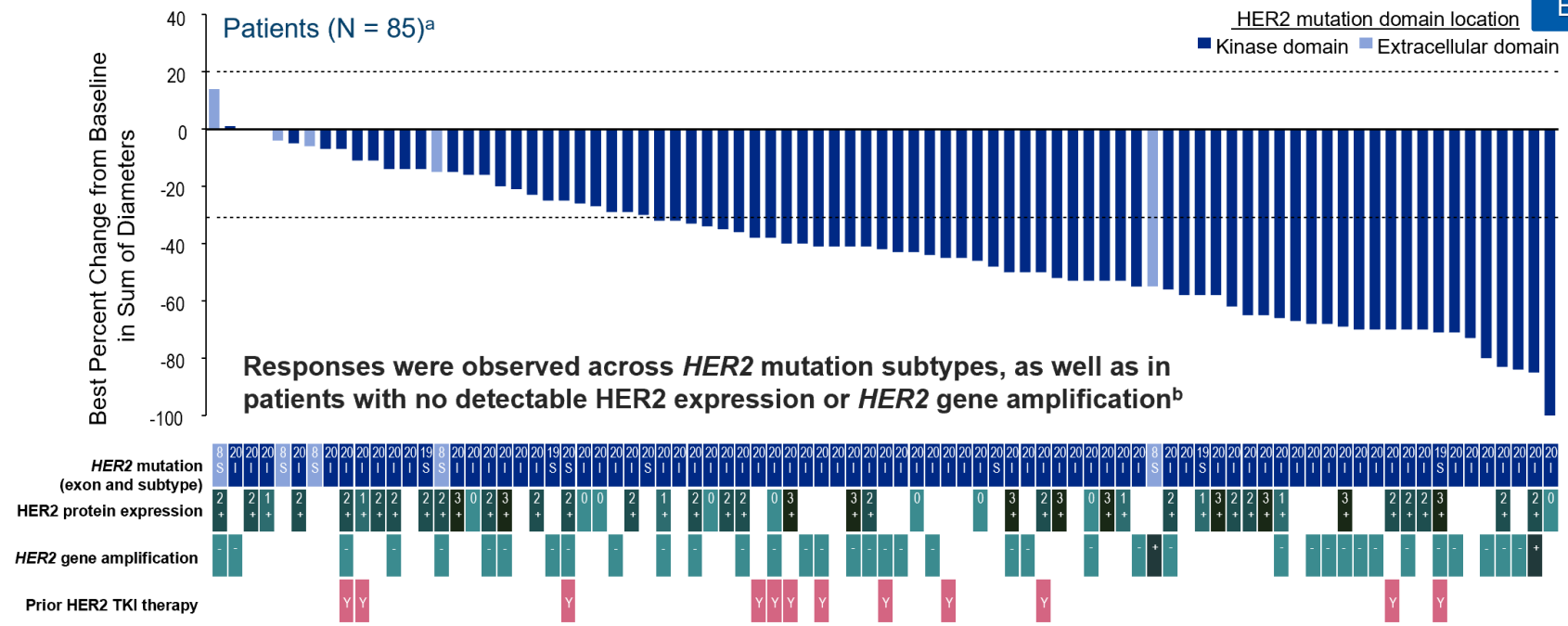
- A global Ph3 study in patients with **HER2 low breast cancer** previously treated with chemotherapy
- The study **met both** the primary endpoint and key secondary endpoints: demonstrated a **statistically significant and clinically meaningful improvement** in both PFS and OS in HR+ patients and patients regardless of HR status
- Feb 2022: Granted for Real Time Oncology Review (RTOR) by FDA
- Apr 2022: Granted breakthrough therapy designation by FDA
- Jun 2022: Data presentation planned at ASCO
- FY2022 H1: Regulatory submission planned

Pioneer HER2 low BC as a new clinically meaningful patient segment

ENHERTU®: DESTINY-Lung01 study

Anti-tumor responses (Best percentage change of tumor size from baseline)

ESMO 2021



[a]Best change in tumor size by ICR for 85 of 91 patients for whom baseline and postbaseline data were available. Baseline is last measurement taken before enrollment. [b]The Oncomine™ Dx Target Test (Thermo Fisher Scientific) was used to confirm local HER2 mutation status and to determine HER2 amplification status. HER2 protein expression status was determined by immunohistochemistry using a modified PATHWAY anti-HER2 (4B5) (Ventana Medical Systems, Inc.) assay. Shown is best (minimum) percentage change from baseline in the sum of diameters for all target lesions; (-), negative; (+), positive; I, insertion; N, no; S, substitution; Y, yes. Blank cells (except for the prior HER2 TKI therapy row) indicate patients whose tumor samples were not evaluable or assessed. The upper dashed horizontal line indicates a 20% increase in tumor size in the patients who had disease progression and the lower dashed line indicates a 30% decrease in tumor size (partial response).

- Breakthrough therapy designation granted by FDA in May 2020
- Data presented at ESMO 2021 and published in NEJM
- Regulatory submission accepted and granted Priority Review in US in Apr 2022 (PDUFA date: Aug 16)

ENHERTU® to potentially become the first treatment option for HER2 mutated NSCLC

NEJM: the New England Journal of Medicine, NSCLC: non small cell lung cancer

ENHERTU®: Additional progress in FY2021

	Neoadjuvant	Post-neoadjuvant	Advanced/Metastatic 1L	Advanced/Metastatic 2L	Advanced/Metastatic 3L
HER2+ breast cancer	**DESTINY-Breast11** Ph3 Started in Nov 2021	**DESTINY-Breast05** Ph3 Started in Dec 2020	**DESTINY-Breast09** Ph3 Started in Jun 2021	**DESTINY-Breast03** Ph3 Filing accepted in Dec 2021 (JP/EU) Filing accepted in Jan 2022 (US) Filing accepted in Mar 2022 (CN)	**DESTINY-Breast01** Ph2 Launched（JP/US/EU）
			DESTINY-Breast07 Ph1b/2 (combo) Started in Jan 2021		**DESTINY-Breast02** Ph3 Started in Sep 2018
HER2+ gastric cancer			**DESTINY-Gastric03** Ph1b/2 (combo) Started in Jun 2020	**DESTINY-Gastric02** Ph2 Filing accepted in Nov 2021 (EU)	**DESTINY-Gastric01** Ph2 Launched (JP/US*)
				DESTINY-Gastric04 Ph3 Started in Jun 2021	**DESTINY-Gastric06** Ph2 Started in Sep 2021 (CN)
HER2 mutated NSCLC			**DESTINY-Lung04** Ph3 Started in Dec 2021	**DESTINY-Lung01** Ph2 Obtained TLR in Jun 2021	
				DESTINY-Lung02 Ph2 Started in Mar 2021	

NSCLC: non small cell lung cancer, TLR: top line results

* Launched in US for 2L indication

☐ Studies which achieved milestones in FY2021, such as study initiation, data acquisition, filing acceptance, etc.

■ Launched indication

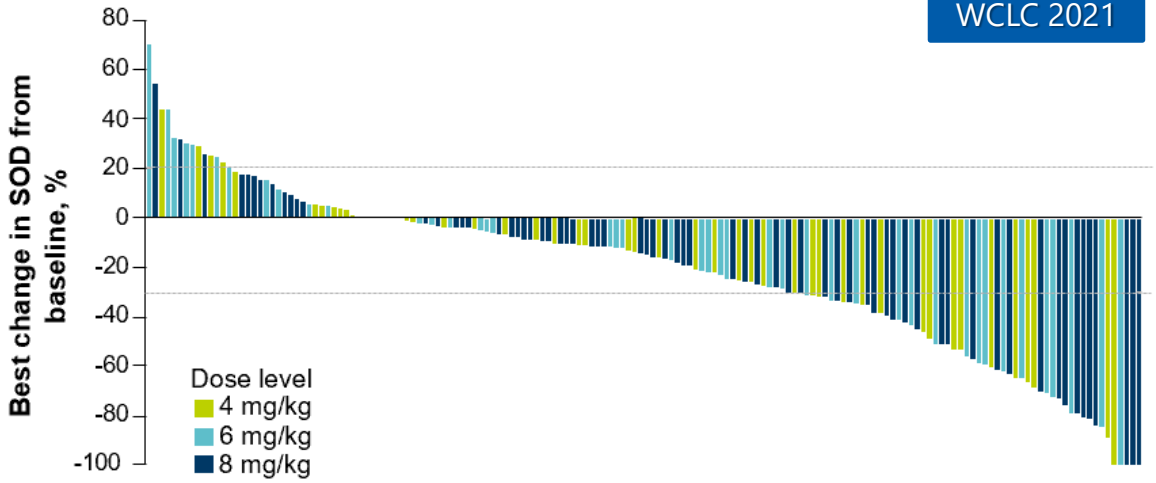
Development in earlier lines of treatment has progressed in multiple cancer types

Dato-DXd: Progress in FY2021

Efficacy data of TROPION-PanTumor01 study

Patients with NSCLC (include both with and without actionable genomic mutations)

WCLC 2021

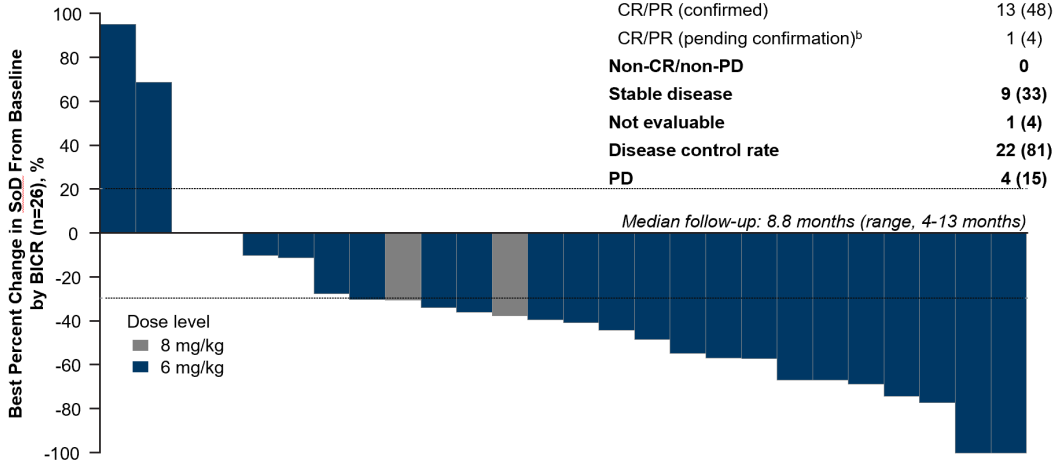


SOD, sum of diameters

- 6mg/kg dose was selected
- Efficacy was also confirmed in the subgroup of patients with actionable genomic mutations

Patients with TNBC (without prior Topo I inhibitor-based ADC)

SABCS 2021



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

Median follow-up: 8.8 months (range, 4-13 months)

[a] Includes response evaluable patients who had ≥1 postbaseline tumor assessment or discontinued treatment. Postbaseline tumor assessments were not yet available for 1 patient at the data cutoff. [b] Includes patients with an unconfirmed response but are ongoing treatment.

- **TROPION-Lung08 study** (NSCLC without actionable genomic mutations, 1L, Ph3, pembrolizumab combo): started in Mar 2022
- **TROPION-Breast01 study** (HR+/HER2- breast cancer, 2/3L, Ph3): started in Nov 2021
- **BEGONIA study** (TNBC 1L, Ph1b/2, durvalumab combo): started in May 2021
- **TROPION-PanTumor01 study:** added cohorts for gastric, esophageal, urothelial cancer and SCLC

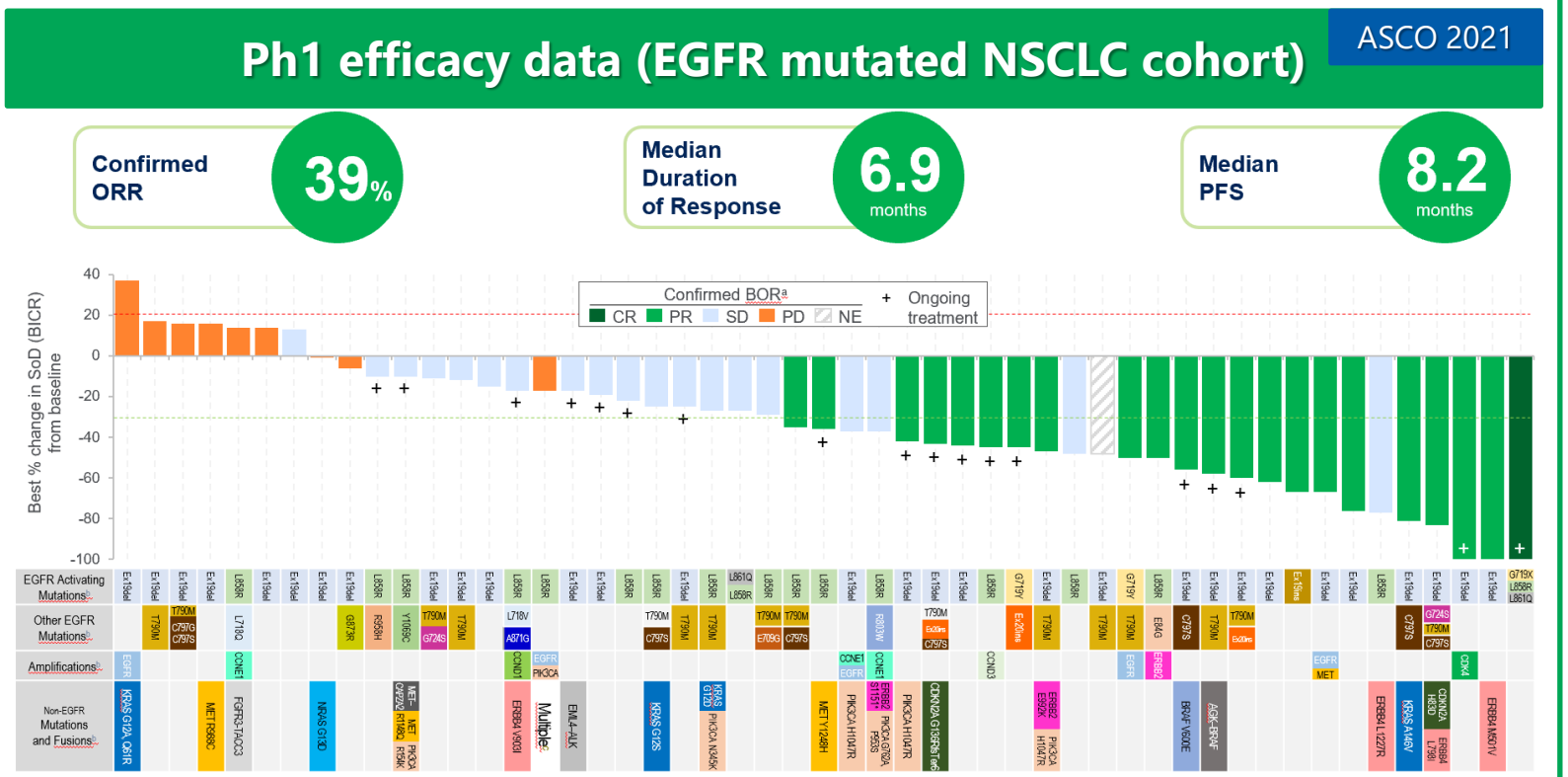
HR: hormone receptor
NSCLC: non small cell lung cancer
SCLC: small cell lung cancer
TNBC: triple negative breast cancer

Development has progressed in lung and breast cancers.
4 new cohorts were added in TROPION-PanTumor01 study.

HER3-DXd: Progress in FY2021

Ph1 efficacy data (EGFR mutated NSCLC cohort)

ASCO 2021



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

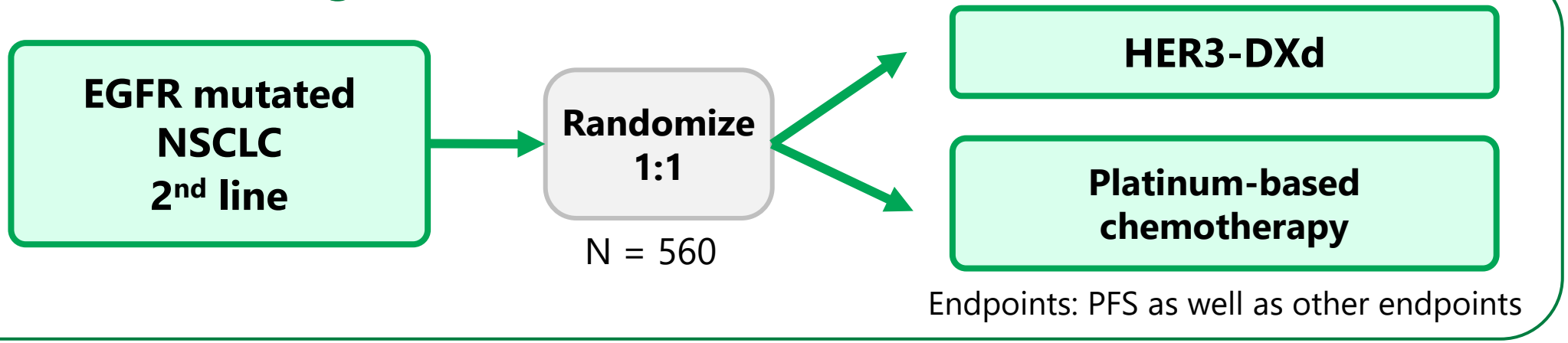
NSCLC: non small cell lung cancer, TKI: tyrosine kinase inhibitor

- HER3-DXd demonstrated tumor responses in patients with NSCLC with multiple EGFR TKI resistance mechanisms in **Ph1 study**. FDA granted breakthrough therapy designation in Dec 2021.
- **HERTHENA-Lung01 study** (EGFR mutated NSCLC 3L, registrational Ph2) is ongoing as scheduled.
- **Ph1b study in combination with osimertinib** (EGFR mutated NSCLC, 1/2L) was initiated in Jun 2021.

Development has progressed in EGFR mutated NSCLC.
Breakthrough therapy designation was granted by FDA

HER3-DXd: New study planned

HERTHENA-Lung02 study design



HER3-DXd NSCLC Dev. status	Advanced/Metastatic 1L	Advanced/Metastatic 2L	Advanced/Metastatic 3L
EGFR mutated NSCLC	Ph1b Combination with osimertinib Started in Jun 2021	**HERTHENA-Lung02** Ph3 Study start planned in FY2022 H1	**HERTHENA-Lung01** Registrational Ph2 Started in Feb 2021

NSCLC: non small cell lung cancer, PFS: progression free survival

Planning to initiate HERTHENA-Lung02 study (EGFR mutated NSCLC 2L, Ph3) in FY2022 H1

Progress towards “Maximize 3ADCs”

Progress towards “Identify and build pillars for further growth”

ASCO 2022

News Flow

Identify new growth drivers following 3ADCs: Rising Stars

	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, Breast							
4	DS-7300 (B7-H3)	ESCC, CRPC, sq-NSCLC, SCLC, etc.							
5	DS-6000 (CDH6)	Renal, Ovarian							
6	DS-3939 (TA-MUC1)	Solid tumors							
7	DS-XXXX (Undisclosed)	Undisclosed							

Rising Stars

Timeline indicates the most advanced stage of each project

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

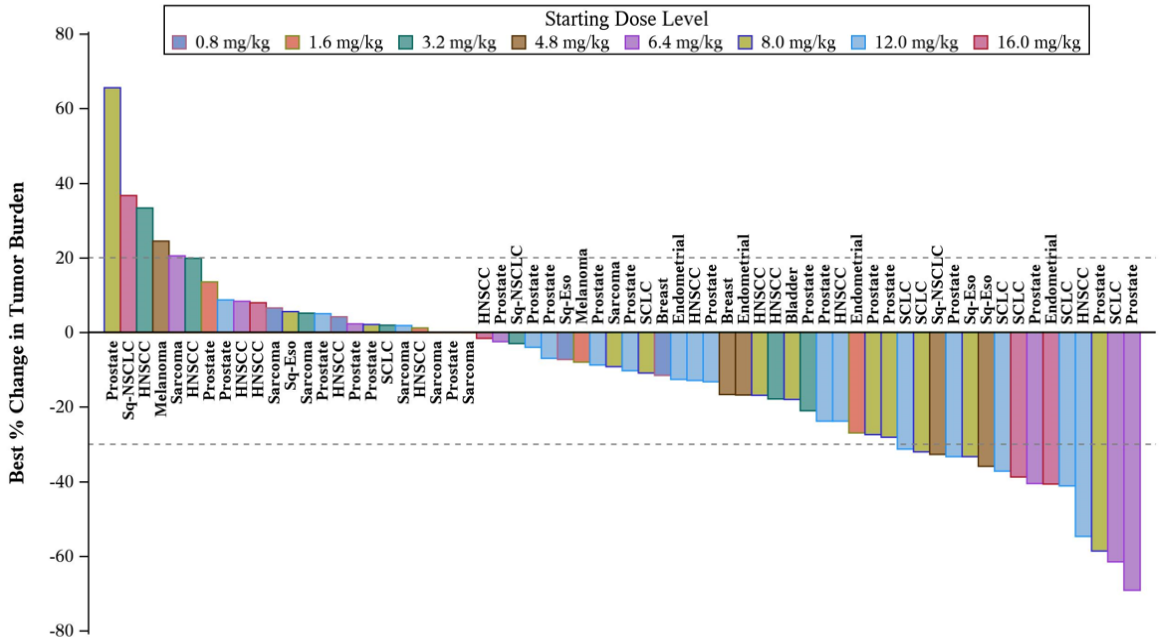
Early efficacy signals are being observed in Ph1 of DS-7300 & DS-6000

DS-7300: Progress in FY2021

Ph1/2 study efficacy data

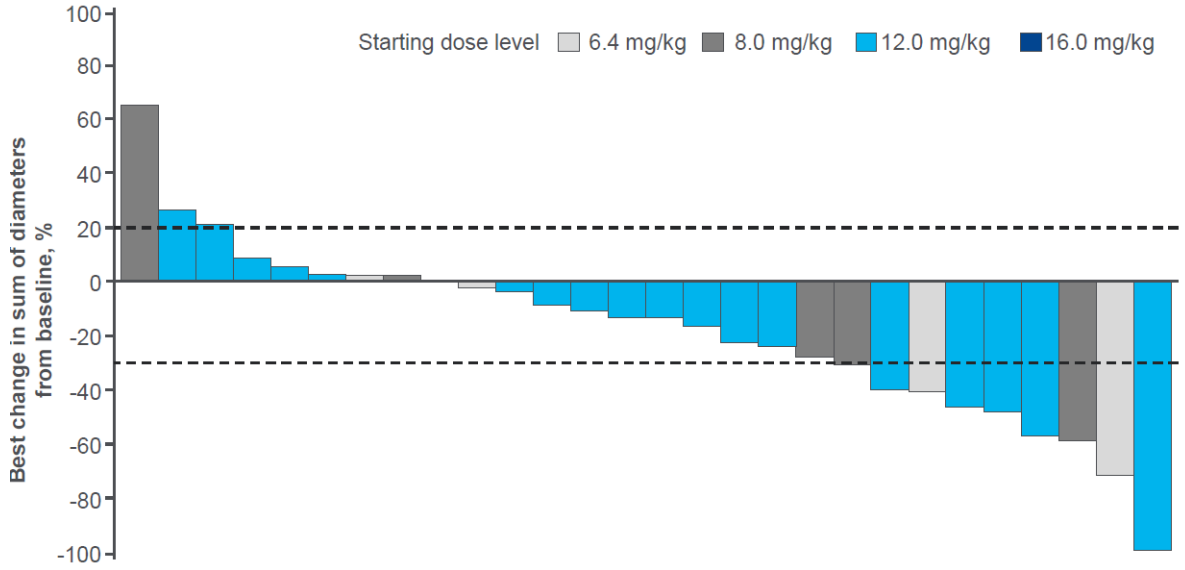
Dose escalation interim data

ESMO 2021



Dose escalation/expansion Interim sub-analysis data in prostate cancer

ASCO GU 2022



- Able to administer up to high dose without severe adverse events
- Showed promising early clinical activity in heavily pre-treated patients with solid tumors
- Planning to present follow up data of Ph1/2 study at an upcoming conference

DS-7300, the fourth DXd-ADC, showed efficacy signal in Ph1.
The first clinical data was presented at ESMO

DS-7300: Future development plan

Ph1/2 study design

Dose escalation (Part 1)	Dose expansion (Part 2)

Advanced/unresectable or metastatic solid tumor
- Head and neck squamous cell carcinoma
- Esophageal squamous cell carcinoma
- Squamous NSCLC
- Adenocarcinoma NSCLC
- SCLC
- Sarcoma
- Endometrial cancer
- Melanoma
- Prostate cancer
- Breast cancer
- Bladder cancer

16.0 mg/kg
12.0 mg/kg
8.0 mg/kg
6.4 mg/kg
4.8 mg/kg
3.2 mg/kg
1.6 mg/kg
0.8 mg/kg

RDE

Cohort 1
ESCC

Cohort 2
CRPC

Cohort 3
Squamous NSCLC

Tumor type changed due to the initiation of SCLC Ph2

SCLC Ph2 study design

SCLC
2nd line

→ **Randomize 1:1**

N = 80

→ **DS-7300** 8mg/kg

→ **DS-7300** 12mg/kg

Endpoints: ORR, etc.

- **SCLC was selected based on Ph1 data**
- No effective treatment and high unmet need for SCLC 2nd line or later
- Study start planned in FY2022 H1

CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, NSCLC: non small cell lung cancer, ORR: objective response rate, SCLC: small cell lung cancer

Ph2 study is planned for SCLC to determine the optimal dose

DS-6000: Progress in FY2021

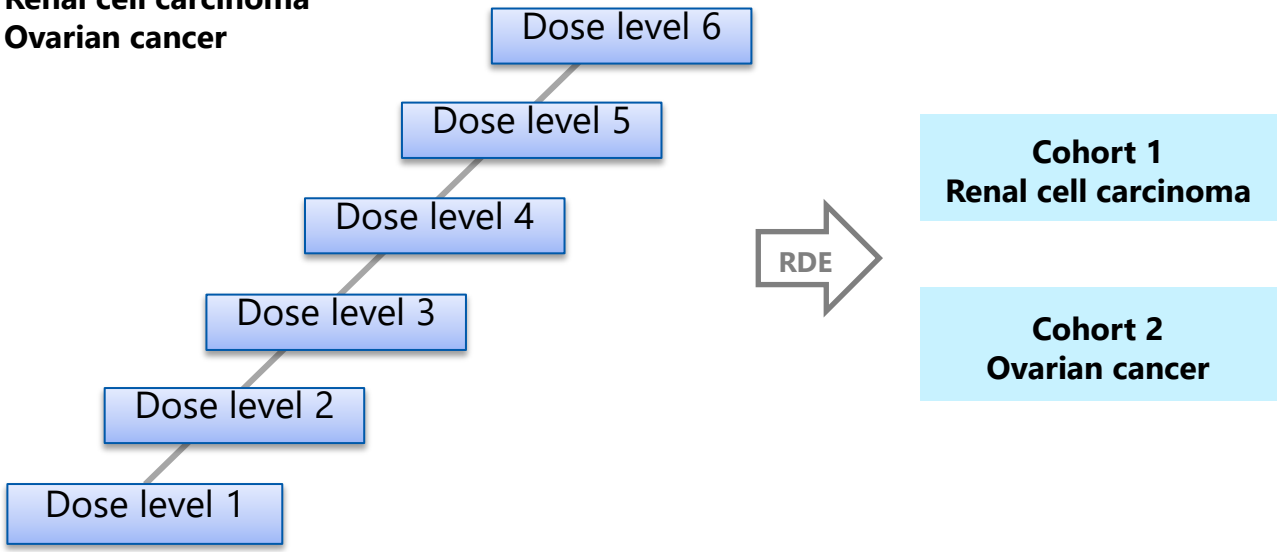
CDH6 (cadherin 6)

- Member of CDH family. The function of CDH6 is still to be fully elucidated. It is said to be related to cell-cell adhesion, epithelial to mesenchymal transition (EMT) and metastasis
- In developmental stage, CDH6 is expressed in kidney, endometrium, placenta and CNS, and minimal expression in adult normal tissues
- Highly expressed in renal cell carcinoma and ovarian cancer

Ph1 study design

Dose escalation (Part 1) | **Dose expansion (Part 2)**

Renal cell carcinoma
Ovarian cancer

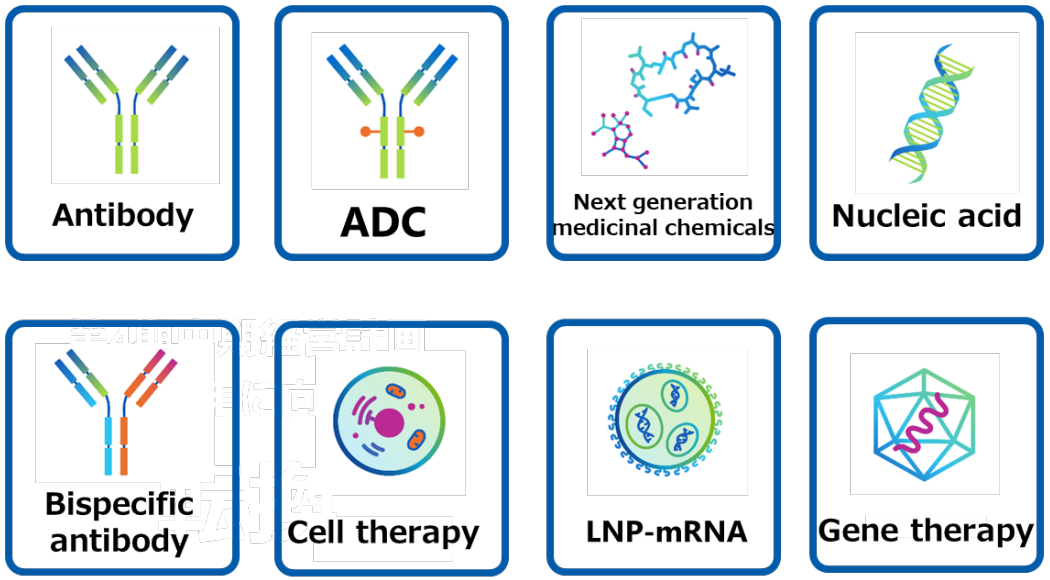


- Ph1 study started in Jan 2021, and dose expansion part is ongoing

Planning to present the first clinical data at ASCO

Select and advance promising post DXd-ADC modalities: Progress of FY2021

Optimized modality



High Unmet Medical Need

Daiichi Sankyo's multi-modality strategy

Establishment of LNP-mRNA technology advanced, built significant knowledge of development and manufacturing.

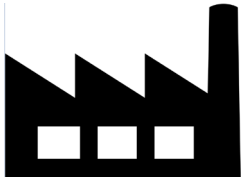
DS-5670: Progress in FY2021

FY2021		FY2022	
H1	H2	H1	H2

Ph1/2/3 booster vaccination (JP)

Ph1/2 study → **Dose setting Ph2**

Establishment of manufacturing system at DS Biotech



◆ Development of booster vaccination

- **Ph1/2/3 study** started in Jan 2022
- Commercialization is expected within CY2022

◆ Development of initial vaccination

- **Ph1/2 study** started in Mar 2021, **dose setting Ph2 study** started in Nov 2021
- **Ph3 study** plan is being continuously discussed with PMDA towards initiation of the study in FY2022 H1

Development of COVID-19 vaccine progressed,
and preparation for commercialization is ongoing

Other progress in FY2021

Oncology

Virus for cancer treatment

- **DELYTACT®** (Oncolytic virus)
  - Approved in JP for malignant glioma

Small molecule

- **Valemetostat** (EZH1/2 inhibitor)
  - Filed in JP for ATL/L
  - Started registrational Ph2 study for PTCL
  - Started Ph2 study for BCL
- **Quizartinib** (FLT3 inhibitor)
  - Obtained TLR of QuANTUM-First study
- **Pexidartinib** (CSF-1/KIT/FLT3 inhibitor)
  - Started Ph2 study in JP for tenosynovial giant cell tumor
- **DS-1594** (Menin-MLL binding inhibitor)
  - Started Ph1 study for AML/ALL

ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, BCL: B cell lymphoma, PTCL: peripheral T-cell lymphoma, TLR: top line results

Specialty Medicine

Small Molecule

- **LIXIANA®** (FXa inhibitor)
  - Approved in JP for additional dosage and administration of prevention of stroke, etc. in very elderly patients with atrial fibrillation
- **EFIENT®** (ADP receptor inhibitor)
  - Approved in JP for prevention of recurrence of ischemic stroke (restricted to cases with a high risk of ischemic stroke)
- **TARLIGE®** ($\alpha_2\delta$ ligand)
  - Approved in JP to change the indication to neuropathic pain

Antibody

- **DS-6016** (Anti-ALK2 antibody)
  - Started single dose Ph1 and obtained data for FOP
- **DS-7011** (Anti-TLR7 antibody)
  - Started Ph1 for systemic lupus erythematosus

Vaccine

- **VN-0200** (RS virus vaccine)
  - Started Ph1 study

FOP: fibrodysplasia ossificans progressiva

Consistently generated outcomes by multi-modality strategy

Progress towards “Maximize 3ADCs”

Progress towards “Identify and build pillars for further growth”

ASCO 2022

News Flow

ASCO Highlights 2022: IR conference call

Sunao Manabe
President and CEO

Ken Takeshita
Head of Global R&D

Gilles Gallant
Head of Global
Oncology Development

Date and time	Jun 8, 2022（Wed）7:30-9:00am JST
Meeting style	Virtual conference by Zoom

Content will be delivered on-demand after the meeting.

Progress towards “Maximize 3ADCs”

Progress towards “Identify and build pillars for further growth”

ASCO 2022

News Flow

FY2022 Future News Flow

As of Apr 2022

Planned major publications

ASCO (Jun 3-7, 2022)	
ENHERTU®	DESTINY-Breast03: HER2 positive BC, 2L, Ph3 • Safety data update DESTINY-Breast04: HER2 low BC, post chemo, Ph3 • Efficacy/safety data DESTINY-Breast07: HER2 positive BC, 1L/2L, Ph1b/2, combo • Initial efficacy/safety data DESTINY-Breast08: HER2 low BC, chemo naïve/post chemo, Ph1b, combo • Initial efficacy/safety data
HER3-DXd	Ph1: NSCLC • Data of cohort with no EGFR mutations Ph1/2: HER3 expressing BC • Efficacy/safety data
DS-6000	Ph1: Renal cell carcinoma/ovarian cancer • Interim data of dose escalation part

ESMO Breast Cancer (May 3-5, 2022)	
ENHERTU®	Ph1b: nivolumab combo • HER2 expressing BC cohort data
Dato-DXd	BEGONIA: TNBC, 1L, Ph1b/2, durvalumab combo • Initial efficacy/safety data

EHA (Jun 9-17, 2022)	
Quizartinib	QuANTUM-First: AML, 1L, Ph3 • Efficacy/safety data

BC: breast cancer, EHA: European Hematology Association

FY2022 Future News Flow

As of Apr 2022

Regulatory decisions

ENHERTU®	DESTINY-Breast03: HER2 positive BC, 2L, Ph3 • US/EU: FY2022 H1, JP: FY2022 H2 DESTINY-Breast04: HER2 low BC, post chemo, Ph3 • US: FY2022 H2 DESTINY-Gastric02: HER2 positive GC, 2L, Ph2 • EU: FY2022 H2 DESTINY-Lung01: HER2 mutated NSCLC, 2L, Ph2 • US: FY2022 H1
Quizartinib	QuANTUM-First: AML, 1L, Ph3 • JP/US: FY2022 H2
Valemetostat	Registrational Ph2: R/R ATL/L • JP: FY2022 H1

Key data readouts

ENHERTU®	DESTINY-Breast02: HER2 positive BC, 3L, Ph3 • FY2022 H1
Dato-DXd	TROPION-Lung01: NSCLC, 2/3L, Ph3 • FY2022 H2
DS-5670	Ph1/2/3: COVID-19 mRNA vaccine, booster • FY2022 H2

Planned regulatory submissions

ENHERTU®	DESTINY-Breast04: HER2 low BC, post chemo, Ph3 • JP/US/EU/CN: FY2022 H1
Quizartinib	QuANTUM-First: AML, 1L, Ph3 • JP/US/EU: FY2022 H1
DS-5670	Ph1/2/3: COVID-19 mRNA vaccine, booster • JP: FY2022 H2

Planned pivotal study initiation

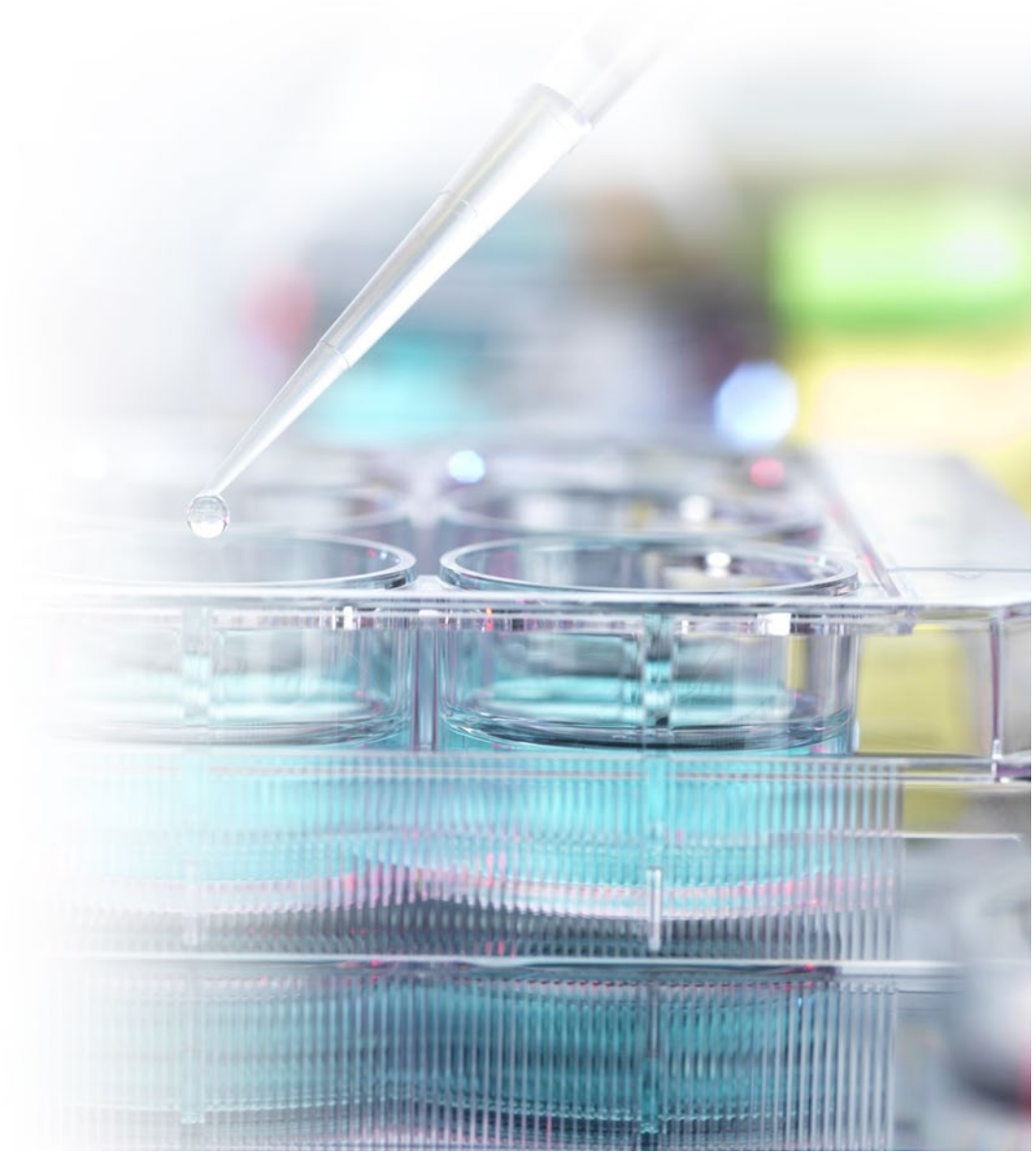
HER3-DXd	HERTHENA-Lung02: EGFR mutated NSCLC, 2L, Ph3 • FY2022 H1

AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, BC: breast cancer, GC: gastric cancer, NSCLC: non small cell lung cancer, R/R: relapsed/refractory

Timeline indicated is based on the current forecast and subject to change.

Agenda

1. FY2021 Financial Results
2. FY2022 Forecast
3. Business Update
4. R&D Update
5. **5-Year Business Plan Update**
6. Appendix



Strategic Pillars for the 5-Year Business Plan (FY2021-FY2025)

Daiichi-Sankyo

Achieve FY2025 Target and Shift to Further Growth

FY2025 Financial Targets

- Revenue: 1.6 Tr JPY (Oncology > 600.0 Bn JPY)
- Core Operating Profit Ratio before R&D Expense: 40%
- ROE > 16%
- DOE* > 8%

Maximize 3ADCs

- Maximize ENHERTU® and Dato-DXd through strategic alliance with AstraZeneca
- Maximize HER3-DXd without a partner
- Expand work force and supply capacity flexibly depending on changes around product potential

Profit growth for current business and products

- Maximize Lixiana® profit
- Grow Tarlige®, Nilemdo®, etc. quickly
- Transform to profit structure focused on patented drugs
- Profit growth for American Regent and Daiichi Sankyo Healthcare

Identify and build pillars for further growth

- Identify new growth drivers following 3ADCs
- Select and advance promising post DXd-ADC modalities

Create shared value with stakeholders

- Patients: Contributing to patients through "Patient Centric Mindset"
- Shareholders: Balanced investment for growth and shareholder returns
- Society: Environment load reduction across the value chain, and actions against pandemic risks
- Employees: Create one DS culture through fostering our core behaviors

- Data-driven management through DX, and company-wide transformation through advanced digital technology
- Agile decision making through new global management structure

*DOE: Dividend on Equity = Total dividend amount / Equity attributable to owners of the company

5-Year Business Plan: Progress in the First Year

Steady progress in each initiative especially for “Maximize 3ADCs”

Maximize 3ADCs

- **ENHERTU®: Increase of product value**
  - DB-03 (HER2+ BC 2L): achieve primary endpoints and submit in each region
  - DB-04 (HER2-low BC post-chemo): achieve primary endpoints
  - Steady revenue increase in each region
- **Dato-DXd, HER3-DXd: Progress of development**

Identify and build pillars for further growth

- **Emerging new growth drivers (Rising Stars) following 3ADCs**
  - Increase of product potential for DS-7300 (B7-H3 ADC) and DS-6000 (CDH6 ADC) by progresses of development
- **Advancement to select post DXd-ADC modalities**
  - Progress of technology establishment for LNP-mRNA

Profit growth for current business and products

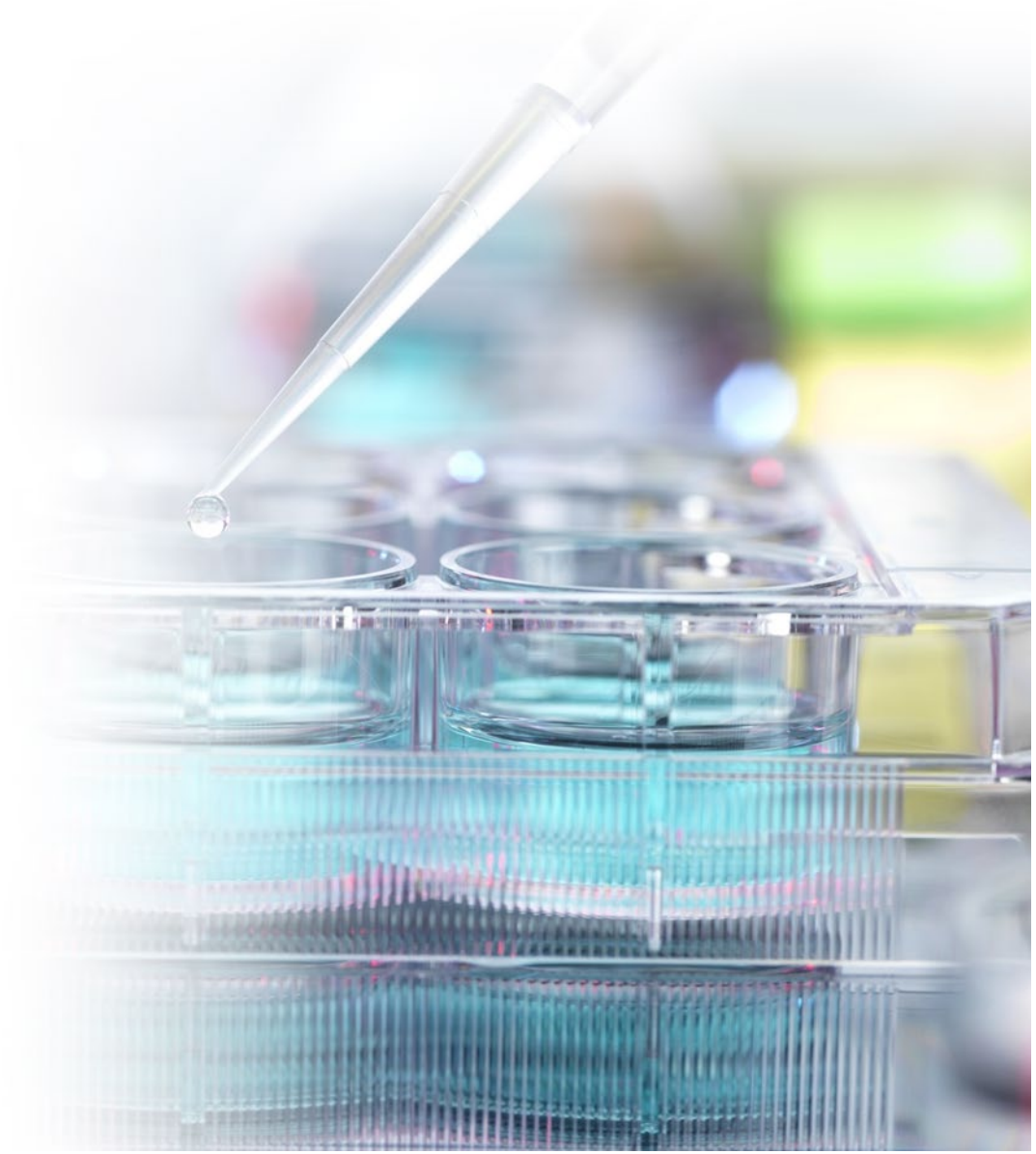
- **Growth of current products**
  - Steady revenue increases of Lixiana®, Injectafer, Tarlige®, Nilemdo® and others
- **Strengthening to transform business structure focused on patented drugs**
  - Progress of transformation by product divesture in each region

Create shared value with stakeholders

- **Progress initiative for environmental issues**
  - Joined RE100, a global initiative aiming to use 100% renewable energy for electricity consumed in business activities
- **Actions against pandemic risks**
  - DS-5670 (COVID-19 mRNA vaccine): Progress of development prioritizing booster injection

Agenda

1. FY2021 Financial Results
2. FY2022 Forecast
3. Business Update
4. R&D Update
5. 5-Year Business Plan Update
6. **Appendix**



Major R&D Milestones (3ADCs)

As of Apr 2022

Project		Target Indications [phase, study name]	FY2021 Q4	FY2022 H1	FY2022 H2	FY2023
ENHERTU®	BC	HER2+, 3L [P3, DESTINY-Breast02]		TLR anticipated		
		HER2+, 2L [P3, DESTINY-Breast03]	Filing accepted (CN)	Approval anticipated (US/EU)	Approval anticipated (JP)	
		HER2 low, post chemo [P3, DESTINY-Breast04]	TLR obtained	Filing anticipated (JP/US/EU/CN)	Approval anticipated (US)	Approval anticipated (JP/EU)
		HER2 low, chemo naive [P3, DESTINY-Breast06]				TLR anticipated
	GC	HER2+, 2L [P2, DESTINY-Gastric02、EU]			Approval anticipated (EU)	
	NSCLC	HER2 mutated, 2L [P2, DESTINY-Lung01]		Filing accepted (US) Approval anticipated (US)		
		HER2 mutated, 2L [P2, DESTINY-Lung05, CN]		Study start planned		
Dato-DXd	NSCLC	2/3L [P3, TROPION-Lung01]			TLR anticipated	
		w/o actionable genomic mutations, 1L, pembrolizumab combo [P3, TROPION-Lung08]	Study started			
HER3-DXd	NSCLC	EGFR mutated, 3L [Registrational P2, HERTHENA-Lung01]				TLR anticipated
		EGFR mutated, 2L [P3, HERTHENA-Lung02]		Study start planned		

Red underlined: new or updated from FY2021 Q3

BC: breast cancer, GC: gastric cancer, NSCLC: non small cell lung cancer, TLR: top line results

The timeline indicated is based on the current forecast and subject to change.

Major R&D Milestones (Alpha)

As of Apr 2022

Project	Target Indications [phase, study name, region]	FY2021 Q4	FY2022 H1	FY2022 H2	FY2023
DS-7300	SCLC, 2L [P2, JP/US/EU/Asia]		Study start planned		
Quizartinib	AML, 1L [P3, JP/US/EU/Asia]		Filing anticipated (JP/US/EU)	Approval anticipated (JP/US)	Approval anticipated (EU)
Valemetostat (DS-3201)	ATL/L [Registrational P2, JP]		Approval anticipated (JP)		
TARLIGE®	Central neuropathic pain [P3, JP]	Approved (JP)			
DS-7011	Systemic lupus erythematosus [P1, US]	Study started			
DS-5670	COVID-19 mRNA vaccine, booster [P1/2/3, JP]	Study started		TLR anticipated Filing anticipated (JP)	

Red underlined: new or updated from FY2021 Q3

TLR: Top Line Results

The timeline indicated is based on the current forecast and subject to change.

Major R&D Pipeline: 3ADCs

As of Apr 2022

Phase 1		Phase 2	Phase 3	Filed
(US/EU/Asia) HER2+ BC 2L~/1L DESTINY-Breast07	(JP/US) NSCLC, TNBC, HR+ BC, SCLC, urothelial, GC, esophageal TROPION-PanTumor01	(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
(US/EU/Asia) HER2 low BC chemo naïve/ post chemo DESTINY-Breast08	(JP/US/EU/Asia) NSCLC (w/o actionable mutation, pembrolizumab combo) TROPION-Lung02	(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/Asia) HER2+ GC combo, 2L~/1L DESTINY-Gastric03	(JP/US/EU) NSCLC (w/o actionable mutation, durvalumab combo) TROPION-Lung04	(JP/US/EU)HER2+/mutated NSCLC 2L~ DESTINY-Lung01	(JP/US/EU/Asia) HER2+ BC post neoadjuvant DESTINY-Breast05	(US) HER2 mutated NSCLC 2L~ DESTINY-Lung01
(EU/Asia)HER2+ NSCLC (durvalumab combo) 1L DESTINY-Lung03	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) HER2 mutated NSCLC 2L~ DESTINY-Lung02	(JP/US/EU/Asia) HER2 low BC chemo naive DESTINY-Breast06	
(US/EU) BC, bladder (nivolumab combo)	(JP/US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(CN) HER2 mutated NSCLC 2L~ DESTINY-Lung05	(JP/US/EU/Asia)HER2+ BC 1L DESTINY-Breast09	
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU/Asia) NSCLC	(US/EU/Asia) NSCLC (durvalumab combo) 2L~ HUDSON	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	
(US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US)EGFR mutated NSCLC (osimertinib combo)	(JP/US/EU) HER2+ CRC 3L DESTINY-CRC01	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	
	(JP/US) HER3+ BC	(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/US/EU/Asia) NSCLC 1L (w/ exon 19 or exon 20 mutation) DESTINY-Lung04	
		(JP/US/EU/Asia) HER2 mutated tumor DESTINY-PanTumor01	(JP/US/EU/Asia) NSCLC 2/3L TROPION-Lung01	
		(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02	(JP/US/EU/Asia) HR+ BC 2/3L TROPION-Breast01	
		(JP/US/EU/Asia) NSCLC (w/ actionable mutation) TROPION-Lung05	(JP/US/EU/Asia) NSCLC (w/o actionable mutation, pembro combo) TROPION-Lung08	
		(JP/US/EU/Asia) EGFR mutated NSCLC 3L HERTHENA-Lung01	(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02	

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 Apr 2022

Phase 1		Phase 2	Phase 3	Filed
DS-7300 (JP/US) B7-H3-directed ADC ESCC, CRPC, squamous NSCLC, etc.	**PLX2853** (US) BET inhibitor AML	**Valemetostat (DS-3201)** (JP/US/EU/Asia) EZH1/2 inhibitor PTCL	**Quizartinib** (JP/US/EU/Asia) FLT3 inhibitor 1L AML	**Valemetostat (DS-3201)** (JP) EZH1/2 inhibitor ATL/L
DS-6000 (US) CDH6-directed ADC Renal cell carcinoma, ovarian cancer	**PLX2853** (US) BET inhibitor Solid tumor	**Valemetostat (DS-3201)** (EU) EZH1/2 inhibitor BCL	**Pexidartinib** (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	**VN-0107/MEDI3250** (JP) Live attenuated influenza vaccine nasal spray
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	**PLX2853** (US) BET inhibitor Gynecologic neoplasms, ovarian cancer	**DS-1001** (JP) Mutant IDH1 inhibitor Glioma	**Minnebro** (JP) MR blocker Diabetic nephropathy	
DS-1211 (US) TNAP inhibitor Pseudoxanthoma elasticum	**PLX2853** (US) BET inhibitor Prostate cancer	**DS-7300** (JP/US/EU/Asia) B7-H3-directed ADC SCLC	**VN-0102/JVC-001** (JP) Measles mumps rubella combined vaccine	
DS-6016 (JP) Anti-ALK2 antibody Fibrodysplasia ossificans progressiva	**DS-1594** (US) Menin-MLL binding inhibitor AML, ALL	**DS-5141** (JP) ENA oligonucleotide DMD	**DS-5670** (JP) SARS-CoV-2 mRNA vaccine COVID-19 (booster vaccination)	
DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus	**VN-0200** (JP) RS virus vaccine RS virus infection	**DS-5670** (JP) SARS-CoV-2 mRNA vaccine COVID-19 (initial vaccination)		

Oncology
Specialty medicine
Vaccine

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, FOP: Fibrodysplasia ossificans progressive, LBCL: large B cell lymphoma, NSCLC: non small cell lung cancer, 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