

FY2020 Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Sunao Manabe
President and CEO

April 27, 2021

Forward-Looking Statements

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Agenda

- ① **FY2020 Financial Results**
- ② FY2021 Forecast
- ③ Business Update
- ④ R&D Update
- ⑤ Actions against COVID-19 Update
- ⑥ Appendix



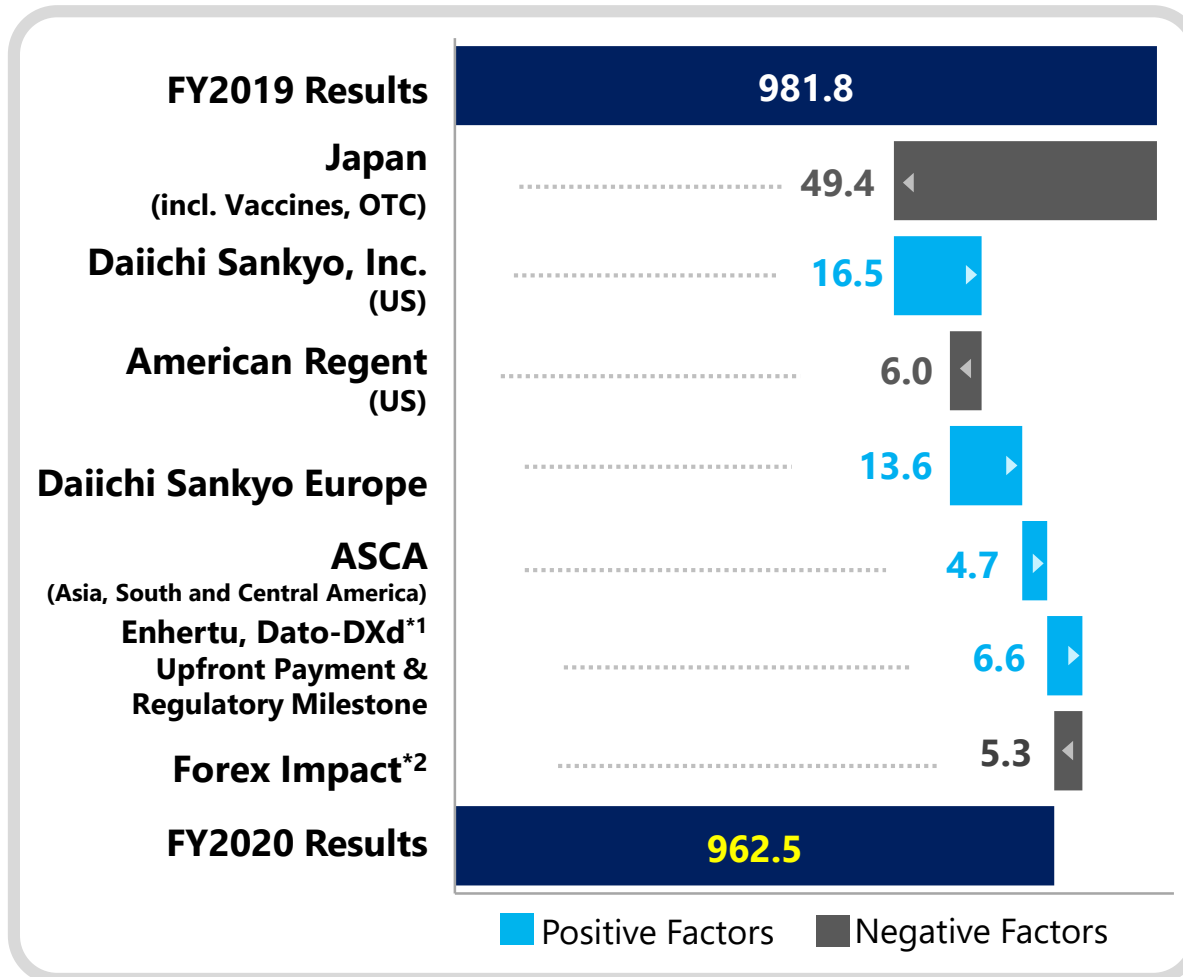
Overview of FY2020 Results

(Bn JPY)

		FY2019 YTD Results	FY2020 YTD Results	YoY
Revenue		981.8	962.5	-2.0% -19.3
Cost of sales		343.2	338.3	-4.9
SG&A expenses		302.3	333.1	30.8
R&D expenses		197.5	227.4	29.9
Operating Profit		138.8	63.8	-54.0% -75.0
Profit before tax		141.2	74.1	-67.0
Profit attributable to owners of the Company		129.1	76.0	-41.2% -53.1
Currency	USD/JPY	108.75	106.06	-2.69
Rate	EUR/JPY	120.83	123.70	+2.87

Decreased by 19.3 Bn JPY (Decreased by 14.0 Bn JPY excl. forex impact)

(Bn JPY)



Positive Factors	Negative Factors
Japan	
Tarlige +12.6	Memary -32.1
Enhertu +4.4	Inavir -15.6
	Lixiana -5.6
Daiichi Sankyo Espha +10.9	Vaccines business -17.1
Memantine AG, Ezetimibe AG etc.	ActHIB
	Daiichi Sankyo Healthcare -1.3
	Lulu
Daiichi Sankyo, Inc. (US)	
Enhertu +23.2	Welchol -4.0
American Regent (US)	
	Injectafer -6.6
Daiichi Sankyo Europe	
Lixiana +13.2	Olmesartan -3.6
Gain on sales of transferring long-listed products +4.5	
Enhertu, Dato-DXd*1 Upfront Payment & Regulatory Milestone	
Dato-DXd upfront payment +3.9	
Enhertu Regulatory Milestone +2.6	

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

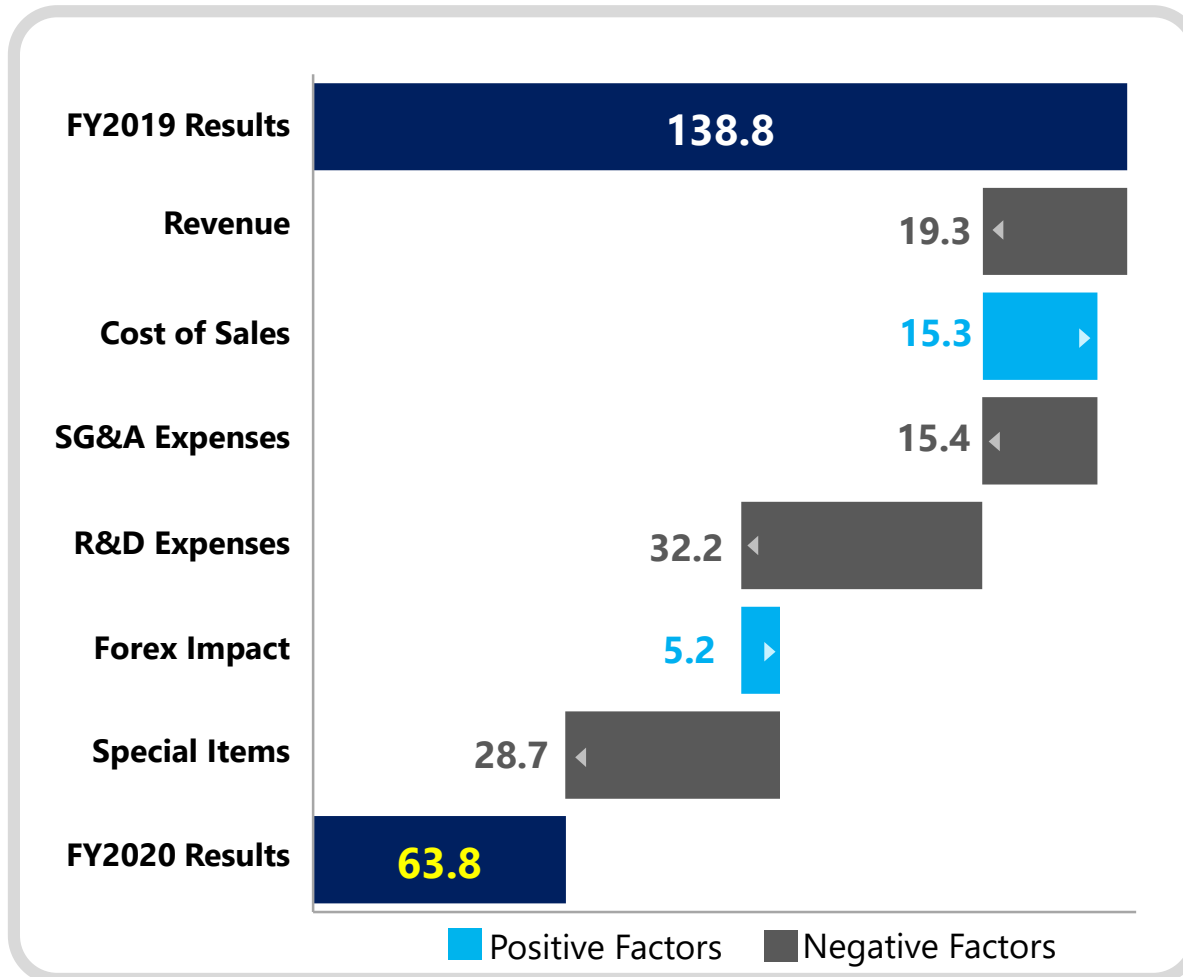
*2 Forex impact USD: -4.5, EUR: +2.6, ASCA: -3.4

Operating Profit

Decreased by 75.0 Bn JPY

(Decreased by 46.3 Bn JPY excl. forex impact and special items)

(Bn JPY)



Revenue -19.3

incl. forex impact of -5.3

Cost of Sales -15.3 (Profit increased)

Decrease by revenue decrease

SG&A Expenses +15.4 (Profit decreased)

Increase in Enhertu related expenses
(including sales promotion expenses and profit share with AstraZeneca)

R&D Expenses +32.2 (Profit decreased)

- Increase in 3ADCs* R&D investments
- Increase due to oncology development structure enhancement

Forex Impact -5.2 (Profit increased)

Cost of Sales -0.8

SG&A Expenses -2.1

R&D Expenses -2.3

Special Items +28.7 (Profit decreased)

See next slide for details

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

Special Items

(Bn JPY)			
	FY2019 YTD Results	FY2020 YTD Results	YoY
Cost of sales	Restructuring costs in SC	1.3	11.2
	Impairment loss (intangible assets) ^{*1}	6.3	
	Gain on sales of subsidiary ^{*2}	-18.8	
SG&A expenses	Gain on sales of fixed assets ^{*3}	-10.6	17.4
	Environmental expenditures ^{*4}	8.2	
R&D expenses	-	-	-
Total	-13.7	15.0	28.7

*1 Morphabond, Roxybond, Zelboraf

*2 Takatsuki Plant

*3 Nihonbashi Building

*4 Former Yasugawa Plant

Booked in Q4

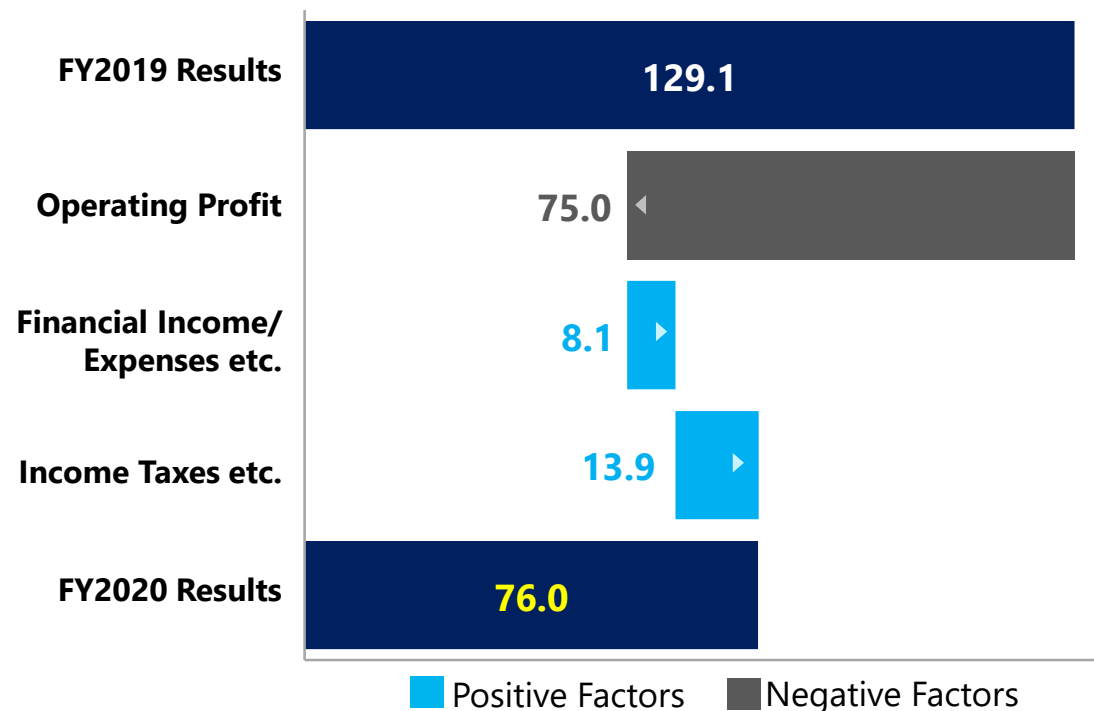
Special items :

Items having a transitory and material impact on operating profit are defined as "Special items". Specifically, gains and losses related to: sale of fixed assets, restructuring, impairment, litigation, etc. amounting to 1 billion JPY or more are defined as "Special items".

Profit Attributable to Owners of the Company

Decreased by 53.1 Bn JPY

(Bn JPY)



Financial Income / Expenses etc. -8.1 (Profit increased)

- Recognition of financial income due to decrease in contingent consideration of Ambit/quizartinib acquisition -4.7
- Improvement in forex gains/losses -3.6

Income Taxes etc. -13.9 (Profit increased)

	FY2019	FY2020	YoY
Profit before Tax	141.2	74.1	-67.0
Income Taxes etc.	12.2	-1.7	-13.9
Tax rate	8.6%	-2.3%	-

(Reference: Tax rate)

FY2019: Impact of introduction of consolidated taxation system

FY2020: Decrease in Income taxes due to an increase in DTA attributable to future expected taxable income increase of 3ADCs

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2019 YTD Results	FY2020 YTD Results	YoY
Japan	533.5	489.1	-44.4
Daiichi Sankyo Healthcare	68.5	67.2	-1.3
Daiichi Sankyo, Inc.	32.1	47.4	+15.3
Enhertu	3.2	25.7	+22.5
Olmesartan	9.8	8.6	-1.3
Welchol	9.1	5.0	-4.1
American Regent, Inc.	130.8	121.7	-9.1
Injectafer	51.8	44.1	-7.7
Venofer	31.0	28.8	-2.2
GE injectables	41.2	41.8	+0.6
Daiichi Sankyo Europe	95.5	111.7	+16.1
Lixiana	61.7	76.7	+15.0
Olmesartan	24.6	21.5	-3.1
Efient	2.5	1.6	-0.9
ASCA (Asia, South and Central America)	98.3	99.7	+1.3

Currency	USD/JPY	108.75	106.06	-2.69
Rate	EUR/JPY	120.83	123.70	+2.87

Revenue: Major Products in Japan

(Bn JPY)

		FY2019 YTD Results	FY2020 YTD Results	YoY
Nexium	ulcer treatment	79.8	77.8	-1.9
Lixiana	anticoagulant	83.0	77.4	-5.6
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	30.9	34.6	+3.7
Memary	Alzheimer's disease treatment	50.5	18.4	-32.1
Tenelia	type 2 diabetes mellitus treatment	24.7	24.2	-0.5
Loxonin	anti-inflammatory analgesic	28.3	24.2	-4.1
Ranmark	treatment for bone complications caused by bone metastases from tumors	17.9	19.3	+1.4
Inavir	anti-influenza agent	19.3	3.6	-15.6
Tarlige	pain treatment	8.0	20.6	+12.6
Canalia	type 2 diabetes mellitus treatment	12.8	15.4	+2.6
Vimpat	anti-epileptic agent	11.2	14.5	+3.4
Efient	antiplatelet agent	14.0	14.1	+0.1
Rezaltas	antihypertensive agent	14.6	13.1	-1.5
Olmetec	antihypertensive agent	11.7	9.2	-2.4
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	-	4.4	+4.4

① FY2020 Financial Results

② **FY2021 Forecast**

③ Business Update

④ R&D Update

⑤ Actions against COVID-19 Update

⑥ Appendix



FY2021 Forecast

(Bn JPY)

	FY2020 Results	FY2021 Forecast	YoY	
Revenue	962.5	990.0	+2.9%	27.5
Cost of sales*	337.8	320.0		-17.8
SG&A expenses*	318.5	334.0		15.5
R&D expenses*	227.4	266.0		38.6
Core Operating Profit*	78.9	70.0	-11.2%	-8.9
Other revenue*	0.6	-		-0.6
Other expenses*	15.6	-		-15.6
Operating Profit	63.8	70.0	+9.7%	6.2
Profit before tax	74.1	70.0		-4.1
Profit attributable to owners of the Company	76.0	50.0	-34.2%	-26.0
Currency	USD/JPY	106.06	105.00	-1.06
Rate	EUR/JPY	123.70	120.00	-3.70

Revenue

Increase factor ↑ Sales expansion of main products (Enhertu, Lixiana, Tarlige, etc.)

Decrease Factor ↓ Termination of joint sales promotion for Nexium, Drug price revision

Cost of sales

Improvement in cost of sales ratio by change in product mix

SG&A expenses

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

R&D expenses

Increase in 3ADCs R&D investments

Other revenue

FY2020: Vaccine business loss compensation

Profit before tax

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

Profit attributable to owners of the Company

FY2020: Decrease in income taxes due to an increase in DTA attributable to future expected taxable income increase related to 3ADCs

COVID-19 Impact

Certain activity restrictions are expected to continue during FY2021, however impact on operating profit is expected to be minor

*As an indicator of ordinary profitability, "core operating profit" which excludes temporary gains and losses (other revenue and other expenses) from operating income is disclosed.

Gains and losses 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 gains and losses".

Temporary gains and losses are excluded from results and forecast for cost of sales, SG&A expenses and R&D expenses shown in the list above.

① FY2020 Financial Results

② FY2021 Forecast

③ **Business Update**

④ R&D Update

⑤ Actions against COVID-19 Update

⑥ Appendix



ENHERTU

Initiatives for Business Growth in Each Region

EDOXABAN

Streamlining Assets

Shareholder Returns

ENHERTU®: Initiatives to Maximize Value

- ◆ Steady expansion in market and indication
- ◆ Product sales: FY2020 results **30.1 Bn JPY** , FY2021 forecast **69.4 Bn JPY**



HER2+ Breast Cancer 3rd Line

- **US**
Launched in January 2020^{*1}
- **JP**
Launched in May 2020^{*2}
- **EU**
Approved in January 2021^{*3}
Launched in February 2021
- **UK**
Approved in February 2021^{*3}



HER2+ Gastric Cancer 3rd Line

- **JP**
Approved in September 2020^{*4}

HER2+ Gastric Cancer 2nd Line

- **US**
Approved in January 2021^{*5}

Underline: Progress in FY2020

*1 Treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti HER2 based regimens in the metastatic setting

*2 Treatment of patients with HER2 positive unresectable or recurrent breast cancer after prior chemotherapy (limit the use to patients who are refractory or intolerant to standard treatments)

*3 Treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti HER2 based regimens

*4 Treatment of patients with HER2 positive unresectable advanced or recurrent gastric cancer that has progressed after chemo therapy

*5 Treatment of adult patients with locally advanced or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab based regimen

ENHERTU®: Revenue

(Bn JPY)

	FY2020 Results	FY2021 Forecast		<Reference> Total Consideration
			YoY	
Product Sales	30.1	69.4	+39.3	-
Japan	4.4	13.4	+9.0	-
US	25.7	50.4	+24.7	-
Europe	0.0	5.4	+5.4	-
ASCA	-	0.2	+0.2	-
Upfront payment	9.8^{*1}	9.8^{*1}	-	149.0
Regulatory milestone payment	3.5^{*1}	4.8^{*1}	+1.3	34.6
US HER2+ Breast Cancer 3L	0.9	0.9	-	13.7
EU HER2+ Breast Cancer 3L	1.0	0.5	-0.5	7.9
US HER2+ Gastric Cancer 2L + 3L	1.6	0.8	-0.8	12.1
US HER2+ or HER2 Mutant NSCLC 2L	-	2.6	+2.6	13.1^{*2}
Total	43.5	84.0	+40.6	183.6

*1 Revenue recognized in each period

*2 Expected consideration based on the assumption of achieving milestones in FY2021

ENHERTU

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EDOXABAN

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Initiatives for Business Growth in Each Region

Initiatives to strengthen the product portfolio and maximize product value are progressing steadily

Japan

- ◆ Prophylaxis of migraine attacks
EMGALITY®
 - **Launched** in Apr. 2021
- ◆ Treatment for large B cell lymphoma
YESCARTA®
 - **Approved** in Jan. 2021,
Listed in NHI price listing in Apr. 2021
- ◆ Anti-epileptic agent
VIMPAT®
 - **New indication*** approved in Dec. 2020

*1 Combination therapy for tonic-clonic seizure in patients with epilepsy

Europe

- ◆ Cholesterol lowering treatment
NILEMDO® and **NUSTENDI®**
 - **Launched** in Nov. 2020

ASCA*2

- ◆ Anticoagulant
LIXIANA (里先安®)
 - **Listed in National Reimbursement Drug List (NRDL) in China** in Dec. 2020 (**Applied** from Mar. 2021)

*2 Asia, South & Central America

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Initiatives for Business Growth in Each Region

EDOXABAN

Streamlining Assets

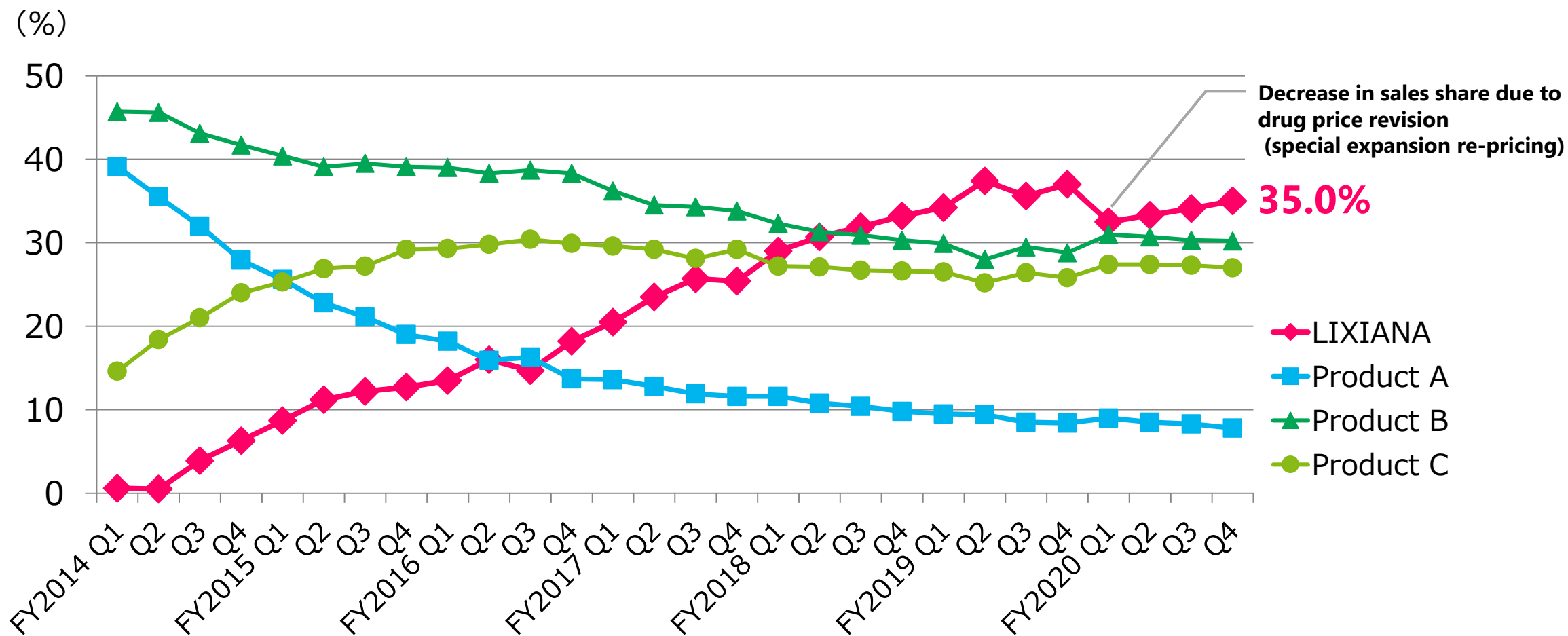
Shareholder Returns

LIXIANA®: Growth in Japan

Sales



- ◆ No.1 sales share (FY2020 Q4: **35.0%**)
- ◆ Revenue FY2020 results: **77.4 Bn JPY** (YoY **-5.6 Bn JPY**, Previous drug price base YoY **+20.2 Bn JPY**)
FY2021 forecast: **90.4 Bn JPY** (YoY **+13.0 Bn JPY**)

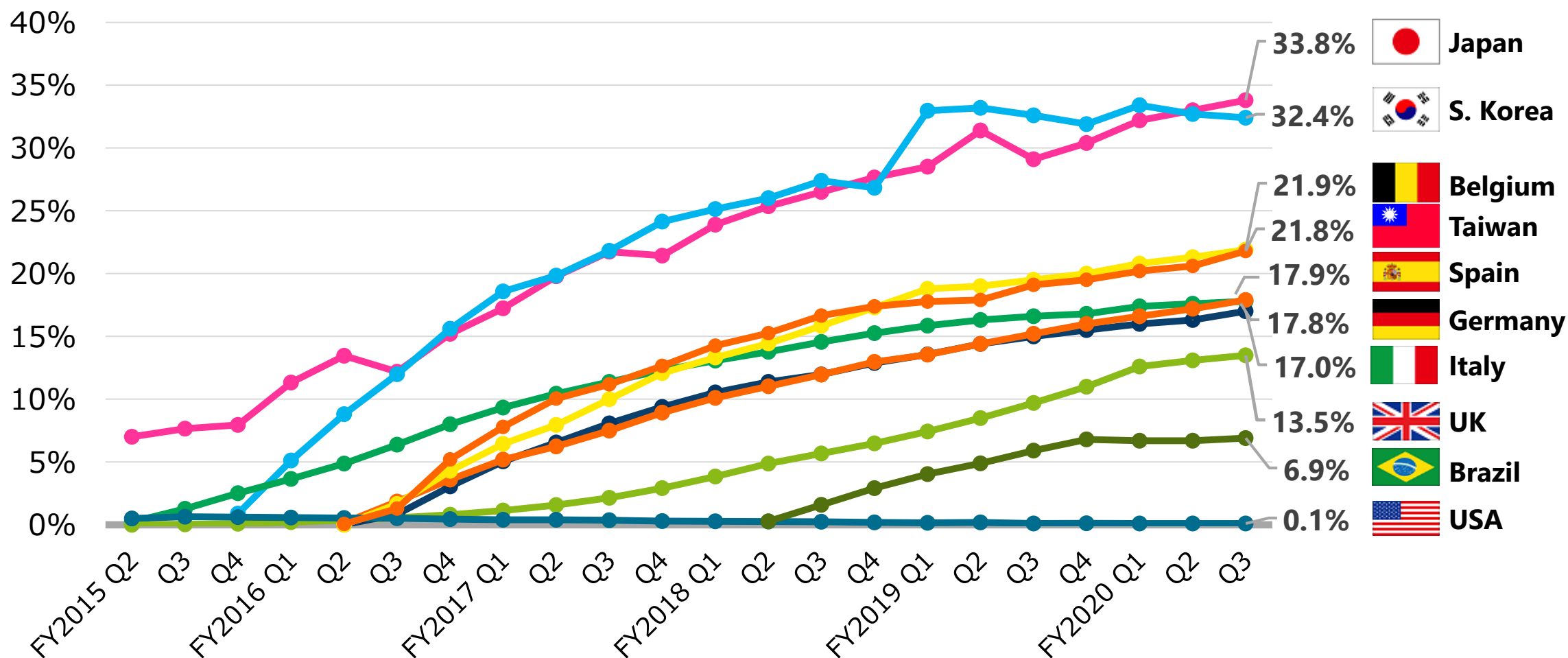


EDOXABAN: Growth in Each Country

Volume



Global revenue FY2020 results: 165.9 Bn JPY (YoY +11.9 Bn JPY)
FY2021 forecast: 188.4 Bn JPY (YoY +22.4 Bn JPY)



ENHERTU

Initiatives for Business Growth in Each Region

EDOXABAN

Streamlining Assets

Shareholder Returns

Cash Generation by Streamlining Assets

During the 5-Year Business Plan period (FY2016 -FY2020), generated cash of **163.2 Bn JPY by streamlining assets**

		FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results	FY2020 Results	Total
Reduce cross-shareholding shares	Sales proceeds (# of Brands)	17.3 Bn JPY (14 Brands)	14.4 Bn JPY (9 Brands)	14.3 Bn JPY (10 Brands)	22.0 Bn JPY (12 Brands)	2.5 Bn JPY (6 Brands)	70.5 Bn JPY (51 Brands)
	Gain on sales*1	9.3 Bn JPY	9.8 Bn JPY	10.6 Bn JPY	14.4 Bn JPY	1.1 Bn JPY	45.3 Bn JPY
Sale of properties	Sales proceeds	3.2 Bn JPY	10.7 Bn JPY	11.0 Bn JPY	14.0 Bn JPY	0.3 Bn JPY	39.2 Bn JPY
	Gain on sales	0.8 Bn JPY	7.6 Bn JPY	9.0 Bn JPY	10.7 Bn JPY	0.1 Bn JPY	28.1 Bn JPY
Gain on sales of business transfer	Sales proceeds	1.5 Bn JPY	-	10.4 Bn JPY	37.1 Bn JPY	4.5 Bn JPY	53.5 Bn JPY
	Gain on sales	0.1 Bn JPY*2	-	6.3 Bn JPY*3	19.1 Bn JPY*4	5.9 Bn JPY*5	31.3 Bn JPY

*1 Booked in other comprehensive income *2 Bethlehem plant in US *3 Long-listed products (JP) *4 Takatsuki plant, Long-listed products (JP)

*5 Long-listed products (JP/EU)

ENHERTU

Initiatives for Business Growth in Each Region

EDOXABAN

Streamlining Assets

Shareholder Returns

Shareholder Returns

- ◆ By dividends increase and own shares acquisition, **achieved total return ratio of 105.6% for the 5-year business plan period (FY2016 – FY2020)**
- ◆ Cancelled own shares in April 2021

Dividends

- Dividend per share for FY2020 (Pre-split base^{*1}): **81 JPY** (vs FY2019: **11 JPY increase**)

Acquisition of own shares

- Acquisition period: **November 2, 2020 – March 12, 2021**
- Aggregate amount of acquisition cost: **100.0 Bn JPY**
- Total number of shares acquired: **29.47 Mn shares**

Cancellation of own shares

- Cancellation date: **April 15, 2021**
- Number of shares cancelled: **180 Mn shares**
(Cancelled except for the number of shares to be used for stock option and restricted share-based remuneration)
ref. ratio of own shares to total number of issued shares after cancellation 1.6%

Total return ratio during the 5-year business plan period (FY2016 - FY2020)

	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results	FY2020 Results
Dividend per share ^{*1}	70 JPY	70 JPY	70 JPY	70 JPY	81 JPY
Acquisition of own shares	50.0 Bn JPY	50.0 Bn JPY	-	-	100.0 Bn JPY
Total return ratio ^{*2}	180.7%	159.1%	48.5%	35.1%	200.3%
	105.6%				

* 1 Pre-split base (Share split, three-for-one (effective date: Oct. 1, 2020))

* 2 Total return ratio = (Dividends + Total acquisition costs of own shares) / Profit attributable to owners of the company

① FY2020 Financial Results

② FY2021 Forecast

③ Business Update

④ **R&D Update**

⑤ Update of Actions against COVID-19

⑥ Appendix



Major progress in FY2020

ASCO 2021

News Flow

3ADCs: Major Progress of Enhertu® in FY2020

HER2 positive BC	<ul style="list-style-type: none"> Started DESTINY-Breast05 study (post neoadjuvant, Ph3), among high risk, early breast cancer patients Started DESTINY-Breast07 study (1/2L, Ph1b/2, combo), a fundamental study for development in earlier treatment lines
HER2 low BC	<ul style="list-style-type: none"> Started DESTINY-Breast06 & DESTINY-Breast08 studies aiming for earlier treatment lines <ul style="list-style-type: none"> ➤ DESTINY-Breast06: chemo naive, Ph3 ➤ DESTINY-Breast08: chemo naive/post chemo, Ph1b, combo
HER2 negative BC	<ul style="list-style-type: none"> Newly added Enhertu cohort in AstraZeneca-led BEGONIA study (TNBC, 1L, Ph1b/2, durvalumab combo)

BC: breast cancer, TNBC: triple negative breast cancer

Started 5 studies including earlier treatment lines, regardless of HER2 expression level

3ADCs: Major Progress of Enhertu® in FY2020

GC	<ul style="list-style-type: none"> Started DESTINY-Gastric03 study (1/2L, Ph1b/2, combo), a fundamental study for development in early treatment lines
NSCLC	<ul style="list-style-type: none"> Started DESTINY-Lung02 study (HER2 mutated NSCLC, 2L+, Ph2) for further evaluation of dose (5.4mg/kg) Newly added Enhertu cohort in AstraZeneca-lead HUDSON study (NSCLC, 2L+, Ph2, durvalumab combo)
Other cancers	<ul style="list-style-type: none"> Started DESTINY-CRC02 study (HER2+ CRC, 3L, Ph2) for further data accumulation and confirmation of optimal dose (5.4 or 6.4mg/kg) Started two basket studies, DESTINY-PanTumor01 & DESTINY-PanTumor02 studies, for further expansion of cancer types <ul style="list-style-type: none"> ➤ DESTINY-PanTumor01: HER2 mutated cancers, Ph2 ➤ DESTINY-PanTumor02: HER2 expressing cancers, Ph2

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

**Started 6 studies in broad cancer types,
also aiming for earlier treatment lines**

3ADCs: Major Progress of Dato-DXd in FY2020

NSCLC (w/o actionable mutation)	<ul style="list-style-type: none">◆ Started TROPION-Lung01 study (2/3L, global Ph3), the first pivotal study for Dato-DXd
NSCLC (w/ actionable mutation)	<ul style="list-style-type: none">◆ Started TROPION-Lung02 & TROPION-Lung04 studies aiming for earlier treatment lines (1/2L)<ul style="list-style-type: none">➤ TROPION-Lung02: Ph1, pembrolizumab combo ± Pt chemo➤ TROPION-Lung04: Ph1, durvalumab combo ± Pt chemo
HER2 negative BC	<ul style="list-style-type: none">◆ Newly added two cohorts (TNBC & HR+) in TROPION-PanTumor01 study. Enrollment of TNBC cohort is completed.

NSCLC: non-small cell lung cancer, TNBC: triple negative breast cancer

Significant progress in the development of NSCLC and TNBC, also aiming for earlier treatment lines

3ADCs: Major Progress of HER3-DXd in FY2020

NSCLC	<ul style="list-style-type: none">◆ Started HERTHENA-Lung01 study, the first pivotal study for HER3-DXd<ul style="list-style-type: none">➤ EGFR mutated NSCLC 3L, pivotal global Ph2
	<ul style="list-style-type: none">◆ Started preparation for Ph1 study in combination with osimertinib, aiming for earlier treatment lines<ul style="list-style-type: none">➤ EGFR mutated NSCLC 1/2L, global Ph1
CRC	<ul style="list-style-type: none">◆ Started global Ph2 study in CRC 3L

CRC : colorectal cancer, NSCLC: non-small cell lung cancer

Significant progress in the development of EGFR mutated NSCLC, also progress in other cancer types

3ADCs: Major presentations at conferences in FY2020

ASCO

Enhertu[®]

- ◆ **DESTINY-Lung01**
(HER2 mt NSCLC, 2L, Ph2)
- ◆ **DESTINY-Gastric01**
(HER2 positive GC, 3L, Ph2)
- ◆ **DESTINY-CRC01**
(HER2 positive CRC, 3L, Ph2)

Dato-DXd

- ◆ **TROPION-PanTumor01**
(NSCLC cohort, Ph1)

ESMO

Enhertu

- ◆ **DESTINY-Gastric01**
(HER2 positive GC, 3L, Ph2)
HER2 low exploratory cohort

HER3-DXd

- ◆ **EGFR mt NSCLC, Ph1**

SABCS

Enhertu

- ◆ **DESTINY-Breast01**
(HER2 positive BC, 3L, Ph2)
- ◆ **HER2 positive BC, Ph1, nivolumab combo**

HER3-DXd

- ◆ **BC, Ph1/2**

WCLC

Enhertu

- ◆ **DESTINY-Lung01**
(HER2 overexpressing NSCLC, 2L, Ph2)

Dato-DXd

- ◆ **TROPION-PanTumor01**
(NSCLC cohort, Ph1)

HER3-DXd

- ◆ **EGFR mt NSCLC, Ph1**

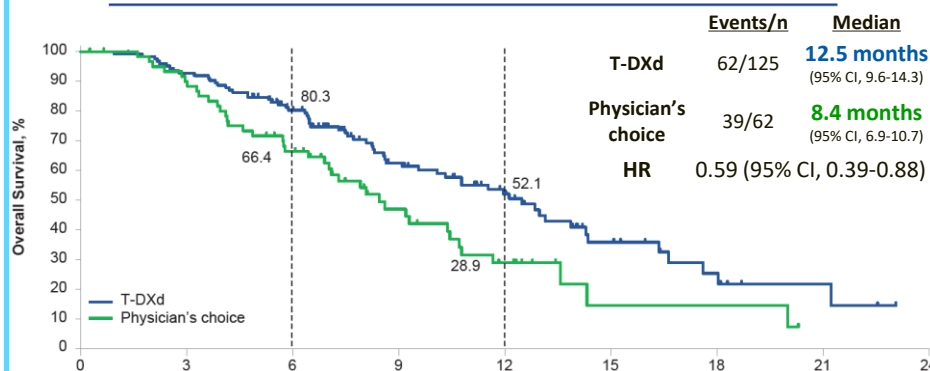
The number of presentations exceeded FY2019, reflecting the progress of development

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

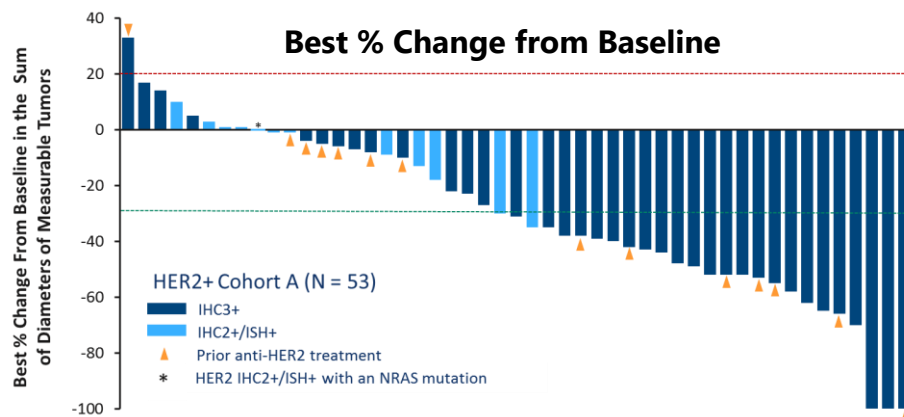


DESTINY-Gastric01 data @ASCO 2020

	T-DXd (n = 119)	PC (n = 56)
ORR by ICR (CR + PR)	51.3% (n = 61) 95% CI, 41.9-60.5; P < .0001	14.3% (n = 8) 95% CI, 6.4-26.2
Confirmed ORR by ICR (CR + PR)	42.9% (n = 51) 95% CI, 33.8-52.3	12.5% (n = 7) 95% CI, 5.2-24.1
CR	8.4% (n = 10)	0
PR	34.5% (n = 41)	12.5% (n = 7)
SD	42.9% (n = 51)	50.0% (n = 28)
PD	11.8% (n = 14)	30.4% (n = 17)
Not evaluable	2.5% (n = 3)	7.1% (n = 4)
Confirmed DCR (CR + PR + SD)	85.7% (n = 102) 95% CI, 78.1-91.5	62.5% (n = 35) 95% CI, 48.5-75.1
Median confirmed DOR	11.3 months 95% CI, 5.6-NE	3.9 months 95% CI, 3.0-4.9



DESTINY-CRC01 data @ASCO 2020

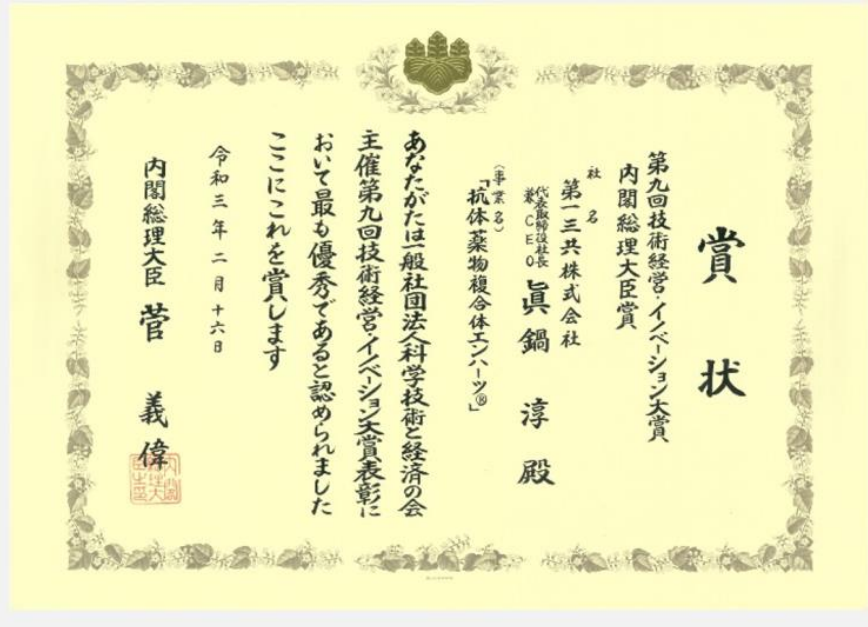


HER2+ Cohort A (N = 53)

Confirmed ORR by ICR	45.3% (n = 24) (95% CI, 31.6%-59.6%)
CR	1.9% (n = 1)
PR	43.4% (n = 23)
SD	37.7% (n = 20)
PD	9.4% (n = 5)
Not evaluable	7.5% (n = 4) ^a
Disease control rate	83.0% (95% CI, 70.2%-91.9%)
Duration of response, median	Not reached (95% CI, 4.2 months-NE)

Enhertu® DESTINY-Gastric01/CRC01 data were selected as ASCO 2021 Advance of the Year

Enhertu[®] received the Japanese Prime Minister's Award



Award Ceremony of the 9th Technology Management and Innovation Awards

The award was given in high recognition of the following:

1. The **creation of Enhertu** based on the many years of knowledge and experience of new drug research & development.
2. Establishment of management system that enabled rapid decision making, which **accelerated research and development**.
3. The efforts toward the **speedy acquisition of data that meet global standards to secure regulatory approvals** through collaboration with academic and medical institutions.
4. The positive use of the new regulatory pathways for exploring new and innovative ways to **deliver Enhertu to patients as quickly as possible**.
5. The development of a successful manufacturing method to **minimize quality issues of the product**.

Oncology



Oncolytic Virus

◆ **DS-1647/G47Δ**

NDA submission (JP)



DXd-ADC

◆ **DS-6157** (GPR20) Ph1 start

◆ **DS-6000** (CDH6) Ph1 start

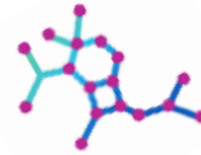


Antibody (Immuno-oncology)

◆ **DS-1055** (GARP) Ph1 start

Specialty Medicine

Small Molecule



◆ **Lixiana[®]**

Atrial fibrillation in the very elderly
sNDA submission (JP)

◆ **Efient[®]**

Ischemic stroke sNDA submission (JP)

◆ **Tarlige[®]**

Central neuropathic pain
TLR obtained from Ph3 study



ENA[®] oligonucleotide

◆ **DS-5141**

Duchenne muscular dystrophy
TLR obtained from Ph1/2 study

Development of various modalities has progressed






Major progress in FY2020

ASCO 2021

News Flow

Planned Presentation at ASCO 2021 (6/4 to 6/8, Virtual Meeting)

- ◆ Abstract available online: May 19th 5pm (EDT)
- ◆ Slides and posters available online: Jun 4th

Enhertu[®]		DESTINY-CRC01 study (HER2 positive CRC, 3L, Ph2) ◆ Oral presentation
		BEGONIA study (TNBC 1L, Ph1b/2, durvalumab combo) ◆ Poster presentation
		DESTINY-Gastric01 study (HER2 positive GC, 3L, Ph2) ◆ Poster presentation
Dato-DXd		TROPION-PanTumor01 study (NSCLC, Ph1) ◆ Poster presentation
HER3-DXd		NSCLC Ph1 study, EGFR mutant cohort ◆ Oral presentation

ASCO 2021: IR Conference Call

Sunao Manabe
President and CEO



Ken Takeshita
Global R&D Head



For investors
located in JP

Monday, June 7 - 6:30-8:00pm EDT

For investors
located in ex-JP

Tuesday, June 8 - 7:00-8:30am EDT

Content will be delivered on-demand after the meeting.

Major Progress in FY2020

ASCO 2021

News Flow

Enhertu®	<u>DESTINY-CRC01 : HER2 positive CRC, 3L, Ph2</u> <ul style="list-style-type: none"> Data presentation planned at ASCO in June 2021 	DS-1647 /G47Δ	Malignant glioma <ul style="list-style-type: none"> JP: <u>Approval anticipated in FY2021 Q1</u>
	<u>BEGONIA : TNBC, 1L, Ph1b/2, durvalumab combo</u> <ul style="list-style-type: none"> Data presentation planned at ASCO in June 2021 	DS-3201	PTCL, Ph2 pivotal <ul style="list-style-type: none"> Planned to start in FY2021 Q1 <u>ATL/Lymphoma, Ph2 pivotal</u> <ul style="list-style-type: none"> <u>TLR anticipated in FY2021 Q2</u> <u>JP: NDA planned in FY2021 Q4</u>
	<u>DESTINY-Gastric01 : HER2 positive GC, 3L, Ph2</u> <ul style="list-style-type: none"> Data presentation planned at ASCO in June 2021 	Quizartinib	<u>QuANTUM-First: AML, 1L, Ph3</u> <ul style="list-style-type: none"> <u>TLR anticipated in FY2021 Q3</u>
	<u>DESTINY-Breast09 : HER2 positive BC, 1L, Ph3</u> <ul style="list-style-type: none"> Planned to start in FY2021 Q1 	Tarlige®	Central neuropathic pain <ul style="list-style-type: none"> JP: NDA planned in FY2021 Q1
	<u>DESTINY-Gastric04 : HER2 positive GC, 2L, Ph3</u> <ul style="list-style-type: none"> Planned to start in FY2021 Q1 	Lixiana®	Atrial fibrillation in the very elderly <ul style="list-style-type: none"> JP: <u>Approval planned in FY2021 Q2</u>
Dato-DXd	<u>DESTINY-Lung01 : HER2 positive/mutated NSCLC, 2L, Ph2</u> <ul style="list-style-type: none"> <u>TLR anticipated in FY2021 Q2</u> 	Efient®	Ischemic stroke <ul style="list-style-type: none"> JP: <u>Approval planned in FY2021 Q3</u>
	DESTINY-Breast03 : HER2 positive BC, 2L, Ph3 <ul style="list-style-type: none"> TLR anticipated in FY2021 Q2 		
	DESTINY-Breast04 : HER2 low BC, post chemo, Ph3 <ul style="list-style-type: none"> <u>TLR anticipated in FY2021 Q4</u> 		
HER3-DXd	DESTINY-Breast02 : HER2 positive BC, 3L, Ph3 <ul style="list-style-type: none"> <u>TLR anticipated in FY2022 Q2</u> 		
	<u>TROPION-PanTumor01 : Ph1 TNBC cohort</u> <ul style="list-style-type: none"> Data presentation planned at ESMO Breast in May 2021 		
	<u>TROPION-PanTumor01 : Ph1 NSCLC cohort</u> <ul style="list-style-type: none"> Data presentation planned at ASCO in June 2021 		
	<u>NSCLC Ph1 EGFR mutated cohort</u> <ul style="list-style-type: none"> Data presentation planned at ASCO in June 2021 		
	<u>EGFR mt NSCLC, Ph1, osimertinib combo</u> <ul style="list-style-type: none"> Planned to start in FY2021 Q1 		

Underlined: New or updated from FY2020 Q3

AML: acute myeloid leukemia, ATL: adult T-cell leukemia, BC: breast cancer, CRC: colorectal cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, PTCL: peripheral T-cell lymphoma, TNBC: triple negative breast cancer, UC: urothelial cancer,

① FY2020 Financial Results

② FY2021 Forecast

③ Business Update

④ R&D Update

⑤ **Update of Actions against COVID-19**

⑥ Appendix



Update of Actions against COVID-19

Development of COVID-19 Vaccines and Therapeutics

◆ Genetic (mRNA) vaccination (DS-5670)

- Participating in fundamental research supported by AMED^{*1} and pursuing the development of genetic (mRNA) vaccine using Daiichi Sankyo's original novel nucleic acid delivery technology^{*2}
- Selected to be a provider for the MHLW's "Emergent Initiative to Build Production Capacity for COVID-19 Vaccines^{*3} (First Round)" – Aug. 7, 2020
 - ✓ Subsidy 6.0 Bn JPY (Utilized to develop production and storage facilities for COVID-19 vaccine)
 - ✓ Develop production capacity at Daiichi Sankyo Biotech
 - ✓ Aim to build production platform technology in Japan that can accommodate not only COVID-19, but also emerging and re-emerging infectious disease vaccines in the future
- Selected to be a company for the AMED's drug discovery support program "Development of a Vaccine for COVID-19 Vaccines^{*4} (Second Round)" – Aug. 31, 2020
- **Phase 1/2 study started in March 2021**

◆ Nafamostat^{*5} inhalation formulation (DS-2319)

- Collaborative R&D with the University of Tokyo, RIKEN, Nichi-Iko Pharmaceutical Co., Ltd for the treatment of COVID-19
- Daiichi Sankyo is responsible for formulation research, non-clinical studies and clinical development using technology gained through the development of Inavir[®]
- Conducted formulation research & non-clinical studies and **started Phase 1 study in March 2021**

Manufacturing, Supply of COVID-19 Vaccines

◆ COVID-19 vaccine by AstraZeneca (AZD1222)

- Daiichi Sankyo Biotech receives undiluted solution from AstraZeneca and **initiated contract manufacturing (vial filling, packaging) in March 2021**

^{*1} "Fundamental Research on the Control of a Novel Coronavirus (2019-nCoV), which is an initiative supported by the Japan Agency for Medical Research and Development (AMED). (Principal investigator: Prof. Yoshiro Kawaoka, Institute of Medical Sciences, The University of Tokyo)

^{*2} Technology focusing on forming lipid nanoparticle structures, stabilizing pharmaceutical active ingredients and delivering nucleic acids into immune cells. Compared to conventional vaccine technology, it has been demonstrated to induce a more optimal immune response

^{*3} The project aims to swiftly develop an actual (large-scale) production system for biologics, including vaccines, in order to ensure that the vaccines necessary for the prevention of the spread and severity of unexpected epidemics, including COVID-19, are produced as soon as possible, and that their supply is secured for the Japanese people.

^{*4} The project aims to support the development of a vaccine against COVID-19, for which R&D is already underway, and aims to ensure the early commercialization of safe and effective vaccines.

^{*5} A treatment for acute pancreatitis and disseminated intravascular coagulation (injectable)

① FY2020 Financial Results

② FY2021 Forecast

③ Business Update

④ R&D Update

⑤ Update of Actions against COVID-19

⑥ **Appendix**



Major R&D Milestones in FY2021 (3ADCs)

As of April 2021

Project		Target Indications [phase, study name]	FY2020 Q4	Q1	FY2021 Q2	Q3	Q4
Enhertu	BC	HER2+, 3L [P2 pivotal, DESTINY-Breast01]	EU approved				
		HER2+, 2L [P3, DESTINY-Breast03]			TLR anticipated		
		HER2 low, post chemo [P3, DESTINY-Breast04]					<u>TLR anticipated</u>
		HER2+, 2L~/1L combo [P1/2, DESTINY-Breast07]	Study started				
		HER2 low, 3L combo [P1, DESTINY-Breast08]	Study started				
		<u>HER2+, 1L [P3, DESTINY-Breast09]</u>		<u>Study start planned</u>			
	GC	HER2+, 3L [P2 pivotal, DESTINY-Gastric01]	US approved (2L)				
		HER2+, 2L [P3, DESTINY-Gastric04]		Study start planned			
	NSCLC	<u>HER2+/mutant [P2, DESTINY-Lung01]</u>			<u>TLR anticipated</u>		
		HER2 mutated [P2, DESTINY-Lung02]	<u>Study started</u>				
	CRC	<u>HER2+, 3L [P2, DESTINY-CRC02]</u>	<u>Study started</u>				
	Others	HER2 mutated [P2, DESTINY-PanTumor01]	Study started				
Dato-DXd		NSCLC, w/o actionable mutation [P3, TROPION-Lung01]	<u>Study started</u>				
		NSCLC, w/o actionable mutation, durvalumab combo [P1, TROPION-Lung04]	<u>Study started</u>				
		NSCLC, with actionable mutation [P2, TROPION-Lung05]	<u>Study started</u>				
		<u>TNBC, durvalumab combo [P1b/2, BEGONIA]</u>		<u>Study start planned</u>			
HER3-DXd		EGFR mutated NSCLC [P2 pivotal, HERTHENA-Lung01]	<u>Study started</u>				
		EGFR mutated NSCLC, osimertinib combo [P1]		<u>Study start planned</u>			

Red underlined: new or updated from FY2020 Q3

BC: breast cancer, CRC: colorectal cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, TLR: Top Line Results, TNBC: triple negative breast cancer, UC: urothelial cancer,

Major R&D Milestones in FY2021 (Alpha)

As of April 2021


Project	Target Indications [phase, study name, region]	FY2020	FY2021			
		Q4	Q1	Q2	Q3	Q4
Quizartinib	<u>AML, 1L [P3, JP/US/EU/Asia]</u>				<u>TLR anticipated</u>	
Pexidartinib	Tenosynovial giant cell tumor [P2, JP]		<u>Study started</u>			
DS-1647/G47Δ	Malignant glioma [IIS, JP]		<u>Approval anticipated</u>			
Yescarta	R/R B-cell lymphoma [P2 pivotal, JP]	Approved				
DS-3201	<u>ATL/lymphoma [P2 registration, JP]</u>			<u>TLR anticipated</u>		<u>Submission planned</u>
	PTCL [P2 pivotal, JP/US/EU/Asia]		Study start planned			
DS-6000	Renal cell carcinoma, ovarian cancer [P1, US]	<u>Study started</u>				
DS-1594	<u>AML, ALL [P1/2, US]</u>		<u>Study started</u>			
Lixiana	AF in the very elderly [P3, ELDERCARE-AF, JP]			Approval anticipated		
Efient	Ischemic stroke [P3, PRASTRO III, JP]				Approval anticipated	
Tarlige	Central neuropathic pain [P3, JP]		Submission planned			
DS-2319	COVID-19 [P1, JP]	<u>Study started</u>				
DS-6016	<u>Fibrodysplasia Ossificans Progressiva [P1, JP]</u>		<u>Study started</u>			
DS-5670	COVID-19 vaccine [P1/2, JP]	<u>Study started</u>				




Red underlined: new or updated from FY2020 Q3



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, TLR: Top Line Results

Major R&D Pipeline: 3ADCs

As of April 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	(JP/US/EU)HER2+/mutated NSCLC 2L~ DESTINY-Lung01 	(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-Lung02	(JP/US/EU/Asia) HER2+ BC post neoadjuvant DESTINY-Breast05	
(JP/US/EU/Asia) NSCLC	(US/EU) BC, bladder (nivolumab combo)	(US/EU/Asia) NSCLC (durvalumab combo) 2L~ HUDSON	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06	
(JP/US)EGFR mutated NSCLC (osimertinib combo)	(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU) HER2+ CRC 3L DESTINY-CRC01	(US)HER2+ BC 1L DESTINY-Breast09	
(JP/US) BC		(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/US/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	
		(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 April 2021

Phase 1		Phase 2	Phase 3	Submitted
DS-7300 (JP/US) B7-H3-directed ADC Solid tumors	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	DS-1647/G47Δ (JP) Oncolytic HSV-1 Malignant glioma IIS
DS-6157 (JP/US) GPR20-directed ADC GIST	DS-3201 (US) EZH1/2 inhibitor AML, ALL	DS-3201 (JP/US/EU/Asia) EZH1/2 inhibitor PTCL	Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	Lixiana (JP) FXa inhibitor AF in the very elderly
DS-6000 (US) CDH6-directed ADC Renal cell carcinoma, ovarian cancer	PLX2853 (US) BET inhibitor AML	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	Tarlige (JP/Asia) α2δ Ligands Central neuropathic pain	Efient (JP) ADP receptor inhibitor Ischemic stroke
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	PLX2853 (US) BET inhibitor Solid tumor	DS-5141 (JP) ENA oligonucleotide DMD	Minnebro (JP) MR blocker Diabetic nephropathy	VN-0107/MEDI3250 (JP) Live attenuated influenza vaccine nasal spray
DS-2741 (JP) Anti-Orai1 antibody Atopic dermatitis	PLX2853 (US) BET inhibitor Gynecologic neoplasms, ovarian cancer		VN-0102/JVC-001 (JP) Measles mumps rubella combined vaccine	
DS-2319 (JP) Nafamostat inhalation COVID-19	PLX2853 (US) BET inhibitor Prostate cancer			
DS-1211 (US) TNAP inhibitor Pseudoxanthoma elasticum	DS-1594 (US) Menin inhibitor AML, ALL			
DS-6016 (JP) Anti-ALK2 antibody Fibrodysplasia Ossificans Progressiva	DS-5670 (JP) mRNA vaccine COVID-19			

- Oncology
- Specialty medicine
- Vaccine

AF: atrial fibrillation, ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, DMD: Duchenne muscular dystrophy, GIST: gastrointestinal stromal tumor, IIS: investigator-initiated study, NSCLC: non-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/EU)

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