Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2019
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Sunao Manabe
President and CEO

April 27, 2020

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Agenda

1. **Actions Against COVID-19 and Impact on Business**
2. FY2019 Financial Results
3. FY2020 Forecast
4. Business Update
5. R&D Update
6. Appendix

Actions Against COVID-19 and Impact on Business

Manufacturing and Distribution

- No significant impact on our ability around stable supply, and below are the focus areas
  - Close monitoring around policies and regulations of each country, and status of business partners
  - Minimizing impact around procurement of raw material, and product distribution
  - Securing stable product inventory
- All manufacturing sites are operating normally
  (as of April 27)

Prescription

- Current impact on prescription of our products is as below and limited
  - The patients on our products continue to get them prescribed
  - Patient visits are decreasing, leading to an increase in longer-term prescription
  - New patient starts are on a decreasing trend
- Prescriptions for certain products used as adjunctive therapy such as iron injectable are on a decreasing trend

Actions Against COVID-19 and Impact on Business

Research and Development

- Clinical trials
  - **Prioritizing patient safety and reducing the burden on healthcare professionals**
  - In some areas, site activation and site addition have been affected, some trials have seen slowed enrollment, overall there is no major impact on development and each study is being continued
- Research
  - No significant impact on non-clinical studies required for IND/BLA/NDA submission

Development of COVID-19 Vaccines and Therapeutics

- **We are utilizing our research power** in cooperation with external institutions to reduce the threat of infection
  - Established company-wide task force to promote the research and development of vaccines and therapeutic agents targeting COVID-19
  - Taking part of the development for genetic (mRNA) vaccination against COVID-19 which is conducted under AMED*

*AMED: Japan Agency for Medical Research and Development

Disaster Relief

- Donations
  - COVID-19 Solidarity Response Fund for WHO among others
- Supply of goods
  - Donation of medicine and masks for hospitals or research institute

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Overview of FY2019 Results

(Bn JPY)

	FY2018 Results	FY2019 Results	YoY	
Revenue	**929.7**	**981.8**	+5.6%	**52.1**
Cost of sales	364.6	343.2		-21.4
SG&A expenses	277.7	302.3		24.6
R&D expenses	203.7	197.5		-6.2
Operating Profit	**83.7**	**138.8**	+65.8%	**55.1**
Profit before tax	**85.8**	**141.2**		**55.3**
Profit attributable to owners of the Company	**93.4**	**129.1**	+38.2%	**35.7**

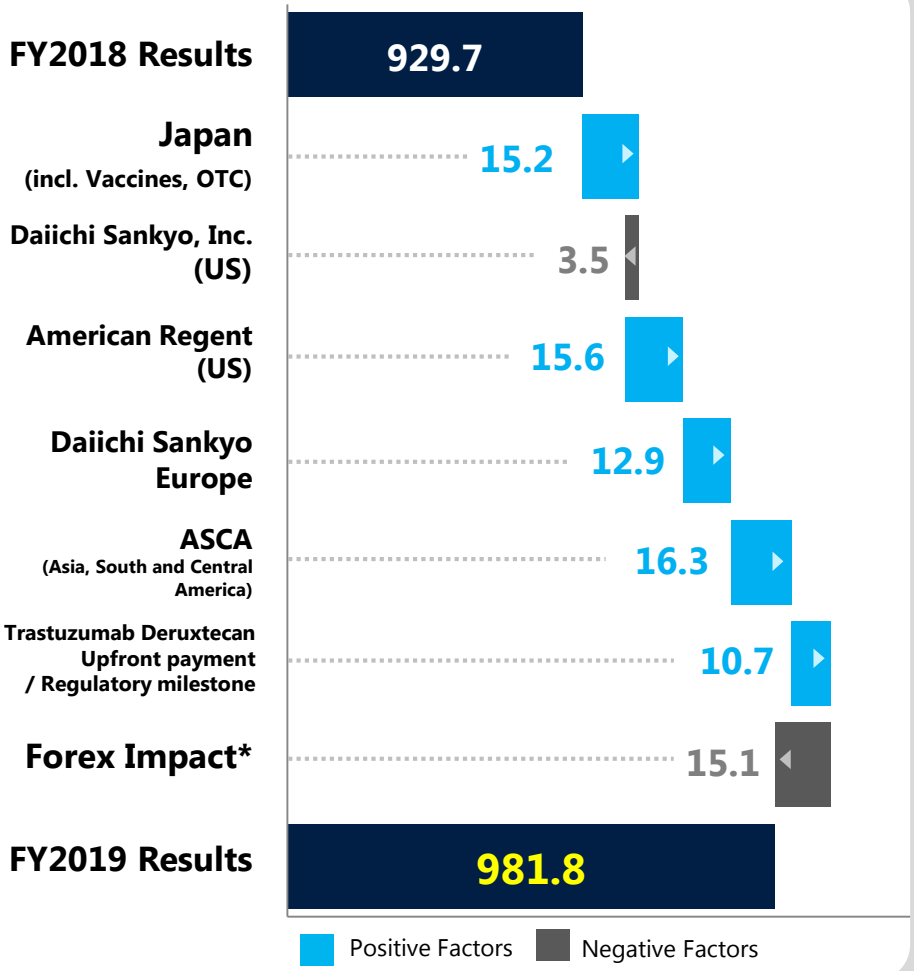
Currency Rate	USD/JPY	110.91	108.75	-2.16
	EUR/JPY	128.40	120.83	-7.57

Impact of COVID-19

- Increase in sales due to securement of stable inventory by medical institutions and wholesalers
- Decrease due to restrictions on sales promotion and R&D activities

Revenue

Increased by 52.1 Bn JPY (Increased by 67.2 Bn JPY excl. forex impact)



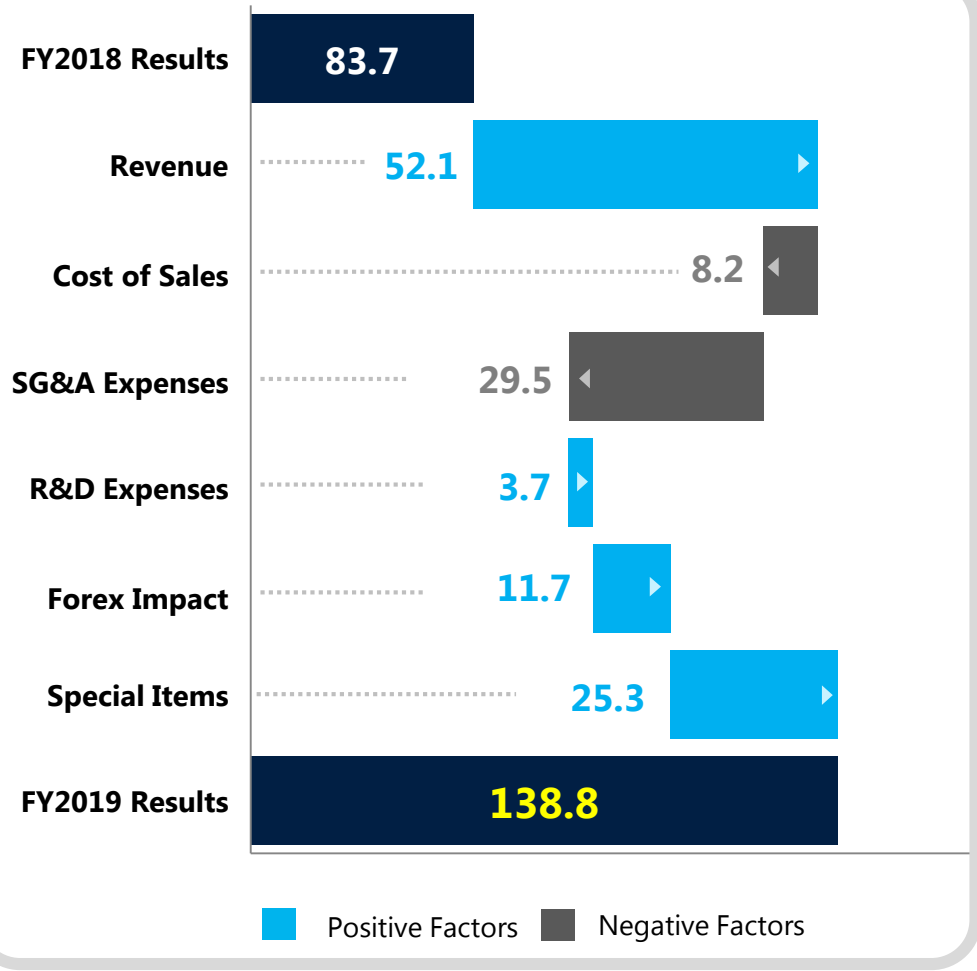
(Bn JPY)

	Positive Factors		Negative Factors	
Japan				
	Lixiana	+18.1	Olmetec	-3.2
	Tarlige	+8.0	Loxonin	-2.2
	Daiichi Sankyo Espha (GE) Silodosin AG	+5.0	Vaccines business ActHIB	-5.9
	Daiichi Sankyo Healthcare	+2.1	Decrease in gain on sales of transferring long-listed products	-6.0
Daiichi Sankyo, Inc. (US)				
	Enhertu	+3.2	Welchol	-4.1
			Effient	-2.0
American Regent, Inc. (US)				
	Injectafer	+8.7		
	GE injectables	+4.5		
Daiichi Sankyo Europe				
	Lixiana	+19.8	Efient	-3.0
ASCA (Asia, South and Central America)				
	China Cravit, Olmetec etc.	+10.4		

* Forex impact USD: -3.5, EUR : -6.0, ASCA: -5.6

Operating Profit

Increased by 55.1 Bn JPY (Increased by 33.2 Bn JPY excl. forex impact and special items)



(Bn JPY)

Revenue +52.1
incl. forex impact of -15.1

Cost of Sales +8.2 (Cost increased)
- Increase by revenue increase
- Improvement in cost of sales ratio by product mix

SG&A Expenses +29.5 (Cost increased)
- Increase by establishment of the oncology business structure in US

R&D Expenses -3.7 (Cost decreased)
- Decrease by trastuzumab deruxtecan cost share with AstraZeneca
- Increase by enhancement of oncology development structure

Forex Impact -11.7 (Cost decreased)

Cost of Sales	-3.3
SG&A Expenses	-5.9
R&D Expenses	-2.5

Special Items -25.3 (Cost decreased)
See next slide for details

Special Items

(Bn JPY)

	FY2018 Results		FY2019 Results		YoY
Cost of Sales	Impairment loss (intangible assets)*1	15.1	Restructuring costs in Supply Chain	1.3	-26.3
			Impairment loss (intangible assets)*2	6.3	
			Gain on sales of subsidiary*3	-18.8	
SG&A Expenses	Gain on sales of fixed assets	-3.5	Gain on sales of fixed assets*4	-10.6	1.0
			Environmental expenditures*5	8.2	
R&D Expenses					
Total		11.6		-13.7	-25.3

- : Cost decreased items

Booked in Q4

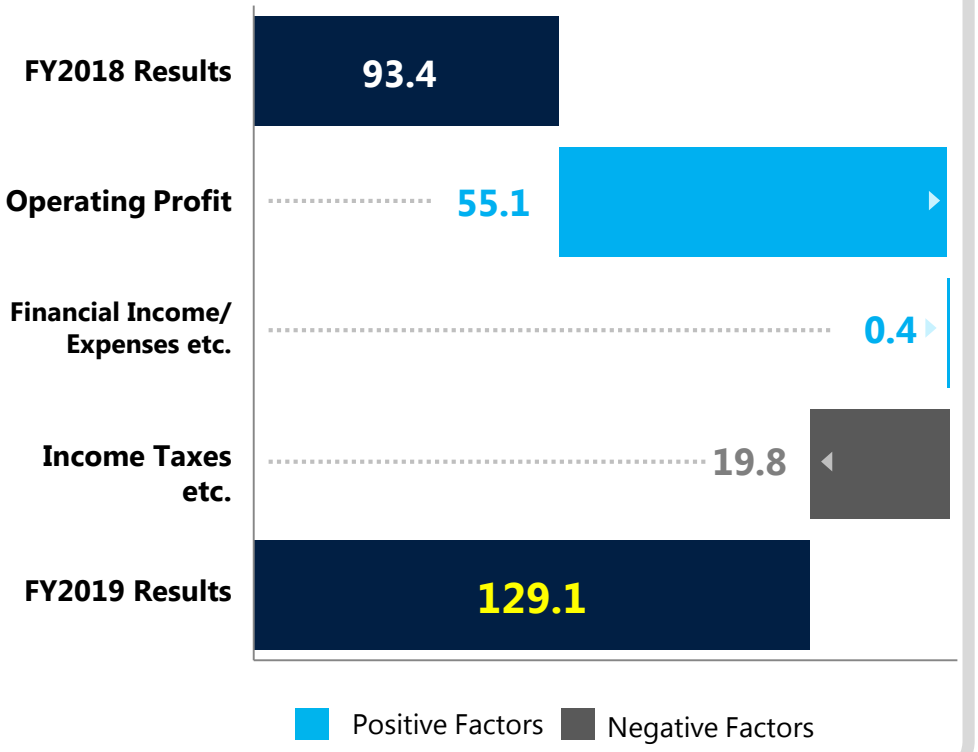
*1 Zelboraf, Movantik

*2 Morphabond, Roxybond, Zelboraf
*3 Takatsuki Plant
*4 Nihonbashi Building
*5 Former Yasugawa Plant

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

Increased by 35.7 Bn JPY



(Bn JPY)

Income Taxes etc. ····· +19.8 (Cost increased)

	FY2018	FY2019	YoY
Profit before Tax	85.8	141.2	+55.3
Income Taxes etc.	-7.6	12.2	+19.8
Tax rate	-8.8%	8.6%	+17.5%

(Reference: Tax rate)

FY2018: Increase in DTA attributable to future expected taxable income increase due to trastuzumab deruxtecan strategic collaboration

FY2019: Impact of introduction of consolidated taxation system

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2018 Results	FY2019 Results	YoY
Japan	523.3	533.5	+10.2
Daiichi Sankyo Healthcare	66.4	68.5	+2.1
Daiichi Sankyo, Inc.	36.3	32.1	-4.2
Enhertu	-	3.2	+3.2
Olmesartan	10.7	9.8	-0.9
Welchol	13.4	9.1	-4.3
American Regent, Inc.	117.8	130.8	+13.0
Injectafer	44.2	51.8	+7.6
Venofer	28.9	31.0	+2.1
GE injectables	38.5	41.2	+2.7
Daiichi Sankyo Europe	88.6	95.5	+6.9
Lixiana	45.8	61.7	+15.9
Olmesartan	27.4	24.6	-2.8
Efient	5.7	2.5	-3.2
ASCA (Asia, South and Central America)	87.7	98.3	+10.7

Currency Rate	USD/JPY	110.91	108.75	-2.16
	EUR/JPY	128.40	120.83	-7.57

Revenue: Major Products in Japan

(Bn JPY)

		FY2018 Results	FY2019 Results	YoY
Lixiana	anticoagulant	**64.9**	**83.0**	**+18.1**
Nexium	ulcer treatment	**78.3**	**79.8**	**+1.5**
Memary	Alzheimer's disease treatment	**50.2**	**50.5**	**+0.3**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone	**27.4**	**30.9**	**+3.6**
Tenelia	type 2 diabetes mellitus treatment	**25.3**	**24.7**	**-0.6**
Loxonin	anti-inflammatory analgesic	**30.5**	**28.3**	**-2.2**
Inavir	anti-influenza agent	**18.2**	**19.3**	**+1.1**
Ranmark	treatment for bone complications caused by bone metastases from	**16.4**	**17.9**	**+1.5**
Efient	antiplatelet agent	**13.9**	**14.0**	**+0.1**
Rezaltas	antihypertensive agent	**15.5**	**14.6**	**-0.9**
Canalia	type 2 diabetes mellitus treatment	**9.2**	**12.8**	**+3.6**
Vimpat	anti-epileptic agent	**6.6**	**11.2**	**+4.6**
Omnipaque	contrast agent	**12.0**	**10.3**	**-1.7**
Olmetec	antihypertensive agent	**14.9**	**11.7**	**-3.2**
Tarlige	pain treatment	**-**	**8.0**	**+8.0**

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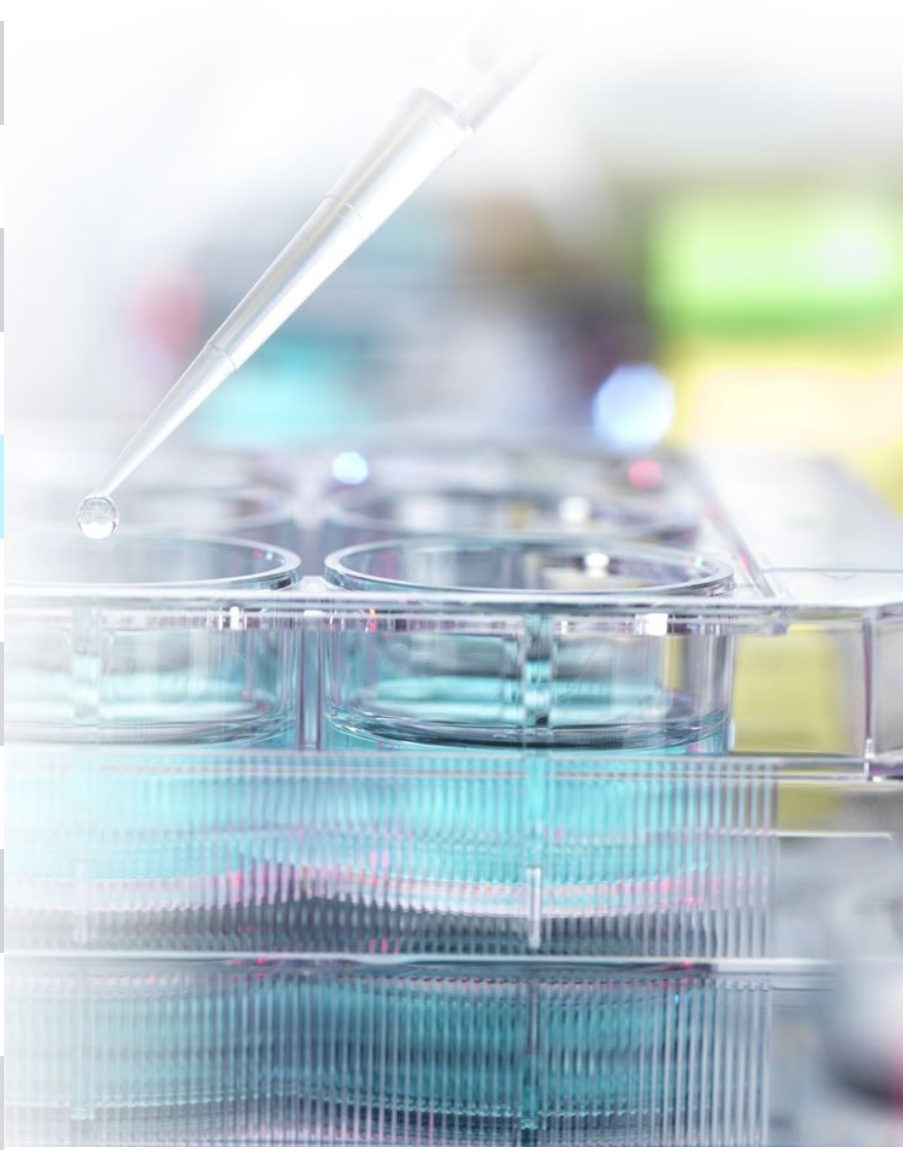

FY2020 Consolidated Forecast

(Bn JPY)

	FY2019 Results	FY2020 Forecast	YoY	
Revenue	**981.8**	**970.0**	-1.2%	**-11.8**
Cost of sales	343.2	337.0		-6.2
SG&A expenses	302.3	325.0		22.7
R&D expenses	197.5	228.0		30.5
Operating Profit	**138.8**	**80.0**	-42.4%	**-58.8**
Profit before tax	**141.2**	**80.0**		**-61.2**
Profit attributable to owners of the Company	**129.1**	**56.0**	-56.6%	**-73.1**

Currency Rate	USD/JPY	108.75	110.00	+1.25
	EUR/JPY	120.83	120.00	-0.83

FY2020 Consolidated Forecast

(Bn JPY)

	FY2019 Results (excl. special items)	FY2020 Forecast	YoY	
Revenue	**981.8**	**970.0**	-1.2%	**-11.8**
Cost of sales	354.4	337.0		-17.4
SG&A expenses	304.8	325.0		20.2
R&D expenses	197.5	228.0		30.5
Operating Profit	**125.1**	**80.0**	-36.1%	**-45.1**

Currency Rate	USD/JPY	108.75	110.00	+1.25
	EUR/JPY	120.83	120.00	-0.83

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

Decrease Factor ↓
Drug price revision, Memary LOE, discontinuation of ActHIB and Rotarix sales activity

Cost of Sales
Decrease in revenue, improvement in cost of sales ratio by product mix

SG&A expenses
Increase in expenses related to trastuzumab deruxtecan
- Increased due to profit share of gross profit with AstraZeneca
- Increase in sales promotion expenses

R&D expenses
Increase in 3ADCs R&D investments, enhancement of oncology development structure

Impact of COVID-19

- The impact of COVID-19 is not reflected in forecast as the situation continues to evolve and timing of resolution remains unclear
- Assuming that global activity restrictions continue until the second quarter, the expectations are as follows
  - Negative impact on sales revenue of 3-5% (approx. 30 - 50 Bn JPY)
  - Expenses expected to be restrained due to an impact on business activities
  - Minor impact on operating income
- The impact in the case of prolonged infection spread are considered separately

Trastuzumab Deruxtecan (DS-8201): Revenue

(Bn JPY)

	FY2019 Results	FY2020 Forecast	(Reference) Total Consideration Received
Product sales	3.2	28.5	-
Japan	-	1.5	-
U.S.	3.2	27.0	-
Upfront payment	9.8 *	9.8 *	149.0
Regulatory milestone payment	0.9 *	0.9 *	13.7
Total	14.0	39.2	162.7

*Revenue recognition amount for the fiscal year

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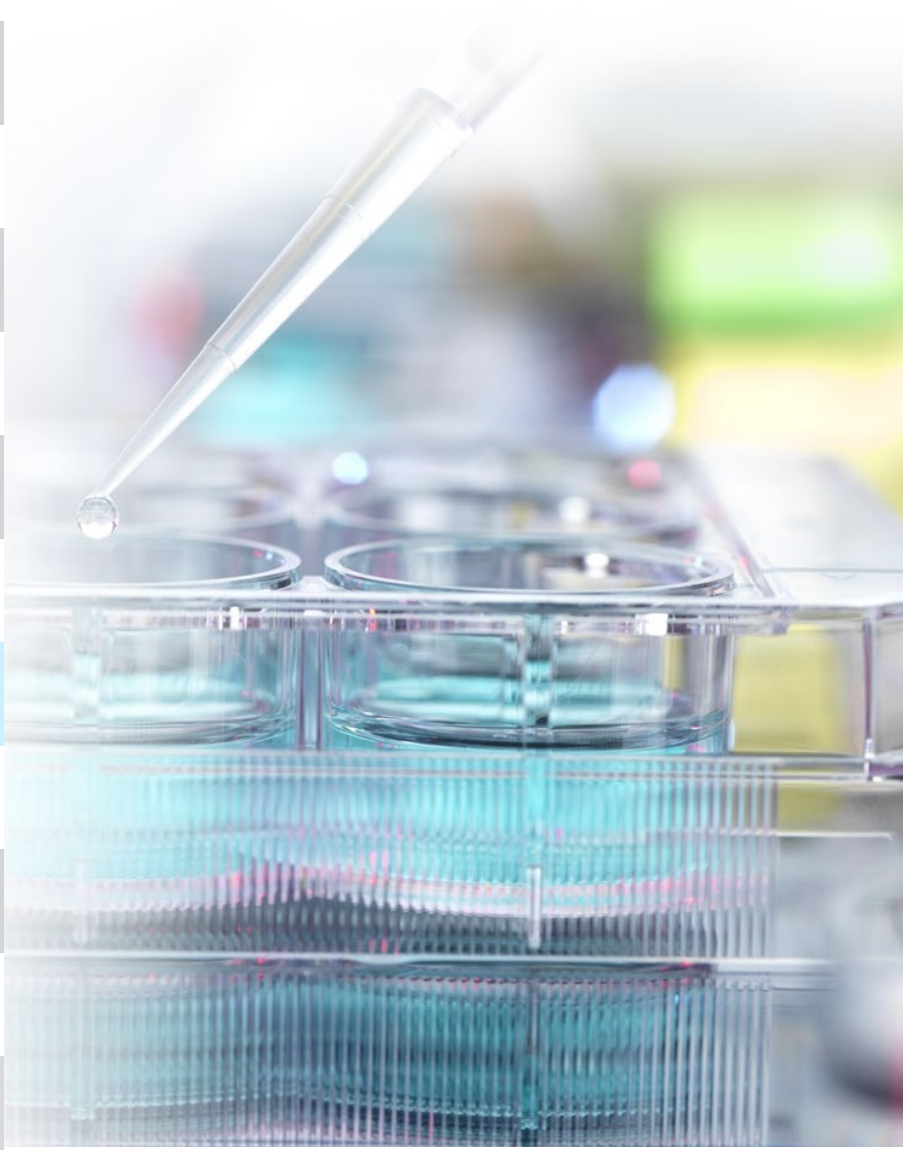

Japan Business

US Business

Europe Business

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Streamlining of Assets

Shareholder Returns

Japan Business: New Products Approval & Launch

Pain treatment

Tarlige® (mirogabalin)

Launched in Apr. 2019

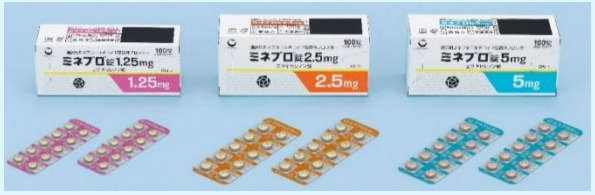
- Indication: peripheral neuropathic pain

Hypertension treatment

Minnebro® (esaxerenone)

Launched in May. 2019

- Indication: hypertension



Anticancer agent

Vanflyta® (quizartinib)

Launched in Oct. 2019

- Indication: treatment of adult patients with relapsed/refractory FLT3-ITD acute myeloid leukemia (AML)

Anticancer agent

Enhertu® (trastuzumab deruxtecan)

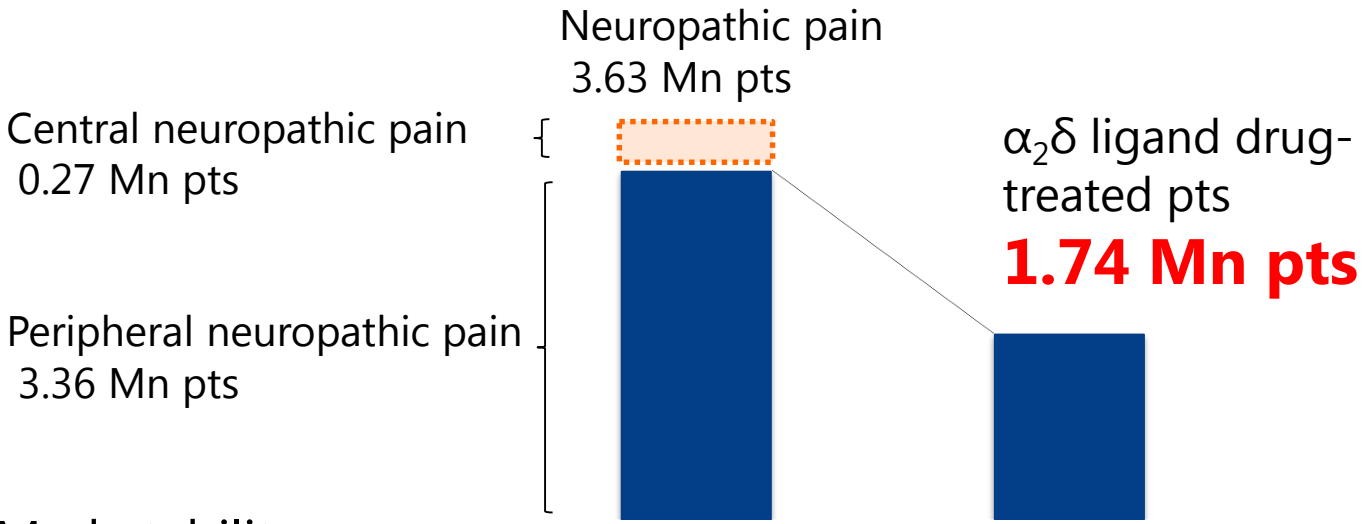
Approved in Mar. 2020

- Indication: 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)

Tarlige: Product Summary and Marketability in Japan

◆ $\alpha_2\delta$ ligand drug product indicated for peripheral neuropathic pain

- Mechanism of action : binds to the calcium channel $\alpha_2\delta$ subunit and inhibits neurotransmitter release, thereby providing pain relief
- Number of patients (DS estimation)

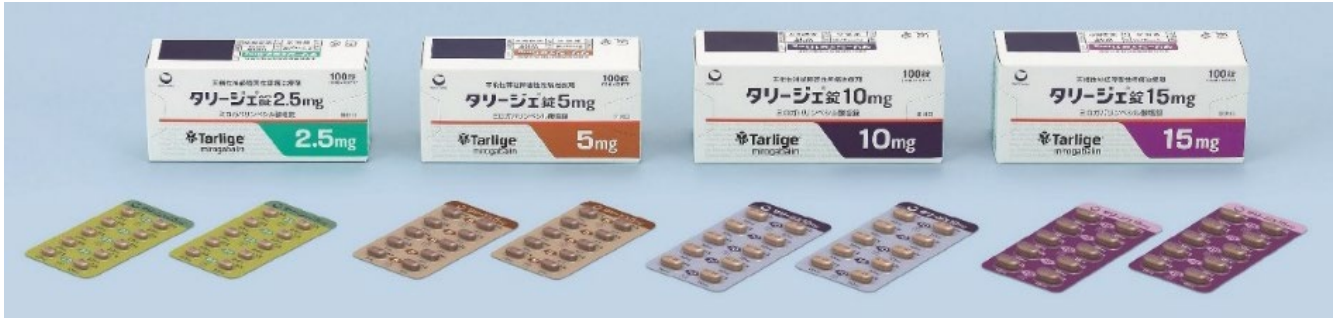


- Marketability （FY2019* ）
  - ✓ Neuropathic Pain Treatment: 160.0 Bn JPY
  - ✓ $\alpha_2\delta$ ligand drug product: 110.0 Bn JPY

Tarlige: Sales Status

- **Strong start-up exceeding the plan**
  - **FY2019 revenue results 8.0 Bn JPY**
    （Forecast at FY2019 beginning 4.0 Bn JPY）
- **FY2020 revenue forecast 16.0 Bn JPY**

タリージェ®



- Published Guidelines*
  Mirogabalin can be used as same as pregabalin for the treatment of peripheral neuropathic pain
- Longer-term prescription is allowed from March 2020, leading to contribution for more patients
- New indication of central neuropathic pain and orally disintegrating tablets is under development

*Supplementary edition of the Guidelines for Neuropathic Pain Drug Therapy, 2nd revised edition
https://www.jspc.gr.jp/Contents/public/kaiin_guideline09.html

Japan Business

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Streamlining of Assets

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US Business: New Products Launch

TGCT (Tenosynovial Giant Cell Tumor) treatment

TURALIO® (pexidartinib)

Launched in Aug. 2019

- Indication

  Treatment of adult patients with symptomatic TGCT associated with severe morbidity or functional limitations and not amenable to improvement with surgery

Anti-cancer agent (HER2 directed antibody drug conjugate)

ENHERTU® (fam-trastuzumab deruxtecan-nxki)

Launched in Jan. 2020

- Indication*

  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

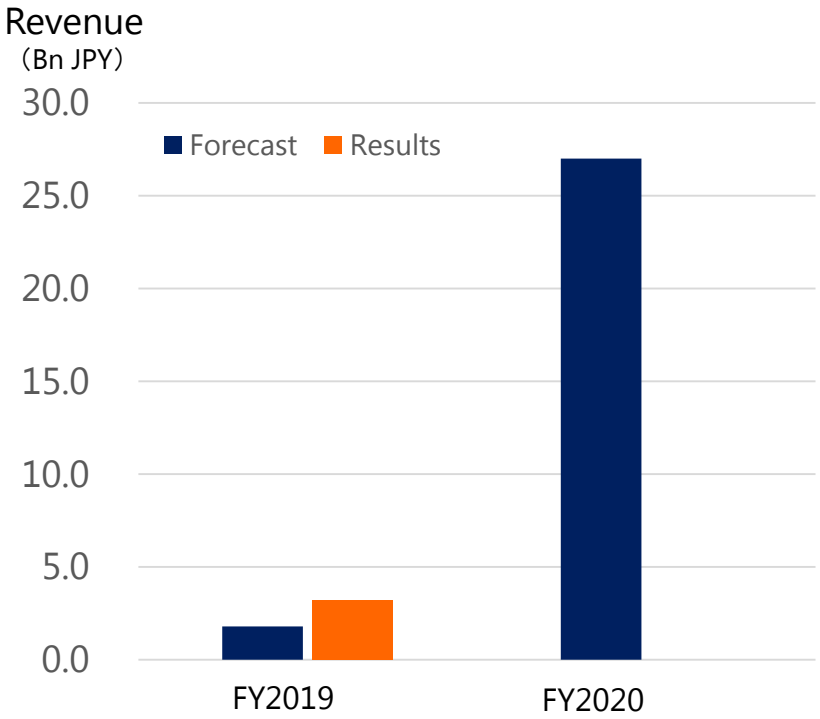
*This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

ENHERTU: Sales in US

- **Strong start-up exceeding the plan**
  - **Revenue results FY2019 3.2 Bn JPY**

    （Forecast as of Jan. 2020 2.0 Bn JPY）
- **Revenue forecast FY2020 27.0 Bn JPY**

ENHERTU®
fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE



- Early market penetration with AstraZeneca co-promotion
  - ✓ Achieved 780 account purchase in three months after launch
  - ✓ 515 accounts repeated purchase (as of Mar. 27, 2020)
- Appropriately educate healthcare professionals and patients about benefits and risks, including risk management methods for ILD

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Europe Business: New Products Approval

- **Approved by European Commission in March and April 2020 for cholesterol-lowering treatment NILEMDO and NUSTENDI, respectively, introduced from Esperion**

NILEMDO® (bempedoic acid)

- Bempedoic acid
- First-in-class oral ACL* inhibitor
- Provides additional LDL-C lowering of up to 28% on top of other lipid-lowering therapies

NUSTENDI® (bempedoic acid and ezetimibe)

- Fixed dose combination tablet of bempedoic acid and ezetimibe
- Combines two complementary ways of reducing cholesterol
  - bempedoic acid: inhibits cholesterol production
  - ezetimibe: reduces absorption of dietary cholesterol in the gut
- Reduces LDL-C by 38% compared to placebo in high-risk patients already taking maximum-tolerated statin therapy

Indication: for use in adults with hypercholesterolaemia or dyslipidaemia

*ACL: adenosine triphosphate citrate lyase, an enzyme which is involved in the production of cholesterol in the liver

Europe Business: Significance of Introducing New Products

Providing therapies that address high unmet medical needs

- Up to 80% of patients do not reach guideline-recommended LDL-C goals despite receiving treatments, such as statins, and are at increased risk of a heart attack or stroke
- The European Society of Cardiology (ESC) recommends combining different treatments to help people at risk to get high blood cholesterol under control

Deliver significant LDL-C reductions as an add-on to current oral lipid-lowering therapies

Synergy in cardiovascular area

- Effective utilization of the European business base in the cardiovascular area built by Daiichi Sankyo Europe

Improve European regional value by synergistic effect with anticoagulant Lixiana

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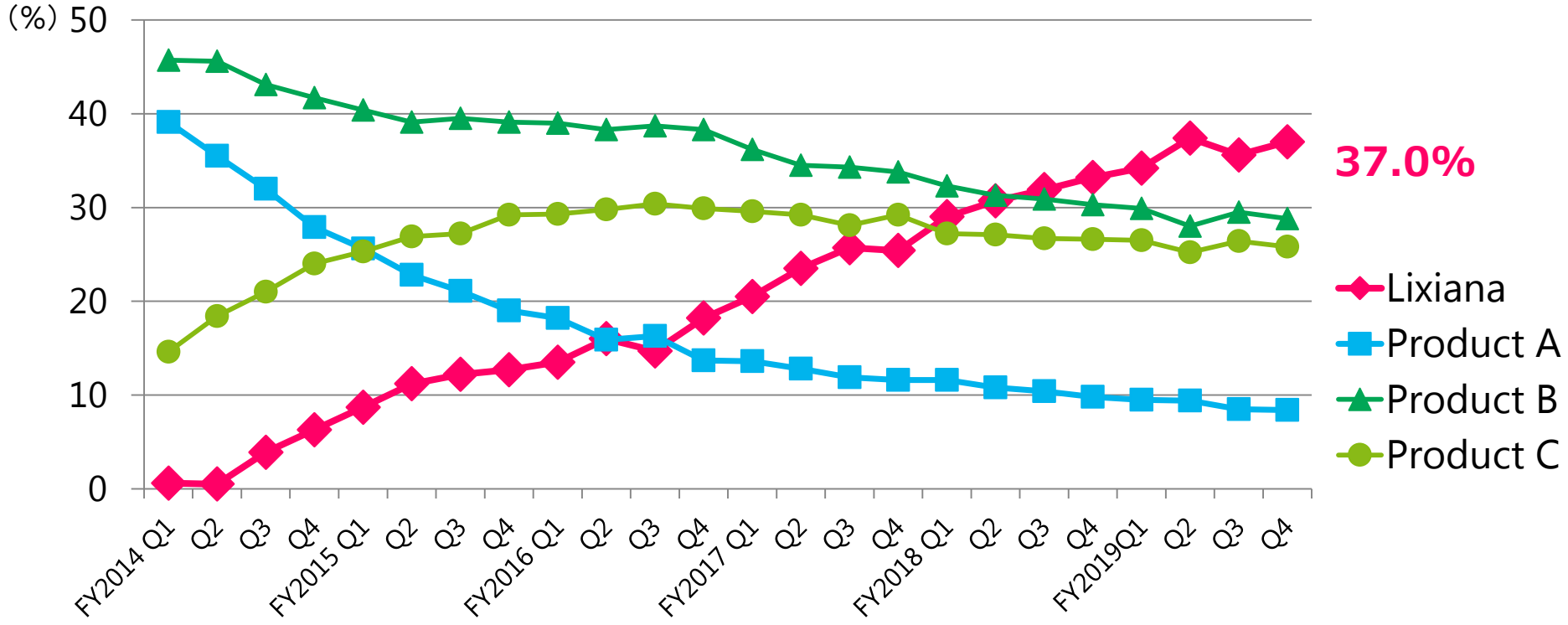
Lixiana: Growth in Japan

Sales

Daiichi-Sankyo

- **FY2019 Q4: No.1 sales share (37.0%)**
  - **FY2019 revenue results : 83.0 Bn JPY (YoY +18.1 Bn JPY)**
  - **FY2020 revenue forecast: 75.0 Bn JPY (YoY -8.0 Bn JPY*)**

*** Previous drug price base YoY +17.0 Bn JPY**



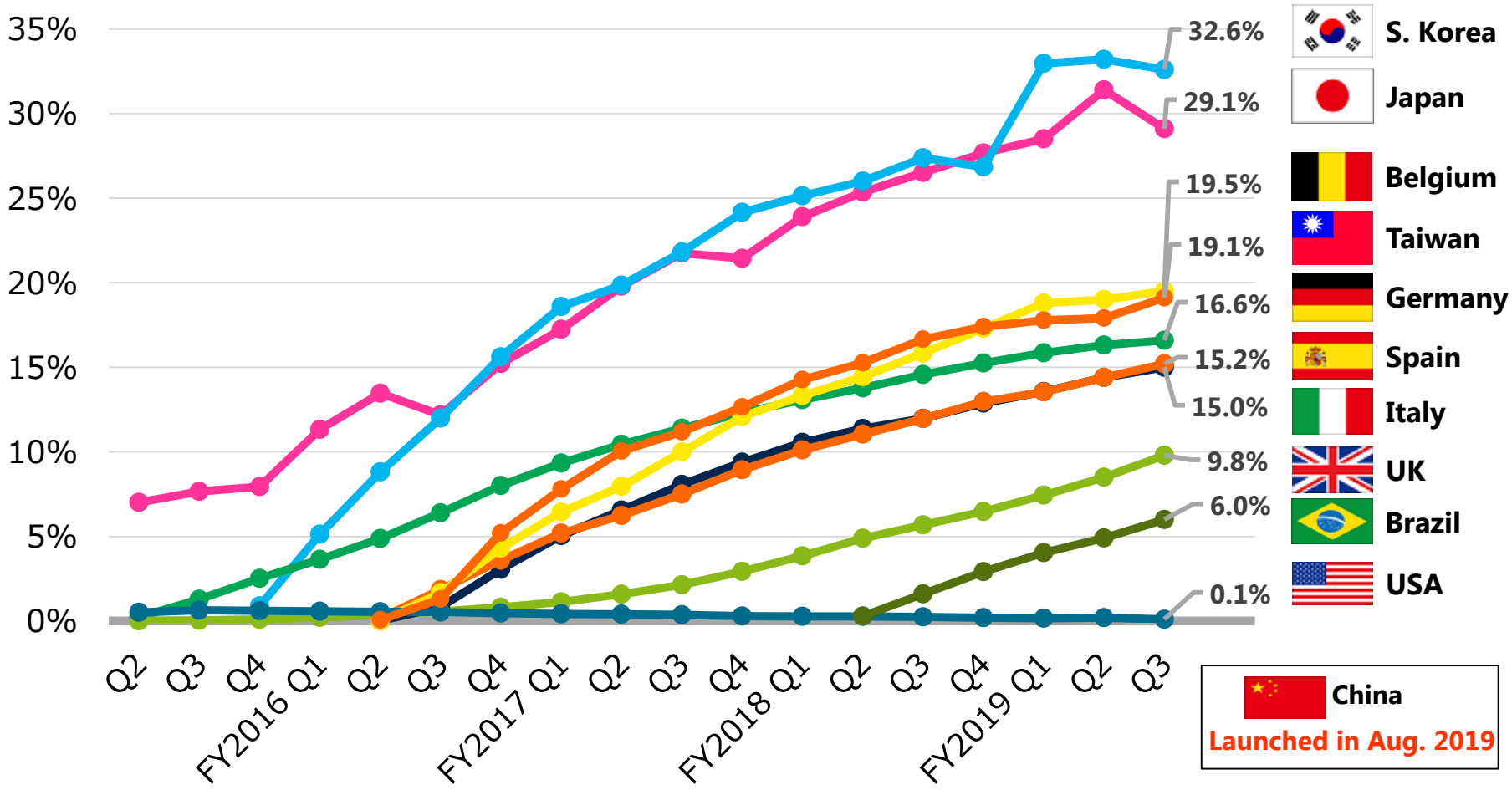
Edoxaban: Growth in Each Country

Volume

Daiichi-Sankyo

Steady growth in each country

- FY2019 global revenue results : 154.0 Bn JPY (YoY +36.3 Bn JPY)
- FY2020 global revenue forecast: 163.0 Bn JPY (YoY +9.0 Bn JPY)



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Streamlining of Assets

Shareholder Returns

Streamlining of Assets

◆ **During the 5-Year Business Plan period (FY2016 - FY2019), generated cash of 154.5 Bn JPY by streamlining assets**

		FY2016 Results	FY2017 Results	FY2018 Results	FY2019 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)	**68.0** Bn JPY (45 Brands)
	Gain on sales*	9.3 Bn JPY	9.8 Bn JPY	10.6 Bn JPY	14.4 Bn JPY	44.2 Bn JPY
Sale of properties	Sales proceeds	**3.2** Bn JPY	**10.7** Bn JPY	**11.0** Bn JPY	**14.0** Bn JPY	**39.0** Bn JPY
	Gain on sales	0.8 Bn JPY	7.6 Bn JPY	9.0 Bn JPY	10.7 Bn JPY	28.1 Bn JPY
Gain on sales of business transfer	Sales proceeds	**-**	**-**	**10.4** Bn JPY*2	**37.1** Bn JPY*3	**47.5** Bn JPY
	Gain on sales	-	-	6.3 Bn JPY*2	19.1 Bn JPY*3	25.3 Bn JPY

＊1 Booked in other comprehensive income ＊2 Long-listed Products ＊3 Takatsuki Plant, Long-listed Products

Japan Business

US Business

Europe Business

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Streamlining of Assets

Shareholder Returns

Share Split & Dividend Increase

- **To increase liquidity, reduce investment price and further broaden our investor base, we have decided to split DS shares**

  - Share split ratio　1:3
  - Record date　Sep. 30, 2020
  - Effective date　Oct. 1, 2020

- **In addition, the dividend will be increased for FY2020 (the year ending Mar. 31, 2021)**
- **Annual dividend forecast (pre-split base) increased by 11 yen per share (70 JPY → 81 JPY)**

  - Interim dividend (before split) : 40.5 JPY per share
  - Year-end dividend (after split) : 13.5 JPY per share

(ref. pre-split base JPY 40.5 per share)

＊Annual dividend (forecast)　approx. 52.5 Bn JPY
(ref. the year ending Mar. 31, 2020　45.4 Bn JPY)

Shareholder Returns

Shareholder Returns Policy: FY2016 - FY2022

	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results	FY2020 Plan
Dividend per share	**70 JPY**	**70 JPY**	**70 JPY**	**70 JPY**	**81 JPY*2**
Acquisition of own shares	**50.0 Bn JPY**	**50.0 Bn JPY**	**-**	**-**	**Flexible**
Total return ratio*1	**180.7%**	**159.1%**	**48.5%**	**35.1%**	**-**
	84.2%				

*1 Total return ratio = (Dividends + Total acquisition costs of own shares) / Profit attributable to owners of the company
*2 Dividend per share (pre-split base)

1 Actions Against COVID-19 and Impact on Business

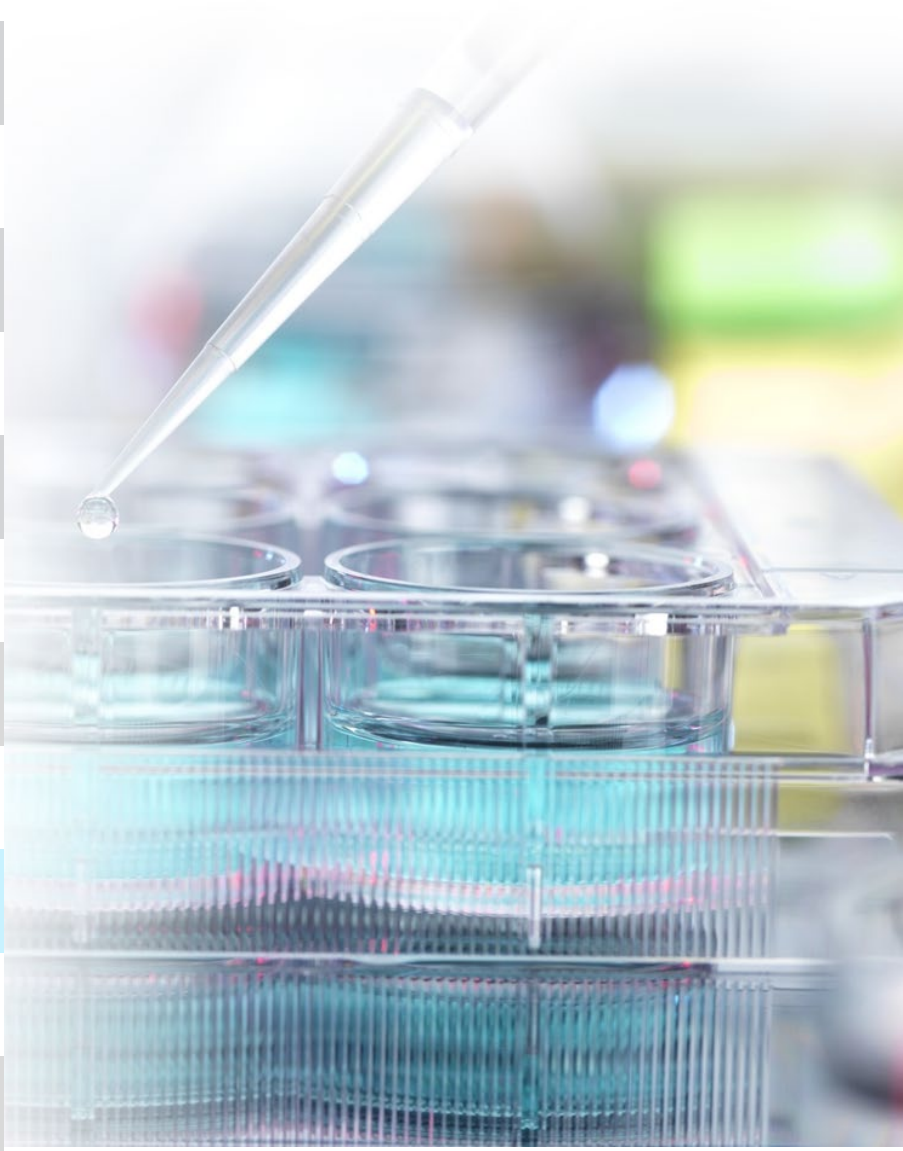
2 FY2019 Financial Results

3 FY2020 Forecast

4 Business Update

5 **R&D Update**

6 Appendix



Daiichi-Sankyo

Review of FY2019

3 ADCs Update

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ASCO 2020

Future News flow

Changing the Strategy for R&D

Daiichi-Sankyo

- **Emerging potential of 3 ADCs in FY2019**

- **3 and Alpha strategy**
  - **Prioritize investment and resource allocation to 3 ADCs**
  - **Alpha focuses on changing SOCs**

3 ADCs			&	Alpha		
DS-8201	DS-1062	U3-1402	Oncology	Specialty Medicine	Vaccine	

Achievements in FY2019: 3 ADCs

Study Initiation | Presentation at conference | TLRs | Approval

Q1	Q2	Q3	Q4
DS-1062 Phase1 NSCLC @ASCO	**DS-1062** Phase1 NSCLC @WCLC	**DS-8201** Phase 2 BC DESTINY-Breast01 @SABCS	**DS-8201** Phase 2 GC DESTINY-Gastric01
U3-1402 Phase1 NSCLC @ASCO	**U3-1402** Phase1 NSCLC @WCLC	**DS-8201** 3L BC (US)	**DS-8201** 3L BC (JP)
	DS-1062 Phase1 NSCLC Dose expansion part	**DS-8201** Phase 2 GC DESTINY-Gastric02	
	U3-1402 Phase1 NSCLC Dose expansion part		

◆ Potential of 3 ADCs has been enhanced

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

Achievements in FY2019: Alpha

Study Initiation | Presentation at conference | Submission | Approval | Not approved

Q1	Q2	Q3	Q4
Quizartinib R/R AML (JP)	**Pexidartinib** TGCT (US)	**DS-7300** Phase 1 Solid tumors	**Axicabtagene ciloleucel/Axi-Cel®** R/R B-cell lymphoma (JP)
Quizartinib R/R AML (US)		**DS-3201** Phase 2 ATL	**DS-2741** Phase 1 Dermatitis atopic
Inavir Nebulizer Influenza treatment (JP)		**Quizartinib** R/R AML (EU)	
DS-1001 Phase 1 Glioma @ASCO			
DS-3201 Phase 1 SCLC			
DS-1205 Phase 1 Osimertinib combo			

- **Needed to redefine AML strategy centered on quizartinib within 3 and Alpha strategy**
- **Obtained approval of first oncology product for US, pexidartinib**

AML: acute myeloid leukemia, ATL: adult T-cell leukemia/lymphoma R/R: relapsed/refractory, SCLC: small cell lung cancer, TGCT: tenosynovial giant cell tumor

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Progress of DS-8201

Breast cancer

Obtained accelerated approval

- Approved in Dec. 2019
  - 4 years and 3 months from start of first-in human study
  - 2 months from FDA acceptance

- Approved in Mar. 2020
  - 6 months after NDA
  - Third drug approved under the Conditional Early Approval Program

Gastric cancer

Obtained primary endpoint

- Obtained TLR in Jan. 2020
  - Primary endpoint: **achieved statistically significant and clinically meaningful improvement in objective response rate (ORR)**, as assessed by an independent review committee, in patients treated with DS-8201 versus investigator's choice of chemotherapy
  - Secondary endpoint: **achieved statistically significant and clinically meaningful improvement in overall survival (OS)** , in patients treated with DS-8201 versus investigator's choice of chemotherapy
- NDA planned in FY2020 Q1 (JP)
  - 6 months or faster review period anticipated under SAKIGAKE Designation
- First EAP of DS-8201 started in JP

EAP: Expanded Access Program

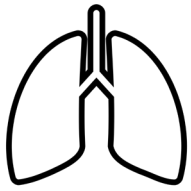
Results from Collaboration with AstraZeneca

DS-8201: significant increase in the number of trials

Prior to collaboration: 17 studies

Following collaboration: 43 studies

Breast



Lung

Gastric

Colorectal

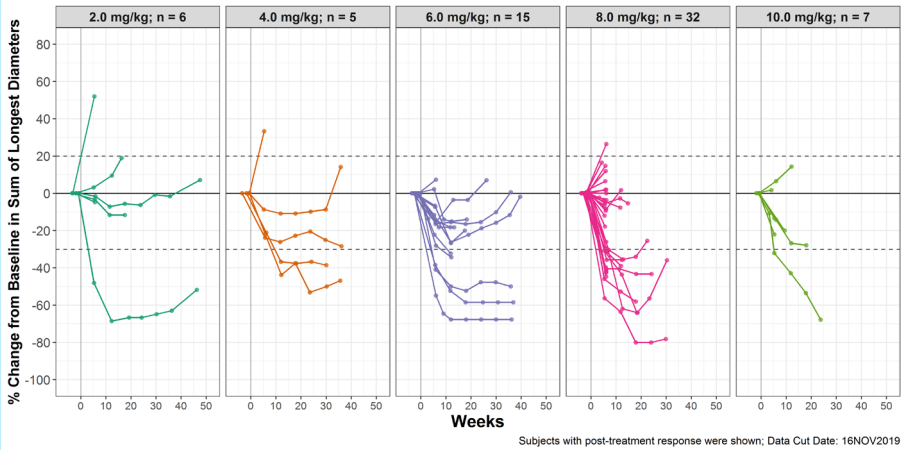
Tumor Agnostic, I/O Combinations, Others

- Expansion of I/O combo studies (adding DS-8201 cohort to IMFINZI® (durvalumab) combo studies conducted by AstraZeneca)
  - HUDSON study (NSCLC)
  - BEGONIA study (TNBC)

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

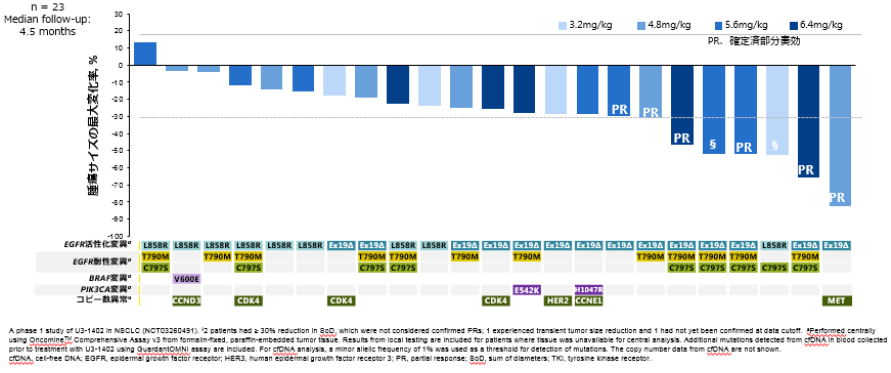
3 ADCs: Progress of DS-1062 and U3-1402

DS-1062



- NSCLC phase 1 clinical trial has progressed steadily
  - Interim data planned to be presented at ASCO 2020
- Next step is under consideration
  - Pivotal study NSCLC without mutation (post IO/platinum)
  - NSCLC with mutation (post TKIs and platinum)
  - NSCLC with PD-1/PD-L1 inhibitors combo

U3-1402



- EGFRm NSCLC phase 1 clinical trial has progressed steadily
  - Interim data planned to be presented at WCLC 2020
- Breast cancer phase 1 study completed patient enrollment
  - Future development plan is under consideration
- Next step is under consideration
  - EGFRm NSCLC pivotal study
  - Colorectal cancer

Development has progressed steadily

NSCLC: non-small cell lung cancer

3 ADCs: Progress of Publications

DS-8201: 5 publications

The LANCET Oncology
Apr. 2019
- Phase 1: HER2+ BC
- Phase 1: HER2+ GC

The NEW ENGLAND JOURNAL of MEDICINE
Dec. 2019
- DESTINY-Breast01: HER2+ BC

Journal of Clinical Oncology
Feb. 2020
- Phase 1: HER2 low BC

CANCER DISCOVERY
Mar. 2020
- Phase 1: HER2-expressing/ mutant, other cancers

Presentations at major international conferences

ASCO 2019
May-Jun. 2019 @ Chicago
- DS-1062 phase 1 NSCLC
- U3-1402 phase 1 NSCLC

WCLC 2019
Sep. 2019 @ Barcelona
- DS-1062 phase 1 NSCLC
- U3-1402 phase 1 NSCLC

SABCS 2019
Dec. 2019 @ San Antonio
- DS-8201 DESTINY-Breast01 HER2+ BC

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

Review of FY2019

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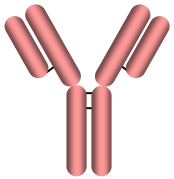
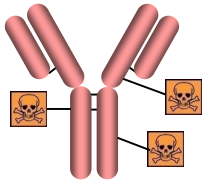
Future news flow

Technology Portfolio at Daiichi Sankyo

Today's Focus: cell therapy and gene therapy

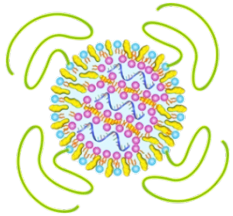

Antibody

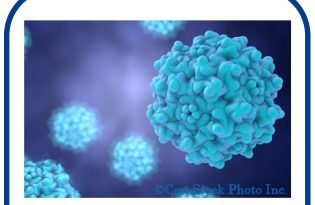

ADC

Oncology

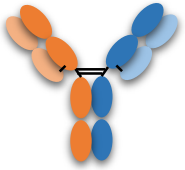
Genetic/
Orphan Disease


MED & ENA
Nucleotide

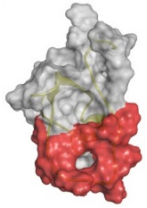

LNP/mRNA

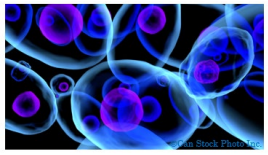

Gene Therapy

Inflammation/
Immunology


Bispecific

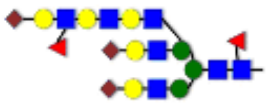
Cardio-renal
diseases

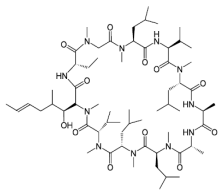

Scaffold


Cell Therapy

Neurology/
Neuroscience

Vaccine

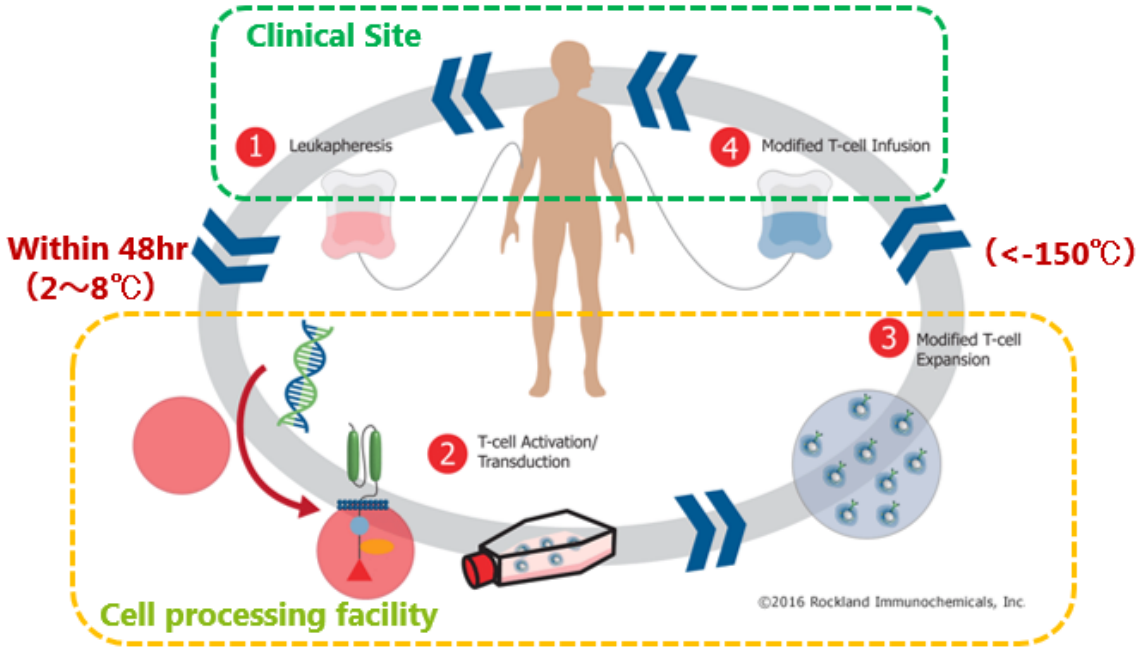

Sugar chain
Modification


Cyclic peptide
Peptide drug

Axi-Cel® : Treatment for R/R B-Cell Lymphoma

- Mar. 30, 2020: NDA submitted in Japan
  - Priority review anticipated (Orphan Drug Designation)

Now establishing manufacturing and supply infrastructure to be ready for launch



- **To further advance regenerative medicine and cell therapy**

R/R: relapsed/refractory

Daiichi Sankyo's Efforts in Gene Therapy

Rare diseases caused by monogenic abnormalities

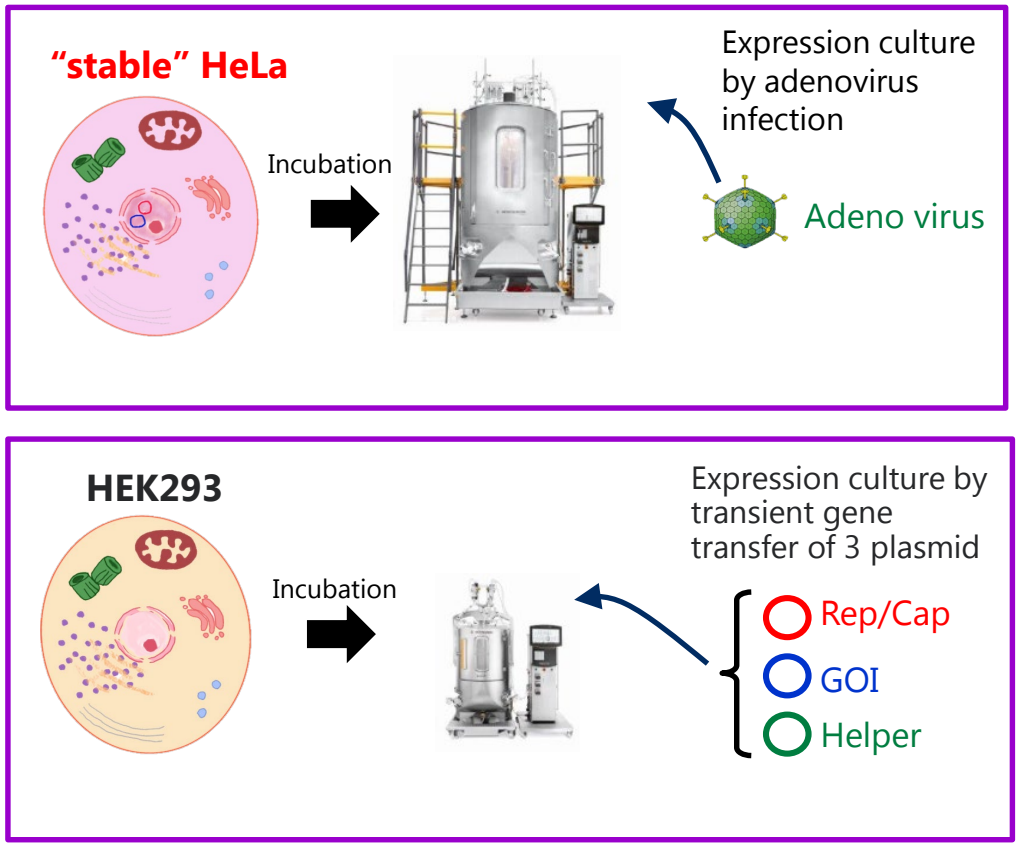
- **Start from inherited disorder**
  - Several projects will start clinical studies after FY2024
  - Focus on gene therapy using adeno-associated virus vector (AAV) which is known to be the safest viral vector

Serious general diseases

- **Establish mass production technology and expand to non-rare diseases**
  - Establish and introduce drug discovery technology
  - Discover treatment drugs that can change SOC

- **Provide innovative medicines to patients suffering from diseases for which effective treatments are not available or where existing treatments are not sufficiently effective**

Ultragenyx: Gene Therapy Manufacturing Technology



Manufacturing technology is the key to gene therapy

- **Ultragenyx has developed its own AAV production system using HeLa and HEK293 cells**
  - **Experience in clinical trials**
  - **Stable quality**
  - **Knowledge in mass production**
  - **Analytical technology for quality control**

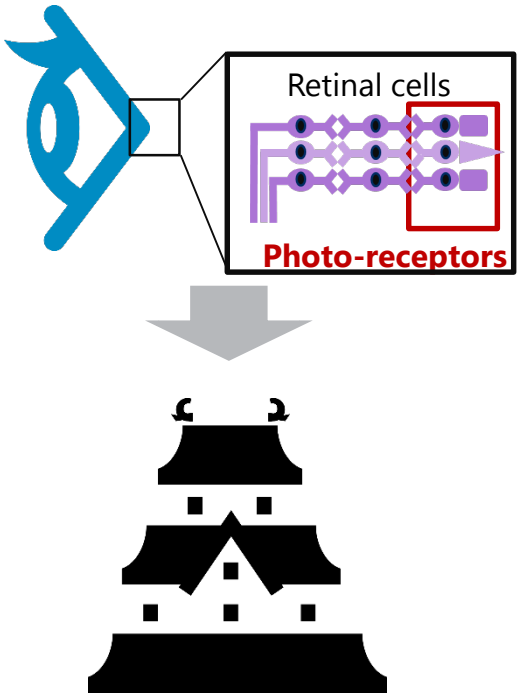
- **Establish DS in-house manufacturing technology and start manufacturing investigational gene therapy drug by the mid-2020s**

Joint Research with Nagoya Institute of Technology

Daiichi-Sankyo

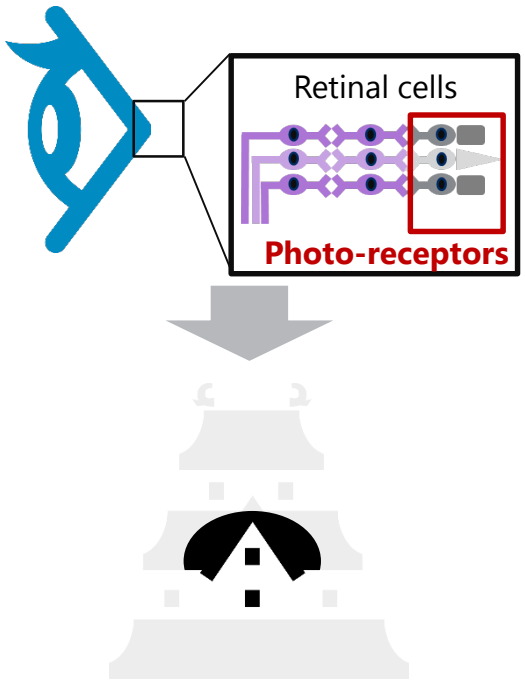
Healthy People

Sensing light through "photoreceptors"



Severe Retinitis Pigmentosa

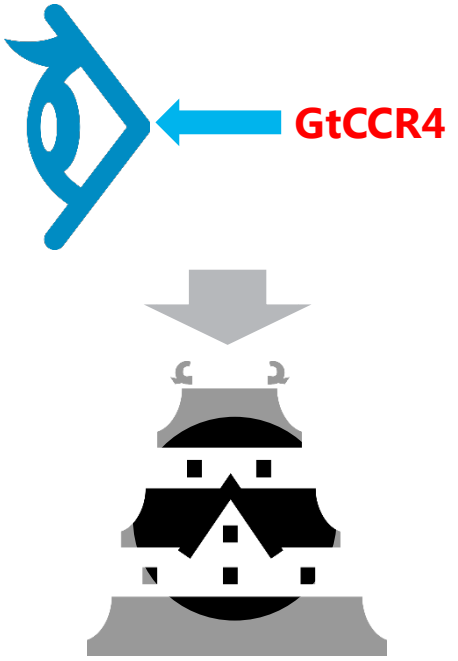
"Photoreceptor" has fallen off and the light cannot be sensed



Severe vision loss

Gene Therapy

Sensing light by expressing **new highly active photoresponsive protein "GtCCR4"**



Vision recovery

- **We aim to provide gene therapy drug for patients with visual loss due to retinitis pigmentosa by combining GtCCR4 and gene therapy**

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Planned Presentation at ASCO 2020 (May 29-31 Held Virtually)

- **Abstract available online: May 13th, 5pm (EDT)**
- **Slides and posters available online: May 29th**

DS-8201	NSCLC	HER2 positive/mutated NSCLC phase 2 Study ◆ **Oral presentation**
	Colorectal	HER2 positive colorectal cancer phase 2 study ◆ **Oral presentation**
	Gastric	HER2 positive GC pivotal phase 2 study ◆ **Poster discussion presentation**
	Breast	HER2 positive BC pivotal phase 2 study sub-analysis results ◆ **Poster presentation**
DS-1062	NSCLC	NSCLC phase 1 study ◆ **Poster presentation**

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

ASCO 2020: IR Conference Call

Sunao Manabe
President and CEO

Antoine Yver
Global Head of Oncology R&D

In Japanese (with consecutive translation)	Monday, June 1, 2020 – 7:30 - 9:00 am JST
In English	Tuesday, June 2, 2020 – 9:00 – 10:30 pm JST

- **Content from both calls will be delivered on-demand later**

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Future News Flow

As of April 2020

Daiichi-Sankyo

DS-8201	Breast	HER2 positive BC pivotal phase 2 study ◆ EU: MAA submission planned for **1Q FY2020**
	Gastric	HER2 Positive GC pivotal phase 2 study ◆ JP: sNDA planned in 1Q FY2020
U3-1402	NSCLC	EGFR mutated NSCLC phase 1 study ◆ Update on dose expansion part planned at WCLC 2020 (WCLC has been postponed to **Jan. 2021** from Aug. 2020)
Pexidartinib	TGCT	Tenosynovial giant cell tumor ◆ EU: under review for 1H FY2020 decision
DS-1647 (G47Δ)	GBM	Malignant glioma ◆ Japan: NDA planned in **1H FY2020**

Underlined: New or Updated from FY2019 Q3

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

1 Actions Against COVID-19 and Impact on Business

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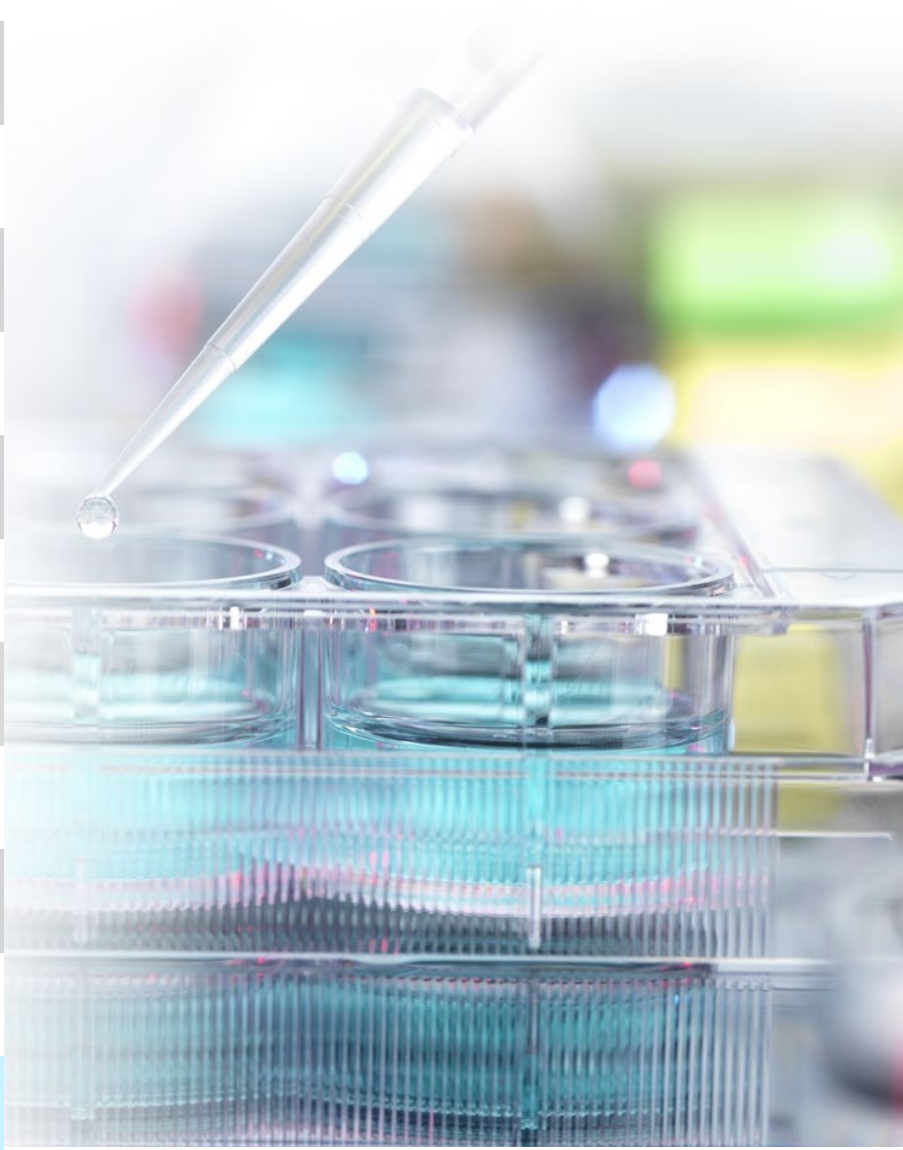
6 **Appendix**



Major R&D Milestones in FY2020

As of April 2020

Daiichi-Sankyo

	Project	Target Indications and Studies	FY2019	FY2020			
			Q4	Q1	Q2	Q3	Q4
3 ADCs	DS-8201	P2 pivotal: HER2+ 3L BC (JP/US/EU/Asia)	US launched JP approved	EU submission			
		P2 pivotal: HER2 + 3L GC (JP/Asia)	TLR obtained	JP submission		JP decision	
		P1: BC, NSCLC (with pembrolizumab) (US/EU)	→	Study started planned			
Alpha	Pexidartinib	P3: tenosynovial giant cell tumor (EU)		EU decision			
	DS-1647	IIS: malignant glioma (JP)	→	JP submission		JP decision	
	Axicabutadine Cilorucell/ Axi-Cel®	P2 pivotal: R/R B-cell lymphoma (JP)	Submission			Decision	
	DS-6157	P1: GIST (JP/US)	→	Study start planned			
	Edoxaban	P3: atrial fibrillation in the very elderly (JP)		Data anticipated		JP submission	
	Prasugrel	P3: ischemic stroke (JP)			Data anticipated		JP submission
	DS-5141	P1/2: Duchenne type muscular dystrophy (JP)				Data anticipated	
	DS-2741	P1: atopic dermatitis (JP)	Study started				

BC: breast cancer, GC: gastric cancer, GIST: gastrointestinal stromal tumors, IIS: investigator-initiated study, NSCLC: non-small-cell lung cancer

Red underlined: new or updated from FY2019 Q3 **Blue: achieved**

Major R&D Pipeline: 3 ADCs

As of April 2020

Daiichi-Sankyo

Phase 1		Phase 2	Phase 3	Submitted
DS-8201(US/EU) Anti HER2-ADC BC, bladder cancer (with nivolumab)	**DS-8201 (US/EU) prep** Anti HER2-ADC BC, NSCLC (with pembrolizumab)	**DS-8201 (EU/Asia)** Anti HER2-ADC 3L BC DESTINY-Breast01	**DS-8201(JP/US/EU/Asia)** Anti HER2-ADC 3L BC DESTINY-Breast02	
U3-1402 (JP/US) Anti HER3-ADC BC	**U3-1402 (JP/US/Asia)** Anti HER3-ADC EGFRm NSCLC	**DS-8201 (JP/Asia)** Anti HER2-ADC 3L GC DESTINY-Gastric01	**DS-8201(JP/US/EU/Asia)** Anti HER2-ADC 2L BC DESTINY-Breast03	
DS-1062(JP/US) Anti TROP2-ADC NSCLC		**DS-8201(JP/US/EU)** Anti HER2-ADC NSCLC DESTINY-Lung01	**DS-8201(JP/US/EU/Asia)** Anti HER2-ADC HER2 low BC DESTINY-Breast04	
		DS-8201(JP/US/EU) Anti HER2-ADC CRC DESTINY-CRC01		
		DS-8201 (US/EU) Anti HER2-ADC 2L GC DESTINY-Gastric02		
		DS-8201(US/EU/Asia) prep Anti HER2-ADC NSCLC (with durvalumab) HUDSON		
		DS-8201(US/EU/Asia) prep Anti HER2-ADC TNBC(with durvalumab) BEGONIA		

DS-8201 U3-1402 DS-1062

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

SAKIGAKE Designation (JP)

Major R&D Pipeline: Alpha

As of April 2020

Daiichi-Sankyo

Phase 1	Phase 2	Phase 3	Submitted
DS-3201 (JP/US) EZH1/2 inhibitor Non-Hodgkin's Lymphomas (PTCL)	**DS-3201 (US)** EZH1/2 inhibitor AML, ALL	**DS-1647 (G47Δ) (JP)** Oncolytic HSV-1 Malignant glioma IIS	**Quizartinib (JP/US/EU)** FLT3 Inhibitor 1L AML	**Pexidartinib (EU)** CSF-1/KIT/FLT3 inhibitor TGCT
DS-3201 (US) EZH1/2 inhibitor SCLC	**DS-3032 (JP/US)** MDM2 Inhibitor Solid tumors (liposarcoma)	**DS-3201 (JP)** EZH1/2 inhibitor ATL/L	**Edoxaban (JP)** FXa inhibitor Atrial fibrillation in the very elderly	**Axicabtagene ciloleucel/Axi-Cel (JP)** Anti CD19 CAR-T cells R/R B-cell lymphoma
DS-3032 (JP/US) MDM2 Inhibitor AML	**PLX2853 (US)** BET inhibitor AML		**Prasugrel (JP)** ADP receptor inhibitor Ischemic stroke	**VN-0107/MEDI3250 (JP)** live attenuated influenza vaccine nasal spray
DS-1001 (JP) Mutant IDH1 inhibitor Glioma	**PLX2853 (US)** BET inhibitor Solid tumor		**Mirogabalin (JP)** $\alpha_2\delta$ Ligands Central neuropathic pain	
DS-1205 (Asia) AXL inhibitor NSCLC (with osimertinib)	**DS-1205 (JP)** AXL inhibitor NSCLC (with gefitinib)		**Esaxerenone (JP)** MR blocker Diabetic nephropathy	
DS-6157 (JP/US) Anti GPR20-ADC GIST	**DS-7300 (JP/US)** Anti B7-H3-ADC Solid Tumors		**VN-0102/JVC-001 (JP)** Measles mumps rubella combined vaccine	
DS-1211 (US) TNAP inhibitor Pseudoxanthoma elasticum	**DS-5141 (JP)** ENA oligonucleotide DMD			
	DS-2741 (JP) Anti-Orai1 antibodies Atopic dermatitis			

Oncology Specialty medicine Vaccine

ALL: acute lymphocytic 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, SCLC: small cell lung cancer, TGCT: tenosynovial giant cell tumor

□: 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)

Projects for Out-Licensing

As of April 2020

Daiichi-Sankyo

Discovery	Preclinical	Phase 1	Phase 2/3
Tryptophanase inhibitor Uremia/Late stage chronic kidney disease **Global**		**DS-1001** Mutant IDH1 inhibitor Glioma **Regions other than Japan**	
Long Acting ANP: long-acting GC-A activator Resistant Hypertension/Chronic Heart Failure **Global**		**DS-3032** MDM2 Inhibitor AML, MDS, solid tumor **Global**	

Oncology Specialty medicine

AML: acute myeloid leukemia, MDS: myelodysplastic syndromes

Abbreviations

Abbreviations	English	Implications
AE	Adverse event	Undesirable experience associated with the use of a medical product in a patient
BTD	Breakthrough therapy designation	Designation granted by US FDA that expedites drug development
CR	Complete response	Complete response (complete resolution of cancer)
CRL	Complete response letter	Letter issued by the FDA after completion of its review and determined the application cannot be approved based on the current submission
DCR	Disease control rate	Disease control rate (percentage of patients with controlled disease status)
DLT	Dose limiting toxicity	Dose-limiting toxicities (toxicities that may explain the inability to escalate doses)
DOR	Duration of response	Length of time that a tumor responds to treatment
EGFR	Epidermal growth factor receptor	Epidermal growth factor receptor
MTD	Maximum tolerated dose	The highest dose of a drug or treatment that does not cause unacceptable side effects
ORR	Overall response rate Objective response rate	Overall response rate (expressed as the proportion of patients who responded to treatment and the sum of CR and PR)
OS	Overall survival	Overall survival (time from start of treatment to death)
PD	Progressive disease	Disease progression (worsening disease despite treatment)
PFS	Progression-free survival	Progression-free survival (without cancer progression)
PR	Partial response	Partial response (a reduction in the size of the cancer by 30% or more that lasts for 4 weeks)
SD	Stable disease	The size of the cancer is almost unchanged before and after treatment
TEAE	Treatment emergent adverse event	Any event not present prior to the initiation of the treatments or any event already present that worsens in either intensity or frequency following exposure to the treatments

Inquiries about this document

Daiichi Sankyo Co., Ltd.

Corporate Communications Dept.

TEL:+81-3-6225-1126

Email: DaiichiSankyoIR@daiichisankyo.co.jp