Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2019 Q2
Financial Results Presentation

DAIICHI SANKYO CO., LTD

Sunao Manabe
President and CEO

October 31, 2019

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1. **FY2019 Q2 Financial Results**
2. FY2019 Forecast
3. Business Update
4. 5-Year Business Plan Update
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Overview of FY2019 Q2 Results

(Bn JPY)

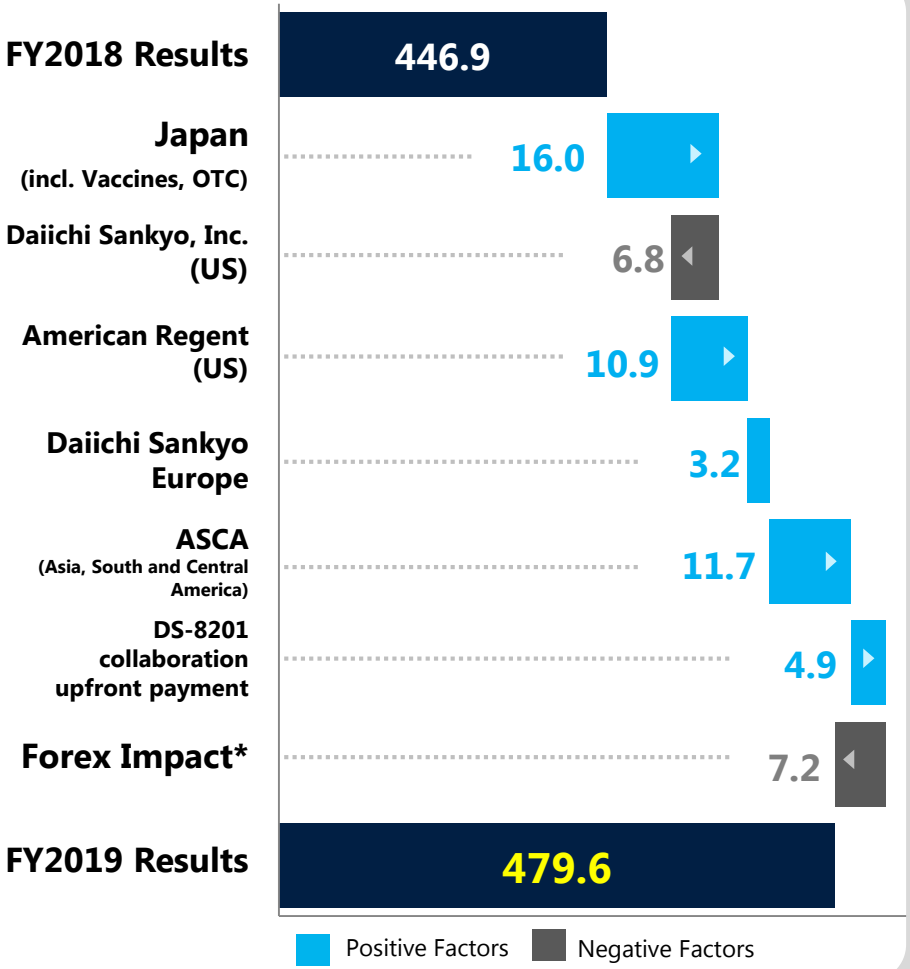
	FY2018 Q2 YTD Results	FY2019 Q2 YTD Results	YoY
Revenue	446.9	479.6	+7.3% +32.7
Cost of Sales	166.6	177.1	+10.5
SG&A Expenses	128.6	130.5	+1.9
R&D Expenses	93.7	85.9	-7.8
Operating Profit	58.0	86.2	+48.6% +28.2
Profit before Tax	58.6	87.0	+28.4
Profit attributable to owners of the Company	44.0	64.4	+46.4% +20.4

Currency Rate	USD/JPY	110.27	108.63	-1.64
	EUR/JPY	129.84	121.41	-8.43

Revenue

Increased by 32.7 Bn JPY (Increased by 39.9 Bn JPY excl. forex impact)

(Bn JPY)



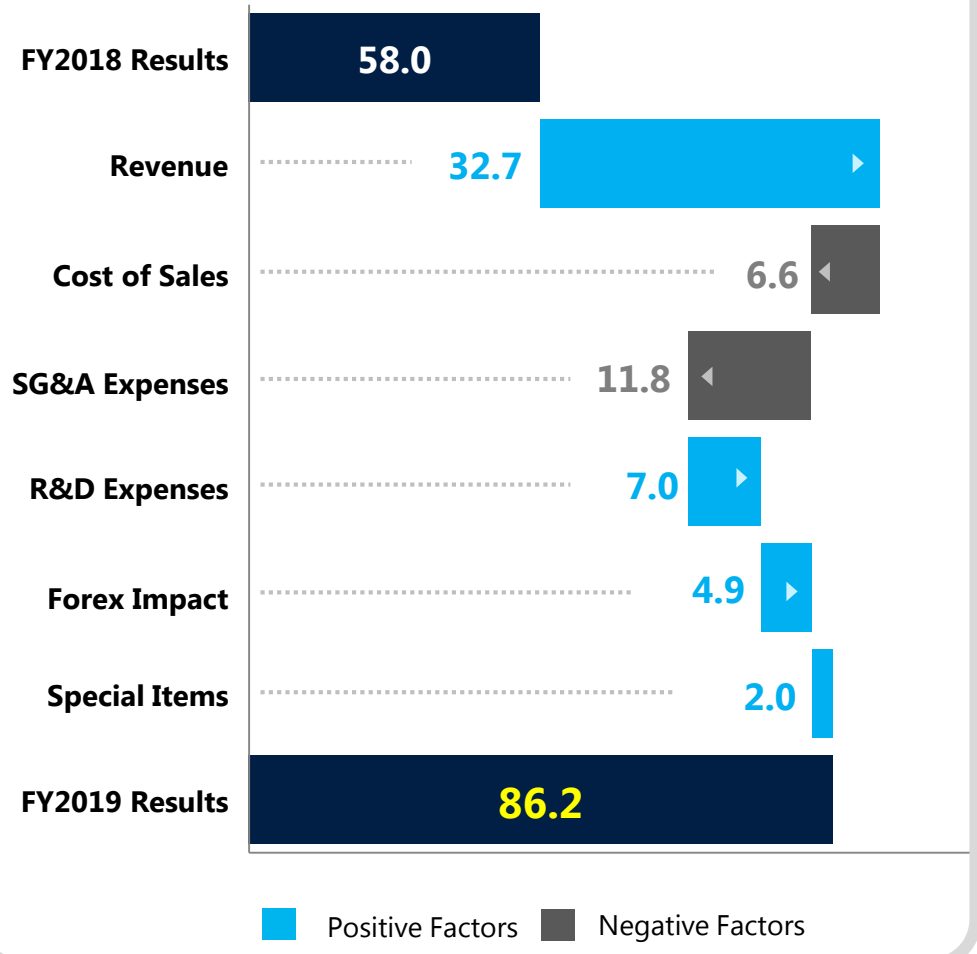
Positive Factors		Negative Factors	
Japan			
Lixiana	+11.7		
Tarlige	+3.3		
Pralia	+2.4		
Vimpat	+2.4		
Canalia	+2.0		
Daiichi Sankyo Espha (GE)	+4.9	Daiichi Sankyo Healthcare	-0.7
Silodosin AG			
Daiichi Sankyo, Inc. (US)			
		Welchol	-3.8
		Effient	-2.4
American Regent, Inc. (US)			
GE injectables	+5.8		
Injectafer	+4.4		
Daiichi Sankyo Europe			
Lixiana	+8.6	Olmesartan	-2.5
ASCA (Asia, South and Central America)			
China	+9.0		
Cravit, Olmetec etc.			

* Forex impact USD: -1.3, EUR : -3.0, ASCA: -2.9

Operating Profit

Increased by 28.2 Bn JPY

(Increased by 28.4 Bn JPY excl. forex impact and special items)



(Bn JPY)

Revenue +32.7
incl. forex impact of -7.2

Cost of Sales +6.6 (Cost increased)
Increase by revenue increase

SG&A Expenses +11.8 (Cost increased)
Increase in personnel expenses in US

R&D Expenses -7.0 (Cost decreased)
Decrease by DS-8201 cost share with AstraZeneca

Forex Impact -4.9 (Cost decreased)
Cost of Sales -1.3
SG&A Expenses -2.7
R&D Expenses -0.9

Special Items -2.0 (Cost decreased)
See next slide for details

Special Items

(Bn JPY)

	FY2018 Q2 YTD Results	FY2019 Q2 YTD Results	YoY
Cost of Sales		Restructuring costs in SC 1.3 Impairment loss (intangible assets)*1 3.8	+5.1
SG&A Expenses	Gain on sales of fixed assets -3.5	Gain on sales of fixed assets*2 -10.6	-7.2
R&D Expenses			
Total	-3.5	-5.5	-2.0

*1 Morphabond, Roxybond
*2 Gain on sales of Nihonbashi building

- : Cost decreased items

Booked in Q2

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".

U.S. : Pain Business

Daiichi Sankyo, Inc. will exit the pain treatment business in order to focus on oncology & injectable iron business

opioid-induced constipation treatment

movantik™

- Daiichi Sankyo, Inc. has transitioned sales efforts back to AstraZeneca as of October 2019

(morphine sulfate) extended release tablets

MORPHABOND™ ER (morphine sulfate) extended-release tablets C II
15 mg • 30 mg • 60 mg • 100 mg

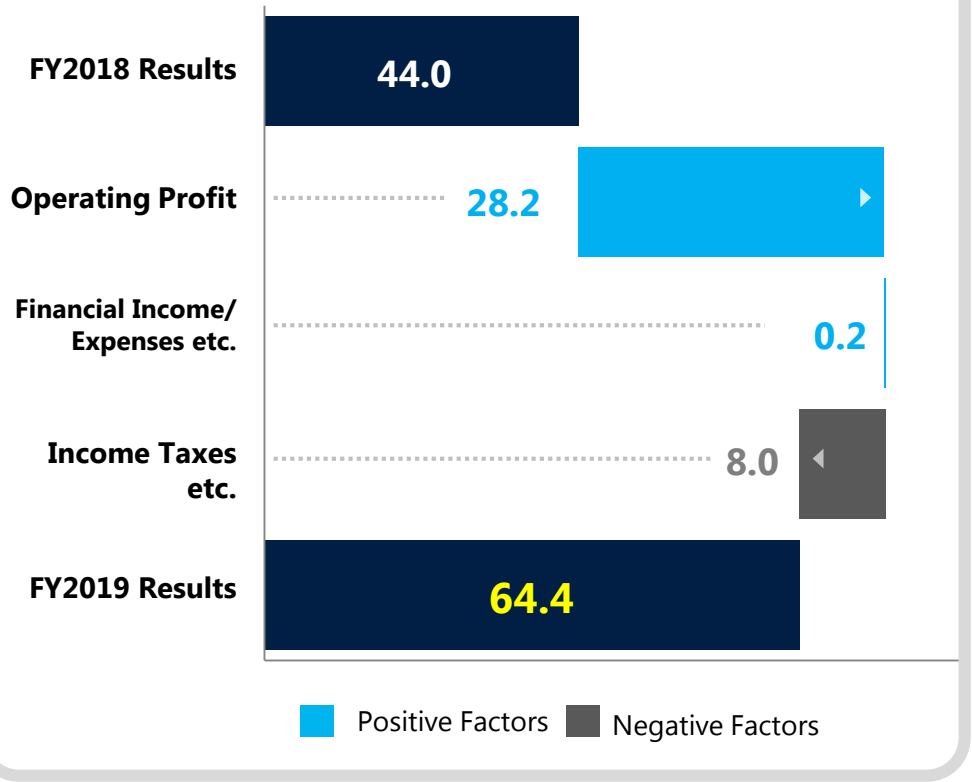
(oxycodone hydrochloride) immediate release tablets

ROXYBOND™ (oxycodone hydrochloride) immediate release tablets C II
5 mg • 15 mg • 30 mg

- In September 2019, Daiichi Sankyo, Inc. notified Inspirion Delivery Sciences that we are terminating the license agreement

Profit Attributable to Owners of the Company

Increased by 20.4 Bn JPY



(Bn JPY)

Income Taxes etc. ····· +8.0 (Cost increased)

	FY2018	FY2019	YoY
Profit before Tax	58.6	87.0	+28.4
Income Taxes etc.	14.6	22.7	+8.0
Tax rate	24.9%	26.0%	+1.1%

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2018 Q2 YTD Results	FY2019 Q2 YTD Results	YoY
Japan	243.7	261.0	+17.2
Daiichi Sankyo Healthcare	34.8	34.1	-0.7
Daiichi Sankyo, Inc.	22.0	14.9	-7.0
Olmesartan	5.8	5.5	-0.3
Welchol	8.7	4.8	-3.9
American Regent, Inc.	58.4	68.3	+9.9
Injectafer	22.0	26.0	+4.0
Venofer	16.6	16.4	-0.2
GE injectables	17.0	22.4	+5.4
Daiichi Sankyo Europe	43.0	43.2	+0.2
Lixiana	20.8	27.5	+6.7
Olmesartan	14.4	11.2	-3.2
Efient	3.3	1.4	-1.9
ASCA (Asia, South and Central America)	40.1	49.0	+8.8

Currency Rate	USD/JPY	110.27	108.63	-1.64
	EUR/JPY	129.84	121.41	-8.43

Revenue: Major Products in Japan

(Bn JPY)

		FY2018 Q2 YTD Results	FY2019 Q2 YTD Results	YoY
Lixiana	anticoagulant	**30.1**	**41.8**	**+11.7**
Nexium	ulcer treatment	**38.6**	**40.2**	**+1.6**
Memary	Alzheimer's disease treatment	**25.2**	**25.7**	**+0.5**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**13.0**	**15.4**	**+2.4**
Tenelia	type 2 diabetes mellitus treatment	**12.6**	**12.8**	**+0.1**
Loxonin	anti-inflammatory analgesic	**15.6**	**14.8**	**-0.8**
Inavir	anti-influenza agent	**0.1**	**1.0**	**+0.9**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**8.1**	**9.2**	**+1.1**
Efient	antiplatelet agent	**7.0**	**7.1**	**+0.1**
Rezaltas	antihypertensive agent	**7.8**	**7.5**	**-0.2**
Canalia	type 2 diabetes mellitus treatment	**4.1**	**6.1**	**+2.0**
Vimpat	anti-epileptic agent	**2.8**	**5.2**	**+2.4**
Omnipaque	contrast agent	**6.2**	**5.6**	**-0.6**
Olmetec	antihypertensive agent	**7.9**	**6.2**	**-1.6**

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FY2019 Forecast

(Bn JPY)

	FY2019 Forecast (as of Apr.)	FY2019 Forecast (as of Oct.)	vs. Forecast (as of Apr.)
Revenue	940.0	955.0	+15.0
Cost of Sales	330.0	330.0	-
SG&A Expenses	285.0	290.0	+5.0
R&D Expenses	225.0	210.0	-15.0
Operating Profit	100.0	125.0	+25.0
Profit before Tax	100.0	125.0	+25.0
Profit attributable to owners of the Company	72.0	90.0	+18.0

Major factors

- Japan (Lixiana) +7.0
- American Regent, Inc. (Injectafer) +9.0

Major factors

- Costs increase for establishment of the oncology business structure

Major factors

- Decrease by DS-8201 cost share with AstraZeneca

Currency Rate	USD/JPY	110.00	109.31
	EUR/JPY	130.00	125.71

Assumption of currency rate for Q3 and Q4
USD/JPY：110, EUR/JPY：130

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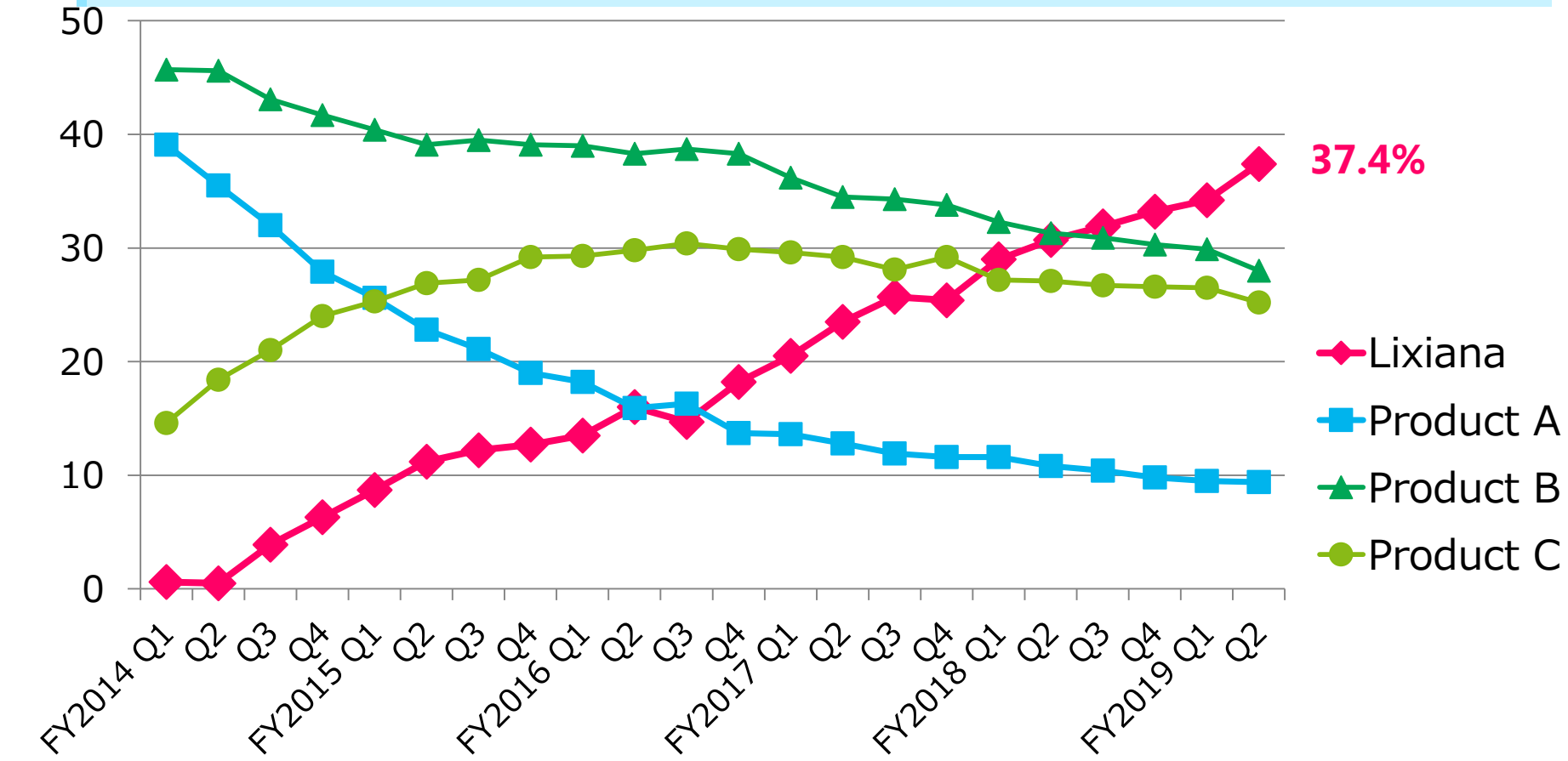
Lixiana: Growth in Japan

Sales

Daiichi-Sankyo

- No.1 sales share (FY2019 Q2: 37.4%)
- Revenue Results: FY2019 Q2 YTD
  41.8 Bn JPY (YoY +11.7 Bn JPY)



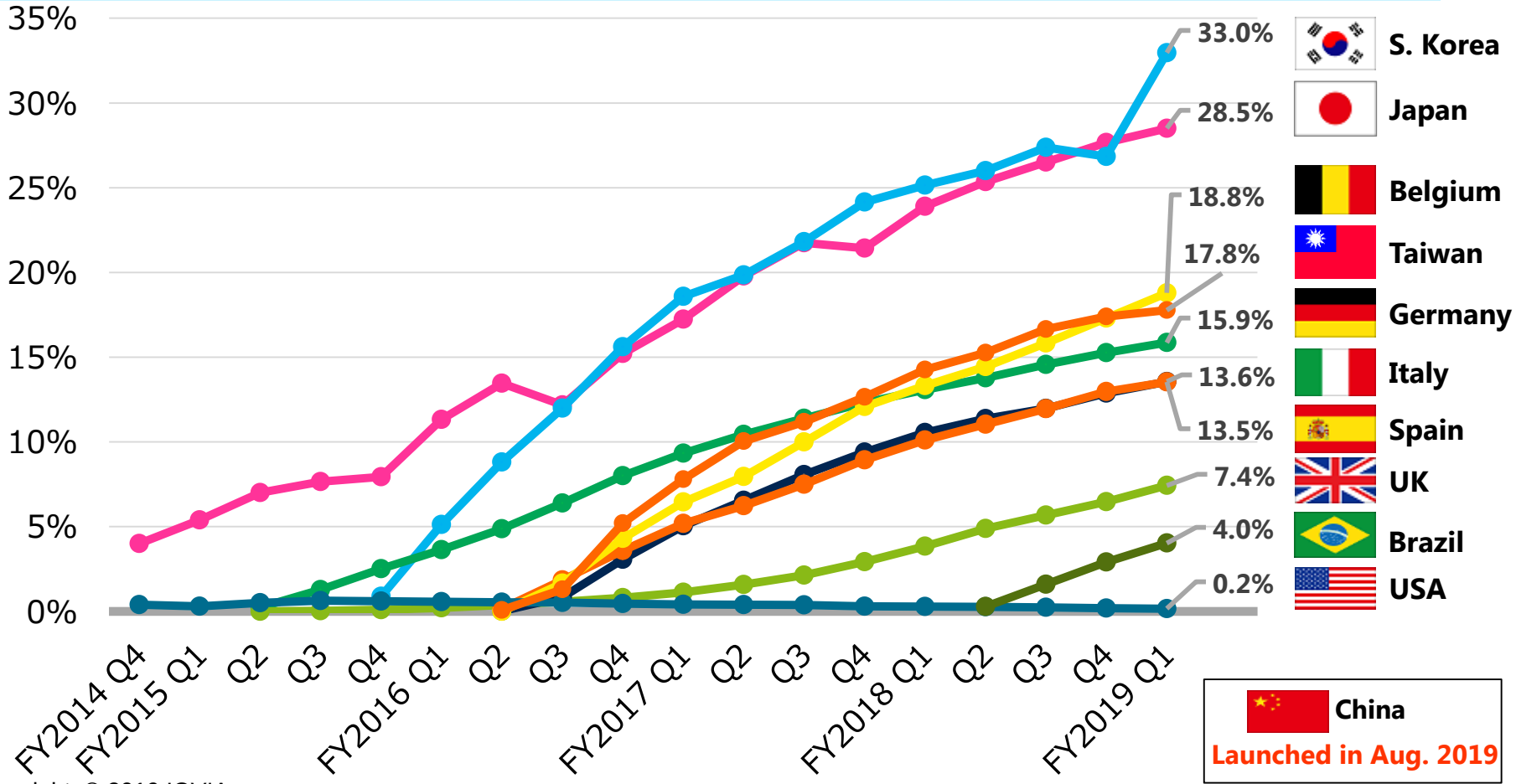
Edoxaban: Growth in Each Country

Volume

Daiichi-Sankyo

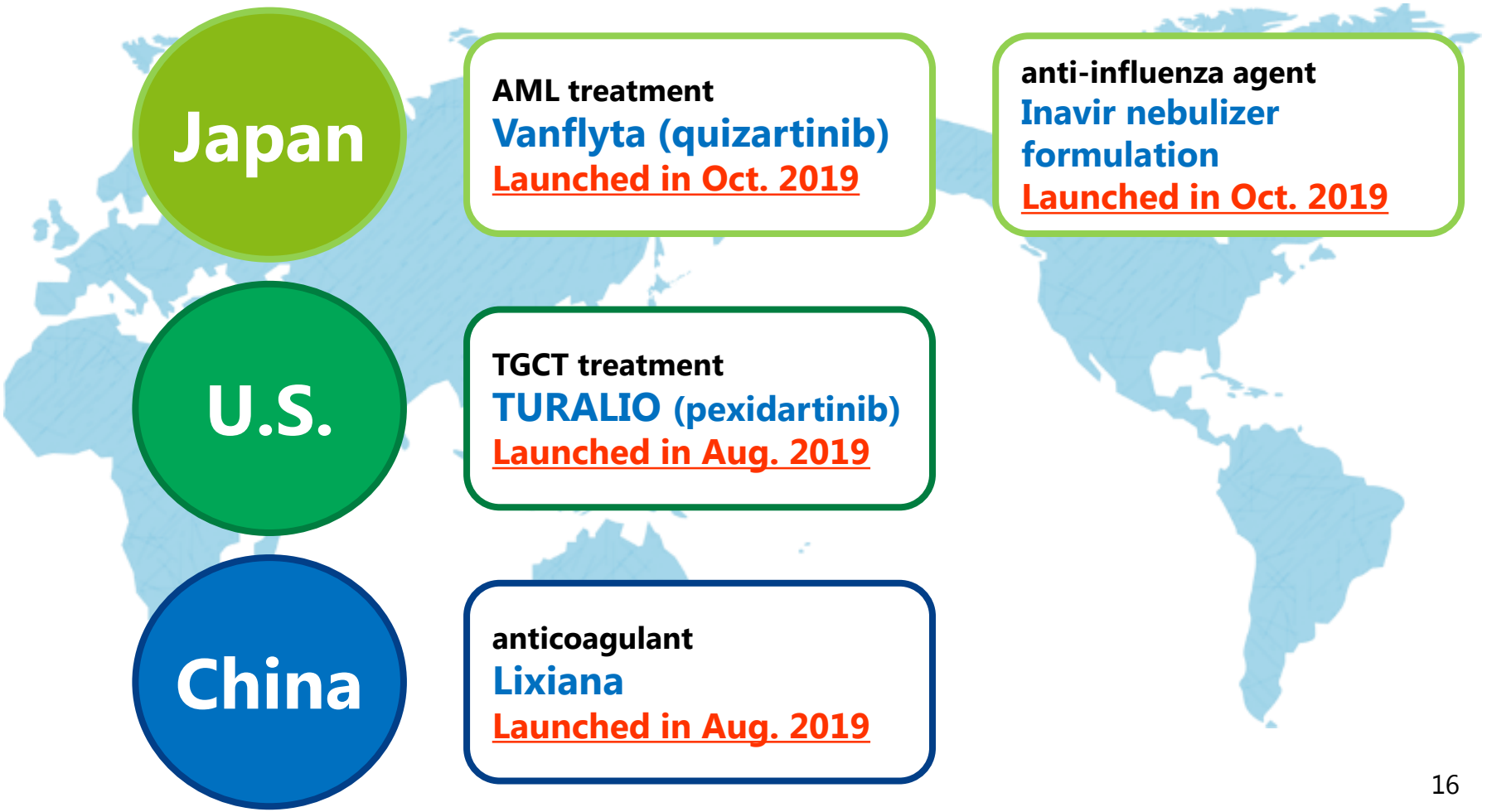
- **Steady growth in each country**
- **Global Revenue Results : FY2019 Q2 YTD**

  73.8 Bn JPY (YoY +19.6 Bn JPY)



Launch of New Products

- **Launched two new oncology products as foundation for future oncology business**
  - **Vanflyta in Japan**
  - **TURALIO in U.S.**



U.S. : New Product Launch

Launched TURALIO™ (pexidartinib), the first and only FDA approved therapy for TGCT (Tenosynovial Giant Cell Tumor) in Aug. 2019

- Indicated for adult patients with symptomatic TGCT associated with severe morbidity or functional limitations and not amenable to improvement with surgery

Localized TGCT	Diffuse TGCT
~80-90% of TGCT cases	~10-20% of TGCT cases
US incidence (2019) ~15,000	US incidence (2019) ~1,500

- National Comprehensive Cancer Network® (NCCN®)*1 has designated pexidartinib as a category 1 treatment in their NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma

- REMS*2 program implemented to manage the risks of serious and potentially fatal liver injury: Prescribed by certified healthcare providers only (70 percent of priority HCPs REMS certified; 110 Total REMS Certifications across U.S.)

*1 Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma V.4.2019. © National Comprehensive Cancer Network, Inc. 2019. All rights reserved. Accessed 10/21/19. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
*2 REMS: Risk Evaluation and Mitigation Strategy

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Further Increase in Value of 3 ADC Projects

Daiichi-Sankyo

DS-8201

- Expand development by strategic collaboration with AstraZeneca
- Achieved submission earlier than planned

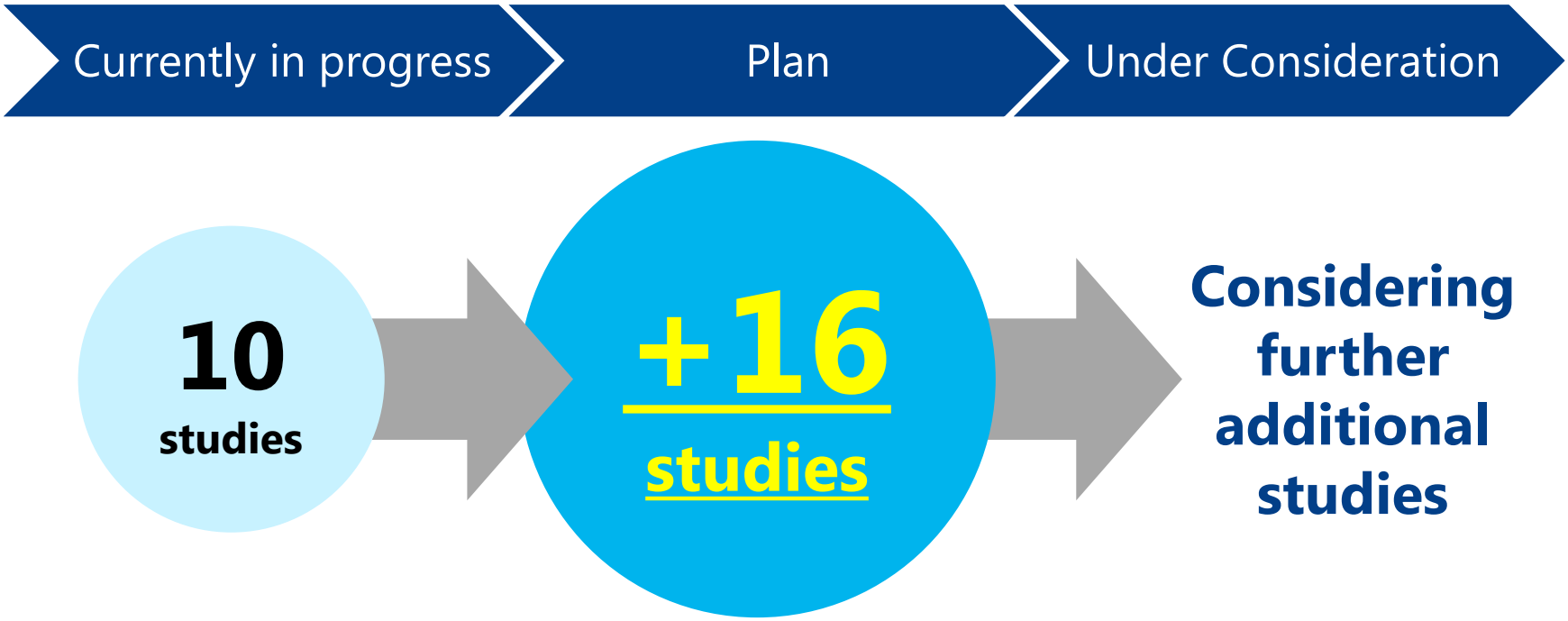
DS-1062

- Accumulated efficacy & safety clinical data by progress of phase 1 studies
- Possibility of expansion to other cancer types other than lung cancer and breast cancer (U3-1402)
- Possibility of fast-to-market

U3-1402

Expansion of DS-8201 Development Plan

- **Expansion of DS-8201 development is planned by strategic collaboration with AstraZeneca**



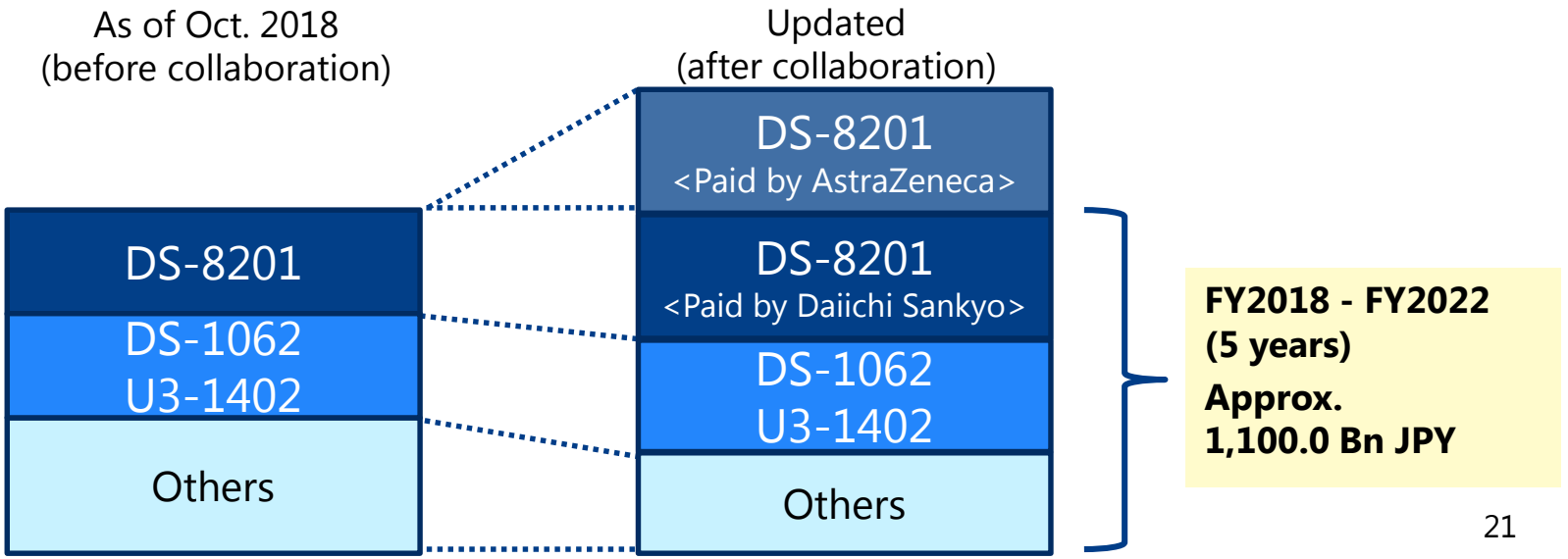
Refer to P27 for details

Investment Expansion to ADC

- **Capital expenditures**
  To be prepared for the increase in demand of ADC franchise's investigational drugs and products, newly invest 100.0 Bn JPY or more (FY2020 - FY2022)

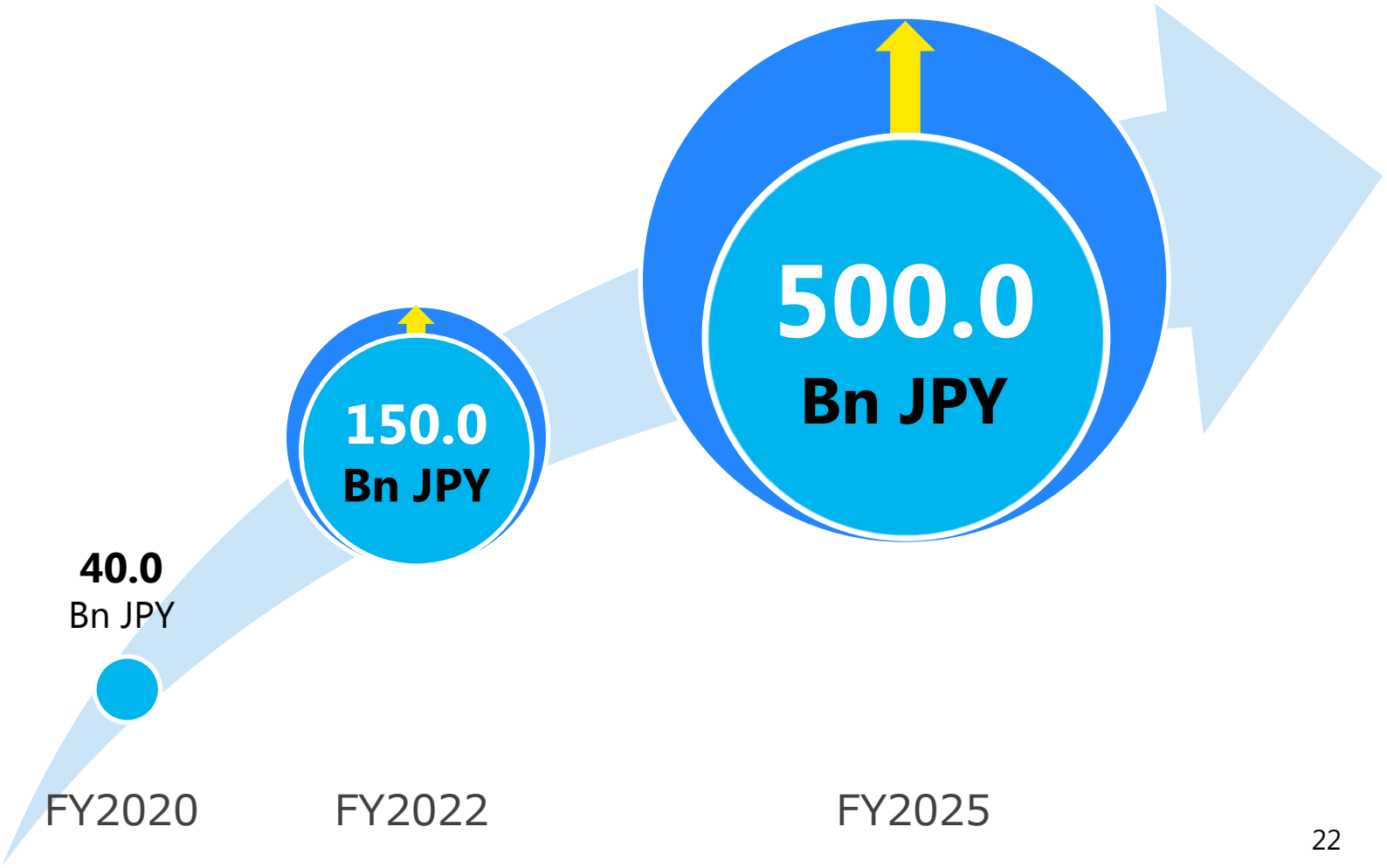
- **R&D investments**
  Concentrate investments in 3 ADC projects
  - **Total R&D investments for FY2018 - FY2022 (5 years): approx. 1,100.0 Bn JPY**

Direction of resource allocation for R&D investment (image)



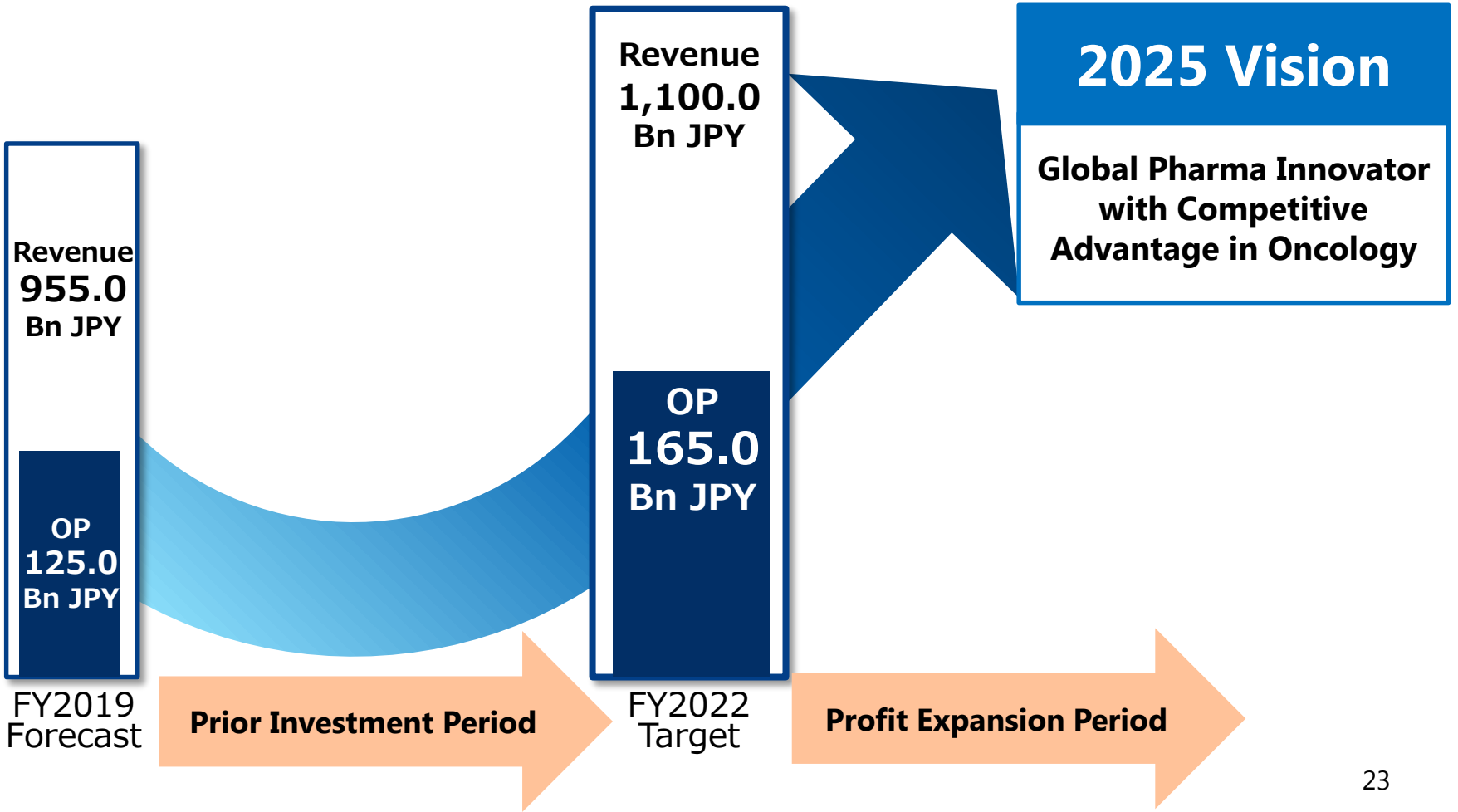
Further Growth in Oncology Business

- **Growth in future oncology business revenue**
  FY2025: Aiming for growth exceeding 500.0 Bn JPY



5-Year Business Plan Target & Next Mid-Term Business Plan

- Period until FY2022 is set as prior investment period, and period after FY2023 is set as profit expansion period
- Maintain revenue & OP target for FY2022
- Detailed targets to be developed in the next mid-term business plan (FY2021 – FY2025)



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DS-8201 Update

Interim Data from DS-1062 NSCLC Phase 1 Study

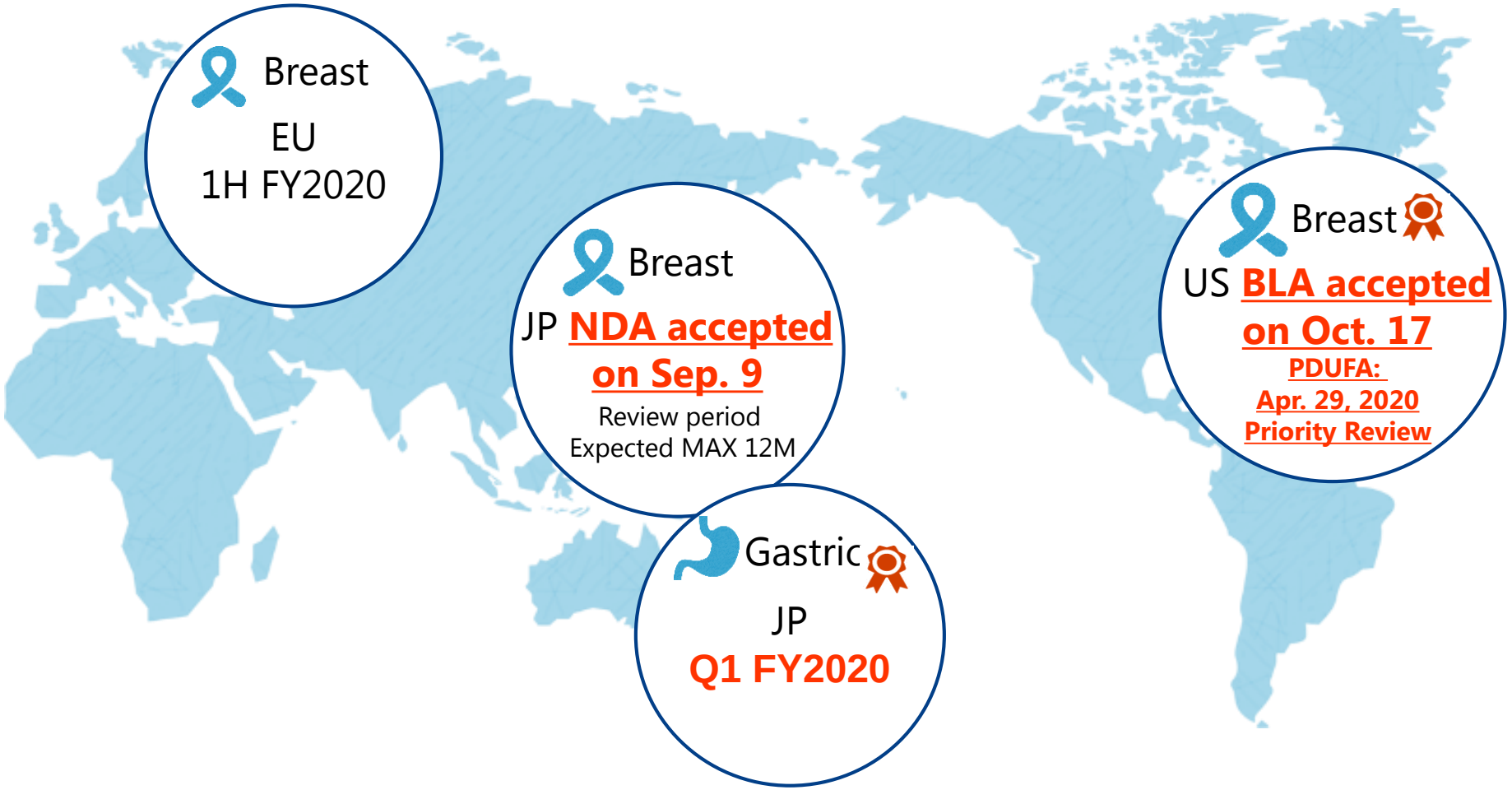
Interim Data from U3-1402 NSCLC Phase 1 Study

DS-7300 Phase 1/2 Study

DS-3201 Update

Announcement of R&D Day

DS-8201: HER2 mBC and mGC Submission Plan



- **Achieved submission within 4-year after first patient dosed**

SAKIGAKE or Breakthrough Therapy Designation

Underlined in red: new or update from FY2019 Q1

DS-8201: Clinical Development Plan Status

Daiichi-Sankyo

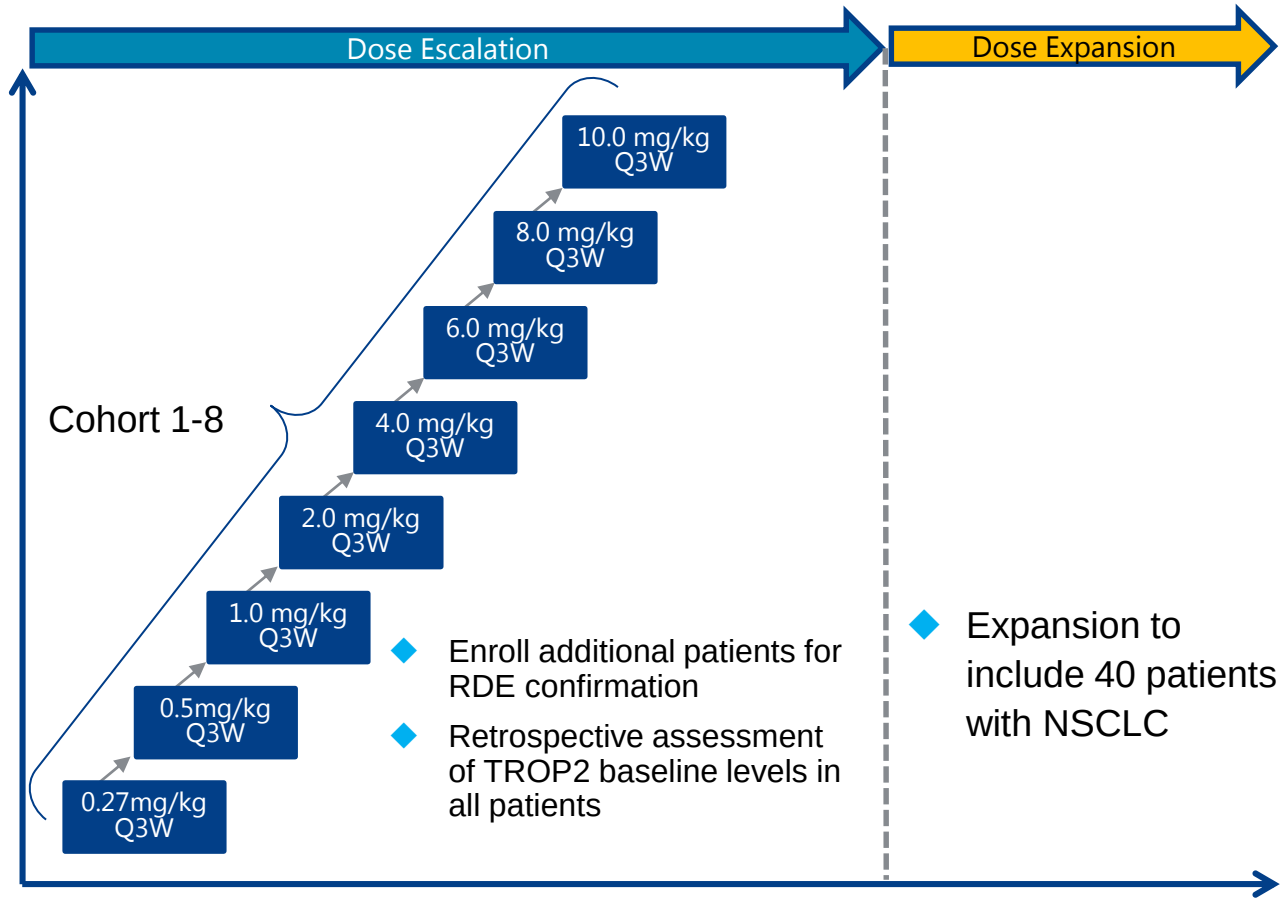
Cancer Type	HER2 status	Neo-adjuvant	Post-neoadjuvant	Adjuvant	1L	2L	3L
Breast	HER2 positive	+7 studies				P3 DESTINY-Breast03	P2 DESTINY-Breast01 P3 DESTINY-Breast02
	HER2 low(HR+)						P3 DESTINY-Breast04
	HER2 low (TNBC)						

Cancer Type	HER2 status	Early disease	1L	2L	3L
Gastric	HER2 positive	+2 studies		P2 (US/EU)	P2 DESTINY-Gastric01 (JP/Asia)
	HER2 low				
NSCLC	HER2 mutant	+3 studies			P2
	HER2 positive				
CRC	HER2 positive	+2 studies			P2
Other	HER2 mutant	+2 studies			
	HER2 positive				
Other	HER2 positive				P1 with nivolumab (breast/bladder) P1 with pembrolizumab (breast/NSCLC)

◆ **Further details will be presented at R&D Day**

DS-1062: Phase 1 Study Design (NCT03401385)

- **For unselected pts with unresectable advanced NSCLC relapsed/refractory (no prior TROP2 selection)**



- Patients demographics
  - Male (57.7%)
  - Stage IV disease (88.5%)
  - Adenocarcinoma histology (73.1%)
  - ECOG PS 1(80.8%)
  - Failed prior immune checkpoint inhibitors (86.5%)

Data cut-off: July 3, 2019

ECOG PS, Eastern Cooperative Oncology Group performance status; NSCLC, non-small cell lung cancer; Q3W, every 3 weeks; RDE, recommended dose for expansion; SOC, standard of care; TROP2, trophoblast cell-surface antigen 2.

Source: Heist-R *et al.*, Abstract #MA25.10, WCLC 2019

DS-1062: Safety in Dose Escalation

TEAE Summary	
	All Grades
Serious TEAEs	14 (26.9)
Death (no deaths were related to study drug)	3 (5.8)
TEAEs associated with dose reduction	5 (9.6)
TEAEs associated with interruption	5 (9.6)
TEAEs associated with dose discontinuation	2 (3.8)

- Median exposure duration was 10.6 (range 3.0–43.1) weeks
- 2 DLTs in 10.0mg/kg cohort
  - Mucosal inflammation
  - Stomatitis

  => **MTD at 8.0mg/kg**
- 8.0mg/kg is selected as RDE
  - Backfilling 6.0mg/kg in escalation part to generate additional data at this dose

TEAEs, regardless of causality, (in ≥10% of pts), n (%) (N=52)		
	All Grades	Grade ≥3
Any TEAE	48 (92.3)	22 (42.3)
Fatigue	19 (36.5)	2 (3.8)
Nausea	19 (36.5)	0
Alopecia	15 (28.8)	0
Decreased appetite	14 (26.9)	0
Anemia	12 (23.1)	0
Stomatitis/ mucosal inflammation	12 (23.1)	2 (3.8)
Vomiting	12 (23.1)	0
Infusion related reaction	11 (21.2)	0
Rash	8 (15.4)	0
Constipation	7 (13.5)	0
Cough	7 (13.5)	0
Diarrhea	7 (13.5)	0
ALT increased	6 (11.5)	0
Weight decreased	6 (11.5)	0
Dehydration	5 (9.6)	0
Dyspnea	5 (9.6)	1 (1.9)
Headache	5 (9.6)	0
Pain	5 (9.6)	1 (1.9)

Data cut-off: July 3, 2019

ALT, alanine aminotransferase; DLT, dose-limiting toxicity; MTD, maximum tolerated dose; RDE, recommended dose for expansion; TEAE, treatment-emergent adverse event.

Source: Heist-R *et al.*, Abstract #MA25.10, WCLC 2019

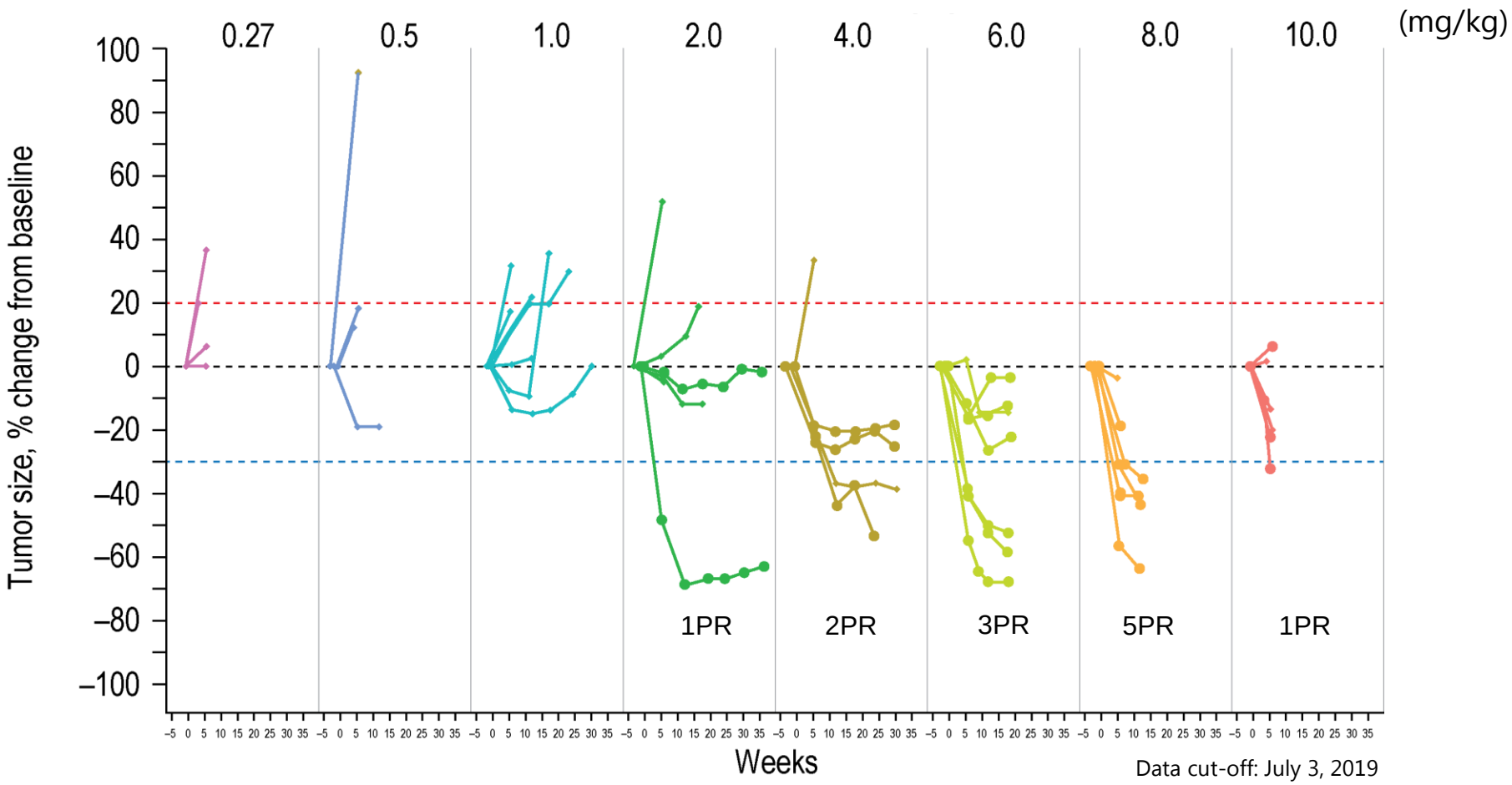
DS-1062: Lung Related Adverse Events

- Based on the experience from DS-8201, signs/symptoms of suspected ILD such as cough, shortness of breath, fever, pneumonia are categorized as "AE of special interest", and cases are compiled in a timely manner
- All consolidated cases are sent to ILD adjudication committee for the evaluation of the following
  - Confirmed as ILD or not
  - If related to study drug
- This procedure is for all ADC studies at Daiichi Sankyo

	AEs reported by investigators	Grade	Dose (mg/kg)	Details
1	Respiratory failure	G5	6.0	• **Not ILD** (respiratory failure from disease progression) • Not related to study drug
Data received post cutoff for WCLC 2019 (July 3, 2019)				
2	Pneumonitis	G2	6.0	• **Pending adjudication committee evaluation**
3	Respiratory failure	G5	8.0	
4	Organized pneumonia	G2	8.0	
5	Pneumonitis	G2	8.0	

AE, adverse event; ILD, interstitial lung disease

DS-1062: Efficacy in Dose Escalation



- **12 PRs (10 confirmed; 2 too early to confirm) across all doses in dose escalation**
  - **At the 8.0mg/kg dose there were 5/7 PRs and 2/7 SDs, and 6/7 pts are ongoing**

PR, partial response; SD, Stable disease

Source: Heist-R *et al.*, Abstract #MA25.10, WCLC 2019

U3-1402: NSCLC Phase 1 Study Design (NCT03260491)

Eligibility Criteria

- **Metastatic/unresectable EGFR-mutant NSCLC and:**
  - T790M-negative after progression on erlotinib, gefitinib, or afatinib; OR
  - Progressed on osimertinib
- **Stable brain metastases allowed**
- **Pretreatment tumor tissue (after progression on TKIs) was required for retrospective analysis of HER3 expression**

U3-1402 Dose Escalation (N = 30)

Received ≥ 1 dose of U3-1402 IV Q3W

- **6.4 mg/kg (n = 5)**
- **5.6 mg/kg (n = 12)**
- **4.8 mg/kg (n = 9)**
- **3.2 mg/kg (n = 4)**

Patient Disposition[a]

- **Ongoing, n = 17**
- **Discontinued, n = 13**
  - Progressive disease: 9
  - Consent withdrawal: 2
  - Clinical progression: 1
  - AE: 1

Objectives	Primary:	Secondary:	Exploratory:
	Safety and tolerability of U3-1402 and RDE determination	Antitumor activity of U3-1402	Biomarkers of U3-1402 antitumor activity

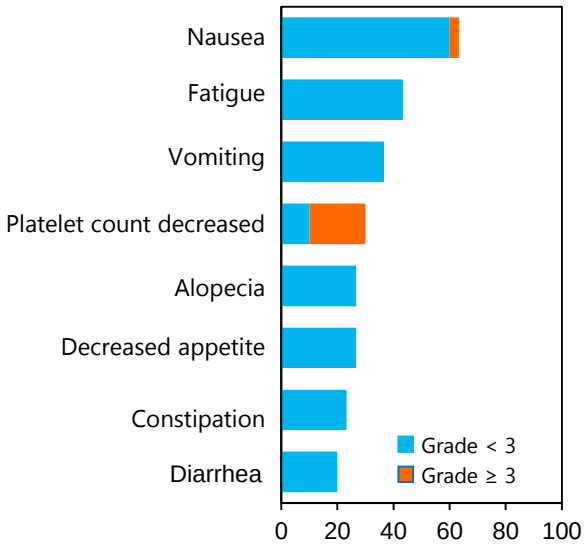
[a]Data cutoff of May 3, 2019.
EGFR, epidermal growth factor receptor; HER3, human epidermal growth factor receptor 3; IV, intravenously; NSCLC, non-small cell lung cancer; Q3W, every 3 weeks; TKI, tyrosine kinase receptor.

Source: Yu-H *et al.*, Abstract #MA21.06, WCLC 2019

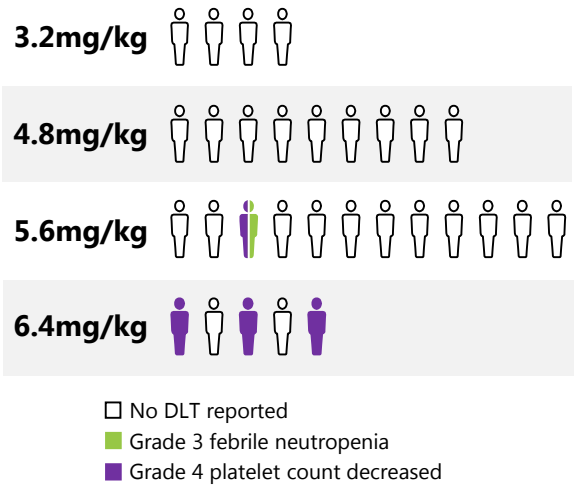
U3-1402: Safety in Dose Escalation

TEAEs & AESI, n (%)	N = 30
TEAEs regardless of causality	29 (97)
Drug-related	28 (93)
Treatment-emergent SAEs regardless of causality	9 (30)
Drug-related	4 (13)
TEAEs associated with drug withdrawal/discontinuation	1 (3)
TEAEs associated with dose reduction	7 (23)
TEAEs associated with dose interruption	7 (23)
TEAEs associated with death	0
AESI	
Interstitial lung disease	0

TEAEs in ≥ 20% of Patients



Dose-Limiting Toxicities (N = 30)



- Safety analysis set included all patients who received at least 1 dose of U3-1402
- For TEAEs in < 20% of patients, there were 15 grade 3 events:
  - Hypoxia and troponin increased, n = 2 each
  - Alanine aminotransferase increased, anemia, confusional state, dyspnea, embolism, febrile neutropenia, hypokalemia, musculoskeletal chest pain, nausea, pleural effusion, psychiatric disorders, N=1 each

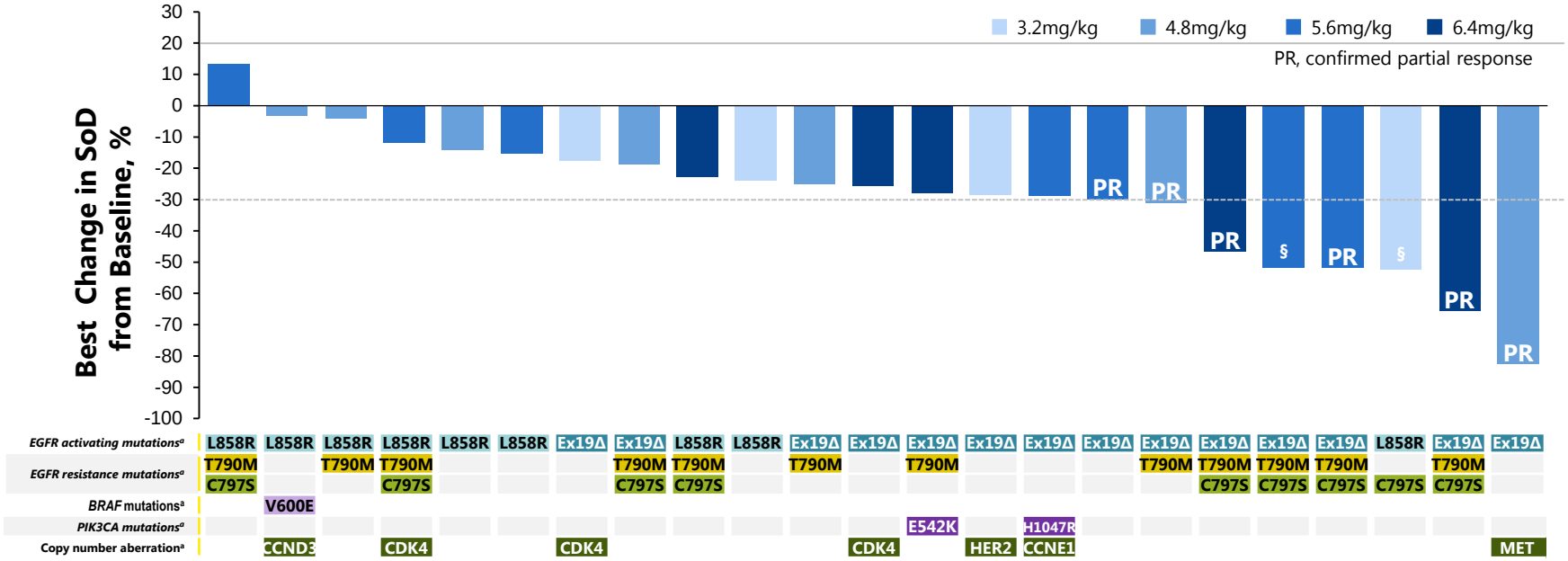
- **MTD not reached**
- **Demonstrated a manageable safety profile**

AESI, adverse event of special interest; DLT, dose-limiting toxicity; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

Source: Yu-H *et al.*, Abstract #MA21.06, WCLC 2019

U3-1402: Efficacy in Dose Escalation

n = 23
Median follow-up: 4.5 months



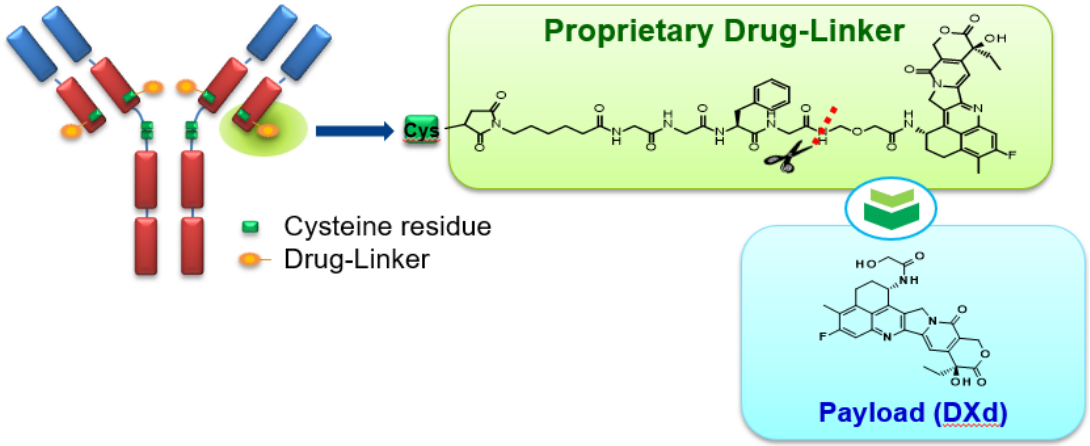
[§]2 patients had ≥ 30% reduction in SoD, which were not considered confirmed PRs; 1 experienced transient tumor size reduction and 1 had not yet been confirmed at data cutoff.
EGFR, epidermal growth factor receptor; PR, partial response; SoD, sum of diameters; TKI, tyrosine kinase receptor.

- **8 PRs (6 confirmed; 2 too early to confirm) across all doses in dose escalation**
- **Antitumor activity across diverse EGFR TKI resistance mechanisms**
- **5.6mg/kg is selected as RDE**

Source: Yu-H *et al.*, Abstract #MA21.06, WCLC 2019

DS-7300: B7-H3 ADC

- **Antibody-drug conjugate with topoisomerase I inhibitor (DXd) targeting B7-H3**
- **Has a selective drug-antibody ratio (DAR) as 4 in order to maintain a better safety margin**



- **B7-H3**
  - Highly expressed in various solid tumors (head and neck, esophageal, NSCLC, prostate, endometrial, breast and, etc.)
  - Its high expression is associated with poor prognosis in some cancers[1]
  - A member of the B7 family which includes PD-L1 and CTLA-4 ligands; likely to be involved in immune regulation (functions of B7-H3 remain to be fully elucidated)

1 Clin Cancer Res. 2016;22(14):3425-31

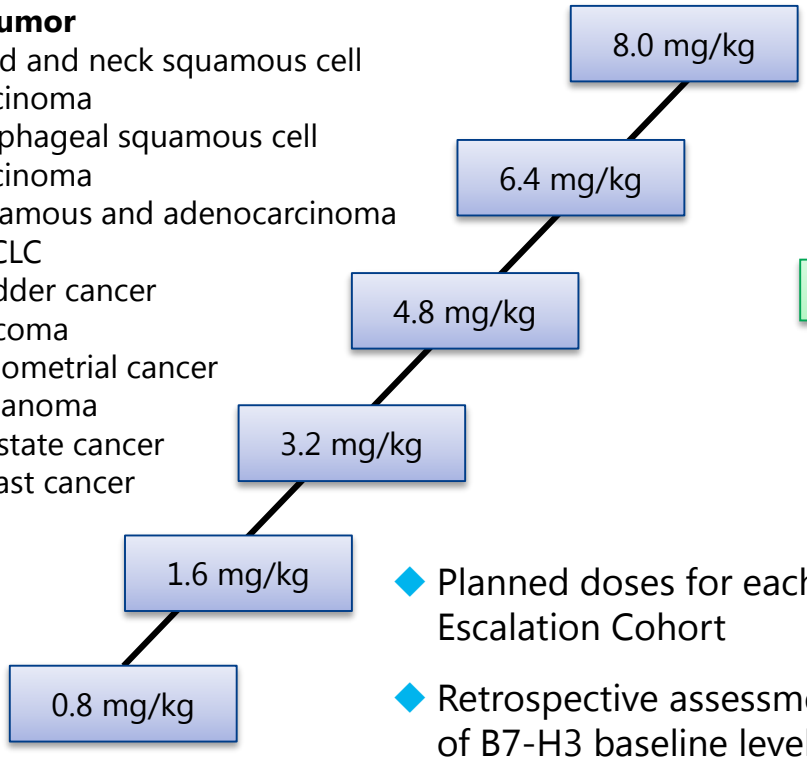
DS-7300: Phase 1/2 Study Design (NCT04145622)

Daiichi-Sankyo

Dose Escalation (Part 1)
DS-7300 IV Q3W monotherapy

Advanced/unresectable or metastatic solid tumor

- head and neck squamous cell carcinoma
- esophageal squamous cell carcinoma
- squamous and adenocarcinoma NSCLC
- bladder cancer
- Sarcoma
- endometrial cancer
- Melanoma
- prostate cancer
- breast cancer



- Planned doses for each Escalation Cohort
- Retrospective assessment of B7-H3 baseline levels in all patients

RDE

Dose Expansion (Part 2)
DS-7300 IV Q3W monotherapy

- Each Expansion Cohort will consist of a single selected solid tumor indication, and enroll up to 40 patients
- Retrospective assessment of B7-H3 baseline levels in all patients

- **Study started from Oct. 2019**
- **No prior B7-H3 selection**

ADC Franchise Summary

Daiichi-Sankyo

DS-8201

HER2 positive mBC pivotal phase 2 study
- JP: **NDA submitted and accepted on Sep. 9, 2019**
- US: **BLA accepted on Oct. 17, 2019, PDUFA: Apr. 29, 2020**
- SABCS：DESTINY-Breast01 study result will be presented orally on **Dec. 11, 2019**

HER2 positive mGC pivotal phase 2 study
- JP: **NDA will be submitted by Q1 FY2020**

DS-1062

- Dose dependent efficacy observed over 2.0–8.0mg/kg
- Demonstrated a manageable safety profile
- Dose expansion part ongoing with 8.0mg/kg
- **Future development plan will be presented at R&D Day**

U3-1402

- Dose dependent efficacy observed
- Demonstrated a manageable safety profile
- Dose expansion part ongoing with 5.6mg/kg
- **Future development plan will be presented at R&D Day**

DS-7300

- **Started phase 1/2 study from Oct. 2019**

Underlined in red: new or update from FY2019 Q1 Earnings Call

DS-3201: Adult T-cell Leukemia/Lymphoma Phase 2 Study

- **EZH1 and EZH2 are histone-methylating enzymes with similar functions**
- **Some cancer cells shows dependent growth on EZH1 and EZH2 and inhibition of them could lead to a novel antitumor therapy**

- Phase 1 clinical studies are in progress for various cancer types

Ongoing DS-3201 Studies	Region
NHL Non-Hodgkin's lymphoma - Peripheral T-cell lymphoma (SAKIGAKE designation in JP) - **Adult T-cell leukemia/lymphoma,** etc （NCT02732275/JapicCTI-163173）	JP/US
AML Relapse/refractory acute myeloid leukemia （NCT03110354）	US
Lung Small cell lung cancer （NCT03879798）	US

- **Decided initiation of adult T-cell leukemia/lymphoma phase 2 study** based on interim results of phase 1 study for non-Hodgkin lymphoma
  - Above result is planned to be presented at American Society of Hematology (ASH)

AML Franchise, Breakthrough Science Update

Daiichi-Sankyo

Quizartinib

Relapsed/refractory *FLT3*-ITD AML

- Japan: **launched on Oct. 10, 2019**
- US: received CRL in Jun. 2019
- EU: **received negative opinion from EMA CHMP on Oct. 18, 2019**

***Future plan for US/EU will be determined with the results of the 1st line study (QuANTUM-First) that has already completed enrollment**

Pexidartinib

Tenosynovial giant cell tumor

- US: **approved on Aug. 2, 2019; launched**
- EU: under review for 1H FY2020 decision

DS-1647 (G47Δ)

Malignant glioma

- NDA submission in 2H FY2019 (Japan)

Underlined in red: new or update from FY2019 Q1 Earnings Call

R&D Day 2019

Date	• Tokyo: Dec. 17 (Tuesday) **3:30pm~,JST** • NY: Dec. 19 (Thursday) **10:30am~,EST** [live & on-demand casting planned]
Speakers	• Sunao Manabe, CEO • Junichi Koga, Global Head of R&D • Antoine Yver, Global Head of Oncology R&D
What to Expect	• New research and development strategy • Data update (DS-8201 SABCS 2019) • Updated development plans (DS-8201, DS-1062, U3-1402)

Agenda

1. FY2019 Q2 Financial Results
2. FY2019 Forecast
3. Business Update
4. 5-Year Business Plan Update
5. R&D Update
6. **Appendix**

FY2019 R&D Major Milestones

As of October 2019

Daiichi-Sankyo

Project	Target Indications and Studies	FY2019				FY2020
		Q1	Q2	Q3	Q4	Q1~
DS-8201	P2 pivotal: breast cancer (HER2 positive post T-DM1)		JP/US submitted			EU submission
	P2 pivotal: gastric cancer (HER2 positive, 3L) (JP/Asia)					JP submission
	P2: gastric cancer (HER2 positive post trastuzumab) (US/EU)		Study started			
	P1: breast cancer and NSCLC with pembrolizumab			Study start planned		
U3-1402	P1: NSCLC		Started dose expansion			
DS-1062	P1: NSCLC		Started dose expansion			
DS-7300	P1/2: solid tumors			Study started		
DS-6157	P1: gastrointestinal stromal tumors (GIST)				Study start planned	
Quizartinib	P3: AML (relapsed/refractory)	JP approved US CRL		JP launched EU received EMA CHMP negative opinion		
DS-3201	P1: small cell lung cancer (US)	Study started				
	P2: Adult T-cell leukemia/lymphoma			Study start planned		
Pexidartinib	P3: tenosynovial giant cell tumor (US/EU)		US approved/ launched			EU decision
DS-1647	IIS: malignant glioma (JP)			Submission		
DS-1205	P1: NSCLC with osimertinib (Asia)	Study started				
Laninamivir	P3: influenza (nebulizer formulation) (JP)	Approved		Launched		

AML: acute myeloid leukaemia, CRL: complete response letter, NSCLC: non-small-cell lung cancer

Underlined in red: new or updated from FY2019 Q1, blue: achieved

Major R&D Pipeline-1

As of October 2019

Daiichi-Sankyo

		Generic Name/Project Code/ MOA	Target Indication	Region	Stage
Oncology	ADC Franchise	[fam-] trastuzumab deruxtecan/ DS-8201/anti-HER2 ADC	Breast cancer (HER2 positive post T-DM1)	EU/Asia	P3
			Breast cancer (HER2 positive vs T-DM1)	JP/US/EU/Asia	P3
			Breast cancer (HER2 low expression)	JP/US/EU/Asia	P3
			Gastric cancer (HER2 positive, 3L)	JP/Asia	P2
			Colorectal cancer (HER2 expressing)	JP/US/EU	P2
			NSCLC (HER2 expressing/mutant)	JP/US/EU	P2
			Breast and bladder cancer (with nivolumab)	US/EU	P1
		U3-1402/anti-HER3 ADC	Breast cancer (HER3 expressing)	JP/US	P1
			EGFRm NSCLC	JP/US	P1
		DS-1062/anti-TROP2 ADC	NSCLC	JP/US	P1
		DS-7300/anti-B7-H3 ADC	Solid tumor	JP/US	P1
	AML Franchise	Quizartinib/FLT3 inhibitor	AML (relapsed/refractory)	Asia	NDA/BLA
			AML (1st line)	JP/US/EU/Asia	P3
		Milademetan/DS-3032/ MDM2 inhibitor	Solid tumor (liposarcoma)	JP/US	P1
			AML	JP/US	P1
		Valemetostat/DS-3201/ EZH1/2 inhibitor	Non-Hodgkin's Lymphoma (PTCL)	JP/US	P1
			Adult T-cell leukemia/lymphoma	JP	P2
			AML, ALL	US	P1
			Small cell lung cancer	US	P1
		PLX2853/BET inhibitor	AML	US	P1
		Axicabtagene ciloleucel/Axi-Cel®/ anti-CD19 CAR-T	B-cell lymphoma	JP	P2

ALL: acute lymphocytic leukemia, AML: acute myeloid leukemia, 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 (Japan), designation for breakthrough therapy (FDA), and designation for orphan drugs

Major R&D Pipeline-2

As of October 2019

Daiichi-Sankyo

		Generic Name/Project Code/ MOA	Target Indication	Region	Stage
Oncology	Breakthrough Science	Pexidartinib/ CSF-1/KIT/FLT3 inhibitor	Tenosynovial giant cell tumor	EU	P3
		DS-1647(G47Δ)/oncolytic HSV-1	Malignant glioma	JP	P2
		DS-1001/ Mutant IDH1 inhibitor	Glioma	JP	P1
		DS-1205/AXL inhibitor	NSCLC (with gefitinib)	JP	P1
			NSCLC (with osimertinib)	Asia	P1
Specialty Medicines		Edoxaban/FXa inhibitor	Atrial fibrillation in the very elderly	JP	NDA
		Prasugrel/anti-platelet agent	Ischemic stroke	JP	NDA
		Esaxerenone/MR-Antagonist	Diabetic nephropathy	JP	NDA
		DS-1040/TAFIa inhibitor	Acute ischemic stroke, acute pulmonary thromboembolism	JP/US/EU	P1
		Mirogabalin/$\alpha_2\delta$ ligand	Central neuropathic pain	JP/Asia	NDA
		DS-5141/ENA-oligonucleotide	Duchenne type muscular dystrophy	JP	P2
		DS-1211/TNAP inhibitor	Inhibition of ectopic calcification	US	P1
Vaccine		VN-0107/MEDI3250/live attenuated influenza vaccine nasal spray	Prophylaxis of seasonal influenza	JP	P3
		VN-0105/DPT-IPV/Hib	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib infection	JP	NDA
		VN-0102/JVC-001/ Measles-mumps-rubella vaccine	For measles, mumps, and rubella prophylaxis	JP	P2

NSCLC: non-small-cell lung cancer

★: Project in Oncology that is planned to be submitted for approval based on the results of Phase 2 trials

:Designation for first review (Japan), designation for breakthrough therapy (FDA), and designation for orphan drugs

DS-3201: Adult T-cell Leukemia/Lymphoma

Daiichi-Sankyo

What is Adult T-cell leukemia/lymphoma?

- A type of malignant lymphoma that occurs frequently in Southwest Japan
- Cause is human T-cell leukemia virus type I (HTLV-1)
- Rare disease with very poor prognosis after onset

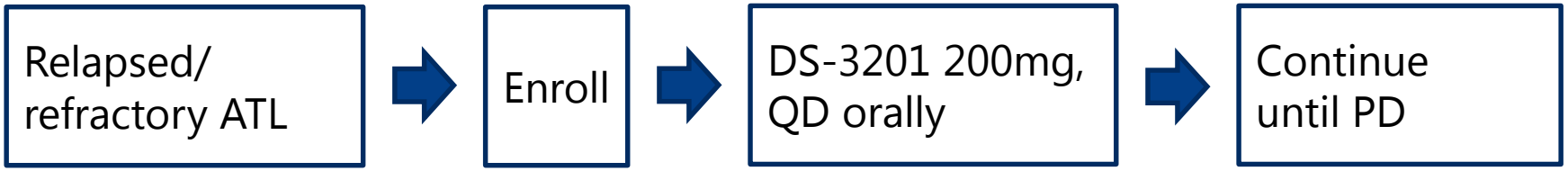
- Patients population in Japan

HTLV-1 carriers	New cases (annual)	Deaths (annual)
1,100,000	600～700	1,000

- Standard of care
  - Chemotherapy
  - Allogeneic hematopoietic stem cell transplantation
- Challenges in treatment
  - As the median age of onset in ATL patients increases, more than half of patients are unable to undergo allogeneic hematopoietic stem cell transplantation
  - **New treatment options are needed**

DS-3201: Adult T-cell Leukemia/Lymphoma Phase 2 Study

- **Pivotal phase 2 study**
  - If the results of this study are clinically meaningful, NDA will be submitted in Japan
- Open label, single arm study



Study sites	Japan
Study patients	Relapsed/refractory adult T-cell leukemia/lymphoma(ATL)
Estimated enrollment	25
Primary endpoint	ORR assessed by central evaluation organization
Secondary endpoints	ORR assessed by investigator, PFS, DOR, OS, Safety, etc.
CTG/JAPIC	NCT04102150/JapicCTI-194964

Out-licensing Projects

As of October 2019

Daiichi-Sankyo

	Pre-clinical	Phase 1
Oncology		**PLX7486: FMS/TRK inhibitor** Solid tumor **PLX9486: KIT inhibitor** Solid tumor (gastrointestinal stromal tumor)
Specialty Medicine	**DS-1515: PI3Kδ inhibitor** Inflammatory disease **DS-1039: new MOA** (CFTR independent fluid secretion) Cystic fibrosis **ASB29609: 5-HT5A receptor agonist** Circadian rhythm sleep-wake disorders	**DS-1093: HIF-PH inhibitor** inflammatory bowel disease (IBD) **DS-7080: angiogenesis inhibitor** Age-related macular degeneration (AMD) **DS-1501: anti Siglec-15 antibody** Osteoporosis *US/EU (other than JP)

Listing of 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

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