Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2019 Q1
Financial Results Presentation

DAIICHI SANKYO CO., LTD

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Executive Vice President and CFO

July 31, 2019

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Agenda

1. **FY2019 Q1 Financial Results**
2. Business Update
3. R&D Update
4. Appendix

Overview of FY2019 Q1 Results

(Bn JPY)

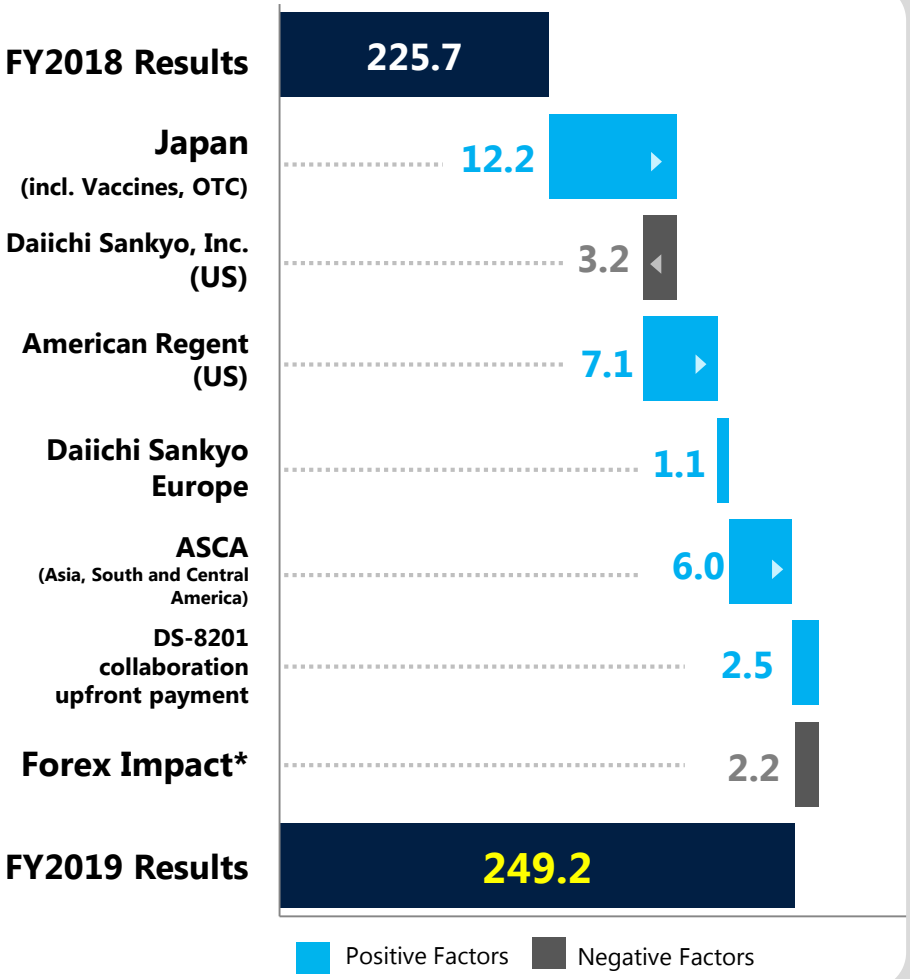
	FY2018 Q1 Results	FY2019 Q1 Results	YoY
Revenue	225.7	249.2	+10.4% +23.5
Cost of Sales	84.7	87.9	+3.2
SG&A Expenses	65.6	63.2	-2.5
R&D Expenses	45.5	41.2	-4.3
Operating Profit	29.9	57.0	+90.5% +27.1
Profit before Tax	29.6	57.1	+27.4
Profit attributable to owners of the Company	24.0	43.3	+81.0% +19.4

Currency Rate	USD/JPY	109.07	109.90	+0.83
	EUR/JPY	130.06	123.49	-6.57

Revenue

Increased by 23.5 Bn JPY (Increased by 25.7 Bn JPY excl. forex impact)

(Bn JPY)



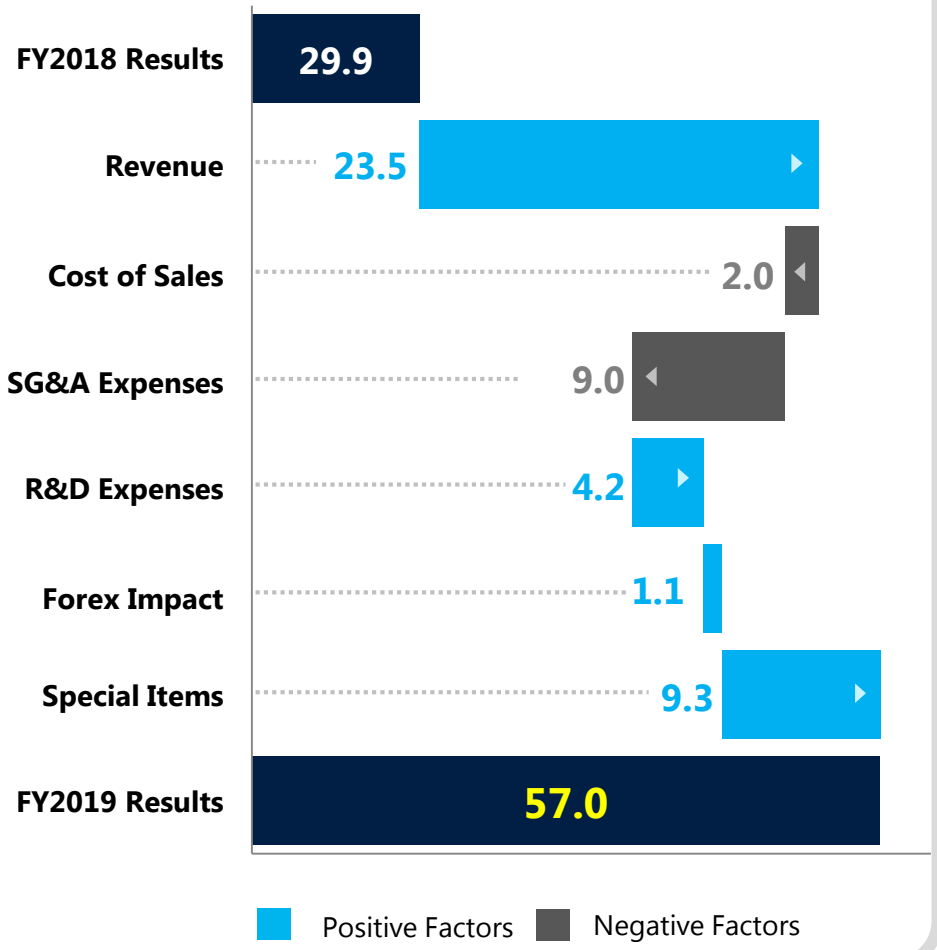
Positive Factors		Negative Factors	
Japan			
Lixiana	+6.8		
Nexium	+2.1		
Pralia	+1.6		
Vimpat	+1.3		
Canalia	+1.2		
Daiichi Sankyo Espha (GE) Silodosin AG	+3.6	Daiichi Sankyo Healthcare (incl. impact of change in accounting treatment)	-3.0
Daiichi Sankyo, Inc. (US)			
		Welchol	-2.3
American Regent, Inc. (US)			
GE injectables	+3.1		
Injectafer	+2.4		
Daiichi Sankyo Europe			
Lixiana	+4.5	Olmesartan	-1.5
ASCA (Asia, South and Central America)			
China Olmetec, Cravit etc.	+4.4		

* Forex impact USD: +0.4, EUR : -1.2, ASCA: -1.4

Operating Profit

Increased by 27.1 Bn JPY

(Increased by 19.0 Bn JPY excl. forex impact and special items)



(Bn JPY)

Revenue +23.5
incl. forex impact of -2.2

Cost of Sales +2.0 **(Cost increased)**
Product mix

SG&A Expenses +9.0 **(Cost increased)**
Increase in personnel expenses in US

R&D Expenses -4.2 **(Cost decreased)**
Decrease by cost share with AstraZeneca

Forex Impact -1.1 **(Cost decreased)**
Cost of Sales -0.2
SG&A Expenses -0.8
R&D Expenses -0.1

Special Items -9.3 **(Cost decreased)**
See next slide for details

Special Items

(Bn JPY)

	FY2018 Q1 Results	FY2019 Q1 Results		YoY
Cost of Sales		Restructuring costs in SC	1.3	+1.3
SG&A Expenses		Gain on sales of fixed assets*	-10.6	-10.6
R&D Expenses				
Total			-9.3	-9.3

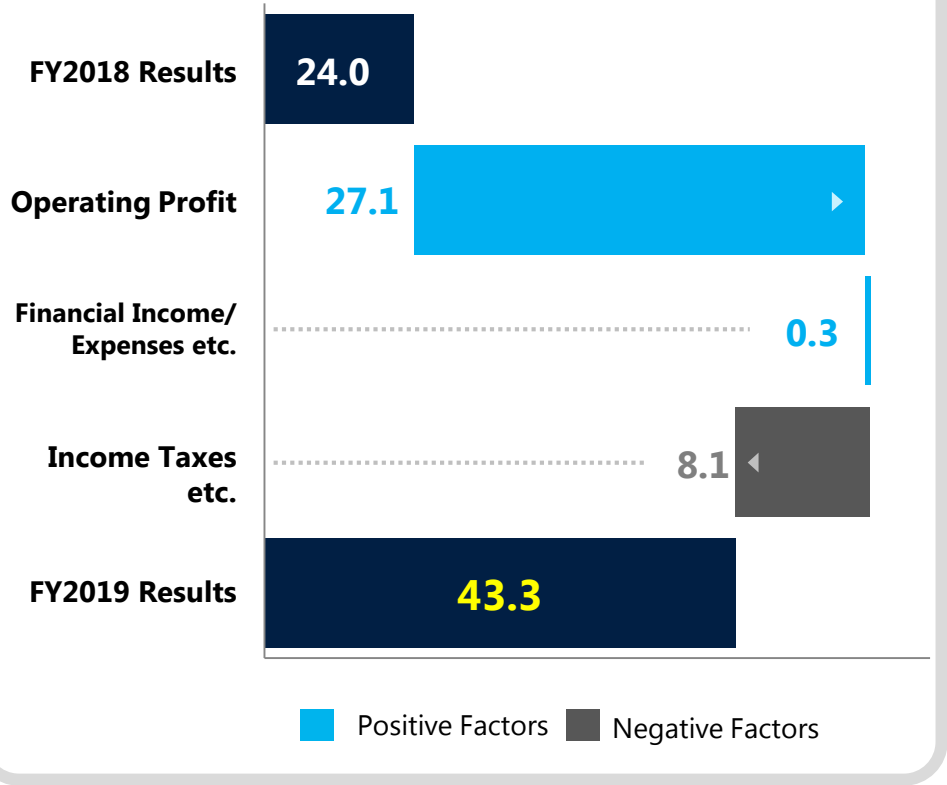
*Gain on sales of Nihonbashi building

- : Cost decreased items

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 19.4 Bn JPY



(Bn JPY)

Income Taxes etc. ····· +8.1 (Cost increased)

	FY2018	FY2019	YoY
Profit before Tax	29.6	57.1	+27.4
Income Taxes etc.	5.7	13.7	+8.1
Tax rate	19.2%	24.1%	+4.9%

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2018 Q1 Results	FY2019 Q1 Results	YoY
Japan	**123.9**	**139.0**	**+15.0**
Daiichi Sankyo Healthcare	**18.4**	**15.4**	**-3.0**
Daiichi Sankyo, Inc.	**11.0**	**7.8**	**-3.1**
Olmesartan	3.2	3.1	-0.1
Welchol	4.9	2.6	-2.3
American Regent, Inc.	**28.6**	**36.0**	**+7.3**
Injectafer	11.2	13.7	+2.5
Venofer	8.2	9.3	+1.1
GE injectables	7.9	11.1	+3.1
Daiichi Sankyo Europe	**22.2**	**22.1**	**-0.1**
Lixiana	9.7	13.5	+3.8
Olmesartan	8.2	6.4	-1.8
Efient	1.9	0.8	-1.1
ASCA (Asia, South and Central America)	**19.7**	**24.3**	**+4.6**

Currency Rate	USD/JPY	109.07	109.90	+0.83
	EUR/JPY	130.06	123.49	-6.57

Revenue: Major Products in Japan

(Bn JPY)

		FY2018 Q1 Results	FY2019 Q1 Results	YoY
Lixiana	anticoagulant	**14.7**	**21.6**	**+6.8**
Nexium	ulcer treatment	**19.8**	**21.9**	**+2.1**
Memary	Alzheimer's disease treatment	**12.9**	**13.7**	**+0.8**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**6.6**	**8.2**	**+1.6**
Tenelia	type 2 diabetes mellitus treatment	**6.4**	**6.9**	**+0.5**
Loxonin	anti-inflammatory analgesic	**7.9**	**7.8**	**-0.1**
Inavir	anti-influenza agent	**0.1**	**0.0**	**-0.0**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**3.9**	**4.7**	**+0.7**
Efient	antiplatelet agent	**3.6**	**3.8**	**+0.2**
Rezaltas	antihypertensive agent	**4.1**	**4.2**	**+0.1**
Canalia	type 2 diabetes mellitus treatment	**2.0**	**3.2**	**+1.2**
Vimpat	anti-epileptic agent	**1.4**	**2.7**	**+1.3**
Omnipaque	contrast agent	**3.3**	**3.0**	**-0.2**
Olmetec	antihypertensive agent	**4.2**	**3.5**	**-0.6**

1 FY2019 Q1 Financial Results

2 **Business Update**

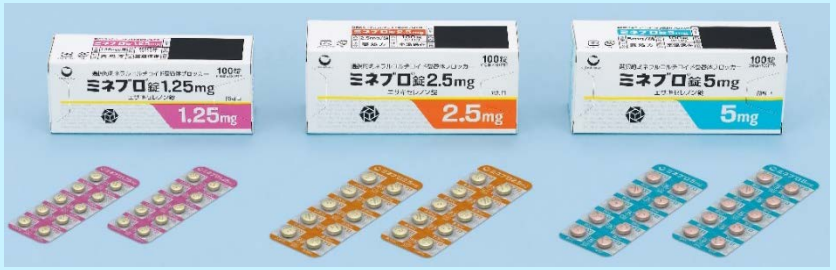
3 R&D Update

4 Appendix

Japan Business: Continuous Launch of Own Products

Tarlige (for pain treatment)
Launched in Apr. 2019

Minnebro (for hypertension)
Launched in May 2019



Vanflyta
(for the treatment of relapsed/refractory FLT3-ITD AML)
Approved in Jun. 2019

Inavir nebulizer* formulation
(anti-influenza agent)
Approved in Jun. 2019

*device which makes mist from drug solution in order to absorb through mouth or nose

Japan Business: Transfer Marketing Authorization Rights for Diagnostic Imaging Agents

◆ Optimization of business portfolio

- Transferred to GE Healthcare
- The diagnostic imaging agents to be transferred

Product name	Product description	Launched	Revenue in FY2018
Omnipaque	Nonionic X-ray contrast agent	1987	13.6 Bn JPY
Omniscan	Linear, nonionic magnetic resonance imaging contrast agent	1996	
Visipaque	Nonionic, iso-osmolar X-ray contrast agent	2000	
Sonazoid	Ultrasound contrast agent	2007	

- Expected Timeline
  - ✓ The transfer of marketing authorization rights and commercialization to be completed in March 2020
  - ✓ Distribution will be transferred in March 2022

1 FY2019 Q1 Financial Results

2 Business Update

3 **R&D Update**

4 Appendix

DS-8201 data published in *The Lancet Oncology*

Interim data from U3-1402 NSCLC phase 1 study

Interim data from DS-1062 NSCLC phase 1 study

Interim data from DS-1001 glioma phase 1 study

Updated data from pexidartinib TGCT phase 3 study

Upcoming milestones

Announcement of R&D Day

DS-8201: P1 Study *The Lancet Oncology*

Breast	Pertuzumab + trastuzumab + docetaxel (1L)[1]	T-DM1 (1L, failed study)[2]	T-DM1 (2L)[3]	T-DM1 (3L+)[4]	DS-8201[5]
mPFS	18.5m	14.1m	9.6m	6.2m	**22.1m**
DoR	20.2m	20.7m	12.6m	9.7m	**20.7m**
OS	56.5m	53.7m	30.9m	22.7m	**NR**
ORR	80%	60%	43.6%	31%	**59.5%**
Median prior Rx for adv. disease	0	0	1	4	**7 100% prior T-DM1 88% prior pertuzumab**

[1]) CLEOPATRA (NEJM 2012), [2]) MARIANNE (J Clin Oncol 2017), [3]) EMILIA (NEJM 2012), [4]) TH3RESA (*The Lancet Oncol* 2017) [5] *The Lancet Oncology*, 29 April 2019, m: Months, NR:Not Reached

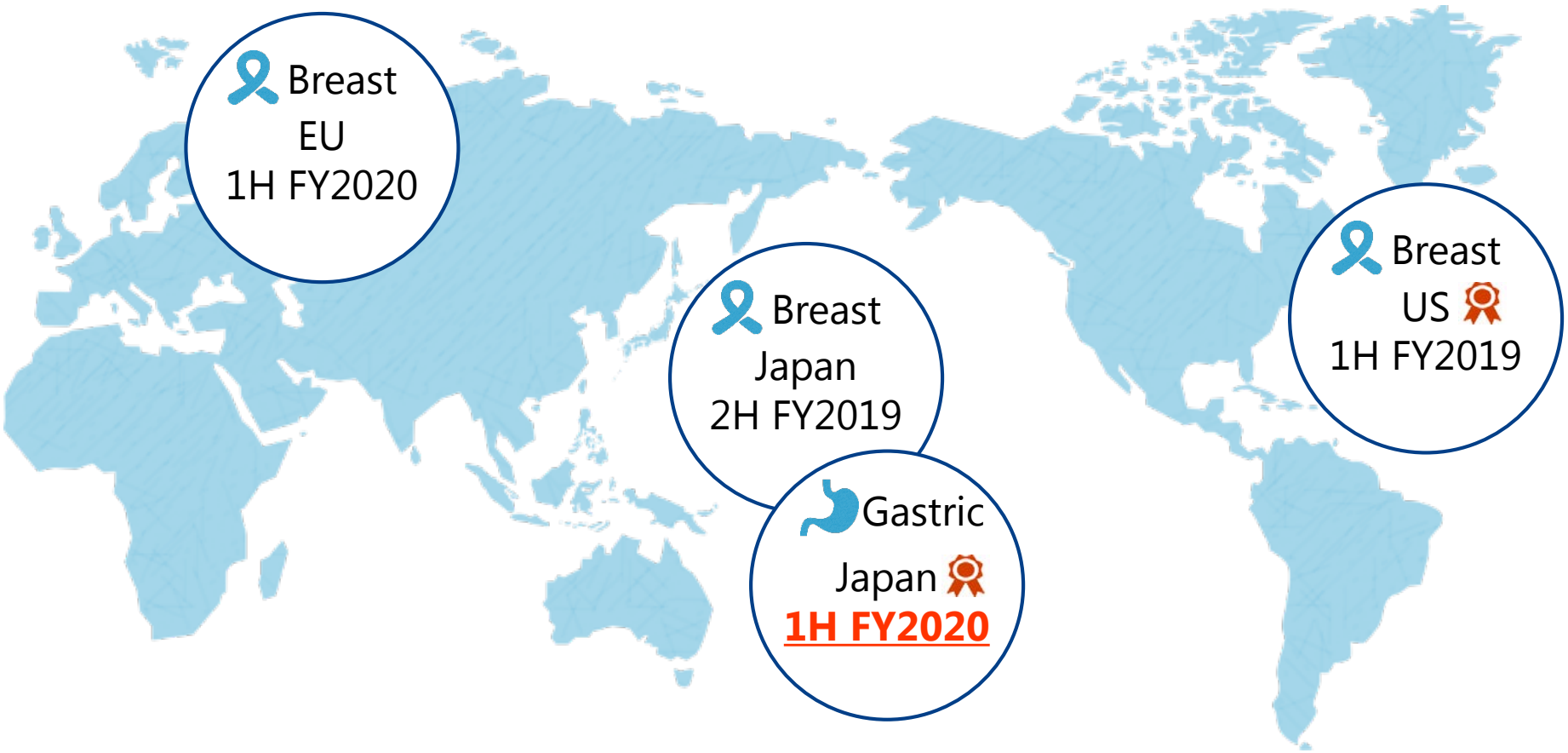
Gastric	Trastuzumab + Chemo (1L)[1]	Ramucirumab + Chemo (2L)[2]	T-DM1 (failed study; 2+L) [3]	DS-8201[4]
mPFS	6.7m	4.4m	2.7m	**5.6m**
DoR	6.9m	4.4m	4.3m	**7.0m**
OS	13.8m	9.6m	7.9m	**12.8m**
ORR	47%	28%	21%	**43.2%**
Median prior LoT	0	1	1	**3**

[1]ToGA (*The Lancet* 2010), [2]RAINBOW (*The Lancet Oncol.* 2014), [3]GATSBY (*The Lancet Oncol.* 2017), [4]*The Lancet Oncology*, published April 29, 2019, LoT: Line of Therapy, m: Month

- **Favorable efficacy confirmed**
- **Safety profile in *The Lancet Oncology* was consistent with past P1 reports**

DS-8201: HER2 mBC and mGC Submission Plan

Preparation for submissions is on track



SAKIGAKE or Breakthrough Therapy Designation

Underlined in red: new or update from FY2018 Q4

U3-1402: P1 Dose Escalation/Expansion Study

Eligibility

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 TKI) required for retrospective analysis of HER3 expression

Dose Escalation[a]

Received ≥1 dose of U3-1402 IV Q3W: N = 23

- **6.4 mg/kg, n = 5**
- **5.6 mg/kg, n = 6**
- **4.8 mg/kg, n = 8**
- **3.2 mg/kg, n = 4**

Ongoing
n = 16

Discontinued[b]
n = 7

Dose Expansion

Will enroll additional patients at the recommended dose for expansion

Study Objectives

Primary:
Safety and tolerability of U3-1402

Secondary:
Antitumor activity of U3-1402

Exploratory:
Biomarkers of U3-1402 antitumor activity

Data cutoff of February 25, 2019. [a]Dose escalation was guided by the modified continuous reassessment method with escalation with overdose control. Additional doses may be added. [b]Reasons for discontinuation included progressive disease per RECIST v1.1, n = 5; clinical progression (definitive clinical signs of disease progression, but did not meet RECIST criteria), n = 1; and adverse event, n = 1. clinicaltrials.gov NCT03260491.

- **Enrolling all-comer EGFRm NSCLC patients without prior HER3 selection**

Source: Janne-P *et al.*, Abstract #9010, ASCO 2019

U3-1402: P1 Study Patients Baseline Characteristics

Baseline clinical characteristics		Dose escalation (N = 23)[a]
Age, median (range), years		63.0 (51.0—80.0)
Sex, n (%)	Female	14 (60.9)
	Male	9 (39.1)
Race, n (%)	White	13 (56.5)
	Asian	7 (30.4)
	Black or African American	1 (4.3)
	Other	2 (8.7)
ECOG performance status, n (%)	0	9 (39.1)
	1	14 (60.9)
Prior therapies, n (%)	Any EGFR TKI	23 (100.0)
	Osimertinib[b]	**21 (91.3)**
	Chemotherapy	10 (43.5)

Baseline disease characteristics		Dose escalation (N = 23)[a]
Sites of metastases, n (%)	CNS[c]	14 (60.9)
	Liver	9 (39.1)
	Lung	4 (17.4)
Tumor stage, n (%)	IV	23 (100.0)
Sum of diameters of target lesions, median (range), mm		69 (20—143)

Baseline molecular characteristics		Dose escalation (N = 23)[a]
HER3 expression[d]		
Evaluable patients[e]	n/n (%)	19/19 (100.0)
Membrane H-score[f] *composite score of 0—300*	median (range)	193 (150—290)
EGFR mutation[g], n (%)	Ex19del	13 (56.5)
	L858R	9 (39.1)
	L861Q	1 (4.3)

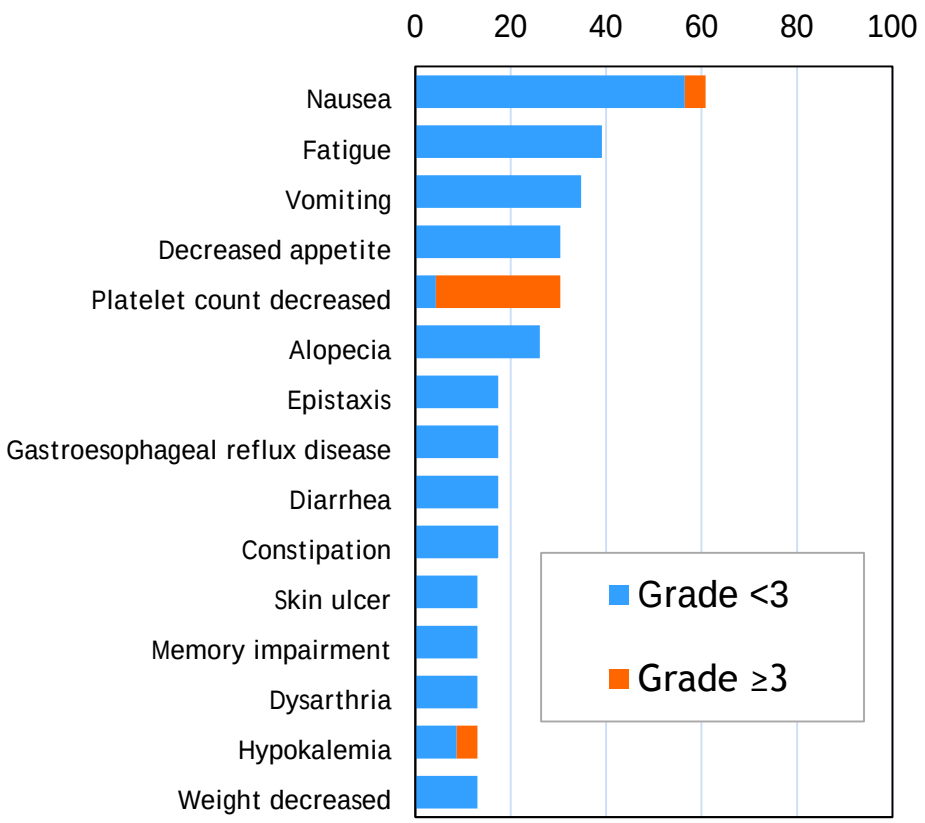
Data cutoff date of February 25, 2019. [a]Safety analysis set included all patients who received ≥1 dose of U3-1402. [b]Additional subject with prior osimertinib reported after snapshot date, not shown. [c]Includes brain and spinal metastases as reported by investigators. [d]Based on central analysis of tumor tissue collected prior to first dose of U3-1402. [e]Includes patients with tumor samples that have completed retrospective analysis. [f]Membrane H-score is a composite of percentage of positively staining cells and intensity of individual cell staining. For patients with multiple H-scores, the highest number was used. [g]As reported locally by the investigator.

- **91.3% patients received prior osimertinib**

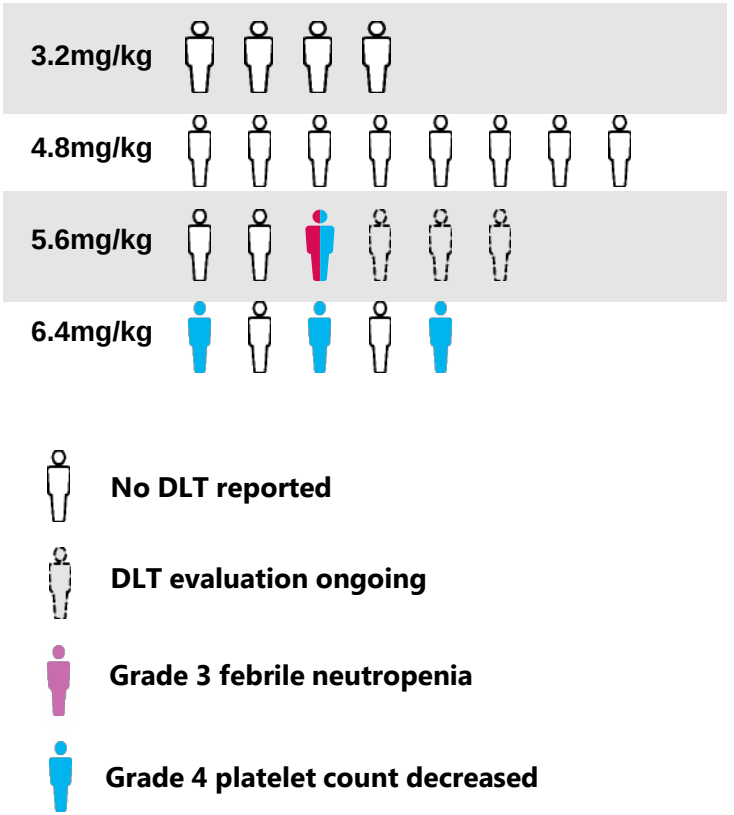
Source: Janne-P *et al.*, Abstract #9010, ASCO 2019

U3-1402: P1 Study Safety TEAEs and DLT

Percentage of patient with TEAEs (>=10%; N =23)



Dose-limiting Toxicities(DLT) (N = 23)

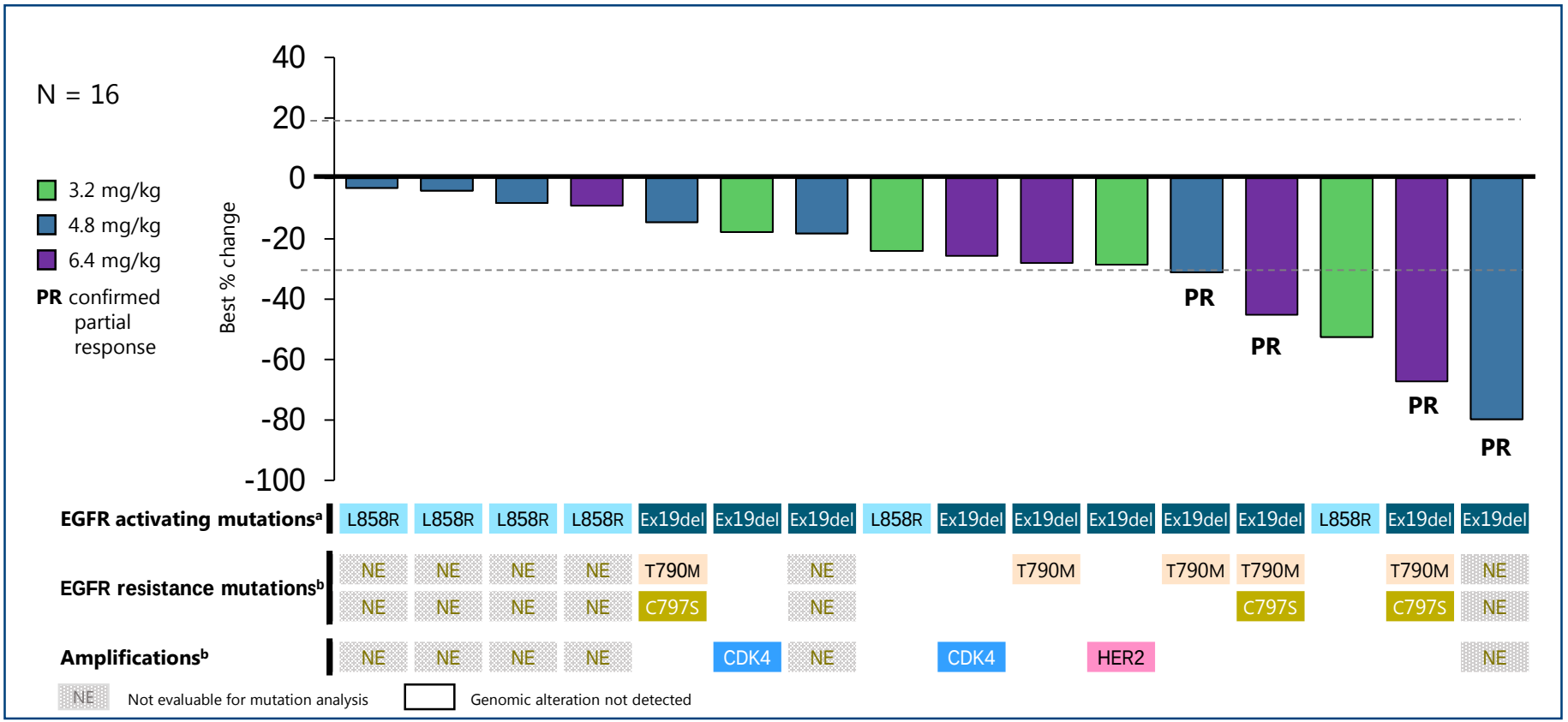


Data cutoff date of February 25, 2019. TEAE analysis used the safety analysis set, which includes all patients who received ≥1 dose of U3-1402 (N = 23). For TEAEs in <10% of patients, there were five Grade 3 events: ALT increased n = 1; troponin increased n = 1; confusional state n = 1; hypoxia n = 1; febrile neutropenia n = 1. DLT, dose-limiting toxicity; TEAE, treatment emergent adverse event

◆ U3-1402 was generally well-tolerated to date

Source: Janne-P *et al.*, Abstract #9010, ASCO 2019

U3-1402: P1 Study Efficacy Waterfall Chart

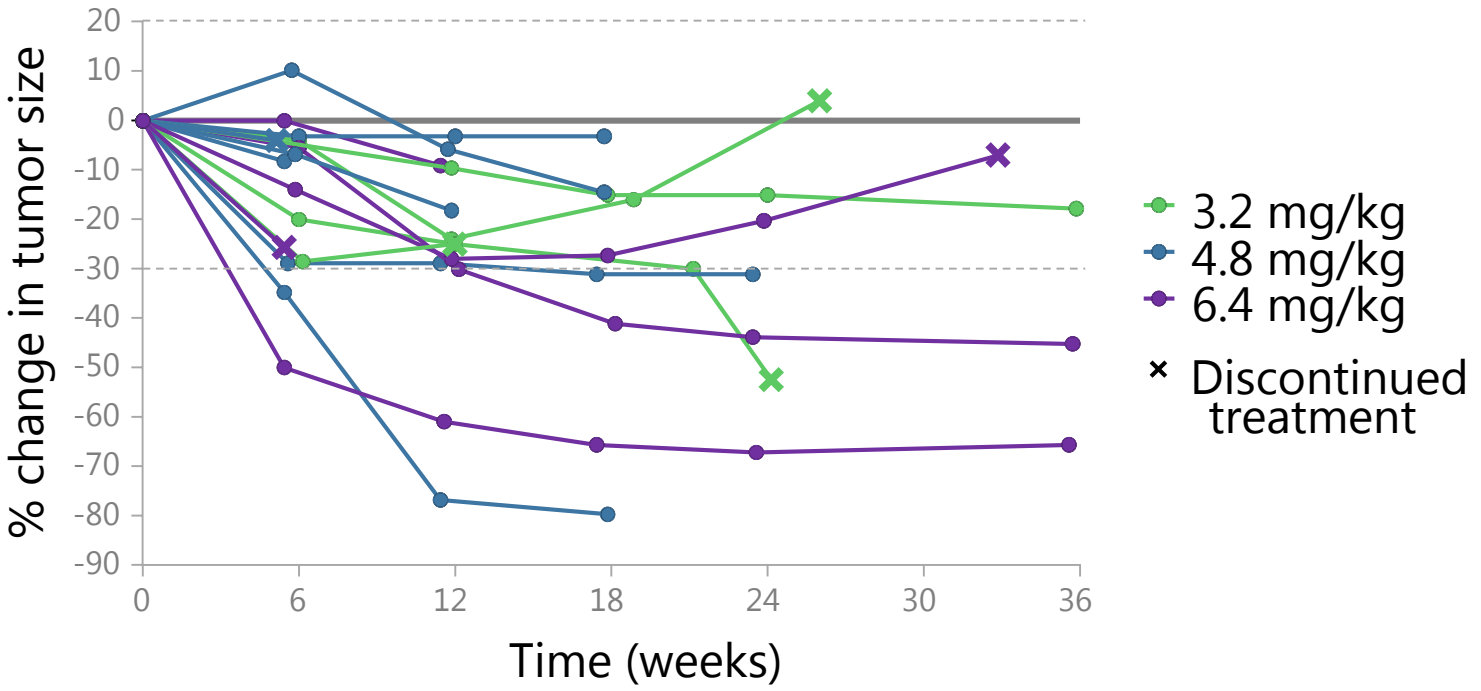


Data cutoff date of February 25, 2019. Dotted lines denote 20% increase and 30% decrease in tumor size. Sixteen patients received ≥1 dose of U3-1402 and had pre- and post-treatment evaluable tumor assessments.
[a]Local testing as reported by the investigator. [b]Performed centrally using Oncomine Comprehensive assay v3 from formalin-fixed, paraffin-embedded tumor tissue.

Antitumor activity across diverse EGFR-TKI resistance mechanisms

Source: Janne-P *et al.*, Abstract #9010, ASCO 2019

U3-1402: P1 Study Efficacy Spider Plot

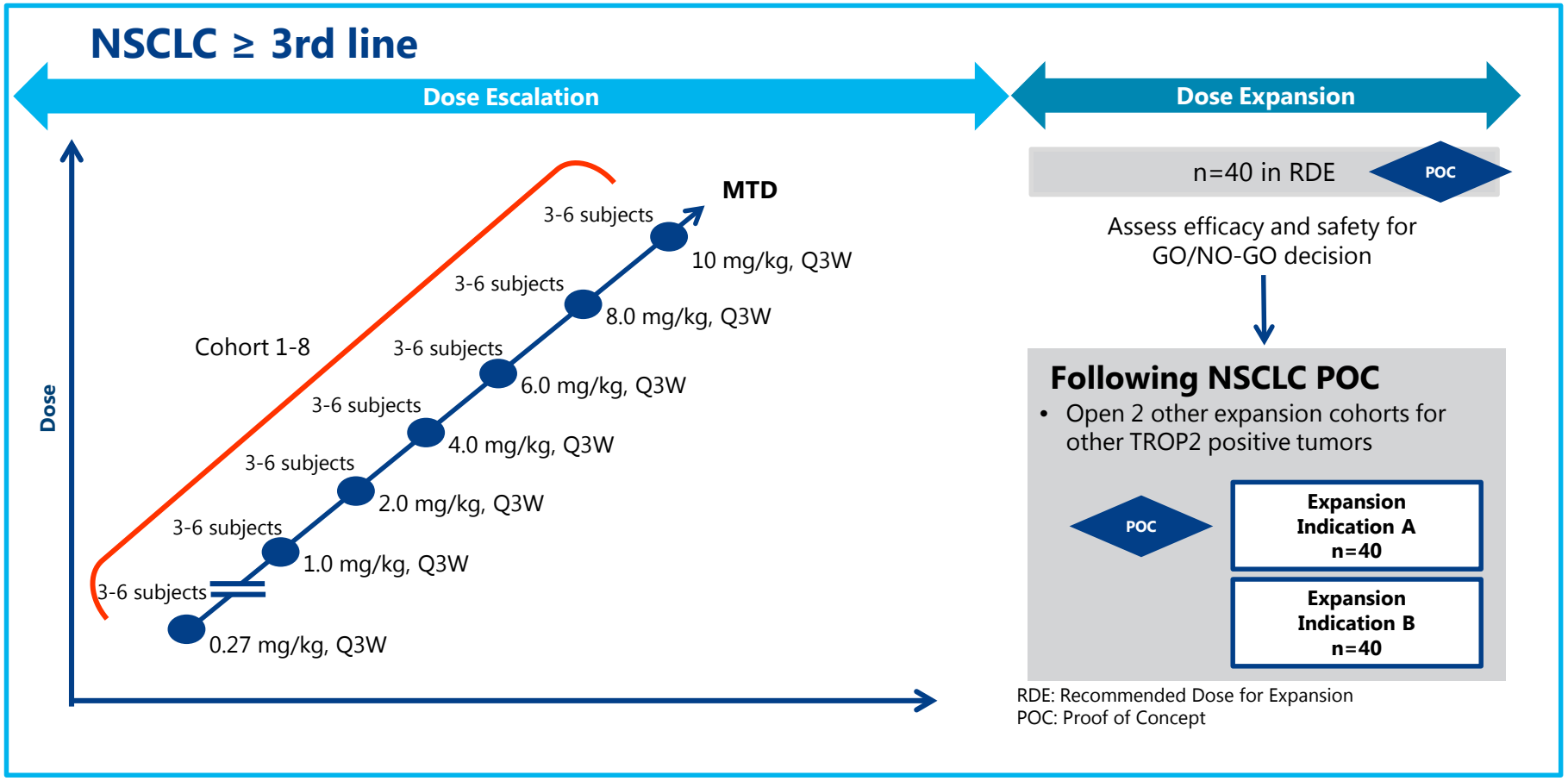


Data cutoff date of February 25, 2019. Sixteen patients received ≥1 dose of U3-1402 and had pre- and post-treatment evaluable tumor assessments.
Dotted lines denote 20% increase and 30% decrease from baseline in tumor size over time.

- **More than 50% of patients continue on study treatment**

Source: Janne-P *et al.*, Abstract #9010, ASCO 2019

DS-1062: Relapsed NSCLC P1 Study



- **Currently enrolling all-comer NSCLC patients without prior TROP2 selection**
- **Dose expansion cohort started in July 2019**

DS-1062: P1 Study Patients Baseline Characteristics

Parameter	DS-1062 doses, mg/kg							Total (N=39)
	0.27(n=4)	0.5(n=5)	1.0(n=7)	2.0(n=6)	4.0(n=6)	6.0(n=8)	8.0(n=3)	
Male sex, n (%)	1 (25.0)	3 (60.0)	4 (57.1)	4 (66.7)	2 (33.3)	6 (75.0)	3 (100)	**23 (59.0)**
Age, y, median (range)	64.0	66.0	67.0	60.5	53.5	53.5	69.0	**60.0**
Country, n (%)								
United States	2	4	5	4	5	5	1	**26 (66.7)**
Japan	2	1	2	2	1	3	2	**13 (33.3)**
Stage at study entry, n (%)								
IIIA	0	0	0	1	0	0	1	**2 (5.1)**
IVA	1	1	0	0	3	4	0	**9 (23.1)**
IVB	0	3	5	2	2	0	1	**13 (33.3)**
Other[a]	3	1	2	3	1	4	1	**15 (38.5)**
Histology, n (%)								
Adenocarcinoma	4	3	6	4	3	6	3	**29 (74.4)**
Large cell	0	0	0	0	1	0	0	**1 (2.6)**
Other (poorly differentiated NSCLC, NOS)	0	1	0	0	0	0	0	**1 (2.6)**
Squamous	0	1	1	2	2	2	0	**8 (20.5)**
ECOG PS, n (%)								
0	0	1	2	0	2	2	1	**8 (20.5)**
1	4	4	5	6	4	6	2	**31(79.5)**

a: Stage IV

- **Background characteristics were balanced**
- **Approximately 90% failed prior immune-checkpoint inhibitors**

Source: Sands-J *et al.*, Abstract #9051, ASCO 2019

DS-1062: P1 Study Safety Summary

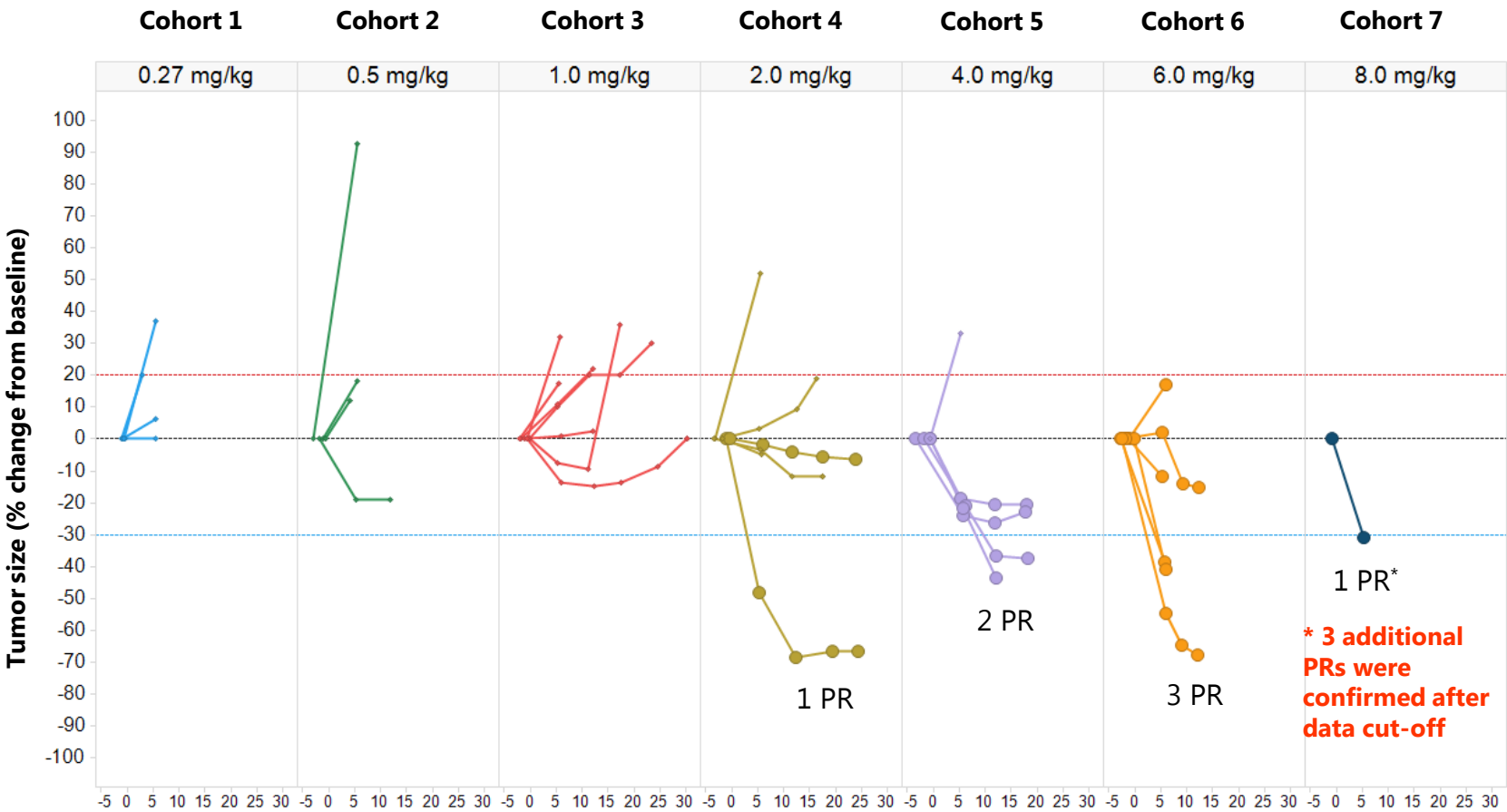
TEAE, n (%)	N=39	
	All grades	Grade≧3[a,b]
Any TEAE	34 (87.2)	16 (41.0)
TEAE, preferred term (in ≥ 10% of patients)		
Fatigue	13 (33.3)	2 (5.1)
Nausea	12 (30.8)	0
Anemia	9 (23.1)	0
Decreased appetite	9 (23.1)	0
Alopecia	8 (20.5)	0
Infusion related reaction	8 (20.5)	0
Constipation	6 (15.4)	0
Vomiting	6 (15.4)	0
Cough	5 (12.8)	0
Dyspnea	5 (12.8)	1 (2.6)
Rash	5 (12.8)	0
Diarrhea	4 (10.3)	0
Pain	4 (10.3)	1 (2.6)
Weight decreased	4 (10.3)	0

[a]TEAEs include 'uncoded (all grades: n=5, 12.8%; grade >=3, n=1, 2.6%); [b]The majority of TEAEs were grade 3 (n=8; 20.5%), except for one grade 2 and 1 grade 5 TEAE (grade 5 sepsis; 6.0 mg/kg treatment group).
TEAE, treatment-emergent adverse event.

- **DS-1062 was generally well-tolerated to date**

Source: Sands-J *et al.*, Abstract #9051, ASCO 2019

DS-1062: P1 Study Efficacy Spider Plot

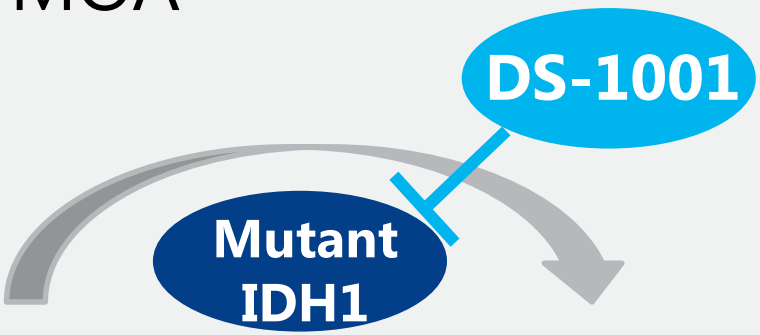


Confirmed PRs in a dose-dependent manner

Source: Sands-J *et al.*, Abstract #9051, ASCO 2019

DS-1001: Mutant IDH1 Inhibitors

MOA

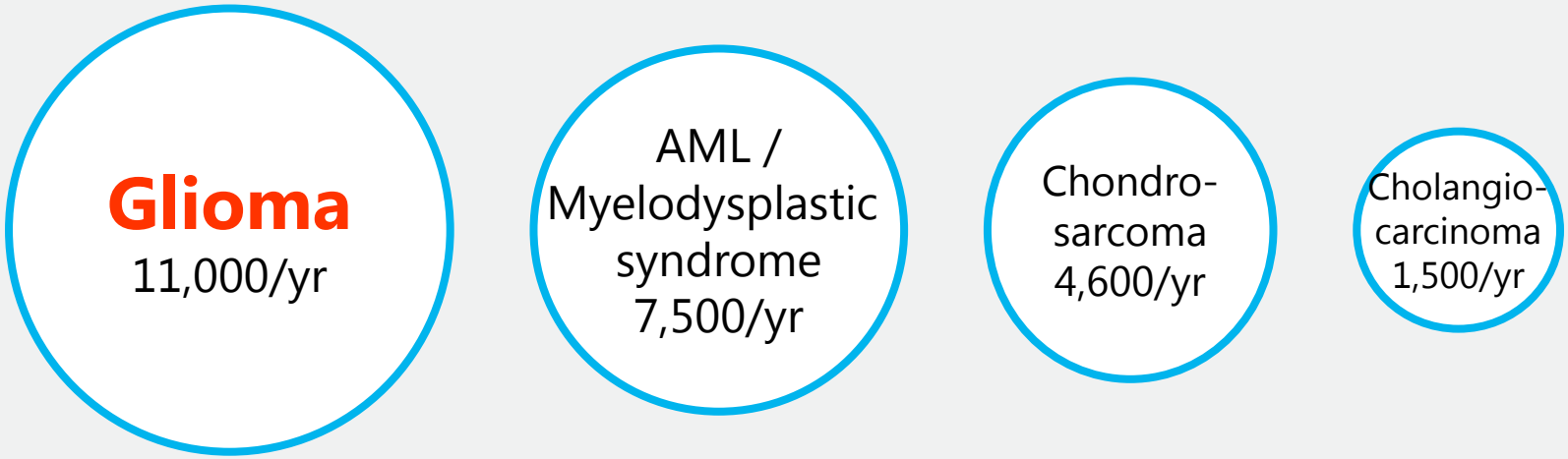


α-ketoglutarate (α-KG)

(R)-2-hydroxyglutarate (2-HG)

- Mutant IDH1 is an enzyme that converts α-KG to 2-HG
- 2-HG is an oncometabolite, accumulation of which leads to oncogenesis and subsequent clonal expansion via epigenetic dysregulation
- Inhibition of mutant IDH1 enzymes could lead to a novel antitumor therapy

Annual incidence of diseases with IDH1 mutations



Numbers and circle sizes indicate the estimated number of patients with IDH1m (annual incidence/year in JP/US/EU: our estimates)

DS-1001: P1 Study Patients Baseline Characteristics

Characteristic	Enhancing (n=35)	Non-enhancing (n=12)	Total (N=47)
Median age, years (range)	46.0 (29–77)	38.5 (28–49)	44.0 (28–77)
Gender: male/female, n (%)	21 (60) / 14 (40)	8 (67) / 4 (33)	29 (62) / 18 (38)
ECOG PS: 0/1/2, n (%)	19(54) / 13(37) / 3(9)	8(67) / 4(33) / 0	27(57) / 17(36)/ 3(6)
IDH1 mutation: R132H/others[a], n (%)	34 (97) / 1 (3)	12 (100) / 0	46 (98) /1 (2)
Most recent diagnosis, n (%)			
Oligodendroglioma	2 (6)	2 (17)	4 (9)
Anaplastic oligodendroglioma	13 (37)	1 (8)	14 (30)
Diffuse astrocytoma	6 (17)	7 (58)	13 (28)
Anaplastic astrocytoma	6 (17)	2 (17)	8 (17)
Anaplastic oligoastrocytoma	1 (3)	0	1 (2)
Glioblastoma	7 (20)	0	7 (15)
Median duration from initial diagnosis, years (range)	4.9 (0.5–15.3)	5.8 (2.4–12.6)	5.2 (0.5–15.3)
Prior radiation therapy, n (%)	35 (100)	12 (100)	47 (100)
Prior chemotherapy, n (%)	30 (86)	8 (67)	38 (81)

Data cutoff was on May 7, 2019. [a] One patient had a IDH-R132L mutation.
ECOG = Eastern Cooperative Oncology Group; IDH = isocitrate dehydrogenase; PS = performance status.

- **Enhancing: patients who have tumor(s) with gadolinium enhancement on MR images. It is common in high-grade gliomas like glioblastoma**
- **Non-enhancing: patients who have no gadolinium-enhanced tumor. Most common in low-grade gliomas**

Source: Natsume-A *et al.*, Abstract #2004, ASCO 2019

DS-1001: P1 Study Safety Summary

AEs occurring in ≥10% of patients, regardless of causality

Preferred term, n (%) [a]	All grades (N=47)	Grade ≥3 (N=47)
Skin hyperpigmentation	25 (53.2)	0
Diarrhea	22 (46.8)	2 (4.3)
Pruritus	14 (29.8)	0
Alopecia	12 (25.5)	0
Arthralgia	12 (25.5)	0
Nausea	12 (25.5)	0
Headache	10 (21.3)	0
Rash	10 (21.3)	0
Dry skin	9 (19.1)	0
Vomiting	9 (19.1)	0
Back pain	7 (14.9)	0
Neutrophil count decreased	7 (14.9)	6 (12.8)
Feces soft	6 (12.8)	0
Nasopharyngitis	6 (12.8)	0
Decreased appetite	5 (10.6)	0

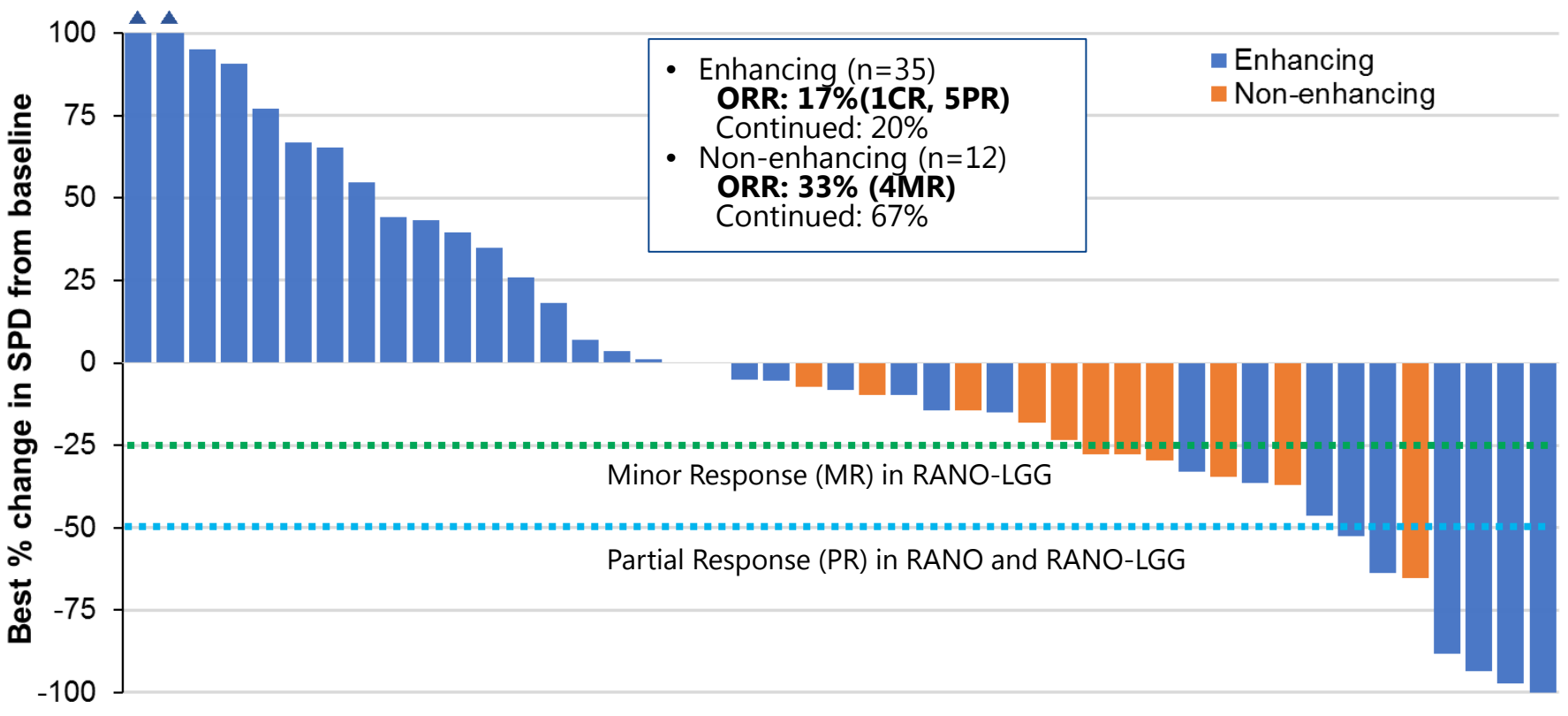
- One DLT was observed at a dose of 1000 mg bid
  - Grade 3 WBC count decreased
- **MTD was not reached up to 1,400mg bid**
- No drug-related serious AEs
- 19 patients (40%) experienced at least one AE of Grade 3
  - No Grade 4 or 5 AEs were reported

Data cutoff was on May 7, 2019.
[a] A patient was counted once if the same AE was reported more than once.
AE = adverse event; DLT = dose-limiting toxicity;
MTD = maximum tolerated dose; WBC = white blood cell.

- **DS-1001 was generally well-tolerated to date**

Source: Natsume-A *et al.*, Abstract #2004, ASCO 2019

DS-1001: Efficacy Waterfall Chart



Data cutoff was on May 7, 2019.
Enhancing gliomas were assessed by RANO criteria, and non-enhancing gliomas were assessed by RANO-LGG criteria.
▲ These two patients showed change over 100% (188% and 155%).
LGG = low-grade gliomas; RANO = Response Assessment in Neuro-Oncology; SPD = sum of the products of perpendicular diameters.

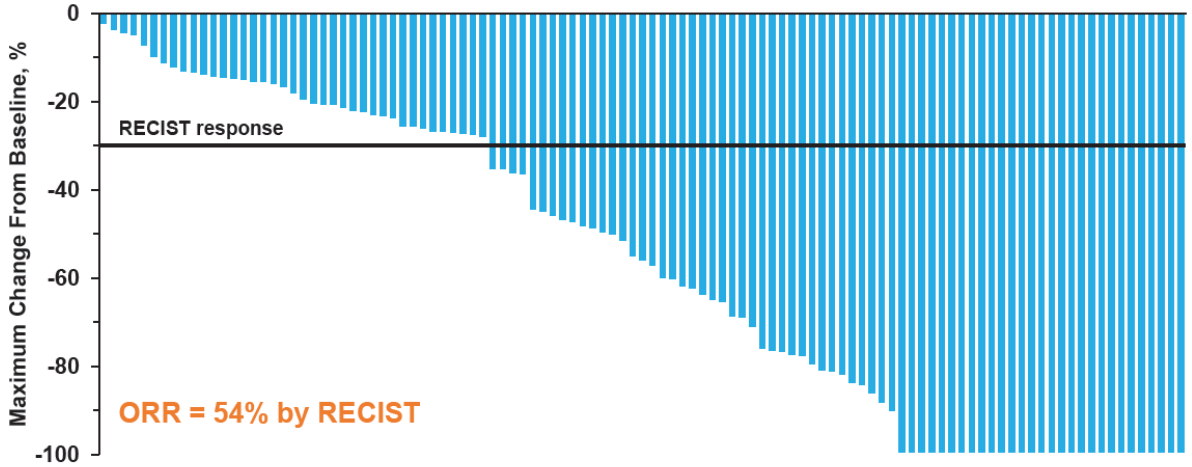
- **Antitumor activity was confirmed in both contrast enhancing and non-enhancing tumors**

Source: Natsume-A *et al.*, Abstract #2004, ASCO 2019

Pexidartinib: Efficacy Update of TGCT

	ASCO2019	ASCO2018	
	Long-term Treatment Pooled Analysis (Updated ENLIVEN & Ph1)	ENLIVEN Primary Endpoint Results	
	Pexidartinib n=130*	Pexidartinib n=61	Placebo n=59
RECIST Best ORR (CR or PR), n (%)	70 (**54%**)	24 (**39%**)	0
Median treatment duration, month (range)	**17** (1-60+)	-	-
Median (range) RECIST duration of response, month (range)	**Not Reached** (2-53+)	-	-

*Breakdown of n=130
- ENLIVEN Randomized (1000mg/d): n=61
- ENLIVEN Crossover (800mg/d): n=30
- PLX106-01 TGCT Cohort (1000mg/d): n=39



ORR improved after long-term treatment

Source: Tap-D *et al.*, Abstract #11502, ASCO 2018, Data cutoff: March 27, 2017
Source: Gelderblom-H *et al.*, Abstract #11042, ASCO 2019, Data cutoff: January 31, 2018

Pexidartinib: Hepatotoxicity Update of TGCT Patients

	ASCO 2019		ASCO 2018	
	Pexidartinib Randomized (1000mg/d) n=61	Pexidartinib Crossover (800mg/d) n=30	Pexidartinib Randomized (1000mg/d) n=61	Pexidartinib Crossover (800mg/d) n=30
ALT or AST ≧ 3 x, Tbili ≧ 2 x, and ALP < 2 x ULN (Hy's law)	0	0	0	0
ALT or AST ≧ 3 x, Tbili ≧ 2 x, and ALP ≧ 2 x ULN	**3* (5%)**	0	**3* (5%)**	0
Tbili ≧ 2 x ULN (in absence of ALT ≧ 3 x ALP ≧ 2 x ULN)	0	0	0	0

*All 3 patients recovered

Safety data of long-term administration of pexidartinib to the same population

- **No new mixed or cholesteric hepatotoxicity, beyond the serious cases in the first 8 weeks of treatment**

Source: Tap-D *et al.*, Abstract #11502, ASCO 2018, Data cutoff: March 27, 2019
Source: Gelderblom-H *et al.*, Abstract #11042, ASCO 2019, Data cutoff: January 31, 2018

Upcoming Milestones

Daiichi-Sankyo

DS-8201

HER2 positive mBC pivotal phase 2 study
- US: BLA submission in 1H FY2019
- JP: NDA submission in 2H FY2019
- EU: MAA submission in 1H FY2020
- Presentation at SABCS: December 2019 (planned)

HER2 positive mGC pivotal phase 2 study
- **JP: NDA submission in 1H FY2020**

U3-1402

EGFRm NSCLC phase 1 study
- **WCLC: interim data update (planned)**

DS-1062

NSCLC phase 1 study
- **WCLC: interim data update (planned)**

WCLC (World Conference on Lung Cancer)
Date: September 7-10, 2019
Location: Barcelona, Spain
- **Abstract Title: August 2, 2019**
- **Full Abstract: 17:00, August 21, 2019 (EDT)**

Underlined in red: new or updated from FY2018 Q4

Upcoming Milestones

Daiichi-Sankyo

Quizartinib		Relapsed/refractory FLT3-ITD AML • **QuANTUM-R published in *The Lancet Oncology* in June 2019** • Japan: **approved on June 18, 2019** • US: **received CRL in June 2019** • EU: under review for 2H FY2019 approval
Pexidartinib		Tenosynovial giant cell tumor • **ENLIVEN published in *The Lancet* in June 2019** • USA: **completed ODAC (80% positive ODAC vote)** FDA PDUFA 2019 August 3 • EU: under review for 1H FY2020 approval
DS-1647 (G47Δ)		Malignant glioma • NDA submission in **2H** FY2019 (Japan)

CRL: complete response letter, ODAC: Oncology Drug Advisory Committee

Underlined in red: new or updated from FY2018 Q4

Announcement of FY2019 R&D Day

R&D Day in Tokyo

Date	December 17 (Tuesday) afternoon [live & on-demand casting planned]
Speakers	Sunao Manabe, CEO Antoine Yver, Global Head of Oncology R&D

R&D Day in New York

Date	December 19 (Thursday) afternoon [on-demand casting planned]
Speakers	Sunao Manabe, CEO Antoine Yver, Global Head of Oncology R&D

◆ **The content will be the same on both days**

1 FY2019 Q1 Financial Results

2 Business Update

3 R&D Update

4 **Appendix**

FY2019 R&D Milestones

As of July 2019

Daiichi-Sankyo

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

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

Underlined in red: new or updated from FY2018 Q4, blue: achieved

Major R&D Pipelines-1

As of July 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)	JP/US/EU/Asia	
			Breast cancer (HER2 positive vs T-DM1)	JP/US/EU/Asia	
			Breast cancer (HER2 low expression)	JP/US/EU/Asia	
			Gastric cancer (HER2 positive post trastuzumab)	JP/Asia	
			Colorectal cancer (HER2 expressing)	JP/US/EU	
			NSCLC (HER2 expressing/mutant)	JP/US/EU	
			Breast and bladder cancer (with nivolumab)	US/EU	
		U3-1402/anti-HER3 ADC	Breast cancer (HER3 expressing)	JP/US	
			EGFRm NSCLC	JP/US	
		DS-1062/anti-TROP2 ADC	NSCLC	JP/US	
	AML Franchise	Quizartinib/FLT3 inhibitor	AML (relapsed/refractory)	EU/Asia	
			AML (1st line)	JP/US/EU/Asia	
		Milademetan/DS-3032/ MDM2 inhibitor	Solid tumor (lyposarcoma)	JP/US	
			AML	JP/US	
		Valemetostat/DS-3201/ EZH1/2 inhibitor	Peripheral T-cell lymphomas	JP/US	
			Adult T-cell leukemia/lymphoma	JP	
			AML, ALL	US	
			Small cell lung cancer	US	
		PLX2853/BET inhibitor	AML	US	
		Axicabtagene ciloleucel/Axi-Cel®/ anti-CD19 CAR-T	B-cell lymphoma	JP	

Stage: P1 | P2 | P3 | NDA/BLA

ALL: acute lymphocytic leukemia, AML: acute myeloid leukemia, 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

Major R&D Pipelines-2

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

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

Out-licensing Projects

As of Jul 2019

Daiichi-Sankyo

	Pre-clinical	Phase 1
Oncology		**PLX7486: FMS/TRK inhibitor** Solid tumor **PLX8394: BRAF 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-2969: GyrB inhibitor** Clostridium difficile infection **DS-1093: HIF-PH inhibitor** inflammatory bowel disease (IBD) **DS-7080: angiogenesis inhibitor** Age-related macular degeneration (AMD) **DS-1501: anti Siglec-15 antibody** *US/EU (other than JP) Osteoporosis

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 of innovative therapeutics
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	Duration of response (duration of response)
EGFR	Epidermal growth factor receptor	Epidermal growth factor receptor
MTD	Maximum tolerated dose	Maximum tolerated dose (dose with intolerable toxicity)
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	Progress 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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