Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Top Management Presentation

Financial Results of FY2018 Q1 (April 1 – June 30, 2018)

DAIICHI SANKYO CO., LTD

Toshiaki Sai
Executive Vice President and CFO

July 31, 2018

Forward-Looking Statements

Management strategies and plans, financial forecasts, future projections and policies, and R&D information that Daiichi Sankyo discloses in this material are all classified as Daiichi Sankyo's future prospects. These forward looking statements were determined by Daiichi Sankyo based on information obtained as of today with certain assumptions, premises and future forecasts, and thus, there are various inherent risks as well as uncertainties involved. As such, please note that actual results of Daiichi Sankyo may diverge materially from Daiichi Sankyo's outlook or the content of this material. Furthermore, there is no assurance that any forward-looking statements in this material will be realized. Regardless of the actual results or facts, Daiichi Sankyo is not obliged and does not have in its policy the duty to update the content of this material from the date of this material onward.

Compounds under discussion are investigational agents and are not approved by the FDA or any other regulatory agency worldwide as a treatment for indications under investigation. Efficacy and safety have not been established in areas under investigation. There are no guarantee that these compounds will become commercially available in indications under investigation.

Daiichi Sankyo takes reasonable care to ensure the accuracy of the content of this material, but shall not be obliged to guarantee the absolute accuracy, appropriateness, completeness and feasibility, etc. of the information described in this material. Furthermore, any information regarding companies, organizations or any other matters outside the Daiichi Sankyo Group that is described within this material has been compiled or cited using publicly available information or other information, and Daiichi Sankyo has not performed in-house inspection of the accuracy, appropriateness, completeness and feasibility, etc. of such information, and does not guarantee the accuracy thereof.

The information described in this material may be changed hereafter without notice. Accordingly, this material or the information described herein should be used at your own judgment, together with any other information you may otherwise obtain.

This material does not constitute a solicitation of application to acquire or an offer to sell any security in the United States, Japan or elsewhere.

This material disclosed here is for reference purposes only. Final investment decisions should be made at your own discretion.

Daiichi Sankyo assumes no responsibility for any damages resulting from the use of this material or its content, including without limitation damages related to the use of erroneous information

Agenda

- **FY2018 Q1 Financial Results**
- **Business Update**
- **R&D Update**
- **Appendix**

FY2018 Q1 Financial Results

Overview of FY2018 Q1 Results

(Bn JPY)

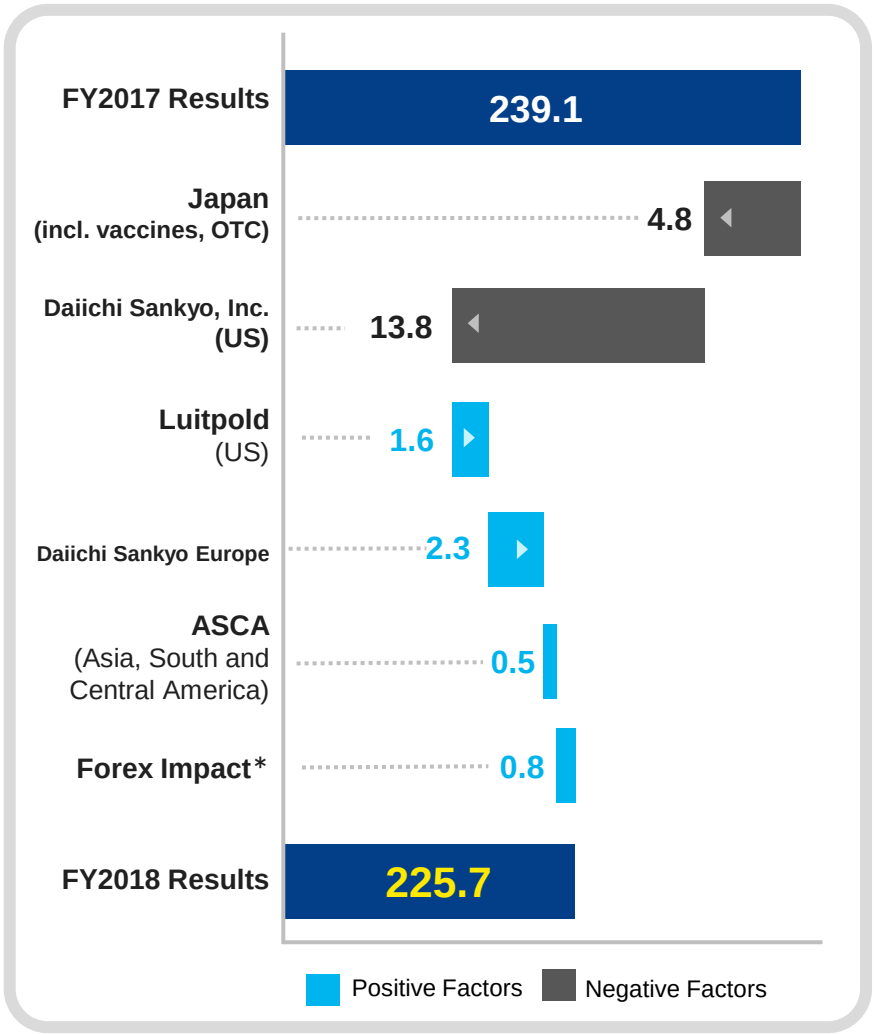
	FY2017 Q1 Results	FY2018 Q1 Results	YoY
Revenue	**239.1**	**225.7**	-5.6% **-13.4**
Cost of Sales	**80.1**	**84.7**	**+4.7**
SG&A Expenses	**70.8**	**65.6**	**-5.2**
R&D Expenses	**48.0**	**45.5**	**-2.5**
Operating Profit	**40.3**	**29.9**	-25.7% **-10.4**
Profit before Tax	**42.2**	**29.6**	**-12.6**
Profit attributable to owners of the Company	**29.2**	**24.0**	-17.8% **-5.2**

Currency Rate	USD/JPY	111.10	109.07	-2.03
	EUR/JPY	122.19	130.06	+7.87

Revenue

Decreased by 13.4 Bn JPY (Decreased by 14.2 Bn JPY excl. forex impact)

(Bn JPY)



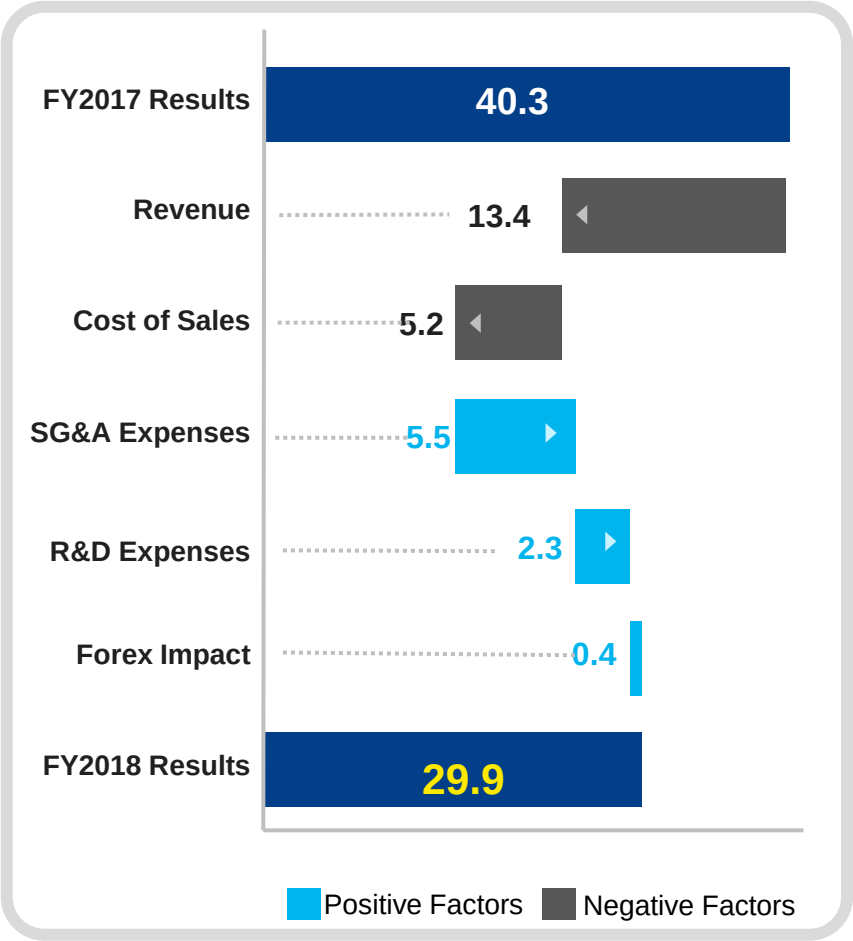
	Positive Factors	Negative Factors
Japan		
	Lixiana +5.4	Olmetec -12.6
	Pralia +1.1	Nexium -2.8
		Loxonin -1.6
		*Incl. impact of price revision in Japan
	Daiichi Sankyo Espha (GE) +6.5	
	Olmesartan AG, Rosuvastatin AG etc.	
	Daiichi Sankyo Healthcare +1.5	
Daiichi Sankyo, Inc.		
		Effient -5.5
		Welchol -5.2
		Olmesartan -3.6
Luitpold		
	Injectafer +3.4	GE injectables -2.6
	Venofer +1.0	
Daiichi Sankyo Europe		
	Lixiana +4.2	Olmesartan -1.3

* Forex impact USD: -0.8, EUR : +1.4, ASCA: +0.2

Operating Profit

Decreased by 10.4 Bn JPY

(Decreased by 11.5 Bn JPY excl. forex impact)



(Bn JPY)

Revenue ..... **-13.4**
incl. forex impact of +0.8

Cost of Sales ..... **+5.2 (Cost increased)**
Product mix due to impact of olmesartan LOE

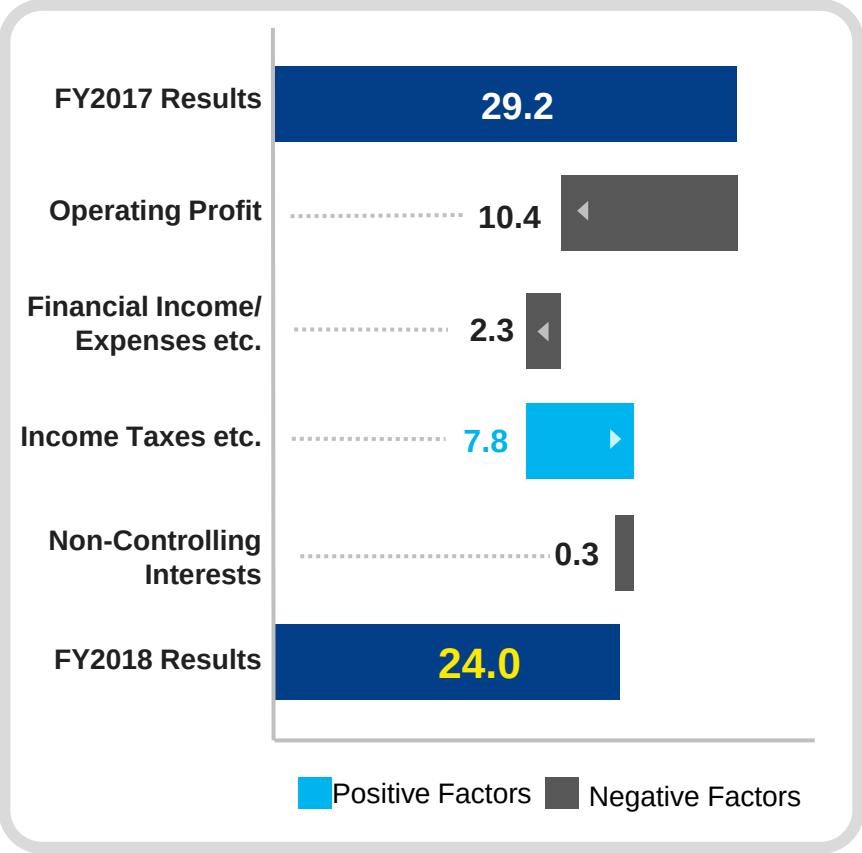
SG&A Expenses ..... **-5.5 (Cost decreased)**
Impact of cost reduction by restructuring in the US etc.

R&D Expenses ..... **-2.3 (Cost decreased)**
Due to completion of P3 studies of Mirogabalin etc.

Forex Impact ..... **-0.4 (Cost decreased)**
Cost of Sales ..... -0.5
SG&A Expenses ..... +0.4
R&D Expenses ..... -0.2

Profit Attributable to Owners of the Company

Decreased by 5.2 Bn JPY



(Bn JPY)

Financial Income/ Expenses etc. ····· 2.3 (Cost increased)

Deterioration of forex gains/ losses

Income Taxes etc. ····· -7.8 (Cost decreased)

Impact of the tax rate reduction in US etc.

	FY2017	FY2018	YoY
Profit before Tax	42.2	29.6	-12.6
Income Taxes etc.	13.4	5.7	-7.8
Tax rate	31.8%	19.2%	-12.6%

Non-Controlling Interests ····· 0.3

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2017 Q1 Results	FY2018 Q1 Results	YoY	vs. Forecast (%)
Japan	**130.0**	**123.9**	**-6.1**	**24.9%**
Daiichi Sankyo Healthcare	**16.8**	**18.4**	**+1.5**	**24.8%**
Daiichi Sankyo Inc.	**25.0**	**11.0**	**-14.0**	**24.9%**
Olmesartan	6.8	3.2	-3.6	45.0%
Welchol	10.1	4.9	-5.3	19.4%
Effient	6.1	0.6	-5.5	-
Savaysa	0.5	0.4	-0.1	20.1%
Movantik	1.3	0.9	-0.4	-
Luitpold	**27.6**	**28.6**	**+1.0**	**26.0%**
Venofer	7.4	8.2	+0.8	30.5%
Injectafer	8.1	11.2	+3.1	28.7%
GE injectables	10.7	7.9	-2.7	-
Daiichi Sankyo Europe	**18.5**	**22.2**	**+3.6**	**26.1%**
Olmesartan	9.0	8.2	-0.8	35.5%
Efient	1.9	1.9	-0.0	27.2%
Lixiana	4.9	9.7	+4.8	21.6%
ASCA (Asia, South and Central America)	**19.0**	**19.7**	**+0.7**	**21.9%**

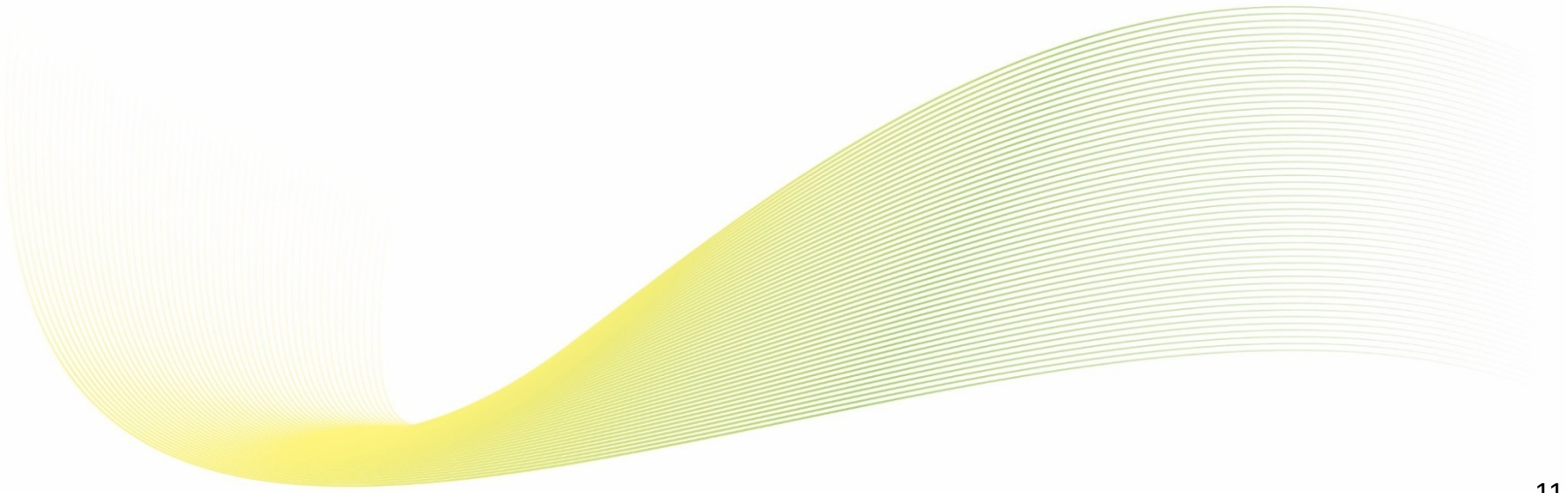
Currency Rate	USD/JPY	111.10	109.07	-2.03
	EUR/JPY	122.19	130.06	+7.87

Revenue: Major Products in Japan

(Bn JPY)

		FY2017 Q1 Results	FY2018 Q1 Results	YoY	vs. Forecast (%)
Nexium	ulcer treatment	**22.6**	**19.8**	**-2.8**	**26.0%**
Lixiana	anticoagulant	**9.4**	**14.7**	**+5.4**	**27.3%**
Memary	Alzheimer's disease treatment	**12.5**	**12.9**	**+0.4**	**25.3%**
Loxonin	anti-inflammatory analgesic	**9.6**	**7.9**	**-1.6**	**25.5%**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**5.5**	**6.6**	**+1.1**	**24.4%**
Tenelia	type 2 diabetes mellitus treatment	**7.6**	**6.4**	**-1.2**	**23.8%**
Inavir	anti-influenza treatment	**0.7**	**0.1**	**-0.7**	**0.3%**
Olmetec	antihypertensive agent	**16.8**	**4.2**	**-12.6**	**21.9%**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**3.8**	**3.9**	**+0.2**	**24.6%**
Efient	antiplatelet agent	**3.3**	**3.6**	**+0.3**	**24.0%**
Rezaltas	antihypertensive agent	**4.5**	**4.1**	**-0.4**	**29.1%**
Urief	treatment for dysuria	**2.9**	**2.7**	**-0.2**	**27.2%**
Omnipaque	contrast medium	**3.6**	**3.3**	**-0.4**	**32.7%**

Business Update

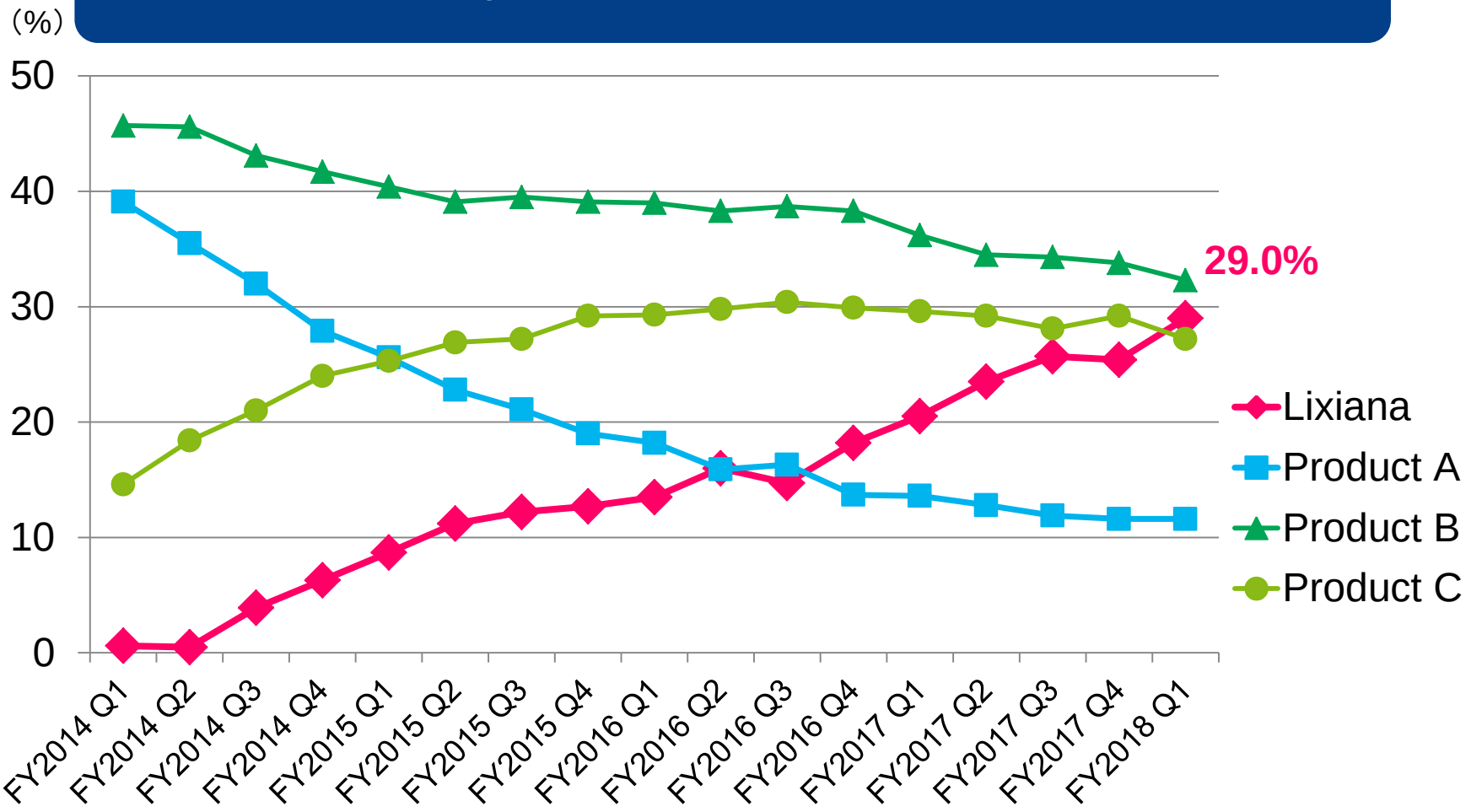


Lixiana: Growth in Japan

Sales

Daiichi-Sankyo

◆ As of FY2018 Q1, Lixiana reached No.2 sales share

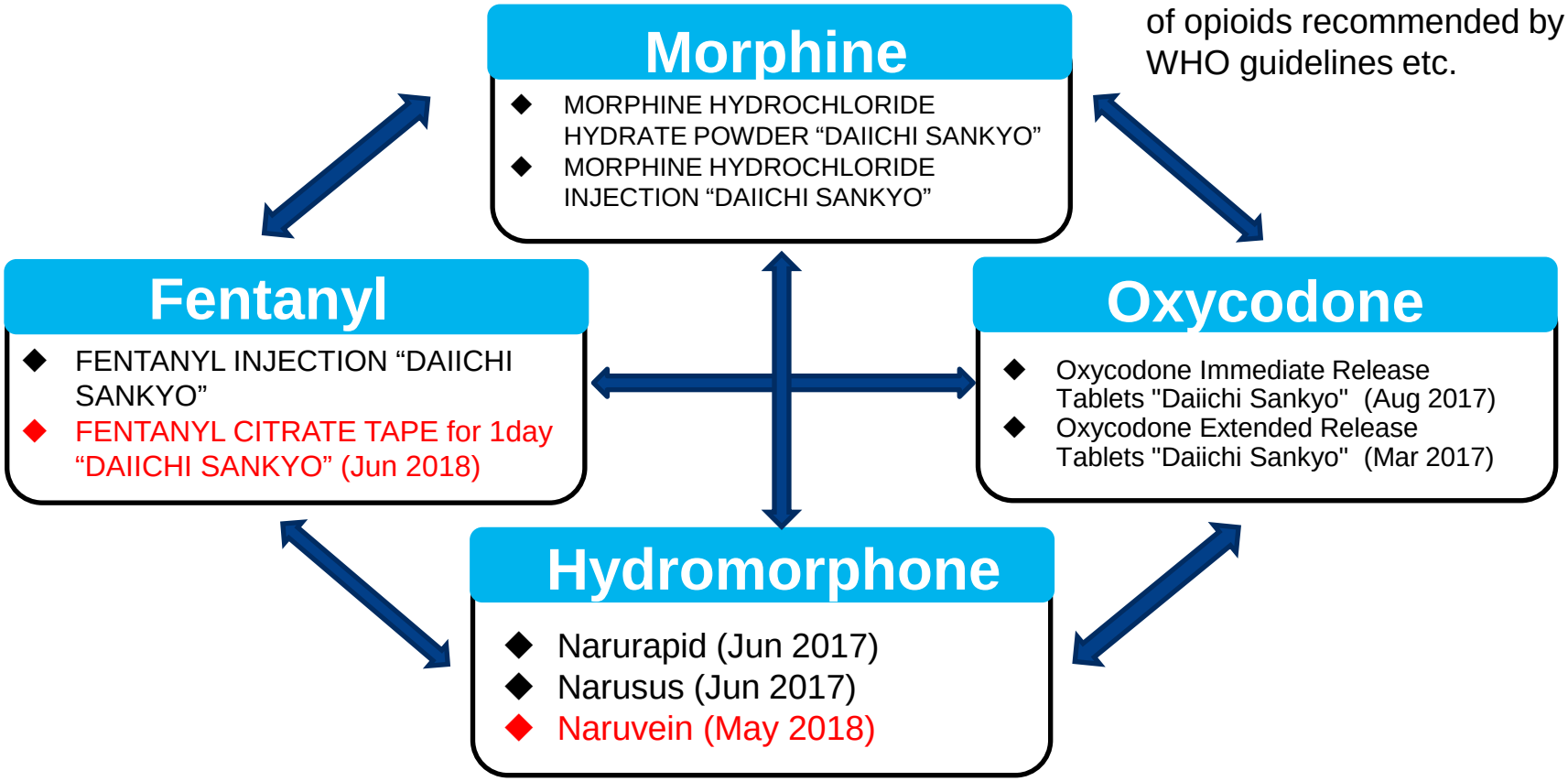


Calculated based on JPM FY2014 Q1 - FY2018 Q1

Japan: Efforts for Cancer Pain

Opioid Switching*

*Switching to another opioids is a global standard way for use of opioids recommended by WHO guidelines etc.



- Opioid analgesics should be important mediation for establishing oncology business since it is prescribed in all clinical departments in which cancer patients are treated

Red: New

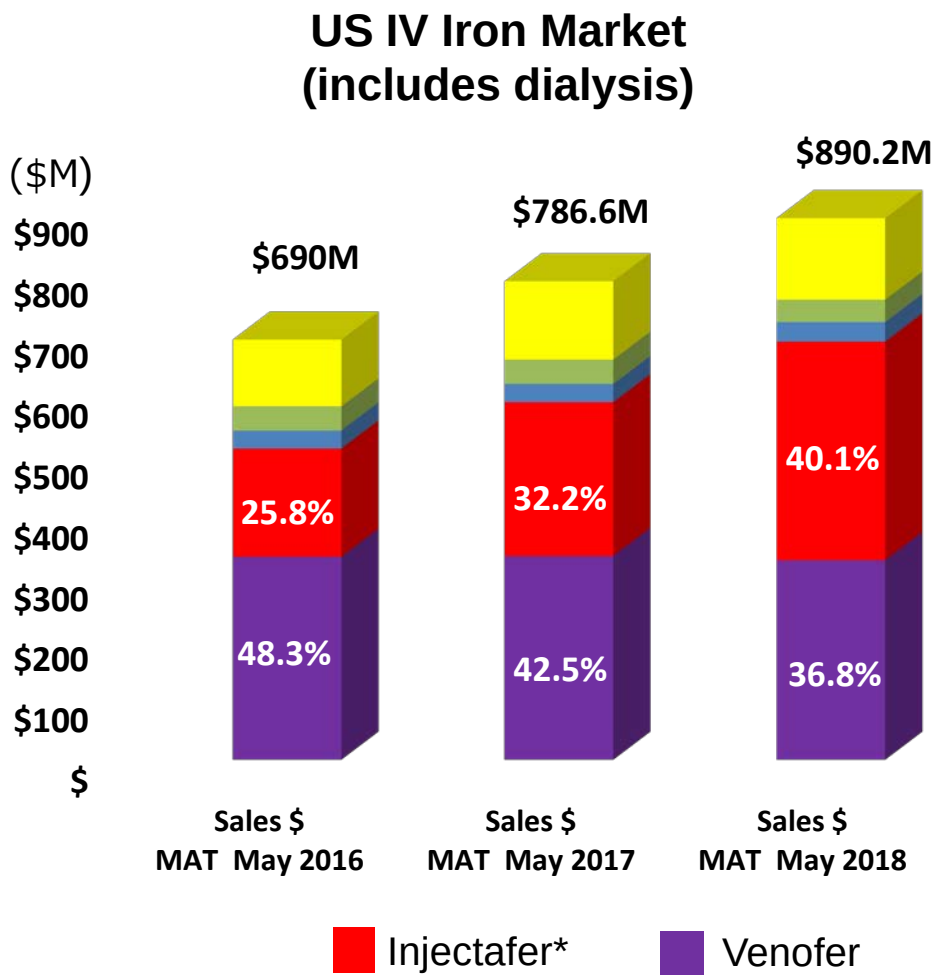
Transfer of Long-listed Products

◆ Decided to transfer partial long-listed products in order to invest management resource preferentially to oncology area

- Transfer Products： 41 long-listed products manufactured and marketed by Daiichi Sankyo and Daiichi Sankyo ESPHA
  (ref. Total revenue in FY2017: JPY 9.2 Bn)
- Transferee： Alfresa Pharma Corporation
- Transfer Timing： Sequentially starting from March 2019
- Transfer Price： JPY 8.4 Bn*

* Excluding transfer price for inventories

LPI: Growth of Iron Franchise



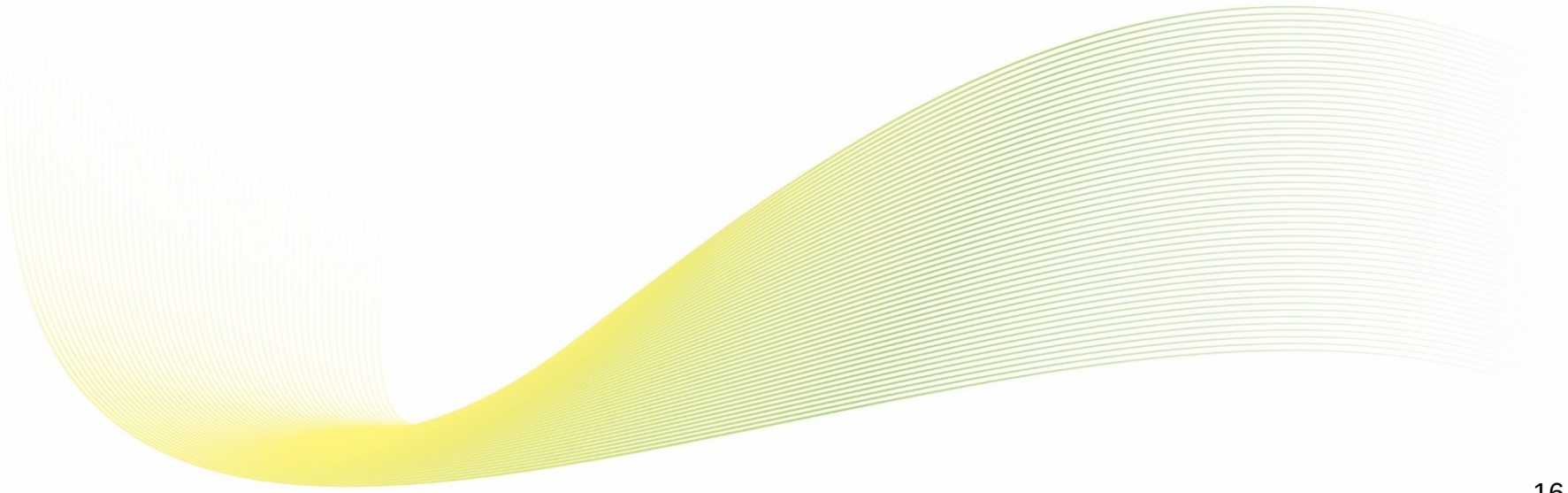
AMERICAN REGENT™
Reliable. Responsive. Respected.

LPI will change its company name to "American Regent" in Jan. 2019.

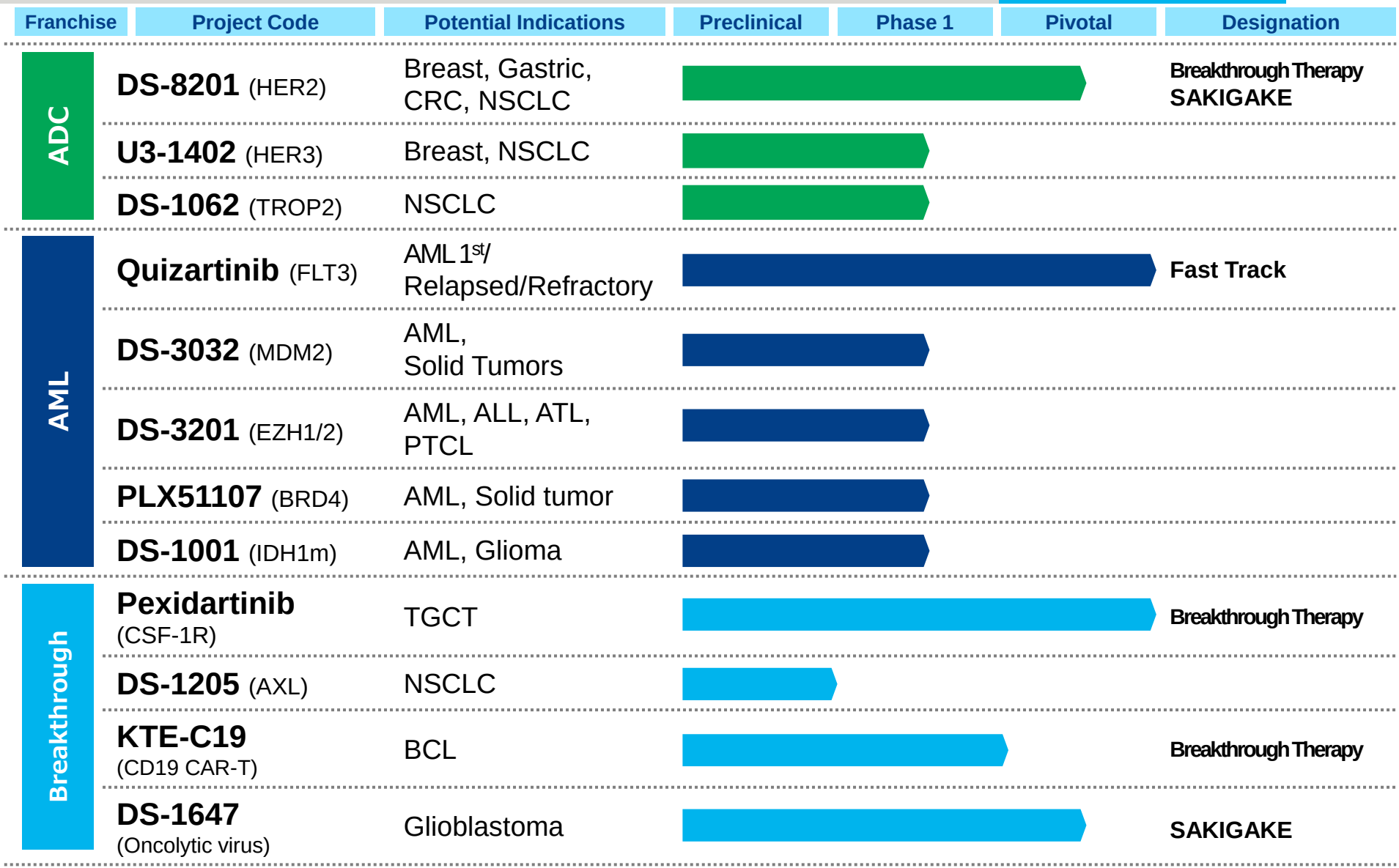
*Injectafer is not indicated for patients who are dialysis dependent

Source: IMS National Sales Perspectives May 2018
(includes all US IV Iron sales in all channels including dialysis chains)

R&D Update



CE Major Clinical Pipeline



ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, ATL: adult T-cell leukemia, BCL: B-cell lymphoma, CRC: colorectal cancer, NSCLC: non-small cell lung cancer , PTCL: peripheral T-cell lymphoma, TGCT: tenosynovial giant cell tumor

Terminology of HER2

◆ Organized terminology related to HER2

Commonly Used	HER2 Status	DS terminology for Future Use
HER2 positive or HER2 overexpressing	IHC 3+	HER2 positive (HER2 overexpressing*)
	IHC 2+/ISH +	
HER2 negative	IHC 2+/ISH -	HER2 low
	IHC 1+/ISH -	
	IHC 0	HER2 negative

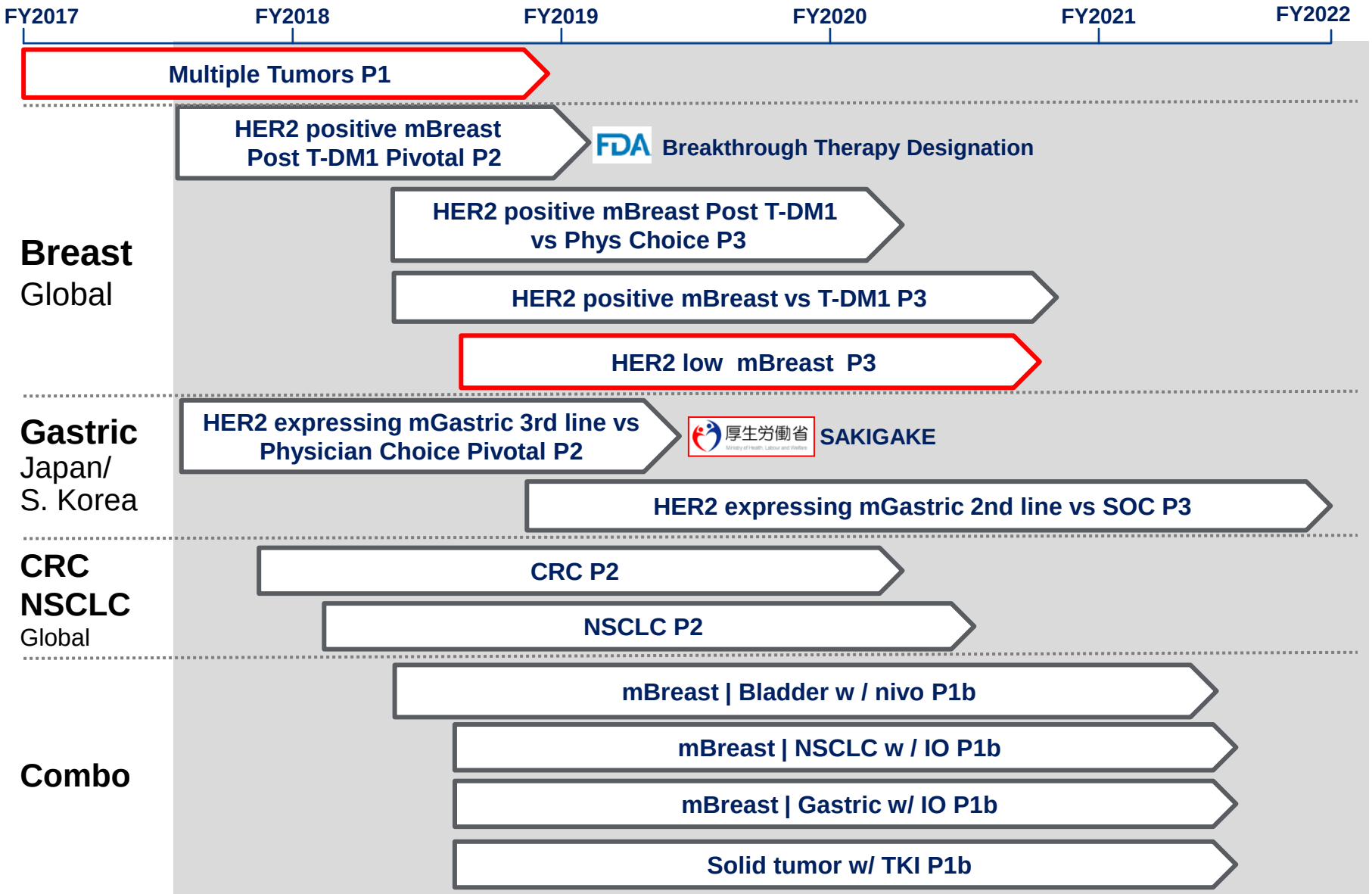
* “Overexpressing” may be used in case the terminology is used in protocol and etc.

- ◆ IHC: immunohistochemistry
  - ➢ Observes protein expression levels of HER2 (surface of cancer cell)
- ◆ ISH : in situ Hybridization
  - ➢ Observes amplification levels of HER2 gene (nuclear of cancer cell)
  - ➢ FISH: fluorescence in situ Hybridization
  - ➢ DISH: dual color in situ Hybridization

ADC DS-8201: Clinical Program

As of July 2018

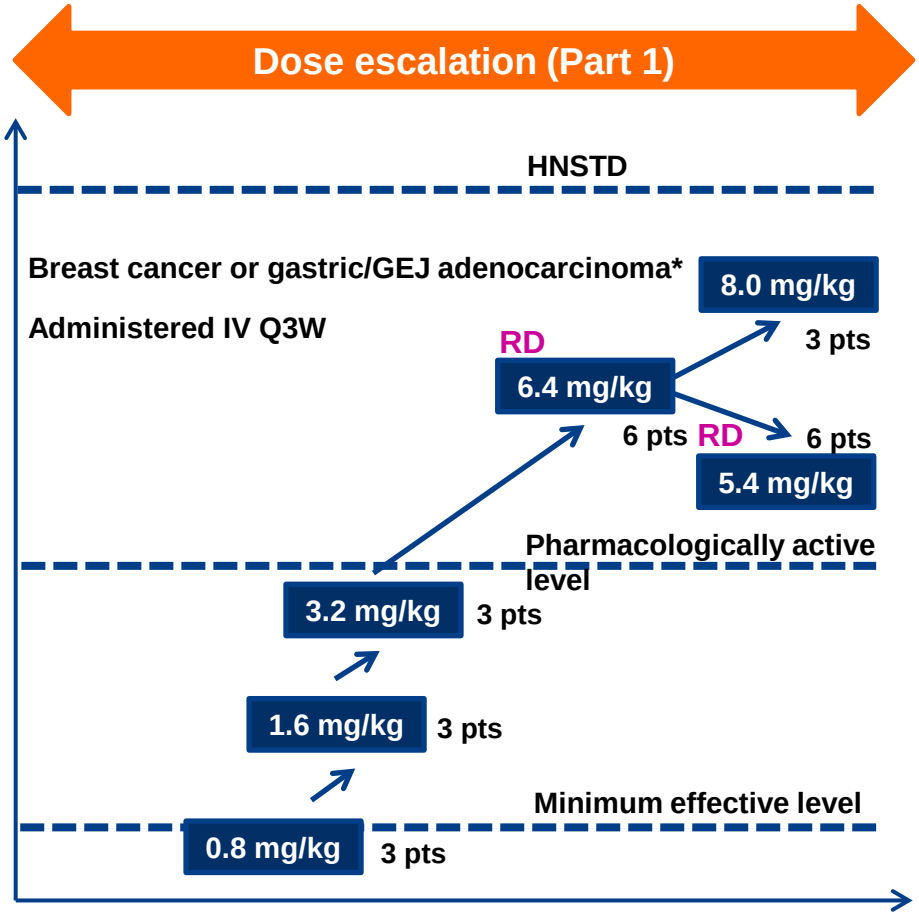
Daiichi-Sankyo

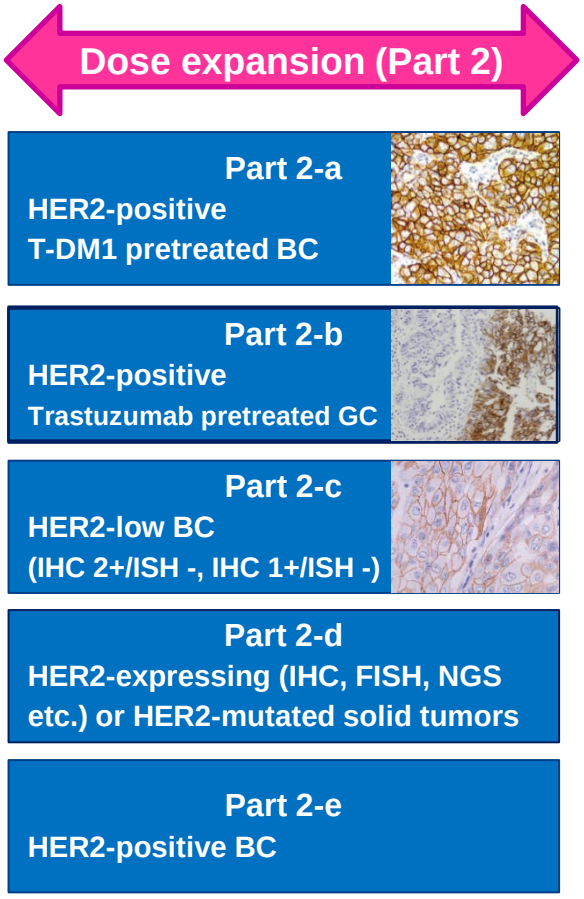


DS-8201: P1 Study Design

ASCO 2018 Presentation

Daiichi-Sankyo





*Subjects in part 1 are not required to have HER2-positive (IHC 3+ or IHC2+/ISH-positive) tumors.

BC, breast cancer; EWOC, escalation with overdose control; FISH, fluorescent in situ hybridization; GC, gastric cancer; GEJ, gastroesophageal junction; HER2, human epidermal growth factor receptor 2; HNSTD, highest non-severely toxic dose; IHC, immunohistochemistry; ISH, in situ hybridization; IV, intravenous; mCRM, modified continuous reassessment method; NGS, next-generation sequencing; Q3W, once every 3 weeks; RD, recommended dose for dose expansion; T-DM1, trastuzumab emtansine.

ADC DS-8201：P1 Study Demographic (5.4, 6.4mg/kg)

ASCO 2018 Presentation

Daiichi-Sankyo

	HER2-Positive BC N = 111[a]	HER2-Low BC N = 34[b]	HER2-Positive GC N = 44[c]	HER2-Expressing Other Cancers N = 51[d]
Age, median (range), years	55.0 (33–77)	54.5 (33–75)	68.0 (38–79)	59 (35–76)
ECOG performance status, N (%)				
0	71 (64.0)	20 (58.8)	32 (72.7)	27 (52.9)
1	40 (36.0)	14 (41.2)	12 (27.3)	24 (47.1)
Prior therapies*, median (range)	7.0 (2–21)	7.5 (3–18)	3.0 (1–7)	3.0 (0–10)
HER2 expression (IHC), N (%)				
3+	75 (67.6)	0 (0.0)	36 (81.8)	16 (31.4)
2+	31 (27.9)	18 (52.9)	8 (18.2)	10 (19.6)
1+	1 (0.9)	16 (47.1)	0 (0.0)	2 (3.9)
Tumor size, median (range), cm	6.0 (1–23)	5.6 (1–19)	5.6 (2–20)	6.6 (2–19)

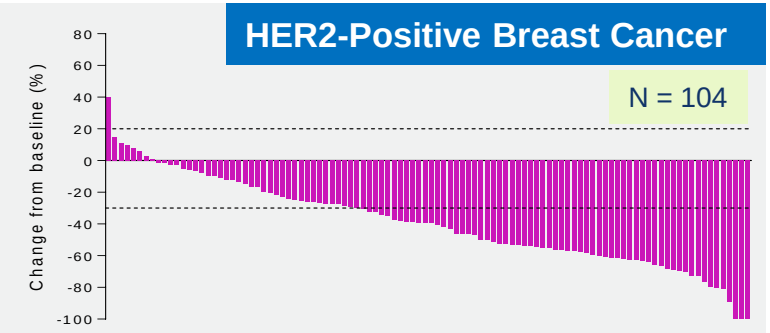
[a]From Part 1, 2a, and 2e; [b]From Part 1, 2c, and 2e; [c]From Part 1 and 2b; [d]From Part 2d. One subject with HER2-low GC is not included in the table.
*Includes neo-adjuvant and adjuvant regimens.

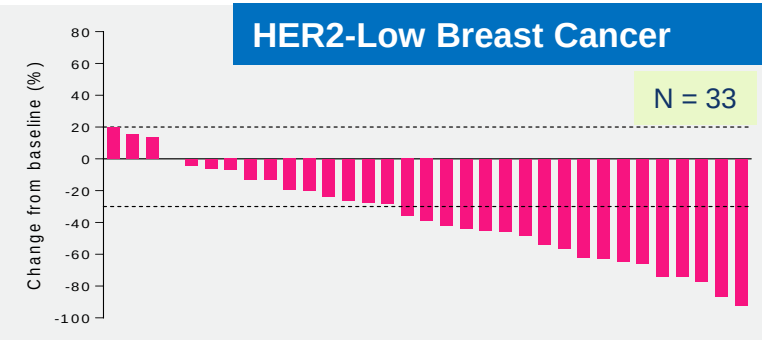
BC, breast cancer, ECOG, Eastern Cooperative Oncology Group; GC, gastric/gastroesophageal junction cancer; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry.
Data cutoff for this analysis is April 18, 2018.

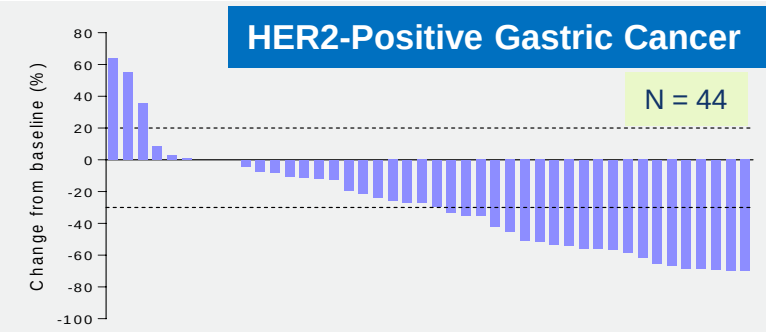
- Patients had multiple prior regimens
- Tumor size with a median of 6cm reflects quite advanced tumor patients were enrolled

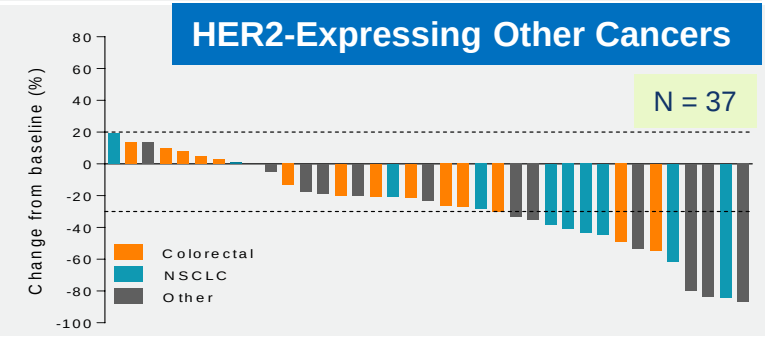
DS-8201: P1 Study Efficacy

Tumor Shrinkage by Tumor Types: (5.4 or 6.4 mg/kg)









Includes subjects who had ≥1 postbaseline scan. Dotted lines denote 20% increase and 30% reduction in tumor size, respectively.
*Confirmed response includes subjects who had ≥2 postbaseline scans, progressive disease, or discontinued treatment for any reason prior to second postbaseline scan.
Data cutoff is April 18, 2018.

- Similar response pattern across all tumor types
- Confirmed ORR in the overall population: 49.3%

DS-8201: P1 Study Efficacy

Efficacy Outcomes by Tumor Type (5.4 or 6.4 mg/kg)

	HER2-Positive BC N = 111	HER2-Low BC N = 34	HER2-Positive GC N = 44	HER2-Expressing Other Cancers N = 51
Confirmed ORR* % (n/N)	**54.5%** (54/99)	**50.0%** (17/34)	**43.2%** (19/44)	**38.7%** (12/31)
DCR % (n/N)	**93.9%** (93/99)	**85.3%** (29/34)	**79.5%** (35/44)	**83.9%** (26/31)
ORR in modified ITT, %** (n/N)	**48.6%** (54/111)	**50.0%** (17/34)	**43.2%** (19/44)	**23.5%** (12/51)
DOR				
Median (95% CI), months	**NR**	**11.0** (NA)	**7.0** (NA)	**12.9** (2.8, 12.9)
PFS				
Median, (95% CI), months	**NR**	**12.9** (NA)	**5.6** (3.0, 8.3)	**12.1** (2.7, 14.1)
Min, max	1.0, 22.2+	0.5, 19.6+	1.2, 19.6+	0.7, 14.1+

* Confirmed response includes subjects who had ≥2 postbaseline scans, had progressive disease, or discontinued treatment for any reason prior to second postbaseline scan.
** Modified ITT population included all subjects who received ≥1 dose of DS-8201a at either 5.4 or 6.4 mg/kg, including those subjects who were too early to assess, but are ongoing on study.
+ after value indicates censoring.
BC, breast cancer; CI, confidence interval; DCR, disease control rate; DOR, duration of response; GC, gastric/gastroesophageal junction cancer; HER2, human epidermal growth factor receptor 2; ITT, intent-to-treat; NA, not available; NR, not reached; ORR, overall response rate; PFS, progression-free survival.
Data cutoff for this analysis is April 18, 2018.

- ORR of HER2-Low BC was 50%, similar result to HER2-positive BC, 54.5%
- PFS of HER2-Low BC was 12.9M and HER2-Positive BC was not reached

DS-8201: P1 Study Safety

ASCO 2018 Presentation

Daiichi-Sankyo

Most Frequent TEAEs (≥10%, 5.4 or 6.4 mg/kg, N = 241)

	Adverse Events	All grades (%)	Grade ≥3 (%)
Gastrointestinal	Nausea	166 (68.9)	6 (2.5)
	Vomiting	84 (34.9)	4 (1.7)
	Diarrhea	64 (26.6)	2 (0.8)
	Constipation	51 (21.2)	0 (0.0)
	Stomatitis	43 (17.8)	0 (0.0)
	Decreased appetite	134 (55.6)	8 (3.3)
Hematologic	Anemia	77 (32.0)	36 (14.9)
	Platelet count decreased	69 (28.6)	25 (10.4)
	Neutrophil count decreased	61 (25.3)	37 (15.4)
	White blood cell count decreased	58 (24.1)	30 (12.4)
Other	Alopecia	87 (36.1)	0 (0.0)
	Fatigue	67 (27.8)	4 (1.7)
	Malaise	50 (20.7)	1 (0.4)
	Pyrexia	25 (10.4)	1 (0.4)
	Dysgeusia	24 (10.0)	0 (0.0)

Data cutoff for this analysis is April 18, 2018.

- Adverse events were generally of low grade
- Most frequent AEs were gastrointestinal or hematologic in nature

DS-8201: P1 Study Safety

Adverse Events of Special Interest (5.4 or 6.4 mg/kg, N = 241)

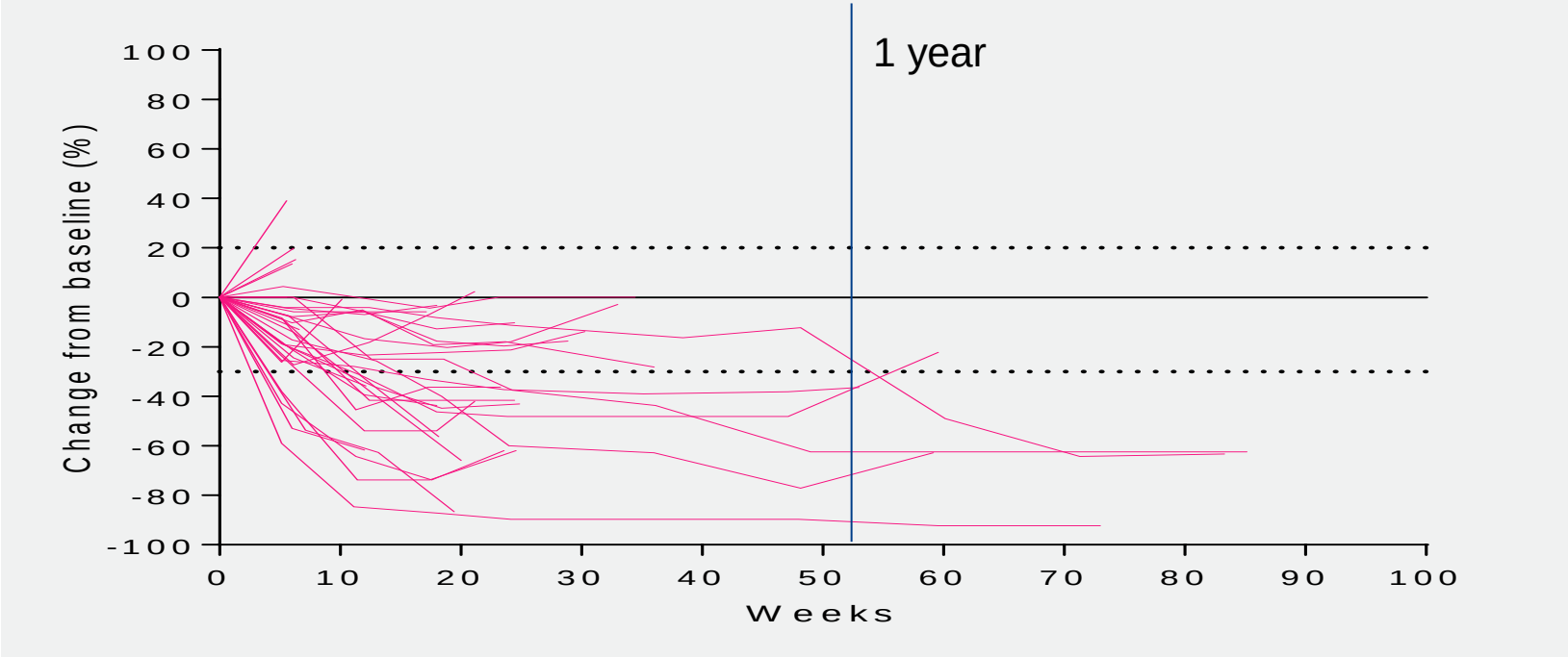
AEs	All grades (%)	Grade ≥3 (%)
AST increased	47 (19.5)	2 (0.8)
ALT increased	38 (15.8)	2 (0.8)
Blood bilirubin increased	6 (2.5)	1 (0.4)
Ejection fraction decreased	2 (0.8)	0 (0.0)
Electrocardiogram QT prolonged	12 (5.0)	1 (0.4)
Interstitial lung disease	8 (3.3)	2 (0.8)
Pneumonitis	16 (6.6)	4 (1.7)
Infusion-related reactions	4 (1.7)	0 (0.0)

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ILD, interstitial lung disease; LFT, liver function tests; LVEF, left ventricular ejection fraction.
Data cutoff for this analysis is April 18, 2018.

- Events of ILD/pneumonitis including 5 fatal cases were observed
- ALL ILD/pneumonitis cases are under evaluation of ILD adjudication committee

DS-8201: HER2-Low Breast Cancer

Tumor Shrinkage Over Time by Tumor Type: (5.4 or 6.4 mg/kg)



Includes subjects who had ≥1 postbaseline scan. Dotted lines denote 20% increase and 30% reduction in tumor size, respectively.
Data cutoff for this analysis is April 18, 2018.

- Response rate in HER2-low breast cancer increases over time
- Response continues and improves as treatment carries on
- Based on this data, HER2-low BC P3 study will start soon

Redefined HER2 Subtype

Classification by Commonly Used Terminology

All Patients of metastatic BC
n=288,550

Approx. 20%

HR-/ HER2 positive 6.8%	**HR+/HER2 positive 13.5%**
HR-/ HER2 negative 12.5%	**HR+/HER2 negative 67.2%**

Classification by DS terminology for Future Use

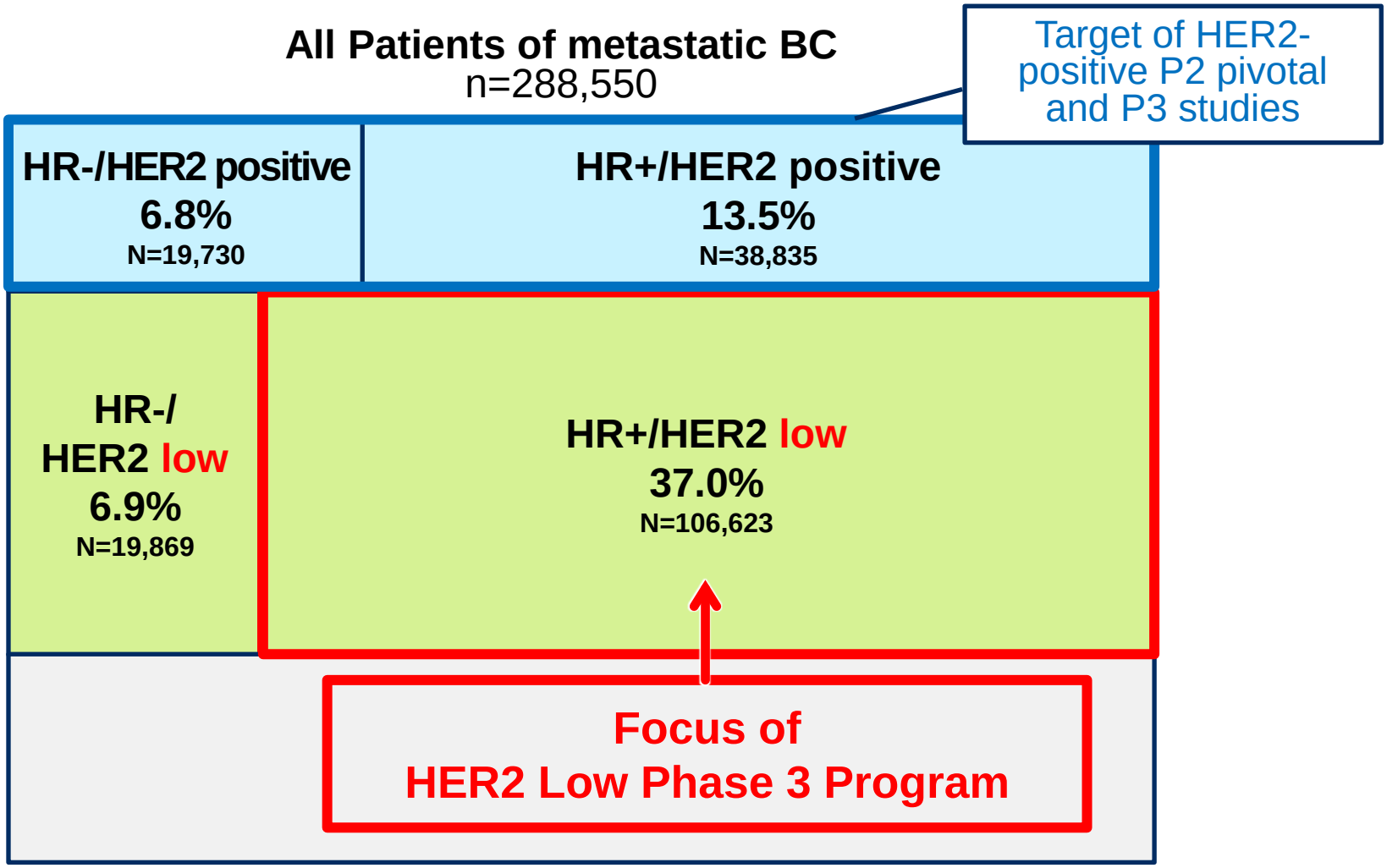
All Patients of metastatic BC
n=288,550

HR-/HER2 positive 6.8%	**HR+/HER2 positive 13.5%**
HR-/ HER2 low 6.9%	**HR+/HER2 low 37.0%**
HER2 negative 35.8%	

Approx. 44%

Source: Decision Resources , inclusive of US, EU5, and Japan (Breast Cancer, Last updated, December 2017, CAncerMPACT (2017))

DS-8201: Target of HER2-Low P3 Study



- Target population of HER2-low P3 study is HR+/HER2 low

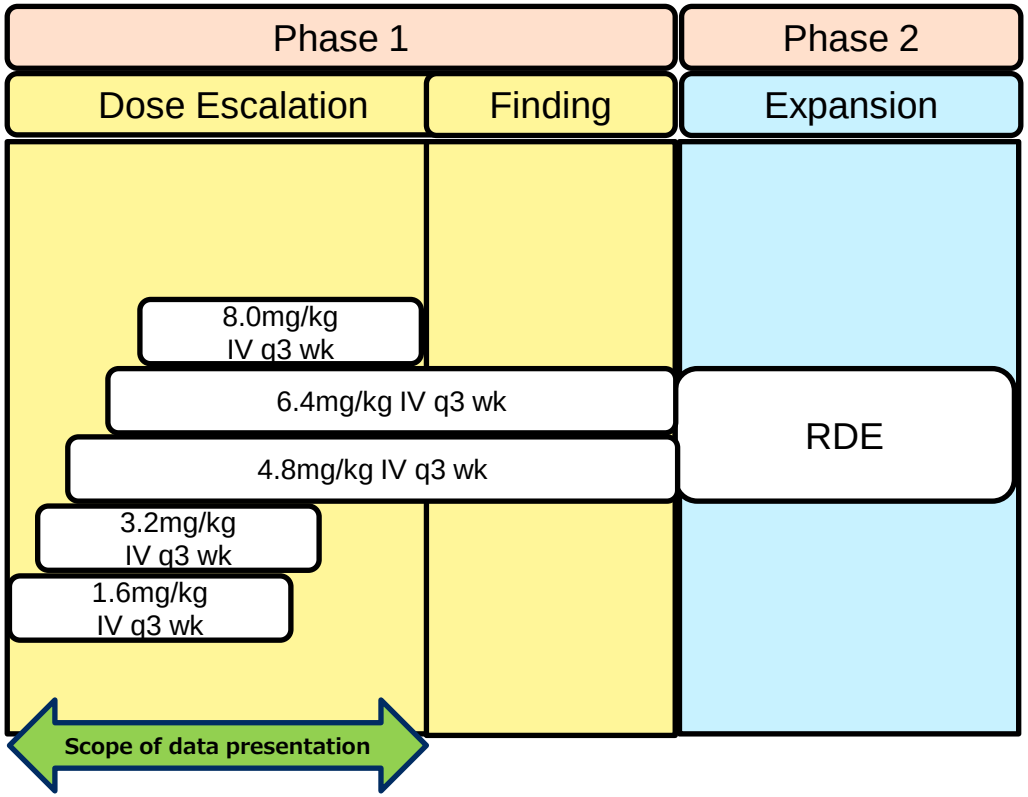
* Source: Decision Resources , inclusive of US, EU5, and Japan (Breast Cancer, Last updated, December 2017, CAncerMPACT (2017))

U3-1402: BC P1/2 Study Overview

ASCO 2018 Presentation

Daiichi-Sankyo

Study Design



Based on April 27, 2018 data cutoff.
RDE: recommended dose(s) for expansion

Demographics

	BC (N=34)
Age, median (range), y	55 (37-81)
ECOG PS, N(%)	
0	25 (74)
1	9 (26)
No. of Prior Treatment Regimens, N(%)	
0-2	2 (6)
≧3	32 (94)
Tumor Molecular Profiles, N(%)	
HER2 BC	3 (9)
Luminal BC	23 (68)
TNBC	7 (21)
Unknown	1 (3)
No. of Patients Receiving ≥ 1 Prior Cancer Regimen, N(%)	
HER2 therapy	7 (21)
HR therapy	23 (68)

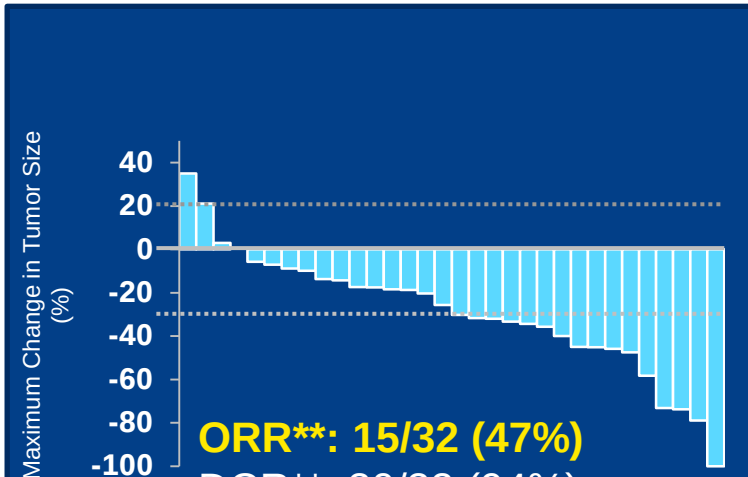
- Target of this study is HER3-positive (IHC3+/2+) advanced/ unresectable or metastatic breast cancer

U3-1402: BC P1/2 Study Efficacy

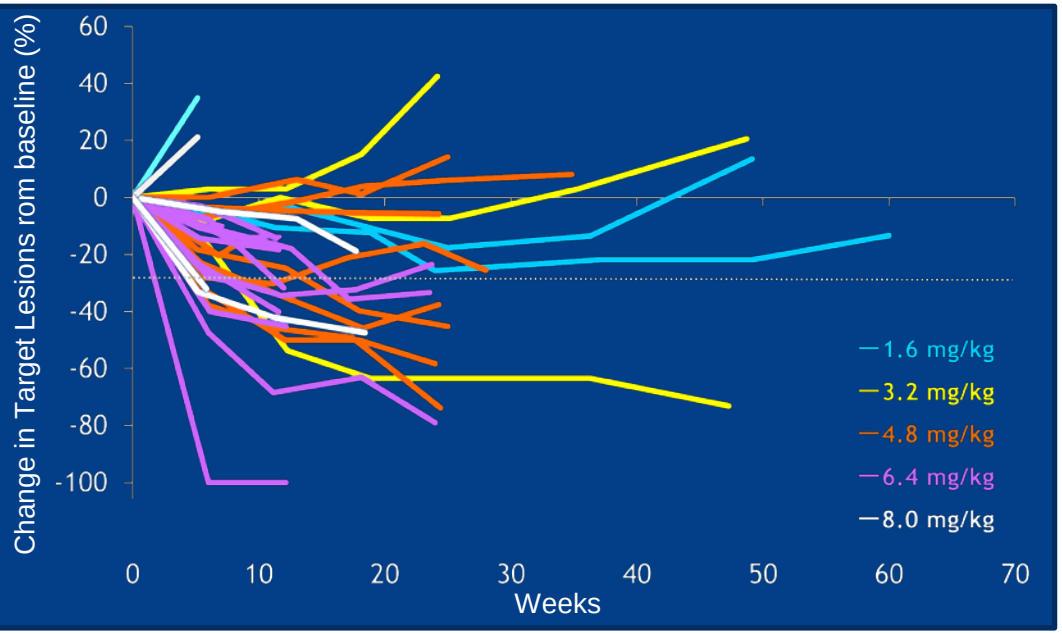
ASCO 2018 Presentation

Daiichi-Sankyo

Best Percentage Change in Sum of Diameters From Baseline in Target Lesions*



Percentage Change in Sum of Longest Diameters



*Analysis set: Efficacy evaluable patients with at least one scan. Baseline is defined as the last measurement taken before the first dose of study drug.
**Investigators assessment. For each patient, the best percent change from baseline in the sum of diameters for all target lesions is represented by a vertical bar.
DCR = disease control rate; ORR = objective response rate.
Based on April 27, 2018 data cutoff.

- U3-1402 data resembles that of early DS-8201 data
  - U3-1402 ASCO 2018 ORR：15/32（47%）
  - DS-8201 ESMO 2016 ORR：7/20（35%）
- Validates portability of ADC technology

U3-1402: BC P1/2 Study Safety

ASCO 2018 Presentation

Daiichi-Sankyo

Treatment-Emergent Blood and Liver related AE in ≥ 15% Patients, Dose Escalation Phase (Total N = 34)*

Preferred Term	All Grades (%)	Grade ≥ 3 (%)
Platelet count decreased/Thrombocytopenia	23 (68)	10 (29)
Neutrophil count decreased/Neutropenia	20 (59)	9 (27)
White blood cell count decreased	18 (53)	6 (18)
Anemia	13 (38)	4 (12)

Preferred Term	All Grades (%)	Grade ≥ 3 (%)
ALT increased	13 (38)	3 (9)
AST increased	13 (38)	3 (9)
Blood alkaline phosphatase increased	6 (18)	0

*Analysis set: Patients who received at least one dose of U3-1402. Percentage is calculated using the number of patients in the column heading as the denominator.
TEAE = treatment-emergent adverse event.
Based on April 27, 2018 data cutoff.

- DLTs consisted of the followings:
  - 4.8 mg/kg: one case of Gr.4 platelet count decreased
  - 6.4 mg/kg: one case of Gr.4 platelet count decreased
  - 8.0 mg/kg: one case of Gr.4 platelet count decreased, Gr.3 AST increased, Gr.3 ALT increased
    one case of Gr.3 ALT increased
- MTD has not been reached
- Serious AE's noted in 11 (32%) of treated patients
- Majority of TEAEs were Grades 1 and 2 and toxicities have so far been manageable

ADC Franchises: Next Data Point

Sep 2018: World Congress of Lung Cancer (WCLC)

DS-8201 P1 **NSCLC**

Abstract: early Sep

Oct 2018: European Society for Medical Oncology (ESMO)

DS-8201 P1 **CRC (plan)**

Poster abstract: Oct 9th, 00:05CEST
Oral abstract: Oct 19th, 12:00 CEST

Dec 2018: San Antonio Breast Cancer Symposium (SABCS)

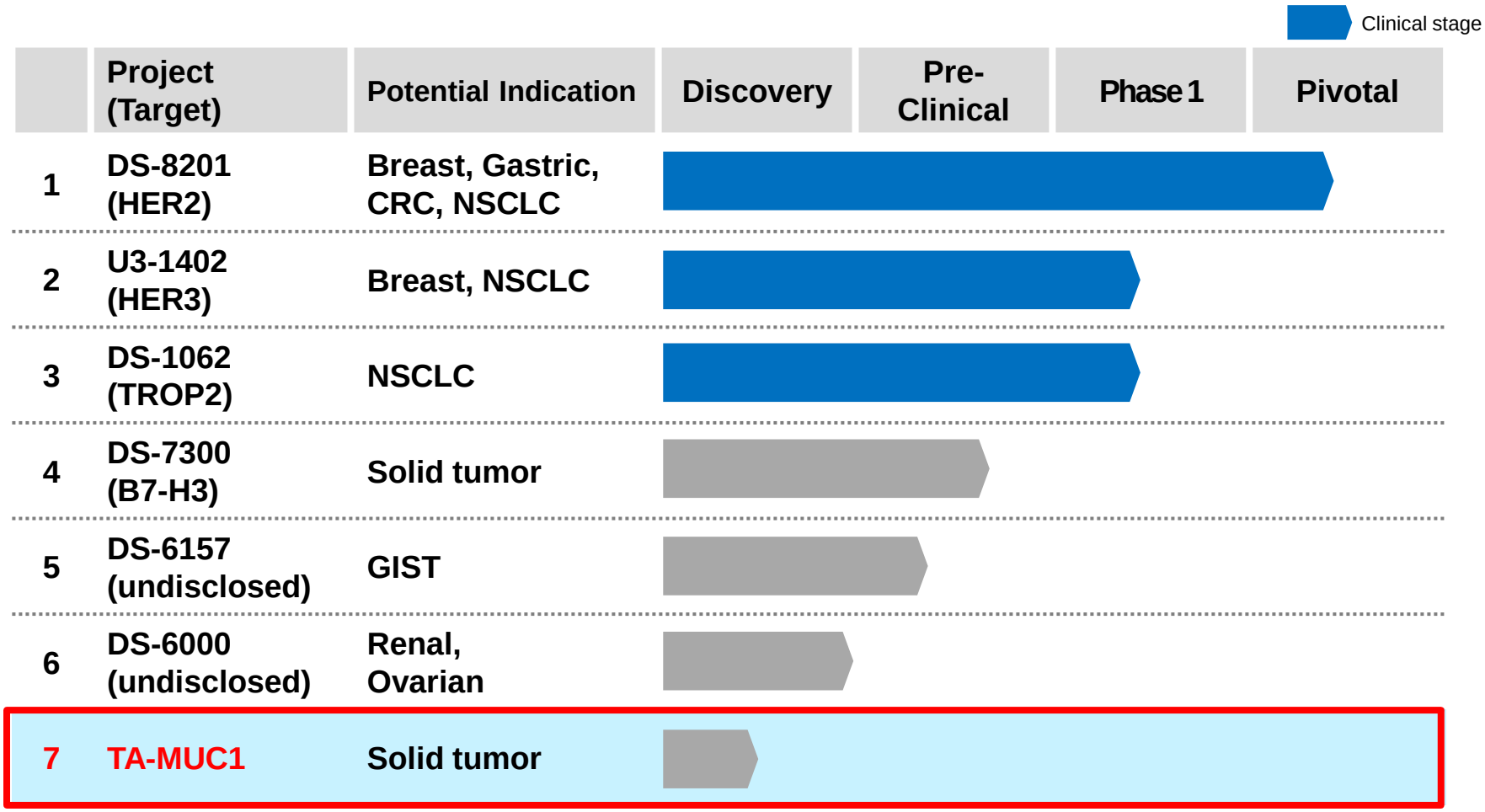
DS-8201 P1 **BC (plan)**

U3-1402 P1 **BC (plan)**

Abstract: early Sep

7th Project in ADC Franchise (with Glycotope)

ADC Franchise



CRC: colorectal cancer, GIST: gastrointestinal stromal tumor, NSCLC: non-small cell lung cancer

◆ Maximizing the potential of our proprietary ADC technology

Summary of ADC Franchise

DS-8201

- For HER2-positive BC, contemplating BLA in FY2019
  - Will not be confirmed before 4Q FY2018
- Interim result of HER2-low BC was similar to that of HER2-positive BC
  - ORR: HER2 low 50.0%, HER2 positive 54.5%
  - Start HER2-low / HR+ BC study soon

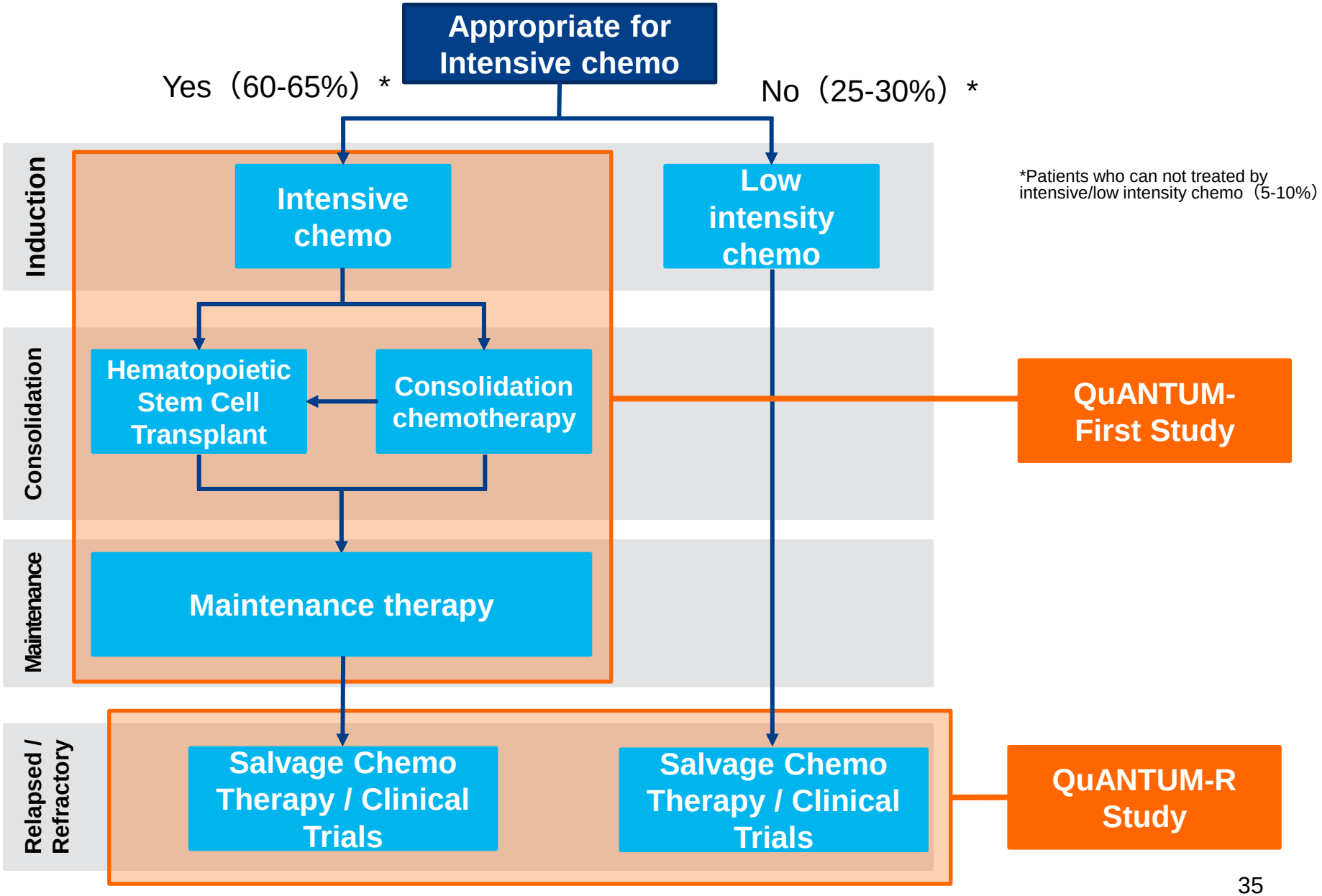
U3-1402

- First U3-1402 data release approximates that of DS-8201 at ESMO 2016
  - U3-1402 ORR 47%（15/32) ASCO 2018
  - DS-8201 ORR 35%（7/20） ESMO 2016
- Validates portability of ADC technology

Other ADC

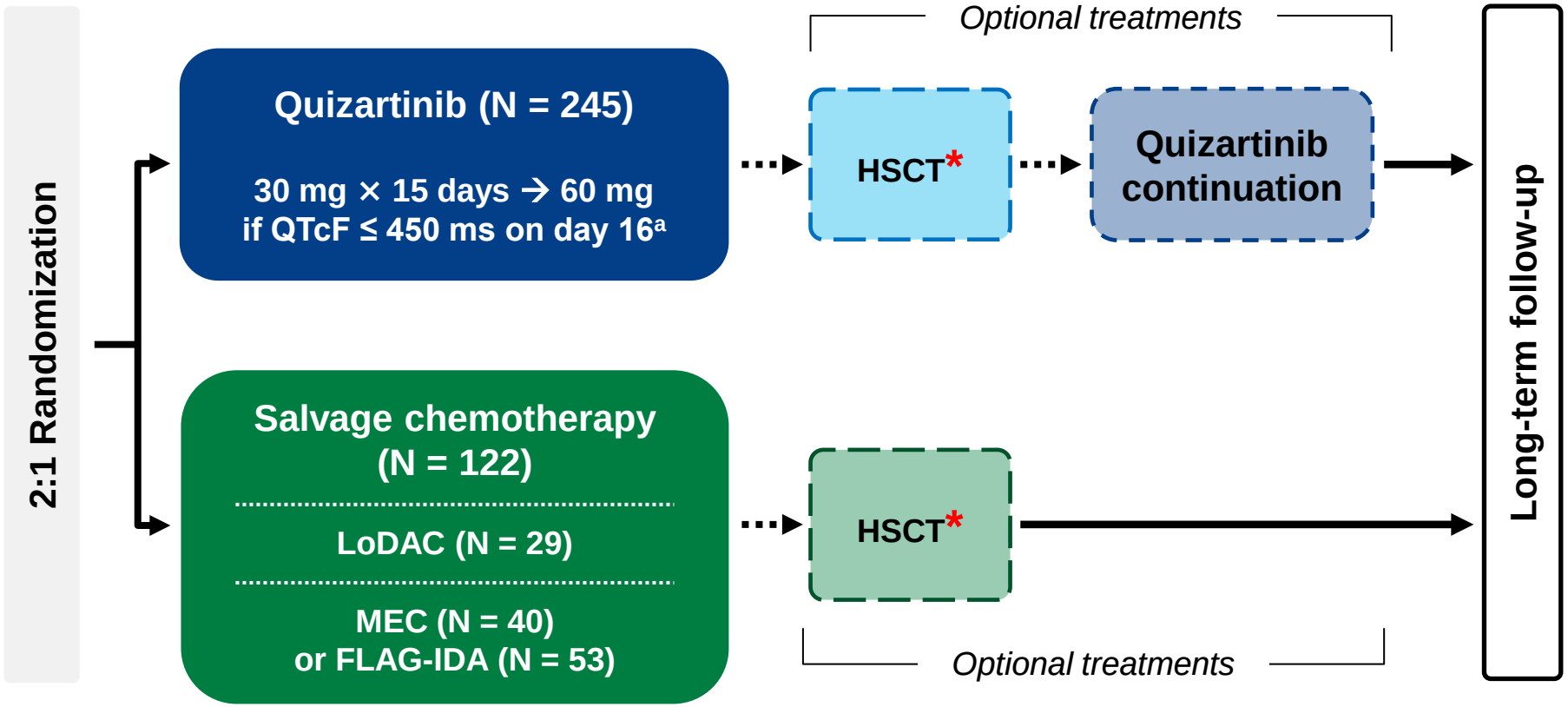
- With license agreement with Glycotope, now ADC franchise has 7 projects

AML Quizartinib: AML Treatment and QuANTUM Studies



*Patients who can not treated by intensive/low intensity chemo（5-10%）

Quizartinib: QuANTUM-R Study Design



Primary endpoint: **OS (ITT population)**
Secondary endpoint: **event-free survival (ITT population)**
Select exploratory endpoints: **transplant rate, etc.**

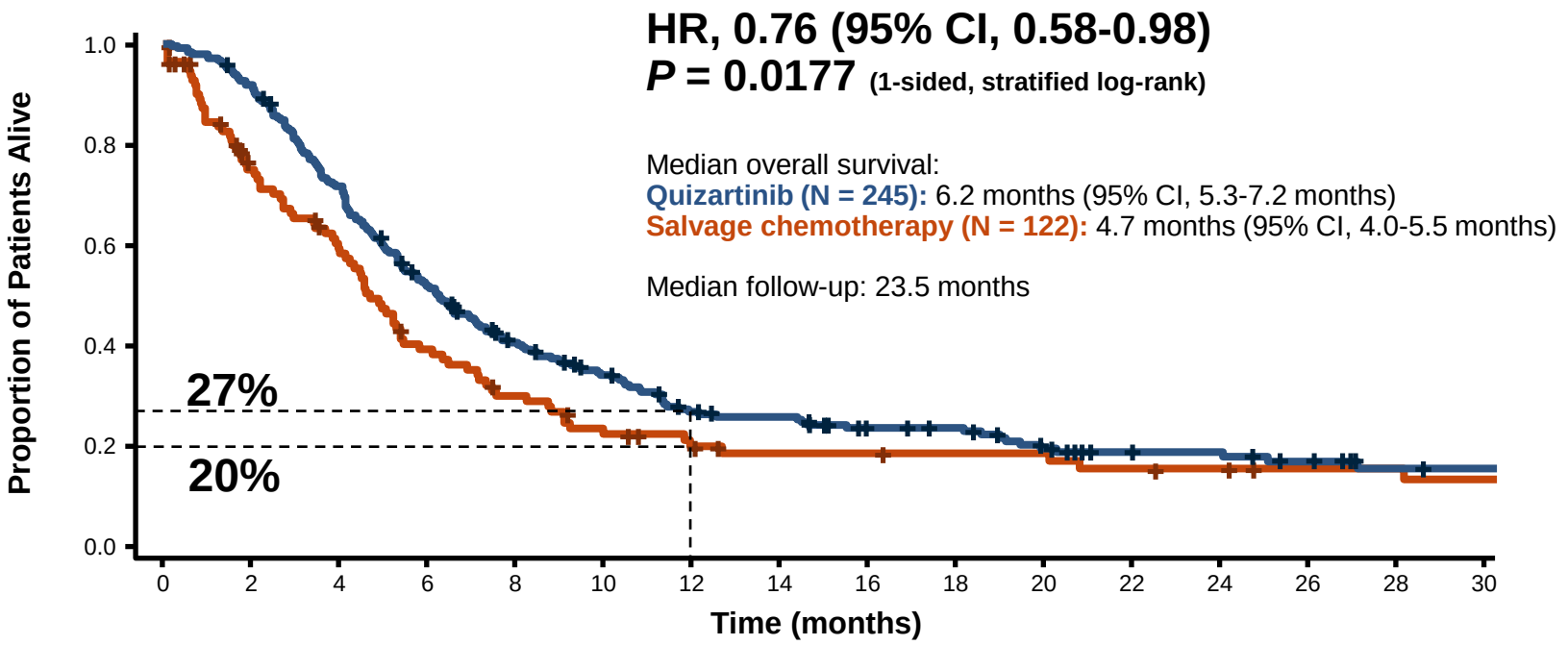
*Moving to HSCT is important factor for AML treatment

[a]20 mg × 15 days → 30 mg if concomitantly taking strong CYP3A4 inhibitors.

Quizartinib: QuANTUM-R Study Efficacy

EHA 2018 Presentation

Daiichi-Sankyo



- Primary endpoint: significantly prolonged OS
  - Quizartinib had 24% risk reduction of death compared to salvage chemotherapy
  - Median OS; salvage chemo 4.7M, Quizartinib 6.2M
  - Estimated survival probability at 1 year: 20% for salvage chemotherapy and 27% for quizartinib

AML Quizartinib: QuANTUM-R Study Efficacy

EHA 2018 Presentation

Daiichi-Sankyo

Characteristic	Percentage (95% CI)	
	Quizartinib N = 245	Salvage Chemotherapy N = 122
Best response		
CRc	48 (42-55)	27 (19-36)
CR	4 (2-7)	1 (0-5)
CRp	4 (2-7)	0 (0-3)
CRi	40 (34-47)	26 (19-35)
PR	21 (16-27)	3 (1-8)
ORR (CRc + PR)	69 (63-75)	30 (22-39)
No response	25 (20-31)	37 (28-46)
Nonevaluable	5 (3-9)	33 (25-42)
Transplant rate , %	32	12

CRc：composite complete response, CR: complete remission, CRp: complete remission with incomplete platelet recovery, CRi: complete remission with incomplete hematologic recovery),

- Transplant rate was substantially higher compared to salvage chemotherapy

Quizartinib: QuANTUM-R Study QT Prolongation

EHA 2018 Presentation

Daiichi-Sankyo

QTcF Parameter	Percentage	
	Quizartinib (N = 241)	Salvage Chemotherapy (N = 94)
Maximum QTcF interval[a]		
Grade 1 (> 450 ms to ≤ 480 ms)	35	6
Grade 2 (> 480 ms to ≤ 500 ms)	12	0
Grade 3 (> 500 ms)	3	0
Maximum QTcF change[a]		
> 60 ms	12	1

[a]Based on central readings of triplicate electrocardiograms.

- 2 patients discontinued quizartinib treatment due to QTcF prolongation
- There were no occurrences of grade 4 QTcF prolongation
- Quizartinib was well-tolerated considering other adverse events

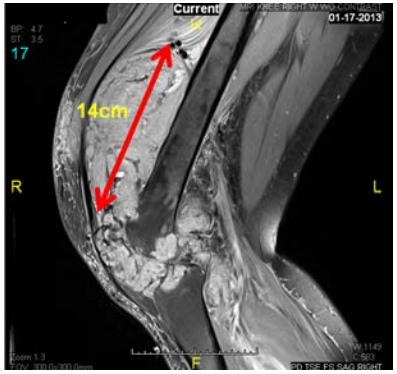
Commitment to global submission 2H FY2018

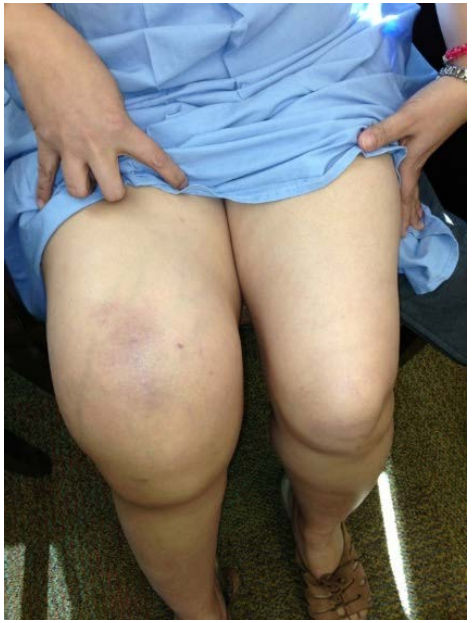
Pexidartinib: TGCT Overview

ASCO 2018 Presentation

- Tenosynovial Giant Cell Tumor (TGCT) is a rare, locally aggressive, inflammatory, nonmalignant neoplasm[1,2]
  - Occurs mainly in the synovium of joints, bursae, or tendon sheaths[1,2]
  - Clinical features include swelling, pain, limited range of motion, and stiffness[1]
- Surgical resection is standard primary treatment[1]
- Global prevalence 38,000
  - US prevalence 17,000
- No currently approved systemic therapies[3-5]

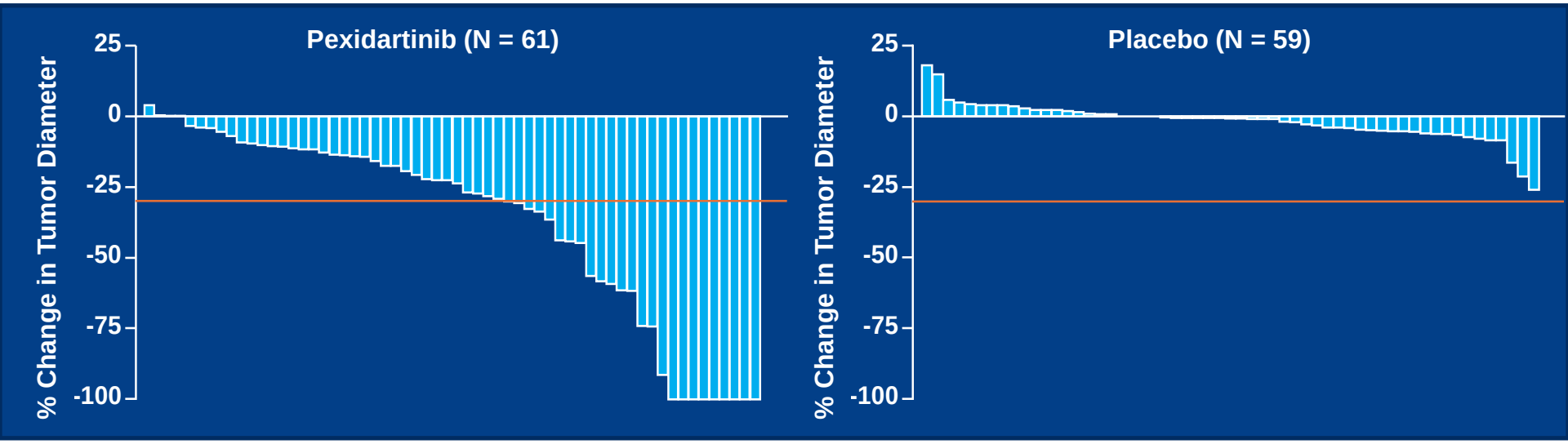
1. Staals et al. *Eur J Cancer.* 2016;63:34-40.
2. de Saint Aubain Somerhausen and van de Rijn. *IARC Press.* 2013;100-103.
3. Tap et al. *N Engl J Med.* 2015;351:1502-1512.
4. Cassier et al. *Cancer*. 2012;118:1649-1655.
5. Gelderblom et al. *Lancet Oncol*. 2018;19:639-648.





Pexidartinib: ENLIVEN Study Efficacy

ASCO 2018 Presentation



Treatment, N (%)	Complete	Partial	Stable Disease	Progressive Disease	Not Evaluable	Overall Response Rate [95% CI]
Pexidartinib N = 61	9 (15)	15 (25)	24 (39)	1 (2)	12 (20)	24 (39) [28.1, 51.9] P < 0.0001
Placebo N = 59	0	0	46 (78)	1 (2)	12 (20)	0 [0, 6.1]

- Primary endpoint overall response rate was 39% in Pexidartinib and 0% in placebo
- Pexidartinib potential to be first-in-class drug in patients with advanced, symptomatic TGCT when surgery is not recommended

Pexidartinib: Extreme Example of Effective Treatment

ASCO 2018 Presentation

- 56 years old female
- Diagnosed TGCT in 1988, followed by multiple surgeries
- Started Pexidartinib in Sep 2016 and still on-going
- Baseline pain: 5.6, decreased to 0.6 at week 25*

Oct 2016 | Nov 2016 | June 2017 | Sep 2017 | May 2018

*Pain score evaluated with the scale of 0 (normal) – 10

Pexidartinib: ENLIVEN Study Safety

ASCO 2018 Presentation

Liver Function, N (%)	Pexidartinib Part 1 N = 61	Placebo Part 1 N = 59	Pexidartinib Crossover[*1] 800 mg/d N = 30
AST or ALT ≥ 3 × ULN	20 (33)	0	4 (13)
TBili ≥ 2 × ULN	3 (5)	0	0
TBili ≥ 2 × ULN and AST or ALT ≥ 3 × ULN	3[*2] (5)	0	0

[*1] Subjects were allowed to start pexidartinib treatment after completion of placebo.
[*2] All were serious AEs with ALP ≥ 2.5 x ULN.

- 8 patients discontinued pexidartinib due to hepatic AEs
  - 4 cases were serious nonfatal AEs with increased bilirubin, 1 lasting ~7 months
- All serious hepatic events emerged during the first 2 months of pexidartinib treatment

- Serious liver toxicity also observed non-TGCT development program (N = 637)
  - 1 case required liver transplant and 1 case associated with death

Commitment to submit US NDA in 2H FY2018

AML

BTS

Summary of Quizartinib and Pexidartinib

Daiichi-Sankyo

Quizartinib
monotherapy

- Improved overall survival in relapse/refractory AML FLT3-ITD compared to salvage chemotherapy
- Commitment to global submission 2H FY2018
- First line study is progressing well

Pexidartinib

- First-in-class for severe TGCT where surgery is not recommended
- Commitment to submit US NDA in 2H FY2018

DS R&D Day 2018

- Date: December 12, 2018 (wed)
  15:00 – 17:00 (plan)

- Location: Daiichi Sankyo Headquarters, Tokyo

Appendix

- R&D Milestone Events
- Major R&D Pipeline
- Out-licensing Projects
- Abbreviations

FY2018 R&D Milestone Events

As of Jul 2018

Daiichi-Sankyo

Project	Study / Indication	FY2018				FY2019
		Q1	Q2	Q3	Q4	Q1
Pexidartinib	P3: TGCT (US)			Submission		
Quizartinib	P3: QuANTUM-R AML Relapsed/Refractory	**TLR**		**Submission**		
DS-3032	P1: AML with Quizartinib	→	Study initiation			
	P1: AML with Azacitidine	→	Study initiation			
DS-8201	P3: HER2 positive mBC Post T-DM1 vs Phys Choice		Study initiation			
	P3: HER2 positive mBC vs T-DM1		Study initiation			
	P3: HER2 low mBC			Study initiation		
	P2: NSCLC	**Study initiation**				
	P1b: mBC/Bladder with nivolumab	→	Study initiation			
	P1b: mBC/NSCLC with IO			→	Study initiation	
	P1b: mBC/GC with IO			→	→	Study initiation
U3-1402	P1/2: mBC	**P2 Part Study initiation**				
DS-1205	P1: EGFRm NSCLC with osimertinib	→	Study initiation			
KTE-C19	P2: BCL (JP)			Study initiation		
Mirogabalin	P3: DPNP/PHN (JP)				Approval	
Esaxerenone	P3: Essential hypertension (JP)				Approval	
Laninamivir	P3: Anti-influenza (nebulizer formulation) (JP)		**Submission**			
DS-5141	P1/2: DMD (JP)	**TLR**	**Extension study initiation**			

AML: acute myeloid leukemia, BCL: B-cell lymphoma, CRC: colorectal cancer, DMD: Duchenne muscular dystrophy, DPNP: diabetic peripheral neuropathic pain, GBM: glioblastoma multiforme, mBC: metastatic breast cancer, mGC: metastatic gastric cancer, NSCLC: non-small cell lung cancer , PHN: Postherpetic neuralgia, TGCT: tenosynovial giant cell tumor

Red: New or update from FY2017 Q4 Blue: achieved

TLR: Top Line Results

Major R&D Pipeline (Oncology)

As of Jul 2018

Daiichi-Sankyo

	Generic Name/Project Code Number (Class)	Target indication	Region	Stage
				Phase 1 / Phase 2 / Phase 3 / NDA/BLA
ADC Franchise	DS-8201 (Anti-HER2 ADC)	mBC (HER2 positive post T-DM1)	JP/US/EU/Asia	
		mBC (HER2 positive vs. T-DM1)	JP/US/EU/Asia	
		mGC (HER2 positive post trastuzumab)	JP/Asia	
		CRC	JP/US/EU	
		NSCLC	JP/US/EU	
		mBC and bladder cancer (w nivolumab)	US/EU	
	U3-1402 (Anti-HER3 ADC)	mBC	JP/US	
		NSCLC	US	
	DS-1062 (Anti-TROP-2 ADC)	NSCLC	JP/US	
AML Franchise	Quizartinib/AC220 (FLT3 inhibitor)	AML (Relapsed/Refractory)	JP/US/EU/Asia	
		AML (1st line)	JP/US/EU/Asia	
	DS-3032 (MDM2 inhibitor)	Solid tumor	JP/US	
		AML	US	
	DS-3201 (EZH1/2 inhibitor)	ATL/L, PTCL	JP	
		AML, ALL	US	
	PLX51107 (BRD4 inhibitor)	AML, solid tumor	US	
	DS-1001 (IDH1m inhibitor)	Glioma	JP	
	PLX2853 (BRD4 inhibitor)	AML, solid tumor	US	
Breakthrough Science	Pexidartinib (CSF-1/KIT/FLT3 inhibitor)	TGCT	US/EU	
	DS-1647 (G47Δ virus)	Glioblastoma	JP	
	KTE-C19 (Anti-CD19 CAR-T cells)	BCL	JP	
	DS-1205 (AXL inhibitor)	NSCLC (w osimertinib(US), gefitinib (JP))	US/JP	

ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, BCL: B-cell lymphoma, CRC: colorectal cancer, mBC: metastatic breast cancer, mGC: metastatic gastric cancer, NSCLC: non-small cell lung cancer , PTCL: peripheral T-cell lymphoma, TGCT: tenosynovial giant cell tumor

Major R&D Pipeline (SM/Vaccine) As of Jul 2018

Daiichi-Sankyo

	Generic Name/Project Code Number (Class)	Target Indication	Region	Stage
				Phase 1 / Phase 2 / Phase 3 / NDA
Specialty medicine (SM)	Edoxaban/DU-176b (Fxa inhibitor)	AF	ASCA	
		VTE	ASCA	
		Very elderly patients AF	JP	
	Prasugrel/CS-747 (anti-platelet agent)	Ischemic stroke	JP	
	Esaxerenone/CS-3150 (MR antagonist)	Hypertension	JP	
		Diabetic nephropathy	JP	
	DS-1040 (TAFIa inhibitor)	Acute ischemic stroke, Acute pulmonary embolism	JP/US/EU	
	DS-2330 (hyperphosphatemia treatment)	Hyperphosphatemia in chronic kidney disease	-	
	Mirogabalin/DS-5565 (α2δ ligand)	DPNP, PHN	JP	
	Laninamivir/CS-8958 (neuraminidase inhibitor)	Influenza	JP	
	DS-5141 (ENA oligonucleotide)	DMD	JP	
	DS-1211(TNAP inhibitor)	Prevention of ectopic calcification diseases	US	
Vaccine	VN-0107/MEDI3250 (live attenuated influenza vaccine)	Prevention of seasonal influenza	JP	
	VN-0105 (DPT-IPV/Hib)	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib	JP	
	VN-100 (intradermal seasonal influenza vaccine)	Prevention of seasonal influenza	JP	
	VN-0102/JVC-001 (Measles-Mumps-Rubella vaccine)	Prevention of Measles, Mumps and Rubella	JP	

AF: atrial fibrillation, DMD: Duchenne muscular dystrophy, DPNP: diabetic peripheral neuropathic pain, PHN: Postherpetic neuralgia, VTE: venous thromboembolism

Out-licensing Projects

As of Jul 2018

Daiichi-Sankyo

	Pre-clinical	Phase1	Phase 2
Oncology		■ **DS-6051** （NTRK/ROS1 inhibitor）	
Specialty Medicine	■ **DS-1515** （Inflammatory disease/PI3Kδ inhibitor） ■ **DS-1039** （Cystic fibrosis / new MOA （CFTR independent fluid secretion）） ■ **DS-7411** （Hemophilia A and B / antibody）	■ **DS-2969** （Clostridium difficile infection / GyrB inhibitor） ■ **DS-1093** （inflammatory bowel disease (IBD)/ HIF-PH inhibitor） ■ **DS-7080** **(AMD / Angiogenesis inhibitor)**	■ **Laninamivir** **(CS-8958/Anti-influenza/ Out-licensing with Vaxart Inc)**

Red: New or update

Abbreviations

Abbreviation	
BTD	Breakthrough therapy designation
CR	Complete response
DCR	Disease control rate
DLT	Dose limiting toxicity
DOR	Duration of response
EGFR	Epidermal growth factor receptor
MTD	Maximum tolerated dose
NSCLC	Non-small-cell lung cancer
ORR	Overall response rate Objective response rate
OS	Overall survival
PD	Progress disease
PFS	Progression-free survival
PR	Partial response

Contact address regarding this material

Daiichi Sankyo Co., Ltd.

Corporate Communications Department

TEL: +81-3-6225-1126

Email: DaiichiSankyoIR@daiichisankyo.co.jp