Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Top Management Presentation

Financial Results of FY2018 Q2 (April 1 – September 30, 2018)

DAIICHI SANKYO CO., LTD

Sunao Manabe
President and COO

October 31, 2018

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Agenda

- FY2018 Q2 Financial Results
- FY2018 Consolidated Forecast
- Business Update
- Revised Target for 5-Year Business Plan
- R&D Update

FY2018 Q2 Financial Results

Overview of FY2018 Q2 Results

(Bn JPY)

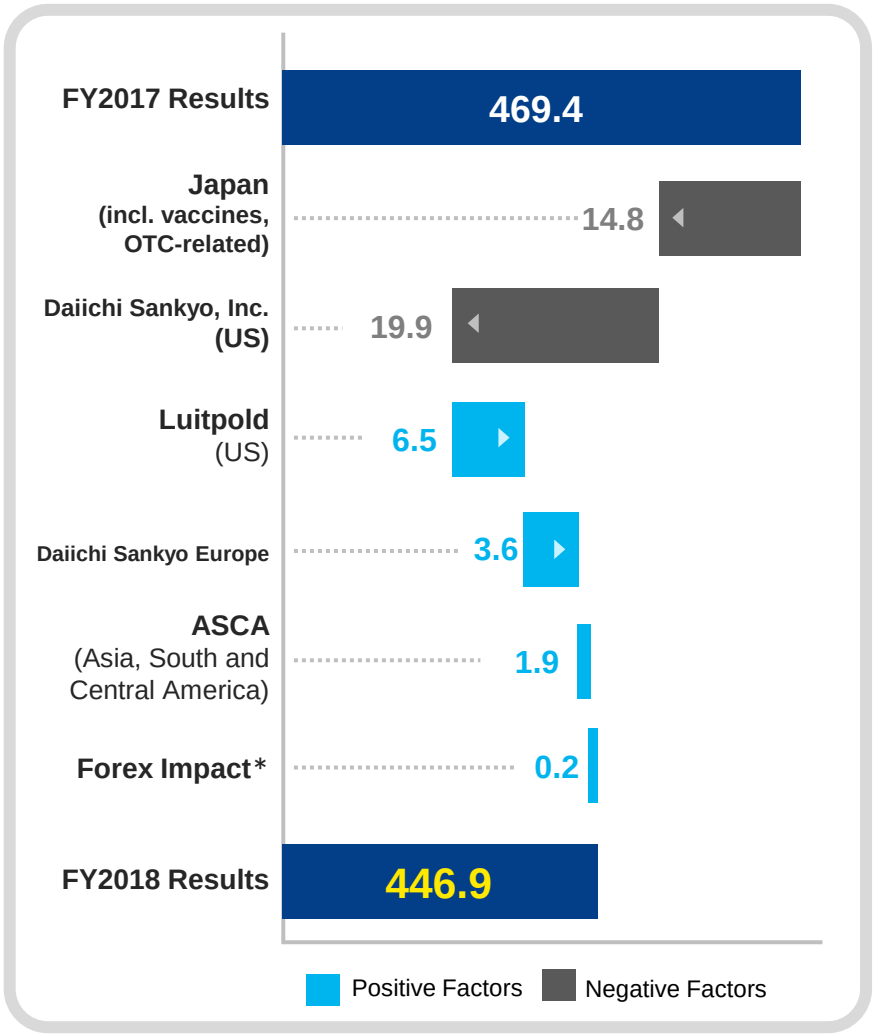
	FY2017 Q2 YTD Results	FY2018 Q2 YTD Results	YoY
Revenue	469.4	446.9	-4.8% -22.5
Cost of Sales	157.1	166.6	+9.6
SG&A Expenses	140.0	128.6	-11.4
R&D Expenses	123.6	93.7	-29.9
Operating Profit	48.8	58.0	+18.9% +9.2
Profit before Tax	51.2	58.6	+7.4
Profit attributable to owners of the Company	34.3	44.0	+28.4% +9.7

Currency Rate	USD/JPY	111.07	110.27	-0.80
	EUR/JPY	126.29	129.84	+3.55

Revenue

Decreased by 22.5 Bn JPY (Decreased by 22.7 Bn JPY excl. forex impact)

(Bn JPY)



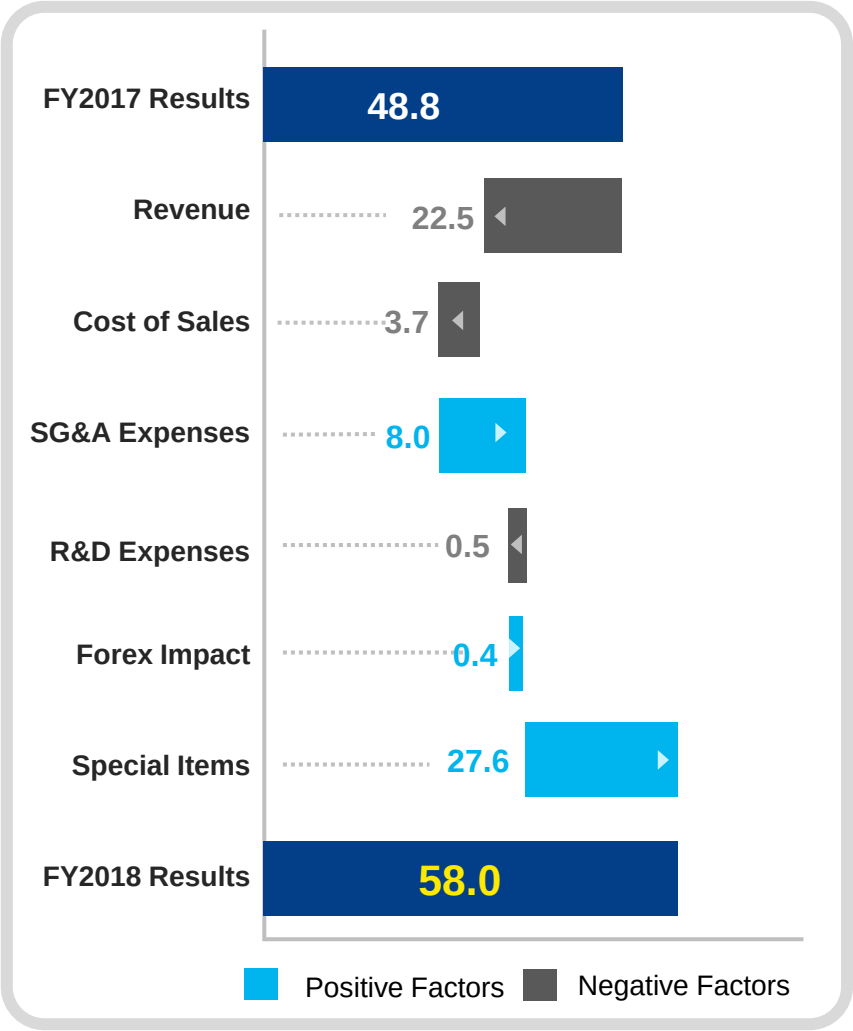
Positive Factors		Negative Factors	
Japan			
Lixiana	+10.5	Olmetec	-24.0
Pralia	+2.1	Nexium	-6.1
		Loxonin	-3.2
		*Incl. impact of price revision in Japan	
Daiichi Sankyo Espha (GE)	+9.2	Daiichi Sankyo Healthcare	-1.0
Olmesartan AG, Rosuvastatin AG etc.		*Incl. impact of change in accounting treatment	
Daiichi Sankyo, Inc.			
		Welchol	-11.0
		Effient	-5.2
		Olmesartan	-4.4
Luitpold			
Injectafer	+6.1	GE injectables	-2.6
Venofer	+1.9		
Daiichi Sankyo Europe			
Lixiana	+9.2	Olmesartan	-3.9

* Forex impact USD: -0.6, EUR : +1.2, ASCA: -0.4

Operating Profit

Increased by 9.2 Bn JPY

(Decreased by 18.9 Bn JPY excl. forex impact and special items)



(Bn JPY)

Revenue ····· -22.5
incl. forex impact of +0.2

Cost of Sales ····· +3.7 (Cost increased)
Product mix due to impact of olmesartan LOE

SG&A Expenses ····· -8.0 (Cost decreased)
Effect of cost reductions in US,
impact of change in accounting treatment etc.

Forex Impact ····· -0.4 (Cost decreased)
Cost of Sales ····· -0.2
SG&A Expenses ····· +0.0
R&D Expenses ····· -0.2

Special Items ····· -27.6 (Cost decreased)
*See next slide for details

Special Items

(Bn JPY)

	FY2017 Q2 YTD Results	FY2018 Q2 YTD Results	YoY
Cost of Sales	Gain on sales of fixed assets -6.1		+6.1
SG&A Expenses		Gain on sales of fixed assets -3.5	-3.5
R&D Expenses	Impairment loss (Intangible) 30.2		-30.2
Total	24.1	-3.5	-27.6

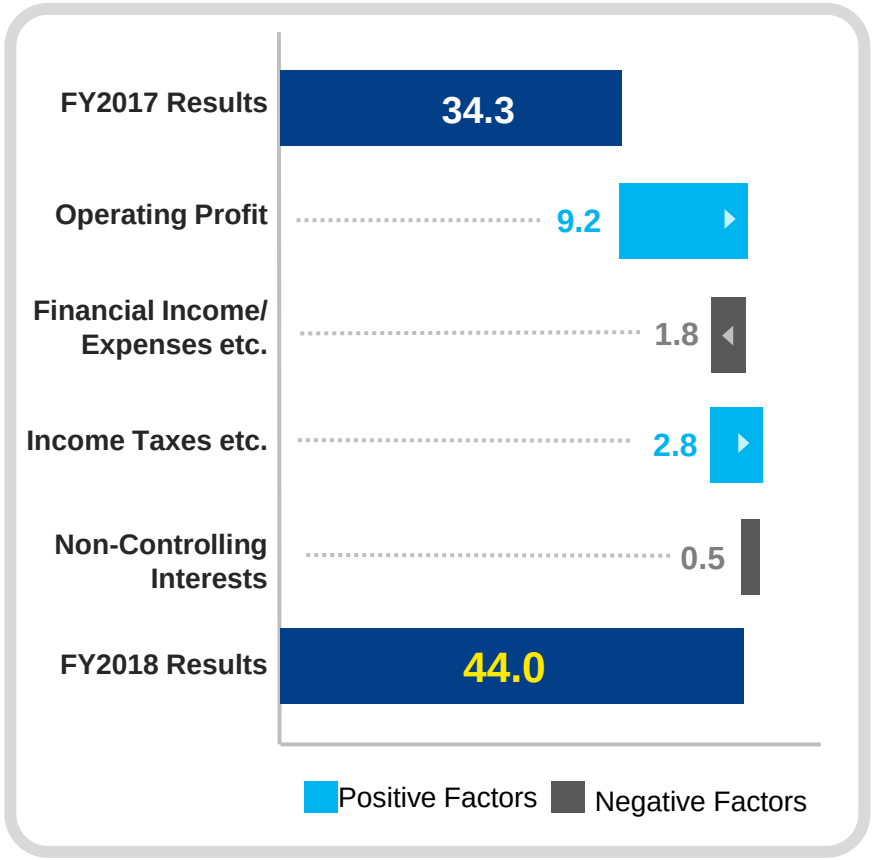
- : Cost decreased items

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".

Profit Attributable to Owners of the Company

Increased by 9.7 Bn JPY



(Bn JPY)

Financial Income/ Expenses etc. ····· +1.8 (Cost increased)

Deterioration of forex gains/ losses

Income Taxes etc. ····· -2.8 (Cost decreased)

Impact of the tax rate reduction in US etc.

	FY2017	FY2018	YoY
Profit before Tax	51.2	58.6	+7.4
Income Taxes etc.	17.4	14.6	-2.8
Tax rate	34.1%	24.9%	-9.2%

Non-Controlling Interests ····· +0.5 (Cost increased)

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2017 Q2 YTD Results	FY2018 Q2 YTD Results	YoY	vs. Forecast* (%)
Japan	**257.6**	**243.7**	**-13.9**	**47.5%**
Daiichi Sankyo Healthcare	**35.8**	**34.8**	**-1.0**	**50.4%**
Daiichi Sankyo Inc.	**42.0**	**22.0**	**-20.1**	**70.8%**
Olmesartan	10.3	5.8	-4.5	64.8%
Welchol	19.7	8.7	-11.0	86.8%
Effient	8.0	2.7	-5.3	-
Savaysa	1.0	1.1	+0.1	54.3%
Movantik	2.5	2.2	-0.4	-
Luitpold	**52.4**	**58.4**	**+6.1**	**51.7%**
Venofer	14.7	16.6	+1.8	57.1%
Injectafer	16.1	22.0	+5.9	53.8%
GE injectables	19.7	17.0	-2.7	-
Daiichi Sankyo Europe	**38.2**	**43.0**	**+4.8**	**50.6%**
Olmesartan	18.0	14.4	-3.5	62.7%
Efient	3.9	3.3	-0.6	46.6%
Lixiana	11.0	20.8	+9.8	46.2%
ASCA (Asia, South and Central America)	**38.6**	**40.1**	**+1.5**	**44.6%**

Currency Rate	USD/JPY	111.07	110.27	-0.80
	EUR/JPY	126.29	129.84	+3.55

* Calculated based on new forecast updated in Oct.

Revenue: Major Products in Japan

(Bn JPY)

		FY2017 Q2 YTD Results	FY2018 Q2 YTD Results	YoY	vs. Forecast* (%)
Nexium	ulcer treatment	44.7	38.6	-6.1	50.8%
Lixiana	anticoagulant	19.7	30.1	+10.5	50.2%
Memary	Alzheimer's disease treatment	24.5	25.2	+0.7	49.4%
Loxonin	anti-inflammatory analgesic	18.9	15.6	-3.2	50.4%
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	10.9	13.0	+2.1	48.1%
Tenelia	type 2 diabetes mellitus treatment	13.2	12.6	-0.6	46.8%
Inavir	anti-influenza treatment	1.1	0.1	-1.0	0.3%
Olmetec	antihypertensive agent	31.9	7.9	-24.0	56.1%
Ranmark	treatment for bone complications caused by bone metastases from tumors	7.6	8.1	+0.5	50.6%
Efient	antiplatelet agent	6.4	7.0	+0.6	46.5%
Rezaltas	antihypertensive agent	8.5	7.8	-0.8	55.6%
Urief	treatment for dysuria	5.6	5.2	-0.4	52.4%
Omnipaque	contrast medium	7.1	6.2	-0.9	51.8%

* Calculated based on new forecast updated in Oct.

FY2018 Consolidated Forecast

FY2018 Consolidated Forecast

(Bn JPY)

	FY2018 Forecast (as of Apr.)	FY2018 Forecast (as of Oct.)	vs. Forecast (as of Apr.)
Revenue	**910.0**	**910.0**	**-**
Cost of Sales	**330.0**	**330.0**	**-**
SG&A Expenses	**292.0**	**287.0**	**-5.0**
R&D Expenses	**210.0**	**215.0**	**+5.0**
Operating Profit	**78.0**	**78.0**	**-**
Profit before Tax	**78.0**	**78.0**	**-**
Profit attributable to owners of the Company	**55.0**	**55.0**	**-**

Major factors

- **Japan** +15.0
  (incl. Lixiana +6.0, gain on transfer of long-listed products)
- **Daiichi Sankyo Healthcare** -5.0
  (incl. impact of change in accounting treatment)
- **Daiichi Sankyo Inc.** -13.0
  (incl. Welchol -15.0)
- **Luitpold** +3.0

Major factors

- Decreased by impact of change in accounting treatment

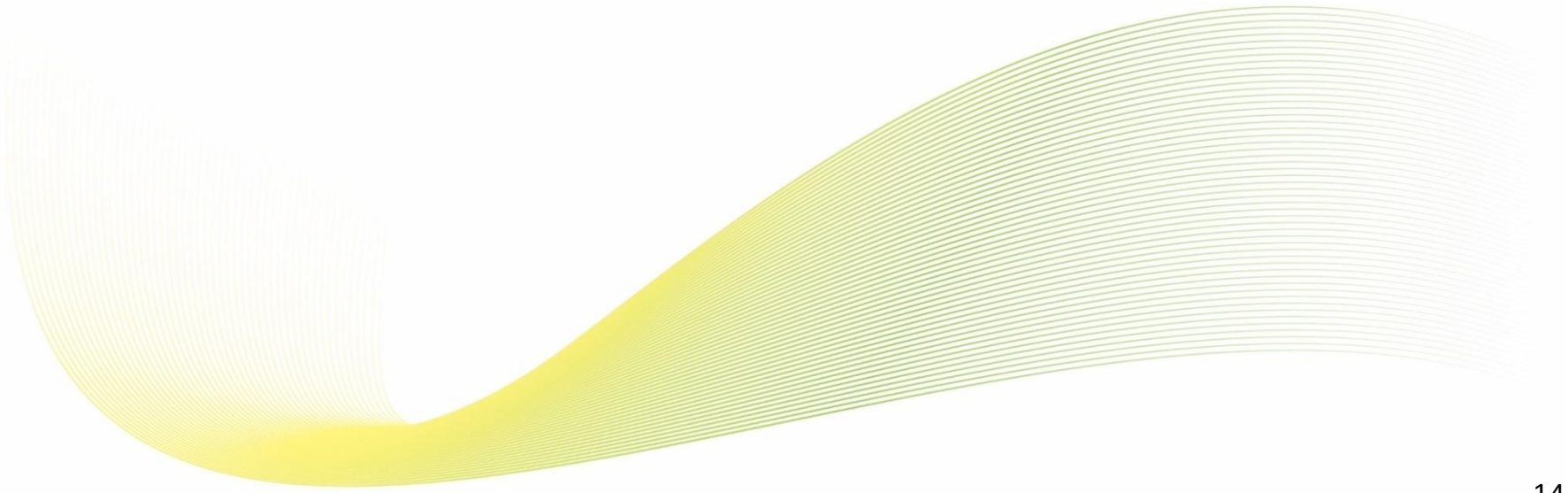
Major factors

- Increased by accelerated R&D

Currency Rate	**USD/JPY**	**110.00**	**110.13**
	EUR/JPY	**130.00**	**129.92**

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

Business Update



Lixiana: Growth in Japan

Sales

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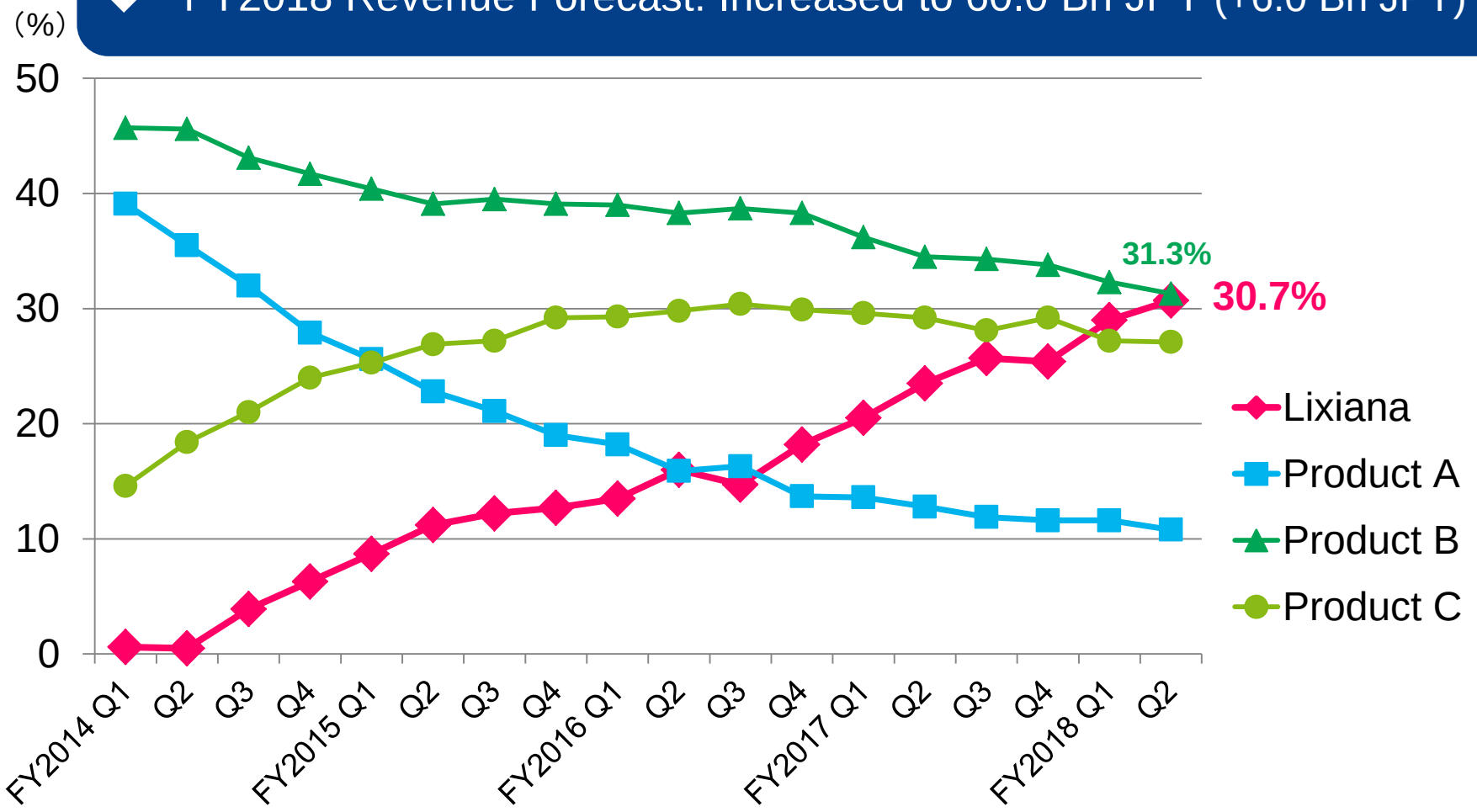
- As of FY2018 Q2, Lixiana closed in on No.1 sales share
- FY2018 Revenue Forecast: Increased to 60.0 Bn JPY (+6.0 Bn JPY)



Edoxaban: Growth in Each Country

Volume

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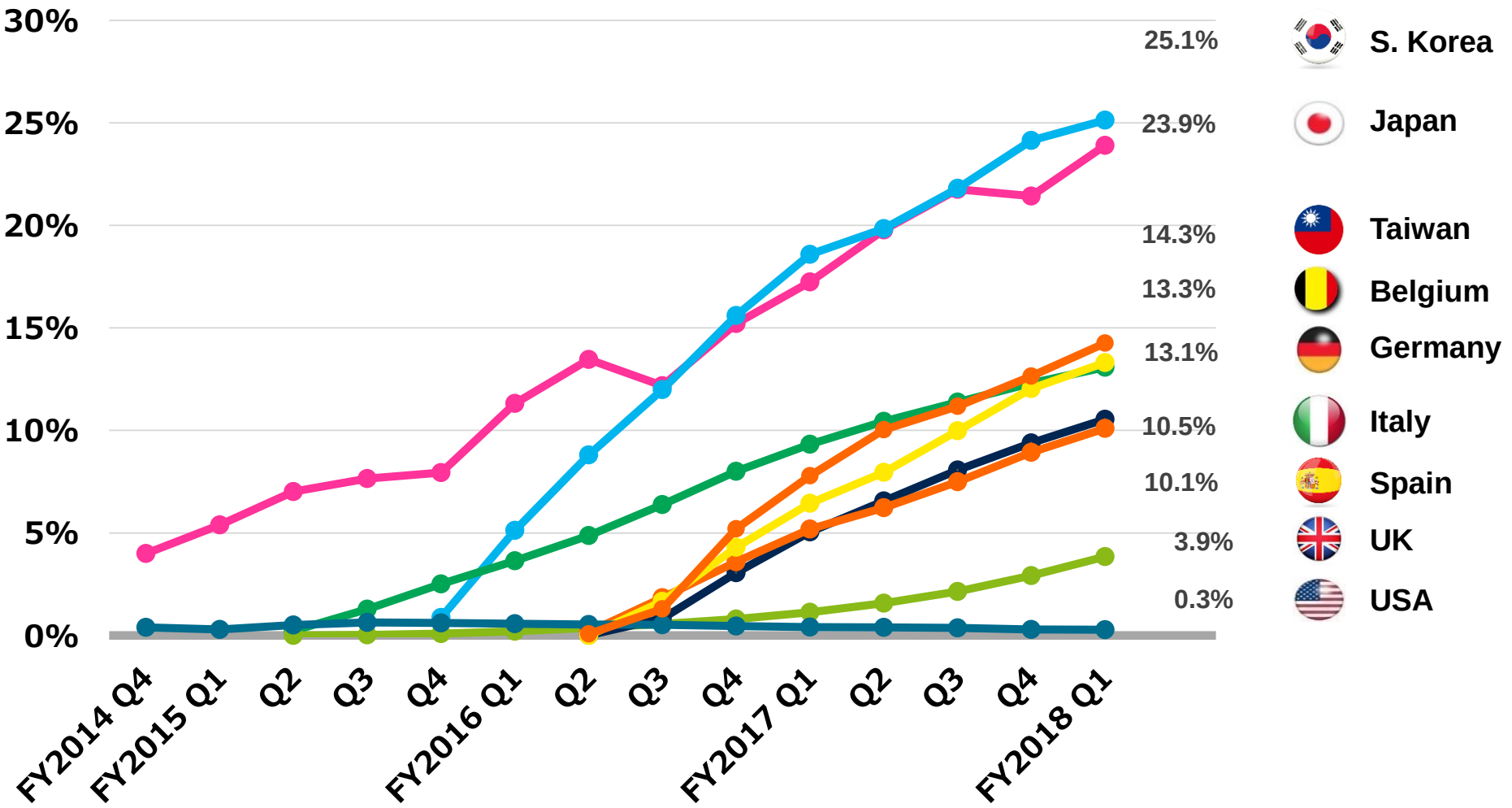
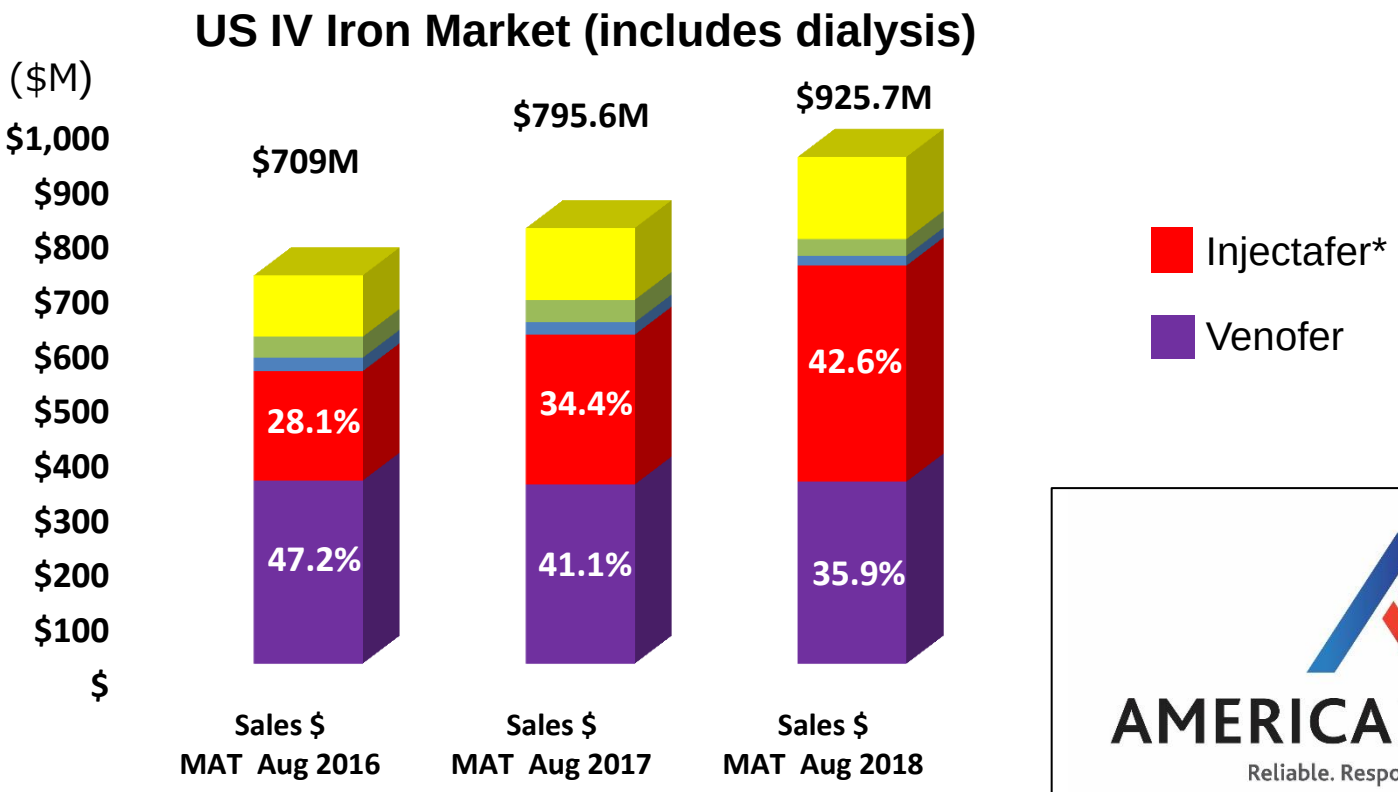
Edoxaban volume (DoT) % share of DOAC markets over time



Brazil: Launched in Aug. 2018

LPI: Growth of Injectafer

- As of Aug. 2018, Injectafer increased its sales share to 42.6% (Increased by 2.5% from May 2018)
- FY2018 Revenue Forecast: Increased to $372 Mn (+$18 Mn)



*Injectafer is not indicated for first line use in patients who are dialysis dependent

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

AMERICAN REGENT™
Reliable. Responsive. Respected.

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

Revised Target for 5-Year Business Plan

Current Progress of 5-Year Business Plan

- **Edoxaban: Growing** in momentum beyond the initial target
- **Luitpold (US): Maintaining** a high level **growth**
- **Oncology: Enriching our pipeline value** including DS-8201
  NDA submission & launch preparation of
  Quizartinib and Pexidartinib are underway
- **Pain Business (US):** Difficult to achieve the initial target
- **Japan Business:** Future business environment getting severe

Difficult to achieve the FY2020 Target : OP 165.0 Bn JPY

Current Progress of 5-Year Business Plan: Oncology Business

◆ Built 3 pillars of oncology business, ADC Franchise, AML Franchise and Breakthrough Science, and focus investments on the pillars

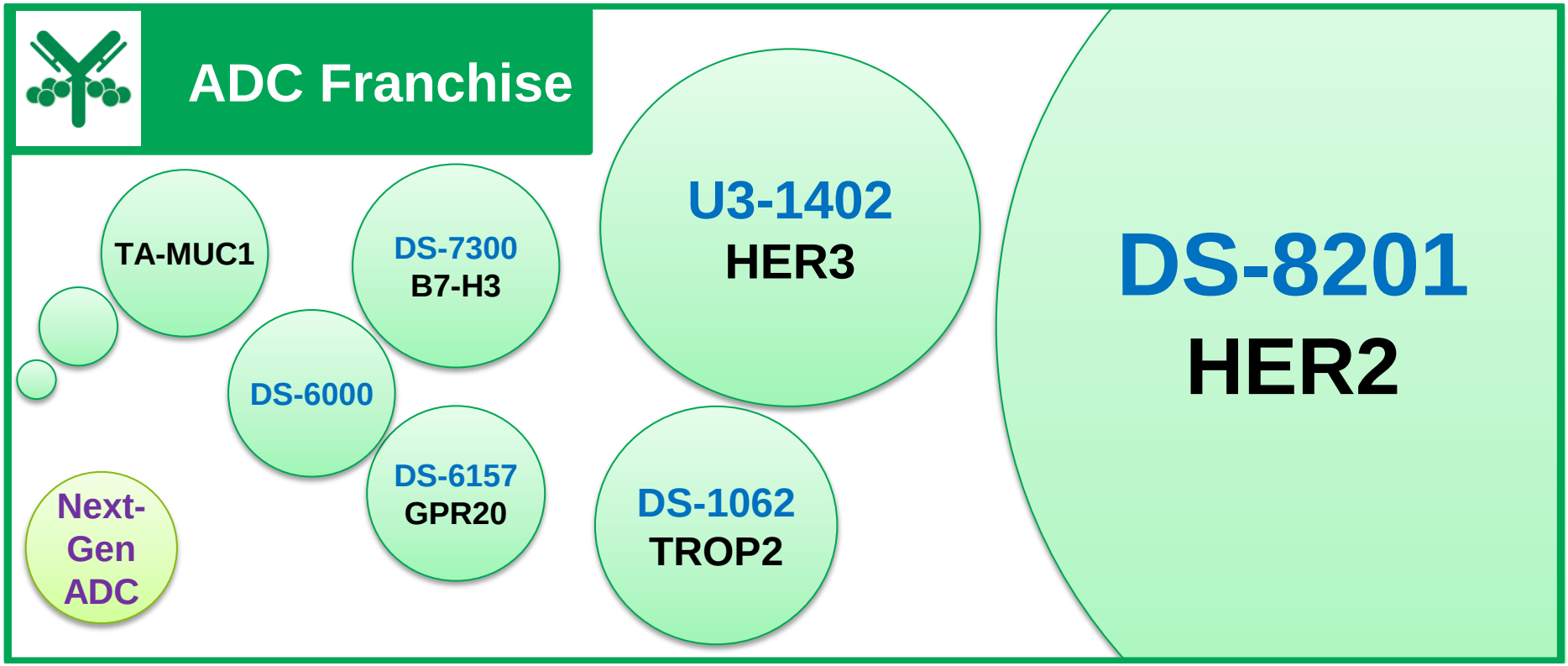
ADC Franchise	AML Franchise	Breakthrough Science
• Refer to next page	• Rich pipeline Quizartinib etc.	• Rich pipeline Pexidartinib etc.
3	3	1

Cancer Enterprise 2025 Vision

7 new molecular entitles in 8 years

Current Progress of 5-Year Business Plan: ADC Franchise

- Established ADC technology as a platform technology
  - DS-8201: Accumulated promising clinical data
  - U3-1402: Disclosed good clinical data
  - Increasing expectation on other ADCs



Policy to Revise the 5-Year Business Plan

- Identify a highly promising investment opportunity for a huge future return, as the value of ADC franchise (DS-8201, U3-1402, etc.) is increasing
- Prioritize investments to maximize the ADC franchise's potential

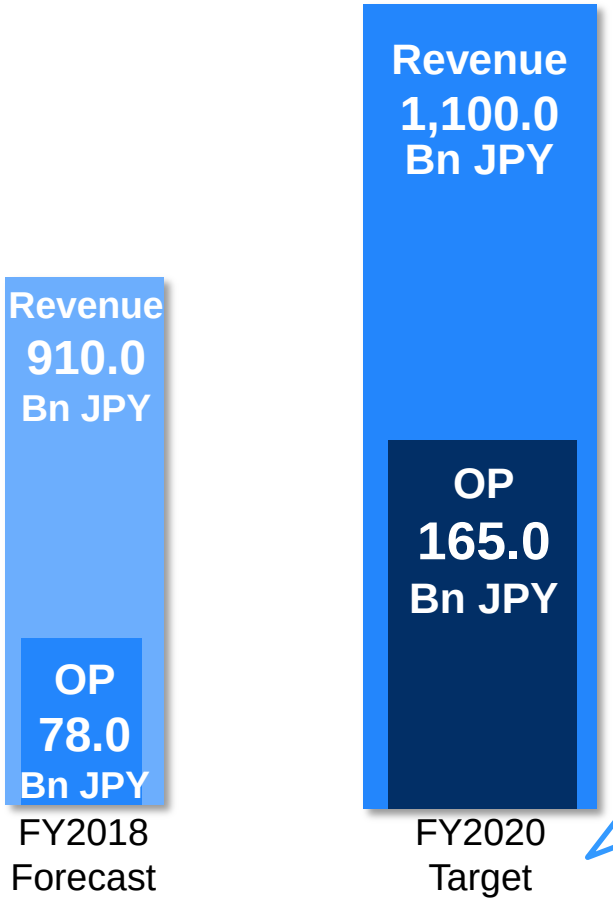
Rather than stick to the original profit target, increase investments in oncology, and accelerate the future growth

5-Year Business Plan (Original)

- Grow beyond FY2017 LOE of olmesartan
- Establish a foundation of sustainable growth

2025 Vision

Global Pharma Innovator with Competitive Advantage in Oncology



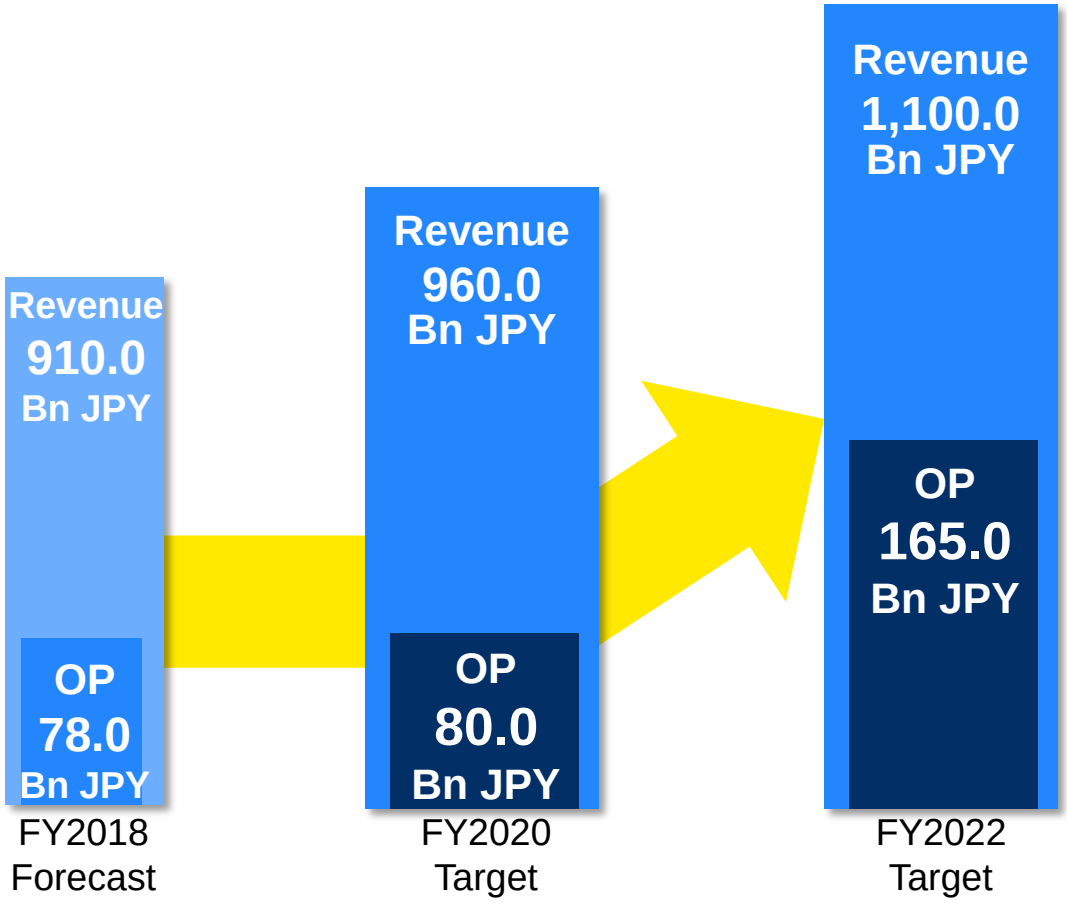
- **Increase value of late-stage pipeline**
  3-5 products with peak-sales of more than 100.0 Bn JPY each
- **ROE: 8% or more**
- **Shareholder Returns**
  (FY2016 - FY2020)
  - **Annual ordinary dividends : 70 JPY or more**
  - **Flexible acquisition of own shares**
  - **Total return ratio: 100% or more**

Revised Target for 5-Year Business Plan

- Revised FY2020 Target
- Achieve original OP target two years behind

2025 Vision

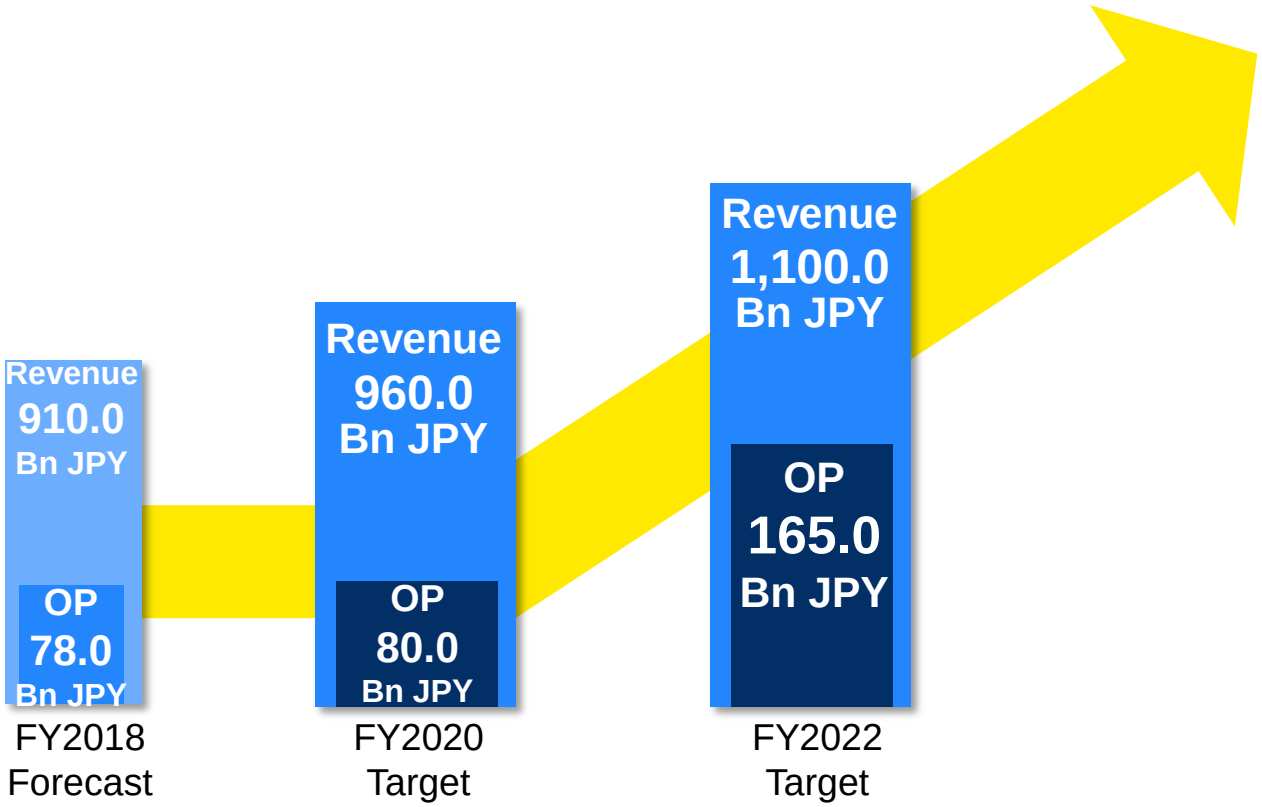
Global Pharma Innovator with Competitive Advantage in Oncology



- **Increase value of late-stage pipeline**
  Total expected revenue at peak
  : 500.0 Bn JPY or more
- **ROE: 8% or more**
- **Shareholder Returns**
  (FY2016 - FY2022)
  - **Annual ordinary dividends**
    : 70 JPY or more
  - **Flexible acquisition of own shares**
  - **Total return ratio: 100% or more**

* The targets excludes the impact of gain on sales of fixed assets, transformation business portfolio and partnering

Toward 2025 Vision



2025 Vision

Global Pharma Innovator with Competitive Advantage in Oncology

Establish a Foundation of Sustainable Growth: Six Strategic Targets

- Grow Edoxaban
- Grow as No.1 Company in Japan
- Expand US Businesses
- Establish Oncology Business
- Continuously Generate Innovative Medicine Changing SOC
- Enhance Profit Generation Capabilities

Mid-term Measures

Blue:
Oncology business related

Daiichi-Sankyo

◆ Mid-term measures to accomplish our strategic targets

Focus resources on oncology business

- Increase R&D and capital expenditures
- Promote partnering (to maximize pipeline value)
- Make the best use of BD investments
- Transform to oncology centered business portfolio

Revise regional strategy

US

- Grow LPI
- Accelerate oncology business establishment

Japan
EU
ASCA

- Maximize edoxaban
- Grow base business (incl. acquisition of new products)
- Accelerate oncology business establishment

Enhance profit generation capabilities

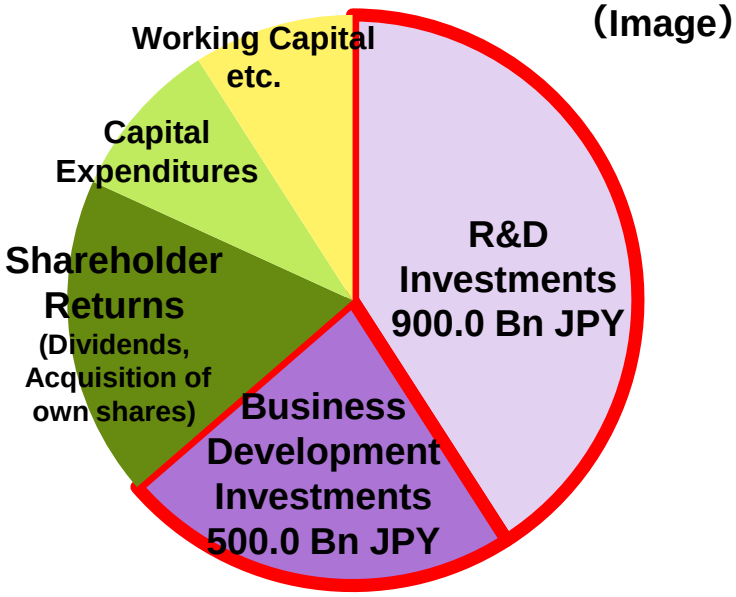
- Reduce investments in non oncology
- Promote further cost reduction initiatives
- Sell non-core assets and cross-shareholdings

Cash Allocation Image

<Original>
FY2016 - FY2020 (5 Years)
cash allocation funds

2,200.0 Bn JPY

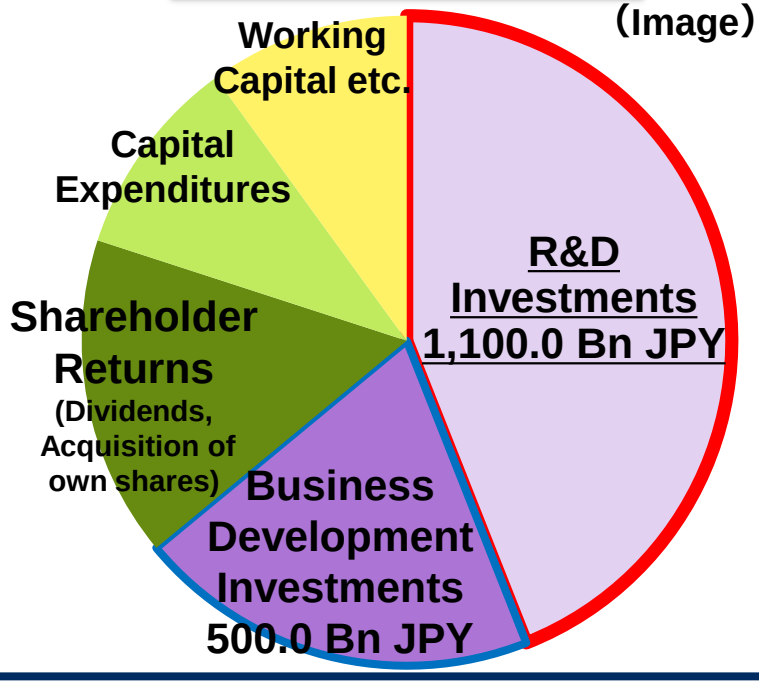
(Image)



< After Revision >
FY2018 - FY2022 (5 Years)
cash allocation funds

2,500.0 Bn JPY

(Image)



- Increase R&D Investments and allocate more to oncology
- Make the best use of Business Development Investments to enhance oncology business

Shareholder Returns

Shareholder Returns Policy: FY2016 - FY2022

- Annual ordinary dividends: 70 JPY dividend in FY2016 and FY2017
- Acquisition of own shares: 50.0 Bn JPY in both FY2016 and FY2017
- Total return ratio : 100% or more (extended to FY2022)

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

Oncology Business: Increase Investments

FY2018 - FY2022 (5 Years)

- R&D Investments: 1,100.0 Bn JPY
  - Prioritize the investments to maximize the potential of ADC franchise
- Capital Exp. to enhance oncology: 25.0 Bn JPY or more

R&D Investments

1,100.0 Bn JPY

200.0 Bn JPY
Additional investment to oncology

900.0 Bn JPY
Allocate more to oncology

900.0 Bn JPY
Allocate furthermore to oncology

<Original>
FY2016 - FY2020 (5 Years)

<After Revision>
FY2018 - FY2022 (5 Years)

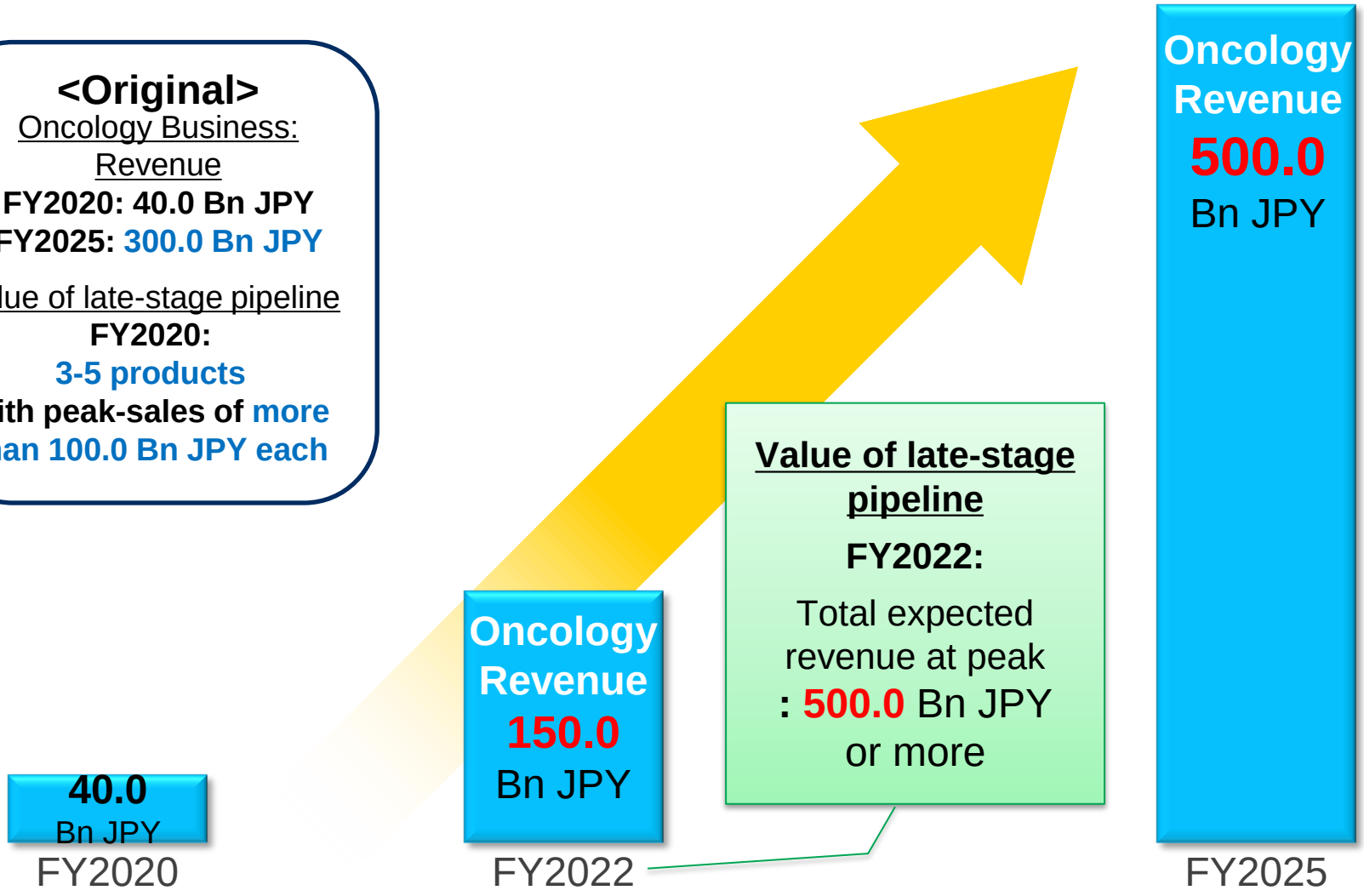
Oncology Business: Revenue Target

◆ Expand the future oncology revenue by accelerating and enhancing the investments

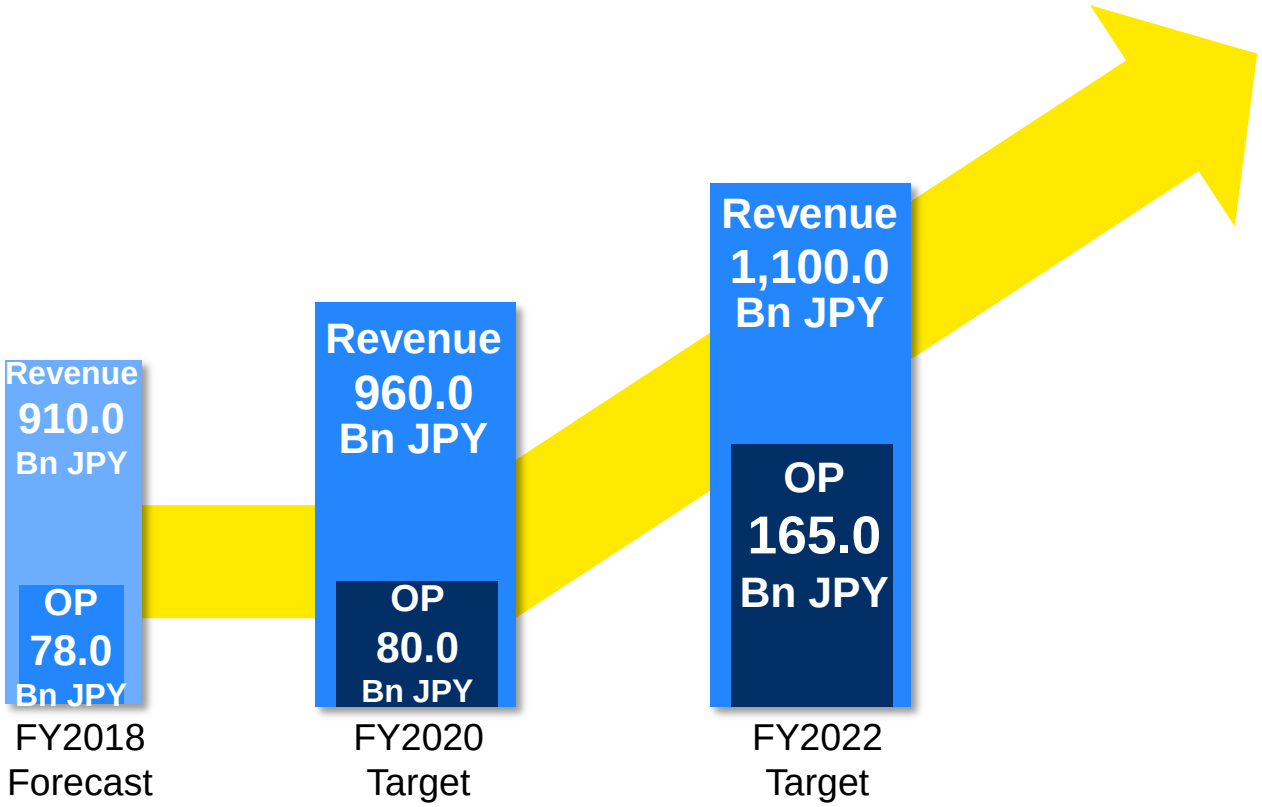
<Original>

Oncology Business:
Revenue
FY2020: 40.0 Bn JPY
FY2025: 300.0 Bn JPY

Value of late-stage pipeline
FY2020:
3-5 products
with peak-sales of more than 100.0 Bn JPY each



Toward 2025 Vision



2025 Vision

Global Pharma Innovator with Competitive Advantage in Oncology

- **Enhance investments and maximize oncology business**
  R&D investments: **1,100 Bn JPY**, Oncology revenue: **500 Bn JPY** in FY2025
- **Commitment of FY2022**
  OP **165 Bn JPY**, ROE **8%** or more, Value of late-stage pipeline* **500 Bn JPY** or more, Total return ratio **100%** or more

* Total expected revenue at peak

R&D Update

Glenn Gormley, MD, PhD

Senior Executive Officer

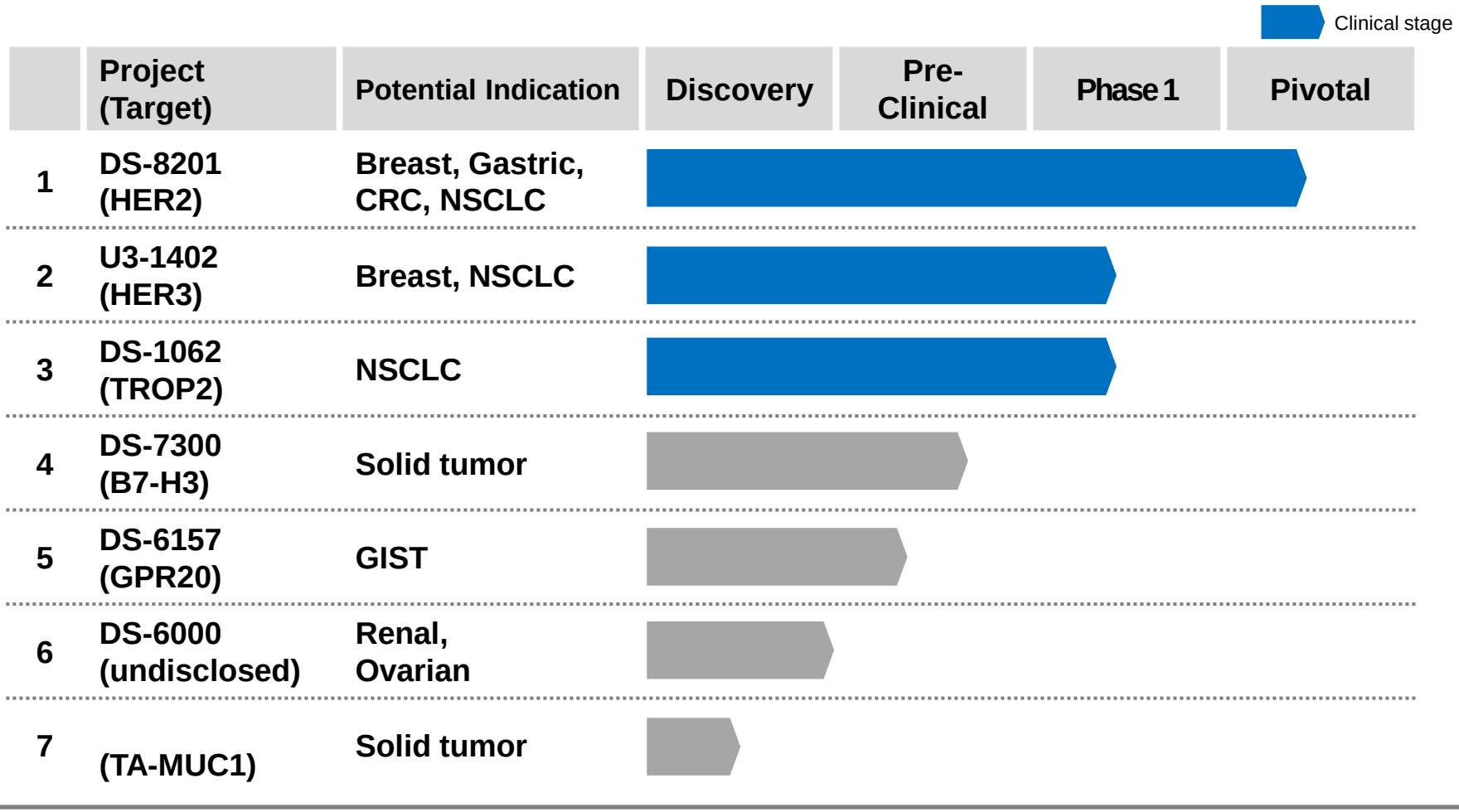
Global Head of R&D

Agenda

- Summary of our ADC franchise
- DS-8201 update
  - P1 study: NSCLC data
  - P1 study: CRC data
  - P3 study: HER2 low BC P3 study target population
  - IO combination studies
- Update on other late stage oncology assets
- Timing for release of new Data prior to R&D Day
- R&D Day 2018

List of ADC Franchise

ADC Franchise



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

Summary of ADC Franchise

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DS-8201

- Details in later pages

U3-1402

- Phase 1 Breast and NSCLC studies are on track
  - Update of BC data planned for SABCS 2018
  - Aiming to present initial NSCLC data at ASCO 2019
- Portability of ADC technology to other antibodies was validated based on BC data presented at ASCO 2018

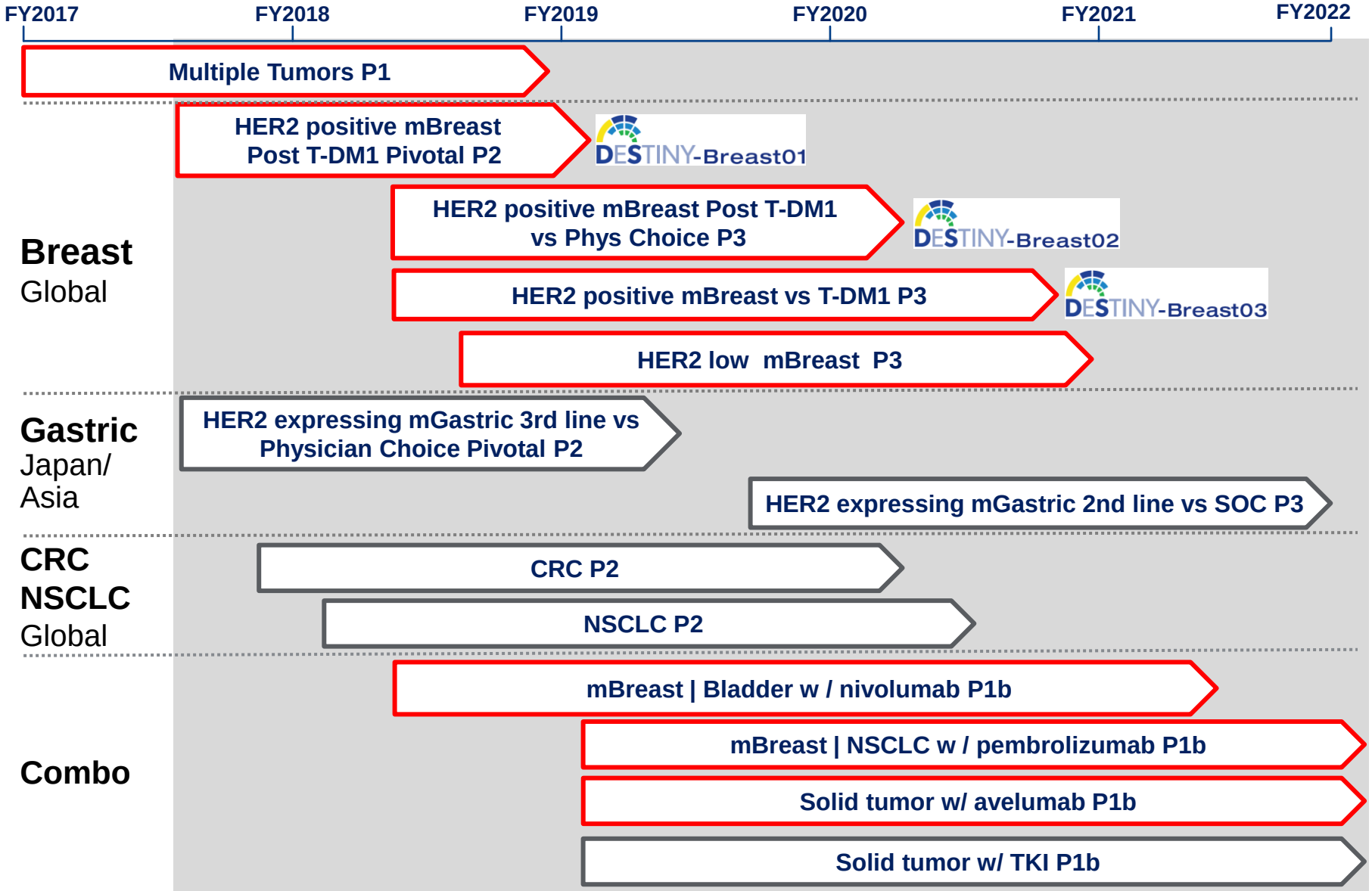
Other ADC

- DS-1062: Phase 1 NSCLC study is on track
  - Aiming to present initial data at ASCO 2019
- DS-7300: preparing for Phase1 study to start in FY2019
- DS-6157: disclosed target antigen=> GPR20

Red: New from FY2018 Q1

DS-8201: Clinical Program

As of Oct 2018



Red studies will be discussed in later pages

DS-8201: Update

P1 Study

- NSCLC: Oral presentation at WCLC 2018 (World Conference on Lung Cancer)
- CRC: Poster presentation at ESMO 2018

Breast Cancer

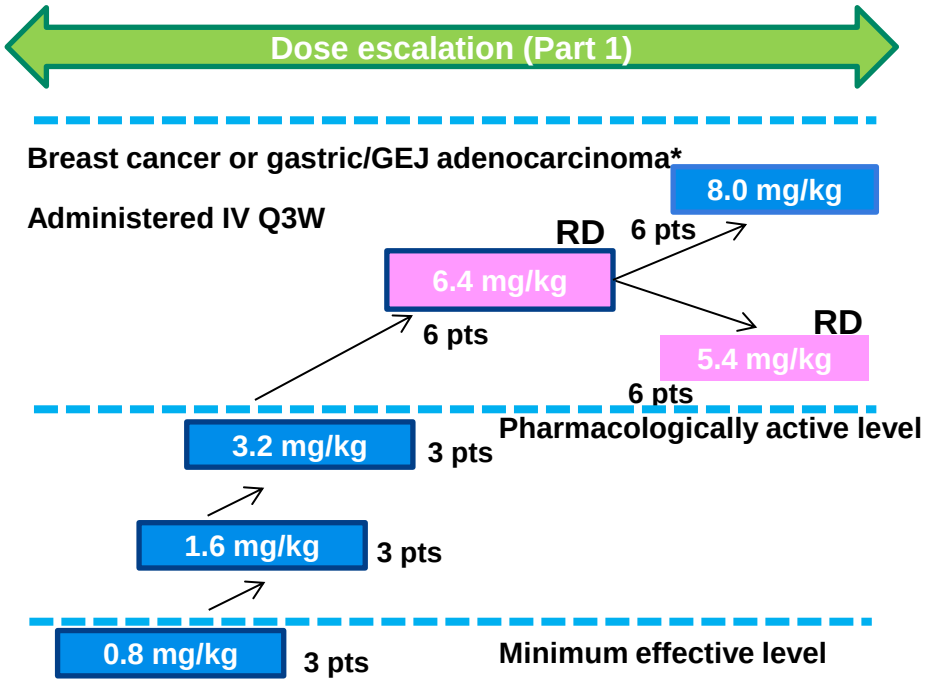
- Completed enrollment of Phase 2 Pivotal study (DESTINY-Breast01 Study)
- Started two Phase 3 studies
  - HER2 positive post T-DM1 (DESTINY-Breast02 Study)
  - HER2 positive vs. T-DM1（DESTINY-Breast03 Study）
- Determined target population for HER2 low P3 study

IO Combo

- First subject dosed for nivolumab combination P1b study
- Pembrolizumab combination clinical research collaboration
- Avelumab combination clinical research collaboration

Red: details in later page

DS-8201: Study Design of Phase 1 Study



Dose expansion (Part 2)

Part 2a, N = 100
T-DM1–treated HER2-positive breast cancer
(IHC 3+ or ISH+)
Doses: 5.4 or 6.4 mg/kg Q3W

Part 2b, N = 40
Trastuzumab-treated HER2-positive gastric cancer
(IHC 3+ or IHC 2+/ISH+)
Doses: 5.4 or 6.4 mg/kg Q3W

Part 2c, N = 40
HER2-low breast cancer
(IHC 2+/ISH−, IHC 1+/ISH−)
Dose: 6.4 mg/kg Q3W

Part 2d, N = 60
HER2-expressing or -mutated solid tumors (including NSCLC and CRC)
Dose: 6.4 mg/kg Q3W

Part 2e (PK cohort), N = 20
HER2-positive or -low breast cancer
(IHC 1+, IHC 2+, IHC 3+, and/or ISH+)
Dose: 6.4 mg/kg Q3W

HER2 status was assessed on archival tissue.

*Subjects in part 1 were not required to have HER2-positive (IHC 3+ or IHC2+/ISH+) tumors.
GEJ, gastro-esophageal; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization; IV, intravenous; NSCLC, non-small cell lung cancer; PK, pharmacokinetic; pts, patients; Q3W, once every 3 weeks; RD, recommended dose for dose expansion; T-DM1, trastuzumab emtansine.

Data Presented @ WCLC 2018 Data presented @ ESMO 2018

DS-8201: Demographics and Baseline Characteristics of NSCLC and CRC Patients (P1 Part 2d)

	NSCLC (N = 18)
Age, median (range), years	58.0 (23.0–83.0)
ECOG performance status 0, n (%)	4 (22.2)
ECOG performance status 1, n (%)	14 (77.8)
HER2-mutated, n (%)	11 (61.1)
Exon 20 insertions	8 (44.4)
Transmembrane domain mutation (G660D)	2 (11.1)
Extracellular domain mutation (S310F)	1 (5.6)
Missing/not examined HER2-mutated status, n (%)	7 (38.9)
Prior cancer regimens, median (range)	3.0 (1.0–10.0)
Sum of tumor diameters, median (range), cm	7.3 (2.0–17.0)

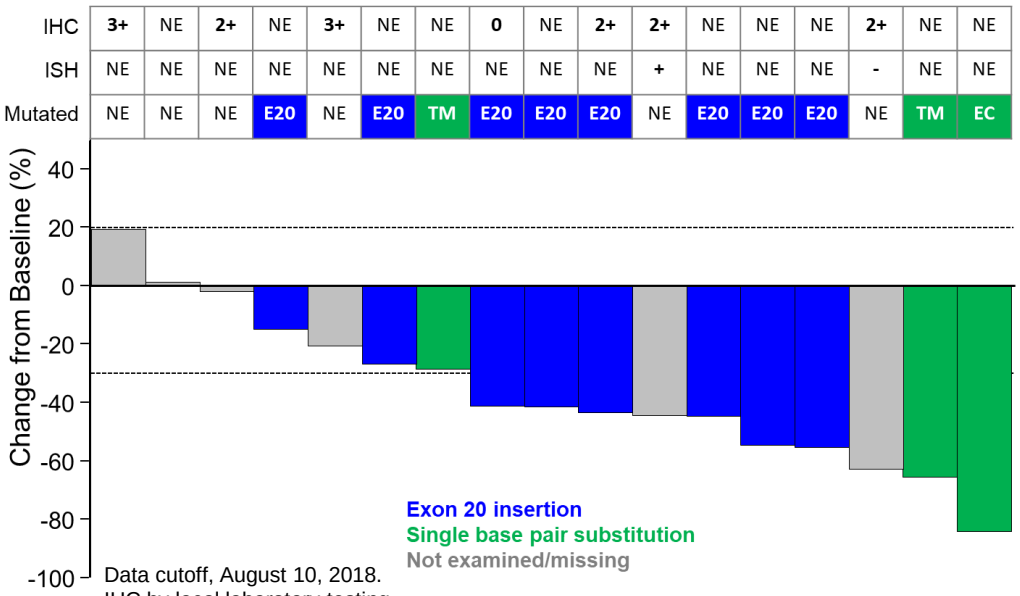
	CRC (N = 20)
Age, median (range), years	59.5 (35.0-75.0)
ECOG performance status 0, n (%)	13 (65.0)
ECOG performance status 1, n (%)	7 (35.0)
HER2 expression (IHC), n (%)	
3+	9 (45.0)
2+	2 (10.0)
FISH positive	1 (5.0)
FISH negative	0
FISH non-evaluable	1 (5.0)
1+	2 (10.0)
0	7 (35.0)
RAS mutation, n (%)	7 (35.0)
KRAS mutation, n (%)	5 (25.0)
NRAS mutation, n (%)	2 (10.0)
Prior cancer regimens, median	4
Prior irinotecan therapy, n (%)	17 (85.0)

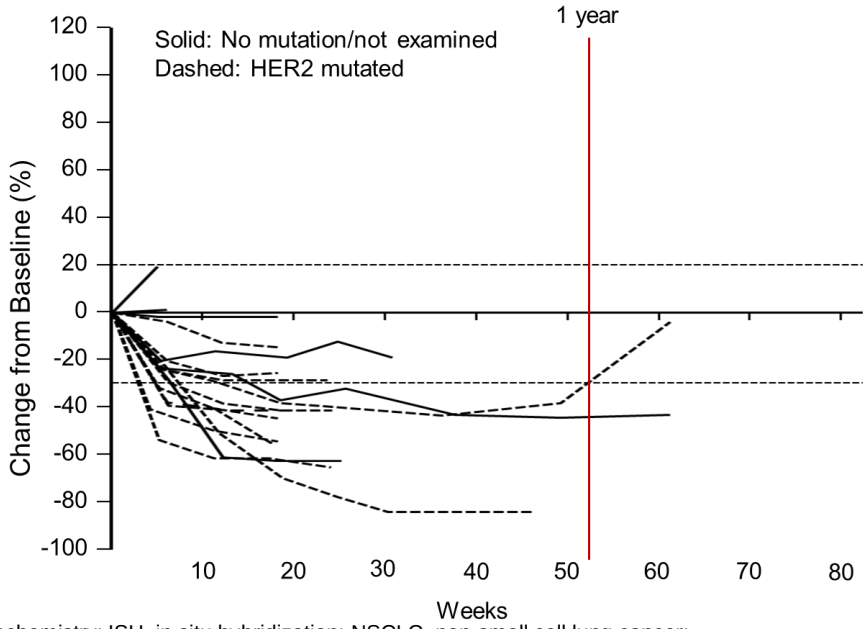
Data cutoff, August 10, 2018.
ECOG, Eastern Cooperative Oncology Group; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; NSCLC, non-small cell lung cancer.

- Most patients received multiple prior therapies for both NSCLC and CRC
- 7 patients of IHC 0 were included in CRC

Data Presented @ WCLC 2018 | Data presented @ ESMO 2018

DS-8201: Phase 1 Part 2d NSCLC Efficacy





Data cutoff, August 10, 2018.
IHC by local laboratory testing.
E20, exon 20 insertion; EC, single base pair substitution at extracellular domain; IHC, immunohistochemistry; ISH, in situ hybridization; NSCLC, non-small cell lung cancer; NE, not examined or missing; TM, single base pair substitution in transmembrane domain.

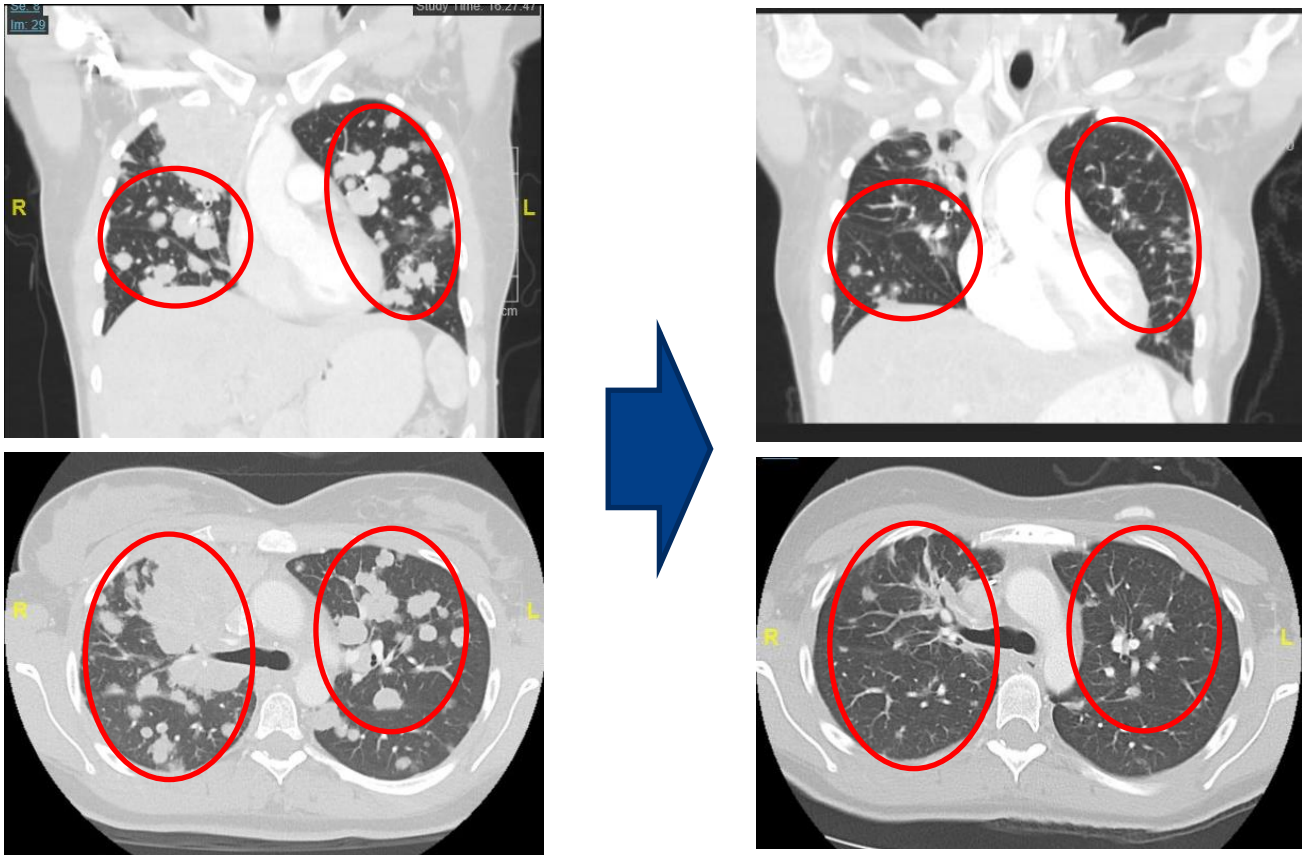
	Confirmed[a] ORR, % (n/N)	Confirmed[a] DCR, % (n/N)	DOR, median (range), months	TTR, median (range), months	PFS, median (range), months
HER2-expressing or HER2-mutated NSCLC N = 18	58.8% (10/17)	88.2% (15/17)	9.9 (0.0+, 11.5)	1.4 (1.0, 4.2)	14.1 (0.9, 14.1)
HER2-mutated NSCLC n = 11	72.7% (8/11)	100% (11/11)	11.5 (0.03+, 11.5)	1.4 (1.0, 4.2)	14.1 (4.0+, 14.1)

[a]CR/PR confirmation includes subjects who had ≥2 post baseline scans, had progressive disease, or discontinued treatment for any reason prior to second post baseline scan.

◆ ORR and PFS of HER2-muated NSCLC were 72.7% and 14.1M

Data Presented @ WCLC 2018

DS-8201: Phase 1 NSCLC Example CT Image from Responder



Feb 2018: baseline

May 2018

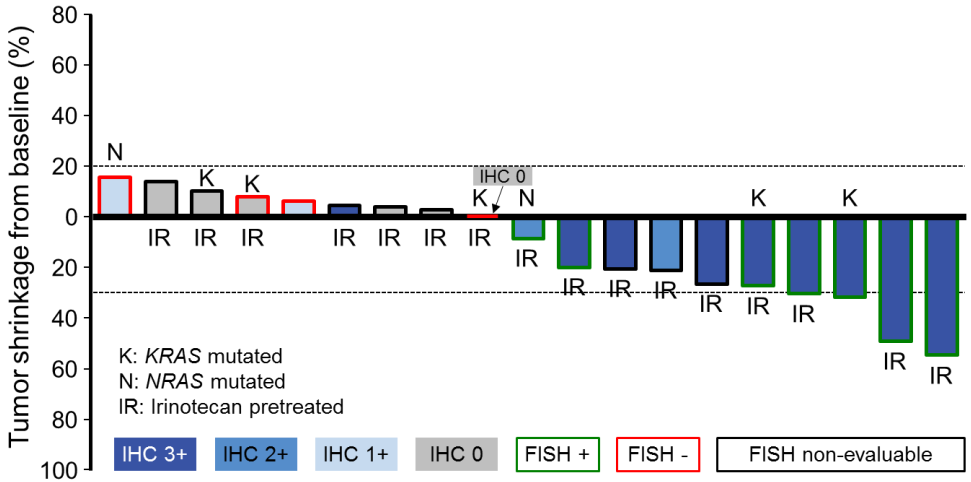
- Female 23 years of age, nonsmoker
- Stage IV, nonsquamous NSCLC, HER2 mutation (exon 20 insertion)
- **45% tumor shrinkage was observed (PR)**

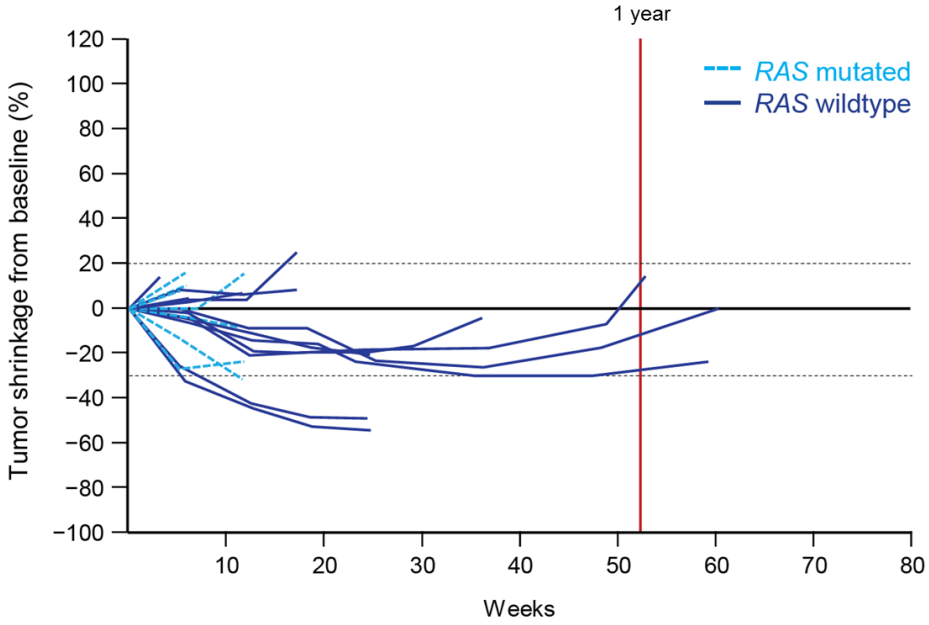
Images courtesy of Dr. Pasi Jänne. Special thanks to Dr. Pasi Jänne and Dr. Ian Krop of Dana-Farber Cancer Institute

CT, computed tomography; HER2, human epidermal growth factor 2; NSCLC, non-small-cell lung cancer; PR, partial response;

Data Presented @ WCLC 2018

DS-8201: Phase 1 Part 2d CRC Efficacy





HER2 status based on centrally assessed retrospective analysis of archival samples.
Dotted lines denote 30% decrease and 20% increase in tumor size cutoffs for partial response and progressive disease, respectively.
FISH, fluorescence in situ hybridization; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; IR, irinotecan pretreated; K, *KRAS* mutation; N, *NRAS* mutation.

	Confirmed[a] ORR, % (n/N)	Confirmed[a] DCR, % (n/N)	DOR, median (range), months	TTR, median (range), months	OS, median (range), months
CRC N=19*	15.8% (3/19)	84.2% (16/19)	NR (0.0+, 5.5+)	2.8 (1.3, 8.1)	NR (1.0+, 17.9+)

[a]CR/PR confirmation includes subjects who had ≥2 post baseline scans, had progressive disease, or discontinued treatment for any reason prior to second post baseline scan.
* Evaluable patients (one IHC 0 patient was non evaluable out of 20 enrollment)

- ORR was 15.8% for the overall population (3/19)
- In HER2 positive (IHC2+, 3+) CRC patients, ORR was 27.3% (3/11)

Data Presented @ ESMO 2018

DS-8201: Frequent TEAEs (≥20%) (all tumor types from part 1 and part 2)

All tumor types from P1 study part 1 and part 2; 5.4 or 6.4 mg/kg[a] (N = 259)		
	Any Grade, n (%)	Grade ≥3, n (%)
Nausea	192 (74.1)	9 (3.5)
Decreased appetite	147 (56.8)	12 (4.6)
Vomiting	113 (43.6)	6 (2.3)
Anemia	98 (37.8)	50 (19.3)
Alopecia	97 (37.5)	0
Fatigue	88 (34.0)	6 (2.3)
Diarrhea	87 (33.6)	6 (2.3)
Constipation	85 (32.8)	2 (0.8)
Platelet count decreased	73 (28.2)	27 (10.4)
Neutrophil count decreased	66 (25.5)	40 (15.4)
White blood cell count decreased	66 (25.5)	32 (12.4)
Malaise	58 (22.4)	1 (0.4)
Pyrexia	53 (20.5)	2 (0.8)
Aspartate aminotransferase increased	53 (20.5)	4 (1.5)

Data cutoff, August 10, 2018. A subject was counted once if the same AE was reported more than once.
[a]All subjects from Part 1 and Part 2 receiving ≥1 dose of [fam-] trastuzumab deruxtecan 5.4 mg/kg or 6.4 mg/kg regardless of tumor type.
AE, adverse event; TEAE, treatment-emergent adverse event.

- Adverse events were generally of low grade
- The most frequent AEs Grade ≥ 3 were hematologic in nature

Data Presented @ WCLC 2018 | Data presented @ ESMO 2018

DS-8201: Adverse Events of Special Interest (all tumor types from part 1 and part 2)

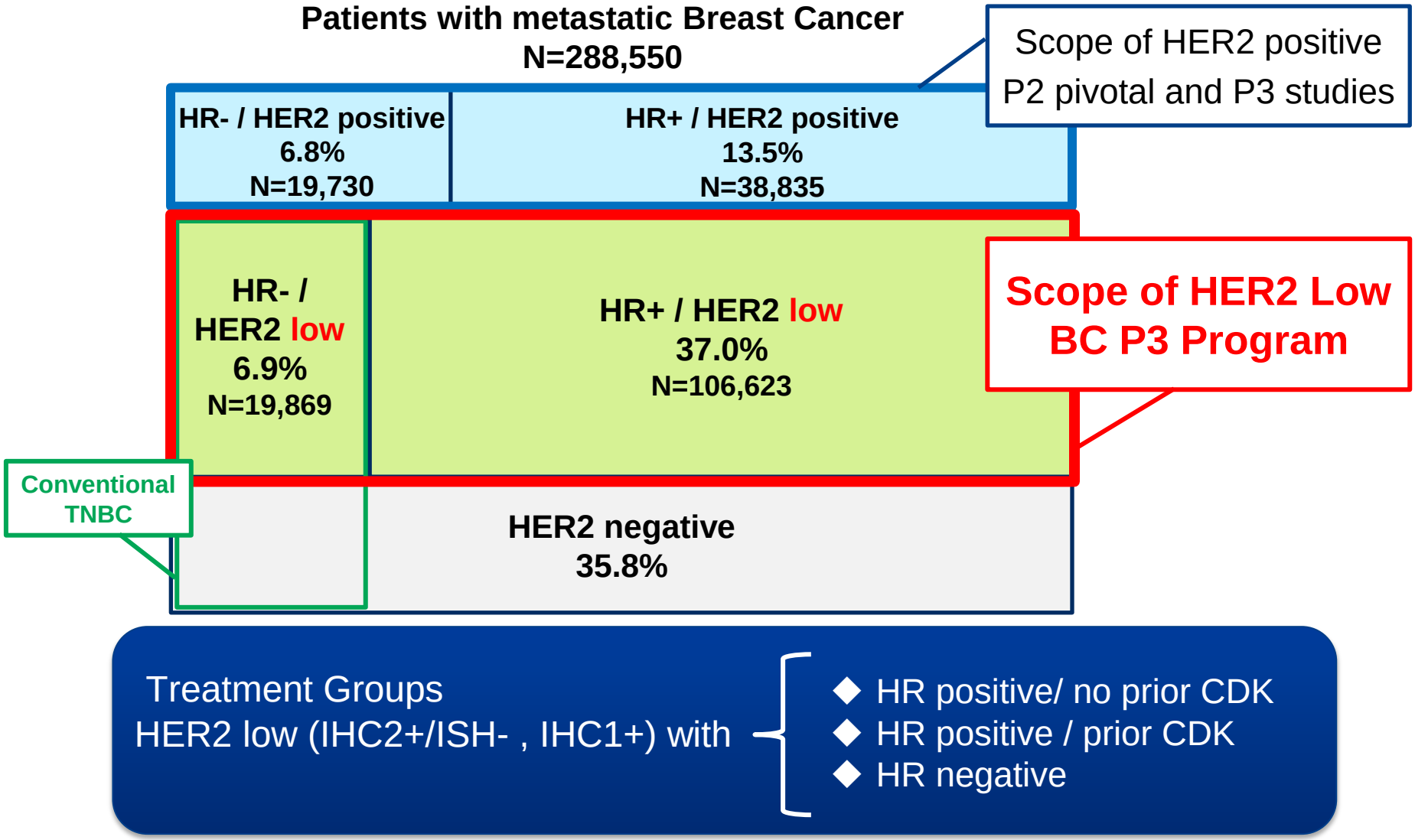
All tumor types from P1 study part 1 and part 2; 5.4 or 6.4 mg/kg[a] (N = 259)		
	Any Grade, n (%)	Grade ≥3, n (%)
AST increased	53 (20.5)	4 (1.5)
ALT increased	40 (15.4)	2 (0.8)
Blood bilirubin increased	6 (2.3)	1 (0.4)
Ejection fraction decreased	2 (0.8)	0
Electrocardiogram QT prolonged	13 (5.0)	1 (0.4)
Interstitial lung disease (ILD)	10 (3.9)	2 (0.8)
Pneumonitis	22 (8.5)	6 (2.3)
Infusion-related reactions	4 (1.5)	0

Data cutoff, August 10, 2018.
[a]All subjects from Part 1 and Part 2 receiving ≥1 dose of [fam-] trastuzumab deruxtecan 5.4 mg/kg or 6.4 mg/kg regardless of tumor type.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; ILD, interstitial lung disease; NSCLC, non-small cell lung cancer; QTc, QT interval corrected for heart rate.

- There were 5 fatal cases of ILD/pneumonitis observed in the overall population
- There was only one grade 5 pneumonitis case in the NSCLC cohort and this case was determined to be unrelated to study drug by the independent adjudication committee

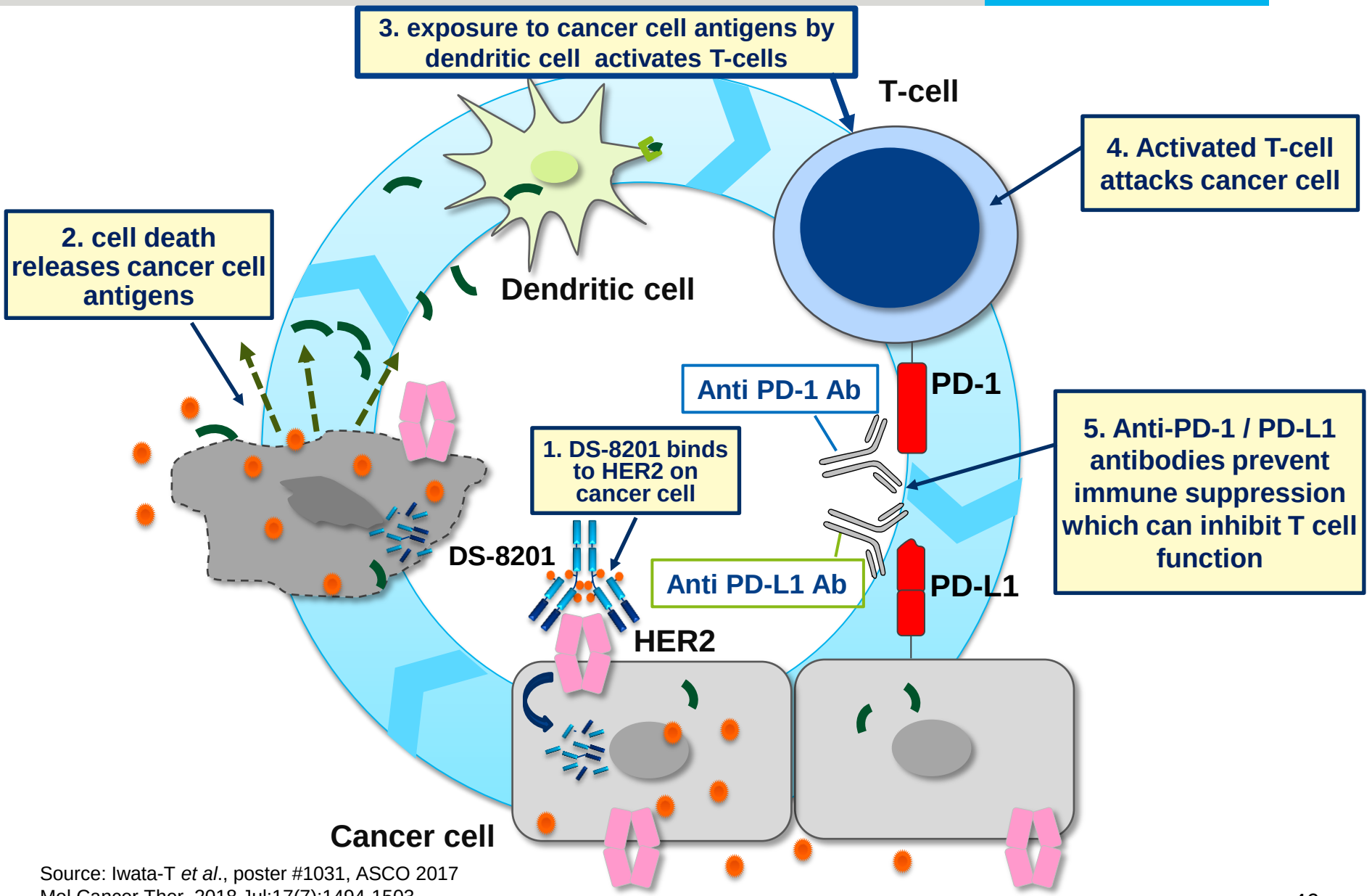
Data Presented @ WCLC 2018 Data presented @ ESMO 2018

DS-8201 : HER2 Low BC Phase 3 Target Population



HR: hormone receptor; TNBC: triple negative breast cancer
HR-: estrogen-receptor (ER) and progesterone-receptor (PR) negative

DS-8201: Hypothesis of IO Combo Effect

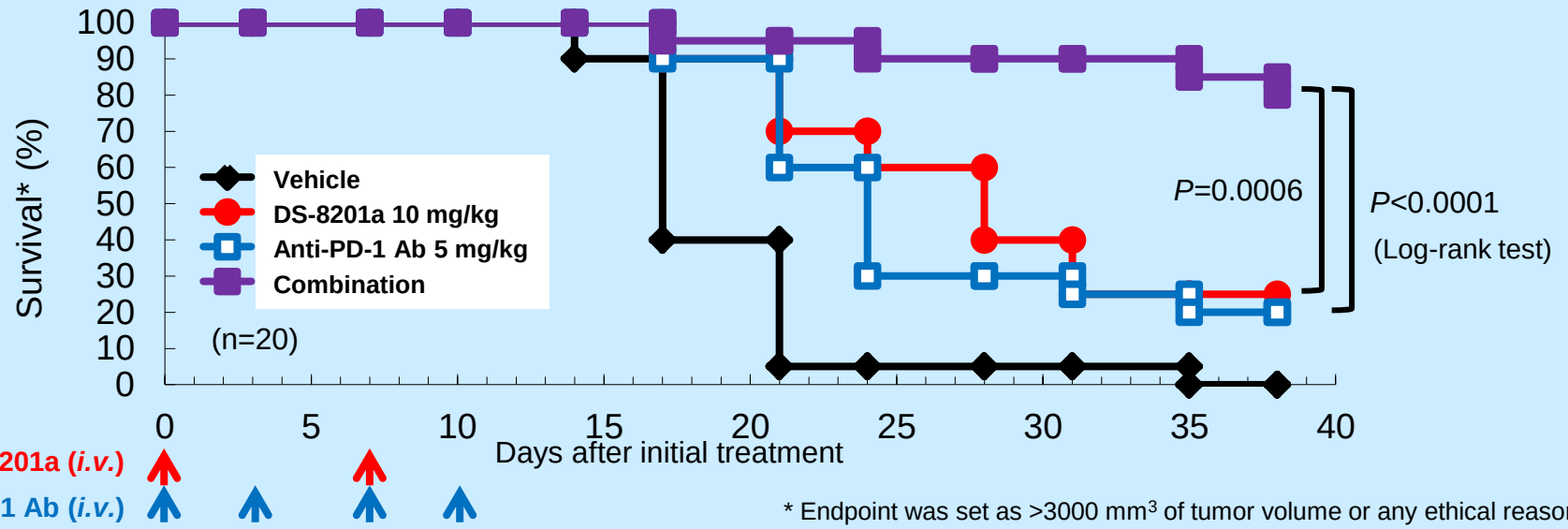


Source: Iwata-T *et al*., poster #1031, ASCO 2017
Mol Cancer Ther. 2018 Jul;17(7):1494-1503.
* Partially modified

DS-8201: Strategy of IO Combo

- Pre-clinical study demonstrated synergetic effect of DS-8201 and anti-PD-1 antibody
- Three P1b studies will be conducted in multiple tumor types to identify the most effective combination for each indication
  - Nivolumab (anti PD-1 antibody): first subject dosed in August 2018 (see page 58)
  - Pembrolizumab (anti-PD-1 antibody): see page 48
  - Avelumab (anti PD-L1 antibody): see page 49

Combination benefit of DS-8201a and an anti-PD-1 antibody in vivo



* Endpoint was set as >3000 mm^3 of tumor volume or any ethical reasons

Source: Iwata-T *et al.*, poster #1031, ASCO 2017
Mol Cancer Ther. 2018 Jul;17(7):1494-1503.

DS-8201: Pembrolizumab combo P1b Study

Dose Escalation

- HER2 expressing BC
- HER2 expressing NSCLC or
- HER2 mutated advanced NSCLC

Dose expansion

Cohort 1	HER2 positive advanced BC post T-DM1
Cohort 2	HER2 low advanced BC post SOC (IHC1+ or IHC2+, ISH-)
Cohort 3	HER2 expressing advanced NSCLC with no prior treatment with anti-PD-1 or anti-PD-L1 agents (IHC1+ ,IHC2+ , or IHC3+)
Cohort 4	HER2 mutated advanced NSCLC with no prior treatment with anti-PD-1 or anti-PD-L1 agents

Estimated enrollment	125 patients
Primary Endpoint	MTD, RDE, ORR
Secondary endpoint	DOR, DCR, PFS, OS, TTR, Safety
JAPIC/CT.gov	N/A

DS-8201: Avelumab Combo P1b Study

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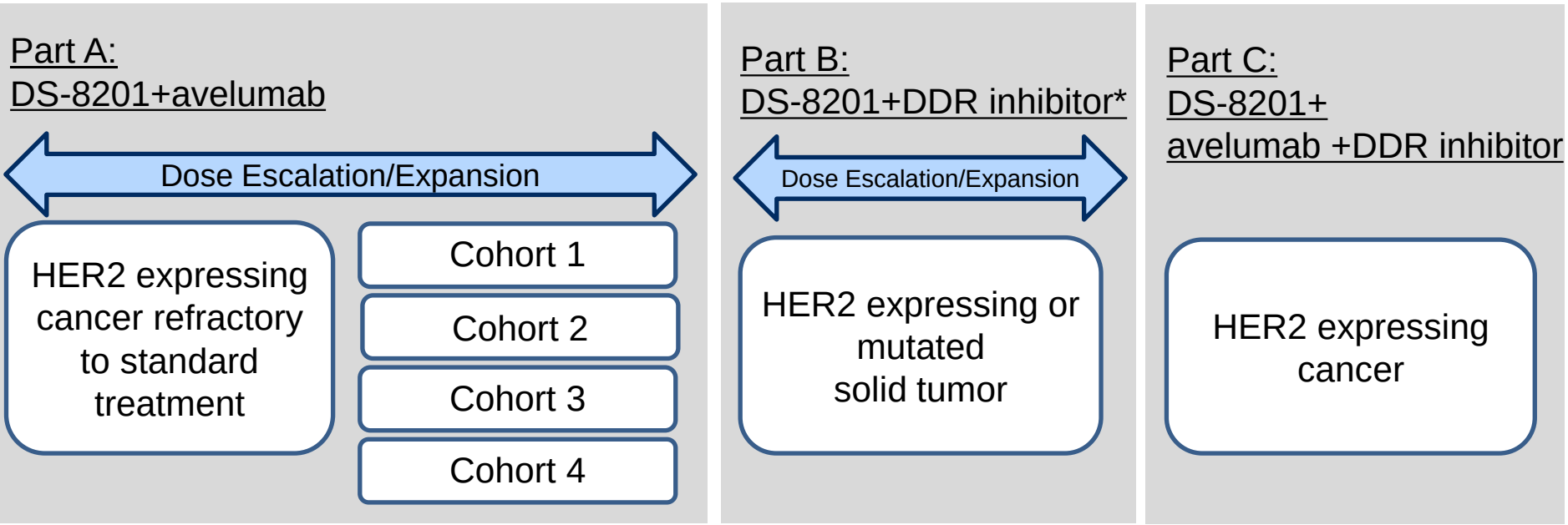


*investigational DNA damage response (DDR) inhibitor of Merck KGaA

Estimated enrollment	200 patients
Primary Endpoint	MTD, RDE, ORR
Secondary endpoint	DOR, DCR, PFS, OS, TTR, Safety
JAPIC/CT.gov	N/A

Other Update

Quizartinib

- Submission in JP/US/EU
  - JP: submitted on October 17th (Orphan Drug Designation)
    - ✓ Based on safety and efficacy data confirmed in JP P2 study (bridging study to QuANTUM-R)
  - US: rolling submission (Breakthrough Therapy Designation)
  - EU: on track for 2H FY2018 (Orphan Drug Designation)

Pexidartinib

- Submit US NDA in 2H FY2018
  - US: Orphan Drug and Breakthrough Therapy Designations
  - EU: Orphan Drug Designation

Axicabtagene ciloleucel (Axi-Cel®) CAR-T

- Will start clinical trial in Japan in 2H FY2018
  - Orphan Drug Designation

Next Data Points until R&D Day

December 1-3, 2018: American Society of Hematology (ASH) @ San Diego

- AML Franchise: Multiple abstracts submitted
  (including Quizartinib QuANTUM-R)

December 4-8, 2018: San Antonio Breast Cancer Symposium (SABCS)

- DS-8201
  - P1 study BC HER2 positive/low update
  - Dose justification for BC P2 and P3 studies
  - Result of ILD Adjudication Committee
- U3-1402
  - BC P1 study update

R&D Day 2018

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

- Location: Daiichi Sankyo Headquarters, Tokyo

- Contents (plan)
  - CE* 2025: overall progress towards our long-term strategy
  - ADC Franchise: critical data and progress / forward plan
  - AML Franchise: critical data and progress / forward plan

*Cancer Enterprise

Appendix

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

FY2018 R&D Milestone Events

As of Oct 2018

Daiichi-Sankyo

Project	Study / Indication	FY2018				FY2019
		Q1	Q2	Q3	Q4	Q1
DS-8201	P1: multiple tumors		Enroll completed			
	P2: HER2 positive mBC Post T-DM1 pivotal study		Enroll completed			
	P3: HER2 positive mBC Post T-DM1 vs Phys Choice		Study started			
	P3: HER2 positive mBC vs T-DM1		Study started			
	P3: HER2 low mBC			Study start planned		
	P2: NSCLC	Study started				
	P1b: mBC/Bladder with nivolumab		Study started			
	P1b: mBC/NSCLC with pembrolizumab				⇨	Study start planned
	P1b: solid tumor with avelumab					Study start planned
U3-1402	P1/2: mBC	P2 part study started				
Quizartinib	P3: QuANTUM-R AML Relapsed/Refractory	TLR		Submission		
DS-3032	P1: AML with Quizartinib		⇨	Study start planned		
	P1: AML with Azacitidine		⇨	Study start planned		
Pexidartinib	P3: TGCT (US)			Submission		
Axi-Cel®	P2: BCL (JP)			Study start planned		
DS-1205	P1: EGFRm NSCLC with osimertinib		⇨	Study start planned		
	P1: EGFRm NSCLC with gefitinib			Study started		
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 started			

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 , TLR: Top Line Results

Red: New or update from FY2018 Q1 Blue: achieved

Major R&D Pipeline (Oncology)

As of Oct 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	★
	Axi-Cel® (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

★: projects in the field of oncology which are planned for application based on the results of P2 studies

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

Daiichi-Sankyo

	Generic Name/Project Code Number (Class)	Target Indication	Region	Stage
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-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

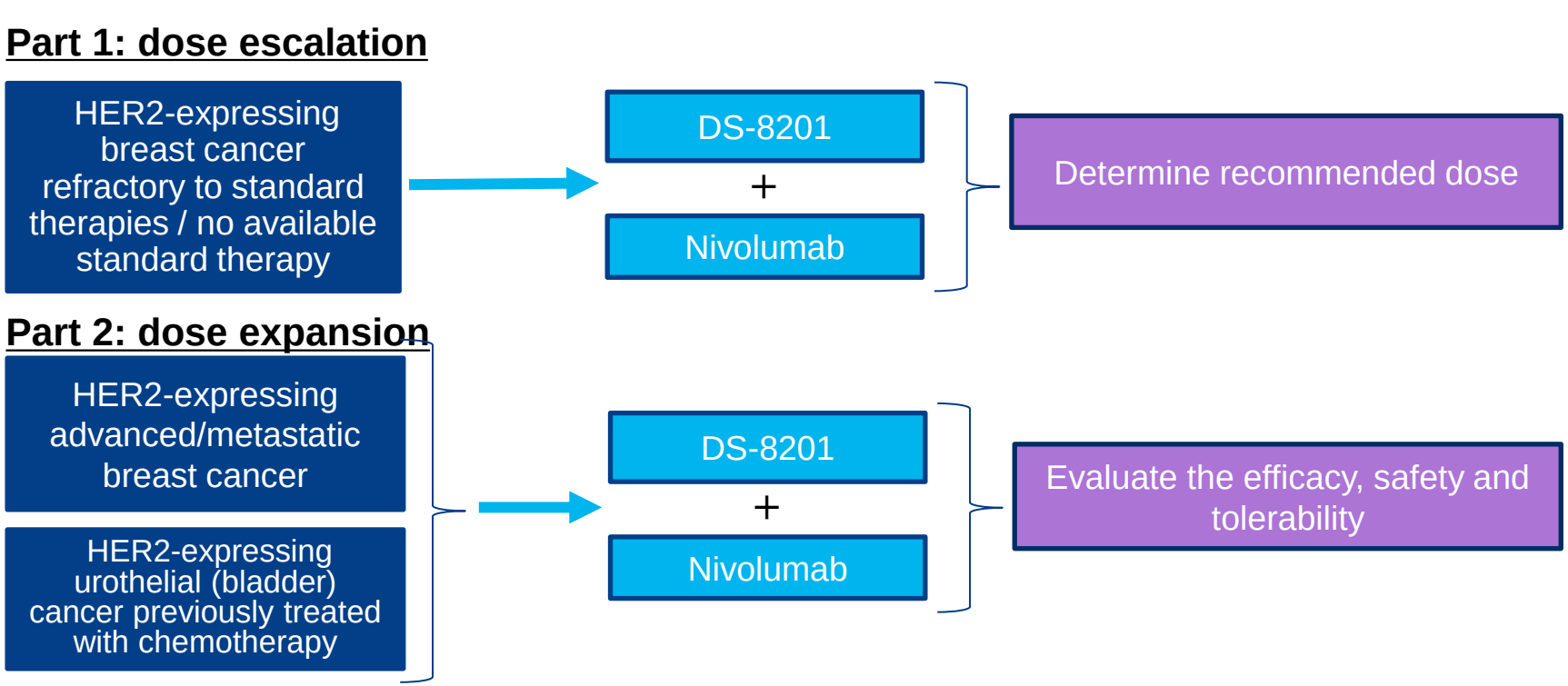
As of Oct 2018

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

DS-8201: P1b Nivolumab Combination Study (US/EU)



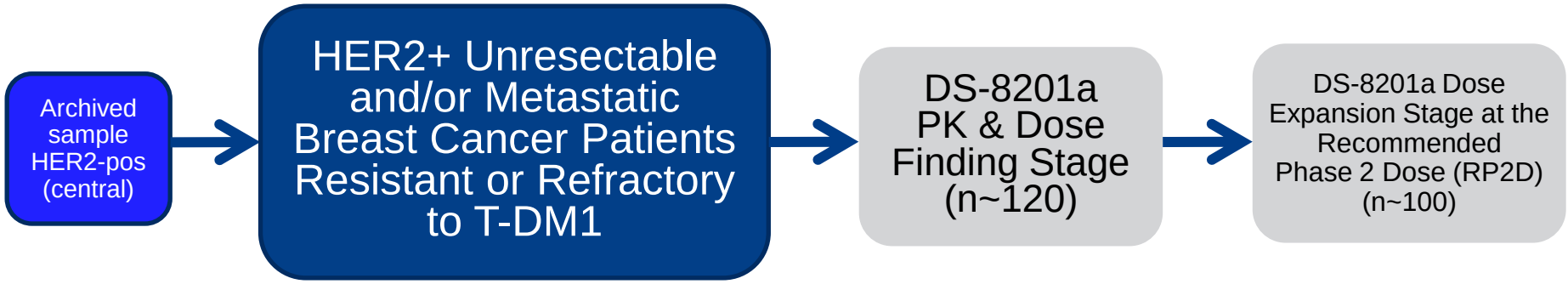
Study patients	• HER2-expressing breast cancer who are refractory to standard therapies or for which no standard therapy is available. • HER2-expressing urothelial (bladder) cancer in patients previously treated with chemotherapy.
Estimated enrollment	117 patients
Primary endpoint	ORR Dose escalation portion is to determine the recommended dose of DS-8201
JAPIC/CT.gov	TBD

DS-8201 BC Pivotal P2 Study

Daiichi-Sankyo

DESTINY-Breast01

DS-8201a in Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer



Summary	A phase 2, multicenter, open-label study of DS-8201, an anti-HER2-antibody drug conjugate (ADC) for HER2 positive, unresectable and/or metastatic breast cancer patients previously treated with ado-trastuzumab emtansine (T-DM1)
Estimated enrollment	230 patients
Primary Endpoint	ORR
Secondary endpoint	OS, PFS, CBR, DOR
JAPIC/CT.gov	JapicCTI-173693 / NCT03248492

CBR: Clinical Benefit Rate, DOR: Duration of Response, ORR: Objective Response Rate, OS: Overall Survival, PFS: Progression Free Survival

DS-8201 BC P3 Study vs Physician's Choice

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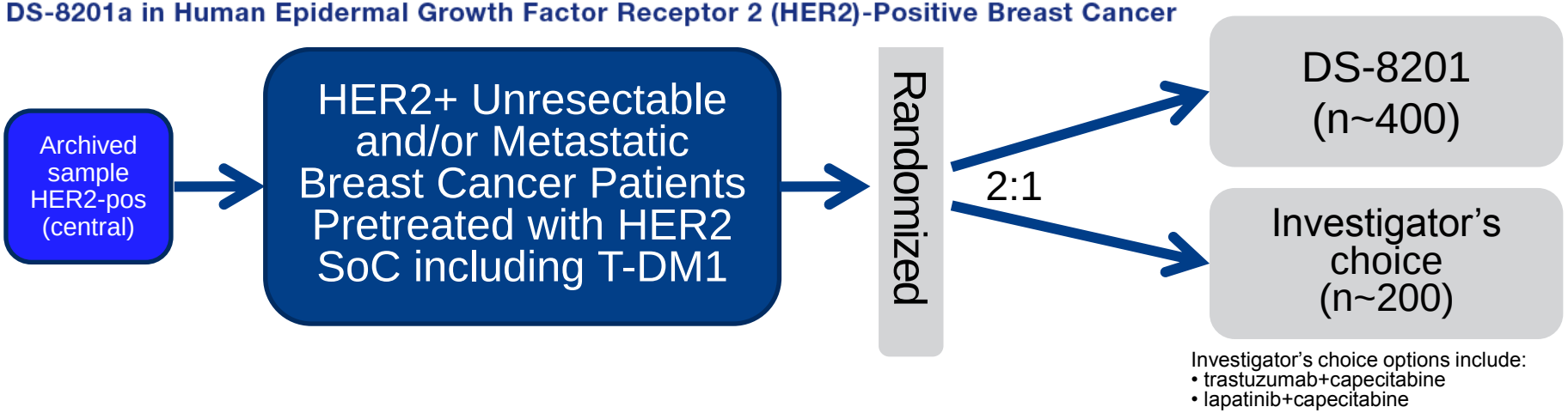
DESTINY-Breast02

DS-8201a in Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer



Investigator's choice options include:
- trastuzumab+capecitabine
- lapatinib+capecitabine

Summary	A phase 3, multicenter, randomized, open-label, active-controlled trial of DS-8201, an anti-HER2-antibody drug conjugate (ADC), versus treatment of investigator's choice for HER2-positive, unresectable and/or metastatic breast cancer patients pretreated with prior standard of care (SOC) HER2 therapies, including ado-trastuzumab emtansine (T-DM1)
Estimated enrollment	600 patients
Primary Endpoint	PFS
Secondary endpoint	OS, PK, ORR, CBR, DOR
JAPIC/CT.gov	JapicCTI-184017 / NCT03523585

CBR: Clinical Benefit Rate, DOR: Duration of Response, ORR: Objective Response Rate, OS: Overall Survival, PFS: Progression Free Survival

DS-8201 BC P3 Study vs T-DM1

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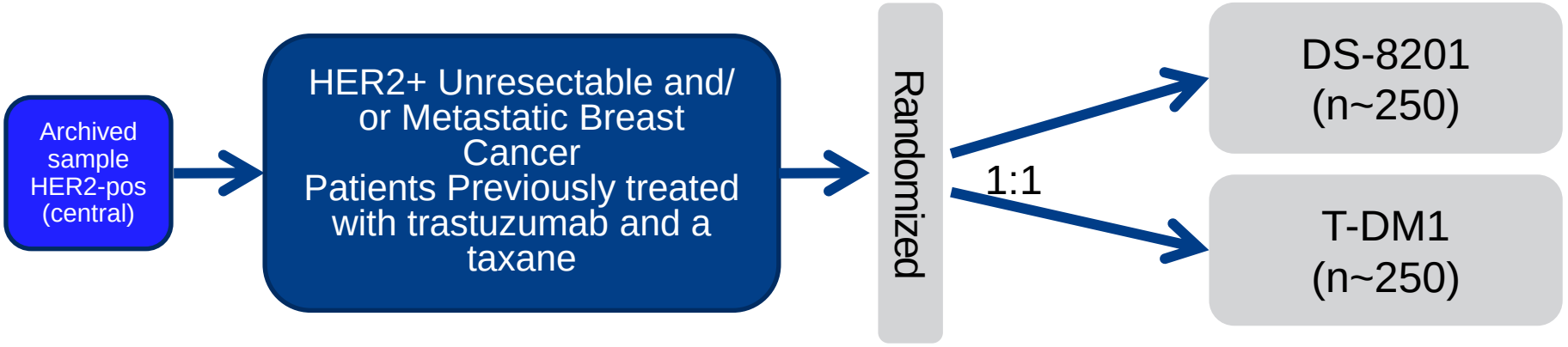
DESTINY-Breast03

DS-8201a in Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer



Summary	A phase 3, multicenter, randomized, open-label, active controlled study of DS-8201, an anti-HER2-antibody drug conjugate, versus ado-trastuzumab emtansine (T-DM1) for HER2-positive, unresectable and/or metastatic breast cancer patients previously treated with trastuzumab and a taxane
Estimated enrollment	500 patients
Primary Endpoint	PFS
Secondary endpoint	OS, PK, ORR, Safety, DOR, CBR
JAPIC/CT.gov	JapicCTI-183976 / NCT03529110

CBR: Clinical Benefit Rate, DOR: Duration of Response, ORR: Objective Response Rate, OS: Overall Survival, PFS: Progression Free Survival

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
RDE	Recommended dose for expansion
TTR	Time to response

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