Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Top Management Presentation

Financial Results of FY2017 Q2 (April 1 – September 30, 2017)

DAIICHI SANKYO CO., LTD

Sunao Manabe
President and COO

October 31, 2017

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Agenda

- FY2017 Q2 Financial Results
- FY2017 Revised Consolidated Forecast
- Major Management Topics
  - Edoxaban (Lixiana)
  - US Pain Business
  - Japan Business
- Shareholder Returns
- R&D Update

FY2017 Q2 Financial Results

Overview of FY2017 Q2 Results

(Bn JPY)

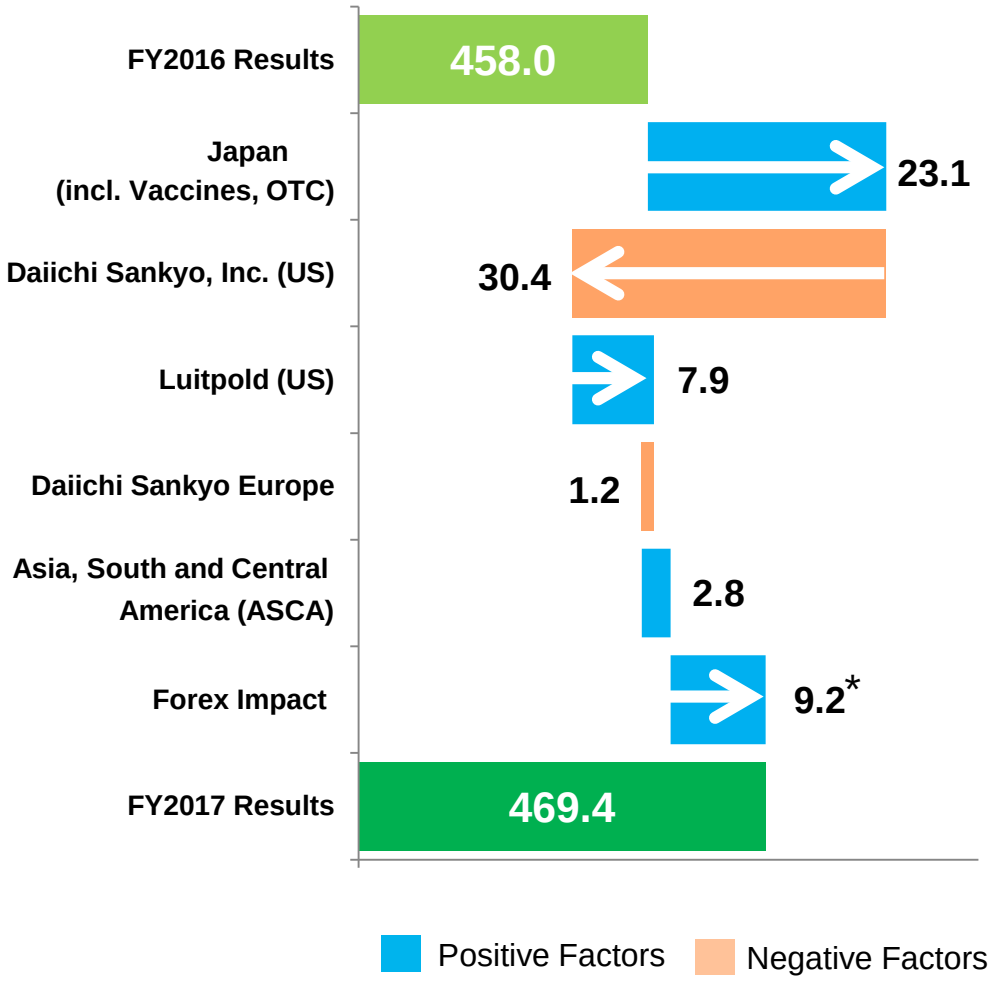
	FY2016 Q2 YTD Results	FY2017 Q2 YTD Results	YoY
Revenue	**458.0**	**469.4**	+2.5% **+11.4**
Cost of Sales	**147.3**	**157.1**	**+9.8**
SG&A Expenses	**141.7**	**140.0**	**-1.7**
R&D Expenses	**95.8**	**123.6**	**+27.8**
Operating Profit	**73.3**	**48.8**	-33.5% **-24.5**
Profit before Tax	**71.9**	**51.2**	**-20.7**
Profit attributable to owners of the Company	**49.0**	**34.3**	-30.0% **-14.7**

Currency Rate	USD/JPY	105.35	111.07	+5.72
	EUR/JPY	118.22	126.29	+8.07

Revenue

Increased by 11.4 Bn JPY (Increased by 2.2 Bn JPY excl. forex impact)

(Bn JPY)



Japan

Positive :	Lixiana	+8.2	Nexium	+2.6
	Pralia	+2.6		
	Daiichi Sankyo Espha (GE) (Telmisartan AG, Olmesartan AG, Rosuvastatin AG etc.)	+7.4		
Negative :	Olmetec	-3.0		

Daiichi Sankyo Healthcare (OTC) +3.6

Global (excl. Forex Impact)

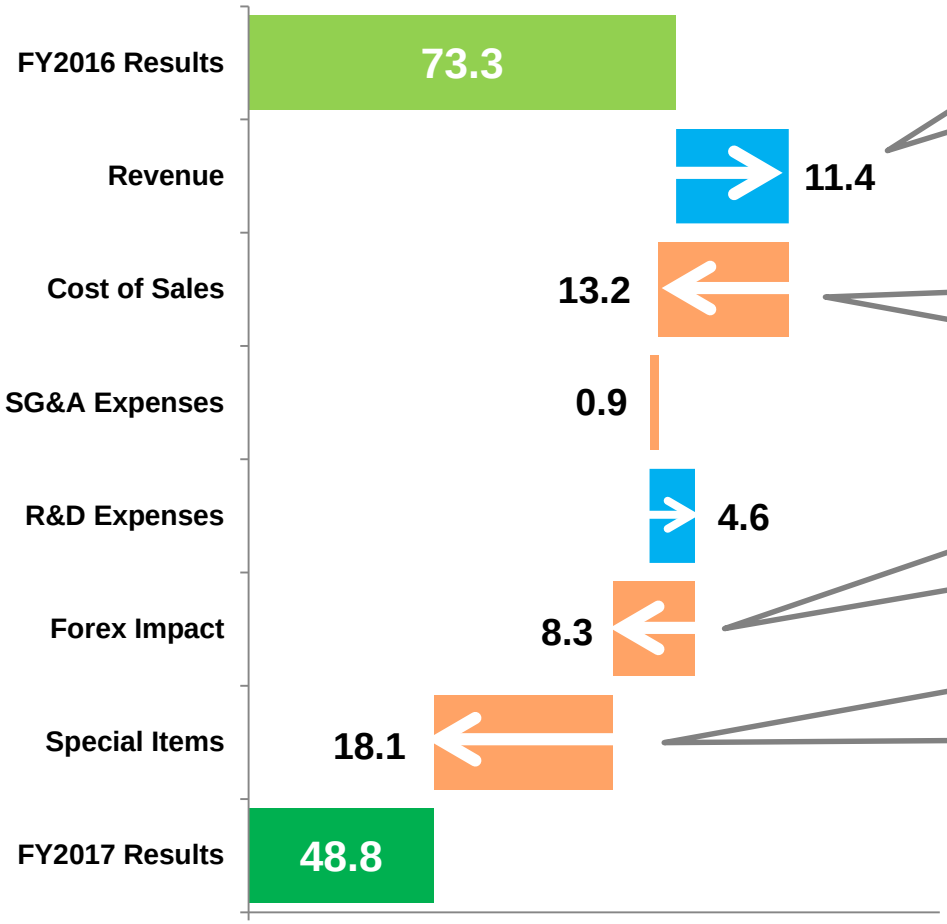
Daiichi Sankyo, Inc. :	Olmesartan	-26.9
	Effient	-3.2
Luitpold :	GE injectables	+4.6
	Injectafer	+4.2
Daiichi Sankyo Europe :	Lixiana	+7.0
	Olmesartan	-7.9

* Forex impact USD: +5.0, EUR : +2.4, ASCA: +1.8

Operating Profit

Decreased by 24.5 Bn JPY
(Decreased by 7.3 Bn JPY excl. forex impact and special items)

(Bn JPY)



Revenue +11.4
incl. forex impact +9.2

Cost of Sales +13.2
Product mix due to impact of olmesartan LOE

Forex impact +8.3
Cost of Sales +2.7
SG&A Expenses +3.4
R&D Expenses +2.2

Special items +18.1
Cost of Sales -6.1
SG&A Expenses -6.0
R&D Expenses +30.2

Positive Factors Negative Factors

Special Items

(Bn JPY)

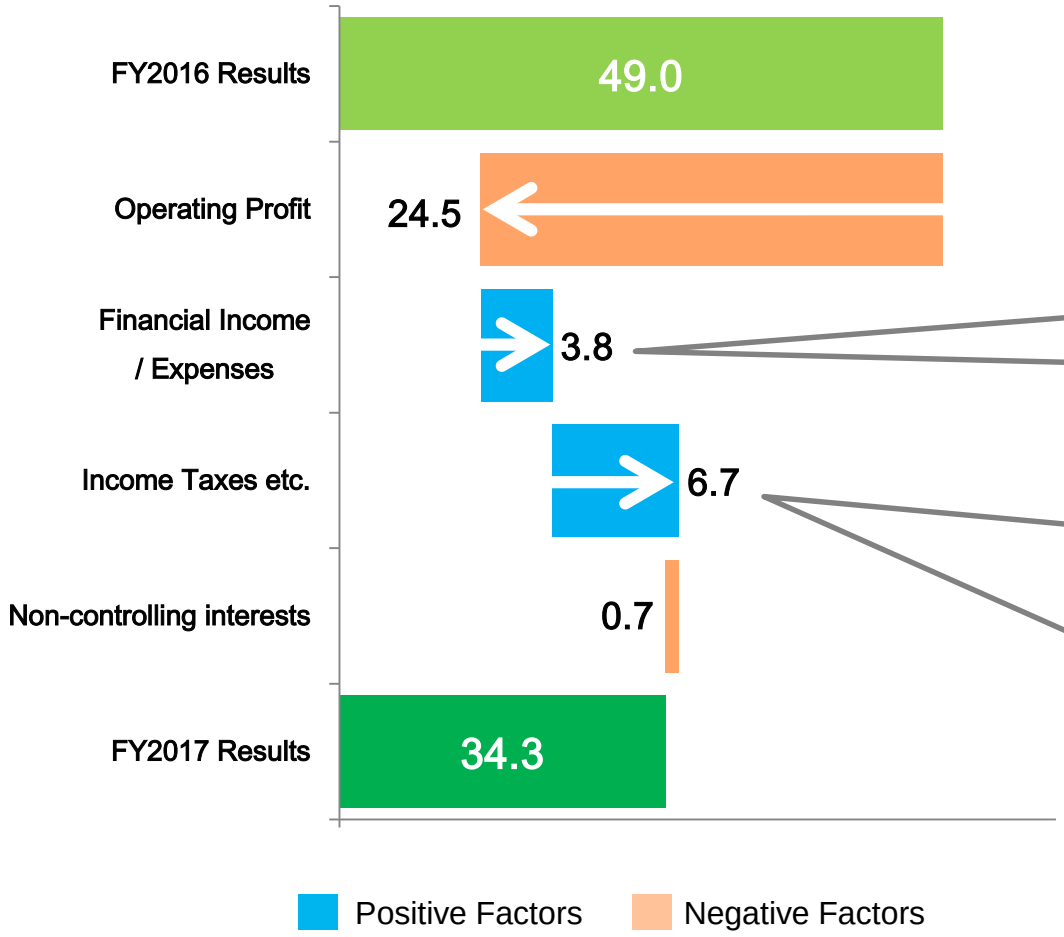
	FY2016 Q2 YTD Results	FY2017 Q2 YTD Results	YoY
Cost of Sales	-	Gain on sales of fixed assets -6.1	-6.1
SG&A Expenses	Restructuring costs in EU +6.0	-	-6.0
R&D Expenses	-	Impairment loss +30.2 (incl. CL-108 +27.8)	+30.2
Total	+6.0	+24.1	+18.1

- : Cost decrease items

Profit Attributable to Owners of the Company

Decreased by 14.7 Bn JPY

(Bn JPY)



Financial Income / Expenses **-3.8**

Improvement of forex gains/ losses

	FY2016 Q2 YTD Results	FY2017 Q2 YTD Results	YoY
Profit before Tax	71.9	51.2	-20.7
Income Taxes etc.	24.1	17.4	-6.7
Tax rate	33.5%	34.1%	+0.6%

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2016 Q2 YTD Results	FY2017 Q2 YTD Results	YoY	vs. Forecast (%)
Japan	**239.0**	**257.6**	**+18.6**	**48.1%**
Daiichi Sankyo Healthcare	**32.2**	**35.8**	**+3.6**	**51.9%**
Daiichi Sankyo Inc.	**70.3**	**42.0**	**-28.2**	**67.8%**
Olmesartan	36.7	10.3	-26.3	73.7%
Welchol	19.5	19.7	+0.2	73.0%
Effient	10.8	8.0	-2.8	-
Savaysa	0.9	1.0	+0.1	50.7%
Movantik	1.9	2.5	+0.7	-
Luitpold	**41.7**	**52.4**	**+10.6**	**50.8%**
Venofer	13.9	14.7	+0.9	52.6%
Injectafer	11.1	16.1	+5.0	48.9%
GE injectables	14.1	19.7	+5.7	-
Daiichi Sankyo Europe	**37.0**	**38.2**	**+1.3**	**58.0%**
Olmesartan	24.7	18.0	-6.7	69.0%
Efient	4.2	3.9	-0.3	55.3%
Lixiana	3.3	11.0	+7.7	50.1%
ASCA (Asia, South and Central America)	**34.0**	**38.6**	**+4.6**	**45.9%**

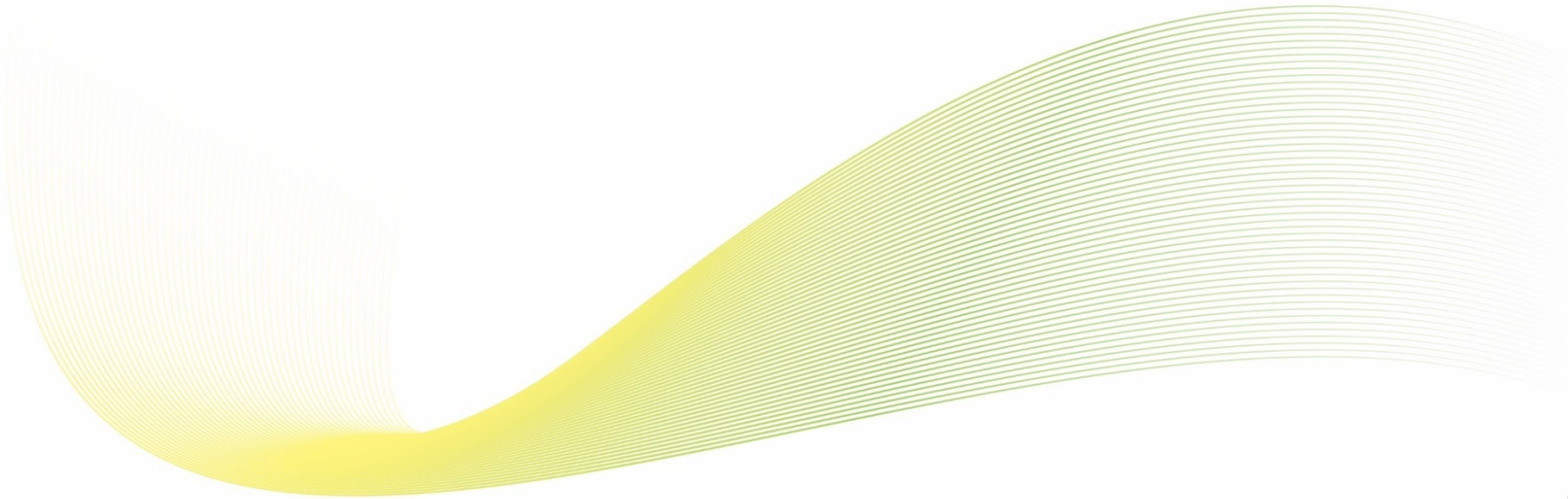
Currency Rate	USD/JPY	105.35	111.07	+5.72
	EUR/JPY	118.22	126.29	+8.07

Revenue: Major Products in Japan

(Bn JPY)

		FY2016 Q2 YTD Results	FY2017 Q2 YTD Results	YoY	vs. Forecast (%)
Nexium	ulcer treatment	**42.0**	**44.7**	**+2.6**	**48.6%**
Memary	Alzheimer's disease treatment	**23.4**	**24.5**	**+1.1**	**45.4%**
Olmetec	antihypertensive agent	**34.9**	**31.9**	**-3.0**	**67.8%**
Lixiana	anticoagulant	**11.5**	**19.7**	**+8.2**	**50.4%**
Loxonin	anti-inflammatory analgesic	**18.8**	**18.9**	**+0.1**	**57.2%**
Tenelia	type 2 diabetes mellitus treatment	**11.8**	**13.2**	**+1.5**	**44.1%**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**8.3**	**10.9**	**+2.6**	**47.2%**
Rezaltas	antihypertensive agent	**8.8**	**8.5**	**-0.3**	**53.4%**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**6.8**	**7.6**	**+0.8**	**50.4%**
Efient	antiplatelet agent	**4.9**	**6.4**	**+1.5**	**49.0%**
Inavir	anti-influenza treatment	**0.6**	**1.1**	**+0.5**	**8.3%**
Cravit	synthetic antibacterial agent	**7.3**	**6.4**	**-1.0**	**49.0%**
Urief	treatment for dysuria	**5.8**	**5.6**	**-0.1**	**51.1%**
Omnipaque	contrast medium	**7.2**	**7.1**	**-0.0**	**64.7%**
Mevalotin	antihyperlipidemic agent	**5.5**	**4.6**	**-0.8**	**46.2%**

FY2017 Revised Consolidated Forecast



FY2017 Revised Consolidated Forecast

(JPY Bn)

	FY2017 Forecast (as of May.)	FY2017 Forecast (as of Oct.)	vs. Forecast (as of May.)
Revenue	**930.0**	**930.0**	**0.0**
Cost of Sales	**340.0**	**337.0**	**-3.0**
SG&A Expenses	**300.0**	**297.0**	**-3.0**
R&D Expenses	**190.0**	**221.0**	**+31.0**
Operating Profit	**100.0**	**75.0**	**-25.0**
Profit before Tax	**100.0**	**75.0**	**-25.0**
Profit attributable to owners of the Company	**66.0**	**50.0**	**-16.0**

Major factors
- Gain on sales of fixed assets -6.1
  *booked in Q2
- Increase due to product mix +3.0

Major factors
- Efficient execution of expenses -3.0

Major factors
- Impairment loss (intangible incl. CL-108) +30.2
  *booked in Q2

Currency Rate	**USD/JPY**	**110.00**	**110.54**
	EUR/JPY	**120.00**	**123.14**

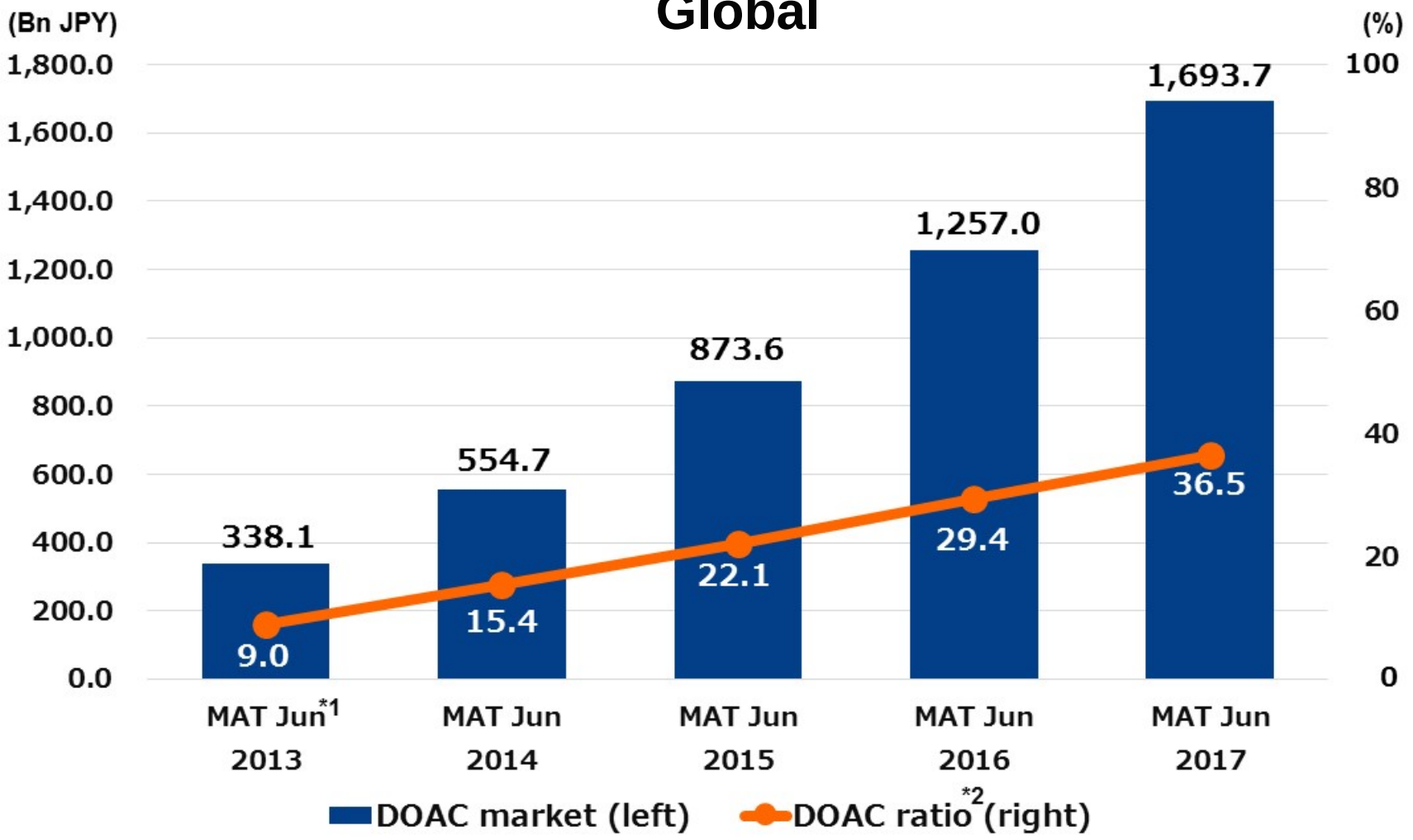
Assumption of currency rate for Q3 and Q4
USD/JPY：110, EUR/JPY：120

Major Management Topics

- **Edoxaban (Lixiana)**
- US Pain Business
- Japan Business

Direct Oral Anticoagulant (DOAC) Market

Global

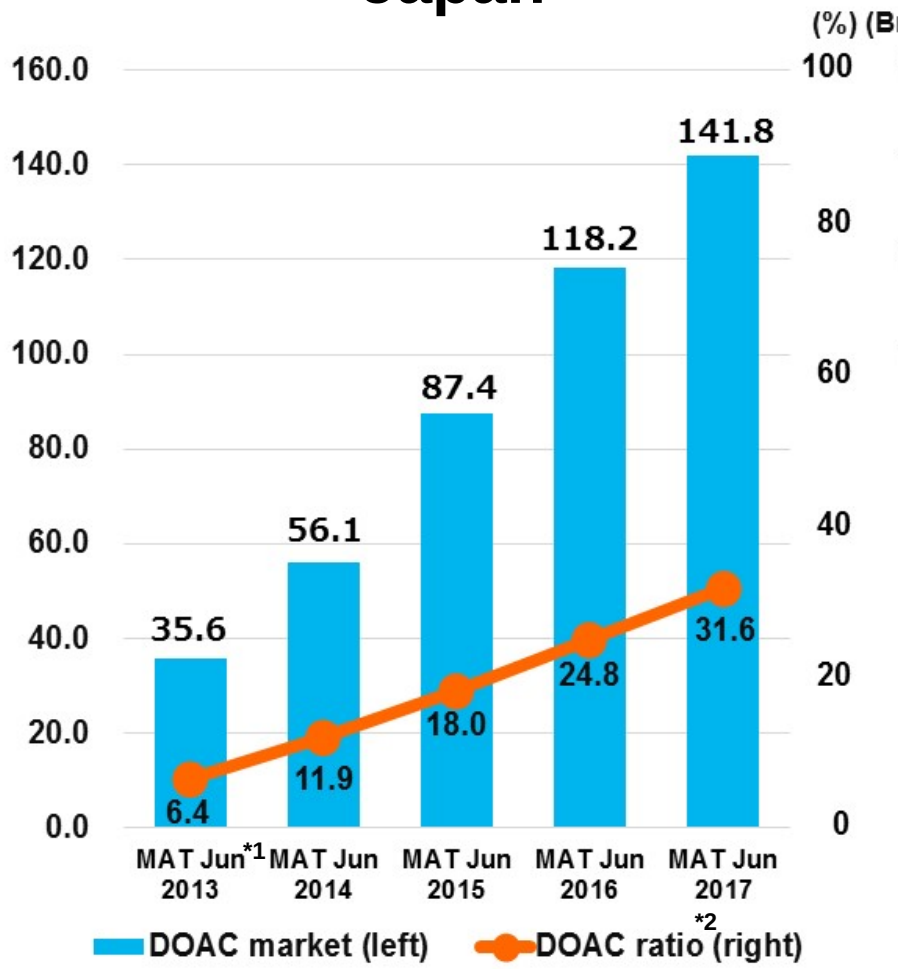


Currency Rate USD/JPY : 110

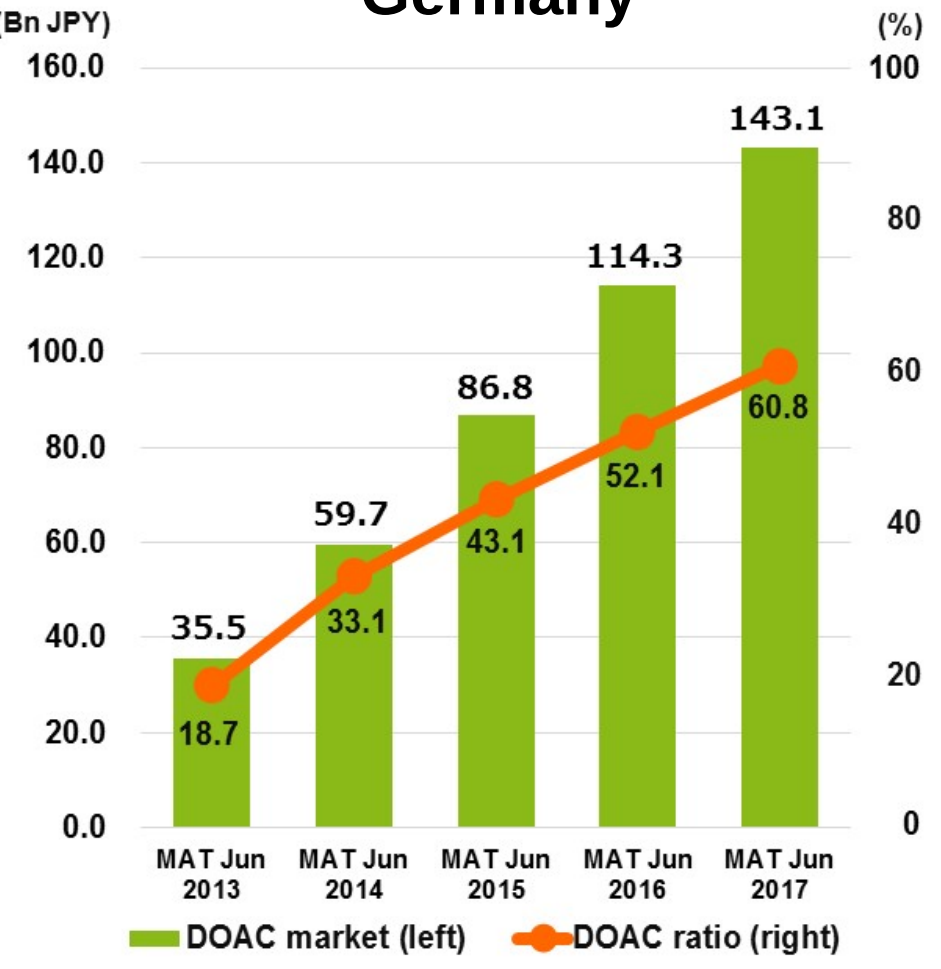
*1: July 2012 – June 2013
*2: Percentage of DOAC prescription counts to total prescriptions of warfarin and DOAC

DOAC Market in Japan and Germany

Japan



Germany

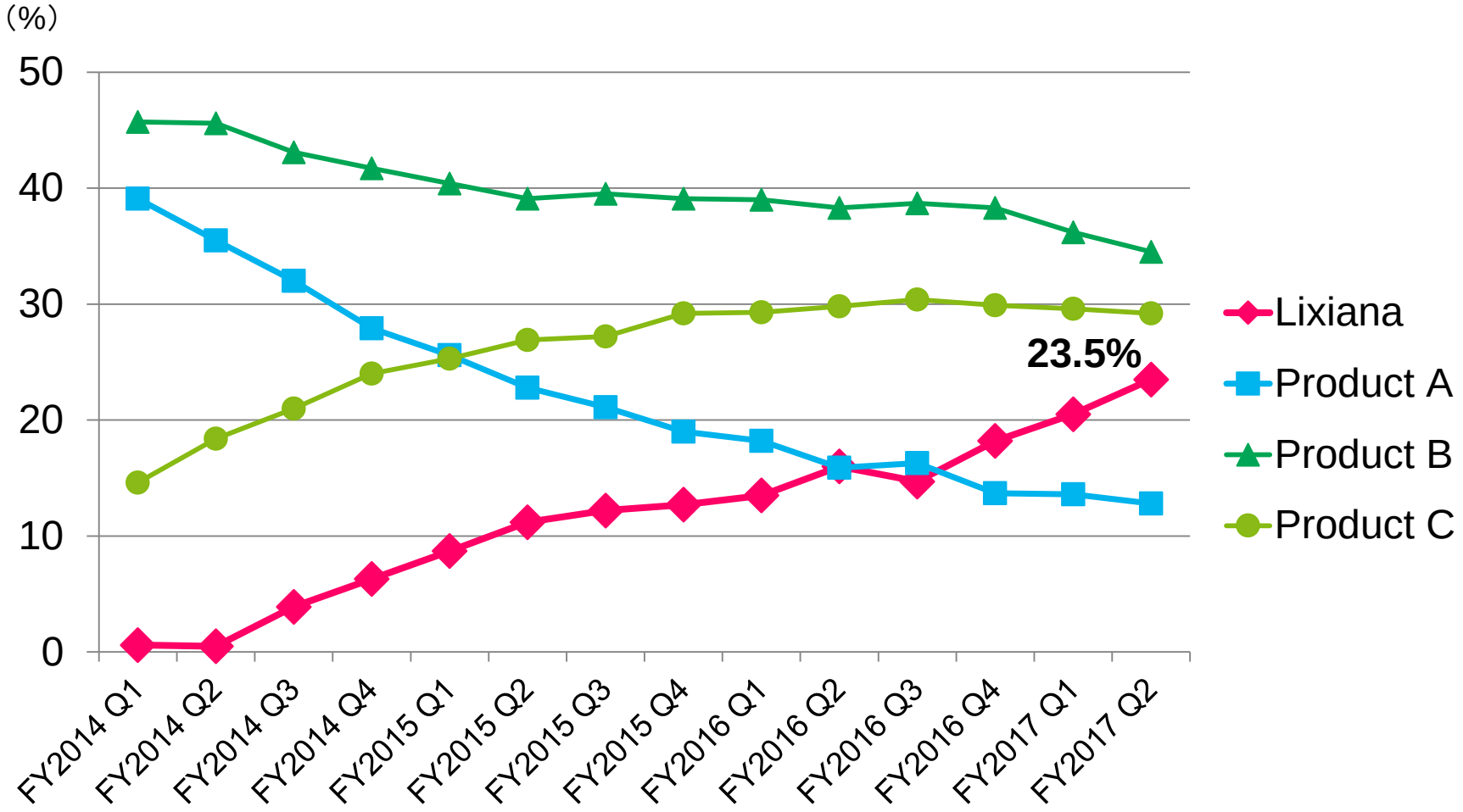


Currency Rate USD/JPY : 110

*1: July 2012 – June 2013
*2: Percentage of DOAC prescription counts to total prescriptions of warfarin and DOAC

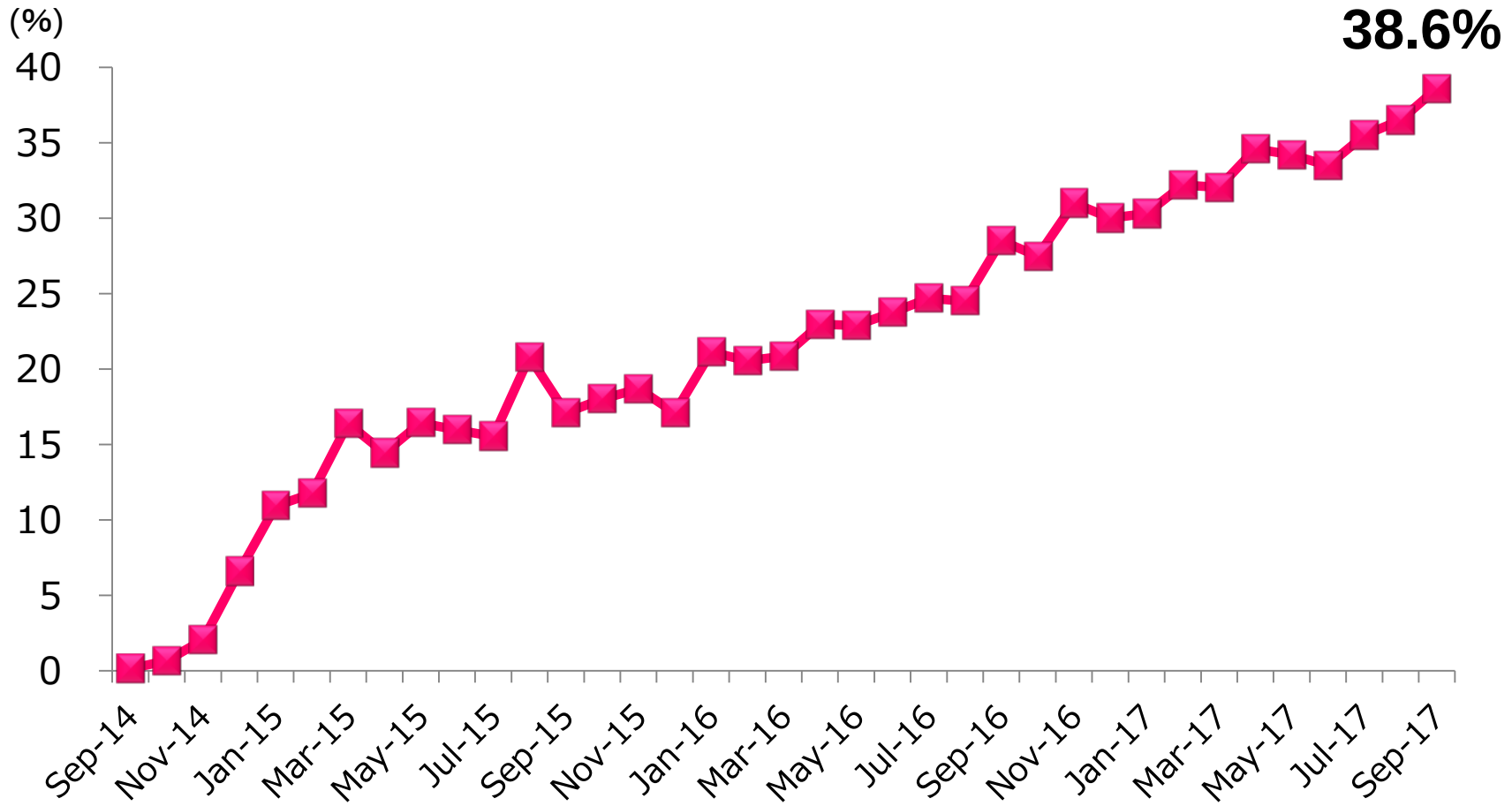
Lixiana: Growth in Japan

As of FY2017 Q2, Lixiana increased its sales share to **23.5%**.



Lixiana: Growth in Japan

Lixiana has reached top Rxs share since Mar. 2017 in prescription number of new patients for AF+VTE. The share expanded to **38.6%** in Sep. 2017.

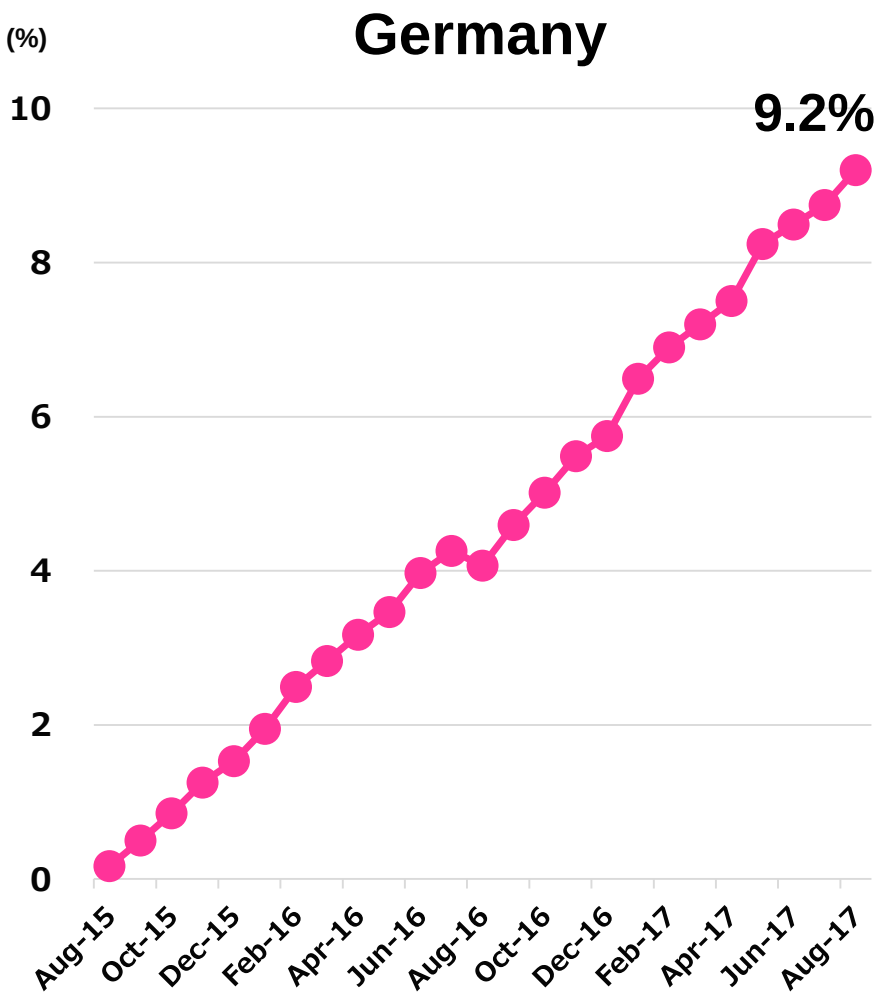


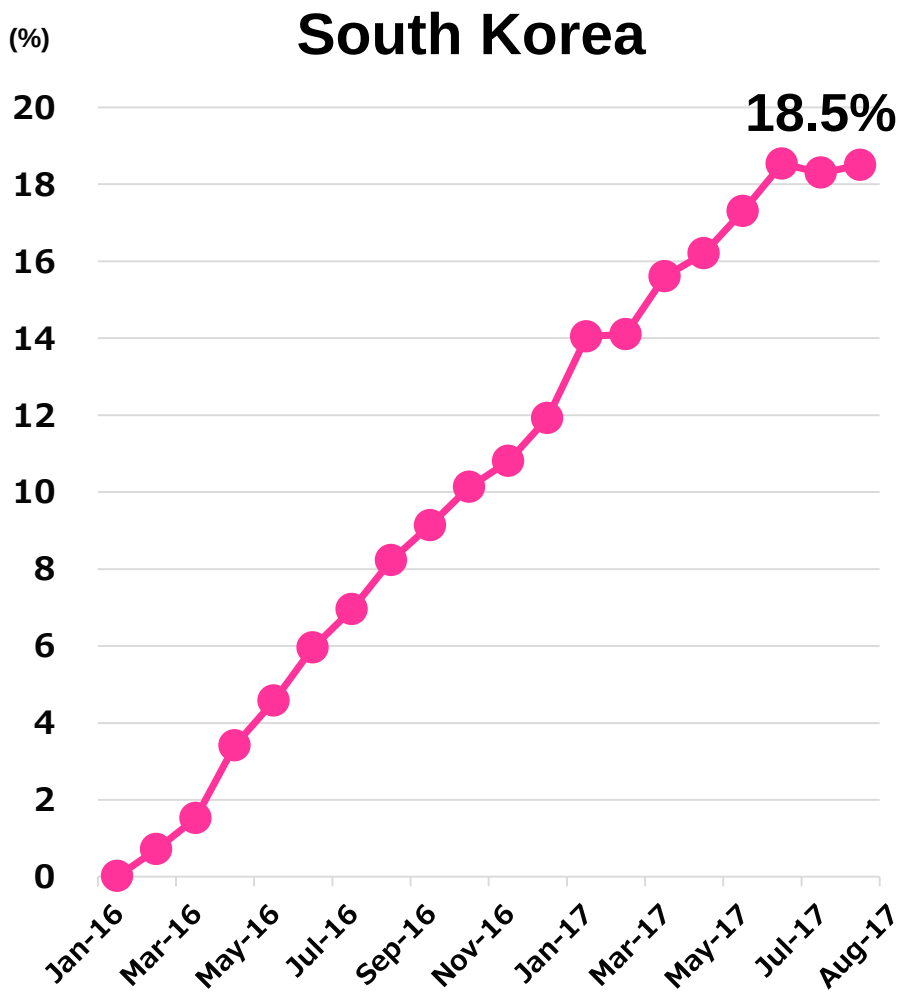
Source : Medi-trend

Lixiana: Growth in Germany and South Korea

Daiichi-Sankyo

Steady uptake of sales share after launch



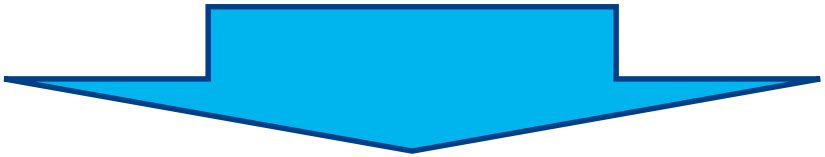


Major Management Topics

- Edoxaban (LIXIANA)
- **US Pain Business**
- Japan Business

Changes in US Pain Business

- CL-108
  - Jan. 2017, received Complete Response Letter from FDA
  - Aug. 2017, decided to return all of rights regarding CL-108 to Charleston Laboratories, Inc.
- Mirogabalin
  - In the phase 3 ALDAY clinical trials evaluating mirogabalin for the treatment of pain associated with fibromyalgia, mirogabalin did not meet the primary efficacy endpoint.



We take the complex issues surrounding the US opioid market very seriously. We are committed to marketing our three pain care medicines, Movantik™, MorphaBond™ ER and RoxyBond™, in a responsible manner while responding to patient needs.

DSI: Commitments in Pain Care

- Daiichi Sankyo recognizes that **pain management may require the appropriate use of prescription medicines** including controlled substances such as opioids, which may be subject to many safety concerns including diversion, misuse, abuse, addiction, or overdose.

- We are also **cognizant of the tragic individual and societal consequences** that can result from the improper use of controlled substances.

- Daiichi Sankyo is deeply **committed to being part of the solution to prescription drug abuse** and we will **undertake the marketing and distribution of our pain management products as well as engagement with our customers with a great sense of responsibility and professionalism.**

- We have **established Commitments in Pain Care** – a program dedicated to **awareness and education around responsible pain management.**

Commitments
IN PAIN CARE

For more information, please visit www.CommitmentsinPainCare.com.

Three Pain Management Products in US

Daiichi-Sankyo

Expand sales of Movantik™

movantik™

- Opioid-Induced Constipation (OIC)
- Raised awareness of burden of OIC

Responsibly launch MorphaBond™ ER

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

- Single-agent, extended release morphine approved by FDA to deter abuse by both the intranasal and intravenous routes of administration
- **Launched October 2017**

Prepare for launch of RoxyBond™

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

- **First and only** immediate-release opioid approved by FDA with approved labeling describing its abuse-deterrent properties (intranasal & intravenous)
- **Launch expected 2018**

- MorphaBond ER and RoxyBond are formulated with SentryBond™, a technology that uses multiple overlapping abuse-deterrent barriers to make the tablet more difficult to adulterate for misuse and abuse.
- MorphaBond ER and RoxyBond are expected to deter common forms of abuse, intranasal and injection. However, abuse by intranasal, intravenous, and oral routes is still possible.

Major Management Topics

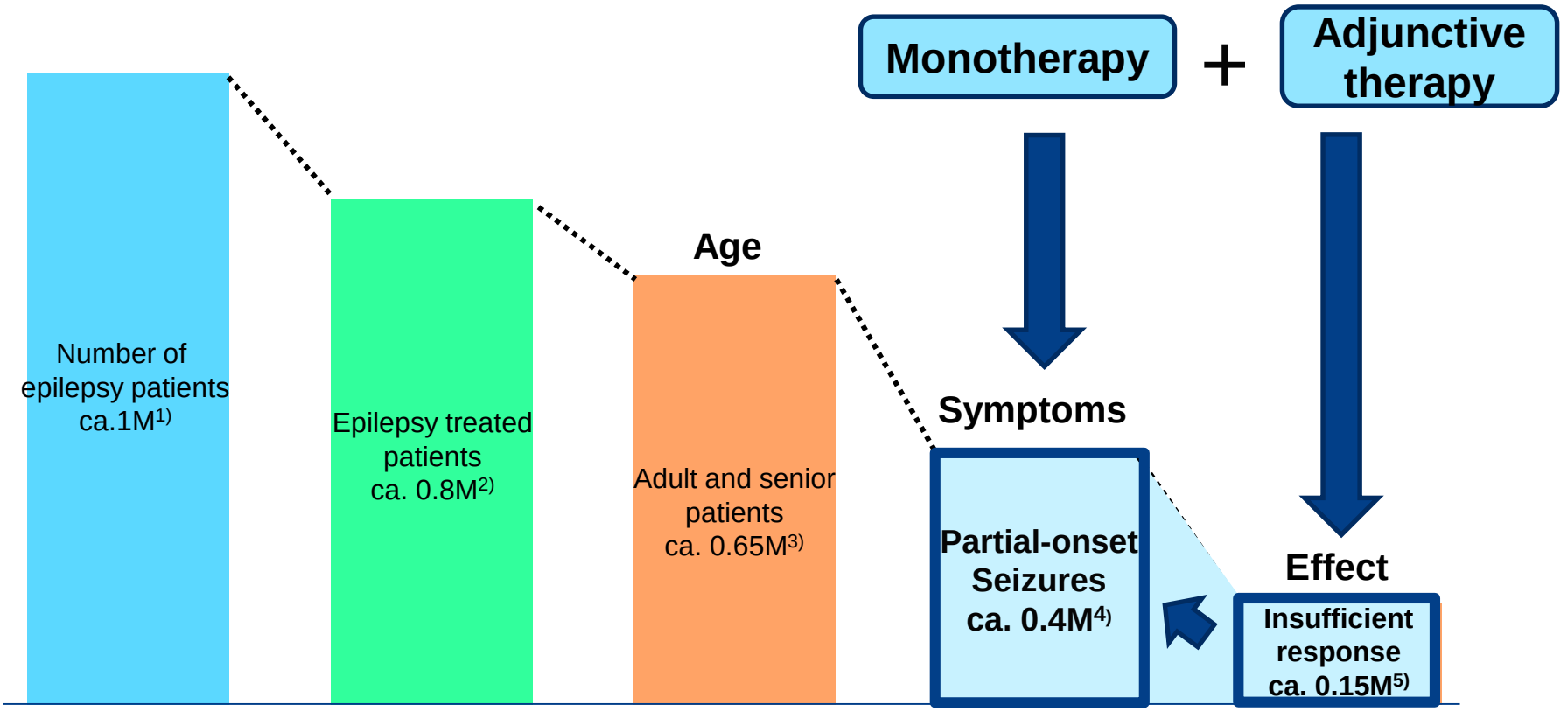
- Edoxaban (Lixiana)
- US Pain Business
- **Japan Business**

VIMPAT: Additional Indication and Lift of Prescription Period Restriction

- Aug. 2017, **approved as monotherapy*** for partial-onset seizure in epilepsy patients
  * Conventionally approved and marketed as an adjunctive therapy
- Sep. 2017, **lifted restriction on prescription period**
- UCB Japan manufacture the product. Daiichi Sankyo distribute/sale VIMPAT with both companies' promotion

VIMPAT: New Options for Epilepsy Medication

- Approval of VIMPAT for monotherapy expand the target patient population



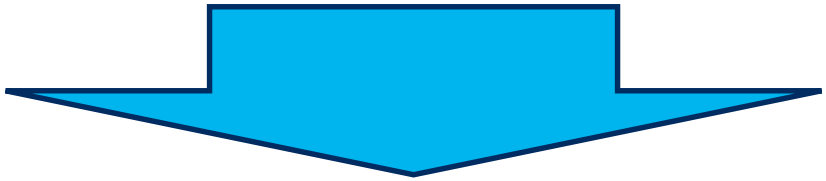
1) "Guide book for epilepsy specialists" ISBN: 9784787820341 (Japanese)
2) Estimated from external data
3) Estimated from patient survey by Ministry of Health, Labor and Welfare
4) Estimated from Hauser WA. et al:Epilepsia 34,453-468,1993
5) Estimated from Kwan P. et al:N.Engl.J.Med. 342,314-319,2002

CANALIA Combination Tablet: Launched in Sep. 2017

- **Combination product of Tenelia and Canaglu tablets**, two agents for **type 2 diabetes mellitus treatments**, created by Mitsubishi Tanabe Pharma Corporation
- DPP-4 inhibitor/SGLT2 inhibitor combination drug, **first launched in Japan**
- **Approximately 10%** of DPP-4 inhibitors are prescribed in combination with SGLT2 inhibitors
- CANALIA Combination Tablets contributes as a new option for diabetes treatment by benefits such as **reduced number of tablets to take** and **improved compliance** of medication
- Marketing by Daiichi Sankyo, and co-promoting with Mitsubishi Tanabe

Expansion of Product Portfolio in Japan

- **Achieved the primary endpoint in Phase 3 studies**
  - **Mirogabalin** (Japan, Asia)
    - ✓ Patients with post-herpetic neuralgia and patients with diabetic peripheral neuropathic pain
    - ✓ Evaluated weekly average daily pain score from baseline
  - **Esaxerenone/CS-3150** (Japan)
    - ✓ Patients with essential hypertension*
    - ✓ Evaluated efficacy and safety compared to eplerenone



NDA Submission in FY2017 Q4

* : hypertension, which cause can not be identified due to blood tests or various imaging tests, accounting for about 90% of hypertension

Shareholder Returns

Shareholder Returns

Shareholder Returns Policy during 5YBP*

- Total return ratio: 100% or more
- Annual ordinary dividend: more than 70 JPY
- Flexible acquisition of own shares

* 5YBP: 5-year Business Plan (FY2016 - FY2020)

	FY2016 Results	FY2017 Plan	(Target during 5YBP)
Total return ratio	**180.7%**		**100% or more**
Dividend	**70 JPY**	**70 JPY**	**more than 70 JPY**
Acquisition of own shares	**50.0 Bn JPY**	**flexible**	**flexible**

<Decided to acquire own shares>

- Acquisition period: From Nov. 1, 2017, to Mar. 23, 2018
- Aggregate amount of acquisition cost: 50.0 billion JPY (maximum)
- Total number of shares to be acquired: 28 million shares (maximum)

R&D Update

Glenn Gormley MD PhD

Senior Executive Officer

Global Head of R&D

Agenda

- R&D Focus and Efficiency
- Oncology Update
  - DS-8201 Update
  - U3-1402 Update
  - New Projects Entered to Clinical Phase
  - New Collaboration in Oncology
- Esaxerenone/CS-3150 Update
- FY2017 Major R&D Milestone Events
- Announcement of R&D Day
- Back-up
  - Pipeline Chart
  - Study Designs of Major Ongoing Clinical Studies
  - Abbreviations

R&D Focus and Efficiency

R&D Focus and Efficiency

- **Prioritize projects**
- **Invest selectively to oncology, especially to ADC/AML Franchises**
- **Accelerate clinical development by focused investment**

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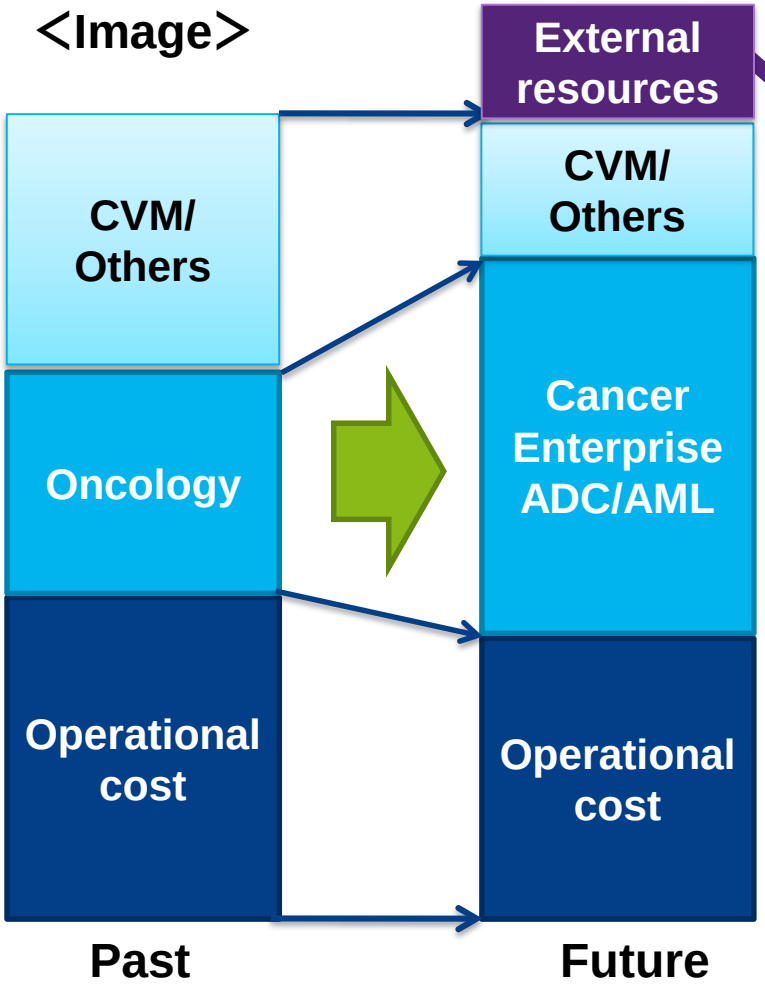


- **Projects which do not align with our strategic focus may be out-licensed to preserve value of the assets**

  - **DS-5010（Selective RET Inhibitor）**
    - ✓ Out-licensed to Boston Pharmaceuticals Inc. global
  - Other possible projects for licensing-out
    - ✓ DS-6051 (NTRK/ROS1 inhibitor) global
    - ✓ DS-2969 (*Clostridium difficile* infection/ GyrB inhibitor) global

DS-8201 Update

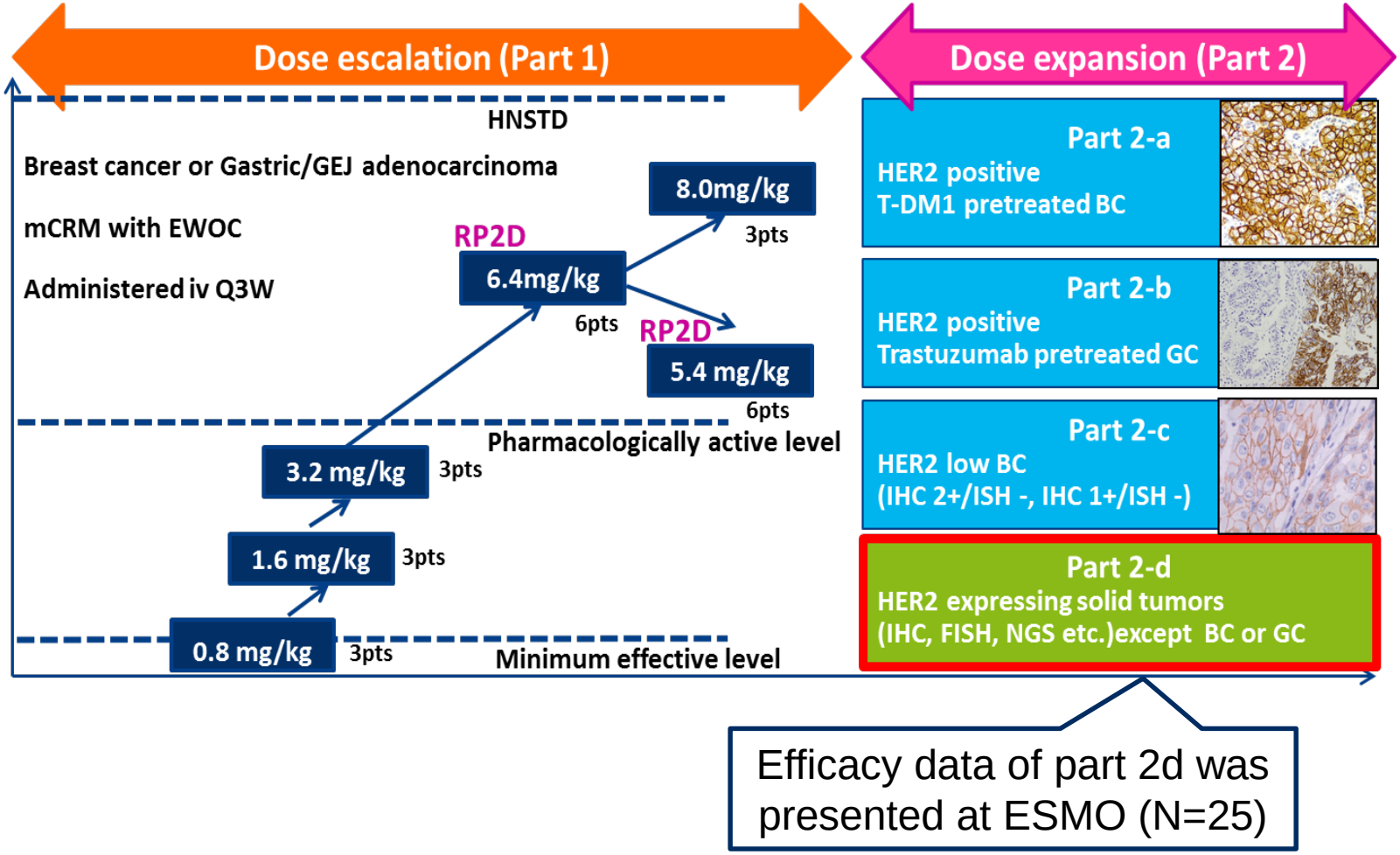
U3-1402 Update

DS-8201: P1 Study Part 2d Result

ESMO2017 Poster

Daiichi-Sankyo

- Results of HER2 expressing solid tumors (other than breast cancer and gastric cancer) in the phase 1 study were presented.
  (BC and GC results were presented at ASCO 2017)



Efficacy data of part 2d was presented at ESMO (N=25)

DS-8201: P1 Study Part 2d Patient Demographics

Patient characteristic	Part 2d (N=25)	
Age, median (range)	60.0	(44-72)
Number of prior regimens, median (range)	3	(0-10)
Tumor Type	**Part 2d (N=25)**	
Colorectal	11	(44.0%)
NSCLC	6	(24.0%)
Salivary	4	(16.0%)
Others†	4	(16.0%)

† 2 Paget's disease, 1 Cholangiocarcinoma, 1 Esophageal cancer

DS-8201: P1 Study Part 2d Efficacy (6.4mg/kg)

	ORR N (%) ‡	DCR N (%)
Part 2d overall †	**7/22 (31.8)**	**18/22 (81.8)**
Colorectal Cancer	**2/10 (20.0)**	**8/10 (80.0)**
NSCLC	**1/5 (20.0)**	**3/5 (60.0)**
Salivary Cancer	**3/4 (75.0)**	**4/4 (100.0)**
Others §	**1/3 (33.3)**	**3/3 (100.0)**

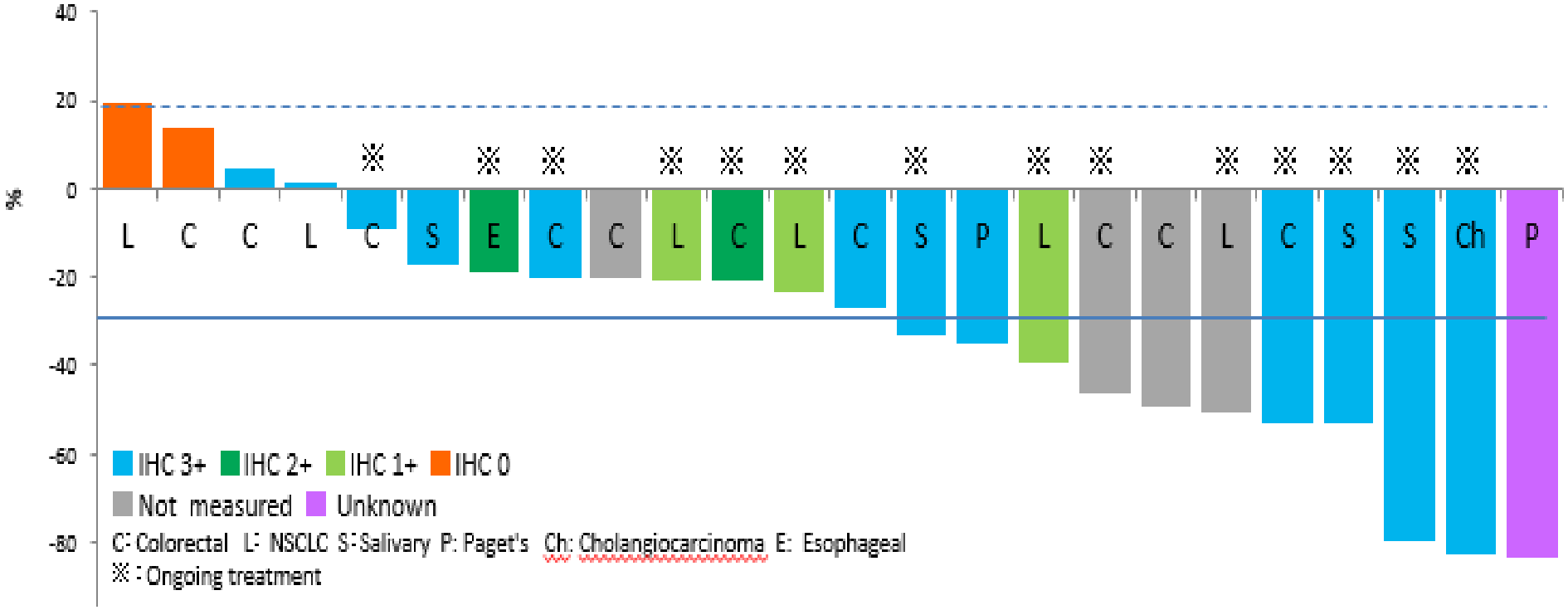
† 3 of 25 patients in 2d were enrolled, but have <2 post-baseline scans and therefore cannot be evaluated for confirmed response.

‡ 1 Colorectal Cancer and 1 Lung Cancer were evaluated once for PR.

§ Others include Paget's Disease, Cholangiocarcinoma and Esophageal Cancer.

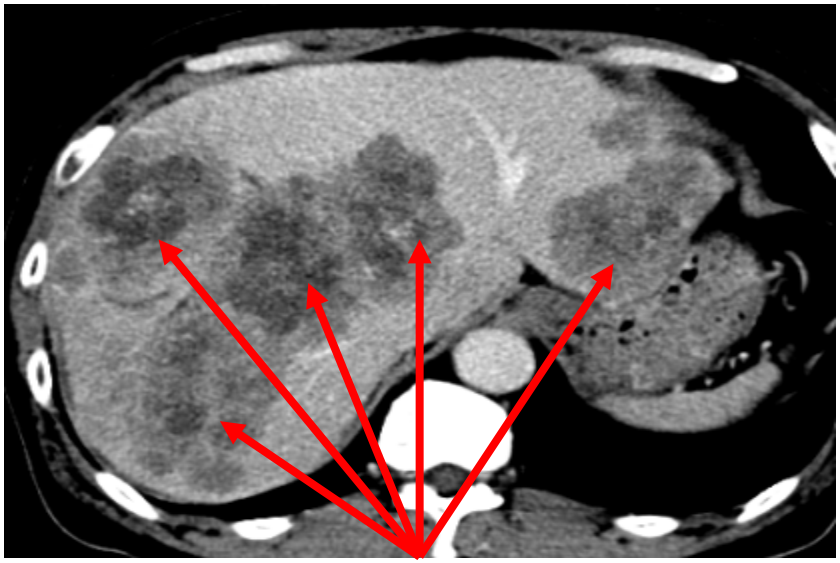
DS-8201: P1 Study Part 2d Efficacy

Tumor size: Maximum % change from baseline



Tumor shrinkage was observed in most patients

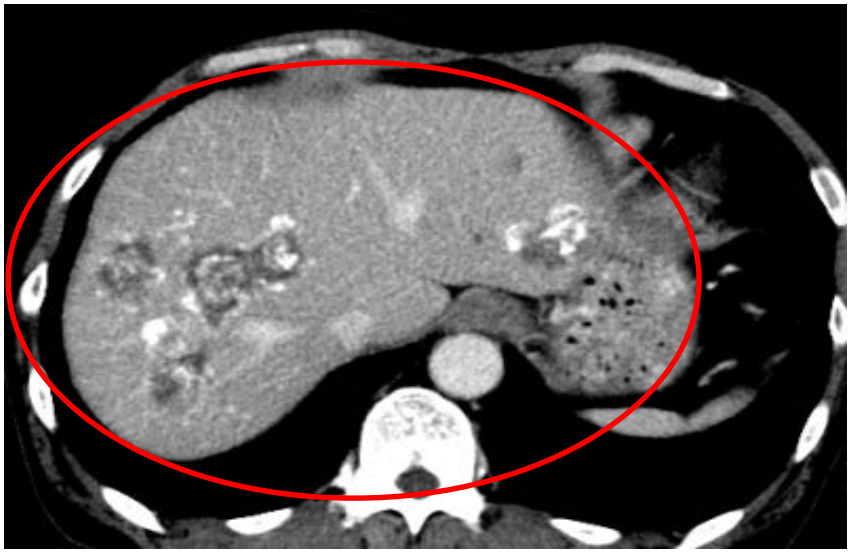
59 y/o Male Colorectal cancer with Liver Mets, IHC 3+ (6.4mg/kg)



Liver metastasis

Day 0

After 8 cycles



Day 175

More than 30% tumor shrinkage was observed (PR)

DS-8201: Part 1 to Part 2 Safety Profile

ESMO2017 Poster

Daiichi-Sankyo

Dose escalation (Part 1)

Dose expansion (Part 2)

HNSTD

Breast cancer or Gastric/GEJ adenocarcinoma

mCRM with EXOC

Administered iv Q3W

8.0mg/kg 3pts

RP2D 6.4mg/kg 6pts

RP2D 5.4 mg/kg 6pts

Pharmacologically active level

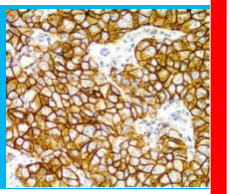
3.2 mg/kg 3pts

1.6 mg/kg 3pts

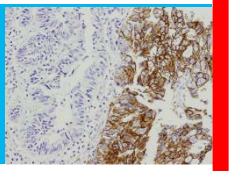
0.8 mg/kg 3pts

Minimum effective level

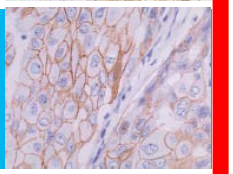
Part 2-a
HER2 positive
T-DM1 pretreated BC



Part 2-b
HER2 positive
Trastuzumab pretreated GC



Part 2-c
HER2 low BC
(IHC 2+/ISH -, IHC 1+/ISH -)



Part 2-d
HER2 expressing solid tumors except BC or GC (IHC, FISH, NGS etc.)

Safety chart in next page covers from part 1 to part 2 (N=168)

DS-8201: P1 Study Safety – TEAE, any grade, >20%

ESMO2017 Poster

Preferred Term Part 1 +Part 2 Total (N=168)	Grade 1 (%)	Grade 2 (%)	Grade 3 (%)	Grade 4 (%)	All (%)
Hematologic					
Anemia	3.6	11.9	13.1	1.2	29.8
Platelet count decreased	11.9	7.7	6.5	3.0	29.2
Neutrophil count decreased	1.2	7.7	13.7	2.4	25.0
White blood cell count decreased	1.2	10.1	11.3	1.8	24.4
Gastrointestinal disorders					
Nausea	51.8	13.1	2.4	0.0	67.3
Decreased appetite	34.5	17.9	3.6	0.0	56.0
Vomiting	28.0	4.2	1.2	0.0	33.3
Diarrhea	19.6	4.8	1.2	0.0	25.6
Constipation	20.8	3.0	0.6	0.0	24.4
Others					
Alopecia	20.8	5.4	0.0	0.0	26.2
Malaise	16.7	4.8	0.6	0.0	22.6

No dose-limiting toxicity (DLT) observed.
Low incidence of grade 4 adverse events.

DS-8201: P1 Study Part 2d Conclusions

ESMO2017 Poster

- DS-8201 was **well tolerated** and MTD was not reached in the dose escalation part.
- Of 22 evaluable patients treated in Part 2d, the **ORR was 31.8%** and **DCR was 81.8%**.
- Most of the patients with HER2 expressing solid tumors had tumor shrinkage on treatment and experienced an acceptable **safety profile**.
- Based on these interim results further investigation of DS-8201 in HER2 expressing **solid tumors beyond BC and GC is possible**.

DS-8201: Development Plan

Current Development | Planned to start 2H FY2017 | Planned

2016 — 2020 — 2024+

- HER2+ breast cancer (T-DM1 failure)
  Phase 2 pivotal study ongoing — BTD
- HER2+ gastric cancer (Herceptin failure)
  Phase 2 pivotal study started (Japan, Korea)

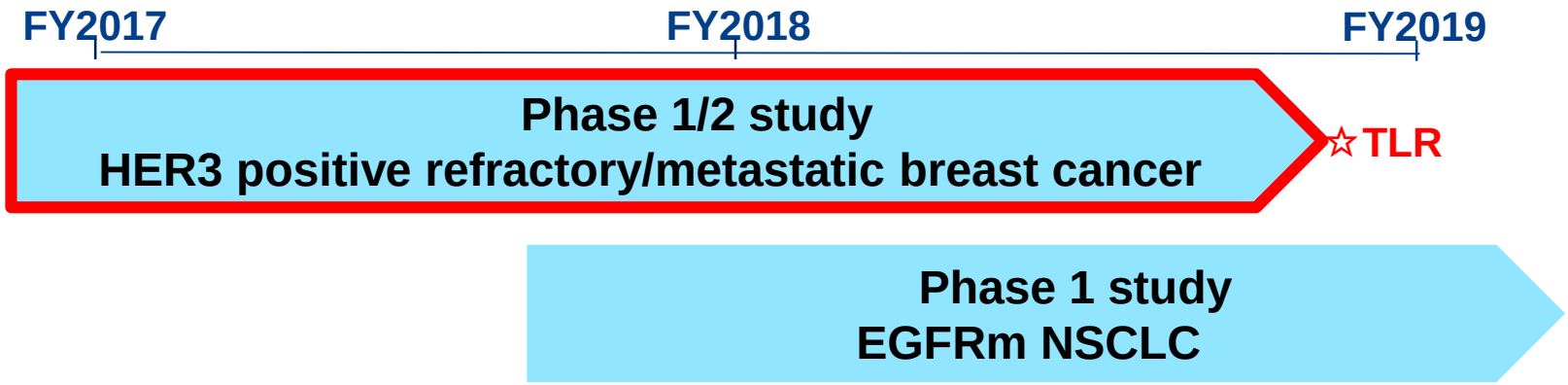
Tracking for 2020 submission

- HER2+ breast and bladder cancer
  Ph 1b nivolumab combination under preparation
- HER2 low breast cancer
- HER2+ NSCLC and CRC
- Earlier lines HER2+ breast cancer

Submission post 2021

U3-1402: Development Plan

- Clinical trial schedule



- HER3 positive refractory/metastatic breast cancer Phase 1/2 study
  - Phase 1 study to be presented at conference in FY2018
  - Phase 2 study starts in FY2018 Q1
  - TLR: FY2018 Q4

  *JapicCTI-163401 / NCT02980341

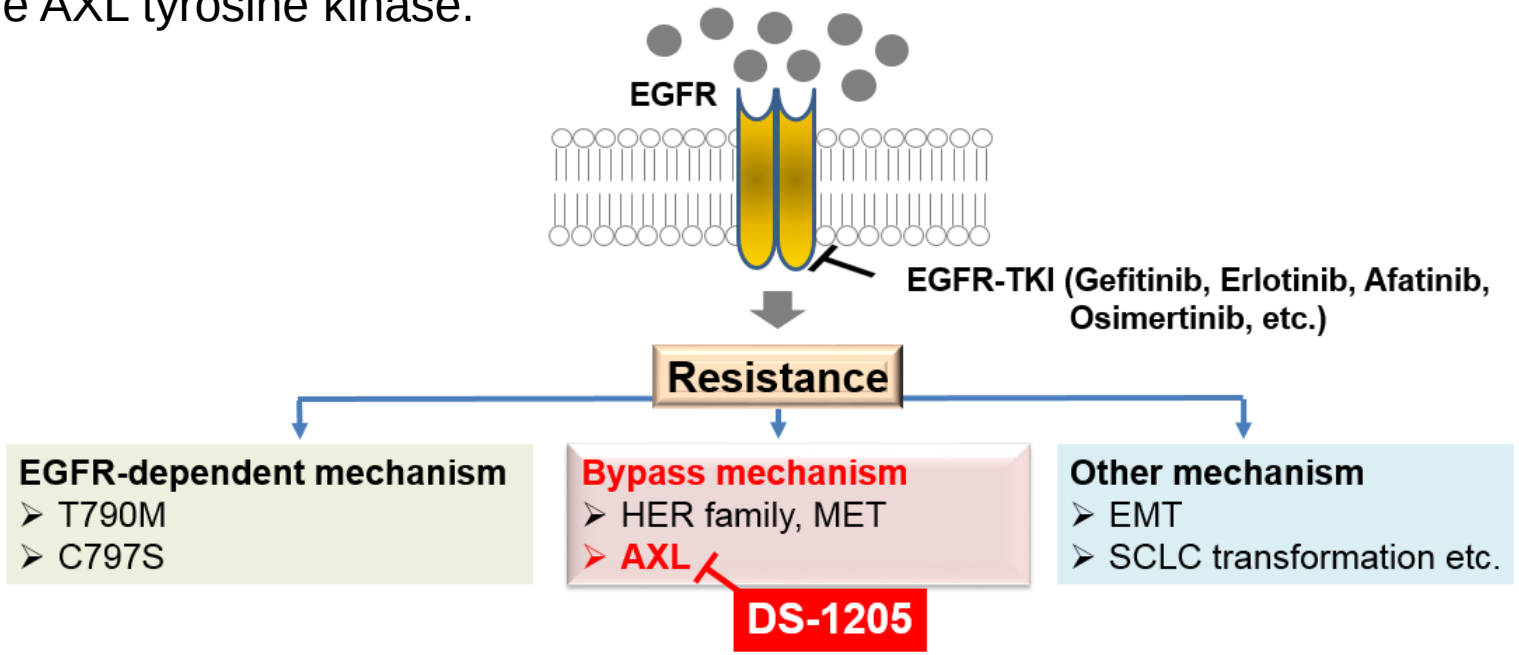
- EGFRm NSCLC Phase 1 study
  - Starts from FY2017 Q3

  *NCT03260491

New Projects Entered to Clinical Phase

DS-1205: AXL Inhibitor Summary

- AXL up-regulation is associated with poor prognosis in several cancers
- Up-regulation of AXL is one mechanism of EGFR-TKI resistance in EGFR-mutant non-small cell lung cancer
- DS-1205 is an orally available, potent and selective small-molecule inhibitor of the AXL tyrosine kinase.



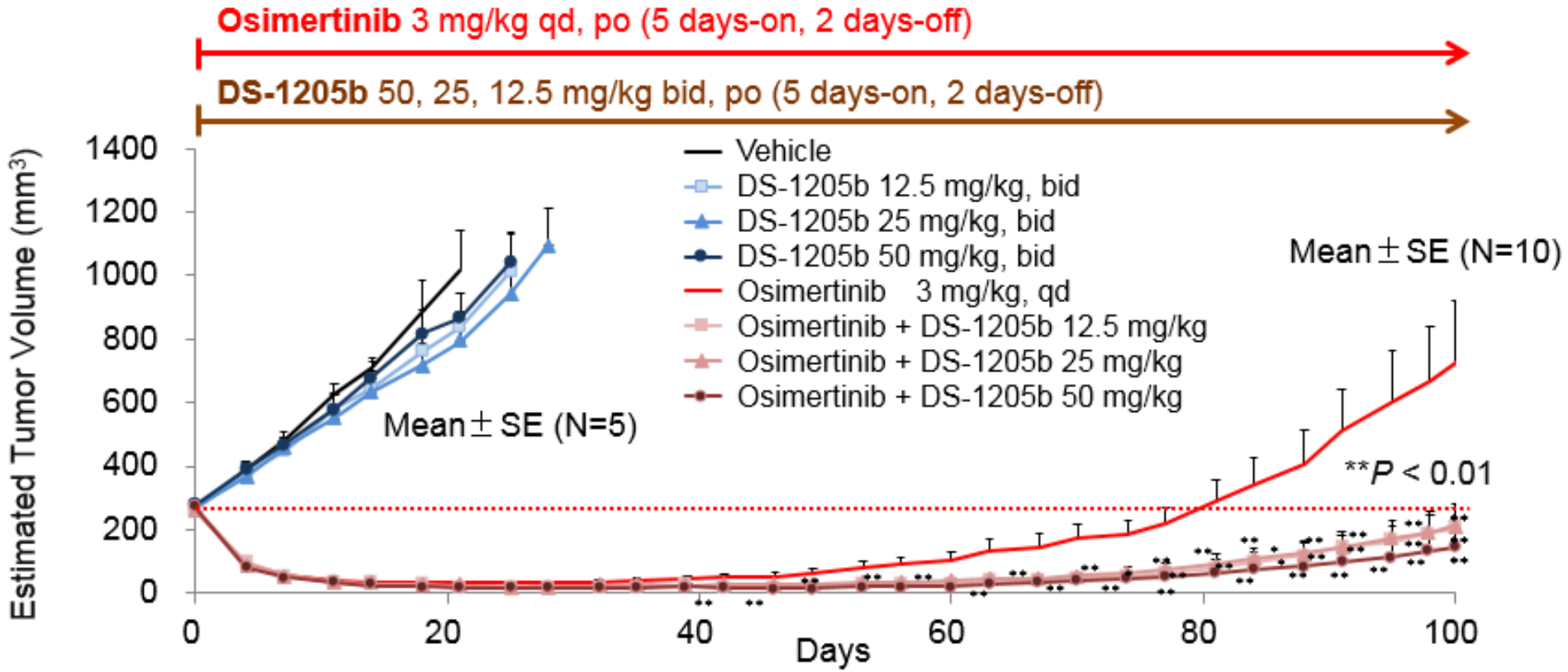
- Pharmacology study result was presented at ESMO 2017 (next page)
- Phase 1 study in combination with osimertinib will start in FY2017 (NCT03255083)

DS-1205: Results of Pharmacology Study

ESMO2017 Poster

Daiichi-Sankyo

Antitumor activity demonstrated in animal pharmacology study



DS-1205 in combination with osimertinib significantly delays resistance in osimertinib acquired-resistance xenograft model

New Collaboration in Oncology

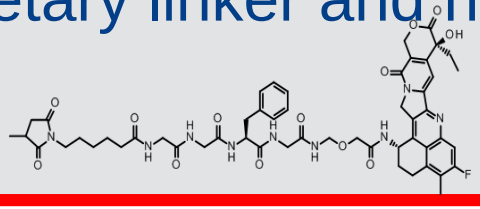
ADC - Glycotope: ADC Franchise

AML - MD Anderson: AML Franchise

Maximize ADC Technology: Collaboration with Glycotope

Partnerships to apply our ADC technology to new antibodies and targets

Our proprietary linker and novel payload



+

PankoMab-GEX® **(Glycotope)**

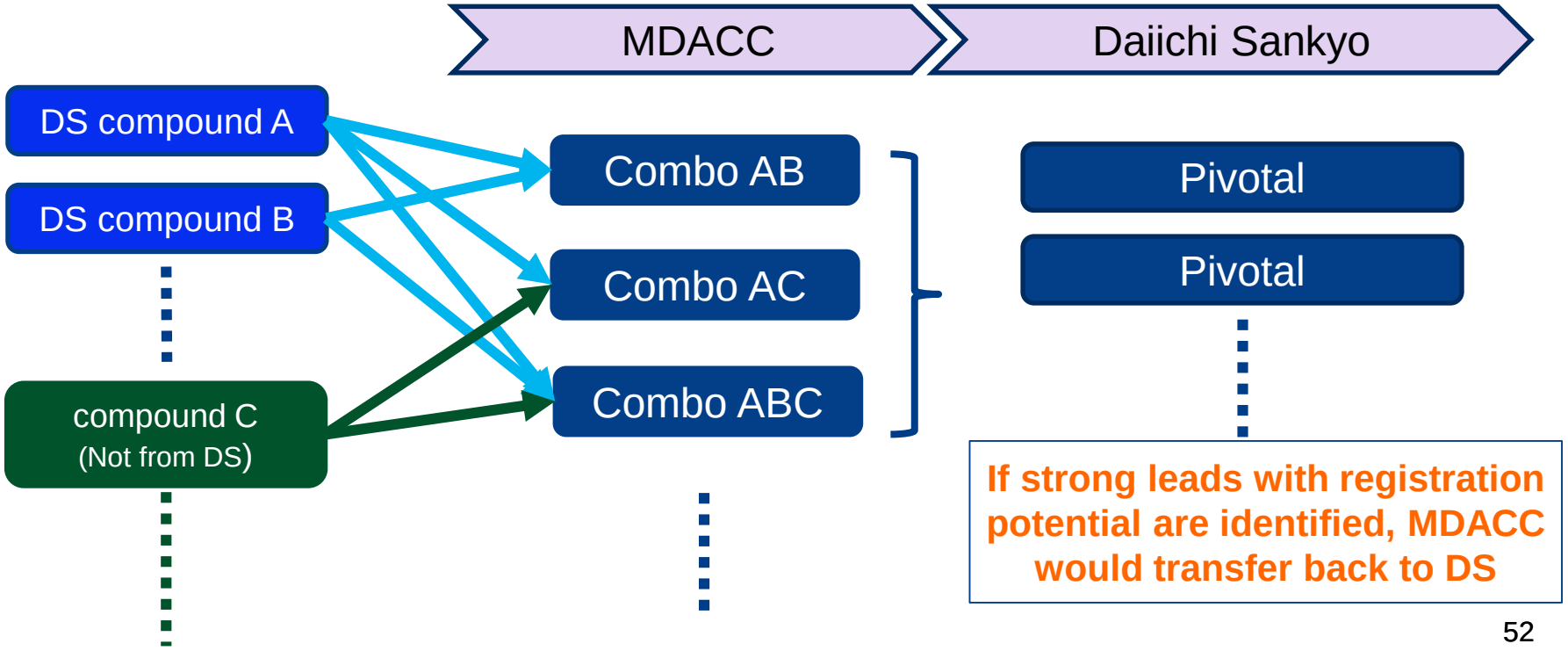
- Strategic collaboration to develop an ADC by combining the TA-MUC1 antibody PankoMab-GEX® with our ADC linker-payload
- PankoMab-GEX® is a humanized monoclonal Ab that binds to the tumor specific epitope of mucin 1 (TA-MUC1) which is highly expressed in ovarian, lung and breast cancers

Collaboration with MD Anderson Cancer Center

- MDACC
  - One of the largest integrated academic centers specializing in leukemia
  - Ideal partner to help advance Daiichi Sankyo's growing AML portfolio
- Purpose
  - Accelerate the development of novel therapies for AML
  - Conduct numerous non-clinical, phase 1 and 2 clinical trials using several investigational compounds from Daiichi Sankyo and multiple agents from outside Daiichi Sankyo in combination regimens
  - Explore novel biomarkers

Target DS Compounds and Image of Collaboration

- **Target DS compounds**
  - **Quizartinib (FLT3-ITD inhibitor)**
  - **DS-3032 (MDM2 inhibitor)**
  - **DS-3201（EZH1/2 inhibitor）**
  - **PLX51107（BRD4 inhibitor）**



ADC

AML

Oncology Future Data Disclosure

Daiichi-Sankyo

Dec. 2017 San Antonio Breast Cancer Symposium

SAN ANTONIO BREAST CANCER SYMPOSIUM®

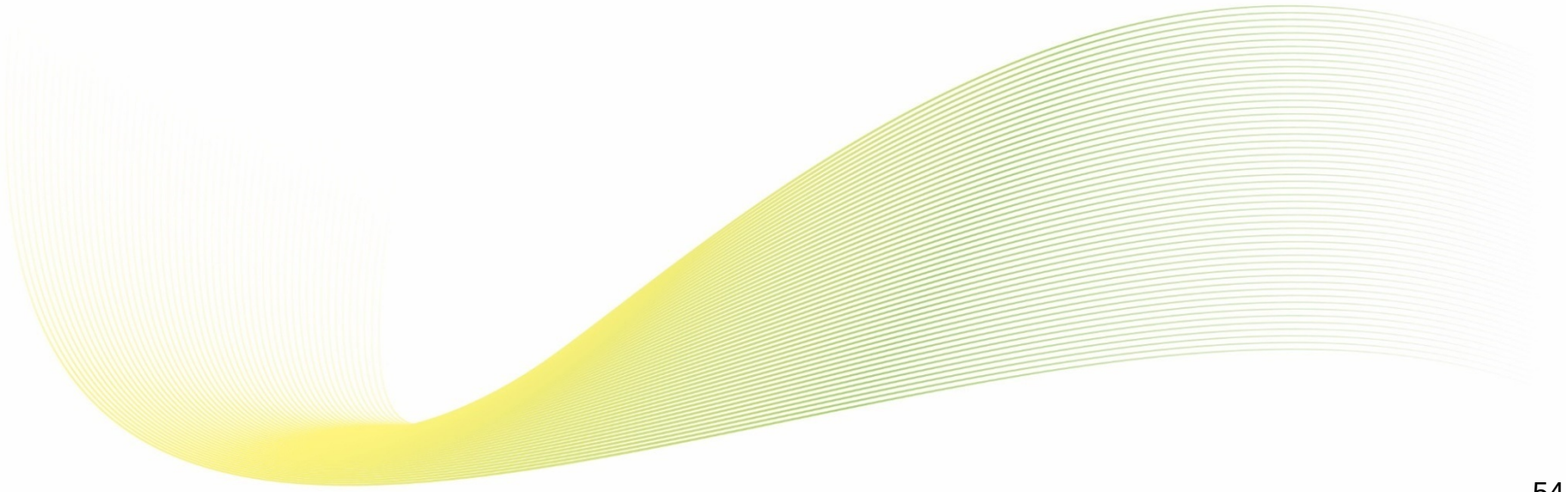
DS-8201: Breast cancer including HER2 low (Ph1)

Dec. 2017 American Society of Hematology (ASH)

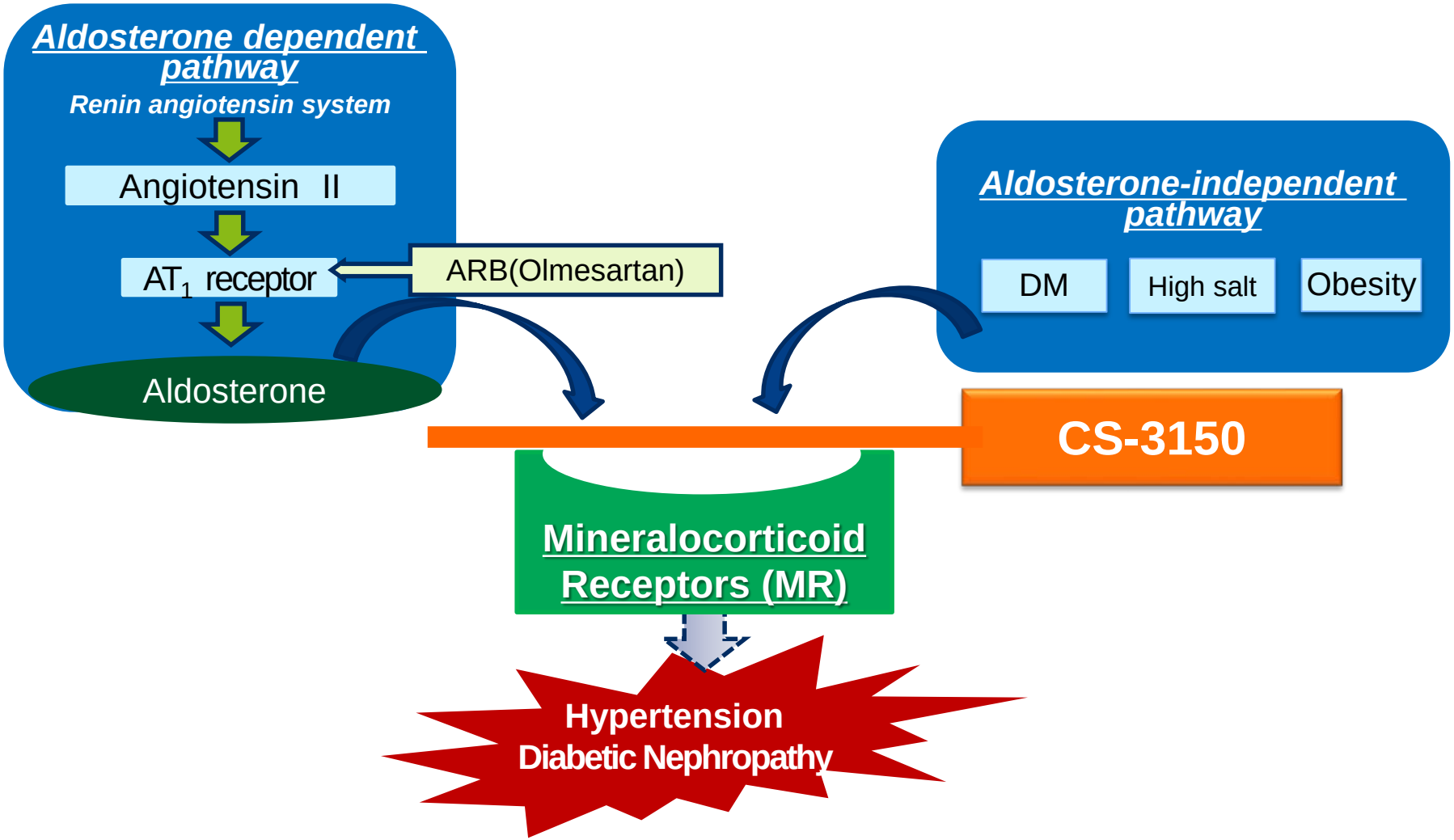
AMERICAN SOCIETY OF HEMATOLOGY

DS-3201: Non-Hodgkin's lymphoma (Ph1)

Esaxerenone/CS-3150 Update



Mineralocorticoid Receptor Related Hypertension and Diabetic Nephropathy



CS-3150 is a non-steroidal Mineralocorticoid Receptor antagonist

Esaxerenone/CS-3150: P3 Study

Hypertension

- Phase 3 pivotal study (ESAX-HTN study)
  - ✓ Efficacy and safety compared to eplerenone in patients with essential hypertension was evaluated
  - ✓ Topline Result: achieved primary endpoint
- NDA submission: FY2017 Q4

Diabetic nephropathy (DN)

- Started phase 3 pivotal study (ESAX-DN Study)
- Only 1 ARB and 1 ACE inhibitor are available for hypertension patient with DN and unmet medical need is still high

  *JapicCTI-173695

FY2017 Major R&D Milestone Events (1)

Project	Indication/Study	Q1	Q2	Q3	Q4	FY18-Q1 ~
Pexidartinib	Tenosynovial giant cell tumor Phase 3 study (US/EU)			**TLR**		Submission
Quizartinib	QuANTUM-R AML 2nd line treatment Phase 3 study (US/EU/Asia)	Interim Analysis				TLR
DS-8201	HER2-positive Breast Cancer (T-DM1 resistance or refractory) Pivotal phase 2 study (JP/US/EU)		**BTD** **Study initiation**			
	HER2-positive Gastric Cancer (Herceptin resistance or refractory) Pivotal phase 2 study (JP/Korea)			**Study initiation**		
	HER2-positive refractory/metastatic breast cancer and urothelial (bladder) cancer Phase 1b nivolumab combination study (US/EU)				**Study initiation**	
U3-1402	HER3 positive refractory/metastatic breast cancer Phase 1/2 study (JP)					**P2 part start**
	EGFRm NSCLC Phase 1 study (US)			Study initiation		
DS-1205	EGFRm NSCLC Phase 1 osimertinib combination study (US)			**Study initiation**		
PLX2853	Advanced refractory solid tumor and non-Hodgkin's lymphoma Phase 1/2 study (US)		**Study initiation**			

Red: new or update Underline: achieved

TLR: Top Line Results
BTD：Breakthrough Therapy Designation

FY2017 Major R&D Milestone Events (2)

Project	Indication/Study	Q1	Q2	Q3	Q4	FY18-Q1 ~
Mirogabalin	Fibromyalgia Phase 3 study (US/EU)	TLR				
	PHN Phase 3 study (JP/Asia)	TLR			**Submission**	
	DPNP Phase 3 study (JP/Asia)		TLR			
Esaxerenone /CS-3150	Hypertension Phase 3 study (JP)		**TLR**		Submission	
	Diabetic nephropathy Phase 3 study (JP)		**Study initiation**			
DS-5141	Duchenne Muscular Dystrophy Phase 1/2 study (JP)	SAKIGAKE			TLR	

Red: new or update Underline: achieved

TLR: Top Line Results

DS R&D Day 2017

- Date: December 13, 2017 (15:30 – 17:30)
- Location: Daiichi Sankyo Headquarter Office
- Presenters:
  - Dr. Glenn Gormley
    - ✓ Sr. Executive Officer, Global R&D Head
  - Dr. Antoine Yver
    - ✓ Global Head of Oncology R&D, Head of Cancer Enterprise

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Email: DaiichiSankyoIR@daiichisankyo.co.jp

Appendix

- Pipeline chart
- Study designs of major clinical studies
- Abbreviations

Major R&D Pipeline

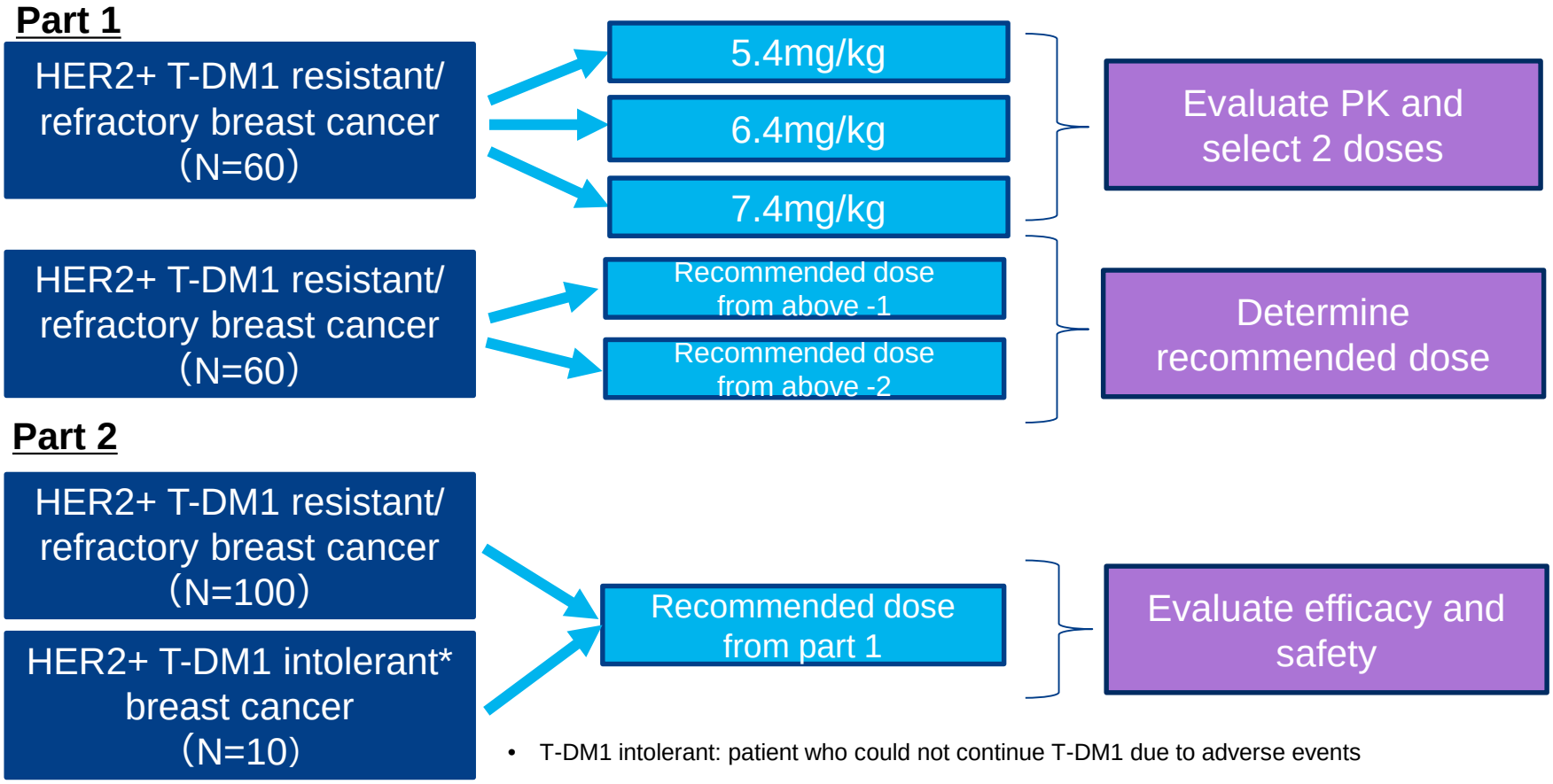
As of October 2017

Daiichi-Sankyo

Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Oncology	■ DS-3032 (US/JP) (MDM2 inhibitor) ■ PLX7486 (US) (FMS / TRK inhibitor) ■ PLX8394 (US) (BRAF inhibitor) ■ PLX9486 (US) (KIT inhibitor) ■ DS-3201 (JP/US) (EZH1/2 inhibitor) ■ PLX73086 (US) (CSF-1R inhibitor) ■ PLX51107 (US) (BRD4 inhibitor) ■ DS-8273 (US) (Anti-DR5 antibody) ■ DS-1123 (JP) (Anti-FGFR2 antibody) ■ U3-1402 (JP) (Anti-HER3 ADC) ■ DS-1001 (JP) (IDH1m inhibitor) ■ DS-1205 (US) (AXL inhbitor) ■ PLX2853 (US) (BRD4 inhibitor)	■ Patritumab (EU) (U3-1287 / Anti-HER3 antibody) ■ Pexidartinib (US) (PLX3397 / Glioblastoma / CSF-1R/ KIT/FLT3-ITD inhibitor) ■ DS-1647 (JP) (Glioblastoma / **G47Δ virus**) ■ Quizartinib (JP) (AC220 / AML-2nd / FLT3-ITD inhibitor) ■ DS-8201 (US/EU/JP) (Breast cancer/anti-HER2 ADC) ■ DS-8201 (JP/Asia) (Gastric cancer/anti-HER2 ADC)	■ Denosumab (JP) (AMG 162 / Breast cancer adjuvant/ Anti-RANKL antibody) ■ Nimotuzumab (JP) (DE-766 / Gastric cancer / Anti-EGFR antibody) ■ Quizartinib (US/EU/Asia) (AC220 / AML-2nd / FLT3-ITD inhibitor) ■ Quizartinib (US/EU/Asia) (AC220 / AML-1st / FLT3-ITD inhibitor) ■ Pexidartinib (US/EU) (PLX3397 / TGCT / CSF-1R/KIT/FLT3-ITD inhibitor)	
Cardiovascular-Metabolic	■ DS-1040 (US/EU/JP) (Acute ischemic stroke / TAFIa inhibitor) ■ DS-2330 (Hyperphosphatemia) ■ DS-9231/TS23 (Thrombosis / **α2**-PI inactivating antibody)		■ Edoxaban (JP) (DU-176b / AF / FXa inhibitor) ■ Prasugrel (JP) (CS-747 / Ischemic stroke / Anti-platelet agent) ■ Esaxerenone (JP) (CS-3150/Hypertension/ MR antagonist) ■ Esaxerenone (JP) (CS-3150 / DM nephropathy / MR antagonist)	■ Edoxaban (ASCA etc.) (DU-176b / AF / FXa inhibitor) ■ Edoxaban (ASCA etc.) (DU-176b / VTE / FXa inhibitor)
Others	■ DS-1971 (Chronic pain) ■ DS-1501 (US) (Osteoporosis / Anti-Siglec-15 antibody) ■ DS-7080 (US) (AMD / Angiogenesis inhibitor) ■ DS-5141 (JP) (DMD / ENA oligonucleotide) ■ VN-0102/JVC-001 (JP) (MMR vaccine) ■ DS-1211 (US) (TNAP inhibitor)		■ Mirogabalin (US/EU) (DS-**5565 / FM / α2δ ligand)** ■ Mirogabalin (JP/Asia) (DS-**5565 / DPNP/ α2δ ligand)** ■ Mirogabalin (JP/Asia) (DS-**5565 / PHN / α2δ ligand)** ■ VN-0105 (JP) (DPT-IPV / Hib vaccine) ■ Laninamivir (JP) (CS-8958 / Anti-influenza / nebulizer)	■ Hydromorphone (JP) (DS-7113 / Cancer pain / Opioid **μ**-receptor agonist) <Injection> ■ Intradermal Seasonal Influenza Vaccine (JP) (VN-100 / prefilled i.d. vaccine for seasonal flu) ■ VN-0107/MEDI3250 (JP) (Nasal spray flu vaccine)
Out-licensing	■ DS-6051 (NTRK/ROS1 inhibitor)	■ DS-2969 (*Clostridium difficile* infection/GyrB inhibitor)	■ Laninamivir (US/EU) (CS-8958 / Anti-influenza /out-licensing with Biota)	

Red: new or update

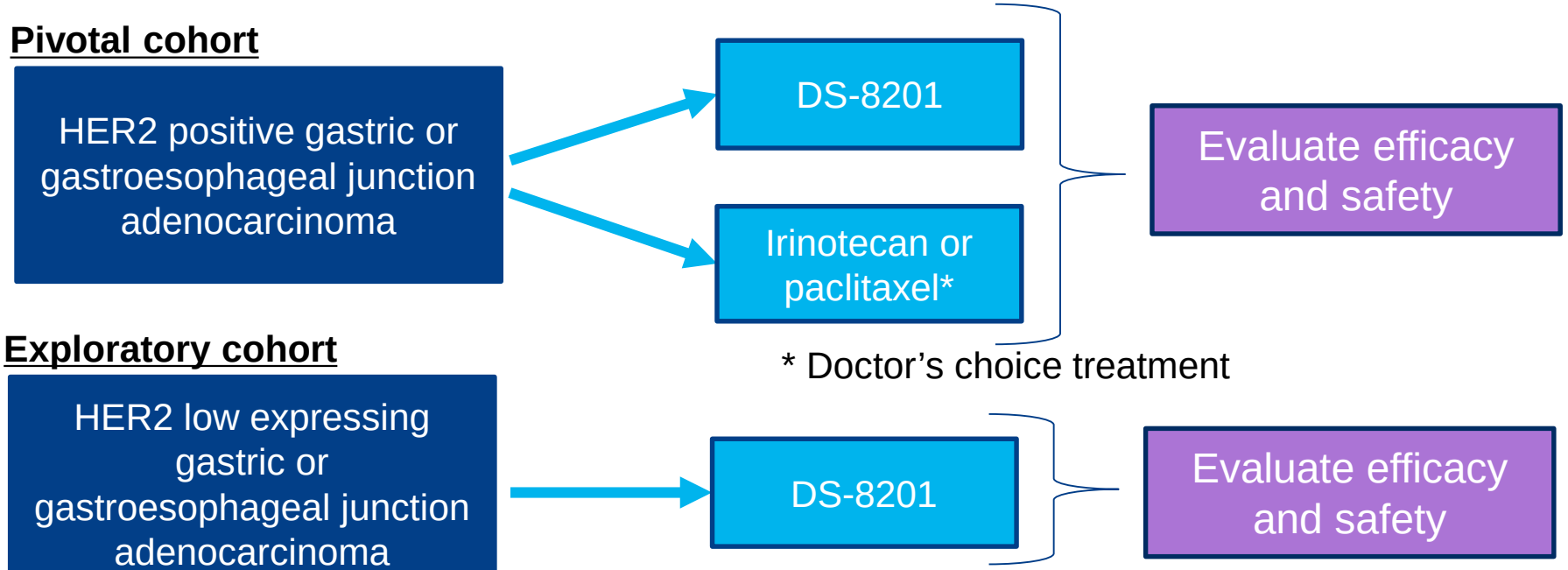
DS-8201: HER2 Positive Breast Cancer Pivotal P2 Study (JP/US/EU)



- T-DM1 intolerant: patient who could not continue T-DM1 due to adverse events

Study patients	• HER2 positive patients with T-DM1 resistant/refractory • HER2 positive patients with T-DM1 intolerant
Estimated enrollment	230 patients
Primary endpoint	ORR
Secondary endpoint	DOR, DCR, PFS, OS etc.
JAPIC/CT.gov	JapicCTI-173693 / NCT03248492

DS-8201: HER2 Positive Gastric Cancer Pivotal P2 Study (JP/Asia)



Study patients	• HER2 positive gastric or gastroesophageal junction adenocarcinoma • HER2 low expressing gastric or gastroesophageal junction adenocarcinoma
Estimated enrollment	220 patients
Primary endpoint	ORR
Secondary endpoint	DOR, DCR, PFS, OS, etc.
JAPIC/CT.gov	JapicCTI-173727/ TBD

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

Part 1: dose escalation

HER2-expressing breast cancer refractory to standard therapies / no available standard therapy

→ DS-8201 + Nivolumab → Determine recommended dose

Part 2: dose expansion

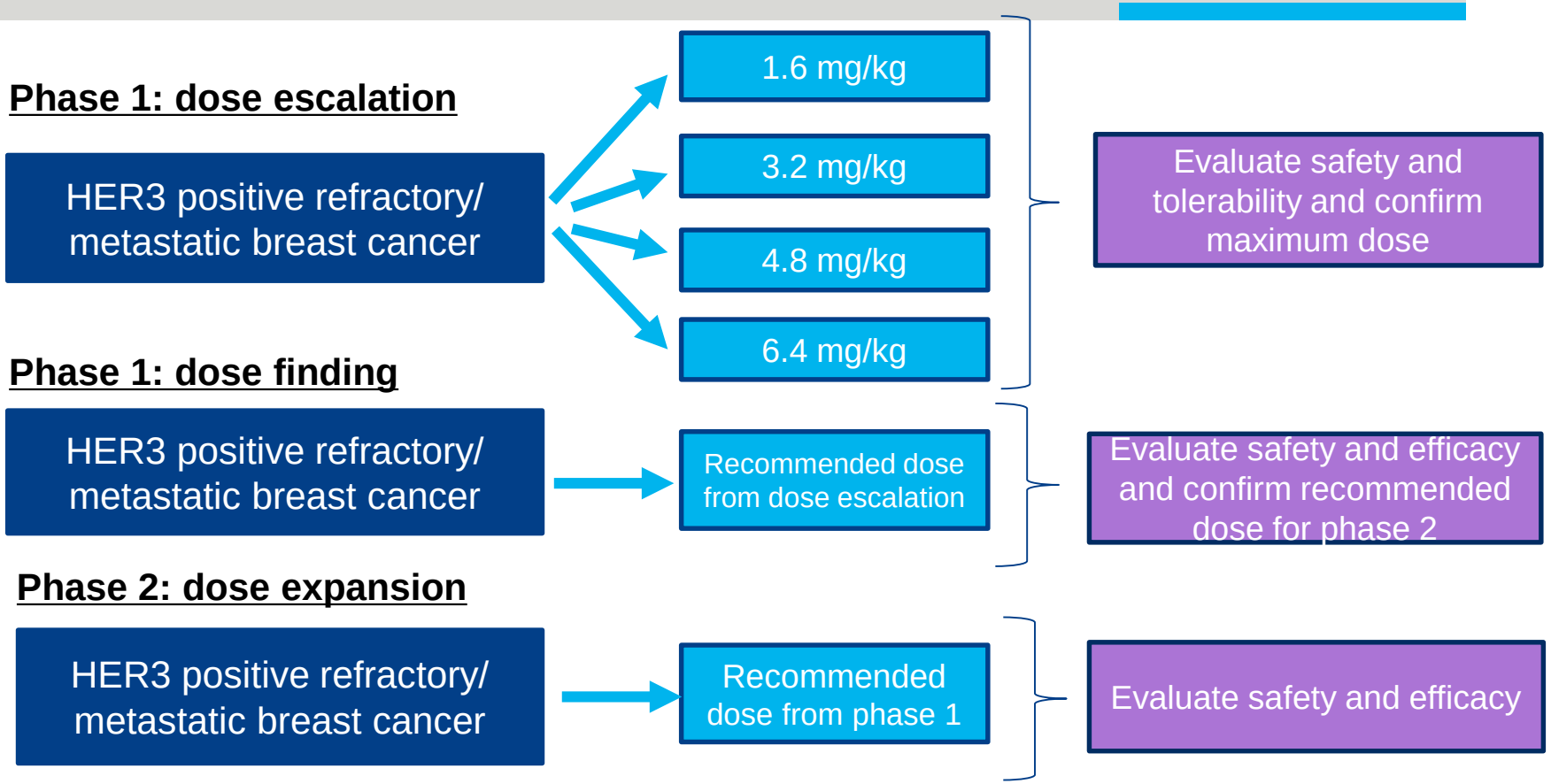
HER2-expressing advanced/metastatic breast cancer

HER2-expressing urothelial (bladder) cancer previously treated with chemotherapy

→ DS-8201 + Nivolumab → Evaluate the efficacy, safety and tolerability

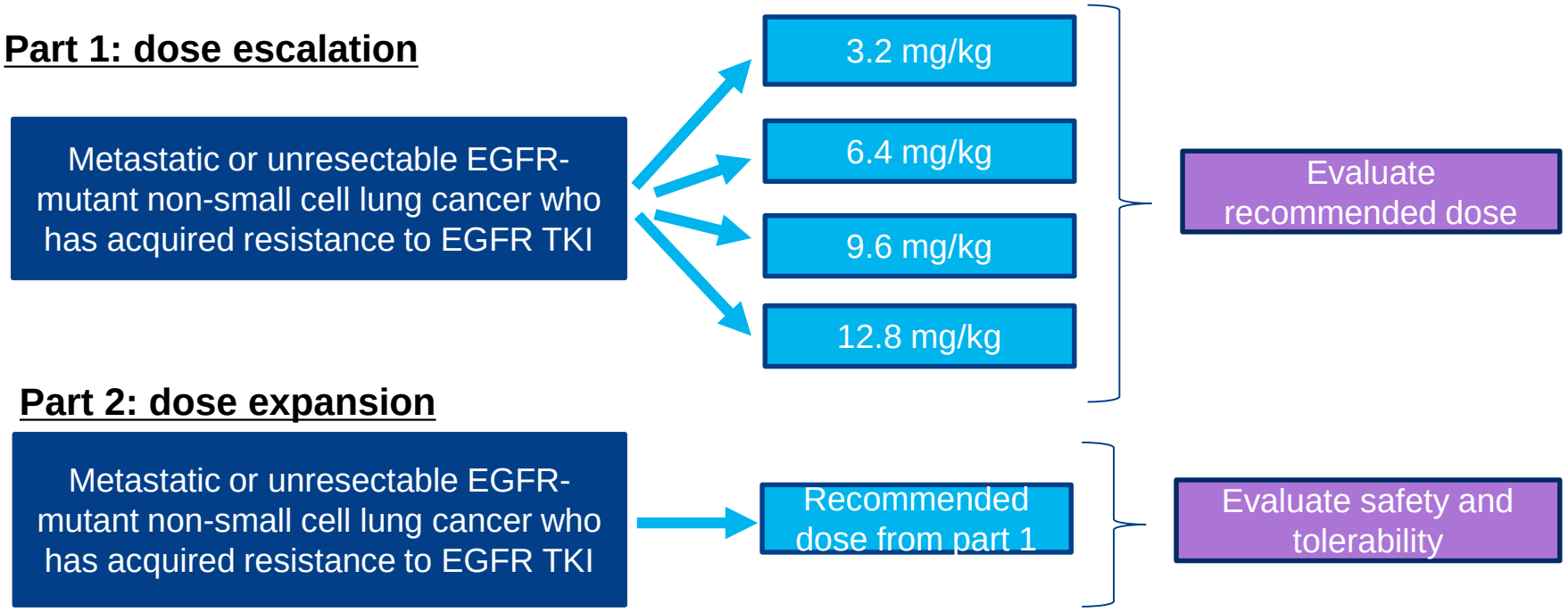
Study patients	• HER2-expressing breast cancer who are refractory to standard therapies or for which no standard therapy is available. • HER2-expressing urothelial (bladder) cancer in patients previously treated with chemotherapy.
Estimated enrollment	117 patients
Primary endpoint	ORR Dose escalation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

U3-1402: HER3 Positive Breast Cancer P1/2 Study (JP)



Study patients	HER3 positive refractory/ metastatic breast cancer
Estimated enrollment	80 patients
Primary endpoint	Safety, tolerability and efficacy
Secondary endpoint	PK, anti-HER3 antibody etc.
JAPIC/CT.gov	JapicCTI-163401 / NCT02980341

U3-1402: EGFRm NSCLC P1 Study (US)



Study patients	Metastatic or unresectable EGFR-mutant non-small cell lung cancer with acquired resistance to EGFR TKI
Estimated enrollment	63 patients
Primary endpoint	Safety, tolerability
Secondary endpoint	ORR, DCR, PFS, OS etc.
JAPIC/CT.gov	TBD / NCT03260491

DS-1205: FIH P1 Osimertinib Combination Study (US)

Part 1: dose escalation

Metastatic or unresectable EGFR-mutant non-small cell lung cancer

→ DS-1205 200/400/600/800mg + Osimertinib 80mg

→ Evaluate safety and tolerability and confirm recommended dose for part 2

Part 2: dose expansion

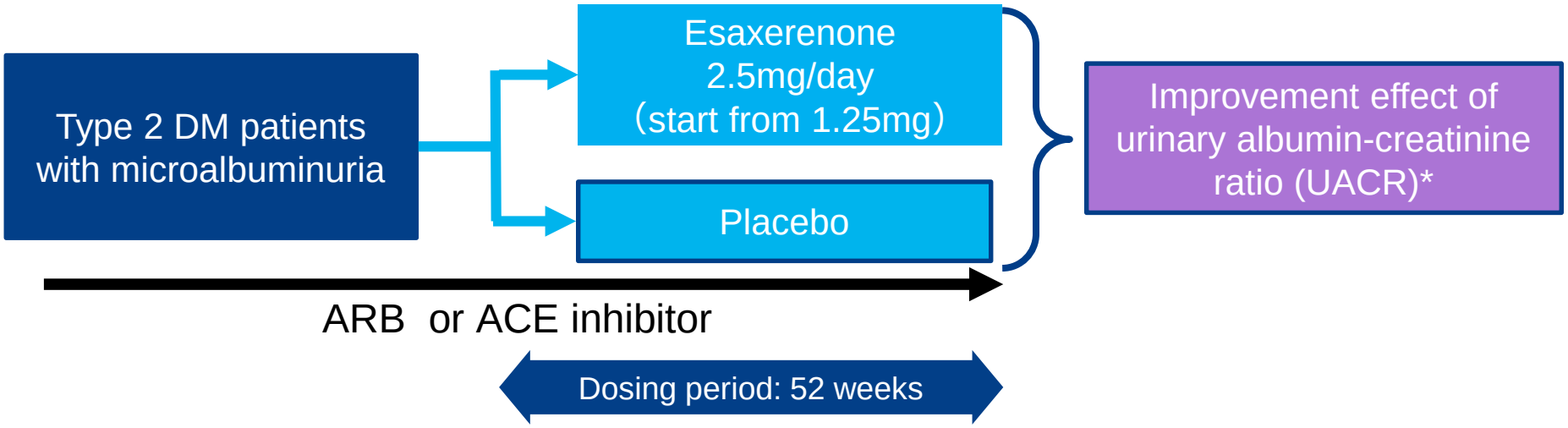
Metastatic or unresectable EGFR-mutant non-small cell lung cancer

→ DS-1205 recommended dose from part 1 + Osimertinib 80mg

→ Evaluate safety, tolerability and efficacy

Study patients	Metastatic or unresectable epidermal growth factor receptor (EGFR)-mutant non-small cell lung cancer
Estimated enrollment	118 patients
Primary endpoint	DLT, safety
Secondary endpoint	PK, ORR, DOR, DCR, PFS, OS etc.
JAPIC/CT.gov	NA / NCT03255083

CS-3150: Diabetic Nephropathy P3 Study (ESAX-DN Study) (JP)



Study patients	Type 2 DM patients with microalbuminuria (stage 2 nephropathy)
Estimated enrollment	400 patients (200 patients/arm)
Primary endpoint	Remission achievement rate of UACR at the end of investigational drug administration*
Secondary endpoint	Change rate in UACR and eGFR from baseline to the end of the treatment etc.
JAPIC/CT.gov	JapicCTI-173695 / TBD

*: UACR reached to normal level (<30 mg/gCr) and 30% reduction from baseline

Abbreviations

Abbreviation	
BTD	Breakthrough 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