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Compassion for Patients.™

Daiichi-Sankyo

Top Management Presentation

Financial Results of FY2017 Q3 (April 1 – December 31, 2017)

DAIICHI SANKYO CO., LTD

Kazunori Hirokawa
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January 31, 2018

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Agenda

- FY2017 Q3 Financial Results
- FY2017 Revised Consolidated Forecast
- Edoxaban (Lixiana)
- R&D Update
- Appendix
  - R&D Milestone Events
  - Major R&D Pipeline
  - Out-licensing Projects
  - Edoxaban (Lixiana)
  - Injectafer
  - Abbreviations

FY2017 Q3 Financial Results

Overview of FY2017 Q3 Results

(Bn JPY)

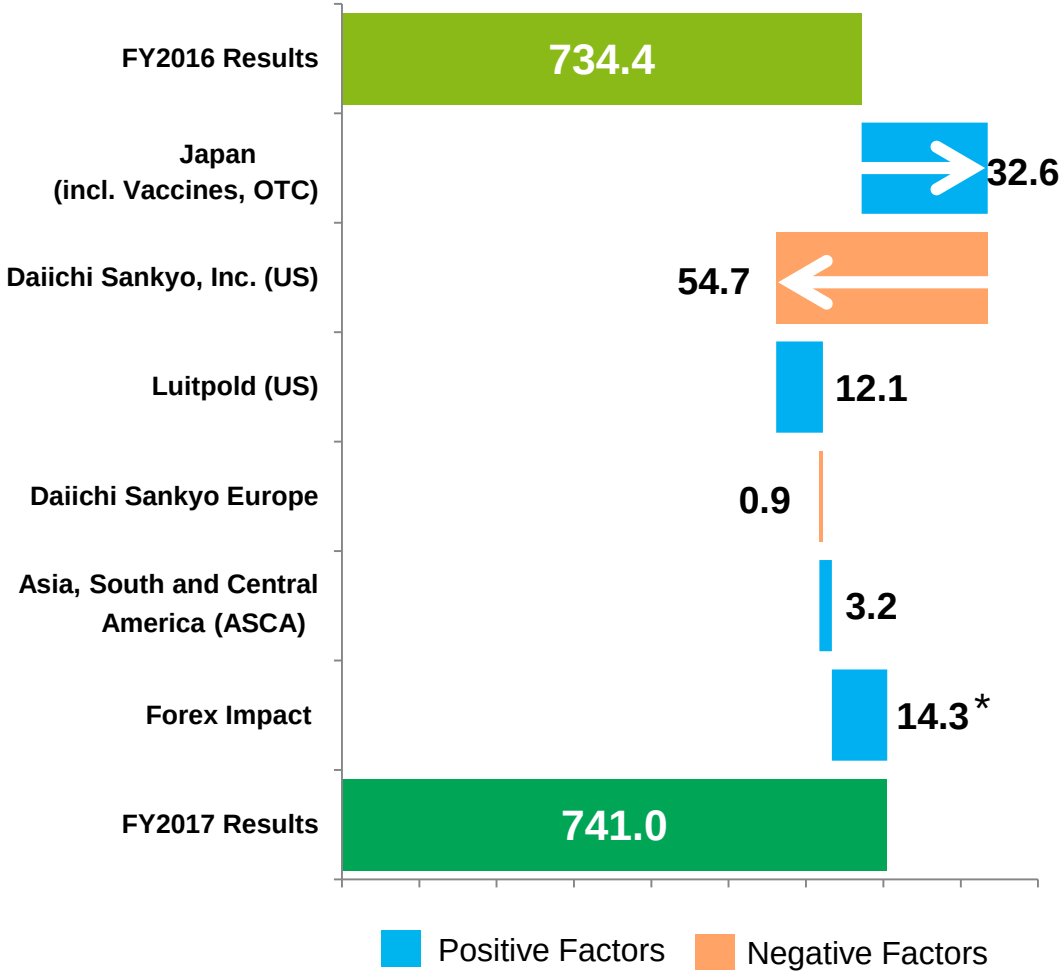
	FY2016 Q3 YTD Results	FY2017 Q3 YTD Results	YoY
Revenue	734.4	741.0	+0.9% +6.6
Cost of Sales	241.7	255.5	+13.7
SG&A Expenses	220.5	216.7	-3.7
R&D Expenses	143.5	175.6	+32.1
Operating Profit	128.7	93.2	-27.6% -35.5
Profit before Tax	132.4	97.7	-34.7
Profit attributable to owners of the Company	88.2	72.6	-17.7% -15.6

Currency Rate	USD/JPY	106.68	111.71	+5.03
	EUR/JPY	118.09	128.53	+10.44

Revenue

Increased by 6.6 Bn JPY (Decreased by 7.7 Bn JPY excl. forex impact)

(Bn JPY)



Japan

Positive :	Lixiana	+16.8	Pralia +4.0
	Nexium	+2.5	Efient +2.1
	Daiichi Sankyo Espha (GE) (Telmisartan AG, Olmesartan AG, Rosuvastatin AG etc.)		+18.7
Negative :	Olmetec	-13.7	

Daiichi Sankyo Healthcare (OTC) +4.7

Global (excl. Forex Impact)

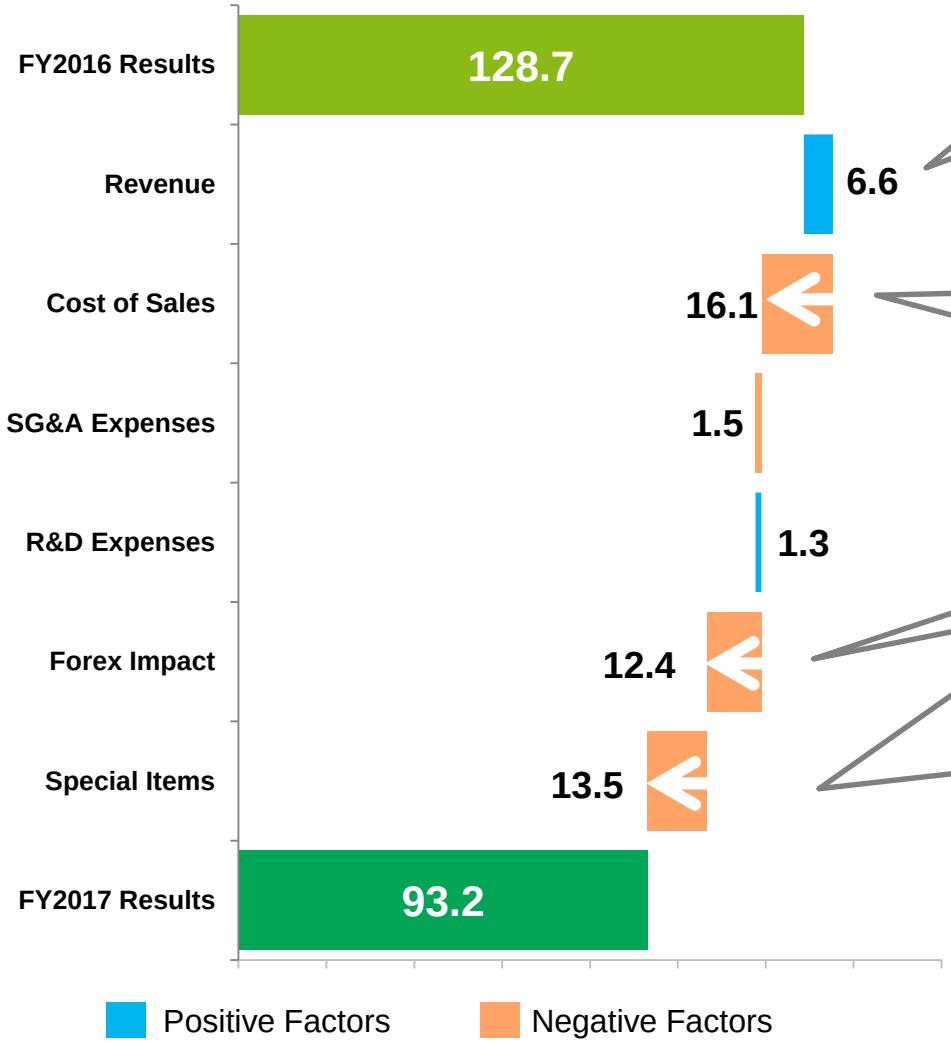
Daiichi Sankyo, Inc. :	Olmesartan	-44.3
	Effient	-6.8
	Welchol	-4.2
Luitpold :	Injectafer	+6.8
	GE injectables	+5.0
Daiichi Sankyo Europe :	Lixiana	+10.8
	Olmesartan	-11.2

* Forex impact USD: +6.6, EUR : +4.7, ASCA: +3.0

Operating Profit

Decreased by 35.5 Bn JPY
(Decreased by 23.9 Bn JPY excl. forex impact and special items)

(Bn JPY)



Revenue +6.6
incl. forex impact +14.3

Cost of Sales +16.1
Product mix due to impact of olmesartan LOE

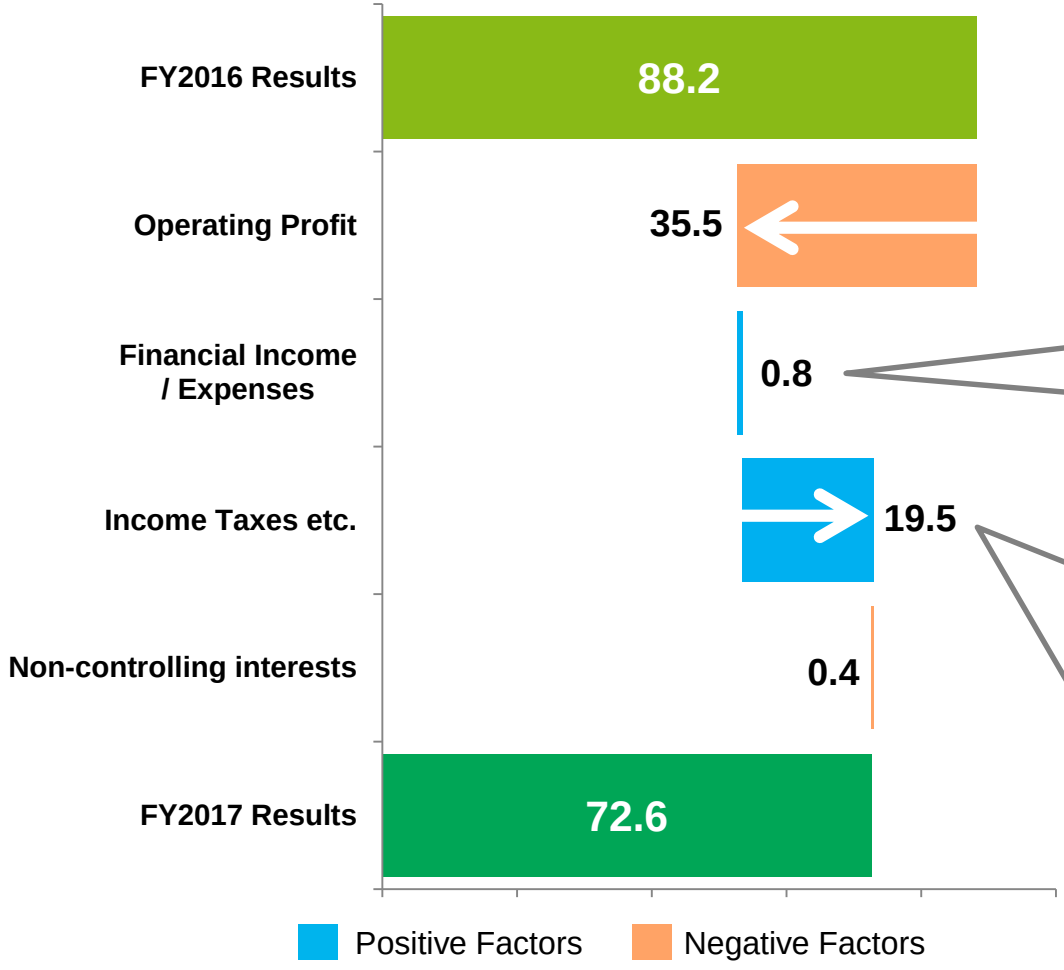
Forex impact +12.4
Cost of Sales +3.7
SG&A Expenses +5.4
R&D Expenses +3.3

Special Items	FY2016 Q3 YTD Results	FY2017 Q3 YTD Results	YoY
COS (Gain on sales of fixed assets)		-6.1	-6.1
SG&A (Restructuring costs in EU)	10.6		-10.6
R&D (Impairment loss)		30.2	+30.2
Total	10.6	24.1	+13.5

Profit Attributable to Owners of the Company

Decreased by 15.6 Bn JPY

(Bn JPY)



Financial Income / Expenses -0.6

Improvement of forex gains/ losses

	FY2016 Q3 YTD Results	FY2017 Q3 YTD Results	YoY
Profit before Tax	132.4	97.7	-34.7
Income Taxes etc.	45.1	25.6	-19.5
Tax rate	34.1%	26.2%	-7.9%

Impact of the tax rate reduction in US

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2016 Q3 YTD Results	FY2017 Q3 YTD Results	YoY	vs. Forecast* (%)
Japan	**390.2**	**418.1**	**+27.9**	**78.0%**
Daiichi Sankyo Healthcare	**51.9**	**56.6**	**+4.7**	**79.7%**
Daiichi Sankyo Inc.	**115.8**	**64.1**	**-51.8**	**91.5%**
Olmesartan	60.9	17.4	-43.6	96.4%
Welchol	32.2	29.3	-2.9	88.7%
Effient	16.5	10.1	-6.4	-
Savaysa	1.4	1.6	+0.2	80.7%
Movantik	2.9	3.7	+0.8	-
Luitpold	**64.3**	**79.9**	**+15.7**	**76.1%**
Venofer	21.2	24.0	+2.8	77.5%
Injectafer	17.2	25.2	+8.0	72.0%
GE injectables	22.0	28.3	+6.2	-
Daiichi Sankyo Europe	**54.4**	**58.2**	**+3.8**	**74.6%**
Olmesartan	34.6	25.5	-9.2	79.6%
Efient	6.1	6.0	-0.1	74.6%
Lixiana	6.1	18.5	+12.3	71.1%
ASCA (Asia, South and Central America)	**52.5**	**58.7**	**+6.2**	**74.3%**

Currency Rate	USD/JPY	106.68	111.71	+5.03
	EUR/JPY	118.09	128.53	+10.44

* Calculated based on new forecast updated in Jan.

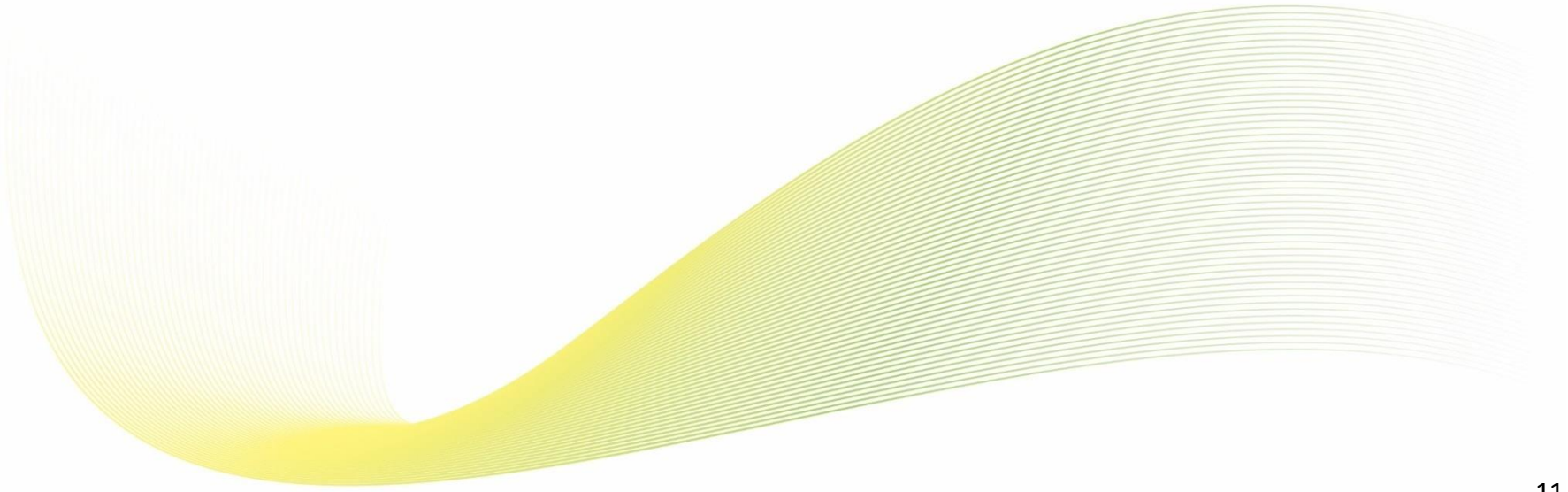
Revenue: Major Products in Japan

(Bn JPY)

		FY2016 Q3 YTD Results	FY2017 Q3 YTD Results	YoY	vs. Forecast* (%)
Nexium	ulcer treatment	**67.4**	**70.0**	**+2.5**	**84.3%**
Memary	Alzheimer's disease treatment	**36.3**	**38.1**	**+1.7**	**76.1%**
Olmetec	antihypertensive agent	**54.1**	**40.5**	**-13.7**	**86.1%**
Lixiana	anticoagulant	**17.9**	**34.7**	**+16.8**	**77.0%**
Loxonin	anti-inflammatory analgesic	**29.3**	**29.0**	**-0.3**	**80.6%**
Tenelia	type 2 diabetes mellitus treatment	**19.7**	**20.9**	**+1.2**	**80.3%**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**13.3**	**17.3**	**+4.0**	**75.0%**
Rezaltas	antihypertensive agent	**13.6**	**13.1**	**-0.5**	**82.2%**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**10.6**	**11.7**	**+1.1**	**78.1%**
Efient	antiplatelet agent	**7.8**	**9.9**	**+2.1**	**76.5%**
Inavir	anti-influenza treatment	**7.9**	**9.3**	**+1.4**	**51.5%**
Cravit	synthetic antibacterial agent	**12.0**	**10.1**	**-1.9**	**77.6%**
Urief	treatment for dysuria	**8.9**	**8.7**	**-0.2**	**78.9%**
Omnipaque	contrast medium	**11.1**	**11.0**	**-0.1**	**84.4%**
Mevalotin	antihyperlipidemic agent	**8.3**	**7.0**	**-1.3**	**77.8%**

* Calculated based on new forecast updated in Jan.

FY2017 Revised Consolidated Forecast



FY2017 Revised Consolidated Forecast

(Bn JPY)

	FY2017 Forecast (as of Oct.)	FY2017 Forecast (as of Jan.)	vs. Forecast (as of Oct.)
Revenue	**930.0**	**950.0**	**+20.0**
Cost of Sales	**337.0**	**347.0**	**+10.0**
SG&A Expenses	**297.0**	**297.0**	**0.0**
R&D Expenses	**221.0**	**231.0**	**+10.0**
Operating Profit	**75.0**	**75.0**	**0.0**
Profit before Tax	**75.0**	**75.0**	**0.0**
Profit attributable to owners of the Company	**50.0**	**50.0**	**0.0**

Major factors
- Daiichi Sankyo Healthcare (OTC) +2.0
- Daiichi Sankyo Inc. +8.0
- Luitpold +2.0
- Daiichi Sankyo Europe +12.0
- ASCA -5.0

Major factors
- Increased by sales increase (incl. transitory costs)

Major factors
- Increased by accelerated R&D

Currency Rate	**USD/JPY**	**110.54**	**111.28**
	EUR/JPY	**123.14**	**126.39**

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

Edoxaban (Lixiana)

Lixiana : For Maximization of Product Value

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Japan

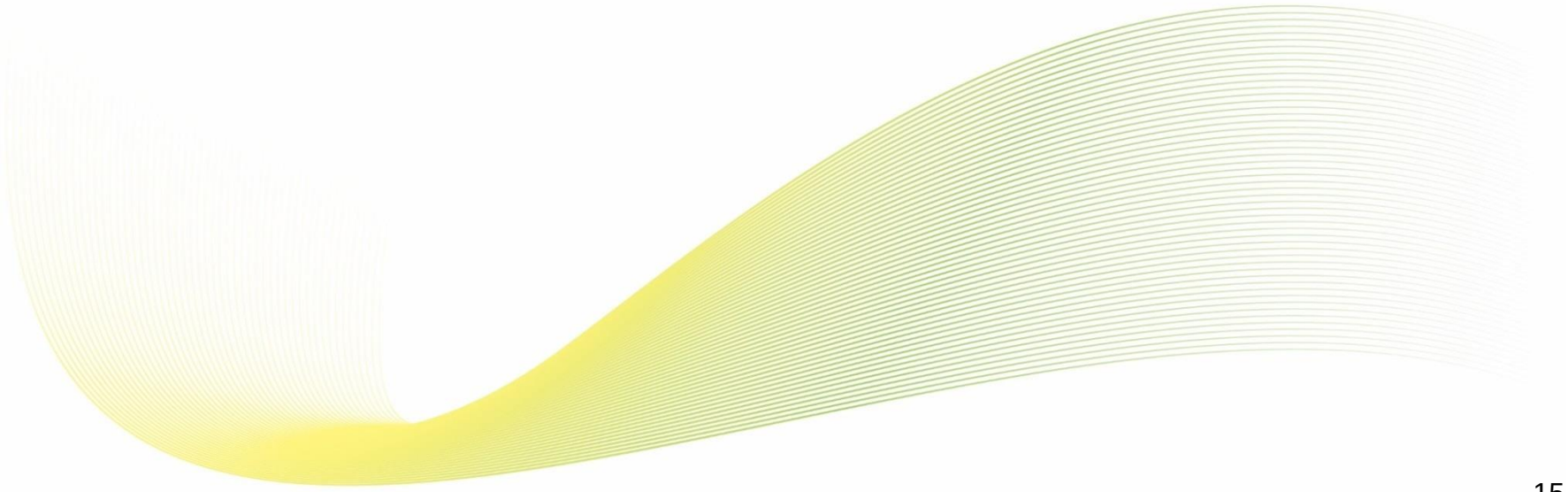
- Launched anticoagulant Lixiana OD (Orally Disintegrating) tablets (Nov. 2017)
  - Only OD tablets in direct oral anticoagulant (DOAC)

Global

Hokusai VTE CANCER

- Met primary endpoint in Investigational Hokusai-VTE CANCER Study evaluating edoxaban versus the standard of care in US/EU dalteparin (injectable) in venous thromboembolism (VTE) associated with cancer (Dec. 2017)
  - The 1st DOAC to show non-inferiority against dalteparin
  - Presented as late breaking at ASH 2017

R&D Update



DS-8201: Broad and Bold Program

From FY2017 R&D Day

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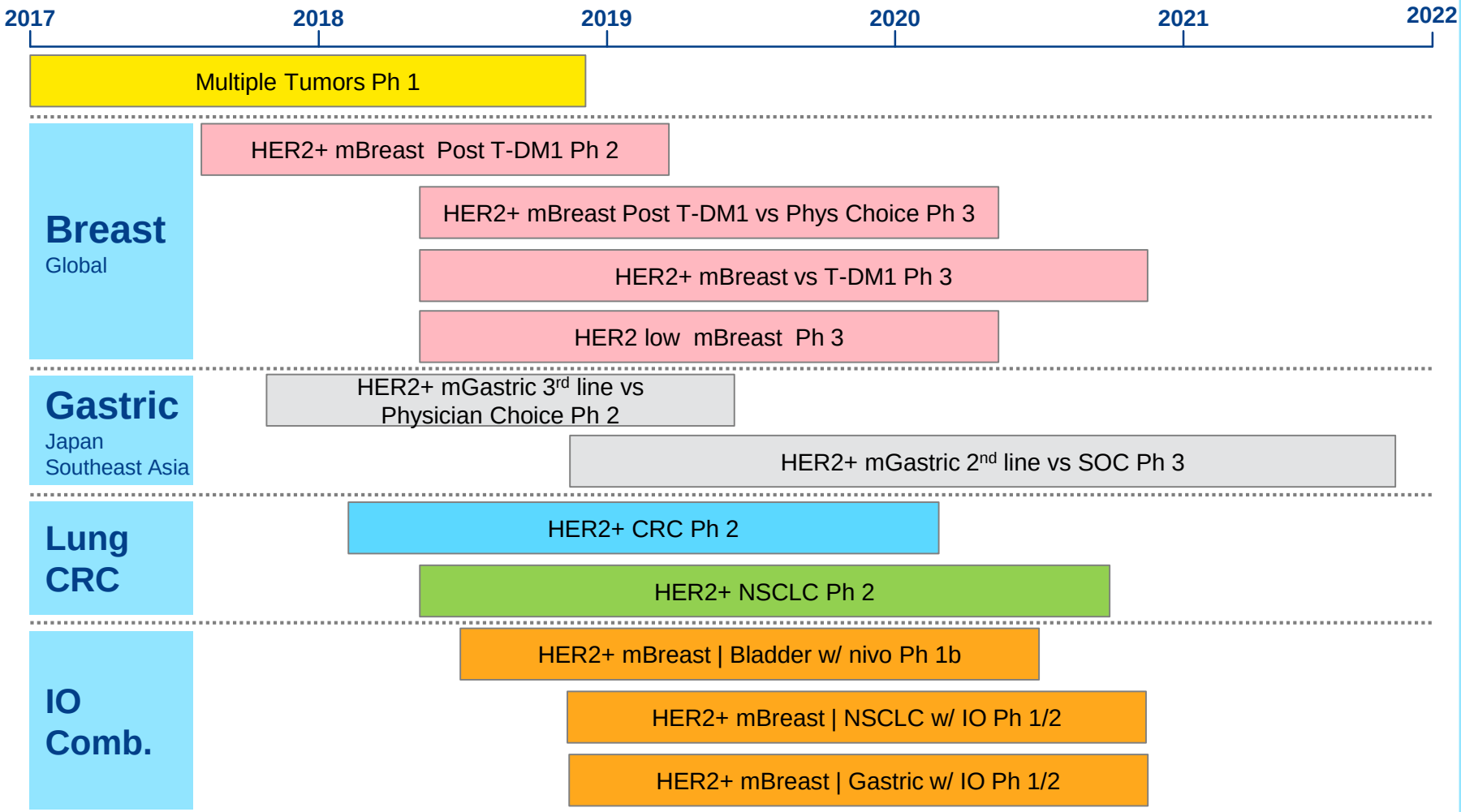
Estimated development timelines



DS-8201: P1 Study Design

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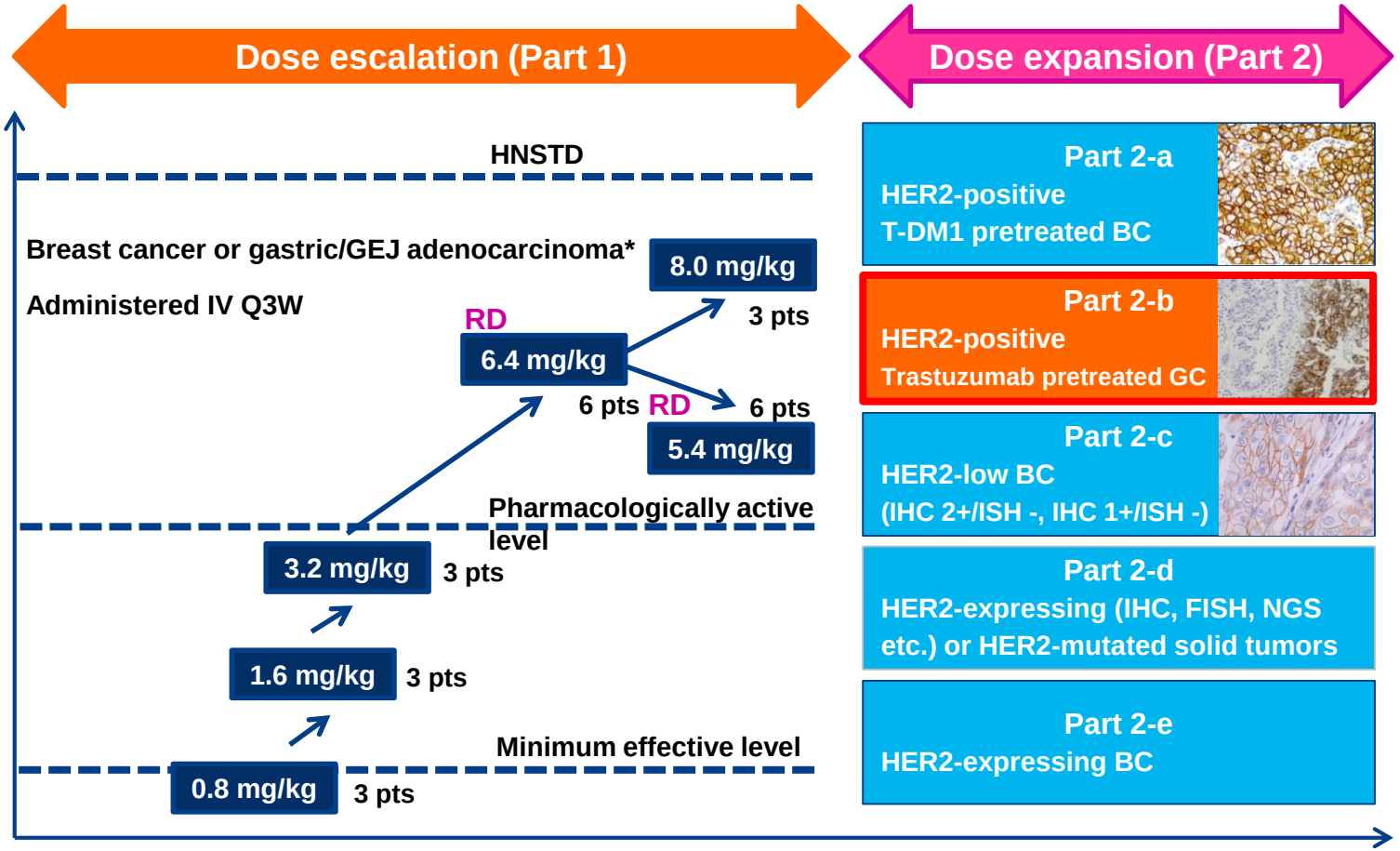
Result of gastric cancer cases from Part 1 and Part 2b was presented



*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.

DS-8201: Patient Background

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	Gastric/GEJ Adenocarcinoma (N = 45)
Age (years), median (range)	68.0 (38–79)
ECOG performance status, n (%)	
:Score to show limitation of patient's daily living abilities.	
(5 has most limitation and anticancer drug can be administered below 2)	
0	33 (73.3)
1	12 (26.7)
HER2 expression (IHC), n (%)*	
3+	36 (80.0)
2+	8 (17.8)
ISH positive	7 (15.6)
ISH negative†	1 (2.2)
1+	0
Missing	1 (2.2)
Number of prior cancer regimens, n (%)	
1	1 (2.2)
2	15 (33.3)
3	8 (17.8)
4	9 (20.0)
5 or more	12 (26.7)
Prior therapy, n (%)	
CPT-11 (irinotecan)	24 (53.3)
Trastuzumab	44 (97.8)

Analysis set: Enrolled to DS-8201 5.4 and 6.4 mg/kg groups.

*Local laboratory testing; Herceptest Scoring Criteria (CAP/ASCO 2013)- 3+: Uniform intense complete membrane staining in >10% of invasive tumor cells; 2+: Incomplete membrane staining that is weak to moderate in >10% of cells, or intense complete membrane staining in ≤10% of invasive tumor cells; 1+: Faint, incomplete membrane staining in >10% of invasive tumor cells; and 0: No staining is observed in invasive tumor cells or faint incomplete membrane staining in ≤10% of cells.

†Negative or examined but not expressing.

ECOG, Eastern Cooperative Oncology Group; GEJ, gastroesophageal junction; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization.

DS-8201: P1 Study Part 1+2b Efficacy

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- ORR was 45.5% in total evaluable patients
- ORR was 43.5% in patients with prior treatment of CPT-11 (irinotecan)

	Gastric / GEJ Adenocarcinoma	
	Total Evaluable (n = 44)	**Prior CPT-11* Treated (n = 23)**
ORR, n (%)	20 (45.5)	10 (43.5)
DCR, n (%)	36 (81.8)	19 (82.6)
PFS (months), median (95% CI)	5.8 (3.0, 8.3)	4.1 (2.5, 8.3)
Duration of follow-up (months), median (95% CI)	5.6 (3.7, 7.6)	4.8 (3.0, 7.8)
Duration of response (months), median (95% CI)	7.0 (NR)	6.9 (NR)

*CPT-11 is irinotecan.
Analysis set for ORR (CR+PR) and DCR (CR+PR+SD): Efficacy evaluable for confirmed overall response, at least 2 postbaseline scans or PD at the first scan (5.4 and 6.4 mg/kg).
Analysis set for PFS: Efficacy evaluable for PFS, at least one postbaseline scan (5.4 and 6.4 mg/kg). At the time of data cutoff, one subject is on treatment but does not have any post baseline scans.
Minimum and maximum of PFS that includes "+" after value indicates censoring.
CI, confidence interval; CR, complete response; DCR, disease control rate; GEJ, gastroesophageal junction; HER2, human epidermal growth factor receptor 2; NR, not recorded; ORR, objective response rate; PFS, progression-free survival; PR, partial response; SD, stable disease.

DS-8201: P1 Study Part 1+2b Efficacy

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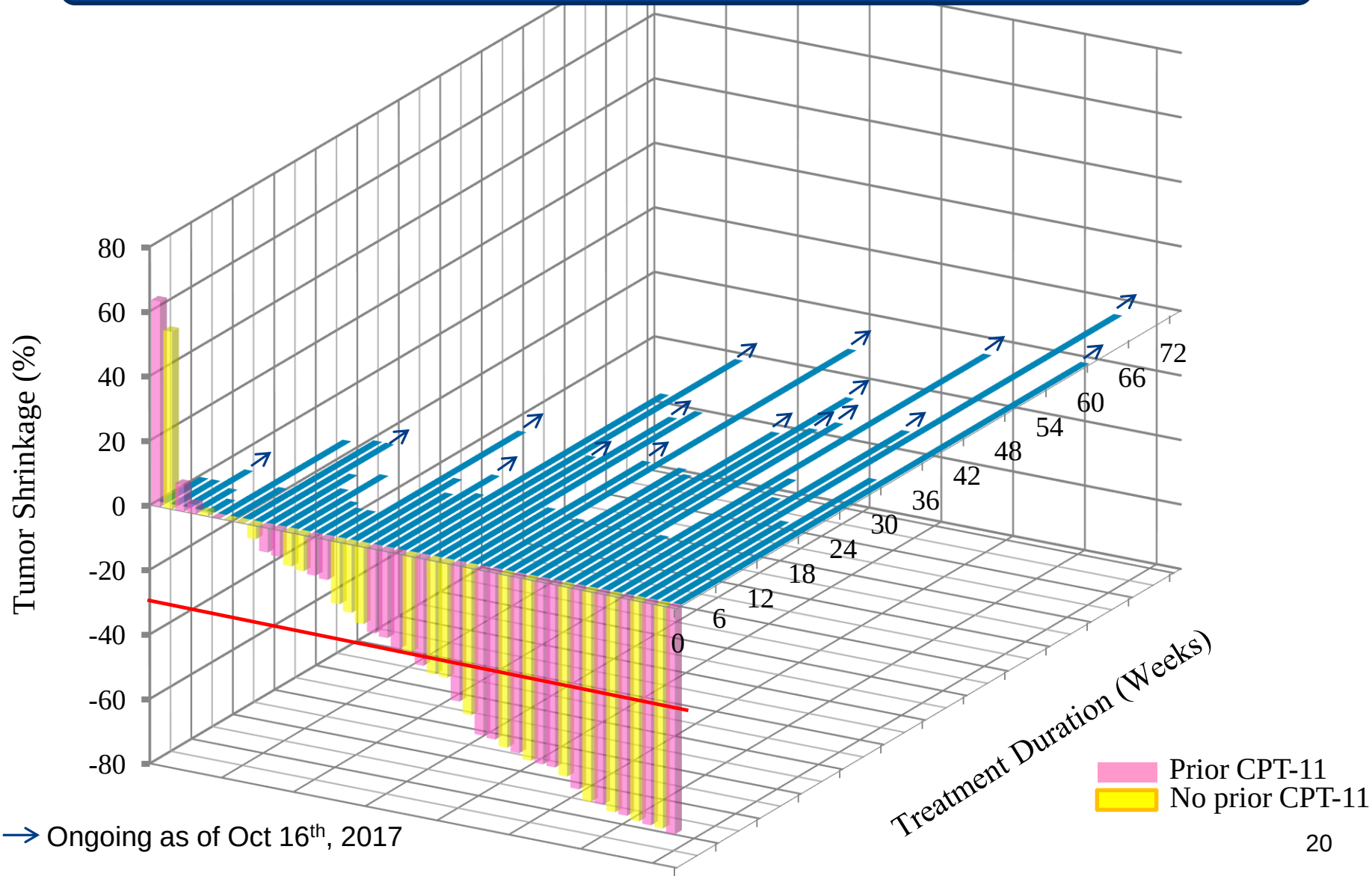
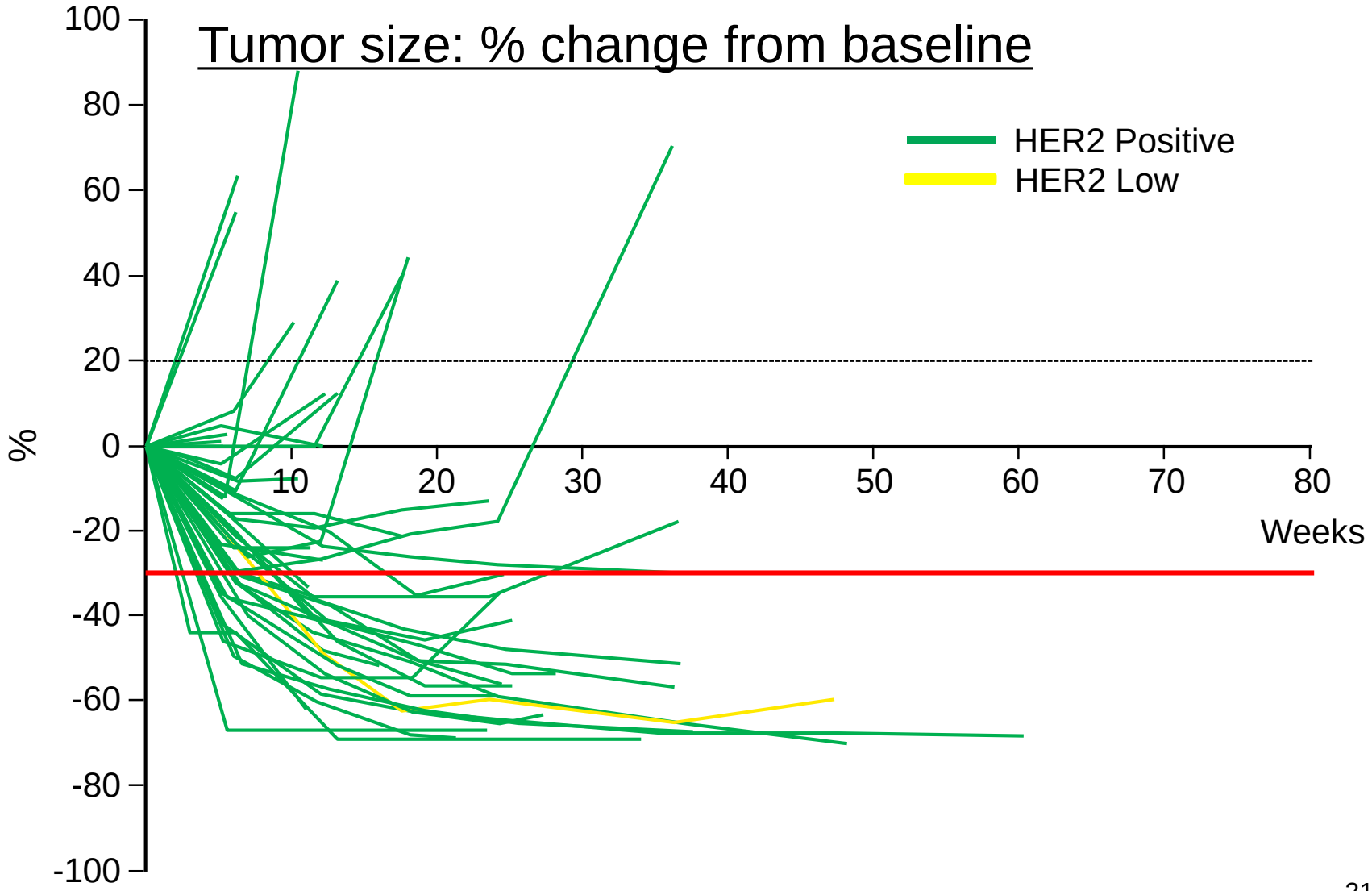
17 patients continue treatment



→ Ongoing as of Oct 16th, 2017

DS-8201: P1 Study Part 1+2b Efficacy

Tumor reductions are continuing in many patients



DS-8201: CT Imaging of PR

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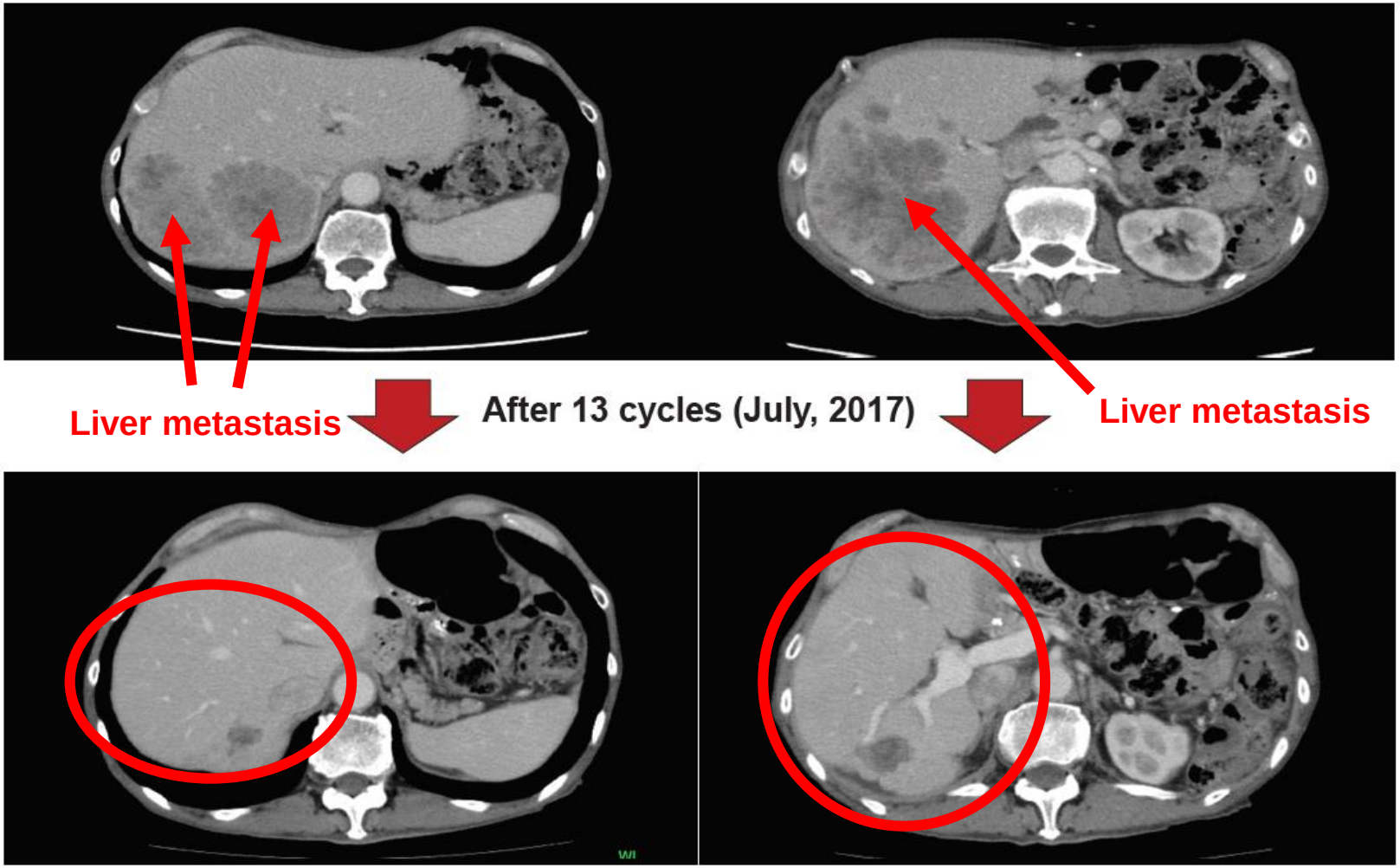
76 y/o Male gastric cancer with liver mets, IHC3+ (6.4mg/kg)

Pretreatment (August, 2016)



More than 30% tumor shrinkage was observed (PR)

DS-8201: Adverse Events >20% (N=45)

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No grade 5 treatment-emergent adverse events

Preferred term*	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	All n (%)
Hematologic					
Anaemia	0	5 (11.1)	11 (24.4)	0	16 (35.6)
Platelet count decreased	6 (13.3)	1 (2.2)	6 (13.3)	2 (4.4)	15 (33.3)
White blood cell count decreased	1 (2.2)	7 (15.6)	5 (11.1)	2 (4.4)	15 (33.3)
Neutrophil count decreased	1 (2.2)	3 (6.7)	7 (15.6)	2 (4.4)	13 (28.9)
Gastrointestinal disorders					
Nausea	29 (64.4)	2 (4.4)	1 (2.2)	0	32 (71.1)
Decreased appetite	18 (40.0)	8 (17.8)	3 (6.7)	0	29 (64.4)
Constipation	12 (26.7)	2 (4.4)	0	0	14 (31.1)
Vomiting	10 (22.2)	0	0	0	10 (22.2)
Diarrhoea	10 (22.2)	0	0	0	10 (22.2)
Others					
Pyrexia	8 (17.8)	2 (4.4)	0	0	10 (22.2)

Analysis set: Safety evaluable, at least one dose of DS-8201a (5.4 and 6.4 mg/kg).
There were no grade 5 treatment-emergent adverse events.
*Coded with MedDRA version 18.0.
GEJ, gastroesophageal junction; MedDRA, Medical Dictionary for Regulatory Activities.

- **Three subjects discontinued treatment due to TEAEs (pneumonia, decreased appetite, and pneumonitis)**
- **One case of grade 2 ejection fraction decrease has been reported by the investigators**
- **Two potential cases of interstitial lung disease (ILD)/pneumonitis were reported by the investigators (one grade 1 and one grade 3), which will be adjudicated by an independent ILD adjudication committee**

DS-8201: Conclusions at ASCO GI

- DS-8201 has shown manageable safety and promising antitumor activity in heavily pretreated subjects with HER2-positive gastric cancer who have previously received trastuzumab, regardless of prior CPT-11 treatment
- Promising efficacy and safety of DS-8201, a novel ADC, in HER2-expressing gastric cancer warrants further investigation

DESTINY

DESTINY-Gastric01 study is on-going

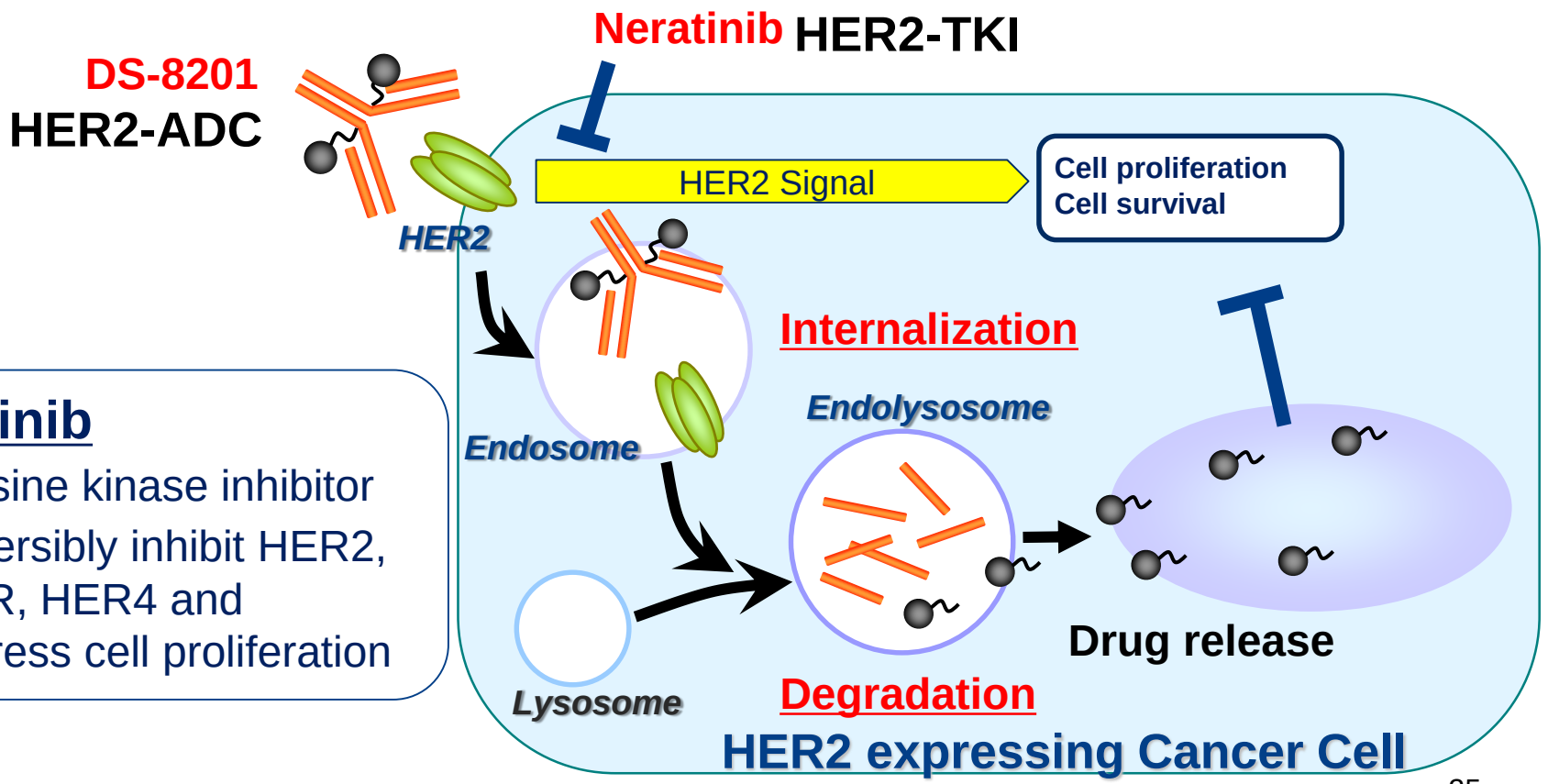
- Pivotal phase 2 study
- Examine the efficacy and safety of DS-8201 in HER2-expressing unresectable and/or metastatic gastric cancer who progressed on 2 or more prior regimens (NCT03329690)

DS-8201: Rationale of Neratinib Combo

- Research collaboration with Puma and Memorial Sloan Kettering Cancer Center (Dec. 2017)

Test synergetic effect hypothesis in non-clinical study

- HER2 dual blockage by combination of DS-8201 and neratinib
- Increase of internalization rate of DS-8201 by neratinib (increase uptake rate of DS-8201 into tumor)



Neratinib

- Tyrosine kinase inhibitor
- Irreversibly inhibit HER2, EGFR, HER4 and suppress cell proliferation

Appendix

- R&D Milestone Events
- Major R&D Pipeline
- Out-licensing Projects
- Edoxaban (Lixiana)
- Injectafer
- Abbreviations

R&D Milestone Events

Project	Indication / Study	FY2017		FY2018		
		3Q	4Q	Q1	Q2	Q3
Quizartinib	P3: QuANTUM-R AML2nd line treatment			TLR		
	P1: AML with DS-3032			Study initiation		
DS-8201	P2: Pivotal HER2+ Gastric (post trastuzumab)	Study initiation				
	P3: HER2+ Breast Post T-DM1 vs Phys Choice			Study initiation		
	P3: HER2+ Breast vs T-DM1			Study initiation		
	P3: HER2 low Breast					Study initiation
	P2: HER2+ CRC		Study initiation			
	P2: HER2+ NSCLC			Study initiation		
	P1b: HER2+ Breast | Bladder with nivolumab			Study initiation		
	P1/2: HER2+ Breast | NSCLC with IO					Study initiation
	P1/2: HER2+ Breast | Gastric with IO					Study initiation
U3-1402	P1/2: HER3+ Breast			P2 part Study initiation		
	P1: EGFRm NSCLC		Study initiation			
DS-1062	P1: Solid tumor (NSCLC)		Study initiation			
DS-1205	P1: EGFRm NSCLC with osimertinib		Study initiation			
Hydromorphone	P3: Cancer pain (injection formulation)		Approved			
Mirogabalin	P3: PHN / DPNP		Submission			
Esaxerenone	P3: Essential hypertension		Submission			
DS-5141	P1/2: Duchenne Muscular Dystrophy		TLR			

Red: New or update from FY2017 Q2 Underline: achieved

TLR: Top Line Results

Major R&D Pipeline

As of January 2018

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	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) ■ U3-1402 (JP/US) (Anti-HER3 ADC) ■ DS-1001 (JP) (IDH1m inhibitor) ■ DS-1205 (US) (AXL inhbitor) ■ PLX2853 (US) (BRD4 inhibitor) ■ DS-1062 (US/JP) (Anti-TROP2 ADC)	■ Patritumab (EU) (U3-1287 / H&N cancer / Anti-HER3 antibody) ■ DS-1647 (JP) (Glioblastoma / G47Δ virus) ■ Quizartinib (JP) (AC220 / AML-2nd / FLT3 inhibitor) ■ DS-8201 (JP/US/EU) (Breast cancer/anti-HER2 ADC) ■ DS-8201 (JP/Asia) (Gastric cancer/anti-HER2 ADC)	■ Denosumab (JP) (AMG 162 / Breast cancer adjuvant/ Anti-RANKL antibody) ■ Quizartinib (US/EU/Asia) (AC220 / AML-2nd / FLT3 inhibitor) ■ Quizartinib (US/EU/Asia) (AC220 / AML-1st / FLT3 inhibitor) ■ Pexidartinib (US/EU) (PLX3397 / TGCT / CSF-1R/KIT/FLT3 inhibitor) ■ Nimotuzumab (JP) (DE-766 / Gastric cancer / Anti-EGFR antibody)	
Specialty Medicine	■ DS-1040 (US/EU/JP) (Acute ischemic stroke, acute pulmonary embolism / TAFIa inhibitor) ■ DS-2330 (Hyperphosphatemia) ■ DS-1971 (Chronic pain) ■ DS-1501 (US) (Osteoporosis / Anti-Siglec-15 antibody) ■ DS-7080 (US) (AMD / Angiogenesis inhibitor) ■ DS-5141 (JP) (DMD / ENA oligonucleotide) ■ DS-1211 (US) (TNAP inhibitor) ■ VN-0102/JVC-001 (JP) (MMR vaccine)		■ Edoxaban (JP) (DU-176b / AF (very elderly) / 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) ■ Mirogabalin (US/EU) (DS-5565 / FM / α2δ ligand) ■ Mirogabalin (JP/Asia) (DS-5565 / DPNP/ α2δ ligand) ■ Mirogabalin (JP/Asia) (DS-5565 / PHN / α2δ ligand) ■ Laninamivir (JP) (CS-8958 / Anti-influenza / nebulizer) ■ VN-0105 (JP) (DPT-IPV / Hib vaccine) ■ Intradermal Seasonal Influenza Vaccine (JP) (VN-100 / prefilled i.d. vaccine for seasonal flu)	■ Edoxaban (ASCA etc.) (DU-176b / AF / FXa inhibitor) ■ Edoxaban (ASCA etc.) (DU-176b / VTE / FXa inhibitor) ■ Hydromorphone (JP) (DS-7113 / Cancer pain / Opioid μ-receptor agonist) <Injection> ■ VN-0107/MEDI3250 (JP) (Nasal spray flu vaccine)

Red: New or update

Out-licensing Projects

As of January 2018

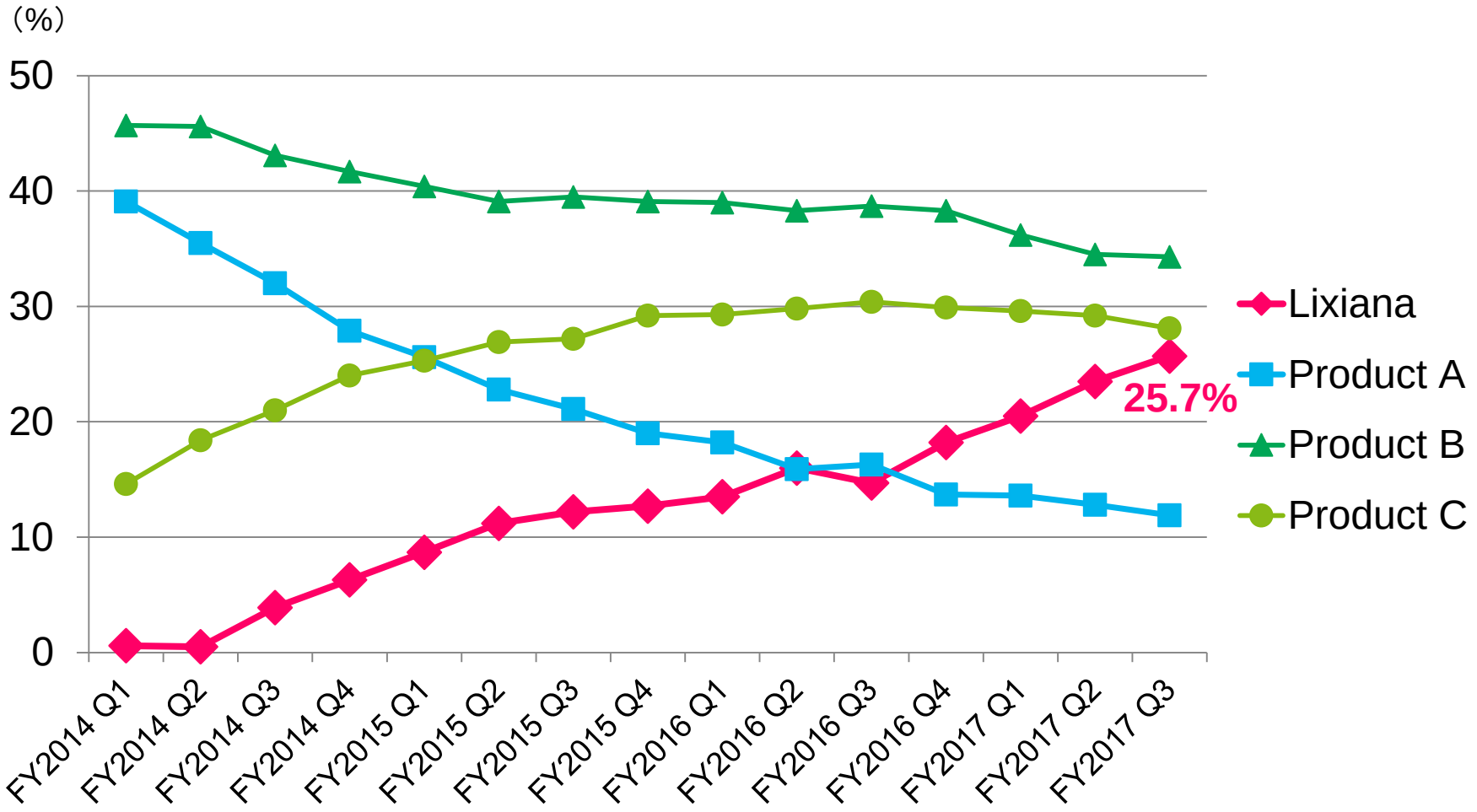
Daiichi-Sankyo

	Pre-clinical	Phase1	Phase 2	Phase 3
Oncology		■ DS-6051 (NTRK/ROS1 inhibitor) ■ U3-1784 (anti-FGFR4 antibody) ■ DS-1123 (anti-FGFR2 antibody)		
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)	■ Laninamivir (CS-8958/Anti-influenza/ Out-licensing with Aviragen)	

Red: New or update

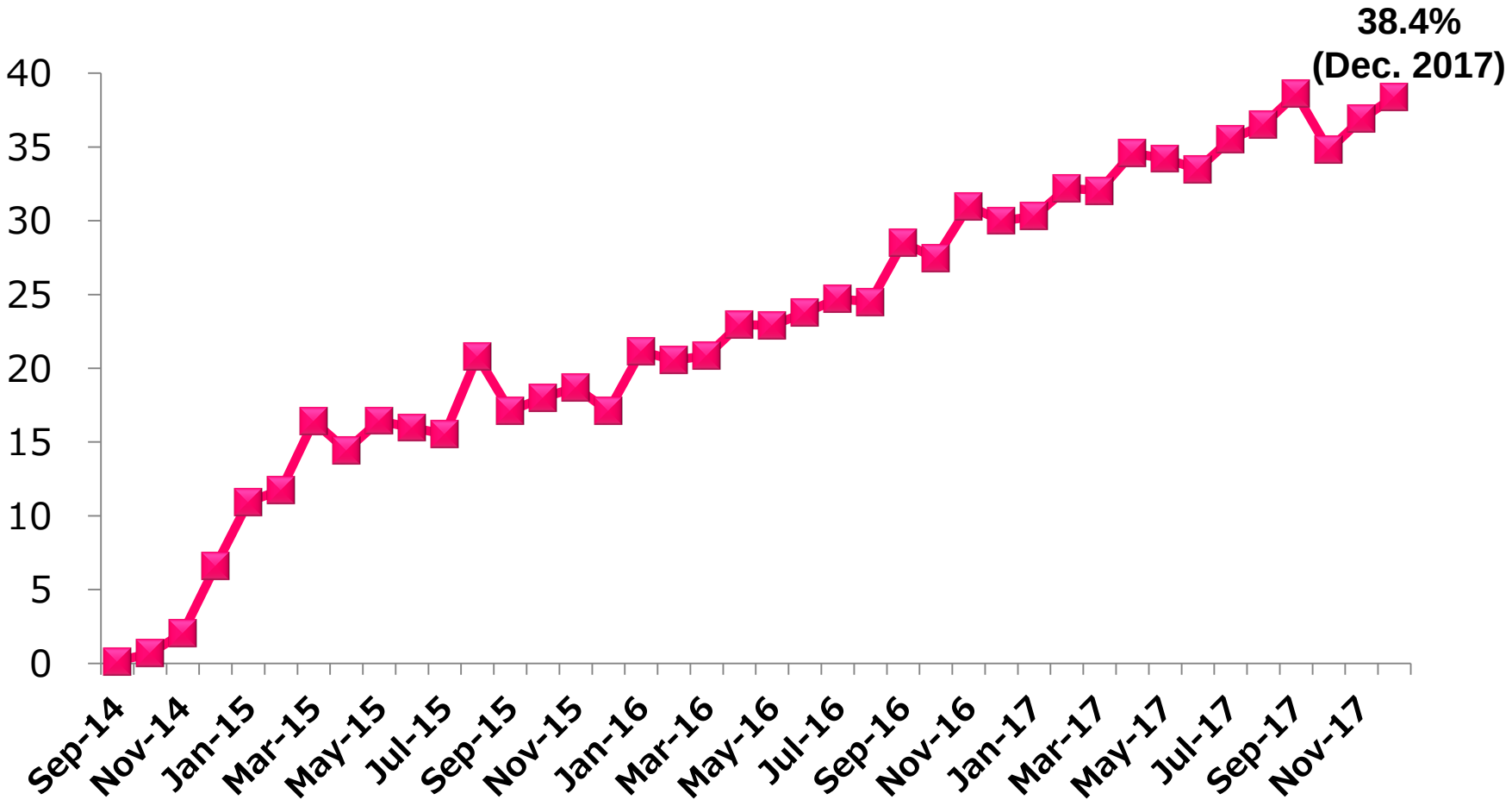
Lixiana: Growth in Japan

As of FY2017 Q3, Lixiana increased its sales share to **25.7%**.



Lixiana: Growth in Japan

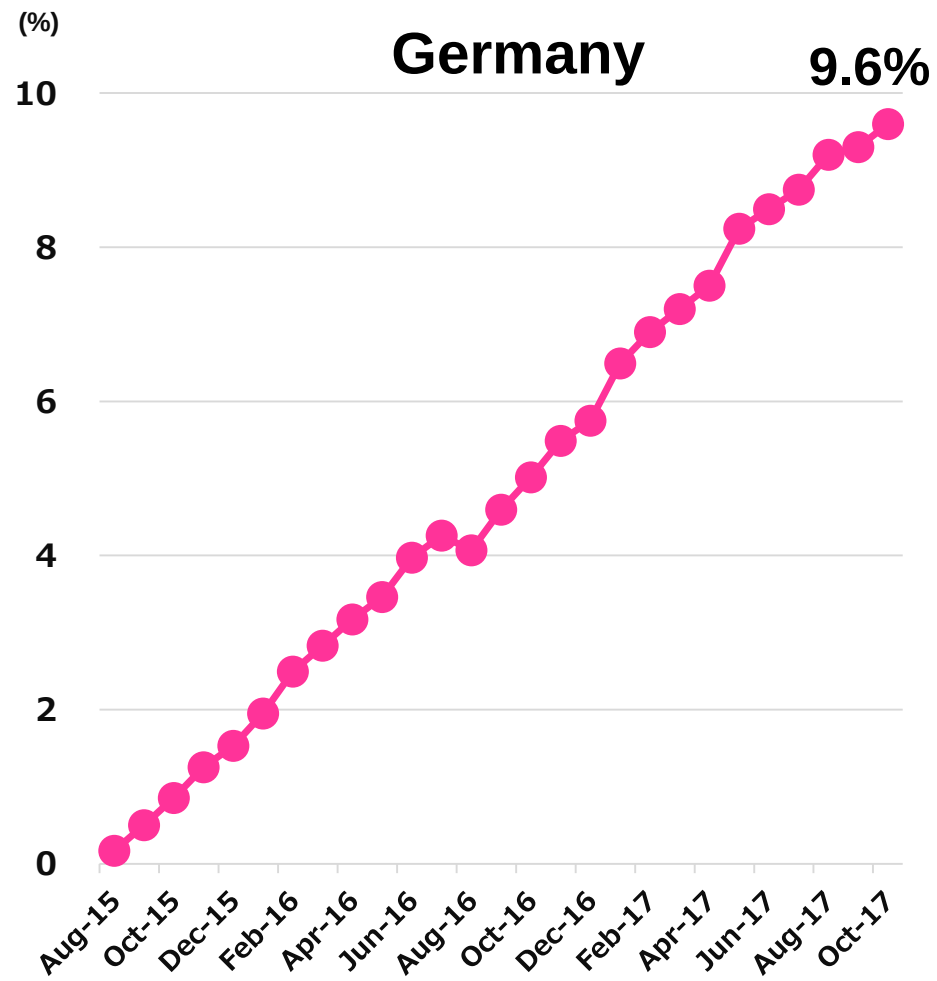
Lixiana has reached top Rxs share since Mar. 2017 in prescription number of new patients for AF+VTE. The share expanded to **38.4%** in Dec. 2017.

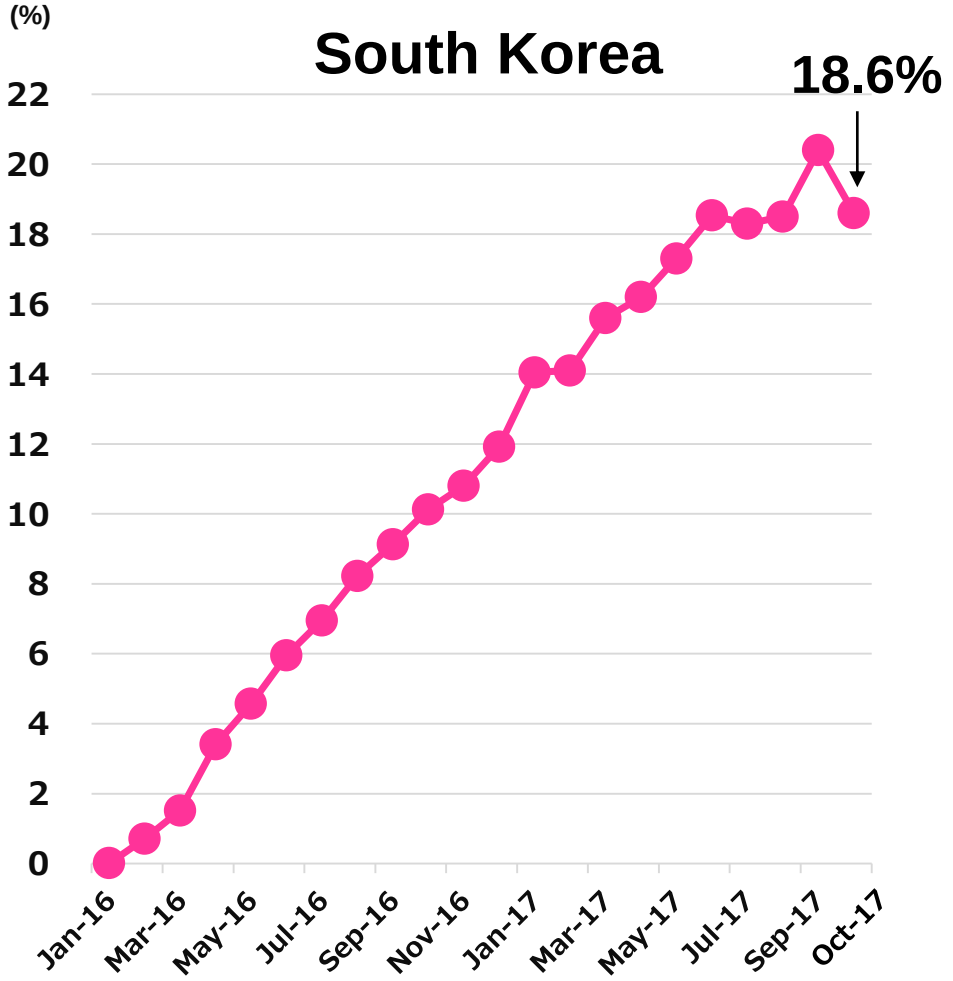


Source ：Medi-trend

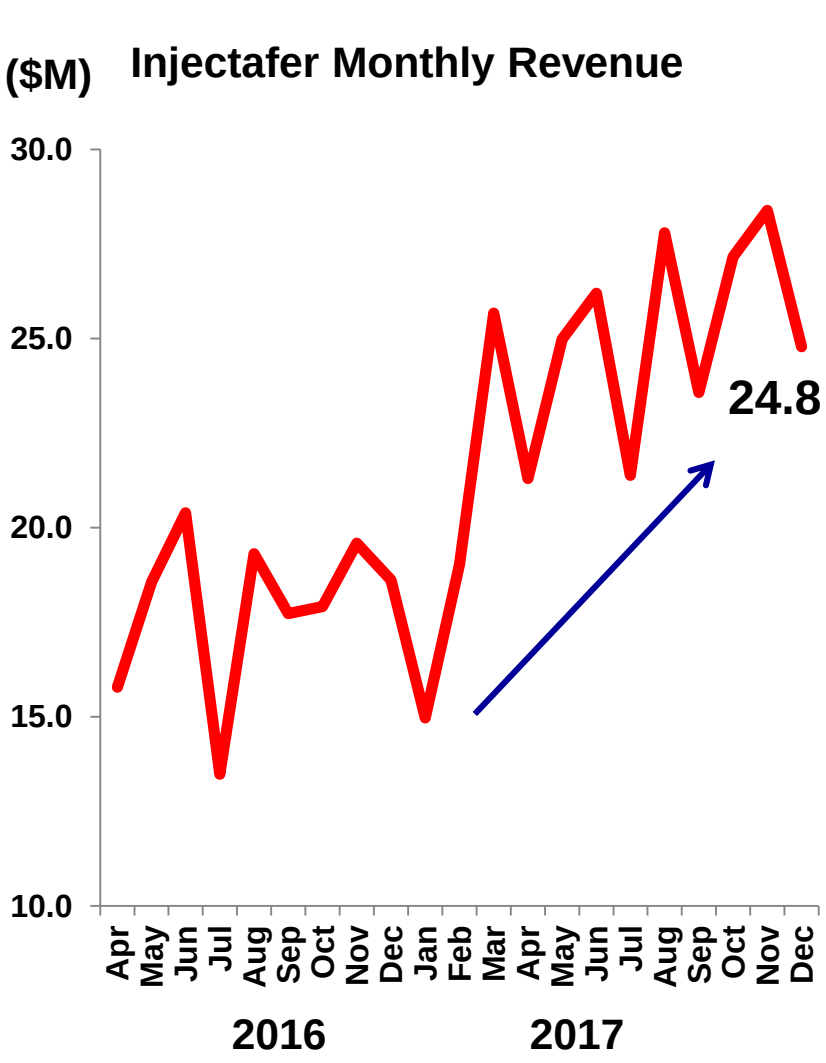
Lixiana : Growth in Germany and South Korea

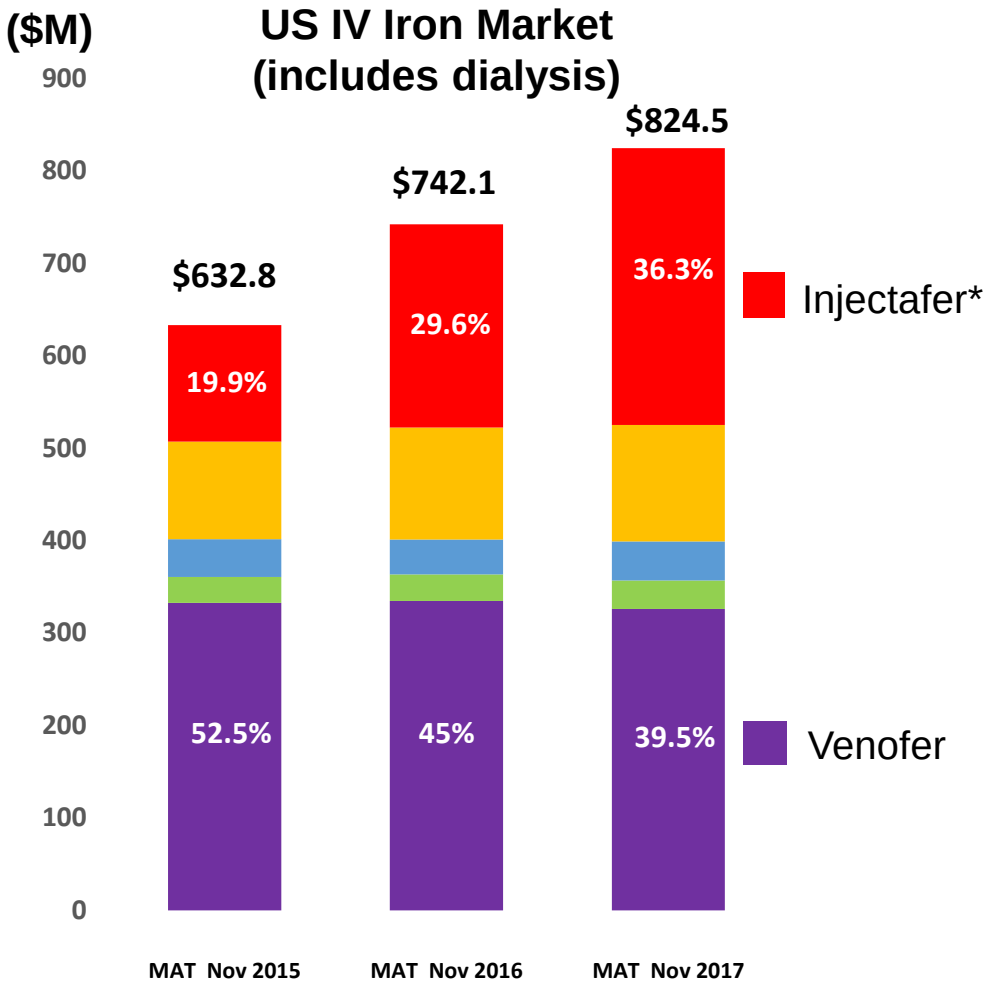
- Steady growth since launch
- Reached 3rd share in Germany and South Korea





Growth of Injectafer





*Injectafer is not indicated for patients who are dialysis dependent

Source: IMS National Sales Perspectives NOV 2017
(includes all US IV Iron sales in all channels including dialysis chains)

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

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