

Top Management Presentation

Financial Results of FY2017 Q1

DAIICHI SANKYO CO., LTD

Kazunori Hirokawa
Executive Vice President and CFO

July 31, 2017

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- ◆ FY2017 Q1 Financial Results

- ◆ Major Management Topics
 - Edoxaban
 - Japan Business
 - Injectafer
 - Business Growth in China

- ◆ R&D Update

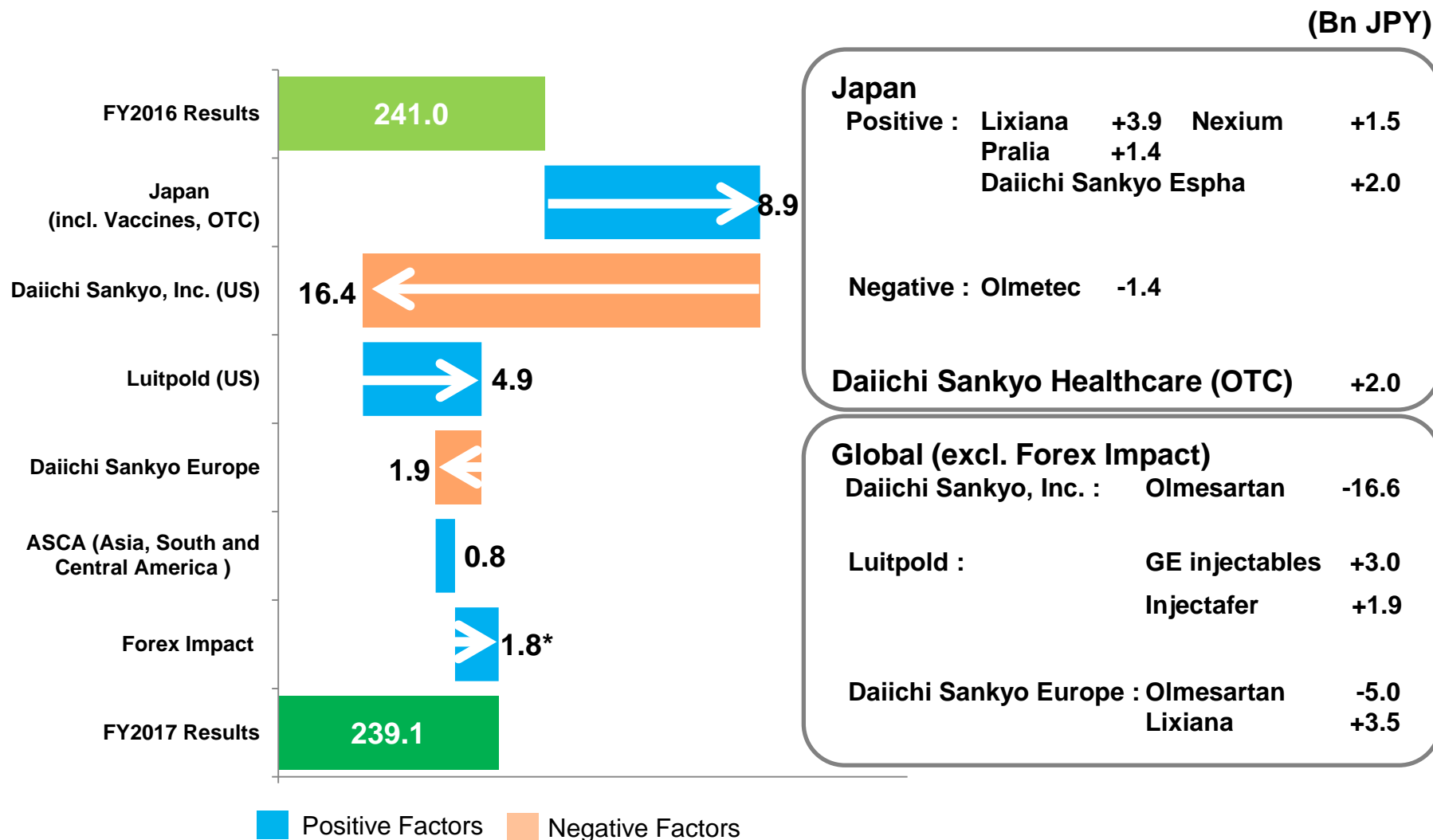
FY2017 Q1 Financial Results

Overview of FY2017 Q1 Results

(Bn JPY)

	FY2016 Q1 Results	FY2017 Q1 Results	YoY	
Revenue	241.0	239.1	-0.8% -1.9	
Cost of Sales	77.6	80.1	+2.5	
SG&A Expenses	69.5	70.8	+1.3	
R&D Expenses	46.6	48.0	+1.4	
Operating Profit	47.3	40.3	-14.8% -7.0	
Profit before Tax	45.2	42.2	-3.0	
Profit attributable to owners of the Company	30.6	29.2	-4.7% -1.4	
Currency Rate	USD/JPY	108.25	111.10	+2.85
	EUR/JPY	122.17	122.19	+0.02

Decreased by 1.9 Bn JPY (Decreased by 3.7 Bn JPY excl. forex impact)

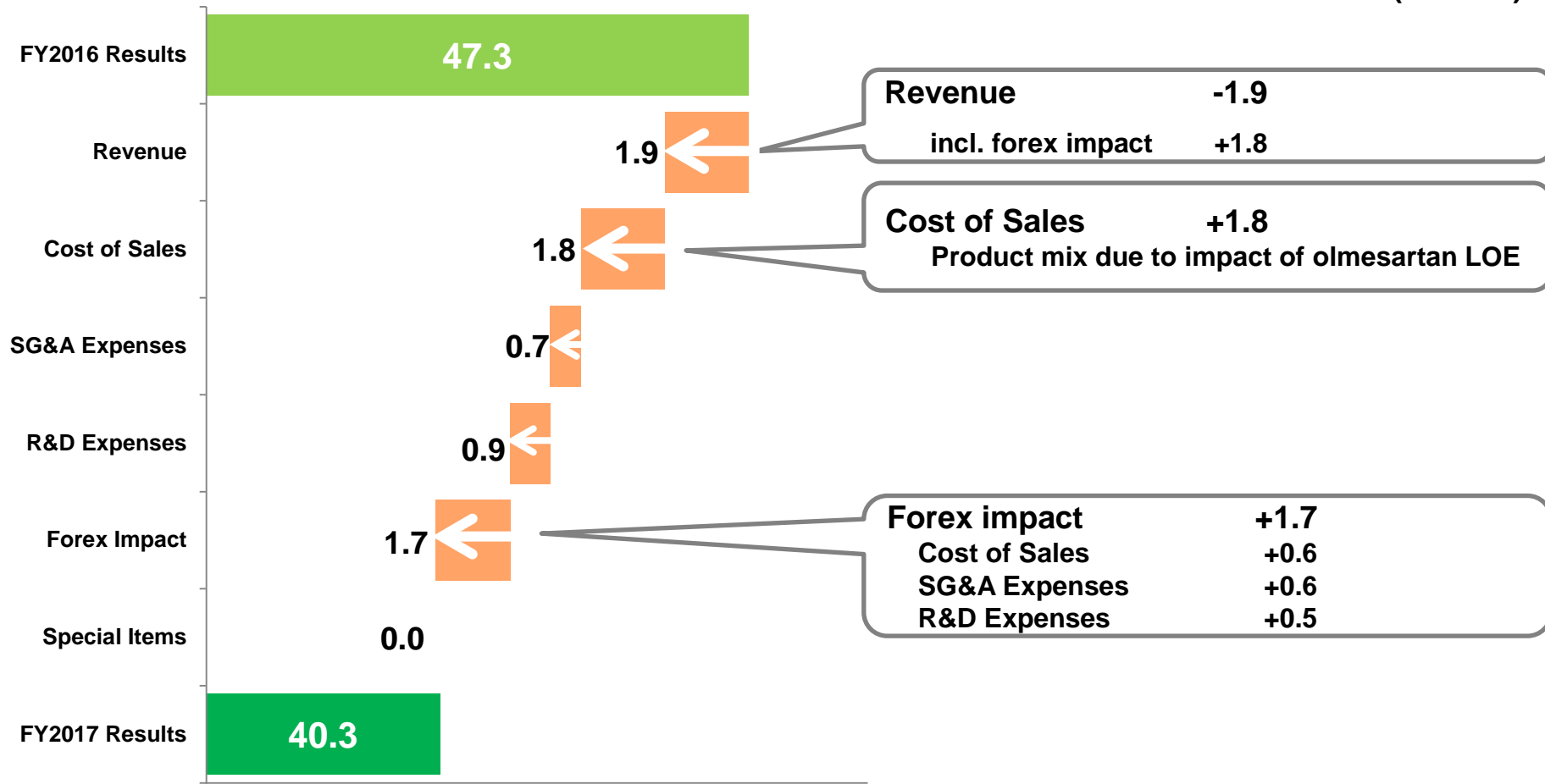


* Forex impact USD: +1.4, ASCA: +0.4

Operating Profit

Decreased by 7.0 Bn JPY
(Decreased by 7.1 Bn JPY excl. forex impact and special items)

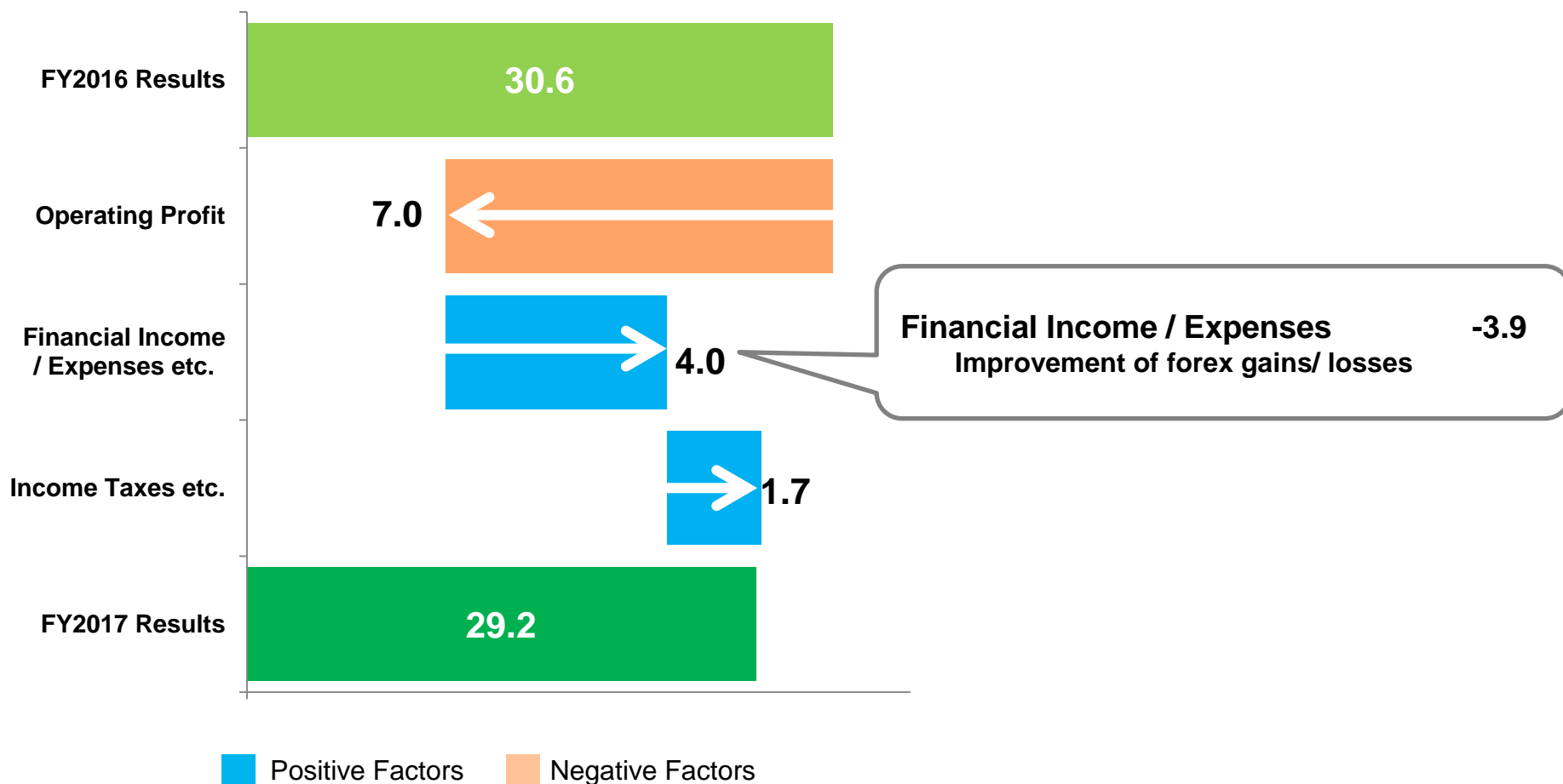
(Bn JPY)



Profit Attributable to Owners of the Company

Decreased by 1.4 Bn JPY

(Bn JPY)



Revenue: Major Business Units (Incl. Forex impact)

(Bn JPY)

	FY2016 Q1 Results	FY2017 Q1 Results	YoY	vs. Forecast (%)
Japan	123.4	130.0	+6.6	24.3%
Daiichi Sankyo Healthcare	14.8	16.8	+2.0	24.4%
Daiichi Sankyo Inc.	40.7	25.0	-15.7	40.3%
Olmesartan	23.2	6.8	-16.4	48.4%
Welchol	10.0	10.1	+0.2	37.5%
Effient	6.0	6.1	+0.1	-
Savaysa	0.3	0.5	+0.2	24.1%
Movantik	0.9	1.3	+0.4	-
Luitpold	22.0	27.6	+5.6	26.8%
Venofer	7.4	7.4	+0.0	26.4%
Injectafer	5.9	8.1	+2.1	24.4%
GE injectables	7.4	10.7	+3.3	-
Daiichi Sankyo Europe	20.4	18.5	-1.9	28.1%
Olmesartan	14.0	9.0	-5.0	34.5%
Efient	2.3	1.9	-0.4	27.2%
Lixiana	1.4	4.9	+3.5	22.3%
ASCA (Asia, South and Central America)	17.7	19.0	+1.2	22.6%

Currency	USD/JPY	108.25	111.10	+2.85
Rate	EUR/JPY	122.17	122.19	+0.02

Revenue: Major Products in Japan

(Bn JPY)

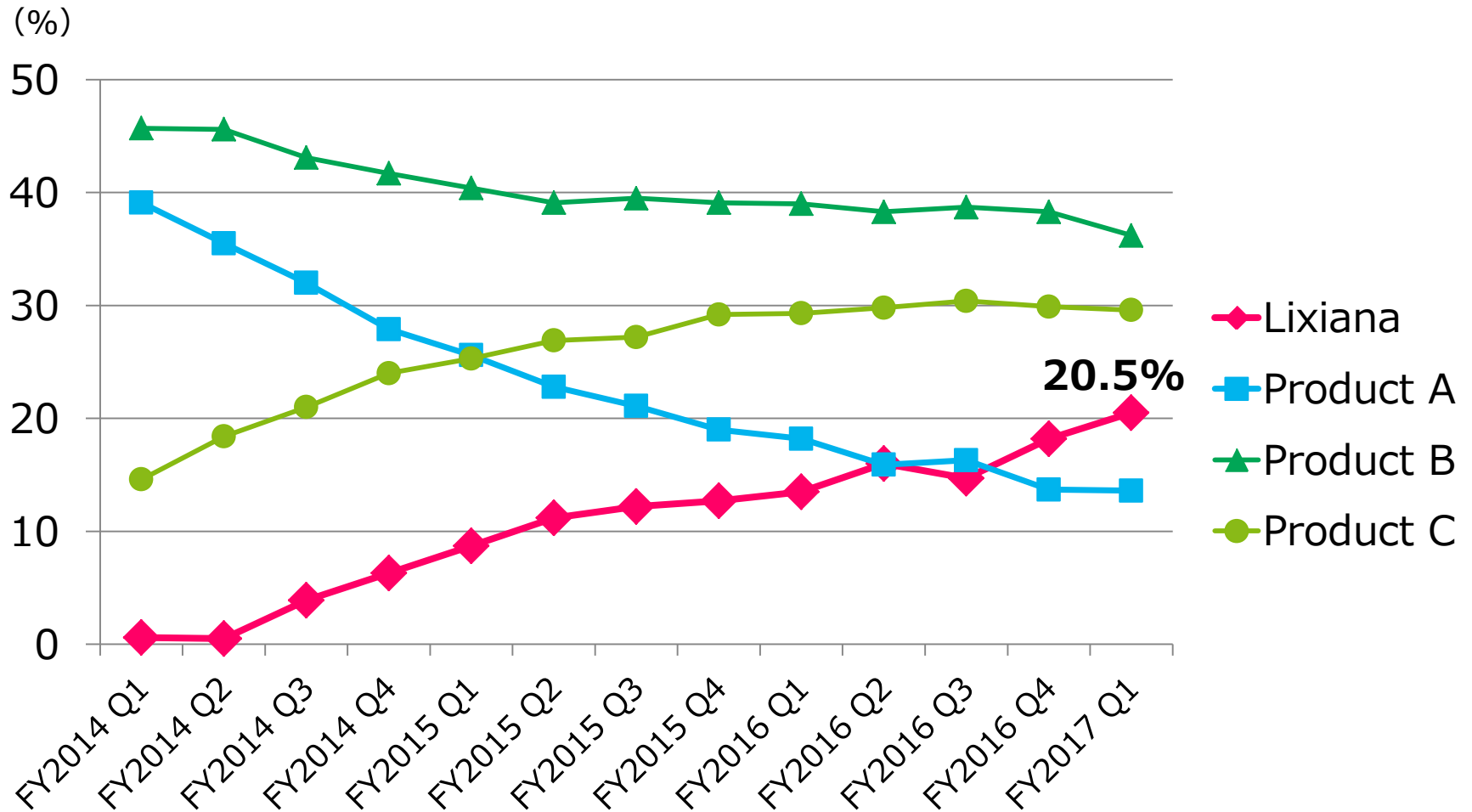
		FY2016 Q1 Results	FY2017 Q1 Results	YoY	vs. Forecast (%)
Nexium	ulcer treatment	21.0	22.6	+1.5	24.6%
Memary	Alzheimer's disease treatment	12.1	12.5	+0.4	23.2%
Olmotec	antihypertensive agent	18.3	16.8	-1.4	35.8%
Lixiana	anticoagulant	5.5	9.4	+3.9	24.0%
Loxonin	anti-inflammatory analgesic	10.3	9.6	-0.7	29.0%
Tenelia	type 2 diabetes mellitus treatment	6.7	7.6	+0.9	25.3%
Pralia	treatment for osteoporosis	4.1	5.5	+1.4	23.9%
Rezaltas	antihypertensive agent	4.7	4.5	-0.2	28.1%
Ranmark	treatment for bone complications caused by bone metastases from tumors	3.4	3.8	+0.4	25.1%
Efient	antiplatelet agent	2.5	3.3	+0.8	25.4%
Inavir	anti-influenza treatment	0.6	0.7	+0.2	5.5%
Cravit	synthetic antibacterial agent	3.8	3.3	-0.4	25.4%
Urief	treatment for dysuria	3.0	2.9	-0.1	26.3%
Omnipaque	contrast medium	3.7	3.6	-0.0	33.1%
Mevalotin	antihyperlipidemic agent	2.9	2.4	-0.5	24.5%

Major Management Topics

Edoxaban Update

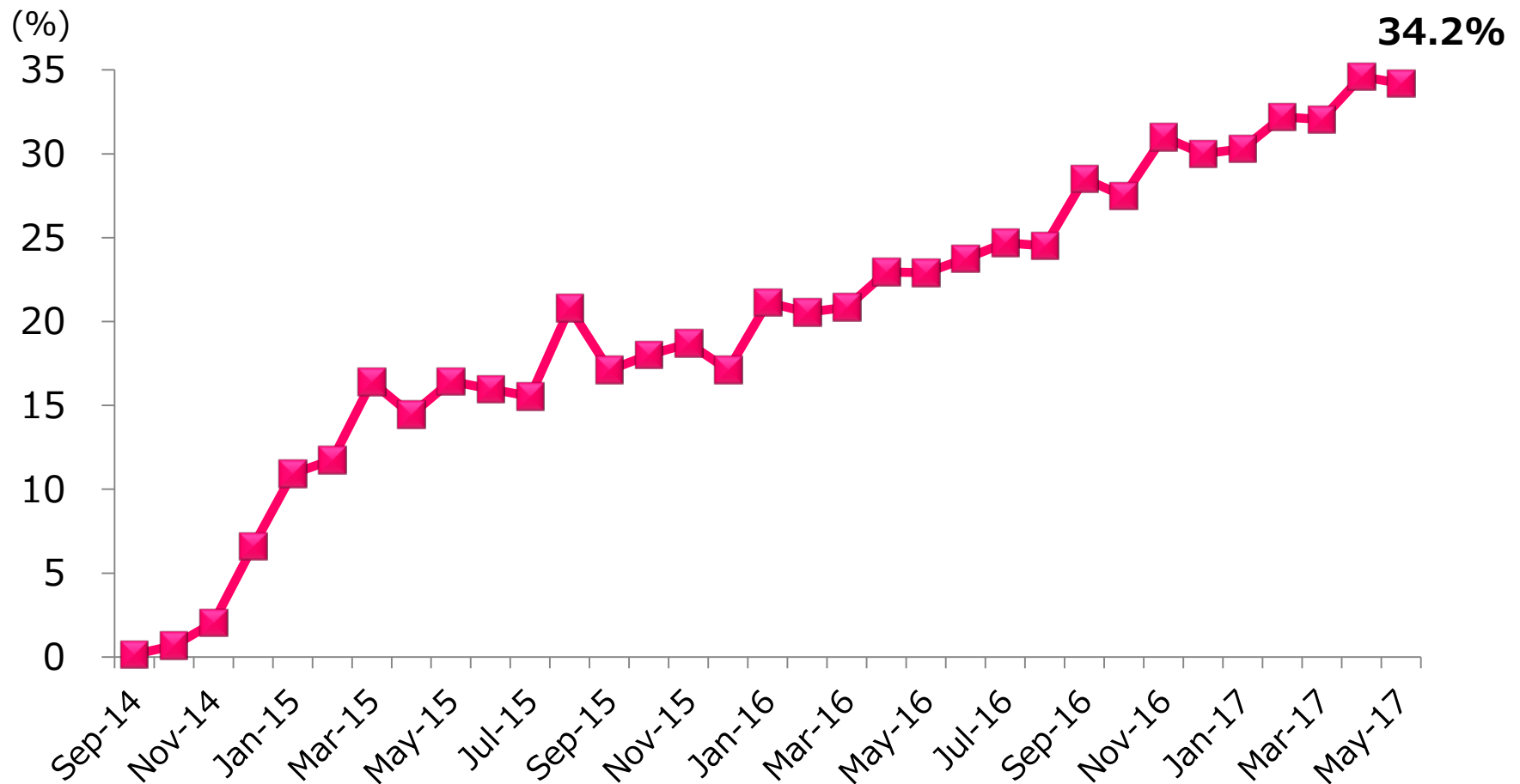
Growth in Japan

As of FY2017 Q1, Lixiana increased its sales share to **20.5%**.



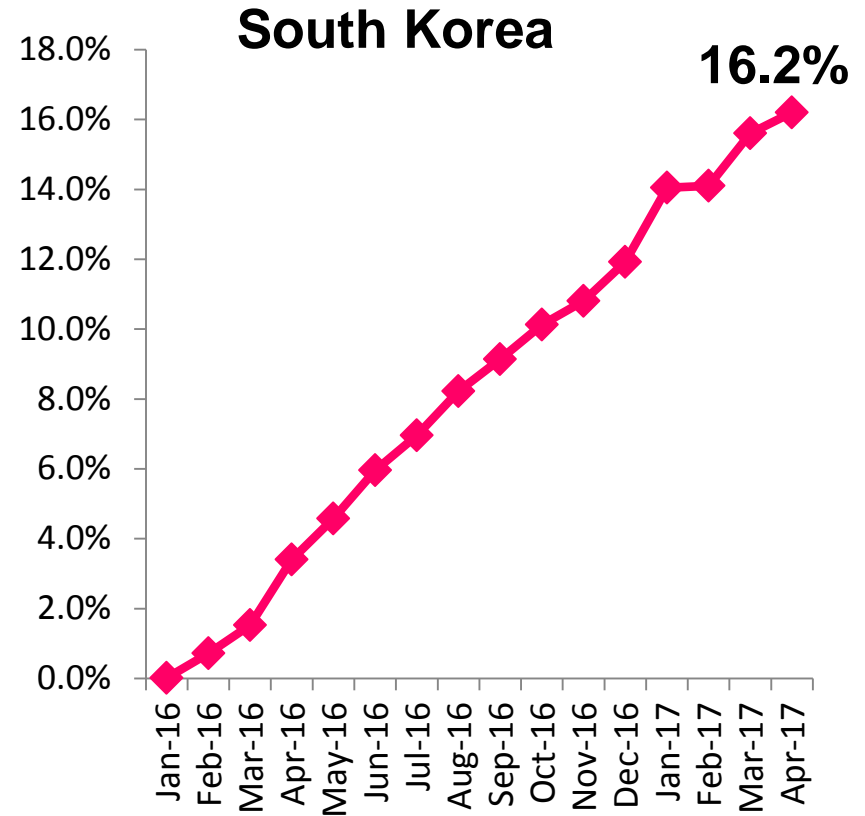
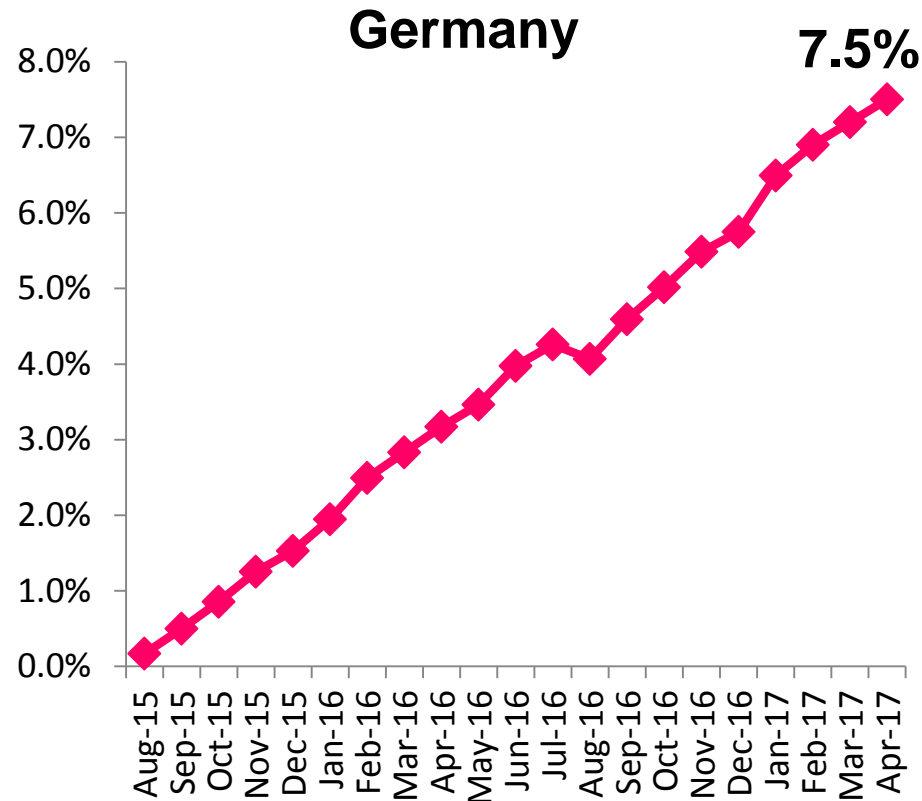
Growth in Japan

Lixiana has reached top Rx's share since Mar. 2017 in prescription number of new patients for AF+VTE. The share expanded to **34.2%** in May 2017.




Growth in Germany and South Korea

Steady uptake of sales share after launch



◆ Based on data from ENSURE-AF

- Following the positive opinion of European CHMP*¹ for LIXIANA (edoxaban) in patients with NVAF undergoing cardioversion, SmPC of LIXIANA was updated in “Posology and method of administration”.
 - ✓ Approx. 24 % of newly diagnosed AF patients estimated to undergo cardioversion*².
- The label update provides guidance on LIXIANA use in NVAF patients undergoing cardioversion. Physicians now rely on the guidance and use LIXIANA for such patients with more confidence than ever.

	Clinical Setting (Comparator)	Primary Outcome	Presentaion
	Cardioversion (enoxaparin/warfarin)	<ul style="list-style-type: none">• Stroke, SEE, MI, CV mortality• Major and CRNM bleeding	ESC 2016

*1: Committee for Medicinal Products for Human Use

*2: Nabauer M., et al. *Europace* (2009) 11, 423–434

Japan Business Update

◆ Approval for PRALIA for additional indication (July 2017)

- Indications: Inhibition of the progression of bone erosion*1 associated with rheumatoid arthritis
- Denosumab's approval for rheumatoid arthritis is **first in the world**
- **First product** to have both indications for **osteoporosis and rheumatoid arthritis**
 - ✓ About 45% of RA patients complicated with osteoporosis*2



◆ Approval for CANALIA combination tablets (July 2017)

- Combination product of Tenelia and Canaglu tablets, two agents for type 2 diabetes mellitus treatments, created by Mitsubishi Tanabe Pharma Corporation
- Marketing by Daiichi Sankyo, and co-promoting with Mitsubishi Tanabe
- **DPP-4 inhibitor/SGLT2 inhibitor combination** drug, **first approval in Japan**



*1: Bone erosion is a radiological term and reflects the fact that imaging is used for detection. Erosions are visible on plain radiographs as breaks and holes in the bone surface.

*2: 2010 Rheumatism White Paper (The Japan Rheumatism Friendship Association)

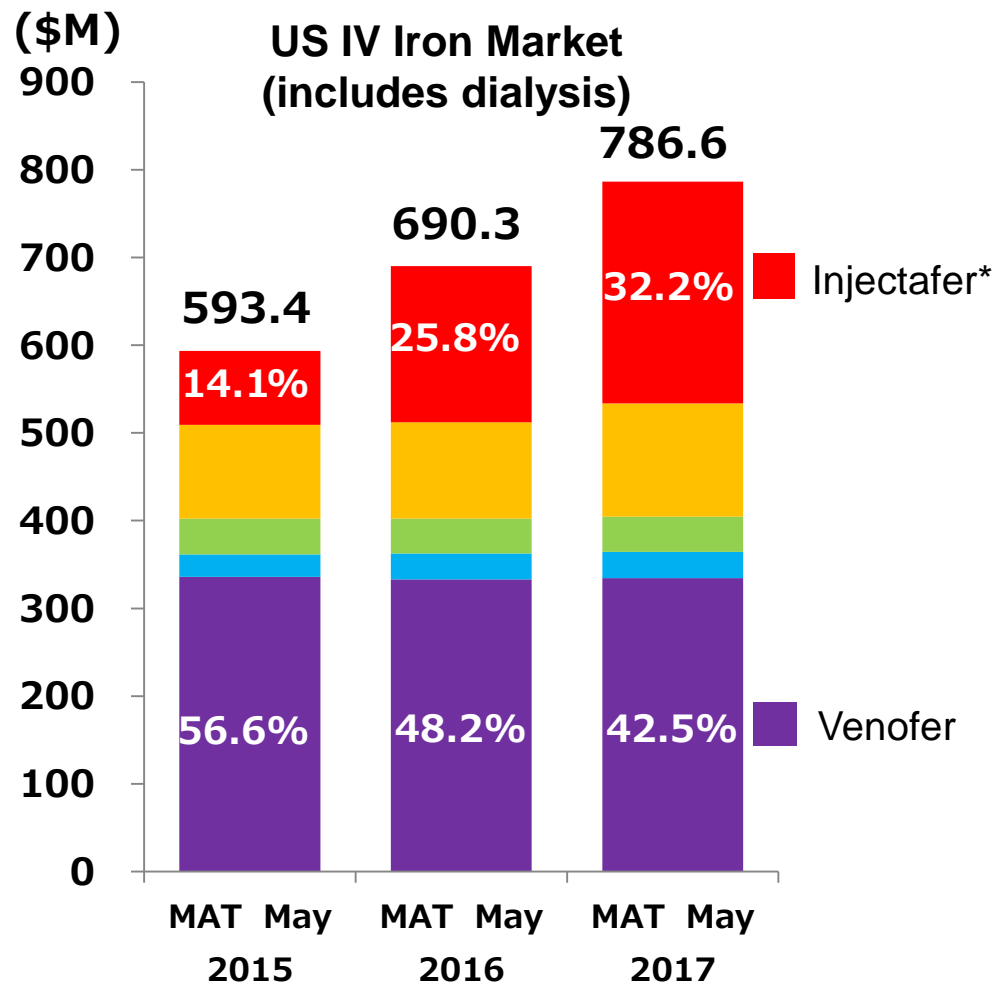
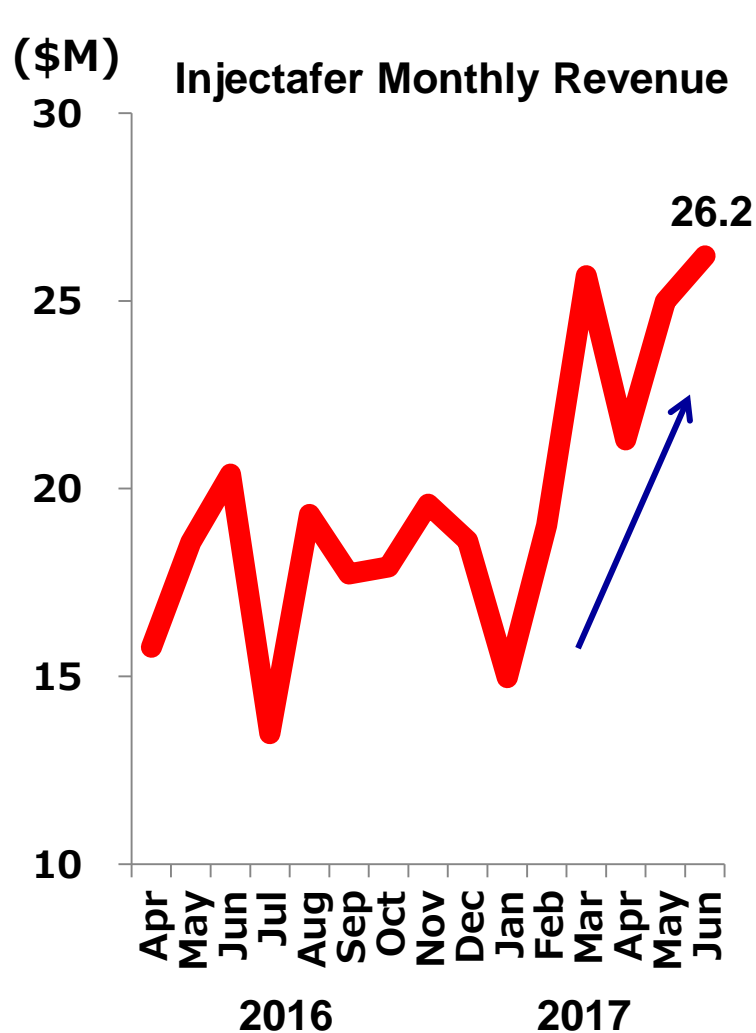
- ◆ **Launch of Narurapid and Narusus for cancer pain treatment (June 2017)**
 - Indications: Analgesic for moderate to severe cancer pain
 - Developed as **unapproved drugs and indications with high medical needs in Japan**
- ◆ **Strengthen authorized generic (AG) business through Daiichi Sankyo Espha**
 - Launched **telmisartan (original brand name: Micardis)** and its combination products (June 2017)
 - Launch **olmesartan** and **rosuvastatin (original brand name: Crestor)** in September **ahead of** competitors' generics



Injectafer Update

Growth of Injectafer

◆ Expanding monthly revenue under the integrated team (Daiichi Sankyo, Inc. and Luitpold) launched in Jan 2017



*Injectafer is not indicated for patients who are dialysis dependent
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 Source: IMS National Sales Perspectives May 2017
 (includes all US IV Iron sales in all channels including dialysis chains)

Heart Failure : HEART-FID (Phase 3 Study)

Randomized, double-blind, placebo-controlled study for patients in heart failure (HF) with reduced ejection fraction (HFrEF) with iron deficiency (ID)

FDA Agreement of Special Protocol Assessment to conduct a single pivotal study in HF

Enrolling more than 3,000 adults across North America, Australia and New Zealand

Primary composite outcome measure includes:

- 12-month rate of death
- 12-month number of hospitalizations for worsening HF
- 6-month change in 6-minute walk test

Started March 2017; expected completion in 2022

Iron deficiency is a comorbid condition in 50% of HF patients

HF prevalence has increased 5.8 million (2014) Americans ≥ 20 years of age.

Restless Leg Syndrome (RLS)

A phase 2, randomized, placebo-controlled study, investigators will assess the efficacy and safety of Injectafer for the treatment of RLS in patients with IDA.

Business Growth in China

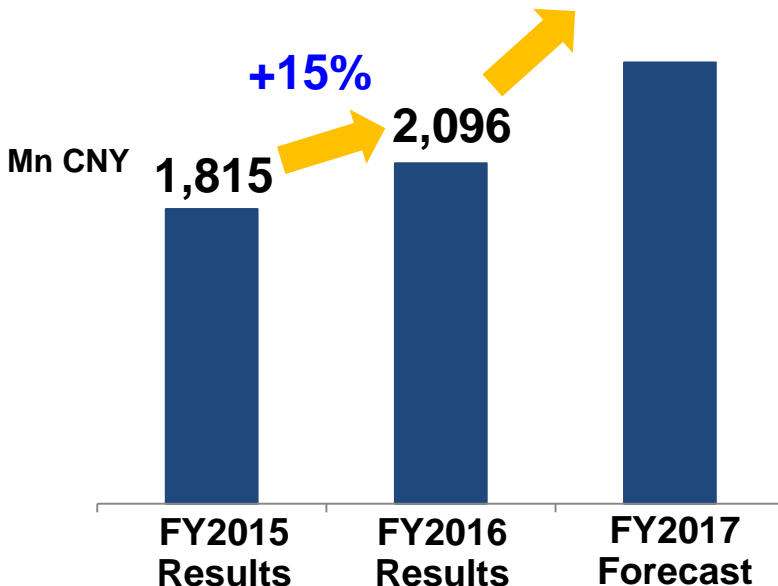
- ◆ Sales promotion activities of each product by partners through alliance initially started from outside of major cities

To maximize revenue and profit of products

- ◆ Partnering has expanded into **major cities** since **April 2016**

<Revenue>

Over 20% growth in FY2017



<Major Alliances>

Products	Alliance Start	Alliance Expansion
Olmetec	2015.12	2016.4
Olmetec HCTZ	2015.12	
Cravit	2015.1	
Asmeton	2013.9	
Mevalotin	2012.7	
Loxonin tablets	2014.2	
Loxonin tape	2016.1	

- ◆ **Daiichi Sankyo Pharmaceutical (Beijing) Co., Ltd.**
[Beijing Factory]

A new manufacturing line for injectable drugs has been activated since Jan. 2017.

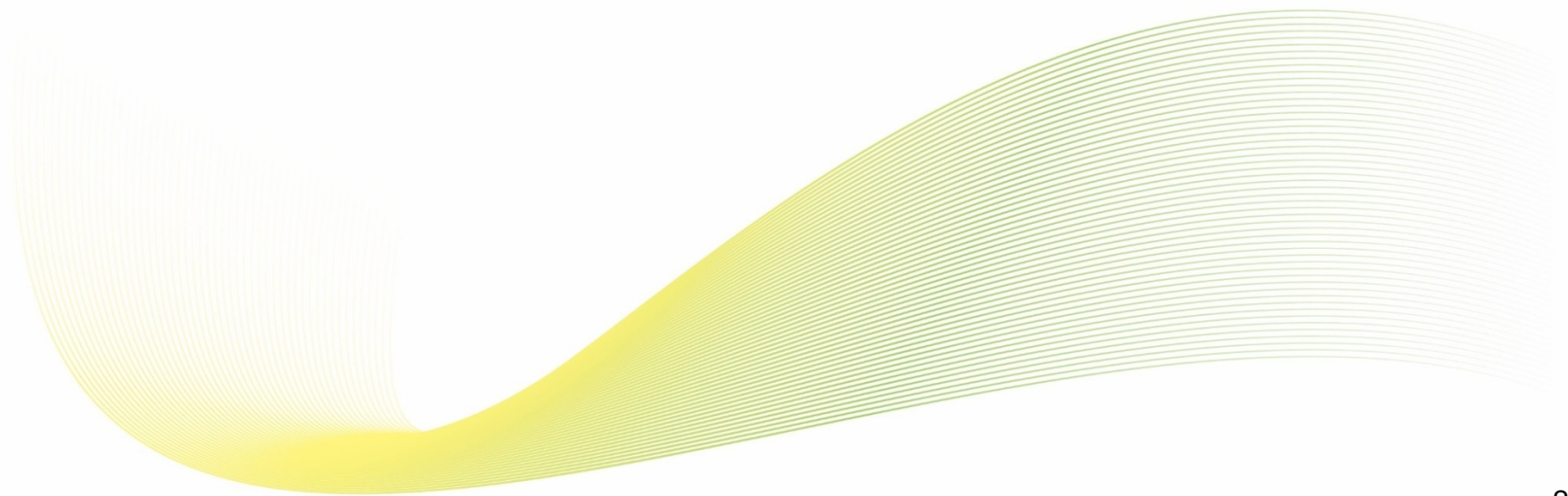
<Cravit IV>

- ◆ **Daiichi Sankyo Pharmaceutical (Shanghai) Co., Ltd.**
[Shanghai Factory]

A new facility for solid-form drugs will be activated in FY2018.

<Olmesartan family, etc.>

R&D Update



	Phase 3 studies	Result (primary endpoint*)
US/EU	Fibromyalgia (FM) –E309	Not-achieved
	Fibromyalgia (FM) –E310	Not-achieved
	Fibromyalgia (FM) –E311	Not-achieved
Japan/ Asia	Post-herpetic neuralgia (PHN)	Achieved
	Diabetic peripheral neuropathic pain (DPNP)	TLR by September 2017

◆ Future schedule

*comparison to placebo

- US/EU
 - ✓ Comprehensive analysis including all studies will be conducted to determine NDA strategy after obtaining TLR of DPNP
- Japan/Asia
 - ✓ NDA strategy and timing will be determined after obtaining TLR of DPNP

- Data disclosure at scientific conferences planned in FY2018

◆ **DS-8201 (HER2-ADC)**

- Progress of ongoing phase 1 study (oral)
- Immune response of DS-8201 (poster)

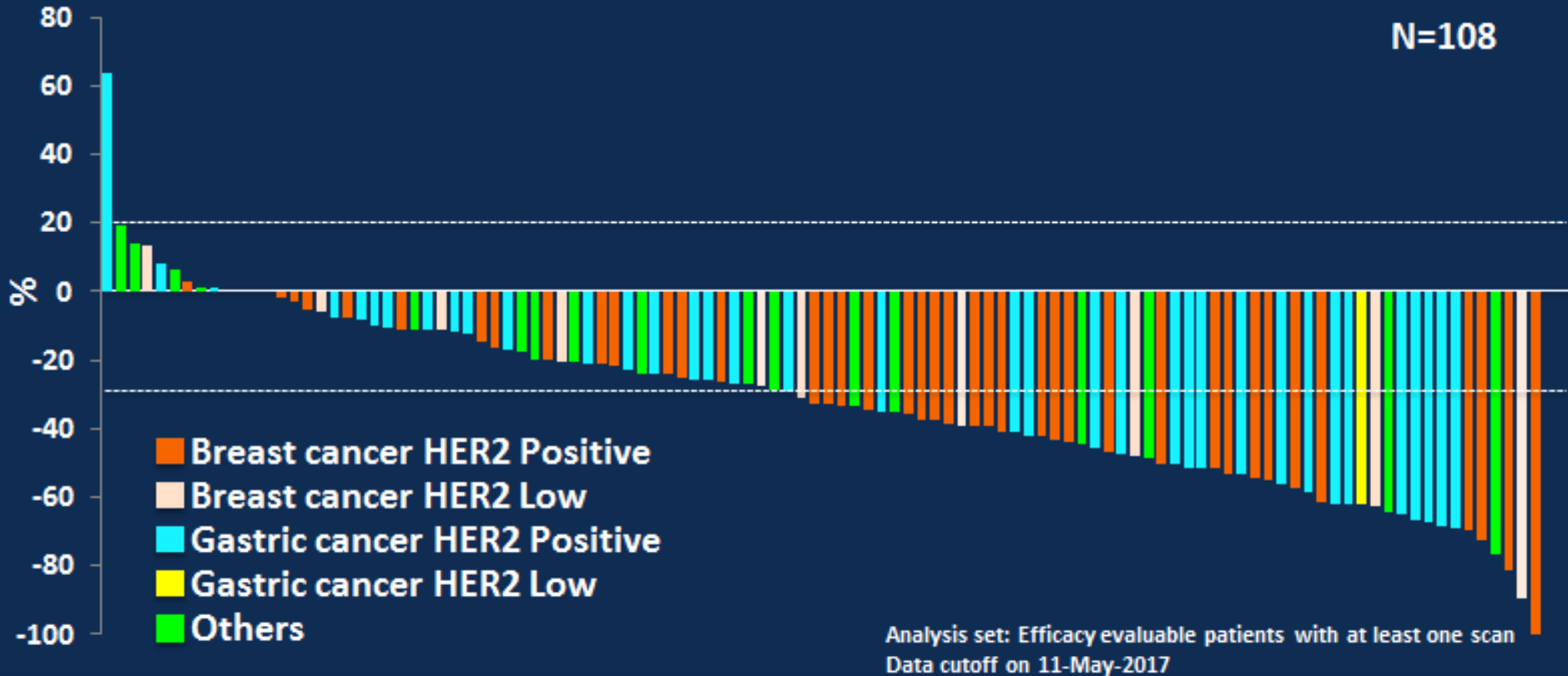
◆ **U3-1402 (HER3-ADC)**

- Study design of ongoing phase 1/2 study (poster)



Tumor size: best % change from baseline (5.4+6.4 mg/kg)

N=108



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Presented by: Toshihiko Doi

**Tumor size reductions were seen in most patients
(reduction is bigger when the bar goes down lower than 0%)**

Confirmed overall response rate (5.4+6.4 mg/kg)

	ORR n (%)	DCR n (%)
Total	39/97 (40.2)	89/97 (91.8)
Breast Cancer	19/45 (42.2)	44/45 (97.8)
BC Prior T-DM1	16/35 (45.7)	35/35 (100.0)
BC Prior T-DM1+Pertuzumab	14/30 (46.7)	30/30 (100.0)
Gastric Cancer	16/36 (44.4)	32/36 (88.9)
GC Prior CPT-11	8/18 (44.4)	17/18 (94.4)

ORR: Overall Response Rate
 DCR: Disease Control Rate

Analysis set: Efficacy evaluable patients for confirmed overall response
 Data cutoff on 11-May-2017

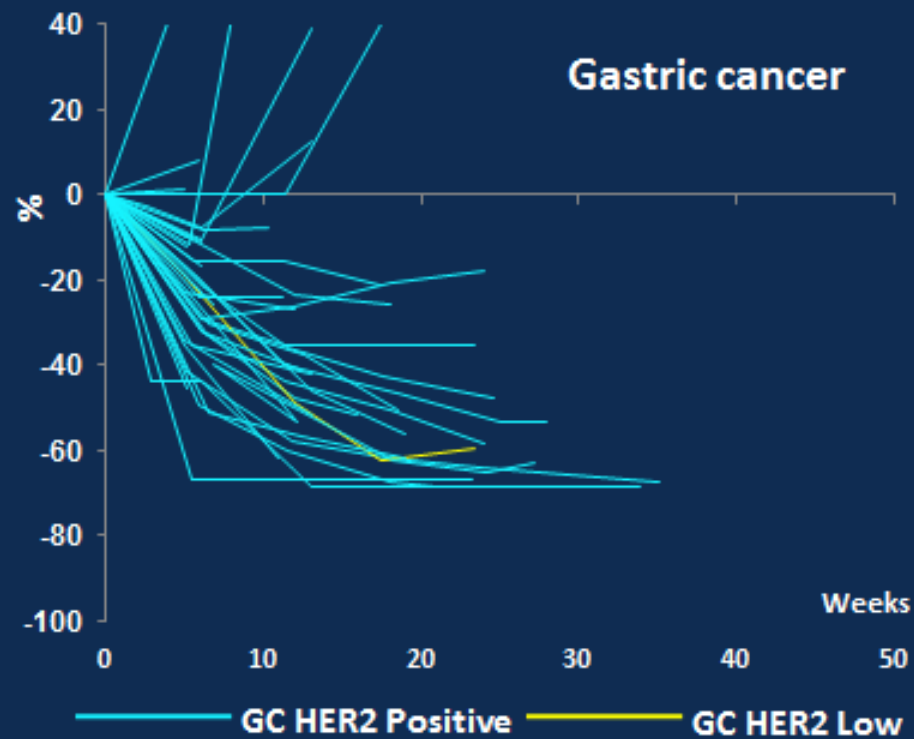
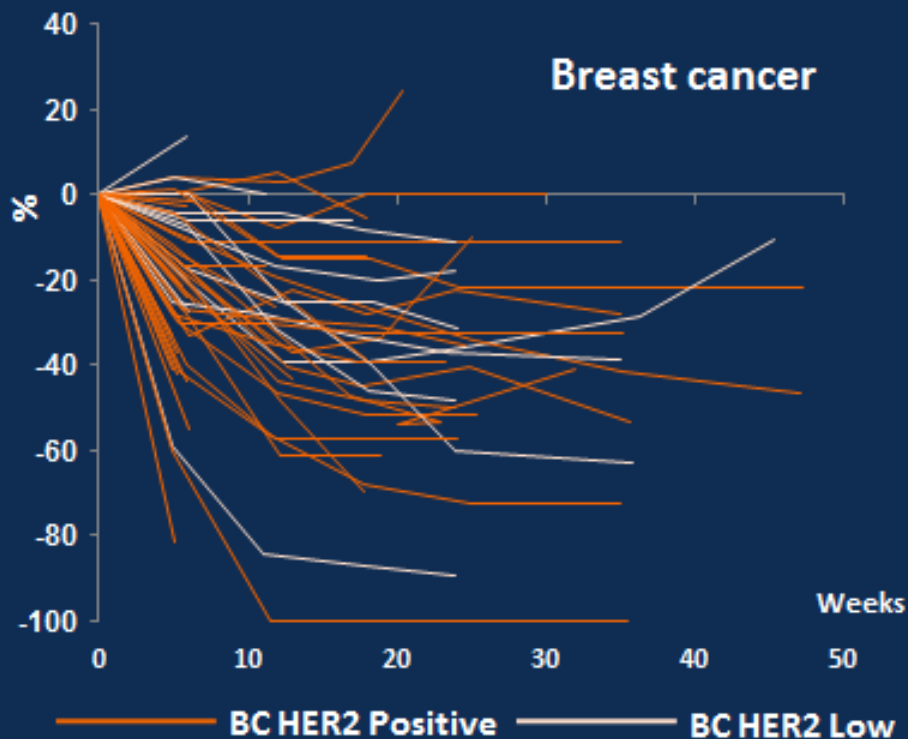
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**ORR was 45.7% in BC patients with prior treatment of T-DM1 (Kadcyla)
 ORR was 44.4 % in GC patients with prior treatment of CPT-11 (irinotecan)**

Tumor size: % Change from baseline (5.4 + 6.4 mg/kg)



Analysis set: Efficacy evaluable patients with at least one scan
Data cutoff on 11-May-2017

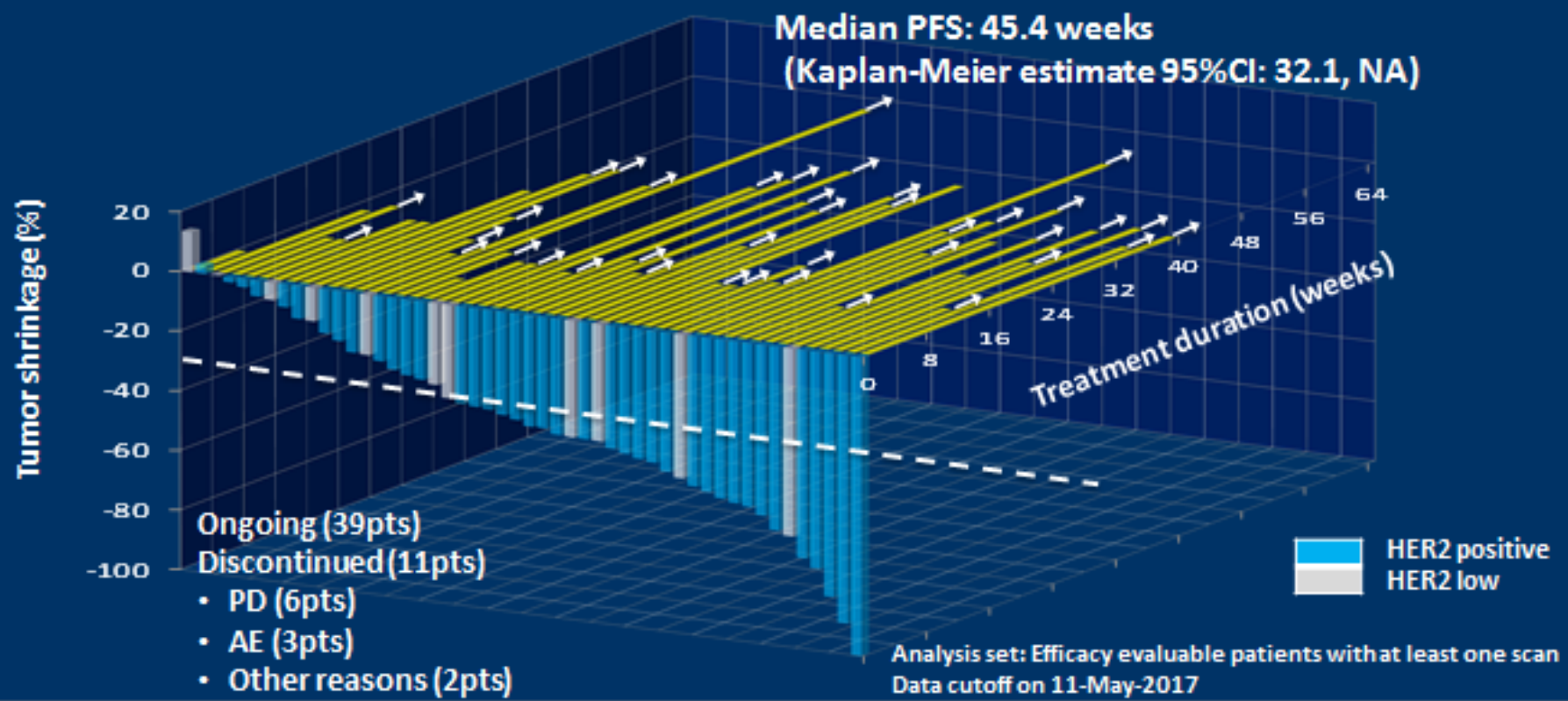
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Tumor reductions confirmed from beginning of treatment and reductions are continuing

Response and treatment duration (Breast cancer, 5.4 + 6.4 mg/kg)



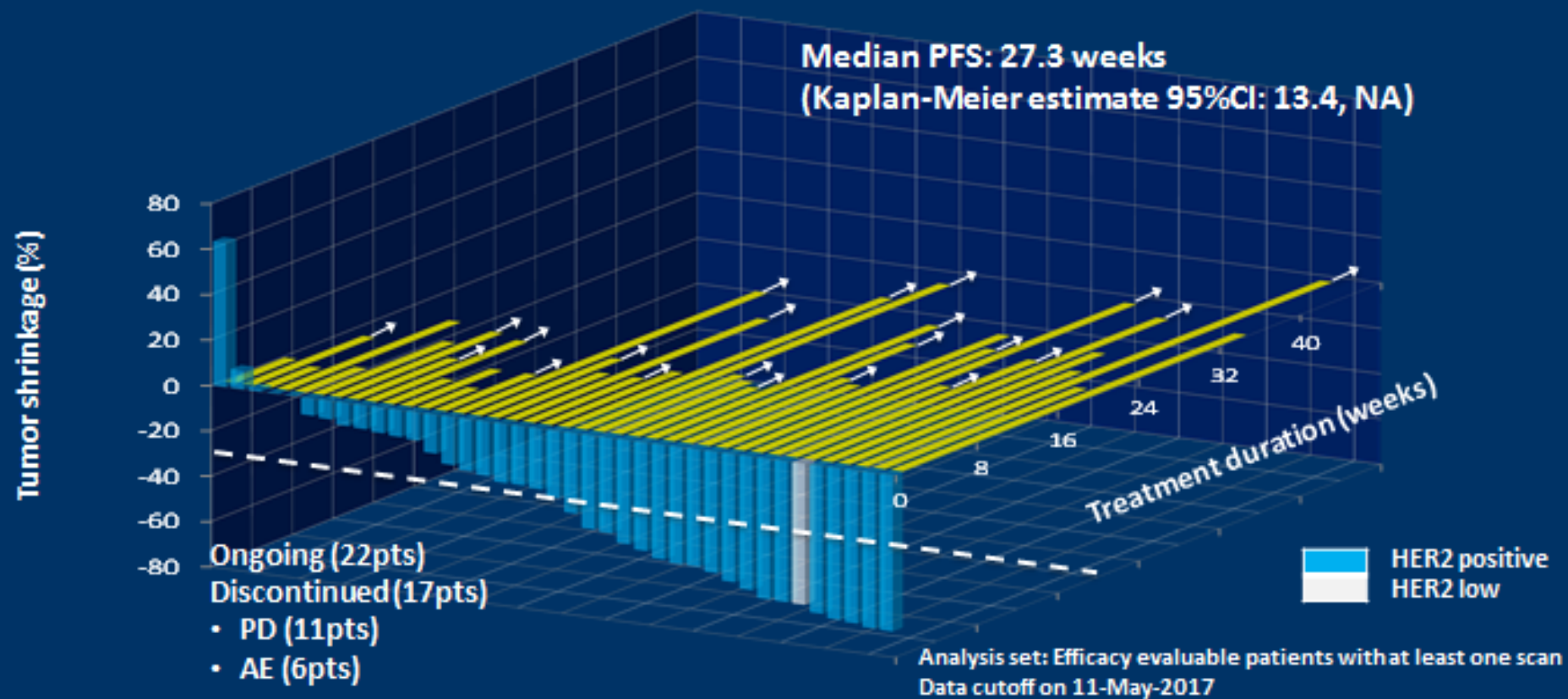
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Median PFS has reached 45.4 weeks
Approximately 80% of patients continue treatment with DS-8201

Response and treatment duration (Gastric cancer, 5.4 + 6.4 mg/kg)



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Median PFS has reached 27.3 weeks

Approximately 50% of patients continue treatment with DS-8201

TEAE, any grade, >20% (No DLT observed)

Preferred Term (N=133)	Grade 1 (%)	Grade 2 (%)	Grade 3 (%)	Grade 4 (%)	All (%)
Hematologic					
Platelet count decreased	13.5	9.0	8.3	3.8	34.6
Anaemia	3.0	12.0	14.3	1.5	30.8
Neutrophil count decreased	0.8	9.8	12.0	3.0	25.6
White blood cell count decreased	0.8	12.8	9.0	1.5	24.1
Gastrointestinal disorders					
Nausea	51.9	13.5	1.5	0.0	66.9
Decreased appetite	33.8	20.3	3.8	0.0	57.9
Vomiting	31.6	3.8	1.5	0.0	36.8
Diarrhea	19.5	5.3	0.8	0.0	25.6
Constipation	18.8	3.0	0.0	0.0	21.8
Others					
Alopecia	21.1	6.0	0.0	0.0	27.1
Malaise	18.0	4.5	0.8	0.0	24.1

Any Grade 3/4 – 43.6%

Analysis set: Safety evaluable patients who received at least one dose of DS-8201a
Data cutoff on 11-May-2017

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**No dose-limiting toxicity (DLT) was seen
Low incidence of grade 4 adverse events**

◆ Presented immune response of DS-8201

Purpose	To analyze MOA of combination benefit of DS-8201 and anti PD-1 antibody by using syngeneic mouse model
Result	<p>When tumor cell was re-challenged to cured mice that were treated with DS-8201, it was rejected. Thus, activation of antitumor immunity was confirmed.</p> <ul style="list-style-type: none">• Up-regulated dendritic cell^{*1} marker• Up-regulated MHC-Class I^{*2} on tumor cells• Up-regulated PD-L1^{*3} on tumor cells
Conclusion	This finding suggests that DS-8201 has ability to activate antitumor immunity and may have additional benefit of combining with immune checkpoint inhibitor

◆ Details will be disclosed in scientific journal.

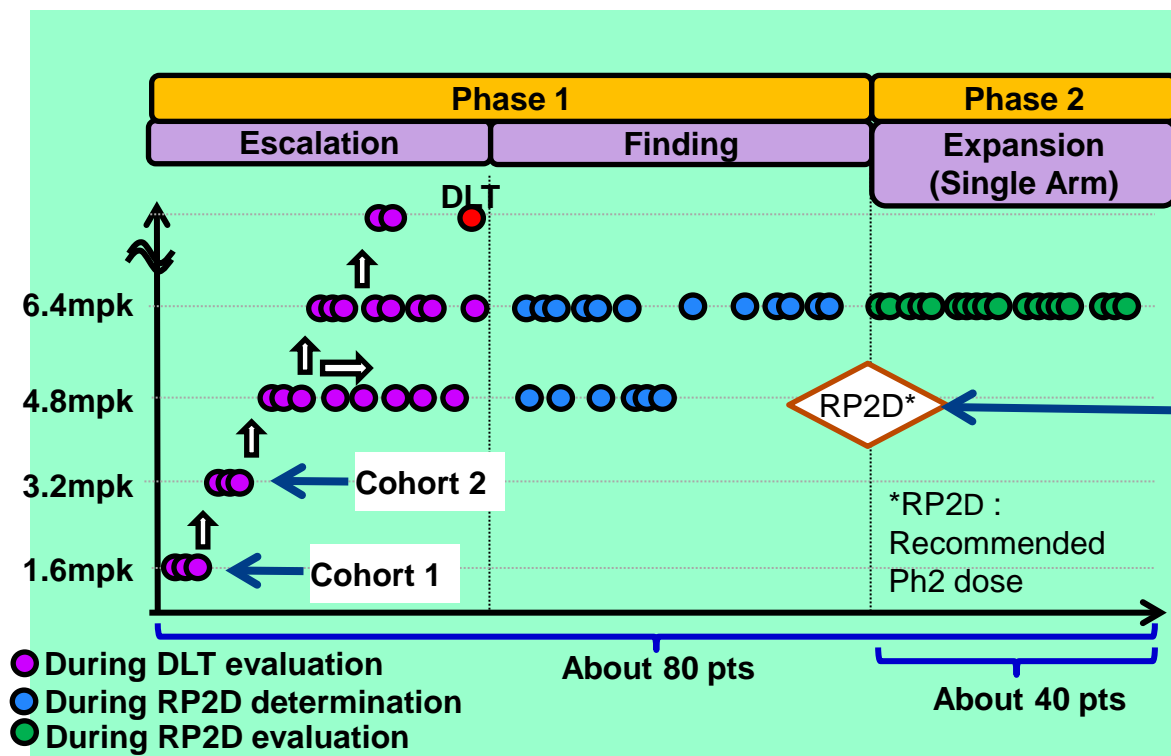
*1 Dendritic cells are a type of antigen-presenting cell that form an important role in the adaptive immune system

*2 MHC-Class I deliver short peptides to the cell surface allowing these peptides to be recognized by T cells

*3 PD-L1 is a protein on tumor cell. When PD-L1 attach to receptors on T cells called PD-1, it inactivate T cells.

◆ Presented Phase 1/2 study design

- Target population: HER3 positive refractory/metastatic breast cancer
- Study status:
 - ✓ Cohort 1 (1.6mg/kg): completed without dose-limiting toxicity (DLT)
 - ✓ Cohort 2 (3.2mg/kg): dosing continues



Recommended phase 2 dose will be determined through dose escalation and dose finding parts.

◆ Future data disclosure (Planned)

September 2017



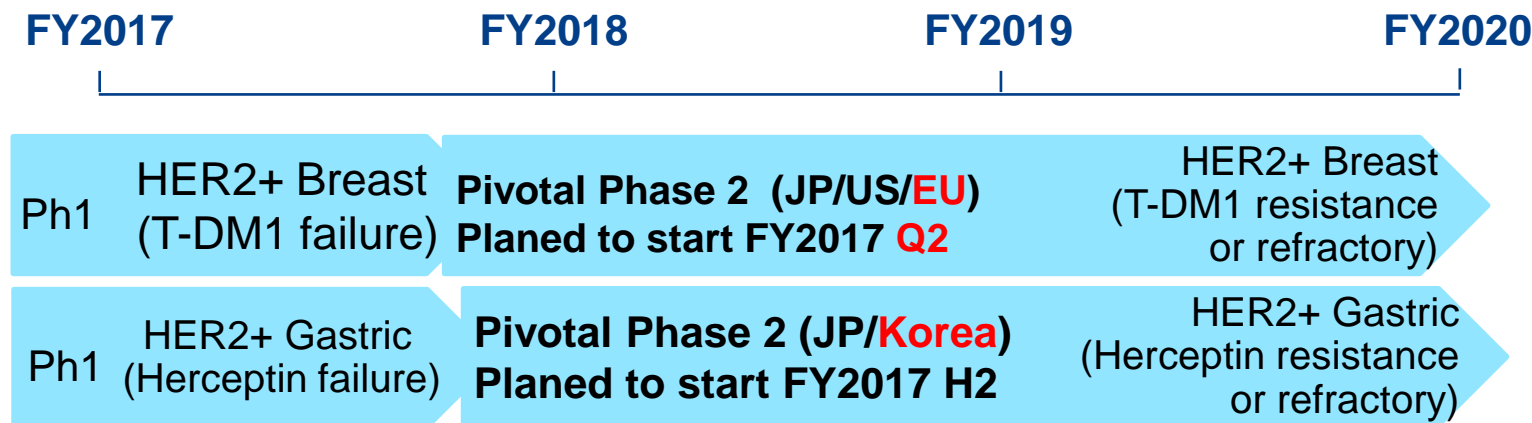
HER2 positive solid tumor (eg colon cancer) excluding breast and gastric cancer

December 2017

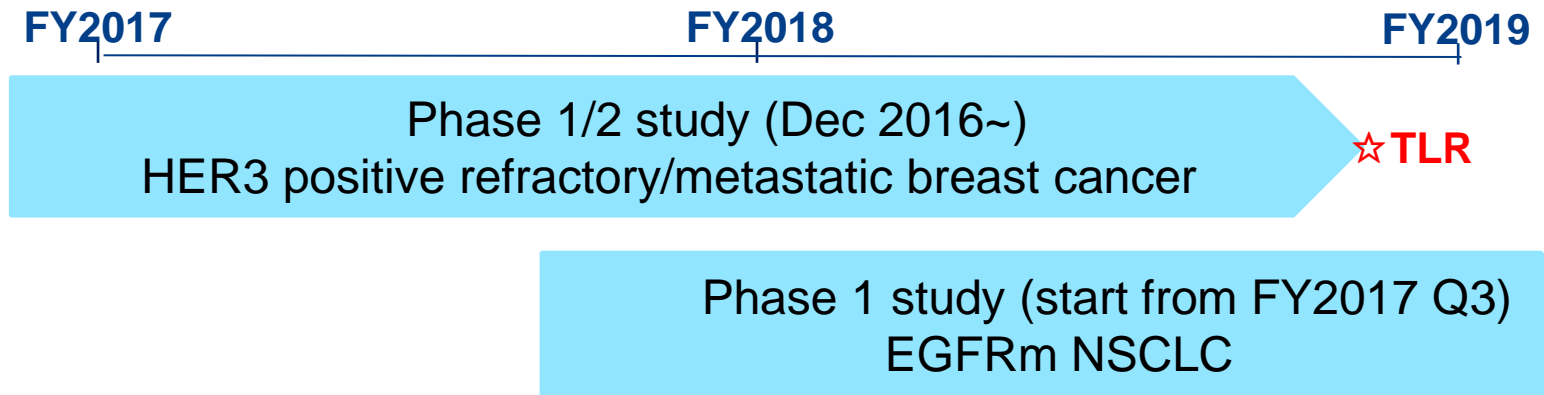


HER2 positive and HER2 low breast cancer

◆ Clinical trial schedule



◆ Clinical trial schedule



◆ Future milestone

- HER3 positive refractory/metastatic breast cancer TLR: FY2018 Q4
- Start of EGFRm NSCLC study: FY2017 Q3

- ◆ Date: December 13, 2017 in the afternoon
- ◆ 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 Daiichi Sankyo Cancer Enterprise)

FY2017 Major R&D Milestone Events

Project	Indication/Study	Q1	Q2	Q3	Q4	FY18-Q1
Denosumab	Rheumatoid arthritis (JP)	Approved				
CL-108	Pain/Opioid-induced nausea and vomiting (US)			Re-submission		
Mirogabalin	Fibromyalgia Phase 3 study (US/EU)	TLR				
	PHN Phase 3 studies (JP/Asia)	TLR				
	DPNP Phase 3 studies (JP/Asia)		TLR			
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
Esaxerenone (CS-3150)	Hypertension Phase 3 study (JP)			TLR	Submission	
	Diabetic nephropathy Phase 3 study (JP)			Study initiation		
DS-8201	HER2-positive Breast Cancer (T-DM1 resistance or refractory) Phase 2 study (pivotal) (JP/US/EU)		Study initiation			
	HER2-positive Gastric Cancer (Herceptin resistance or refractory) Phase 2 study (pivotal) (JP/Korea)			Study initiation		
U3-1402	EGFRm NSCLC Phase 1 study			Study initiation		
DS-5141	Duchenne Muscular Dystrophy Phase 1/2 study (JP)	SAKIGAKE				TLR

Red: Update

*TLR: Top Line Results

Major R&D Pipeline

As of July 2017



Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Oncology	<ul style="list-style-type: none"> ■ DS-3032 (US/JP) (MDM2 inhibitor) ■ PLX7486 (US) (FMS / TRK inhibitor) ■ PLX8394 (US) (BRAF inhibitor) ■ DS-6051 (US/JP) (NTRK/ROS1 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-8201 (JP/US) (anti-HER2 ADC) ■ DS-1123 (JP) (Anti-FGFR2 antibody) ■ U3-1402 (JP) (Anti-HER3 ADC) ■ DS-1001 (JP) (IDH1m inhibitor) 	<ul style="list-style-type: none"> ■ 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) 	<ul style="list-style-type: none"> ■ Denosumab (JP) (AMG 162 / Breast cancer adjuvant / Anti-RANKL antibody) ■ Nimotuzumab (JP) (DE-766 / Gastric cancer / Anti-EGFR antibody) ■ Vemurafenib (US/EU) (PLX4032 / Melanoma Adjuvant / BRAF inhibitor) ■ 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-Metabolics	<ul style="list-style-type: none"> ■ DS-1040 (US/EU/JP) (Acute ischemic stroke / TAF1a inhibitor) ■ DS-2330 (Hyperphosphatemia) ■ DS-9231/TS23 (Thrombosis / α2-PI inactivating antibody) 	<ul style="list-style-type: none"> ■ Esaxerenone (JP) (CS-3150 / DM nephropathy / MR antagonist) 	<ul style="list-style-type: none"> ■ Edoxaban (JP) (DU-176b / AF / FXa inhibitor) ■ Prasugrel (JP) (CS-747 / Ischemic stroke / Anti-platelet agent) ■ Esaxerenone (JP) (CS-3150 / Hypertension / MR antagonist) 	<ul style="list-style-type: none"> ■ Edoxaban (ASCA etc.) (DU-176b / AF / FXa inhibitor) ■ Edoxaban (ASCA etc.) (DU-176b / VTE / FXa inhibitor)
Others	<ul style="list-style-type: none"> ■ DS-1971 (Chronic pain) ■ DS-1501 (US) (Osteoporosis / Anti-Siglec-15 antibody) ■ DS-7080 (US) (AMD / Angiogenesis inhibitor) ■ DS-2969 (US) (<i>Clostridium difficile</i> infection / GyrB inhibitor) ■ DS-5141 (JP) (DMD / ENA oligonucleotide) ■ VN-0102/JVC-001 (JP) (MMR vaccine) 	<ul style="list-style-type: none"> ■ Laninamivir (US/EU) (CS-8958 / Anti-influenza / out-licensing with Biota) 	<ul style="list-style-type: none"> ■ Mirogabalin (US/EU) (DS-5565 / Fibromyalgia / 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) 	<ul style="list-style-type: none"> ■ Hydromorphone (JP) (DS-7113 / Cancer pain / Opioid μ-receptor agonist) <Injection> ■ CL-108 (US) (Acute pain / Opioid μ-receptor agonist) ■ Intradermal Seasonal Influenza Vaccine (JP) (VN-100 / prefilled i.d. vaccine for seasonal flu) ■ VN-0107/MEDI3250 (JP) (Nasal spray flu vaccine)

Contact address regarding this material

Daiichi Sankyo Co., Ltd.

Corporate Communications Department

TEL: +81-3-6225-1126

Email: DaiichiSankyoIR@daiichisankyo.co.jp