Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Top Management Presentation

Financial Results for FY2016 Q2 (April 1 – September 30, 2016)

DAIICHI SANKYO CO., LTD

Joji Nakayama
President and CEO

November 1, 2016

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Agenda

- **FY2016 Q2 Financial Results**
- **FY2016 Revised Consolidated Forecast**
- **Progress of 5-Year Business Plan**
- **R&D Update**

FY2016 Q2 Financial Results

Overview of FY2016 Q2 Results

Daiichi-Sankyo

(JPY Bn)

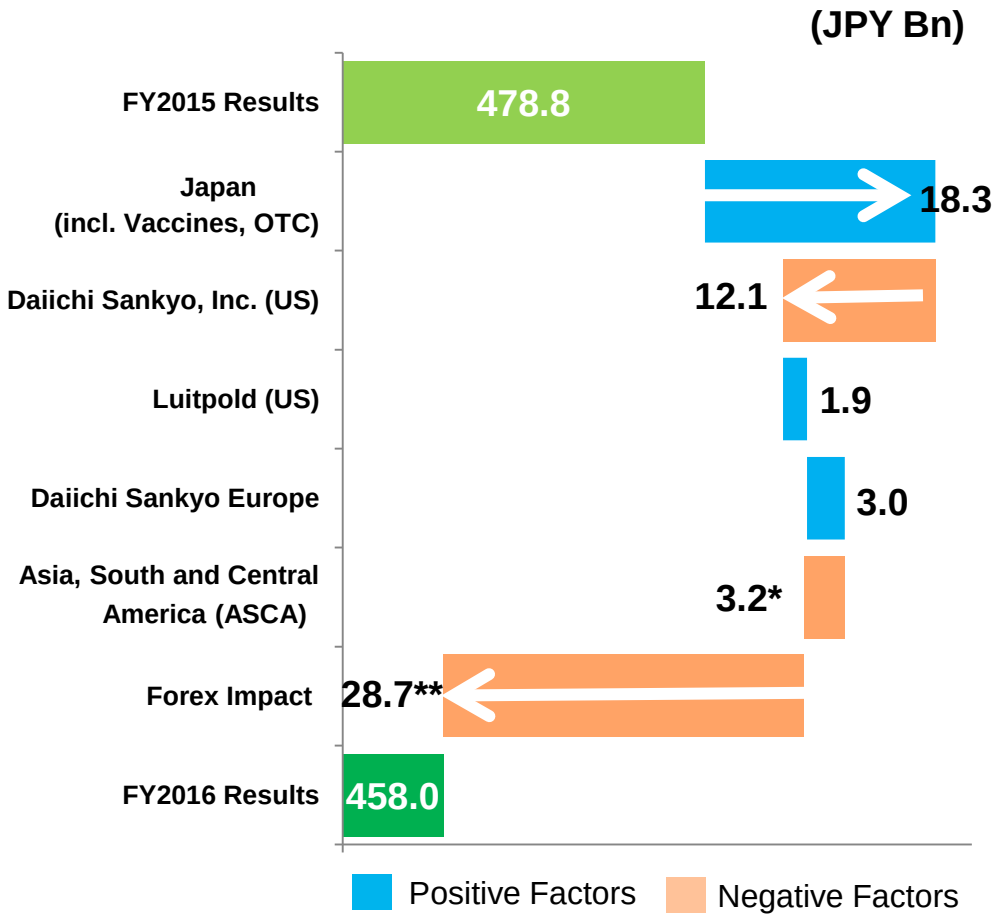
	FY2015 Q2 YTD Results	FY2016 Q2 YTD Results	YoY
Revenue	**478.8**	**458.0**	-4.3% **-20.8**
Cost of Sales	**148.9**	**147.3**	**-1.7**
SG&A Expenses	**144.5**	**141.7**	**-2.8**
R&D Expenses	**88.4**	**95.8**	**+7.4**
Operating Profit	**97.0**	**73.3**	-24.5% **-23.7**
Profit before Tax	**90.8**	**71.9**	**-18.9**
Profit attributable to owners of the Company	**70.7**	**49.0**	-30.7% **-21.7**

Currency Rate	USD/JPY	121.80	105.35	-16.45
	EUR/JPY	135.07	118.22	-16.85

Revenue

Decreased by 20.8 Bn JPY

- **Increase in Japan, Luitpold and Europe**
- **Decrease in DSI and ASCA**
- **Negative forex impact by yen appreciation**



Japan

Positive :	**Tenelia**	**+6.4**	**Lixiana**	**+6.1**
	Nexium	**+3.4**	**Efient**	**+3.1**
	Memary	**+2.9**	**Pralia**	**+2.9**
	Ranmark	**+0.9**	**DSHC**	**+7.6**
Negative :	**Loxonin**	**-5.6**	**Artist**	**-2.2**
	Cravit	**-1.7**	**Mevalotin**	**-1.5**

Global (excl. Forex Impact)

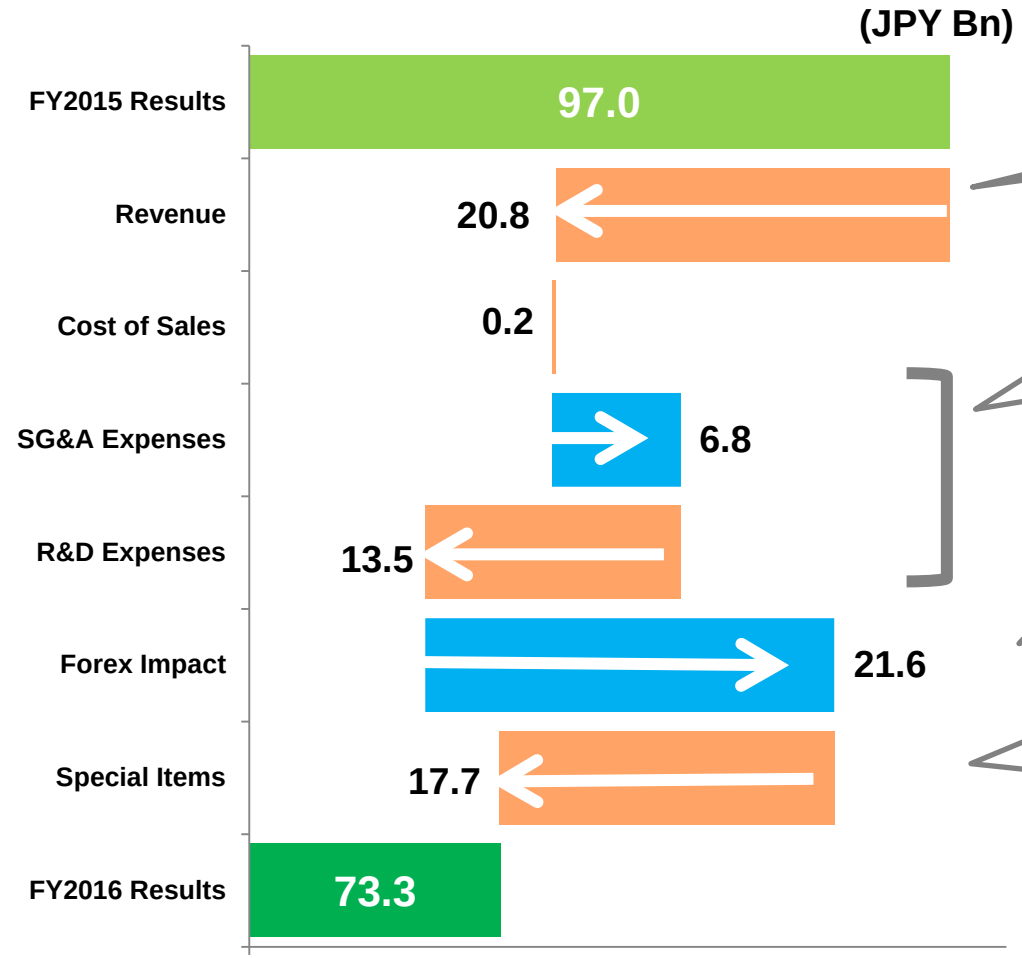
Daiichi Sankyo, Inc. :	**Olmesartan**	**-14.8**
	Welchol	**-1.7**
	Effient	**+1.9**
	Movantik	**+1.6**
Luitpold :	**Injectafer**	**+4.9**
Daiichi Sankyo Europe :	**Olmesartan**	**-2.0**
	Lixiana	**+3.6**
	Efient	**+2.6**

* Increase 2.3 Bn JPY excluding negative impact of 5.5 Bn JPY in Venezuela
**Forex impact USD: -17.8, EUR: -5.3, ASCA: -5.5

Operating Profit

Decreased by 23.7 Bn JPY

- **Decrease in revenue**
- **Increase in R&D expenses by progress of projects, and special items included in FY2015**
- **SG&A cost reduction and positive forex impact on expenses**



Revenue -20.8
incl. forex impact -28.7

SG&A Expenses
Impact of restructuring in US in FY2015

R&D Expenses Progress of projects

Forex impact -21.6
Cost of Sales -5.3
SG&A Expenses -10.2
R&D Expenses -6.1

Special items +17.7
Cost of Sales +3.5
SG&A Expenses +14.2

Special Items

（JPY Bn）

	FY2015 Q2 YTD Results		FY2016 Q2 YTD Results		YoY
Cost of Sales	Gain on sales of subsidiary Gain on sales of fixed assets	-2.4 -1.1	-		+3.5
SG&A Expenses	Gain on sales of fixed assets	-8.2	Restructuring costs	6.0	+14.2
R&D Expenses	-		-		-
Total	-11.7		6.0		+17.7

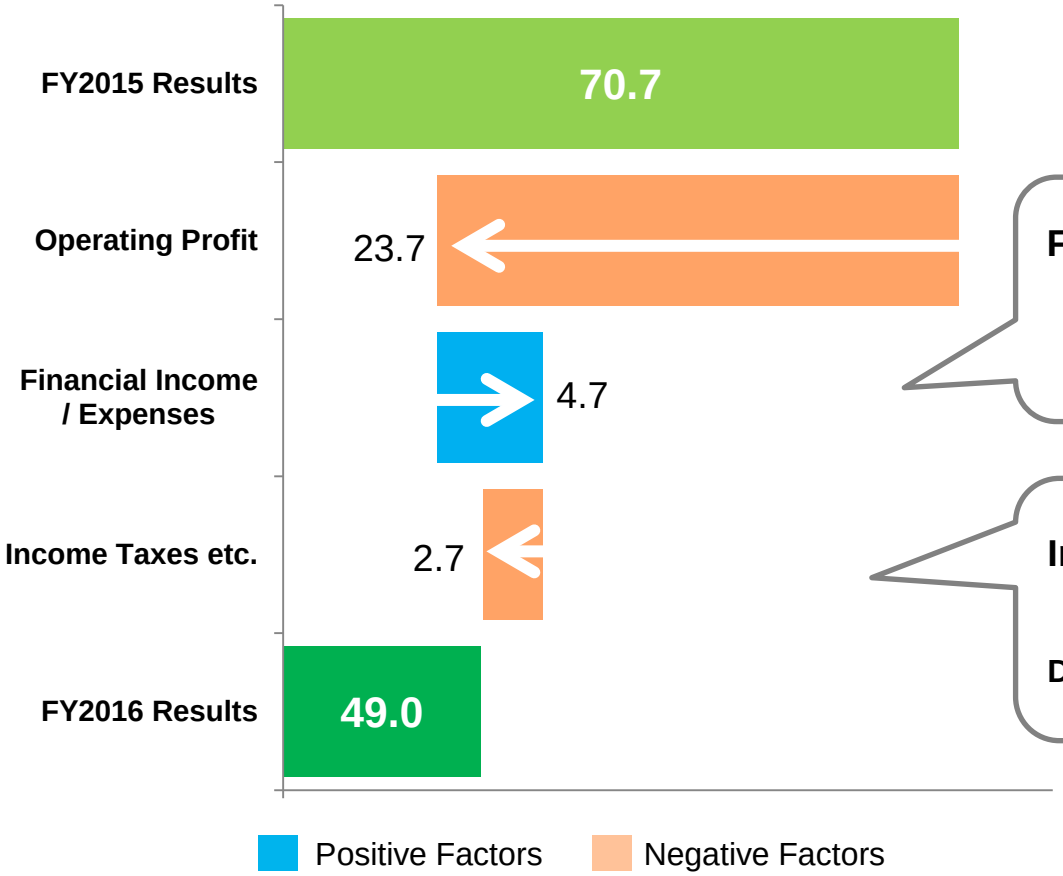
- : Cost decrease items

Profit Attributable to Owners of the Company

Decreased by 21.7 Bn JPY

- **Decrease in operating profit**
- **Increase of income taxes caused by decrease in R&D tax credit**

(JPY Bn)



Financial Income / Expenses **-4.7**

FY2015: Expenses relating to the sales of Sun Pharma shares etc.

FY2016: Increase in forex loss

Income Taxes **+2.7**

Tax rate FY2015 : 23.5% FY2016 : 33.5%

Decrease in R&D tax credit

*Excl. increase and decrease of share of profit or loss of investments accounted for using the equity method and non-controlling interests

Major Business Units

(JPY Bn)

	FY2015 Q2 YTD Results	FY2016 Q2 YTD Results	YoY	vs. Forecast* (%)
Japan	**227.8**	**239.0**	**+11.2**	**47.8%**
Daiichi Sankyo Healthcare	**24.6**	**32.2**	**+7.6**	**49.5%**
Daiichi Sankyo Inc.	**93.4**	**70.3**	**-23.1**	**53.2%**
Olmesartan	57.1	36.7	-20.5	53.9%
Welchol	24.2	19.5	-4.7	54.1%
Effient	10.6	10.8	+0.2	-
Savaysa	-0.2	0.9	+1.1	57.0%
Movantik	0.6	1.9	+1.3	-
Luitpold	**46.4**	**41.7**	**-4.7**	**50.3%**
Venofer	16.0	13.9	-2.2	55.5%
Injectafer	7.9	11.1	+3.2	46.2%
Daiichi Sankyo Europe	**39.2**	**37.0**	**-2.3**	**56.0%**
Olmesartan	30.2	24.7	-5.6	61.7%
Efient	2.2	4.2	+2.0	-
Lixiana	0.2	3.3	+3.1	41.2%
Asia, South and Central America (ASCA)	**42.7**	**34.0**	**-8.7**	**48.6%**

* Calculated based on new forecast updated in Oct.

Major Products in Japan

(JPY Bn)

		FY2015 Q2 YTD Results	FY2016 Q2 YTD Results	YoY	vs. Forecast* (%)
Nexium	ulcer treatment	**38.7**	**42.0**	**+3.4**	**50.7%**
Olmetec	antihypertensive agent	**36.2**	**34.9**	**-1.3**	**51.3%**
Memary	Alzheimer's disease treatment	**20.5**	**23.4**	**+2.9**	**45.9%**
Loxonin	anti-inflammatory analgesic	**24.4**	**18.8**	**-5.6**	**50.9%**
Tenelia	type 2 diabetes mellitus inhibitor	**5.3**	**11.8**	**+6.4**	**42.0%**
Lixiana	anticoagulant agent	**5.4**	**11.5**	**+6.1**	**46.0%**
Rezaltas	antihypertensive agent	**8.9**	**8.8**	**-0.1**	**46.5%**
Pralia	treatment for osteoporosis	**5.4**	**8.3**	**+2.9**	**51.8%**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**5.9**	**6.8**	**+0.9**	**52.2%**
Inavir	anti-influenza treatment	**0.0**	**0.6**	**+0.5**	**4.3%**
Cravit	synthetic antibacterial agent	**9.0**	**7.3**	**-1.7**	**56.4%**
Omnipaque	contrast medium	**8.5**	**7.2**	**-1.3**	**59.7%**
Urief	treatment for dysuria	**5.7**	**5.8**	**+0.1**	**52.3%**
Artist	treatment for hypertension, angina pectoris and chronic heart failure	**7.9**	**5.7**	**-2.2**	**51.9%**
Mevalotin	antihyperlipidemic agent	**7.0**	**5.5**	**-1.5**	**54.5%**
Efient	antiplatelet agent	**1.8**	**4.9**	**+3.1**	**49.0%**

* Calculated based on new forecast updated in Oct.

FY2016 Revised Consolidated Forecast

FY2016 Revised Consolidated Forecast

(JPY Bn)

	FY2016 Forecast (as of May.)	FY2016 Forecast (as of Oct.)	vs. Forecast (as of May.)
Revenue	**920.0**	**920.0**	**0.0**
Cost of Sales	**320.0**	**307.0**	**-13.0**
SG&A Expenses	**310.0**	**313.0**	**+3.0**
R&D Expenses	**190.0**	**200.0**	**+10.0**
Operating Profit	**100.0**	**100.0**	**0.0**
Profit before Tax	**100.0**	**100.0**	**0.0**
Profit attributable to owners of the Company	**65.0**	**65.0**	**0.0**

Major factors
-Forex impact -25.0
-Japan +9.0
-Overseas +16.0

Major factors
-Forex impact -9.0
-Cost reduction -6.0
-Increase of COGs by increase of volume +2.0

Major factors
-Forex impact -10.0
-Increase of promotion (incl. new products) and others +13.0

Major factors
-Forex impact -6.0
-Acceleration of RD and edoxaban LCM +16.0

Currency Rate	**USD/JPY**	**110.00**	**102.67**
	EUR/JPY	**125.00**	**114.11**

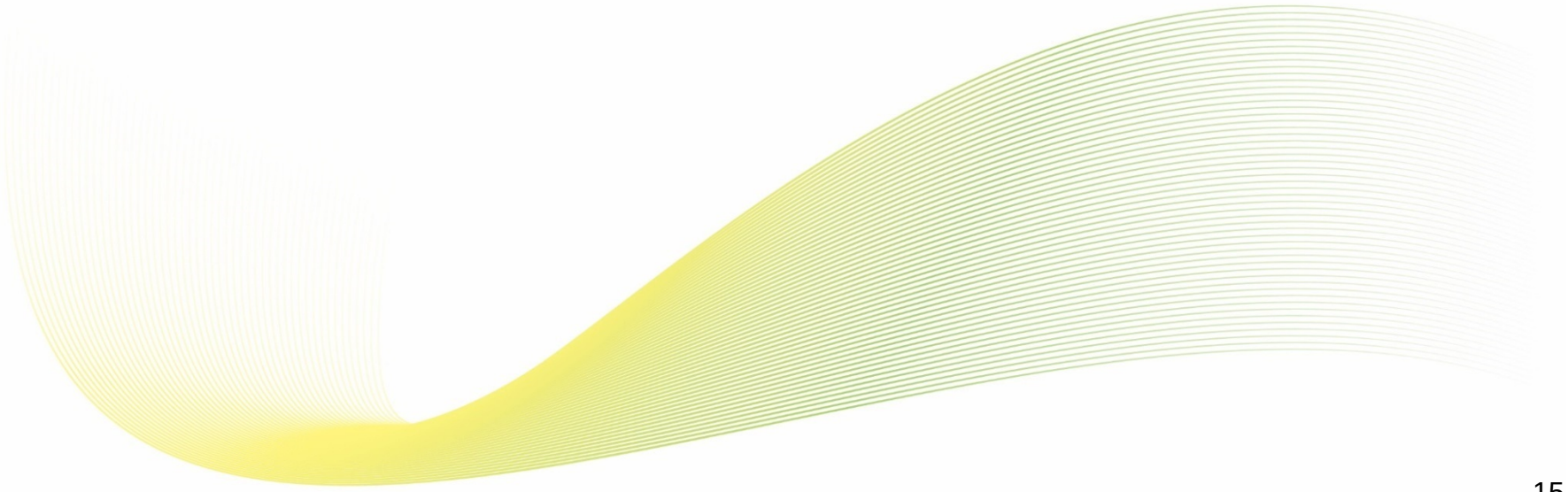
Assumption of currency rate for Q3 and Q4
USD/JPY：100, EUR/JPY：110

Progress of 5-Year Business Plan

Business Strategy

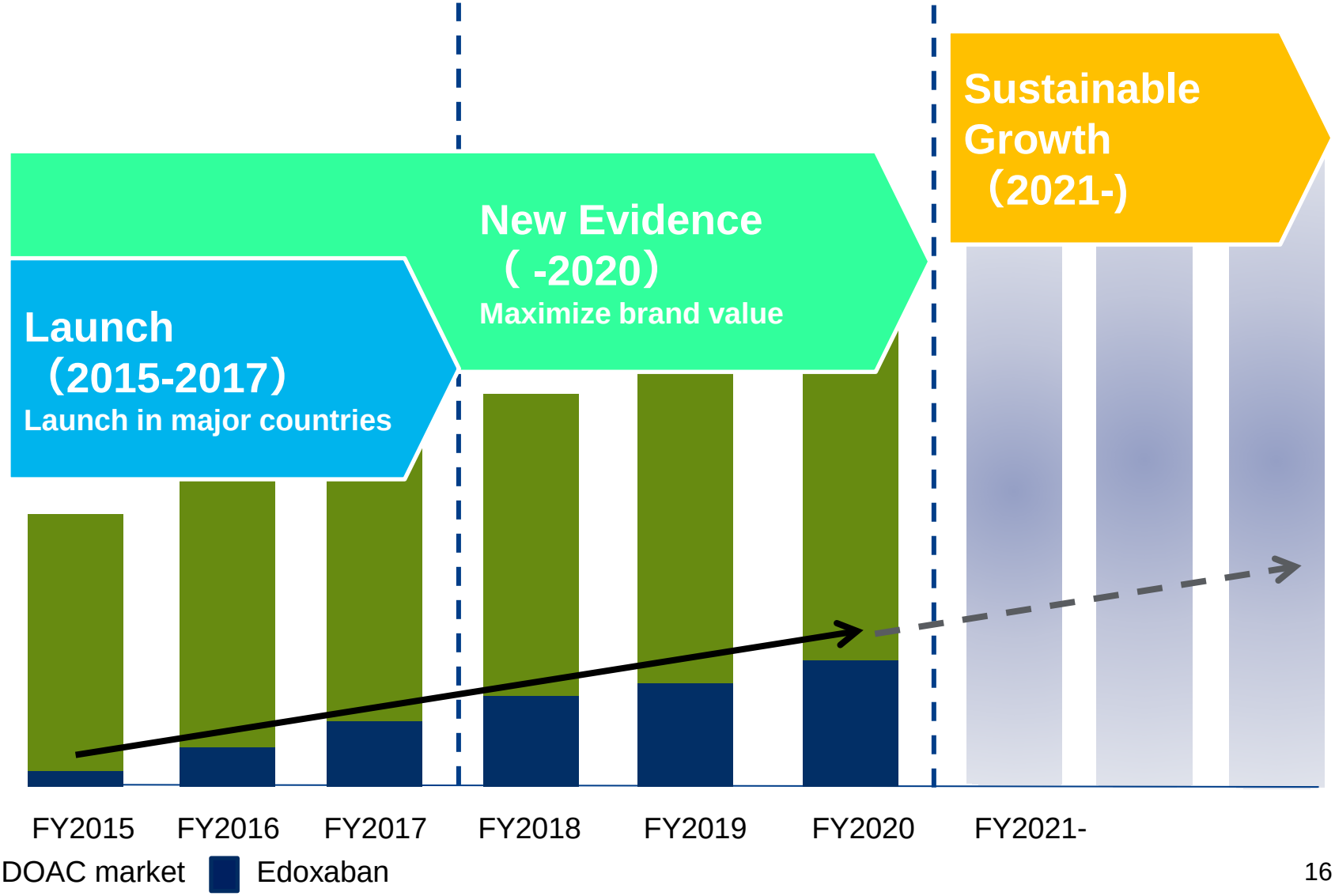
- Strategic Target 1：Grow Edoxaban
- Strategic Target 2：Establish Oncology Business
- Strategic Target 3：Grow as No.1 company in Japan
- Strategic Target 4：Expand US Businesses
- Strategic Target 5：Continuously Generate Innovative Medicine Changing Standard of Care (SOC)
- Strategic Target 6：Enhance Profit Generation Capabilities

Strategic Target 1：Grow Edoxaban



Growth of Edoxaban

Grow sales with the expanding DOAC market



Edoxaban: Launch & Alliance

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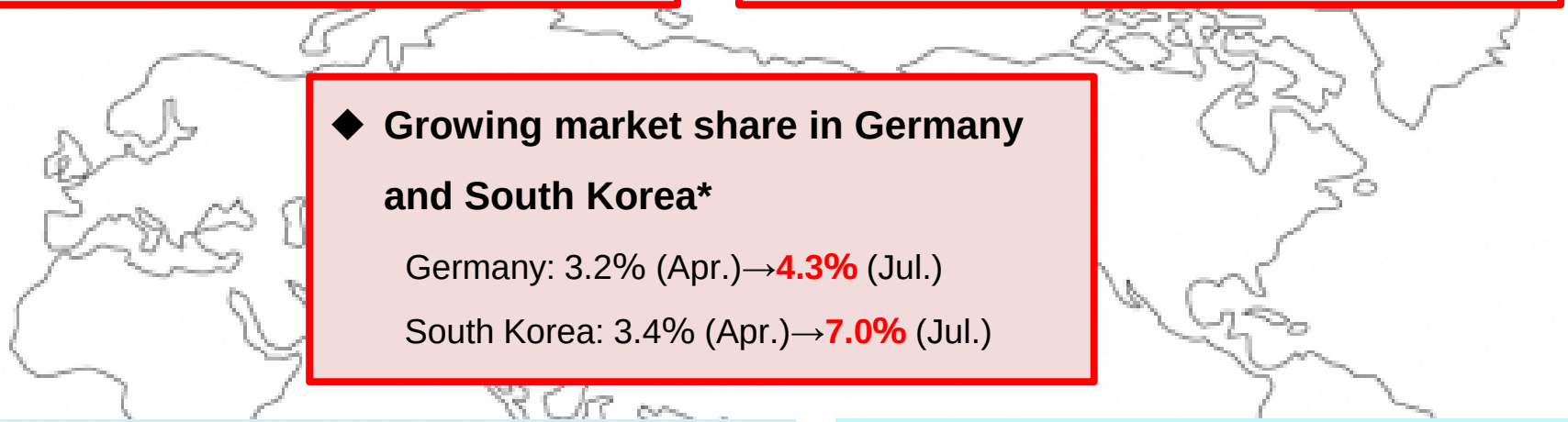
◆ **Expand launched countries/regions**

Italy, Spain, Taiwan (Sep. 2016)

Belgium, Hong Kong (Oct. 2016)

◆ **Expand alliance**

Partner with Servier Canada inc.** in Canada (Jun. 2016)



◆ **Growing market share in Germany and South Korea***

Germany: 3.2% (Apr.)→**4.3%** (Jul.)

South Korea: 3.4% (Apr.)→**7.0%** (Jul.)

◆ **Launched countries/regions & alliance by FY2015**

Japan, the U.S, Switzerland, the U.K, Germany, Ireland, the Netherlands, South Korea

Partner with MSD*** in EU

◆ **Under regulatory review**

Brazil, Thailand, China, Canada, Turkey

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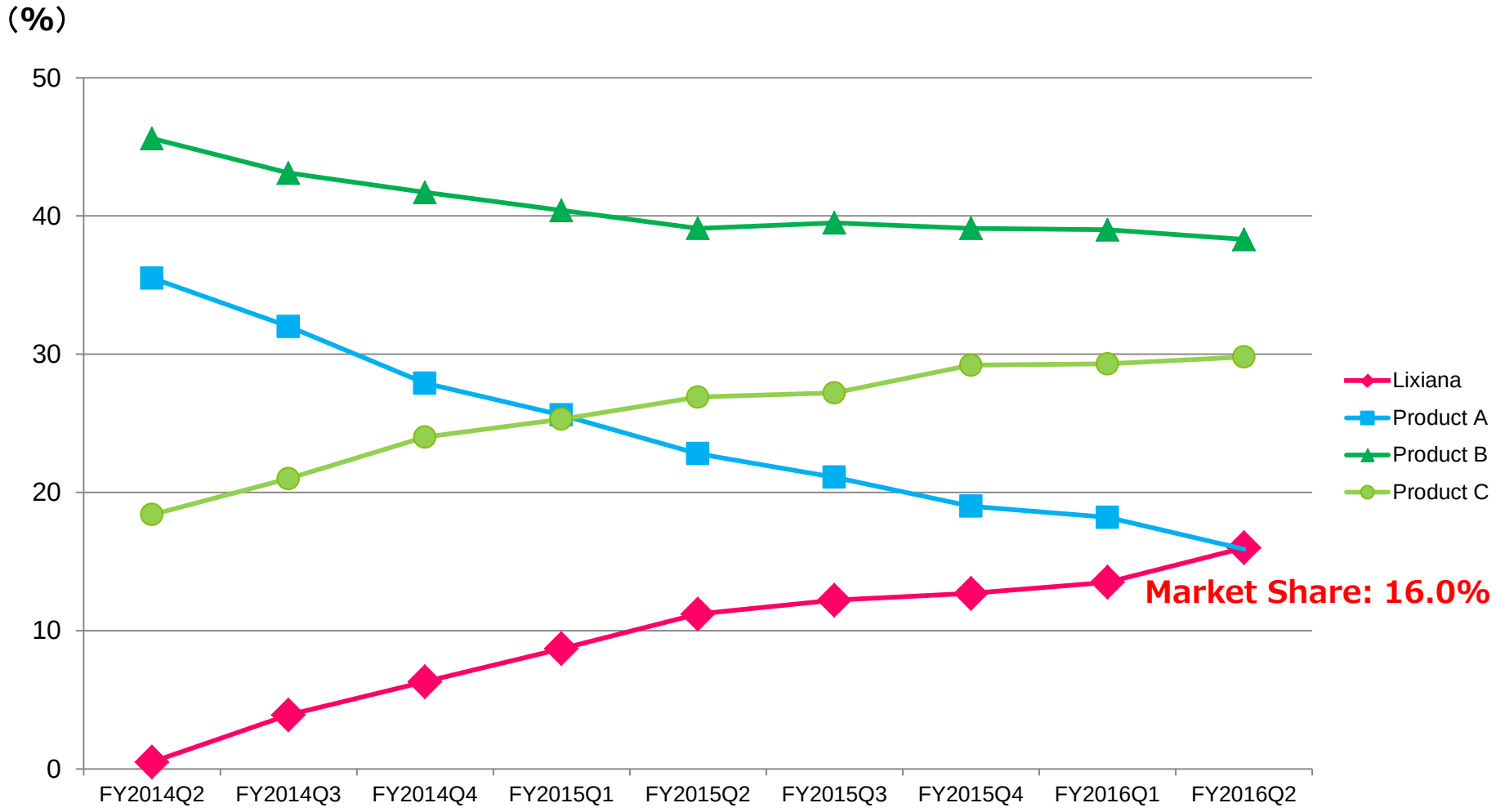
**Canadian Subsidiary of LES LABORATORIRES SERVIER

***MSD: Merck Sharp and Dohme European Subsidiary of Merck & Co., Inc.

Edoxaban: Growth in Japan

Latest market share reached: 16.0% (Jul. 2016 - Sep. 2016)



Edoxaban Clinical Research Program (1)

Daiichi-Sankyo

Ongoing randomized controlled trials in various clinical settings

	Clinical Setting (Comparator)	Primary Outcome	Primary Completion
ENSURE-AF	Cardioversion (enoxaparin/warfarin)	• Stroke, SEE, MI, CV mortality • Major and CRNM bleeding	Presented at ESC 2016
ENTRUST-AF PCI	PCI (VKA)	• Major and CRNM bleeding	Nov. 2018
ELIMINATE-AF	Cardiac ablation (VKA)	• Composite of All cause mortality, Stroke and Major bleeding • Major bleeding	Dec. 2018
ENVISAGE-TAVI AF	Transcatheter aortic valve implantation (VKA)	• Net adverse clinical events • Major bleeding	May. 2020
ELDERCARE-AF	80 years or older who are ineligible for current OAC therapy (placebo)	• Stroke, SEE	Dec. 2019
Hokusai VTE CANCER	VTE associated with cancer (dalteparin)	• Recurrent VTE • Clinically relevant bleeding	Dec. 2017

New program after announcement of 5-Year Business Plan

Edoxaban Clinical Research Program (2)

Daiichi-Sankyo

Ongoing non-interventional studies to generate real-world data with more than 60,000 patients

ETNA-AF Global	Edoxaban Treatment in routiNe clinical prActice in Patients with non valvular Atrial Fibrillation
PREFER in AF Prolongation	Prolongation PREFER in AF PREvention oF thromboembolic events-European Registry in Atrial Fibrillation
ETNA-VTE Global	Edoxaban Treatment in routiNe clinical prActice in Patients with Venous ThromboEmbolism
ANAFIE	All Nippon AF In Elderly registry in Japan to study NVAF in elderly patients aged 75 years and older
EMIT-AF/VTE	Edoxaban Management In diagnostic and Therapeutic procedures–AF/VTE

New program after announcement of 5-Year Business Plan

Strategic Target 2：Establish Oncology Business

Progress in Late Stage Pipeline

Summary of update since 5YBP publication written in red

TLR：anticipated Top Line Result

Quizartinib	Acute myeloid leukemia (AML) 2nd line (P3) **DMC Interim Analysis: 1H CY2017** --- 1st line (P3)	• Orphan Drug Designation by the FDA and EMA • Fast Track Status by the FDA • Targeting patients with FLT3-ITD mutation --- • Started global study (Oct 2016). Estimated Primary Completion Date: Q4 FY2019
Tivantinib	Hepatocellular carcinoma (HCC)(P3) **TLR: 1H CY2017**	• Orphan Drug Designation by the FDA and EMA • Target is patients with Refractory HCC • Based on the planned interim analysis, the independent data monitoring committee recommended in Mar 2016 the trial should continue to its final analysis
Pexidartinib	Tenosynovial giant cell tumor (TGCT) (P3) **TLR: 1H CY2018** --- Solid tumor(P1/2a) **TLR: 2H CY2019**	• Orphan Drug Designation by the FDA and EMA • Breakthrough Therapy designation by FDA • Based on the DMC recommendation in Oct 2016, the study will continue to completion but new recruitment has stopped • Additional indications include combination therapy with Merck's anti-PD-1 antibody
Patritumab	~~Non-small cell lung cancer (P2/3)~~ ~~**TLR: 2H CY2018**~~ --- Head and Neck cancer（P2）	• NSCLC indication discontinued based on DMC recommendation (May 2016) • New indication based on phase 1 data in patients with metastatic head and neck cancer • Phase 1b data published at ASCO in June 2016

Progress in Early Stage Pipeline

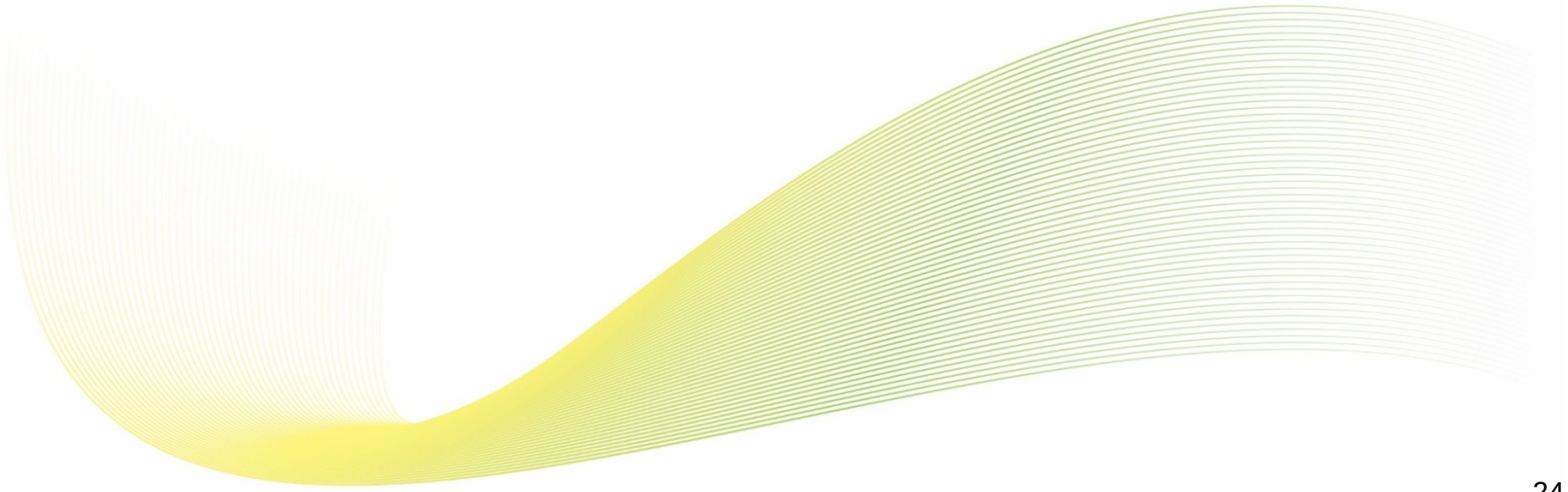
Daiichi-Sankyo

Summary of update since 5YBP publication written in red

DS-8201 (HER2-ADC)	Solid tumor (P1)	• Demonstrated activity in patients resistant to Herceptin or Kadcyla • Validates DS proprietary ADC* technology • Early phase 1 data reported at ESMO Congress (Oct 2016) * Antibody Drug Conjugate
DS-3201 (EZH1/2)	Non-Hodgkin's lymphoma (incl. adult T-cell leukemia) (P1)	• Targeted epigenetics** • Goal is eradication of cancer stem cells • FIC as an EZH 1 / 2 dual inhibitor • Phase 1 study is ongoing (Mar 2016) • Completion of phase 1 anticipated in FY2018 ** chemical modification of DNA or histone leading to a change in gene expression
DS-3032 (MDM2)	Solid tumor Hematologic tumor(P1)	• FIC MDM2 inhibitor • Target is cancer with MDM2 gene amplification / Wt p53 • Based on early phase 1 data, liposarcoma (LPS), may be selected as a potential indication for further development
DS-6051 (NTRK/ROS1)	Solid Tumor (Lung cancer) (P1)	• ROS1 fusion is a major driver mutations in lung cancer • Phase 1 is anticipated to complete in FY2017 (US/JP) • Early Phase 1 data presented at AACR in April 2016. • Program is utilizing SCRUM-Japan*** for patient selection in Japan

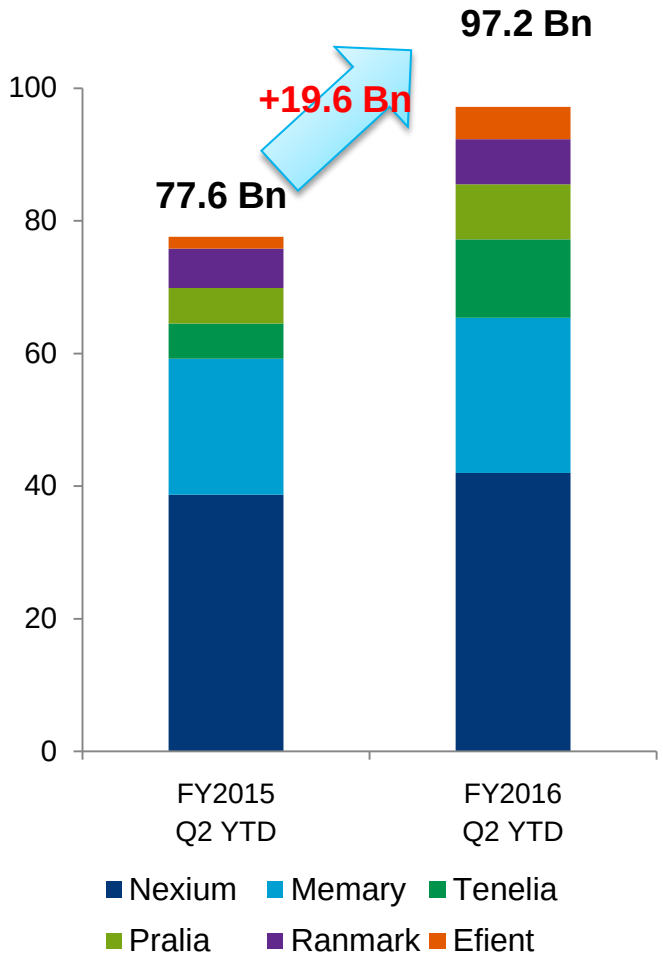
***SCRUM-Japan: National project led by National Cancer Center Japan to screen oncogenic abnormality of cancer patients in order to provide the best-fit medicines to them

Strategic Target 3：Grow as No.1 company in Japan



Grow as No.1 company in Japan

Many of innovative major products reached No. 1 share and continue to expand market share



- **Nexium (ulcer treatment)**

  Reached No. 1 share in Jan. 2014 with rapid expansion and continue to expand market share

- **Memary (Alzheimer's disease treatment)**

  Reached No. 1 share in Jan. 2016 catching up with Aricept

- **Pralia (treatment for osteoporosis)**

  In highly competitive market, reached No. 1 share in Feb. 2016 and continue to expand market share

- **Ranmark (treatment for bone complications caused by bone metastases from tumors)**

  Reached No. 1 share in May 2014 and continue to expand market share promoting appropriate use

Other Updates

Launched anti epilepsy VIMPAT and filed an new indication

- Launched in Aug. 2016 as an adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy and filed in Aug. 2016 for partial amendment of approval to add a new indication in mono therapy for partial-onset seizure in patients with epilepsy.

Biosimilars in-licensed from Amgen

- Signed in Jul. 2016 an exclusive agreement to commercialize nine biosimilars in Japan, which include adalimumab (Humira), bevacizumab (Avastin) and trastuzumab (Herceptin).

Ranked No. 1 on MR activities by physicians

- For four consecutive years Daiichi Sankyo has been ranked in Japan as No.1 company by all surveyed physicians and cardiologists in an overall assessment on MR activities surveyed by ANTERIO Inc..

Strategic Target 4：Expand US Businesses

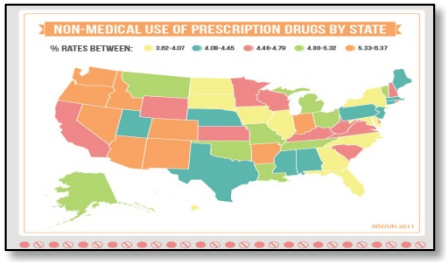
DSI: Licensed abuse-deterrent opioids

Licensed two abuse-deterrent formulations including MorphaBond™

Compound	MorphaBond™	The agreement also provides Daiichi Sankyo, Inc. with the rights to commercialize a separate investigational Inspirion compound in the U.S., if approved by the U.S. Food and Drug Administration (FDA). Both MorphaBond and the second product feature SentryBond™, a unique, patent-protected abuse-deterrent technology.
	Morphine ER (ADF*)	
Development Stage	Approved in US (Oct 5, 2015)	
Indication	Management of severe pain: •severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate	
Dosage Form	Tablet (15, 30, 60, 100 mg)	
Territory	US	

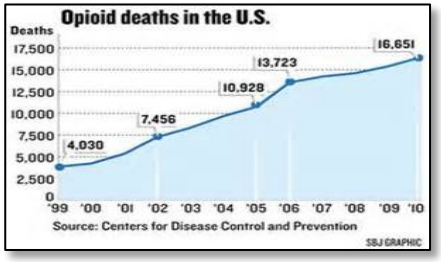
* ADF: Abuse-Deterrent Formulation

The Epidemic of Opioid Prescription Abuse is Real in US



12,000,000
non-medical Rx opioid users*in 2010

425,000
ER visits from accidental opioid overdoses* in 2010



16,650
fatal overdoses involving Rx opioids* in 2010

How Does Abuse Occur?

- The intent of abusers is to extract the opioid as fast as possible, seeking to elicit a high
- People attempt to crush, grind, melt
- Abuse and misuse via injection or insufflation

Cheese Grater | **Coffee Grinder** | **Hammer** | **Knife** | **Mortar & Pestle** | **Pill Crusher** | **Spoon**

*Sources: Centers for Disease Control and Prevention (“CDC”) and FDA.

Growing number of federal and state initiatives to address the epidemic of abuse

Daiichi-Sankyo

Abuse Deterrent Formulations (ADF) are one part of the multifaceted solution to the opioid epidemic

- FDA has created a multi-faceted Action Plan. They are on record stating it has the authority to remove non-ADF opioids from the market once an ADF version becomes available
- FDA recently announced all NDAs without an ADF will have an advisory committee meeting
- DEA has aggressively worked to close down "pill mills'" in the U.S.
- 27 states introduced legislation requiring ADF formulations to be comparably accessible as non-ADF formulations; and 5 states have passed legislation

DSI: Expand Pain Franchise

Two ADF products are complementary and requires no additional headcount

Morphine ER (ADF*)
FDA Approved 2015.10.5
Management of severe pain**

MorphaBond

MOVANTIK
Opioid-Induced Constipation

Mirogabalin
Fibromyalgia
Phase 3

CY2015 | CY2016 | CY2017 | CY2018 | CY2019

CL-108
Pain & Opioid-Induced Nausea & Vomiting
Under review
PDUFA: 2017.1.31

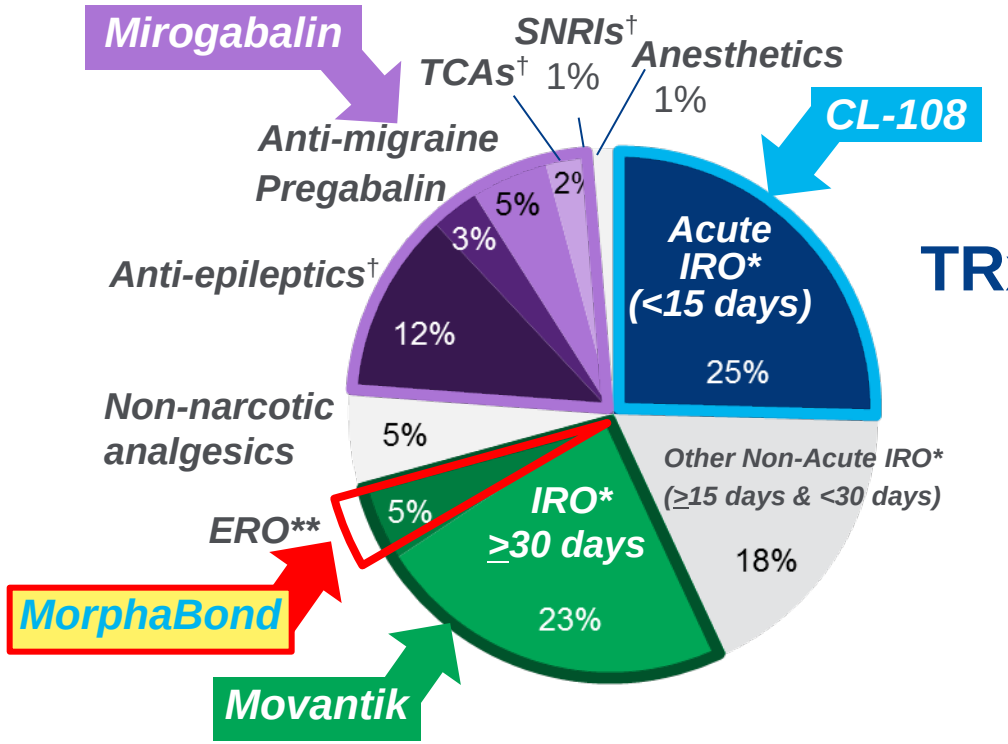
Second IDS ADF Product

Phase 3 completed

*ADF: Abuse-Deterrent Formulation
**indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate

DSI Pain Franchise: Target Segment

Large Market with Diverse Segments
330~ Million TRx Market size $28 billion



TRx by Segment

* Immediate-Release Opioid, ** Extended-Release Opioid
† Pain management use only

Source: Internal analysis based on Symphony Health Solutions, PHAST Integrated Monthly, 2007-2015 and Encuity 2007-2015

CL-108: Initiate OINV education

Expand DSI presence in Pain management community

Opioid-Induced Constipation

MOVANTIK

Start DTC to educate OIC

May 2015　Start co-promotion

CY2015　CY2016　CY2017　CY2018　CY2019

Start OINV education activity

Starting promotion（Planned）

CL-108

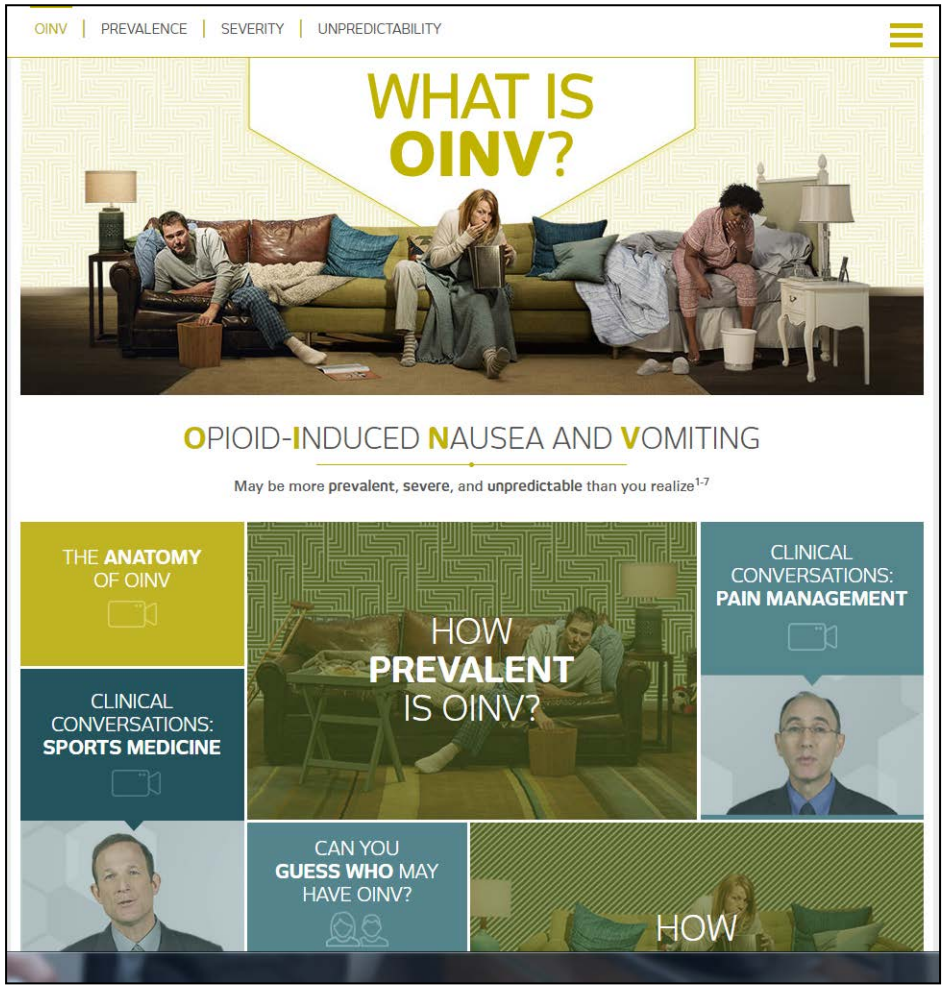
Pain & Opioid-Induced Nausea & Vomiting

OINV education

August 2016 started multi-channel campaign to educate about OINV for 70,000 HCP

Started as of August 15, 2016

www.knowOINV.com



OINV education

Various conventions across the country

Come see us at various conventions across the country.

See the list below for dates and locations.

Convention	2016 Dates	Location	Register at
PAINWeekEnd	11/12-11/13	Woodcliff Lake, NJ	painweek.org
PAINWeekEnd	12/3	Honolulu, HI	painweek.org

Convention	2017 Dates	Location	Register at
PriMed South	2/3-2/5	Fort Lauderdale, FL	pri-med.org

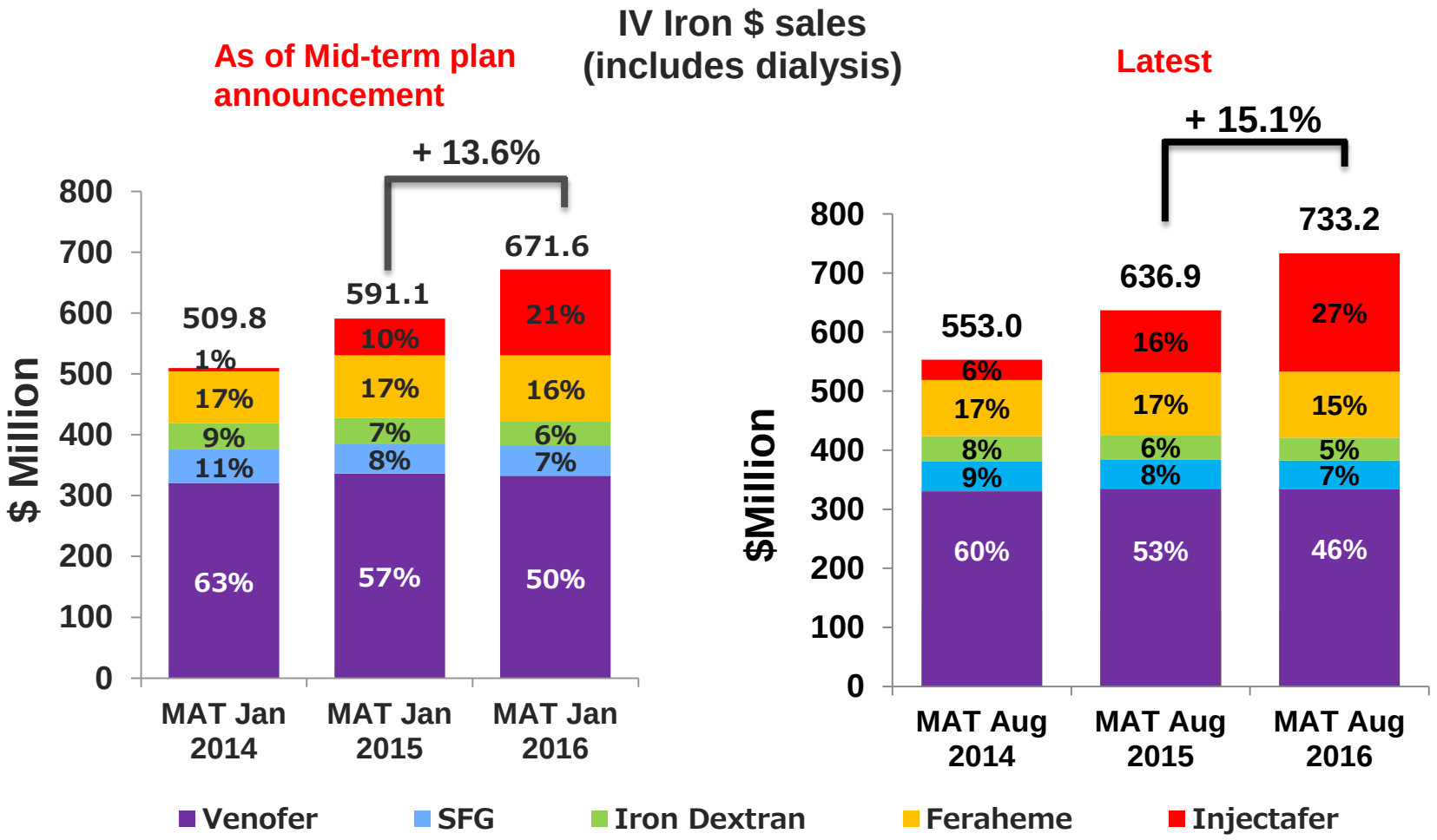
DSI Commitments in Pain Care

Inappropriate usage of opioids (i.e. diversion, misuse, abuse, addiction, or overdose) has become an epidemic in the US.

DSI launched www.CommitmentsinPainCare.com, which hosts an overview of our company's approach to responsible pain management and our dedication to being part of the solution to controlled substance abuse as we prepare to enter the opioid marketplace.

LPI : Growth of Injectafer

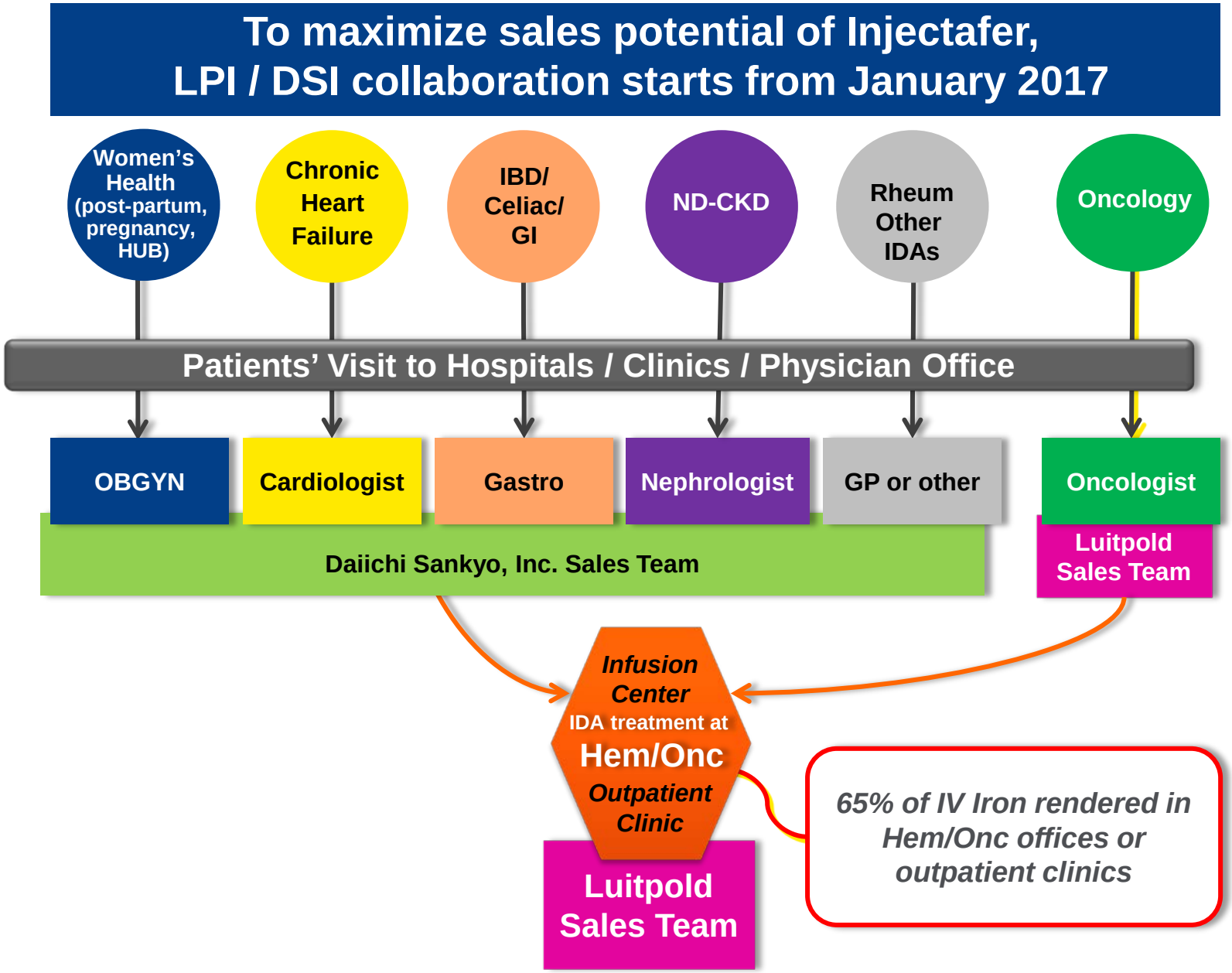
Injectafer* drives the growth of US IV Iron Market
Market share has reached 27% in terms of MAT



*Injectafer is not indicated for patients who are dialysis dependent

Source: IMS National Sales Perspectives Jan 2016, Aug 2016 (includes all US IV Iron sales in all channels including dialysis chains)

Collaboration between DSI and LPI



Strategic Target 5：Continuously Generate Innovative Medicine Changing SOC

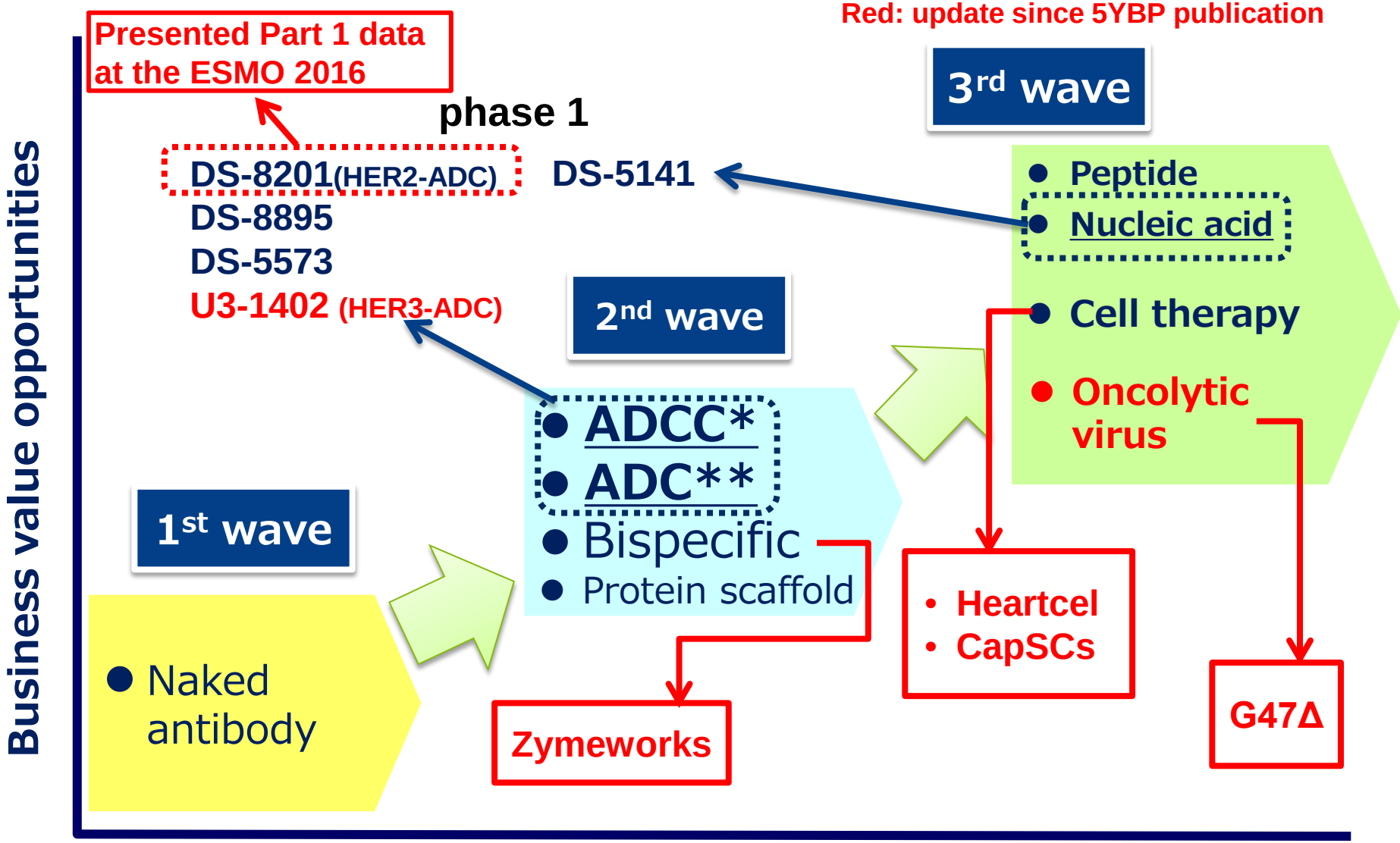
Partnership with Academia and Biotech

Create new drugs in Oncology/New Horizon area	Lung cancer therapeutics	Collaboration with Dana-Farber Cancer Institute to evaluate DS compounds including HER3-ADC
	Immune-Oncology	Collaboration with AgonOx
Realize clinical application of innovative technology	Oncolytic virus (G47Δ)	Collaboration with Professor Todo, Medical Institute of University of Tokyo
	Bispecific antibody	Collaboration with Zymeworks
	Nucleic acid drug	Ongoing study for Duchenne muscular dystrophy.
	Cell therapy	In-licensed Heartcel from Celixir Ltd. （former Cell Therapy Ltd.）
		Research collaboration with Asahikawa Medical University on CapSCs
	DS originated ADC technology	DS-8201（HER２-ADC)
		U3-1402 （HER3-ADC）

New information

Progress towards realization for Clinical Application of Innovative Technology

Red: update since 5YBP publication



*ADCC: Antibody Dependent Cellular Cytotoxicity
**ADC: Antibody Drug Conjugate

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)

Acquired our own shares based on the policy

- Acquisition period: From June 21, 2016, to October 24, 2016
- Aggregate amount of acquisition cost: 50.0 billion JPY
- Total number of shares to be acquired: 20.25 million shares

R&D Update

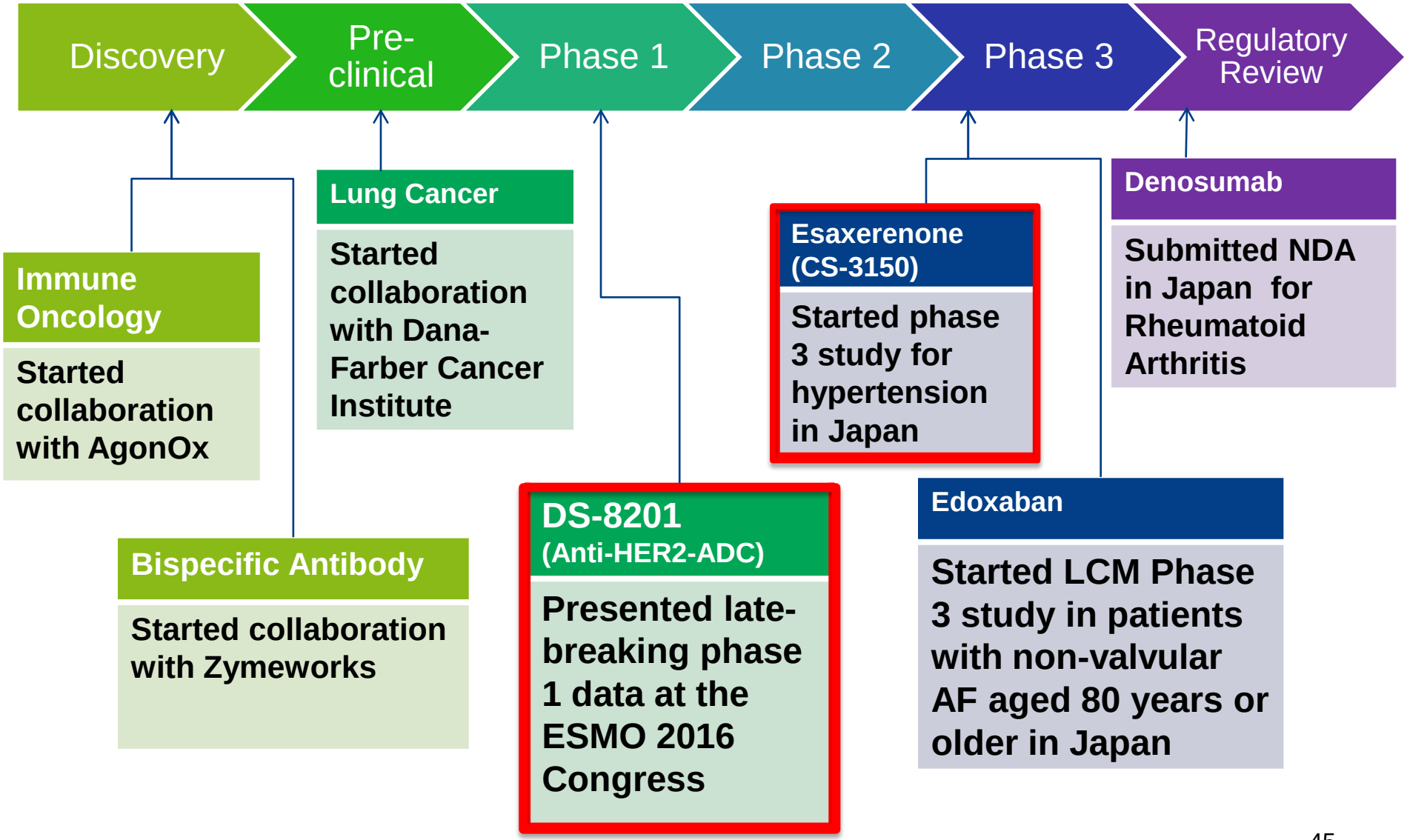
Glenn Gormley MD PhD

Senior Executive Officer

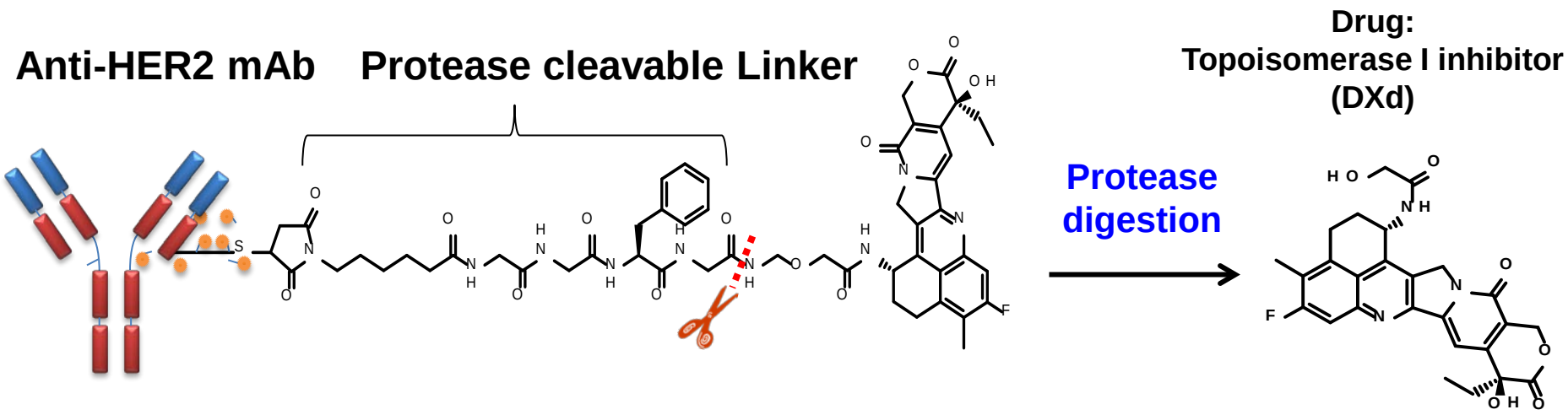
Global Head of R&D

Daiichi Sankyo Co., Ltd

Major Update in R&D Pipeline in Q2 FY2016



DS-8201: Structure

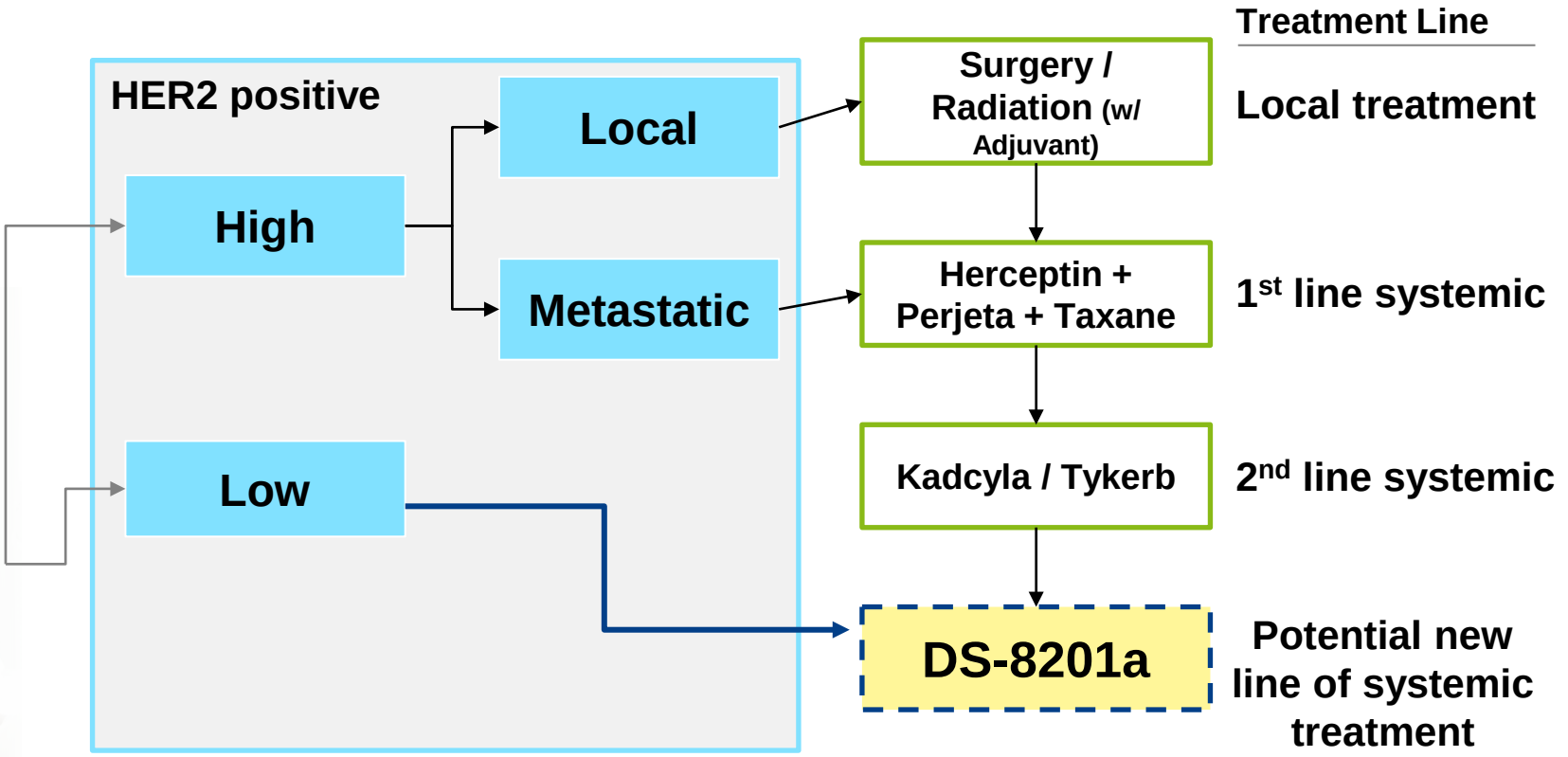


	DS-8201a	Kadcyla (T-DM1)
Antibody	Anti-HER2 mAb	Trastuzumab (Tmab)
Payload	Topoisomerase I inhibitor (DXd)	Tubulin inhibitor (DM1)
DAR*	7-8	3.5

Tamura *et al*. Abstract ID 4585 (LBA17), ESMO 2016

*** DAR: Average drug-to-antibody Ratio**

Breast cancer patient journey: No good treatment options for patients who fail Kadcyla or with low HER2 expression



- HER2+ patients who fail Kadcyla have no good options for treatment
- HER2 low-expressing patients have few options other than chemo

DS-8201 Phase 1 Study: Study Design

- Open Label, Multiple Dose, First-in-Human Study

Part 1: Dose Escalation in Japan

- **Advanced/Unresectable or metastatic Breast Cancer or Gastric Cancer or GEJ* adenocarcinoma**
- **Refractory to or intolerable with standard treatment, or for which no standard treatment is available**

***GEJ: Gastro Esophageal Junction**

DS-8201 Phase 1 Study: Patient Demographics

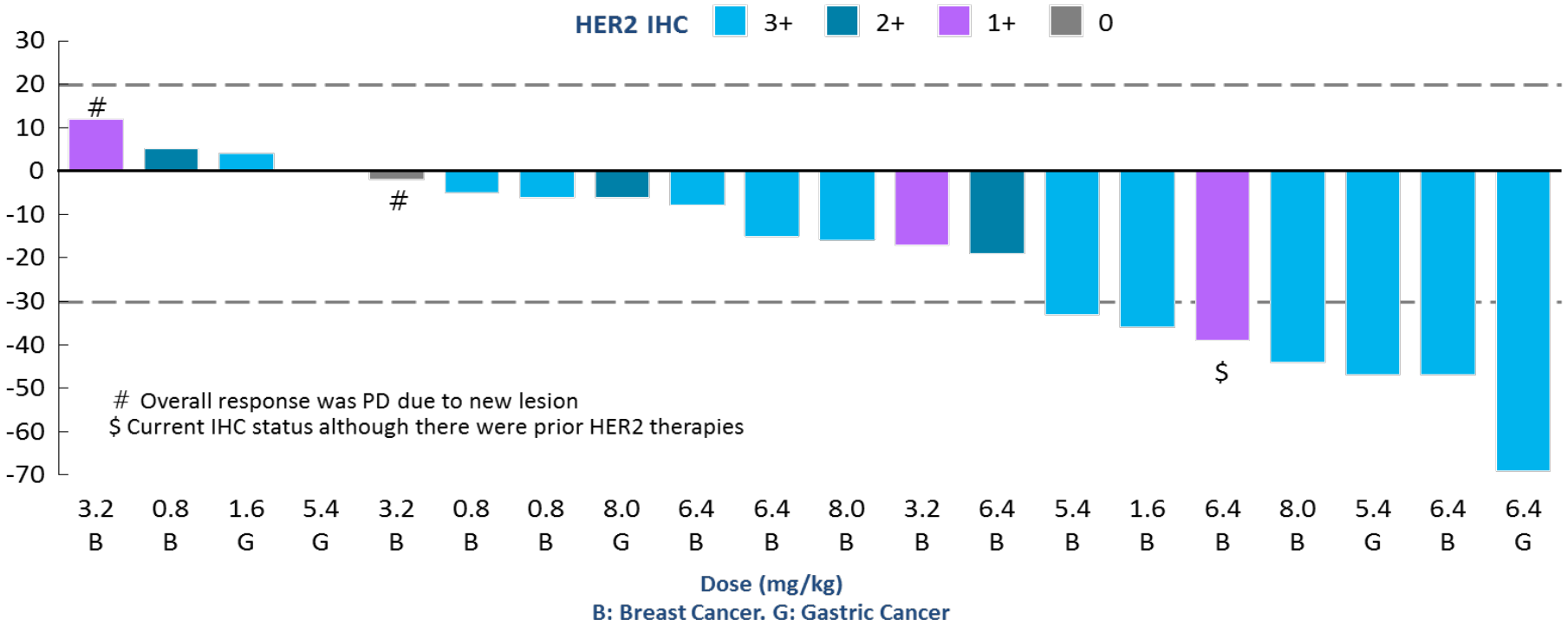
Patient characteristics	
Number of patients treated	22
Age median (range)	66 (38-79)
Number of Prior Chemotherapy Regimens (range)	5 (1-11)
Tumor type	
Breast	16
Gastric	5
Gastroesophageal junction	1

HER2 Status		
IHC		
0	1	
1+	3	
2+	3	
3+	15	
Prior therapy		
Anti-HER2 Therapy	18	
Trastuzumab	18	
Pertuzumab	5	
Lapatinib	4	
Kadcyla	13	

Tamura *et al*. Abstract ID 4585 (LBA17), ESMO 2016

DS-8201 Phase 1 Study: Efficacy (% change)

Best percent change of tumor volume from baseline



- **ORR* was 35% (7 PRs)**
- **DCR** was 90%**

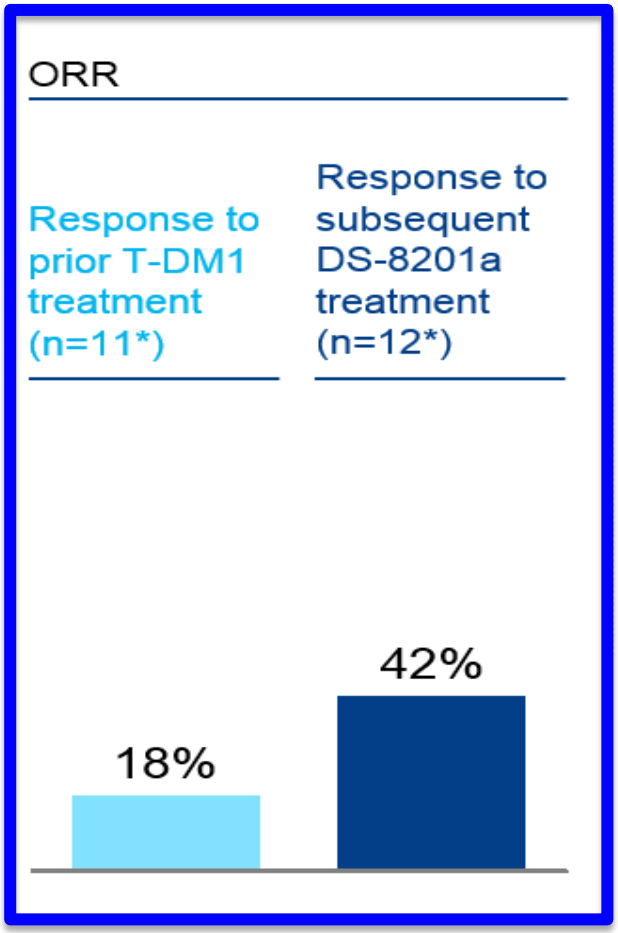
***ORR (Objective Response Rate) : CR + PR**
****DCR (Disease Control Rate): CR + PR + SD**

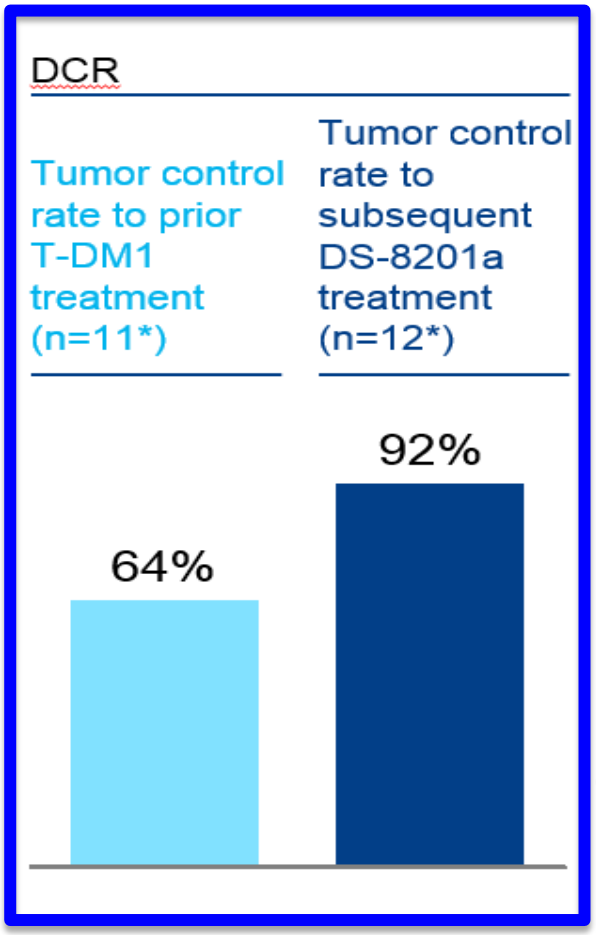
CR: Complete Response
Disappearance of all target lesions
PR: Partial Response
At least a 30% decrease in target lesions
SD: Stable Disease
From 30% shrinkage to 20% increase in target lesions

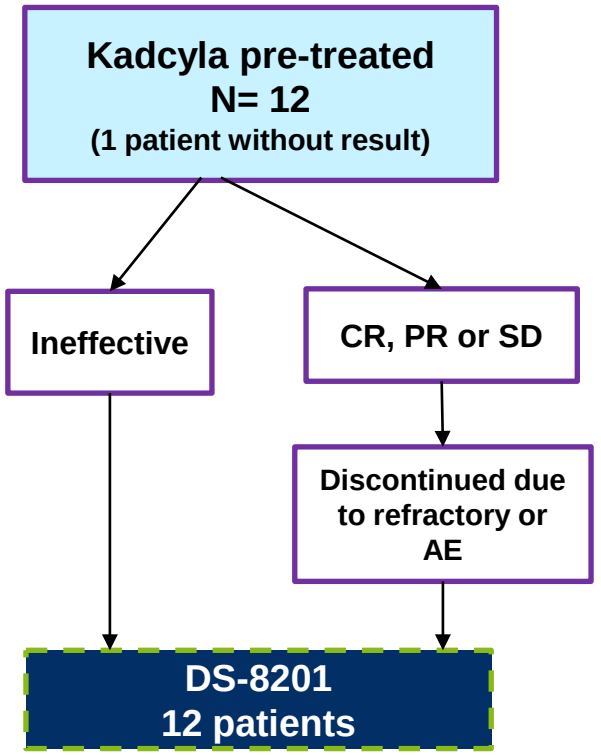
Tamura *et al*. Abstract ID 4585 (LBA17), ESMO 2016

DS-8201 Phase 1 Study: Efficacy in Kadcycla pre-treated patients

Subgroup Results in Kadcyla (T-DM1) pre-treated patients with HER2-positive Breast Cancer







ORR (Objective Response Rate) : CR + PR
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SD: Stable Disease
30% shrinkage to 20% increase in target lesions

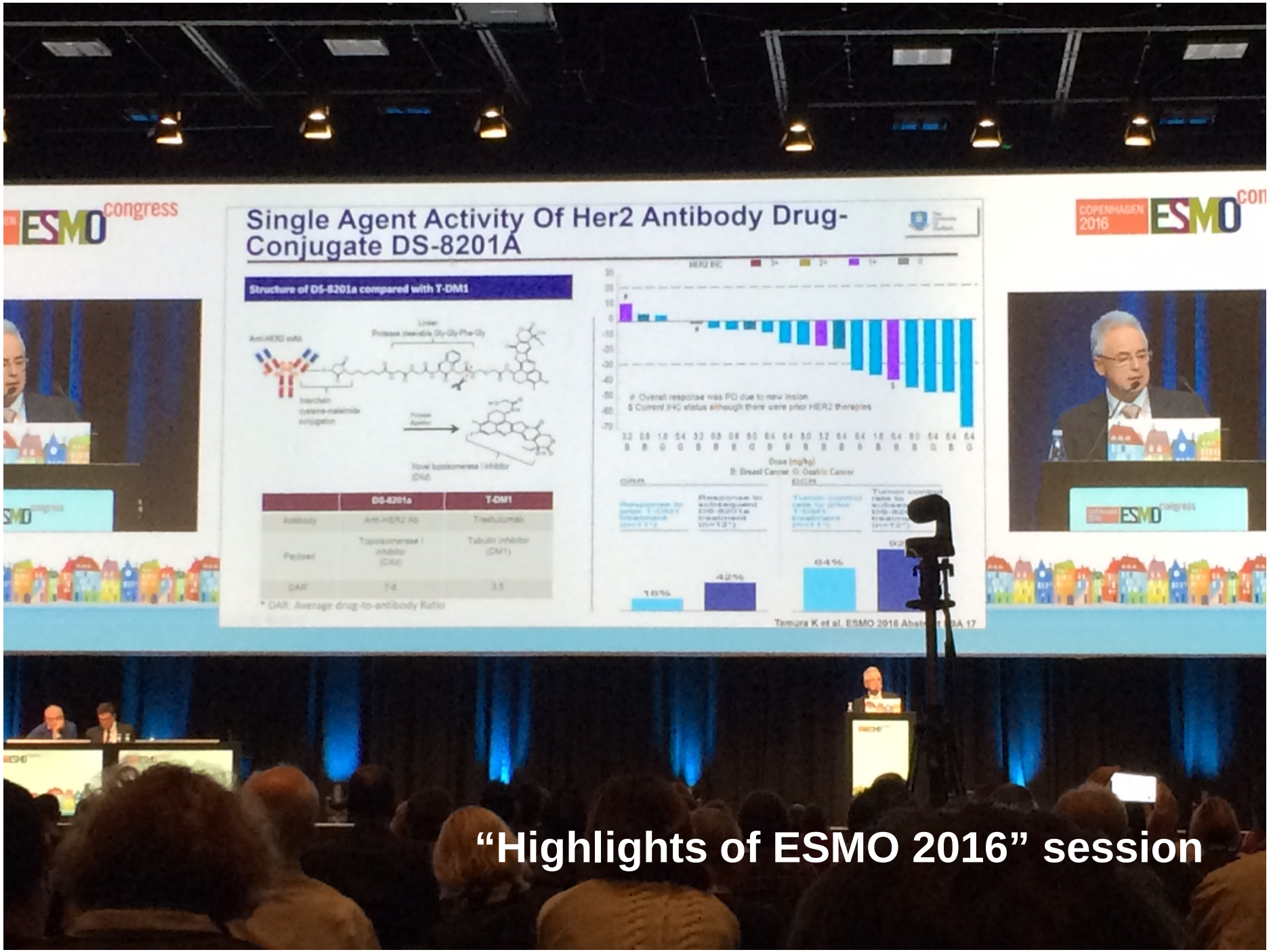
Tamura *et al*. Abstract ID 4585 (LBA17), ESMO 2016

Summary of Safety and Tolerability

- **MTD* was not reached in 0.8~8.0 mg/kg tri-weekly cohorts**
- **No DLT**, or cardio toxicities at any dose level so far**
- **Most common adverse events (AEs) were mild or moderate gastrointestinal and hematological events**

*MTD: Maximum Tolerated Dose
**DLT: Dose Limiting Toxicity

Tamura *et al*. Abstract ID 4585 (LBA17), ESMO 2016



“Highlights of ESMO 2016” session

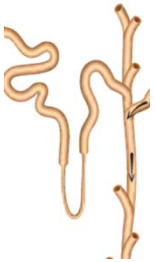
CS-3150 (esaxerenone)

- **CS-3150 is a Non-steroidal Mineralocorticoid Receptor (MR) antagonist licensed from Exelixis with :**
  - **High MR selectivity**
  - **Superior preclinical MR antagonistic effects vs eplerenone**
  - **Long half-life (20hrs)**

- **Target indication and development status in Japan**
  - **Hypertension : Phase 3 studies on-going**
  - **Diabetic nephropathy (DN) : Phase 2b study finished**

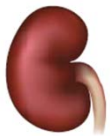
Esaxerenone: MOA

Aldosoterone → MR ⊣ **esaxerenone**



Tubular epithelia

- Na^+ reabsorption / K^+ excretion
- Body fluid retention

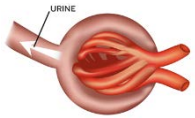


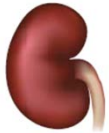
- **Hypertension**
- Serum electrolyte homeostasis

⊣

- Anti-hypertensive effect
- Hyperkalemia

Classical pathway

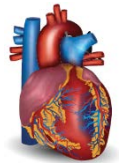




Non-epithelial tissue

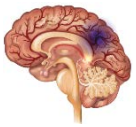
- Inflammation, ROS production
- Fibrosis
- Activation of sympathetic nerve

- Hypertension
- **Heart failure**
- **CKD**



⊣

- Anti-hypertensive effect
- Cardioprotective effect
- Renal protective effect



Emerging pathway

Unmet Medical Need in Diabetic Nephropathy (DN)

- **There is an Increased incidence in patients diagnoss with diabetes and one third develop DN[1)]**
- **Without appropriate treatment at an early stage, patients often progress to renal failure which can require hemodialysis[2)]**
- **Medical cost of hemodialysis in Japan exceeds 1.84 T JPY per year[3)]**
- **Only two drugs, losartan and imidapril, are available for treatment of DN in Japan**

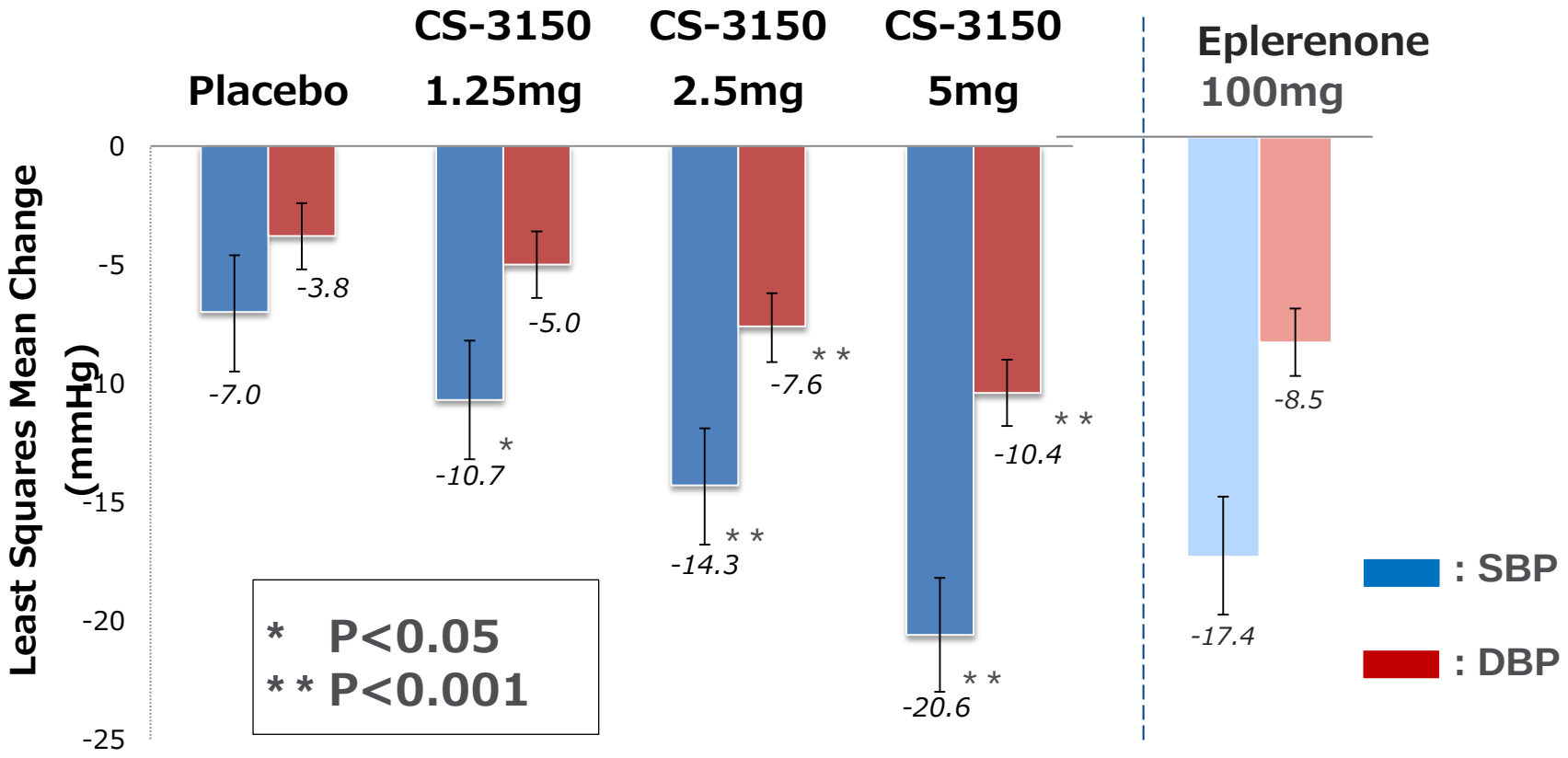
There is a significant need for new innovative therapies to treat early Diabetic Nephropathy

Reference:
1) According to International Diabetes Federation
2) Evidence-based Practice Guideline for the Treatment for Diabetes in Japan 2013（Japan Diabetes Society）
3) Japan Health Insurance Association 2010

Esaxerenone: Hypertension

Phase 2b Study Results

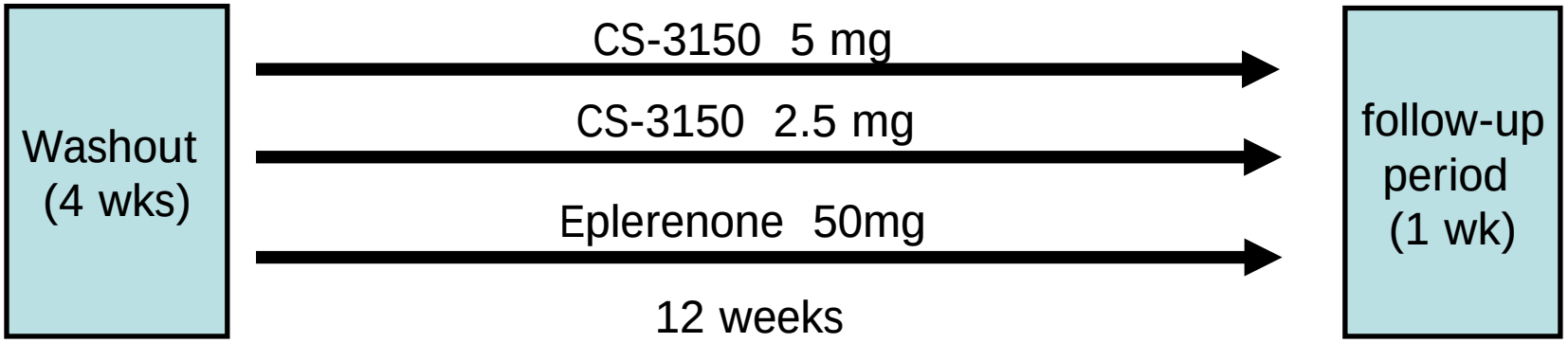
change from baseline in sitting blood pressure at the end of treatment



- **There was a clear dose-response.**
- **Significant antihypertensive effects vs placebo in both SBP and DBP are observed at 2.5mg and 5mg once daily.**

Esaxerenone: Hypertension

Japan phase 3 study design



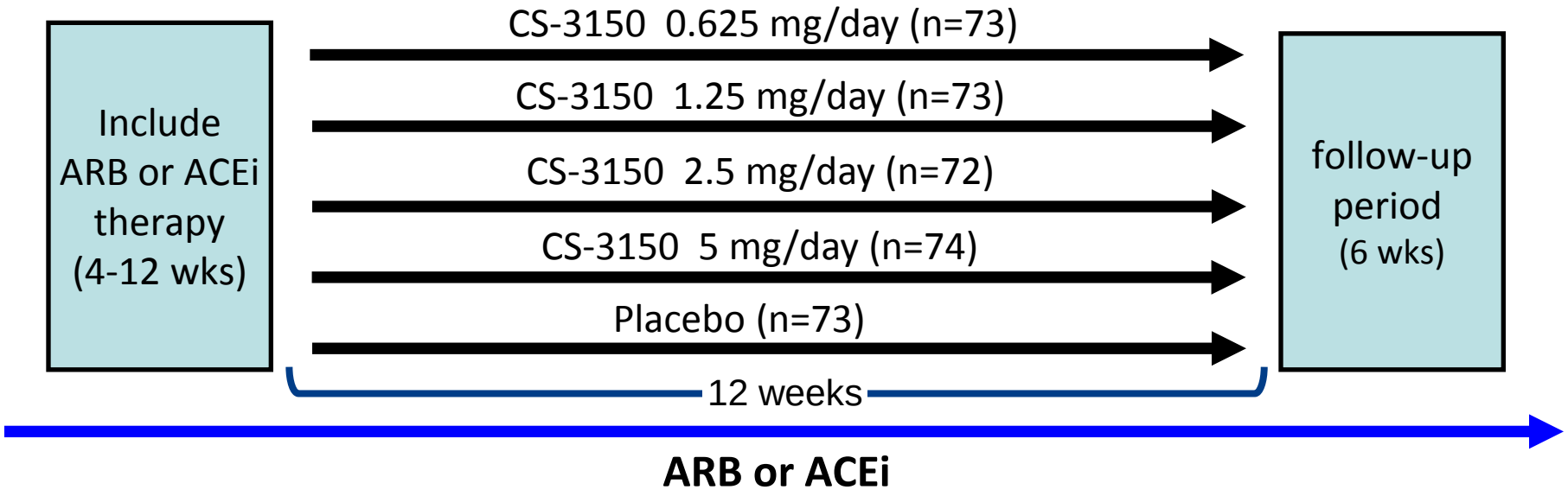
Objectives	**Primary objective: non-inferior antihypertensive effect to EPLERENONE**
Duration	**Washout: 4 weeks, Treatment: 12 weeks**
Sample size	**930 pts. (310 pts./group)**
Endpoints	**Primary endpoint: sitting SBP / DBP**
	Safety endpoint: hyperkalemia incidence (sK: ≥5.5mEq/L)

Anticipated TLR: H2 FY2017

Esaxerenone: Diabetic Nephropathy (DN)

Daiichi-Sankyo

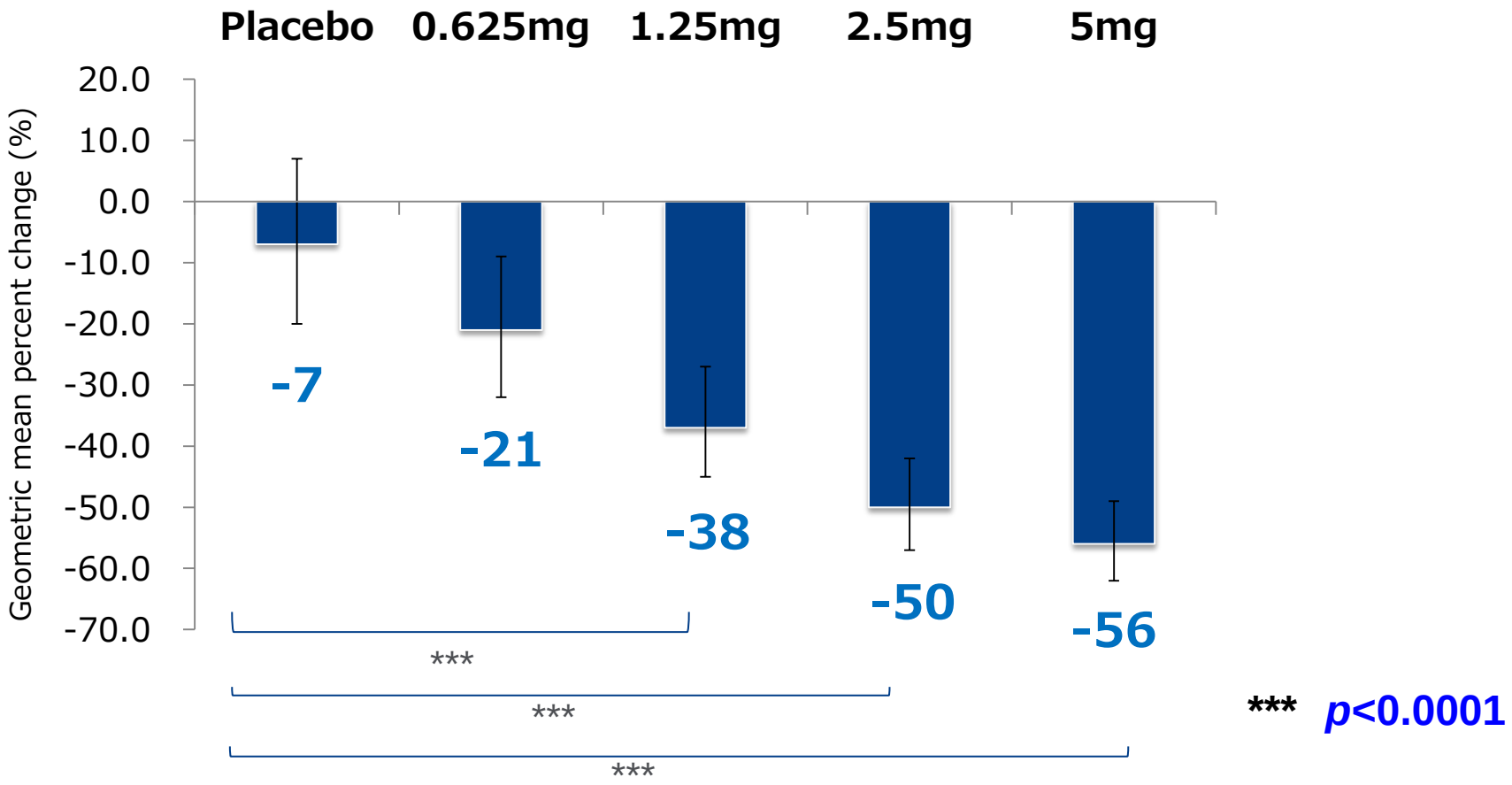
◆ Japan phase 2b study



Objective	**dose-dependent efficacy and safety in T2DM with microalbuminuria**
Subject	**T2DM, UACR: ≥ 45 <300(mg/g·Cr),** **eGFR: ≥30 (mL/min/1.73m^2),**
Sample size	**365 pts.**
Study Endpoints	• **Primary: ⊿UACR from baseline,** • **Safety: hyperkalemia rate (sK: ≥5.5mEq/L)**

Primary Endpoint:
UACR*change from baseline at end of treatment

*UACR: Urine Albumin-to-Creatinine Ratio



*** $p<0.0001$

Significant UACR reduction vs placebo on top of ARB / ACEi confirmed in 1.25, 2.5, and 5 mg/day by 12 weeks treatment.

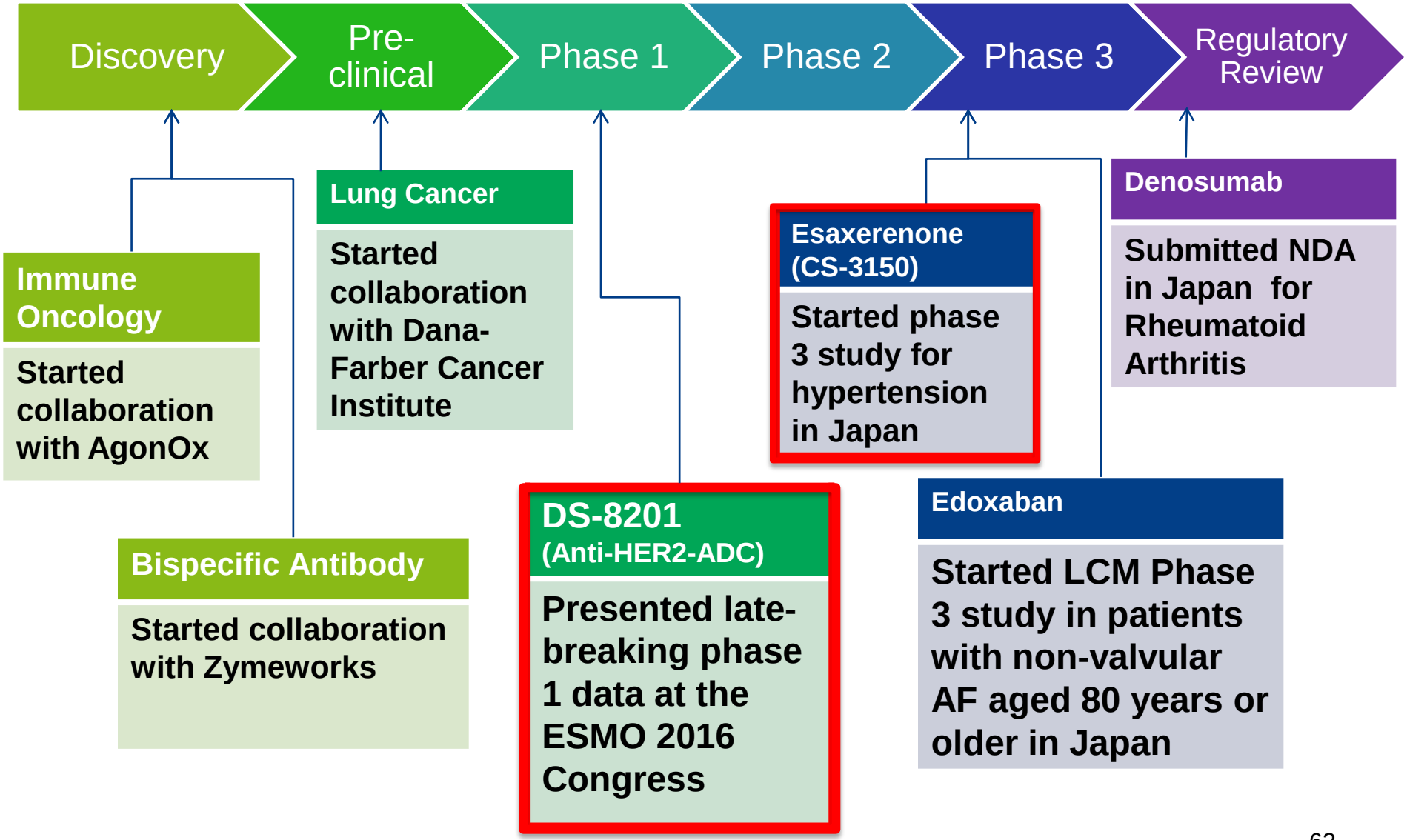
Safety data for DN study

Incidence of Hyperkalemia

	Placebo N=72 n	0.625 mg N=71 n	1.25mg N=72 n	2.5 mg N=70 n	5.0mg N=73 n
Confirmed Hyperkalemia Serum K ≥ 6.0 mEq/L or two Successive Measurements of Serum K ≥ 5.5 mEq/L	1	2	2	2	7

Confirmed hyperkalemia was comparable to placebo at 0.625-2.5mg but numerically greater than placebo in 5mg treatment group

Major Update in R&D Pipeline in Q2 FY2016



Reference

Major R&D milestone events

Project	Indication/Study	Event	Target
CL-108	**Pain/Opioid-induced nausea and vomiting (US)**	Approval	PDUFA date Jan. 31, 2017
Denosumab	**Rheumatoid arthritis (JP)**	Approval	FY2017
CHS-0214 （etanercept BS）	**Rheumatoid arthritis (JP)**	NDA	FY2016
Tivantinib	**METIV・HCC Hepatocellular carcinoma Phase 3 study (US/EU)**	TLR	CY2017 H1
Mirogabalin	**Fibromyalgia Phase 3 study (US/EU)**	TLR	CY2017 H1
Quizartinib	**QuANTUM-R AML 2nd line treatment Phase 3 study (US/EU/Asia)**	DMC interim analysis	CY2017 H1
DS-8500	**Type 2 Diabetes phase 2b study (JP) (US)**	TLR	FY2016 Q4 FY2017 H1

Red: update during Q2 FY2016

TLR*: Top Line Results

Major R&D Pipeline

As of October 2016

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) ■ DS-6051 (US/JP) (NTRK/ROS1 inhibitor) ■ PLX9486 (US) (KIT inhibitor) ■ DS-3201 (JP) (EZH1/2 inhibitor) ■ PLX73086 (US) (CSF-1R inhibitor) ■ PLX51107 (US) (BRD4 inhibitor) ■ DS-8895 (JP) (Anti-EPHA2 antibody) ■ DS-8273 (US) (Anti-DR5 antibody) ■ DS-5573 (JP) (Anti-B7-H3 antibody) ■ DS-8201 (JP/US) (Anti-HER2 ADC) ■ U3-1784 (EU) (Anti-FGFR4 antibody) ■ DS-1123 (JP) (Anti-FGFR2 antibody) ■ U3-1402 (JP) (Anti-HER3 ADC)	■ Patritumab (EU) (U3-1287 / Anti-HER3 antibody) ■ Pexidartinib (US) (PLX3397 / CSF-1R/KIT/FLT3-ITD inhibitor) ■ DS-1647 (JP) (Glioblastoma / **G47Δ virus**)	■ Tivantinib (US/EU) (ARQ 197 / HCC / MET inhibitor) ■ 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	■ DS-1040 (Acute ischemic stroke / TAFIa inhibitor) ■ DS-2330 (Hyperphosphatemia) ■ DS-9231/TS23 (Thrombosis / **α2**-PI inactivating antibody) ■ DS-9001 (Dyslipidemia / Anti-PCSK9 Anticalin-Albumod)	■ Esaxerenone (JP) (CS-3150 / DM nephropathy / MR antagonist) ■ DS-8500 (JP/US) (Diabetes / GPR119 agonist)	■ Edoxaban (JP) (DU-176b / AF / FXa inhibitor) ■ Prasugrel (JP) (CS-747 / Ischemic stroke / Anti-platelet agent) ■ Esaxerenone (JP) (CS-3150 / Hypertension / 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 (Osteoporosis / Anti-Siglec-15 antibody) ■ DS-7080 (US) (AMD / Angiogenesis inhibitor) ■ DS-2969 (*Clostridium difficile* infection /GyrB inhibitor) ■ DS-5141 (JP) (DMD / ENA oligonucleotide) ■ VN-0102/JVC-001 (JP) (MMR vaccine)	■ Laninamivir (US/EU) (CS-8958 / Anti-influenza / out-licensing with Biota)	■ Mirogabalin (US/EU) (DS-5565 / Fibromyalgia / **α2δ ligand**) ■ Mirogabalin (JP/Asia) (DS-5565 / DPNP/ **α2δ ligand**) ■ Mirogabalin (JP/Asia) (DS-5565 / PHN / **α2δ ligand**) ■ Hydromorphone (JP) (DS-7113 / Cancer pain / Opioid **μ**-receptor regulator) <Injection> ■ CHS-0214 (JP) (Etanercept BS / Rheumatoid arthritis / TNF**α** inhibitor) ■ VN-0105 (JP) (DPT-IPV / Hib vaccine)	■ Hydromorphone (JP) (DS-7113 / Cancer pain / Opioid **μ**-receptor agonist)<Oral> ■ 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) ■ Denosumab (JP) (AMG 162 / Rheumatoid arthritis / Anti-RANKL antibody)

Red: Major changes after the FY2016 Q1 financial announcement on July 31, 2016

DS R&D Day 2016

- Date: December 13, 2016 (15:30 – 17:00)

- Location: Daiichi Sankyo Co. Ltd
  Nihonbashi HQ

- Speakers:
  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)
  and Others

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