

FY2018 Q3 Financial Results Presentation

DAIICHI SANKYO CO., LTD

Toshiaki Sai
Executive Vice President and CFO

January 31, 2019

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◆ **FY2018 Q3 Financial Results**

◆ **Business Update**

- **Edoxaban**
- **Regional Value**
- **Optimizing Supply Chain**

◆ **R&D Update**

FY2018 Q3 Financial Results

Overview of FY2018 Q3 Results

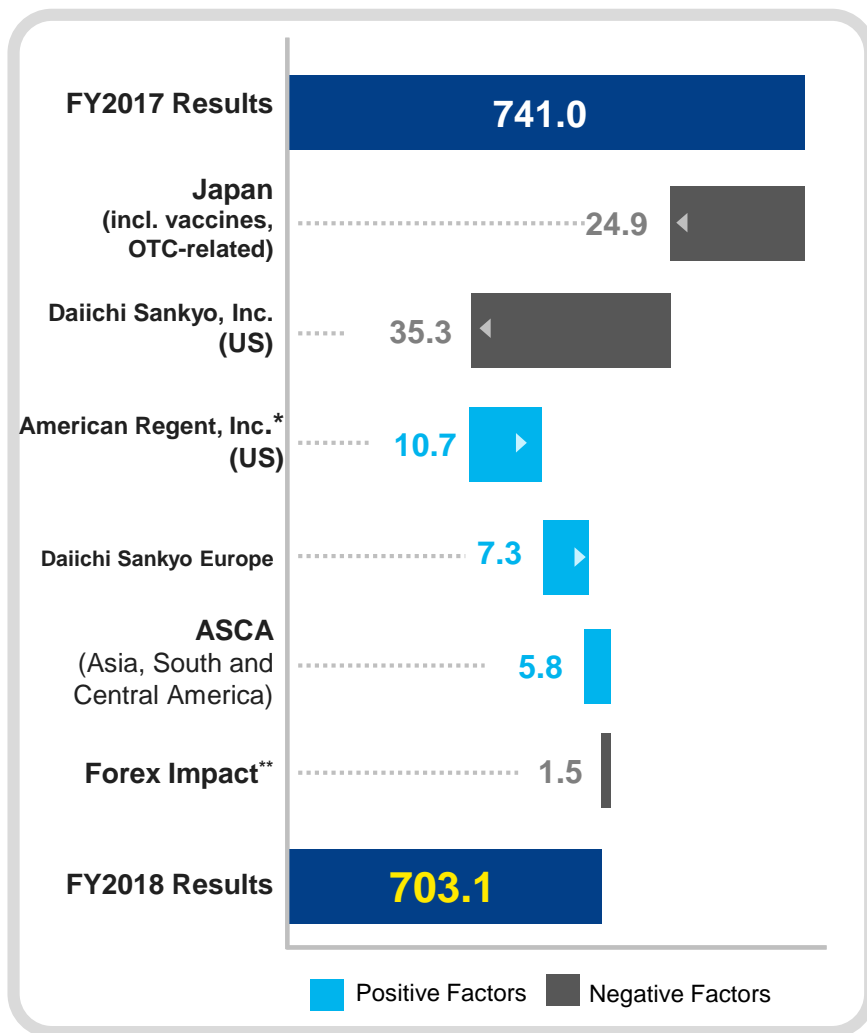
(Bn JPY)

	FY2017 Q3 YTD Results	FY2018 Q3 YTD Results	YoY
Revenue	741.0	703.1	-5.1% -38.0
Cost of Sales	255.5	264.9	+9.5
SG&A Expenses	216.7	198.5	-18.2
R&D Expenses	175.6	142.6	-33.0
Operating Profit	93.2	97.1	+4.1% +3.9
Profit before Tax	97.7	98.0	+0.2
Profit attributable to owners of the Company	72.6	78.8	+8.5% +6.2

Currency Rate	USD/JPY	111.71	111.15	-0.56
	EUR/JPY	128.53	129.49	+0.96

Revenue

Decreased by 38.0 Bn JPY (Decreased by 36.5 Bn JPY excl. forex impact) (Bn JPY)



Positive Factors		Negative Factors	
Japan			
Lixiana	+14.6	Olmetec	-28.5
Pralia	+3.7	Nexium	-9.0
		Inavir	-4.8
		Loxonin	-4.7
		(Incl. impact of price revision in Japan)	
Daiichi Sankyo Espha (GE)	+8.1	Daiichi Sankyo Healthcare	-3.6
Olmesartan AG, Rosuvastatin AG etc.		(Incl. impact of change in accounting treatment)	
Daiichi Sankyo, Inc.		Welchol	-18.3
		Olmesartan	-9.4
		Effient	-7.7
American Regent, Inc.*			
Injectafer	+8.7		
Daiichi Sankyo Europe			
Lixiana	+14.6	Olmesartan	-4.6

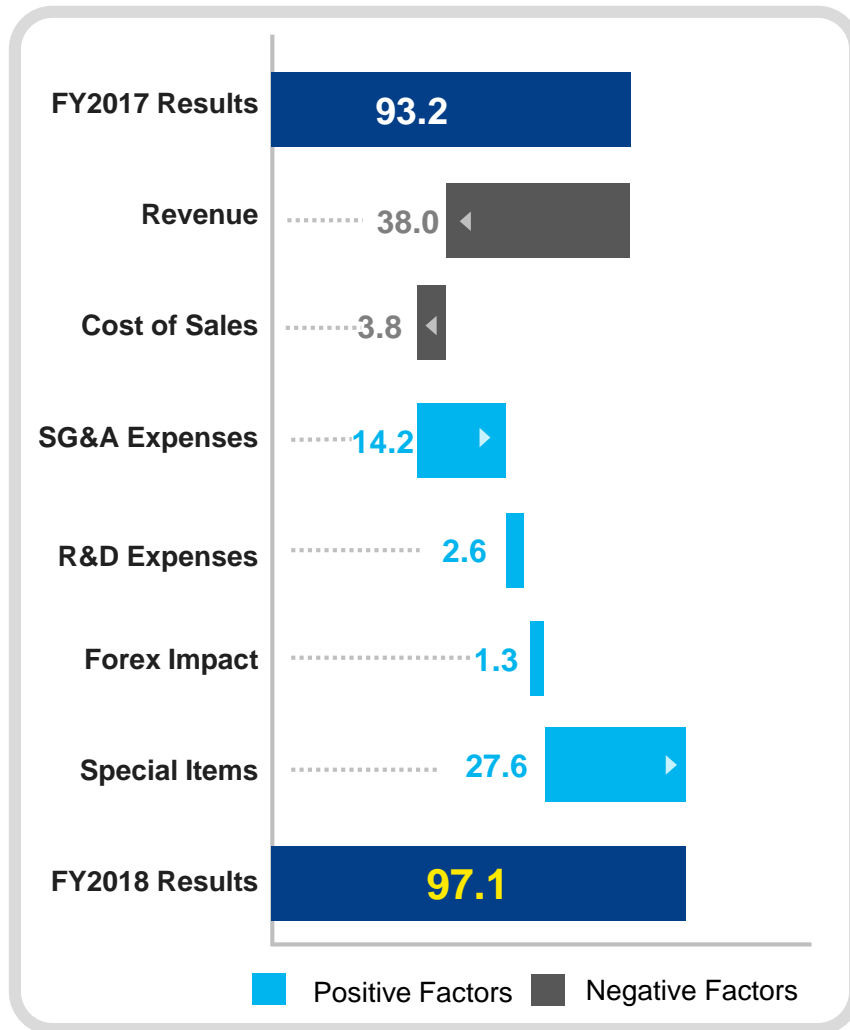
* Formerly, Luitpold Pharmaceuticals, Inc.

** Forex impact USD: -0.6, EUR : +0.5, ASCA: -1.4

Operating Profit

Increased by 3.9 Bn JPY

(Decreased by 23.4 Bn JPY excl. forex impact and special items)



(Bn JPY)

Revenue-38.0
incl. forex impact of -1.5

Cost of Sales +3.8 (Cost increased)
Product mix due to impact of olmesartan LOE

SG&A Expenses-14.2 (Cost decreased)
Effect of cost reductions in US,
impact of change in accounting treatment etc.

Forex Impact -1.3 (Cost decreased)
Cost of Sales -0.4
SG&A Expenses -0.6
R&D Expenses -0.3

Special Items -27.6 (Cost decreased)

*See next slide for details

Special Items

(Bn JPY)

	FY2017 Q3 YTD Results		FY2018 Q3 YTD Results		YoY
Cost of Sales	Gain on sales of fixed assets	-6.1			+6.1
SG&A Expenses			Gain on sales of fixed assets	-3.5	-3.5
R&D Expenses	Impairment loss (Intangible)	30.2			-30.2
Total		24.1		-3.5	-27.6

- : Cost decreased items

* No items booked in Q3

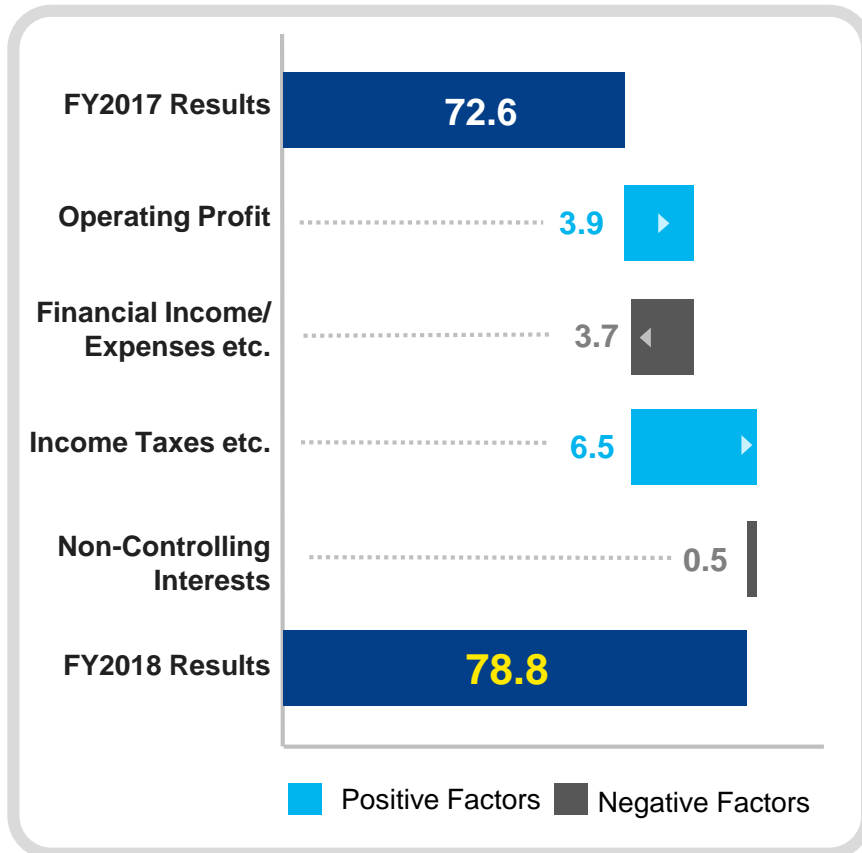
Special items :

Items having a transitory and material impact on operating profit are defined as "Special items".

Specifically, gains and losses related to: sale of fixed assets, restructuring, impairment, litigation, etc. amounting to 1 billion JPY or more are defined as "Special items".

Profit Attributable to Owners of the Company

Increased by 6.2 Bn JPY



(Bn JPY)

Financial Income/ Expenses etc. +3.7 (Cost increased)
 Deterioration of forex gains/ losses

Income Taxes etc. -6.5 (Cost decreased)
 Impact of the tax rate reduction in US etc.

	FY2017	FY2018	YoY
Profit before Tax	97.7	98.0	+0.2
Income Taxes etc.	25.6	19.1	-6.5
Tax rate	26.2%	19.5%	-6.7%

Non-Controlling Interests +0.5 (Cost increased)

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

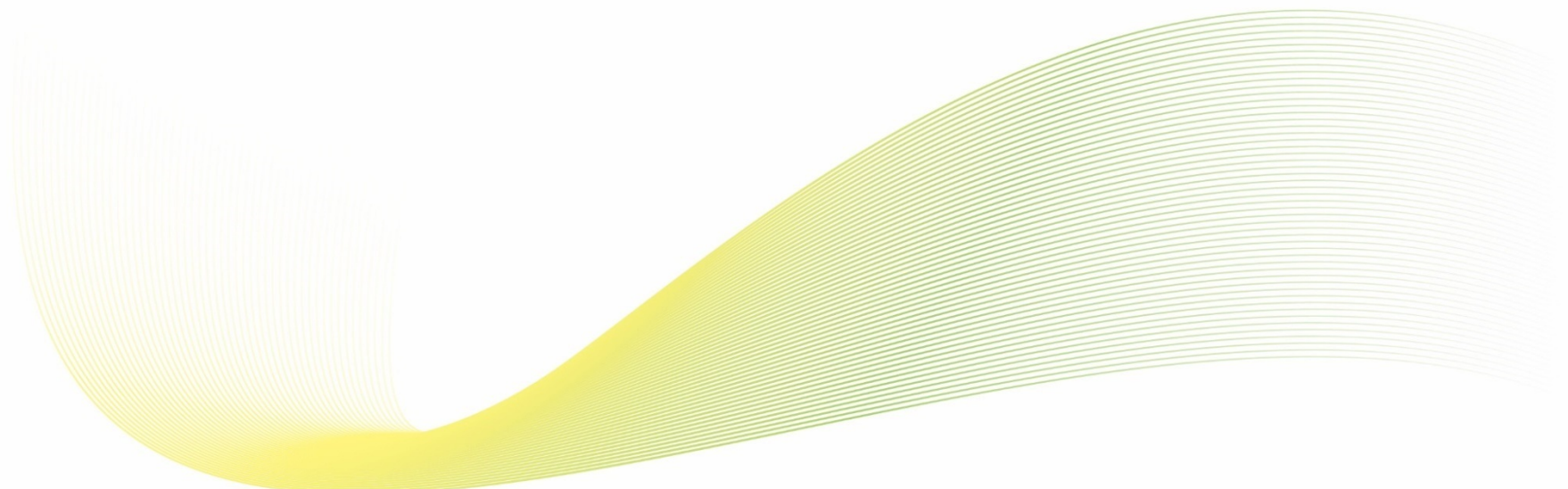
	FY2017 Q3 YTD Results	FY2018 Q3 YTD Results	YoY	
Japan	418.1	395.7	-22.4	
Daiichi Sankyo Healthcare	56.6	52.9	-3.6	
Daiichi Sankyo, Inc.	64.1	28.6	-35.5	
Olmesartan	17.4	7.9	-9.4	
Welchol	29.3	11.0	-18.3	
Effient	10.1	2.4	-7.7	
Savaysa	1.6	1.6	+0.0	
Movantik	3.7	3.3	-0.5	
American Regent, Inc.	79.9	90.1	+10.2	
Venofer	24.0	24.1	+0.1	
Injectafer	25.2	33.7	+8.5	
GE injectables	28.3	28.2	-0.0	
Daiichi Sankyo Europe	58.2	66.0	+7.8	
Olmesartan	25.5	21.0	-4.5	
Efient	6.0	4.6	-1.4	
Lixiana	18.5	33.3	+14.9	
ASCA (Asia, South and Central America)	58.7	63.1	+4.4	
Currency Rate	USD/JPY	111.71	111.15	-0.56
	EUR/JPY	128.53	129.49	+0.96

Revenue: Major Products in Japan

(Bn JPY)

		FY2017 Q3 YTD Results	FY2018 Q3 YTD Results	YoY
Nexium	ulcer treatment	70.0	61.0	-9.0
Lixiana	anticoagulant	34.7	49.3	+14.6
Memary	Alzheimer's disease treatment	38.1	39.5	+1.4
Loxonin	anti-inflammatory analgesic	29.0	24.3	-4.7
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	17.3	21.0	+3.7
Tenelia	type 2 diabetes mellitus treatment	20.9	19.9	-1.0
Inavir	anti-influenza treatment	9.3	4.5	-4.8
Olmotec	antihypertensive agent	40.5	11.9	-28.5
Ranmark	treatment for bone complications caused by bone metastases from tumors	11.7	12.7	+1.0
Efient	antiplatelet agent	9.9	10.9	+0.9
Rezaltas	antihypertensive agent	13.1	12.2	-1.0
Urief	treatment for dysuria	8.7	8.2	-0.5
Omnipaque	contrast medium	11.0	9.5	-1.4

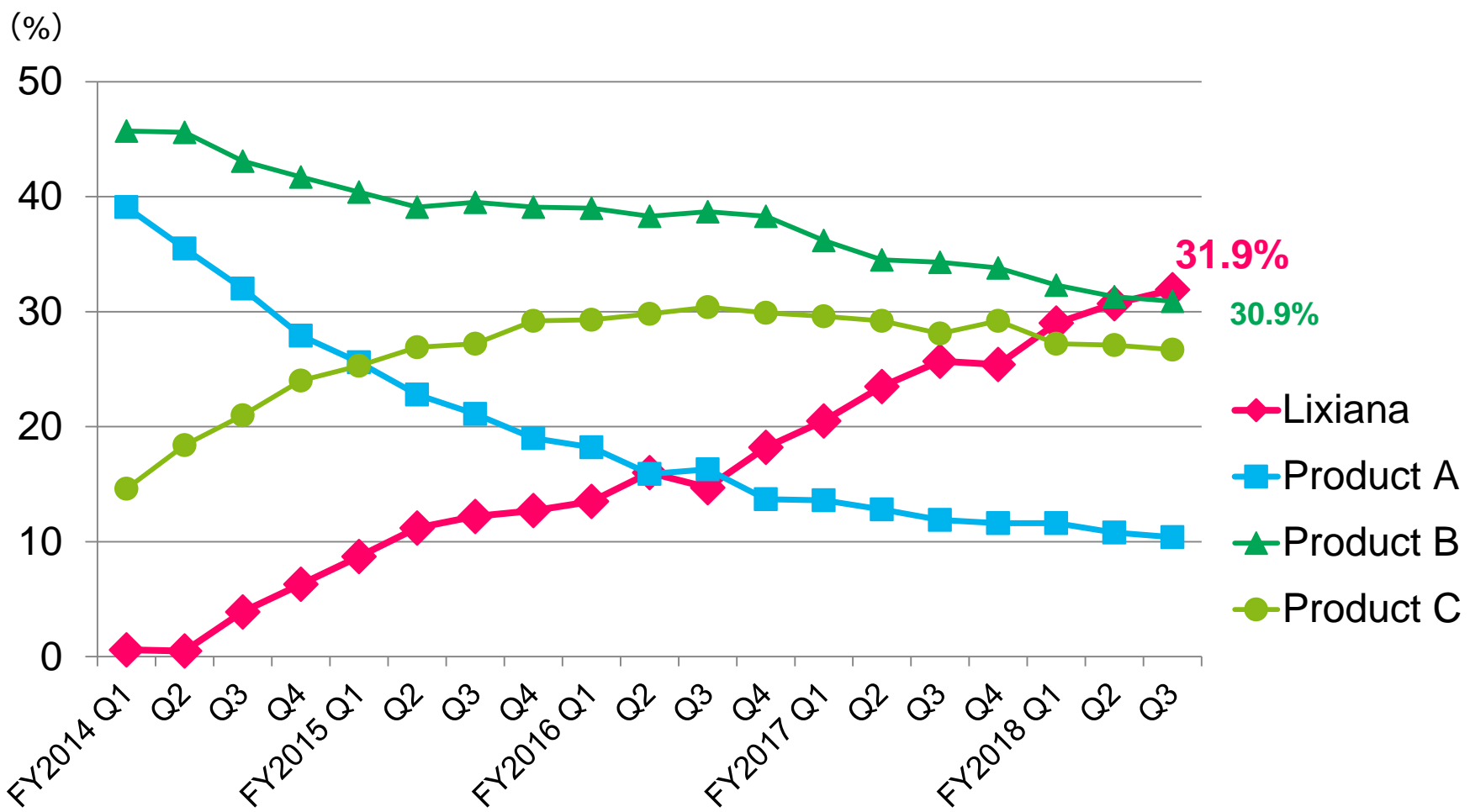
Edoxaban



Lixiana: Growth in Japan



Lixiana reached No.1 sales share at FY2018 Q3

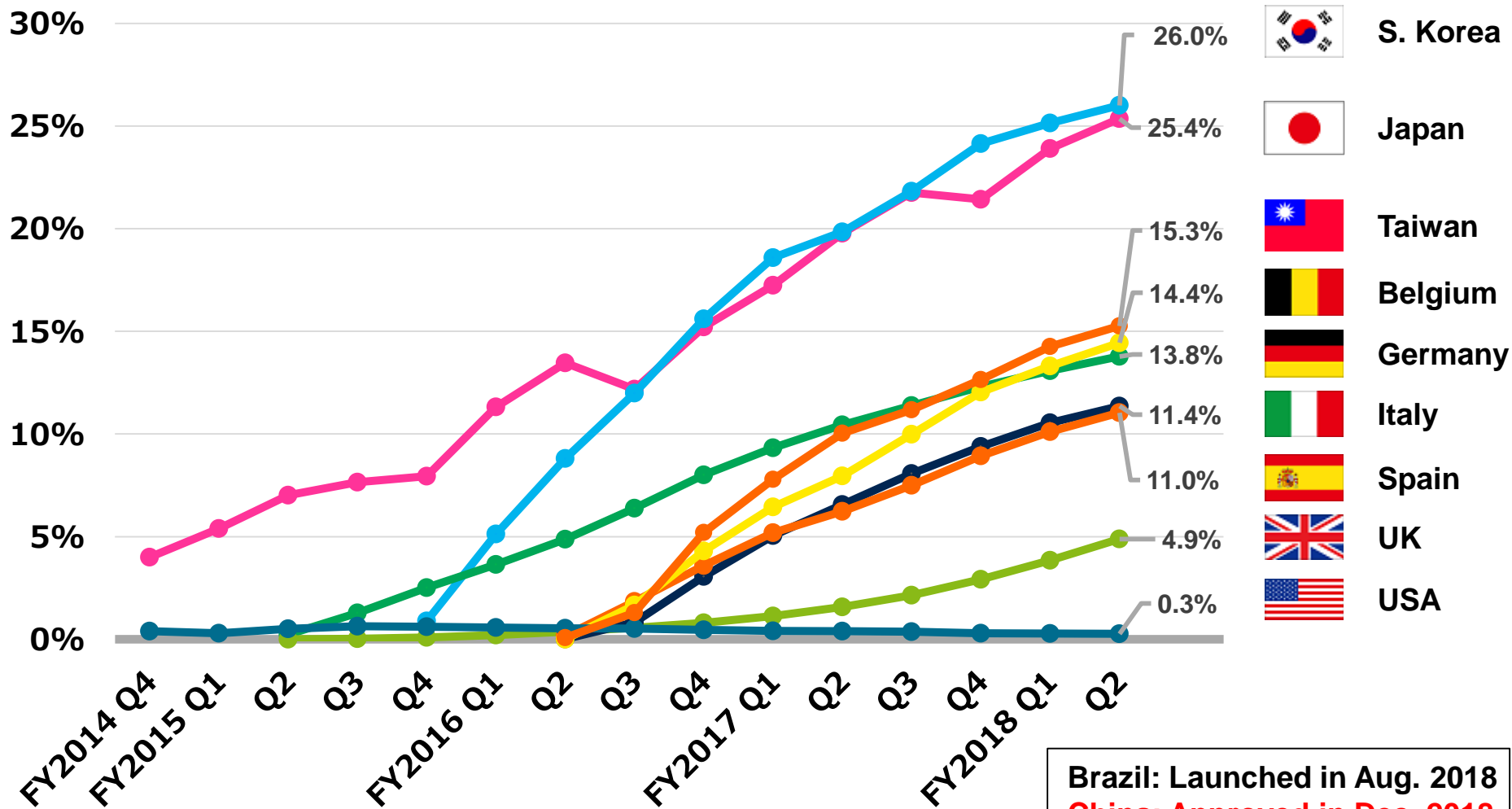


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Edoxaban: Growth in Each Country



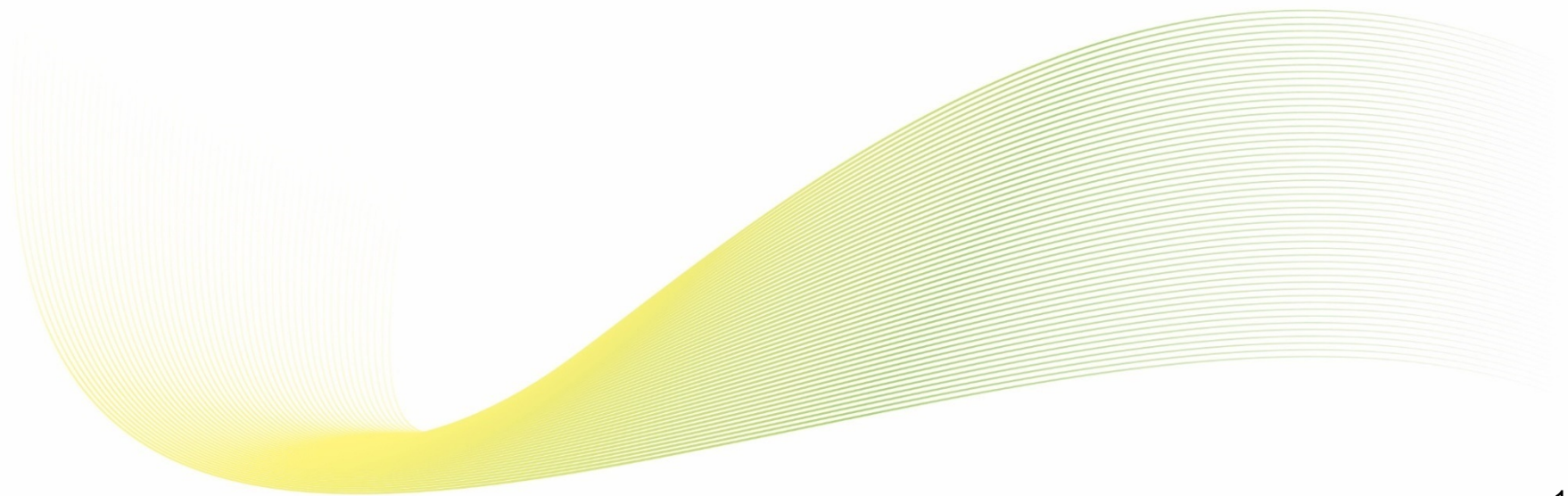
- ◆ Steady growth in each country
- ◆ Approved in China (Dec. 2018)



Brazil: Launched in Aug. 2018
China: Approved in Dec. 2018



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Regional Value



Aim to have enriched "**regional value products**" aligned with regional business strategy in addition to "global products" such as edoxaban and new oncology products toward 2025 Vision

2025 Vision



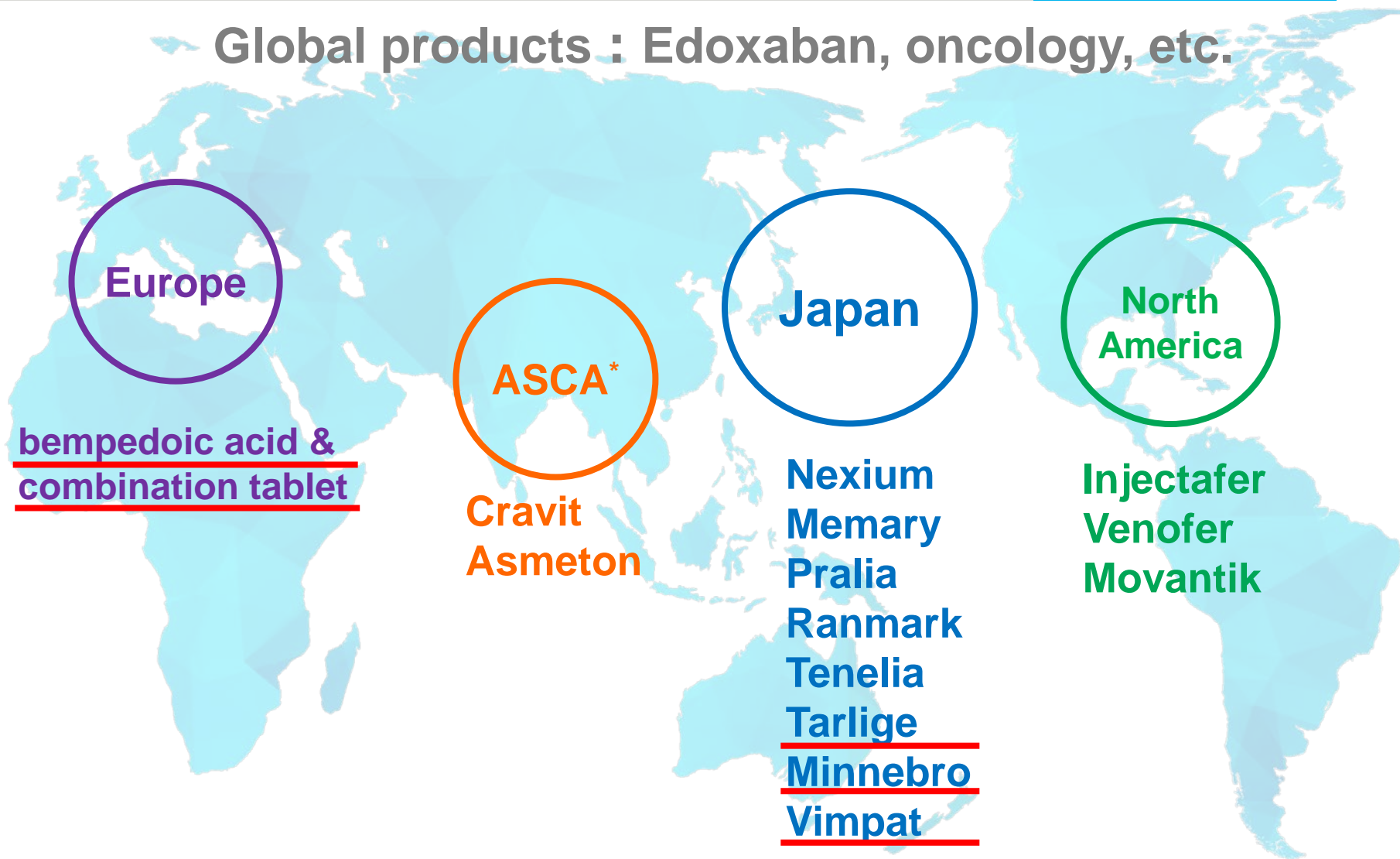
**Global Pharma Innovator
with Competitive Advantage in Oncology**

- *Build a specialty area* centered on oncology as the core business*
- *Enrich regional value aligned with market needs*
- *Create innovative products*
– *change SOC (Standard of Care)*
- *Realize shareholder value through highly efficient management*

*specialty area: Drugs mainly prescribed at hospital and/or by specialty practitioners

Enrichment of Regional Value Products

Global products : Edoxaban, oncology, etc.



New products

*ASCA: Asia, South & Central America

◆ **Tarlige (mirogabalin): Approved in Jan. 2019**

- MOA: $\alpha_2\delta$ ligand
- Indication: peripheral neuropathic pain

◆ **Minnebro (esaxerenone): Approved in Jan. 2019**

- MOA: mineralocorticoid blocker
- Indication: hypertension

◆ **Vimpat (lacosamide): Additional approved in Jan. 2019**

- Antiepileptic Drug (launched in Aug. 2016)
- Indication: monotherapy/adjunct therapy for partial-onset seizures in patients with epilepsy

<Additional approval and new dosage>

- ✓ Additional approval: treatment of pediatric patients
- ✓ New dosage: dry syrup, I.V. infusion

Europe: In-licensed LDL-C Lowering Drug

◆ Originator: Esperion Therapeutics, Inc.



◆ Licensing Agreement

- **bempedoic acid and bempedoic acid / ezetimibe combination tablet**
 - ✓ MOA : ACL (ATP citrate lyase) inhibitor (First-in-class)
 - ✓ Route, dosage : Oral, once-daily
- Territory : Europe
- Role and responsibility
 - ✓ Daiichi Sankyo Europe : commercialization
 - ✓ Esperion : development and manufacturing
- Total milestone : Max. \$900 Mn
(incl. upfront payment \$150 Mn and first commercial sale payment \$150 Mn)

◆ Value of this deal

- Leverage our operational infrastructure which Daiichi Sankyo Europe have established in current cardiovascular portfolio
- Improve regional value in Europe by the synergies with anticoagulant LIXIANA

◆ Expected Timeline

- Filing for EMA : CY2019 H1, Launch : CY2020
- A global cardiovascular outcomes trial is ongoing and the data are expected during CY2022

Optimizing Supply Chain

Future oriented SC structure transformation



FY2015

Transfer of Akita Plant (Daiichi Sankyo Propharma)

FY2016

Sale of Bethlehem Plant in U.S.

FY2017

Closure of Hiratsuka Plant (Daiichi Sankyo Chemical Pharma)

FY2018

Decision of Takatsuki Plant transfer (Daiichi Sankyo Propharma)

- ◆ **Transferee:**  **TAIYO HOLDINGS CO., LTD.**
 - Employees: continue to be employed by the transferee
 - Products: continue to be produced and stably supplied at the Takatsuki Plant

- ◆ **Transfer Date: Oct. 1st ,2019**

- ◆ **Compensation: JPY 37.6 Bn**

- ◆ **The net assets of the Takatsuki Plant**
 - The book value including the land owned by Daiichi Sankyo at the end of March 2018: JPY 18.5 Bn

***Profit on transfer expected to be booked in FY2019**

Reference: Production Sites (as of Oct. 2019)

Japan

13 Sites

Formulation
/ packaging

**Daiichi Sankyo
Propharma**

➤ Hiratsuka

API

**Daiichi Sankyo
Chemical
Pharma**

➤ Onahama
➤ Tatebayashi
➤ Odawara

Formulation
/ packaging

API

**Daiichi Sankyo
Biotech***

➤ Kitamoto

US/EU/ASCA

Formulation
/ packaging

API

**Daiichi Sankyo
Europe**

➤ Pfaffenhofen
➤ Altkirch

Formulation
/ packaging

**Daiichi Sankyo
China**

➤ Beijing
➤ Shanghai

Formulation
/ packaging

**American
Regent**

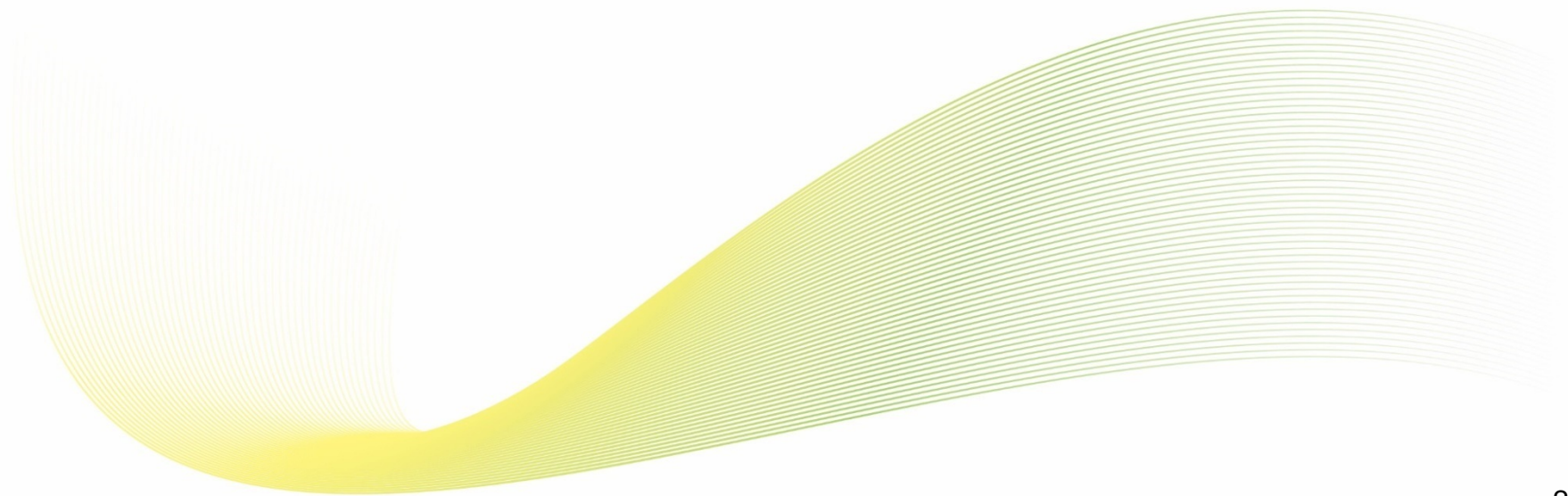
➤ Shirley
➤ New Albany
➤ Hiliard

Formulation
/ packaging

**Daiichi Sankyo
Brazil**

➤ Alphavill

R&D Update



R&D Investment Focus and Efficiency

Prioritize projects in order to invest selectively in oncology, especially in ADC & AML/Hem Franchises and Breakthrough Science

	Major Projects	On-going Clinical studies*	
		JAN 2018	JAN 2019
ADC	DS-8201	3	9
	U3-1402	1	2
	DS-1062	-	1
AML/Hematology	Quizartinib	3	1
	Other AML/Hem	6	7
Breakthrough Science	Pexidartinib	2	1
	DS-1205	-	1
Specialty Medicines	Edoxaban LCM etc.	9	7
Next Gen Modality	Axi-Cel® etc.	4**	5**

Invest selectively in oncology, especially in ADC franchise

Beyond "2025 Vision" P.27,28

	Major Projects	Number of Projects	
		JAN 2018	JAN 2019
Out-licensed	DS-5010, DS-6051	1	2
Candidate for Out-license		8	11

Out-license actively P.26

*Based on Reference Data of Consolidated Financial Results

**Number of projects. Based on presentation from DS

Accelerate out-licensing activity and choose additional candidates

- ◆ **DS-5010 (selective RET inhibitor)**
 - Out-licensed to Boston Pharmaceuticals Inc. (AUG 2017)
- ◆ **DS-6051 (NTRK/ROS1 inhibitor)**
 - Out-licensed to AnHeart (DEC 2018)

List of Out-licensing Projects

Phase 2	◆ Laninamivir: influenza / neuraminidase inhibitor
Phase 1	<ul style="list-style-type: none">◆ DS - 2 9 6 9 : clostridium difficile infection / GyrB inhibitor◆ DS - 1 0 9 3 : inflammatory bowel disease (IBD) / HIF-PH inhibitor◆ DS - 7 0 8 0 : AMD / angiogenesis inhibitor◆ DS - 1 5 0 1 : osteoporosis / anti-siglec-15 antibody [US/EU (other than JP)]◆ PLX 7 4 8 6 : solid tumor / FMS/TRK inhibitor◆ PLX 8 3 9 4 : solid tumor / BRAF inhibitor◆ PLX 9 4 8 6 : solid tumor (gastrointestinal stromal tumor) / KIT inhibitor
Pre-clinical	<ul style="list-style-type: none">◆ DS - 1 5 1 5 : DS-1515: inflammatory disease / PI3Kδ inhibitor◆ DS - 1 0 3 9 : DS-1039: cystic fibrosis / (CFTR independent fluid secretion)◆ ASB29609: ASB29609: circadian rhythm sleep-wake disorders / 5-HT5A receptor agonist

◆ Activities within the company until today

- Strengthen DS RD structure (established Cell Therapy Lab.)
- Explore compounds through alliances and move forward to commercialization

Program	Indications	Partners	Development Status		
			Discovery	Pre-clin	Clinical
Axi-Cel®	B cell lymphoma	Kite/Gilead	▶		
Heartcel®	Ischemic heart failure	Celixir	▶		
Capillary stem cells "CapSCs"	Peripheral vascular disease, Cardiovascular disease etc.	Asahikawa Medical Univ.	▶		
iPS cell-derived cardiomyocyte sheet	Severe heart failure	Osaka Univ.	▶		
iPS cell-derived β cells	Type 1 diabetes	Tokyo Institute of Technology	▶		

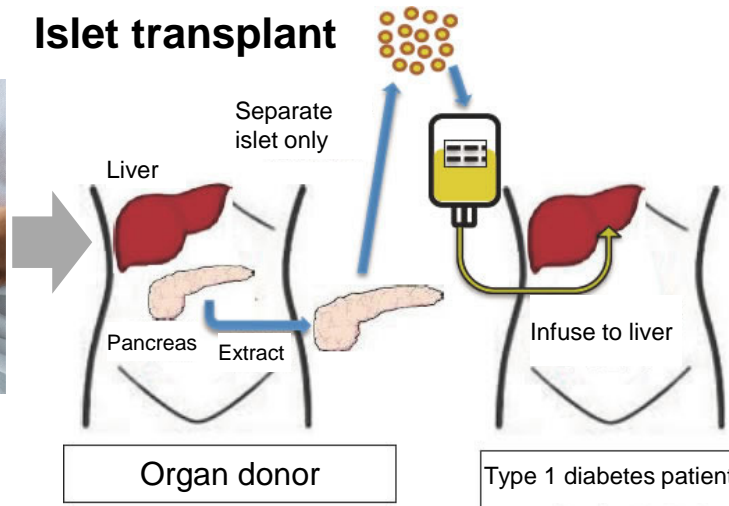
New

Treatments of Type 1 diabetes

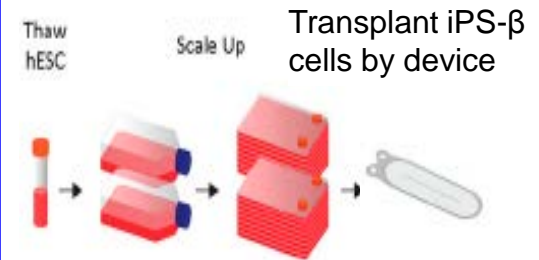
Insulin injection



Islet transplant



iPS-β



Alternative treatment to insulin injection and islet transplant

- ◆ 4th OiDE Fund investment*
- ◆ Commence open innovation research with [Tokyo Institute of Technology](#) with the aim of creating insulin producing cells from [iPS cells](#) for use in regenerative medicine and cell therapy (January 2019)
- ◆ Aim for practical application as an innovative treatment for [severe type 1 diabetes](#)

*A fund jointly established by Mitsubishi UFJ Capital and Daiichi Sankyo in 2013, and operated by Mitsubishi UFJ Capital.



◆ DS-8201: Decision for early BLA submission in FY2018 Q4~

◆ ASCO 2019 (May 31 ~ June 4, 2019)

- U3-1402: P1 NSCLC dose escalation part is planned
- DS-1062: P1 NSCLC dose escalation part is planned



◆ Quizartinib: US PDUFA May 25, 2019

Appendix

- R&D Milestone Events
- Major R&D Pipeline
- Out-licensing Projects
- DS-8201 presentation at Scientific Conference
- Abbreviations

FY2018 R&D Milestone Events

As of Jan 2019



Project	Study / Indication	FY2018				FY2019
		Q1	Q2	Q3	Q4	Q1~
DS-8201	P1: multiple tumors		Enroll completed			
	P2 pivotal: BC (HER2 positive Post T-DM1)		Enroll completed			
	P3: BC (HER2 positive Post T-DM1 vs Phys Choice)		Study started			
	P3: BC (HER2 positive vs T-DM1)		Study started			
	P3: BC (HER2 low)				Study started	
	P2: NSCLC	Study started				
	P1b: BC/Bladder (with nivolumab)		Study started			
	P1b: BC/NSCLC (with pembrolizumab)					Study start planned
	P1b: solid tumor (with avelumab)					Study start planned
U3-1402	P1b: BC	P2 part study started				
Quizartinib	P3: QuANTUM-R AML Relapsed/Refractory	TLR		Submitted		
DS-3032	P1: AML (with Quizartinib)			Study started		
	P1: AML (with Azacitidine)				Study started	
Axi-Cel®	P2: BCL (JP)			Study started		
Pexidartinib	P3: TGCT (US)				Submission	
DS-1205	P1: EGFRm NSCLC with osimertinib				Study start planned	
	P1: EGFRm NSCLC with gefitinib			Study started		
Edoxaban	P3: AF, VTE (China)			Approved		
Mirogabalin	P3: PNP (JP)				Approved	
Esaxerenone	P3: hypertension (JP)				Approved	
Laninamivir	P3: anti-influenza (nebulizer formulation) (JP)		Submitted			
DS-5141	P1/2: DMD (JP)	TLR	Extension study started			

AF: atrial fibrillation, AML: acute myeloid leukemia, BCL: B-cell lymphoma, CRC: colorectal cancer, DMD: Duchenne muscular dystrophy, GBM: glioblastoma multiforme, BC: breast cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, PNP: peripheral neuropathic pain, TGCT: tenosynovial giant cell tumor, TLR: Top Line Results, VTE: venous thromboembolism

Red: New or update from FY2018 Q2 Blue: achieved

Major R&D Pipeline (Oncology)

As of Jan 2019



	Generic Name/Project Code Number (Class)	Target indication	Region	Stage			
				Phase 1	Phase 2	Phase 3	NDA/BLA
ADC Franchise	DS-8201 (Anti-HER2 ADC)	BC (HER2 positive post T-DM1)	JP/US/EU/Asia				
		BC (HER2 positive vs. T-DM1)	JP/US/EU/Asia				
		BC (HER2 low)	JP/US/EU/Asia				
		GC (HER2 positive post trastuzumab)	JP/Asia				
		CRC	JP/US/EU				
		NSCLC	JP/US/EU				
		BC and bladder cancer (w nivolumab)	US/EU				
	U3-1402 (Anti-HER3 ADC)	BC	JP/US				
		NSCLC	US				
	DS-1062 (Anti-TROP-2 ADC)	NSCLC	JP/US				
AML/HEM Franchise	Quizartinib/AC220 (FLT3 inhibitor)	AML (Relapsed/Refractory)	JP/US/EU/Asia				
		AML (1 st line)	JP/US/EU/Asia				
	DS-3032 (MDM2 inhibitor)	Solid tumor	JP/US				
		AML	US				
	DS-3201 (EZH1/2 inhibitor)	ATL/L, PTCL	JP				
		AML, ALL	US				
	PLX2853 (BRD4 inhibitor)	AML, solid tumor	US				
	DS-1001 (IDH1m inhibitor)	Glioma	JP				
Axi-Cel® (Anti-CD19 CAR-T cells)	BCL	JP					
Breakthrough Science	Pexidartinib (CSF-1/KIT/FLT3 inhibitor)	TGCT	US/EU				
	DS-1647 (G47Δ virus)	Glioblastoma	JP				
	DS-1205 (AXL inhibitor)	NSCLC [w osimertinib(Asia), gefitinib (JP)]	JP/Asia				

ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, BCL: B-cell lymphoma, CRC: colorectal cancer, BC: breast cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, PTCL: peripheral T-cell lymphoma, TGCT: tenosynovial giant cell tumor

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

Major R&D Pipeline (SM/Vaccine)

As of Jan 2019



	Generic Name/Project Code Number (Class)	Target Indication	Region	Stage			
				Phase 1	Phase 2	Phase 3	NDA
Specialty medicine (SM)	Edoxaban/DU-176b (Fxa inhibitor)	AF	ASCA	▶			
		VTE	ASCA	▶			
		Very elderly patients AF	JP	▶			
	Prasugrel/CS-747 (anti-platelet agent)	Ischemic stroke	JP	▶			
	Esaxerenone/CS-3150 (MR antagonist)	Hypertension	JP	▶			
		Diabetic nephropathy	JP	▶			
	DS-1040 (TAFIa inhibitor)	Acute ischemic stroke, Acute pulmonary embolism	JP/US/EU	▶			
	DS-2330 (hyperphosphatemia treatment)	Hyperphosphatemia in chronic kidney disease	-	▶			
	Mirogabalin/DS-5565 ($\alpha_2\delta$ ligand)	PNP	JP	▶			
	Laninamivir/CS-8958 (neuraminidase inhibitor)	Influenza	JP	▶			
DS-5141 (ENA oligonucleotide)	DMD	JP	▶				
DS-1211 (TNAP inhibitor)	Prevention of ectopic calcification diseases	US	▶				
Vaccine	VN-0107/MEDI3250 (live attenuated influenza vaccine)	Prevention of seasonal influenza	JP	▶			
	VN-0105 (DPT-IPV/Hib)	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib	JP	▶			
	VN-0102/JVC-001 (Measles-Mumps-Rubella vaccine)	Prevention of Measles, Mumps and Rubella	JP	▶			

AF: atrial fibrillation, DMD: Duchenne muscular dystrophy, PNP: peripheral neuropathic pain, VTE: venous thromboembolism

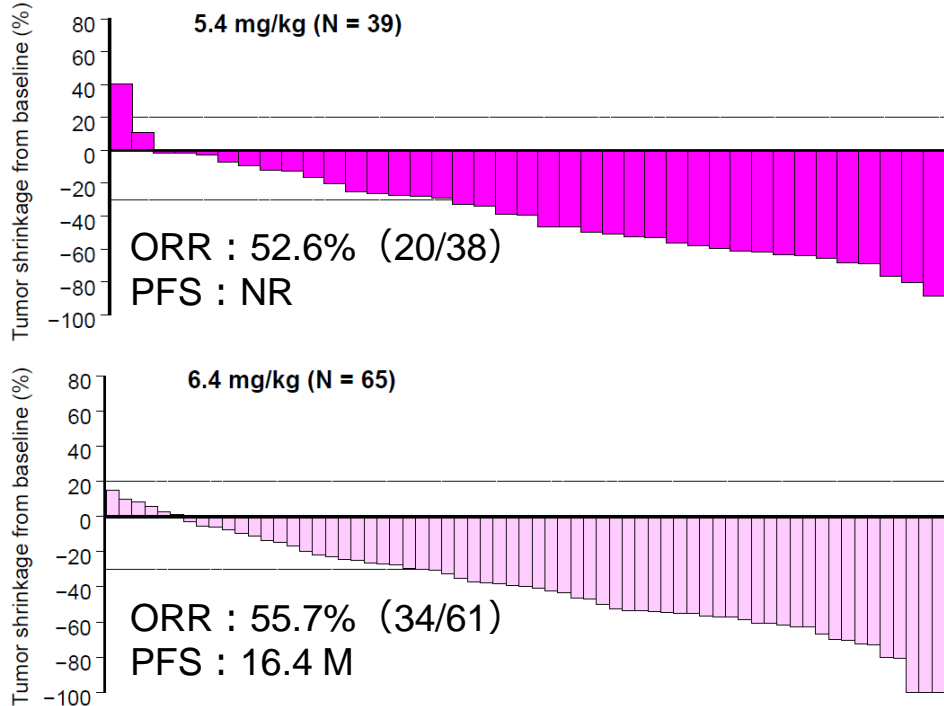
Out-licensing Projects

As of Jan 2019

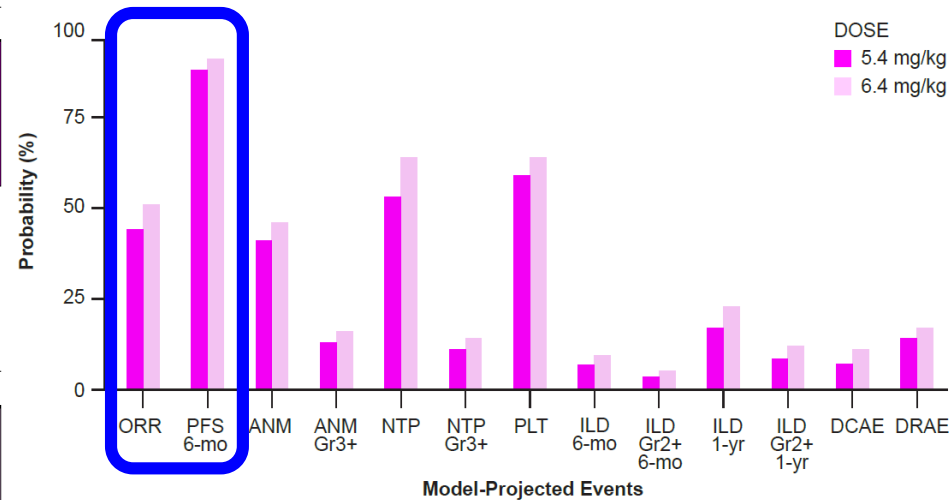


	Pre-clinical	Phase 1	Phase 2
Oncology		<ul style="list-style-type: none"> ■ PLX7486 (Solid tumor / FMS/TRK inhibitor) ■ PLX8394 (Solid tumor / BRAF inhibitor) ■ PLX9486 (Solid tumor (gastrointestinal stromal tumor) / KIT inhibitor) 	
Specialty Medicine	<ul style="list-style-type: none"> ■ DS-1515 (Inflammatory disease / PI3Kδ inhibitor) ■ DS-1039 (Cystic fibrosis / new MOA (CFTR independent fluid secretion)) ■ ASB29609 (Circadian rhythm sleep-wake disorders / 5-HT5A receptor agonist) 	<ul style="list-style-type: none"> ■ DS-2969 (Clostridium difficile infection / GyrB inhibitor) ■ DS-1093 (inflammatory bowel disease (IBD) / HIF-PH inhibitor) ■ DS-7080 (AMD / angiogenesis inhibitor) ■ DS-1501: US/EU (other than JP) (Osteoporosis / anti Siglec-15 antibody) 	<ul style="list-style-type: none"> ■ Laninamivir (CS-8958/anti-influenza / out-licensing with Vaxart Inc)

P1 Study: Best Percent Change in HER2-positive Breast Tumor Size from Baseline as of April 18, 2018



Model-projected Event Rates for DS-8201 Doses of 5.4 and 6.4 mg/kg



Based on the predicted benefit/risk profile, 5.4 mg/kg was chosen as the recommended dose for continued development in HER2-positive breast cancer for DESTINY-Breast01 and in the phase 3 trials (DESTINY-Breast02, DESTINY-Breast03)

Abbreviations

Abbreviation	
BTD	Breakthrough therapy designation
CR	Complete response
DCR	Disease control rate
DLT	Dose limiting toxicity
DOR	Duration of response
EGFR	Epidermal growth factor receptor
MTD	Maximum tolerated dose
NSCLC	Non-small-cell lung cancer
ORR	Overall response rate Objective response rate
OS	Overall survival
PD	Progress disease
PFS	Progression-free survival
PR	Partial response
RDE	Recommended dose for expansion
TTR	Time to response

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