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Compassion for Patients.™

Daiichi-Sankyo

FY2018 Q3 Financial Results Presentation

DAIICHI SANKYO CO., LTD

Toshiaki Sai
Executive Vice President and CFO

January 31, 2019

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Agenda

- **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)

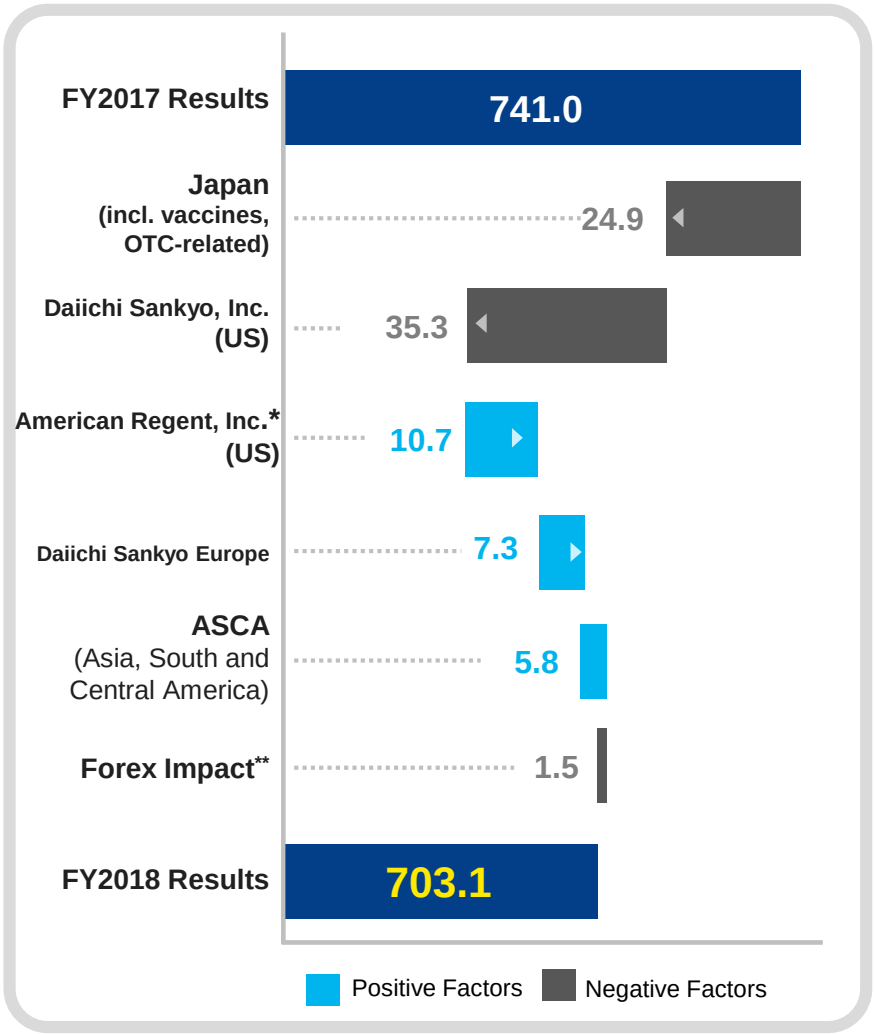
	FY2017 Q3 YTD Results	FY2018 Q3 YTD Results	YoY
Revenue	**741.0**	**703.1**	-5.1% **-38.0**
Cost of Sales	**255.5**	**264.9**	**+9.5**
SG&A Expenses	**216.7**	**198.5**	**-18.2**
R&D Expenses	**175.6**	**142.6**	**-33.0**
Operating Profit	**93.2**	**97.1**	+4.1% **+3.9**
Profit before Tax	**97.7**	**98.0**	**+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

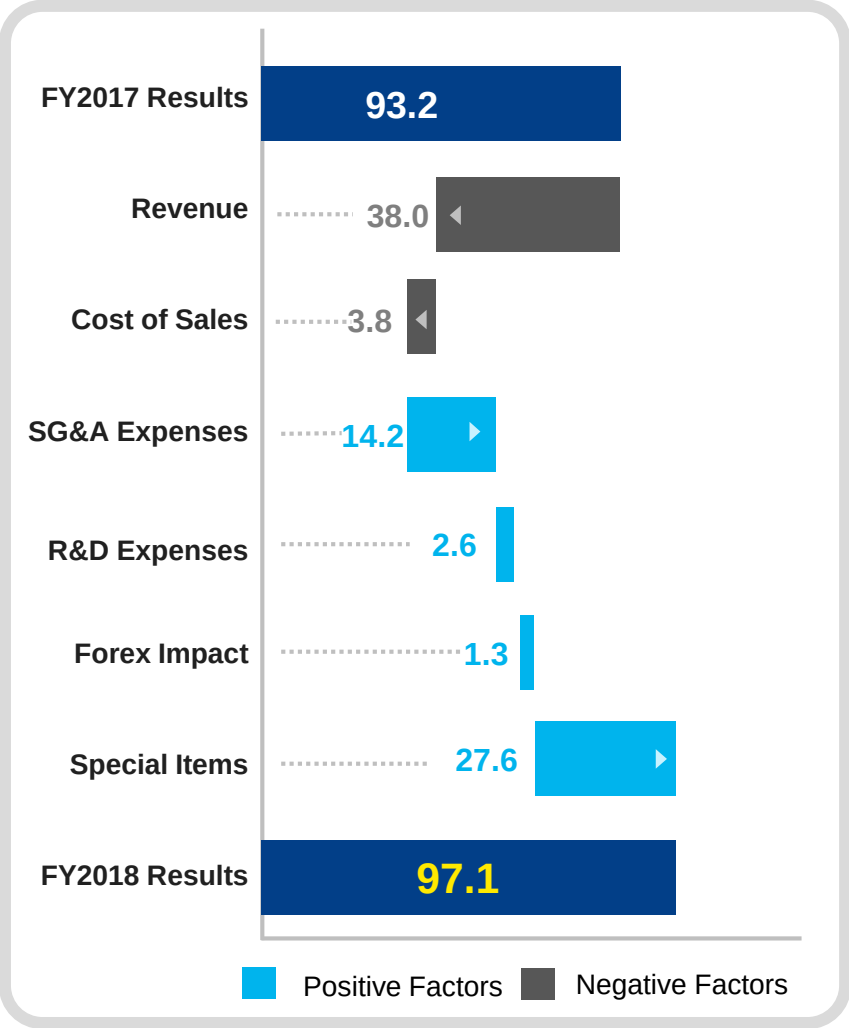
* Formerly, Luitpold Pharmaceuticals, Inc.

** 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

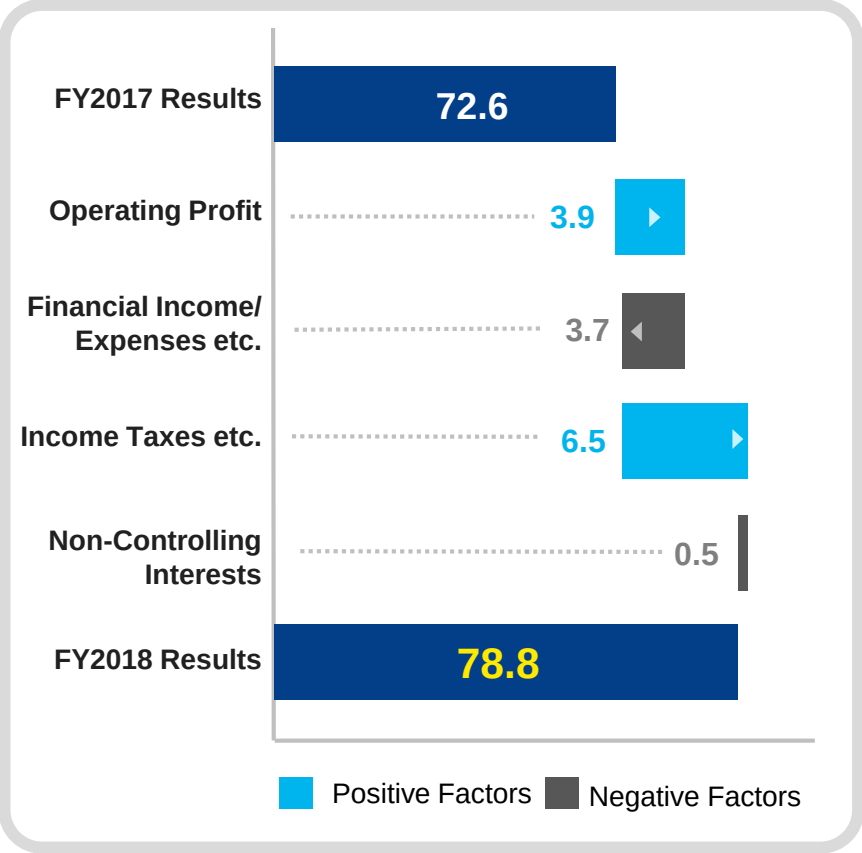
- : Cost decreased items

* 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**
Olmetec	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

Sales

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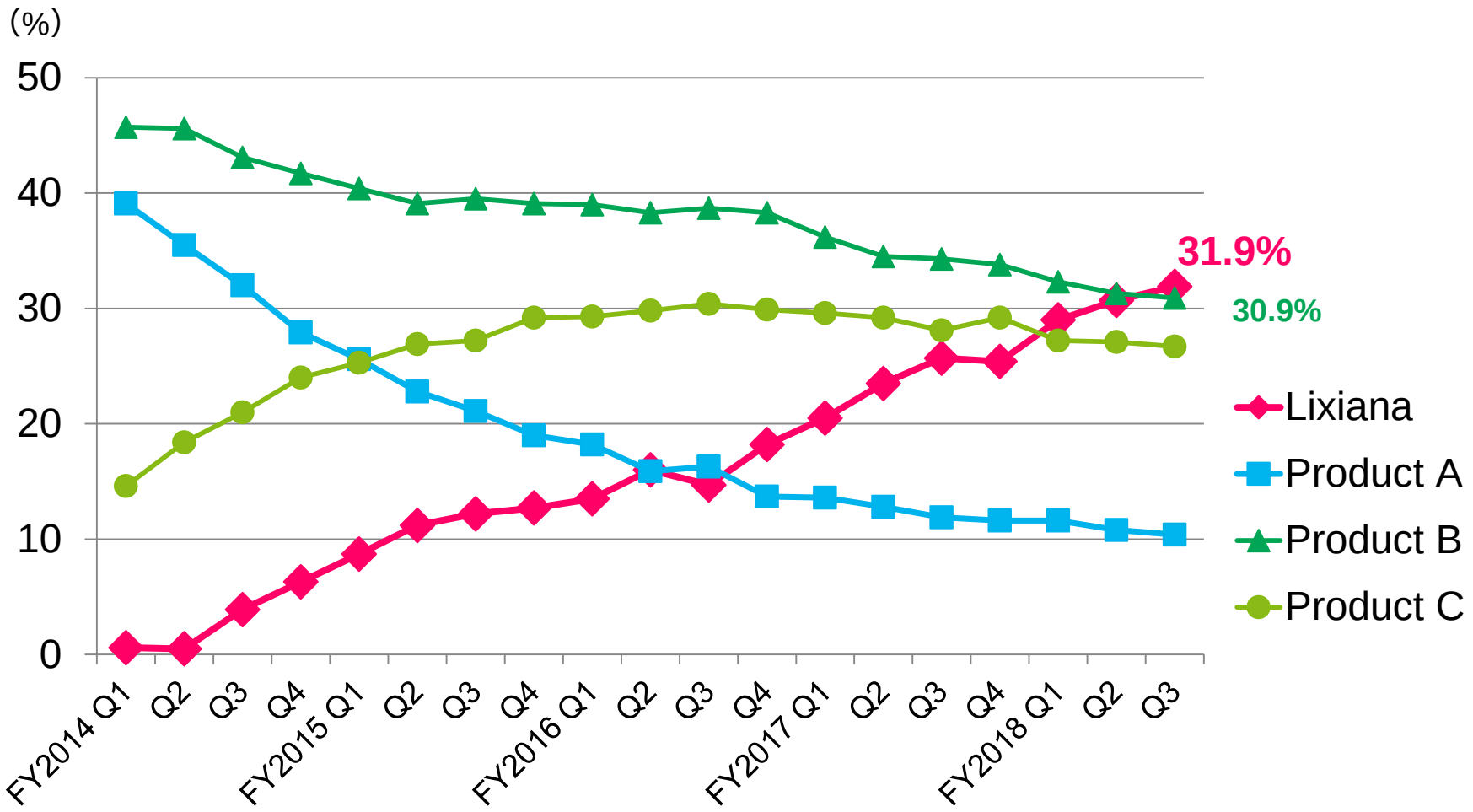
Lixiana reached No.1 sales share at FY2018 Q3



Calculated based on JPM FY2014 Q1 - FY2018 Q3

Edoxaban: Growth in Each Country/**Region**

Volume

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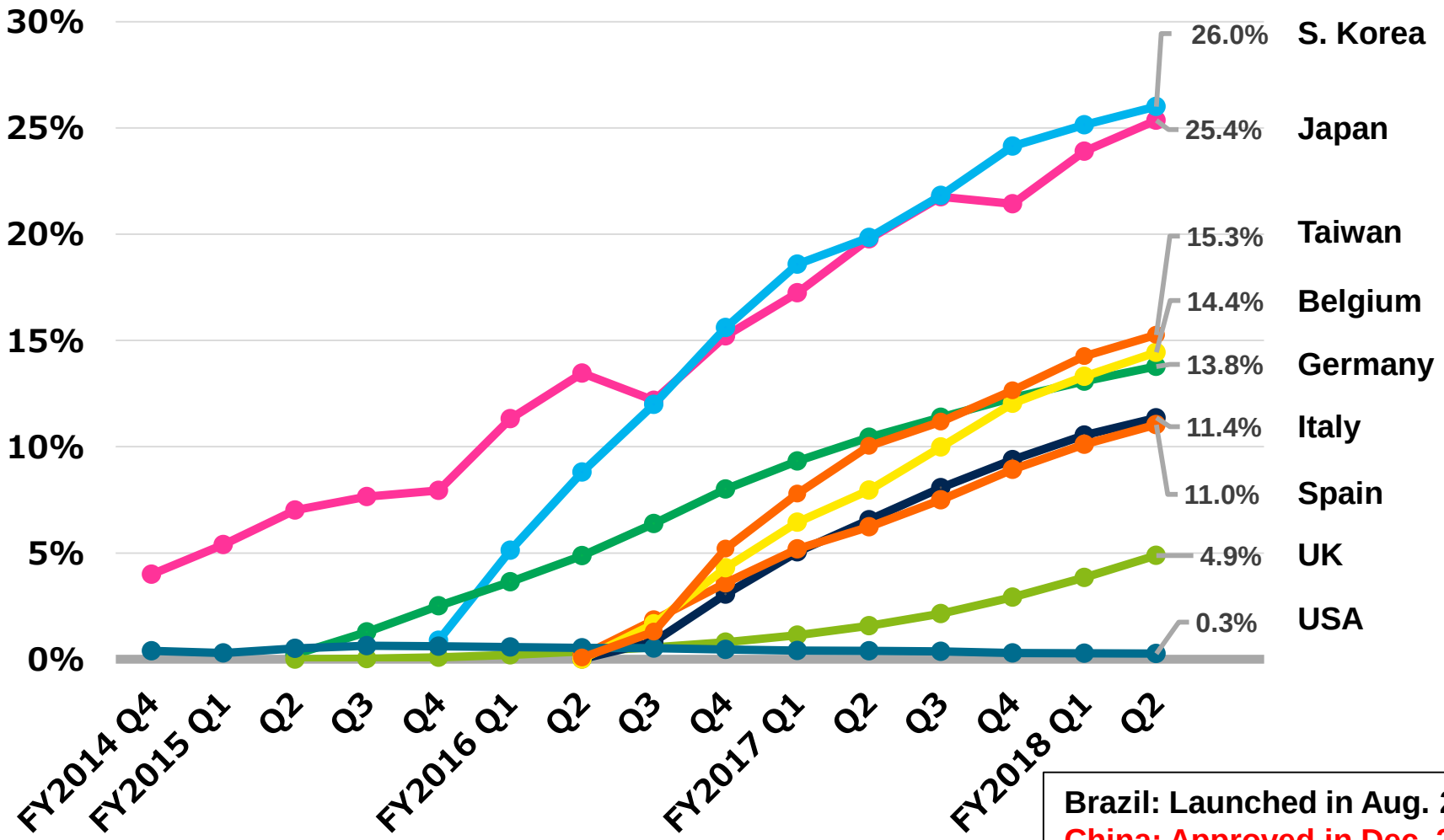
Steady growth in each country/region
Approved in China (Dec. 2018)

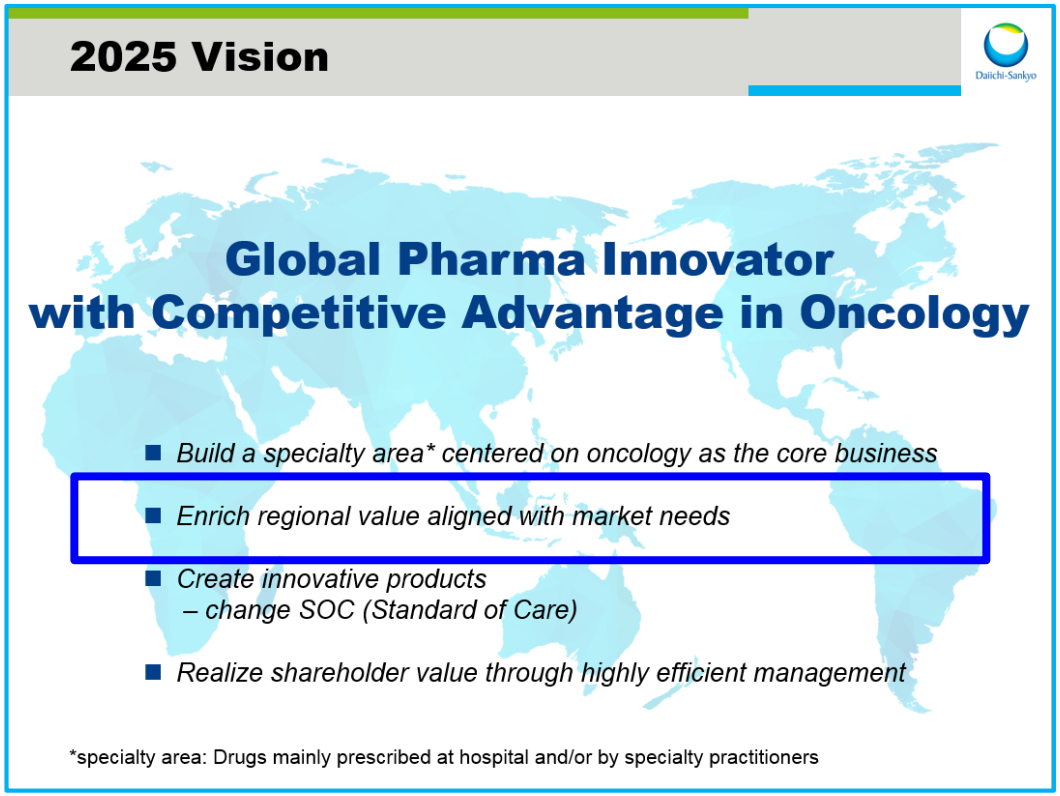


Brazil: Launched in Aug. 2018
China: Approved in Dec. 2018

Regional Value

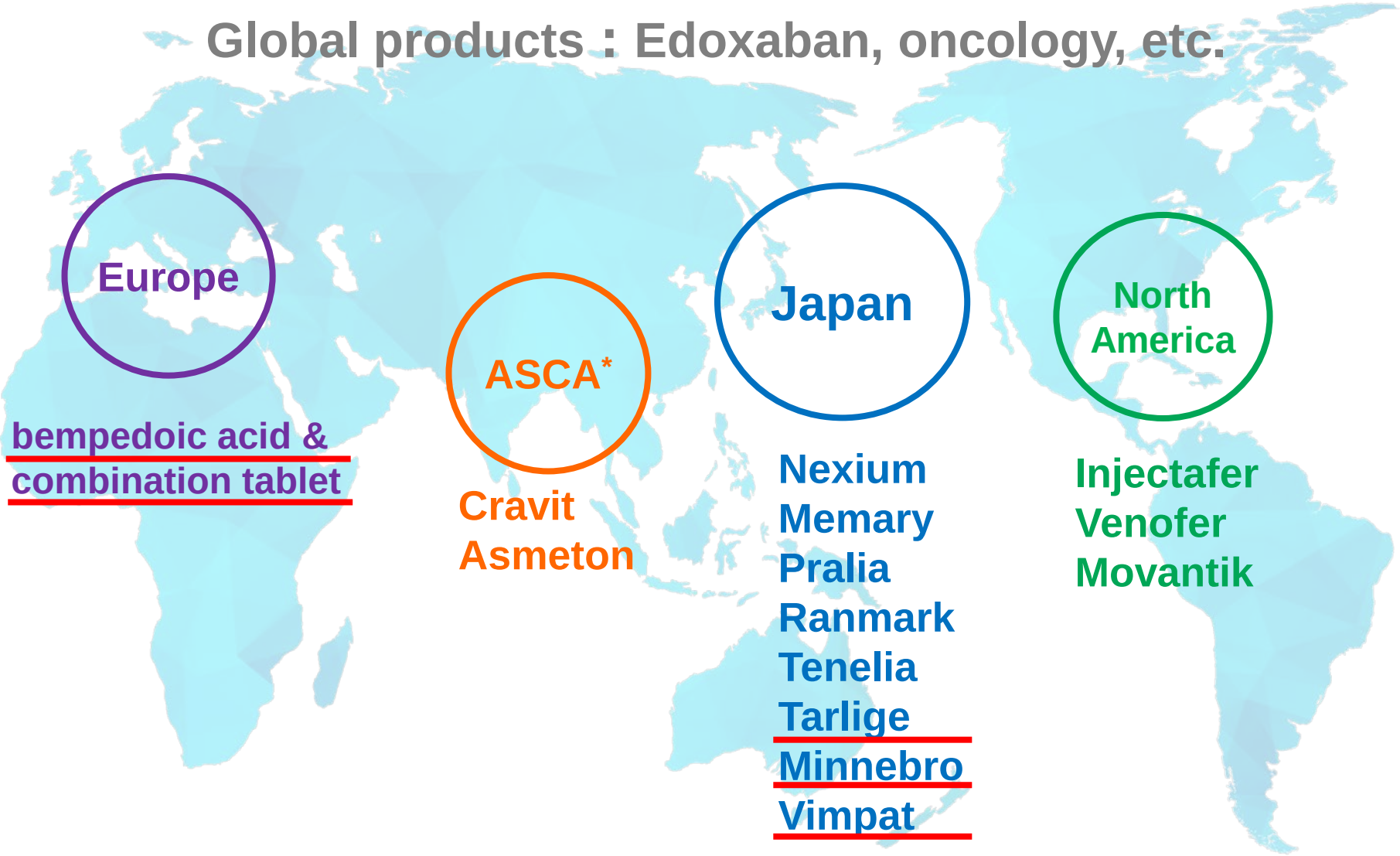
Regional Value Products

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



Enrichment of Regional Value Products

Global products : Edoxaban, oncology, etc.



New products

*ASCA: Asia, South & Central America

Japan: New Products Approval and Additional Approval for Existing Products

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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

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- **Originator: Esperion Therapeutics, Inc.**

Esperion
The Lipid Management Company

- **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

Optimizing SC

Future oriented SC structure transformation

Until now
- Mass-produced products
- Small molecule compounds
- Solid formulations

Transformation toward the future

Future
- Multiple, smaller volume medicines
- Large molecule compounds
- Injectable formulations

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)**

Takatsuki Plant Transfer

- **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)

13 Sites

Japan

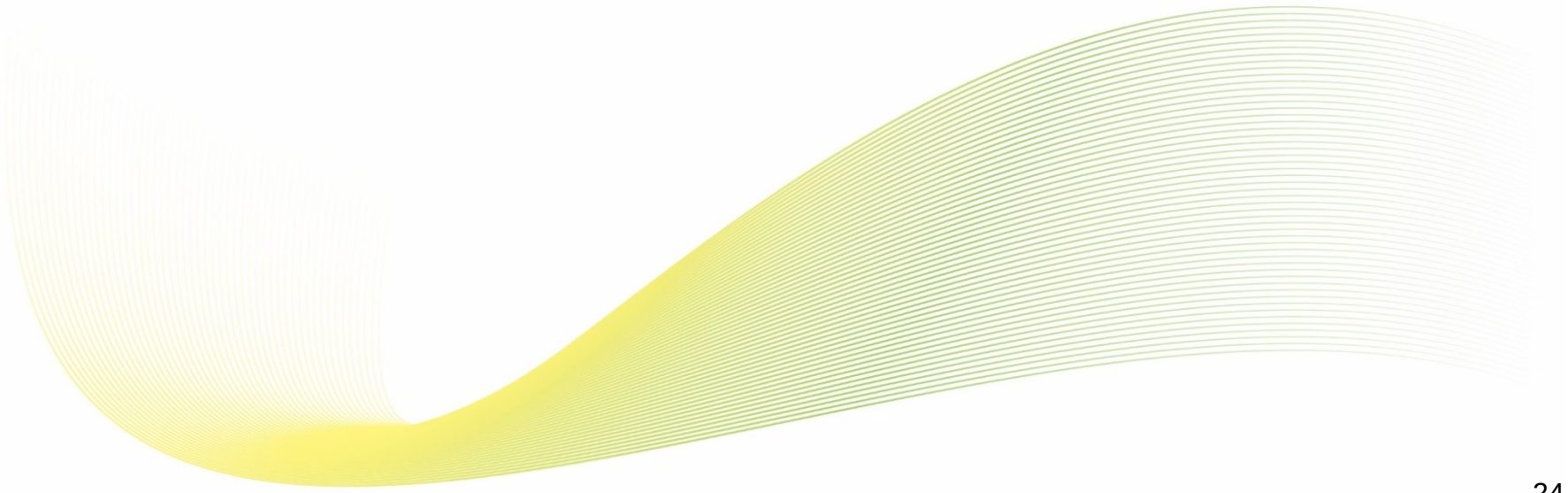
Formulation / packaging	API	Formulation / packaging	API
Daiichi Sankyo Propharma	**Daiichi Sankyo Chemical Pharma**	**Daiichi Sankyo Biotech***	
➢ Hiratsuka	➢ Onahama ➢ Tatebayashi ➢ Odawara	➢ Kitamoto	

US/EU/ASCA

Formulation / packaging	API	Formulation / packaging	Formulation / packaging	Formulation / packaging
Daiichi Sankyo Europe		**Daiichi Sankyo China**	**American Regent**	**Daiichi Sankyo Brazil**
➢ Pfaffenhofen ➢ Altkirch		➢ Beijing ➢ Shanghai	➢ Shirley ➢ New Albany ➢ Hiliard	➢ Alphavill

*Operation starting from Apr. 2019

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 selectivity 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

List of Compounds for Out-Licensing

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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	◆ DS-2969: clostridium difficile infection / GyrB inhibitor ◆ DS-1093: inflammatory bowel disease (IBD) / HIF-PH inhibitor ◆ DS-7080: AMD / angiogenesis inhibitor ◆ **DS-1501: osteoporosis / anti-siglec-15 antibody [US/EU (other than JP)]** ◆ **PLX7486: solid tumor / FMS/TRK inhibitor** ◆ **PLX8394: solid tumor / BRAF inhibitor** ◆ **PLX9486: solid tumor (gastrointestinal stromal tumor) / KIT inhibitor**
Pre-clinical	◆ DS-1515: DS-1515: inflammatory disease / PI3Kδ inhibitor ◆ DS-1039: DS-1039: cystic fibrosis / (CFTR independent fluid secretion) ◆ **ASB29609: ASB29609: circadian rhythm sleep-wake disorders / 5-HT5A receptor agonist**

Red: new

DS Advancing in Regenerative Medicine / Cell Therapy

- 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**	

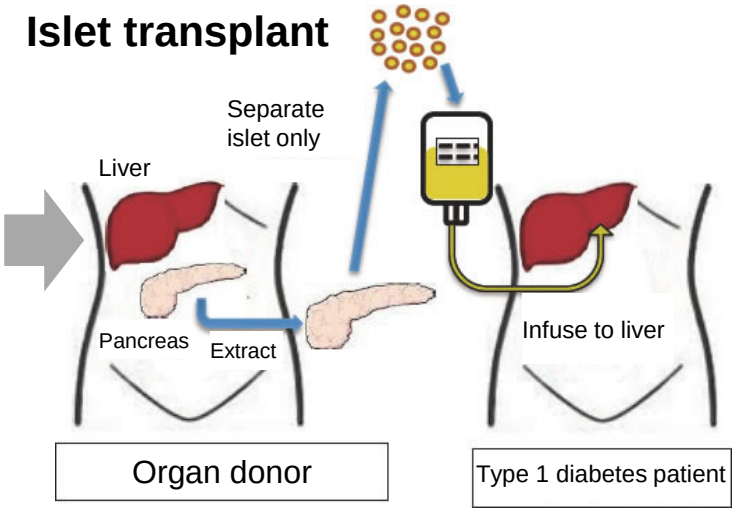
New

Open Innovation Research on iPS-β cell

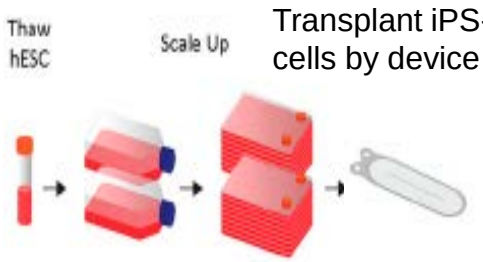
Treatments of Type 1 diabetes

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.

Next Data Point until ASCO 2019

- 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

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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

Daiichi-Sankyo

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

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

Daiichi-Sankyo

	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

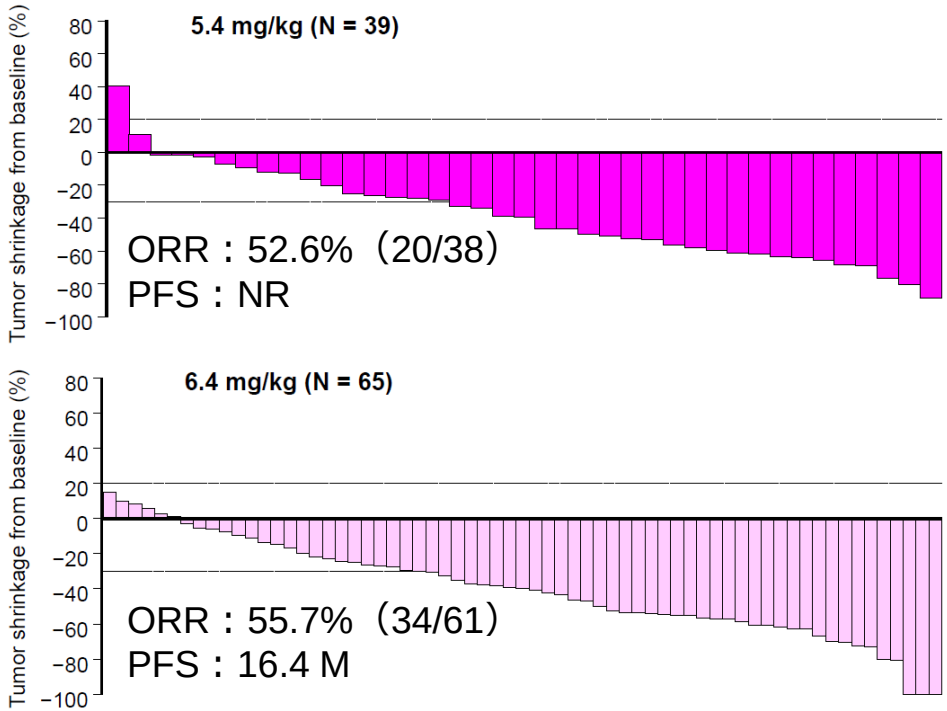
Daiichi-Sankyo

	Pre-clinical	Phase 1	Phase 2
Oncology		■ **PLX7486** **（Solid tumor / FMS/TRK inhibitor）** ■ **PLX8394** **（Solid tumor / BRAF inhibitor）** ■ **PLX9486** **（Solid tumor (gastrointestinal stromal tumor) / KIT inhibitor）**	
Specialty Medicine	■ **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)**	■ **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)**	■ **Laninamivir** **(CS-8958/anti-influenza / out-licensing with Vaxart Inc)**

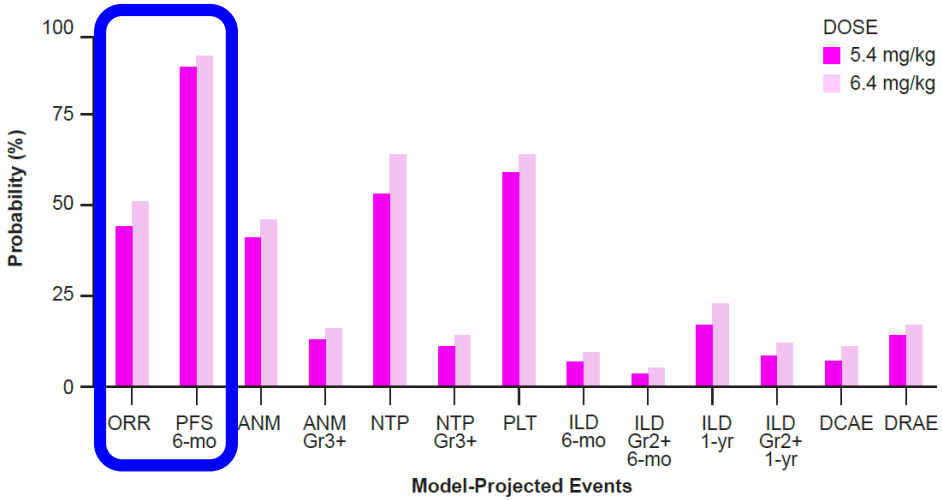
Red: New or update

DS-8201: Poster at SABCS Efficacy comparison of 5.4・6.4mg/kg

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)

Tamura et al, SABCS, 2018; Poster # P6-17-10, Abstract #682

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

Contact address regarding this material

Daiichi Sankyo Co., Ltd.

Corporate Communications Department

TEL: +81-3-6225-1126

Email: DaiichiSankyoIR@daiichisankyo.co.jp