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Compassion for Patients.™

Daiichi-Sankyo

FY2018
Financial Results Presentation

DAIICHI SANKYO CO., LTD

Sunao Manabe
President and COO

April 25, 2019

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Agenda

1 **FY2018 Financial Results**

2 FY2019 Consolidated Forecast

3 Business Update

4 R&D Update

5 Appendix

Overview of FY2018 Results

(Bn JPY)

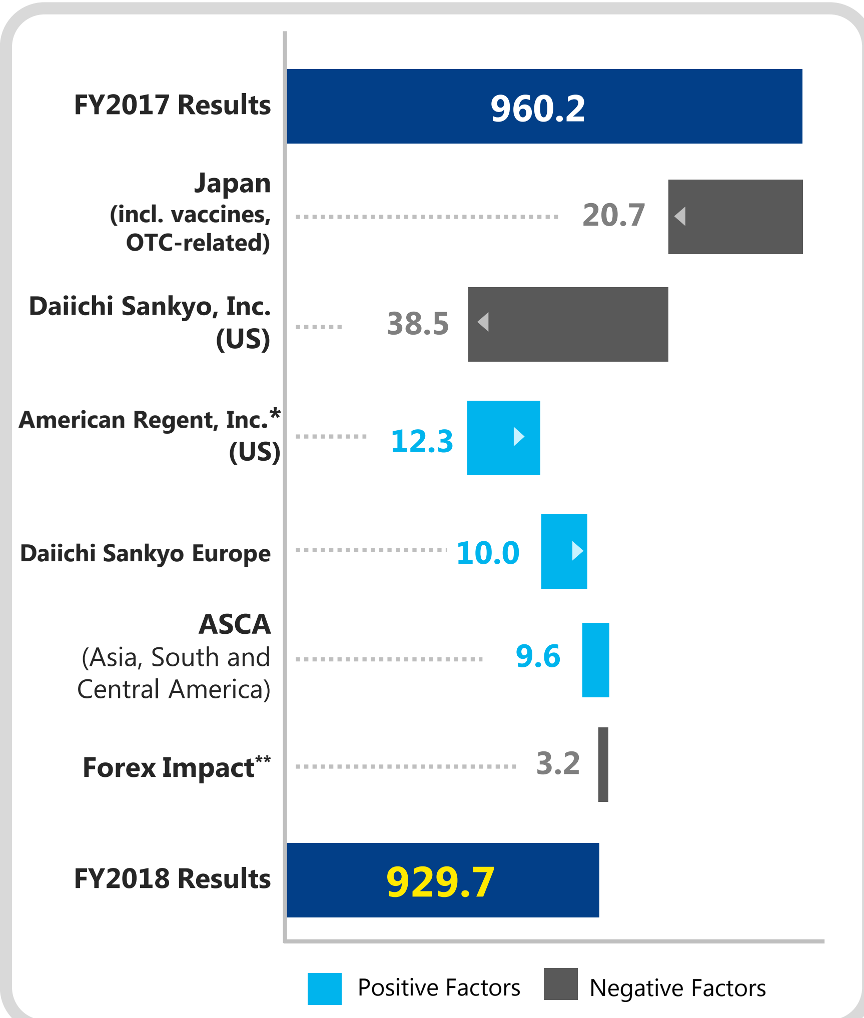
	FY2017 Results	FY2018 Results	YoY
Revenue	960.2	929.7	-3.2% -30.5
Cost of Sales	346.0	364.6	+18.6
SG&A Expenses	301.8	277.7	-24.2
R&D Expenses	236.0	203.7	-32.3
Operating Profit	76.3	83.7	+9.7% +7.4
Profit before Tax	81.0	85.8	+4.8
Profit attributable to owners of the Company	60.3	93.4	+55.0% +33.1

Currency Rate		FY2017	FY2018	YoY
	USD/JPY	110.86	110.91	+0.05
	EUR/JPY	129.70	128.40	-1.30

Revenue

Decreased by 30.5 Bn JPY (Decreased by 27.3 Bn JPY excl. forex impact)

(Bn JPY)



Positive Factors		Negative Factors	
Japan			
Lixiana	+19.6	Olmetec	-29.7
Canalia	+6.5	Nexium	-8.3
		Inavir	-7.1
Gain on sales of transferring long-listed products	+6.3	Loxonin	-6.0
		(incl. impact of price revision in Japan)	
Daiichi Sankyo Espha (GE)	+8.8	Daiichi Sankyo Healthcare	-6.5
Olmesartan AG, Rosuvastatin AG etc.		(incl. impact of change in accounting treatment)	
Daiichi Sankyo, Inc. (US)		Welchol	-20.5
		Olmesartan	-10.6
		Effient	-8.2
American Regent, Inc.* (US)			
Injectafer	+9.9		
Daiichi Sankyo Europe			
Lixiana	+19.2	Olmesartan	-5.9

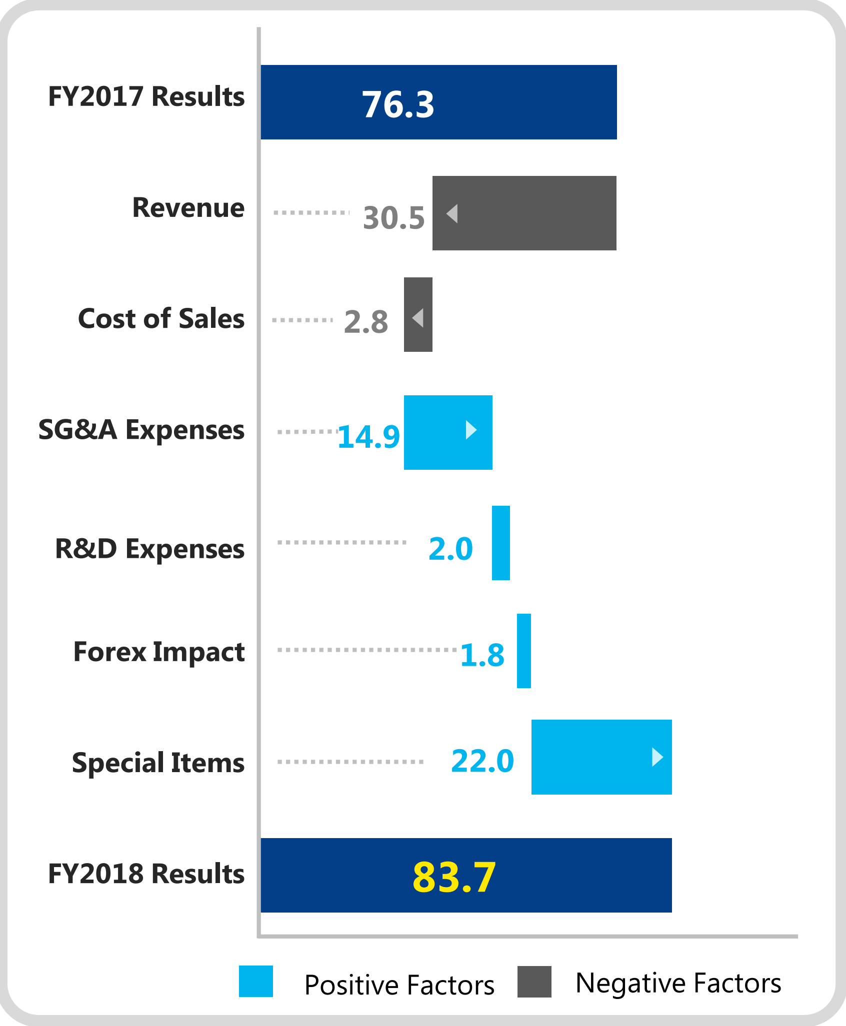
* Formerly, Luitpold Pharmaceuticals, Inc.

** Forex impact USD: +0.1, EUR : -0.9, ASCA: -2.3

Operating Profit

Increased by 7.4 Bn JPY

(Decreased by 13.2 Bn JPY excl. forex impact and special items)



(Bn JPY)

Revenue ········ **-30.5**
incl. forex impact of -3.2

Cost of Sales ········ **+2.8 (Cost increased)**
Product mix due to impact of olmesartan LOE

SG&A Expenses ······ **-14.9 (Cost decreased)**
Effect of cost reductions in US,
impact of change in accounting treatment etc.

Forex Impact ········ **-1.8 (Cost decreased)**
Cost of Sales ········ **-0.3**
SG&A Expenses ······ **-1.3**
R&D Expenses ········ **-0.2**

Special Items ········ **-22.0 (Cost decreased)**
*See next slide for details

Special Items

(Bn JPY)

	FY2017 Results	FY2018 Results	YoY
Cost of Sales	Gain on sales of fixed assets -6.1 Impairment loss (Intangible) 5.1	Impairment loss (Intangible)** 15.1	+16.1
SG&A Expenses	Restructuring costs in US 2.8 Litigation fee 1.7	Gain on sales of fixed assets -3.5	-7.9
R&D Expenses	Impairment loss (Intangible)* 30.2		-30.2
Total	33.6	11.6	-22.0

*CL-108 and others

**Zelboraf and Movantik

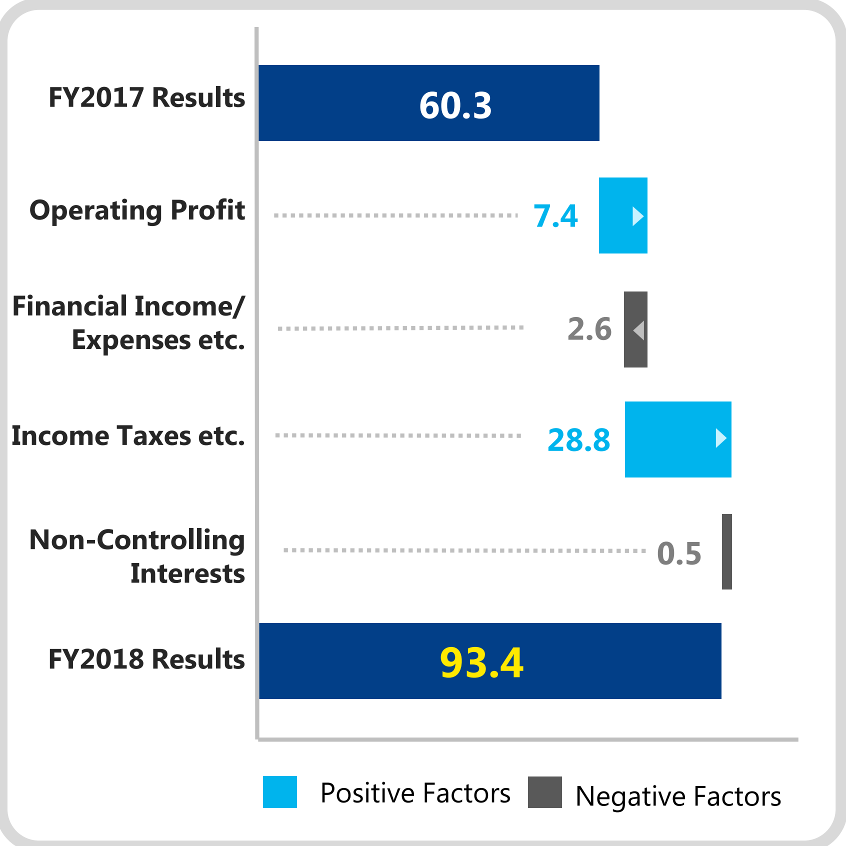
- : Cost decreased items

Booked in Q4

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 33.1 Bn JPY



(Bn JPY)

Financial Income/ Expenses etc. +2.6 (Cost increased)

Deterioration of forex gains/ losses

Income Taxes etc. -28.8 (Cost decreased)

Increase in DTA attributable to future expected taxable income increase due to DS-8201 strategic collaboration

	FY2017	FY2018	YoY
Profit before Tax	81.0	85.8	+4.8
Income Taxes etc.	21.2	-7.6	-28.8
Tax rate	26.2%	-8.8%	-35.0%

Non-Controlling Interests +0.5 (Cost increased)

Revenue: Major Business Units (incl. Forex Impact)

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(Bn JPY)

	FY2017 Results	FY2018 Results	YoY
Japan	540.0	523.3	-16.7
Daiichi Sankyo Healthcare	72.9	66.4	-6.5
Daiichi Sankyo, Inc.	74.8	36.3	-38.5
Olmesartan	21.3	10.7	-10.6
Welchol	33.9	13.4	-20.5
Effient	10.7	2.4	-8.2
Savaysa	2.2	2.3	+0.1
Movantik	4.7	4.2	-0.5
American Regent, Inc.	105.4	117.8	+12.4
Venofer	31.0	28.9	-2.0
Injectafer	34.3	44.2	+9.9
GE injectables	37.1	38.5	+1.5
Daiichi Sankyo Europe	79.4	88.6	+9.1
Olmesartan	33.5	27.4	-6.1
Efient	8.0	5.7	-2.3
Lixiana	27.0	45.8	+18.8
ASCA (Asia, South and Central America)	80.4	87.7	+7.3

Currency Rate	USD/JPY	110.86	110.91	+0.05
	EUR/JPY	129.70	128.40	-1.30

Revenue: Major Products in Japan

(Bn JPY)

		FY2017 Results	FY2018 Results	YoY
Nexium	ulcer treatment	86.5	78.3	-8.3
Lixiana	anticoagulant	45.3	64.9	+19.6
Memary	Alzheimer's disease treatment	48.6	50.2	+1.7
Loxonin	anti-inflammatory analgesic	36.5	30.5	-6.0
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	23.2	27.4	+4.2
Tenelia	type 2 diabetes mellitus treatment	26.3	25.3	-1.0
Inavir	anti-influenza treatment	25.3	18.2	-7.1
Olmetec	antihypertensive agent	44.6	14.9	-29.7
Ranmark	treatment for bone complications caused by bone metastases from tumors	15.4	16.4	+1.0
Efient	antiplatelet agent	12.8	13.9	+1.1
Rezaltas	antihypertensive agent	16.8	15.5	-1.3
Urief	treatment for dysuria	11.1	10.3	-0.9
Omnipaque	contrast medium	14.0	12.0	-2.0
Canalia	type 2 diabetes mellitus treatment	2.7	9.2	+6.5
Vimpat	anti-epileptic agent	2.6	6.6	+3.9

FY2019 Consolidated Forecast

(Bn JPY)

	FY2018 Results	FY2019 Forecast	YoY
Revenue	929.7	940.0	+1.1% +10.3
Cost of Sales	364.6	330.0	-34.6
SG&A Expenses	277.7	285.0	+7.3
R&D Expenses	203.7	225.0	+21.3
Operating Profit	83.7	100.0	+19.5% +16.3
Profit before Tax	85.8	100.0	+14.2
Profit attributable to owners of the Company	93.4	72.0	-22.9% -21.4

		FY2018 Results	FY2019 Forecast
Currency Rate	USD/JPY	110.91	110.00
	EUR/JPY	128.40	130.00

FY2019 Consolidated Forecast

(Bn JPY)

	FY2018 Results (excl. special items)	FY2019 Forecast	YoY
Revenue	929.7	940.0	+1.1% +10.3
Cost of Sales	349.5	330.0	-19.5
SG&A Expenses	281.2	285.0	+3.8
R&D Expenses	203.7	225.0	+21.3
Operating Profit	95.3	100.0	+4.9% +4.7

Currency Rate	USD/JPY	110.91	110.00
	EUR/JPY	128.40	130.00

- Deferred revenue for DS-8201 strategic collaboration upfront payment +10.0
- Gain on sales of Takatsuki Plant transfer -19.0
- Gain on sales of Nihonbashi building -10.6
- Costs increase for the establishment of the oncology business structure
- Increase in R&D investments to DS-8201

*Regarding the impact of DS-8201 strategic collaboration, only deferred revenue for upfront payment is included in FY2019 forecast

1 FY2018 Financial Results

2 FY2019 Consolidated Forecast

3 **Business Update**

4 R&D Update

5 Appendix

Edoxaban

Japan Business

Streamlining of Assets

Shareholder Returns

Edoxaban

Japan Business

Streamlining of Assets

Shareholder Returns

Lixiana: Growth in Japan

Sales

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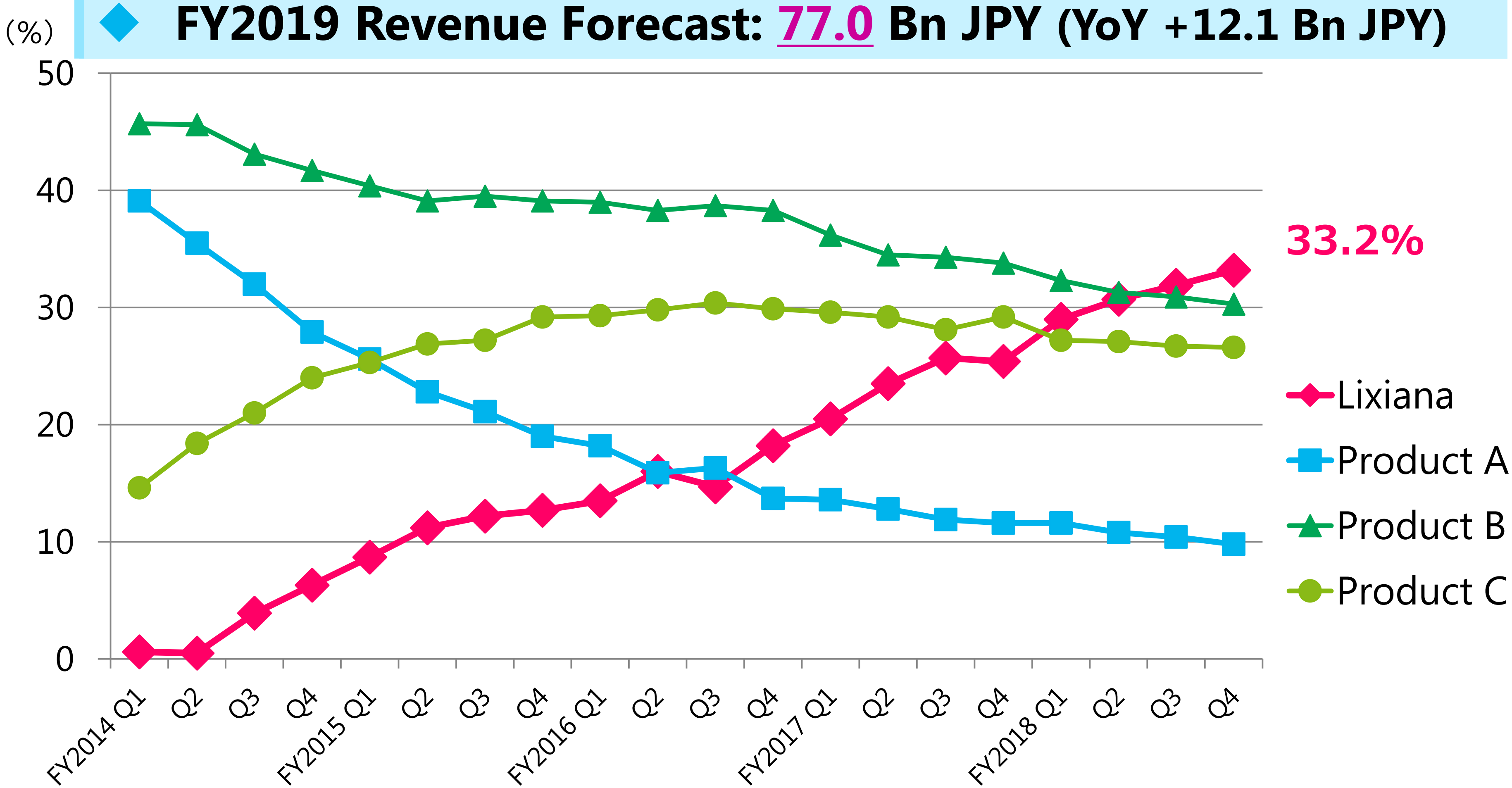
- FY2018 Q4: No.1 sales share (33.2%)
- FY2018 Revenue Results : 64.9 Bn JPY (YoY +19.6 Bn JPY)
- FY2019 Revenue Forecast: 77.0 Bn JPY (YoY +12.1 Bn JPY)



Calculated based on JPM FY2014 Q1 - FY2018 Q4

Edoxaban: Growth in Each Country

Volume

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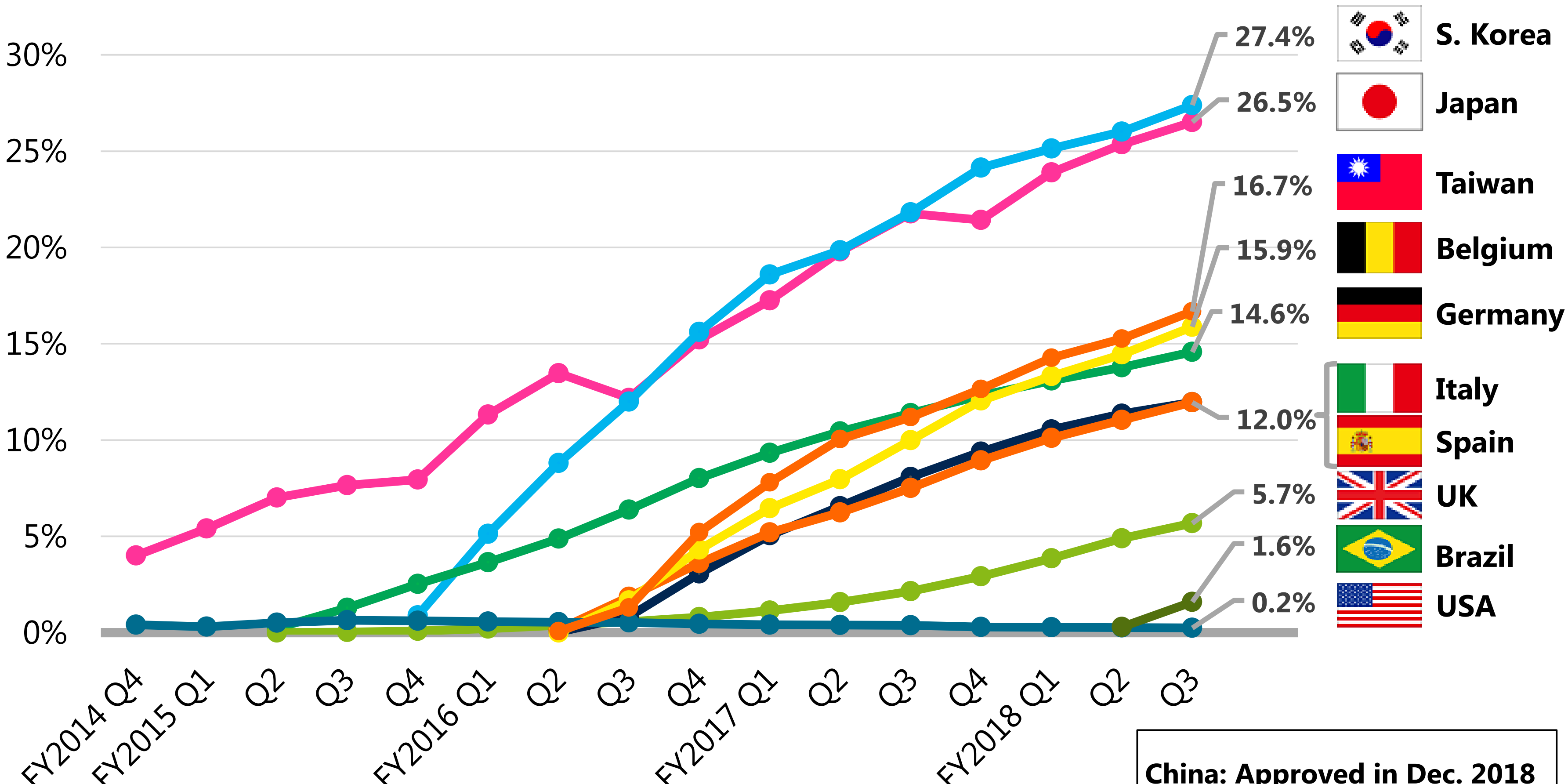
- **Steady growth in each country**
- **FY2018 Global Revenue Results : 117.7 Bn JPY (YoY +40.6 Bn JPY)**
- **FY2019 Global Revenue Forecast: 149.0 Bn JPY (YoY +31.3 Bn JPY)**



China: Approved in Dec. 2018

Calculated based on MIDAS Data: FY2014 Q4 - FY2018 Q3
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Edoxaban: Life Cycle Management

EDOSURE
Edoxaban Clinical Research Program
more than 10 studies, more than 100,000 patients worldwide

Daiichi-Sankyo

◆ Conducting randomized controlled trials in various clinical settings in AF and VTE to expand the scientific knowledge

Study Name	Clinical Setting (Comparator)	Primary Completion
ENSURE-AF	Cardioversion (enoxaparin/ warfarin)	Presented at ESC 2016
ENTRUST-AF PCI	PCI (warfarin)	June 2019
ELIMINATE-AF	Cardiac ablation (warfarin)	Presented at EHRA* 2019
ENVISAGE-TAVI AF	Transcatheter aortic valve implantation (warfarin)	November 2020
ELDERCARE-AF	80 years or older who are ineligible for current OAC therapy (placebo)	December 2019
Hokusai VTE CANCER	VTE associated with cancer (dalteparin)	Presented at ASH 2017

FY2018 Results

Patient enrollment progressed as planned
- Data will be disclosed in FY2019

Late-breaking data presented at EHRA* in Mar. 2019
- Confirmed the efficacy and safety of edoxaban in the treatment of patients undergoing catheter ablation of AF

*European Heart Rhythm Association

Edoxaban: Life Cycle Management

EDOSURE
Edoxaban Clinical Research Program
more than 10 studies, more than 100,000 patients worldwide

Daiichi-Sankyo

◆ Conducting non-interventional studies and registries to generate real-world data to expand the scientific knowledge

Study Name	Clinical Setting
ETNA-AF Global	Edoxaban Treatment in routine clinical practice in AF
ETNA-VTE Global	Edoxaban Treatment in routine clinical practice in VTE
EMIT-AF/VTE	Edoxaban Management In diagnostic and Therapeutic procedures–AF/VTE
PREFER in AF Prolongation	Prolongation PREFER in AF, European Registry
ANAFIE	All Nippon AF In Elderly Registry (in more than 75 years in Japan)
Cancer–VTE Registry Venous Thromboembolism in Cancer Patients	Multicenter Prospective Registry in VTE patients associated with cancer

FY2018 Results

ETNA-AF Global: Baseline data presented at ESC in Aug. 2018
- One-year follow-up data will be presented during FY2019

EMIT-AF/VTE: Data presented at EHRA in Mar. 2019
- Confirmed the efficacy and safety of periprocedural edoxaban management in clinical practice

ANAFIE: Baseline data presented at Japanese College of Cardiology (JCC) in Sep. 2018

Edoxaban

Japan Business

Streamlining of Assets

Shareholder Returns

Japan Business: New Products Launch

◆ Tarlige (mirogabalin): Launched in Apr. 2019

- MOA: α2δ ligand
- Indication: peripheral neuropathic pain

◆ Minnebro (esaxerenone): Launch in May. 2019

- MOA: mineralocorticoid blocker
- Indication: hypertension

Edoxaban

Japan Business

Streamlining of Assets

Shareholder Returns

Streamlining of Assets

		FY2016 Results	FY2017 Results	FY2018 Results	Total
Reduce cross-shareholding shares	Number of stock brands	**14** brands	**9** brands	**10** brands	**33** brands
	Sales proceeds	**17.3** Bn JPY	**14.4** Bn JPY	**14.3** Bn JPY	**46.0** Bn JPY
	Gain on sales*	9.3 Bn JPY	9.8 Bn JPY	10.6 Bn JPY	29.7 Bn JPY
Sale of properties	Sales proceeds	**3.2** Bn JPY	**10.7** Bn JPY	**11.0** Bn JPY	**25.0** Bn JPY
	Gain on sales	0.8 Bn JPY	7.6 Bn JPY	9.0 Bn JPY	17.5 Bn JPY
Gain on sales of business transfer	Gain on sales	-	-	(transferring long-listed products) **6.3** Bn JPY	**6.3** Bn JPY

* Booked in other comprehensive income

Gain on sales of Takatsuki Plant transfer (19.0 Bn JPY) and Nihonbashi building (10.6 Bn JPY) will be booked in FY2019

Edoxaban

Japan Business

Streamlining of Assets

Shareholder Returns

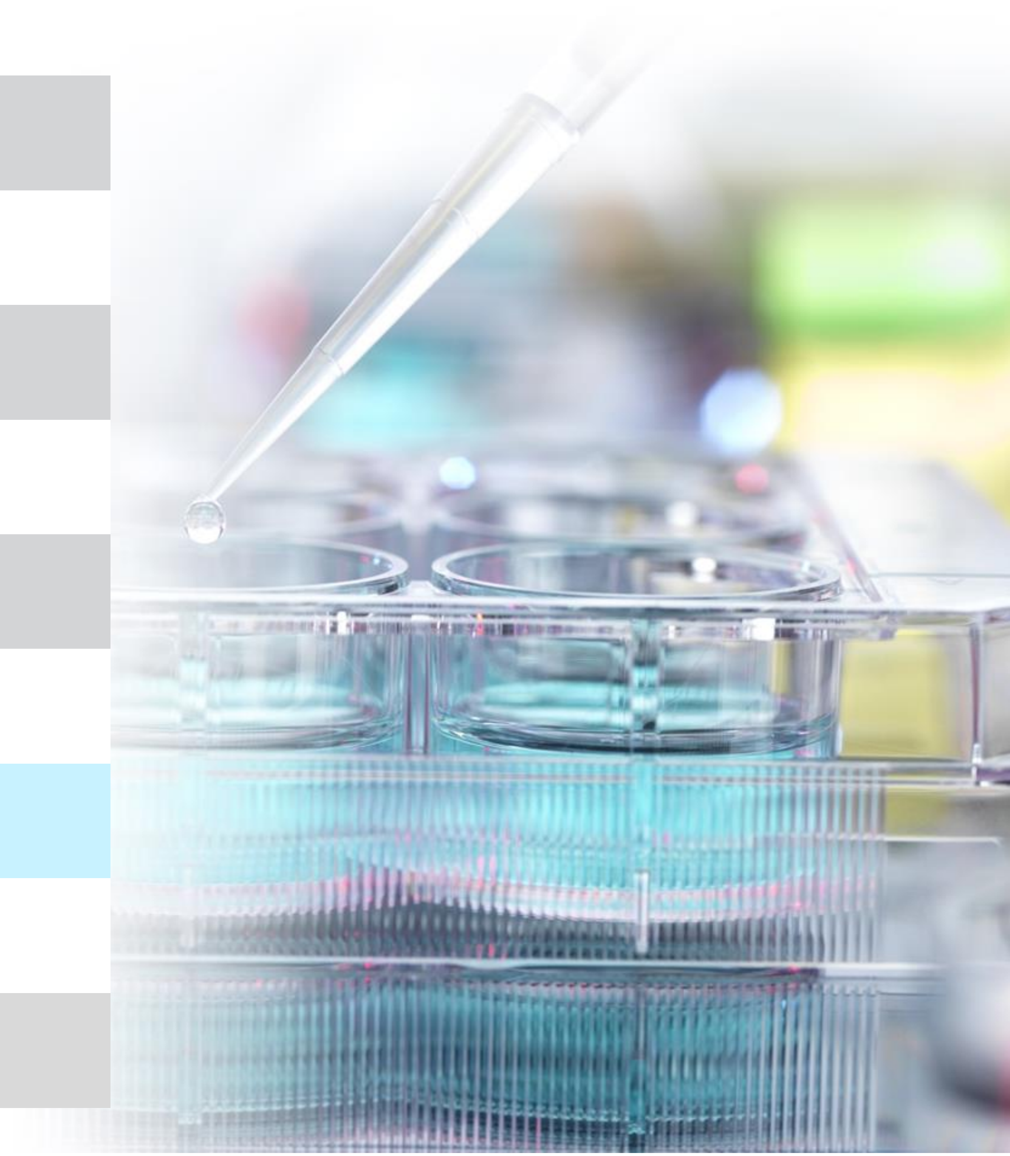
Shareholder Returns

Shareholder Returns Policy: FY2016 - FY2022

Annual ordinary dividends **70 JPY** or more + **Flexible** acquisition of own shares = Total return ratio* **100%** or more

	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Plan
Dividend	**70 JPY**	**70 JPY**	**70 JPY**	**70 JPY**
Acquisition of own shares	**50.0 Bn JPY**	**50.0 Bn JPY**	**-**	**Flexible**
Total return ratio*	**180.7%**	**159.1%**	**48.5%**	**-**
	114.8%			

*Total return ratio = (Dividends + Total acquisition costs of own shares) / Profit attributable to owners of the company



FY2018 Results

Progress of DS-8201

SAKIGAKE Designation of DS-3201

DS-1647 (G47Δ) P2 IIS Study Result

New Phase 3 Study of Mirogabalin

Upcoming Milestones

ASCO IR Events

FY2018 Results

Progress of DS-8201

SAKIGAKE Designation of DS-3201

DS-1647 (G47Δ) P2 IIS Study Result

New Phase 3 Study of Mirogabalin

Upcoming Milestones

ASCO IR Events

DS-8201: FY2018 Results

Fiscal year		FY2018											
Month		4	5	6	7	8	9	10	11	12	1	2	3
Multiple tumors P1				ASCO			WCLC	ESMO		SABCS			
Breast (Global)	Post T-DM1	Complete P2 DESTINY-Breast01 study enrollment											
							Started P3 DESTINY-Breast02 study						
	vs. T-DM1					Started P3 DESTINY-Breast03 study							
	HER2 low									Started P3 DESTINY-Breast04 study			
Lung (Global)			Started P2 study										
IO combo (US/EU)	Nivolumab					Started P1 study							
	Pembrolizumab						Merck						
	Avelumab							Merck KGaA/Pfizer					
Partnership	CDx development								Ventana (Roche Group)				
	Strategic collaboration												AstraZeneca

Other Oncology: FY2018 Results

Fiscal year		FY2018											
Month		4	5	6	7	8	9	10	11	12	1	2	3
U3-1402	Breast cancer			ASCO						SABCS			
Quizartinib	Relapsed/ refractory AML			EHA	BTD	US	US NDA						
				Orphan drug designation			Japan	JP NDA					
								EU MAA					
DS-3032	Liposarcoma			ASCO									
	AML+quizartinib									Started P1 study			
PLX2853	AML												Started P1 study
Axi-Cel® (Japan)	BCL			Orphan drug designation				Japan	Started P2 study				
Pexidartinib (US/EU)	TGCT			ASCO						US NDA			
													EU MAA
DS-1647(G47Δ) (Japan)	Glioblastoma multiforme											AACR-JCA	
DS-1205	NSCLC+gefitinib							Started P1 study					

BCL: B-cell lymphoma, NSCLC: non-small-cell lung cancer, TGCT: tenosynovial giant cell tumor

Specialty Medicine: FY2018 Results

Fiscal year		FY2018											
Month		4	5	6	7	8	9	10	11	12	1	2	3
Edoxaban	AF/VTE									Approved	China		
Mirogabalin	PNP									Japan		Approved	
	CNP												Started P3 study
Esaxerenone	Hyper-tension									Japan		Approved	
Laninamivir (nebulizer)	Influenza				JP NDA								

AF: atrial fibrillation, CNP: central neuropathic pain, PNP: peripheral neuropathic pain, VTE: venous thromboembolism

FY2018 Results

Progress of DS-8201

SAKIGAKE Designation of DS-3201

DS-1647 (G47Δ) P2 IIS Study Result

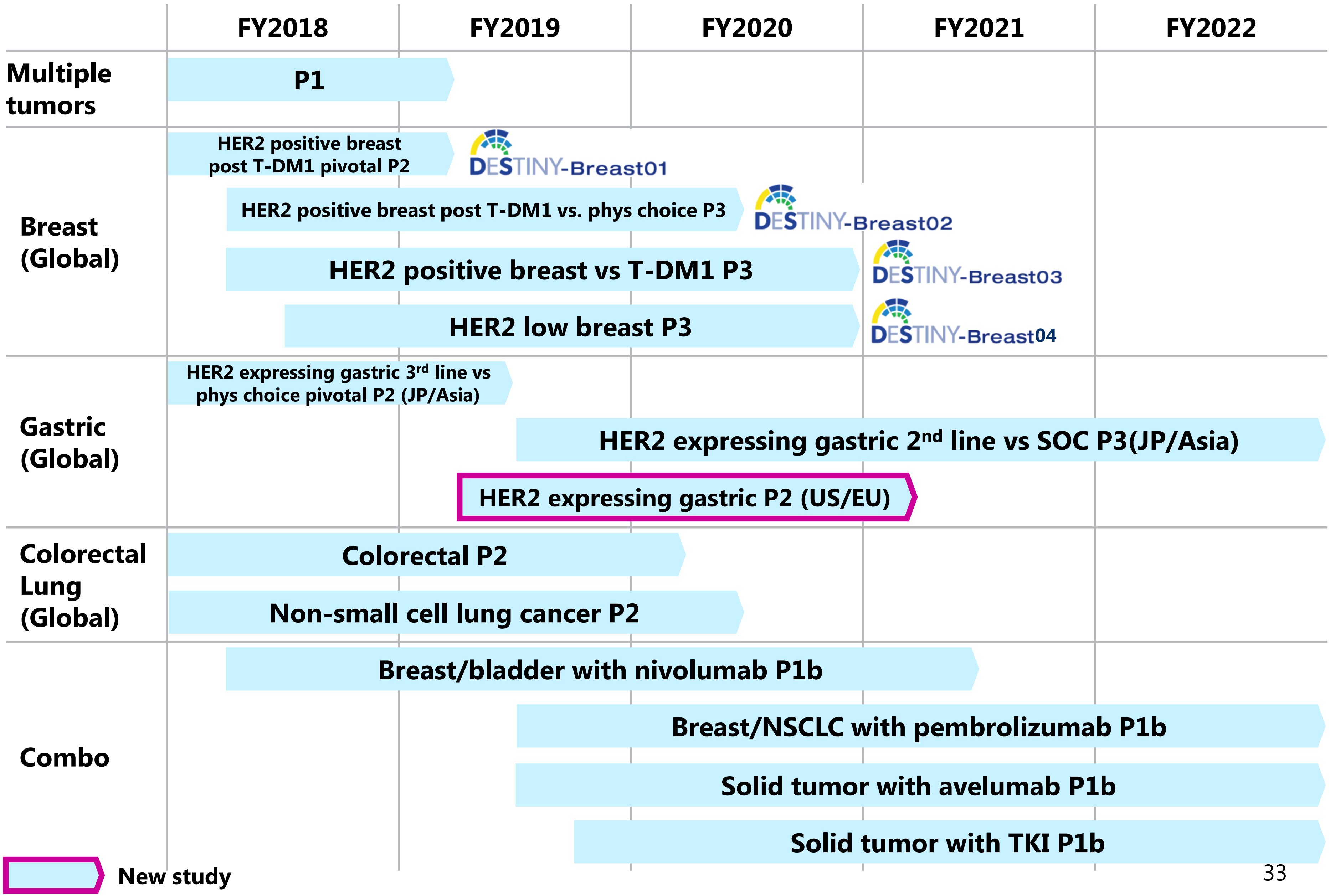
New Phase 3 Study of Mirogabalin

Upcoming Milestones

ASCO IR Events

DS-8201: Study Plan

As of April 2019



HER2 Positive mBreast Cancer 3rd-line Application Plan

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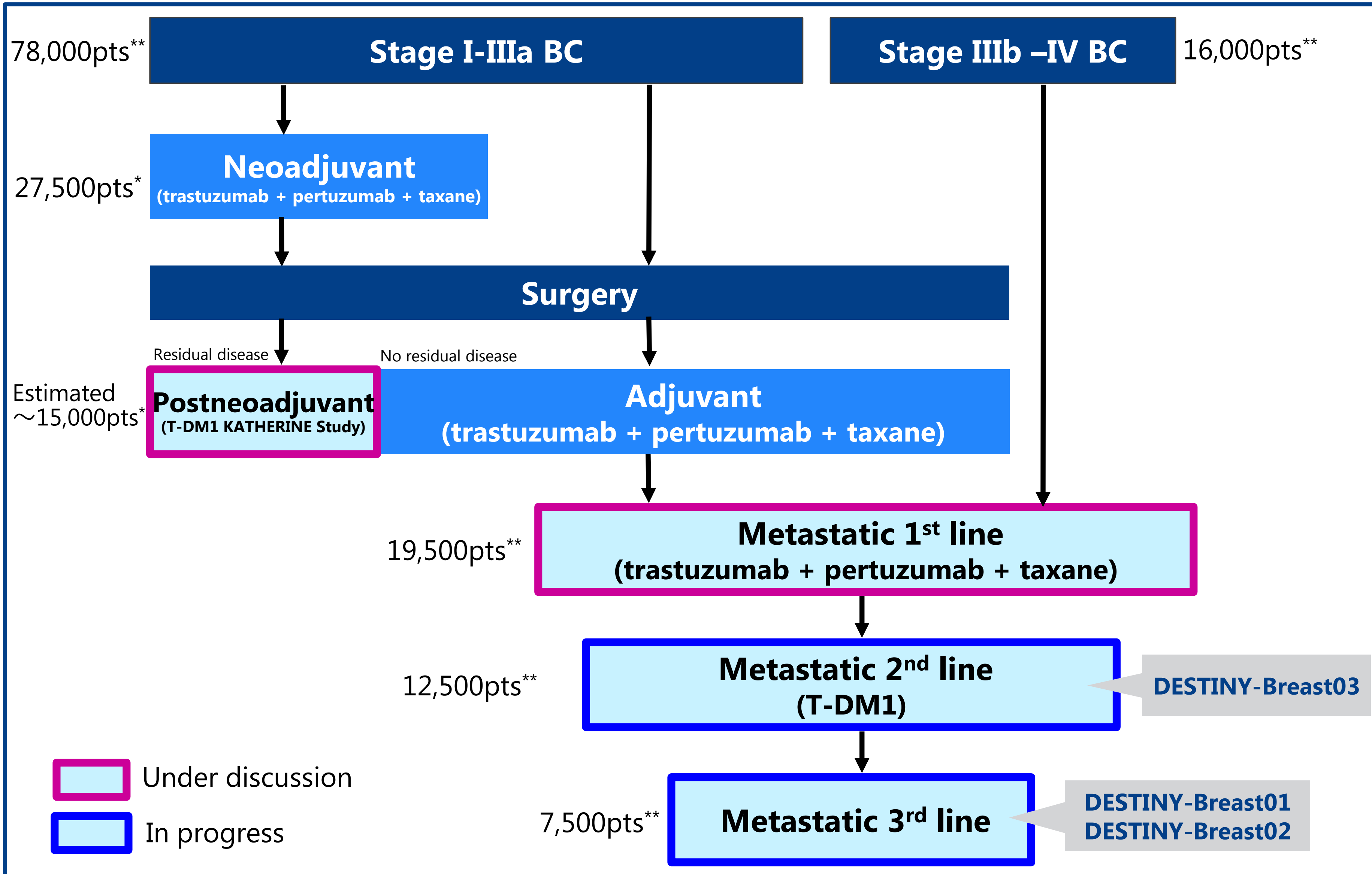
Preparation for BLA submission is progressing steadily

US	Japan	EU
BLA submission 1H FY2019	**NDA submission 2H FY2019**	**MAA submission 1H FY2020**
Estimated Review Period: 6M after acceptance of the application	Estimated Review Period: Maximum 12M after application	Estimated Review Period: 12M after application
Fast-track status BTD designation		

BTD: Breakthrough therapy designation

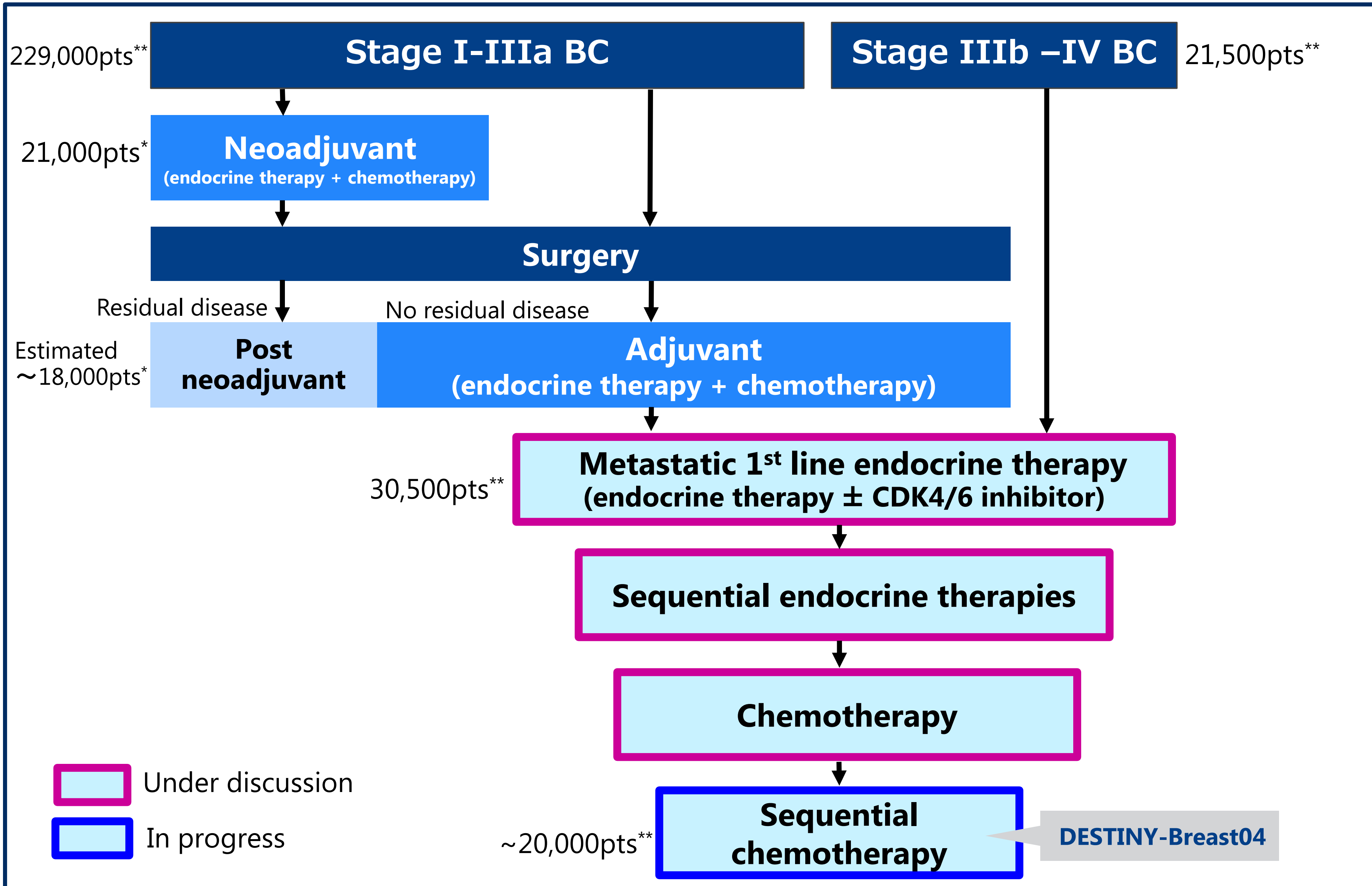
Underlined in red: new or updated from FY2018 Q3

HER2 Positive BC Treatment Flow and Ongoing DS-8201 Studies



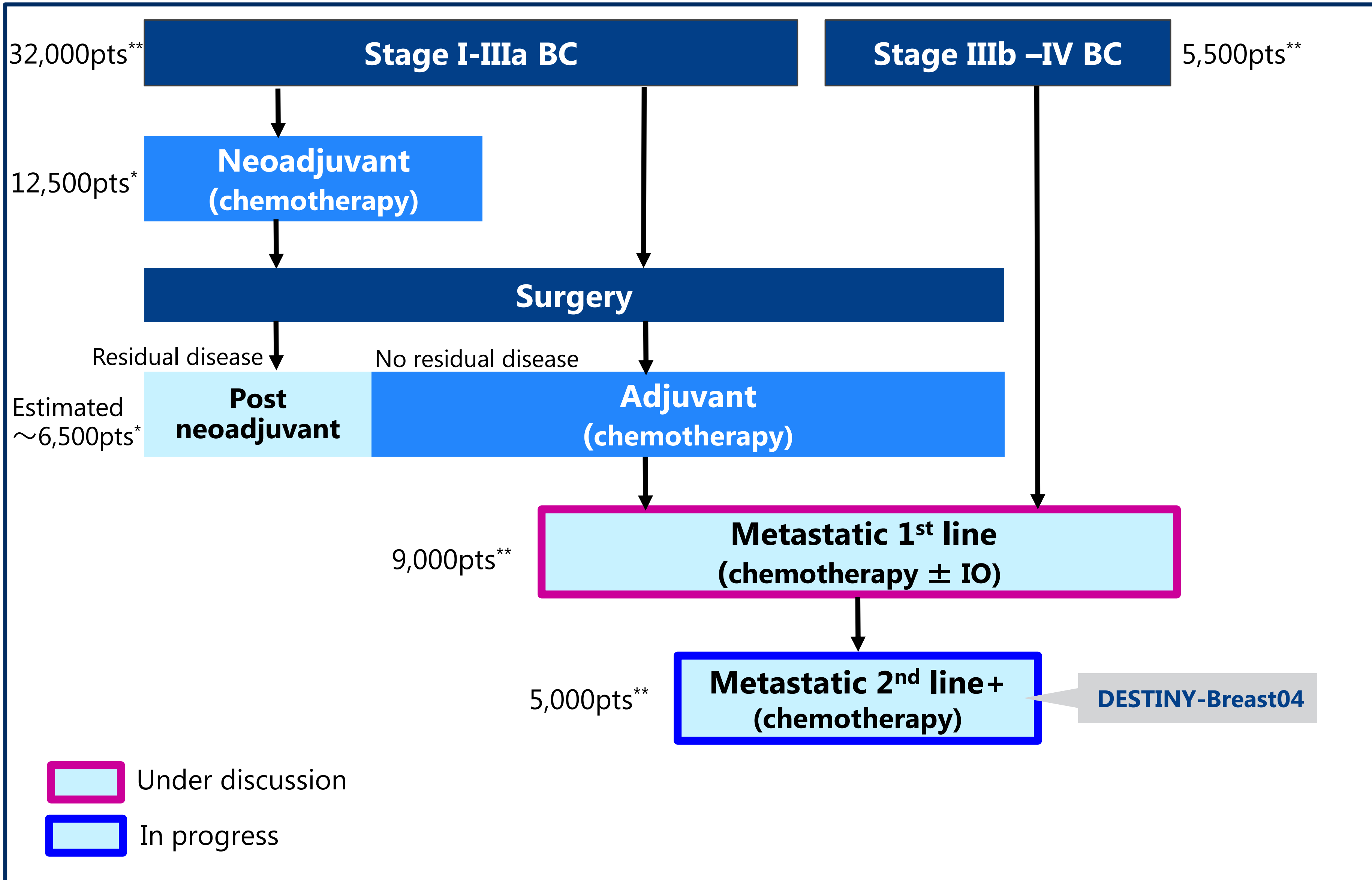
* JP/US/EU5, DS estimation, **JP/US/EU5; Source: CancerMPact®, Kantar Health/ Synix inc.（Strict diversion of confidential information)

HER2 Low(HR+) BC Treatment Flow and Ongoing DS-8201 Study



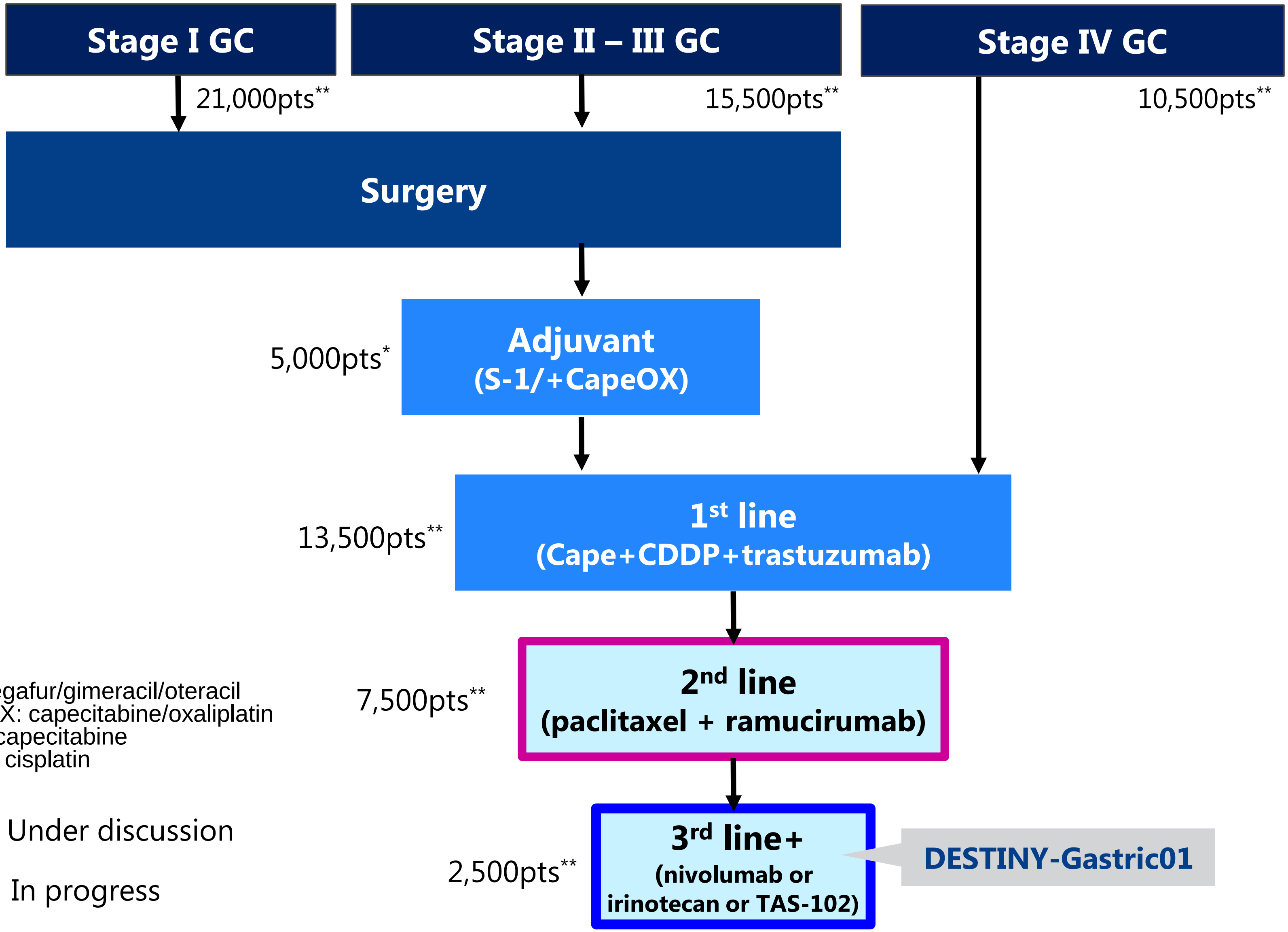
* JP/US/EU5, DS estimation, **JP/US/EU5; Source: CancerMPact®, Kantar Health/ Synix inc.（Strict diversion of confidential information)

HER2 Low(HR-) BC Treatment Flow and Ongoing DS-8201 Study



* JP/US/EU5, DS estimation, **JP/US/EU5; Source: CancerMPact®, Kantar Health/ Synix inc.（Strict diversion of confidential information）

HER2 Expressing GC Treatment Flow and Ongoing DS-8201 Study



- S-1: Tegafur/gimeracil/oteracil
- CapeOX: capecitabine/oxaliplatin
- Cape: capecitabine
- CDDP: cisplatin

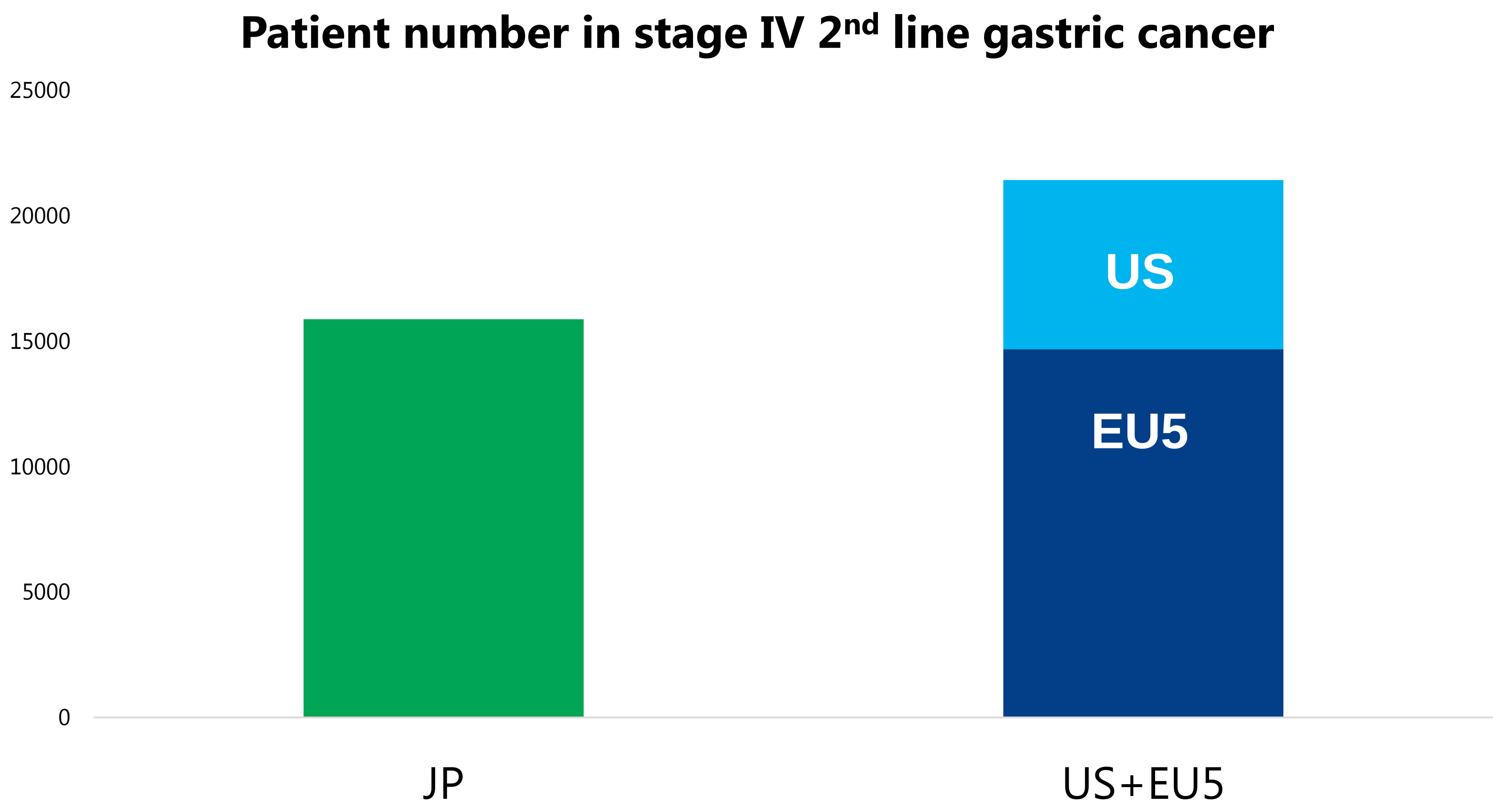
Under discussion

In progress

* JP/US/EU5, DS estimation, **JP/US/EU5; Source: CancerMPact®, Kantar Health/ Synix inc.（Strict diversion of confidential information）

Gastric Cancer Patients in West

West (US+EU5) GC patients are larger than Japan



JP/US/EU5; Source: CancerMPact®, Kantar Health/ Synix inc.（Strict diversion of confidential information）

HER2 Expressing GC US/EU P2 Study Design

- Historical data of comparable drug suggests East and West gastric cancer patients may have different efficacy
- Planned to start the study from Q2 FY2019

- HER2 positive gastric and gastroesophageal junction cancer
- Re-confirm HER2 status
- Post trastuzumab

DS-8201 (N=72) → Primary Analysis ORR → PFS and Survival Follow-up

Study patients	HER2 positive gastric and gastroesophageal junction cancer
Primary endpoint	ORR
Secondary endpoint	PFS, OS
CTG/JAPIC	TBD

FY2018 Results

Progress of DS-8201

SAKIGAKE Designation of DS-3201

DS-1647 (G47Δ) P2 IIS Study Result

New Phase 3 Study of Mirogabalin

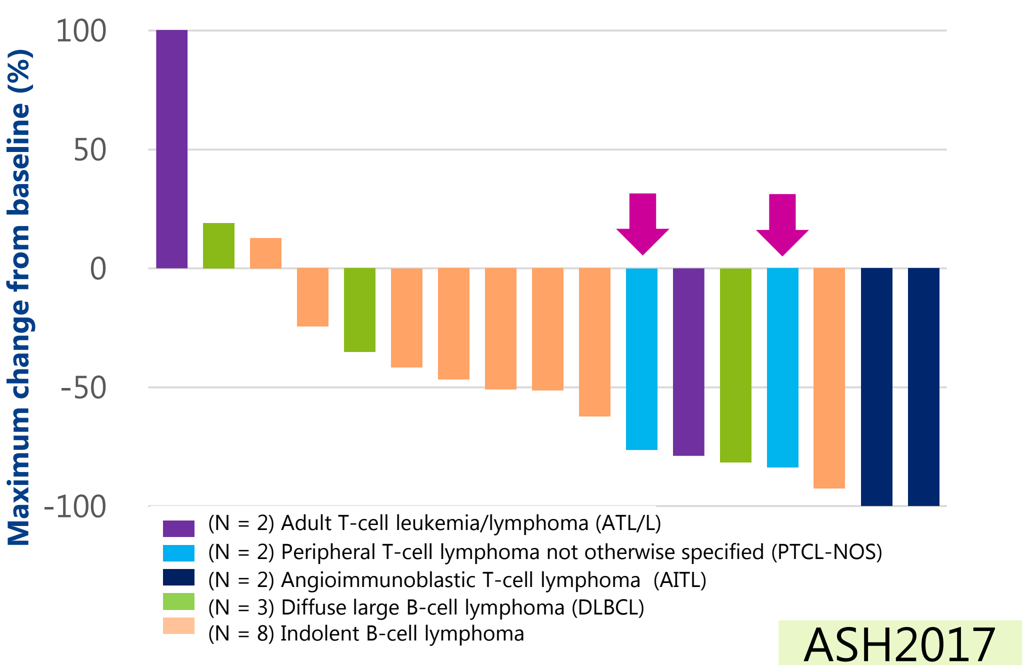
Upcoming Milestones

ASCO IR Events

SAKIGAKE Designation: DS-3201 PTCL

- Potential first-in-class **EZH1/2 dual inhibitor**
- Received SAKIGAKE Designation for **relapsed/refractory peripheral T-cell lymphoma (PTCL)** treatment based on the preliminary result of Phase 1 Non-Hodgkin lymphomas trial including PTCLs

Preliminary results in relapsed or refractory Non-Hodgkin Lymphoma



PTCL

- Non-Hodgkin lymphoma arising from T cells
- Tend to be aggressive and associated with poor prognosis, particularly for relapsed disease
- **High unmet medical needs** (very few treatment options)

DS-1647 (G47Δ) Oncolytic Virus

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G47Δ: Innovative cancer therapy with most advanced oncolytic virus

- Third-generation oncolytic virus: herpes simplex virus type 1 (HSV-1) was modified to grow exclusively in cancer cells by genetic recombination
- Developing this treatment for various solid cancers, including Glioblastoma, in collaboration with Professor Tomoki Todo of the Institute of Medical Sciences of the University of Tokyo

Synosis of Phase 2 IIS Trial (glioblastoma multiforme)	
Objective	Evaluating the efficacy and safety of G47Δ in patients with glioblastoma with residual or recurrent tumors after radiation alone or radiation plus temozolomide
Design	Open-label study (no control group)
Primary endpoint	1 year survival rate
Secondary endpoints	Overall survival; Progression-free survival; Tumor response; Safety
Case	Target 30 cases (interim analysis in 13 cases)
Dosage and administration	Stereotactic brain surgery for intratumoral administration, up to 6 doses

Interim Analysis Results of Phase 2 Clinical Trials (IIS)

- **Interim analysis lead to stop study early after confirming efficacy**
- **Professor Todo presented the results at AACR-JCA**
- **Planning to submit NDA in Japan in 1H FY2019 (SAKIGAKE Designation)**

Efficacy

Primary endpoint
- **1 year survival rate: 92.3%** (12/13 cases survived)

Secondary endpoint
- PFS: 8.6 months
- Tumor response : SD for all 4 patients at the end of follow-up

Safety

Good safety profile is suggested

- Side effect leading prolonged hospitalization: 2/16 (12.5%)
- AEs leading to discontinue treatment: 1/16 (6.3%)

Glioblastoma
- Gliomas represent about a quarter of brain tumors
- Glioblastoma is the most common and most aggressive type of glioma
- The 5-yr survival rate with standard therapy is about 10% and healing is extremely difficult
- About 1,000 patients per year in Japan

FY2018 Results

Progress of DS-8201

SAKIGAKE Designation of DS-3201

DS-1647 (G47Δ) P2 IIS Study Result

New Phase 3 Study of Mirogabalin

Upcoming Milestones

ASCO IR Events

Mirogabalin: Life Cycle Management

Started P3 study for indication expansion

Neuropathic Pain	Classification	Diseases	Status
	Peripheral	・Diabetic peripheral neuropathic pain ・Postherpetic neuralgia, etc.	Approved
	Central	・**Neuropathic pain after spinal cord injury** ・Pain related to Parkinson's disease ・Post stroke pain, etc.	**P3 started**

Double blind phase (14W) N=274

Mirogabalin

Placebo

Open-label extension phase (52W) N=180

Mirogabalin

Target	**Central neuropathic pain (neuropathic pain after spinal cord injury, etc.)**
Primary endpoint	Change in the weekly average daily pain score from baseline to Week 14
CTG/JAPIC	NCT03901352/JapicCTI-194653

FY2018 Results

Progress of DS-8201

SAKIGAKE Designation of DS-3201

DS-1647 (G47Δ) P2 IIS Study Result

New Phase 3 Study of Mirogabalin

Upcoming Milestones

ASCO IR Events

Upcoming Milestones: ASCO

Daiichi-Sankyo

ASCO abstract release: 5/15, 5pm (ET)

U3-1402	Lung	EGFRm NSCLC P1 Study ASCO: **oral presentation on May 31, 2019**
DS-1062	Lung	NSCLC P1 Study ASCO: **poster presentation on June 2, 2019**
DS-1001	Glioma	Glioma **ASCO: oral presentation on June 3, 2019**

Underlined in red: new or updated from FY2018 Q3

ASCO IR Events

On-site conference

Date	June 2 (Sunday) 5:00-8:00 pm CDT (planned)
Speaker	Sunao Manabe, COO Antoine Yver, Oncology R&D Head
Contents	About presentation in ASCO * This content will be distributed on-demand at a later date

Conference call

Date	June 3 (Monday) 9:00-10:00 pm JST
Speaker	Sunao Manabe, COO Antoine Yver, Oncology R&D Head
Contents	About presentation in ASCO * This content will be distributed on-demand at a later date

Upcoming Milestones

Daiichi-Sankyo

DS-8201	Breast	HER2 positive mBC 3rd-line BLA submission in 1H FY2019 (US) **NDA submission in 2H FY2019 (Japan)** DESTINY-BREAST01 (Pivotal P2 study) **SABCS: December 2019 (planned)**
Quizartinib	AML	Relapsed/refractory AML **ODAC May 14, 2019** FDA PDUFA **August 25, 2019 (3M delay)**
Pexidartinib	TGCT	Tenosynovial giant cell tumor **ODAC May 14, 2019** FDA PDUFA August 3, 2019
DS-1647 (G47Δ)	GBM	Glioblastoma multiforme **NDA submission in 1H FY2019 (Japan)**

ODAC: Oncology Drug Advisory Committee

Underlined in red: new or updated from FY2018 Q3

1. FY2018 Financial Results
2. FY2019 Consolidated Forecast
3. Business Update
4. R&D Update
5. **Appendix**

FY2019 R&D Milestones

As of April 2019

Project	Indications and Studies	FY2018	FY2019			
		Q4	Q1	Q2	Q3	Q4
DS-8201	P2 pivotal: BC (HER2 positive post T-DM1)		US submission		JP Submission	
DS-8201	P2: GC (US/EU)			Study start		
DS-8201	P1b: BC/NSCLC (with pembrolizumab)				Study start	
DS-8201	P1b: solid tumor (with avelumab)				Study start	
Quizartinib	P3: relapsed/refractory AML			US approval		
Pexidartinib	P3: TGCT (US/EU)	EU Submitted		US approval		
DS-1647	IIS: glioblastoma multiforme (JP)	TLR	Submission			
DS-1205	P1: NSCLC with osimertinib (Asia)		Study started			
Mirogabalin	P3: PNP (JP)	Approved	Launched			
Mirogabalin	P3: central neuropathic pain (JP/Asia)	Study started				
Esaxerenone	P3: hypertension (JP)	Approved	Launch			
Laninamivir	P3: influenza (nebulizer formulation) (JP)			Approval		

AML: acute myeloid leukemia, EGFRm: EGFR mutation, NSCLC: non-small cell lung cancer, PNP: peripheral neuropathic pain, TGCT: tenosynovial giant cell tumor, TLR: top line results

Underlined in red: new or updated from FY2018 Q3   Blue: achieved

Major R&D Pipeline (Oncology)

As of April 2019

Daiichi-Sankyo

	Generic name/Project number (drug efficacy/mechanism of action)	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 expressing post trastuzumab)	JP/Asia		★		
		CRC	JP/US/EU				
		NSCLC	JP/US/EU				
		BC and bladder cancer (with nivolumab)	US/EU				
	U3-1402 (anti-HER3 ADC)	BC	JP/US				
		NSCLC	US				
	DS-1062 (anti-TROP2 ADC)	NSCLC	JP/US				
AML/HEM Franchise	Quizartinib/AC220 (FLT3 inhibitor)	AML (relapsed/refractory)	JP/US/EU/Asia				
		AML (1st line)	JP/US/EU/Asia				
	DS-3032 (MDM2 inhibitor)	Solid tumor	JP/US				
		AML	JP/US				
	DS-3201 (EZH1/2 inhibitor)	PTCL	JP				
		ATL/L	JP				
		AML、ALL	US				
	PLX2853 (BRD4 inhibitor)	AML, solid cancer	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 multiforme	JP		★		
	DS-1205 (AXL inhibitor)	NSCLC [with 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, 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 registration application based on the results of P2 studies, designated as breakthrough therapy (FDA)/SAKIGAKE (JP)

Major R&D Pipeline (SM/Vaccination)

As of April 2019

	Generic Name/Project Code Number (Drug Efficacy/Mechanism of Action)	Target Indications	Region	Stage			
				Phase 1	Phase 2	Phase 3	NDA
Specialty Medicine (SM)	Edoxaban / DU-176b (Fxa-inhibitor)	Very elderly patients AF	JP				
Specialty Medicine (SM)	Prasugrel / CS-747 (anti-platelet agent)	Ischemic stroke	JP				
Specialty Medicine (SM)	Esaxerenone / CS-3150 (MR-antagonist)	Diabetic nephropathy	JP				
Specialty Medicine (SM)	DS-1040 (TAFIa inhibitor)	Acute ischemic stroke, acute pulmonary embolism	JP/US/EU				
Specialty Medicine (SM)	DS-2330 (hyperphosphatemia treatment)	Hyperphosphatemia in chronic kidney disease	-				
Specialty Medicine (SM)	Mirogabalin (α2δ ligand)	Central neuropathic pain	JP/Asia				
Specialty Medicine (SM)	Laninamivir / CS-8958 (neuraminidase inhibitor)	Influenza	JP				
Specialty Medicine (SM)	DS-5141 (ENA-oligonucleotide)	DMD	JP				
Specialty Medicine (SM)	DS-1211 (TNAP inhibitor)	Inhibition of ectopic calcification	US				
Vaccination	VN-0107/MEDI3250 (live attenuated influenza vaccine)	Prophylaxis of seasonal influenza	JP				
Vaccination	VN-0105 (DPT-IPV/Hib)	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib)	JP				
Vaccination	VN-0102/JVC-001 (Measles-mumps-rubella vaccine)	For measles, mumps, and rubella Prophylaxis	JP				

AF: atrial fibrillation, DMD: Duchenne muscular dystrophy

designated as breakthrough therapy (FDA)/SAKIGAKE (JP)

Out-licensing Projects

As of Apr 2019

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	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)

Status of Accelerated Development Support Program

Project (indication)	Japan	US	Europe
DS-8201 (BC 3rd line)		Fast track Breakthrough therapy	
DS-8201 (GC 2nd line)	SAKIGAKE		
Quizartinib (AML)	Orphan drug	Fast track Breakthrough therapy Orphan drug	Orphan drug
DS-3201 (PTCL)	SAKIGAKE		
Axi-Cel® (BCL)	Orphan drug		
Pexidartinib (TGCT)		Breakthrough therapy Orphan drug Priority review	Orphan drug
DS-1647(G47Δ) Glioblastoma multiforme	SAKIGAKE		
DS-5141 (DMD)	SAKIGAKE		

AML: acute myeloid leukemia, BCL: B-cell lymphoma, DMD: Duchenne muscular dystrophy, PTCL: peripheral T-cell lymphoma, TGCT: tenosynovial giant cell tumor

Listing of abbreviations

Daiichi-Sankyo

Abbreviations	English	Implications
BTD	Breakthrough therapy designation	Designation of innovative therapeutics
CR	Complete response	Complete response (complete resolution of cancer)
DCR	Disease control rate	Disease control rate (percentage of patients with controlled disease status)
DLT	Dose limiting toxicity	Dose-limiting toxicities (toxicities that may explain the inability to escalate doses)
DOR	Duration of response	Duration of response (duration of response)
EGFR	Epidermal growth factor receptor	Epidermal growth factor receptor
MTD	Maximum tolerated dose	Maximum tolerated dose (dose with intolerable toxicity)
ORR	Overall response rate Objective response rate	Overall response rate (expressed as the proportion of patients who responded to treatment and the sum of CR and PR)
OS	Overall survival	Overall survival (time from start of treatment to death)
PD	Progress disease	Disease progression (worsening disease despite treatment)
PFS	Progression-free survival	Progression-free survival (without cancer progression)
PR	Partial response	Partial response (a reduction in the size of the cancer by 30% or more that lasts for 4 weeks)
SD	Stable disease	The size of the cancer is almost unchanged before and after treatment

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