Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2019 Q3
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

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Executive Vice President and CFO

January 31, 2020

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Agenda

1. **FY2019 Q3 Financial Results**
2. FY2019 Forecast
3. Business Update
4. R&D Update
5. Appendix

Overview of FY2019 Q3 Results

(Bn JPY)

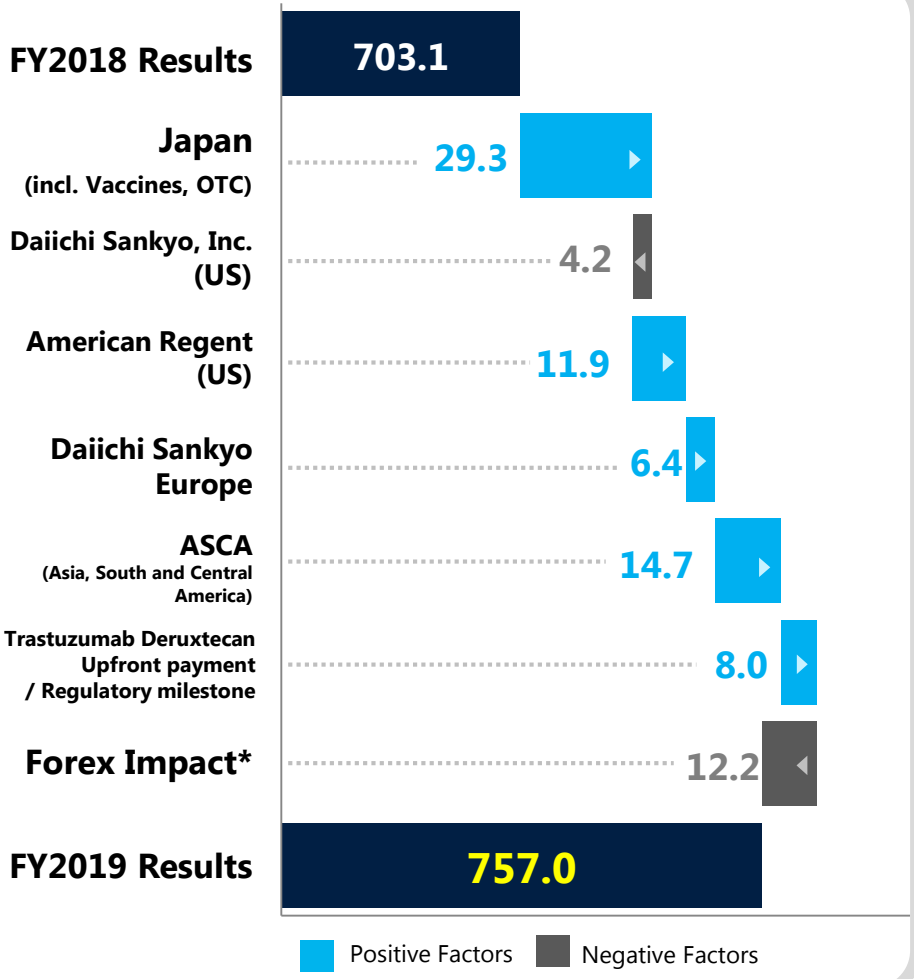
	FY2018 Q3 YTD Results	FY2019 Q3 YTD Results	YoY
Revenue	703.1	757.0	+7.7% +54.0
Cost of Sales	264.9	256.3	-8.6
SG&A Expenses	198.5	208.2	+9.7
R&D Expenses	142.6	136.9	-5.6
Operating Profit	97.1	155.6	+60.3% +58.5
Profit before Tax	98.0	160.0	+62.0
Profit attributable to owners of the Company	78.8	134.3	+70.4% +55.5

Currency Rate	USD/JPY	111.15	108.67	-2.48
	EUR/JPY	129.49	121.05	-8.44

Revenue

Increased by 54.0 Bn JPY (Increased by 66.2 Bn JPY excl. forex impact)

(Bn JPY)



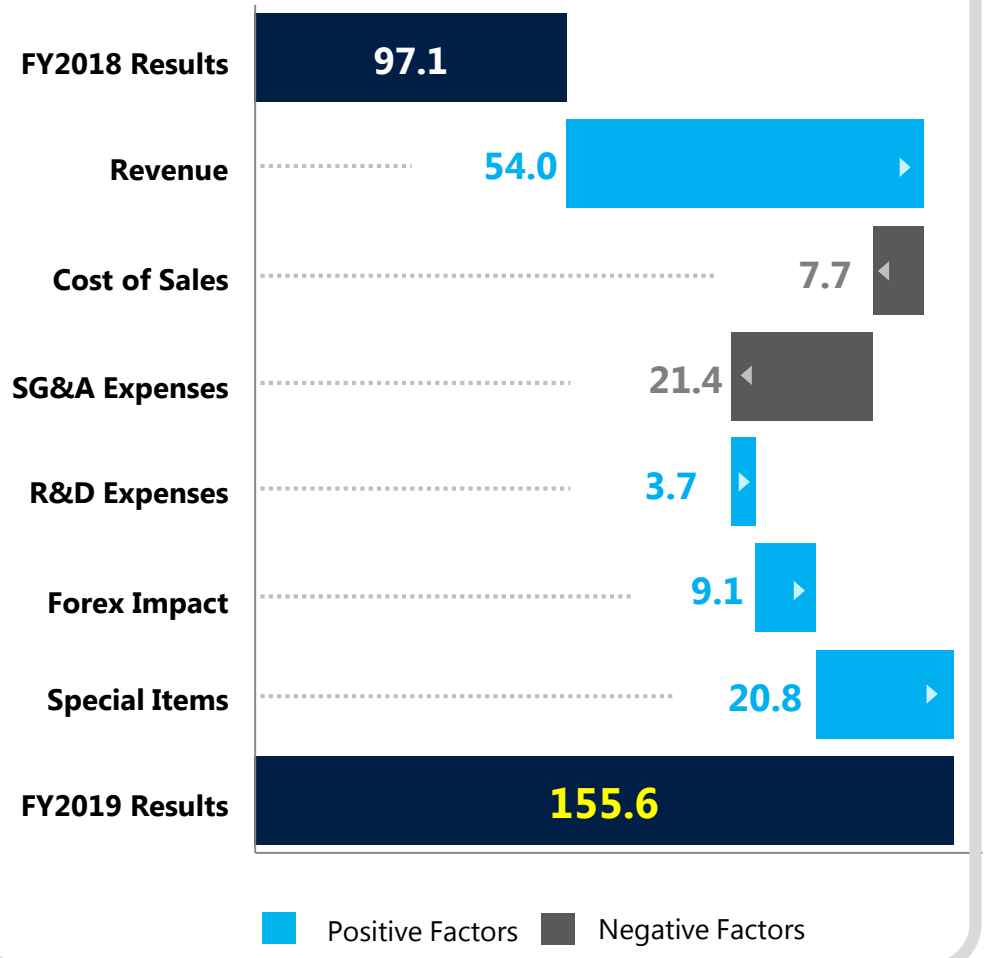
Positive Factors		Negative Factors	
Japan			
Lixiana	+16.3		
Inavir	+7.1		
Tarlige	+5.4		
Daiichi Sankyo Espha (GE) Silodosin AG	+5.5	Daiichi Sankyo Healthcare	-0.1
Daiichi Sankyo, Inc. (US)			
		Welchol	-2.2
		Effient	-2.1
American Regent, Inc. (US)			
Injectafer	+6.6		
GE injectables	+4.6		
Daiichi Sankyo Europe			
Lixiana	+13.6	Olmesartan	-2.9
		Efient	-2.5
ASCA (Asia, South and Central America)			
China Cravit, Olmetec etc.	+10.3		

* Forex impact USD: -3.1, EUR : -4.7, ASCA: -4.3

Operating Profit

Increased by 58.5 Bn JPY

(Increased by 40.8 Bn JPY excl. forex impact and special items)



(Bn JPY)

Revenue +54.0

incl. forex impact of -12.2

Cost of Sales +7.7 **(Cost increased)**

- Increase by revenue increase
- Improvement in cost of sales ratio by product mix

SG&A Expenses +21.4 **(Cost increased)**

- Increase by establishment of the oncology business structure in US

R&D Expenses -3.7 **(Cost decreased)**

- Decrease by trastuzumab deruxtecan cost share with AstraZeneca
- Increase by enhancement of oncology development structure

Forex Impact -9.1 **(Cost decreased)**

Cost of Sales -2.7
SG&A Expenses -4.5
R&D Expenses -1.9

Special Items -20.8 **(Cost decreased)**

See next slide for details

Special Items

(Bn JPY)

	FY2018 Q3 YTD Results		FY2019 Q3 YTD Results		YoY
Cost of Sales			Restructuring costs in Supply Chain	1.3	-13.7
			Impairment loss (intangible assets)*1	3.8	
			Gain on sales of subsidiary*2	-18.8	
SG&A Expenses	Gain on sales of fixed assets	-3.5	Gain on sales of fixed assets*3	-10.6	-7.2
R&D Expenses					
Total		-3.5		-24.3	-20.8

*1 Morphabond, Roxybond
*2 Takatsuki Plant
*3 Nihonbashi building

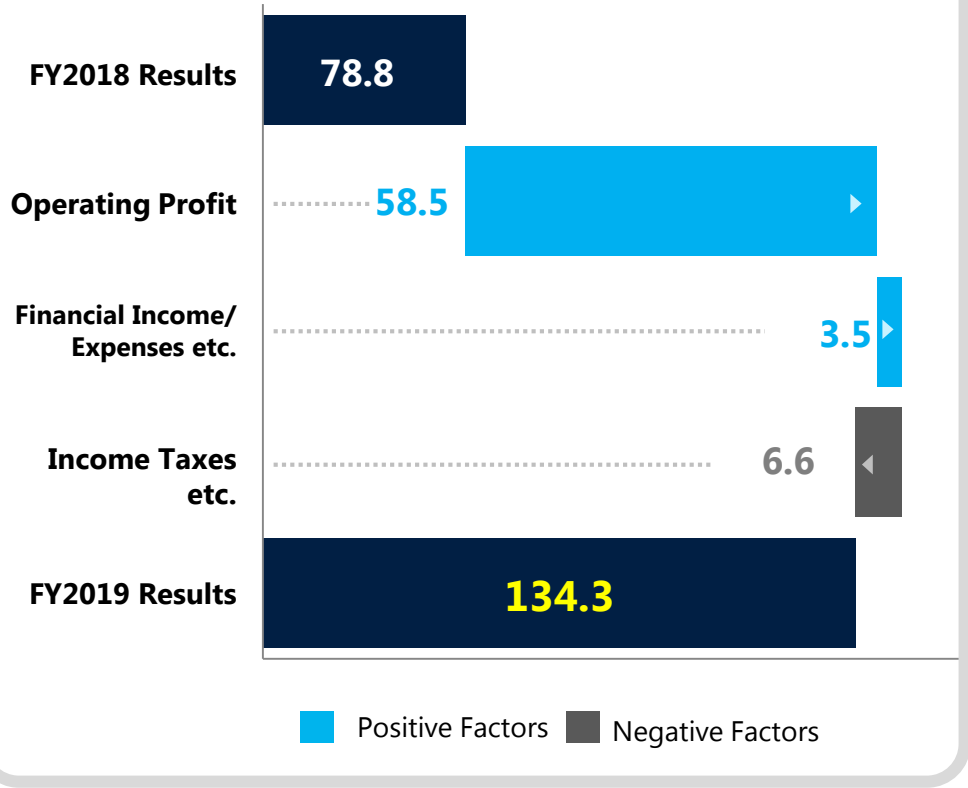
- : Cost decreased items

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 55.5 Bn JPY



(Bn JPY)

Income Taxes etc. ····· +6.6 (Cost increased)

	FY2018	FY2019	YoY
Profit before Tax	98.0	160.0	+62.0
Income Taxes etc.	19.1	25.8	+6.6
Tax rate	19.5%	16.1%	-3.4%

(Reference: Tax rate)
FY2018: Impact of the tax rate reduction in US
FY2019: Impact of introduction of consolidated taxation system

Revenue: Major Business Units (incl. Forex Impact)

(Bn JPY)

	FY2018 Q3 YTD Results	FY2019 Q3 YTD Results	YoY
Japan	395.7	422.3	+26.6
Daiichi Sankyo Healthcare	52.9	52.9	-0.1
Daiichi Sankyo, Inc.	28.6	23.8	-4.8
Olmesartan	7.9	7.8	-0.1
Welchol	11.0	8.6	-2.4
American Regent, Inc.	90.1	99.7	+9.6
Injectafer	33.7	39.3	+5.7
Venofer	24.1	23.3	-0.8
GE injectables	28.2	32.1	+3.8
Daiichi Sankyo Europe	66.0	67.7	+1.7
Lixiana	33.3	43.9	+10.5
Olmesartan	21.0	16.9	-4.1
Efient	4.6	1.9	-2.7
ASCA (Asia, South and Central America)	63.1	73.5	+10.4

Currency Rate	USD/JPY	111.15	108.67	-2.48
	EUR/JPY	129.49	121.05	-8.44

Revenue: Major Products in Japan

(Bn JPY)

		FY2018 Q3 YTD Results	FY2019 Q3 YTD Results	YoY
Lixiana	anticoagulant	**49.3**	**65.6**	**+16.3**
Nexium	ulcer treatment	**61.0**	**62.3**	**+1.3**
Memary	Alzheimer's disease treatment	**39.5**	**40.2**	**+0.7**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**21.0**	**24.3**	**+3.3**
Tenelia	type 2 diabetes mellitus treatment	**19.9**	**19.7**	**-0.2**
Loxonin	anti-inflammatory analgesic	**24.3**	**22.7**	**-1.6**
Inavir	anti-influenza agent	**4.5**	**11.5**	**+7.1**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**12.7**	**14.0**	**+1.3**
Efient	antiplatelet agent	**10.9**	**11.1**	**+0.2**
Rezaltas	antihypertensive agent	**12.2**	**11.6**	**-0.6**
Canalia	type 2 diabetes mellitus treatment	**6.9**	**9.8**	**+3.0**
Vimpat	anti-epileptic agent	**4.8**	**8.5**	**+3.7**
Omnipaque	contrast agent	**9.5**	**8.4**	**-1.1**
Olmetec	antihypertensive agent	**11.9**	**9.4**	**-2.5**

1 FY2019 Q3 Financial Results

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FY2019 Forecast

(Bn JPY)

	FY2019 Forecast (as of Oct.)	FY2019 Forecast (as of Jan.)	vs. Forecast (as of Oct.)
Revenue	955.0	970.0	+15.0
Cost of Sales	330.0	335.0	+5.0
SG&A Expenses	290.0	290.0	-
R&D Expenses	210.0	210.0	-
Operating Profit	125.0	135.0	+10.0
Profit before Tax	125.0	135.0	+10.0
Profit attributable to owners of the Company	90.0	110.0	+20.0

Major factors

- Japan +9.0
- Daiichi Sankyo, Inc. +4.0
  (incl. ENHERTU +2.0)
- Trastuzumab Deruxtecan regulatory milestone +0.9

Major factors

- Increase by revenue increase

Major factors

- Profit before Tax +10.0
- Decrease in income taxes etc. +10.0
  - ✓ Impact of introduction of consolidated taxation system

(Ref. FY2019 Forecast (as of Jan.) Tax rate : 18.5%)

Currency Rate	USD/JPY	109.31	109.01
	EUR/JPY	125.71	123.29

Assumption of currency rate for Q4
USD/JPY : 110, EUR/JPY : 130

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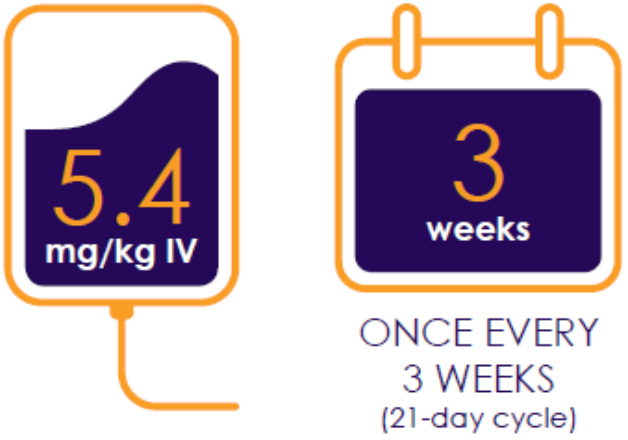
ENHERTU(DS-8201): Approved & Launched in U.S.

- **Approved in Dec. 2019 (First-time-in-human to US approval 4 years 3 months)**
- **Launched in Jan. 2020**

ENHERTU®
fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE

Indication*:
Treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting



*This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. ENHERTU is approved with a Boxed WARNING for Interstitial Lung Disease (ILD)/pneumonitis and Embryo-Fetal Toxicity.

Trastuzumab Deruxtecan (DS-8201): Revenue

(Bn JPY)

	FY2019 Q3 YTD Results	FY2019 Forecast	(Reference) Total Consideration (Received/ Receivable)
Product sales (U.S. ENHERTU)	0.0	2.0	
Upfront payment	7.4*	9.8*	149.0
Regulatory milestone payment	0.7*	0.9*	13.7
Total	8.1	12.7	162.7

*Revenue recognized in FY2019

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R&D Update

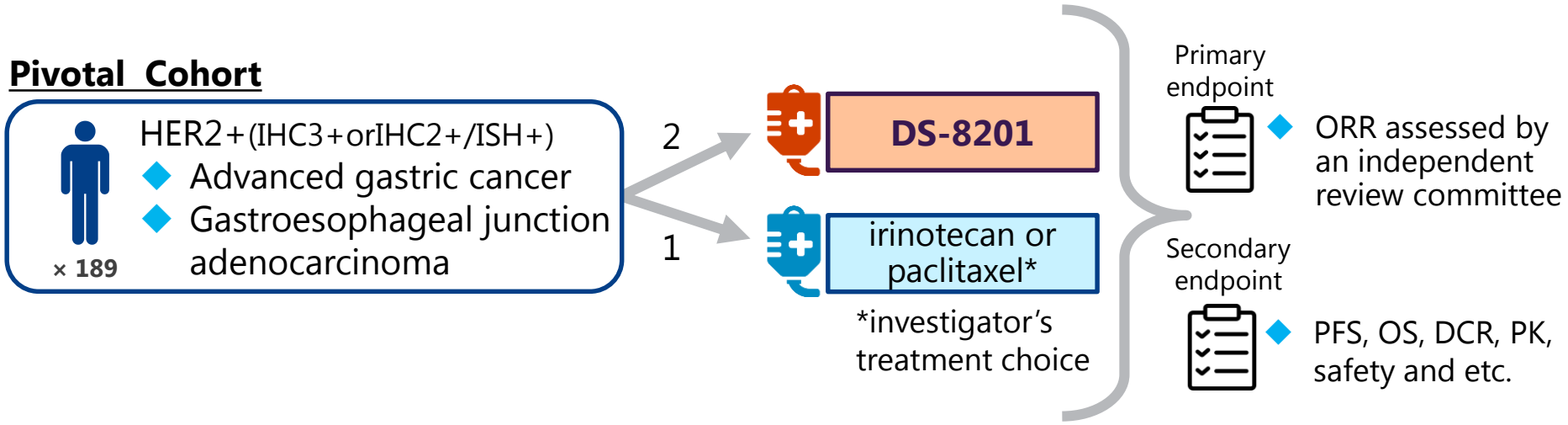
3ADCs: DS-8201 Update

Alpha: Specialty Medicine Update

Upcoming News

DS-8201 : DESTINY-Gastric01 Results

◆DS-8201's first study results with a control arm



About gastric cancer (GC)

- ◆ Approximately 1 million new cases and 800,000 deaths worldwide (in 2018), half of which occured in East Asia (especially in JP and S. Korea) *
- ◆ HER2 positive rate in GC is about 20%, 1st line treatment is Herceptin + chemotherapy and no other HER2 treatment has been approved **

*Source: World Cancer Research Fund International. Stomach Cancer Statistics. 2018. Accessed January 6, 2019: https://www.wcrf.org/dietandcancer/cancer-trends/stomach-cancer-statistics
**Source: NCCN Guidelines® Gastric Cancer. Version 4.2019. December 20, 2019

DS-8201 : DESTINY-Gastric01 Results

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Efficacy

- Primary endpoint: achieved **statistically significant and clinically meaningful improvement in objective response rate (ORR)**, as assessed by an independent review committee, in patients treated with DS-8201 versus investigator's choice of chemotherapy
- Secondary endpoint: achieved **statistically significant and clinically meaningful improvement in overall survival (OS)** within interim analysis, in patients treated with DS-8201 versus investigator's choice of chemotherapy

Safety

- **No new safety concerns** were identified
- **About interstitial lung disease (ILD) and pneumonitis**
  - Majority of drug-related ILD and pneumonitis were grade 1 and 2
  - Two grade 3 and one grade 4, no grade 5

- **sNDA planned in FY2020 Q1 in Japan (SAKIGAKE)**
- **Results are planned to be presented at ASCO 2020**

R&D Update

3ADCs: DS-8201 Update

Alpha: Specialty Medicine Update

Upcoming News

Today's Focus

- Announced new strategy at R&D Day 2019

3 Lead ADCs

Science-informed precision medicine

&

Alpha

Cutting-edge science and power of true innovation delivering drugs that change SOC

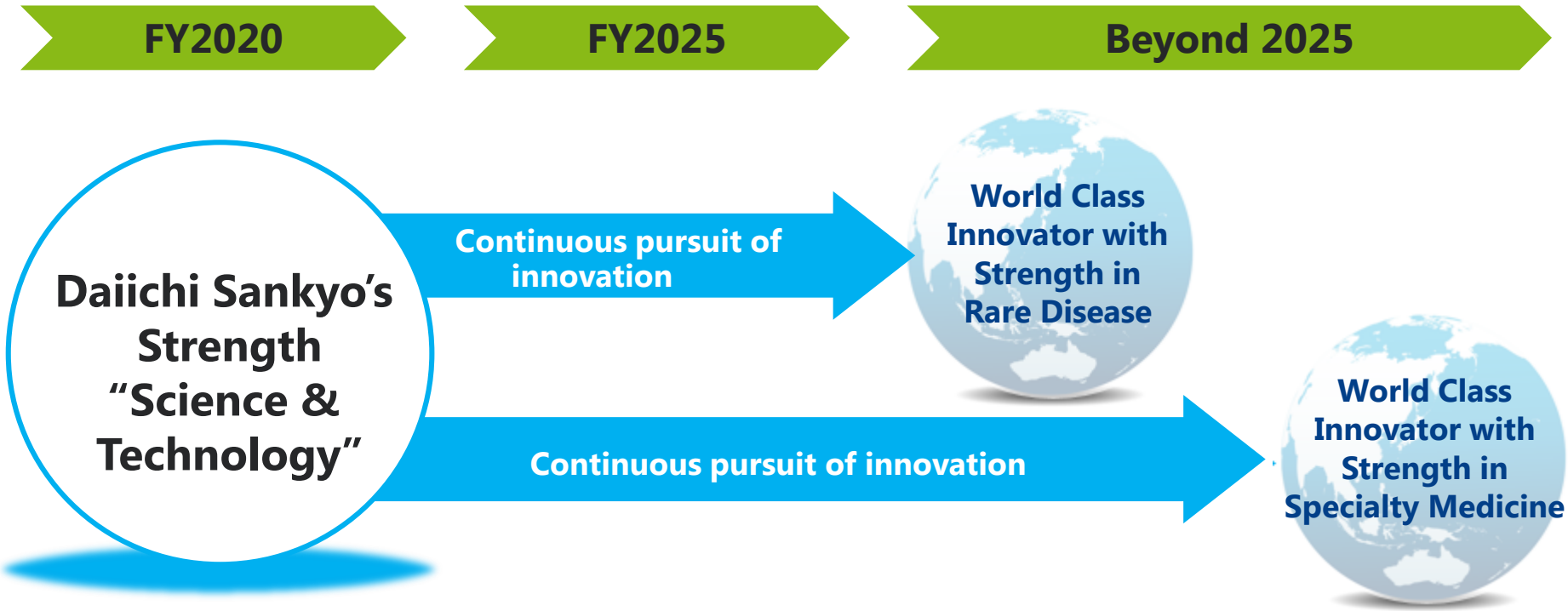
DS-8201	DS-1062	U3-1402	Oncology	**Specialty Medicine**	Vaccine

Today's focus

- **Specialty Medicine Area within Alpha**

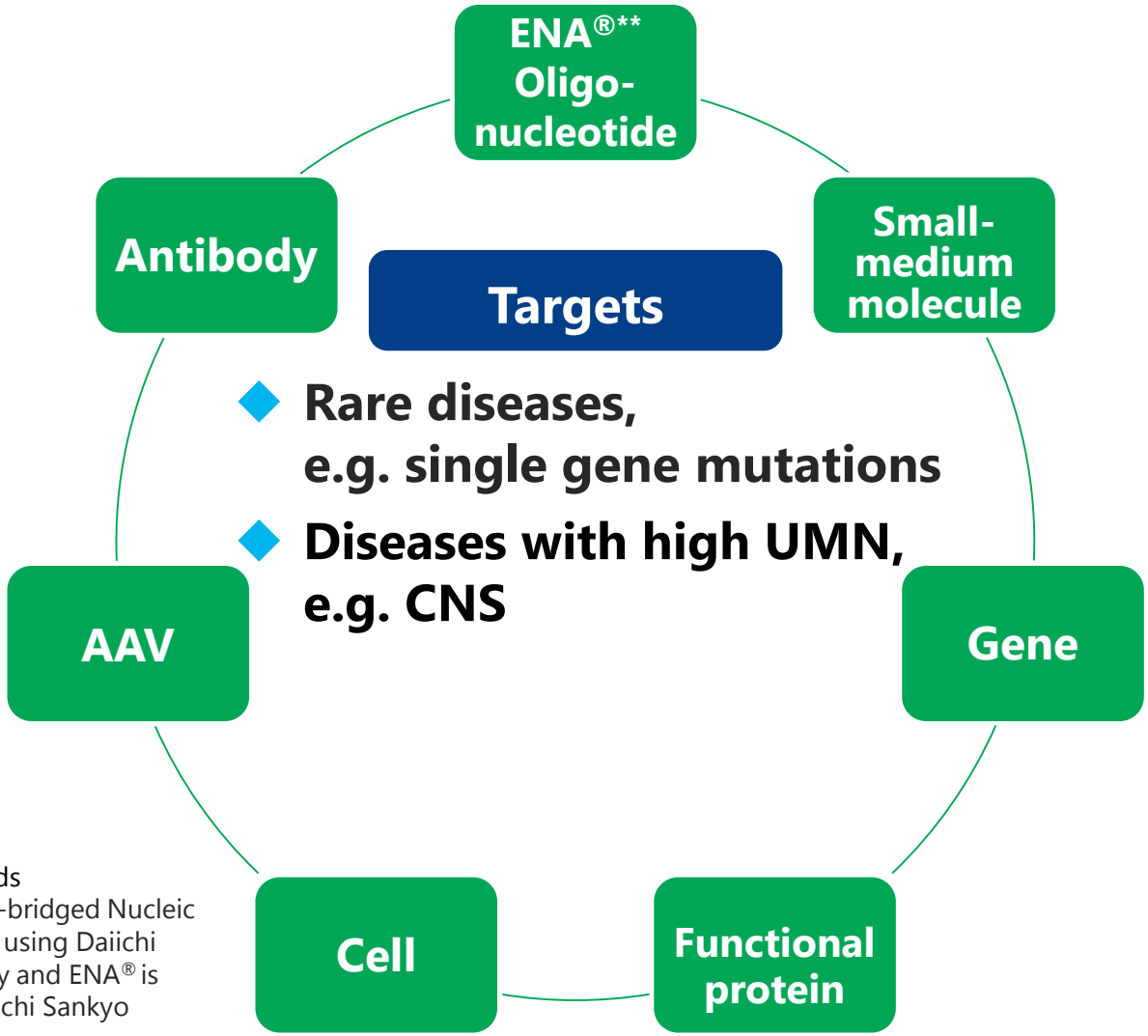
Mid-Long Term Specialty Medicine Vision

- **Provide innovative medicines to patients suffering from diseases for which effective treatments are not available or where existing treatments are not sufficiently effective**



Direction for Specialty Medicine

- Target diseases without effective treatment and with high UMN*
- Leverage our various modalities for a variety of etiologies



*UMN：unmet medical needs
** ENA®: 2′-O,4′-C-Ethylene-bridged Nucleic Acids, modified nucleic acid using Daiichi Sankyo's original technology and ENA® is registered trademark of Daiichi Sankyo

Projects Using ENA® Technology

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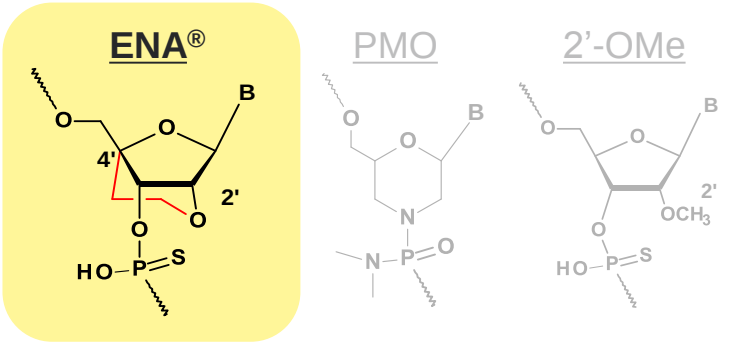
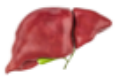
Superior profile

- **High affinity to DNA and RNA**
- **Excellent nuclease resistance**

=>Strong efficacy expected

e.g. effect on myocardial in Duchenne Muscular Dystrophy (DMD) patients



Target Organ	Target Disease (MoA)	DS#	Dosing Route	Stage
	DMD (Exon 45 skipping)	DS-5141	s.c.	Ph1/2
	DMD (Exon 44 skipping)	DS-5144	s.c.	Preclin.
	DMD (Exon 50 skipping)	DS-5150	s.c.	Preclin.
	DMD (Exon 51 skipping)	DS-5151	s.c.	Preclin.
	DMD (Exon 53 skipping)	DS-5153	s.c.	Preclin.
	GSD Ia* (splicing correction)	DS-4108	s.c.	Preclin.

*GSD Ia : glycogen storage disease type Ia

Project Using ENA® Technology: DS-5141

- **Co-development with ODTI***
- **Stage: Phase 1/2 (planning to obtain TLR at the end of CY2020)**

ENA® Oligo-nucleotide

Target Disease

Duchenne Muscular Dystrophy (amenable to Exon 45 skipping)

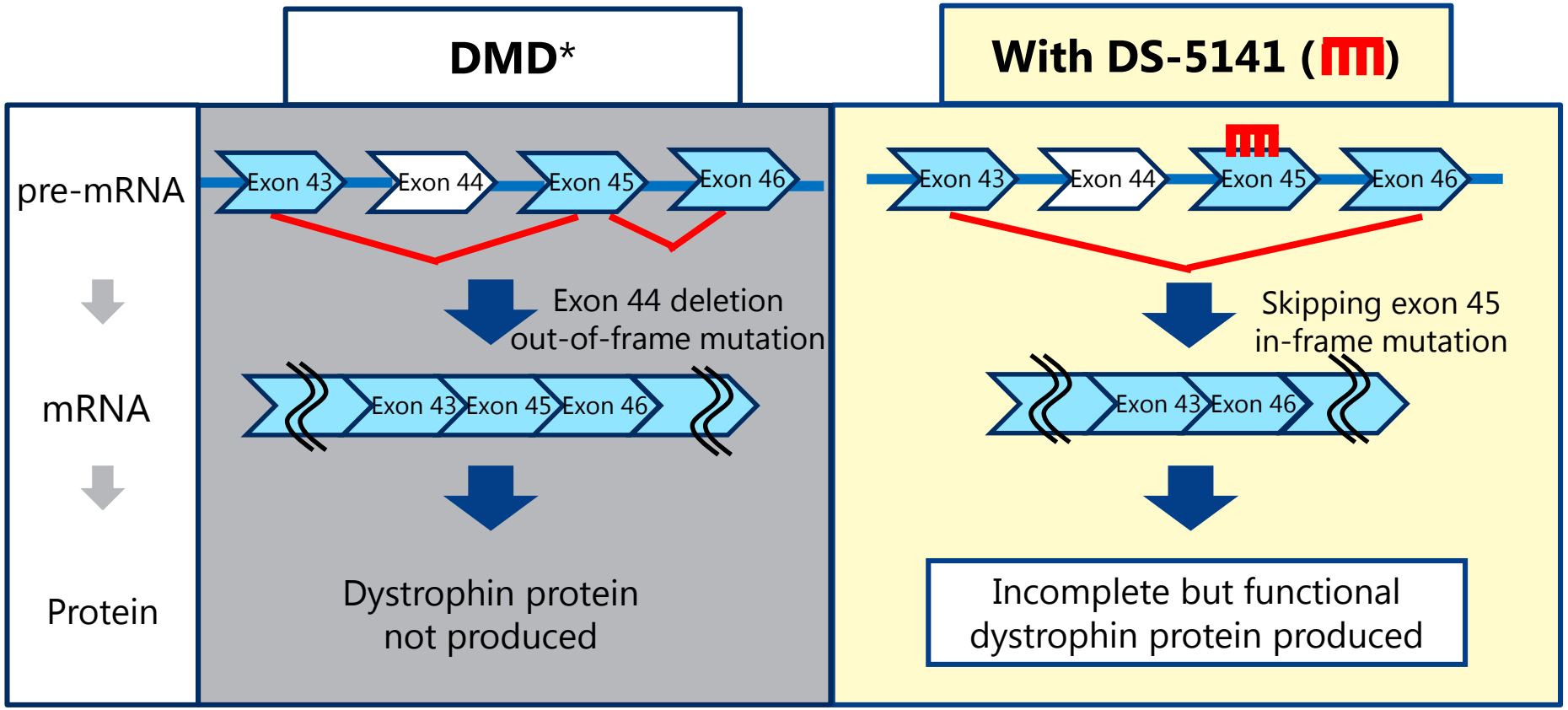
- X-linked recessive muscle disorder caused by abnormalities in the dystrophin gene resulting in the absence of dystrophin protein production
- Muscle weakness progresses with age, and many patients die of respiratory or cardiac failure in their 20s or 30s

Approved Drug Therapy	Prevalence**
◆ No Exon 45 skipping drug is available ➢ Exon 51 skipping: Eteplirsen (Sarepta) ➢ Exon 53 skipping: Golodirsen (Sarepta)	1 in 3,500 boys Source: Ann Neurol. 2012 Mar;71(3):304-13

*Orphan Disease Treatment Institute Co., Ltd. (ODTI was founded in 2013 through joint investment with a fund run by the Innovation Network Corporation of Japan and Mitsubishi UFJ Capital Company Limited.)
**Patients expected to benefit from Exon 45 Skipping treatment

DS-5141: Potential Treatment Pathway for DMD

- **ENA® oligonucleotide modifies the reading frame by skipping Exon 45 during the splicing process, leading to the production of incomplete but functional dystrophin proteins**



* DMD: Duchenne Muscular Dystrophy

Project Using ENA® Technology: DS-4108

- **Collaborative research with Kobe Gakuin University, National Center for Child Health and Development, and Hiroshima University**
- **Stage: Preclinical**

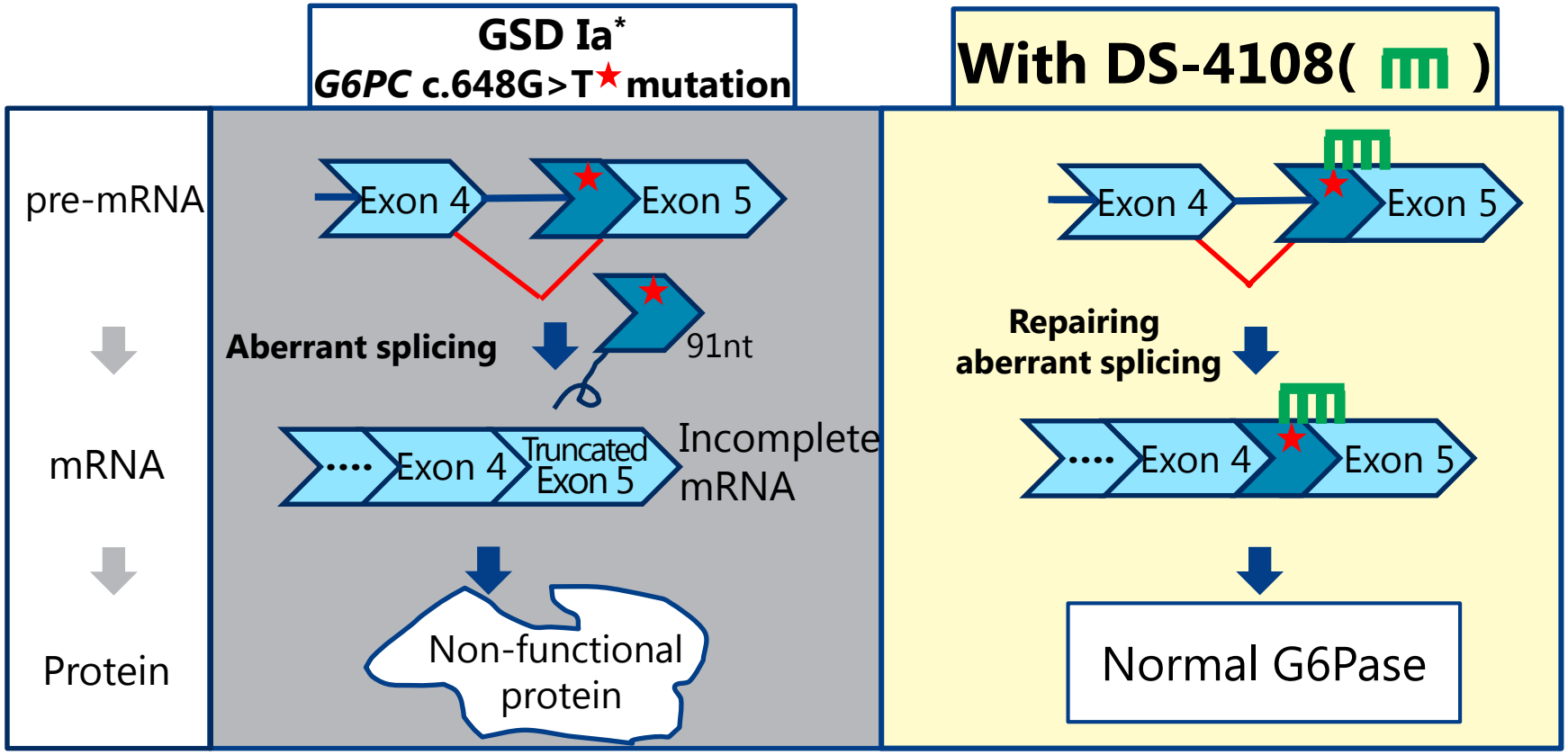
ENA® Oligo-nucleotide

Target Disease
Glycogen storage disease type Ia (with *G6PC* c.648G>T) ◆ Congenital deficiency of glucose-6-phosphatase (G6Pase, gene name: *G6PC*) causes fasting hypoglycemia, hepatomegaly, and hepatic adenomal ◆ *G6PC* c.648G>T is common mutation in East Asia including Japan and aberrant splicing causes lack of G6Pase function

Approved Drug Therapy	Prevalence
◆ No medical therapy currently available ➢ Symptom management with strict diet: frequent intake (7-8/day) of unheated corn starch / special milk for the treatment of glycogen disease and continuous infusion at night to prevent hypoglycemia. Lactose, sucrose, fructose intake restriction to prevent acidosis	1 in 100,000 new born Source: https://www.shouman.jp/disease/details/08_05_066/

DS-4108: Potential Treatment Pathway for GSD Ia

- **Correct the aberrant splicing by ENA® oligonucleotide and induce production of normal G6Pase**



*GSD Ia : Glycogen storage disease type Ia

Other Rare Disease Project: DS-1211

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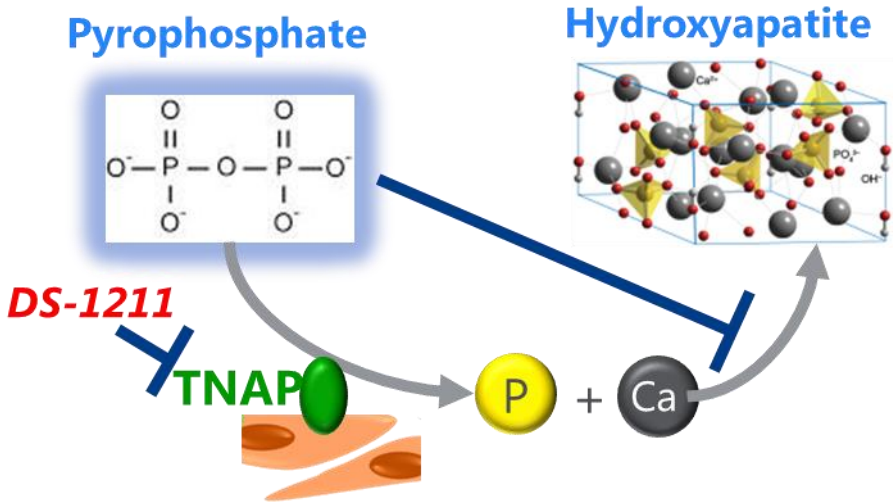
◆Stage: Phase 1

Low Molecule

Mode of Action	Target Disease
TNAP* inhibitor  	**Pseudoxanthoma elasticum (PXE)** ◆ Mutation in *ABCC6* gene results in low level of a calcification inhibitor, pyrophosphate, leading to skin lesions, visual impairments, cardiovascular diseases, and gastrointestinal disorders
Approved Drug Therapy	**Estimated Number of Patients**
◆ No medical therapy currently available	JP/US/EU5: 160,000 Source: Calculated based on Uitto et al., Expert Opin Orphan Drugs. 2014

*TNAP: tissue nonspecific alkaline phosphatase

Other Rare Disease Project: DS-6016

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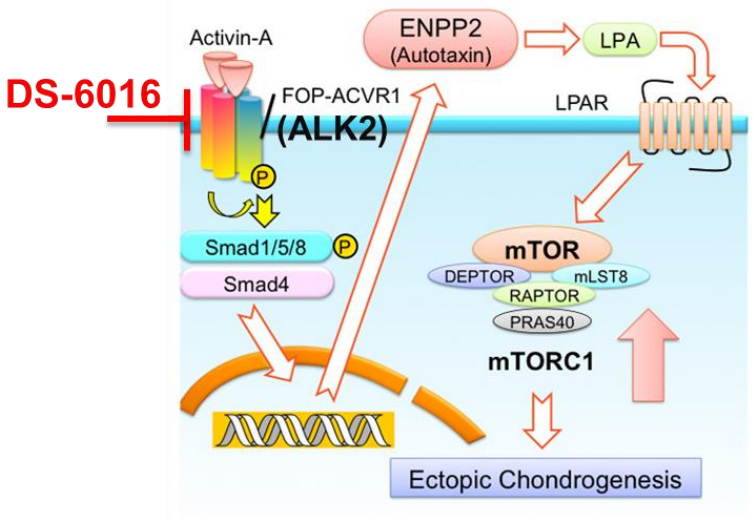
Novel Antibody

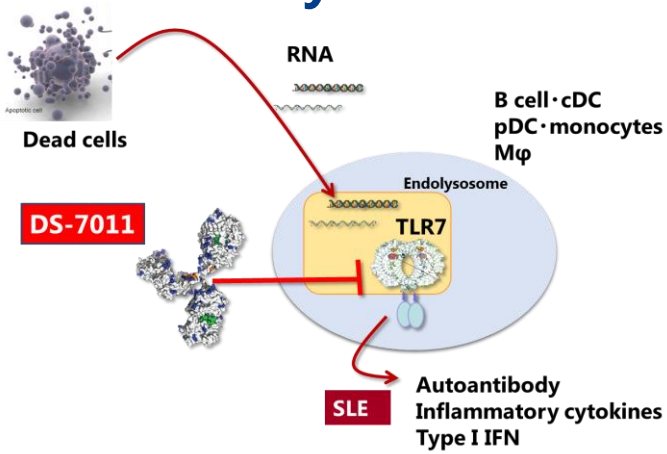
- **Collaborative research with Saitama Medical University**
- **Stage: Preclinical**
- **August 2017: adopted for support under CiCLE program of AMED**

Mode of Action	Target Disease
Anti-ALK2 antibody 	**Fibrodysplasia Ossificans Progressiva (FOP)** ◆ *ALK2* genes (responsible for osteogenesis) mutation cause activated *ALK2* to transmit excessive osteogenic signals and form bone in tissues that are not normally formed ◆ Decreased mobility due to osteogenesis worsens with age and total mobility assistance is usually required in people aged 40 years and older
Approved Drug Therapy	**Estimated Number of Patients**
◆ No medical therapy currently available	Japan: 60-84, US: 285 Source: https://www.nanbyou.or.jp/entry/54 Source: https://www.ifopa.org/what_is_fop

Non-Rare Disease Project: DS-7011

- **Collaborative research with the Institute of Medical Science, The University of Tokyo**
- **Stage: Preclinical**
- **December 2019: adopted for support under CiCLE program of AMED**

Novel Antibody

Mode of Action	Target Disease
Anti-TLR7 antibody 	**Systemic lupus erythematosus(SLE)** ◆ Autoimmune diseases that cause systemic symptoms such as fever and malaise, and inflammation of joints, kidneys, and skin
Approved Drug Therapy	**Estimated Number of Patients**
◆ Belimumab (GSK)	JP/US/EU5: 530,000 Source: DRG Landscape & Forecast Systemic Lupus Erythematosus Nov 2018

R&D Update

3ADCs: DS-8201 Update

Alpha: Specialty Medicine Update

Upcoming News

3ADCs: Upcoming News

As of January 2020

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DS-8201

HER2 Positive mBC Pivotal Phase 2 Study

- US: **approved in Dec. 2019 and launched in Jan. 2020**
- JP: NDA submitted and accepted on Sep. 9, 2019
- EU: MAA submission planned for 1H FY2020
- **Updated data presentation planned at ASCO 2020**

HER2 Positive mGC Pivotal Phase 2 Study

- JP: **TLR obtained in Jan. 2020**
  sNDA planned in 1Q FY2020
- **Presentation planned at ASCO 2020**

CRC, NSCLC phase 2 studies

- **Presentation planned at ASCO 2020**

DS-1062

NSCLC phase 1 study

- **Update on dose expansion part planned at ASCO 2020**

U3-1402

EGFRmNSCLC phase 1 study

- **Update on dose expansion part planned at WCLC 2020**

Underlined in red: new or updated from Q2 FY2019

Alpha: Upcoming News

As of January 2020

Daiichi-Sankyo

Pexidartinib		Tenosynovial Giant Cell Tumor • EU: under review for 1H FY2020 decision
DS-1647 (G47Δ)		Malignant Glioma • JP: NDA submission in 2H FY2019

Underlined in red: new or updated from Q2 FY2019

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FY2019 R&D Major Milestones

As of January 2020

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	Project	Target Indications and Studies	FY2019				FY2020
			Q1	Q2	Q3	Q4	Q1~
3 ADCs	DS-8201	P2 pivotal: breast cancer (HER2 positive post T-DM1)		JP/US submitted	**US approved**	**US launched**	EU submission
		P2 pivotal: gastric cancer (HER2 positive, 3L) (JP/Asia)				**TLR**	JP submission
		P2: gastric cancer (HER2 positive post trastuzumab) (US/EU)			**Study started**		
		P1: breast cancer and NSCLC with pembrolizumab (US/EU)			→	**Study start planned**	
	U3-1402	P1: NSCLC (JP/US)		Started dose expansion			
	DS-1062	P1: NSCLC(JP/US)		Started dose expansion			
Alpha	Quizartinib	P3: AML (relapsed/refractory)	JP approved US CRL		JP launched EU EMA CHMP negative opinion		
	Pexidartinib	P3: tenosynovial giant cell tumor (US/EU)		US approved/ launched			EU decision
	DS-1647	IIS: malignant glioma (JP)				Submission	
	DS-3201	P2: Adult T-cell leukemia/lymphoma (JP)			**Study started**		
		P1: small cell lung cancer (US)	Study started				
	DS-1205	P1: NSCLC with osimertinib (Asia)	Study started				
	DS-7300	P1/2: solid tumors (JP/US)			Study started		
	DS-6157	P1: gastrointestinal stromal tumors (GIST)				Study start planned	
	Laninamivir	P3: influenza (nebulizer formulation) (JP)	Approved		Launched		
	DS-2741	P1: atopic dermatitis (JP)				**Study started**	

AML: acute myeloid leukemia, CRL: complete response letter, IIS: investigator initiated study, NSCLC: non-small-cell lung cancer

Underlined in red: new or updated from Q2 FY2019, blue: achieved

Major R&D Pipeline

As of January 2020

Daiichi-Sankyo

		Generic Name/Project Code/ MOA	Target Indication	Region	Stage
3 ADCs		Trastuzumab deruxtecan/ DS-8201/anti-HER2 ADC	Breast cancer (HER2 positive post T-DM1)	JP/EU/Asia	NDA ★P2
			Breast cancer (HER2 positive vs T-DM1)	JP/US/EU/ Asia	P3
			Breast cancer (HER2 low expression)	JP/US/EU/ Asia	P3
			Gastric cancer (HER2 positive, 3L)	JP/Asia	★P2
			Gastric cancer (HER2 positive, 2L	US/EU	P2
			Colorectal cancer (HER2 positive)	JP/US/EU	P2
			NSCLC (HER2 positive/mutant)	JP/US/EU	P2
			Breast and bladder cancer (with nivolumab)	US/EU	P1
			Breast and NSCLC (with pembrolizumab)	US/EU	P1 prep
		U3-1402/anti-HER3 ADC	Breast cancer (HER3 expressing)	JP/US	P1
			EGFRm NSCLC	JP/US	P1
		DS-1062/anti-TROP2 ADC	NSCLC	JP/US	P1
Alpha	Oncology	Quizartinib/FLT3 inhibitor	AML (relapsed/refractory)	US/EU/Asia	P3
			AML (1st line)	JP/US/EU/ Asia	P3 LCM
		Pexidartinib/ CSF-1/KIT/FLT3 inhibitor	Tenosynovial giant cell tumor	EU	NDA
		Axicabtagene ciloleucel/ Axi-Cel®/anti-CD19 CAR-T	B-cell lymphoma	JP	★P2
		DS-1647(G47Δ)/oncolytic HSV-1	Malignant glioma	JP	★P2
		Valemetostat/ DS-3201/EZH1/2 inhibitor	Adult T-cell leukemia/lymphoma	JP	★P2
			Non-Hodgkin's Lymphoma (PTCL)	JP/US	P1
			AML, ALL	US	P1
			Small cell lung cancer	US	P1
		Milademetan/ DS-3032/MDM2 inhibitor	Solid tumor (liposarcoma)	JP/US	P1
			AML	JP/US	P1

		Generic Name/Project Code/ MOA	Target Indication	Region	Stage
Alpha	Oncology	PLX2853/BET inhibitor	AML	US	P1
		DS-1001/ Mutant IDH1 inhibitor	Glioma	JP	P1
		DS-1205/AXL inhibitor	NSCLC (with gefitinib)	JP	P1
			NSCLC (with osimertinib)	Asia	P1
		DS-7300/anti-B7-H3 ADC	Solid tumor	JP/US	P1
	Specialty Medicines	Edoxaban/FXa inhibitor	Atrial fibrillation in the very elderly	JP	P3 LCM
		Prasugrel/anti-platelet agent	Ischemic stroke	JP	P3 LCM
		Esaxerenone/MR-Antagonist	Diabetic nephropathy	JP	P3 LCM
		Mirogabalin/$\alpha_2\delta$ ligand	Central neuropathic pain	JP/Asia	P3 LCM
		DS-1040/TAFIa inhibitor	Acute ischemic stroke, acute pulmonary thromboembolism	JP/US/EU	P1
		DS-5141/ENA-oligonucleotide	Duchenne type muscular dystrophy	JP	P1
		DS-1211/TNAP inhibitor	Inhibition of ectopic calcification	US	P1
		DS-2741/anti-Orai 1 antibody	Atopic dermatitis	JP	P1
	Vaccine	VN-0107/MEDI3250/ live attenuated influenza vaccine nasal spray	Prophylaxis of seasonal influenza	JP	NDA
		VN-0105/DPT-IPV/Hib	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib infection	JP	P3
		VN-0102/JVC-001/ Measles-mumps-rubella vaccine	For measles, mumps, and rubella prophylaxis	JP	P3 prep

ALL: acute lymphocytic leukemia, AML: acute myeloid leukemia, IIS: investigator initiated study, NSCLC: non-small-cell lung cancer, PTCL: peripheral T-cell lymphoma
★: Project in Oncology that is planned to be submitted for approval based on the results of Phase 2 trials
: SAKIGAKE Designation (Japan) and Orphan Drug Designation (JP/US/EU)

Projects for Out-Licensing

As of January 2020

	Discovery/Pre-clinical	Phase 1
Oncology		**DS-1001: IDH1 mutant inhibitor** Glioma (other than JP)
Specialty Medicine	**Tryptophanase inhibitor** Uremia / Late stage chronic kidney disease **Long Acting ANP: Long Acting GC-A activator** Resistant hypertension / Chronic heart failure	

Abbreviations

Abbreviations	English	Implications
AE	Adverse event	Undesirable experience associated with the use of a medical product in a patient
BTD	Breakthrough therapy designation	Designation granted by US FDA that expedites drug development
CR	Complete response	Complete response (complete resolution of cancer)
CRL	Complete response letter	Letter issued by the FDA after completion of its review and determined the application cannot be approved based on the current submission
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	Length of time that a tumor responds to treatment
EGFR	Epidermal growth factor receptor	Epidermal growth factor receptor
MTD	Maximum tolerated dose	The highest dose of a drug or treatment that does not cause unacceptable side effects
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	Progressive 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
TEAE	Treatment emergent adverse event	Any event not present prior to the initiation of the treatments or any event already present that worsens in either intensity or frequency following exposure to the treatments

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