

A large, dark green geometric shape, resembling a stylized 'S' or a folded corner, occupies the left side of the slide. It has a lighter green horizontal bar at the top right.

Conference on Q1 FY2026 (April 1, 2026 to June 30, 2026) **Financial Results**

Sumitomo Pharma Co., Ltd.
July 31, 2026

■ Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of disclosure of such statements and involve both known and unknown risks and uncertainties.

Accordingly, due to various subsequent factors, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.

Information concerning pharmaceuticals and other products (including those under development) contained herein is not intended as advertising or as medical advice.



Financial Results for Q1 FY2026

Financial Results for Q1 FY2026

Financial Results for Q1 FY2026 (Core Basis)

The forecasts for FY2026 are not revised

Billions of JPY

	Q1YTD FY2025 Results	Q1YTD FY2026 Results	Change			FY2026	
			Value	FX impact	%	May 13 forecasts	Progress %
Revenue	108.0	129.5	21.5	9.5	19.9	540.0	24.0
Cost of sales	44.1	61.4	17.3	3.1	39.2	245.0	25.1
Gross profit	63.9	68.1	4.2	6.4	6.6	295.0	23.1
SG&A expenses	35.4	39.0	3.6	2.1	10.1	155.0	25.1
R&D expenses	8.1	11.4	3.3	0.7	41.2	51.0	22.4
Others (core basis)	(0.1)	0.4	0.5			2.0	
Core operating profit	20.4	18.1	(2.2)	3.5	(11.0)	91.0	19.9
Adjustment items (negative number indicates net expense)	0.0	0.1	0.0			(1.0)	
Operating profit	20.4	18.2	(2.2)		(10.8)	90.0	20.2
Finance income/costs	(8.5)	0.1	8.6			(6.5)	
Profit before taxes	11.9	18.3	6.4		53.3	83.5	21.9
Income tax expenses	0.7	1.3	0.6			6.5	
Net profit attributable to owners of the parent	11.2	17.0	5.8		51.7	77.0	22.1

- **Revenue**
Revenue increased primarily due to growth in the U.S., which more than offset the decrease resulting from the partial transfer of the Asian business
- **Gross profit**
Gross profit margin decreased mainly due to the partial transfer of the Asian business
- **R&D expenses**
R&D expenses increased due to increased momentum in clinical studies in the oncology area and advancement of programs in the CNS area

Average rates:

Q1 FY2025 Results : 1US\$ = ¥144.60

Q1 FY2026 Results : 1US\$ = ¥159.57

FY2026 forecasts : 1US\$ = ¥155.00

Period end rates:

As of the end of March 2026 : 1US\$ = ¥159.90

As of the end of June 2026 : 1US\$ = ¥162.39

Financial Results for Q1 FY2026

Revenue of Major Products in U.S.

	Q1YTD FY2025 Results	Q1YTD FY2026 Results	Change	Q1YTD FY2025 Results	Q1YTD FY2026 Results	Change			FY2026		
						Value	FX impact	%	May 13 forecasts		JPY-basis Progress %
U.S.	Millions of USD			Billions of JPY					Millions of USD	Billions of JPY	
ORGOVYX®	226	323	97	32.7	51.6	18.9	4.8	57.6	1,354	209.9	24.6
GEMTESA®	147	189	42	21.3	30.2	9.0	2.8	42.1	686	106.3	28.4
MYFEMBREE®	20	30	11	2.9	4.9	2.0	0.5	70.0	100	15.4	31.4
RETHYMIC®	6	11	6	0.8	1.8	1.0	0.2	121.3	35	5.4	33.2
APTiom®	49	8	(41)	7.1	1.3	(5.8)	0.1	(81.9)	35	5.4	23.7
Others	36	28	(8)	5.2	4.5	(0.7)	0.4	(13.6)	412	63.9	7.1
Total	484	591	107	69.9	94.3	24.4	8.9	34.9	2,622	406.4	23.2

■ ORGOVYX® and GEMTESA® quarterly revenue increased significantly year-on-year

■ APTiom® revenue decreased due to loss of exclusivity

Average rates:

Q1 FY2025 Results : 1US\$ = ¥144.60

Q1 FY2026 Results : 1US\$ = ¥159.57

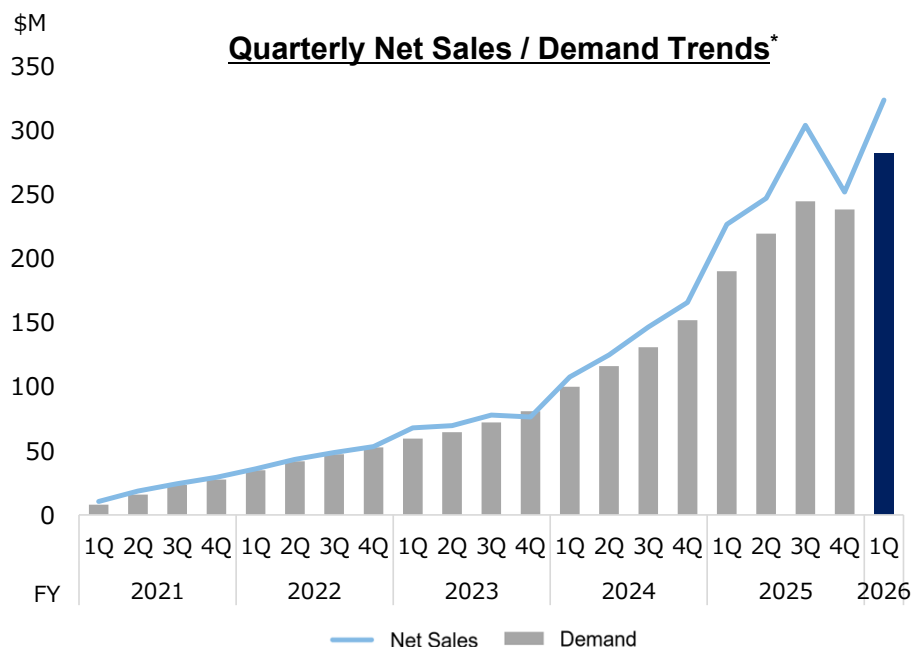
Financial Results for Q1 FY2026



Plan for Q1 YTD FY2026	Actual for Q1 YTD FY2026	Year-over-year comparison
\$318M	\$323M (Achievement 102%)	143%

□ Volume: In line with expectations

□ Price: Favorable payer mix



<Topics>

- New patient starts have grown and reached all-time quarterly high, driven by deep penetration of Orgovyx's clinical benefits and improved patient affordability in Medicare following out-of-pocket cost cap reductions
- Continued share expansion not only in key segments such as urology clinics, but also in oncology accounts
- DTC promotional campaign to further increase patient awareness and drive patient requests

* Number of bottles (Internal calculation)

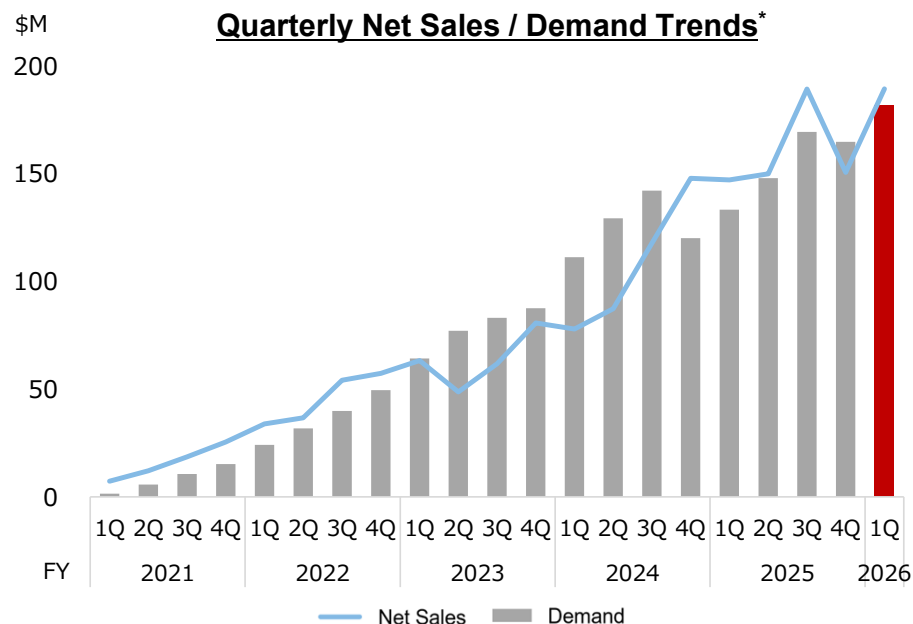
Financial Results for Q1 FY2026



Plan for Q1 YTD FY2026	Actual for Q1 YTD FY2026	Year-over-year comparison
\$163M	\$189M (Achievement 116%)	129%

□ Volume: In line with expectations

□ Price: Favorable payer mix



<Topics>

- Continued share gains through clinical differentiation in the growing β 3 market
- Prescription volume reached near parity with competitors; expanding initiatives to drive incremental demand
- Advancing both market access expansion and price optimization amid evolving payer dynamics

Financial Results for Q1 FY2026

Revenue of Major Products in Japan

Billions of JPY

	Q1YTD FY2025 Results	Q1YTD FY2026 Results	Change		FY2026	
			Value	%	May 13 forecasts	Progress %
Japan						
XEPLION®/XEPLION TRI®	—	4.1	4.1	—	17.1	24.0
LATUDA®	3.5	3.7	0.2	6.8	13.6	27.3
TWYMEEG®	2.4	3.3	0.8	33.5	11.9	27.3
METGLUCO®	1.9	1.9	0.1	3.4	7.6	25.1
Equa®/EquMet®	4.2	—	(4.2)	—	—	—
AG products	3.1	3.0	(0.1)	(2.2)	11.2	26.8
Others	6.2	6.3	0.0	0.3	26.2	23.9
Total	21.3	22.2	1.0	4.6	87.6	25.4

- Commencement of sales of XEPLION[®]/XEPLION TRI[®]
- Continued growth of TWYMEEG[®]
- Termination of sales of Equa[®]/EquMet[®]

Note: Sales of each product are shown by invoice price

Financial Results for Q1 FY2026

Gross Profit by Region (Core Basis)

Billions of JPY

		Japan	U.S.	Other	Total
Q1YTD FY2026 Results	Revenue	22.2	94.3	13.0	129.5
	Cost of sales	12.5	37.3	11.6	61.4
	Gross profit	9.7	57.0	1.3	68.1

Q1YTD FY2025 Results	Revenue	21.3	69.9	16.8	108.0
	Cost of sales	10.8	27.5	5.9	44.1
	Gross profit	10.5	42.4	11.0	63.9

Change	Revenue	1.0	24.4	(3.9)	21.5
	Cost of sales	1.7	9.8	5.8	17.3
	Gross profit	(0.8)	14.6	(9.6)	4.2

Japan

- XEPLION®/XEPLION TRI® contributed to keeping revenue stable, but gross profit decreased due to the change in product mix

U.S.

- Gross profit increased due to increased revenue

Other

- Gross profit decreased due to the partial transfer of the Asian business

Marketing and Sales in Japan

■ Wegovy® Subcutaneous Injection Receives Additional Approval for Metabolic Dysfunction-Associated Steatohepatitis (MASH) Without Cirrhosis

- Wegovy® Subcutaneous Injection, co-promoted with Novo Nordisk Pharma for obesity disease, receives approval for an additional indication for MASH*¹
- In accordance with the Package Insert and the Proper Use Promotion Guideline, Sumitomo Pharma and Novo Nordisk Pharma will work closely to provide information to healthcare professionals to support the appropriate use of the product

Wegovy®



Estimated MASH data in Japan*^{2,3}

Number of patients	Approximately 3.7M (Approximately 3.0% of the population)
Direct medical costs	Approximately ¥180B
Productivity loss	Approximately ¥2.1T

*These estimates represent the total MASH patient population in Japan and are not indicative of the number of patients eligible for Wegovy® or future sales forecasts. Wegovy® is indicated for patients with MASH without cirrhosis who have moderate or advanced liver fibrosis

Providing the first approved treatment in Japan for MASH, an area with high unmet medical needs

Key products in the diabetes area, including obesity disease

TWYMEEG®

METGLUCO®

Ozempic®

Wegovy®

- The diabetes area (including obesity disease) is one of our key strengths and focus areas in Japan
- Leveraging our accumulated expertise and network with healthcare institutions

*1 MASH is a chronic progressive disease characterized by liver inflammation and fibrosis associated with metabolic dysfunction. This approval covers an additional indication for metabolic dysfunction-associated steatohepatitis (MASH) without cirrhosis in patients with moderate to advanced fibrosis.

*2 Based on a prevalence of 3% reported in Journal of Hepatology 69.4 (2018): 896–904, the number of patients was estimated using a Japanese population of 124 million

*3 The Japan Research Institute, Limited. Report on Improving Access to Diagnosis and Treatment for Patients with MASLD/MASH in Japan. April 24, 2026, p.8



Research and Development

Research and Development

Development Pipeline (As of July 31, 2026)

Revisions since the announcement in May 2026 are shown in red

Area	Generic Name/Product Code	Mechanism of Action, etc.	Planned Indication(s)	Development Stage
Psychiatry & Neurology	DSP-0038	Serotonin 5-HT _{2A} receptor antagonist and serotonin 5-HT _{1A} receptor agonist	Alzheimer's disease psychosis	Phase 1
	DSP-0187	Selective orexin-2 receptor agonist	Narcolepsy	Phase 1
	DSP-3456	Metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM)	Treatment resistant depression	Phase 1
	DSP-0378	Gamma-aminobutyric acid (GABA) _A receptor positive allosteric modulator	Progressive Myoclonic Epilepsy Developmental Epileptic Encephalopathy	Phase 1
	DSP-2342	Serotonin 5-HT _{2A} and 5-HT ₇ receptor antagonist	To be determined	Phase 1
	DSP-0551	Multi-ion channel modulator	Tremor associated with Parkinson's disease	Phase 1
	CT1-DAP001/DSP-1083 (Japan)	Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells	Parkinson's disease	Conditional and time-limited approval obtained (Mar 2026) ⇒ Post-marketing clinical study ongoing
	CT1-DAP001/DSP-1083 (U.S.)	Allogeneic iPS cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study, Company- sponsored clinical study	Phase 1/2
	HLCR011(Japan)	Allogeneic iPS cell-derived retinal pigment epithelial cells	Retinal pigment epithelium tear	Phase 1/2
	DSP-3077(U.S.)	Allogeneic iPS cell-derived retinal sheet	Retinitis pigmentosa	Phase 1/2
Oncology	Enzomenib	Selective menin inhibitor	Acute leukemia	Phase 2
	Nuvisertib	PIM1 kinase inhibitor	Myelofibrosis	Phase 1/2
	SMP-3124	CHK1 inhibitor	Solid tumors	Phase 1/2
	DSP-0390	EBP inhibitor	Glioblastoma	Phase 1
Others	KSP-1007	β-lactamase inhibitor	Complicated urinary tract and intraabdominal infections, Hospital-acquired bacterial pneumonia	Phase 1
	fH1/DSP-0546LP	Split, Adjuvanted vaccine	Influenza virus prophylaxis	Phase 1

Research and Development

■ Major Topics in Clinical Development (May 14 – July 31, 2026)

● Psychiatry & Neurology

■ AMCHEPRY® (Japan)

Post-marketing Clinical Study (Phase 4 Study)

- Entered into an agreement with Kyoto University Hospital
- Clinical study information was published in the Japan Registry of Clinical Trials (jRCT) and patient enrollment has commenced (See page 13 for details)

Received the 10th Japan Bioindustry Award

【Award Theme】 Development of the regenerative medicine product “AMCHEPRY®”

【Award Recipients】 Sumitomo Pharma Co., Ltd., RACTHERA Inc., Kyoto University Joint Research Group

● Oncology

■ Enzomenib (U.S., Japan)

- Completed enrollment required for the interim analysis in the pivotal Phase 2 study of monotherapy in patients with relapsed or refractory KMT2A-rearranged Acute Leukemia
- Initiated patient enrollment in the pivotal Phase 2 study of monotherapy in patients with relapsed or refractory NPM1-mutated Acute Myeloid Leukemia (see page 14 for details)
- Received Orphan Drug Designation (ODD) from the U.S. FDA for Acute Lymphoblastic Leukemia in July 2026

■ Nuvisertib (U.S., Japan)

- Presented interim analysis data from the Phase 1/2 study of nuvisertib in combination with momelotinib at the European Hematology Association (EHA) Congress held in June 2026 (see page 15 for details)

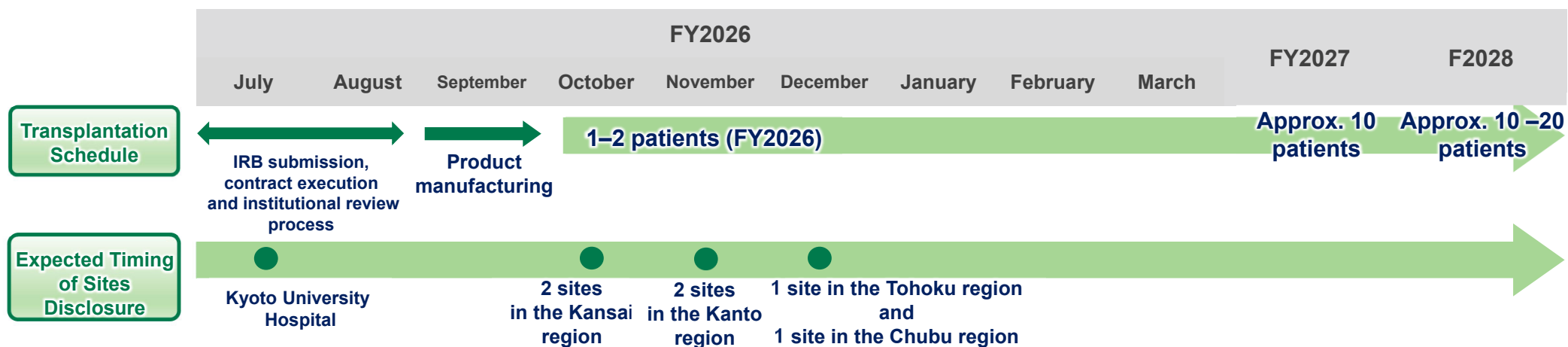
■ SMP-3124 (U.S., Japan)

- Presented the first clinical data at the American Society of Clinical Oncology (ASCO) Annual Meeting held in June 2026 (see page 17 for details)

Research and Development

■ AMCHEPRY® Post-Marketing Clinical Study (Phase 4 Study) Schedule

- Advancing site activation and patient enrollment readiness for the Phase 4 study
- The first patient transplantation is planned for fall 2026, followed by approximately 10 patients in FY2027 and approximately 10–20 patients in FY2028
- Priority will be given to patients enrolled in the Phase 4 study. Following completion of the Phase 4 study, treatment availability will be expanded to additional sites and a broader patient population



Please note that inquiries regarding the AMCHEPRY® post-marketing clinical study (Phase 4 study) are not accepted by participating medical institutions. Please contact us via our [corporate inquiry form](#)

Research and Development

Enzomenib Monotherapy Phase 2 Study (Pivotal Portion)

KMT2A Rearrangement

- Completed enrollment required for the interim analysis of the pivotal portion in relapsed/refractory acute leukemia study

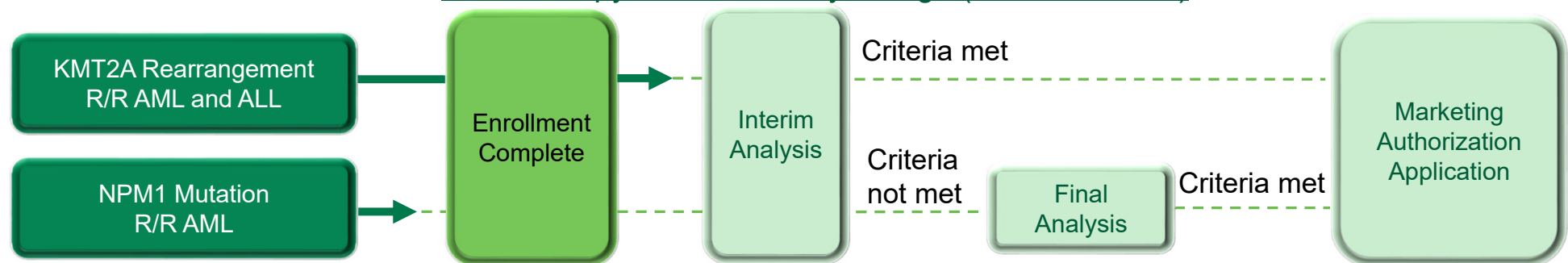
* Enrollment was successfully completed across approximately 90 sites globally through continuous collaboration with physicians via scientific congresses, investigator meetings, and other activities

- Based on the results of the interim analysis planned for Q3 FY2026, we aim to promptly submit marketing authorization applications in Japan and the U.S.

NPM1 Mutation

- Determined the recommended dose of 300 mg BID and initiated enrollment in the pivotal portion of the relapsed/refractory acute myeloid leukemia study
- Planned to complete enrollment required for the interim analysis by FY2026 Q4

Monotherapy Phase 2 Study Design (Pivotal Portion)



R/R: Relapsed/Refractory AML: Acute Myeloid Leukemia ALL: Acute Lymphoblastic Leukemia

Key development milestones for enzomenib remain on track for FY2026

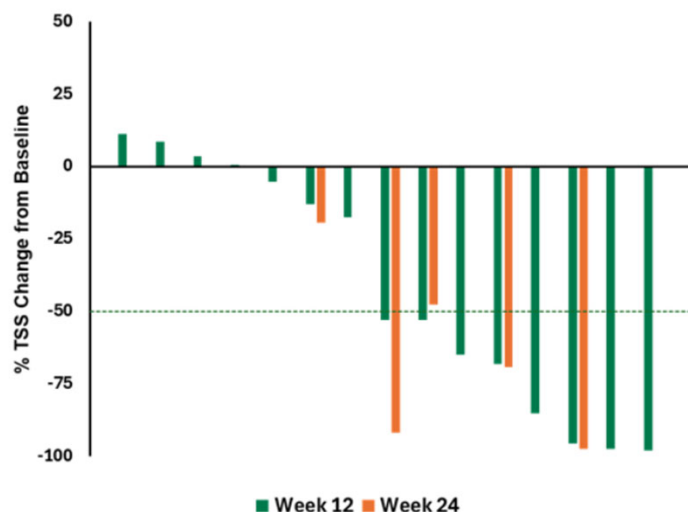
Nuvisertib Combination Therapy with Mometotinib for Relapsed/Refractory Myelofibrosis

【Efficacy】 In patients with myelofibrosis treated with nuvisertib (administered after meals) in combination with momelotinib, improvements were observed in two key efficacy endpoints: Total Symptom Score (TSS) and Spleen Volume (SV)

Percentage of Patients with $\geq 50\%$ Improvement in Total Symptom Score

At Week 12: 53% (8/15)

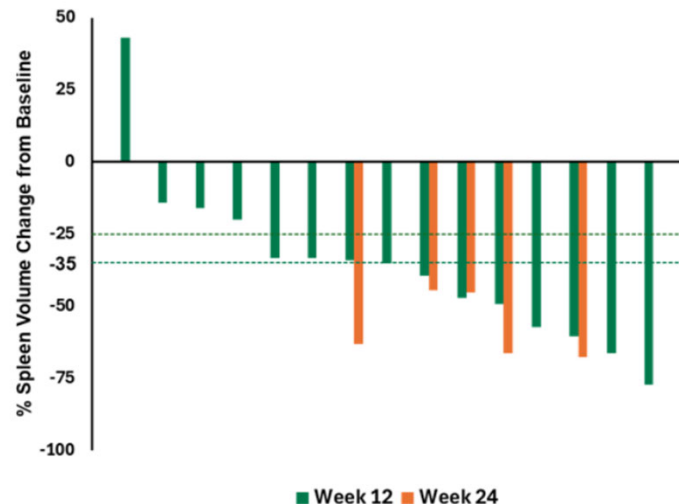
At Week 24: 60% (3/5)



Percentage of Patients with $\geq 25\%$ Reduction in Spleen Volume

At Week 12: 73% (11/15)

Week 24: 100% (5/5)

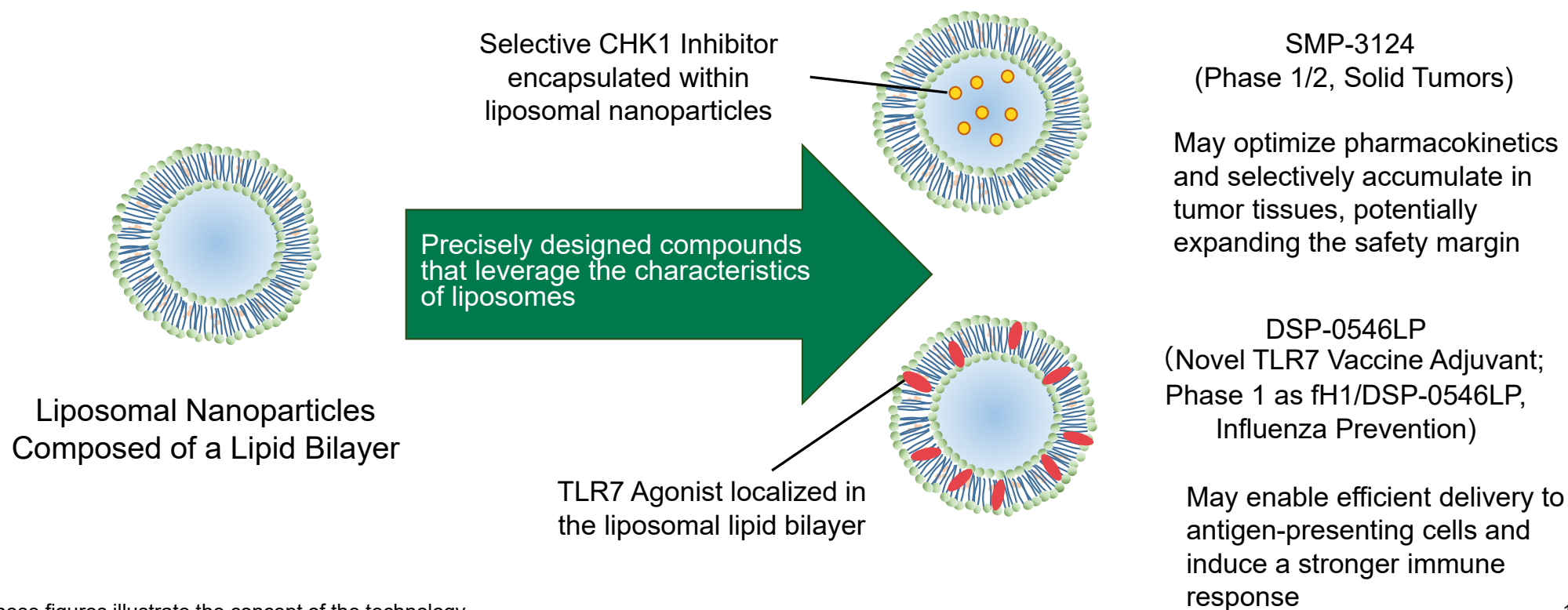


【Safety】

- No dose-limiting toxicities (DLTs) were observed in combination with momelotinib
- The most common adverse events were nausea (42.3%), diarrhea (23.1%), and constipation (23.1%), with no Grade 3 events observed. Platelet count decreased was observed in 6 of 26 patients (23.1%); however, three of these patients had thrombocytopenia at baseline

Expansion of the Liposomal Nanoparticle Technology Platform

- Proprietary drug discovery platform integrating compound design capabilities and liposomal DDS technology
- Creation of molecules optimized to maximize DDS functionality based on therapeutic area needs
- Drug delivery platform applicable across multiple discovery programs



* These figures illustrate the concept of the technology

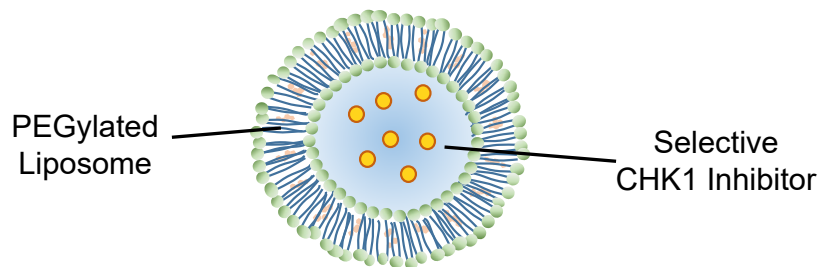
SMP-3124 First Clinical Data Presented at ASCO 2026

- Liposomal nanoparticle formulation may overcome limitations associated with conventional CHK1 inhibitors, including hematologic toxicity
- Currently advancing dose-optimization in tumor types that demonstrated signs of antitumor activity, including platinum-resistant ovarian cancer and squamous cell carcinoma of the anus

Overview of SMP-3124

Formulation / Modality

Injectable formulation of a selective CHK1 inhibitor delivered via a PEGylated liposome formulation



Proposed Mechanism of Action

CHK1 inhibition is believed to induce additional DNA damage in cancer cells with high replication stress, leading to cell death

Summary of Preliminary Results of SMP-3124

Safety

Generally well tolerated with a manageable safety profile

- Dose-limiting toxicities (DLTs) were observed only in higher-dose cohorts
- Hematologic adverse events were generally transient and did not lead to treatment discontinuation

Preliminary Antitumor Activity

- Disease control rate (DCR): 48.2%
- Five partial responses (PRs) were observed:
 - Platinum-resistant ovarian cancer: 2 patients
 - Squamous cell carcinoma of the anus: 2 patients
 - Colorectal cancer: 1 patient

Pharmacokinetics (PK)

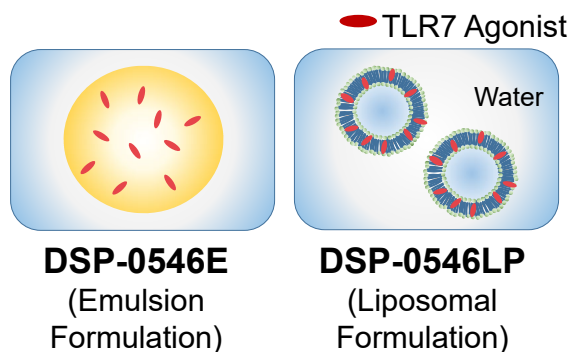
- Pharmacokinetic profile consistent with the characteristics of a liposomal formulation, including a long half-life and low volume of distribution

Business Strategy

Established the Vaccines and Adjuvants Business Development Office to Accelerate Commercialization of Our Proprietary TLR7 Adjuvant Technology

- Leveraging our proprietary adjuvant technology and vaccine R&D expertise, we aim to become an adjuvant solution provider, addressing diverse customer needs and building a global presence
- We envision a new business model that can address structural challenges facing the traditional pharmaceutical business by capturing market growth opportunities and establishing stable earnings

Our Proprietary Core Technology Novel TLR7 Adjuvant



- ✓ Extensive expertise in interferon research (Sumiferon, since the 1980s)
- ✓ Enhancement of cellular immunity
- ✓ Favorable safety profile

Growing Adjuvant Demand and Market Expansion



- ✓ Global adjuvant market
2024: JPY 570 billion
2030: JPY 735 billion (forecast)*¹
- ✓ Growing expectations for efficacy and safety
- ✓ Pandemic preparedness
- ✓ CEPI*²-supported library program

Vaccine Development Through Open Innovation

- ✓ Universal influenza vaccines
- ✓ Malaria vaccines

Expansion of the Adjuvant Business

- ✓ Partnerships with global vaccine developers
- ✓ Supply chain reshaping initiatives and others
- ✓ International network through CEPI programs

* 1 Source: Vaccine Adjuvants Market Size & Outlook, 2030

* 2 CEPI (Coalition for Epidemic Preparedness Innovations): An international funding organization that supports pharmaceutical companies and research institutions engaged in vaccine development

Research and Development

Revisions since the announcement in May 2026 are shown in red

Key Development Products: Major Milestones Scheduled in FY2026 (as of July 31, 2026)

Area	Program	Q1	Q2	Q3	Q4	Remarks
Psychiatry & Neurology	DSP-0378 (Progressive Myoclonic Epilepsy Developmental Epileptic Encephalopathy)				Initial PoC* ¹ acquisition	
	CT1-DAP001 / DSP-1083 (Parkinson's disease)			(Japan) First transplantation * ²		* ² Post-marketing clinical study
	DSP-3077 (Retinitis pigmentosa)			(U.S.) First transplantation * ³		* ³ Phase 1/2
Oncology	Enzomenib (Monotherapy, relapsed or refractory KMT2A-rearranged Acute Leukemia)	☑ Phase 2 Completion of enrollment for interim analysis		Phase 2 Interim analysis Top-line results		NDA filing (Q1 FY2027)
	Enzomenib (Monotherapy, relapsed or refractory NPM1-mutated Acute Myeloid Leukemia)	☑ Phase 2 Enrollment initiation			Phase 2 Completion of enrollment for interim analysis	
	Nuvisertib (Combination with momelotinib, newly diagnosed and relapsed or refractory Myelofibrosis)			Phase 3 Decision on recommended dose* ⁴		* ⁴ To be determined in consultation with the FDA
	SMP-3124 (Monotherapy, solid tumors)				Phase 2 Decision on recommended dose* ⁴	
Others	fH1/DSP-0546LP (Universal Influenza Vaccine)		Final analysis of 1-year follow-up* ⁵		CHIS* ⁶ study Initiation	* ⁵ One-year follow-up safety data, antibody persistence, and subtype specific immune response analyses (e.g., IgG2, IgG4)

* 1 Initial PoC (Proof of Concept): Preliminary confirmation of efficacy in patients based on a limited number of cases * 6 Controlled Human Infection Studies: Human challenge studies

Appendix

<Contents>

P.21	Q1FY2026
P.22	Q1FY2026
P.23	Q1FY2026
P.24	Q2FY2026 Forecast
P.25	R&D
P.26	R&D
P.27	R&D

Financial Results for Q1 FY2026 (Full Basis)
Financial Position and Cash Flow
Prescription Trends of GEMTESA®
FY2026 Forecast for the First Six Months (Core Basis)
Status of Preparations at Clinical Sites for the AMCHEPRY®
Post-marketing Clinical Study
Product Launch Target
Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (RACTHERA Co., Ltd.)

Appendix (Financial Results for Q1 FY2026)

Financial Results for Q1 FY2026 (Full Basis)

Billions of JPY

	Q1YTD FY2025 Results	Q1YTD FY2026 Results	Change	
			Value	%
Revenue	108.0	129.5	21.5	19.9
Cost of sales	44.1	61.4	17.3	39.2
Gross profit	63.9	68.1	4.2	6.6
SG&A expenses	35.7	39.2	3.6	10.0
R&D expenses	8.2	11.4	3.3	39.8
Other operating income and expenses	0.3	0.8	0.4	
Operating profit	20.4	18.2	(2.2)	(10.8)
Finance income and costs	(8.5)	0.1	8.6	
Profit before taxes	11.9	18.3	6.4	53.3
Income tax expenses	0.7	1.3	0.6	
Net profit attributable to owners of the parent	11.2	17.0	5.8	51.7

Appendix (Financial Results for Q1 FY2026)

Financial Position and Cash Flow

Billions of JPY

B / S	As of March 2026	As of June 2026	Change
Assets	804.6	844.9	40.3
Goodwill / Intangible assets	371.6	371.7	0.2
Other non-current assets	64.4	67.7	3.3
Cash and deposit / Short-term loan receivable	44.3	76.6	32.3
Liabilities	512.1	436.3	(75.8)
Bonds and borrowings	217.2	160.7	(56.5)
Other non-current liabilities	23.5	16.4	(7.0)
Other current liabilities	50.8	35.3	(15.5)
Equity	292.5	408.6	116.1
Share Capital	22.4	71.3	48.9
Capital Surplus	0.0	48.3	48.3
(Ratio of equity attributable to owners of the parent to total assets)	36.4%	48.4%	
C / F	Q1 FY2025	Q1 FY2026	Change
Operating CF	(0.2)	(7.4)	(7.3)
Investment CF	(4.3)	0.0	4.4
Financial CF	3.2	39.2	35.9
Cash and cash equivalents at beginning of year	23.1	44.3	21.2
Cash and cash equivalents at end of period	20.5	76.6	56.2

← Repayment of borrowings

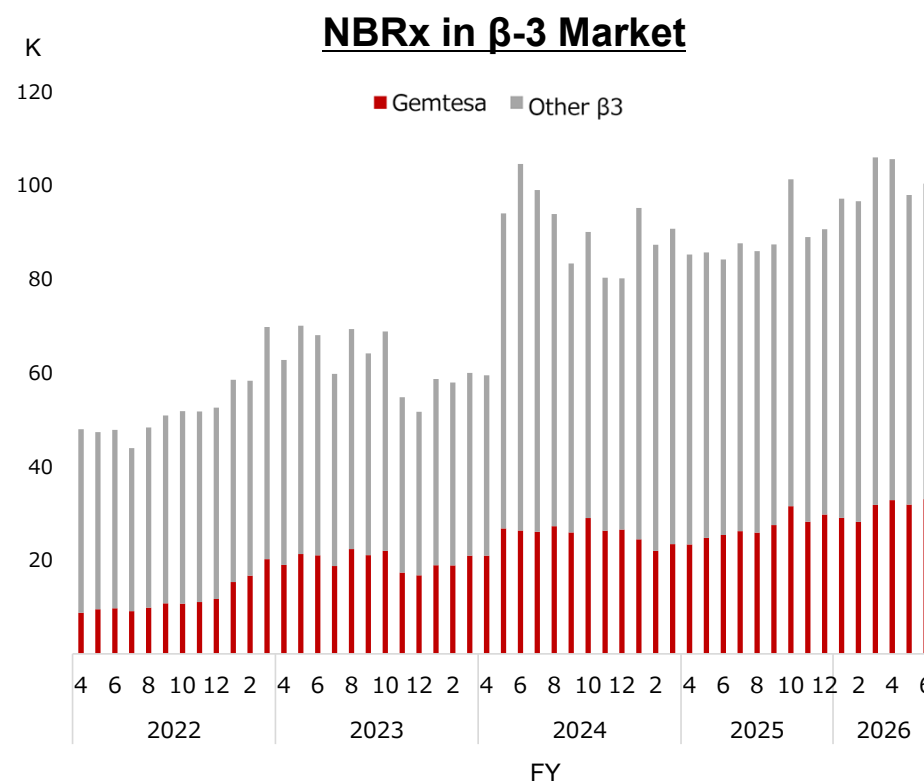
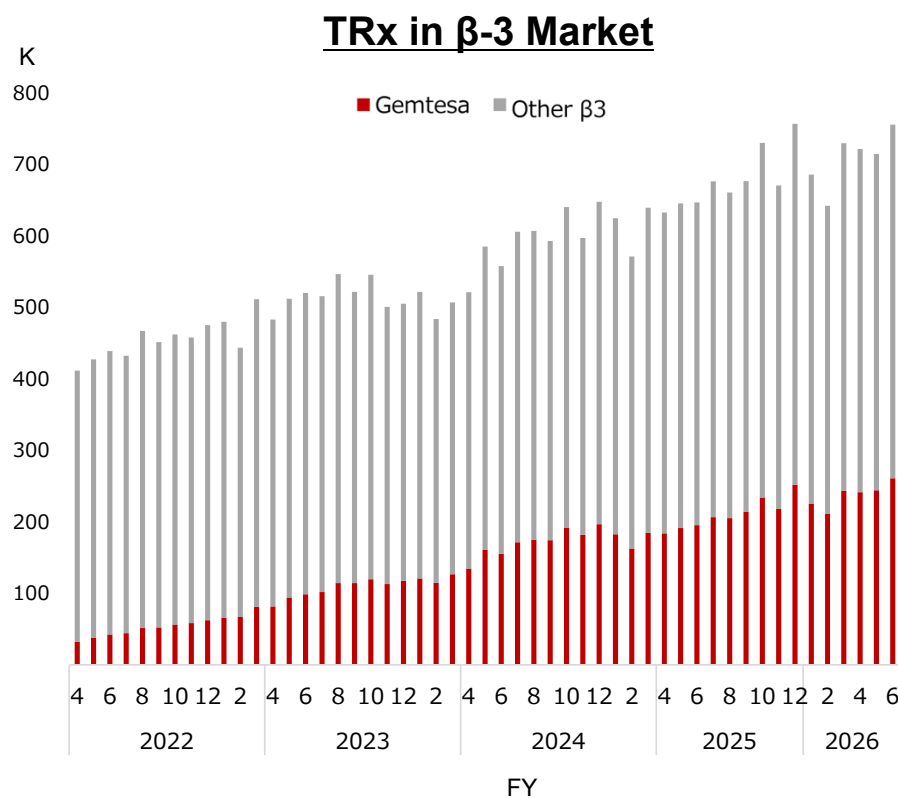
← Increase due to issuance of new shares

← Proceeds from issuance of new shares, repayment of borrowings

Appendix (Financial Results for FY2026 Q1)

■ Prescription Trends of GEMTESA®

- GEMTESA® prescriptions, including total and new prescriptions, continued to increase despite the launch of Mirabegron generics in Apr. 2024



Appendix (Financial Forecasts for the First Half of FY2026)

Financial Forecasts for the First Half of FY2026 (Core Basis)

FX rates:

FY2026 Forecasts : 1US\$ = ¥155.00

- Full-year forecast remains unchanged

Billions of JPY

	FY2026 1H Forecasts	FY2026 Q1YTD Results	Progress
			%
Revenue	251.0	129.5	51.6
Core operating profit	30.0	18.1	60.4
Operating profit	30.0	18.2	60.6
Net profit attributable to owners of the parent	26.0	17.0	65.4

Appendix (Research and Development)

AMCHEPRY® Post-Marketing Clinical Study (Phase 4 Study) Site Preparation Status

Preparations for patient enrollment are underway,
and the status of activities at each participating site is as follows



	IRB	Contract	Investigator meeting	Procedure training	Ready for patient enrollment
Kyoto University Hospital					
Site A (Kansai region)					
Site B (Kansai region)					
Site C (Kanto region)					
Site D (Kanto region)					
Site E (Chubu region)					
Site F (Tohoku region)					

Please note that inquiries regarding the AMCHEPRY® post-marketing clinical study (Phase 4 study) are not accepted by participating medical institutions. Please contact us via our [corporate inquiry form](#)

Appendix (Research and Development)

Revisions since the announcement in May 2026 are shown in red

Product Launch Target (as of July 31, 2026)

Psychiatry & Neurology Oncology

	FY2026	2027	2028	2029	2030
CT1-DAP001/DSP-1083 (Allogeneic iPS cell-derived dopaminergic neural progenitor cells) (RACTHERA Co., Ltd.)	Parkinson's disease Conditional and time-limited approval (Mar 2026) ⇒ Post-marketing clinical study ongoing 				Development in the U.S
HLCR011 (Allogeneic iPS cell-derived retinal pigment epithelial cells) (RACTHERA Co., Ltd.)			Retinal pigment epithelium tear 		Expand indications
Enzomenib (Selective menin inhibitor)		Acute leukemia*  			Expand indications
Nuvisertib (PIM1 kinase inhibitor)			Myelofibrosis  		Expand indications

* Relapsed or refractory acute leukemia with KMT2A rearrangement or acute myeloid leukemia with NPM1 mutation

Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (RACTHERA Co., Ltd.) (as of July 31, 2026)

Brand name/Cell type Product code	Indications	JP/ US	Pre-clinical	Clinical research	Phase 1/2	Phase 3	Approval application	Approval→ Launch
RETHYMIC®	Congenital athymia	US						
Dopaminergic neural progenitor cells (Allo iPS cell-derived) CT1-DAP001/DSP-1083	Parkinson's disease	JP US			 			 Conditional and time-limited approval obtained in Japan (Mar. 2026)
Retinal pigment epithelial cells (Allo iPS cell-derived) HLCR011	Retinal pigment epithelium tear	JP						
Retinal sheet (3D retinal tissue) (Allo iPS cell-derived) DSP-3077	Retinitis pigmentosa	JP US						
Neural progenitor cells (Allo iPS cell-derived)	Spinal cord injury	JP US						
Nephron progenitor cells (organ) (Auto/ Allo iPS cell-based induced)	Kidney failure	JP/ US						

