

Supplementary Financial Data (IFRS) for the Third Quarter of the Year Ending March 31, 2026

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January 30, 2026

Sumitomo Pharma Co., Ltd.

- 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.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

I. Consolidated Financial Highlights

1. Consolidated Statement of Profit or Loss (Core Basis)

(Billions of JPY)

	Q3 FY2024	Q3 FY2025	Change %	FY2024	FY2025 (Forecasts)	Change % YoY
Revenue	293.2	347.7	18.6	398.8	429.0	7.6
Cost of sales *1	113.5	145.1	27.9	153.2	186.5	21.7
Gross profit	179.7	202.6	12.8	245.6	242.5	(1.3)
SG&A expenses *1	124.4	116.4	(6.4)	167.7	152.0	(9.4)
R&D expenses *1	35.4	27.8	(21.3)	48.5	44.0	(9.3)
Others (core basis) *2	1.6	51.1		13.7	50.5	
Core operating profit	21.5	109.4	408.5	43.2	97.0	124.8
Adjustments *3 (negative number indicates net expense)	(8.3)	0.3		(14.3)	1.0	
Operating profit	13.2	109.8	730.0	28.8	98.0	240.2
Net profit attributable to owners of the parent	21.2	107.7	407.5	23.6	92.0	289.3
Basic earnings per share (JPY)	53.41	271.03		59.49	231.57	
Net profit/ Equity attributable to owners of the parent (ROE)				14.5%	43.0%	
Return on invested capital (ROIC)				9.4%	20.7%	

2. Consolidated Statement of Profit or Loss (Full Basis)

(Billions of JPY)

	Q3 FY2024	Q3 FY2025	Change %
Revenue	293.2	347.7	18.6
Cost of sales	113.8	145.1	27.6
Gross profit	179.4	202.6	12.9
SG&A expenses	131.0	119.5	(8.8)
R&D expenses	36.7	27.9	(24.1)
Other operating income/expenses, etc.	1.6	54.5	
Operating profit	13.2	109.8	730.0
Finance income/costs	10.8	(8.2)	
Profit before taxes	24.0	101.5	322.6
Income tax expenses	2.8	(6.1)	
Net profit attributable to owners of the parent	21.2	107.7	407.5

*1 Exclude adjustments
 *2 Including P/L on business transfers, share of P/L of associates accounted for using equity method
 *3 Impairment loss, business structure improvement expenses, and changes in fair value of contingent consideration, etc.

3. Consolidated Statement of Cash Flows

(Billions of JPY)

	Q3 FY2024	Q3 FY2025
Net cash provided by (used in) operating activities	5.5	42.3
Net cash provided by (used in) investing activities	97.4	24.4
Net cash provided by (used in) financing activities	(45.3)	(48.7)
Cash and cash equivalents at the end of period	85.4	57.3

4. Foreign Exchange Rates

	Period end rate		Average rate		FY2025 assumption	Forex sensitivity FY2025 (Impact of JPY depreciation by ¥ 1)	
	Mar. 31 2025	Dec. 31 2025	FY2024 Apr.-Dec.	FY2025 Apr.-Dec.	Average rate	Revenue	Core operating profit
JPY / USD	149.53	156.53	152.64	148.71	145.00	2.2	0.4
JPY / RMB	20.59	20.74	21.17	20.12	20.12	-	-

(Billions of JPY)

II. Consolidated Statement of Profit or Loss

1. Consolidated Statement of Profit or Loss (Core Basis) (Billions of JPY)

Consolidated Statement of Profit or Loss (Core Basis)					(Millions of ¥)																								
	Q3 FY2024	Q3 FY2025	Change	Change %																									
Revenue	293.2	347.7	54.6	18.6	<table><tr><th colspan="2">Change</th><th>FX impact</th></tr><tr><td>Japan</td><td>(9.3)</td><td></td></tr><tr><td>North America</td><td>78.1</td><td>(6.8)</td></tr><tr><td>Asia</td><td>(14.3)</td><td>(0.8)</td></tr></table>	Change		FX impact	Japan	(9.3)		North America	78.1	(6.8)	Asia	(14.3)	(0.8)												
Change		FX impact																											
Japan	(9.3)																												
North America	78.1	(6.8)																											
Asia	(14.3)	(0.8)																											
Overseas revenue	220.0	285.2	65.2	29.7																									
% of Revenue	75.0%	82.0%																											
Cost of sales	113.5	145.1	31.6	27.9																									
% of Revenue	38.7%	41.7%																											
Gross profit	179.7	202.6	22.9	12.8	<table><tr><th colspan="4">Change by segment</th></tr><tr><th></th><th>Japan</th><th>North America</th><th>Asia</th></tr><tr><td>Labor costs</td><td>(2.0)</td><td>5.0</td><td>(2.4)</td></tr><tr><td>Sales promotion/ Advertising costs</td><td>(1.1)</td><td>(2.9)</td><td>(0.6)</td></tr><tr><td>Amortization/ Depreciation</td><td>(1.0)</td><td>(1.7)</td><td>(0.3)</td></tr><tr><td>Others</td><td>(2.6)</td><td>3.3</td><td>(1.6)</td></tr></table>	Change by segment					Japan	North America	Asia	Labor costs	(2.0)	5.0	(2.4)	Sales promotion/ Advertising costs	(1.1)	(2.9)	(0.6)	Amortization/ Depreciation	(1.0)	(1.7)	(0.3)	Others	(2.6)	3.3	(1.6)
Change by segment																													
	Japan	North America	Asia																										
Labor costs	(2.0)	5.0	(2.4)																										
Sales promotion/ Advertising costs	(1.1)	(2.9)	(0.6)																										
Amortization/ Depreciation	(1.0)	(1.7)	(0.3)																										
Others	(2.6)	3.3	(1.6)																										
SG&A expenses	124.4	116.4	(8.0)	(6.4)																									
Labor costs	56.5	57.0	0.5	1.0																									
Sales promotion/ Advertising costs	20.3	15.7	(4.6)	(22.6)																									
Amortization/Depreciation	15.5	12.5	(3.0)	(19.5)																									
Others	32.2	31.3	(0.9)	(2.9)																									
R&D expenses	35.4	27.8	(7.5)	(21.3)																									
% of Revenue	12.1%	8.0%																											
Others (core basis)	1.6	51.1	49.5		FY25: Gains on partial transfer of the Asian business +49.0																								
Core operating profit	21.5	109.4	87.9	408.5																									
Adjustments (negative number indicates net expense)	(8.3)	0.3	8.6		FY24: Business structure improvement expenses in Japan (5.7) Business structure improvement expenses in North America (2.8) FY25: Impairment loss in North America (2.0) Changes in fair value of contingent consideration +1.8																								
Operating profit	13.2	109.8	96.5	730.0																									
Finance income	16.8	1.5	(15.4)																										
Finance costs	6.0	9.7	3.7																										
Profit before taxes	24.0	101.5	77.5	322.6																									
Income tax expenses	2.8	(6.1)	(8.9)																										
Net profit attributable to owners of the parent	21.2	107.7	86.5	407.5																									

2. Adjustments to Core Operating Profit

Q3 FY2025 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	347.7	347.7	—	
Cost of sales	145.1	145.1	—	
Gross profit	202.6	202.6	—	
SG&A expenses	119.5	116.4	(3.1)	Impairment loss in North America (2.0)
R&D expenses	27.9	27.8	(0.0)	
Other operating income/expenses, etc.	54.5	51.1	(3.4)	Changes in fair value of contingent consideration (1.9) Gain on reversal of impairment loss in North America (1.0)
Operating profit	109.8	109.4	(0.3)	

III. Segment Information (Core Basis)

(Billions of JPY)

Q3 FY2025 Results	Japan	North America	Asia	Total
Revenue	69.2	257.5	21.0	347.7
Cost of sales	35.6	102.4	7.2	145.1
Gross profit	33.7	155.1	13.8	202.6
SG&A expenses	22.1	89.9	4.4	116.4
Core segment profit	11.5	65.2	9.4	86.2
R&D expenses *1				27.8
Others (core basis) *2				51.1
Core operating profit				109.4

(Billions of JPY)

Q3 FY2024 Results	Japan	North America	Asia	Total
Revenue	78.5	179.4	35.3	293.2
Cost of sales	40.3	64.9	8.3	113.5
Gross profit	38.2	114.4	27.0	179.7
SG&A expenses	28.9	86.2	9.4	124.4
Core segment profit	9.3	28.3	17.6	55.2
R&D expenses *1				35.4
Others (core basis) *2				1.6
Core operating profit				21.5

(Billions of JPY)

FY2025 Forecasts	Japan	North America	Asia	Total
Revenue	92.5	313.6	22.9	429.0
Cost of sales	48.8	128.9	8.8	186.5
Gross profit	43.7	184.7	14.1	242.5
SG&A expenses	31.5	115.8	4.7	152.0
Core segment profit	12.2	68.9	9.4	90.5
R&D expenses *1				44.0
Others (core basis) *2				50.5
Core operating profit				97.0

*1 R&D expenses are controlled globally and not allocated to each segment.

*2 Including P/L on business transfers and share of P/L of associates accounted for using equity method.

IV. Revenue Information

1. Revenue by segment

(Billions of JPY)

Segment	Q3 FY2024	Q3 FY2025	Change	Change %	FY2025 (Forecasts)	Progress %
Japan	78.5	69.2	(9.3)	(11.8)	92.5	74.8
North America	179.4	257.5	78.1	43.6	313.6	82.1
Asia	35.3	21.0	(14.3)	(40.5)	22.9	91.8

2. Revenue of Major Products (1)

(Invoice price basis, Billions of JPY)

Brand name Therapeutic indication	Q3 FY2024	Q3 FY2025	Change	Change %	FY2025 (Forecasts)	Progress %
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Japan

Promoted products

LATUDA® Atypical antipsychotic	10.2	10.7	0.4	4.2	13.5	78.9
TWYMEEG® Therapeutic agent for type 2 diabetes (Sep. 2021~)	5.7	7.9	2.2	39.4	11.2	70.7
METGLUCO® Therapeutic agent for type 2 diabetes	5.7	5.7	0.0	0.2	7.5	75.8
Equa®/EquMet® Therapeutic agent for type 2 diabetes	20.9	8.7	(12.2)	(58.3)	9.0	97.1
LONASEN® Tape Atypical antipsychotic	3.6	3.9	0.3	8.2	5.0	77.4

Other products

Authorized Generics	8.8	9.4	0.6	6.6	11.6	80.6
Export products, One-time revenue, Others	23.6	23.0	(0.6)	(2.6)	34.7	66.2

2. Revenue of Major Products (2)

(Billions of JPY)

Brand name Therapeutic indication	Q3 FY2024	Q3 FY2025	Change	Change %	FY2025 (Forecasts)	Progress %
North America						
ORGOVYX® Therapeutic agent for advanced prostate cancer (Jan. 2021~)	57.8	115.6	57.8	99.9	147.9	78.1
MYFEMBREE® Therapeutic agent for uterine fibroids and endometriosis (Jun. 2021~/Aug. 2022~)	10.1	10.9	0.8	8.4	12.3	88.6
GEMTESA® Therapeutic agent for overactive bladder (Apr. 2021~)	43.2	72.3	29.1	67.5	85.3	84.8
RETHYMIC® Cultured thymus tissue for pediatric congenital athymia (Mar. 2022~)	5.1	4.6	(0.5)	(10.5)	6.5	70.0
APTOM® Antiepileptic	30.5	12.6	(17.9)	(58.7)	12.3	102.2
Export products, One-time revenue, Others	32.8	41.6	8.8	26.9	49.3	84.4

(Ref.) Products sales in North America (based on local currency)

(Millions of USD)

Brand name	Q3 FY2024	Q3 FY2025	Change	Change %	FY2025 (Forecasts)	Progress %
ORGOVYX®	379	777	398	105.2	1,020	76.2
MYFEMBREE®	66	73	7	11.2	85	86.2
GEMTESA®	283	486	203	71.9	588	82.7
RETHYMIC®	33	30	(3)	(8.6)	45	67.7
APTOM®	200	85	(115)	(57.6)	85	99.4

V. Consolidated Statement of Financial Position

	(Billions of JPY)		
	Mar. 31 2025	Dec. 31 2025	Change
Assets	742.6	815.5	72.9
Non-current assets	489.4	519.6	30.2
Property, plant and equipment	46.6	44.6	(2.0)
Goodwill	197.4	206.6	9.2
Intangible assets	172.5	163.5	(9.0)
Patent rights/Marketing rights	167.7	158.9	(8.7)
In-process R&D	0.5	0.7	0.2
Others	4.4	3.9	(0.5)
Other financial assets	44.1	46.1	1.9
Other non-current assets	28.2	58.3	30.1
Deferred tax assets	0.5	0.5	(0.1)
Current assets	253.2	295.9	42.8
Inventories	94.2	82.3	(11.9)
Trade and other receivables	74.8	132.8	57.9
Other financial assets	16.8	10.0	(6.8)
Other current assets	13.8	13.6	(0.2)
Cash and cash equivalents	23.1	57.3	34.2
Assets held for sale	30.4	—	(30.4)
Liabilities	573.1	526.6	(46.5)
Non-current liabilities	332.5	314.8	(17.7)
Bonds and borrowings	259.0	259.0	(0.0)
Other financial liabilities	15.8	17.5	1.6
Retirement benefit liabilities	6.5	6.2	(0.3)
Other non-current liabilities	24.6	17.5	(7.2)
Deferred tax liabilities	26.6	14.7	(11.9)
Current liabilities	240.6	211.8	(28.8)
Borrowings	46.4	—	(46.4)
Trade and other payables	38.5	35.1	(3.4)
Other financial liabilities	32.9	37.1	4.2
Income taxes payable	1.6	1.2	(0.4)
Provisions	72.0	89.5	17.5
Other current liabilities	45.7	48.9	3.2
Liabilities directly associated with assets held for sale	3.5	—	(3.5)
Equity	169.5	288.9	119.5
Share capital	22.4	22.4	—
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	46.8	156.4	109.6
Other components of equity	97.5	110.8	13.3
Other comprehensive income associated with assets held for sale	3.5	—	(3.5)
Equity attributable to owners of the parent	169.5	288.9	119.5

Major patent rights	25/3	25/12
ORGOVYX® (relugolix)	63.8	59.9
MYFEMBREE® (relugolix)	9.7	9.1
GEMTESA® (vibegron)	92.2	88.4

← Increase in investments accounted for using the equity method

← Increase in accounts receivable due to sales growth, etc.

← Reversal of deferred tax liabilities due to assignment of intangible assets within our group

← Repayment of short-term borrowings, etc.

← Increase in provisions due to sales growth, etc.

VI. Changes in Quarterly Results

1. Consolidated Statement of Profit or Loss (Core Basis)

(Billions of JPY)

	FY2024				FY2025		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Revenue	90.7	90.1	112.4	105.6	108.0	119.1	120.6
Cost of sales	34.9	37.3	41.3	39.7	44.1	45.6	55.4
Gross profit	55.7	52.8	71.2	66.0	63.9	73.5	65.2
SG&A expenses	43.8	39.6	41.0	43.3	35.4	38.6	42.5
R&D expenses	12.8	12.3	10.2	13.1	8.1	9.4	10.4
Others (core basis)	(0.0)	(0.0)	1.7	12.1	(0.1)	50.1	1.0
Core operating profit (loss)	(0.9)	0.9	21.6	21.6	20.4	75.7	13.4
Adjustments (negative number indicates net expense)	(2.2)	(5.9)	(0.2)	(6.1)	0.0	0.0	0.3
Operating profit (loss)	(3.1)	(5.1)	21.4	15.6	20.4	75.8	13.6
Net profit (loss) attributable to owners of the parent	15.9	(48.2)	53.4	2.4	11.2	87.7	8.8

2. Revenue of Major Products

	FY2024				FY2025		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Japan	(Invoice price basis, Billions of JPY)						
LATUDA®	3.4	3.3	3.6	2.9	3.5	3.4	3.8
TWYMEEG®	1.7	1.8	2.1	1.9	2.4	2.6	2.9
METGLUCO®	1.9	1.9	1.9	1.7	1.9	1.8	2.0
Equa®/EquMet®	7.4	6.8	6.8	4.0	4.2	3.3	1.2
LONASEN® Tape	1.1	1.2	1.3	1.0	1.2	1.2	1.4
Authorized Generics	2.8	2.7	3.2	2.7	3.1	3.0	3.3
Export products, One-time revenue, Others	8.7	8.2	6.7	7.2	6.9	8.4	7.7

North America

(Millions of USD)

ORGOVYX®	108	125	146	166	226	247	304
MYFEMBREE®	19	20	26	18	20	24	30
GEMTESA®	78	87	118	148	147	150	189
RETHYMIC®	11	8	14	11	6	17	8
APTiom®	65	65	69	59	49	24	11
Export products, One-time revenue, Others	52	43	120	73	54	150	75

VII. Major Group Companies (As of December 31, 2025)

Domestic	Establish- ment	Ownership	Businesses
Sumitomo Pharma Promo Co., Ltd.	1998/ 6	100%	Manufacturing and sales of pharmaceuticals, etc.
Marubeni Pharmaceuticals Corporation*1	2025/ 5	40.0%	Manufacturing and sales of pharmaceuticals and others
RACTHERA Co., Ltd. *1	2024/11	33.4%	Research, development, manufacture, sales, and import and export of regenerative medicine and cell therapy products, cell processing products, and regenerative medicine and cell therapy-related products
S-RACMO Co., Ltd. *1	2020/ 9	33.4%	Contract development and manufacturing services in the field of regenerative and cellular medicine
Overseas	Establish- ment	Ownership	Businesses
Sumitomo Pharma America, Inc.	1984/ 1	100%	Manufacturing and sales of pharmaceuticals

*1 Associates

VIII. Development Pipeline (As of January 30, 2026)

- This table shows key clinical studies in indications for which the Sumitomo Pharma Group aims to obtain approval.
- The study for the most advanced development stage is listed if there are multiple studies with the same region and indication.
- The development stage is changed when Investigational New Drug Application/amended IND/ Clinical Trial Notification is filed and/or approved by the applicable authority.

1. Psychiatry & Neurology

Brand name/ Generic name/ Product code		Planned indication(s)	Development stage
Small molecule	LATUDA®/ lurasidone hydrochloride	(New usage: pediatric) Schizophrenia	Phase 3
	DSP-0038	Alzheimer's disease psychosis	Phase 1
	DSP-0187*	Narcolepsy	Phase 1
	DSP-3456	Treatment resistant depression	Phase 1
	DSP-0378	Progressive Myoclonic Epilepsy and Developmental Epileptic Encephalopathy	Phase 1
	DSP-2342	To be determined	Phase 1
Regenerative medicine / cell therapy (Collaboration with RACTHERA Co., Ltd.)	CT1-DAP001/DSP-1083 (Allogeneic iPS [induced pluripotent stem] cell- derived dopaminergic neural progenitor cells) (JAPAN)	Parkinson's disease (Investigator-initiated study)	MAA submitted in August 2025
	CT1-DAP001/DSP-1083 (Allogeneic iPS cell- derived dopaminergic neural progenitor cells) (U.S.)	Parkinson's disease	Phase 1/2 (Investigator-initiated study)
			Phase 1/2 (Company-sponsored clinical study)
	HLCR011 (Allogeneic iPS cell- derived retinal pigment epithelial cells) (JAPAN)	Retinal pigment epithelium tear	Phase 1/2
	DSP-3077 (Allogeneic iPS cell- derived retinal sheet) (U.S.)	Retinitis pigmentosa	Phase 1/2

*Development rights: Japan, China, and certain Asian countries

2. Oncology

Brand name/ Generic name/ Product code	Planned indication(s)	Development stage
enzomenib/DSP-5336	Acute leukemia	Phase 2
nuvisertib/TP-3654	Myelofibrosis	Phase 1/2
SMP-3124	Solid tumors	Phase 1/2
DSP-0390	Glioblastoma	Phase 1

3. Others

Brand name/ Generic name/ Product code	Planned indication(s)	Development stage
KSP-1007	Complicated urinary tract infections and complicated intra-abdominal infections, hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia	Phase 1
fH1/DSP-0546LP	Influenza	Phase 1

IX. Profiles of Major Products under Development (As of January 30, 2026)

1. Psychiatry & Neurology

(Small molecule)

DSP-0038 Origin: in-house (Joint research with Recursion (formerly Exscientia Ltd.)), Formulation: oral

- Planned indication: Alzheimer's disease psychosis
- DSP-0038 is a novel compound discovered at Sumitomo Pharma using Recursion's AI technologies. DSP-0038 is a serotonin 5-HT_{2A} receptor antagonist and a serotonin 5-HT_{1A} receptor agonist. DSP-0038 is expected to demonstrate a greater antipsychotic effect, based on the additive effect of 5-HT_{2A} receptor antagonist and 5-HT_{1A} receptor agonist. The compound could also have broader efficacy in the treatment of behavioral and psychological symptoms of dementia (BPSD) which include agitation, aggression, anxiety, and depression. Furthermore, DSP-0038 has negligible affinity for dopamine D₂ receptors, and therefore it can be expected to show improved safety and tolerability compared to existing antipsychotics.

DSP-0187

Origin: in-house, Formulation: oral

- Planned indication: Narcolepsy
- DSP-0187 is an orexin 2 receptor agonist. It is expected to improve excessive daytime sleepiness (EDS) and cataplexy of narcolepsy caused by orexin deficiency. DSP-0187 is also expected to demonstrate efficacy in EDS (Excessive Daytime Sleepiness) conditions other than narcolepsy. Sumitomo Pharma granted Jazz Pharmaceuticals plc the exclusive development and commercialization rights in the United States, Europe and other territories, except for Japan, China, and certain other Asia/Pacific markets in April 2022.

DSP-3456

Origin: in-house, Formulation: oral

- Planned indication: Treatment resistant depression
- DSP-3456 is a metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM). DSP-3456 is expected to exhibit a ketamine-like antidepressant effect through selective activation of the prefrontal cortex by enhancing the glutamate release, while avoiding side effects (psychotic symptoms, cognitive dysfunction).

DSP-0378

Origin: in-house, Formulation: oral

- Planned indications: Progressive Myoclonic Epilepsy and Developmental Epileptic Encephalopathy
- DSP-0378 is a gamma-aminobutyric acid (GABA)_A receptor positive allosteric modulator. DSP-0378 acts on various subtypes of GABA_A receptors expressed in synaptic and extrasynaptic regions in a manner different from common GABA_A receptor potentiators such as benzodiazepines and neurosteroids. DSP-0378 is expected to exhibit an antiepileptic effect against broad epilepsies including Progressive Myoclonic Epilepsy and Developmental Epileptic Encephalopathy.

DSP-2342 Origin: in-house (Joint research with Recursion (formerly Exscientia Ltd.)), Formulation: oral

- Planned indication: TBD
- DSP-2342 is a novel compound discovered at Sumitomo Pharma using Recursion's AI technologies. DSP-2342 is a serotonin 5-HT_{2A} and 5-HT₇ receptor antagonist. DSP-2342 is expected to demonstrate a broader antipsychotic effect in psychosis, anxiety, and depression, based on the additive effect of 5-HT_{2A} and 5-HT₇ receptor antagonist. Furthermore, DSP-2342 has high selectivity for 5-HT_{2A} and 5-HT₇ receptors, so is expected to show a high level of safety and tolerability.

(Regenerative medicine / cell therapy (Collaboration with RACTHERA Co., Ltd.))

In collaboration with RACTHERA Co., Ltd., and our partners in the industry-academia collaboration, we are developing allogeneic iPS cell-derived products using iPS cells from healthy donors for the treatment of Parkinson's disease, RPE (retinal pigment epithelium) tear, AMD (age-related macular degeneration), retinitis pigmentosa, and spinal cord injury.

CT1-DAP001/DSP-1083 (Allogeneic iPS cell-derived dopaminergic neural progenitor cells)

- Partnering: Kyoto University CiRA, UC San Diego
- Planned indication: Parkinson's disease
- The Ministry of Health, Labour and Welfare (MHLW) granted CT1-DAP001/DSP-1083 "Sakigake Designation Scheme" status as a regenerative medicine & cell therapy in February 2017 and Orphan Regenerative Medical Product Designation in December 2025 for the indication of Parkinson's disease.

HLCR011 (Allogeneic iPS cell-derived retinal pigment epithelial cells)

- Partnering: HEALIOS K.K.
- Planned indication: Retinal pigment epithelium tear

DSP-3077 (Allogeneic iPS cell-derived retinal sheet)

- Partnering: Massachusetts Eye and Ear in Boston, Massachusetts (Teaching hospital of Harvard Medical School), USA
- Planned indication: Retinitis pigmentosa

2. Oncology**enzomenib/DSP-5336**

Origin: in-house (Joint research with Kyoto University), Formulation: oral

- Planned indication: Acute leukemia
- Enzomenib (DSP-5336) is a small molecule inhibitor against the binding of menin and lysine methyltransferase 2A (KMT2A) protein. Acute myeloid leukemia with KMT2A rearrangement or nucleophosmin 1 (NPM1) mutation rely on the menin-KMT2A interaction for upregulation of genes instrumental to leukemogenesis. Enzomenib has been shown to have anti-cancer activity through downregulation of these genes by inhibition of menin-KMT2A interaction in pre-clinical studies. The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for enzomenib for the indication of acute myeloid leukemia in June 2022 and granted Fast Track Designation for the treatment of relapsed or refractory acute myeloid leukemia with KMT2A rearrangement or NPM1 mutation in June 2024. Furthermore, the Ministry of Health, Labour and Welfare in Japan granted Orphan Drug Designation for enzomenib for the indication of relapsed or refractory acute myeloid leukemia with KMT2A rearrangement or NPM1 mutation in September 2024.

nuvisertib/TP-3654 Origin: in-house (former Tolero Pharmaceuticals, Inc.), Formulation: oral

- Planned indication: Myelofibrosis
- Nuvisertib (TP-3654) inhibits the inflammatory signaling pathways through inhibition of PIM1 (proviral integration site for Moloney murine leukemia virus 1) kinase. PIM1 kinase is frequently overexpressed in various hematologic malignancies and solid tumors, allowing cancer cells to evade apoptosis and promoting tumor growth. The U.S. Food and Drug Administration (FDA), the Japanese Ministry of Health, Labour and Welfare, and the European Medicines Agency (EMA) granted Orphan Drug Designation for nuvisertib for the indication of myelofibrosis in May 2022, November 2024, and July 2025, respectively. Additionally, the FDA granted nuvisertib Fast Track Designation in June 2025, also for the indication of myelofibrosis.

SMP-3124 Origin: in-house, Formulation: injection (Liposomal Nanomedicine)

- Planned indication: Solid tumors
- SMP-3124 is an injection including a liposome encapsulated CHK1 (checkpoint kinase 1) inhibitor. CHK1 is activated by the DNA damage response, leading to cell-cycle arrest, and DNA repair via serine-threonine kinase. CHK1 inhibition leads cancer cells with high replication stress to apoptosis by inducing further DNA damage. SMP-3124 is expected to strengthen the anti-tumor activity and attenuate side effects by changing pharmacokinetics of the compound with liposomal nanomedicinal encapsulation.

DSP-0390 Origin: in-house, Formulation: oral

- Planned indication: Glioblastoma
- DSP-0390 is an inhibitor of Emopamil Binding Protein (EBP), an endoplasmic reticulum membrane protein involved in cholesterol biosynthesis. EBP mediates de novo cholesterol synthesis for cell membrane structure and signaling, enabling aberrant growth of tumors. Inhibition of EBP causes depletion of cellular cholesterol, which is expected to lead to anti-cancer activity. The FDA granted Orphan Drug Designation for DSP-0390 for the indication of brain cancer in May 2022.

3. Others

KSP-1007 Origin: in-house (Joint research with The Kitasato Institute), Formulation: injection

- Planned indications: Complicated urinary tract and intra-abdominal infections, hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia
- KSP-1007 broadly and strongly inhibits β -lactamases, enzymes produced by bacteria that can degrade carbapenem antibiotics. KSP-1007 is expected to become an effective treatment option against carbapenem-resistant bacterial infections as a component of a combination drug with meropenem hydrate, a carbapenem antibiotic in general use worldwide (name of Sumitomo Pharma's product for the Japanese market: MEROPEN®). The FDA granted Qualified Infectious Disease Product (QIDP) status and Fast Track Designation for KSP-1007 for the indications of complicated urinary tract infections, complicated intra-abdominal infections, and hospital-acquired bacterial pneumonia including ventilator-associated bacterial pneumonia in August 2022.

fH1/DSP-0546LP Origin: in-house (Joint research with the National Institutes of Biomedical Innovation, Health and Nutrition), Formulation: injection

- Planned indication: Influenza
- fH1/DSP-0546LP is a next-generation candidate vaccine formulation composed of the post-fusion hemagglutinin antigen (fH1) that is expected to be effective against a broad range of influenza viruses, and TLR7 adjuvant "DSP-0546LP" that enhances the quantity, quality, and durability of immune response. Conventional influenza vaccines lose effectiveness due to viral mutations, making it necessary to select, produce, and inoculate a vaccine to immunize against strains predicted to circulate each year. They may also not respond well to emerging strains of influenza. The pre-clinical study of fH1/DSP-0546LP demonstrated broad cross protection against influenza viruses antigenically different from those used in vaccine formulations, and the significance of the TLR7 adjuvant, DSP-0546LP. It is expected that fH1/DSP-0546LP will improve the breadth and durability of protection

against seasonal influenza viruses and will be effective against novel and potentially pandemic strains.