Securities Code: 4506

Supplementary Financial Data (IFRS) for the Three Months Ended June 30, 2026

July 31, 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)

	Q1 FY2025	Q1 FY2026	Change %	FY2025	FY2026 (Forecasts)	Change % YoY
Revenue	108.0	**129.5**	19.9	453.3	540.0	19.1
Cost of sales *1	44.1	**61.4**	39.2	196.4	245.0	24.7
Gross profit	63.9	**68.1**	6.6	256.9	295.0	14.8
SG&A expenses *1	35.4	**39.0**	10.1	159.3	155.0	(2.7)
R&D expenses *1	8.1	**11.4**	41.2	43.9	51.0	16.0
Others (core basis) *2	(0.1)	**0.4**		52.3	2.0	
Core operating profit	20.4	**18.1**	(11.0)	105.9	91.0	(14.1)
Adjustments *3 (negative number indicates net expense)	0.0	**0.1**		1.4	(1.0)	
Operating profit	20.4	**18.2**	(10.8)	107.3	90.0	(16.2)
Net profit attributable to owners of the parent	11.2	**17.0**	51.7	106.9	77.0	(27.9)
Basic earnings per share (JPY)	28.21	**39.02**		268.99	172.89	
Net profit/ Equity attributable to owners of the parent (ROE)				46.3%	20.3%	
Return on invested capital (ROIC)				22.8%	15.1%	

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

(Billions of JPY)

	Q1 FY2025	Q1 FY2026	Change %
Revenue	108.0	**129.5**	19.9
Cost of sales	44.1	**61.4**	39.2
Gross profit	63.9	**68.1**	6.6
SG&A expenses	35.7	**39.2**	10.0
R&D expenses	8.2	**11.4**	39.8
Other operating income/expenses, etc.	0.3	**0.8**	
Operating profit	20.4	**18.2**	(10.8)
Finance income/costs	(8.5)	**0.1**	
Profit before taxes	11.9	**18.3**	53.3
Income tax expenses	0.7	**1.3**	
Net profit attributable to owners of the parent	11.2	**17.0**	51.7

*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)

	Q1 FY2025	Q1 FY2026
Net cash provided by (used in) operating activities	(0.2)	**(7.4)**
Net cash provided by (used in) investing activities	(4.3)	**0.0**
Net cash provided by (used in) financing activities	3.2	**39.2**
Cash and cash equivalents at the end of period	20.5	**76.6**

4. Foreign Exchange Rates

	Period end rate		Average rate		FY2026 assumption	Forex sensitivity FY2026 (Impact of JPY depreciation by ¥1)	
	Mar. 31 2026	**June 30 2026**	FY2025 Apr.-June	**FY2026 Apr.-June**	**Average rate**	Revenue	Core operating profit
JPY / USD	159.90	**162.39**	144.60	**159.57**	**155.00**	2.8	0.6

(Billions of JPY)

II. Consolidated Statement of Profit or Loss

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

(Billions of JPY)

	Q1 FY2025	Q1 FY2026	Change	Change %
Revenue	108.0	**129.5**	21.5	19.9
Overseas revenue	86.9	**107.2**	20.3	23.4
% of Revenue	80.5%	**82.8%**		
Cost of sales	44.1	**61.4**	17.3	39.2
% of Revenue	40.8%	**47.4%**		
Gross profit	63.9	**68.1**	4.2	6.6
SG&A expenses	35.4	**39.0**	3.6	10.1
Labor costs	17.1	**17.8**	0.7	4.4
Sales promotion/ Advertising costs	4.5	**6.7**	2.1	47.1
Amortization/Depreciation	4.1	**3.9**	(0.3)	(6.1)
Others	9.6	**10.5**	0.9	9.9
R&D expenses	8.1	**11.4**	3.3	41.2
% of Revenue	7.5%	**8.8%**		
Others (core basis)	(0.1)	**0.4**	0.5	
Core operating profit	20.4	**18.1**	(2.2)	(11.0)
Adjustments (negative number indicates net expense)	0.0	**0.1**	0.0	
Operating profit	20.4	**18.2**	(2.2)	(10.8)
Finance income	0.6	**2.2**	1.6	
Finance costs	9.1	**2.1**	(7.0)	
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

	Change	FX impact
Japan	1.0	
U.S.	24.4	8.9
Other	(3.9)	0.7

2. Adjustments to Core Operating Profit

(Billions of JPY)

Q1 FY2026 Results	Full Basis	Adjustment items				Core Basis
		Impairment losses	Business structure improvement expenses	Change in fair value of contingent consideration	Other	
Revenue	129.5	—	—	—	—	**129.5**
Cost of sales	61.4	—	—	—	—	**61.4**
Gross profit	68.1	—	—	—	—	**68.1**
SG&A expenses	39.2	—	—	—	(0.3)	**39.0**
R&D expenses	11.4	—	—	—	—	**11.4**
Other operating income/expenses, etc.	0.8	—	—	(0.3)	(0.1)	**0.4**
Operating profit	18.2	—	—	(0.3)	0.2	**18.1**

(Billions of JPY)

Q1 FY2025 Results	Full Basis	Adjustment items				Core Basis
		Impairment losses	Business structure improvement expenses	Change in fair value of contingent consideration	Other	
Revenue	108.0	—	—	—	—	**108.0**
Cost of sales	44.1	—	—	—	—	**44.1**
Gross profit	63.9	—	—	—	—	**63.9**
SG&A expenses	35.7	—	(0.1)	(0.0)	(0.1)	**35.4**
R&D expenses	8.2	—	(0.1)	—	—	**8.1**
Other operating income/expenses, etc.	0.3	—	—	(0.2)	(0.2)	**(0.1)**
Operating profit	20.4	—	0.2	(0.1)	(0.1)	**20.4**

III. Revenue Information

1. Revenue by Region

(Billions of JPY)

Segment	Q1 FY2025	**Q1 FY2026**	Change	Change %	FY2026 (Forecasts)	Progress %
Japan	21.3	**22.2**	1.0	4.6	87.6	25.4
U.S.	69.9	**94.3**	24.4	34.9	406.4	23.2
Other	16.8	**13.0**	(3.9)	(22.9)	46.0	28.2
Total	108.0	**129.5**	21.5	19.9	540.0	24.0

2. Revenue of Major Products (1)

(Invoice price basis, Billions of JPY)

Brand name Therapeutic indication	Q1 FY2025	**Q1 FY2026**	Change	Change %	FY2026 (Forecasts)	Progress %
Japan						
XEPLION®/XEPLION TRI® Long-acting injectable antipsychotics (Jan. 2026～)	—	**4.1**	4.1	—	17.1	24.0
LATUDA® Atypical antipsychotic	3.5	**3.7**	0.2	6.8	13.6	27.3
TWYMEEG® Therapeutic agent for type 2 diabetes (Sep. 2021～)	2.4	**3.3**	0.8	33.5	11.9	27.3
METGLUCO® Therapeutic agent for type 2 diabetes	1.9	**1.9**	0.1	3.4	7.6	25.1
Equa®/EquMet® Therapeutic agent for type 2 diabetes	4.2	**—**	(4.2)	—	—	—
Authorized Generics	3.1	**3.0**	(0.1)	(2.2)	11.2	26.8

2. Revenue of Major Products (2)

(Billions of JPY)

Brand name Therapeutic indication	Q1 FY2025	**Q1 FY2026**	Change	Change %	FY2026 (Forecasts)	Progress %
U.S.						
ORGOVYX® Therapeutic agent for advanced prostate cancer	32.7	**51.6**	18.9	57.6	209.9	24.6
GEMTESA® Therapeutic agent for overactive bladder	21.3	**30.2**	9.0	42.1	106.3	28.4
MYFEMBREE® Therapeutic agent for uterine fibroids and endometriosis (Jun. 2021～/Aug. 2022～)	2.9	**4.9**	2.0	70.0	15.4	31.4
RETHYMIC® Cultured thymus tissue for pediatric congenital athymia (Mar. 2022～)	0.8	**1.8**	1.0	121.3	5.4	33.2
APTIOM® Antiepileptic	7.1	**1.3**	(5.8)	(81.9)	5.4	23.7

(Ref.) Products sales in U.S. (based on local currency)

(Millions of USD)

Brand name	Q1 FY2025	**Q1 FY2026**	Change	Change %	FY2026 (Forecasts)	Progress %
ORGOVYX®	226	**323**	97	42.8	1,354	23.9
GEMTESA®	147	**189**	42	28.8	686	27.6
MYFEMBREE®	20	**30**	11	54.0	100	30.5
RETHYMIC®	6	**11**	6	100.0	35	32.1
APTIOM®	49	**8**	(41)	(83.6)	35	23.0

IV. Gross Profit by Region (Core Basis)

(Billions of JPY)

Q1 FY2026 Results	Japan	U.S.	Other	Total
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

(Billions of JPY)

Q1 FY2025 Results	Japan	U.S.	Other	Total
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

(Billions of JPY)

FY2026 Forecasts	Japan	U.S.	Other	Total
Revenue	87.6	406.4	46.0	540.0
Cost of sales	52.1	152.7	40.2	245.0
Gross profit	35.5	253.7	5.8	295.0

V. Consolidated Statement of Financial Position

(Billions of JPY)

	Mar. 31 2026	June 30 2026	Change
Assets	**804.6**	**844.9**	**40.3**
Non-current assets	**525.3**	**527.4**	**2.1**
Property, plant and equipment	44.2	**44.5**	0.3
Goodwill	211.1	**214.4**	3.3
Intangible assets	160.5	**157.4**	(3.1)
Patent rights/Marketing rights	155.9	**152.8**	(3.1)
In-process R&D	0.7	**0.7**	—
Others	3.9	**3.8**	(0.1)
Other financial assets	44.7	**42.9**	(1.8)
Other non-current assets	64.4	**67.7**	3.3
Deferred tax assets	0.4	**0.6**	0.2
Current assets	**279.3**	**317.5**	**38.2**
Inventories	85.4	**79.7**	(5.7)
Trade and other receivables	131.4	**139.5**	8.1
Other financial assets	5.3	**7.4**	2.1
Other current assets	12.8	**14.2**	1.5
Cash and cash equivalents	44.3	**76.6**	32.3
Liabilities	**512.1**	**436.3**	**(75.8)**
Non-current liabilities	**240.6**	**174.5**	**(66.1)**
Bonds and borrowings	179.1	**119.7**	(59.4) ← Repayment of long-term Borrowings
Other financial liabilities	16.6	**17.0**	0.4
Retirement benefit liabilities	5.7	**5.7**	(0.0)
Other non-current liabilities	23.5	**16.4**	(7.0)
Deferred tax liabilities	15.8	**15.7**	(0.2)
Current liabilities	**271.5**	**261.9**	**(9.6)**
Borrowings	38.1	**41.0**	2.9
Trade and other payables	56.7	**48.9**	(7.8)
Other financial liabilities	35.2	**38.6**	3.4
Income taxes payable	1.1	**1.9**	0.8
Provisions	89.6	**96.2**	6.6
Other current liabilities	50.8	**35.3**	(15.5)
Equity	**292.5**	**408.6**	**116.1**
Share capital	22.4	**71.3**	48.9 ← Increase due to share issuance
Capital surplus	—	**48.3**	48.3 ← Increase due to share issuance
Treasury shares	(0.7)	**(0.7)**	(0.0)
Retained earnings	159.0	**176.5**	17.5
Other components of equity	111.8	**113.2**	1.4
Equity attributable to owners of the parent	**292.5**	**408.6**	**116.1**

Major patent rights	26/3	26/6
ORGOVYX® (relugolix)	58.6	57.3
MYFEMBREE® (relugolix)	8.9	8.8
GEMTESA® (vibegron)	86.9	85.4

VI. Changes in Quarterly Results

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

(Billions of JPY)

	FY2025				FY2026
	Q1	Q2	Q3	Q4	Q1
Revenue	**108.0**	**119.1**	**120.6**	**105.5**	**129.5**
Cost of sales	44.1	45.6	55.4	51.3	61.4
Gross profit	63.9	73.5	65.2	54.3	68.1
SG&A expenses	35.4	38.6	42.5	42.9	39.0
R&D expenses	8.1	9.4	10.4	16.1	11.4
Others (core basis)	(0.1)	50.1	1.0	1.2	0.4
Core operating profit (loss)	**20.4**	**75.7**	**13.4**	**(3.5)**	**18.1**
Adjustments (negative number indicates net expense)	0.0	0.0	0.3	1.1	0.1
Operating profit (loss)	**20.4**	**75.8**	**13.6**	**(2.4)**	**18.2**
Net profit (loss) attributable to owners of the parent	**11.2**	**87.7**	**8.8**	**(0.8)**	**17.0**

2. Revenue of Major Products

	FY2025				FY2026
	Q1	Q2	Q3	Q4	Q1
Japan					(Invoice price basis, Billions of JPY)
XEPLION®/XEPLION TRI®	—	—	—	3.2	4.1
LATUDA®	3.5	3.4	3.8	3.0	3.7
TWYMEEG®	2.4	2.6	2.9	2.7	3.3
METGLUCO®	1.9	1.8	2.0	1.7	1.9
Equa®/EquMet®	4.2	3.3	1.2	—	—
Authorized Generics	3.1	3.0	3.3	2.8	3.0
U.S.					(Millions of USD)
ORGOVYX®	226	247	304	252	323
GEMTESA®	147	150	189	151	189
MYFEMBREE®	20	24	30	22	30
RETHYMIC®	6	17	8	11	11
APTIOM®	49	24	11	15	8

VII. Major Group Companies (As of June 30, 2026)

Domestic	Establish-ment	Ownership	Businesses
Sumitomo Pharma Promo Co., Ltd.	1998/ 6	100%	Manufacturing and sales of pharmaceuticals
Marubeni Pharmaceuticals Corporation*	2025/ 5	40.0%	Manufacturing and sales of pharmaceuticals and others
RACTHERA Co., Ltd. *	2024/11	33.4%	Research and development of regenerative medicine –related products
S-RACMO Co., Ltd. *	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

* Associates

VIII . Development Pipeline (As of July 31, 2026)

- This table shows key clinical studies for indications of products for which the Sumitomo Pharma Group aims to obtain regulatory 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 updated based on the date when the relevant 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 dosage and administration: pediatric) Schizophrenia	Submitted (March 2026)
	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
	DSP-0551	Tremor associated with Parkinson's disease	Phase 1
Regenerative medicine / cell therapy (Collaboration with RACTHERA Co., Ltd.)	AMCHEPRY®/Raguneprocel /CT1-DAP001/DSP-1083 (Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells) (JAPAN)	Parkinson's disease	Conditional and time-limited approval (March 2026) Post-marketing clinical study
	Raguneprocel /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	Retinitis pigmentosa	Phase 1/2

	retinal sheet）(U.S.)		

2. Oncology

Brand name/ Generic name/ Product code	Planned indication(s)	Development stage
Enzomenib	Acute leukemia	Phase 2
Nuvisertib	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 virus prophylaxis	Phase 1

IX. Profiles of Major Products under Development (As of July 31, 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 great 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 no dopamine D_2 receptor antagonistic activity, 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 a selective 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 have potential in hypersomnia disorders other than narcolepsy.

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 via enhanced 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 a broad range of 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-HT_7 receptor antagonist. DSP-2342 is expected to demonstrate a broad antipsychotic effect in psychosis, anxiety, and depression, based on the dual antagonism of 5-HT_{2A} and 5-HT_7 receptors. Furthermore, DSP-2342 has high selectivity for 5-HT_{2A} and 5-HT_7 receptors, and is therefore expected to show a high level of safety and tolerability.

DSP-0551 Origin: in-house, Formulation: oral

- Planned indication: Tremor associated with Parkinson's disease
- DSP-0551 is a multi-ion channel modulator identified through phenotype-based drug discovery. It exhibits inhibitory activity against multiple calcium and sodium ion channels that have been implicated in tremor. Through these mechanisms, DSP-0551 is expected to modulate abnormal neuronal firing and excessive synchronization in neural circuits associated with tremor, thereby improving tremor associated with Parkinson's disease.

(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 advancing the research and development of regenerative medicine / cell therapy using iPS cells 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, and others
- Planned indication: Parkinson's disease
- In Japan, CT1-DAP001/DSP-1083 obtained manufacturing and marketing approval under the conditional and time-limited approval framework in March 2026 for the indication of the improvement of motor symptoms in patients with Parkinson's disease who have an inadequate response to existing pharmacological therapies, including levodopa-containing products. The product name is AMCHEPRY® (INN: raguneprocel).
- In the U.S., an investigator-initiated clinical study is being conducted at UC San Diego and other institutions, while company-sponsored studies are also being pursued in parallel.

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

- Partnering: HEALIOS K.K., Kyushu University, and others
- 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) and the University of Minnesota
- Planned indication: Retinitis pigmentosa
- The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for the indication of retinitis pigmentosa in March 2026.

2. Oncology

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

- Planned indication: Acute leukemia
- Enzomenib (DSP-5336) is a small molecule inhibitor of the menin and lysine methyltransferase 2A (KMT2A) protein interaction. Acute myeloid leukemia with KMT2A rearrangement or nucleophosmin 1 (NPM1) mutation relies 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 preclinical studies. The FDA granted Orphan Drug Designation for enzomenib for the indication of acute myeloid leukemia in June 2022 and for acute lymphoblastic leukemia in July 2026, 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 MHLW 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 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 FDA, the MHLW, 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 injectable formulation of a CHK1 inhibitor encapsulated in PEGylated liposomes. CHK1 is a serine/threonine kinase activated by the DNA damage response, leading to cell-cycle arrest and DNA repair. CHK1 inhibition leads cancer cells with high replication stress to apoptosis by inducing further DNA damage. SMP-3124 is expected to enhance the anti-tumor activity and reduce side effects of the CHK1 inhibitor through optimized pharmacokinetics of the compound by liposomal nanoparticle formulation.

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 tumor in May 2022.

3. Others

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

- Planned indications: Complicated urinary tract infections and complicated 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 virus prophylaxis
- 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 responses. 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.