Conference on Q3 FY2023
(April 1 to December 31, 2023)
Financial Results

Sumitomo Pharma Co., Ltd.

Sumitomo Pharma
Innovation today, healthier tomorrows

January 31, 2024

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

Financial Results for Q3 FY2023

Financial Results for Q3 FY2023 (Core Basis)

Billions of yen

	Q3YTD FY2022 Results	Q3YTD FY2023 Results	Change			FY2023	
			Value	FX impact	%	May 15 forecasts	%
Revenue	460.3	**235.0**	(225.2)	5.9	(48.9)	362.0	64.9
Cost of sales	139.7	**93.2**	(46.5)	(12.5)	(33.3)	132.0	70.6
Gross profit	320.5	**141.8**	(178.7)	18.4	(55.7)	230.0	61.7
SG&A expenses	227.5	**176.6**	(50.9)	6.1	(22.4)	220.0	80.3
R&D expenses	74.9	**68.0**	(6.9)	2.1	(9.2)	84.0	80.9
Other operating income/expenses	24.8	**6.4**	(18.4)	—	—	12.0	
Core operating profit	42.9	**(96.4)**	(139.3)	10.1	—	(62.0)	155.5
Non-recurring items (negative number indicates net loss)	(60.7)	**(21.4)**	39.3			(16.0)	
Operating profit	(17.8)	**(117.7)**	(100.0)		—	(78.0)	151.0
Finance income/costs	20.0	**12.6**	(7.4)			(3.0)	
Profit before taxes	2.2	**(105.2)**	(107.4)		—	(81.0)	
Income tax expenses	34.8	**12.5**	(22.3)			(1.0)	
Net profit	(32.6)	**(117.7)**	(85.1)		—	(80.0)	147.1
Net profit attributable to owners of the parent	(18.5)	**(117.7)**	(99.2)		—	(80.0)	147.1

Average rates:
Q3 FY2022 Results : 1US$ = ¥136.51, 1RMB = ¥19.88
Q3 FY2023 Results : 1US$ = ¥143.33, 1RMB = ¥19.98
FY2023 forecasts : 1US$ = ¥130.00, 1RMB = ¥19.50

Period end rates:
As of the end of March 2023 : 1US$ = ¥133.54, 1RMB = ¥19.42
As of the end of December 2023 : 1US$ = ¥141.83, 1RMB = ¥19.94

Revised full-year forecasts (See P.9)

- Revenue decreased significantly due to LATUDA®'s loss of exclusivity in the U.S.
- Main breakdown of Other operating income/expenses (FY2023)
  Share transfer of Sumitomo Pharma Animal Health Co., Ltd. (FY2022)
  Certain product transfers and Priority Review Voucher sale in the U.S.
- Main breakdown of Non-recurring items (FY2023)
  Business structure improvement expenses in North America (FY2022)
  Impairment loss on KYNMOBI®

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Financial Results for Q3 FY2023 (Core Basis) - vs. Q3 YTD FY2023 Plans

Billions of yen

	Q3YTD FY2023 Plans	**Q3YTD FY2023 Results**	Change			
			Value	%	FX impact	% (w/o FX)
Revenue	261.3	**235.0**	(26.3)	89.9	11.9	85.4
Cost of sales	95.4	**93.2**	(2.2)	97.7	5.2	92.3
Gross profit	165.9	**141.8**	(24.1)	85.5	6.7	81.5
SG&A expenses	167.6	**176.6**	9.0	105.4	12.1	98.2
R&D expenses	63.1	**68.0**	4.9	107.7	4.0	101.3
Other operating income/expenses	7.0	**6.4**	(0.6)		—	
Core operating profit	(57.8)	**(96.4)**	(38.6)	—	(9.4)	—

Average rates:
Q3 FY2023 Results : 1US$ = ¥143.33, 1RMB = ¥19.98
FY2023 Plans : 1US$ = ¥130.00, 1RMB = ¥19.50

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Revenue of Major Products in North America

	Q3YTD FY2022 Results	Q3YTD FY2023 Results	Change	Q3YTD FY2022 Results	Q3YTD FY2023 Results	Change			FY2023		
						Value	FX impact	%	May 15 forecasts		Yen-basis %
North America	Million $			Billions of yen					Million $	Billions of yen	
ORGOVYX®	128	**215**	87	17.5	**30.9**	13.4	1.5	76.6	396	51.5	60.0
MYFEMBREE®	21	**49**	29	2.9	**7.1**	4.2	0.3	148.2	192	24.9	28.5
GEMTESA®	125	**174**	49	17.0	**24.9**	7.9	1.2	46.5	362	47.0	53.0
APTIOM®	191	**175**	(15)	26.0	**25.2**	(0.9)	1.2	(3.3)	273	35.5	70.9
RETHYMIC®	22	**30**	8	3.0	**4.3**	1.3	0.2	44.3	54	7.0	61.5
LATUDA®	1,313	**36**	(1,278)	179.3	**5.1**	(174.2)	0.2	(97.2)	161	20.9	24.4
Others	74	**12**	(62)	10.1	**1.7**	(8.4)	0.1	(83.5)	167	22.0	81.5
Export products/ One-time revenue, etc. *	173	**114**	(60)	23.7	**16.3**	(7.4)	0.8	(31.2)			
Total	2,046	**805**	(1,241)	279.4	**115.4**	(164.0)	5.5	(58.7)	1,605	208.8	55.3

(Ref.) Achievement rate against Q3 YTD plans for three key products

Million $

Plans	Results	%
265	215	81.4
116	49	42.6
246	174	70.8

- Of the “Export products/One-time revenue, etc.” in Q3 FY2022, the one-time revenue under the license agreement for ORGOVYX® in EU was $50M. (See the breakdown below the table)

* Major items included in Export products/One-time revenue, etc.

Q3YTD FY2022	Deferred revenue from the collaboration with Pfizer of $109M	Q3YTD FY2023	Deferred revenue from the collaboration with Pfizer of $88M
	Revenue from the license agreement for ORGOVYX® in EU of $50M		Milestone revenue from the approval of MYFENBREE® for endometriosis in EU of $9M

Average rates:
Q3 FY2022 Results : 1US$ = ¥136.51
Q3 FY2023 Results : 1US$ = ¥143.33
FY2023 forecasts : 1US$ = ¥130.00

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Revenue of Major Products in Japan & Asia

Billions of yen

	Q3YTD FY2022 Results	Q3YTD FY2023 Results	Change		FY2023	
			Value	%	May 15 forecasts	%
Japan						
Equa®/EquMet®	27.3	**24.6**	(2.7)	(9.8)	32.4	76.0
TRERIEF®	13.1	**13.1**	0.0	0.2	15.0	87.4
LATUDA®	7.3	**9.0**	1.7	24.1	12.5	72.0
METGLUCO®	6.0	**5.7**	(0.3)	(5.2)	7.5	75.7
TWYMEEG®	1.3	**3.5**	2.2	174.2	4.2	83.1
LONASEN® Tape	2.2	**2.9**	0.7	31.3	3.3	89.0
AG products	7.1	**7.1**	0.0	0.0	8.6	82.2
Trulicity® *	24.8	**—**	(24.8)	—	—	—
Others	13.1	**16.9**	3.8	28.7	30.6	76.0
Export products/ One-time revenue, etc.	10.6	**5.1**	(5.5)	(52.2)		
Non-pharmaceutical operations	34.0	**1.3**	(32.7)	(96.1)		
Total	146.7	**89.2**	(57.5)	(39.2)	114.1	78.1
Asia						
MEROPEN® （China)	23.8	**15.3**	(8.5)	(35.8)	18.7	81.8
Others	10.4	**15.2**	4.8	45.9	20.4	74.4
Total	34.2	**30.5**	(3.7)	(10.9)	39.1	78.0

Japan

- Progress is fundamentally on track in total
- Sales of LATUDA®, TWYMEEG®, and LONASEN® Tape continue to grow
- Export products/One-time revenue, etc. in Q3 YTD FY2022 includes one-time revenue ¥6.1B under the license agreement for DSP-0187
- NHI drug price revision effect (¥3.0B) in total

Asia

- MEROPEN® (China) revenue decreased due to Volume-Based Procurement application

Note: Sales of each product in Japan are shown by invoice price (* Trulicity® is shown by NHI drug price)

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
Q3 YTD FY2023 Results	Revenue	89.2	115.4	30.5	235.0
	Cost of sales	42.1	43.4	7.7	93.2
	Gross profit	47.0	72.0	22.8	141.8
	SG&A expenses	35.7	132.1	8.8	176.6
	Core segment profit	11.3	(60.1)	14.0	(34.8)
	R&D expenses				68.0
	Core operating profit				(96.4)
Q3 YTD FY2022 Results	Revenue	146.7	279.4	34.2	460.3
	Cost of sales	83.9	49.1	6.8	139.7
	Gross profit	62.8	230.2	27.5	320.5
	SG&A expenses	43.1	174.6	9.8	227.5
	Core segment profit	19.7	55.7	17.7	93.0
	R&D expenses				74.9
	Core operating profit				42.9
Change	Revenue	(57.5)	(164.0)	(3.7)	(225.2)
	SG&A expenses	(7.4)	(42.5)	(1.0)	(50.9)
	Core segment profit	(8.4)	(115.8)	(3.7)	(127.8)
	R&D expenses				(6.9)
	Core operating profit				(139.3)

Japan

- Despite a decrease in selling, general and administrative expenses, core segment profit decreased due to a decrease in gross profit due to revenue decline

North America

- Core segment profit decreased owing to the significant decrease in gross profit due to revenue decline, despite the reduction in selling, general and administrative expenses

Asia

- Core segment profit decreased owing to a decrease in gross profit due to revenue decline

Financial Forecasts for FY2023

Financial Forecasts for FY2023 (Core Basis)

Billions of yen

	FY2023 May 15 Forecasts	FY2023 Revised Forecasts	Change from Previous forecasts	
			Value	FX impact
Revenue	362.0	**317.0**	(45.0)	18.2
Cost of sales	132.0	**125.0**	(7.0)	8.0
Gross profit	230.0	**192.0**	(38.0)	10.2
SG&A expenses	220.0	**240.0**	20.0	18.4
R&D expenses	84.0	**92.0**	8.0	6.3
Other operating income and expenses (Core basis)	12.0	**6.0**	(6.0)	
Core operating profit	(62.0)	**(134.0)**	(72.0)	(14.5)
Non-recurring items (negative number indicates loss)	(16.0)	**(22.0)**	(6.0)	
Operating profit	(78.0)	**(156.0)**	(78.0)	
Income tax expenses	(1.0)	**3.0**	4.0	
Net profit	(80.0)	**(141.0)**	(61.0)	
Net profit attributable to owners of the parent	(80.0)	**(141.0)**	(61.0)	
R O E	(21.9%)	(38.8%)		
R O I C	(8.5%)	(18.6%)		

FX rates:
FY2023 Previous forecasts :
1US$ = ¥130.00, 1RMB = ¥19.50
Revised forecasts :
1US$ = ¥145.00, 1RMB = ¥20.00

- **Revenue:** Revised down by ¥45.0B
  (FX impact +¥18.2B)
  Excluding FX impact
  Japan +¥1.7B
  North America (¥64.4B)
  China (¥0.5B)
- **SG&A expenses:** FX impact +¥18.4B
- **R&D expenses:** FX impact +¥6.3B
- **Non-recurring items:** Increase in business structure improvement expenses due to the combination of group companies in North America, etc.

＊Although impairment testing will be conducted in the fourth quarter, this forecast does not include any impairment losses

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Revenue of Major Products in North America

	FY2023 May 15 Forecasts	FY2023 Revised Forecasts	Change	FY2023 May 15 Forecasts	FY2023 Revised Forecasts	Change
North America	Million $			Billions of yen		
ORGOVYX®	396	290	(106)	51.5	42.1	(9.4)
MYFEMBREE®	192	70	(122)	24.9	10.1	(14.8)
GEMTESA®	362	260	(102)	47.0	37.7	(9.3)
APTIOM®	273	236	(37)	35.5	34.2	(1.3)
RETHYMIC®	54	48	(6)	7.0	7.0	0.0
LATUDA®	161	47	(114)	20.9	6.9	(14.0)
Others Export products/ One-time revenue, etc.	167	162	(5)	22.0	23.1	1.1
Total	1,605	1,113	(492)	208.8	161.1	(47.7)

FX rates:
FY2023 Previous forecasts : 1US$ = ¥130.00
Revised forecasts : 1US$ = ¥145.00

- Sales of three key products revised down to reflect the progress of sales and changes in the payer-mix that have resulted in price decreases
- Sales of LATUDA® revised down due to faster-than-expected erosion by generics

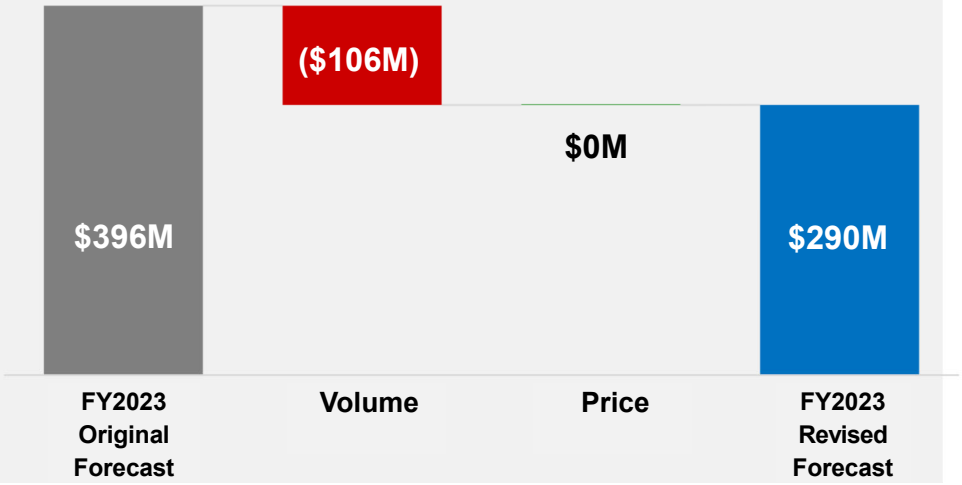
Financial Forecasts for FY2023

Marketing Status of ORGOVYX®

Original plan for Q3 YTD FY2023	Actual for Q3 YTD FY2023	Achievement rate against original plan for Q3 YTD FY2023	Volume and price of influence against actual for Q3 YTD FY2023, $215M	
$265M	**$215M**	**81%**	Volume	Unfavorable. approx. ($59M)
			Price	Favorable. approx. $9M

- Q3 YTD FY2023 revenue increased approx. 68% compared to Q3 YTD FY2022
- Original plan for Q3 YTD FY2023 was not achieved mainly due to slower than expected market share uptake

Analysis of FY2023 Original Forecast vs Revised Forecast



Future Marketing Strategies

- Promoting combination therapy through the use of publications on combination data, including the results of the combination group sub-analysis of the Phase 3 study (HERO study) of ORGOVYX®
- Educating all stakeholders including Patients/HCPs/Reimbursement representatives on changes to Medicare Part D benefit design (From Jan. 2024, the Medicare Part D benefit design was changed, including eliminating of out of pocket following catastrophic phase and increasing the low income subsidy threshold)
- Utilizing a tool (Video messages from patients taking ORGOVYX® and Discussion Guide) to support meaningful conversations with patients and their physicians on treatment options

Financial Forecasts for FY2023

Marketing Status of MYFEMBREE®

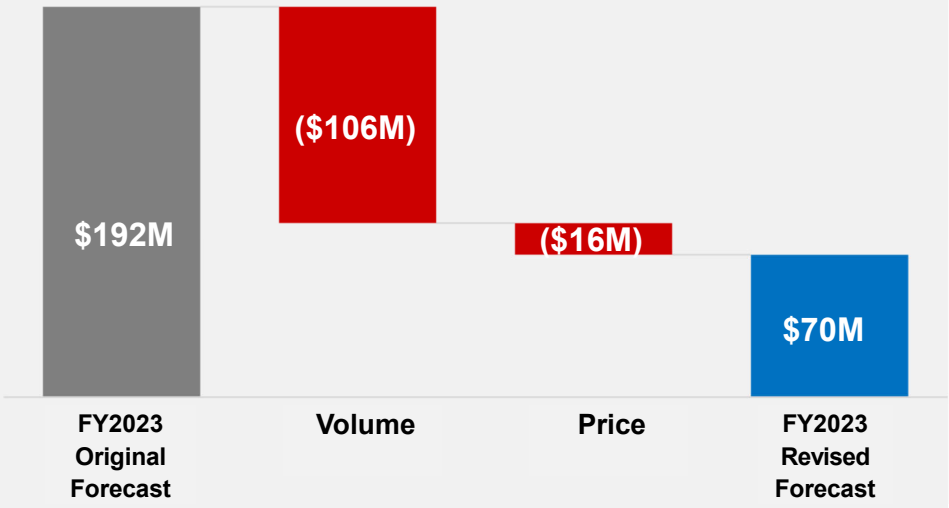
Myfembree® (relugolix, estradiol, and norethindrone acetate) tablets 40 mg, 1 mg, 0.5 mg

Original plan for Q3 YTD FY2023	Actual for Q3 YTD FY2023	Achievement rate against original plan for Q3 YTD FY2023	Volume and price of influence against actual for Q3 YTD FY2023, $49M	
$116M	**$49M**	**43%**	Volume	Unfavorable. approx. ($58M)
			Price	Unfavorable. approx. ($9M)

- Q3 YTD FY2023 revenue increased approx. 133% compared to Q3 YTD FY2022. TRx and NBRx share* in uterine fibroids (UF) and endometriosis (EM) of GnRH antagonists market are 42% and 48% in Dec. 2023 (30% and 40% in March 2023)
- Original plan for Q3 YTD FY2023 was not achieved mainly due to slower than anticipated GnRH class growth in both UF and EM, and slower than expected market share uptake in EM

*Source: Symphony METYS – Data through December 2023, IDV®

Analysis of FY2023 Original Forecast vs Revised Forecast



Future Marketing Strategies

- Optimizing the appeal of GnRH therapy as treatment of choice after first oral contraceptive failure for both UF and EM
- Ensuring that patients with UF and EM are aware of MYFEMBREE® by DTC including SNS
  (Utilizing Endometriosis Awareness Month in March 2024)
- Improving market access in UF and EM, and increasing awareness of appropriate timing of start dosing for successful treatment

Financial Forecasts for FY2023

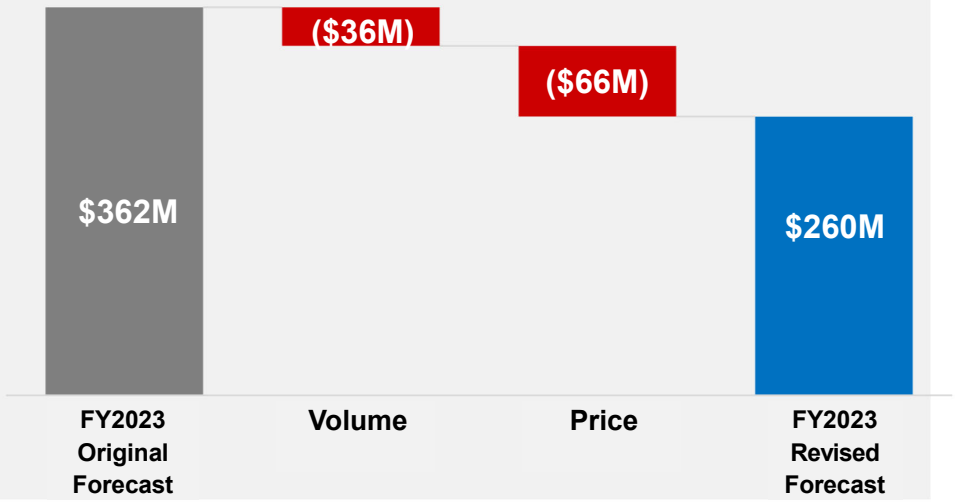
Marketing Status of GEMTESA®

Original Plan for Q3 YTD FY2023	Actual for Q3 YTD FY2023	Achievement rate against original plan for Q3 YTD FY2023	Volume and price of influence against actual for Q3 YTD FY2023, $174M	
$246M	**$174M**	**71%**	Volume	Unfavorable. approx. ($25M)
			Price	Unfavorable. approx. ($47M)

- Q3 YTD FY2023 revenue increased approx. 39% compared to Q3 YTD FY2022. TRx and NBRx Share* in Beta3 are 23% and 33% in Dec. 2023 (16% and 28% in March 2023)

  * Source IQVIA NPA
- Original plan for Q3 YTD FY2023 was not achieved mainly due to price down by higher proportion of Medicare Part D prescriptions

Analysis of FY2023 Original Forecast vs Revised Forecast



Future Marketing Strategies

- Optimizing structure and effectiveness of the sales team to strengthen the primary care market
- Strengthening to educate HCPs on the differentiated clinical profile of GEMTESA®, including safety for OAB patients with hypertension
- Enhancing the provision of GEMTESA® information to payors to maintain and improve market access for patients to continue to have affordable access

Financial Forecasts for FY2023

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
FY2023 Revised Forecasts	Revenue	115.8	161.1	40.1	317.0
	Cost of sales	55.2	59.4	10.4	125.0
	Gross profit	60.6	101.7	29.7	192.0
	SG&A expenses	47.4	180.6	12.0	240.0
	Core segment profit	13.2	(78.9)	17.7	(48.0)
	R&D expenses				92.0
	Core operating profit				(134.0)
FY2023 May 15 Forecasts	Revenue	114.1	208.8	39.1	362.0
	Cost of sales	54.2	68.8	9.0	132.0
	Gross profit	59.9	140.0	30.1	230.0
	SG&A expenses	47.7	160.3	12.0	220.0
	Core segment profit	12.2	(20.3)	18.1	10.0
	R&D expenses				84.0
	Core operating profit				(62.0)
Change	Revenue	1.7	(47.7)	1.0	(45.0)
	SG&A expenses	(0.3)	20.3	(0.0)	20.0
	Core segment profit	1.0	(58.6)	(0.4)	(58.0)
	R&D expenses				8.0
	Core operating profit				(72.0)

Japan

- Profit expected to increase due to increase in revenue

North America

- Profit decreased due to the significant impact of the downward revision of revenue

Asia

- Profit decreased due to the impact of the downward revision of revenue in local currency

Research and Development

Development Pipeline (as of January 31, 2024)

: Psychiatry & Neurology : Oncology : Others

Revisions since the announcement of October 2023 are shown in red

Area	Phase 1		Phase 2	Phase 3	NDA submitted
Japan	**DSP-0187** (Narcolepsy) **DSP-0378** (Dravet syndrome, Lennox–Gastaut syndrome)	**TP-3654** (Myelofibrosis) **DSP-5336** (Acute leukemia) **DSP-0390** (Glioblastoma) **KSP-1007** (Complicated urinary tract and intra-abdominal infections, Hospital-acquired bacterial pneumonia)	**EPI-589** (ALS/Investigator-initiated study) **Allo iPS cell-derived products** (Parkinson's disease/ Investigator-initiated study) **Allo iPS cell-derived products** (Retinal pigment epithelium tear)	**ulotaront** (Schizophrenia)* **ulotaront** (Generalized anxiety disorder)*	
U.S.	**SEP-378614** (To be determined) **SEP-380135** (To be determined) **DSP-0038** (Alzheimer's disease psychosis) **DSP-3456** (Treatment resistant depression) **DSP-2342** (To be determined)	**TP-3654** (Myelofibrosis) **DSP-5336** (Acute leukemia) **DSP-0390** (Glioblastoma) **TP-1287** (Solid tumors) **TP-1454** (Solid tumors) **KSP-1007** (Complicated urinary tract and intra-abdominal infections, Hospital-acquired bacterial pneumonia) **SP-101** (cystic fibrosis)	**EPI-589** (Parkinson's disease/ALS) **ulotaront** (Parkinson's disease psychosis) **Allo iPS cell-derived products** (Parkinson's disease/ Investigator-initiated study)	**ulotaront** (Schizophrenia) **ulotaront** (Adjunctive major depressive disorder)* **ulotaront** (Generalized anxiety disorder)* **GEMTESA® (vibegron)** (New indication: OAB in men with BPH)	
China				**ulotaront** (Schizophrenia)* **vibegron** (Overactive bladder)	

*Phase 2/3 study

Clinical Development Status

- **Allo iPS cell-derived products (dopaminergic neural progenitor cells)**
  U.S.: Parkinson's disease (Phase 1/2)
  - Started investigator-initiated study by University of California San Diego School of Medicine

  Japan: Parkinson's disease (Phase 1/2)
  - In an investigator-initiated study by Kyoto University, completed the two-year observation period at the end of 2023
  - Aiming for potential approval and launch in FY2024

- **ulotaront**
  Future development strategy of ulotaront for schizophrenia continues to be discussed with Otsuka

- **XENLETA®（lefamulin）**
  China: Approved for community-acquired pneumonia in November 2023

- **KSP-1007**
  Japan: Started Phase 1 study

Allogeneic iPS cell-derived Dopaminergic Neural Progenitor Cells Started Investigator-Initiated Study in the U.S.

Overview of this clinical study

Test product	Allogeneic iPS cell-derived dopaminergic neural progenitor cells (CT1-DAP001)
Development stage	Phase 1/2
Study patients	Patients with Parkinson's disease
Study design (Target number of patients)	Single center, open, non-placebo-controlled (Seven patients)
Primary endpoint	Safety: Frequency and severity of adverse events
Secondary endpoint (Efficacy)	Motor symptoms and others

The role of each organization, etc.

- ✓ Clinical study institution: The Sanford Stem Cell Institute CIRM Alpha Clinic at University of California San Diego School of Medicine
- ✓ Provided cell: Allogeneic iPS cell-derived dopaminergic neural progenitor cells (derived from QHJI donor-iPS cells, provided by the iPS Cell Stock Project of CiRA Foundation)
- ✓ Technical support: Kyoto University Hospital and a research group led by Professor Jun Takahashi of CiRA
- ✓ Cell manufacturing: Sumitomo Pharma (Produce dopaminergic neural progenitor cells at SMaRT in Japan and transported to U.S.)
- ✓ Financial support: Sumitomo Pharma

Oncology Area: Overview of TP-3654

- ✓ Target indication: Myelofibrosis
- ✓ Unmet Medical Needs in Myelofibrosis:
  - ➢ Myelofibrosis is a rare hematological malignancy. It is characterized by extramedullary hematopoiesis associated with the fibrosis of the bone marrow and erythrocytosis in peripheral blood, which is caused by abnormal regulation of the JAK-STAT signal
  - ➢ Improvement of splenomegaly and systemic symptoms such as fatigue is an important treatment goal, as they are symptoms that appear with the myelofibrosis
  - ➢ JAK inhibitors, the current standard treatment of myelofibrosis, have been associated with adverse events such as anemia and thrombocytopenia, posing challenges with treatment discontinuation. Furthermore, the presence of anemia or low platelet counts has been identified as poor prognostic factors in myelofibrosis

It is desirable to develop novel therapies that can improve splenomegaly and systemic symptoms with fewer hematologic adverse events

- ✓ Origin: In-house
- ✓ Mechanism of action: Inhibition of PIM1 (proviral integration site for Moloney murine leukemia virus 1) kinases

From data presented at ASH 2023

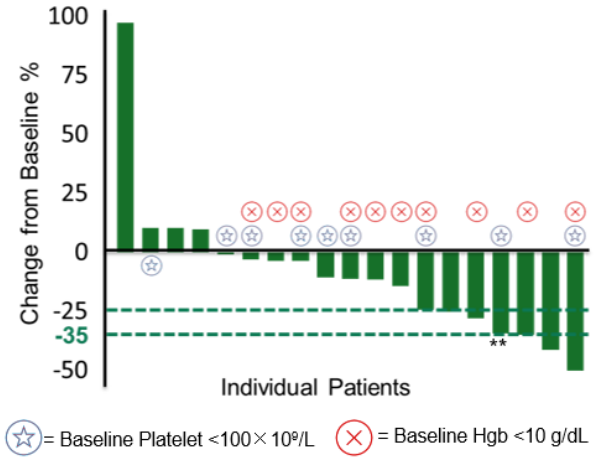
Oncology Area: Phase 1/2 Study of TP-3654 (Myelofibrosis, Interim Results)

- ✓ Although the data include low doses and are from a small number of patients, reduction in spleen volume and improvement in total symptom score were observed even in patients who did not respond to JAK inhibitors and in patients with Hb <10g/dL and platelets <100 × 10^9/L, who are known to have poor prognoses
- ✓ These efficacy measures are used as primary endpoints in pivotal studies of approved drugs, and favorable signals of clinical significance have been demonstrated in the study

Efficacy measures

Spleen Volume Reduction, Best Effect (N=20)

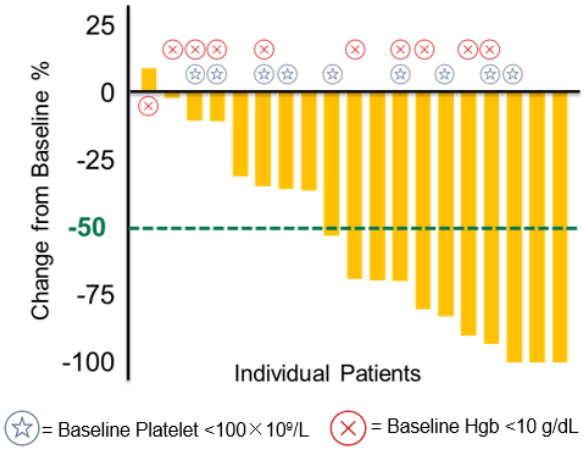
Best Change in Spleen Volume at Any Time (N=20)
SVR35: 20%; SVR25: 30%; SVR10: 55%



- 4/20 cases had spleen volume reduced by 35% or more
  **This case experienced 34.4% reduction
- 25% or more reduction in 7/20 cases
- 10% or more reduction in 11/20 cases

Improvement in Total Symptom Score, Best Effect (N=20)

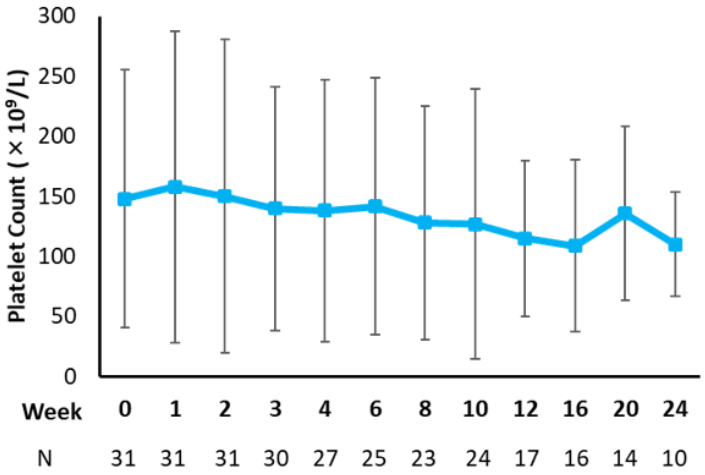
Best Change in Symptom at Any Time (N=20)
TSS50: 55% (11 of 20)



- 11/20 (55%) improved total symptom score by 50% or more

Safety measure

Changes in platelet counts (N=31, Mean±SD)



- Platelet counts remained stable during treatment
- Well-tolerated with no dose limiting toxicity (DLT)
- Most common adverse events were diarrhea, nausea, and vomiting

Reference: Efficacy results from a pivotal study of Momelotinib approved by the U.S. Food and Drug Administration (FDA) in September 2023 (similar target population: JAKi failure / PLT ≥25,000/μL / Hgb <10 g/dL): ≥35% spleen volume reduction in 22% of patients, ≥50% total symptom score improvement in 25% of patients *(Srdan V et al., Lancet 2023; 401; 269-80)*

Oncology Area: Development Status and Future Plans for TP-3654

- ✓ Development stage/progress:
  - ➢ Conducting the Phase 1/2 monotherapy study in Japan, U.S., Australia, Italy, and the UK
  - ➢ Canada regulatory agency had granted the permission to conduct the clinical study, and we are expanding to other regions
  - ➢ The FDA granted Orphan Drug Designation for TP-3654 for the indication of myelofibrosis in May 2022

- ✓ Future Plans:
  - ➢ Consider starting a clinical study in combination with a JAK inhibitor, aiming for obtaining top-line result of the pivotal study for myelofibrosis in FY2027

Oncology Area: Overview of DSP-5336

- ✓ Target indication: Acute leukemia (Acute myeloid leukemia, etc.)
- ✓ Unmet Medical Needs in Acute myeloid leukemia:
  - ➢ Acute myelogenous leukemia (AML) is a hematological malignancy. It is caused by a genetic mutation of hematopoietic cells in the bone marrow and is a lethal disease in which the normal hematopoietic function is disrupted by the abnormal growth of leukemic cells
  - ➢ AML is classified according to morphological abnormalities and genetic mutations of leukemic cells, and prognosis and treatment based on genetic mutations are being established
  - ➢ No targeted therapy has been established for AML with MLL rearrangements or AML with NPM1 mutation, which are the targets of DSP-5336 treatment, and the development of novel therapies are desired

AML with MLL rearrangements

- Approximately 5~10% of AML patients
- Most are classified as poor prognosis group, with very poor prognosis (5-year survival rate: ~30%)

AML with NPM1 mutations

- Approximately 30% of AML patients
- Classified as good or intermediate prognosis, dependent on concomitant genetic mutations, but difficult to cure without bone marrow transplantation

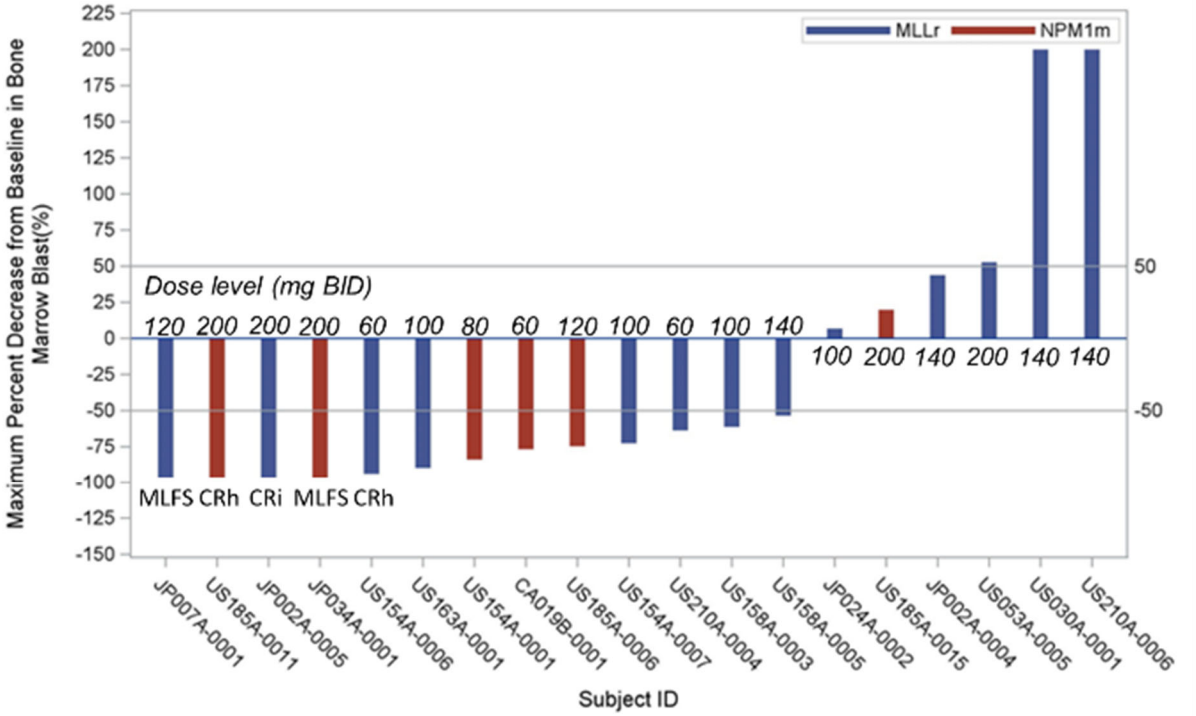
- ✓ Origin: In-house (Joint research with Kyoto University)
  - ➢ Started as a joint research “DSK Project” with Dr. Akihiko Yokoyama (then at Kyoto University) who was the first in the world to discover the necessity of MENIN in AML with MLL rearrangements, and others
  - ➢ Adopted for the AMED Acceleration of Transformative research for Medical innovation (ACT-M) (2020-2023), collaborated with the National Cancer Center to promote the start of clinical studies, expand AML target segments, and expand cancer indications through translational research
- ➢ Mechanism of action: Inhibition of the binding of menin and mixed-lineage leukemia (MLL) protein

From data presented at ASH 2023

Oncology Area: Phase 1/2 Study of DSP-5336 (Acute Leukemia, Interim Results)

Changes in Bone Marrow Blasts (%)

Patients with MLLr or NPM1m across all dose levels



CRh: clinical remission with partial hematologic recovery
CRi: clinical remission with incomplete count recovery
MLFS: morphologic leukemia-free state

Safety (43 patients)

- ✓ Well-tolerated with no dose limiting toxicity (DLT)
- ✓ Most common adverse events were nausea, vomiting, and fatigue
- ✓ No QTc prolongation or other cardiotoxicity associated with DSP-5336
- ✓ No differentiation syndromes have been observed among patients positive for DSP-5336 target mutations (MLLr or NPM1m)

Efficacy (19 patients with DSP-5336 target mutations, MLLr or NPM1m)

- ✓ Significant bone marrow blasts loss was observed in numerous efficacy-evaluable patients with DSP-5336 target mutations (MLLr or NPM1m)

Oncology Area: Development Status and Future Plans for DSP-5336

- ✓ Development stage/progress:
  - Conducting the Phase 1/2 monotherapy study in Japan, U.S., Canada, Korea, Taiwan, Singapore
  - EU regulatory agency had granted the permission to conduct the clinical study, and we are expanding to other regions
  - The FDA granted Orphan Drug Designation for DSP-5336 for the indication of acute myeloid leukemia in June 2022

- ✓ Future Plans:
  - Aiming for potential approval in a single-arm Phase 2 study without a control treatment due to the scarcity of treatment options in relapsed and refractory acute myeloid leukemia
  - The Phase 2 part is scheduled to start in the first half of FY2024 after discussion with regulatory agencies
  - Aiming for potential approval for the indication of acute myeloid leukemia in Japan and U.S. in FY2026

Appendix

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Appendix (Financial Results for Q3 FY2023)

Financial Results for Q3 FY2023 (Full Basis)

Billions of yen

	Q3YTD FY2022 Results	Q3YTD FY2023 Results	Change	
			Value	%
Revenue	460.3	235.0	(225.2)	(48.9)
Cost of sales	139.8	93.2	(46.6)	(33.3)
Gross profit	320.5	141.8	(178.7)	(55.7)
SG&A expenses	289.5	191.6	(97.9)	(33.8)
R&D expenses	76.0	73.6	(2.3)	(3.1)
Other operating income and expenses	27.2	5.6	(21.6)	
Operating profit	(17.8)	(117.7)	(100.0)	—
Finance income and costs	20.0	12.6	(7.4)	
Profit before taxes	2.2	(105.2)	(107.4)	—
Income tax expenses	34.8	12.5	(22.3)	
Net profit	(32.6)	(117.7)	(85.1)	—
Net profit attributable to owners of the parent	(18.5)	(117.7)	(99.2)	—

Appendix (Financial Forecasts for FY2023)

Revenue of Major Products in Japan & Asia

Billions of yen

	FY2023 May 15 Forecasts	FY2023 Revised Forecasts	Change
Japan			
Equa®/EquMet®	32.4	**31.1**	(1.3)
TRERIEF®	15.0	**15.5**	0.5
LATUDA®	12.5	**12.0**	(0.5)
METGLUCO®	7.5	**7.5**	—
TWYMEEG®	4.2	**4.2**	—
LONASEN® Tape	3.3	**3.8**	0.5
AG products	8.6	**9.4**	0.8
Others Export products/ One-time revenue, etc. Non-pharmaceutical operations	30.6	**32.3**	1.7
Total	114.1	**115.8**	1.7
Asia			
MEROPEN® (China)	18.7	**20.5**	1.8
Others	20.4	**19.6**	(0.8)
Total	39.1	**40.1**	1.0

Japan

- Sales of Equa®/EquMet® revised down due to the harsh market environment

Asia

- Sales of MEROPEN® (China) have slightly exceeded expectations, even on a local currency basis
- The decline in sales of Others was largely due to the decline in LATUDA® in China

Appendix (Research and Development)

Main Events / Targets for FY2023 (as of January 31, 2024)

Revisions since the announcement of October 2023 are shown in red

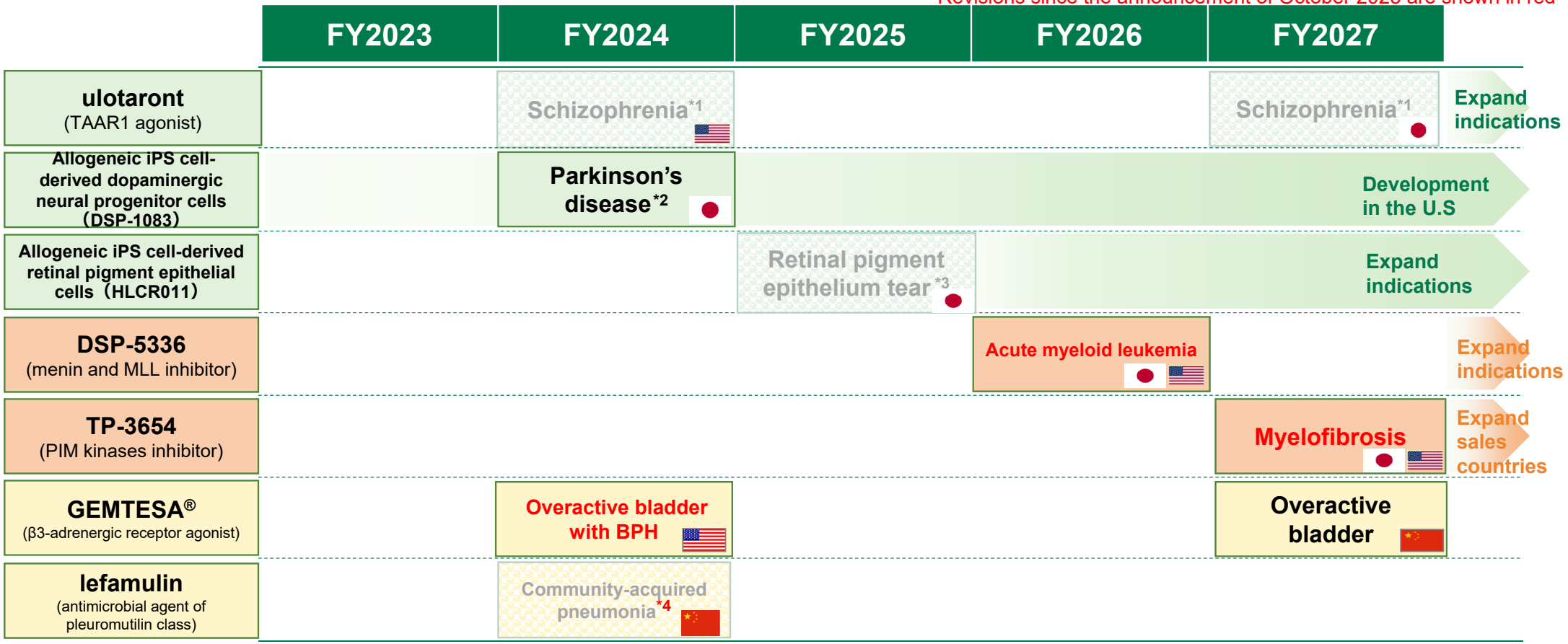
Psychiatry & Neurology	☐ ulotaront: ☑ Obtain results from two Phase 3 studies for schizophrenia〔☑ DIAMOND 1 ☑ DIAMOND 2〕 ☐ Submit NDA for schizophrenia in the U.S. ☐ Advance Phase 2/3 study in Japan and China for schizophrenia ☐ Advance Phase 2/3 studies for two additional indications (aMDD, GAD) ~~☐ SEP-4199: Advance Phase 3 studies for Bipolar I depression~~ ☑ Allogeneic iPS cell-derived products（Retinal pigment epithelium tear): Start clinical study in Japan ☑ Allogeneic iPS cell-derived products（Parkinson's disease): Start clinical study in the U.S. ☐ Complete manufacturing plant in the U.S. (for RETHYMIC® and allogeneic iPS cell-derived products)
Oncology	☐ Advance early Phase studies
Others	☑ relugolix: Obtain approval for endometriosis in Europe ☐ vibegron: Obtain results from Phase 3 study and submit sNDA for overactive bladder (OAB) with benign prostatic hyperplasia in the U.S. ☑ rodatristat ethyl: Obtain results from Phase 2 study for pulmonary arterial hypertension (PAH) ☐ universal influenza vaccine, malaria vaccines : Promote joint research and development projects
Frontier	~~☐ Launch product: (Japan) Automated blood collection/stabilization device~~ ☐ Promoting the current themes and generating evidence data for maximizing the value of the launched products

Appendix (Research and Development)

Product Launch Target (as of January 31, 2024)

Psychiatry & Neurology | Oncology | Others

Revisions since the announcement of October 2023 are shown in red



*1 To be revised for launch target based on development strategy for schizophrenia
*2 Launch schedule is based on our goal pending agreement with partner
*3 Under review for launch target based on clinical study status
*4 Under review for launch target

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Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (as of January 31, 2024)

Revisions since the announcement of October 2023 are shown in red

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) DSP-1083	Parkinson's disease	JP US			●1 ●4			Launch Target* (FY2024)
Retinal pigment epithelial cells (Allo iPS cell-derived) HLCR011	Retinal pigment epithelium tear	JP			●			
Photoreceptor (3D) (Allo iPS cell-derived) DSP-3077	Retinitis pigmentosa	JP US	●	●2				
Neural progenitor cells (Allo iPS cell-derived)	Spinal cord injury	JP US		●3				
Nephron progenitor cells (organ) (Auto/ Allo iPS cell-based induced)	Kidney failure	JP/ US	●					

1. Kyoto University Hospital 2. Kobe City Eye Hospital 3. Keio University Hospital 4. University of California San Diego School of Medicine

* Subject to conditional and time-limited approval

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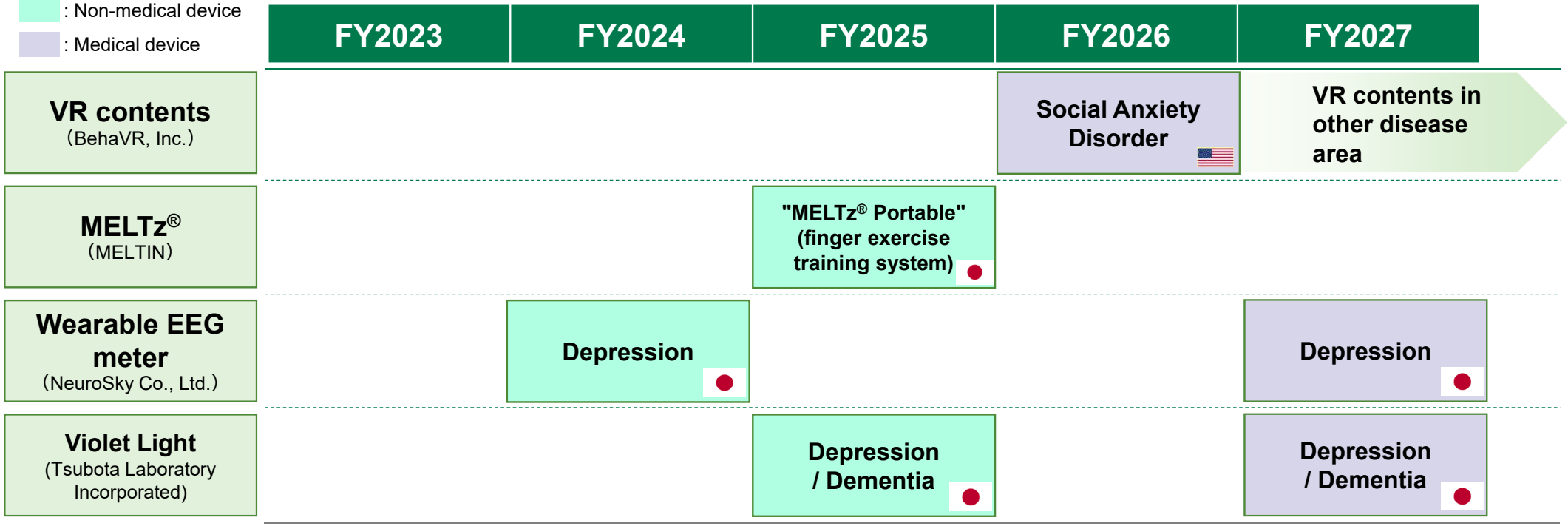
Appendix (Research and Development)

Frontier Business Product Launch Target (as of January 31, 2024)

Revisions since the announcement of October 2023 are shown in red

: Non-medical device
: Medical device



The automatic blood collection/storage device was deleted because a business contract could not be concluded with Drawbridge Health, Inc.
Deleted neurorehabilitation device for hand/fingers of MELTz® (Japan, FY2027) due to expecting to launch after FY2028 as an approved medical device

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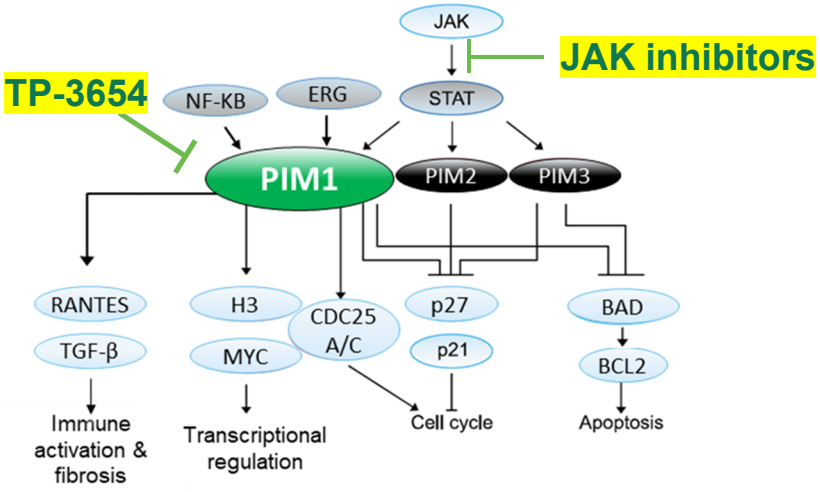
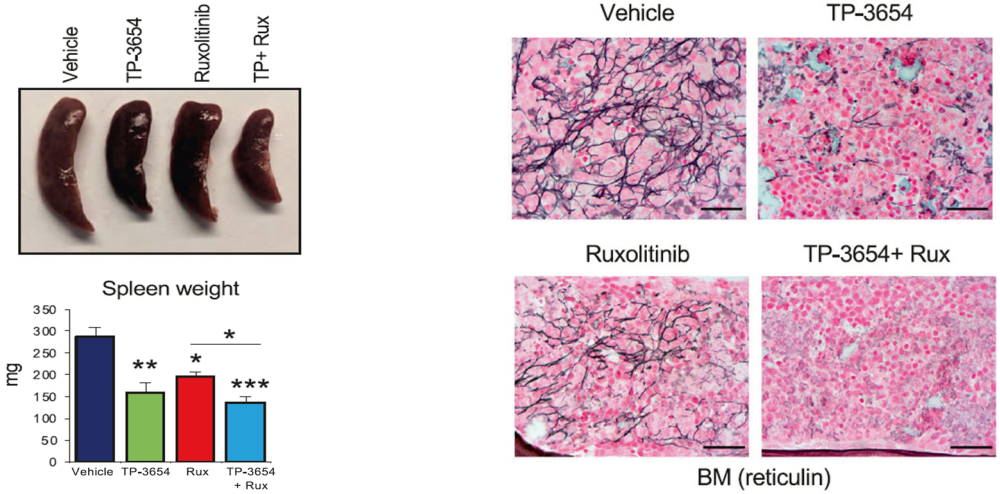
Oncology Area: Mechanism of Action of TP-3654

- PIM1 (proviral integration site for Moloney murine leukemia virus 1) kinase inhibitor
- PIM1 kinase is overexpressed in various cancers, including hematological malignancies. It plays a role in evading apoptosis and promoting tumorigenic growth, and thus PIM1 kinase inhibition is expected to have an suppressive effect on tumor growth. Furthermore, pre-clinical studies have strongly implicated PIM1 in the progression of myelofibrosis
- Pre-clinical studies have demonstrated improvement in splenomegaly, bone marrow fibrosis, and survival with administration of TP-3654
- By selectively inhibiting PIM1 kinase, a downstream signaling factor of the JAK2 pathway, TP-3654 is expected to exert its pharmacological effects while avoiding hematologic toxicity observed with JAK inhibitors. Pre-clinical studies suggest that hematologic toxicity concerns, such as thrombocytopenia, are small

TP-3654 concept: PIM1 kinase inhibitor



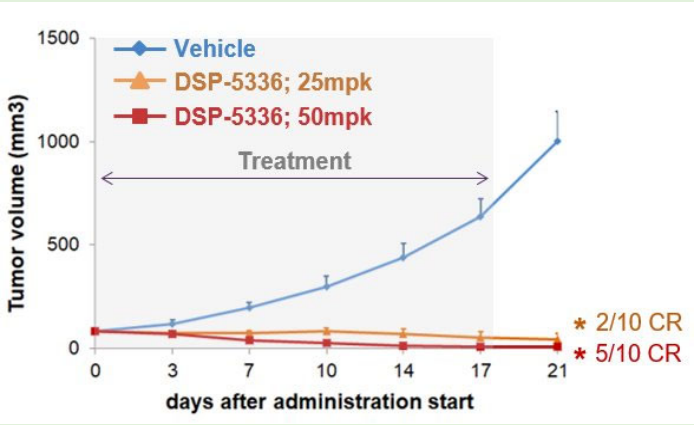
Improvement of splenomegaly (left) and bone marrow fibrosis (right) with TP-3654 (pre-clinical)



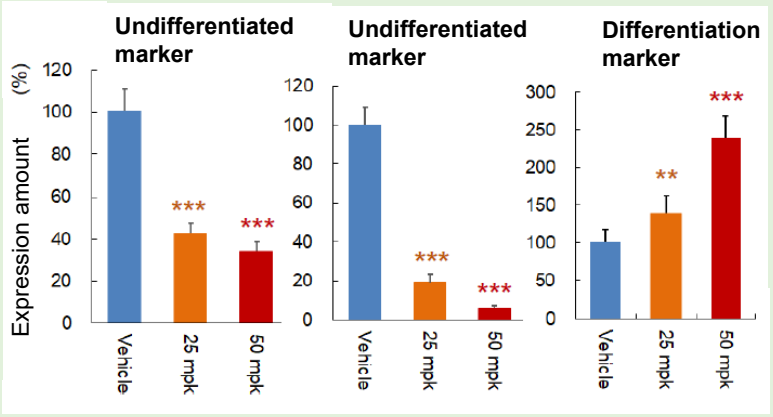
Oncology Area: Mechanism of Action of DSP-5336

- Inhibition of the binding of menin and mixed-lineage leukemia (MLL) protein
- Menin protein-MLL protein interaction is essential for the development and maintenance of acute leukemia with MLL rearrangements and NPM1 mutation
- By inhibiting the binding between menin protein and MLL protein, it is expected to show strong anti-tumor activity by suppressing the expression of leukemia-related genes caused by this protein-protein interaction and promoting differentiation into normal blood cells
- Strong pharmacological effects in pre-clinical data and wide margins in toxicity (especially QTc prolongation)

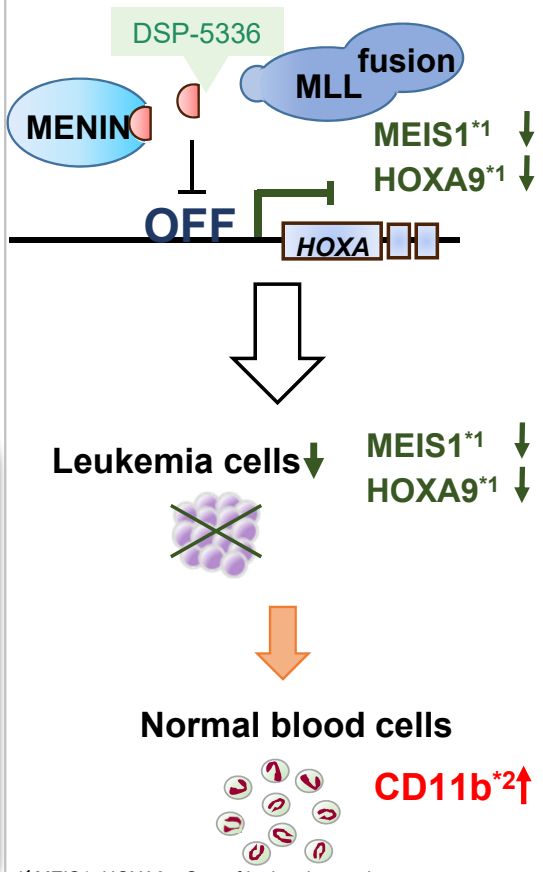
MLL rearrangements-positive AML xenograft model



Changes in pharmacodynamic markers



Mechanism of action of DSP-5336



*1 MEIS1, HOXA9 : One of leukemia-causing genes
*2 CD11b : Differentiation marker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