Conference on Q1 FY2023
(April 1 to June 30, 2023)
Financial Results

Sumitomo Pharma Co., Ltd.

Sumitomo Pharma
Innovation today, healthier tomorrows

July 31, 2023

Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, targets, 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.

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Financial Results for Q1 FY2023

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Sumitomo Pharma America (SMPA) Launches as New Combined Organization

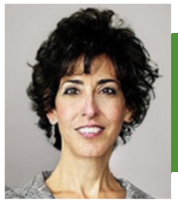
- SMPA launched on July 1, 2023 through consolidation the functions and human resources of Sumitomo Pharma's seven U.S. subsidiaries including Sunovion, Sumitovant, Myovant, Urovant, etc.
- The combination is expected to reduce the total number of employees in North America by approx. 500*1 by the end of FY2023, with cost synergies (SG&A and R&D expenses) of approx. US$260M in FY2023 and US$400M in FY2024*2

*1: VS end of FY2022, *2: VS not combination

Sumitomo Pharma America, Inc.

- U.S. Flagship Location: Cambridge, Massachusetts, U.S. with additional offices across NA and Europe
- Commercial Products: ORGOVYX®, MYFEMBREE®, GEMTESA®, APTIOM®, RETHYMIC®, and LATUDA®
- R&D & Pipeline: More than 30 assets including small molecule compounds and regenerative medicine/cell therapies in Psychiatry & Neurology such as ulotaront and Oncology as well as Other Areas, with dozens of clinical studies underway
- Number of employees: Approx. 1,700 (as of July 1, 2023)
- Leadership team: Comprised of industry-leading experts with deep life sciences expertise. Additionally, the following three leaders have been appointed Executive Officers of Sumitomo Pharma effective July 1, 2023

Myrtle Potter
President & CEO



Adele Gulfo
CEO of Biopharma Commercial Unit

Armin Szegedi
Chief Medical Officer

Financial Results for Q1 FY2023 (Core Basis)

The forecasts are not revised

Billions of yen

	Q1YTD FY2022 Results	Q1YTD FY2023 Results	Change			FY2023	
			Value	FX impact	%	May 15 forecasts	%
Revenue	159.9	**75.7**	(84.2)	2.2	(52.7)	362.0	20.9
Cost of sales	46.1	**30.4**	(15.6)	(3.2)	(33.9)	132.0	23.1
Gross profit	113.8	**45.3**	(68.6)	5.4	(60.2)	230.0	19.7
SG&A expenses	76.0	**61.8**	(14.2)	2.4	(18.7)	220.0	28.1
R&D expenses	24.4	**22.8**	(1.6)	0.9	(6.6)	84.0	27.2
Other operating income/expenses	0.0	**5.9**	5.9	—	—	12.0	49.0
Core operating profit	13.4	**(33.5)**	(46.9)	2.2	—	(62.0)	54.1
Non-recurring items (negative number indicates loss)	1.2	**(18.1)**	(19.3)			(16.0)	
Operating profit	14.6	**(51.6)**	(66.2)		—	(78.0)	66.1
Finance income/costs	32.0	**20.5**	(11.5)			(3.0)	
Profit before taxes	46.6	**(31.1)**	(77.7)		—	(81.0)	
Income tax expenses	18.5	**7.8**	(10.7)			(1.0)	
Net profit	28.1	**(38.9)**	(67.0)		—	(80.0)	48.6
Net profit attributable to owners of the parent	31.1	**(38.9)**	(70.0)		—	(80.0)	48.6

- Revenue decreased significantly due to LATUDA®'s loss of exclusivity in the U.S.
- Share transfer of Sumitomo Pharma Animal Health Co., Ltd. Included in Other operating income/ expenses
- Business structure improvement expenses in North America recognized as Non-recurring item

From Q1 FY2023, segments have been changed from four (Japan, North America, China, and Other Regions) to three (Japan, North America, and Asia)

Average rates:
Q1 FY2022 Results : 1US$ = ¥129.73, 1RMB = ¥19.60
Q1 FY2023 Results : 1US$ = ¥137.50, 1RMB = ¥19.57
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 June 2023 : 1US$ = ¥144.99, 1RMB = ¥19.95

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Revenue of Major Products in Japan

Billions of yen

	Q1YTD FY2022 Results	Q1YTD FY2023 Results	Change		FY2023	
			Value	%	May 15 forecasts	%
Equa®/EquMet®	8.8	**8.2**	(0.6)	(7.0)	32.4	25.2
TRERIEF®	4.4	**4.4**	0.0	0.2	15.0	29.6
LATUDA®	2.3	**2.8**	0.6	24.0	12.5	22.7
METGLUCO®	2.0	**1.9**	(0.1)	(4.3)	7.5	25.4
TWYMEEG®	0.1	**1.2**	1.1	—	4.2	27.6
LONASEN® Tape	0.7	**0.9**	0.2	35.3	3.3	27.0
AG products	2.3	**2.3**	0.0	1.1	8.6	27.2
Trulicity® *	8.6	**—**	(8.6)	—	—	—
Others	4.4	**5.4**	1.0	22.9	30.6	28.2
Export products/ Lump-sum revenue, etc.	7.4	**1.9**	(5.5)	(74.9)		
Non-pharmaceutical operations	11.0	**1.3**	(9.7)	(88.1)		
Total	52.1	**30.4**	(21.7)	(41.7)	114.1	26.6

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

- Progress is fundamentally on track in total
- Sales of LATUDA® continue to grow
- Sales of TWYMEEG® increased since the restriction on the number of prescription days was lifted in September 2022
- Of the “Export products/Lump-sum revenue, etc." in Q1 FY2022, the one-time income from the license agreement for DSP-0187 was ¥6.1B
- NHI drug price revision effect (¥1.0B) in total

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Revenue of Major Products in North America & Asia

	Q1YTD FY2022 Results	Q1YTD FY2023 Results	Change	Q1YTD FY2022 Results	Q1YTD FY2023 Results	Change			FY2023		
						Value	FX impact	%	May 15 forecasts		Yen-basis %
North America	Million $			Billions of yen					Million $	Billions of yen	
ORGOVYX®	36	**68**	32	4.7	**9.3**	4.7	0.5	99.7	396	51.5	18.1
MYFEMBREE®	4	**13**	9	0.5	**1.8**	1.3	0.1	245.7	192	24.9	7.2
GEMTESA®	34	**63**	29	4.4	**8.7**	4.3	0.5	98.1	362	47.0	18.5
APTIOM®	65	**58**	(7)	8.4	**7.9**	(0.4)	0.4	(5.3)	273	35.5	22.4
RETHYMIC®	5	**11**	5	0.7	**1.5**	0.8	0.1	112.0	54	7.0	21.4
LATUDA®	482	**8**	(473)	62.5	**1.2**	(61.3)	0.1	(98.1)	161	20.9	5.5
Others	31	**4**	(27)	4.0	**0.5**	(3.5)	0.0	(86.5)	167	22.0	22.8
Export products/ Lump-sum revenue, etc.*	77	**33**	(44)	10.0	**4.5**	(5.5)	0.3	(55.1)			
Total	733	**258**	(476)	95.2	**35.5**	△59.7	2.0	△62.7	1,605	208.8	17.0
Asia	Million RMB			Billions of yen					Million RMB	Billions of yen	
MEROPEN® （China）	464	**227**	(237)	9.1	**4.4**	(4.7)	(0.0)	(51.2)	958	18.7	23.8
Others				3.6	**5.4**	1.9	0.2	52.2		20.4	26.5
Total				12.7	**9.9**	(2.8)	0.2	(22.1)		39.1	25.2

North America segment

- Revenue significantly decreased due to the impact of the loss of exclusivity for LATUDA®, despite growth in the three key products
- Of the “Export products/Lump-sum revenue, etc.” in Q1 FY2022, the one-time income from the license agreement for ORGOVYX® in EU. (See the breakdown below the table)

Asia segment

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

* Major items included in Export products/Lump-sum revenue, etc.

Q1YTD FY2022	Deferred revenue from the collaboration with Pfizer of $25M	Q1YTD FY2023	Deferred revenue from the collaboration with Pfizer of $29M
	Revenue from the license agreement for ORGOVYX® in EU of $50M		

Average rates:
Q1 FY2022 Results : 1US$ = ¥129.73, 1RMB = ¥19.60
Q1 FY2023 Results : 1US$ = ¥137.50, 1RMB = ¥19.57
FY2023 forecasts : 1US$ = ¥130.00, 1RMB = ¥19.50

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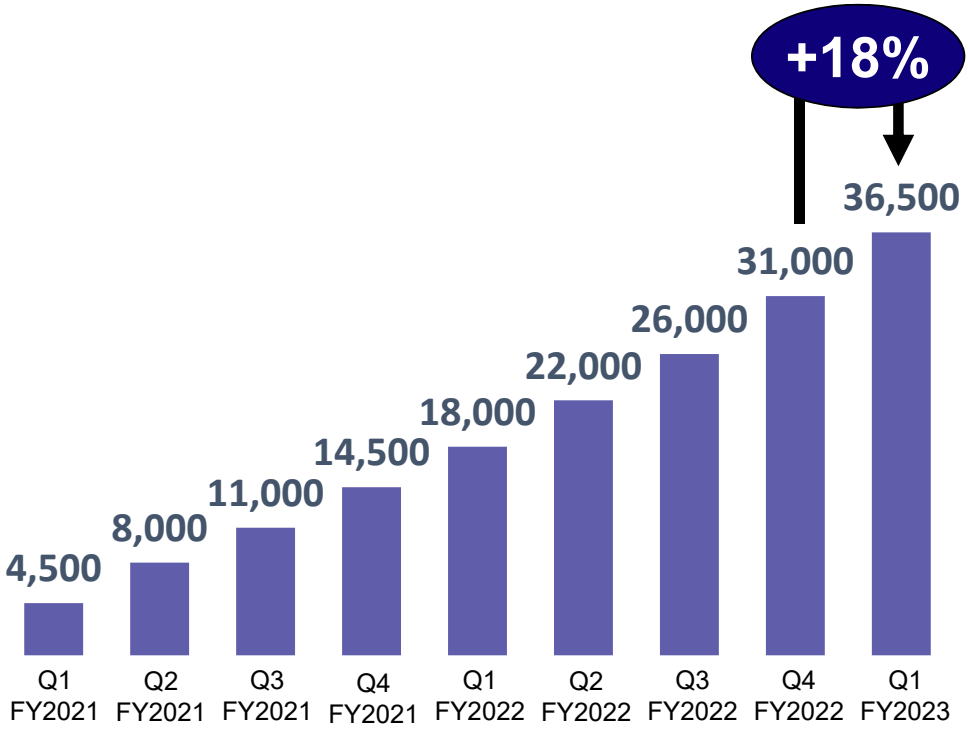
Marketing Status of ORGOVYX®

- Although there was a slight decrease in price against the FY2023 forecast, the number of new patients started treatment with ORGOVYX® increased, and progress is generally in line with the FY2023 forecast
- The number of cumulative patients treated with ORGOVYX® by Q1 FY2023 was approx. 36,500 (18% growth vs. Q4 FY2022)



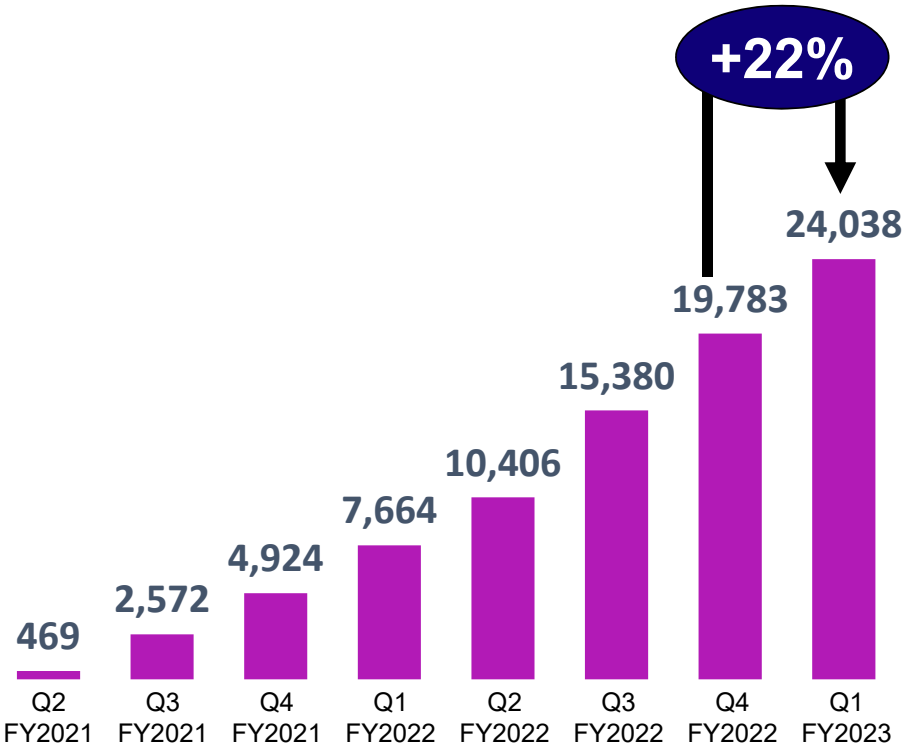
Estimated Cumulative Patients Treated with ORGOVYX®

(includes patients on free and commercial drug, excludes patients utilizing product samples)

- Marketing Activities
  - ✓ Improved Commercial payer coverage (Commercial: 94% of total lives and Medicare Part D: 99% of total lives as of June, 2023)
  - ✓ Optimize targeting and field force deployment
- Medical Activities
  - ✓ Utilize evidence on combination therapy published in March and April 2023, and continue focusing on generating data in combination therapy

Marketing Status of MYFEMBREE®

- Although the rate of progress against the FY2023 forecast is low due to a delay in the acquisition of prescriptions for EM and lower price resulting from increased use of Co-pay card, the plan is to grow toward the second half of FY2023
- Approx. 24,000 total prescriptions (TRx) in Q1 FY2023 (22% growth vs. Q4 FY2022)



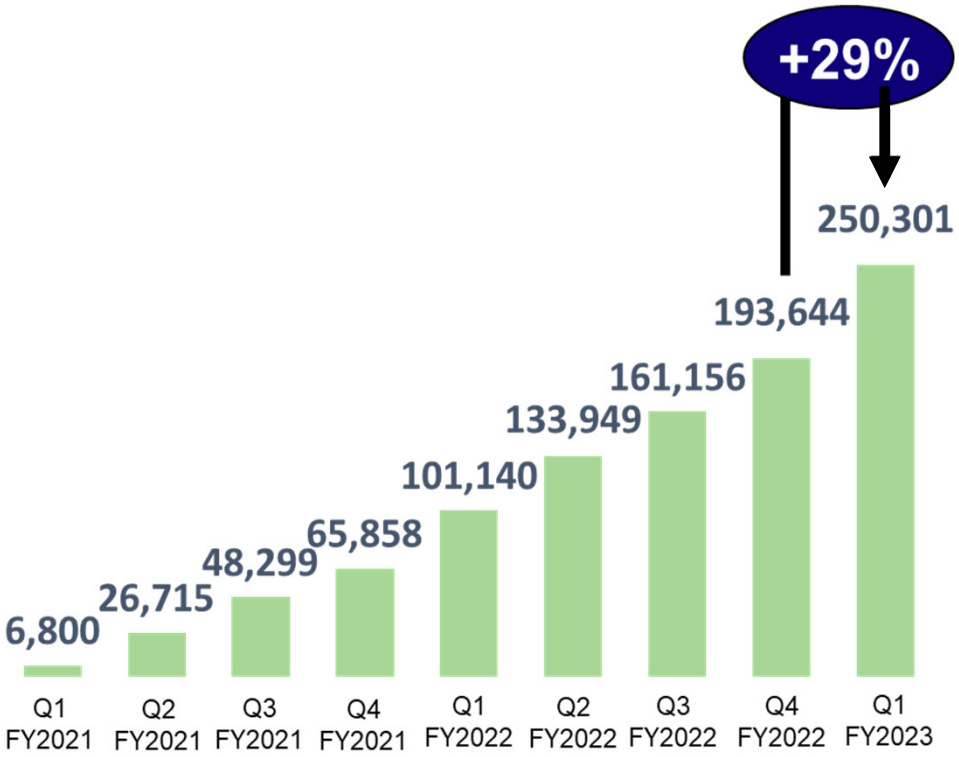
Number of prescriptions per quarter with MYFEMBREE®*1

- Marketing Activities
  - ✓ Total GnRH antagonist market continuing to expand; driven primarily by MYFEMBREE® (38% growth of GnRH antagonist TRx volume since MYFEMBREE®'s launch*2
  - ✓ Continue to improve Gross to Net by ensuring appropriate Co-pay card usage and communicating broad commercial coverage for EM (Commercial total lives covered as of June, UF: 93% and EM: 82%)
  - ✓ New HCP campaign incorporating UF & EM launched June 2023
- Medical Activities
  - ✓ Data of long-term administration for EM was filed with the FDA in June 2023 (review results expected to be obtained in Q1 FY2024)

Uterine Fibroids (UF): Endometriosis (EM)
*1 Source Symphony Health, an ICON plc Company, IDV®
*2 Incremental growth in 4 week moving average of weekly TRx volume of GnRH antagonist class (UF+EM) from MYFEMBREE® launch in Jun 2021 to Jun 2023

Marketing Status of GEMTESA®

- Although there was a decrease in price against the FY2023 forecast, volume increased steadily and progress is generally in line with the FY2023 forecast
- Approx. 250,000 TRx in Q1 FY2023 (29% growth vs. Q4 FY2022)



Number of prescriptions per quarter with GEMTESA®*

- Marketing Activities
  - ✓ Increased product awareness and website visits due to digital and TV DTC activities conducting since Jan. 2023
  - ✓ Sales reps responsible for co-promoting GEMTESA® at the former Sunovion Pharmaceuticals Inc. were integrated under the same organization with the launch of SMPA in July 2023, enabling a more unified organizational management
  - ✓ Maintaining broad coverage (Commercial: 72% of total lives and Medicare Part D: 84% of total lives as of July, 2023)
- Medical Activities
  - ✓ Phase 3 study results for OAB in men with BPH expected in 1H of FY2023

*Source IQVIA NPA TRx as of end of Jun. 2023.

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
Q1 YTD FY2023 Results	Revenue	30.4	35.5	9.9	75.7
	Cost of sales	14.7	13.0	2.7	30.4
	Gross profit	15.6	22.5	7.1	45.3
	SG&A expenses	12.8	46.2	2.8	61.8
	Core segment profit	2.8	(23.7)	4.3	(16.6)
	R&D expenses				22.8
	Core operating profit				(33.5)
Q1 YTD FY2022 Results	Revenue	52.1	95.2	12.7	159.9
	Cost of sales	28.6	13.5	3.9	46.1
	Gross profit	23.5	81.7	8.7	113.8
	SG&A expenses	14.6	58.6	2.9	76.0
	Core segment profit	8.9	23.1	5.8	37.8
	R&D expenses				24.4
	Core operating profit				13.4
Change	Revenue	(21.7)	(59.7)	(2.8)	(84.2)
	SG&A expenses	(1.8)	(12.4)	(0.1)	(14.2)
	Core segment profit	(6.0)	(46.8)	(1.5)	(54.4)
	R&D expenses				(1.6)
	Core operating profit				(46.9)

- **Japan:** Core segment profit decreased owing 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

From Q1 FY2023, segments have been changed from four (Japan, North America, China, and Other Regions) to three (Japan, North America, and Asia)

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Research and Development

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Research and Development

Development Pipeline (as of July 31, 2023)

: Psychiatry & Neurology : Oncology : Others

Revisions since the announcement of May 2023 are shown in red

Area	Phase 1	Phase 2	Phase 3	NDA submitted
Japan	**DSP-9632P** (Levodopa-induced dyskinesia in Parkinson's disease) **DSP-0187** (Narcolepsy) **DSP-0378** (Dravet syndrome, Lennox–Gastaut syndrome) **TP-3654** (Myelofibrosis) **DSP-5336** (Acute leukemia) **DSP-0390** (Glioblastoma)	**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 (SEP-363856)** (Schizophrenia) **ulotaront (SEP-363856)** (Generalized anxiety disorder)* **SEP-4199** (Bipolar I depression)	
U.S.	**DSP-3905** (Neuropathic pain) **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 infections, Complicated intra-abdominal infections) **SP-101** (cystic fibrosis)	**EPI-589** (Parkinson's disease/ALS) **ulotaront (SEP-363856)** (Parkinson's disease psychosis)	**ulotaront (SEP-363856)** (Schizophrenia) **ulotaront (SEP-363856)** (Adjunctive major depressive disorder)* **ulotaront (SEP-363856)** (Generalized anxiety disorder)* **SEP-4199** (Bipolar I depression) **GEMTESA® (vibegron)** (New indication: OAB in men with BPH)	
China			**ulotaront (SEP-363856)** (Schizophrenia) **vibegron** (Overactive bladder)	**lefamulin** (Bacterial community-acquired pneumonia)

*Phase 2/3 study

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Clinical Development Status (Major Changes since May 15, 2023)

- **Allo iPS cell-derived products (retinal pigment epithelial cells)**
  Japan: Started Phase 1/2 study (Retinal pigment epithelium tear)

- **rodatristat ethyl**
  U.S.: Pulmonary arterial hypertension (PAH)
  - Phase 2b study did not meet primary endpoint of percent change from baseline of PVR (pulmonary vascular resistance) at Endpoint (Week 24)
  - Based on the study results, including an analysis of the safety data, the ongoing studies have been discontinued and the development strategy is under consideration

- **MVT-602**
  Germany: Discontinued development for female infertility (Phase 2 study)

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Ulotaront: Topline Results from Phase 3 DIAMOND 1, 2 Clinical Studies in Schizophrenia (Co-Development with Otsuka Pharmaceutical)

✓ **Study design**
- Multicenter, randomized, placebo-controlled, double-blind, fixed-dose studies
  DIAMOND 1: 435 acutely psychotic adults with schizophrenia (randomized 1:1:1 to ulotaront 50 mg/day, 75 mg/day, or placebo)
  DIAMOND 2: 464 acutely psychotic adults with schizophrenia (randomized 1:1:1 to ulotaront 75 mg/day, 100 mg/day, or placebo)
- Primary endpoint: Change from baseline in the Positive and Negative Syndrome Scale (PANSS) total score at Endpoint (Week 6)

✓ **Efficacy**
- DIAMOND 1:
  - All three groups showed a reduction in PANSS total score over time, however neither ulotaront treatment group was superior to placebo on the primary endpoint of change from baseline in PANSS total score at Week 6
- DIAMOND 2:
  - Ulotaront 75 mg/day and 100 mg/day treatment groups did not demonstrate statistically significant improvement compared to placebo on the primary endpoint
  - At Week 6 both ulotaront treatment groups showed numerically larger mean reductions in PANSS total score from baseline compared to placebo
- A large placebo effect was observed in both studies which may have masked the molecule's therapeutic effect
- In a pooled analysis of the DIAMOND 1 and 2 subjects enrolled prior to the beginning of the COVID-19 pandemic, ulotaront showed a similar trend in efficacy as seen in the Phase 2 study (SEP361-201 study)

✓ **Safety**
- Overall, ulotaront was generally safe and well-tolerated throughout both studies

✓ **Future outlook**
- We continue to analyze the data to determine our next steps in alliance with Otsuka and plan to discuss with the U.S. FDA

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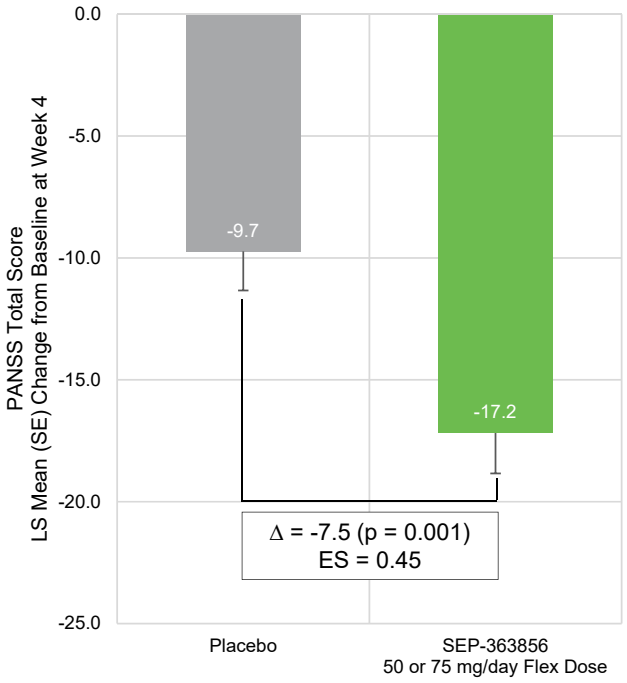
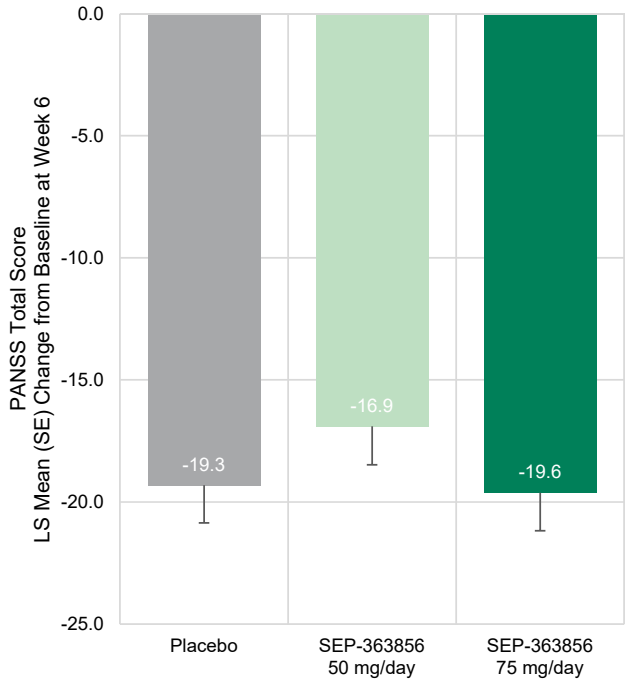
Ulotaront: Primary Endpoint from Phase 2 SEP361-201 and Phase 3 DIAMOND 1 and DIAMOND 2

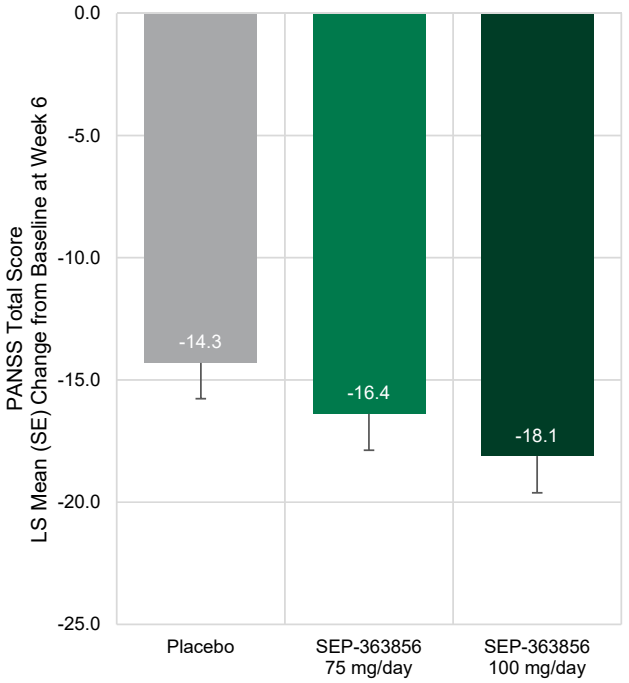
Study SEP361-201



Study SEP361-301 (DIAMOND 1)



Study SEP361-302 (DIAMOND 2)



* SEP361-201 primary endpoint: Change from Baseline in PANSS total score at Week 4.
DIAMOND 1 and DIAMOND 2 primary endpoint: Change from Baseline in PANSS total score at Week 6.

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Appendix

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Financial Results for Q1 FY2023 (Full Basis)

Billions of yen

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Gross profit	113.8	45.3	(68.6)	(60.2)
SG&A expenses	77.3	74.9	(2.4)	(3.1)
R&D expenses	24.4	27.8	3.4	14.0
Other operating income and expenses	2.5	5.9	3.4	
Operating profit	14.6	(51.6)	(66.2)	—
Finance income and costs	32.0	20.5	(11.5)	
Profit before taxes	46.6	(31.1)	(77.7)	—
Income tax expenses	18.5	7.8	(10.7)	
Net profit	28.1	(38.9)	(67.0)	—
Net profit attributable to owners of the parent	31.1	(38.9)	(70.0)	—

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Appendix (Research and Development)

Main Events / Targets for FY2023 (as of July 31, 2023)

Psychiatry & Neurology	☐ ulotaront (SEP-363856) : ☑ 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

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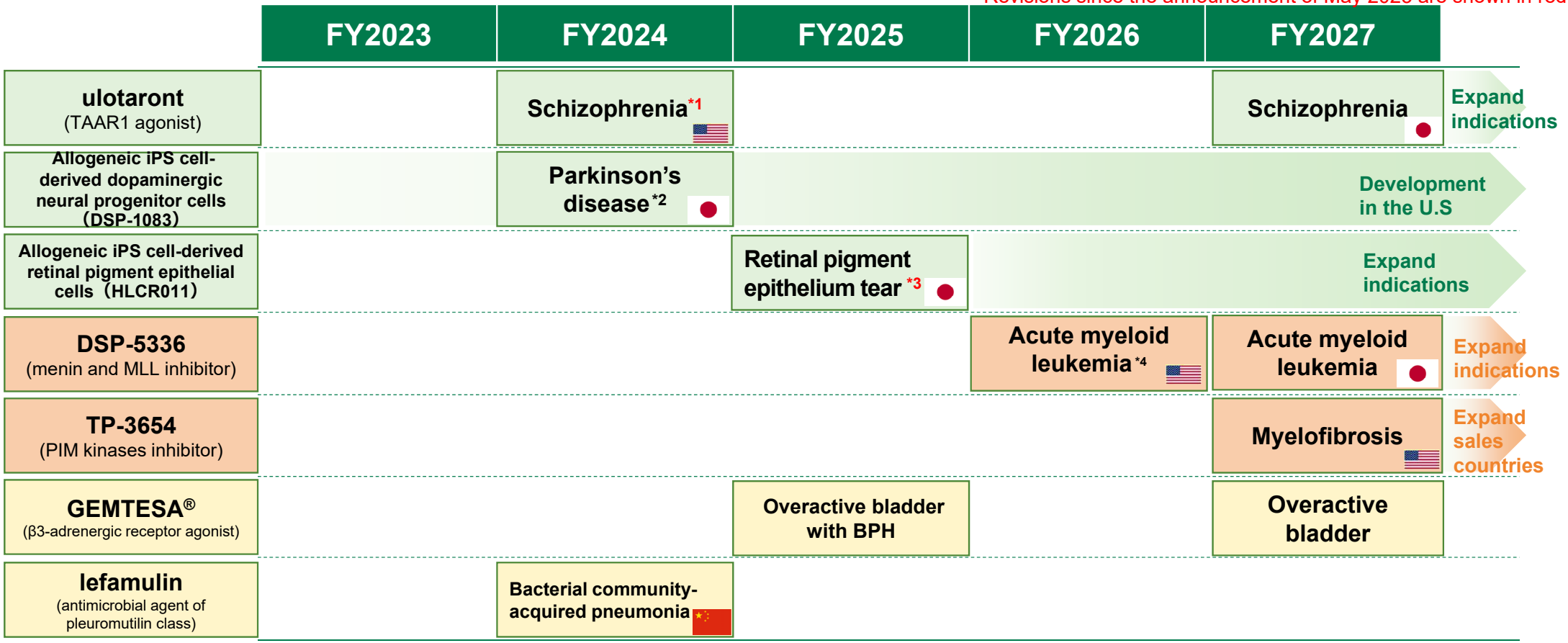
Appendix (Research and Development)

Product Launch Target (as of July 31, 2023)

Psychiatry & Neurology | Oncology | Others

Revisions since the announcement of May 2023 are shown in red



*1 To be revised for launch target based on consultation with the FDA, etc.
*2 Launch schedule is based on our goal pending agreement with partner
*3 Under review for launch target based on clinical study status
*4 Premise to utilize an application of accelerated approval program (Plan to consult with the FDA)

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Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (as of July 31, 2023)

Revisions since the announcement of May 2023 are shown in red

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Pediatric congenital athymia (RETHYMIC®)	Duke University	Global	Cultured thymus tissue	**Launched in March 2022 (U.S.)**
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor cells	**In progress: investigator-initiated study (Phase 1/2 study: Japan)** **Preparing to start clinical study (U.S.)**
RPE tear AMD (age-related macular degeneration)	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelial cells	**Started Phase 1/2 study for retinal pigment epithelium tear (Japan)**
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	**In progress: clinical research**
Spinal cord injury	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor cells	**In progress: clinical research (Sub-Acute Phase)** **In progress: pre-clinical study (Chronic Phase)**
Kidney failure	Jikei University Bios	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	**In progress: pre-clinical study**

Aim to launch in FY2024 (Japan)*1

Aim to launch in FY2025 (Japan)*2

*1 Launch schedule is based on our goal pending agreement with partners

*2 Under review for launch target based on clinical study status

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Frontier Business Product Launch Target (as of July 31, 2023)

Revisions since the announcement of May 2023 are shown in red

: Non-medical device
: Medical device

	FY2023	FY2024	FY2025	FY2026	FY2027
VR contents (BehaVR, Inc.)				Social Anxiety Disorder	VR contents in other disease area
MELTz® (MELTIN)			"MELTz® Portable" (finger exercise training system)		Neurorehabilitation device for hand/fingers
Wearable EEG meter (NeuroSky Co., Ltd.)		Depression			Depression
Violet Light (Tsubota Laboratory Incorporated)			Depression / Dementia		Depression / Dementia
Automated blood collection/ stabilization device (Drawbridge Health, Inc.)	Self-management solutions for metabolic diseases*				

* At the start of the business, we plan to provide management solutions for metabolic disease management
The details and rights regarding business rights in Japan are currently under discussion with Drawbridge Health, and they have not been agreed upon with the company

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