Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Q3 FY2021 （April 1 to December 31, 2021）
Conference Call

January 31, 2022

Sumitomo Dainippon Pharma Co., Ltd.

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Sumitomo Dainippon Pharma

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 preparation of such statements and involve both known and unknown risks and uncertainties.

Accordingly, 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.

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Financial Results for Q3 FY2021

Financial Results for Q3 FY2021 (Core Basis)

Billions of yen

	Q3YTD FY2020 Results	Q3YTD FY2021 Results	Change			FY2021	
			Value	FX impact	%	May 12 forecasts	%
Revenue	394.8	**432.1**	37.3	14.2	9.5	578.0	74.8
Cost of sales	104.8	**117.8**	13.0	6.9	12.4	156.0	75.5
Gross profit	290.0	**314.2**	24.3	7.3	8.4	422.0	74.5
SG&A expenses	145.7	**188.6**	42.9	6.8	29.5	263.0	71.7
R&D expenses	71.7	**67.8**	(3.9)	2.2	(5.4)	95.0	71.3
Other operating income/expenses	(0.0)	**1.1**	1.2	–	–	–	–
Core operating profit	72.6	**59.0**	(13.6)	(1.8)	(18.7)	64.0	92.1
Changes in fair value of contingent consideration (negative number indicates loss)	(0.4)	**(0.2)**	0.1			(1.0)	
Other non-recurring items (negative number indicates loss)	15.4	**(0.5)**	(15.8)			(2.0)	
Operating profit	87.5	**58.2**	(29.3)		(33.5)	61.0	95.5
Profit before taxes	79.7	**65.6**	(14.1)		(17.7)		
Income tax expenses	21.8	**30.4**	8.6				
Net profit	57.9	**35.2**	(22.7)		(39.2)		
Net profit attributable to owners of the parent	70.3	**46.4**	(23.9)		(34.0)	41.0	113.1

Revised full-year forecasts (See P.9)

(Ref.) Earnings related to Sumitovant

Billions of yen

Q3YTD	FY20	FY21
Revenue	**3.8**	**25.1**
SG&A expenses *	26.6	65.3
R&D expenses	18.8	17.5
Core operating profit	**(41.6)**	**(62.5)**
Operating profit	**(41.7)**	**(62.5)**
Net profit	(41.2)	(63.4)
Net profit attributable to owners of the parent	**(28.9)**	**(52.2)**

The figures include intra-group transaction

* Include amortization of patent rights

FX rates:
Q3FY2020 Results : 1US$ = ¥106.1, 1RMB = ¥15.5
Q3FY2021 Results : 1US$ = ¥111.1, 1RMB = ¥17.3
FY2021 forecasts : 1US$ = ¥110.0, 1RMB = ¥16.5

Financial Results for Q3 FY2021

Revenue of Major Products in Japan

Billions of yen

	Q3 YTD FY2020 Results	Q3 YTD FY2021 Results	Change		FY2021	
			Value	%	May 12 forecasts	%
Equa®/EquMet®	31.3	**29.4**	(1.9)	(5.9)	37.4	78.7
Trulicity® *	25.9	**25.8**	(0.1)	(0.5)	38.2	67.4
TRERIEF®	12.7	**12.9**	0.2	1.8	17.9	72.0
REPLAGAL®	10.6	**10.7**	0.1	1.0	13.8	77.2
METGLUCO®	7.2	**6.3**	(0.9)	(12.5)	6.9	91.2
LATUDA®	1.6	**5.0**	3.4	213.0	6.7	75.0
LONASEN® Tape	0.9	**1.5**	0.6	64.3	2.5	61.6
AMLODIN®	5.1	**4.5**	(0.7)	(12.8)	5.0	89.3
AG products	5.9	**7.5**	1.6	27.4	10.1	73.8
Others	17.4	**13.6**	(3.8)	(21.8)	11.5	118.7
Total	118.5	**117.2**	(1.4)	(1.2)	150.0	78.1

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

- 78.1% progress in the segment total is slow considering Q4 sales
- Decrease in Equa® /EquMet® is attributed to NHI price revision
- LATUDA® showing steady growth
- Long listed products in “Others” are higher than forecast “Others” include TWYMEEG® launched in September
- NHI price revision affected (¥5.4B) on Japan segment total

Revenue of Major Products in North America & China

	Q3 YTD FY2020 Resuts	Q3 YTD FY2021 Results	Change	Q3 YTD FY2020 Resuts	Q3 YTD FY2021 Results	Change			FY2021		
						Value	FX impact	%	May 12 forecasts		Yen-basis %
North America	Million $			Billions of yen					Million $	Billion yen	
LATUDA®	1,513	1,413	(99)	160.5	157.1	(3.4)	7.1	(2.1)	2,004	220.4	71.3
APTIOM®	187	186	(1)	19.8	20.7	0.9	0.9	4.5	249	27.4	75.6
BROVANA®	212	103	(109)	22.5	11.5	(11.0)	0.5	(49.0)	106	11.7	98.1
KYNMOBI®	1	4	4	0.2	0.4	0.4	0.0	152.7	28	3.1	12.9
ORGOVYX®	—	54	54	—	6.0	6.0	0.3	—	792	87.1	70.1
MYFEMBREE®/ RYEQO®	—	8	8	—	0.9	0.9	0.0	—			
GEMTESA®	—	38	38	—	4.2	4.2	0.2	—			
Others	142	449	308	15.0	49.9	34.9	2.3	232.4			
Total	2,055	2,256	201	218.0	250.7	32.7	11.3	15.0	3,179	349.7	71.7
China	Million RMB			Billions of yen					Million RMB	Billion yen	
MEROPEN®	992	1,226	235	15.3	21.2	5.8	2.2	38.1	1,364	22.5	94.1
Others	242	339	97	3.7	5.9	2.1	0.6	56.6	442	7.3	80.2
Total	1,234	1,566	332	19.1	27.0	8.0	2.8	41.8	1,806	29.8	90.7

FX rates:
Q3FY2020 Results : 1US$ = ¥106.1, 1RMB = ¥15.5
Q3FY2021 Results : 1US$ = ¥111.1, 1RMB = ¥17.3
FY2021 forecasts : 1US$ = ¥110.0, 1RMB = ¥16.5

- **North America segment**
  Revenue increased y-o-y, slow progress on full-year forecast
- LATUDA® decreased due largely to down-stream inventory destocking and lower price
- BROVANA® decreased due to loss of exclusivity in June
- Revenue from the alliance with Otsuka $270M (¥30.0B) is recorded in “Others”
- **China segment**
  Increased sales by recovering from the effect of COVID-19
  Progress is higher than forecast

Financial Results for Q3 FY2021

Covered Lives and Cumulative Number of Patients/Monthly TRx of ORGOVYX®, MYFEMBREE® and GEMTESA®

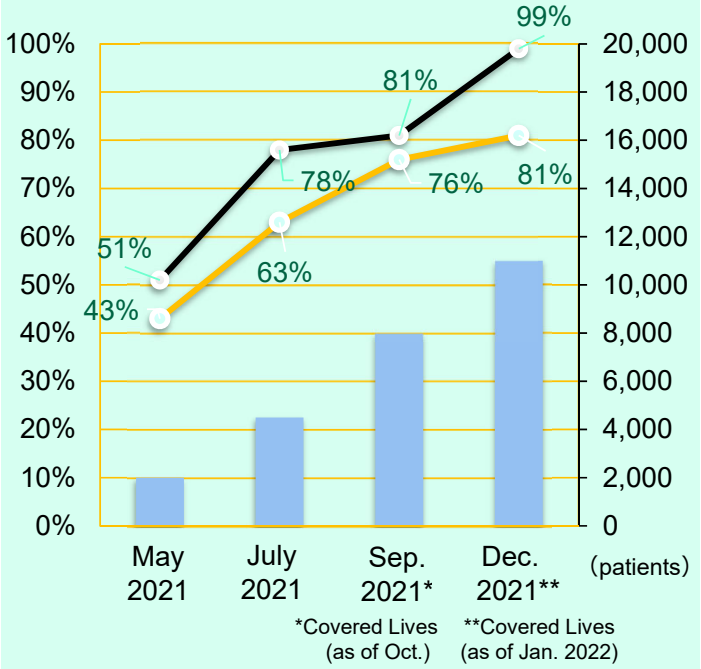
Sumitomo Dainippon Pharma

■ Trends in gaining of covered lives and cumulative number of patients/monthly TRx in the U.S.

（As of Jan. 2022, ratio of gaining of covered lives to total number of Commercial/ Medicare Part D lives, including Pre-review Coverage）

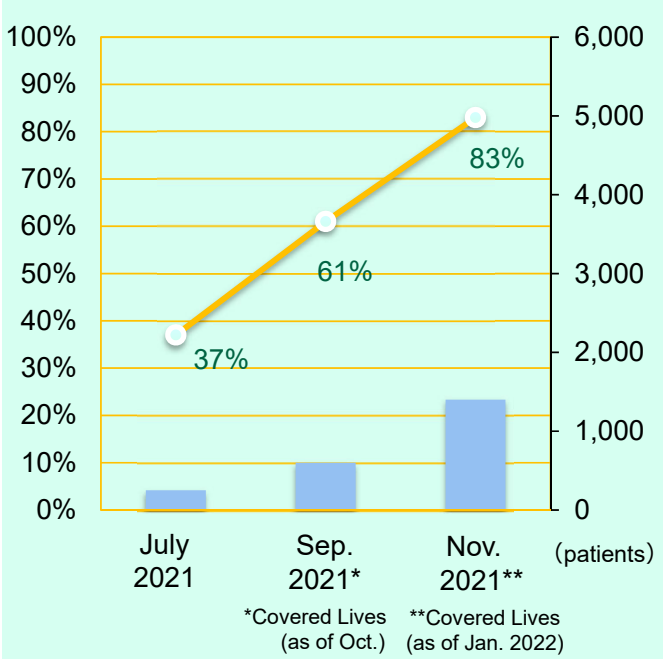
ORGOVYX®

（Launched in January 2021）



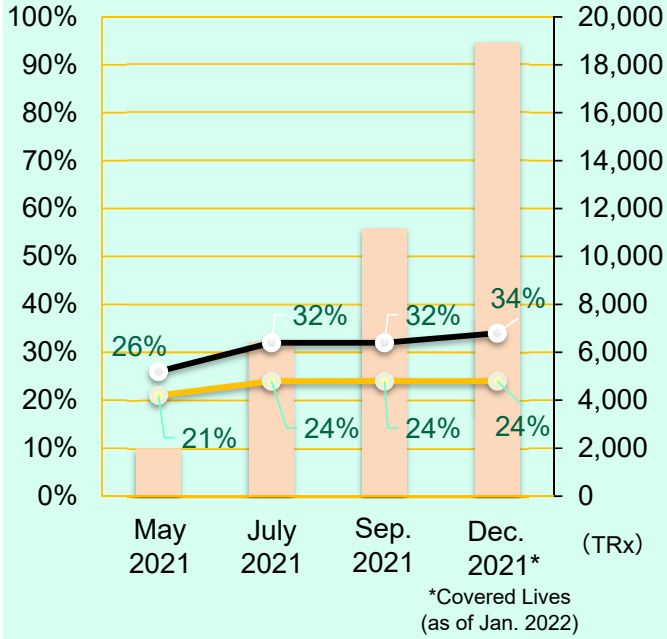
MYFEMBREE®

（Launched in June 2021）



GEMTESA®

（Launched in April 2021）



Left axis: % (——: Commercial lives, ——: Medicare Part D lives), Right axis: people (■:Cumulative number of patients, ■:Number of monthly TRx)

MYFEMBREE®'s main coverage is Commercial lives

The total number of Commercial lives (including exchange) are approx. 178 million and Medicare Part D lives are approx. 47 million in the U.S.

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Q3 YTD FY2021 Results	Revenue (Sales to customers)	117.2	250.7	27.0	7.3	402.2	29.9	432.1
	Cost of sales	61.9	23.6	5.3	4.0	94.8	23.0	117.8
	Gross profit	55.3	227.1	21.8	3.3	307.5	6.8	314.2
	SG&A expenses	38.3	135.6	8.8	1.9	184.7	4.0	188.6
	Core segment profit	17.0	91.5	12.9	1.4	122.8	2.8	125.6
	R&D expenses					67.2	0.6	67.8
	Core operating profit					56.7	2.2	59.0
Q3 YTD FY2020 Results	Revenue (Sales to customers)	118.5	218.0	19.1	11.5	367.1	27.7	394.8
	Cost of sales	59.5	16.3	3.9	4.2	83.8	21.0	104.8
	Gross profit	59.1	201.7	15.2	7.3	283.3	6.6	290.0
	SG&A expenses	36.1	97.2	6.7	2.0	142.0	3.8	145.7
	Core segment profit	23.0	104.5	8.5	5.3	141.4	2.9	144.2
	R&D expenses					71.1	0.6	71.7
	Core operating profit					70.3	2.2	72.6
Change	Revenue (Sales to customers)	(1.4)	32.7	8.0	(4.1)	35.1	2.2	37.3
	SG&A expenses	2.2	38.4	2.1	(0.1)	42.7	0.2	42.9
	Core segment profit	(6.1)	(13.1)	4.4	(3.9)	(18.6)	(0.1)	(18.6)
	R&D expenses					(3.9)	(0.0)	(3.9)
	Core operating profit					(13.6)	(0.0)	(13.6)

- **Japan:** Lower profit due to declined gross profit and increased expenses
- **North America:** Lower profit mainly due to incremental costs related to Sumitovant despite lump-sum revenue from the alliance
- **China:** Profit increased mainly due to higher revenue
- **Other Regions:** Lower profit due to decrease in export

Financial Forecasts for FY2021

Financial Forecasts for FY2021 (Core Basis)

Billions of yen

	FY2021 May 12 Forecasts	FY2021 Revised Forecasts	Change
Revenue	578.0	**554.0**	(24.0)
Cost of sales	156.0	**154.0**	(2.0)
Gross profit	422.0	**400.0**	(22.0)
SG&A expenses	263.0	**252.0**	(11.0)
R&D expenses	95.0	**92.0**	(3.0)
Other operating income and expenses (Core basis)	—	**1.0**	1.0
Core operating profit	64.0	**57.0**	(7.0)
Changes in fair value of contingent consideration (negative number indicates loss)	(1.0)	**(1.0)**	—
Other non-recurring item (negative number indicates loss)	(2.0)	**(1.0)**	1.0
Operating profit	61.0	**55.0**	(6.0)
Net profit attributable to owners of the parent	41.0	**37.0**	(4.0)
ROE (%)	6.9	**6.2**	
ROIC (%)	N/A	**N/A**	

FX rates:
FY21 Previous forecasts : 1US$ = ¥110.0, 1RMB = ¥16.5
Revised forecasts : 1US$ = ¥110.0, 1RMB = ¥17.0

- **Revenue: Revised down by ¥24.0B**
  North America (¥30.4B)
  LATUDA® (¥13.5B)
  China +¥6.0B
- **SG&A expenses:**
  Amortization of intangible asset decreased by change in amortization period
- **R&D expenses:**
  Revised down mainly in oncology area

(Ref.) Expenses related to Sumitovant (¥B)

	2021 Previous	2021 Revised	Change
SG&A expenses	96.0	90.0	(6.0)
Amortization of patent rights in above	24.5	17.0	(7.5)
R&D expenses	21.0	21.0	–

The figures are before intra-group elimination

Financial Forecasts for FY2021

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2021 Revised Forecasts	Revenue (Sales to customers)	148.4	319.3	35.8	12.0	515.5	38.5	554.0
	Cost of sales	79.0	31.7	6.9	6.7	124.3	29.7	154.0
	Gross profit	69.4	287.6	28.9	5.3	391.2	8.8	400.0
	SG&A expenses	52.9	179.4	11.7	2.4	246.4	5.6	252.0
	Core segment profit	16.5	108.2	17.2	2.9	144.8	3.2	148.0
	R&D expenses					91.0	1.0	92.0
	Core operating profit					54.8	2.2	57.0
FY2021 May 12 Forecasts	Revenue (Sales to customers)	150.0	349.7	29.8	10.3	539.8	38.2	578.0
	Cost of sales	78.1	38.5	5.5	4.6	126.7	29.3	156.0
	Gross profit	71.9	311.2	24.3	5.7	413.1	8.9	422.0
	SG&A expenses	52.9	191.9	10.9	1.6	257.3	5.7	263.0
	Core segment profit	19.0	119.3	13.4	4.1	155.8	3.2	159.0
	R&D expenses					94.0	1.0	95.0
	Core operating profit					61.8	2.2	64.0
Change	Revenue (Sales to customers)	(1.6)	(30.4)	6.0	1.7	(24.3)	0.3	(24.0)
	SG&A expenses	—	(12.5)	0.8	0.8	(10.9)	(0.1)	(11.0)
	Core segment profit	(2.5)	(11.1)	3.8	(1.2)	(11.0)	—	(11.0)
	R&D expenses					(3.0)	—	(3.0)
	Core operating profit					(7.0)	—	(7.0)

- **Japan segment:** Profit will decrease because revenue down due to decrease in sales and increase in cost of goods
- **North America segment:** Profit will decrease due to decreased sales of LATUDA® despite reduction of SG&A expenses include amortization
- **China segment:** Revenue and profit will increase due to increase of MEROPEN® sales

Financial Forecasts for FY2021

Revenue of Major Products in Japan

Billions of yen

	FY2021 May 12 Forecasts	FY2021 Forecasts	Change
Equa®/EquMet®	37.4	37.4	—
Trulicity® *	38.2	33.9	(4.3)
TRERIEF®	17.9	16.5	(1.4)
REPLAGAL®	13.8	12.1	(1.7)
METGLUCO®	6.9	8.1	1.2
LATUDA®	6.7	6.7	—
LONASEN® Tape	2.5	2.0	(0.5)
AMLODIN®	5.0	5.5	0.5
AG products	10.1	9.8	(0.3)
Others	11.5	16.4	4.9
Total	150.0	148.4	(1.6)

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

- Revised down by ¥1.6B in the segment total
- Revised down Trulicity® and TRERIEF®
- Revised down REPLAGAL®
  Will terminate sales in February
- Revised up “Others” in line with mainly higher progress of long-listed products

Financial Forecasts for FY2021

Revenue of Major Products in North America & China

	FY2021 May 12 Forecasts	FY2021 Revised Forecasts	Change	FY2021 May 12 Forecasts	FY2021 Revised Forecasts	Change
North America	Million $			Billions of yen		
LATUDA®	2,004	1,881	(123)	220.4	206.9	(13.5)
APTIOM®	249	239	(10)	27.4	26.3	(1.1)
BROVANA®	106	115	9	11.7	12.6	0.9
KYNMOBI®	28	5	(23)	3.1	0.6	(2.5)
ORGOVYX® MYFEMBREE®/ RYEQO® GEMTESA® Others	792	663	(129)	87.1	72.9	(14.2)
Total	3,179	2,903	(276)	349.7	319.3	(30.4)
China	Million RMB			Billions of yen		
MEROPEN®	1,364	1,635	271	22.5	27.8	5.3
Others	442	470	28	7.3	8.0	0.7
Total	1,806	2,105	299	29.8	35.8	6.0

FX rates:
FY21 Previous forecasts: 1US$ = ¥110.0, 1RMB = ¥16.5
Revised forecasts: 1US$ = ¥110.0, 1RMB = ¥17.0

- **North America**: Revised down by ¥30.4B
- Revised down LATUDA® due to down-stream inventory destocking and assumed lower price
- Revised down APTIOM® and KYNMOBI®
- Revised down “Others” including such as the alliance revenue (Approx. ¥11B) included in the first forecasts of FY2021
- **China:** Revised up MEROPEN® and other

Research and Development

Research and Development

Development Pipeline (as of January 31, 2022)

Sumitomo Dainippon Pharma

: Psychiatry & Neurology : Oncology : Regenerative medicine / Cell therapy : Others : Frontier business Revisions since the announcement of October 2021 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-0390** (Solid tumors) **TP-3654** (Hematologic malignancies) **DSP-5336** (Hematologic malignancies)	**EPI-589** (ALS/Investigator-initiated study) **Allo iPS cell-derived products** (Parkinson's disease/ Investigator-initiated study)	**ulotaront (SEP-363856)** (Schizophrenia) **SEP-4199** (Bipolar I depression)	
U.S.	**DSP-6745** (Parkinson's disease psychosis) **SEP-378608** (Bipolar disorder) **DSP-3905** (Neuropathic pain) **SEP-378614** (To be determined) **SEP-380135** (To be determined) **DSP-0038** (Alzheimer's disease psychosis) **KSP-1007** (Complicated urinary tract infections, Complicated intra-abdominal infections)	**guretolimod (DSP-0509)** (Solid tumors) **itacnosertib (TP-0184)** (Hematologic malignancies) **TP-1287** (Solid tumors) **TP-3654** (Hematologic malignancies) **TP-1454** (Solid tumors) **DSP-0390** (Solid tumors) **DSP-5336** (Hematologic malignancies)	**EPI-589** (Parkinson's disease/ALS) **ulotaront (SEP-363856)** (Parkinson's disease psychosis) **dubermatinib (TP-0903)** (AML/Research group-initiated study) **DSP-7888** (Solid tumors) **rodatristat ethyl** (Pulmonary arterial hypertension) **URO-902** (Overactive bladder)	**ulotaront (SEP-363856)** (Schizophrenia) **SEP-4199** (Bipolar I depression) **GEMTESA® (vibegron)** (New indication: OAB in men with BPH)	**MYFEMBREE® (relugolix)** (New indication: Endometriosis)
China				**LATUDA®** (New indication: Bipolar I depression) **ulotaront (SEP-363856)** (Schizophrenia)	**lefamulin** (Bacterial community-acquired pneumonia)
Europe					**relugolix** (Prostate cancer)

Clinical Development Status (Major Changes since October 27, 2021)

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- **SEP-4199**
  Japan : Started Phase 3 study for bipolar I depression (Joined global Phase 3 study)

- **DSP-0187**
  Japan : Started Phase 1 study for narcolepsy

- **DSP-1181**
  Japan : Discontinued development
  - ➢ As a result of Phase 1 study, not reach expected criteria

- **DSP-7888**
  U.S., Japan : Terminated Phase 3 study for glioblastoma
  - ➢ As a result of its interim analysis, determined there is a low probability of meeting the primary endpoint of overall survival (OS) at the final analysis

- **DSP-5336**
  Japan : Started Phase 1 study for hematologic malignancies

- **KSP-1007**
  U.S. : Started Phase 1 study for complicated urinary tract infections and complicated intra-abdominal infections

- **SMC-01**
  Japan : Discontinued development
  - ➢ As a result of Phase 3 study, the primary endpoint of change from baseline in HbA1c did not reach statistical significance

Appendix (Research and Development)

Product Launch Target (as of January 31, 2022)

Revisions since the announcement of October 2021 are shown in red

RETHYMIC®
(Pediatric congenital athymia)
Approved in Oct. 2021

TWYMEEG®
(Type 2 diabetes)
Launched in Sep. 2021

MYFEMBREE®
(Uterine fibroids)
Launched in June 2021

GEMTESA®
(OAB)
Launched in April 2021

MYFEMBREE®
(New indication: Endometriosis)
PDUFA date May 2022

ulotaront (SEP-363856)
(Schizophrenia)

LATUDA®
(New indication: Bipolar I depression)

Allo iPS cell-derived products *
(Parkinson's disease)

lefamulin
(Bacterial community -acquired pneumonia)

Allo iPS cell-derived products
(AMD) *

FY2021	FY2022	FY2023	FY2024	FY2025

Planning to launch multiple frontier business items after FY2022 (separately listed)

: Psychiatry & Neurology
: Regenerative medicine / cell therapy
: Frontier business
: Oncology
: Others

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

Appendix

＜Contents＞

P.18 Financial Results for Q3 FY2021 (Full Basis)
P.19 Main Event/Target for FY2021
P.20 Product Launch Target (Frontier business)
P.21 Regenerative Medicine/Cell Therapy Business Plan
P.22 New Chemical Entity: DSP-0187
P.23 New Chemical Entity: KSP-1007
P.24 Development Status of Relugolix and GEMTESA® (Vibegron)

Financial Results for Q3 FY2021 (Full Basis)

Billions of yen

	Q3 YTD FY2020 Results	Q3 YTD FY2021 Results	Change	%
Revenue	394.8	432.1	37.3	9.5
Cost of sales	104.8	117.8	13.0	12.4
Gross profit	290.0	314.2	24.3	8.4
SG&A expenses	147.0	189.0	42.0	28.6
R&D expenses	71.7	67.8	(3.9)	(5.4)
Other operating income and expenses	16.3	0.8	(15.5)	
Operating profit	87.5	58.2	(29.3)	(33.5)
Finance income and costs	(7.8)	7.4	15.2	
Profit before taxes	79.7	65.6	(14.1)	(17.7)
Income tax expenses	21.8	30.4	8.6	
Net profit	57.9	35.2	(22.7)	(39.2)
Net profit attributable to owners of the parent	70.3	46.4	(23.9)	(34.0)

Appendix (Research and Development)

Main Event / Target for FY2021 (as of January 31, 2022)

Sumitomo Dainippon Pharma

✓ Completed action / target Revisions since the announcement of October 2021 are shown in red

Psychiatry & Neurology	☐ ulotaront (SEP-363856) : ☐ Start clinical program for the development (global study) of new indication ☐ Advance Phase 3 study in the U.S. and Phase 2/3 study in Japan and China for schizophrenia ☑ SEP-4199: Start Phase 3 study for Bipolar I depression
Oncology	☐ DSP-7888 : Advance global Phase 3 study for glioblastoma → Terminated
Regenerative medicine / Cell therapy	☑ RVT-802 : Obtain approval for pediatric congenital athymia in the U.S. ☐ Allogeneic iPS cell-derived products（AMD: age-related macular degeneration) : Start clinical study ☑ Allogeneic iPS cell-derived products（Parkinson's disease) : Complete transplant in investigator-initiated study
Infectious Diseases	☐ Antimicrobial resistance (AMR), universal influenza vaccine, malaria vaccines : Promote joint research and development projects
Others	☐ relugolix : (U.S.) ☑ Obtain approval for uterine fibroids ☑ Submit NDA for endometriosis (Europe) ☑ Obtain approval for uterine fibroids ☐ Submit MAA for endometriosis ☑ imeglimin : Obtain approval for type 2 diabetes in Japan
Frontier	☐ Promote the current themes (Type 2 diabetes management app, Neurorehabilitation device for hand/fingers, Digital device for relieving BPSD, Automated blood collection/Stabilization device, VR contents for Social Anxiety Disorder, and internal themes, etc.) and development of new themes

Appendix (Research and Development)

Product Launch Target (Frontier business) (as of January 31, 2022)

FY2022	FY2023	FY2024	FY2025	FY2026	FY2027 onward
Digital device for relieving BPSD *1	Automated blood collection/ Stabilization device	Violet Light (Depression)	Violet Light (Depression)		Digital medical device for depression diagnosis
VR contents for Social Anxiety Disorder *2	Smart glasses for hard of hearing people	Violet Light (Dementia)	Violet Light (Dementia)		Digital device for relieving BPSD
	Wearable EEG meter		Neurorehabilitation device for hand/fingers	VR contents for Social Anxiety Disorder	VR business (Disease area expansion)

*1 Sales by partners

*2 Sales by partners, and planning to expand target symptoms continuously

: Medical device

: Non-medical device

The project description varies with the product (device sales, solution business, royalties, etc.)

Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Business Plan (as of January 31, 2022)

Sumitomo Dainippon Pharma

Revisions since the announcement of October 2021 are shown in red

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Pediatric congenital athymia (RETHYMIC®)	Duke University	Global	Cultured thymus tissue	**Approved in October 2021 (U.S.)**
AMD (age-related macular degeneration)	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	**In progress: clinical research Preparing to start clinical study (Japan)**
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	**In progress: investigator-initiated study (Phase 1 / 2 study) (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	**In progress: clinical research**
Kidney failure	Jikei University Bios PorMedTec	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	**In progress: pre-clinical study**

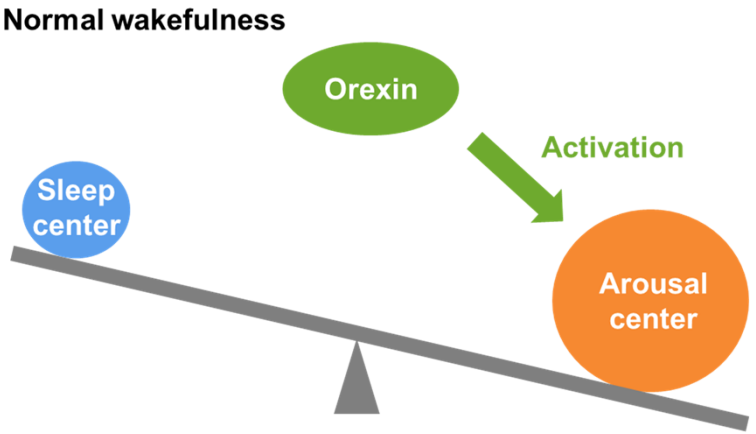
Aim to start clinical study in FY2022

Aim to launch in FY2024 *

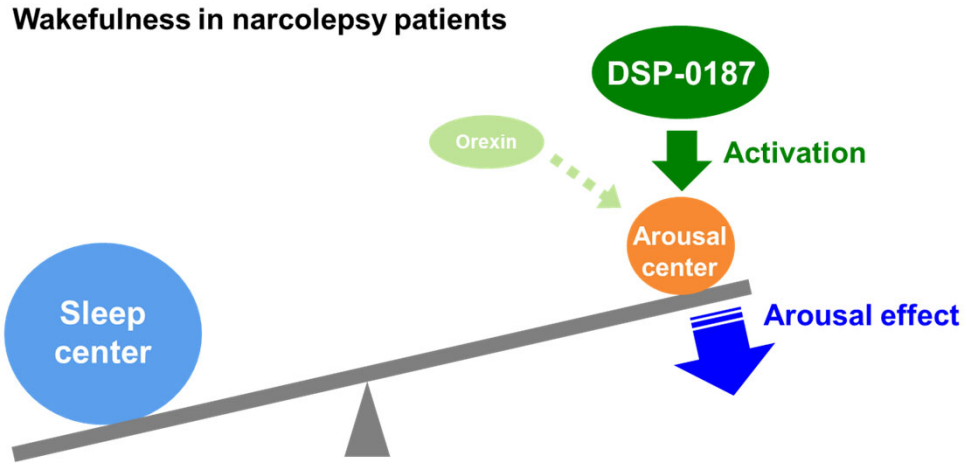
* Launch schedule is based on our goal pending agreement with partners

New Chemical Entity: DSP-0187

- ✓ Target indication: Narcolepsy
- ✓ Origin: In-house
- ✓ Mechanism of action: Orexin 2 receptor agonist
- ✓ Stage: Phase1 (Japan)
- ✓ Expected profile:
  - ➢ DSP-0187 is expected to improve excessive daytime sleepiness (EDS) and cataplexy by activating orexin signals in patients with orexin-deficient narcolepsy.
  - ➢ The compound could also have a higher efficacy than existing drugs and is expected to demonstrate an efficacy for EDS other than narcolepsy



Orexin stimulates the arousal center to induce wakefulness

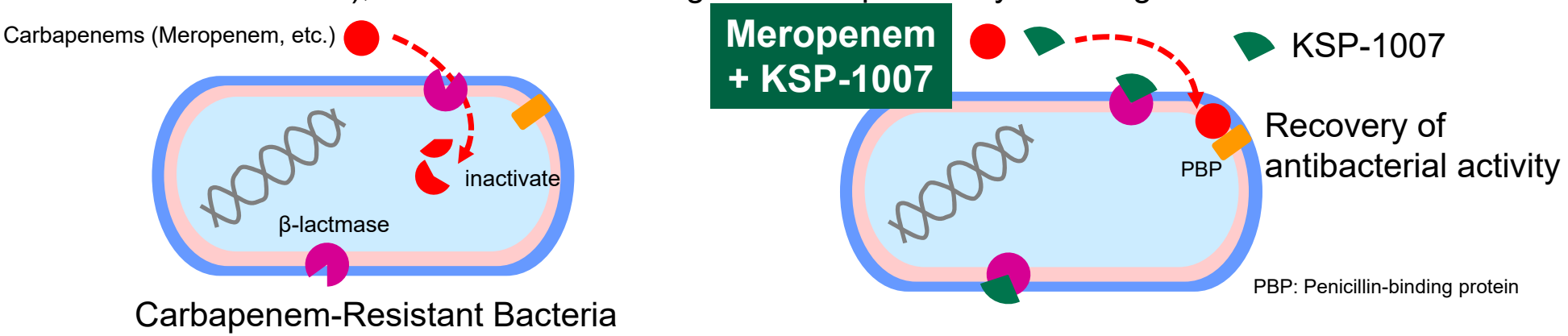


DSP-0187 stimulates the arousal center to induce wakefulness

New Chemical Entity: KSP-1007

Sumitomo Dainippon Pharma

- ✓ Target indication: Complicated urinary tract infections and Complicated intra-abdominal infections
- ✓ Origin: In-house (Joint research with The Kitasato Institute)
- ✓ Mechanism of action: Inhibition of β-lactamases
- ✓ Stage: Phase 1 (the U.S.)
- ✓ Expected profile:
  - ➢ KSP-1007 was discovered through a joint research and development initiative with The Kitasato Institute, selected by Japan Agency for Medical Research and Development (AMED) for its Cyclic Innovation for Clinical Empowerment (CiCLE) program.
  - ➢ KSP-1007 can broadly and strongly inhibit β-lactamases. It is expected to be an effective treatment option against infectious disease caused by bacteria with carbapenem-resistance, one of the global threat AMR (Antimicrobial Resistance), in a combination drug with meropenem hydrate in general use worldwide



Appendix (Research and Development)

Development Status of Relugolix and GEMTESA® (Vibegron)

Revisions since the announcement of October 2021 are shown in red

■ Development status of relugolix

Oncology area (monotherapy) U.S. : ORGOVYX®	Prostate cancer U.S. : Launched in January 2021 Europe : MAA submitted in March 2021 ➢ (North America) Myovant entered into a collaborative development and commercialization agreement with Pfizer Inc. in December 2020 ➢ (Outside North America, excluding certain Asia) Pfizer Inc. declined its option for commercialization, Myovant is currently assessing partnership opportunities
Women's health area (combination tablet) U.S. : MYFEMBREE® Europe : RYEQO®	Uterine fibroids U.S. : Approved in May 2021 and launched in June 2021 Europe : Approved in July 2021 and launched by Gedeon Richter Plc. Endometriosis U.S. : sNDA submitted by Myovant in July 2021, PDUFA date May 6, 2022 Europe : Gedeon Richter Plc. plans to submit in 2022 ➢ (North America) Myovant entered into a collaborative development and commercialization agreement with Pfizer Inc. in December 2020 ➢ (Europe, Russia etc.) Myovant entered into a collaborative development and commercialization agreement with Gedeon Richter Plc. in March 2020

■ Development status of GEMTESA® (vibegron)

Overactive bladder (OAB)	U.S. : Launched in April 2021
OAB in men with BPH	U.S. : Phase 3 study stage and expecting topline results in FY2022

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Innovation today, healthier tomorrows