Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Q1 FY2021 (April 1 to June 30, 2021) Conference Call

July 29, 2021

Sumitomo Dainippon Pharma Co., Ltd.

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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.

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

Myovant Sciences Ltd. ("Myovant") is listed on the New York Stock Exchange, and the Group holds approximately 53% of the outstanding shares of Myovant. This material contains information about Myovant, which is based on information disclosed by Myovant. For more information on Myovant, please visit https://www.myovant.com/.

Financial Results for Q1 FY2021

Financial Results for Q1 FY2021 (Core Basis)

Billions of yen

	Q1 FY2020 Results	Q1 FY2021 Results	Change			FY2021	
			Value	FX impact	%	May 12 forecasts	%
Revenue	133.9	**131.2**	(2.7)	2.0	(2.0)	578.0	22.7
Cost of sales	36.0	**38.5**	2.5	1.5	7.0	156.0	24.7
Gross profit	97.9	**92.7**	(5.2)	0.5	(5.3)	422.0	22.0
SG&A expenses	47.8	**62.0**	14.2	0.9	29.7	263.0	23.6
R&D expenses	25.7	**22.4**	(3.3)	0.3	(12.9)	95.0	23.6
Core operating profit	24.4	**8.5**	(15.8)	(0.7)	(65.0)	64.0	13.3
Changes in fair value of contingent consideration (negative number indicates loss)	(1.2)	**(0.1)**	1.2			(1.0)	
Other non-recurring items (negative number indicates loss)	0.1	**(0.1)**	(0.3)			(2.0)	
Operating profit	23.3	**8.3**	(15.0)		(64.3)	61.0	13.6
Profit before taxes	22.0	**8.0**	(14.0)		(63.8)		
Income tax expenses	6.4	**7.2**	0.7				
Net profit	15.6	**0.8**	(14.8)		(94.8)		
Net profit attributable to owners of the parent	18.3	**4.8**	(13.5)		(73.7)	41.0	11.7

The forecasts are not revised

- Expecting revenue from possible new alliance and sales growth of new products in North America

(Ref.) Earnings related to Sumitovant

Billions of yen

	Q1 FY20	Q1 FY21
Revenue	**3.7**	**5.8**
SG&A expenses *	6.4	19.9
R&D expenses	7.3	5.9
Core operating profit	**(10.0)**	**(20.7)**
Operating profit	**(10.0)**	**(20.7)**
Net profit	(10.2)	(21.0)
Net profit attributable to owners of the parent	**(7.5)**	**(17.0)**

The figures include intra-group transaction

* Include amortization of patent rights

FX rates:
Q1FY2020 Results : 1US$ = ¥107.6, 1RMB = ¥15.2
Q1FY2021 Results : 1US$ = ¥109.5, 1RMB = ¥17.0
FY2021 forecasts : 1US$ = ¥110.0, 1RMB = ¥16.5

Financial Results for Q1 FY2021

Revenue of Major Products in Japan

Billions of yen

	Q1 FY2020 Results	Q1 FY2021 Results	Change		FY2021	
			Value	%	May 12 forecasts	%
Equa®/EquMet®	10.3	**9.8**	(0.5)	(4.7)	37.4	26.3
Trulicity® *	8.4	**8.8**	0.4	5.3	38.2	23.1
TRERIEF®	4.3	**4.3**	0.1	1.4	17.9	24.1
REPLAGAL®	3.5	**3.5**	0.0	1.0	13.8	25.3
METGLUCO®	2.5	**2.1**	(0.4)	(14.7)	6.9	30.4
LATUDA®	0.5	**1.4**	0.9	167.1	6.7	20.7
LONASEN® Tape	0.3	**0.5**	0.2	78.5	2.5	18.6
AMLODIN®	1.7	**1.5**	(0.2)	(13.1)	5.0	29.8
AG products	1.9	**2.4**	0.5	27.6	10.1	24.0
Others	6.5	**4.3**	(2.2)	(33.6)	11.5	37.7
Total	39.8	**38.7**	(1.1)	(2.8)	150.0	25.8

- Progress is almost as forecasted in the segment total
- LATUDA® is on track
  Prescription days limit was lifted in June

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

Revenue of Major Products in North America & China

	Q1 FY2020 Resuts	Q1 FY2021 Results	Change	Q1 FY2020 Resuts	Q1 FY2021 Results	Change			FY2021		
						Value	FX impact	%	May 12 forecasts		Yen-basis %
North America	Million $			Billions of yen					Million $	Billion yen	
LATUDA®	493	469	(24)	53.0	51.4	(1.7)	0.9	(3.1)	2,004	220.4	23.3
APTIOM®	63	63	0	6.8	6.9	0.1	0.1	1.9	249	27.4	25.2
BROVANA®	72	51	(21)	7.8	5.6	(2.2)	0.1	(28.3)	106	11.7	47.6
KYNMOBI™	—	2	2	—	0.2	0.2	0.0	—	28	3.1	7.4
ORGOVYX™	—	11	11	—	1.2	1.2	0.0	—	792	87.1	8.4
MYFEMBREE®	—	1	1	—	0.1	0.1	0.0	—			
GEMTESA®	—	7	7	—	0.8	0.8	0.0	—			
Others	61	48	(13)	6.5	5.2	(1.3)	0.1	(20.4)			
Total	689	652	(37)	74.1	71.4	(2.7)	1.2	(3.7)	3,179	349.7	20.4
China	Million RMB			Billions of yen					Million RMB	Billion yen	
MEROPEN®	260	392	132	3.9	6.6	2.7	0.7	67.6	1,364	22.5	29.4
Others	78	111	32	1.2	1.9	0.7	0.2	61.9	442	7.3	26.3
Total	338	503	165	5.1	8.5	3.4	0.9	66.3	1,806	29.8	28.6

FX rates:
Q1FY2020 Results : 1US$ = ¥107.6, 1RMB = ¥15.2
Q1FY2021 Results : 1US$ = ¥109.5, 1RMB = ¥17.0
FY2021 forecasts : 1US$ = ¥110.0, 1RMB = ¥16.5

- **North America segment**
  Revenue dropped y-o-y, progress in line with full-year forecast
- LATUDA® dropped due to impact of high sellout in the last December
- BROVANA® decreased due to loss of exclusivity in June
- Launched MYFEMBREE® in June, GEMTESA® in April
- Revenue from possible new alliance included in full-year forecast has not incurred in Q1 yet

- **China segment**
  Increased y-o-y since Q1 FY2020 sales dropped due to the effect of COVID-19.
  Progress is as forecasted.

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Q1 FY2021 Results	Revenue (Sales to customers)	38.7	71.4	8.5	2.7	121.3	9.9	131.2
	Cost of sales	20.0	8.0	1.6	1.3	30.9	7.6	38.5
	Gross profit	18.7	63.4	6.9	1.4	90.5	2.3	92.7
	SG&A expenses	11.9	45.3	2.7	0.8	60.7	1.3	62.0
	Core segment profit	6.7	18.1	4.3	0.6	29.8	1.0	30.8
	R&D expenses					22.3	0.2	22.4
	Core operating profit					7.7	0.9	8.5
Q1 FY2020 Results	Revenue (Sales to customers)	39.7	74.1	5.1	5.5	124.5	9.3	133.9
	Cost of sales	20.4	5.4	0.8	2.4	29.0	7.0	36.0
	Gross profit	19.4	68.8	4.3	3.1	95.6	2.3	97.9
	SG&A expenses	11.4	32.9	1.6	0.7	46.5	1.2	47.8
	Core segment profit	8.0	35.9	2.7	2.4	49.0	1.1	50.1
	R&D expenses					25.6	0.2	25.7
	Core operating profit					23.4	0.9	24.4
Change	Revenue (Sales to customers)	(1.1)	(2.7)	3.4	(2.8)	(3.2)	0.5	(2.7)
	SG&A expenses	0.6	12.4	1.1	0.1	14.2	0.0	14.2
	Core segment profit	(1.3)	(17.7)	1.6	(1.8)	(19.3)	(0.1)	(19.3)
	R&D expenses					(3.3)	(0.0)	(3.3)
	Core operating profit					(15.8)	(0.1)	(15.8)

- **Japan:** Lower profit due to declined sales and increased expenses
- **North America:** Lower profit mainly due to incremental costs of Sumitovant in addition to lower revenue
- **China:** Profit increased mainly due to higher revenue
- **Other Regions:** Lower profit mainly due to decrease in export

Research and Development

Research and Development

Development Pipeline (as of July 29, 2021)

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: Psychiatry & Neurology : Oncology : Regenerative medicine / Cell therapy : Others : Frontier business Revisions since the announcement of May 2021 are shown in red

Area	Phase 1		Phase 2	Phase 3	NDA/BLA submitted
Japan	**EPI-589** (ALS) **DSP-1181** (Obsessive compulsive disorder)	**DSP-0390** (Solid tumors)	**SEP-4199** (Bipolar I depression) **Allo iPS cell-derived products** (Parkinson's disease/ Investigator-initiated clinical study)	**ulotaront (SEP-363856)** (Schizophrenia) **DSP-7888** (Glioblastoma) **SMC-01** (Mobile App for management of type 2 diabetic patients)	
U.S.	**DSP-6745** (Parkinson's disease psychosis) **SEP-378608** (Bipolar disorder) **DSP-3905** (Neuropathic pain) **SEP-378614** (Treatment resistant depression) **SEP-380135** (Alzheimer's disease agitation) **DSP-0038** (Alzheimer's disease psychosis)	**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) **SEP-4199** (Bipolar I depression) **dubermatinib (TP-0903)** (AML/Research group-initiated clinical study) **rodatristat ethyl** (Pulmonary arterial hypertension) **URO-902** (Overactive bladder)	**ulotaront (SEP-363856)** (Schizophrenia) **DSP-7888** (Glioblastoma) **GEMTESA® (vibegron)** (New indication: OAB in men with BPH)	**RVT-802** (Pediatric congenital athymia) BLA resubmitted **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 May 12, 2021)

- **DSP-7888**
  Japan : Changed from Phase 2 study to Phase 3 study for glioblastoma

- **DSP-0390**
  Japan : Started Phase 1 study for solid tumors

- **DSP-5336**
  U.S. : Started Phase 1 study for hematologic malignancies

- **TWYMEEG® (imeglimin)**
  Japan : Approved for type 2 diabetes in June 2021 and planning to launch in September 2021

- **MYFEMBREE® (relugolix combination tablet)**
  U.S. : Approved for uterine fibroids in May 2021 and launched in June 2021
  U.S. : Submitted sNDA for endometriosis in July 2021

- **RYEQO® (relugolix combination tablet)**
  Europe : Approved for uterine fibroids in July 2021 and planning to launch sequentially in Gedeon Richter Plc.'s territory from the second half of 2021

- **Lefamulin**
  China : Acquired exclusive development and marketing rights from Sinovant in June 2021
  - In preparation to submit NDA based on positive Phase 3 study results for bacterial community-acquired pneumonia

Appendix

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Financial Results for Q1 FY2021 (Full Basis)

Billions of yen

	Q1 FY2020 Results	Q1 FY2021 Results	Change	
			Value	%
Revenue	133.9	131.2	(2.7)	(2.0)
Cost of sales	36.0	38.5	2.5	7.0
Gross profit	97.9	92.7	(5.2)	(5.3)
SG&A expenses	49.0	62.1	13.0	26.6
R&D expenses	25.7	22.4	(3.3)	(12.9)
Other operating income and expenses	0.1	0.1	(0.1)	
Operating profit	23.3	8.3	(15.0)	(64.3)
Finance income and costs	(1.3)	(0.3)	0.9	
Profit before taxes	22.0	8.0	(14.0)	(63.8)
Income tax expenses	6.4	7.2	0.7	
Net profit	15.6	0.8	(14.8)	(94.8)
Net profit attributable to owners of the parent	18.3	4.8	(13.5)	(73.7)

Appendix (Research and Development)

Main Event / Target for FY2021 (as of July 29, 2021)

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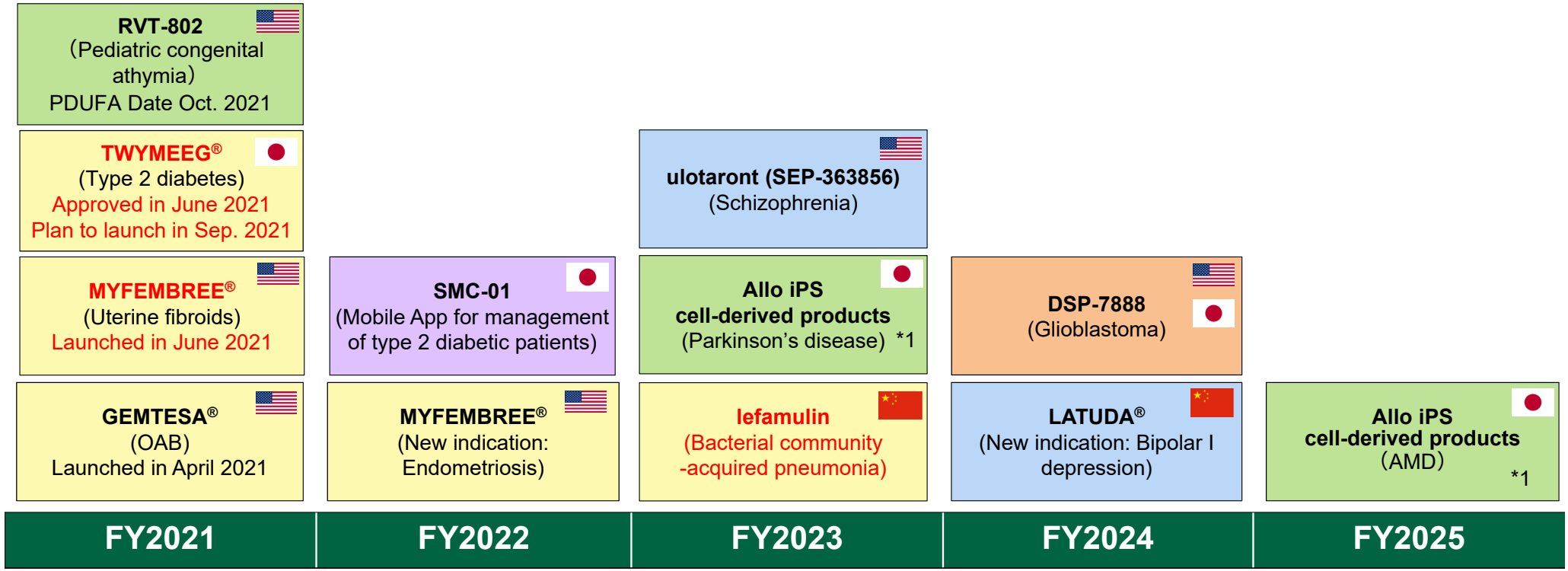
✓ Completed action / target Revisions since the announcement of May 2021 are shown in red

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
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 clinical 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 (Save Medical, MELTIN, Aikomi, Drawbridge, BehaVR, and internal themes, etc.), development of new themes

Appendix (Research and Development)

Product Launch Target (as of July 29, 2021)

Revisions since the announcement of May 2021 are shown in red



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

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

New Chemical Entity: Lefamulin

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- ✓ Target indication：Bacterial community-acquired pneumonia
- ✓ Origin： Nabriva Therapeutics (Marketed by Nabriva Therapeutics in the U.S. as XENLETA®)
- ✓ Mechanism of action：Pleuromutilin antimicrobial agent
- ✓ Stage：Phase 3 (China)
- ✓ Expected profile：
  - ➢ Lefamulin is a antimicrobial agent of pleuromutilin class and a novel treatment for infectious diseases with a mechanism of action that differs from existing antibiotics
  - ➢ Lefamulin is designed to inhibit the synthesis of bacterial protein, which is required for bacteria to grow. Lefamulin's binding occurs with high affinity, high specificity and at molecular sites that are distinct from other antibiotic classes

Positive Phase 3 Study Results for Bacterial Community-acquired Pneumonia in Chinese

Study design: Randomized, double-blind study
lefamulin: 150 mg IV every 12 hours, 600 mg oral every 12 hours; moxifloxacin: 400 mg IV once daily, 400 mg oral once daily

Efficacy: Shown to be non-inferior to moxifloxacin meeting the primary endpoint of Investigator Assessment of Clinical Response (IACR) at Test of Cure (TOC)
lefamulin: 76.8% (n=63/82), moxifloxacin: 71.4% (n=30/42)

Safety: Generally well tolerated, adverse events were similar to moxifloxacin

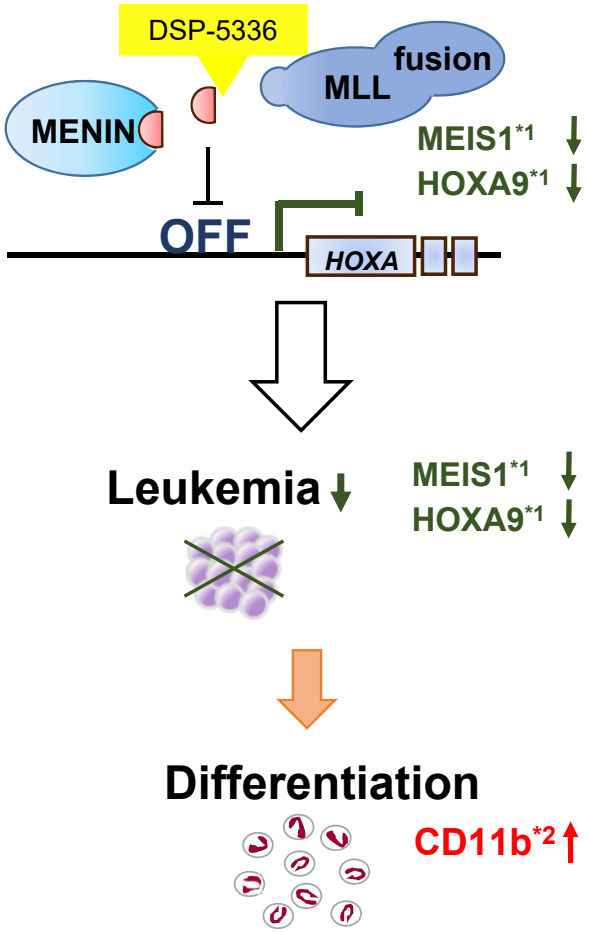
Future plan: Plan to submit NDA to China's NMPA with Phase 3 study results

Announced by Sinovant Sciences and Nabriva Therapeutics on 25 May 2021

New Chemical Entity: DSP-5336

- ✓ Target indication： Hematologic malignancies
- ✓ Origin：In-house (Joint research with Kyoto University)
- ✓ Mechanism of action：Inhibition of Menin-MLL interaction
- ✓ Stage：Phase 1 (U.S.)
- ✓ Expected profile：
  - ➢ DSP-5336 is a small molecule inhibitor against the binding of menin and mixed-lineage leukemia (MLL) protein
  - ➢ DSP-5336 has been shown to have anti-cancer activity through downregulation of the genes by inhibition of menin-MLL interaction in pre-clinical studies

    (Reference) Acute leukemia with MLL rearrangements or nucleophosmin 1 (NPM1) mutations rely on the menin-MLL interaction for upregulation of genes instrumental to leukemogenesis
- ✓ DSP-5336 is a novel compound created by "DSK Project", a joint research project for anti-cancer agents of Kyoto University and Sumitomo Dainippon Pharma, and has received research support (funding) from AMED with the National Cancer Center Japan as the representative research institution



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

Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Business Plan (as of July 29, 2021)

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Pediatric congenital athymia (RVT-802)	Duke University	Global	Cultured thymus tissue	**BLA resubmitted (April 2021)**
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 clinical 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 FY2021

Aim to launch in FY2023 *

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

Appendix (Research and Development)

Development Status of Relugolix and GEMTESA® (Vibegron)

Revisions since the announcement of May 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) Myovant granted an option to commercialize to Pfizer Inc.
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 planning to launch by Gedeon Richter Plc. from the second half of 2021 Endometriosis U.S. : sNDA submitted in July 2021 Europe : Planning to submit in 2021 ➢ (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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