Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Q3 FY2020 (April 1 to December 31, 2020) Conference Call

January 28, 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.

Financial Results for Q3 FY2020

Financial Results for Q3 FY2020 (Core Basis)

Billions of yen

	Q3 YTD FY2019 Results	Q3 YTD FY2020 Results	Change			FY2020	
			Value	FX impact	%	Oct. 28 forecasts	%
Revenue	357.0	**394.8**	37.7	(5.4)	10.6	506.0	78.0
Cost of sales	93.1	**104.8**	11.7	(0.6)	12.6	141.0	74.3
Gross profit	264.0	**290.0**	26.0	(4.8)	9.9	365.0	79.4
SG&A expenses	138.6	**145.7**	7.1	(2.3)	5.1	215.0	67.8
R&D expenses	61.2	**71.7**	10.5	(1.2)	17.1	103.0	69.6
Core operating profit	64.3	**72.6**	8.3	(1.2)	12.9	47.0	154.4
Changes in fair value of contingent consideration (negative number indicates loss)	① 40.8	**(0.4)**	(41.2)			(4.0)	
Other non-recurring items (negative number indicates loss)	② (23.6)	② **15.4**	39.0			15.0	
Operating profit	81.5	**87.5**	6.1		7.5	58.0	150.9
Profit before taxes	84.4	**79.7**	(4.7)		(5.6)	57.0	139.9
Income tax expenses	40.4	**21.8**	(18.6)			36.0	
Net profit	44.0	**57.9**	13.9		31.7	21.0	275.8
Net profit attributable to owners of the parent	44.0	**70.3**	26.3		59.8	42.0	167.3

Results of Sumitovant:

Q3 YTD FY2020	¥B
Revenue	**3.8**
SG&A expenses ＊	26.6
R&D expenses	18.8
Core operating profit	**(41.6)**
Operating profit	**(41.7)**
Net profit	(41.2)
Net profit attributable to owners of the parent	**(28.9)**

＊Include amortization of patent rights through Sumitovant acquisition

① Cost reversal for FY19 due to:
- Discontinued development for napabucasin pancreatic cancer
- Revised business plans for alvocidib
- Discontinued development for amcasertib

② Non-recurring items due to:
(FY19) Impairment losses from revised business plans for alvocidib, discontinued development for amcasertib, discontinued joint development for SB623
(FY20) Gain on sale of former Ibaraki plant of the Company ¥16.7B

FX rates:
Q3YTD FY19 Results : 1US$ = ¥108.7, 1RMB = ¥15.6
Q3YTD FY20 Results : 1US$ = ¥106.1, 1RMB = ¥15.5
FY20 forecasts : 1US$ = ¥108.0, 1RMB = ¥15.5

Revenue of Major Products in Japan

Billions of yen

	Q3 YTD FY2019 Results	Q3 YTD FY2020 Results	Change Value	Change %	FY2020 Oct. 28 forecasts	FY2020 %
Equa®/EquMet®	7.8	**31.3**	23.5	301.2	40.5	77.3
Trulicity® *	22.9	**25.9**	3.0	13.2	36.6	70.7
TRERIEF®	12.6	**12.7**	0.1	0.5	17.0	74.5
REPLAGAL®	10.3	**10.6**	0.2	2.4	13.7	77.0
METGLUCO®	7.4	**7.2**	(0.2)	(3.1)	8.8	81.8
AmBisome®	3.3	**2.8**	(0.5)	(14.8)	4.0	70.1
LATUDA®	—	**1.6**	1.6	—	2.2	73.0
LONASEN® Tape	0.3	**0.9**	0.6	211.3	2.5	37.5
Promoted products Total	64.6	**92.9**	28.3	43.9	125.3	74.2
AMLODIN®	6.0	**5.1**	(0.9)	(14.8)	6.1	83.9
SUREPOST®	5.2	**3.5**	(1.8)	(33.9)	3.5	99.1
AG products	5.8	**5.9**	0.1	1.7	7.2	81.3
Others	22.7	**11.2**	(11.5)	(50.7)	11.2	99.7
Total	104.3	**118.5**	14.3	13.7	153.3	77.3

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

Equa®/EquMet® contributed to increased revenue with sales recorded from November 2019

LATUDA® is on track amid limited sales activities since launched in June 2020

LONASEN® Tape is still slow after prescription days limit was lifted in October 2020

Financial Results for Q3 FY2020

Revenue of Major Products in North America & China

	Q3 FY2019 Resuts	Q3 FY2020 Results	Change	Q3 FY2019 Resuts	Q3 FY2020 Results	Change			FY2020		
						Value	FX impact	%	Oct. 28 forecasts		Yen-basis %
North America	Million $			Billions of yen					Million $	Billion yen	
LATUDA®	1,308	1,513	205	142.1	160.5	18.4	(3.9)	12.9	1,843	199.0	80.7
BROVANA®	239	212	(27)	26.0	22.5	(3.5)	(0.5)	(13.4)	275	29.7	75.7
APTIOM®	156	187	31	17.0	19.8	2.8	(0.5)	16.7	228	24.6	80.6
LONHALA® MAGNAIR®	21	16	(5)	2.3	1.7	(0.6)	(0.0)	(26.0)	28	3.0	55.5
XOPENEX®	25	34	8	2.8	3.6	0.8	(0.1)	30.2	43	4.6	78.2
KYNMOBI™	—	1	1	—	0.2	0.2	(0.0)	—	10	1.1	14.4
Sunovion Others	51	56	5	5.6	5.9	0.4	(0.1)	6.8	55	6.1	97.3
Sumitovant	—	36	36	—	3.8	3.8	(0.1)	—	37	4.0	95.6
Total	1,801	2,055	254	195.7	218.0	22.4	(5.2)	11.4	2,519	272.1	80.1
China	Million RMB			Billions of yen					Million RMB	Billion yen	
MEROPEN®	1,083	992	(91)	16.9	15.3	(1.6)	(0.1)	(9.3)	1,452	22.5	68.1
Others	209	242	33	3.3	3.7	0.5	(0.0)	14.6	335	5.2	71.9
Total	1,292	1,234	(58)	20.2	19.1	(1.1)	(0.2)	(5.4)	1,787	27.7	68.8

Impact of COVID-19 was smaller than anticipated in North America segment. LATUDA® and APTIOM® showed growth y-o-y

KYNMOBI™ was launched at the end of September 2020

In China, sales are still recovering from impact of COVID-19 and showed slow progress to forecast

FX rates: Q3YTD FY19 Results : 1US$ = ¥108.7, 1RMB = ¥15.6
Q3YTD FY20 Results : 1US$ = ¥106.1, 1RMB = ¥15.5
FY20 forecasts : 1US$ = ¥108.0, 1RMB = ¥15.5

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
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
Q3 YTD FY2019 Results	Revenue (Sales to customers)	104.3	195.7	20.2	8.7	328.8	28.2	357.0
	Cost of sales	46.5	17.8	3.8	3.1	71.2	21.9	93.1
	Gross profit	57.8	177.8	16.4	5.6	257.6	6.3	264.0
	SG&A expenses	37.7	87.6	7.0	2.4	134.7	3.9	138.6
	Core segment profit	20.1	90.2	9.4	3.2	122.9	2.5	125.3
	R&D expenses					60.6	0.6	61.2
	Core operating profit					62.4	1.8	64.3
Change	Revenue (Sales to customers)	14.3	22.4	(1.1)	2.8	38.3	(0.6)	37.7
	SG&A expenses	(1.6)	9.6	(0.3)	(0.4)	7.2	(0.1)	7.1
	Core segment profit	2.9	14.3	(0.9)	2.1	18.5	0.4	18.9
	R&D expenses					10.5	(0.0)	10.5
	Core operating profit					7.9	0.4	8.3

Japan:
Profit increased due to higher margin and decreased costs

North America:
Profit increased due to higher revenue and reduced costs at Sunovion which covered the incremental costs of Sumitovant

China:
Decreased profit mainly due to lower revenue

Financial Forecasts for FY2020

Collaboration to Develop and Commercialize Relugolix

Sumitomo Dainippon Pharma

Myovant and Pfizer entered into a collaborative development and commercialization agreement on relugolix in Dec. 2020

Outline	Myovant grants Pfizer the right to jointly develop and commercialize relugolix. Myovant/Pfizer will begin co-promoting ORGOVIX™ for advanced prostate cancer in early 2021 Myovant records sales revenues. Myovant/Pfizer equally share profits and certain expenses for developing and selling
Disease Area	Oncology area, Women's health area
Territory	North America（U.S., Canada）
Consideration	Upfront $650M, Regulatory milestones for FDA approvals in women's health $200M Myovant will receive up to $4.2B including sales milestones and above payments
Option right	Myovant grants Pfizer an exclusive option to commercialize relugolix in oncology outside U.S. and Canada, excluding certain Asian countries Myovant will receive $50M and be entitled to receive double-digit % royalties when the option exercised

■ Accounting treatment

Upfront and regulatory milestones are expected to record deferred revenue on a straight-line basis over a certain period

Financial Forecasts for FY2020 (Core Basis)

Billions of yen

	FY2020 Oct. 28 forecasts
Revenue	506.0
Cost of sales	141.0
Gross profit	365.0
SG&A expenses	215.0
R&D expenses	103.0
Core operating profit	47.0
Changes in fair value of contingent consideration (negative number indicates loss)	(4.0)
Other non-recurring items (negative number indicates loss)	15.0
Operating profit	58.0
Income tax expenses	36.0
Net profit	21.0
Net profit attributable to owners of the parent	42.0
R O E (%)	7.7
R O I C (%)	1.2

FX rates:
FY20 forecasts : 1US$ = ¥ 108.0, 1RMB = ¥15.5

Financial forecasts are not revised at this time

Positive factors for profit:
- Business performance remained strong until 3Q, mainly in LATUDA®
- A part of the consideration for the relugolix collaboration with Pfizer will be recorded as revenue
- Although the appreciation of yen will decrease revenue, core operating profit will be increased

The topline results of the phase 3 study of napabucasin for colorectal cancer will be obtained in February 2021

If it's necessary to revise the financial forecasts for FY2020 based on the results, we will announce it promptly

Research and Development

Research and Development

Development Pipeline (as of January 28, 2021)

Sumitomo Dainippon Pharma

: Psychiatry & Neurology : Oncology : Regenerative medicine / Cell therapy : Others : Frontier business Revisions since the announcement of Oct. 2020 are shown in red

Area	Phase 1		Phase 2	Phase 3	NDA/BLA submitted
Japan	**SEP-363856** (Schizophrenia) **EPI-589** (ALS) **DSP-1181** (Obsessive compulsive disorder)	**dubermatinib (TP-0903)** (Solid tumors)	**SEP-4199** (Bipolar I depression) **DSP-7888** (Solid tumors) **Allo iPS cell-derived products** (Parkinson's disease) Investigator-initiated clinical study	**EPI-743** (Leigh syndrome) **napabucasin** (Colorectal cancer) **SMC-01** (Mobile App for management of type 2 diabetic patient)	**imeglimin** (Type 2 diabetes)
U.S.	**DSP-6745** (Parkinson's disease psychosis) **SEP-378608** (Bipolar disorder) **DSP-3905** (Neuropathic pain) **SEP-378614** (Treatment resistant depression) **SEP-380135** (Agitation in Alzheimer's disease)	**alvocidib** (MDS) **dubermatinib (TP-0903)** (Solid tumors) **DSP-0509** (Solid tumors) **TP-0184** (Solid tumors / Hematologic malignancies) **DSP-0337** (Solid tumors) **TP-1287** (Solid tumors) **TP-3654** (Solid tumors/ Hematologic malignancies) **TP-1454** (Solid tumors)	**EPI-589** (Parkinson's disease/ALS) **SEP-363856** (Parkinson's disease psychosis) **SEP-4199** (Bipolar I depression) **alvocidib** (AML) **DSP-7888** (Solid tumors) **rodatristat ethyl** (Pulmonary arterial hypertension) **URO-902** (Overactive bladder)	**SEP-363856** (Schizophrenia) **napabucasin** (Colorectal cancer) **relugolix** (Endometriosis) **GEMTESA® (vibegron)** (New indication: OAB in men with BPH)	**RVT-802** (Pediatric congenital athymia) Received Complete Response Letter **relugolix** (Uterine fibroids)
China				**LATUDA®** (New indication: Bipolar I depression)	
Europe					**relugolix** (Uterine fibroids)

Clinical Development Status (Major Changes since October 28, 2020)

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LATUDA® (lurasidone)

China : Started Phase 3 study for Bipolar I depression

ORGOVYX™ (relugolix)

U.S. : Approved for prostate cancer in December 2020, Launched in January 2021

GEMTESA® (vibegron)

U.S. : Approved for overactive bladder (OAB) in December 2020, Plan to launch in April 2021

U.S. : Obtained results from Phase 2 study for irritable bowel syndrome (IBS) associated pain in November 2020

- The study did not meet the primary endpoint, Discontinued development of IBS associated pain

  Primary endpoint : Number of responders with at least 30% improvement in abdominal pain associated with diarrhea predominant IBS at week 12

Relugolix

U.S., etc. : Obtained results from one-year extension-study of Phase 3 studies (SPIRIT) for endometriosis

- Achieved and maintained clinically meaningful reductions in dysmenorrhea (menstrual pain) and non-menstrual pelvic pain over one year with minimal bone mineral density loss, and observed well-tolerated safety profile
- In preparation to submit NDA in the U.S. based on positive results from SPRIT 1 & 2 and one-year extension-study

Appendix

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Financial Results for Q3 FY2020 (Full Basis)

Billions of yen

	Q3 YTD FY2019 Results	Q3 YTD FY2020 Results	Change	
			Value	%
Revenue	357.0	394.8	37.7	10.6
Cost of sales	93.3	104.8	11.5	12.3
Gross profit	263.7	290.0	26.3	10.0
SG&A expenses	97.8	147.0	49.2	50.3
R&D expenses	83.7	71.7	(12.0)	(14.4)
Other operating income and expenses	(0.7)	16.3	17.0	
Operating profit	81.5	87.5	6.1	7.5
Finance income and costs	3.0	(7.8)	(10.8)	
Profit before taxes	84.4	79.7	(4.7)	(5.6)
Income tax expenses	40.4	21.8	(18.6)	
Net profit	44.0	57.9	13.9	31.7
Net profit attributable to owners of the parent	44.0	70.3	26.3	59.8

Adjustments to Core Operating Profit

Sumitomo Dainippon Pharma

Q3 YTD FY2020 Results

Billions of yen

	IFRS Full Basis	Adjusted amount	IFRS Core Basis	Adjusted items
Revenue	394.8	-	394.8	
Cost of sales	104.8	-	104.8	
Gross profit	290.0	-	290.0	
SG&A expenses	147.0	(1.3)	145.7	Changes in fair value of contingent consideration (0.4) Business structure improvement expense (0.9)
R&D expenses	71.7	-	71.7	
Other operating income and expenses	16.3	(16.3)	(0.0)	Gain on sale of former Ibaraki plant (16.7)
Operating profit	87.5	(15.0)	72.6	Core operating profit

IFRS Full Basis ： Each item is shown by original financial value under IFRS

IFRS Core Basis ： Each item is shown by value after adjustment for calculating core operating profit

Finalized Purchase Price Allocation of Sumitovant

- 1 year have passed since the acquisition date, the company finalized the purchase price allocation. Reflecting the new information obtained about facts and circumstances that existed as of the acquisition date, retrospective adjustment to provisional fair value was made as below.

Million $

	Q4 FY2019 provisional value	Q3 FY2020 finalized value	Changes	Notes
Intangible assets (In-process R&D, etc.)	2,659	2,652	(7)	relugolix(oncology) 573 relugolix(women's health) 1,203 vibegron 827
Deferred tax liabilities (of the above)	(247)	(245)	+2	
Other assets & liabilities (net)	(66)	(66)	-	
Non-controlling interests	(958)	(993)	(35)	
Goodwill	659	699	+40	
Total acquisition cost	2,047	2,047	-	

Appendix (Research and Development)

Product Launch Target (as of January 28, 2021)

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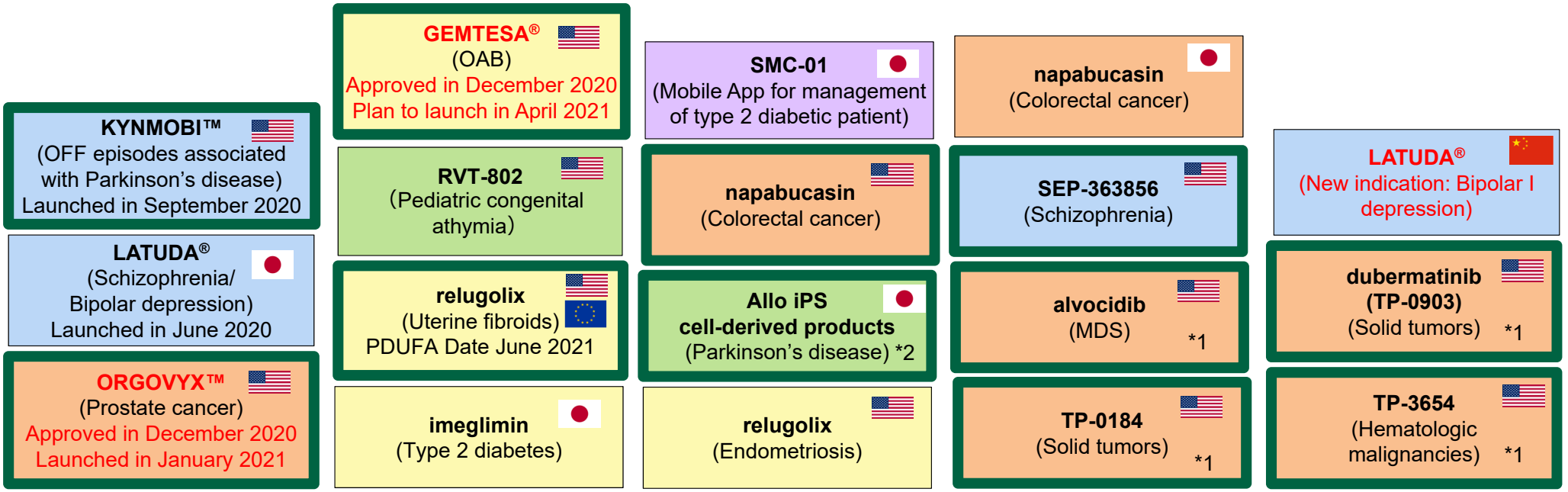
Revisions since the announcement of Oct. 2020 are shown in red



: Psychiatry & Neurology : Oncology

: Regenerative medicine / cell therapy : Others

: Frontier business

Expect peak annual sales to be 50 billion yen or more (described in the first launch)

*1 Premise to utilize an application of accelerated approval program (Plan to consult with the FDA)

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

Appendix (Research and Development)

Development Status of Relugolix and GEMTESA® (Vibegron)

Sumitomo Dainippon Pharma

■ Development status of relugolix

Oncology area (monotherapy: ORGOVYX™)	Prostate cancer U.S. : Launched in January 2021 Europe : Plan to submit in the first half of 2021 ➢ (North America) Entered into a collaborative development and commercialization agreement with Pfizer in December 2020 ➢ (Outside North America, excluding certain Asia) Granted an option to commercialize to Pfizer
Women's health area (combination tablet)	Uterine fibroids U.S. : NDA submitted in May 2020, PDUFA date June 1st, 2021 Europe : MAA submitted in March 2020 Endometriosis Phase 3 study stage U.S. : Plan to submit in the first half of 2021 ➢ (North America) Entered into a collaborative development and commercialization agreement with Pfizer in December 2020 ➢ (Europe, Russia etc.) 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. : Approved in December 2020, Plan to launch in April 2021
OAB in men with BPH	U.S. : Phase 3 study stage, Expect topline results in FY2022

Appendix (Research and Development)

Main Event / Target for FY2020 (as of January 28, 2021)

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Revisions since the announcement of Oct. 2020 are shown in red ✓ Completed action / target

Psychiatry & Neurology	☑ Apomorphine : Obtain approval for OFF episodes associated with Parkinson's disease in the U.S. ☐ SEP-363856 : ☐ Determine new indication for development (global study) ☐ Start Phase 2/3 study for schizophrenia in Asia including Japan and China ☑ SEP-4199 : Obtain results from Phase 2 study for Bipolar I depression
Oncology	☐ Napabucasin : Obtain results from global Phase 3 study for colorectal cancer ☑ Relugolix : Submit NDA for prostate cancer in the U.S. → ☑ Obtain approval
Regenerative medicine / Cell therapy	☐ RVT-802 : Resubmit BLA 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 (transmission-blocking/blood-stage) : Promote research and development projects
Others	☑ Vibegron : Obtain approval for overactive bladder in the U.S. ☐ Relugolix : ☑ Obtain results from Phase 3 study for endometriosis (SPRIT 1, SPIRIT 2) ☑ Submit NDA for uterine fibroids in the U.S. ☐ Obtain approval for uterine fibroids in Europe ☑ Imeglimin : Submit NDA for type 2 diabetes in Japan
Frontier	☐ Promotion of the current themes (MELTIN, Aikomi, Drawbridge and internal themes), development of new themes

Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Business Plan (as of January 28, 2021)

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Revisions since the announcement of Oct. 2020 are shown in red

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Pediatric congenital athymia (RVT-802)	Duke University	Global	Cultured thymus tissue	**In preparation to resubmit BLA**
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 FY2022 *

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

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