Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Investors Meeting Presentation for FY2019

(Year ended March 31, 2020)

May 14, 2020

Hiroshi Nomura, President and CEO
Sumitomo Dainippon Pharma Co., Ltd.

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 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 FY2019

Major Topics in FY2019

Sumitomo Dainippon Pharma

Increase in revenue y-o-y,
core operating profit decrease due to incremental costs of newly consolidated Sumitovant

Japan	Revenue increased in diabetes area including Equa®/EquMet® offset by decrease in long-listed products Profit decreased since margin down due to product mix
North America	LATUDA® and APTIOM® contributed to revenue increase Consolidation of Sumitovant at end of Q3 led to incremental costs
China/ Other	MEROPEN® revenue increased, LATUDA® launched in China
R&D	Success in 3 approvals ・LATUDA® in Japan (schizophrenia, bipolar depression) ・LONASEN® Tape in Japan (schizophrenia) ・RETHIO® in Japan (conditioning treatment prior to autologous HSCT for malignant lymphoma) Resubmission for approval: Apomorphine in the U.S. (OFF episodes associated with Parkinson's disease) Started Phase 3 study: SEP-363856 (U.S.: schizophrenia) Initiated clinical studies: DSP-1181 (Japan: obsessive compulsive disorder) Obtained 10 products due to the strategic alliance with Roivant Sciences ・vibegron, relugolix, RVT-801, RVT-802, rodatristat ethyl, MVT-602, URO-902, SPIRO-2101, SPIRO-2102, ALTA-2530

Financial Results for FY2019 (Core Basis)

Billions of yen

	FY2018 Results	FY2019 Results	Change Value	Change FX impact	Change %	FY2019 Forecasts
Revenue	459.3	482.8	23.5	(7.1)	5.1	475.0
Cost of sales *1	113.1	128.3	15.2	(2.0)	13.5	125.0
Gross profit	346.2	354.4	8.3	(5.1)	2.4	350.0
SG&A expenses *1	186.1	190.0	3.8	(2.9)	2.1	192.0
R&D expenses *1	82.9	92.6	9.7	(1.3)	11.7	94.0
Core operating profit	77.3	72.0	(5.3)	(0.9)	(6.9)	64.0
Changes in fair value of contingent consideration (negative number indicates loss)	9.1	① 48.5	39.3			34.5
Other non-recurring items *2 (negative number indicates loss)	(28.5)	② (37.2)	(8.7)			(23.5)
Operating profit	57.9	83.2	25.4		43.8	75.0
Profit before taxes	65.0	83.9	18.9		29.1	78.0
Income tax expenses	16.4	48.0	31.6			52.0
Net profit	48.6	35.9	(12.7)		(26.1)	26.0
Net profit attributable to owners of the parent	48.6	40.8	(7.9)		(16.2)	31.0

*1 Exclude non-recurring items (impairment losses, changes in fair value of contingent consideration, etc.)
*2 Non-recurring items (Other operating income and expenses, impairment losses, etc.)

Impact on consolidating Sumitovant:

SG&A expenses*	6.5
R&D expenses	9.0
Core operating profit	(15.6)
Operating profit	(15.5)
Net profit	(16.7)
Attributable to owners of the parent	(11.9)

*Exclude acquisition related cost 3.9

① Cost reversal due to:
- Stopped Ph3 study for napabucasin pancreatic cancer (Q1)
- Revised business plans for alvocidib (Q2)
- Stopped amcasertib development (Q2)
- Revised business plan for Lonhala Magnair (Q4)

② Non-recurring items due to:
Impairment losses from
- Revised business plans for alvocidib (Q2)
- Stopped amcasertib development (Q2)
- Stopped SB623 joint development (Q3)
- Revised business plan for Lonhala Magnair (Q4)

FX rates: FY2018 Results : 1US$ = ¥ 110.9, 1RMB = ¥16.5
FY2019 Results : 1US$ = ¥ 108.7, 1RMB = ¥15.6
FY2019 Forecasts : 1US$ = ¥ 108.5, 1RMB = ¥15.5

Financial Results for FY2019

Revenue of Major Products in Japan

Billions of yen

	FY2018 Results	FY2019 Results	Change	
			Value	%
Trulicity® *	23.1	30.0	6.9	29.6
TRERIEF®	15.7	16.2	0.5	3.4
REPLAGAL®	12.5	13.3	0.8	6.3
Equa®/EquMet®	—	17.1	17.1	—
METGLUCO®	10.1	9.6	(0.4)	(4.3)
SUREPOST®	6.1	6.9	0.8	13.2
AmBisome®	4.0	4.2	0.1	3.6
LONASEN® Tape	—	0.5	0.5	—
Promoted products Total	71.5	97.8	26.3	36.8
AMLODIN®	9.1	7.6	(1.5)	(16.2)
LONASEN® tablet/powder	12.2	5.6	(6.7)	(54.6)
AIMIX®	8.2	4.0	(4.2)	(50.9)
PRORENAL®	4.0	3.2	(0.8)	(21.0)
GASMOTIN®	3.8	3.1	(0.7)	(18.4)
AG products	5.5	7.4	1.9	34.0
Others	15.0	11.0	(4.0)	(26.7)
Total	129.3	139.7	10.4	8.1

Trulicity®, SUREPOST® showed high growth rate

Started Equa®/EquMet® delivery in November 2019

LONASEN® Tape was launched in September 2019

GEs of LONASEN® tablet/powder were launched in June 2019

Impact of NHI price revision in FY2019 : 2.7

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

Revenue of Major Products in North America & China

	FY2018 Results	FY2019 Results	Change	FY2018 Results	FY2019 Results	Change		
						Value	FX impact	%
North America	Million $			Billions of yen				
LATUDA®	1,663	1,743	80	184.5	189.5	5.0	(3.9)	2.7
BROVANA®	304	317	13	33.7	34.5	0.8	(0.7)	2.3
APTIOM®	185	215	30	20.5	23.4	2.9	(0.5)	14.1
LONHALA® MAGNAIR®	13	27	14	1.4	2.9	1.5	(0.1)	105.0
XOPENEX®	42	38	(4)	4.6	4.1	(0.5)	(0.1)	(10.3)
Others	70	72	2	7.8	7.9	0.1	(0.2)	0.7
Total	2,277	2,413	136	252.5	262.3	9.8	(5.4)	3.9
China	Million RMB			Billions of yen				
MEROPEN®	1,284	1,542	258	21.2	24.1	2.8	(1.4)	13.2
Others	212	292	80	3.5	4.6	1.0	(0.3)	29.8
Total	1,496	1,834	337	24.7	28.6	3.9	(1.7)	15.6

North America sales were strong mainly due to LATUDA® and APTIOM®

MEROPEN® sales remained strong

LATUDA® was launched in September 2019

FX rates: FY2018 Results : 1US$ = ¥ 110.9, 1RMB = ¥16.5
FY2019 Results : 1US$ = ¥ 108.7, 1RMB = ¥15.6

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2019 Results	Revenue (Sales to customers)	139.7	262.3	28.6	14.8	445.4	37.4	482.8
	Cost of sales	65.0	24.0	5.4	5.0	99.5	28.9	128.3
	Gross profit	74.7	238.3	23.2	9.8	346.0	8.4	354.4
	SG&A expenses	51.8	120.8	8.8	3.4	184.8	5.2	190.0
	Core segment profit	22.9	117.5	14.4	6.4	161.2	3.2	164.4
	R&D expenses					91.7	0.9	92.6
	Core operating profit					69.7	2.3	72.0
FY2018 Results	Revenue (Sales to customers)	129.3	252.5	24.7	14.3	420.9	38.4	459.3
	Cost of sales	52.4	21.7	3.7	5.6	83.4	29.7	113.1
	Gross profit	77.0	230.8	21.0	8.7	337.5	8.6	346.2
	SG&A expenses	51.9	116.3	8.7	3.6	180.6	5.6	186.1
	Core segment profit	25.1	114.5	12.3	5.0	157.0	3.1	160.0
	R&D expenses					81.8	1.1	82.9
	Core operating profit					75.3	2.0	77.3
Change	Revenue (Sales to customers)	10.4	9.8	3.9	0.5	24.5	(1.0)	23.5
	SG&A expenses	(0.0)	4.5	0.0	(0.3)	4.2	(0.4)	3.8
	Core segment profit	(2.2)	3.0	2.1	1.4	4.3	0.2	4.4
	Core operating profit					(5.6)	0.3	(5.3)

Japan:
Despite revenue increase, profit decreased due to rise in cost of sales for product mix

North America:
Increased revenue covered incremental cost of strategic alliance

Valuations and Accounting Procedures by Strategic Alliance with Roivant

Valuation of assets and accounting procedures associated with the acquisition are as follows:

Million $

	Before purchase price allocation	After purchase price allocation	Valuation differences	Accounting procedures
Intangible assets (In-process R&D, etc.)	—	2,659	2,659	Capitalize (amortize IPR&D after approval)
Deferred tax liabilities (of the above)	—	(247)	(247)	
Other assets & liabilities (net)	(41)	(41)	—	
Non-controlling interests	(25)	(983)	(958)	
Goodwill	—	659	659	
Total acquisition cost	(65)	2,047	2,113	

IPR&D consist of
relugolix：1,609
vibegron：1,002
Other：39

Financial Forecasts for FY2020

Financial Forecasts for FY2020 (Core Basis)

Billions of yen

	FY2019 Results	FY2020 Forecasts	Change from FY2019	
			Value	%
Revenue	482.8	**510.0**	27.2	5.6
Cost of sales	128.3	**145.0**	16.7	13.0
Gross profit	354.4	**365.0**	10.6	3.0
SG&A expenses	190.0	**229.0**	39.0	20.5
R&D expenses	92.6	**103.0**	10.4	11.2
Core operating profit	72.0	**33.0**	(39.0)	(54.2)
Changes in fair value of contingent consideration (negative number indicates loss)	48.5	**(24.0)**	(72.5)	
Other non-recurring items (negative number indicates loss)	(37.2)	**15.0**	52.2	
Operating profit	83.2	**24.0**	(59.2)	(71.2)
Income tax expense	48.0	**38.0**	(10.0)	
Net profit	35.9	**(14.0)**	(49.9)	–
Net profit attributable to owners of the parent	40.8	**7.0**	(33.8)	(82.8)
R O E (%)	7.9	**1.3**		
R O I C (%)	3.3	**(0.6)**		

Impact of COVID-19 is not counted in FY2020 forecasts

(Reference)

	Sumitovant			Other than Sumitovant		
	2019	2020	Change	2019	2020	Change
Revenue		4.0	4.0	482.8	506.0	23.2
SG&A expenses	6.5	46.0	39.5	183.4	183.0	(0.4)
R&D expenses	9.0	24.0	15.0	83.6	79.0	(4.6)
Core operating profit	(15.6)	(66.0)	(50.4)	87.6	99.0	11.4
Operating profit	(15.5)	(66.0)	(50.5)	98.7	90.0	(8.7)
Net profit	(16.7)	(68.0)	(51.3)	52.6	54.0	1.4
Attributable to owners of the parent	(11.9)	(47.0)	(35.1)	52.6	54.0	1.4

FX rates: FY2019 Results : 1US$ = ¥ 108.7, 1RMB = ¥15.6
FY2020 Forecasts : 1US$ = ¥ 108.0, 1RMB = ¥15.5

Financial Forecasts for FY2020

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total (Core basis)
		Japan	North America	China	Other Regions	Subtotal		
FY2020 Forecasts	Revenue (Sales to customers)	154.4	268.0	30.8	18.8	472.0	38.0	510.0
	Cost of sales	80.0	23.0	5.8	6.9	115.7	29.3	145.0
	Gross profit	74.4	245.0	25.0	11.9	356.3	8.7	365.0
	SG&A expenses	55.0	154.3	10.4	3.6	223.3	5.7	229.0
	Core segment profit	19.4	90.7	14.6	8.3	133.0	3.0	136.0
	R&D expenses					102.0	1.0	103.0
	Core operating profit					31.0	2.0	33.0
FY2019 Results	Revenue (Sales to customers)	139.7	262.3	28.6	14.8	445.4	37.4	482.8
	Cost of sales	65.0	24.0	5.4	5.0	99.5	28.9	128.3
	Gross profit	74.7	238.3	23.2	9.8	346.0	8.4	354.4
	SG&A expenses	51.8	120.8	8.8	3.4	184.8	5.2	190.0
	Core segment profit	22.9	117.5	14.4	6.4	161.2	3.2	164.4
	R&D expenses					91.7	0.9	92.6
	Core operating profit					69.7	2.3	72.0
Change	Revenue (Sales to customers)	14.7	5.7	2.2	4.0	26.6	0.6	27.2
	SG&A expenses	3.2	33.5	1.6	0.2	38.5	0.5	39.0
	Core segment profit	(3.5)	(26.8)	0.2	1.9	(28.2)	(0.2)	(28.4)
	R&D expenses					10.3	0.1	10.4
	Core operating profit					(38.7)	(0.3)	(39.0)

Japan segment
- Profit decrease due to higher cost of sales ratio based on sales mix changes and incremental SG&A expenses despite increased revenue

North America segment
- Profit decrease due to SG&A expenses (recording full-year Sumitovant costs and sales related cost of new products) offsetting revenue increase

China segment
- Profit remain unchanged due to revenue and SG&A increase

R&D expenses
- Increase due to the full-year Sumitovant costs that were recorded

Revenue of Major Products in Japan

Billions of yen

	FY2019 Results	FY2020 Forecasts	Change	
			Value	%
Equa®/EquMet®	17.1	40.5	23.4	136.3
Trulicity® *	30.0	36.6	6.6	22.1
TRERIEF®	16.2	17.0	0.8	5.0
REPLAGAL®	13.3	13.3	(0.0)	(0.3)
METGLUCO®	9.6	7.8	(1.8)	(19.0)
LONASEN® Tape	0.5	5.3	4.8	907.0
AmBisome®	4.2	4.0	(0.2)	(4.4)
LATUDA®	—	2.2	2.2	—
Promoted products Total	91.0	126.7	35.7	39.2
AMLODIN®	7.6	6.1	(1.5)	(20.2)
SUREPOST®	6.9	3.0	(3.9)	(56.2)
AG products	7.4	9.4	2.0	26.4
Others	26.8	9.2	(17.6)	(65.6)
Total	139.7	154.4	14.7	10.5

Equa®/EquMet®, Trulicity®, LONASEN® Tape will contribute revenue increase

LATUDA® will be launched in June

Impact of NHI price revision：
About ¥10 billion
(Change from 2019/4 price, FY2020 forecast basis)

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

Financial Forecasts for FY2020

Revenue of Major Products in North America & China

	FY2019 Results	FY2020 Forecasts	Change	FY2019 Results	FY2020 Forecasts	Change	
						Value	%
North America	Million $			Billions of yen			
LATUDA®	1,743	1,798	55	189.5	194.2	4.7	2.5
BROVANA®	317	288	(29)	34.5	31.1	(3.4)	(9.8)
APTIOM®	215	216	1	23.4	23.3	(0.1)	(0.4)
LONHALA®MAGNAIR®	27	35	8	2.9	3.8	0.9	29.3
XOPENEX®	38	38	(0)	4.1	4.1	(0.0)	(0.8)
Apomorphine	—	10	10	—	1.1	1.1	—
Others	72	96	24	7.9	10.4	2.5	32.3
Total	2,413	2,481	68	262.3	268.0	5.7	2.2
China	Million RMB			Billions of yen			
MEROPEN®	1,542	1,632	90	24.1	25.3	1.2	5.2
Others	292	355	63	4.6	5.5	0.9	20.8
Total	1,834	1,987	153	28.6	30.8	2.2	7.7

LATUDA® sales remain growing

Others in North America include revenue from relugolix out-license to Europe and other region

MEROPEN® and other products remain strong in China

FX rates: FY2019 Results : 1US$ = ¥ 108.7, 1RMB = ¥15.6
FY2020 Forecasts : 1US$ = ¥ 108.0, 1RMB = ¥15.5

Finance / Dividend Policy

Sumitomo Dainippon Pharma

Financial Policy after the strategic alliance with Roivant

- R&D : Optimize investments against our forecast exceeding the 5-years MTBP (FY2018-2022) target total of ¥450 billion
- M&A : Refrain from large-sized investments for the present, but continue seeking investment opportunities to acquire pipeline after investing ¥330 billion as part of the 5-years MTBP target of ¥300 to 600 billion
- Consider use of hybrid financing for shifting bridge loan to long-term financing

Dividend Policy

- Maintain a consistent payment policy but also consider reflecting any improvement in the Company's performance
- 5-year (FY2018-2022) average payout ratio: 20% or higher

	FY2018 actual	FY2019 plan	FY2020 plan
Dividend per share (yen)	28.00	28.00	28.00
Payout ratio (%)	22.9	27.3	158.9
Return on Invested Capital (ROIC) (%)	11.8	3.3	(0.6)
Return on Equity (ROE) (%)	10.2	7.9	1.3

ROIC: (core operating profit – income taxes) / (capital + interest-bearing liabilities)

Activities for FY2020

Activities for FY2020 (1)

Japan：Aim to be No.1 in Psychiatry & Neurology and Diabetes fields

Psychiatry & Neurology (CNS-dedicated MRs (350))

- LATUDA®: Achieve early market penetration with indications of schizophrenia and bipolar depression (plan to launch in June 2020)
- LONASEN® Tape: Expand sales following release of medication period restriction at the end of Sept. 2020 (launched in Sept. 2019)

Diabetes field

- Trulicity®, Equa®, and EquMet®: Expand sales based on information provision according to disease status
- Imeglimin (plan to submit NDA in 1H FY2020): Further strengthen the lineup for diabetes field

North America：Further strengthen foundation and prepare to launch new products

- Sunovion: Continued strong revenue contribution from LATUDA® and launch of apomorphine sublingual film (planned for Sept. 2020)
- Sumitomo Dainippon Pharma America (parent company for 3 companies)
  - Improve management efficiency of Sunovion and other affiliated companies through shared services (from April 2020)
  - Improve efficiency by integration of Boston Biomedical and Tolero pharmaceuticals (plan in July 2020)
- Sumitovant (parent company for 5 companies)
  - Support the successful launch of vibegron (Urovant) and relugolix (Myovant) by helping build efficient commercial structure in the U.S.
  - Consider using Sunovion's commercial infrastructure as appropriate

China： Enhance support for expanding MEROPEN® and early penetration of LATUDA®

Activities for FY2020 (2)

Initiatives to strengthen foundations, such as Digital Innovation

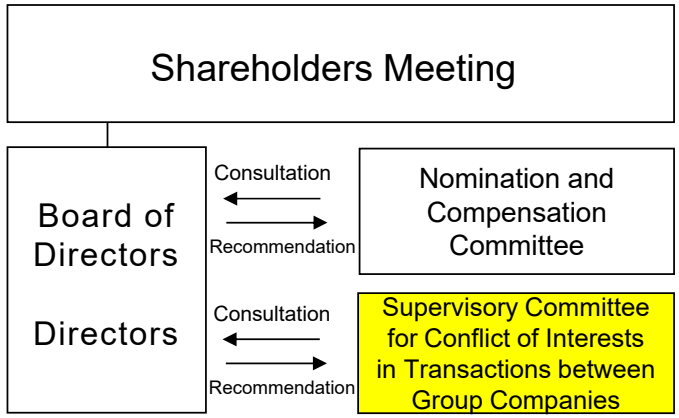
- **Review the digital strategy of Sumitomo Dainippon Pharma Group based on the strategic alliance with Roivant**
  - Improve flexibility and agility regarding changes in the business environment by introducing agile business styles

- **Promote the utilization of digital technologies, such as DrugOme and Digital Innovation throughout the Group**
  - In order to solve business problems by utilizing DrugOme in each department such as Research and Development, the person in charge in Japan will be trained in addition to the person in charge of DrugOme at Sumitovant
  - In addition to about 10 Digital Innovators in charge of Digital Innovation at our North American subsidiary companies, several Digital Innovators will be deployed in Japan

Strengthen of Corporate Governance

- Establish the "Supervisory Committee for Conflict of Interests in Transactions between Group Companies" (April 2020)
  - Strengthen supervision of transactions among parent company group to prevent conflicts of interest
  - Serve as consultative body to the Board of Directors
  - Consist of independent outside directors only
  - Deliberate with the perspective of protecting the interests of minority shareholders

Positioning of the new committee: simplified schematic



Research and Development

Research and Development

Main Event / Target for FY2020 (as of May 13, 2020)

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. (Submitted in April 2020)
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 (Obtained SPIRIT 2 results in April 2020) 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

Research and Development

Development Pipeline (as of May 13, 2020)

Sumitomo Dainippon Pharma

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

Revisions since the announcement of March 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) **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) **vibegron** (IBS-associated pain) **rodatristat ethyl** (Pulmonary arterial hypertension) **URO-902** (Overactive bladder)	**SEP-363856** (Schizophrenia) **napabucasin** (Colorectal cancer) **relugolix** (Uterine fibroids/Endometriosis) **vibegron** (OAB in men with BPH)	**apomorphine** (OFF episodes associated with Parkinson's disease) NDA resubmitted in November 2019 **relugolix** (Prostate cancer) **RVT-802** (Pediatric congenital athymia) Received Complete Response Letter **vibegron** (OAB)
Europe					**relugolix** (Uterine fibroids)

Clinical Development Status (1) (Major Changes since March 3, 2020)

Sumitomo Dainippon Pharma

- **LATUDA® (lurasidone)**
  Japan : Approved for schizophrenia and bipolar depression in March 2020

- **SEP-363856**
  U.S. : Obtained results from Phase 2 study (exploratory study) for Parkinson's disease psychosis
  - The primary endpoint did not reach statistical significance. However, SEP-363856 did result in numerical improvement when compared to placebo
    Primary endpoint : change from baseline in total SAPS-PD score at 6 weeks

- **RETHIO® (thiotepa)** [Development for the use of unapproved or off-labeled drugs]
  Japan : Approved for conditioning treatment prior to autologous HSCT for malignant lymphoma in March 2020

- **Relugolix**
  U.S. : Submitted NDA for prostate cancer submitted in April 2020

- **TP-1454**
  U.S. : Started Phase 1 study for solid tumors
  - TP-1454 inhibits tumor growth through activation of PKM2 (pyruvate kinase M2) which lead to the inhibition of tumor cell proliferation and the enhancement of antitumor immune response

- **Relugolix**
  Europe : Submitted MAA for uterine fibroids submitted in March 2020
  U.S., etc. : Obtained results from global Phase 3 study (SPIRIT2) for endometriosis

Clinical Development Status (2) (Major Changes since March 3, 2020)

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Discontinuation of dasotraline (U.S., Japan)

Withdrew the U.S. NDAs for BED and ADHD in April 2020 and discontinued development in Japan and the U.S.

- This decision was made because the Company believes that additional clinical studies would be needed due to the benefit/risk profile of the evidence generated to date

Impact on clinical studies associated with the spread of COVID-19

Prioritize patient safety and continue clinical studies wherever possible consistent with the latest regulations and guidelines

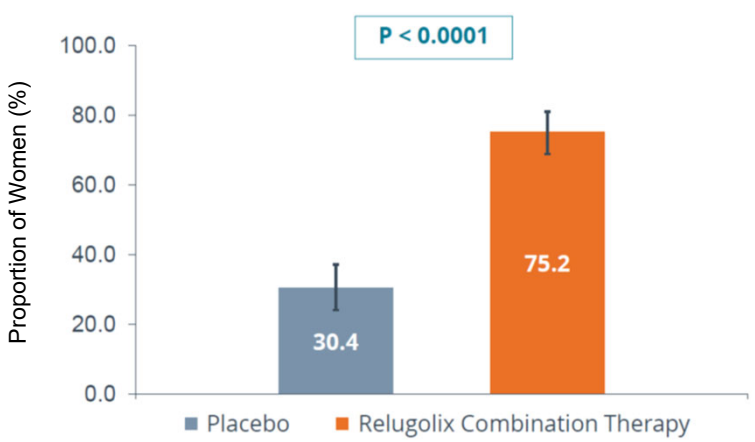
- Studies to recruit activation of new study sites or enrollment of new patients: Potential delay of clinical studies because some clinical studies suspended new patients enrollment
- Studies with completed patient enrollment : Potential delay in obtaining study results

Relugolix : Endometriosis Phase 3 Study Results (SPIRIT2)

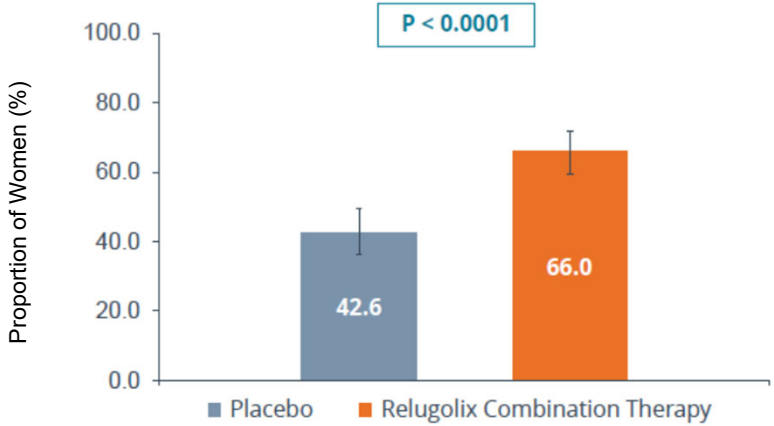
- **Study design:** Randomized, double-blind, placebo-controlled study
  Relugolix Combination Therapy : relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

- **Efficacy:**
  - Achieved co-primary endpoints with significant pain reduction (p<0.0001)
    (Co-primary endpoints : proportion of women with clinically meaningful reduction in dysmenorrhea (menstrual pain) and non-menstrual pelvic pain as assessed using the Numerical Rating Scale (NRS))
  - Achieved six key secondary endpoints

Dysmenorrhea



Non−menstrual pelvic pain



- **Safety:** Generally well tolerated including minimal bone mineral density loss, adverse events were similar to placebo

- **Future plan:** Plan to be obtained SPIRIT1 results in Q1 FY2020

* Myovant announced the positive result for SPIRIT2 study in the press release on April 22, 2020

Activities for Infectious Diseases Area

"Contribution to Global Health" through research and development

Universal influenza vaccine
Joint research with NIBIOHN
(Supported by AMED)

Malaria transmission-blocking vaccine
Joint research and development with
Ehime University and PATH
(Supported by GHIT Fund)

AMED
国立研究開発法人 日本医療研究開発機構
Japan Agency for Medical Research and Development

GHIT Fund
Global Health Innovative Technology Fund

NIBIOHN
国立研究開発法人
医薬基盤・健康・栄養研究所
National Institutes of Biomedical Innovation, Health and Nutrition

Sumitomo Dainippon Pharma

Novel TLR7 adjuvants

愛媛大学
EHIME UNIVERSITY

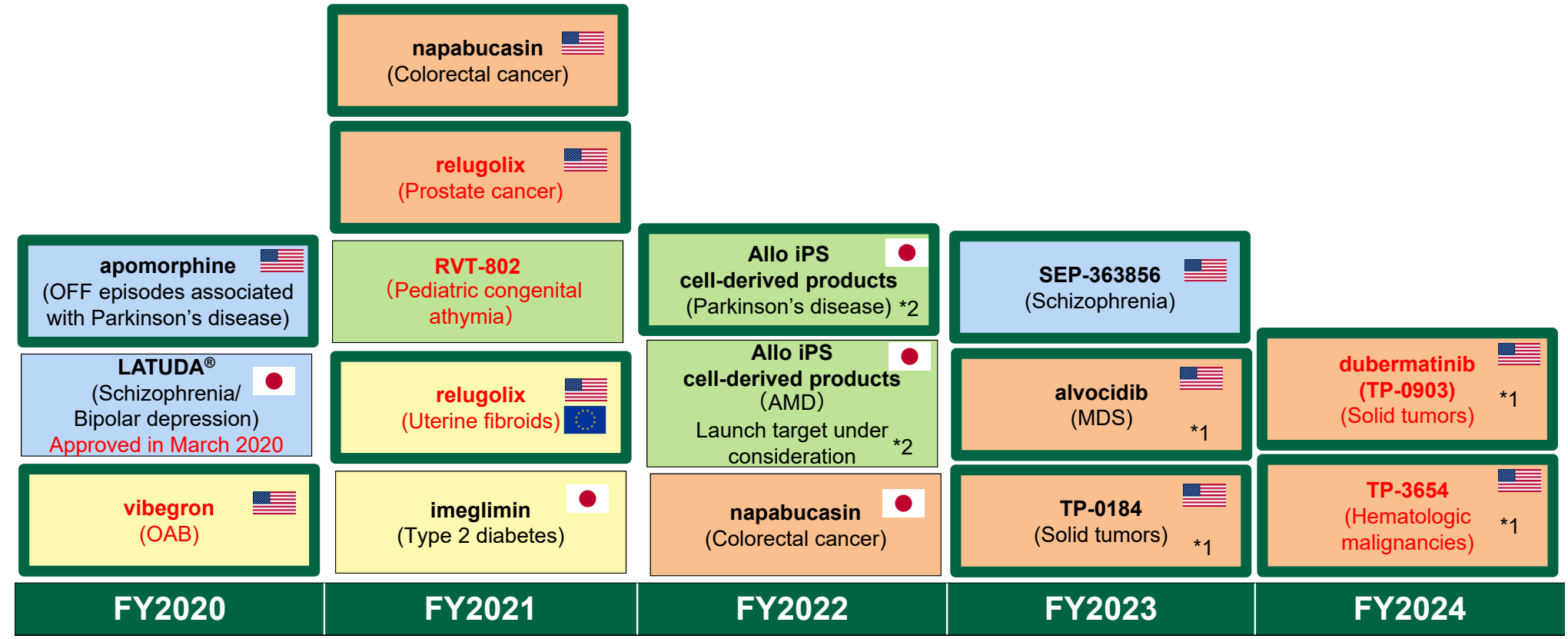
PATH

Aim to prevent new strains of influenza in addition to response to antigen mutation of seasonal influenza

Aim for malaria elimination

Product Launch Target (as of May 13, 2020)

Revisions since the announcement of March 2020 are shown in red



: Psychiatry & Neurology : Oncology

: Regenerative medicine / cell therapy : Others

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

＜Contents＞

Financial Results for FY2019 (Full Basis)

Billions of yen

	FY2018 Results	FY2019 Results	Change	
			Value	%
Revenue	459.3	482.7	23.5	5.1
Cost of sales	113.6	129.7	16.1	14.2
Gross profit	345.7	353.1	7.3	2.1
SG&A expenses	180.4	154.3	(26.1)	(14.5)
R&D expenses	102.4	115.1	12.7	12.5
Other operating income and expenses	(5.0)	(0.4)	4.7	
Operating profit	57.9	83.2	25.4	43.8
Finance income and costs	7.2	0.7	(6.5)	
Income tax expenses	16.4	48.0	31.6	
Net profit	48.6	35.9	(12.7)	(26.1)
Net profit attributable to owners of the parent	48.6	40.8	(7.9)	(16.2)

Adjustments to Core Operating Profit

FY2019 Results

Billions of yen

IFRS Full Basis		Adjusted amount
Revenue	482.7	0
Cost of sales	129.7	(1.3)
Gross profit	353.1	1.4
SG&A expenses	154.3	35.6
R&D expenses	115.1	(22.5)
Other operating income and expenses	(0.4)	0.5
Operating profit	83.2	(11.3)

IFRS Core Basis		Adjusted items
Revenue	482.8	
Cost of sales	128.3	Impairment loss (0.6)
Gross profit	354.4	
SG&A expenses	190.0	Changes in fair value of contingent consideration 48.5 Impairment loss (12.1)
R&D expenses	92.6	Impairment loss (22.5)
Other operating income and expenses *1 (profit/loss on business transfer, share of profit/loss of associates accounted for using equity method)	0.2	
Core operating profit	72.0	
Changes in fair value of contingent consideration (Positive number indicates profit)	48.5	From SG&A expenses 48.5
Other non-recurring items *2 (Negative number indicates loss)	(37.2)	Impairment loss (35.2)

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

*1 "P/L on business transfer" and "share of P/L of associates accounted for using equity method" included in "other operating income and expenses" are used for calculation for core operating profit

*2 Non-recurring items including "other operating income and expenses" except for *1 items, and impairment losses, etc.

Appendix (Financial Results for FY2019)

Financial Position

Billions of yen

B / S	As of March 31,2019	As of March 31,2020	Change
Assets	834.7	1,252.9	418.2
Goodwill	99.3	169.0	69.7
Intangible assets	171.4	421.8	250.4
Other financial assets (Non-current)	74.7	200.9	126.3
Cash and deposit/ Short-term loan receivable	180.0	127.6	(52.4)
Liabilities	336.6	620.8	284.2
Loan payable	30.9	298.0	267.0
Fair value of contingent consideration (Other financial liaiabilities)	81.4	31.2	(50.1)
Deferred tax assets	–	26.9	26.9
Equity	498.1	632.1	134.0
Attributable to owners of the parent	498.1	529.5	31.3
Ratio of equity attributable to owners of the parent to total assets	59.7%	42.3%	

C / F	FY2018	FY2019	Change
Operating CF	48.7	46.1	(2.6)
Investment CF	(35.0)	(312.7)	(277.6)
Financial CF	(28.6)	231.1	259.7
Cash and cash equivalents	137.3	101.7	(35.6)
(Operating funds)	180.0	127.6	(52.5)

Goodwill and IPR&D associated with acquisition of Sumitovant

Acquired Roivant stocks

Financing for alliance with Roivant
Bridge loan ¥270 billion

Acquired Roivant stocks
Acquired Sumitovant

Financing for alliance with Roivant
Bridge loan ¥270 billion

Appendix (Research and Development)

Main Event/Target for FY2019 (as of May 13, 2020)

Sumitomo Dainippon Pharma

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

Psychiatry & Neurology	☑ LONASEN® (New formulation : transdermal patch) : Obtain approval for schizophrenia in Japan ☑ Lurasidone : Submit NDA and obtain approval for schizophrenia and bipolar depression in Japan ☑ Dasotraline : NDA submission for BED in the U.S. ☑ Dasotraline : Determine development strategy for ADHD in the U.S. ☑ Apomorphine : Resubmit NDA for OFF episodes associated with Parkinson's disease in the U.S. ☐ SEP-363856* : Start next phase study (☑ Phase 3 study in the U.S., ☐ Phase 2 study in Japan)
Oncology	☐ Napabucasin : Promote global Phase 3 studies for colorectal cancer and pancreatic cancer (☑ Completed interim analysis in H1 FY2019, interim analysis results: Phase 3 study for colorectal cancer to be continued, Phase 3 study for pancreatic cancer discontinued)
Regenerative medicine / Cell therapy	☑ SB623 : Determine development policy for chronic stroke in the U.S. ☐ Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study
Infectious Diseases	☑ Promote joint research with academia and others (antimicrobial resistance (AMR), universal influenza vaccines, malaria vaccines)
Others	☑ Imeglimin : Obtain two Phase 3 study results (☑ TIMES 2, ☑ TIMES 3) in Japan
Frontier	☑ Promotion of the current themes (MELTIN, Aikomi), development of new themes

* Sunovion discovered SEP-363856 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms

Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Business Plan (as of May 13, 2020)

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Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Pediatric congenital athymia (RVT-802)	Duke University	Global	Cultured thymus tissue	**Under consideration 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 FY2020 (Launch target under consideration)

Aim to launch in FY2022 *

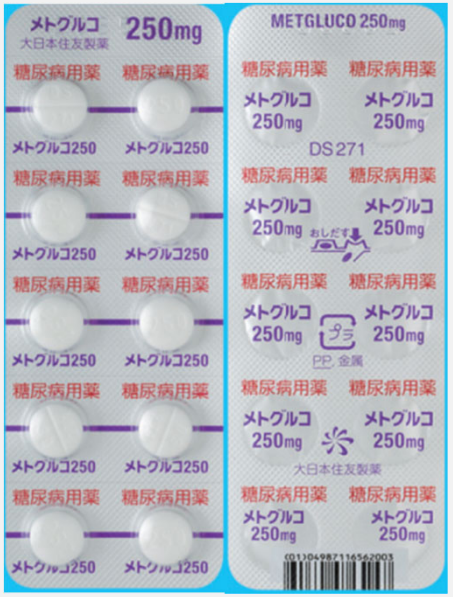
* Launch schedule is based on our goal pending agreement with partners

Planned Changes for Blister Packages of METGLUCO® Tablets

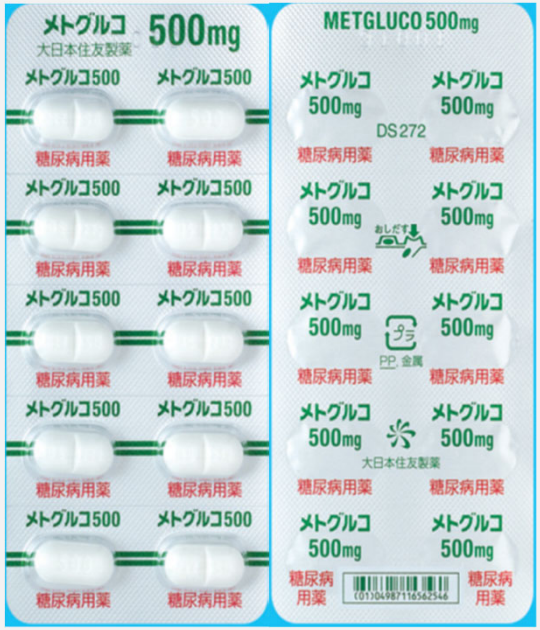
Sumitomo Dainippon Pharma

Before the changes

METGLUCO® tablets 250 mg



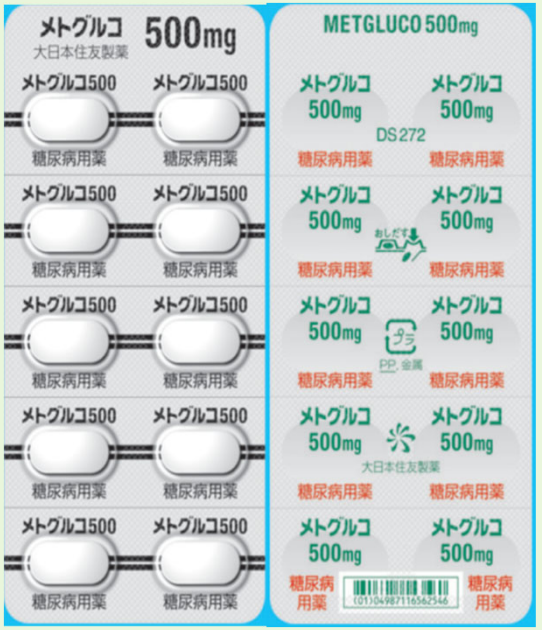
METGLUCO® tablets 500 mg



After the changes (illustration purposes only)

METGLUCO® tablets 250 mg

METGLUCO® tablets 500 mg



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Innovation today, healthier tomorrows