Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Q1 FY2019　(April 1 to June 30, 2019) Conference Call

July 29, 2019

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

Financial Results for Q1 FY2019

Financial Results for Q1 FY2019 (Core Basis)

Billions of yen

	Q1 FY2018 Results	Q1 FY2019 Results	Change			Q2 FY2019 (Apr.-Sep.)		FY2019	
			Value	FX rate impact	%	Forecasts	Progress %	Forecasts	Progress %
Revenue	115.9	117.5	1.6	0.0	1.4	226.5	51.9	460.0	25.5
Cost of sales *1	28.9	28.8	(0.1)	0.1	(0.2)	56.0	51.5	116.0	24.9
Gross profit	87.0	88.6	1.6	(0.0)	1.9	170.5	52.0	344.0	25.8
SG&A expenses *1	47.8	46.3	(1.4)	0.1	(2.9)	91.0	50.9	181.0	25.6
R&D expenses *1	20.9	20.0	(0.8)	0.1	(3.9)	41.0	48.9	86.0	23.3
Other operating income and expenses (Core basis) *2	0.0	0.0	(0.0)	–	(43.5)	–	–	–	–
Core operating profit	18.4	22.3	3.9	(0.2)	20.9	38.5	57.9	77.0	28.9
Changes in fair value of contingent consideration (negative number indicates loss)	(2.5)	18.5	21.0			(3.5)		(7.0)	
Other non-recurring items (negative number indicates loss) *3	(0.1)	(0.3)	(0.2)			(0.5)		(1.0)	
Operating profit	15.8	40.4	24.6		155.6	34.5	117.2	69.0	58.6
Profit before taxes	20.6	36.9	16.3		78.9	36.5	101.1	72.0	51.3
Income tax expenses	5.4	30.2	24.8						
Net profit attributable to owners of the parent	15.2	6.7	(8.5)		(56.0)	25.0	26.8	49.0	13.7

*1 Exclude non-recurring items (impairment losses, changes in fair value of contingent consideration, etc.)
*2 P/L on business transfer and Share of P/L of associates accounted for using equity method
*3 Non-recurring items (Other operating income and expenses except for *2 items, impairment losses, etc.)

FX rates: Q1FY2018 Results : 1US$ = ¥ 109.1, 1RMB = ¥17.1
Q1FY2019 Results : 1US$ = ¥ 109.9, 1RMB = ¥15.7

Revenue of Major Products in Japan

Billions of yen

	Q1 FY2018 Results	Q1 FY2019 Results	Change		Q2 FY2019 (Apr.-Sep.)	
			Value	%	Forecasts	Progress %
Trulicity® *	5.2	7.2	2.0	37.7	14.0	51.6
TRERIEF®	4.2	4.2	0.1	2.0	8.6	49.4
REPLAGAL®	3.2	3.4	0.2	4.7	6.1	55.5
METGLUCO®	2.6	2.5	(0.2)	(6.1)	4.7	52.6
SUREPOST®	1.5	1.8	0.3	16.5	3.1	56.9
AmBisome®	0.9	1.0	0.1	6.5	1.8	55.0
LONASEN® tape	–	–	–	–	0.2	–
Promoted products Total	17.7	20.1	2.4	13.4	38.5	52.2
AMLODIN®	2.5	2.1	(0.3)	(13.6)	4.1	52.2
LONASEN® tablet/powder	3.3	2.9	(0.5)	(13.8)	4.0	71.8
AIMIX®	4.5	1.2	(3.3)	(74.0)	2.0	58.7
PRORENAL®	1.1	0.9	(0.2)	(18.1)	1.8	50.8
GASMOTIN®	1.0	0.9	(0.2)	(17.5)	1.6	53.9
AG products	1.0	2.0	1.0	94.3	3.4	58.7
Others	4.1	2.6	(1.5)	(36.9)	5.6	46.0
Total	35.3	32.6	(2.7)	(7.6)	61.0	53.5

Trulicity® continued to grow.

LONASEN® tape is expected to be launched in Q2 FY2019.

GEs of LONASEN® tablet/powder were launched in June 2019.
The AG products were launched by the Company. (Its figure is included in “AG products”)

Revenue is expected to be affected by NHI price revision from 2nd half of FY2019.

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 FY2018 Results	Q1 FY2019 Results	Change	Q1 FY2018 Results	Q1 FY2019 Results	Change		Q2 FY2019 (Apr.-Sep.)		
						Value	%	Forecasts		Yen-based progress
North America	Million $			Billion yen				Million $	Billion yen	%
LATUDA®	402	445	44	43.8	49.0	5.1	11.7	850	93.5	52.4
BROVANA®	75	74	(1)	8.2	8.1	(0.1)	(0.7)	151	16.6	48.9
APTIOM®	43	48	6	4.7	5.3	0.7	14.0	99	10.9	48.7
LONHALA® MAGNAIR®	3	6	3	0.3	0.7	0.4	114.1	12	1.3	50.7
XOPENEX®	12	8	(5)	1.3	0.8	(0.5)	(37.3)	20	2.2	37.8
Others	22	19	(2)	2.4	2.1	(0.3)	(10.6)	33	3.6	58.5
Total	556	600	45	60.6	66.0	5.3	8.8	1,165	128.1	51.5
China	Million RMB			Billion yen				Million RMB	Billion yen	%
MEROPEN®	273	364	91	4.7	5.9	1.2	25.4	655	10.8	54.2
Others	45	61	16	0.8	1.0	0.2	28.4	127	2.1	47.0
Total	318	425	108	5.4	6.8	1.4	25.8	782	12.9	53.0

LATUDA® and APTIOM® sales showed growth.

MEROPEN® sales remained strong.

FX rates: Q1FY2018 Results : 1US$ = ¥ 109.1, 1RMB = ¥17.1
Q1FY2019 Results : 1US$ = ¥ 109.9, 1RMB = ¥15.7

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total (Core basis)
		Japan	North America	China	Other Regions	Subtotal		
Q1 FY2019 Results	Revenue (Sales to customers)	32.6	66.0	6.8	2.5	107.9	9.6	117.5
	Cost of sales	13.4	6.3	1.0	0.8	21.4	7.4	28.8
	Gross profit	19.3	59.7	5.8	1.7	86.5	2.1	88.6
	SG&A expenses	12.0	30.2	2.0	0.8	45.1	1.3	46.3
	Core segment profit	7.3	29.5	3.8	0.9	41.5	0.8	42.3
	R&D expenses					19.8	0.2	20.0
	Other operating income/expenses					0.0	(0.0)	0.0
	Core operating profit					21.7	0.6	22.3
Q1 FY2018 Results	Revenue (Sales to customers)	35.3	60.6	5.4	4.7	106.1	9.8	115.9
	Cost of sales	13.6	4.6	1.1	2.1	21.3	7.6	28.9
	Gross profit	21.8	56.0	4.3	2.6	84.8	2.2	87.0
	SG&A expenses	12.4	31.0	2.1	0.9	46.4	1.4	47.8
	Core segment profit	9.4	25.0	2.3	1.7	38.4	0.8	39.2
	R&D expenses					20.6	0.2	20.9
	Other operating income/expenses					0.0	0.0	0.0
	Core operating profit					17.8	0.6	18.4
Change	Revenue (Sales to customers)	(2.7)	5.3	1.4	(2.3)	1.8	(0.2)	1.6
	SG&A expenses	(0.3)	(0.8)	(0.0)	(0.1)	(1.3)	(0.1)	(1.4)
	Core segment profit	(2.2)	4.5	1.5	(0.8)	3.1	(0.0)	3.1
	Core operating profit					3.9	(0.0)	3.9

In Japan segment, both revenue and profit decreased.

In North America and China segment, both revenue and profit increased.

Financial Forecasts for FY2019

Financial Forecasts for FY2019 (Core Basis)

Billions of yen

	Q2 FY2019 Previous Forecasts	Q2 FY2019 Revised Forecasts	Change	FY2019 Previous Forecasts	FY2019 Revised Forecasts	Change
Revenue	226.5	228.5	2.0	460.0	475.0	15.0
Cost of sales *1	56.0	55.5	(0.5)	116.0	126.0	10.0
Gross profit	170.5	173.0	2.5	344.0	349.0	5.0
SG&A expenses *1	91.0	92.5	1.5	181.0	186.0	5.0
R&D expenses *1	41.0	41.0	–	86.0	86.0	–
Core operating profit	38.5	39.5	1.0	77.0	77.0	–
Changes in fair value of contingent consideration (negative number indicates loss)	(3.5)	17.0	20.5	(7.0)	12.0	19.0
Other non-recurring items *2 (negative number indicates loss)	(0.5)	(0.5)	–	(1.0)	(1.0)	–
Operating profit	34.5	56.0	21.5	69.0	88.0	19.0
Income tax expenses	11.5	36.0	24.5	23.0	55.0	32.0
Net profit attributable to owners of the parent	25.0	22.0	(3.0)	49.0	36.0	(13.0)
R O E (%)				9.5	7.1	
R O I C (%)				9.9	4.1	

Revenue forecast was revised upward.
- Updated incremental sales from Equa®/EquMet® alliance.

Unchanged core operating profit for full-year forecast because cost of sales/sales expenses are expected to increase.

Operating profit was revised upward
- Updated reversal of cost for fair value of contingent consideration adjustment due to discontinued Phase 3 study for pancreatic cancer of napabucasin.

Net profit attributable to owners of the parent was revised downward
- Updated incremental income tax expense in U.S.

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

FX rates: FY2018 Results : 1US$ = ¥ 110.9, 1RMB = ¥16.5
FY2019 Forecasts : 1US$ = ¥ 110.0, 1RMB = ¥16.5

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total (Core basis)
		Japan	North America	China	Other Regions	Subtotal		
FY2019 Revised Forecasts	Revenue (Sales to customers)	135.0	260.0	28.3	13.7	437.0	38.0	475.0
	Cost of sales	62.0	23.2	6.2	5.2	96.6	29.4	126.0
	Gross profit	73.0	236.8	22.1	8.5	340.4	8.6	349.0
	SG&A expenses	53.8	114.0	9.5	3.2	180.5	5.5	186.0
	Core segment profit	19.2	122.8	12.6	5.3	159.9	3.1	163.0
	R&D expenses					85.0	1.0	86.0
	Core operating profit					74.9	2.1	77.0
FY2019 Previous Forecasts	Revenue (Sales to customers)	119.3	260.0	27.0	13.7	420.0	40.0	460.0
	Cost of sales	50.8	23.2	5.5	5.2	84.7	31.3	116.0
	Gross profit	68.5	236.8	21.5	8.5	335.3	8.7	344.0
	SG&A expenses	50.0	112.8	9.5	3.2	175.5	5.5	181.0
	Core segment profit	18.5	124.0	12.0	5.3	159.8	3.2	163.0
	R&D expenses					85.0	1.0	86.0
	Core operating profit					74.8	2.2	77.0
Change	Revenue (Sales to customers)	15.7	–	1.3	–	17.0	(2.0)	15.0
	SG&A expenses	3.8	1.2	–	–	5.0	–	5.0
	Core segment profit	0.7	(1.2)	0.6	–	0.1	(0.1)	–
	Core operating profit					0.1	(0.1)	–

Japan segment
- Incremental revenue and SG&A expenses from Equa®/EquMet® alliance.
- Sales forecast of Equa®/ EquMet® : ¥16.0B

China segment
- Expected revenue increase due to strong sales of MEROPEN®, etc.

Research and Development

Development Pipeline (as of July 29, 2019)

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

Revisions since the announcement of May 2019 are shown in red.

Area	Phase 1		Phase 2	Phase 3	NDA submitted
Japan	**dasotraline** (ADHD) **SEP-363856** (Schizophrenia) **EPI-589** (ALS)	**alvocidib** (AML) **TP-0903** (Solid tumors)	**amcasertib** (Solid tumors) **DSP-7888** (Solid tumors/ Hematologic malignancies) **SEP-4199** (Bipolar I depression) **Allo iPS cell-derived products** (Parkinson's disease) Investigator-initiated clinical study	**lurasidone** (Schizophrenia/ Bipolar I depression) **EPI-743** (Leigh syndrome) **napabucasin** (Colorectal cancer) **imeglimin** (Type 2 diabetes)	**RETHIO®** (Conditioning treatment prior to autologous HSCT for malignant lymphoma)
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** (AML/MDS) **TP-0903** (Solid tumors/ Hematologic malignancies) **DSP-0509** (Solid tumors) **TP-0184** (Solid tumors) **DSP-0337** (Solid tumors) **TP-1287** (Solid tumors) **TP-3654** (Solid tumors)	**EPI-589** (Parkinson's disease/ALS) **SEP-363856** (Parkinson's disease psychosis) **SEP-4199** (Bipolar I depression) **alvocidib** (r/r AML) **amcasertib** (Solid tumors) **DSP-7888** (Solid tumors/ Hematologic malignancies) **SB623** (Chronic stroke)	**SEP-363856** (Schizophrenia) **napabucasin** (Colorectal cancer)	**dasotraline** (BED) **dasotraline** (ADHD) Development strategy under consideration **apomorphine** (OFF episodes associated with Parkinson's disease) Received Complete Response Letter

Clinical Development Status (1) (Major Changes since May 10, 2019)

LONASEN® Tape

Japan : Approved in June 2019 for schizophrenia

- ✓ Launch target: H1 FY2019
- ✓ The world's first transdermal patch formulation of an antipsychotic agent

Dasotraline

U.S. : NDA for binge eating disorder (BED) submitted in May 2019

SEP-363856

U.S. : Started two Phase 3 studies (SEP361-301, SEP361-302) for schizophrenia

- ✓ Double-blind, placebo-controlled studies
- ✓ Administration period: 6 weeks
- ✓ Daily dose: 50mg, 75mg (SEP361-301) / 75mg, 100mg (SEP361-302)

Napabucasin

Japan and U.S. : Received a recommendation from the independent Data and Safety Monitoring Board based on the interim analysis results at the point where 50% of the total events of the studies occurred

- ✓ Colorectal cancer: Recommendation to continue Phase 3 study received in June 2019
- ✓ Pancreatic cancer: Recommendation to discontinue Phase 3 study received in July 2019

Clinical Development Status (2) (Major Changes since May 10, 2019)

Alvocidib

U.S. : Started new Phase 2 study for acute myeloid leukemia (AML)

- ✓ Study for relapsed or refractory AML following treatment with venetoclax combination therapy
  - * Venetoclax: anti-cancer drug of AbbVie Inc.

Imeglimin

Japan : Obtained results from Phase 3 study (TIMES 3: insulin combination therapy) for type 2 diabetes in June 2019

- ✓ Second positive topline results following TIMES 1 study (Phase 3 study, monotherapy)

Allogeneic iPS cell-derived products（AMD: age-related macular degeneration)

Japan：Changed the joint development structure with Healios K.K. in June 2019

- ✓ Sumitomo Dainippon Pharma will be primarily responsible for the clinical study
- ✓ Both companies will be able to submit applications for manufacturing and marketing approval

Frontier business

Invested in Drawbridge Health, Inc. in July 2019

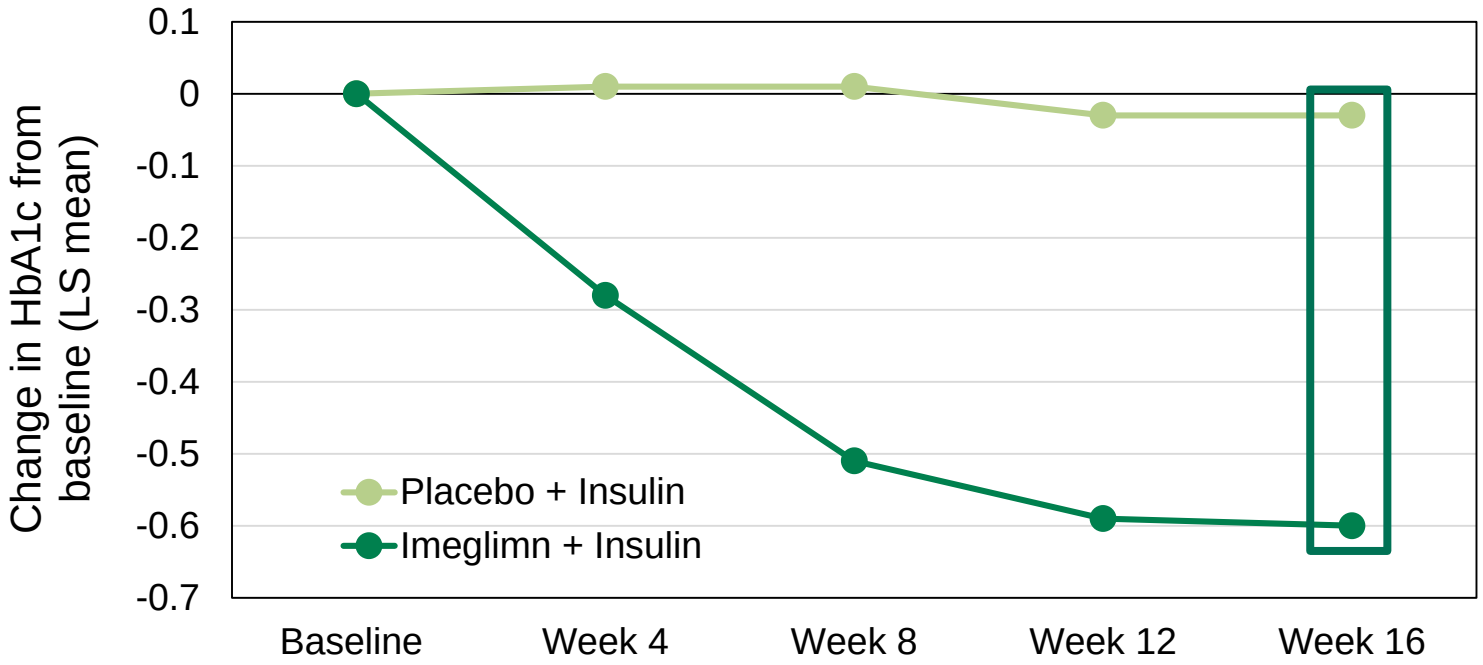
- ✓ Plan to pursue a frontier business utilizing the blood collection devices of Drawbridge Health, Inc.

Update on progress of proposal to acquire Cynata Therapeutics Limited (announced on July 19, 2019)

Still under consideration

Imeglimin : Type 2 Diabetes Phase 3 Study Results (TIMES 3)

- **Study design :** Double-blind, placebo-controlled study (insulin combination therapy) (1,000 mg twice-daily)
- **Efficacy :** Met primary endpoint



Primary endpoint:
Difference of change in HbA1c from baseline at week 16 between imeglimin (N=106) and placebo (N=108) groups: -0.60% (p<0.0001)

- **Safety :** Imeglimin was generally well-tolerated, adverse events were similar to previous studies
- **Future plan :** The results of TIMES 2 study (Phase 3 study, long-term study including combination therapy with hypoglycemic agents) will be obtained around the end of 2019. Plan to submit NDA in FY2020 in Japan based on those results.
  * Announced the positive result for TIMES 1 study (Phase 3 study, monotherapy) in the press release on April 9, 2019

Appendices

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Financial Results for Q1 FY2019 (Full Basis)

Billions of yen

	Q1 FY2018 Results	Q1 FY2019 Results	Change	
			Value	%
Revenue	115.9	117.5	1.6	1.4
Cost of sales	28.9	29.0	0.0	0.1
Gross profit	87.0	88.5	1.5	1.8
SG&A expenses	50.3	27.9	(22.4)	(44.5)
R&D expenses	20.9	20.1	(0.8)	(3.9)
Other operating income and expenses	(0.1)	(0.2)	(0.1)	
Operating profit	15.8	40.4	24.6	155.6
Finance income and costs	4.8	(3.5)	(8.3)	
Net profit attributable to owners of the parent	15.2	6.7	(8.5)	(56.0)

Adjustments to Core Operating Profit

Q1 FY2019 Results

Billions of yen

IFRS Full Basis		Adjusted amount	IFRS Core Basis		Adjusted items
Revenue	117.5	–	Revenue	117.5	
Cost of sales	29.0	(0.1)	Cost of sales	28.8	
Gross profit	88.5	0.1	Gross profit	88.6	
SG&A expenses	27.9	18.5	SG&A expenses	46.3	Changes in fair value of contingent consideration 18.5
R&D expenses	20.1	(0.0)	R&D expenses	20.0	
Other operating income and expenses	(0.2)	0.2	Other operating income and expenses *1 (profit/loss on business transfer, share of profit/loss of associates accounted for using equity method)	0.0	
Operating profit	40.4	(19.4)	Core operating profit	22.3	
			Changes in fair value of contingent consideration (Positive number indicates profit)	18.5	From SG&A expenses 18.5
			Other non-recurring items *2 (Negative number indicates loss)	(0.3)	

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.

Product Launch Target (as of July 29, 2019)

Area	FY2019	FY2020	FY2021	FY2022	FY2023
Japan	**LONASEN®** (Schizophrenia/ Transdermal patch) Approved in June 2019	**lurasidone** (Schizophrenia/ Bipolar depression)	**napabucasin** (Colorectal cancer)	**Allo iPS cell-derived products** *2 (AMD)	
	RETHIO® (Conditioning treatment prior to autologous HSCT for malignant lymphoma)		**imeglimin** (Type 2 diabetes)	**Allo iPS cell-derived products** *2 (Parkinson's disease)	
U.S.	**dasotraline** (ADHD) Launch target under consideration	**Apomorphine** (OFF episodes associated with Parkinson's disease)	**napabucasin** (Colorectal cancer)	**SB623** *2 (Chronic stroke) Launch target under consideration	**SEP-363856** (Schizophrenia)
		dasotraline (BED)			**TP-0903** *1 (Solid tumors/ Hematologic malignancies)
		alvocidib *1 (AML) Launch target under consideration			**TP-0184** *1 (Solid tumors)

: 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.

Regenerative Medicine/Cell Therapy Business Plan (as of July 29, 2019)

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Chronic stroke (SB623)	SanBio	North America	Allo mesenchymal stem cell	**Completed Phase 2b study Development strategy and launch target under consideration**
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)	**Preparing to start 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 launch in FY2022 *

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

Main Event/Target for FY2019 (as of July 29, 2019)

✓ Done event / target

Psychiatry & Neurology	☑ LONASEN® (New formulation : transdermal patch) : Obtain approval for schizophrenia in Japan ☐ Lurasidone : Submit NDA 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
Other	☐ Imeglimin：Obtain two Phase 3 study results (☐ TIMES 2, ☑ TIMES 3) in Japan
Infectious Diseases	☐ Promote joint research with academia and others (antimicrobial resistance (AMR), universal influenza vaccines , malaria vaccines)
Frontier	☐ Promotion of the current themes (MELTIN, Aikomi), development of new themes

Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows