Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Q3 FY2018 (April 1 to December 31, 2018) Conference Call

January 31, 2019

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 Q3 FY2018

Financial Results for Q3 FY2018 (Apr.-Dec.) -Core Basis-

Billions of yen

	Q3 FY2017 (Apr.-Dec.) Results	Q3 FY2018 (Apr.-Dec.) Results	Change			FY2018	
			Value	FX rate impact	%	Forecasts	Progress%
Revenue	355.2	**346.9**	(8.3)	(1.0)	(2.3)	467.0	74.3
Cost of sales	88.4	**85.2**	(3.2)	(2.1)	(3.7)	112.5	75.7
Gross profit	266.7	**261.7**	(5.0)	1.2	(1.9)	354.5	73.8
SG&A expenses *1	134.8	**144.0**	9.2	(0.4)	6.8	190.5	75.6
R&D expenses	63.1	**62.0**	(1.1)	(0.2)	(1.7)	87.0	71.2
Other operating income and expenses (Core basis) *2	9.2	**0.1**	(9.0)	–	(98.5)	0.0	–
Core operating profit	78.0	**55.9**	(22.1)	1.8	(28.4)	77.0	72.5
Changes in fair value of contingent consideration (negative number indicates loss)	(4.3)	**(5.5)**	(1.2)			(20.0)	
Other non-recurring items (negative number indicates loss) *3	(2.8)	**(3.6)**	(0.7)			(4.0)	
Operating profit	70.9	**46.8**	(24.1)		(33.9)	53.0	88.4
Net profit attributable to owners of the parent	43.9	**40.0**	(3.9)		(8.9)	35.0	114.2

*1 Exclude non-recurring items (changes in fair value of contingent consideration, impairment losses, 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: Q3FY2017 Results : 1US$ = ¥ 111.7, 1RMB = ¥16.6
Q3FY2018 Results : 1US$ = ¥ 111.2, 1RMB = ¥16.6
FY2018 Forecasts : 1US$ = ¥ 110.0, 1RMB = ¥16.5

Revenue of Major Products in Japan

Billions of yen

	Q3 FY2017 (Apr.-Dec.) Results	Q3 FY2018 (Apr.-Dec.) Results	Change		FY2018	
			Value	%	Forecasts	Progress%
Trulicity® *	11.8	17.4	5.6	47.5	22.8	76.3
TRERIEF®	12.7	12.2	(0.5)	(3.7)	16.0	76.5
LONASEN®	10.0	9.6	(0.4)	(4.1)	12.5	77.0
REPLAGAL®	9.0	9.7	0.7	7.8	12.4	78.1
METGLUCO®	8.5	7.8	(0.7)	(7.9)	10.4	75.5
SUREPOST®	3.9	4.6	0.8	20.6	5.9	78.7
AmBisome®	3.4	3.1	(0.3)	(8.6)	4.3	72.4
Promoted products Total	59.3	64.6	5.2	8.9	84.3	76.6
AIMIX®	14.6	7.1	(7.4)	(51.0)	8.7	82.1
AVAPRO®	7.6	2.2	(5.4)	(70.5)	2.9	77.5
AMLODIN®	9.1	7.2	(2.0)	(21.4)	9.1	78.7
PRORENAL®	4.4	3.2	(1.2)	(26.9)	4.3	74.4
GASMOTIN®	4.0	3.0	(1.0)	(24.2)	3.9	76.8
Others	14.0	13.4	(0.7)	(4.8)	16.8	79.5
Total	113.0	100.6	(12.3)	(10.9)	130.0	77.4

Note: Sales of each product above are shown on an invoice price basis (* Trulicity® is shown on NHI price basis).

Japan segment as a whole showed steady progress.

Trulicity® grew significantly.

AIMIX® and AVAPRO® decreased due to GEs erosion.

Impact of NHI price revision was 6.7 billion yen.

Revenue of Major Products in North America & China

	Q3 FY2017 (Apr.-Dec.) Results	Q3 FY2018 (Apr.-Dec.) Results	Change	Q3 FY2017 (Apr.-Dec.) Results	Q3 FY2018 (Apr.-Dec.) Results	Change			FY2018		
						Value	FX rate impact	%	Forecasts		Yen-based progress
North America	Million $			Billion yen					Million $	Billion yen	%
LATUDA®	1,210	1,256	46	135.1	139.6	4.5	(0.7)	3.3	1,759	193.5	72.2
BROVANA®	227	228	1	25.3	25.3	0.0	(0.1)	0.0	315	34.7	73.0
APTIOM®	102	140	38	11.4	15.5	4.2	(0.1)	36.5	184	20.2	76.9
LONHALA® MAGNAIR®	–	8	8	–	0.9	0.9	–	–	11	1.2	77.6
Therapeutic agent for COPD (in-licensed 3 products) *	3	4	0	0.4	0.4	0.0	(0.0)	6.8	5	0.6	67.8
XOPENEX®	24	29	5	2.7	3.3	0.6	(0.0)	20.4	37	4.1	79.6
Others	67	50	(17)	7.5	5.5	(1.9)	(0.0)	(25.9)	64	7.0	78.8
Total	1,633	1,715	82	182.4	190.6	8.2	(0.9)	4.5	2,375	261.3	72.9
China	Million RMB			Billion yen					Million RMB	Billion yen	%
MEROPEN®	801	838	37	13.3	13.9	0.6	(0.0)	4.4	1,211	20.0	69.5
Others	127	146	19	2.1	2.4	0.3	(0.0)	14.5	200	3.3	73.5
Total	928	984	56	15.4	16.3	0.9	(0.0)	5.8	1,411	23.3	70.1

LATUDA® and APTIOM® sales showed growth in North America.

Sales in China have been in line with the forecast including MEROPEN®.

* UTIBRON®, SEEBRI®, ARCAPTA®

FX rates: Q3FY2017 Results : 1US$ = ¥ 111.7, 1RMB = ¥16.6
Q3FY2018 Results : 1US$ = ¥ 111.2, 1RMB = ¥16.6

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total (Core basis)
		Japan	North America	China	Other Regions	Subtotal		
Q3 FY2018 Results	Revenue (Sales to customers)	100.6	190.6	16.3	10.2	317.8	29.1	346.9
	Cost of sales	39.6	15.7	2.9	4.4	62.6	22.6	85.2
	Gross profit	61.1	174.9	13.4	5.8	255.2	6.5	261.7
	SG&A expenses	37.9	92.4	6.8	2.8	139.9	4.1	144.0
	Core segment profit	23.2	82.5	6.7	3.0	115.4	2.3	117.7
	R&D expenses					61.2	0.8	62.0
	Other operating income/expenses					0.1	0.0	0.1
	Core operating profit					54.3	1.6	55.9
Q3 FY2017 Results	Revenue (Sales to customers)	113.0	182.4	15.4	10.6	321.3	33.8	355.2
	Cost of sales	40.1	13.3	3.3	5.0	61.7	26.7	88.4
	Gross profit	72.9	169.1	12.1	5.6	259.7	7.0	266.7
	SG&A expenses	37.8	83.3	6.3	2.7	130.0	4.8	134.8
	Core segment profit	35.1	85.8	5.8	2.9	129.6	2.2	131.9
	R&D expenses					62.3	0.8	63.1
	Other operating income/expenses					9.2	0.0	9.2
	Core operating profit					76.5	1.5	78.0
Change	Revenue (Sales to customers)	(12.3)	8.2	0.9	(0.4)	(3.6)	(4.7)	(8.3)
	SG&A expenses	0.1	9.1	0.5	0.1	9.8	(0.6)	9.2
	Core segment profit	(11.9)	(3.3)	0.9	0.1	(14.3)	0.1	(14.2)
	Core operating profit					(22.3)	0.1	(22.1)

Core segment profit in Japan decreased mainly due to NHI price revision and drop of long listed drugs.

Core segment profit in North America decreased due to increase in LATUDA® related cost and amortization, etc.

Other operating income for Q3 FY2017 includes profit on business transfer.

Financial Results for Q3 FY2018 (Full Basis)

Billions of yen

	Q3 FY2017 (Apr.-Dec.) Results	Q3 FY2018 (Apr.-Dec.) Results	Change	
			Value	%
Revenue	355.2	346.9	(8.3)	(2.3)
Cost of sales	88.4	85.2	(3.2)	(3.7)
Gross profit	266.7	261.7	(5.0)	(1.9)
SG&A expenses	139.1	149.5	10.3	7.4
R&D expenses	63.1	62.0	(1.1)	(1.7)
Other operating income and expenses	6.4	(3.4)	(9.8)	
Operating profit	70.9	46.8	(24.1)	(33.9)
Finance income and costs	2.9	6.3	3.5	
Net profit attributable to owners of the parent	43.9	40.0	(3.9)	(8.9)

Financial Forecasts for FY2018

Financial Forecasts for FY2018 (Core Basis)

Billions of yen

	Q3 FY2018 Results	FY2018 Forecasts	Progress %
Revenue	346.9	467.0	74.3
Cost of sales	85.2	112.5	75.7
Gross profit	261.7	354.5	73.8
SG&A expenses	144.0	190.5	75.6
R&D expenses	62.0	87.0	71.2
Other operating income and expenses (Core basis)	0.1	0.0	–
Core operating profit	55.9	77.0	72.5
Changes in fair value of contingent consideration (negative number indicates loss)	(5.5)	(20.0)	
Other non-recurring items (negative number indicates loss)	(3.6)	(4.0)	
Operating profit	46.8	53.0	88.4
Net profit attributable to owners of the parent	40.0	35.0	114.2

FY2018 forecasts are unchanged.

Both revenue and expenses have been almost in line with the plan.

Expected that changes in fair value of contingent consideration are likely to decrease (increase in profit) , but expected uncertain variable factors at the same time, therefore the forecasts of operating profit and net profit are unchanged.

FX rates: Q3FY2018 Results : 1US$ = ¥ 111.2, 1RMB = ¥16.6
FY2018 Forecasts : 1US$ = ¥ 110.0, 1RMB = ¥16.5

Status of LATUDA® ANDA Litigations

Status of LATUDA® ANDA Litigations (U.S. Patent No.9,815,827 / 9,907,794)

Outcome of the consolidated litigation filed in February 2018

✓ The lawsuit against all defendants (sixteen generic companies) was resolved
(See press release on December 5, 2018)

- Certain generic companies that were defendants of the lawsuit may distribute their generic versions starting on February 20, 2023
- Other terms and conditions of the settlement agreements will not be disclosed

Status of the three additional litigations filed during August to October 2018

✓ Two out of the three litigations were resolved through settlements in January 2019

- Generic companies that were defendants of these lawsuits may distribute their generic versions starting on February 20, 2023
- Other terms and conditions of the settlement agreements will not be disclosed

✓ One litigation remains pending

Research and Development

Development Pipeline (as of January 2019)

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

Revisions since the announcement of October 2018 are shown in red.

Area	Phase 1		Phase 2	Phase 3	NDA submitted
Japan	**dasotraline** (ADHD) **SEP-363856** (Schizophrenia) **DSP-2230** (Neuropathic pain) **EPI-589** (ALS)	**alvocidib** (AML)	**amcasertib** (Solid tumors) **DSP-7888** (Solid tumors / Hematologic malignancies) **SEP-4199** (Bipolar I depression)	**lurasidone** (Schizophrenia / Bipolar I depression) **EPI-743** (Leigh syndrome) **napabucasin** (Colorectal cancer / Pancreatic cancer) **imeglimin** (Type 2 diabetes)	**LONASEN®** (Schizophrenia /Transdermal patch) **thiotepa** (Conditioning treatment prior to autologous HSCT for pediatric solid tumors)
U.S.	**DSP-2230** (Neuropathic pain) **DSP-6745** (Parkinson's disease psychosis) **SEP-378608** (Bipolar disorder) **DSP-3905** (Neuropathic pain) **SEP-378614** (Treatment resistant depression)	**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** (Schizophrenia / (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)	**dasotraline** (BED) **napabucasin** (Colorectal cancer / Pancreatic cancer)	**dasotraline** (ADHD) Received Complete Response Letter **apomorphine** (OFF episodes associated with Parkinson's disease) Received Complete Response Letter

Clinical Development Status (Major Changes since October 30, 2018)

Lurasidone

China : Approved for schizophrenia in January 2019

✓ Plan to launch in FY2019

Japan：Obtained positive topline results from Phase 3 study for schizophrenia

✓ Plan to submit NDA for schizophrenia and bipolar depression in H1 FY2019

Apomorphine (APL-130277)

U.S. : Received Complete Response Letter in January 2019

✓ Plan to work with FDA to address their requests

SEP-363856

U.S. : Obtained positive topline results from Phase 2 study for schizophrenia

SEP-4199

Japan : Joined global Phase 2 study for bipolar I depression

SEP-378614

U.S. : Started Phase 1 study (proposed indication : treatment resistant depression)

➢ Novel CNS-active compound discovered by using PsychoGenics' SmartCube® System

Clinical Development Status (Major Changes since October 30, 2018)

TP-3654

U.S. : Started Phase 1 study for solid tumors (monotherapy)

- TP-3654 inhibits inflammatory signaling pathways through PIM kinase inhibition

*PIM (proviral integration site for Moloney murine leukemia virus) kinases are frequently overexpressed in various hematologic malignancies and solid tumors, allowing cancer cells to evade apoptosis and promoting tumor growth

SB623

U.S. : Phase 2b study for chronic stroke did not meet primary endpoint
Additional analyses being conducted

Discontinuation

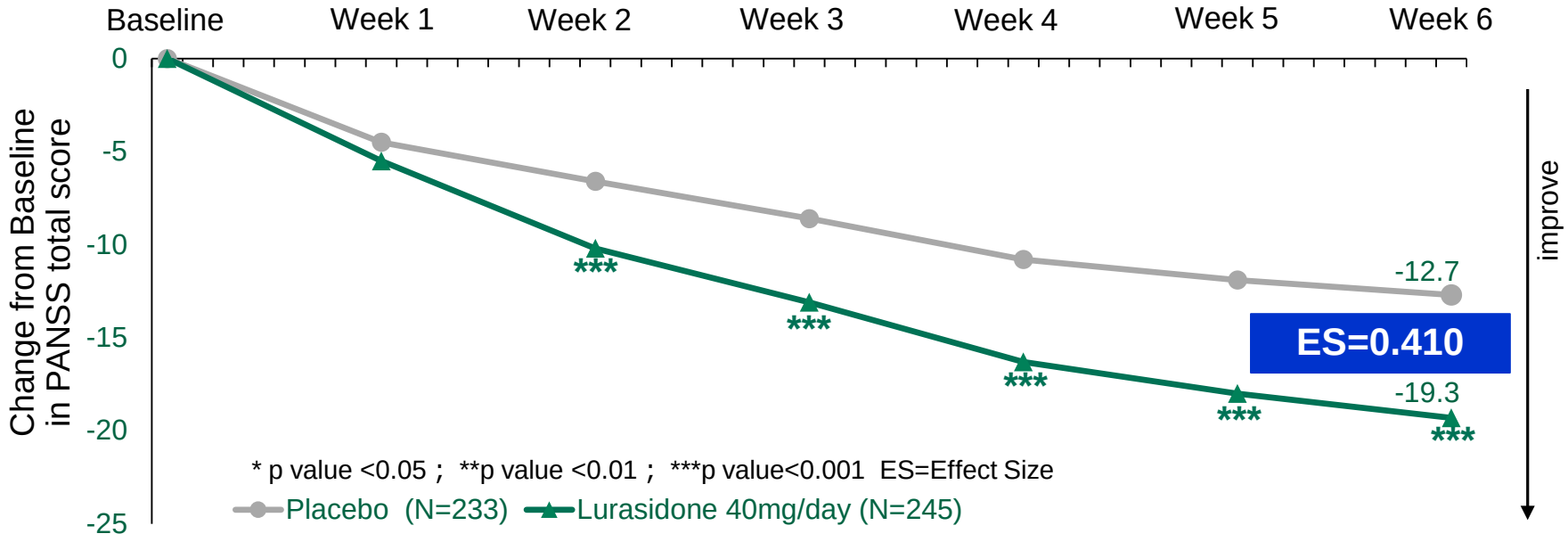
DSP-6952 : IBS with constipation, chronic idiopathic constipation (Japan : Phase 2 study)
(Reason for discontinuation : Phase 2 study did not show expected efficacy)

Lurasidone : Schizophrenia Phase 3 Study Results (JEWEL)

- **Study design :** Randomized, double-blind, placebo-controlled study (Lurasidone group: 40mg/day)

- **Efficacy :** Lurasidone group met primary endpoint
  (Primary endpoint : Change from baseline in PANSS total score after 6 weeks of treatment)
  In addition, lurasidone group demonstrated significant improvement in CGI-S, a secondary efficacy endpoint

- **Safety :** Lurasidone was generally well-tolerated, adverse events observed were generally mild



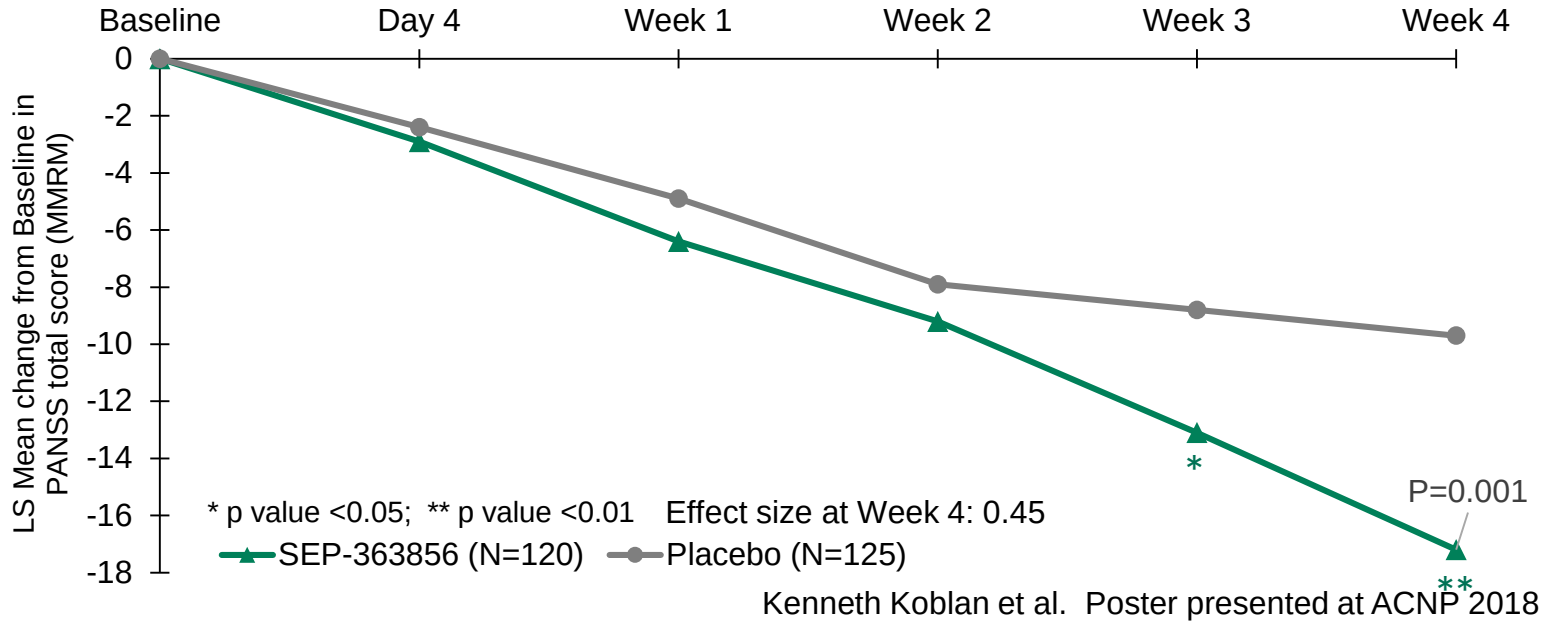
- **Future plan :** Plan to submit NDA for schizophrenia and bipolar depression in H1 FY2019 in Japan

SEP-363856 : Schizophrenia Phase 2 Study Results (SEP361-201)

- **Study design :** Randomized, double-blind, placebo-controlled study in adults with schizophrenia
  (SEP-363856 group: 50mg or 75mg/day)

- **Efficacy :** SEP-363856 group met primary endpoint
  (Primary endpoint : Change from baseline in PANSS total score after 4 weeks of treatment)
  In addition, SEP-363856 group demonstrated significant improvement in CGI-S and PANSS (positive, negative and general psychopathology) subscales, secondary efficacy endpoints

- **Safety :** SEP-363856 was generally well-tolerated, adverse events were similar to placebo



Kenneth Koblan et al. Poster presented at ACNP 2018

- ✓ SEP-363856 does not bind to dopamine 2 (D_2) receptors, distinct from currently marketed antipsychotics
- ✓ Plan to accelerate development based on the positive results

- **Future plan :** Plan to start Phase 3 study in FY2019

Appendices

＜Contents＞

Adjustments to Core Operating Profit

Q3 FY2018 Results

Billions of yen

IFRS Full Basis		Adjusted amount	IFRS Core Basis		Adjusted items
Revenue	346.9		Revenue	346.9	
Cost of sales	85.2		Cost of sales	85.2	
Gross profit	261.7		Gross profit	261.7	
SG&A expenses	149.5	(5.5)	SG&A expenses	144.0	Changes in fair value of contingent consideration (5.5)
R&D expenses	62.0		R&D expenses	62.0	
Other operating income and expenses	(3.4)	3.6	Other operating income and expenses *1 (profit/loss on business transfer, share of profit/loss of associates accounted for using equity method)	0.1	To Other non-recurring items (Restructuring cost 2.6)
Operating profit	46.8	9.0	Core operating profit	55.9	
			Changes in fair value of contingent consideration (Positive number indicates profit)	(5.5)	From SG&A expenses (5.5)
			Other non-recurring items *2 (Negative number indicates loss)	(3.6)	From Other operating income and expenses (Restructuring cost (2.6))

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.

Activities in FY2018 : Clinical Development Status

Area	Products	Proposed indication	Area	FY2018 target (Revised in July 27, 2018)	Status as of January 31, 2019
Psychiatry & Neurology	TRERIEF®	Parkinsonism in dementia with Lewy bodies (DLB)	Japan	Approval	**Approved in July 2018**
	dasotraline	Attention-deficit hyperactivity disorder (ADHD)	U.S.	Approval and launch	**NDA submitted, received Complete Response Letter / development strategy under consideration**
		Binge eating disorder (BED)	U.S.	NDA submission	**Preparing NDA submission**
	apomorphine (APL-130277)	OFF episodes associated with Parkinson's disease	U.S.	Approval (Previous target : Approval and launch)	**NDA submitted, received Complete Response Letter**
	LONASEN®	(New formulation: Transdermal patch) Schizophrenia	Japan	NDA submission	**NDA submitted**
Oncology	alvocidib	Acute myeloid leukemia (AML) (Refractory or relapsed patients)	U.S.	Promotion of Phase 2 study (Previous target : NDA submission for accelerated approval)	**Stage 2 of Phase 2 study ongoing**
	napabucasin	Pancreatic cancer, Colorectal cancer	U.S., Japan	Promotion of Phase 3 studies	**Phase 3 study ongoing**
Regenerative medicine / Cell therapy	SB623	Chronic stroke	U.S.	Obtain Phase 2b study results in 1H 2019	**Phase 2b study did not meet primary endpoint. Under additional results analyses**
	Allo iPS cell-derived products	AMD (age-related macular degeneration)	Japan	Start a clinical study (corporate-initiated)	**Preparing for start of clinical study**
	Allo iPS cell-derived products	Parkinson's disease	Japan	Start a clinical study (investigator-initiated)	**Phase 1 / 2 study ongoing (investigator-initiated clinical study)**

Product Launch Target (as of January 2019)

Area	FY2018	FY2019	FY2020	FY2021	FY2022
Japan	**TRERIEF®** (Parkinsonism in dementia with Lewy bodies) * Approved in July 2018	**LONASEN®** (Schizophrenia / Transdermal patch) **thiotepa** (Conditioning treatment prior to autologous HSCT for pediatric solid tumors)	**lurasidone** (Schizophrenia / Bipolar depression)	**napabucasin** (Colorectal cancer / Pancreatic cancer) **imeglimin** (Type 2 diabetes)	**Allo iPS cell-derived products** *2 (AMD) **Allo iPS cell-derived products** *2 (Parkinson's disease) **DSP-7888** *1 (Solid tumors / Hematologic malignancies)
U.S.	**dasotraline** (ADHD) Launch target under consideration	**Apomorphine** (OFF episodes associated with Parkinson's disease) Launch target under consideration **dasotraline** (BED)	**alvocidib** *1 (AML)	**napabucasin** (Colorectal cancer / Pancreatic cancer) **DSP-7888** *1 (Solid tumors / Hematologic malignancies)	**SB623** *2 (Chronic stroke) Launch target under consideration

: 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 January 2019)

Proposed indication, etc.	Partnering	Region (planned)	Cell type	Clinical research	Clinical study
Chronic stroke (SB623)	SanBio	North America	Allo mesenchymal stem cell		In progress (Phase 2b study) Development strategy and launch target under consideration
AMD (age-related macular degeneration)	Healios RIKEN	Japan	Allo iPS cell-derived retinal pigment epithelium	In progress	Preparing for start
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto Univ CiRA	Global	Allo iPS cell-derived dopamine neural progenitor		In progress of investigator-initiated clinical study (Phase 1 / 2 study) (Japan)
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor	Preparing for start	
Spinal cord injury	Keio Univ Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	Preparing for start	

Aim to launch in FY2022 *

* Launch schedule is based on our goal that is not agreed with partners.

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