



Sumitomo Dainippon  
Pharma

Innovation today, healthier tomorrows

# **Q3 FY2019 (April 1 to December 31, 2019) Conference Call**

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January 30, 2020

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 FY2019

## Progress Status of Strategic Alliance with Roivant

- Completed the procedure related to stock transfers, etc. (12/27/2019)
  - Completed payment of total about US\$3 billion (about ¥330 billion) to Roivant
  - Financing was secured by own resources and bridge loans (¥270 billion)
  - Acquired all shares of newly established company, to which Roivant has transferred its ownership interests in five subsidiaries and certain key employees involved in its healthcare technology platforms
  - Acquired Roivant's healthcare technology platforms and 11% of Roivant's shares
  
- Consolidated the new company from the end of Q3 FY2019
  - The consolidation of the new company will not materially affect the consolidated statement of profit of loss for Q3 FY2019
  - The value of acquired assets and assumed liabilities is provisional as the purchase price allocation (PPA) procedure is not completed
  
- Revised FY2019 forecasts



## Financial Results for Q3 FY2019

# Financial Results for Q3 FY2019 (Core Basis)



Billions of yen

	Q3 FY2018	Q3 FY2019	Change			FY2019	
	Results	Results	Value	FX impact	%	Previous forecasts	%
<b>Revenue</b>	346.9	357.0	10.1	(5.8)	2.9	475.0	75.2
Cost of sales *1	85.2	93.1	7.9	(1.7)	9.2	125.0	74.4
Gross profit	261.7	264.0	2.3	(4.1)	0.9	350.0	75.4
SG&A expenses *1	144.0	138.6	(5.4)	(2.4)	(3.7)	187.0	74.1
R&D expenses *1	62.0	61.2	(0.8)	(0.9)	(1.2)	86.0	71.2
Other operating income/expenses *2	0.1	0.1	(0.0)	—	(16.3)	0.0	—
<b>Core operating profit</b>	55.9	64.3	8.4	(0.8)	15.0	77.0	83.4
Changes in fair value of contingent consideration (negative number indicates loss)	(5.5)	① 40.8	46.3			35.0	
Other non-recurring items *3 (negative number indicates loss)	(3.6)	② (23.6)	(20.0)			(24.0)	
<b>Operating profit</b>	46.8	81.5	34.6		73.9	88.0	92.6
Profit before taxes	53.2	84.4	31.3		58.8	87.0	97.0
Income tax expenses	13.2	40.4	27.3			51.0	
<b>Net profit attributable to owners of the parent</b>	40.0	44.0	4.0		10.0	36.0	122.2

① Cost reversal due to:

- Discontinued Ph3 study for napabucasin pancreatic cancer (Q1)
- Revised business plans for alvocidib (Q2)
- Discontinued development for amcasertib (Q2)

② Non-recurring items due to:

- Impairment losses from
- Revised business plans for alvocidib, discontinued development for amcasertib (Q2)
- Discontinued joint development for SB623 (Q3)

- \*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: Q3FY2018 Results : 1US\$ = ¥ 111.2, 1RMB = ¥16.6  
 Q3FY2019 Results : 1US\$ = ¥ 108.7, 1RMB = ¥15.6  
 FY2019 Previous forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥15.5

## Financial Results for Q3 FY2019

# Revenue of Major Products in Japan



Billions of yen

	Q3 FY2018	Q3 FY2019	Change		FY2019	
	Results	Results	Value	%	Previous forecasts	%
Trulicity® *	17.4	22.9	5.5	31.4	28.2	81.1
TRERIEF®	12.2	12.6	0.4	2.9	17.1	73.7
REPLAGAL®	9.7	10.3	0.6	6.4	12.6	81.8
Equa®/EquMet®	—	7.8	7.8	—	16.0	48.7
METGLUCO®	7.8	7.4	(0.4)	(5.4)	9.3	79.8
SUREPOST®	4.6	5.2	0.6	13.0	6.2	84.6
AmBisome®	3.1	3.3	0.2	5.8	3.9	84.4
LONASEN® Tape	—	0.3	0.3	—	1.8	16.7
<b>Promoted products Total</b>	<b>54.9</b>	<b>69.8</b>	<b>14.9</b>	<b>27.1</b>	<b>95.1</b>	<b>73.4</b>
AMLODIN®	7.2	6.0	(1.2)	(16.1)	7.5	80.1
LONASEN® tablet/powder	9.6	4.9	(4.7)	(49.2)	5.2	94.1
AIMIX®	7.1	3.2	(3.9)	(55.2)	3.7	86.4
PRORENAL®	3.2	2.6	(0.6)	(19.7)	3.3	77.9
GASMOTIN®	3.0	2.4	(0.6)	(18.6)	3.1	78.7
AG products	4.1	5.8	1.7	41.2	6.9	83.4
Others	11.5	9.6	(1.9)	(16.7)	11.2	85.7
<b>Total</b>	<b>100.6</b>	<b>104.3</b>	<b>3.6</b>	<b>3.6</b>	<b>136.0</b>	<b>76.7</b>

Trulicity®, SUREPOST® show 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

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

## Financial Results for Q3 FY2019

# Revenue of Major Products in North America & China



	Q3	Q3	Change	Q3	Q3	Change			FY2019		
	FY2018	FY2019		FY2018	FY2019	Value	FX	%	Previous forecasts		Yen-basis
	Results	Results		Results	Results		impact		Million \$	Billion yen	%
<b>North America</b>	Million \$			Billion yen					Million \$	Billion yen	
LATUDA®	1,256	1,308	52	139.6	142.1	2.5	(3.3)	1.8	1,721	189.3	75.1
BROVANA®	228	239	11	25.3	26.0	0.6	(0.6)	2.5	300	33.0	78.7
APTIOM®	140	156	17	15.5	17.0	1.4	(0.4)	9.3	205	22.5	75.5
LONHALA® MAGNAIR®	8	21	12	0.9	2.3	1.3	(0.1)	141.7	38	4.2	53.6
XOPENEX®	29	25	(4)	3.3	2.8	(0.5)	(0.1)	(15.3)	37	4.1	67.4
Others	53	51	(2)	5.9	5.6	(0.4)	(0.1)	(6.3)	63	6.9	80.5
<b>Total</b>	<b>1,715</b>	<b>1,801</b>	<b>86</b>	<b>190.6</b>	<b>195.7</b>	<b>5.0</b>	<b>(4.5)</b>	<b>2.6</b>	<b>2,364</b>	<b>260.0</b>	<b>75.3</b>
<b>China</b>	Million RMB			Billion yen					Million RMB	Billion yen	
MEROPEN®	838	1,087	250	13.9	17.0	3.1	(1.1)	22.0	1,488	23.1	73.4
Others	146	204	58	2.4	3.2	0.8	(0.2)	31.4	273	4.2	75.9
<b>Total</b>	<b>984</b>	<b>1,292</b>	<b>308</b>	<b>16.3</b>	<b>20.2</b>	<b>3.8</b>	<b>(1.3)</b>	<b>23.4</b>	<b>1,761</b>	<b>27.3</b>	<b>73.8</b>

North America sales are generally in line with forecast

MEROPEN® sales remained strong

LATUDA® was launched in September 2019

There is no pending LATUDA® ANDA lawsuit in the U.S. at present because one remaining lawsuit has been settled

FX rates: Q3FY2018 Results : 1US\$ = ¥ 111.2, 1RMB = ¥16.6  
 Q3FY2019 Results : 1US\$ = ¥ 108.7, 1RMB = ¥15.6  
 FY2019 Previous forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥15.5

## Financial Results for Q3 FY2019

### Segment Information (Core Basis)



Billions of yen

		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
Q3 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
	Other operating income/expenses						0.1	0.0	0.1
	Core operating profit						62.4	1.8	64.3
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
Change	Revenue (Sales to customers)	3.6	5.0	3.8	(1.5)	11.0	(0.9)	10.1	
	SG&A expenses	(0.2)	(4.8)	0.2	(0.4)	(5.1)	(0.3)	(5.4)	
	Core segment profit	(3.1)	7.7	2.7	0.2	7.5	0.1	7.7	
	Core operating profit						8.2	0.2	8.4

Decline in expenses in North America mainly due to ANDA litigation expense

# Financial Forecasts for FY2019

## Financial Forecasts for FY2019

# Financial Forecasts for FY2019 (Core Basis)



Billions of yen

	FY2018 Results	FY2019 Previous forecasts	FY2019 Revised forecasts	Change from Previous forecasts	
				Value	FX impact
Revenue	459.3	475.0	<b>475.0</b>	—	(3.6)
Cost of sales	113.1	125.0	<b>125.0</b>	—	(1.3)
Gross profit	346.2	350.0	<b>350.0</b>	—	(2.3)
SG&A expenses	186.1	187.0	<b>192.0</b>	5.0	(1.6)
R&D expenses	82.9	86.0	<b>94.0</b>	8.0	(0.8)
Core operating profit	77.3	77.0	<b>64.0</b>	(13.0)	0.1
Changes in fair value of contingent consideration (negative number indicates loss)	9.1	35.0	<b>34.5</b>	(0.5)	
Other non-recurring items (negative number indicates loss)	(28.5)	(24.0)	<b>(23.5)</b>	0.5	
Operating profit	57.9	88.0	<b>75.0</b>	(13.0)	
Income tax expense	16.4	51.0	<b>52.0</b>	1.0	
Net profit	48.6	36.0	<b>26.0</b>	(10.0)	
Net profit attributable to owners of the parent	48.6	36.0	<b>31.0</b>	(5.0)	
R O E (%)	10.2	7.1	—		
R O I C (%)	11.8	4.8	—		

Impact on FY2019 forecasts by the  
alliance with Roivant:

SG&A expenses	10.0
Acquisition related cost * (included in above)	4.1
R&D expenses	9.0
Core operating profit	(19.0)
Net profit	(20.0)
Attributable to owners of the parent	(15.0)

\*Acquisition related cost was  
expected ¥4.0B in the previous  
forecasts

FX rates: FY2018 Results : 1US\$ = ¥ 110.9, 1RMB = ¥16.5  
 FY2019 Previous forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥15.5  
 FY2019 Revised forecasts : 1US\$ = ¥ 108.5, 1RMB = ¥15.5

ROE/ROIC forecasts have not calculated since the fair value valuation of assets and liabilities which were acquired or assumed through the strategic alliance with Roivant has not completed yet

## Financial Forecasts for FY2019

### Segment Information (Core Basis)



Billions of yen

		Pharmaceuticals Business					Other Business	Total (Core basis)	
		Japan	North America	China	Other Regions	Subtotal			
Revised Forecasts	FY2019	Revenue (Sales to customers)	137.0	257.3	28.2	14.5	437.0	38.0	475.0
		Cost of sales	63.1	22.4	5.1	5.0	95.6	29.4	125.0
		Gross profit	73.9	234.9	23.1	9.5	341.4	8.6	350.0
		SG&A expenses	52.5	121.5	9.3	3.2	186.5	5.5	192.0
		Core segment profit	21.4	113.4	13.8	6.3	154.9	3.1	158.0
		R&D expenses					93.0	1.0	94.0
		Core operating profit					61.9	2.1	64.0
Previous Forecasts	FY2019	Revenue (Sales to customers)	136.0	260.0	27.3	13.7	437.0	38.0	475.0
		Cost of sales	63.0	22.7	5.0	4.9	95.6	29.4	125.0
		Gross profit	73.0	237.3	22.3	8.8	341.4	8.6	350.0
		SG&A expenses	53.3	116.0	9.0	3.2	181.5	5.5	187.0
		Core segment profit	19.7	121.3	13.3	5.6	159.9	3.1	163.0
		R&D expenses					85.0	1.0	86.0
		Core operating profit					74.9	2.1	77.0
Change		Revenue (Sales to customers)	1.0	(2.7)	0.9	0.8	—	—	—
		SG&A expenses	(0.8)	5.5	0.3	—	5.0	—	5.0
		Core segment profit	1.7	(7.9)	0.5	0.7	(5.0)	—	(5.0)
		R&D expenses					8.0	—	8.0
		Core operating profit					(13.0)	—	(13.0)

- Japan segment  
- Incremental revenue of Trulicity®, REPLAGAL®, etc.
- North America segment  
- Incremental expenses due to increase in consolidated subsidiaries related to strategic alliance with Roivant
- China segment  
- Revised upward MEROPEN® sales forecast from its strong trend

## Business performance outline after FY2020

Impact on Performance by the Alliance with Roivant (as of January 30, 2020)



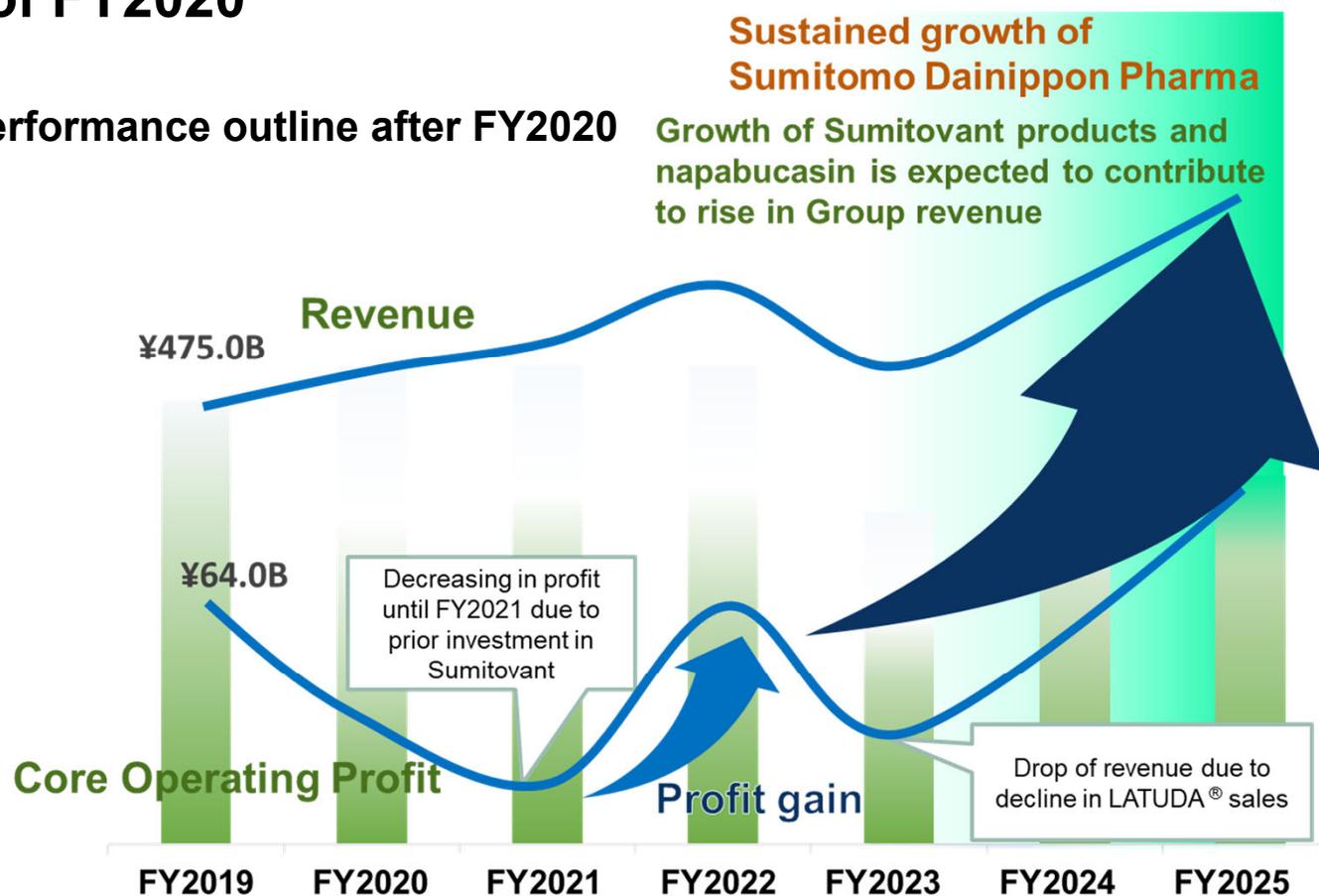
# Plan to review FY2022 Business Goals of Mid-term Business Plan 2022 by the end of FY2020

(Reference)

Business performance outline after FY2020

**Sustained growth of Sumitomo Dainippon Pharma**

Growth of Sumitovant products and napabucasin is expected to contribute to rise in Group revenue



# Research and Development

## Research and Development

# Development Pipeline (as of January 30, 2020)



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

Revisions since the announcement of October 2019 are shown in red

Area	Phase 1		Phase 2	Phase 3	NDA/BLA submitted
Japan	dasotraline (ADHD)	alvocidib (Hematologic malignancies)	SEP-4199 (Bipolar I depression)	EPI-743 (Leigh syndrome)	lurasidone (Schizophrenia/ Bipolar depression)
	SEP-363856 (Schizophrenia)	dubermatinib (TP-0903) (Solid tumors)	DSP-7888 (Solid tumors/ Hematologic malignancies)	napabucasin (Colorectal cancer)	RETHIO® (Conditioning treatment prior to autologous HSCT for malignant lymphoma)
	EPI-589 (ALS)		Allo iPS cell-derived products (Parkinson's disease) Investigator-initiated clinical study	imeglimin (Type 2 diabetes)	
	DSP-1181 (Obsessive compulsive disorder)				
U.S.	DSP-6745 (Parkinson's disease psychosis)	alvocidib (MDS)	EPI-589 (Parkinson's disease/ALS)	SEP-363856 (Schizophrenia)	dasotraline (BED)
	SEP-378608 (Bipolar disorder)	dubermatinib (TP-0903) (Solid tumors/ Hematologic malignancies)	SEP-363856 (Parkinson's disease psychosis)	napabucasin (Colorectal cancer)	dasotraline (ADHD) Development strategy under consideration
	DSP-3905 (Neuropathic pain)	DSP-0509 (Solid tumors)	SEP-4199 (Bipolar I depression)	relugolix (Prostate cancer)	apomorphine (OFF episodes associated with Parkinson's disease) NDA resubmitted in November 2019
	SEP-378614 (Treatment resistant depression)	TP-0184 (Solid tumors)	alvocidib (AML)	relugolix (Uterine fibroids/Endometriosis)	RVT-802 (Pediatric congenital athymia) Received Complete Response Letter
	SEP-380135 (Agitation in Alzheimer's disease)	DSP-0337 (Solid tumors)	DSP-7888 (Solid tumors)	vibegron (OAB in men with BPH)	vibegron (OAB)
		TP-1287 (Solid tumors)	vibegron (IBS-associated pain)		
		TP-3654 (Solid tumors/ Hematologic malignancies)	rodatristat ethyl (Pulmonary arterial hypertension)		
		URO-902 (Overactive bladder)			

# Clinical Development Status (Major Changes since October 28, 2019)

## ■ DSP-1181

Japan: Started Phase 1 study (proposed indication: obsessive compulsive disorder)

- DSP-1181 is a novel compound created by Sumitomo Dainippon Pharma using Exscientia's AI technologies
- DSP-1181 has a potent full agonistic activity for serotonin 5-HT<sub>1A</sub> receptors and is expected to have a long half-life, therefore it is suggested that DSP-1181 has strong efficacy over a long period of time

## ■ Imeglimin

Japan : Obtained results from Phase 3 study (TIMES 2: monotherapy and combination therapy with other hypoglycemic agent at 52 week) for type 2 diabetes in December 2019

- Plan to submit NDA in FY2020 in Japan based on three positive Phase 3 results

## ■ Expanded development pipeline due to strategic alliance with Roivant

RVT-802: pediatric congenital athymia (U.S.: NDA submitted, Received Complete Response Letter in December 2019)

Vibegron: overactive bladder (OAB) (U.S.: NDA submitted in December 2019)

OAB in men with Benign prostatic hyperplasia (BPH) (U.S.: Phase 3 study)

IBS-associated pain (U.S.: Phase 2 study)

Relugolix: uterine fibroids (U.S.: global Phase 3 study completed), endometriosis (U.S.: global Phase 3 study )  
prostate cancer (U.S.: global Phase 3 study completed)

Rodatristat ethyl: pulmonary arterial hypertension (U.S.: Phase 2 study)

MVT-602: female infertility (Germany: Phase 2 study)

URO-902: OAB (U.S.: Phase 2 study)

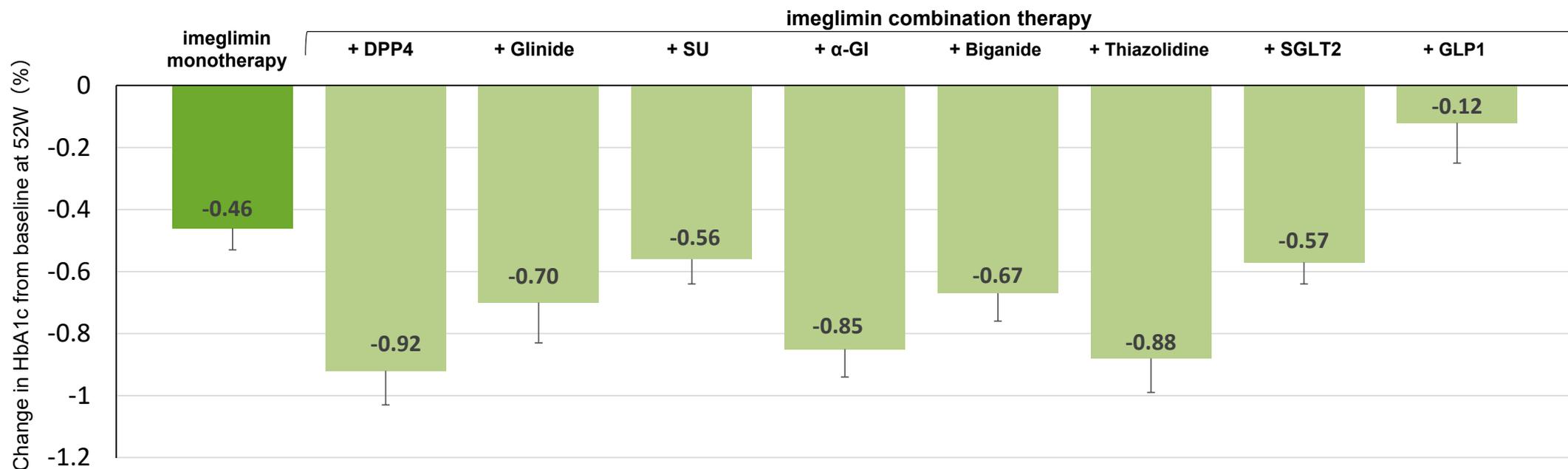
## ■ Discontinuation

SB623: chronic stroke (U.S.: Phase 2 study)

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

**Study design :** long-term study (monotherapy and combination therapy with other oral hypoglycemic agent and GLP1 receptor agonist at 52 week) (1,000 mg twice-daily)

- **Safety :** Imeglimin was generally well-tolerated, adverse events were similar to previous studies
- **Efficacy :** Reduced HbA1c 52 weeks after administration (change from baseline: LS Mean = least mean square)



- **Future plan :** Plan to submit NDA in FY2020 in Japan based on three Phase 3 results

\* Announced the positive result for TIMES 1 study (Phase 3 study, monotherapy) in the press release on April 9, 2019

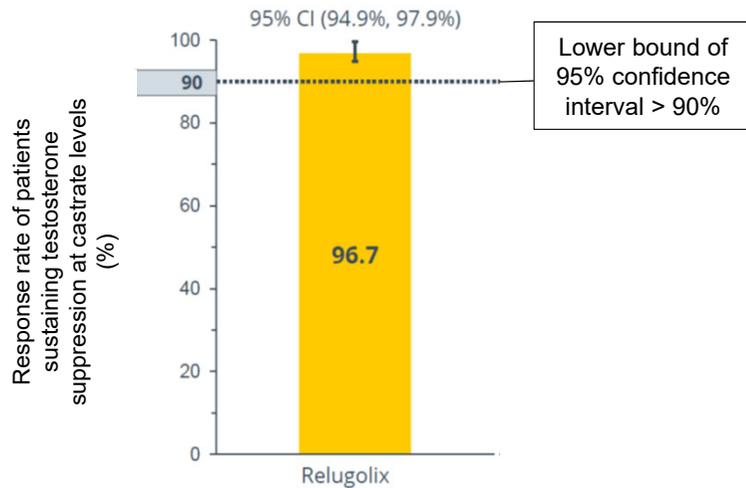
\* Announced the positive result for TIMES 3 study (Phase 3 study, insulin combination therapy) in the press release on June 25, 2019 15

# Relugolix : Prostate cancer Phase 3 Study Results (HERO)

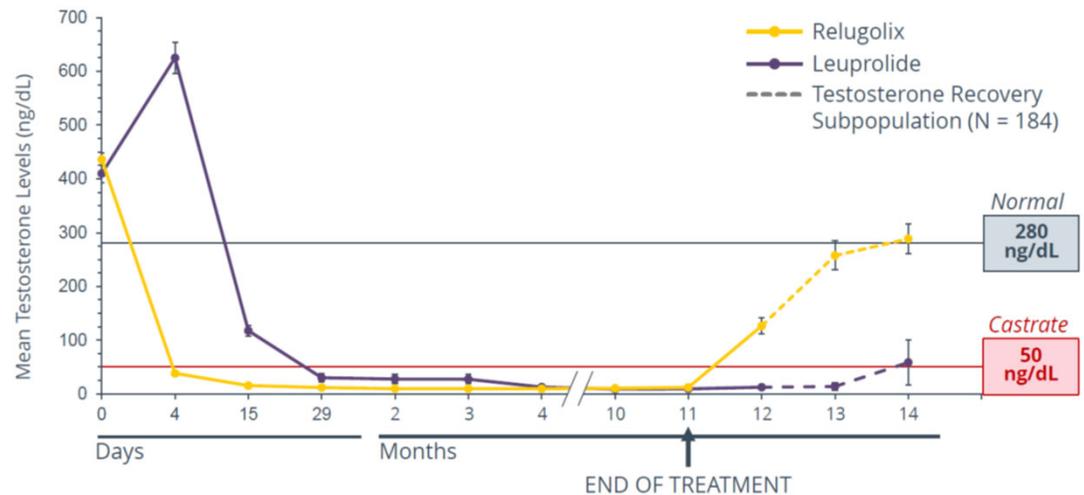
- Study design:** Randomized, open-label, parallel group efficacy and safety study in men with androgen-sensitive prostate cancer  
 Two arms: relugolix: 120 mg orally once-daily and active comparator, leuprolide depot suspension: 22.5 mg (or 11.25 mg in some Asian countries) every 3-months by subcutaneous or intramuscular injection

- Efficacy:** Met primary endpoint with ~97% of men achieving sustained testosterone suppression through 48 weeks. Achieved all six key secondary endpoints, including superiority to leuprolide on rapid suppression of testosterone and PSA, all with p-values < 0.0001

U.S. Primary endpoint achieved: Sustained testosterone suppression to castrate levels (< 50 ng/dl) through 48 weeks



Relugolix achieved faster onset and recovery than Leuprolide



- Safety:** Relugolix was generally well-tolerated, with half the rate of major adverse CV events compared to leuprolide acetate (Relugolix 2.9% vs Leuprolide 6.2%)

- Future plan:** Plan to submit NDA in the U.S. in Q1 FY2020. HERO data to be submitted for presentation and publication in 1H of CY2020.

\* Myovant announced the positive result for HERO study in the press release on November 19, 2019

# Appendix

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## Appendix (Financial Results for Q3 FY2019)

# Financial Results for Q3 FY2019 (Full Basis)



Billions of yen

	Q3 FY2018 Results	Q3 FY2019 Results	Change	
			Value	%
Revenue	346.9	357.0	10.1	2.9
Cost of sales	85.2	93.3	8.2	9.6
Gross profit	261.7	263.7	2.0	0.8
SG&A expenses	149.5	97.8	(51.7)	(34.6)
R&D expenses	62.0	83.7	21.7	35.1
Other operating income and expenses	(3.4)	(0.7)	2.7	
Operating profit	46.8	81.5	34.6	73.9
Finance income and costs	6.3	3.0	(3.4)	
Net profit attributable to owners of the parent	40.0	44.0	4.0	10.0

## Appendix (Financial Results for Q3 FY2019)



# Adjustments to Core Operating Profit

### Q3 FY2019 Results

Billions of yen

IFRS Full Basis		Adjusted amount	IFRS Core Basis		Adjusted items
Revenue	357.0	—	Revenue	357.0	
Cost of sales	93.3	(0.3)	Cost of sales	93.1	
Gross profit	263.7	0.3	Gross profit	264.0	
SG&A expenses	97.8	40.8	SG&A expenses	138.6	Changes in fair value of contingent consideration 40.8
R&D expenses	83.7	(22.5)	R&D expenses	61.2	Impairment loss (22.5)
Other operating income and expenses	(0.7)	0.8	Other operating income and expenses *1 (profit/loss on business transfer, share of profit/loss of associates accounted for using equity method)	0.1	
Operating profit	81.5	(17.2)	Core operating profit	64.3	
			Changes in fair value of contingent consideration (Positive number indicates profit)	40.8	From SG&A expenses 40.8
			Other non-recurring items *2 (Negative number indicates loss)	(23.6)	Impairment loss (22.5)

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 Q3 FY2019)

# Financial Position



Billions of yen

	Billions of yen		
	As of March 31,2019	As of Dec. 31,2019	Change
Assets	834.7	1,115.2	280.4
Non-current assets	461.4	766.9	305.5
Current assets	373.3	348.2	(25.1)
Liabilities	336.6	592.8	256.2
Non-current liabilities	138.4	103.7	(34.7)
Current liabilities	198.2	489.1	290.9
Equity	498.1	522.4	24.2
Attributable to owners of the parent	498.1	519.9	21.8
Ratio of equity attributable to owners of the parent to total assets	59.7%	46.6%	

### 【Assets】

#### Non-current

- PP&E +11.6 - Adopted IFRS16"Leases"
- Goodwill +232.0 - Acquired Sumitovant
- Intangible assets (26.5) - Impairment of IPR&D
- Deferred tax assets (11.8) - Reversed
- Other financial assets +100.5 - Acquired Roivant's shares

#### Current

- Other financial assets (39.9) - Decrease in loan receivable

### 【Liabilities】

#### Non-current

- Other financial liabilities (31.3)
  - Decrease in fair value of contingent consideration

#### Current

- Bonds and borrowings +274.8
  - Financing for consideration of the alliance

\* The value of assets and liabilities which were acquired or assumed is provisional since the fair value valuation has not completed yet

## Appendix (Financial Forecasts for FY2019)

# Revenue of Major Products in Japan



Billions of yen

	FY2018	FY2019 Previous Forecasts	FY2019 Revised Forecasts	Change from Previous Forecasts
Trulicity®*	23.1	28.2	30.0	1.8
TRERIEF®	15.7	17.1	16.3	(0.8)
Equa®/EquMet®	—	16.0	16.0	—
REPLAGAL®	12.5	12.6	13.1	0.5
METGLUCO®	10.1	9.3	9.3	—
SUREPOST®	6.1	6.2	6.7	0.5
AmBisome®	4.0	3.9	3.9	—
LONASEN® Tape	—	1.8	1.0	(0.8)
<b>Promoted products Total</b>	<b>71.5</b>	<b>95.1</b>	<b>96.3</b>	<b>1.2</b>
AMLODIN®	9.1	7.5	7.5	—
LONASEN® tablet/powder	12.2	5.2	5.2	—
AIMIX®	8.2	3.7	3.7	—
PRORENAL®	4.0	3.3	3.3	—
GASMOTIN®	3.8	3.1	3.1	—
AG products	5.5	6.9	6.9	—
Others	15.0	11.2	11.0	(0.2)
<b>Total</b>	<b>129.3</b>	<b>136.0</b>	<b>137.0</b>	<b>1.0</b>

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

## Appendix (Financial Forecasts for FY2019)

# Revenue of Major Products in North America & China



	FY2018	FY2019 Previous Forecasts	FY2019 Revised Forecasts	Change from Previous Forecasts	FY2018	FY2019 Previous Forecasts	FY2019 Revised Forecasts	Change from Previous Forecasts
<b>North America</b>	Million \$				Billion yen			
LATUDA <sup>®</sup>	166.3	172.1	172.1	—	184.5	189.3	186.7	(2.6)
BROVANA <sup>®</sup>	30.4	30.0	30.0	—	33.7	33.0	32.6	(0.4)
APTIOM <sup>®</sup>	18.5	20.5	20.5	—	20.5	22.5	22.2	(0.3)
LONHALA <sup>®</sup> MAGNAIR <sup>®</sup>	1.3	3.8	3.8	—	1.4	4.2	4.1	(0.1)
XOPENEX <sup>®</sup>	4.2	3.7	3.7	—	4.6	4.1	4.0	(0.1)
Others	7.1	6.3	7.1	0.8	7.8	6.9	7.7	0.8
<b>Total</b>	<b>227.7</b>	<b>236.4</b>	<b>237.1</b>	<b>0.7</b>	<b>252.5</b>	<b>260.0</b>	<b>257.3</b>	<b>(2.7)</b>
<b>China</b>	Million RMB				Billion yen			
MEROPEN <sup>®</sup>	128.4	148.8	153.5	4.7	21.2	23.1	23.8	0.7
Others	21.2	27.3	28.4	1.1	3.5	4.2	4.4	0.2
<b>Total</b>	<b>149.6</b>	<b>176.1</b>	<b>181.9</b>	<b>5.8</b>	<b>24.7</b>	<b>27.3</b>	<b>28.2</b>	<b>0.9</b>

Revised downward in North America forecast due to stronger yen

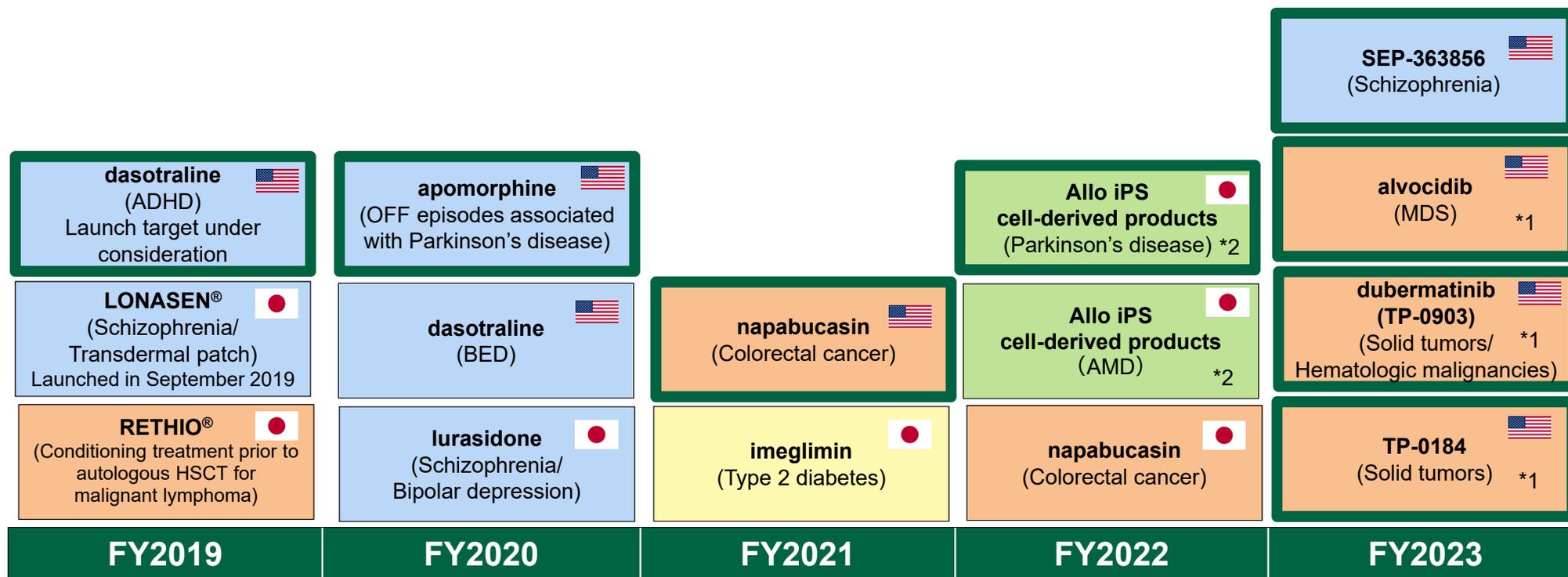
China sales remained strong

FX rates: FY2018 Results : 1US\$ = ¥ 110.9, 1RMB = ¥16.5  
 FY2019 Previous forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥15.5  
 FY2019 Revised forecasts : 1US\$ = ¥ 108.5, 1RMB = ¥15.5

## Appendix (Research and Development)



# Product Launch Target (as of January 30, 2020)



: 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

**\* Plan to launch RVT-802, vibegron and relugolix from FY2019 to FY2023 (launch targets are not disclosed)**

- RVT-802 (Pediatric congenital athymia) Submitted in April 2019 , Received Complete Response Letter in December 2019
- Vibegron (OAB) Submitted in December 2019
- Relugolix (Uterine fibroids) Plan to submit NDA in April 2020
- (Prostate cancer) Plan to submit NDA in Q1 FY2020

## Appendix (Research and Development)

### Regenerative Medicine/Cell Therapy Business Plan (as of January 30, 2020)



Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
<b>Pediatric congenital athymia (RVT-802)</b>	Duke University	Global	Cultured thymus tissue	<b>BLA submitted in the U.S. in April 2019 Under consideration to resubmit BLA</b>
<b>AMD (age-related macular degeneration)</b>	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	<b>In progress: clinical research Preparing to start clinical study (Japan)</b>
<b>Parkinson's disease (Designated as a "SAKIGAKE")</b>	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	<b>In progress: investigator-initiated clinical study (Phase 1 / 2 study) (Japan)</b>
<b>Retinitis pigmentosa</b>	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	<b>Preparing to start clinical research</b>
<b>Spinal cord injury</b>	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	<b>In progress: clinical research</b>
<b>Kidney failure</b>	Jikei University Bios PorMedTec	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	<b>In progress: pre-clinical study</b>

**Aim to launch in FY2022 \***

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

## Appendix (Research and Development)



# Main Event/Target for FY2019 (as of January 30, 2020)

✓ Done event / target    Revisions since the announcement of October 2019 are shown in red

### 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

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



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