

Supplementary Financial Data for the Year Ended March 31, 2018

I.	Consolidated Financial Highlights	1
II.	Consolidated Statement of Profit or Loss	2
III.	Segment Information	4
IV.	Revenues Information	5
V.	Consolidated Statement of Financial Position	7
VI.	Major Consolidated Subsidiaries	8
VII.	Shareholder Positioning	9
VIII.	Development Pipeline	10
IX.	Profile of Major Products under Development	14

May 11, 2018

Sumitomo Dainippon Pharma Co., Ltd.

- 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.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

I. Consolidated Financial Highlights

1. Consolidated Statement of Profit or Loss (IFRS Core Basis)

(Billions of yen)

	FY2016	FY2017	Change % YoY	FY2018 Apr.-Sep. (Forecast)	Change % YoY	FY2018 (Forecast)	Change % YoY
Revenue	408.4	466.8	14.3	230.0	—	467.0	0.0
Cost of sales	94.5	112.3	18.9	53.5	—	110.0	(2.1)
Gross profit	313.8	354.5	13.0	176.5	—	357.0	0.7
SG&A expenses *1	171.4	186.2	8.6	94.5	—	195.0	4.7
R&D expenses	81.4	86.9	6.8	41.0	—	85.0	(2.2)
Other operating income/expenses (Core Basis) *2	3.3	9.2	178.2	—	—	—	—
Core operating profit	64.4	90.6	40.8	41.0	—	77.0	(15.0)
Changes in fair value of contingent consideration (negative number indicates loss)	(8.1)	6.4		(8.5)		(19.0)	
Other non-recurring items *3 (negative number indicates loss)	(16.0)	(8.8)		(0.5)		(5.0)	
Operating profit	40.3	88.2	118.9	32.0	—	53.0	(39.9)
Net profit attributable to owners of the parent	31.3	53.4	70.7	22.0	—	35.0	(34.5)
Earnings per share (yen)	78.82	134.53		55.37		88.10	
Return on equity (ROE)	7.8%	12.4%		—		7.5%	
Payout ratio	25.4%	20.8%		—		22.7%	

2. Consolidated Statement of Profit or Loss (IFRS Full Basis)

(Billions of yen)

	FY2016	FY2017	Change % YoY
Revenue	408.4	466.8	14.3
Cost of sales	94.6	112.3	18.7
Gross profit	313.7	354.5	13.0
SG&A expenses	181.7	183.7	1.1
R&D expenses	81.4	86.9	6.8
Other operating income/expenses	(10.4)	4.3	
Operating profit	40.3	88.2	118.9
Finance income/costs	2.5	(3.3)	
Net profit attributable to owners of the parent	31.3	53.4	70.7

- *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 included in SG&A expenses, etc.)

3. Consolidated Statement of Cash Flows

(Billions of yen)

	FY2016	FY2017
Net cash provided by operating activities	19.1	93.4
Net cash used in investing activities	(56.1)	(16.5)
Net cash provided by (used in) financing activities	8.8	(29.6)
Cash and cash equivalents at the end of period	105.6	147.8

4. Foreign Exchange Rates

Forex sensitivity FY2018
(Impact of yen appreciation by 1 yen)

	FY2016		FY2017		FY2018 Assumed rate	Revenue		Core operating profit	
	Fiscal year end rate	Average rate	Fiscal year end rate	Average rate		Revenue	Core operating profit	Revenue	Core operating profit
Yen / USD	112.2	108.4	106.3	110.9	105.0	2.5	0.0		
Yen / RMB	16.3	16.1	16.9	16.7	16.5	1.3	0.1		

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization

(Billions of yen)

	FY2016	FY2017	Change % YoY	FY2018 (Forecast)	Change % YoY
Capital expenditures	7.8	10.2	2.4	10.0	(0.2)
Property, plant and equipment	8.0	7.6	(0.4)	7.9	0.3
Intangible assets	4.7	5.2	0.6	7.9	2.7

Note: The amount of capital expenditures are for tangible fixed assets and software.

Major capital expenditure project in FY2018

Workspace reform (Osaka/Tokyo head office), total budget ¥1.5billion, to be completed in FY2018

II. Consolidated Statement of Profit or Loss

1. Consolidated Statement of Profit or Loss (IFRS Core Basis) (Billions of yen)

	FY2016	FY2017	Change	Change %	
Revenue	408.4	466.8	58.5	14.3	•Japan Segment ¥2.5B •North America Segment ¥46.1B [incl. FX rate impact ¥5.4B] •China Segment ¥5.8B [incl. FX rate impact ¥0.9B]
Overseas revenue	224.2	281.4	57.2	25.5	
% of Revenue	54.9%	60.3%			
Cost of sales	94.5	112.3	17.8	18.9	•FX impact of unrealized profit of inventory ¥8.7B
% of Revenue	23.1%	24.1%			
Gross profit	313.8	354.5	40.7	13.0	
SG&A expenses	171.4	186.2	14.8	8.6	
Labor costs	75.4	77.4	2.0	2.7	
Advertising and promotion costs	24.1	22.6	(1.5)	(6.2)	•Decrease mainly in LATUDA-related cost in North America
Sales promotion costs	13.0	15.6	2.7	20.7	•Increase mainly in new COPD products-related cost in North America
Amortization/Depreciation	5.8	6.5	0.7	12.3	
Others	53.2	64.0	10.9	20.5	•Increase mainly in new COPD products-related cost in North America
R&D expenses	81.4	86.9	5.5	6.8	
% of Revenue	19.9%	18.6%			
Other operating income/expenses (Core Basis)	3.3	9.2	5.9	178.2	•Increase in profit on business transfer •Reversal of cost by decrease in fair value of contingent consideration associated with review of a development program
Core operating profit	64.4	90.6	26.2	40.8	
Changes in fair value of contingent consideration *	(8.1)	6.4	14.5		
Other non-recurring items *	(16.0)	(8.8)	7.2		
Operating profit	40.3	88.2	47.9	118.9	
Finance income	3.2	2.4	(0.8)		
Finance costs	0.7	5.7	5.1		
Profit before taxes	42.8	84.9	42.1	98.4	
Income tax expenses	11.5	31.4	20.0		
Net profit	31.3	53.4	22.1	70.7	
Net profit attributable to owners of the parent	31.3	53.4	22.1	70.7	

* Negative number indicates loss.

Changes in fair value of contingent consideration	FY16	FY17
LONHALA® MAGNAIR®	(0.6)	(6.9)
BBI	(7.3)	14.7
Tolero	(0.2)	(1.5)

Major other non-recurring items	FY16	FY17
Restructuring expenses	(10.9)	(3.7)
Impairment losses	(2.3)	(2.1)
Loss on discontinuation of R&D programs	(2.0)	-

2. Adjustments to Core Operating Profit

(Billions of yen)

FY2017 Results	IFRS (Full basis)	IFRS (Core basis)	Adjustment	Major adjustment items
Revenue	466.8	466.8	-	
Cost of sales	112.3	112.3	-	
Gross profit	354.5	354.5	-	
SG&A expenses	183.7	186.2	2.5	Changes in fair value of contingent consideration +6.4 Impairment losses (2.1)
R&D expenses	86.9	86.9	-	
Other operating income	9.4	9.2	(0.2)	Other operating income except for "profit on business transfer" and "share of profit of associates accounted for using equity method" is excluded from core operating profit (0.2)
Other operating expenses	5.2	-	(5.2)	Other operating expenses are excluded from core operating profit (5.2)
Operating profit	88.2	90.6	2.4	

(Reference) IFRS – JGAAP Comparison (FY2017)

(Billions of yen)

JGAAP		Difference	IFRS	Major different items
Net sales	478.0	(11.2)	Revenue	466.8 Profit on business transfer (to other income) (9.2)
Cost of sales	119.9	(7.6)	Cost of sales	112.3 Unification of valuation method of inventory (5.6)
Gross profit	358.1	(3.6)	Gross profit	354.5
SG&A expenses	200.9	(17.2)	SG&A expenses	183.7 Goodwill not amortized (6.7) Changes in fair value of contingent consideration (14.7) Impairment losses (from extraordinary losses) +2.1
R&D costs	91.4	(4.5)	R&D expenses	86.9 Intangible assets by separate purchase
		9.4	Other operating income	9.4 Profit on business transfer (from net sales) +9.2
		5.2	Other operating expenses	5.2 Business structure improvement expenses (from extraordinary losses) +3.7
Operating income	65.8	22.3	Operating profit	88.2
Non-operating income	2.6	(0.2)	Finance income	2.4
Non-operating expenses	7.5	(1.8)	Finance costs	5.7
Ordinary income	60.9			
Extraordinary income				
Extraordinary losses	14.1	(14.1)		Business structure improvement expenses (to other expense) (3.7) Impairment losses (to SG&A expenses) (2.1) Loss on valuation of investment securities (to retained earnings) (6.4)
Income before income tax	46.8	38.0	Profit before taxes	84.9
Income taxes	9.3	22.1	Income tax expenses	31.4 Impact from change in tax rate applied to tax effect for elimination of unrealized gain of inventory +11.6
Net income attributable to owners of the parent	37.5	15.9	Net profit attributable to owners of the parent	53.4

(Reference) JGAAP Consolidated financial results

(Billions of yen)

	FY2016	FY2017	Change %
Net sales	411.6	478.0	16.1
Cost of sales	100.1	119.9	19.8
SG&A expenses	259.1	292.3	12.8
SG&A expenses less R&D costs	178.2	200.9	12.7
R&D costs	80.8	91.4	13.1
Operating income	52.5	65.8	25.4
Ordinary income	54.1	60.9	12.6
Net income attributable to owners of the parent	28.7	37.5	30.6

FY2016 results have been revised retroactively associated with finalizing purchase price allocation related to Tolero acquisition. As a result, operating income, ordinary income, net income attributable to owners of the parent decreased by 0.3 billion yen.

III. Segment Information (IFRS Core Basis)

(Billions of yen)

FY2017 Results (Core basis)	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	143.3	240.8	23.4	16.5	424.0	42.8	466.8
Cost of sales	51.7	15.1	4.6	7.3	78.7	33.7	112.3
Gross profit	91.7	225.7	18.9	9.1	345.4	9.1	354.5
SG&A expenses	51.5	116.2	8.2	4.0	179.8	6.4	186.2
Core segment profit	40.3	109.5	10.7	5.1	165.6	2.7	168.3
R&D expenses *1					85.8	1.1	86.9
Other operating income/expenses (Core basis)*2					9.2	0.0	9.2
Core operating profit					89.0	1.6	90.6

(Billions of yen)

FY2018 Forecasts (Core basis)	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	131.8	260.8	22.0	14.4	429.0	38.0	467.0
Cost of sales	52.3	18.8	3.7	6.0	80.8	29.2	110.0
Gross profit	79.5	242.0	18.3	8.4	348.2	8.8	357.0
SG&A expenses	52.5	124.2	8.5	3.5	188.7	6.3	195.0
Core segment profit	27.0	117.8	9.8	4.9	159.5	2.5	162.0
R&D expenses *1					84.0	1.0	85.0
Other operating income/expenses (Core basis)*2					—	—	—
Core operating profit					75.5	1.5	77.0

(Billions of yen)

(Ref.) FY2016 Results (Core basis)	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	140.8	194.7	17.6	11.5	364.7	43.7	408.4
Cost of sales	46.8	4.0	3.4	5.6	59.8	34.8	94.5
Gross profit	94.1	190.6	14.3	5.9	305.0	8.9	313.8
SG&A expenses	56.2	98.1	7.5	3.1	164.9	6.5	171.4
Core segment profit	37.9	92.6	6.7	2.8	140.0	2.4	142.4
R&D expenses *1					80.4	1.0	81.4
Other operating income/expenses (Core basis)*2					3.2	0.1	3.3
Core operating profit					62.8	1.5	64.4

*1 R&D expenses for pharmaceuticals business are controlled globally and not allocated to each segment.

*2 P/L on business transfer and share of P/L of associates accounted for using equity method

IV. Revenues Information (IFRS)

1. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

Segment	FY2016	FY2017	Change	Change %	FY2018 Apr.-Sep. (Forecast)	FY2018 (Forecast)
Japan	140.8	143.3	2.5	1.8	68.0	131.8
North America	194.7	240.8	46.1	23.7	124.7	260.8
China	17.6	23.4	5.8	33.0	11.5	22.0
Other Regions	11.5	16.5	4.9	42.7	7.1	14.4

2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	FY2016	FY2017	Change	Change %	FY2018 Apr.-Sep. (Forecast)	FY2018 (Forecast)
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Japan

Promoted products

AIMIX[®] Therapeutic agent for hypertension	17.1	18.8	1.6	9.6	6.5	10.4
TRERIEF[®] Therapeutic agent for Parkinson's disease	15.1	16.1	0.9	6.2	7.2	14.5
Trulicity[®] * Therapeutic agent for type 2 diabetes (Launch: Sep. 2015)	6.8	15.9	9.2	135.1	10.8	22.8
LONASEN[®] Atypical antipsychotic	12.8	12.6	(0.2)	(1.3)	6.4	12.5
REPLAGAL[®] Anderson-Fabry disease	10.7	11.7	1.0	9.7	6.2	12.2
METGLUCO[®] Therapeutic agent for type 2 diabetes	11.2	10.9	(0.3)	(2.8)	5.6	11.1
AVAPRO[®] Therapeutic agent for hypertension	10.3	8.4	(2.0)	(18.9)	2.2	4.0
SUREPOST[®] Therapeutic agent for type 2 diabetes	4.3	5.0	0.7	15.9	2.9	5.9
AmBisome[®] Therapeutic agent for systemic fungal infection	4.4	4.3	(0.1)	(1.8)	2.2	4.3
Other products						
AMLODIN[®] Therapeutic agent for hypertension and angina pectoris	13.0	11.4	(1.6)	(12.2)	4.8	9.1
PRORENAL[®] Vasodilator	6.5	5.4	(1.1)	(17.4)	2.3	4.3
GASMOTIN[®] Gastroprokinetic	6.0	4.9	(1.1)	(18.7)	2.1	3.9
MEROPEN[®] Carbapenem antibiotic	4.3	3.3	(1.0)	(22.4)	1.4	2.7

* Revenue of Trulicity[®] is shown on NHI price basis.

2. Sales of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	FY2016	FY2017	Change	Change %	FY2018 Apr.-Sep. (Forecast)	FY2018 (Forecast)
North America						
LATUDA [®] Atypical antipsychotic	135.9	178.6	42.7	31.4	90.6	184.7
BROVANA [®] Therapeutic agent for COPD	33.1	33.1	0.1	0.3	16.4	34.2
APTIOM [®] Antiepileptic (Launch: Apr. 2014)	11.6	15.7	4.1	35.5	10.0	22.1
LONHALA [®] MAGNAIR [®] Therapeutic agent for COPD (Launch: Apr. 2018)	—	—	—	—	1.0	5.0
Therapeutic agent for COPD (in-licensed 3 products) *	0.0	0.5	0.5	—	1.0	2.9
XOPENEX [®] Therapeutic agent for asthma	5.1	4.0	(1.1)	(22.1)	1.8	3.6
Ciclesonide Antiallergic	5.1	1.4	(3.7)	(72.1)	—	—
Industrial property revenues	0.8	1.2	0.4	50.6	0.5	0.9

China

MEROPE [®]	15.4	20.4	5.0	32.6	10.0	19.0
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Other Regions

MEROPE [®] (Export)	6.8	10.2	3.4	50.9	4.6	7.4
Industrial property revenues	1.3	1.7	0.5	38.2	—	1.5

(Ref.) Products sales in North America (based on local currency)

(Millions of dollar)

品目	FY2016	FY2017	Change	Change %	FY2018 Apr.-Sep. (Forecast)	FY2018 (Forecast)
LATUDA [®]	1,254	1,611	357	28.4	863	1,759
BROVANA [®]	305	299	(6)	(2.0)	156	326
APTIOM [®]	107	141	35	32.4	95	210
LONHALA [®] MAGNAIR [®]	—	—	—	—	10	48
Therapeutic agent for COPD (in-licensed 3 products) *	0	5	5	—	10	28
XOPENEX [®]	47	36	(11)	(23.8)	17	34
Ciclesonide	47	13	(34)	(72.8)	—	—
Industrial property revenues	7	11	4	47.2	5	9

* UTIBRON[™], SEEBRI[™], ARCAPTA[®]

V. Consolidated Statement of Financial Position

(Billions of yen)

	Apr. 1 2016	Mar.31 2017 (A)	Mar. 31 2018 (B)	Change (B)-(A)
Assets	705.5	779.1	809.7	30.6
Non-current assets	362.1	471.5	461.1	(10.4)
Property, plant and equipment	63.7	61.1	58.2	(2.9)
Buildings and structures	39.7	37.9	36.7	(1.3)
Machinery, equipment and carriers	10.3	9.3	9.7	0.4
Tools, equipment and fixtures	5.9	4.6	4.1	(0.4)
Land	6.3	6.3	5.1	(1.2)
Construction in progress	1.5	3.1	2.7	(0.4)
Goodwill	77.0	100.2	95.1	(5.1)
Intangible assets	78.9	197.1	189.7	(7.4)
Patent rights/Marketing rights	15.0	14.0	30.8	16.9
In-process research & development	58.3	178.0	153.9	(24.1)
Others	5.5	5.2	4.9	(0.2)
Other financial assets	65.2	52.7	71.0	18.3
Other non-current assets	4.6	3.3	5.5	2.2
Deferred tax assets	73.6	57.1	41.6	(15.5)
Current assets	343.4	307.6	348.6	41.0
Inventories	44.5	60.3	60.2	(0.1)
Trade and other receivables	108.7	112.7	113.0	0.3
Other financial assets	49.4	17.5	22.1	4.6
Other current assets	5.3	11.4	5.6	(5.9)
Cash and cash equivalents	135.6	105.6	147.8	42.2
Liabilities	315.9	366.8	357.0	(9.8)
Non-current liabilities	130.2	134.7	146.7	12.0
Bonds and borrowings	28.0	10.0	30.9	20.9
Trade and other payables	0.2	0.0	0.0	0.0
Other financial liabilities	69.9	100.9	88.4	(12.4)
Retirement benefit liabilities	21.9	16.4	20.7	4.3
Other non-current liabilities	6.2	7.4	6.6	(0.8)
Deferred tax liabilities	4.1	0.1	0.1	0.0
Current liabilities	130.2	232.1	210.2	(21.9)
Bonds and borrowings	23.0	58.0	16.5	(41.5)
Trade and other payables	43.5	47.4	58.7	11.3
Other financial liabilities	6.6	13.9	6.3	(7.6)
Income taxes payable	28.5	10.0	14.4	4.4
Provisions	57.8	76.9	84.4	7.5
Other current liabilities	26.3	25.9	30.0	4.1
Equity	389.6	412.3	452.7	40.5
Share capital	22.4	22.4	22.4	—
Capital surplus	15.9	15.9	15.9	0.0
Treasury shares	(0.7)	(0.7)	(0.7)	(0.0)
Retained earnings	326.4	357.8	396.0	38.3
Other components of equity	25.6	16.9	19.1	2.2
Equity attributable to owners of the parent	389.6	412.3	452.7	40.5

Goodwill	16/4	17/3	18/3
Sunovion	74.8	75.9	71.8
Oncology	2.2	24.3	23.3

IPR&D	16/4	17/3	18/3
LONHALA®MAGNAIR®	21.3	21.2	* -
apomorphine		75.0	71.1
BBI products	30.4	30.3	28.7
Tolero products		44.9	42.5
Others	6.6	6.6	11.7

*Transferred to patent right

Increase in stock price

Impact of change in tax rate in U.S.

Total interest-bearing debt	68.0 → 47.4
[Repayment/Redemption 20.6]	

Fair value of contingent consideration liabilities *	16/4	17/3	18/3
LONHALA®MAGNAIR®	9.0	9.6	10.3
BBI	56.6	63.9	46.4
Tolero		30.0	29.8
Total	65.6	103.5	86.6

*Included in "Other financial liabilities (Non current/Current)"

Increase in reserve for sales rebates of LATUDA

FX rate 17/3 18/3
USD ¥112.2 ⇒ ¥106.3
RMB ¥16.3 ⇒ ¥16.9

Accounts receivable turnover period (in months) 3.25 2.84

VI. Major Consolidated Subsidiaries (As of Mar. 31, 2018)

Domestic	DSP Gokyo Food & Chemical Co., Ltd.	DS Pharma Animal Health Co., Ltd.	DS Pharma Biomedical Co., Ltd.
Establishment	October 1947	July 2010	June 1998
Ownership	100%	100%	100%
Number of employees	177	74	49
Businesses	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.	Manufacturing, and sales of veterinary medicines, etc.	Manufacturing and sales of pharmaceuticals and diagnostics, etc.

Overseas	Sunovion Pharmaceuticals Inc.	Boston Biomedical, Inc.	Tolero Pharmaceuticals, Inc.	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Establishment	January 1984	November 2006	June 2011	December 2003
Ownership	100%	100%	100%	100%
Number of employees	1,711	116	35	665
Businesses	Manufacturing and sales of pharmaceuticals	R&D in the oncology area	R&D in the oncology area	Manufacturing and sales of pharmaceuticals

(Reference) Number of employees and MRs

	As of Mar. 31, 2016	As of Mar. 31, 2017	As of Mar. 31, 2018
consolidated	6,697	6,492	6,268
non-consolidated	4,000	3,572	3,402
MRs			
Japan (excluding managers)	1,300	1,130	1,130
(including managers)	1,460	1,260	1,260
U.S. (excluding managers)	710	870	830
(including managers)	810	990	930
China (excluding managers)	300	340	330
(including managers)	370	410	400

Number of contracted MRs is included in MRs.

VII. Shareholder Positioning (As of March 31, 2018)

1. Total number of authorized shares: 1,500,000,000
2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 601,983)
3. Number of shareholders by category:

	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	59	90,449	22.73
Securities companies	48	2,314	0.58
Other Japanese corporations	309	235,523	59.19
Corporations outside Japan, etc.	557	41,706	10.48
Individuals and others (Including treasury stock)	25,837	27,906	7.02
Total	26,810	397,900	100

Note: The numbers of shares are rounded down to the nearest thousand shares.

4. Major shareholders:

Shareholders	Number of shares held (Thousands)	Percentage of shareholding(%)
Sumitomo Chemical Co., Ltd.	204,834	51.56
Inabata & Co., Ltd.	21,882	5.51
The Master Trust Bank of Japan, Ltd. (Trust account)	21,478	5.41
Japan Trustee Services Bank, Ltd. (Trust account)	12,976	3.27
Nippon Life Insurance Company	7,581	1.91
SMBC Trust Bank Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Aioi Nissay Dowa Insurance Co., Ltd.	4,435	1.12
Trust & Custody Services Bank, Ltd. (Security investment trust account)	3,597	0.91
Sumitomo Dainippon Pharma Employee shareholders' association	3,486	0.88

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (601,983 stocks).

2: The numbers of shares held are rounded down to the nearest thousand shares.

VIII. Development Pipeline (As of May 11, 2018)

- This table shows clinical studies on indications for which the Sumitomo Dainippon Pharma group aims to obtain approval in Japan, U.S. or China, and does not cover all clinical studies.
- For oncology area, the study for the most advanced development stage is listed if there are multiple studies with the same indication.
- The development stage is changed when Investigational New Drug Application/amended IND/ Clinical Trial Notification is filed/approved by the authority.

1. Psychiatry & Neurology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
SM-13496 (lurasidone hydrochloride)	Schizophrenia	China	Submitted in December 2015
	Schizophrenia	Japan	Phase 3
	Bipolar I depression	Japan	Phase 3
	Bipolar maintenance	Japan	Phase 3
SEP-225289 (dasotraline)	Attention-deficit hyperactivity disorder (ADHD)	U.S.	Submitted in August 2017
		Japan	Phase 1
	Binge eating disorder (BED)	U.S.	Phase 3
APL-130277 (apomorphine hydrochloride)	OFF episodes associated with Parkinson's disease	U.S.	Submitted in March 2018
TRERIEF® (zonisamide)	(New indication) Parkinsonism in dementia with Lewy bodies (DLB)	Japan	Submitted in August 2017
LONASEN® (blonanserin)	(New usage: pediatric) Schizophrenia	Japan	Phase 3
	(New formulation – Transdermal patch) Schizophrenia	Japan	Phase 3
EPI-743 (vatiquinone)	Leigh syndrome	Japan	Phase 2/3
EPI-589	Parkinson's disease	U.S.	Phase 2
	Amyotrophic lateral sclerosis (ALS)	U.S.	Phase 2
		Japan	Phase 1
SEP-363856	Schizophrenia	U.S.	Phase 2
		Japan	Phase 1
	Parkinson's disease psychosis	U.S.	Phase 2
SEP-4199	Bipolar I depression	U.S.	Phase 2
		Japan	Phase 1
DSP-2230	Neuropathic pain	U.S., Japan	Phase 1
DSP-6745	Parkinson's disease psychosis	U.S.	Phase 1
SEP-378608	Bipolar disorder	U.S.	Phase 1
DSP-3905	Neuropathic pain	U.S.	Phase 1

2. Oncology (1/2)

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
BBI608 (napabucasin)	Colorectal cancer (Combination therapy)	U.S., Japan	Phase 3 (Global clinical study)
	Pancreatic cancer (Combination therapy)	U.S., Japan	Phase 3 (Global clinical study)
	Malignant pleural mesothelioma (Combination therapy)	Japan	Phase 1/2
	Hepatocellular carcinoma (Combination therapy)	U.S.	Phase 1/2
	Gastrointestinal cancer (Combination therapy)	U.S.	Phase 1/2
	Solid tumors (Combination therapy)	U.S.	Phase 1/2
	Hematologic malignancies (Monotherapy / Combination therapy)	U.S.	Phase 1
BBI503 (amcasertib)	Hepatocellular carcinoma (Combination therapy)	U.S.	Phase 1/2
	Solid tumors (Monotherapy/ Combination therapy)	U.S.	Phase 1/2
	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	Japan	Phase 1
DSP-2033 (alvocidib)	Acute myeloid leukemia (AML) (Combination therapy) (Refractory or relapsed patients)	U.S.	Phase 2 (Global clinical study)
	Acute myeloid leukemia (AML) (Combination therapy) (Newly diagnosed patients)	U.S.	Phase 1
	Acute myeloid leukemia (AML) (Combination therapy) (Newly diagnosed and refractory or relapsed patients)	Japan	Phase 1
DSP-7888 (adegramotide/ relatimotide)	Glioblastoma (Combination therapy)	U.S., Japan	Phase 2 (Global clinical study)
	Myelodysplastic syndromes (Monotherapy)	Japan	Phase 1/2
	Pediatric malignant gliomas (Monotherapy)	Japan	Phase 1/2
	Solid tumors, Hematologic malignancies (Monotherapy)	U.S.	Phase 1
	Solid tumors (Combination therapy)	U.S.	Phase 1

3. Oncology (2/2)

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
BBI608+BBI503 (napabucasin +amcasertib)	Solid tumors (Combination therapy)	U.S.	Phase 1
DSP-1958 (thiotepa)	Conditioning treatment prior to hematopoietic cell transplantation (HPCT)(Monotherapy) * Development for the use of unapproved or off-labeled drugs	Japan	Phase 1
TP-0903	Solid tumors (Monotherapy)	U.S.	Phase 1
DSP-0509	Solid tumors (Monotherapy)	U.S.	Phase 1
TP-0184	Solid tumors (Monotherapy)	U.S.	Phase 1
DSP-0337	Solid tumors (Monotherapy)	U.S.	Phase 1

4. Regenerative medicine / cell therapy

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
SB623	Chronic stroke	U.S.	Phase 2
HLCR011 (Allo iPS cell- derived retinal pigment epithelium)	Age-related macular degeneration (AMD)	Japan	Preparing for start to clinical study
Allo iPS cell-derived dopamine neural progenitor	Parkinson's disease	Japan	Preparing for start to clinical study (Investigator-initiated)

5. Others

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
PXL008 (imeglimin)	Type 2 diabetes	Japan	Phase 3
DSP-6952 (minesapride)	IBS with constipation, Chronic idiopathic constipation	Japan	Phase 2

【Main revisions since the announcement of January 2018】

Changes	Product code (Generic name)	Proposed indication	Area	Development stage	
Approval	SM-13496 (lurasidone hydrochloride)	(New usage: pediatric) Bipolar I depression	U.S.	Approved in December 2017	
Submitted	APL-130277 (apomorphine hydrochloride)	OFF episodes associated with Parkinson's disease	U.S.	NDA submitted in March 2018	
New	SEP-4199	Bipolar I depression	U.S.	Started Phase 2 study	
			Japan	Started Phase 1 study	
	DSP-3905	Neuropathic pain	U.S.	Started Phase 1 study	
	EPI-589	Amyotrophic lateral sclerosis(ALS)	Japan	Started Phase 1 study	
	TP-0184	Solid tumors (Monotherapy)	U.S.	Started Phase 1 study	
	DSP-0337	Solid tumors (Monotherapy)	U.S.	Started Phase 1 study	
Discontinued	DSP-1747 (obeticholic acid)	Nonalcoholic steatohepatitis (NASH)	Japan	(Phase 2)	
	BBI608 (napabucasin)	Hepatocellular carcinoma (Combination therapy)	Japan	(Phase 1)	
	BBI503 (amcasertib)	Ovarian cancer (Monotherapy)	U.S.	(Phase 2)	
	WT4869		Myelodysplastic syndromes (Monotherapy)	Japan	(Phase 1/2)
			Solid tumors (Monotherapy)	Japan	(Phase 1)
	WT2725		Solid tumors,Hematologic malignancies (Monotherapy)	U.S.	(Phase 1)
Solid tumors (Monotherapy)			Japan	(Phase 1)	

IX. Profile of Major Products under Development (As of May 11, 2018)

1. Psychiatry & Neurology

LATUDA® (lurasidone hydrochloride) Developed in-house, Formulation: oral

- LATUDA® (lurasidone hydrochloride) is an atypical antipsychotic agent that is believed to have an affinity for dopamine D₂, serotonin 5-HT_{2A} and serotonin 5-HT₇ receptors where it has antagonist effects. In addition, LATUDA is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine H₁ or muscarinic M₁ receptors.
- Approved country and area:
Schizophrenia 2010: U.S., 2012: Canada, 2013: Switzerland, 2014: Europe and Australia, 2016: Taiwan, Russia, Singapore, Thailand and Hong Kong, 2017: Brazil and UAE
Bipolar I depression 2013: U.S., 2014: Canada, 2017: Russia, Brazil and Taiwan
- Development stage:

Stage	Proposed indication	Country/ Area	Partners
Submitted	Schizophrenia	Venezuela	Daiichi Sankyo
	Schizophrenia	Colombia	
	Bipolar I depression		
	Schizophrenia	Turkey	In-house
	Schizophrenia	China	
	Bipolar I depression	Switzerland	
Phase 3	Schizophrenia	Japan	In-house
	Bipolar I depression, Bipolar maintenance	Japan	
	Schizophrenia	Korea	Bukwang Pharmaceutical

dasotraline (SEP-225289) Developed in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral

- SEP-225289 is a dopamine and norepinephrine reuptake inhibitor (DNRI). SEP-225289 has an extended half-life (47-77 hours) that supports the potential for plasma concentrations yielding a continuous therapeutic effect over the 24-hour dosing interval.
- Development stage:
Attention-deficit hyperactivity disorder (ADHD): NDA submitted in the U.S. in August 2017.
Binge eating disorder (BED): Phase 3 in the U.S.
Attention-deficit hyperactivity disorder (ADHD): Phase 1 in Japan

apomorphine hydrochloride (APL-130277) Developed in-house (Sunovion Pharmaceuticals Inc., from former Cynapsus Therapeutics), Formulation: sublingual film

- APL-130277 is a sublingual film formulation of apomorphine, a dopamine agonist, which is the only molecule approved in the U.S. for acute intermittent treatment of OFF episodes associated with Parkinson's disease. It is designed to rapidly, safely and reliably convert a Parkinson's disease patient from the OFF to the ON state while avoiding many of the issues associated with subcutaneous delivery of apomorphine.
- Development stage: NDA submitted in the U.S. in March 2018.

vatiquinone (EPI-743) In-licensed from BioElectron Technology Corporation (former Edison Pharmaceuticals, Inc.), Formulation: oral

- EPI-743 is expected to show efficacy by removing the oxidative stress which is generated excessively by decreased mitochondrial function. It is expected to be the world's first treatment for mitochondrial diseases, beginning with Leigh syndrome, for which there is no effective therapy.
- Development stage:
A Phase 2 / 3 study for Leigh syndrome in Japan completed, development strategy under consideration

EPI-589

In-licensed from BioElectron Technology Corporation
(former Edison Pharmaceuticals, Inc.), Formulation: oral

- EPI-589 is expected to show efficacy by removing the oxidative stress which is generated excessively by decreased mitochondrial function. It is expected to be developed for neurodegenerative indications arising through redox stress.
Development stage:
Parkinson's disease: Phase 2 in the U.S. by BioElectron Technology Corporation
Amyotrophic lateral sclerosis (ALS): Phase 2 in the U.S. by BioElectron Technology Corporation
Amyotrophic lateral sclerosis (ALS): Phase 1 in Japan

SEP-363856

Developed in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral

- SEP-363856 is an antipsychotic agent with a novel mechanism of action, and doesn't show affinity to dopamine D₂ receptors. The molecular target(s) responsible for the profile of effects is unknown, but may include agonist effects at serotonin 5-HT_{1A} and TAAR1 (trace amine-associated receptor 1) receptors. Results obtained with the preclinical models suggest that SEP-363856 may be able to treat the positive and negative symptoms of schizophrenia as well as Parkinson's disease psychosis. SEP-363856 is expected to have high efficacy in the treatment of schizophrenia and Parkinson's disease psychosis, while improving patients' QOL.
- Development stage:
Schizophrenia: Phase 2 in the U.S.
Parkinson's disease psychosis: Phase 2 in the U.S.
Schizophrenia: Phase 1 in Japan

SEP-4199

Developed in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral

- SEP-4199 will be investigated for the treatment of major depressive episodes associated with bipolar I disorder. The mechanism of action is not disclosed at this time.
- Development stage:
Bipolar I depression: Phase 2 in the U.S.
Bipolar I depression: Phase 1 in Japan

DSP-2230

Developed in-house, Formulation: oral

- DSP-2230 is an agent that selectively inhibits voltage-gated sodium channels Nav1.7 and Nav1.8 with higher potencies than those against the other sodium channel subtypes studied. In addition, DSP-2230 has demonstrated antiallodynic effects in preclinical models of neuropathic pain that have been shown to be predictive of efficacy in humans. Due to its novel mechanism, DSP-2230 is expected not to produce central nervous system or cardiovascular system side effects, which are present with the current drugs, such as non-selective sodium channel blockers and anti-epilepsy medicines.
- Development stage: Neuropathic pain: Phase 1 in the U.S. and Japan

DSP-6745

Developed in-house, Formulation: oral

- DSP-6745 is a serotonin 5-HT_{2A} and serotonin 5-HT_{2C} receptors dual antagonist, which is expected to be effective for Parkinson's disease psychosis and one or more Parkinson's disease non-motor symptoms (depression, anxiety, or cognitive impairment). In addition, DSP-6745 has negligible affinity for dopamine D₂ receptors.
- Development stage: Parkinson's disease psychosis: Phase 1 in the U.S.

SEP-378608

Developed in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral

- SEP-378608 is a novel CNS-active molecule discovered using preclinical models phenotypic screening platform. Pre-clinical studies suggest that it may modulate neuronal activity in key areas of brain associated with the regulation of mood.
- Development stage: Bipolar disorder: Phase 1 in the U.S.

DSP-3905

Developed in-house, Formulation: oral

- DSP-3905 is an agent that selectively inhibits voltage-gated sodium channels Nav1.7. Based on its inhibitory mode of action, the agent is expected to show a potent analgesic effect on the pain occurring when neurons get excessively excited. In addition, DSP-3905, which has a high selectivity for Nav1.7 expressed in peripheral neuron, is expected not to produce central nervous system or cardiovascular system side effects, which are present with the current drugs for neuropathic pain.
- Development stage: Neuropathic pain: Phase 1 in the U.S.

2. Oncology**napabucasin (BBI608)**

Developed in-house (Boston Biomedical, Inc.), Formulation: oral

- BBI608 is an orally administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways by targeting STAT3. By inhibiting pathways involved in the maintenance of cancer stemness, it may provide a new therapeutic option against the challenges in cancer treatment such as treatment resistance, recurrence and metastasis. BBI608 has been shown to inhibit STAT3 pathways, Nanog pathways and β -catenin pathways in pre-clinical studies.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 3	Colorectal cancer (combination therapy)	U.S., Japan	FOLFIRI ^{*3} , FOLFIRI ^{*3} + bevacizumab	CanStem303C
	Pancreatic cancer (combination therapy)	U.S., Japan	gemcitabine + nab-paclitaxel	CanStem111P
Phase 2	Colorectal cancer (combination therapy)	U.S.	cetuximab, panitumumab, capecitabine	224
Phase 1 / 2	Solid tumors ^{*1} (combination therapy)	U.S.	paclitaxel	201
	Malignant pleural mesothelioma ^{*2} (combination therapy)	Japan	cisplatin + pemetrexed	D8807005
	Hepatocellular carcinoma ^{*2} (combination therapy)	U.S.	sorafenib	HCC-103
	Glioblastoma (combination therapy)	Canada	temozolomide	251
	Solid tumors (combination therapy)	U.S.	ipilimumab, pembrolizumab, nivolumab	201CIT
Phase 1	Gastrointestinal cancer (combination therapy)	U.S., Canada	FOLFOX ^{*3} , FOLFOX ^{*3} + bevacizumab, CAPOX ^{*3} , FOLFIRI ^{*3} , FOLFIRI ^{*3} + bevacizumab, regorafenib, irinotecan	246
	Pancreatic cancer (combination therapy)	U.S.	gemcitabine + nab-paclitaxel, FOLFIRINOX ^{*3} , FOLFIRI ^{*3} , irinotecan liposome injection + fluorouracil + leucovorin	118
	Hematologic malignancies (monotherapy / combination therapy)	U.S.	dexamethasone, bortezomib, imatinib, Ibrutinib	103HEME
	Solid tumors (combination therapy)	U.S.	amcasertib	401-101

*1 Phase 2 stage: Ovarian cancer, Breast cancer, Melanoma, etc.

*2 Phase 2 stage

- *3 FOLFOX: Combination therapy with fluorouracil, leucovorin, oxaliplatin
- CAPOX: Combination therapy with capecitabine, oxaliplatin
- FOLFIRI: Combination therapy with fluorouracil, leucovorin, irinotecan
- FOLFIRINOX: Combination therapy with fluorouracil, leucovorin, irinotecan, oxaliplatin

amcasertib (BBI503) Developed in-house (Boston Biomedical, Inc.), Formulation: oral

- BBI503 is an orally administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways, including Nanog, by targeting stemness kinases. By inhibiting pathways involved in the maintenance of cancer stemness, it may provide a new therapeutic option against the challenges in cancer treatment such as treatment resistance, recurrence and metastasis. BBI503 has been shown to inhibit multiple kinases in pre-clinical studies.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 2	Hepatocellular carcinoma, Cholangiocarcinoma (monotherapy)	Canada	-	205b
	Gastrointestinal stromal tumor (monotherapy)	Canada	-	205c
Phase 1 / 2	Solid tumors* (monotherapy)	U.S.	-	101
	Hepatocellular carcinoma (combination therapy)	U.S.	sorafenib	HCC-103
	Solid tumors (combination therapy)	U.S.	capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel, sunitinib	201
Phase 1	Solid tumors (monotherapy), Hepatocellular carcinoma (combination therapy)	Japan	sorafenib	DA101003
	Solid tumors (combination therapy)	U.S.	napabucasin	401-101

* Phase 2 stage: Colorectal cancer, Head and neck cancer, Ovarian cancer, etc.

alvocidib (DSP-2033) In-licensed from Sanofi S.A., Formulation: injection

- Alvocidib is a small molecule inhibitor of cyclin-dependent kinase 9 (CDK9), a member of cyclin-dependent kinase family, which activates transcription of cancer-related genes. The subsequent down-regulation of MCL-1, an anti-apoptotic gene, may be responsible for the potential clinical anti-cancer activity observed with alvocidib.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 2	Acute myeloid leukemia (AML) (combination therapy) (refractory or relapsed patients)	U.S.	cytarabine, mitoxantrone	TPI-ALV-201
Phase 1	Acute myeloid leukemia (AML) (combination therapy) (newly diagnosed patients)	U.S.	cytarabine, daunorubicin	TPI-ALV-101
	Acute myeloid leukemia (AML) (combination therapy) (newly diagnosed and refractory or relapsed patients)	Japan	newly diagnosed: cytarabine, daunorubicin refractory or relapsed : cytarabine, mitoxantrone	DC850101
	Acute myeloid leukemia (AML) (combination therapy) (refractory or relapsed patients)	U.S.	venetoclax	M16-186*

* Co-development with AbbVie

adegramotide/nelatimotide (DSP-7888)

Developed in-house, Formulation: injection

- DSP-7888 is a therapeutic cancer peptide vaccine derived from Wilms' tumor gene 1 (WT1) protein. DSP-7888 is a vaccine containing peptides that induces WT1-specific cytotoxic T lymphocytes (CTLs) and helper T cells. DSP-7888 is expected to become a treatment option for patients with various types of hematologic malignancies and solid tumors that express WT1, by inducing WT1-specific CTLs that attack WT1-expressing cancer cells. By adding a helper T cell-inducing peptide, improved efficacy over that observed with a CTL-inducing peptide alone may be achieved. DSP-7888 is expected to be an option for a wide range of patients.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 2	Glioblastoma (combination therapy)	U.S., Japan	Bevacizumab	BBI-DSP7888-201G
Phase 1/2	Myelodysplastic syndromes * (MDS) * (monotherapy)	Japan	-	DB650027
	Pediatric malignant gliomas * (monotherapy)	Japan	-	DB601001
Phase 1	Solid tumors, Hematologic malignancies (monotherapy)	U.S.	-	BBI-DSP7888-101
	Solid tumors (combination therapy)	U.S.	nivolumab, atezolizumab	BBI-DSP7888-102CI

* Phase 2 stage

TP-0903

Developed in-house (Tolero Pharmaceuticals, Inc.), Formulation: oral

- TP-0903 is an AXL receptor tyrosine kinase inhibitor, which is known to be involved in acquiring resistance to conventional agents and developing metastatic capacity in cancer cells. TP-0903 may have anti-cancer activities on various cancer types through blocking transition from epithelial to mesenchymal phenotype by inhibiting AXL. TP0903 has been shown to inhibit AXL signaling and reverse the mesenchymal to epithelial phenotype in pre-clinical studies.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

DSP-0509

Developed in-house, Formulation: injection

- DSP-0509 is a novel Toll-Like receptor (TLR) 7 agonist. DSP-0509 may promote the cytokine induction and cytotoxic T lymphocyte (CTL) activation mediated by agonistic effect of TLR 7 expressing in plasmacytoid dendritic cell. Furthermore, DSP-0509 is expected to sustain the immune-mediated anti-cancer activity by induction of immune system memory T cells.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

TP-0184

Developed in-house (Tolero Pharmaceuticals, Inc.), Formulation: oral

- TP-0184 inhibits ALK2 (activin receptor-like kinase-2), a member of the bone morphogenetic protein (BMP) receptors. Mutations in the ALK2 gene have been identified in various tumors, including diffuse intrinsic pontine glioma (DIPG; one of common pediatric brain tumors). TP-0184 has been shown to inhibit the growth of tumors harboring ALK2 mutations in the pre-clinical studies.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

DSP-0337

Developed in-house, Formulation: oral

- DSP-0337 is a small molecule oral prodrug of napabucasin to inhibit cancer stemness pathways by targeting STAT3. DSP-0337 is expected to be stable and dispersed in stomach, and converted to napabucasin in intestine, which may be absorbed and exert its pharmacologic activities.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

3. Regenerative medicine / cell therapy

SB623 In-licensed from and co-developed with SanBio, Inc., Formulation: injection

- SB623 is an allogeneic cell product, derived from bone marrow stromal cells isolated from healthy donors. SB623 is expected to be effective for chronic stroke that has no effective treatments available, by promoting regeneration of central nerve cells. Unlike autologous cell therapies that require individualized cell preparation at the clinical site, SB623 production can be scaled up from a single donor's cells, enabling delivery of uniform-quality products to a large number of stroke patients.
- Development stage: Chronic stroke: Phase 2 in the U.S.

Allo iPS cell-derived products

- In cooperation with the collaboration of university and academia, we are promoting regenerative medicine / cell therapy business using allo iPS cell (healthy patients) for AMD (age-related macular degeneration), Parkinson's disease, retinitis pigmentosa, and spinal cord injury.
- Development stage:

Development code	Partnering	Proposed indication	Area	Development stage
HLCR011	RIKEN, Healios	Age-related macular degeneration (AMD)	Japan	Preparing for start to clinical study
-	Kyoto University CiRA	Parkinson's disease	Japan	Preparing for start to clinical study (Investigator-initiated)

4. Others

Imeglimin (PXL008) In-licensed from and co-developed with Poxel SA, Formulation: oral

- Imeglimin is the first clinical candidate in a new chemical class of oral agents called the Glimins by the World Health Organization. Imeglimin has a unique mechanism of action that targets mitochondrial bioenergetics. Imeglimin acts on all three key organs which play an important role in the treatment of type 2 diabetes: the liver, muscles, and the pancreas, and it has demonstrated glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity and suppressing gluconeogenesis.
- Development stage: Type 2 diabetes: Phase 3 in Japan (Co-development with Poxel)

DSP-6952 (minesapride) Developed in-house, Formulation: oral

- DSP-6952 is an enterokinetic agent with a high affinity for serotonin 5-HT4 receptor where it has partial agonist effects. DSP-6952 is expected to be effective for IBS with constipation and chronic idiopathic constipation by increasing complete spontaneous bowel movement.
- Development stage: IBS with constipation, Chronic idiopathic constipation : Phase 2 in Japan