

Supplementary Financial Data
for the Third Quarter of the Year Ending March 31, 2011

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February 3, 2011

Dainippon Sumitomo Pharma Co., Ltd.

- Forecasts provided in this document are based on the management's assumptions and beliefs, made in light of information available up to the day of announcement. Actual financial results may differ materially from those presented in this document, being dependent upon a number of factors.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

I. Consolidated Financial Highlights

I. Highlights of the Statements of Income

(Billions of yen)

	Nine months ended 12/31/09	Nine months ended 12/31/10	Change (%)	Year ended	Change (%)	Year ending	Change (%)
				3/31/10		3/31/11 (Forecasts)*3	
Net sales	203.8	280.8	37.8	296.3	12.2	365.0	23.2
Cost of sales	79.1	83.7	5.9	112.3	8.2	108.5	(3.4)
SG&A expenses	92.7	170.0	83.4	148.4	14.9	234.5	58.0
SG&A expenses less R&D costs	57.0	123.7	116.9	97.0	27.1	170.5	75.8
R&D costs	35.7	46.3	29.9	51.4	(2.7)	64.0	24.6
Operating income	32.0	27.1	(15.4)	35.6	14.3	22.0	(38.2)
Ordinary income	31.8	26.2	(17.6)	33.8	7.8	19.5	(42.4)
Net income	21.2	14.8	(30.1)	21.0	4.9	11.0	(47.5)

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.

2: Change (%) represent ratio of changes from the corresponding period of the previous year.

3: Forecasts released on October 29, 2010 are revised.

EBITDA (Billions of yen)	40.1	64.0	56.4	69.5
Earnings per share (yen)	53.24	37.22	52.75	27.69
Return on equity (ROE)	6.4%	4.4%	6.3%	3.3%
Payout ratio	25.4%	36.3%	34.1%	65.0%

2. Financial Results of U.S. Subsidiary

(1) Excluding Impact of Valuations and Accounting Procedures

(Billions of yen)

	Nine months ended 12/31/10	Oct-Dec 2010 (Unaudited)	Jan-Dec 2010 (Unaudited)
Net sales	91.8	30.3	122.1
Cost of sales	9.0	3.5	12.6
SG&A expenses	60.4	25.9	86.3
SG&A expenses less R&D costs	44.0	19.4	63.4
R&D costs	16.4	6.5	22.9
Operating income	22.4	0.9	23.3
Ordinary income	22.8	0.6	23.4
Net income	14.3	1.3	15.5

(2) Impact of Valuations and Accounting Procedures

(Billions of yen)

	Nine months ended 12/31/10	Oct-Dec 2010 (Unaudited)	Jan-Dec 2010 (Unaudited)
Net sales	—	—	—
Cost of sales	3.4	(0.1)	3.3
SG&A expenses	24.0	7.4	31.4
Operating income	(27.4)	(7.4)	(34.7)
Ordinary income	(27.4)	(7.4)	(34.7)
Extraordinary loss	2.2	—	2.2
Net income	(19.7)	(5.0)	(24.6)

3. Currency Exchange Rates

(Billions of yen)

	FY2009 Nine months ended average rate	FY2010 Nine months ended average rate	FY2010 average rate		Forex sensitivity (2010 Jan-Dec) (Impact of yen strength by 1yen/\$)	
			Oct-Dec	Jan-Dec	Sales	Operating income
Yen / USD	95	89	83	88	(1.3)	
Yen / RMB	14	13	12	13		0.2

4. Capital Expenditures and Depreciation

(Billions of yen)

	Nine months ended 12/31/09	Nine months ended 12/31/10	Change	Year ended 3/31/10	Year ending 3/31/11 (Forecasts)	Change
Capital expenditures (including intangible assets)	3.9	5.9	1.9	6.5	13.5	7.0
Depreciation and amortization	7.8	8.8	1.0	11.0	13.5	2.5

Note: Excluding the depreciation associated with acquisition of Sunovion Pharmaceuticals Inc.

II. Consolidated Statements of Income

1. Statements of Income

(Billions of yen)

	Nine months ended 12/31/09 (A)	Nine months ended 12/31/10 (B)	(B)-(A)	Change (%)	Breakdown of (B)-(A)	
					U.S. Subsidiaries	Except U.S. Subsidiaries
Net sales	203.8	280.8	77.1	37.8	88.5	(11.4)
Overseas sales	16.1	106.6	90.5	562.1	88.5	2.0
[% of net sales]	[7.9%]	[38.0%]				
Cost of sales	79.1	83.7	4.7	5.9	12.4	(7.7)
Gross profit	124.7	197.1	72.4	58.1	76.1	(3.7)
SG&A expenses	92.7	170.0	77.3	83.4	81.0	(3.7)
Labor costs	25.5	50.5	25.0	97.8	24.3	0.7
Advertising and promotion costs	3.0	10.8	7.9	266.0	8.3	(0.4)
Sales promotion costs	8.1	9.7	1.7	20.6	2.0	(0.4)
Other costs	20.5	52.7	32.2	156.9	33.4	(1.2)
SG&A expenses less R&D costs	57.0	123.7	66.6	116.9	68.0	(1.3)
R&D costs	35.7	46.3	10.7	29.9	13.1	(2.4)
Operating income	32.0	27.1	(4.9)	(15.4)	(4.9)	0.0
Non-operating income	1.9	2.6	0.7		0.8	(0.1)
Non-operating expenses	2.1	3.5	1.4		0.4	1.0
Ordinary income	31.8	26.2	(5.6)	(17.6)	(4.6)	(1.1)
Extraordinary loss	—	2.2	2.2		2.2	—
Impairment loss	—	2.2	2.2		2.2	—
Income before income taxes and minority interests	31.8	24.0	(7.8)	(24.6)	(6.8)	(1.1)
Income taxes	10.6	9.2	(1.5)		(1.4)	(0.1)
Minority interests in net income	0.0	—	(0.0)		—	(0.0)
Net income	21.2	14.8	(6.4)	(30.1)	(5.4)	(1.0)

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.

2: Overseas sales includes the sales of export.

(Reference) Statements of Income (Non-Consolidated) (Billions of yen)

	Nine months ended 12/31/09 (A)	Nine months ended 12/31/10 (B)	Change (%)	Group-to- parent ratio
Cost of sales	70.0	54.0	(22.9)	
SG&A expenses	88.7	83.9	(5.5)	
SG&A expenses less R&D costs	53.1	50.9	(4.1)	
R&D costs	35.6	33.0	(7.4)	
Operating income	31.3	32.2	3.0	0.84
Ordinary income	31.2	31.0	(0.6)	0.84
Net income	20.3	20.1	(0.9)	0.73
Earnings per share (yen)	51.14	50.70		

2. Segment Information (Nine months ended 12/31/10)

(Billions of yen)

	Pharmaceuticals Segment						Others	Total
	Japan	U.S.*1	Impact of purchase price allocation*2	China	Elimination	Total		
Net sales	158.6	91.8	—	4.6	(8.7)	246.3	34.5	280.8
Sales to customers	153.6	88.5	—	4.1	—	246.2	34.6	280.8
Intersegment	5.0	3.4	—	0.5	(8.7)	0.1	(0.1)	—
Cost of sales	44.2	9.0	3.4	1.5	(2.1)	56.0	27.8	83.7
Gross profit	114.5	82.8	(3.4)	3.0	(6.6)	190.3	6.7	197.1
SG&A expenses	82.6	60.4	24.0	1.8	(3.9)	164.9	5.1	170.0
SG&A expenses less R&D costs	49.8	44.0	24.0	1.8	(0.5)	119.2	4.5	123.7
R&D costs	32.7	16.4	—	—	(3.4)	45.8	0.5	46.3
Operating income	31.9	22.4	(27.4)	1.2	(2.8)	25.4	1.7	27.1

Notes: *1: Excluding the impact of purchase price allocation by acquisition of Sunovion Pharmaceuticals Inc.

*2: Mainly amortization of patent rights and goodwill

(Reference) Segment Information (Year ending 3/31/11 forecasts)

(Billions of yen)

	Pharmaceuticals Segment						Others	Total
	Japan	U.S.*1	Impact of purchase price allocation*2	China	Elimination	Total		
Net sales	203.9	122.1	—	6.0	(11.4)	320.6	44.4	365.0
Sales to customers	197.1	117.9	—	5.4	—	320.4	44.6	365.0
Intersegment	6.8	4.3	—	0.6	(11.4)	0.2	(0.2)	—
Cost of sales	57.9	12.6	3.3	2.1	(2.7)	73.2	35.3	108.5
Gross profit	146.0	109.6	(3.3)	3.9	(8.7)	247.4	9.1	256.5
SG&A expenses	112.1	86.3	31.4	2.9	(5.2)	227.5	7.0	234.5
SG&A expenses less R&D costs	67.4	63.4	31.4	2.9	(0.7)	164.4	6.1	170.5
R&D costs	44.7	22.9	—	—	(4.5)	63.1	0.9	64.0
Operating income	33.9	23.3	(34.7)	1.0	(3.5)	19.9	2.1	22.0

Notes: *1: Excluding the impact of purchase price allocation by acquisition of Sunovion Pharmaceuticals Inc.

*2: Mainly amortization of patent rights and goodwill

*3: Forecasts released on October 29, 2010 are revised.

(Reference) Segment Information (Nine months ended 12/31/09)

(Billions of yen)

	Pharmaceuticals Segment				Others	Total
	Japan	China	Elimination	Total		
Net sales	156.7	3.3	(1.4)	158.7	45.1	203.8
Cost of sales	41.1	1.0	(0.9)	41.2	37.8	79.1
Gross profit	115.6	2.3	(0.5)	117.4	7.2	124.7
SG&A expenses	86.6	1.4	(0.4)	87.6	5.1	92.7
Operating income	29.1	0.9	(0.1)	29.8	2.2	32.0

3. Sales of Pharmaceuticals Segment (Sales to customers)

(Billions of yen)

	Nine months ended 12/31/09(A)	Nine months ended 12/31/10 (B)	(B)-(A)	Change (%)	Progress (%)	Year ended 3/31/10	Year ending 3/31/11 (Forecasts)
Japan	155.7	153.6	(2.1)	(1.3)	78.0	204.0	[197.3] 197.1
Domestic	143.0	139.9	(3.1)	(2.2)	78.0	184.2	[179.4] 179.2
Export	12.8	13.8	1.0	8.1	77.0	19.8	17.9
U.S.	—	88.5	88.5	—	75.0	28.6	[117.0] 117.9
China	2.9	4.1	1.1	38.3	75.5	4.1	[5.7] 5.4

Overseas Sales Total

Overseas sales (Pharmaceuticals)	15.7	106.3	90.6	577.3	75.3	52.6	[140.6] 141.2
% of net sales (Pharmaceuticals)	9.9%	43.2%				22.2%	44.1%

4. Sales of Major Products

Pharmaceuticals (Domestic)

(Billions of yen)

Brand name (Generic name) Therapeutic indication	Nine months ended 12/31/09(A)	Nine months ended 12/31/10 (B)	(B)-(A)	Change (%)	Progress (%)	Year ended 3/31/10	Year ending 3/31/11 (Forecasts)
AMLODIN [®] (amlodipine) Therapeutic agent for hypertension and angina pectoris	41.6	32.7	(8.9)	(21.3)	81.9	52.0	[39.5] 40.0
GASMOTIN [®] (mosapride citrate) Gastroprokinetic	16.2	16.0	(0.1)	(0.8)	78.6	20.7	20.4
PRORENAL [®] (limaprost alfadex) Vasodilator	12.1	11.5	(0.6)	(4.8)	76.9	15.4	[15.5] 15.0
MEROPEN [®] (meropenem) Carbapenem antibiotic	11.6	9.9	(1.8)	(15.2)	81.5	14.7	[11.6] 12.1
LONASEN [®] (blonanserin) Antipsychotic	4.7	6.8	2.1	44.2	71.7	6.3	[10.5] 9.5
AVAPRO [®] (irbesartan) Therapeutic agent for hypertension	2.4	6.1	3.7	149.7	76.2	3.7	8.0
EBASTEL [®] (ebastine) Antiallergic	6.4	5.0	(1.4)	(22.3)	68.4	9.2	7.3
REPLAGAL [®] (agalsidase alfa) Anderson-Fabry disease drug	1.7	4.4	2.8	164.8	74.1	2.5	[5.0] 6.0
SUMIFERON [®] (interferon-α NAMALWA) Natural alpha interferon	4.5	4.0	(0.6)	(13.0)	74.7	5.8	5.3
AmBisome [®] (amphotericin B) Therapeutic agent for systemic fungal infection	3.1	3.5	0.5	15.1	72.0	4.0	4.9
MELBIN [®] (metformin) Oral hypoglycemic	3.0	3.4	0.4	12.0	79.9	3.9	4.2
EXCEGRAN [®] (zonisamide) Antiepileptic	2.8	2.7	(0.1)	(4.6)	79.3	3.6	3.4
DOPS [®] (droxidopa) Neural function ameliorant	2.8	2.6	(0.2)	(8.7)	78.8	3.6	3.3
QVAR [™] (beclomethasone dipropionate) Bronchial asthma	2.3	2.2	(0.1)	(3.0)	88.5	3.0	2.5
GLIMICRON [®] (gliclazide) Oral hypoglycemic	2.6	2.2	(0.4)	(16.0)	74.9	3.2	2.9
ALMARL [®] (arotinolol) Therapeutic agent for hypertension, angina pectoris and arrhythmia	2.2	2.0	(0.2)	(9.8)	80.5	2.8	2.5
LULLAN [®] (perospirone) Antipsychotic	2.0	1.9	(0.1)	(5.3)	73.8	2.6	2.6
SEDIEL [®] (tandospirone) Serotonin-agonist antianxiety drug	2.0	1.8	(0.2)	(9.5)	76.4	2.5	2.4

Note: Figures in parentheses [] are forecasts released on October 29, 2010.

Pharmaceuticals (Domestic, New Products)

(Billions of yen)

Brand name (Generic name) Therapeutic indication	Nine months ended 12/31/09(A)	Nine months ended 12/31/10 (B)	(B)-(A)	Change (%)	Progress (%)	Year ended 3/31/10	Year ending 3/31/11 (Forecasts)
TRERIEF [®] (zonisamide) Parkinson's disease drug (Launch: March, 2009)	0.6	2.7	2.1	350.1	78.6	0.8	3.4
MIRIPLA [®] (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma (Launch: January, 2010)	—	1.2	1.2	—	78.9	0.2	1.5
METGLUCO [®] (metformin) Oral hypoglycemic (Launch: May, 2010)	—	0.2	0.2	—	54.3	—	0.3

Pharmaceuticals (Export)

(Billions of yen)

MEROPEN [®] (meropenem) Carbapenem antibiotic	10.1	10.5	0.4	4.4	77.2	15.7	13.6
GASMOTIN [®] (mosapride citrate) Gastroprokinetic	0.8	1.0	0.2	22.2	90.3	1.1	1.1
EXCEGRAN [®] (zonisamide) Antiepileptic	0.4	1.3	0.9	247.1	78.2	0.6	1.6
Industrial property revenues	1.4	0.9	(0.5)	(36.1)	67.4	2.2	1.3

Note: Sales to customers

U.S.

(Billions of yen)

LUNESTA [®] (eszopiclone) Sedative hypnotic	—	41.7	41.7	—	77.3	10.5	[52.8] 53.9
XOPENEX [®] (levalbuterol HCl) Short-acting beta-agonist	—	27.4	27.4	—	71.4	13.6	38.4
BROVANA [®] (arformoterol tartrate) Long-acting beta-agonist	—	6.9	6.9	—	74.3	1.7	9.3
OMNARIS [®] (ciclesonide) Corticosteroid nasal spray	—	3.6	3.6	—	75.3	0.6	[4.9] 4.8
Industrial property revenues	—	5.3	5.3	—	77.5	1.5	6.8

China

(Billions of yen)

MEROPEN [®] (meropenem) Carbapenem antibiotic	2.7	3.7	1.0	35.5	74.9	3.8	[5.2] 4.9
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Note: Figures in parentheses [] are forecasts released on October 29, 2010.

(Reference) Business Results of U.S. Subsidiary (based on local currency)

(1) Excluding Impact of Valuations and Accounting Procedures (Millions of dollar)

	Jan-Sep 2010	Oct-Dec 2010 (Unaudited)	Jan-Dec 2010 (Unaudited)
Net sales	1,027	364	1,391
Cost of sales	101	42	143
SG&A expenses	674	309	983
SG&A expenses less R&D costs (Excluding depreciation of patent rights)	490	232	722
R&D costs	184	77	261
Operating income	252	13	265
Ordinary income	256	10	267
Net income	161	16	177

(2) Impact of Valuations and Accounting Procedures

(Millions of dollar)

	Jan-Sep 2010	Oct-Dec 2010 (Unaudited)	Jan-Dec 2010 (Unaudited)
Net sales	—	—	—
Cost of sales	38	0	38
SG&A expenses	268	90	358
Operating income	(306)	(90)	(396)
Ordinary income	(306)	(90)	(396)
Extraordinary loss	25	—	25
Net income	(220)	(61)	(281)

(3) Sales of Products

(Millions of dollar)

Brand name (Generic name) Therapeutic indication	Jan-Sep 2010	Oct-Dec 2010 (Unaudited)	Jan-Dec 2010 (Unaudited)
LUNESTA [®] (eszopiclone) Sedative hypnotic	466	148	614
XOPENEX [®] (levalbuterol HCl) Short-acting beta-agonist	307	131	437
BROVANA [®] (arformoterol tartrate) Long-acting beta-agonist	77	28	105
OMNARIS [®] (ciclesonide) Corticosteroid nasal spray	40	14	54
Industrial property revenues	59	19	78
Others	78	25	103
Total	1,027	364	1,391

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of 3/31/10 (A)	As of 12/31/10 (B)	(B)-(A)	
[Assets]	626.7	588.2	(38.5)	
Current assets:	287.6	313.2	25.7	
Cash and time deposits	13.8	10.3	(3.6)	
Notes and accounts receivable	94.0	100.5	6.5	
Marketable securities	51.2	80.9	29.7	• Transfer from investment securities • Increase in short-term operating funds
Inventories	65.2	59.6	(5.7)	• Decrease in inventories added according to accounting for business combinations
Deferred tax assets	32.4	32.2	(0.2)	
Short-term loans	25.0	25.0	—	
Others	6.1	5.0	(1.1)	
Allowance for doubtful receivables	(0.2)	(0.1)	0.1	
Fixed assets:	339.2	275.0	(64.2)	
Property, plant and equipment:	74.1	71.0	(3.1)	
Buildings and structures	43.0	42.2	(0.8)	
Machinery, equipment and carriers	12.8	12.0	(0.8)	
Land	10.3	10.3	(0.0)	
Construction in progress	2.7	1.4	(1.3)	
Others	5.3	5.1	(0.2)	
Intangible assets:	199.5	154.1	(45.3)	
Goodwill	83.6	73.3	(10.3)	• Decrease by amortization • Decrease in yen amounts by yen strength
Patent rights	104.0	69.2	(34.9)	
Others	11.9	11.7	(0.2)	
Investments and other assets:	65.6	49.9	(15.7)	
Investment securities	53.2	35.1	(18.1)	• Transfer to marketable securities • Decrease by revaluation of investment securities
Deferred tax assets	2.4	4.8	2.4	
Others	10.2	10.1	(0.0)	
Allowance for doubtful receivables	(0.1)	(0.1)	(0.0)	
Total assets	626.7	588.2	(38.5)	

Accounts receivable turnover period (in months)	Year ended 3/31/10	Nine months ended 12/31/10
	3.81	3.22

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of 3/31/10 (A)	As of 12/31/10 (B)	(B)-(A)
[Liabilities]	283.3	259.8	(23.5)
Current liabilities:	265.0	197.6	(67.4)
Notes and accounts payable	16.9	16.8	(0.1)
Short-term loans payable	165.5	100.0	(65.5)
Current portion of long-term loans payable	0.3	10.6	10.3
Income taxes payable	8.6	5.6	(3.0)
Reserve for bonuses	7.4	3.8	(3.6)
Reserve for sales returns	2.7	2.2	(0.5)
Reserve for sales rebates	15.7	14.7	(1.0)
Accounts payable-other	33.4	26.5	(6.9)
Others	14.5	17.4	2.8
Long-term liabilities:	18.3	62.2	44.0
Long-term loans payable	0.6	45.5	44.9
Liability for retirement benefits	9.8	10.2	0.4
Liability for directors' retirement benefits	0.1	0.0	(0.0)
Others	7.8	6.5	(1.3)
[Net assets]	343.5	328.4	(15.0)
Shareholders' equity:	332.3	340.0	7.6
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	—
Retained earnings	294.7	302.3	7.6
Treasury stock	(0.6)	(0.6)	(0.0)
Valuation, translation adjustments and others:	11.2	(11.5)	(22.7)
Unrealized gains on available-for- sale securities, net of tax	7.9	6.1	(1.9)
Foreign currency translation adjustment	3.2	(17.6)	(20.8)
Total liabilities and net assets	626.7	588.2	(38.5)

• Repayment of loans
 • Shift from short-term to long-term

• Impact of yen strength

IV. Quarterly Business Results

(Billions of yen)

	FY2009				FY2010		
	1Q	2Q	3Q	4Q	1Q	2Q	3Q
Net sales	66.0	66.2	71.5	92.5	101.8	86.8	92.2
Cost of sales	25.4	25.9	27.8	33.2	32.6	25.2	25.9
SG&A expenses	29.4	32.6	30.7	55.7	54.4	61.4	54.2
SG&A expenses less R&D costs	17.5	20.2	19.3	40.0	39.9	43.1	40.7
R&D costs	11.9	12.4	11.4	15.7	14.5	18.3	13.5
Operating income	11.2	7.7	13.1	3.6	14.8	0.1	12.1
Non-operating income	1.1	0.3	0.5	0.4	1.1	0.8	0.7
Non-operating expenses	0.5	0.8	0.8	2.0	1.1	1.4	1.0
Ordinary income	11.8	7.2	12.8	2.0	14.8	(0.5)	11.8
Extraordinary loss	—	—	—	2.4	—	—	2.2
Income before income taxes and minority interests	11.8	7.2	12.8	(0.4)	14.8	(0.5)	9.6
Net income	7.8	4.8	8.5	(0.2)	9.3	(0.6)	6.1

Note: Cost of sales includes provision for (reversal of) reserve for sales returns.

VII. Development Pipeline (as of February 3, 2011)

Major Products under Development in Japan

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
Approved (awaiting NHI pricing)	SUREPOST® (SMP-508) Oral	repaglinide	The reduction of postprandial blood glucose in patients with type 2 diabetes	Novo Nordisk	Rapid insulin secretagogue
NDA filed	MEROPEN® Injection	meropenem hydrate	Change of the maximum daily dose from 2g to 3g	In-house	Approved maximum daily dose:2g for patients with severe/refractory infection
Phase III	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Pan-Asia study (Japan, Korea and Taiwan)
	SUREPOST® (SMP-508) Oral	repaglinide	(New Indication) Type 2 diabetes Combination therapy with biguanide Type 2 diabetes Combination therapy with thiazolidine	Novo Nordisk	approved indication: The reduction of postprandial blood glucose in patients with type 2 diabetes
Phase II	AS-3201 Oral	ranirestat	Diabetic neuropathy	In-house	Co-developed with Kyorin Pharmaceutical
	DSP-8153 Oral	amlodipine besilate / irbesartan	Hypertension	In-house	Combination product
	SMP-986 Oral	TBD	Overactive bladder	In-house	
Phase I/II	WT4869 Injection	TBD	Myelodysplastic syndromes	In-house (with Chugai Pharmaceutical)	Co-developed with Chugai Pharmaceutical
Phase I	DSP-3235 Oral	TBD	Diabetes	Kissei Pharmaceutical	SGLT1 inhibitor
	DSP-3025 Intranasal	TBD	Bronchial asthma, Allergic rhinitis	In-house	TLR7 agonist

[Main revisions since the announcement of Oct. 2010]

SUREPOST® (repaglinide)

Changed from “NDA filed” to “Approved (awaiting NHI pricing)”

<Approved in Jan.2011>

WT4869

Newly added in Phase I/II

SMP-028

Deleted due to discontinuation of development for bronchial asthma

Major Products under Development in Foreign Markets

Stage	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Country/Area	Remarks
Approved	LATUDA [®] Oral	lurasidone hydrochloride	Schizophrenia	In-house	U.S.	Approved in Oct.2010
NDA submitted	STEDESA [™] Oral	eslicarbazepine acetate	Epilepsy-adjunct	BIAL	U.S.	NDA submitted in Mar.2009
Phase III	LATUDA [®] Oral	lurasidone hydrochloride	(New Indication) Bipolar depression	In-house	U.S. and Europe, etc.	approved indication: Schizophreni a
	amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Brand name in Japan: CALSED [®]
	ciclesonide Nasal Aerosol (HFA) Collunarium	ciclesonide	(New Formulation) Allergic rhinitis	Nycomed	U.S.	approved formulation: OMNARIS [®] Nasal Spray, an aqueous solution nasal spray
	STEDESA [™] Oral	eslicarbazepine acetate	Epilepsy-adult monotherapy	BIAL	U.S.	
Phase II	SMP-986 Oral	TBD	Overactive bladder	In-house	U.S. and Europe	
Phase I	DSP-7238 Oral	TBD	Diabetes	In-house	Europe	DPPIV inhibitor
	DSP-8658 Oral	TBD	Diabetes, Alzheimer's disease	In-house	U.S.	PPAR α/γ modulator
	SEP-228432 Oral	TBD	Neuropathic pain, Major depressive disorder (MDD)	In-house (Sunovion)	U.S.	

[Main revisions since the announcement of Oct. 2010]

DSP-8658
ALVESCO[®] HFA

Added Alzheimer's disease in therapeutic indication
Deleted due to discontinuation of new indication development (pediatric)
for asthma

SMP-028

Deleted due to the discontinuation of development for bronchial asthma

Major Products under Development by Licensees

Generic / Product code (Brand name in JPN)	Therapeutic indications	Status of development
AG-7352	Cancer	Out-licensed to Sunesis Pharmaceuticals Inc. for the worldwide territory in October 2003 Phase III study ongoing in North America by Sunesis (Sunesis' product code: SNS-595)
amrubicin hydrochloride (CALSED [®])	Small cell lung cancer	Out-licensed to Celgene (former Pharmion) for the U.S. and European territories in June 2005 Phase III study ongoing in the U.S. and Europe by Celgene
ranirestat AS-3201	Diabetic neuropathy	Out-licensed to Eisai for the worldwide territory, excluding Japan, in September 2005. Phase II / III study ongoing in the U.S., Canada and Europe by Eisai
droxidopa (DOPS [®])	Neurogenic orthostatic hypotension, Intradialytic hypotension, Fibromyalgia	Out-licensed to Chelsea Therapeutics for the worldwide territory, excluding Japan, China, Korea and Taiwan in May 2006. Phase III study of neurogenic orthostatic hypotension in the U.S. and Europe, and phase II study of fibromyalgia in the UK are ongoing by Chelsea. Phase II study of intradialytic hypotension completed in the U.S. by Chelsea.
DSP-3025	Bronchial asthma, Allergic rhinitis	Entered into a development and marketing agreement concluded in March 2005. AstraZeneca has the right for the worldwide territory, excluding Japan, China, Korea and Taiwan. Phase II study is ongoing in Europe by AstraZeneca (AstraZeneca' product code: AZD-8848)
eszopiclone	Insomnia	Out-licensed by Sunovion to Eisai for the Japanese territory in July, 2007. (Brand name in U.S.: LUNESTA [®]) NDA filed in Japan by Eisai

[Main revisions since the announcement of Oct. 2011]

AG-7352
eszopiclone

Changed from "Phase II" to "Phase III"
NDA filed in Japan by Eisai <Filed in Nov. 2010>

VIII. Profile of Major Products under Development (as of February 3, 2011)

SUREPOST® (repaglinide) Diabetes

- In-licensed from Novo Nordisk
- SUREPOST® is a rapid-acting insulin secretagogue that is approved and marketed in over 90 countries worldwide. SUREPOST® binds to the sulfonylurea receptors in the pancreatic beta cells to stimulate the postprandial insulin secretion rapidly, thereby reducing postprandial blood glucose and lowering HbA1c in type 2 diabetes patients.
- Development stage:
The reduction of postprandial blood glucose in patients with type 2 diabetes : Approved (awaiting NHI pricing) in Japan
Type 2 diabetes: (Combination therapy with biguanide) : Phase III in Japan
Type 2 diabetes: (Combination therapy with thiazolidine) : Phase III in Japan

LATUDA® (lurasidone hydrochloride) Schizophrenia, Bipolar depression

- Developed in-house
- LATUDA® (lurasidone hydrochloride) tablets was approved for the treatment of schizophrenia in the United States in October 2010. LATUDA is an atypical antipsychotic agent with 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 or muscarinic receptors. The efficacy of LATUDA for the treatment of schizophrenia was established in four, short-term (6-week), placebo-controlled clinical studies in adult patients who met DSM-IV criteria for schizophrenia. In these studies, LATUDA demonstrated significantly greater improvement versus placebo on the primary efficacy measures [the Positive and Negative Syndrome Scale (PANSS) total score and the Brief Psychiatric Rating Scale-derived from PANSS (BPRSd)] at study endpoint. A total of five clinical trials contributed to the understanding of the tolerability and safety profile of LATUDA. LATUDA was launched in the United States for the treatment of schizophrenia in February 2011.
- Development stage:
Schizophrenia: Phase III as Pan-Asia study (Japan, Korea and Taiwan)
Planning to develop in other countries including Europe by using global Phase III data
Bipolar depression: Phase III in the U.S. and Europe, etc.

STEDESATM (eslicarbazepine acetate) Epilepsy

- In-licensed from BIAL Portela & C^a, S.A
- STEDESA is a novel voltage-gated sodium channel blocker. STEDESA has been studied in Phase III, multi-center, randomized, placebo-controlled studies, which involved patients from over 20 countries. Patients involved in the studies were required to have at least four partial-onset seizures per month despite treatment with one to three concomitant antiepileptic drugs. After a two-week titration period, patients were assessed over a 12-week maintenance period with continued follow-up over a one-year, open-label period. STEDESA is expected to have clear dose-response correlation and marked and sustained seizure reduction with favorable tolerability and safety profiles.
- NDA submitted in March 2009 in the U.S.
- NDA Complete Response received April 2010.
- Sunovion is committed to seeking FDA approval of STEDESA as a once-daily, adjunctive therapy in the treatment of partial-onset seizures in adults with epilepsy in the U.S.

AS-3201 (ranirestat) Diabetic neuropathy

- Developed in-house
- AS-3201 alleviates diabetic neuropathy, a complication of diabetes, by inhibiting aldose reductase and thereby inhibiting the accumulation of intracellular sorbitol that causes diabetic neuropathy. This compound has a stronger inhibitory effect and is longer-acting compared to other drugs in this therapeutic area. Clinical studies have shown AS-3201 to have good penetration into nerve tissues, resulting in dose-dependent inhibition of intraneural accumulation of sorbitol and fructose. Based on the results of clinical studies, AS-3201 is expected to show improvement of neuronal function and symptoms related to diabetic neuropathy.
- AS-3201 was out-licensed to Eisai for the overseas territory in September 2005. Eisai is conducting Phase II / III study in the U.S., Canada and Europe.
- Development stage: Phase IIb in Japan (co-developed with Kyorin Pharmaceutical)

DSP-8153 Hypertension

- Developed in-house
- Combination product of amlodipine besilate (AMLODIN[®]; calcium channel blocker) and irbesartan (AVAPRO[®]; angiotensin II receptor blocker). DSP-8153 is expected to have an antihypertensive activity for the patients with essential hypertension who do not have sufficient antihypertensive effect by irbesartan or amlodipine treatment. In addition, the product is expected to have cerebroprotective, cardioprotective and renoprotective effect for patients with essential hypertension, because irbesartan has renoprotective effect and amlodipine has cerebroprotective and cardioprotective effects.
- Development stage: Phase II in Japan

SMP-986 Overactive bladder

- Developed in-house
- SMP-986 possesses the dual pharmacological actions of muscarinic receptor antagonism (non-selective) and inhibition of the bladder afferent pathway through Na⁺-channel blockade. This compound is expected to ease urinary urgency and reduce the frequency of both urination and incontinence. The compound is also expected to have lower incidence of side effects related to muscarinic receptor antagonism, such as dry mouth.
- Development stage: Phase II in the U.S. and Europe. Phase II in Japan

WT4869 Myelodysplastic syndromes (MDS)

- Developed in-house (Co-developed with Chugai Pharmaceutical)
- WT4869 is applied as a therapeutic cancer vaccine targeting various types of cancer. It is expected that administration of WT4869 will show efficacy in the treatment of leukemia and other types of cancers that express WT1, by inducing WT1-specific cytotoxic T-lymphocytes that have the potential to attack tumor cells. The compound is under development for MDS.
- Development stage: Phase I/II in Japan

DSP-3235 Diabetes

- In-licensed from Kissei Pharmaceutical
- DSP-3235 is a selective inhibitor for an isoform of sodium-dependent glucose cotransporters (SGLT1). It is expected to improve postprandial hyperglycemia by suppressing glucose absorption from the intestine with a novel mechanism of action different from that of conventional alpha-glucosidase inhibitors.
- Development stage: Phase I in Japan

DSP-3025 Bronchial asthma, Allergic rhinitis

- Developed in-house
- An immune response modifier with agonistic activity against Toll-like receptor 7 (TLR7). It is expected to become a therapeutic agent providing long-term disease remission in bronchial asthma and allergic rhinitis.
- A series of promising compounds were identified from drug discovery research for a therapeutic agent with a novel mechanism of action against allergic disorders. With this as a turning point, we started a research collaboration with AstraZeneca in 2004 and discovered a drug candidate as an outcome based on this research collaboration.
- We entered into a development and marketing agreement with AstraZeneca in March 2005. Under the agreement, we will retain development and commercialization rights in Japan, China, Korea and Taiwan and AstraZeneca will retain development and commercialization rights worldwide excluding the four countries. AstraZeneca is conducting Phase II study in Europe. (AstraZeneca' product code: AZD-8848)
- Development stage: Phase I in Japan

DSP-7238 Diabetes

- Developed in-house
- DSP-7238 is a dipeptidyl peptidase IV (DPP IV) inhibitor and improves hyperglycemia through the GLP-1-induced acceleration of insulin secretion. Since DSP-7238 has a selective and strong inhibitory activity for the GLP-1-degrading enzyme DPP IV, it may be a promising DPP IV inhibitor that achieves better glycemic control.
- Development stage: Phase I in Europe

DSP-8658 Diabetes, Alzheimer's disease

- Developed in-house
- DSP-8658 is a novel PPAR α/γ modulator that exhibits potent antihyperglycemic and lipid lowering activity in several animal models.
- Non-clinical studies suggest that DSP-8658 may offer advantages over marketed PPAR γ agonists, particularly with respect to improvements in lipid metabolism and incidence of fluid retention or body weight gain in the treatment of diabetes.
- Also it is expected that DSP-8658 may improve symptomatic cognitive decline and show disease modification with mechanism of reduction in β amyloid by impacting a number of different mechanism in marketed compound.
- Development stage: Phase I in the U.S.

SEP-228432 Neuropathic pain, Major depressive disorder (MDD)

- Developed in-house (Sunovion)
- SEP-228432 is a new triple unbalanced reuptake inhibitor (TRI) that inhibits reuptake of serotonin, norepinephrine and dopamine. The compound is under development for neuropathic pain and MDD in central nervous disorders (CNS) area.
- Development stage: Phase I in the U.S.