Financial Results for FY2010
（ended March 31, 2011 ）

May 12, 2011

Masayo Tada, President and CEO
Dainippon Sumitomo Pharma Co., Ltd.

Financial Results for FY2010

DAINIPPON
SUMITOMO
PHARMA

Financial Results

Billions of yen

	FY2009	FY2010	Change		FY2010	
			Value	Percentage	Forecast (as of May.2010)	Difference
Net sales	296.3	379.5	83.3	28.1 %	354.0	25.5
SG&A expenses	148.4	238.5	90.2	60.8 %	242.5	- 4.0
R&D Costs	51.4	68.2	16.8	32.7 %	67.5	0.7
Operating income	35.6	31.0	- 4.7	- 13.1 %	3.5	27.5
Ordinary income	33.8	28.6	- 5.2	- 15.4 %	1.0	27.6
Net income	21.0	16.8	- 4.2	-19.9 %	0.0	16.8

Note: All values are rounded to the nearest 100 million yen.

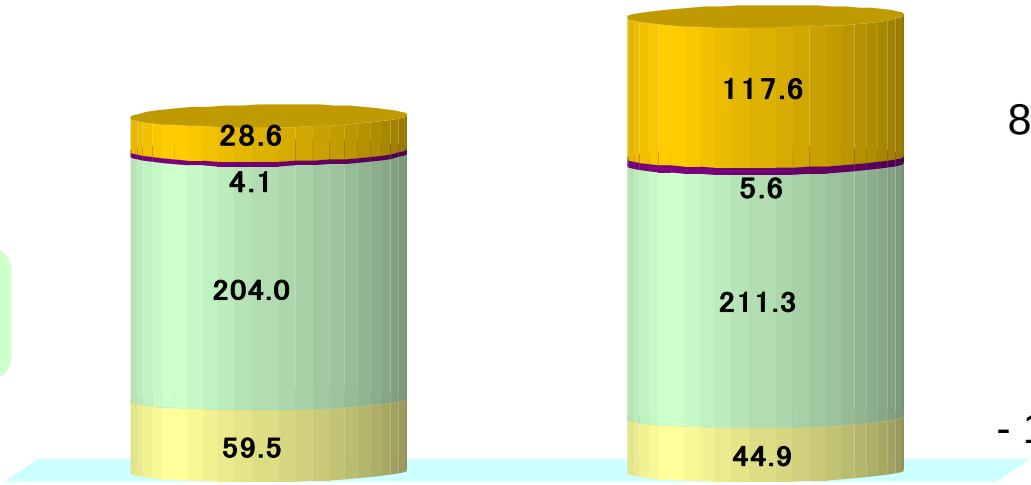
【Main reason of differences from initial forecast】

- Delay of launch of a generic of competitor for a major product of U.S. subsidiary
- The influences of generic of AMLODIN and MEROPEN were below our expectation.
  Increase in sales for REPLAGAL
- Upfront payment revenue regarding out-licensing of lurasidone

Breakdown of Sales

Billions of yen

	FY2009	FY2010	Change	
Net Sales	296.3	379.5	83.3	28.1 %
U.S.	28.6	117.6	89.0	310.7 %
China	4.1	5.6	1.4	34.8 %
Japan（Pharmaceuticals）	204.0	211.3	7.4	3.6 %
Others	59.5	44.9	- 14.6	- 24.5 %
Overseas Sales(%)	**17.9 %**	**40.1 %**		



【Japan (Pharmaceuticals)】

・The influence of NHI price revision was covered by sales increase of strategic products and new products.

・Upfront payment revenue regarding development and commercialization agreement for lurasidone in Europe.

【Others】

・Only the commission equivalent part was recorded as sales on pet foods along with the split of the Animal Health Products business into a separate company.

Sales in Japan（Pharmaceuticals）

Billions of yen

	FY2009	FY2010	Change	
			Value	Percentage
AVAPRO®	3.7	8.3	4.6	122.7 %
LONASEN®	6.3	9.0	2.6	42.0 %
PRORENAL®	15.4	14.9	- 0.4	- 2.9 %
Strategic Products Total	25.4	32.2	6.8	26.7 %
TRERIEF®	0.8	3.7	2.9	367.6 %
MIRIPLA®	0.2	1.5	1.3	530.7 %
METGLUCO® (Including MELBIN®)	3.9	4.7	0.7	19.0 %
New Products Total	4.9	9.9	4.9	99.7 %
AMLODIN®	52.0	41.4	- 10.6	- 20.4 %
GASMOTIN®	20.7	21.0	0.3	1.3 %
MEROPEN®	14.7	12.6	- 2.1	- 14.0 %
AmBisome®	4.0	4.6	0.5	13.3 %
REPLAGAL®	2.5	6.2	3.7	148.5 %
Others	59.9	54.9	- 5.0	- 8.5 %
Export	17.7	17.3	- 0.4	- 2.2 %
Industrial property revenues	2.2	11.3	9.2	422.6 %
Total	204.0	211.3	7.4	3.6 %

Note: Sales figures exclude internal transactions.

Sales in U.S. & China

Billions of yen

	FY2009	FY2010	Change
LUNESTA®	10.5	53.9	43.3
XOPENEX®	13.6	38.4	24.8
BROVANA®	1.7	9.3	7.6
OMNARIS®	0.6	4.8	4.2
ALVESCO®	0.3	2.5	2.2
Industrial property revenues	1.5	6.6	5.1
Others	0.4	2.2	1.8
U.S. Total	28.6	117.6	89.0
MEROPEN®	3.8	5.0	1.2
Others	0.4	0.6	0.2
China Total	4.1	5.6	1.4

Sales figures exclude internal transactions.

Segment Information

FY2010

Billions of yen

	Pharmaceuticals						Other business	Total
	Japan	U.S.*1	Impact of purchase price allocation*2	China	Elimination	Total		
Net sales	217.8	121.9	—	6.1	- 11.1	334.8	44.7	379.5
Sales to customers	211.3	117.6	—	5.6	—	334.6	44.9	379.5
Intersegment	6.5	4.3	—	0.5	- 11.1	0.2	- 0.2	—
Cost of sales	59.0	12.5	3.3	2.1	- 2.8	74.2	35.9	110.0
Gross profit	158.8	109.4	- 3.3	4.0	- 8.3	260.6	8.9	269.5
SG&A expenses	115.4	86.4	31.4	3.2	- 4.8	231.6	6.9	238.5
SG&A expenses	66.7	63.5	31.4	3.1	- 0.4	164.3	6.1	170.4
R&D costs	48.8	22.9	—	0.1	- 4.4	67.4	0.8	68.2
Operating income	43.3	23.0	- 34.7	0.8	- 3.5	29.0	2.0	31.0

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

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

*2: Mainly amortization of patent rights and goodwill.

Financial Results of Japan
(Pharmaceuticals)

Billions of yen

	FY2009		FY2010		Change	
		% of net sales		% of net sales	Value	Percentage
Net Sales	205.3	—	217.8	—	12.5	6.1
Sales to customers	204.0	—	211.3	—	7.4	3.6
Intersegment	1.3	—	6.5	—	5.2	398.6
Cost of Sales	56.0	27.3	59.0	27.1	3.1	5.5
Gross Profit	149.3	72.7	158.8	72.9	9.4	6.3
SG&A expenses	115.0	56.0	115.4	53.0	0.4	0.4
SG&A expenses	67.2	32.7	66.7	30.6	- 0.5	- 0.8
R&D Costs	47.8	23.3	48.8	22.4	1.0	2.0
Operating income	34.3	16.7	43.3	19.9	9.0	26.1

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

（Gross Profit）

・The influence of NHI price revision was covered by increase of sales volume and industrial property revenues.

（R&D costs）

・Increase in cost related to in-licensing, and decrease in the overseas clinical development cost of lurasidone.

DAINIPPON SUMITOMO PHARMA

Ordinary income & Net income

Billions of yen

	FY2009	FY2010	Change	
			Value	Percentage
Operating Income	35.6	31.0	- 4.7	- 13.1 %
Non-operating income and expenses	- 1.8	- 2.3	- 0.5	
Finance income and expenses including dividend income	0.2	- 0.7	- 0.9	
Contributions	- 1.8	- 1.8	0.1	
Others	- 0.2	0.2	0.4	
Ordinary income	33.8	28.6	- 5.2	- 15.4 %
Extraordinary loss	- 2.4	- 3.6	- 1.2	
Impairment loss	—	- 3.2	- 3.2	
Loss on valuation of investment securities	- 0.8	- 0.3	0.5	
Compensation for revision of personnel system	- 1.6	—	1.6	
Income taxes	- 10.5	- 8.3	2.2	
Net income	21.0	16.8	- 4.2	- 19.9 %

Financial Position

Billions of yen

	as of Mar.31,2010	as of Mar.31,2011	Change
Assets	626.7	589.9	- 36.9
Current assets	287.6	333.0	45.4
Fixed assets	339.2	256.9	- 82.3
Liabilities	283.3	265.9	- 17.4
Current liabilities	265.0	157.2	- 107.8
Long-term liabilities	18.3	108.7	90.4
Net assets	343.5	324.0	- 19.5

(Shareholders' equity ratio) 54.8% 54.9%

（**Assets**）
Decrease in patent rights and goodwill ・・・・・・・・・・・・・・・・・・・・・・ 56.2 billion yen
（**Liabilities**）
Decrease in interest-bearing debt ・・・・・・・・・・・・・・・・・・・・・・・・・・ 12.8 billion yen
（**Net Assets**）
Decrease in foreign currency translation adjustment ・・・・・・・・・ 26.5 billion yen

Cash Flows

FY2010 Billions of yen

Ⅰ Net cash provided by operating activities	＋ 55.0
・Income before income taxes and minority interests	＋ 25.0
・Depreciation and amortization	＋ 44.6
・Income taxes paid	- 14.9
Ⅱ Net cash used in investing activities	- 6.6
・Purchase of property, plant and equipment	- 7.1
・Purchase of intangible assets	- 2.0
Ⅲ Net cash used in financing activities	- 20.3
・Net increase (decrease) in short-term loans payable	- 115.5
・Proceeds from long-term loans payable	+ 52.7
・Proceeds from issuance of bonds	+ 49.8
・Cash dividends paid	- 7.1

Cash and cash equivalents at the end of period : 82.9 billion yen
(compared with the beginning of period +24.7 billion yen)

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Financial Forecast for FY2011

DAINIPPON SUMITOMO PHARMA

Major Challenges for FY2011

- Toward the achievement of Mid-term Business Plan -

Five Basic Principles set forth in the Mid-term Business Plan	Major Business Challenges for FY2011
Transform the earnings structure in Japan	・Strengthen our sales base by boosting sales of Strategic Products and New Products ・Maximize sales of CNS drugs under the newly established CNS division
Expand overseas operation and maximize earnings	・Invest in management resources to exploit the full potential of LATUDA® ・Reinforce the global governance and management system
Expand the pipeline for continuous new drug creation	・Select and develop post-LATUDA® candidates ・Strengthen efforts in continuous in-licensing and other alliances
Promote CSR management and continuous increases in management efficiency	・Promote CSR management in DSP and its group companies ・Continue improving operational efficiency globally
Establish a challenging corporate culture and cultivate human resources	・Implement the new HR system steadily ・Put in place the “DSP Ambition”

Financial Forecast for FY2011

Billions of yen

	Results FY2010	Forecast FY2011	Change	
			Value	Percentage
Net sales	379.5	362.0	-17.5	-4.6%
SG&A expenses	238.5	241.2	2.7	1.1%
R&D Costs	68.2	62.0	-6.2	-9.0%
Operating income	31.0	17.0	-14.0	- 45.1%
Ordinary income	28.6	15.5	-13.1	-45.8%
Net income	16.8	8.5	-8.3	-49.4%

EBITDA	78.0	59.5	-18.5	-23.7%

Note: All values are rounded to the nearest 100 million yen.

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Forecast for FY2011 (by Segment)

-Pharmaceuticals Segmentation is changed from FY2011 to reflect profitability of each segment more properly.

-“Others” is added to Pharmaceuticals Segment, including “Export” and “Industrial property revenues (overseas)” which were included in "Japan".

- R&D costs of Pharmaceuticals are not allocated to each segment.

		Pharmaceuticals						Other Business	Total
		Japan	North America*1	Impact of P.P.A*2	China	Other	Total		
Results FY2010	Net sales	183.0	117.6	—	5.7	28.4	334.8	44.7	379.5
	Cost of sales	49.2	12.5	3.3	1.2	8.0	74.2	35.9	110.0
	Gross profit	133.9	105.2	-3.3	4.5	20.4	260.6	8.9	269.5
	SG&A expenses	65.7	63.6	31.4	3.3	0.3	164.3	6.1	170.4
	Segment profit	68.2	41.6	-34.7	1.2	20.1	96.4	2.8	99.1
	R&D costs						67.4	0.8	68.2
	Operating income						29.0	2.0	31.0
Forecast FY2011	Net sales	180.1	115.5	—	7.0	18.1	320.7	41.3	362.0
	Cost of sales	46.2	13.3	—	1.6	10.8	71.9	31.9	103.8
	Gross profit	133.9	102.2	—	5.4	7.3	248.8	9.4	258.2
	SG&A expenses	66.4	72.5	29.7	4.2	0.3	173.1	6.1	179.2
	Segment profit	67.5	29.7	-29.7	1.2	7.0	75.7	3.3	79.0
	R&D costs						61.1	0.9	62.0
	Operating income						14.6	2.4	17.0
Change	Net sales	-2.9	-2.1	—	1.3	-10.3	-14.1	-3.4	-17.5
	Segment profit	-0.7	-11.9	5.0	0.0	-13.1	-20.7	0.5	-20.1
	Operating income						-14.4	0.4	-14.0

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

*1 Excluding impact of purchase price allocation by acquisition

*2 Mainly amortization of patent rights and goodwill

Exchange rate:
Forecast ¥85 to US$1
¥13 to RMB1

Financial Forecast for FY2011
Japan Segment (Pharmaceuticals)

Billions of yen

	Results FY 2010	Forecast FY 2011	Change	
			Value	Percentage
Net sales	183.0	180.1	-2.9	-1.6%
Sales to customers	182.9	179.9	-3.0	-1.6%
Intersegment	0.2	0.2	0.0	0.0%
Cost of sales	26.9% 49.2	25.7% 46.2	-3.0	-6.1%
Gross profit	133.9	133.9	0.0	0.0%
SG&A expenses	65.7	66.4	0.7	1.1%
Segment profit	37.2% 68.2	37.5% 67.5	-0.7	-1.0%

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

Sales and profit remain unchanged from the previous year

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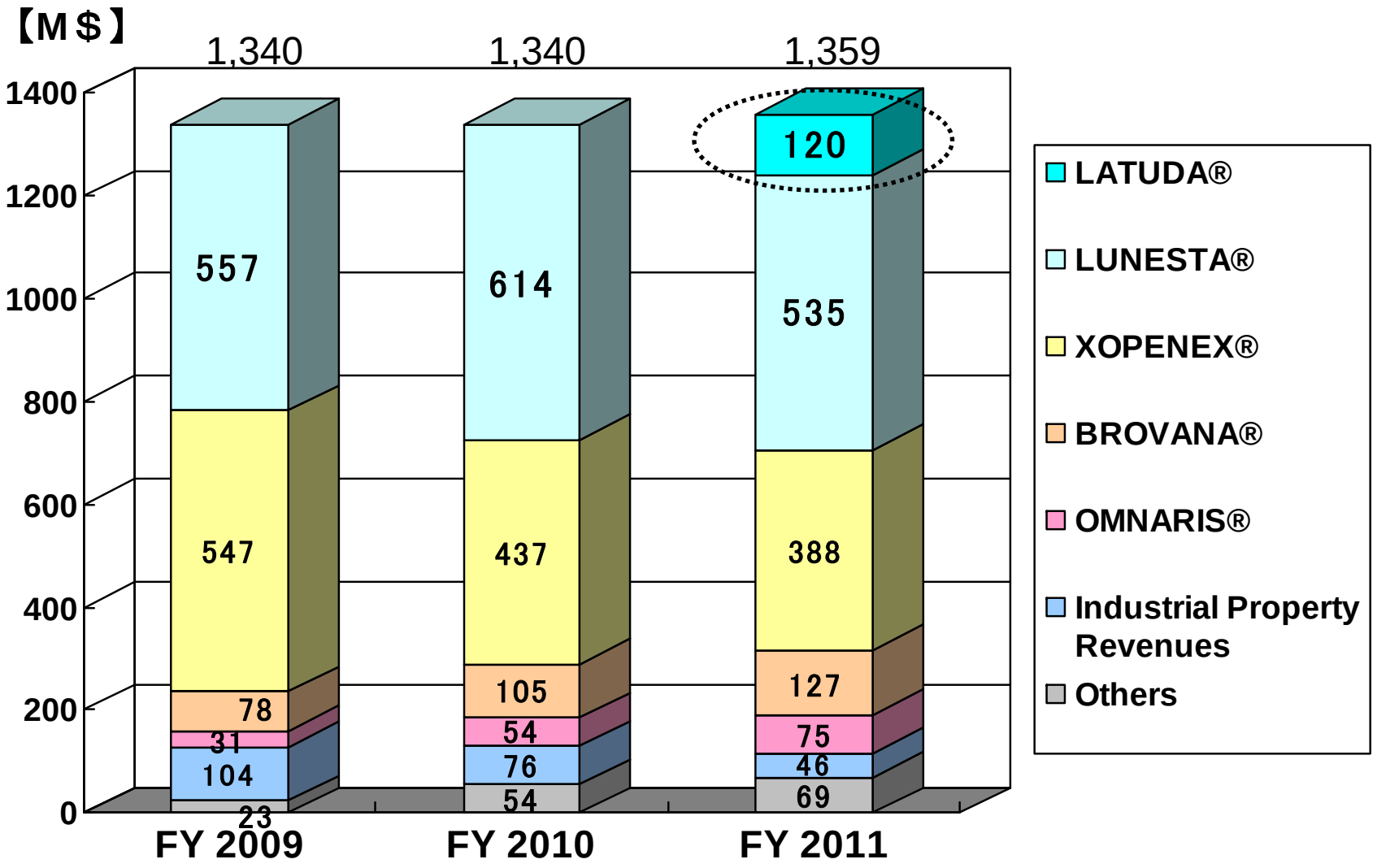
Sales Forecast in Japan (Pharmaceuticals)

Billions of yen

	Results FY2010	Forecast FY2011	Change	
			Value	Percentage
AVAPRO®	8.3	12.0	3.7	44.6 %
LONASEN®	9.0	13.0	4.0	44.4 %
PRORENAL®	14.9	17.0	2.1	14.1 %
Strategic Products Total	32.2	42.0	9.8	30.4 %
TRERIEF®	3.7	4.6	0.9	24.3 %
MIRIPLA ®	1.5	1.7	0.2	13.3 %
METGLUCO® (Including MELBIN ®)	4.7	6.0	1.3	27.7 %
SUREPOST®	—	0.2	0.2	—
New Products Total	9.9	12.5	2.6	26.3 %
AMLODIN®	41.4	31.0	-10.4	- 25.1 %
GASMOTIN®	21.0	21.0	0.0	—
MEROPEN®	12.6	10.0	-2.6	- 20.6 %
AmBisome®	4.6	5.0	0.4	8.7 %
REPLAGAL®	6.2	7.5	1.3	21.0 %
Others	55.0	50.9	- 4.1	- 7.5 %
Total	182.9	179.9	- 3.0	- 1.6 %

Note: Sales figures exclude internal transactions.

Sales Forecast in U.S.



With regard to forecasts of FY2011, "North America" is replaced with "U.S.".

Financial Forecast for FY2011
North America Segment

	Results FY 2010		Forecast FY 2011		Change			
						Billions of yen		
	Million $	Billions of yen	Million $	Billions of yen	Million $	Difference	Actual	Impact of foreign currency fluctuations
Net sales	1,340	117.6	1,359	115.5	19	-2.1	1.7	-3.8
LATUDA®	—	—	120	10.2	120	10.2	10.5	-0.3
LUNESTA®	614	53.9	535	45.5	-79	-8.4	-6.9	-1.5
XOPENEX®	437	38.4	388	33.0	-49	-5.4	-4.3	-1.1
BROVANA®	105	9.3	127	10.8	22	1.5	1.9	-0.4
Others	184	16.0	189	16.0	5	0.0	0.5	-0.5
Cost of sales	10.6% 142	10.6% 12.5	11.5% 156	11.5% 13.3	14	0.8	1.2	-0.4
Gross profit	1,198	105.2	1,202	102.2	4	-3.0	0.4	-3.4
SG&A expenses	724	63.6	853	72.5	129	8.9	11.3	-2.4
Segment profit	35.3% 474	35.3% 41.6	25.7% 349	25.7% 29.7	-125	-11.9	-10.9	-1.0

Notes: Excluding impact of purchase price allocation by acquisition

Exchange rate:
Results ¥87.79 to US$1
Forecast ¥85 to US$1

Increase in sales and SG&A expenses due to expansion of LATUDA®

Decrease in sales of LUNESTA ® and XOPENEX ®

Returns to Shareholders

- Dividend Policy
  - Allot appropriate dividends in line with performance while balancing aggressive investment and internal reserves for future growth
  - Also consider stable dividends
- Changes in dividends

	FY2009	FY2010 (planned)	FY2011 (planned)
Dividends per share (yen)	18.00	18.00	18.00
Payout ratio (%)	34.1	42.6	84.2

〈reference〉

Dividends to net assets ratio (%)	2.1	2.1	2.1

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R&D Pipeline

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Development Pipeline (as of May 11, 2011)

	NDA filed	Phase III	Phase II	Phase I
Japan		Lurasidone (Schizophrenia) SUREPOST® (repaglinide) (Diabetes/ Combination therapy with TZD/BG) METGLUCO® (Diabetes/Pediatrics)	Ranirestat (Diabetic neuropathy) SMP-986 (Overactive bladder) DSP-8153 (Hypertension/ Combination product)	DSP-3235 (Diabetes) DSP-3025 (Bronchial asthma, Allergic rhinitis) WT4869 (Myelodysplastic syndromes)
Foreign Markets	STEDESA™ US＊ (Epilepsy-adjunct) Ciclesonide Nasal Aerosol (HFA) US＊ (Allergic rhinitis)	LATUDA® (lurasidone) US･EU etc. (Bipolar Disorder) Amurubicin hydrochloride China (Small cell lung cancer) STEDESA™ US＊ (Epilepsy-adult monotherapy)	SMP-986 US･EU (Overactive bladder)	DSP-7238 EU (Diabetes) DSP-8658 US (Diabetes) DSP-8658 US (Alzheimer's diseases) SEP-228432 US＊ (Neuropathic pain, Depressive disorder) DSP-1053 US (Depressive disorder)

New Chemical Entities

New Indication etc.

＊ Sunovion Pipeline Candidates

Revisions since the announcement of Feb. 2011 are in red.

Note: WT4869 is on Phase I of Phase I/II study

Development Pipeline Highlights

- **MEROPEN® : Approved in Japan**
  - Approved in March, 2011
  - Change of the maximum daily dose from 2 g to 3 g for patients with severe/refractory infection

- **Ciclesonide Nasal Aerosol (HFA) : NDA submitted to the U.S. Food and Drug Administration**
  - Submitted in March, 2011

- **METGLUCO® (metformin hydrochloride) : Newly added in Phase III study in Japan**
  - Indication :Type 2 diabetes (Addition of pediatric usage)
  - Started a Phase III Study for the treatment of pediatric patients

- **DSP-1053 : Newly added in Phase I study in the U.S.**
  - A new antidepressant drug candidate that shows an inhibitory effect on serotonin transporter and modulatory effects on monoamine receptors
  - Started a Phase I Study in the U.S.

LATUDA®（Lurasidone）– Clinical development status (1)

US (schizophrenia)

- **Launch of LATUDA®**
  - Launched in the U.S. on February 4, 2011 (Indicated for the treatment of patients with schizophrenia)
- **Key Current LATUDA® Studies in Schizophrenia**
  - PEARL 3 Study：Placebo controlled (with comparator [Quetiapine XR]) Phase III study

    6 week double blind study completed, 12-month safety and tolerability study in progress.
  - Switch Study: initiated in 3Q 2010, in progress.
- **Planned LATUDA® Studies in Schizophrenia**
  - Schizophrenia Maintenance Study: to be initiated in 3Q 2011
  - Low-dose Schizophrenia Study with 20mg/d: to be initiated in 2Q 2012
  - Pediatric (10-17 yrs) PK Study: to be initiated in 3Q 2011
  - Pediatric (13-17 yrs) Efficacy Study: to be initiated in 2Q 2012

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LATUDA®（Lurasidone）– Clinical development status (2)

U.S. (Bipolar disorder, others)

- **Bipolar disorder (depression) Phase III study (PREVAIL Studies)**
  - PREVAIL#1：Placebo controlled, lithium or divalproex add-on study initiated in April 2009
  - PREVAIL#2：Placebo controlled, monotherapy initiated in April 2009
  - PREVAIL#3：Placebo controlled, lithium or divalproex add-on study initiated in December 2010

sNDA planned for 2012

- **Other studies under consideration**
  - Bipolar maintenance： to be initiated in 3Q 2011
  - MDD with mixed features: to be initiated in 2Q 2011
  - IM depot formulation

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LATUDA®（Lurasidone）– Clinical development status (3)

Outside the US

- Japan: Phase III (Pan-Asia study, data analysis completed)
- Canada: Expected filing in 2011
- China: Expected submitting IND in 2011
- Europe: Expansion in Europe through agreement with Takeda Pharmaceutical Company Limited. DSP plans to commercialize lurasidone independently in the UK.

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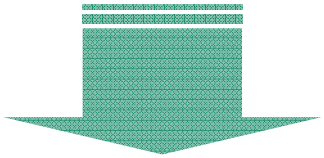
Lurasidone Pan-Asia Study (Results outline)

- Lurasidone did not demonstrate a statistically significant improvement vs placebo in PANSS total score change at the 6-week study endpoint, despite a significant within group reduction of the total PANSS score after treatment with lurasidone at 40 mg/day and 80 mg/day.



This clinical trial is viewed as a failed study, as it was unsuccessful in establishing assay sensitivity.

- With respect to safety, the most commonly observed adverse events for lurasidone 40mg/day and 80mg/day in the study were comparable to the collective results from these overseas clinical studies.

Useful data was obtained as a result of conducting the trial that will assist us with the design of future studies to support the registration of lurasidone in Japan.

DAINIPPON SUMITOMO PHARMA

Outline of Lurasidone License Agreement

- **Territory**: 26 member states of the EU excluding the UK, Switzerland, Norway, Turkey, Russia
- **Licensed Formulation**：The present oral formulation.（40, 80mg film-coated tablets）
- **Target Indications**：Schizophrenia and Bipolar disorder
- **Development**： Aiming for early Marketing Authorization Application (MAA) filing with joint development based on the global studies carried out by DSP.
- **Commercialization**：
  Takeda has exclusive commercialization rights in the Territory.
  DSP plans to commercialize lurasidone independently in the UK with a view to expand into EU in the future, and examines the establishment of a sales subsidiary in the UK.

Financial Conditions
Initial Payment：JPN10Bn (Ten Billion Japanese Yen)
Milestone Payments：MAA Filing, MAA Approval, up to approx USD 180MM (One hundred and eighty million US Dollars)
Development costs：Development costs for approval are shared
After Commercialization：Royalty payments

Ranirestat P2b Study in Japan

- Study Patients

  Patients with diabetic sensorimotor polyneuropathy

- Design

  Multicenter, randomized, double blind, placebo-controlled study

- Dosage and Administration

  Oral administration after breakfast, Once daily (2 tablets)

- Study Duration

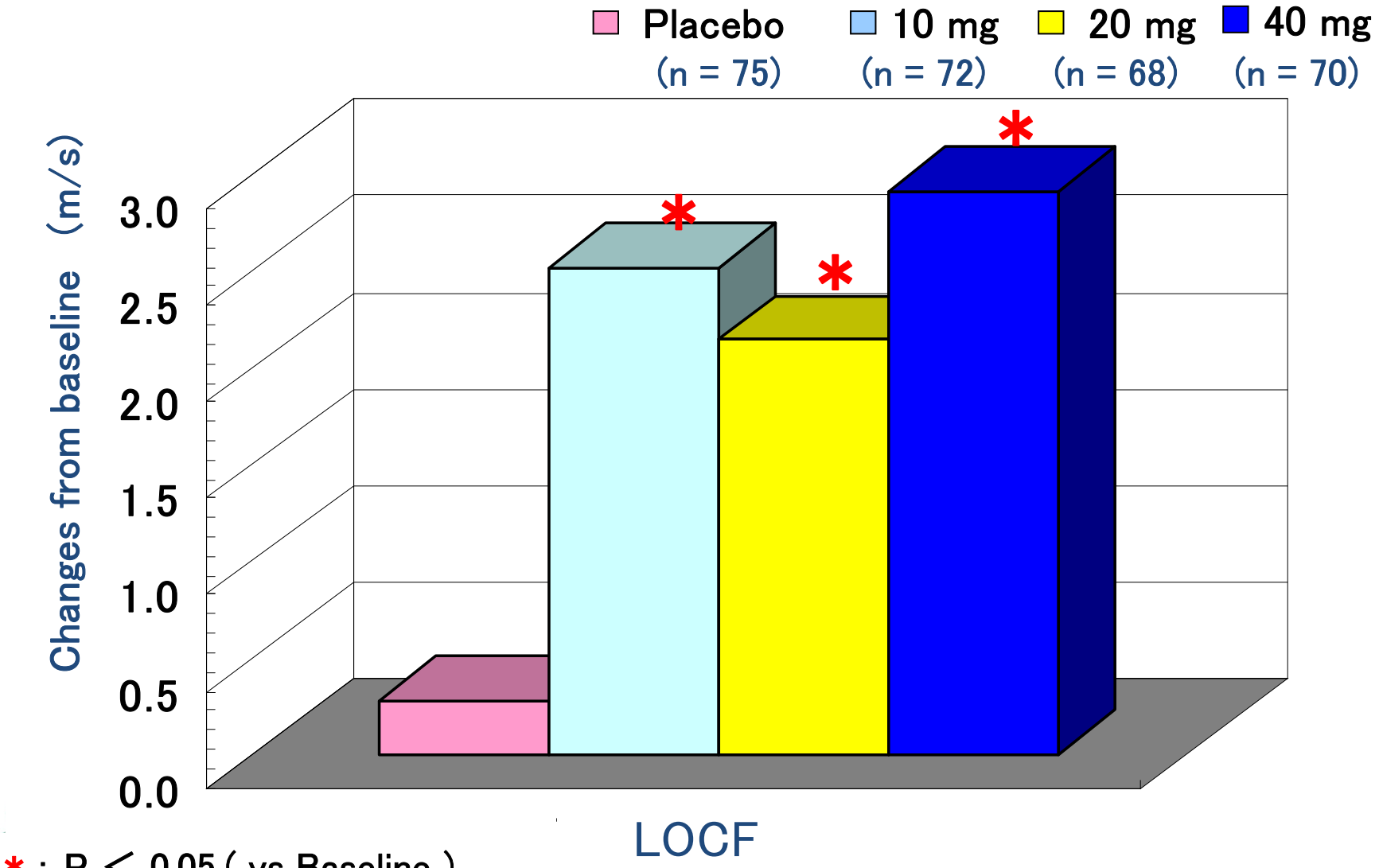
  Total duration of study drug administration (58 weeks)

  - ◆ Observation period（6weeks）⇒ Placebo
  - ◆ Treatment period（52weeks）⇒ ranirestat 10mg、20mg、40mg or Placebo

  Observation period after treatment（4 weeks）

Ranirestat P2b Study in Japan (Efficacy)

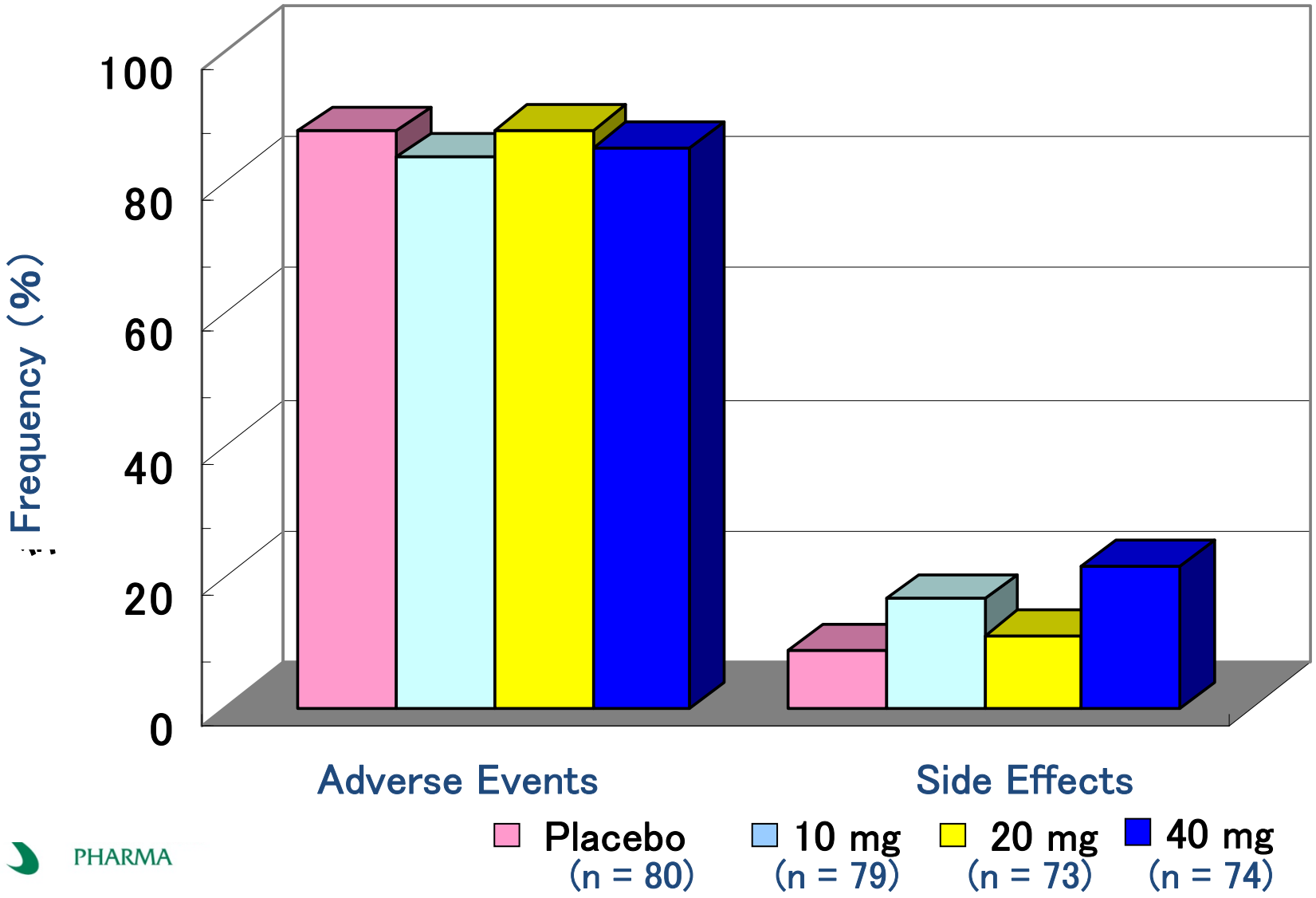
Summed nerve conduction velocity



＊：P ＜ 0.05（vs Baseline）

Ranirestat P2b Study in Japan (Safety)

Frequency of adverse events and side effects



PHARMA

Summary of Ranirestat P2b Study in Japan

- The results of the trial showed that although a dose response relationship was not established, a significant increase in summed nerve conduction velocity as the primary endpoint was seen in all ranirestat arms compared to before administration.
- As a result of the analysis for the 40mg treatment group as compared to placebo after excluding patients with markedly decreased nerve functions, a significant increase was seen in tibial nerve conduction velocity which is suggested to be associated with the appearance of lower leg ulcers.
- A significant difference in mTCNS, a score for evaluating clinical symptoms, between the treatment and placebo groups was not confirmed due to appearance of a larger placebo effect than originally assumed. However, excluding subjects who showed a large change in symptoms during the observation period, the results suggested that efficacy may be confirmed in a phase III study.
- No specific safety issues were observed

DAINIPPON SUMITOMO PHARMA

Outline of DSP-8658（NCE for CNS area (1))

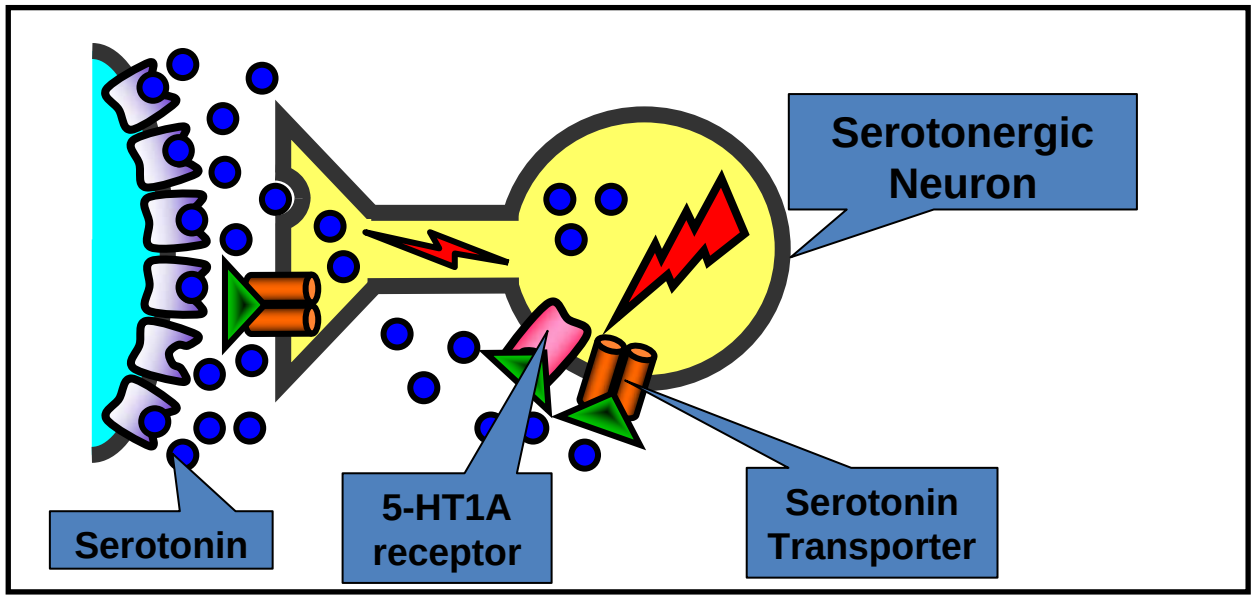
- Indication：Alzheimer disease（AD) / Diabetes
- Mode of action：Peroxisome proliferator-activated receptors（PPAR）α and γ modulator
- Formulation：Oral tablet
- In-house/license-in：In-house
- Development stage：Submitted IND to FDA in December 2010 for the AD indication. Completed clinical part of the elderly PK study in March, 2011
- Profile：The mode of action for DSP-8658 differs from currently approved acetyl cholinesterase inhibitors or the NMDA receptor antagonist. DSP-8658 is expected to have additional effects when used in combination with current treatments.

  DSP-8658 is expected to become a novel option in the management of the Alzheimer Disease as improvement of cognitive decline and also disease modification by a β–amyloid lowering effect can be anticipated.

DAINIPPON SUMITOMO PHARMA

Outline of DSP-1053（NCE for CNS area (2) ）

- Indication: Depressive Disorder
- Mode of action: DSP-1053 acts on monoamine receptors such as 5-HT1A receptor in addition to having selective serotonin reuptake inhibitory (SSRI) activity, the latter being a common mode of action among current antidepressants.
- In-house/license-in: In-house
- Development stage: Phase I (initiate in 2Q/2011)
- Profile: Early onset of action for DSP-1053 has been confirmed in various antidepressant animal models, suggesting that this compound may improve on the slow onset of action, which is a major drawback for current antidepressants.



The launch of research alliances

To create innovative drugs using good science in academia

- Laboratory for Malignant Control Research, a cooperative project with Kyoto Univ., to discover innovative approaches for life-threatening cancers
- Joint research project with CiRA (Center for iPS Cell Research and Application, Kyoto Univ.) to create a new treatment for a rare intractable disease
- Collaboration with Dr.Toru Miyazaki at Tokyo Univ. on Apoptosis Inhibitor of Macrophage, AIM
- Collaboration with Karolinska Institutet (KASPAC), the third stage

Option Agreement of BBI608

- **Product: BBI608**
- **Originator: Boston Biomedical, Inc.**
- **MoA: Cancer Stem Cell Inhibitor**
- **Development status:**
  - **Phase I extension in colorectal cancer**
  - **Phase Ib/II trials for selected solid tumor types**
- **Territory: Japan**
- **Indication: all oncology indications**
- **License:**
  - **Exclusive option to acquire exclusive rights for the development and commercialization of BBI608 in Japan**
- **Payment:**
  - **Upfront and clinical trial support payments: $15M**
- **Rational to license the Product:**
  - **Raise the presence and strengthen the pipeline in the therapeutic area of cancer, defining it as a major specialty area.**

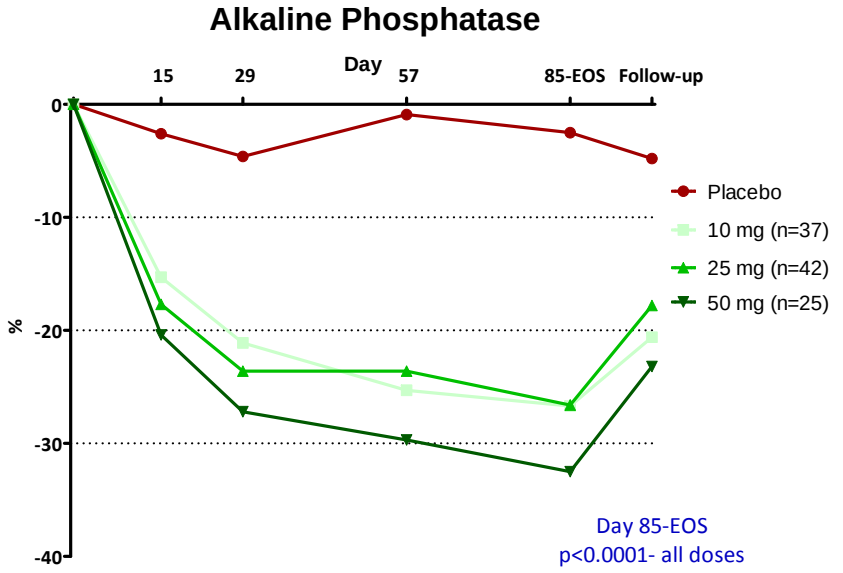
- **BBI is currently conducting phase I extension clinical studies in colorectal cancer and phase Ib/II trials in multiple solid tumor types in the United States and Canada.**

- **Adult patients with various advanced cancers and resistance to existing treatment were subjects in the phase I trial.**
  - **Dose-limiting toxicity was not seen while excellent safety and high tolerability was confirmed.**
  - **About 50% of evaluable patients with refractory cancer of various types of solid tumors showed signs of regression or prolonged progression free survival for 12 weeks or beyond.**

License Agreement of INT−747

- **Product: INT-747 (obeticholic acid)**
- **Originator: Intercept Pharmaceuticals, Inc.**
- **MoA: FXR agonist**
- **Development status:**
  - **Preparation of phase III for primary biliary cirrhosis (PBC)**
  - **Phase II for nonalcoholic steatohepatitis (NASH)**
  - **Preparation of Phase II for portal hypertension**
- **Initial territory: Japan and China**
- **Initial indication: PBC, NASH**
- **License:**
  - **Exclusive right for the development and commercialization in Japan and China**
  - **Exclusive option right to add Asian countries and to pursue additional indications**
- **Payment:**
  - **Upfront fee: $15M**
  - **Development milestones: Approximately $50M**
- **Rational to license the Product**
  - **Reinforcement of the pipeline of hepatology drugs and reflects DSP's strong commitment to specialty therapeutic areas**
  - **Market as an important new therapy for PBC and the first drug approved for NASH.**

- **Multi-center, double-blind, randomized, placebo-controlled study in combination with Urso™in PBC patients with persistently elevated alkaline phosphatase**
- **12 week treatment duration with 2 week follow-up**
- **165 patients at 30 centers in 8 countries, including US, Canada and Europe**
- **Primary approvable endpoint: reduction in alkaline phosphatase – a standard liver function test**



License Agreement of Ceftaroline fosamil

- **Product: ceftaroline fosamil**
- **Originator: Takeda Pharmaceutical Company Limited**
- **MoA: cephem antibiotic**
- **Development status: Launch in US, MAA filed in EU**
- **Territory: Japan**
- **Indication: bacterial infection including MRSA infections**
- **License: exclusive right for development, manufacturing and commercialization of cefraroline in Japan**
- **Payment:**
  - **Upfront payment: ¥500M**
  - **Development milestone: ¥2.5B**
  - **Additional milestone and royalty based on sales**
- **Rational to license the Product:**
  - **Contribute to the treatment of severe infections in Japan by ceftaroline that can satisfy the unmet medical needs as a treatment of MRSA infections.**
  - **Strengthen pipeline in an infectious disease area, which is one of our company's core therapeutic areas for domestic business**

- **Forest Laboratories obtained an approval from the U.S. FDA of the product for the treatment of acute bacterial skin and skin structure infection (ABSSSI) and community-acquired bacterial pneumonia (CABP) on October 29, 2010.**
- **Ceftaroline has strong activities against gram-positive bacteria including MRSA and multiply-resistant Streptococcus pneumonia and also gram-negative bacteria**

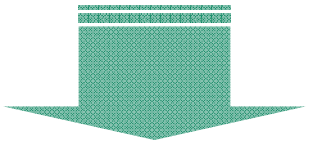
Comparative in vitro MIC90s of ceftaroline and other comparators (μg/ml)

Organism (No. of isolated tested)	Ceftaroline	Vancomycin	Daptomycin	Linezolid
S. aureus				
MSSA (348)	0.25	1	0.5	2
MRSA (92)	1	1	1	2
VISA (20)	1	8	4	2
VRSA (10)	0.5	>64	1	2
S. Pneumoniae				
PSSP (202)	0.015	0.5	NA	1
PISP (103)	0.06	0.5	NA	1
PRSP (296)	0.12	0.5	NA	1

(Ref. Louis D. Saravolatz, et.al. Clinical Infectious Disease 2011; 52 (9): 1156-1163)

“Post-Latuda”

- **Targeted areas**
  Our primary focus is the CNS area and secondary focus is on areas for specialty physicians, such as the **oncology** area, in which effective marketing can be expected.
- **Candidates for “Post-Latuda”**
  - Development pipeline in the US, such as DSP-8658（AD）, DSP-1053（depression）, SEP-228432 (pain, depression), and, although in a different area, SMP-986 (overactive bladder), etc.
  - Compounds in pre-clinical stage in CNS and **oncology** areas
  - Compounds from in-licensing and alliance activities〔SB623（stroke）, etc.〕



Establish POC as quickly as possible, select several promising candidates, and then accelerate clinical development as “Post-Latuda”.

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DAINIPPON SUMITOMO PHARMA