

Financial Results for FY2011 (ended March 31, 2012)

May 11, 2012

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

Financial Results for FY2011

Financial Results

Billions of yen

	FY2010	FY2011	Change			FY2011	
			Value	Impact of exchange fluctuations	Percentage	Forecast (as of Feb. 3)	Percentage
Net sales	379.5	350.4	- 29.1	- 10.2	- 7.7 %	352.0	99.5 %
Cost of sales	110.0	98.9	- 11.2	- 1.3	- 10.2 %	99.5	99.4 %
Gross profit	269.5	251.5	- 17.9	- 8.9	- 6.7 %	252.5	99.6 %
SG&A expenses	238.5	231.1	- 7.4	- 12.1	- 3.1 %	230.5	100.3 %
SG&A expenses less R&D costs	170.4	174.2	3.9	- 9.8	2.3 %	173.5	100.4 %
R&D costs	68.2	56.9	- 11.3	- 2.3	- 16.5 %	57.0	99.8 %
Operating income	31.0	20.4	- 10.5	3.2	- 34.1 %	22.0	92.7 %
Ordinary income	28.6	18.9	- 9.7	/	- 34.0 %	22.0	85.8 %
Extraordinary income or loss	- 3.6	- 2.5	1.0		—	—	—
Net income	16.8	8.6	- 8.2		- 48.6 %	10.0	86.3 %

- Notes:
1. All values are rounded to the nearest 100 million yen.
 2. Cost of sales includes provision for (reversal of) reserve for sales returns.
 3. Exchange rate FY2010:1US\$=¥87.8 , 1RMB=¥13.0 FY2011:1US\$=¥79.8 , 1RMB=¥12.4

Transition of Financial Forecasts

Billions of yen

	Forecasts May 2011	Forecasts Oct 2011	Forecasts Feb 2012	Results
Net sales	362.0	352.0	352.0	350.4
Cost of sales	103.8	100.0	99.5	98.9
Gross Profit	258.2	252.0	252.5	251.5
SG&A expenses	241.2	232.0	230.5	231.1
SG&A expenses less R&D costs	179.2	173.5	173.5	174.2
R&D costs	62.0	58.5	57.0	56.9
Operating Income	17.0	20.0	22.0	20.4
Ordinary income	15.5	19.0	22.0	18.9
Extraordinary income or loss	—	1.2	- 2.4	- 2.5
Net income	8.5	12.0	10.0	8.6

Exchange rate (¥ to US\$1)

85.0

80.0

80.0

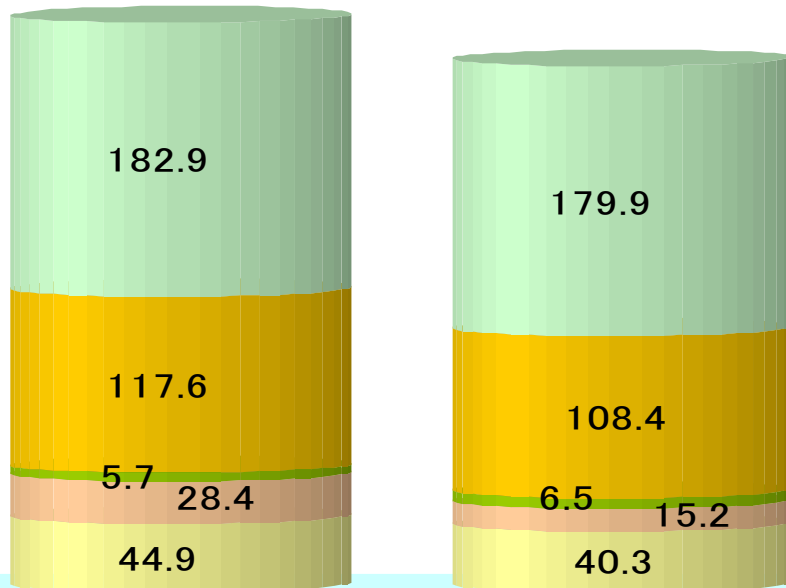
79.8

Net Sales by Segment

FY2010
379.5

FY2011
350.4

Billions of yen
Change
Value Percentage
- 29.1 - 7.7%



Japan - 3.0 - 1.6%

North America - 9.2 - 7.8%

China 0.9 15.0%

Other Regions - 13.2 - 46.4%

Other Business - 4.6 - 10.2%

Overseas Sales 40.1 %

37.2 %

【North America】

- Decreased sales due to the effect of strong yen.

【Other Regions】

- Decrease due to the FY2010 lump-sum income for the out-licensing of lurasidone and a decrease in exports of MEROPEN®

【Other Business】

- Decrease because only the commission equivalent part was recorded as sales on pet foods since July, 2010.

Sales in Japan Segment

Billions of yen

	FY2010	FY2011	Change	
			Value	Percentage
AVAPRO®	8.3	10.7	2.4	28.5 %
LONASEN®	9.0	9.8	0.9	9.8 %
PRORENAL®	14.9	15.5	0.6	3.8 %
Strategic Products Total	32.2	36.0	3.8	11.9 %
TRERIEF®	3.7	5.3	1.6	44.0 %
MIRIPLA®	1.5	1.3	- 0.2	- 16.0 %
SUREPOST®	—	0.1	0.1	—
METGLUCO® (Including MELBIN®)	4.7	8.5	3.9	83.0 %
New Products Total	9.9	15.2	5.3	54.0 %
AMLODIN®	41.4	36.0	- 5.4	- 13.0 %
GASMOTIN®	21.0	21.2	0.2	0.9 %
MEROPEN®	12.6	12.2	- 0.5	- 3.6 %
AmBisome®	4.6	4.5	- 0.1	- 1.7 %
REPLAGAL®	6.2	9.1	3.0	48.1 %
Others	55.0	45.6	- 9.4	- 17.0 %
Japan Total	182.9	179.9	- 3.0	- 1.6 %

FY2011	
Forecast (as of Feb. 3)	Change
11.5	- 0.8
11.0	- 1.2
15.5	0.0
38.0	- 2.0
5.4	- 0.1
1.4	- 0.1
0.2	- 0.1
8.2	0.3
15.2	0.0
35.5	0.5
21.0	0.2
11.9	0.3
4.5	- 0.0
8.9	0.2
46.1	- 0.5
181.1	- 1.2

Note: Sales figures of each product are before reduction of rebates.

Sales in North America & China Segments

Billions of yen [M\$]

	FY2010		FY2011		Change		
					Value	Percentage	
LATUDA®	[-]	—	[86]	6.9	[86]	6.9	—
LUNESTA®	[614]	53.9	[528]	42.1	[- 86]	- 11.8	- 21.9 %
XOPENEX®	[437]	38.4	[419]	33.4	[- 18]	- 5.0	- 12.9 %
BROVANA®	[105]	9.3	[127]	10.2	[22]	0.9	9.9 %
OMNARIS®	[54]	4.8	[64]	5.1	[10]	0.4	7.9 %
Industrial property revenues	[76]	6.6	[72]	5.8	[- 3]	- 0.9	- 13.2 %
Others	[54]	4.7	[62]	5.0	[8]	0.2	5.0 %
North America Total	[1,340]	117.6	[1,359]	108.4	[19]	- 9.2	- 7.8 %
MEROPEN®		5.0		5.5		0.6	11.1 %
Others		0.7		1.0		0.3	42.1 %
China Total		5.7		6.5		0.9	15.0 %

Segment Breakdown for North America

Billions of yen [M\$]

< Excluding mainly the impact of amortization of patent rights and goodwill >

	FY2010		FY2011		Change	
Net sales	[1,340]	117.6	[1,359]	108.4	[19]	- 9.2
Cost of sales	[142]	12.5	[140]	11.2	[- 2]	- 1.3
Gross profit	[1,198]	105.2	[1,218]	97.2	[21]	- 7.9
SG&A expenses	[724]	63.6	[875]	69.8	[151]	6.2
Income (loss) of Segment	[474]	41.6	[343]	27.4	[- 130]	- 14.2

Breakdown	
Exchange	Others
- 10.2	1.0
- 1.3	- 0.0
- 8.9	1.0
- 7.0	13.2
- 1.9	- 12.3

< Mainly the impact of amortization of patent rights and goodwill >

	FY2010		FY2011		Change	
Net sales	[-]	-	[-]	-	[-]	-
Cost of sales	[38]	3.3	[-]	-	[- 38]	- 3.3
Gross profit	[- 38]	- 3.3	[-]	-	[38]	3.3
SG&A expenses	[357]	31.4	[347]	27.7	[- 10]	- 3.6
Income (loss) of Segment	[- 395]	- 34.7	[- 347]	- 27.7	[48]	7.0

Breakdown	
Exchange	Others
-	-
-	- 3.3
-	3.3
- 2.8	- 0.9
2.8	4.2

Segment Information

Billions of yen

		Pharmaceuticals Business					Subtotal	Other Business	Total	
		Japan	North America ^{※1}	Amortization ^{※2}	China	Other Regions				
FY2011 Results	Net sales	179.9	108.4	—	6.5	15.2	310.1	40.3	350.4	
	Cost of sales	46.8	11.2	—	1.9	7.9	67.8	31.0	98.9	
	Gross profit	133.3	97.2	—	4.6	7.3	242.4	9.1	251.5	
	SG&A expenses less R&D costs	66.8	69.8	27.7	3.6	0.3	168.3	5.9	174.2	
	Income (loss) of Segment	66.4	27.4	- 27.7	1.0	7.0	74.1	3.2	77.3	
	R&D costs							56.2	0.7	56.9
	Operating income							17.9	2.5	20.4
FY2010 Results	Net sales	182.9	117.6	—	5.7	28.4	334.6	44.9	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 less R&D costs	65.7	63.6	31.4	3.3	0.3	164.3	6.1	170.4	
	Income (loss) of Segment	68.2	41.6	- 34.7	1.2	20.1	96.3	2.8	99.1	
	R&D costs							67.4	0.8	68.2
	Operating income							29.0	2.0	31.0
Change	Net sales	- 3.0	- 9.2	—	0.9	- 13.2	- 24.5	- 4.6	- 29.1	
	Income (loss) of Segment	- 1.7	- 14.2	7.0	- 0.2	- 13.1	- 22.3	0.4	- 21.8	
	R&D costs							- 11.2	- 0.1	- 11.3
	Operating income							- 11.0	0.5	- 10.5



- ※ 1. Excluding mainly amortization of patent rights and goodwill
 ※ 2. Mainly amortization of patent rights and goodwill

Ordinary income & Net income

Billions of yen

	FY2010	FY2011	Change	
			Value	Percentage
Operating Income	31.0	20.4	- 10.5	- 34.1 %
Non-operating income and expenses	- 2.3	- 1.5	0.8	
Finance income and expenses including dividend income	- 0.7	- 0.1	0.6	
Contributions	- 1.8	- 1.6	0.2	
Others	0.2	0.2	0.0	
Ordinary income	28.6	18.9	- 9.7	- 34.0 %
Extraordinary income	—	1.2	1.2	
Gain on sales of property, plant and equipment	—	1.2	1.2	
Extraordinary loss	3.6	3.8	0.2	
Impairment loss	3.2	2.3	- 0.9	
Business structure improvement expenses	—	1.2	1.2	
Loss on valuation of investment securities	0.3	0.2	- 0.1	
Income taxes	8.3	7.7	- 0.6	
Net income	16.8	8.6	- 8.2	- 48.6 %

Financial Position

Billions of yen

	as of Mar.31,2011	as of Mar.31,2012	Change
Assets	589.9	559.4	- 30.5
Current assets	333.0	334.3	1.3
Fixed assets	256.9	225.2	- 31.7
Liabilities	265.9	240.2	- 25.7
Current liabilities	157.2	106.0	- 51.2
Long-term liabilities	108.7	134.2	25.5
Net assets	324.0	319.2	- 4.8

(Shareholders' equity ratio)

54.9%

57.1%

(Assets)

Decrease in patent rights and goodwill 34.5 billion yen

(Liabilities)

Decrease in interest-bearing debt 25.6 billion yen

(Net Assets)

Decrease in foreign currency translation adjustment 8.8 billion yen

Cash Flows

FY2011

Billions of yen

I Net cash provided by operating activities	+ 48.4
▪ Income before income taxes and minority interests	+ 16.3
▪ Depreciation and amortization	+ 40.2
▪ Income taxes paid	- 14.5

II Net cash used in investing activities	- 4.4
▪ Purchase of property, plant and equipment	- 6.7

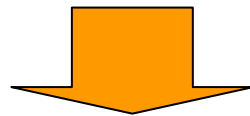
III Net cash used in financing activities	- 32.9
▪ Net increase (decrease) in short-term loans payable	- 50.0
▪ Proceeds from long-term loans payable	+ 4.4
▪ Proceeds from issuance of bonds	+ 19.9
▪ Cash dividends paid	- 7.1

Cash and cash equivalents at the end of period : 92.2 billion yen
 (compared with the beginning of period + 9.3 billion yen)

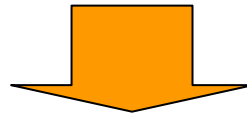
Financial Forecast for FY2012

FY2012 Financial Forecast - Brief Summary

- Japan Segment: Ensure profit comparable to FY2011
 - ✓ Make up for decrease in sales due to NHI drug price revision by focusing on Strategic products and New products
 - ✓ Reduction in SG&A expenses by more efficient spending and saving
- North America Segment: Ensure profit exceeding FY2011
 - ✓ Make up for decrease in sales due to expiration of XOPENEX® exclusivity by increasing revenue of LATUDA® and BROVANA® etc.
 - ✓ Reduction in SG&A expenses with improvement of business structure implemented in 2011
- China Segment: Increase both in sales and profit
- Other Segment: Decrease in sales and profit by decline in export of MEROPEN® due to impact of generics
- Other Businesses: Increase both in sales and profit
- R&D costs: Increase with acquisition of BBI and activity for additional indication of LATUDA®



Rise in Segment Profits Make up for the Increase in R&D Costs



Slight Increase in Both Operating Income and Net Income

Financial Forecast for FY2012

Billions of yen

	Results FY2011	Forecast FY2012	Change		
			Value		Percentage
				Exchange gain/loss	
Net sales	350.4	348.0	- 2.4	4.2	- 0.7 %
Cost of sales	98.9	101.0	2.1	0.6	2.2 %
Gross Profit	251.5	247.0	- 4.5	3.6	- 1.8 %
SG&A expenses	231.1	225.0	- 6.1	4.5	- 2.7 %
SG&A expenses less R&D costs	174.2	163.0	- 11.2	3.4	- 6.5 %
R&D costs	56.9	62.0	5.1	1.1	9.0 %
Operating Income	20.4	22.0	1.6	- 0.9	7.8 %
Ordinary income	18.9	21.0	2.1		11.3 %
Extraordinary income or loss	- 2.5	- 1.5	1.0		—
Net income	8.6	10.5	1.9		21.7%
EBITDA	59.9	58.5	- 1.4		- 2.3 %

Note:

- All values are rounded to the nearest 100 million yen.
- EBITDA: earning before interest, taxes, depreciation and amortization

Exchange rate

Results FY2011: ¥79.8=US\$1 ¥12.4=RMB1

Forecast FY2012: ¥83=US\$1 ¥12=RMB1

Progress in the Second Mid-term Business Plan

Financial Performance

Billions of yen

	FY2012		Change	
	Forecast	2nd MTBP Reference		Exchange
Net Sales	348.0	380.0	- 32.0	- 9.2
Operating Income	22.0	30.0	- 8.0	+1.9

- **Japan is mostly in line with the MTBP, while North America is falling short of the MTBP**
 - Falling short of sales in main products
 - Delay in launch of STEDESA™
 - Increase in sales expenses of LATUDA®

Progress towards the Mid- to Long-term Vision

- **Progress as planned in Japan and North America**
- **Business Expansion in the Oncology Field (Acquisition of Boston Biomedical, Inc., etc.)**

Forecast for FY2012 (by Segment)

Billions of yen

		Pharmaceuticals						Other Business	Total	
		Japan	North America*1	Amortization*2	China	Other	Total			
Results FY2011	Net sales	180.1	108.4	—	6.5	15.2	310.3	40.1	350.4	
	Cost of sales	46.8	11.2	—	1.9	7.9	67.8	31.0	98.9	
	Gross profit	133.3	97.2	—	4.6	7.3	242.4	9.1	251.5	
	SG&A expenses	66.8	69.8	27.7	3.6	0.3	168.3	5.9	174.2	
	Segment profit	66.4	27.4	-27.7	1.0	7.0	74.1	3.2	77.3	
	R&D costs							56.2	0.7	56.9
	Operating income							17.9	2.5	20.4
Forecast FY2012	Net sales	180.0	109.1	—	7.1	9.7	305.9	42.1	348.0	
	Cost of sales	49.8	11.8	—	1.8	5.2	68.6	32.4	101.0	
	Gross profit	130.2	97.3	—	5.3	4.5	237.3	9.7	247.0	
	SG&A expenses	63.4	61.7	27.2	4.1	0.4	156.8	6.2	163.0	
	Segment profit	66.8	35.6	-27.2	1.2	4.1	80.5	3.5	84.0	
	R&D costs							61.1	0.9	62.0
	Operating income							19.4	2.6	22.0
Change	Net sales	- 0.1	0.7	—	0.6	- 5.5	- 4.4	2.0	- 2.4	
	Segment profit	0.4	8.2	0.5	0.2	- 2.9	6.4	0.3	6.7	
	R&D costs							4.9	0.2	5.1
	Operating income							1.5	0.1	1.6

*1 Excluding amortization of patent rights and goodwill

*2 Amortization of patent rights and goodwill

Exchange rate

Results FY2011: ¥79.8=US\$1 ¥12.4=RMB1

Forecast FY2012: ¥83=US\$1 ¥12=RMB1

Sales Forecast by Product in Japan Segment

Billions of yen

	Results FY2011	Forecast FY2012	Change	
			Value	Percentage
AVAPRO®	10.7	14.3	3.6	33.6 %
LONASEN®	9.8	13.0	3.2	32.1 %
PRORENAL®	15.5	15.8	0.3	1.9 %
TRERIEF®	5.3	7.0	1.7	31.3 %
Strategic Products Total	41.4	50.1	8.7	21.1 %
MIRIPLA®	1.3	1.3	0	2.1 %
METGLUCO® (Including MELBIN®)	8.5	11.9	3.4	39.6 %
SUREPOST®	0.1	2.2	2.1	2764.6 %
New Products Total	9.9	15.4	5.5	55.9 %
AMLODIN®	36.0	28.7	- 7.3	- 20.3 %
GASMOTIN®	21.2	18.5	- 2.7	- 12.7 %
MEROPEN®	12.2	10.2	- 2.0	- 16.2 %
AmBisome®	4.5	4.8	0.3	7.2 %
REPLAGAL®	9.1	10.0	0.9	9.4 %
Others	45.6	42.0	- 3.6	- 8.0 %
Total	179.9	179.7	- 0.2	- 0.1 %

Promotion of new products expected for launch in Japan in FY2012

SUREPOST®

- **2-week limit on the prescription period lifted (April 2012)**
- **Additional indication**
 - Combination therapy with thiazolidinediones and with biguanides (submitted in April 2012)
 - Conducting Phase 3 clinical studies in Japan for combination therapy with all other diabetes drugs (including DPP-4 inhibitors) (Started Phase 3 studies in February 2012)

Irbesartan/amlodipine Combination Product (DSP-8153) (submitted In November 2011)

- Two types: irbesartan 100mg/amlodipine 5mg and irbesartan 100mg/amlodipine 10mg
- The first combination product in Japan containing amlodipine 10mg
- Single product expected to have a strong antihypertensive effect with cerebroprotective, cardioprotective and renoprotective effects

Paxil® CR (scheduled for launch in June 2012)

- Co-promotion with GSK
- First controlled-release anti-depressant in Japan
- Expected to alleviate gastrointestinal symptoms in the early stages of administration and contribute to improving the continuity of long-term treatment.

Sales Forecast in Segments of North America and China

	Results FY 2011	Forecast FY 2012	Change	Results FY 2011	Forecast FY 2012	Change	
							Impact of Exchange Rate
North America	(Million \$)			(Billion yen)			
LATUDA®	86	190	104	6.9	15.8	8.9	0.6
LUNESTA®	528	513	-14	42.1	42.6	0.5	1.6
XOPENEX®	419	257	-161	33.4	21.4	-12.0	0.8
BROVANA®	127	158	31	10.2	13.2	3.0	0.5
Ciclesonide products	99	67	-32	7.9	5.5	-2.4	0.2
Industrial property revenues	72	93	21	5.8	7.7	1.9	0.3
Others	27	37	9	2.2	2.9	0.7	0.1
Total	1,359	1,315	-44	108.4	109.1	0.7	4.2
China	(Million RMB)			(Billion yen)			
MEROPEN®	447	484	37	5.5	5.8	0.3	
Others	82	106	21	1.0	1.3	0.3	
Total	529	590	58	6.5	7.1	0.6	

Exchange rate

Results FY2011: ¥79.8=US\$1 ¥12.4=RMB1

Forecast FY2012: ¥83=US\$1 ¥12=RMB1

Future Prospects in the North America Business

Sunovion Pharmaceuticals Inc.

- Management setup after the resignation of Mark Iwicki (President & CEO) on April 11
 - ✓ Started activities for the recruitment of a successor
 - ✓ Hiroshi Nomura (EVP & Chief Financial Officer) has assumed acting CEO responsibilities supported by Richard Russell (EVP & Chief Commercial Officer), Antony Loebel, M.D. (EVP & Chief Medical Officer) and Yoshiharu Ikeda, Ph.D. (EVP, Corporate Strategy) in management
- LATUDA®
 - ✓ Bipolar I depression: Results of Phase III studies (PREVAIL) released (April 2012), sNDA submission scheduled in the second half of 2012
 - ✓ Change of maximum dose approved (160 mg/day) (April 2012); concurrently received approval of 120 mg tablets
 - ✓ Will permit greater flexibility in dosing for patients with schizophrenia who may require higher doses
 - ✓ Efficacy and weight data from the PEARL 3 study (including LATUDA®, a reference drug and placebo) was approved to be included in the revised label
 - ✓ Switch Study Results
 - ✓ Results showing effectiveness of switch to LATUDA presented in May 2012 at the APA (American Psychiatric Association) Annual Meeting in the U.S.
 - ✓ The treatment failure rate for all Latuda doses was as low as 8%. Patients experienced improvements in efficacy measures as well as weight and metabolic parameters after switch to LATUDA.
- STEDESA™
 - ✓ Resubmission of New Drug Application scheduled for 3Q 2012

Boston Biomedical, Inc.

- Wholly owned subsidiary of DSP as of April 24 (U.S. time). Start of Phase III trial for BBI608

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

	FY2010	FY2011 (planned)	FY2012 (planned)
Dividends per share (yen)	18.00	18.00	18.00
Payout ratio (%)	42.6	82.9	68.1

〈reference〉

Dividend on equity (%)	2.1	2.2	2.2
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Clinical Development Status

Development Pipeline (1) (as of May 10, 2012)

Central Nervous System Field

Domestic Overseas



Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
LATUDA (SM-13496)	lurasidone hydrochloride	Schizophrenia	Canada	Overseas			
		Schizophrenia	Japan	Domestic			
		(New indication) Bipolar I Depression	US/Europe, etc.	Overseas			
		(New indication) Bipolar Maintenance	US/Europe, etc.	Overseas			
		(New indication) MDD with mixed features	US	Overseas			
STEDESA™	eslicarbazepine acetate	Epilepsy-Adjunct	US	Overseas			
		Epilepsy-Adult monotherapy	US	Overseas			
LONASEN®	blonanserin	Schizophrenia	China	Overseas			
		(Addition of pediatric usage) Schizophrenia	Japan	Domestic			
DSP-8658	TBD	Alzheimer's disease	US	Overseas			
SEP-228432	TBD	Neuropathic Pain, Depression	US	Overseas			
DSP-1053	TBD	Depression	US	Overseas			
DSP-0565	TBD	Epilepsy	US	Overseas			
DSP-2230	TBD	Neuropathic Pain	UK	Overseas			










LATUDA(SM-13496) : Co-development with Takeda Pharmaceutical in Europe (Phase III Study : Schizophrenia , Bipolar disorder)

Revisions since the previous announcement are in red.

Development Pipeline (2) (as of May 10, 2012)



Cancer Field

 Domestic  Overseas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
CALSED® (Brand name in Japan)	amrubicin hydrochloride	Small cell lung cancer	China				
BBI608	TBD	Colorectal Cancer (2nd/3rd line) (Monotherapy)	US/Canada				
		Colorectal Cancer (2nd/3rd line) (Combination therapy)	US/Canada				
		Solid Cancer (2nd/3rd line) (Combination therapy with paclitaxel)	US/Canada		※		
WT4869	TBD	Myelodysplastic syndromes	Japan		※		
		Solid cancer	Japan				
WT2725	TBD	Solid cancer	US				
BBI503	TBD	Solid cancer (monotherapy)	US/Canada				

Respiratory Field

※on Phase I of Phase I/II study  Under Preparation

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
Ciclesonide Nasal Aerosol (Brand name: ZETONNA™)	ciclesonide	(New dose form: HFA Propellant) Allergic rhinitis	US				
DSP-3025	TBD	Asthma/Allergic Rhinitis	Japan				

 Approved/Preparing for Launch

Revisions since the previous announcement are in red.

Development Pipeline (3) (as of May 10, 2012)

Cardiovascular/ Diabetes Field

Domestic Overseas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
DSP-8153	amlodipine besilate/irbesartan	Hypertension/Combination agent	Japan				
SUREPOST®	repaglinide	(New indication) Type 2 diabetes (Combination therapy with thiazolidine or biguanide)	Japan				
		(New indication) Type 2 diabetes (All combination therapies including DPP4 inhibitors)	Japan				
METGLUCO®	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes	Japan				
AS-3201	ranirestat	Diabetic neuropathy	Japan				
DSP-8658	TBD	Type 2 diabetes	US				
DSP-9599	TBD	Hypertension	Japan				

Other Fields

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
MEROPEN®	meropenem hydrate	(Change of maximum dose) Purulent meningitis: 6g daily	Japan				
SMP-986	afacifenacin fumarate	Overactive bladder	Japan				
			US/Europe				
PRORENAL®	limaprost alfadex	(New Indication) Carpal-tunnel syndrome	Japan				
DSP-1747	obeticholic acid	Primary biliary cirrhosis (PBC), Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				
DSP-5990	ceftaroline fosamil	MRSA Infection	Japan				

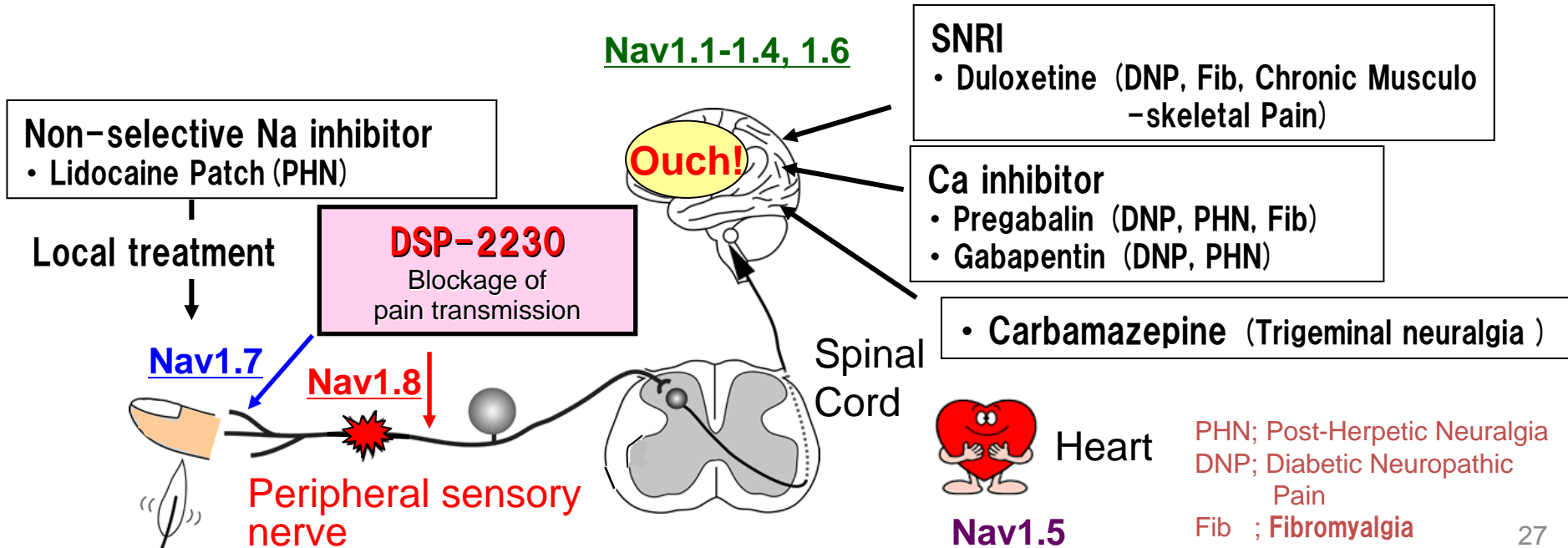
Revisions since the previous announcement are in red.

Development Pipeline State of Progress (Main changes after February 3, 2012)

- **LATUDA[®]** (lurasidone hydrochloride)
 - US: Approval for change of maximum dose. (approved in April 2012)
- **SUREPOST[®]**
 - Japan: NDA Submitted for Type 2 diabetes combination therapy with thiazolidine/biguanide (Submitted in April 2012)
 - Japan: Newly added in Phase III for Type 2 diabetes, all combination therapies including DPP4 inhibitors
- **MEROPEN[®]**
 - Japan: Newly added in Phase III (Change of maximum dose)
- **BBI 608** (Colorectal cancer/Solid cancer Treatment)
 - US/Canada: Phase III under preparation (Colorectal cancer monotherapy), Newly added in Phase II (Colorectal cancer combination therapy), Phase I/II (Solid cancer monotherapy)
- **DSP-9599** (Hypertension)
 - Japan: Newly added in Phase I
- **DSP-2230** (Neuropathic pain)
 - UK: Newly added in Phase I
- **WT2725** (Solid cancer Treatment)
 - US: Newly added in Phase I
- **BBI 503** (Solid cancer Treatment)
 - US/Canada: Newly added in Phase I

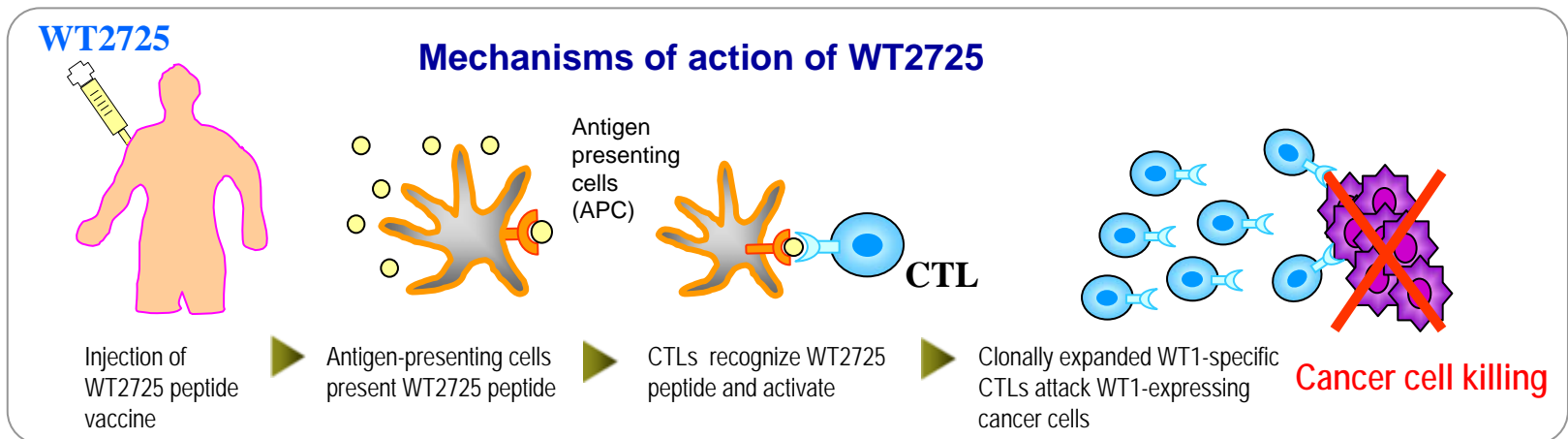
Profile of DSP-2230

- Indication: Neuropathic Pain
- Mechanism of action: Selective blockade of voltage-dependent sodium channel Nav1.7 and Nav1.8
- Origin: DSP
- Development stage: CTA submitted to MHRA in 1Q 2012
- Characteristics: Because DSP-2230 is a selective Nav1.7 and Nav1.8 inhibitor, which are principally expressed in peripheral sensory neurons, this compound is expected to be devoid of CV or CNS side-effects, which are present with current drugs such as non-selective sodium channel blockers and anti-epilepsy medicines.



Profile of WT2725

- **Target indication:** Hematologic and solid malignancies
- **Mechanism of action:** Induction of WT1(Wilms' tumor 1) -specific cytotoxic T-lymphocytes (CTLs) to attack cancer cells expressing WT1 protein
- **Origin:** Joint research with Chugai Pharmaceutical
- **Development phase:** IND submitted to FDA in April 2012
- **Key features:**
 - Co-development with Chugai Pharmaceutical, based on the results from basic and clinical research performed by Dr. Haruo Sugiyama, Professor of Osaka University Graduate School of Medicine
 - Vaccination with peptide derived from WT1 protein that is over-expressed in various types of cancer may be beneficial in cancer treatment, by activating patients' own immunity that could combat with cancer cells
 - With CTLs that selectively attack cancer cells, it is expected that the vaccination has minimum effect on normal cells, therefore low toxicity compared with chemotherapeutics. Combination with chemotherapy can be expected



PREVAIL 1,2(Study 235, 236) Top Line Results

Study Design

PREVAIL 1 (Adjunctive therapy)

- 6-week, placebo-controlled study
- 56 clinical sites worldwide
- 348 patients with bipolar I depression
- LATUDA 20 mg/day-120 mg/day
- lithium or valproate was administered on both LATUDA and placebo arms

PREVAIL 2 (Monotherapy)

- 6-week, placebo-controlled study
- 55 clinical sites worldwide
- 505 patients with bipolar I depression
- LATUDA 20 mg/day-60 mg/day
- LATUDA 80 mg/day-120 mg/day

Top Line Results

First Positive Placebo-Controlled Study among atypical antipsychotics added to mood stabilizers

- LATUDA experienced significant improvements in MADRS scores (primary endpoint) and CGI-BP-S scores (key secondary endpoint) compared to placebo

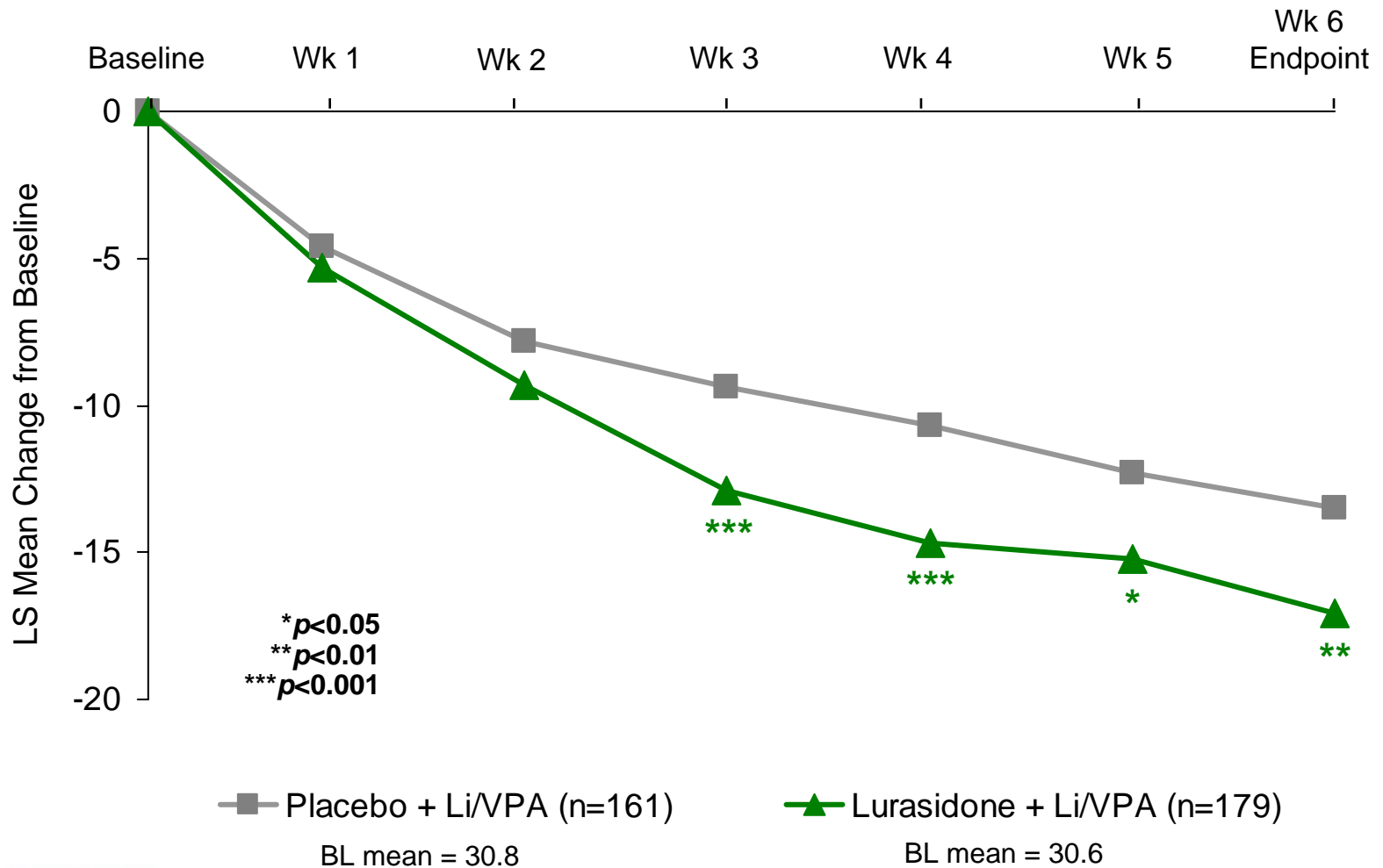
Consistent Safety & Tolerability Profile

- In the study, LATUDA was well tolerated with the same level of discontinuation rate as placebo
- The most common adverse events reported for the lurasidone group (greater than 5% and twice the rate of placebo) were: nausea, headache, somnolence, tremor, akathisia, insomnia and sedation

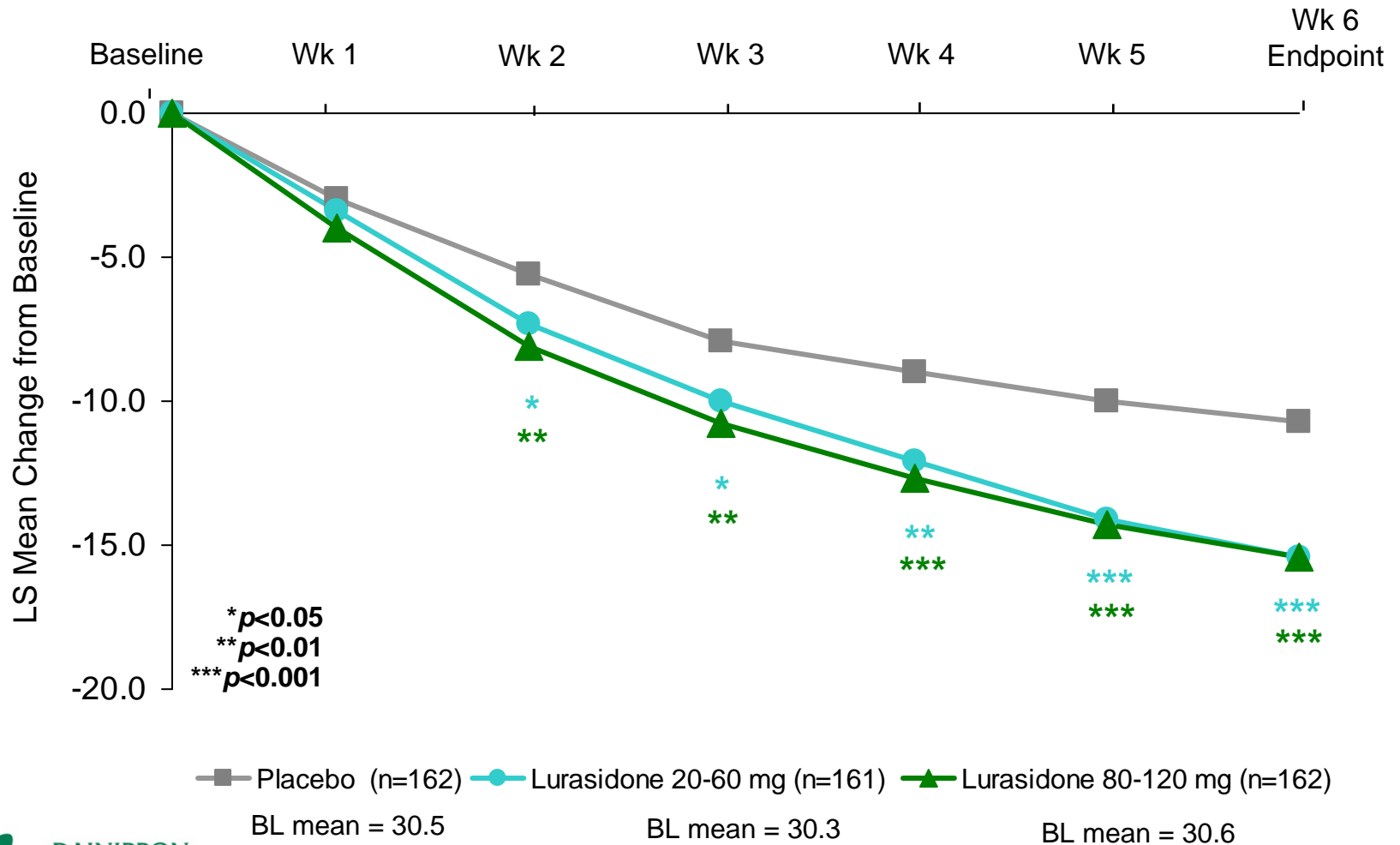
Data was presented in May 2012 at the APA (American Psychiatric Association) Annual Meeting in the U.S.;

Note: LATUDA is not approved by the US FDA for the treatment of bipolar disorder, including bipolar I depression. LATUDA is only approved by the FDA in the US for the treatment of adult patients with schizophrenia.

PREVAIL 1 (Study 235): MADRS (MMRM) – primary endpoint



PREVAIL 2 (Study 236): MADRS (MMRM) – primary endpoint (ITT)



LATUDA® (Lurasidone) – Other Clinical Development Status

- **New Phase 3 Study started in Japan (IND submitted in April, 2012)**

- **Bipolar I depression Phase III studies (PREVAIL Studies)**
 - PREVAIL 3: Placebo controlled study, LATUDA adjunctive to lithium or valproate
Initiated in December 2010

- **Bipolar maintenance**
 - Phase III study initiated in 2Q 2011

- **MDD with mixed features**
 - Phase III study initiated in 2Q 2011

- **Other studies under consideration**
 - IM depot formulation

Initiative in Oncology Domain

Japan

Research base
(Own Research/ Alliances/ In-licensing)

Development/
Marketing base

**Establish
Global R&D
System
In Oncology**

China

Development base

US: Acquisition of BBI

**President, CEO & CMO
- Dr. Chiang J. Li**

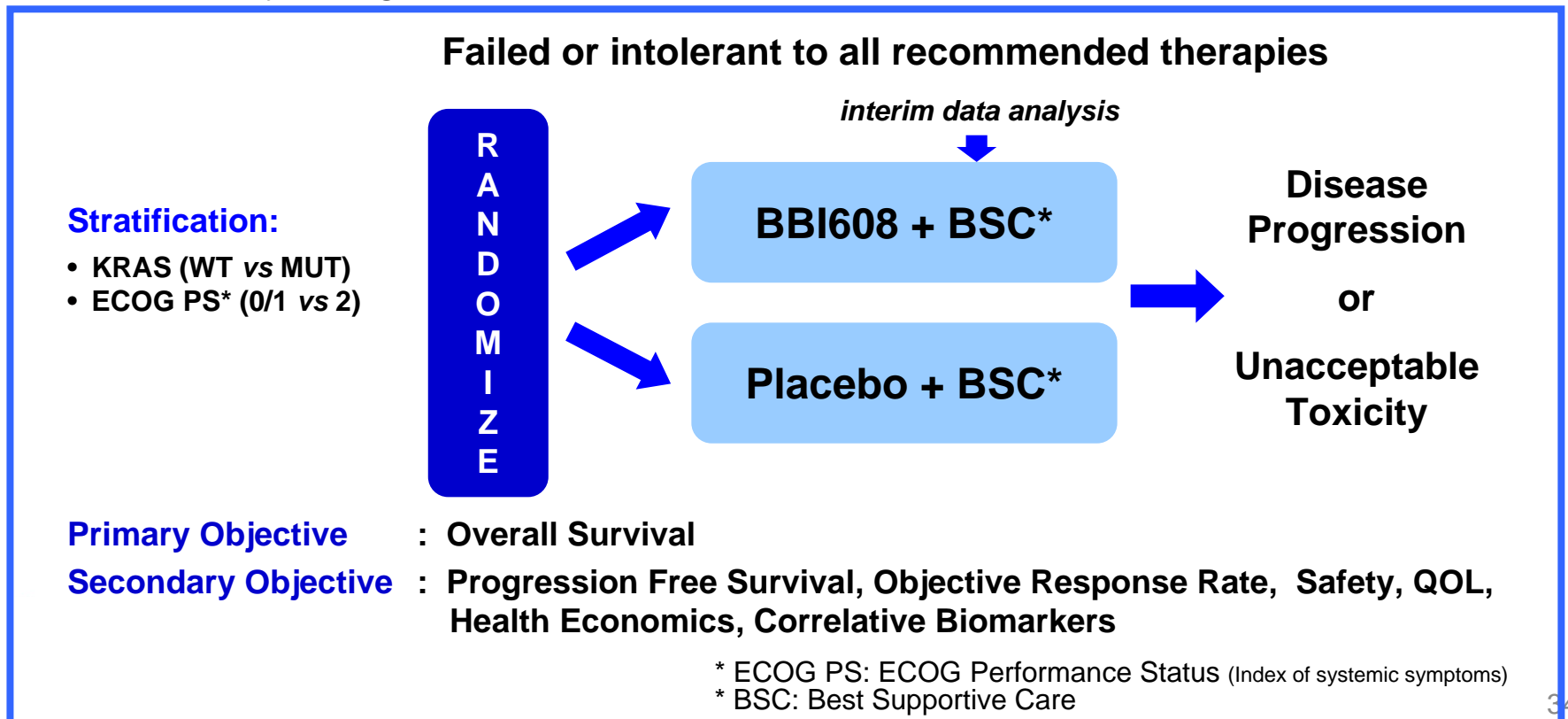
- Set up a global R&D organization for oncology (up to 100 staff) in Boston area with BBI as the core.
- Marketing organization to be established

BBI 608: Phase III Trial in Colorectal Cancer (2nd/ 3rd line)

BBI608 has been selected as only one Phase III trial in 2012 to be funded and conducted by National Cancer Institute of Canada - Clinical Trial Group (NCIC-CTG).

- Sponsor :BBI
- Clinical site : NCIC Clinical Trial Group that is going to conduct with a phase III clinical trial testing BBI608 in advanced CRC.
- Clinical cost : The Phase III costs will be co-funded by both NCIC-CTG and BBI.
- To be initiated 4Q 2012.

Phase III study design



NCIC Clinical Trials Group

- **NCIC Clinical Trials Group** (National Cancer Institute of Canada Clinical Trials Group)
 - The NCIC Clinical Trials Group is a cooperative oncology group which carries out clinical trials in cancer therapy, supportive care and prevention across Canada and internationally
- **Mission**
 - To develop and conduct clinical trials aimed at improving the treatment and prevention of cancer with the ultimate goal of reducing morbidity and mortality from this disease.
- **Structure**
 - Network of 70 investigative sites in Canada, over 1000 investigators and other research personnel
 - Collaboration with major cooperative groups internationally
 - Head office in Kingston; 125+ staff, 14 faculty
 - Formulate, implement group policy, Methodology and data management, Statistical expertise, Trial coordination, Quality management / assurance, Auditing & Monitoring, Safety, Regulatory / Ethics
- **Funding**
 - Core grant : Canadian Cancer Society Research Institute (Canadian Cancer Society).
- **Conducted 252 Phase III trials since 1980**

Their major trials are as below;

- Aromatase inhibitors for breast cancer (MA.17)* , prevent breast cancer (MAP.3)
- Cetuximab for colon cancer (CO.17)*
- Brivanib for colon cancer (CO.20)
- Temozolomide in GMB (CE.6)
- Erlotinib for lung cancer (BR.21)* , prostate cancer (PA.3)*
- Cediranib for lung cancer (BR.24 & BR.29)
- Lapatanib for breast cancer (MA.31)

*Leading to indication approval

Disclaimer Regarding Forward-looking Statements

The statements made in this presentation material are forward-looking statements based on management's assumptions and beliefs in light of information available up to the day of announcement, and involve both known and unknown risks and uncertainties.

Actual financial results may differ materially from those presented in this document, being dependent on a number of factors.

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