



Sumitomo Dainippon
Pharma

Innovation today, healthier tomorrows

Financial Results for 1Q FY2016

(April 1 to June 30, 2016)

July 27, 2016

Sumitomo Dainippon Pharma Co., Ltd.

1st
Anniversary

Financial Results for 1Q FY2016

Financial Results for 1Q FY2016

Billions of yen

	FY2015 1Q Results	FY2016 1Q Results	Change			FY2016 2Q (Apr.-Sep.)		FY2016	
			Value		%	Forecasts	Progress %	Forecasts	Progress %
				FX rate impact					
Net sales	98.1	103.5	5.4	(6.7)	5.5	199.0	52.0	410.0	25.2
Cost of sales	26.4	23.9	(2.4)	* (1.4)	(9.2)	49.0	48.8	99.5	24.0
Gross profit	71.8	79.6	7.8	(5.3)	10.9	150.0	53.0	310.5	25.6
SG&A expenses	67.3	65.0	(2.3)	(5.1)	(3.4)	134.0	48.5	270.5	24.0
SG&A expenses less R&D costs	47.2	45.7	(1.6)	(3.6)	(3.3)	93.5	48.8	186.0	24.6
R&D Costs	20.1	19.3	(0.8)	(1.4)	(3.8)	40.5	47.8	84.5	22.9
Operating income	4.4	14.6	10.1	(0.2)	227.7	16.0	91.0	40.0	36.4
Ordinary income	4.7	12.7	8.0		168.4	16.0	79.3	40.0	31.7
Extraordinary income (loss)	5.9	—	(5.9)			2.5		2.5	
Net income attributable to owners of the parent	5.9	8.4	2.4		40.8	8.0	104.6	25.0	33.5
E B I T D A	9.7	17.4	7.7		78.5	26.0		61.0	

* Amount of impact by profit realized in 1Q FY2016 out of unrealized profit of inventory in FY2015 is included.

FX rates:

FY2015 1Q Results : 1US\$ = ¥ 121.4, 1RMB = ¥19.6

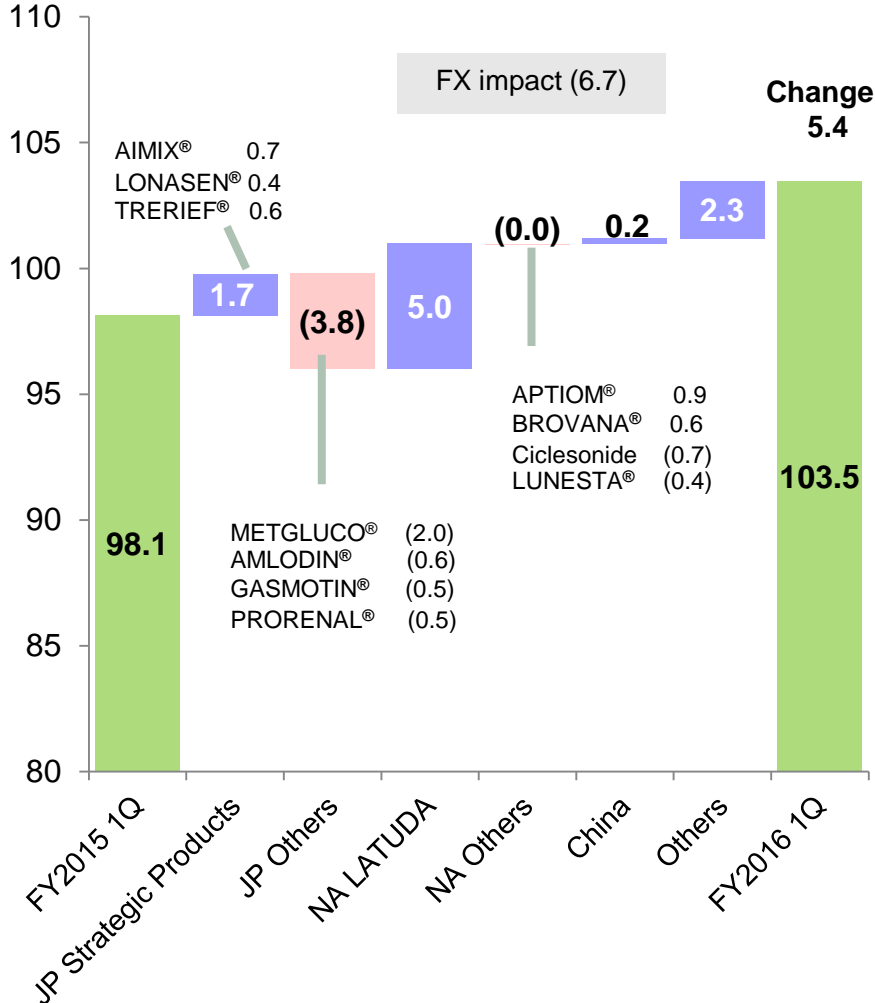
FY2016 1Q Results : 1US\$ = ¥ 108.1, 1RMB = ¥16.5

FY2016 Forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥17.0

Changes from FY2015 1Q

Sales

Billions of yen



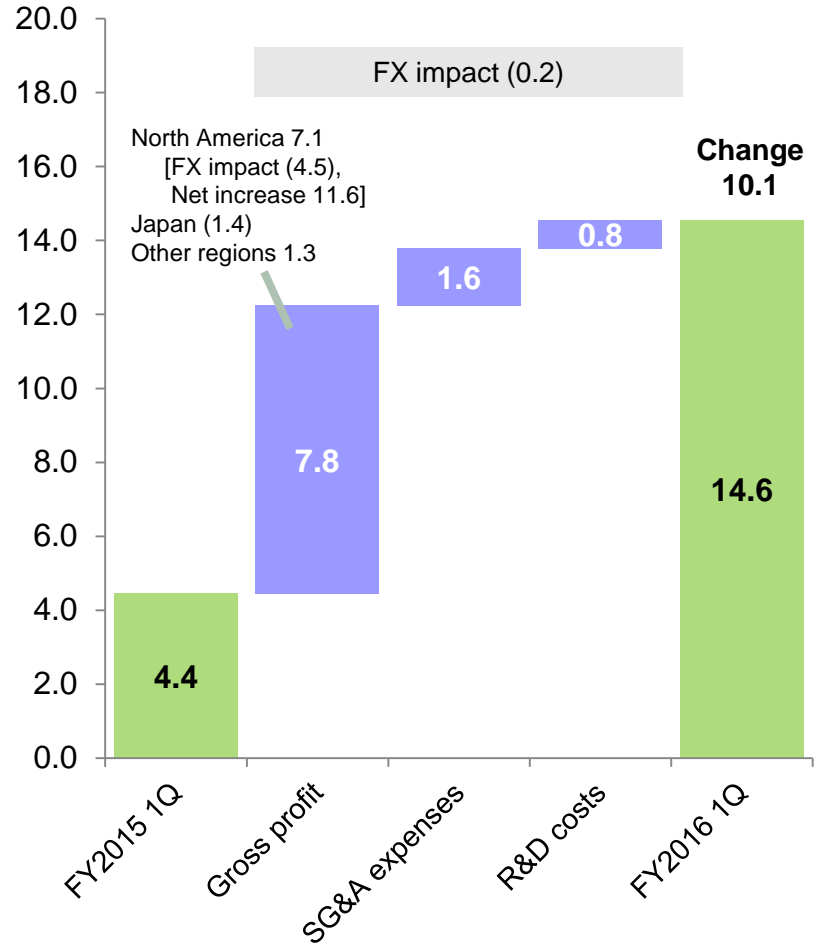
FX rates:

FY2015 1Q : 1US\$ = ¥121.4, 1RMB = ¥19.6

FY2016 1Q : 1US\$ = ¥108.1, 1RMB = ¥16.5

Operating Income

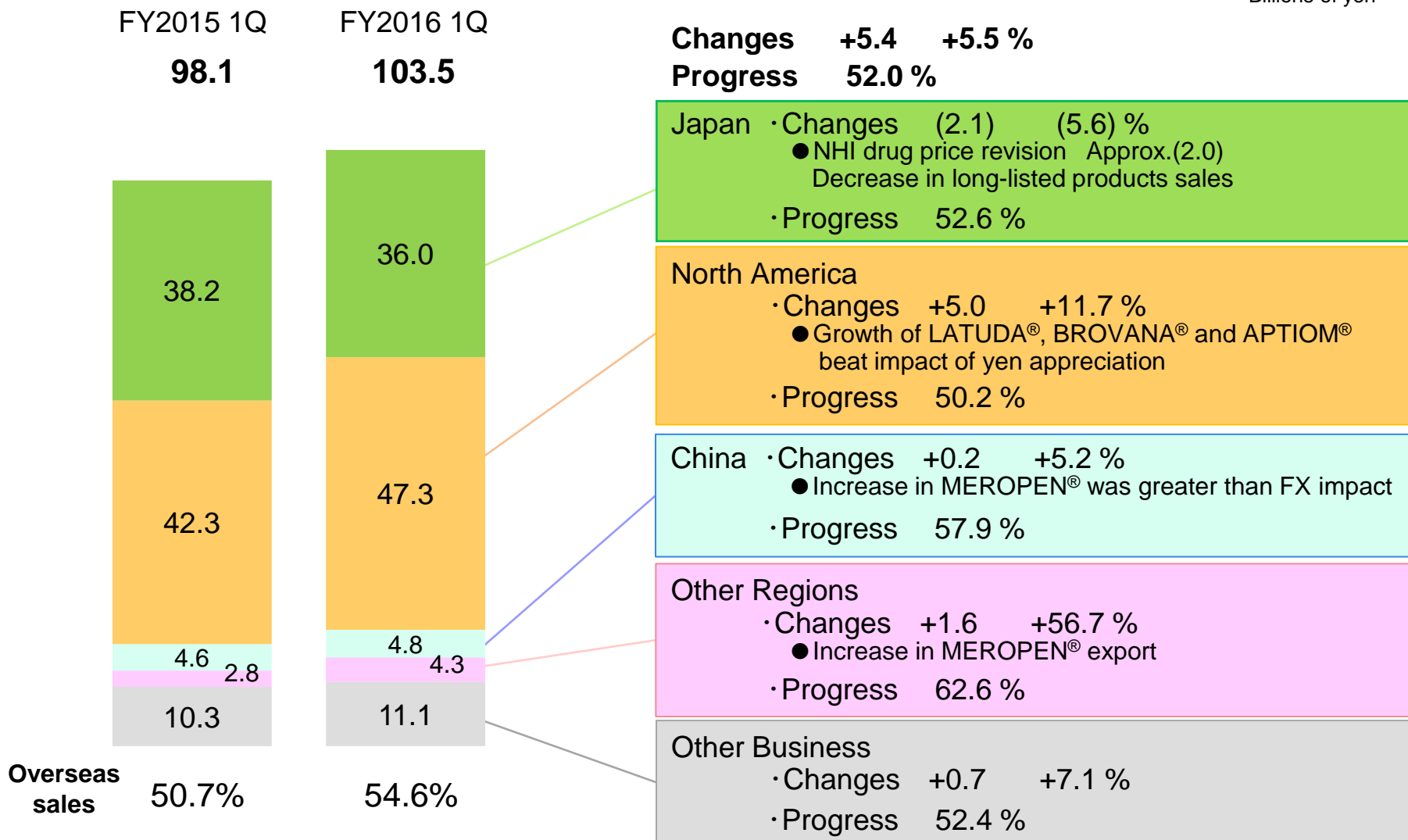
Billions of yen



Financial Results for 1Q FY2016

Net Sales by Segment

Billions of yen



FX rates:

FY2015 1Q : 1US\$ = ¥ 121.4, 1RMB = ¥19.6

FY2016 1Q : 1US\$ = ¥ 108.1, 1RMB = ¥16.5

Sales of Major Products in Japan

Billions of yen

	FY2015 1Q Results	FY2016 1Q Results	Change		2016 2Q (Apr.-Sep.)	
			Value	%	Forecasts	Progress %
AIMIX®	3.5	4.2	0.7	19.6	7.9	52.9
LONASEN®	3.1	3.5	0.4	12.0	6.9	50.1
TRERIEF®	3.3	3.9	0.6	18.8	6.9	56.1
Strategic Products Total	9.8	11.5	1.7	16.9	21.7	53.0
REPLAGAL®	2.8	2.7	(0.1)	(4.1)	5.2	51.0
AmBisome®	1.0	1.0	0.0	4.3	2.2	46.9
AVAPRO®	2.7	2.7	0.0	1.2	4.8	56.7
SUREPOST®	0.8	1.1	0.3	35.6	2.2	50.4
METGLUCO®	4.9	2.9	(2.0)	(40.2)	5.0	58.4
AMLODIN®	4.2	3.6	(0.6)	(15.0)	6.4	56.0
PRORENAL®	2.3	1.8	(0.5)	(20.8)	3.6	50.7
GASMOTIN®	2.2	1.7	(0.5)	(24.0)	3.2	52.8
MEROPEN®	1.6	1.2	(0.5)	(29.7)	2.4	48.2
Others	5.8	5.8	0.0	0.7	11.8	49.4
Other Products Total	28.3	24.5	(3.8)	(13.4)	46.8	52.4
Japan Total	38.2	36.0	(2.1)	(5.6)	68.5	52.6

Note: Sales of each product above are shown by gross sales basis.

Sales of Major Products in North America & China

	FY2015 1Q Results	FY2016 1Q Results	Change	FY2015 1Q Results	FY2016 1Q Results	Change			FY2016 2Q (Apr.-Sep.)		
						Value	%	FX rate impact	Forecasts		Yen- based progress
North America	Million \$			Billion yen			Million \$	Billion yen	%		
LATUDA®	218	291	73	26.5	31.5	5.0	18.8	(3.9)	558	61.4	51.2
APTIOM®	13	23	10	1.5	2.4	0.9	60.5	(0.3)	54	6.0	40.6
BROVANA®	58	71	13	7.0	7.6	0.6	8.7	(0.9)	130	14.3	53.3
Ciclesonide	17	13	(4)	2.1	1.4	(0.7)	(34.0)	(0.2)	28	3.1	43.8
XOPENEX®	13	12	(1)	1.6	1.3	(0.3)	(18.5)	(0.2)	25	2.8	46.8
LUNESTA®	11	8	(3)	1.3	0.9	(0.4)	(34.1)	(0.1)	13	1.5	57.2
Others	19	21	1	2.3	2.2	(0.1)	(4.9)	(0.3)	46	5.1	43.6
Total	349	438	89	42.3	47.3	5.0	11.7	(5.8)	856	94.2	50.2
China	Million RMB			Billion yen			Million \$	Billion yen	%		
MEROPEN®	193	257	65	3.8	4.2	0.5	12.7	(0.8)	418	7.1	59.8
Others	41	33	(7)	0.8	0.6	(0.2)	(30.2)	(0.1)	71	1.2	46.3
Total	233	291	58	4.6	4.8	0.2	5.2	(0.9)	488	8.3	57.9

FX rates:

FY2015 1Q Results : 1US\$ = ¥ 121.4, 1RMB = ¥19.6

FY2016 1Q Results : 1US\$ = ¥ 108.1, 1RMB = ¥16.5

FY2016 Forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥17.0

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2016 1Q Results	Net sales (Sales to customers)	36.0	47.3	4.8	4.3	92.4	11.1	103.5
	Cost of sales	10.7	1.8	0.6	2.0	15.1	8.9	23.9
	Gross profit	25.3	45.5	4.2	2.3	77.4	2.2	79.6
	SG&A expenses less R&D costs	14.2	27.4	1.8	0.7	44.1	1.6	45.7
	Income (loss) of Segment	11.1	18.1	2.5	1.6	33.3	0.6	33.9
	R&D costs					19.1	0.2	19.3
	Operating income					14.2	0.4	14.6
FY2015 1Q Results	Net sales (Sales to customers)	38.2	42.3	4.6	2.8	87.8	10.3	98.1
	Cost of sales	11.4	3.9	1.0	1.8	18.1	8.3	26.4
	Gross profit	26.8	38.4	3.6	1.0	69.7	2.0	71.8
	SG&A expenses less R&D costs	14.2	28.9	1.9	0.7	45.7	1.6	47.2
	Income (loss) of Segment	12.6	9.5	1.6	0.3	24.1	0.5	24.6
	R&D costs					19.9	0.2	20.1
	Operating income					4.2	0.3	4.4
Change	Net sales (Sales to customers)	(2.1)	5.0	0.2	1.6	4.6	0.7	5.4
	SG&A expenses less R&D costs	0.0	(1.5)	(0.2)	0.1	(1.6)	0.0	(1.6)
	Income (loss) of Segment	(1.5)	8.6	0.8	1.2	9.2	0.1	9.3
	R&D costs					(0.8)	0.0	(0.8)
	Operating income					10.0	0.1	10.1

FX rates:

FY2015 1Q : 1US\$ = ¥ 121.4, 1RMB = ¥19.6

FY2016 1Q : 1US\$ = ¥ 108.1, 1RMB = ¥16.5

Ordinary income & Net income attributable to owners of parent

Billions of yen

	FY2015 1Q Results	FY2016 1Q Results	Change	
			Value	%
Operating Income	4.4	14.6	10.1	227.7
Non-operating income and expenses	0.3	(1.9)	(2.2)	
Ordinary income	4.7	12.7	8.0	168.4
Extraordinary income	6.0	—	(6.0)	
Gain on sales of investment securities	6.0	—		
Extraordinary loss	0.2	—	(0.2)	
Impairment loss	0.2	—		
Income taxes	4.6	4.3	(0.3)	
Net income attributable to owners of the parent	5.9	8.4	2.4	40.8

FX rates:

FY2015 1Q : 1US\$ = ¥ 121.4, 1RMB = ¥19.6

FY2016 1Q : 1US\$ = ¥ 108.1, 1RMB = ¥16.5

Clinical Development Status

Development Pipeline (1) (as of July 27, 2016)

Psychiatry & Neurology Area

Revisions since the previous announcement are in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
APTIOM® (SEP-0002093)	eslicarbazepine acetate	(New indication) Epilepsy- Monotherapy	Canada				
LONASEN®	blonanserin	Schizophrenia	China				
		(Addition of pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
LATUDA® (SM-13496)	lurasidone hydrochloride	Schizophrenia	China				
		Schizophrenia	Japan				
		Bipolar I depression, Bipolar maintenance	Japan				
EPI-743	vatiquinone	Leigh syndrome	Japan				※1
SEP-225289	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				※2
		Binge eating disorder (BED)	U.S.				※2
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
SB623	TBD	Chronic stroke	U.S.				
EPI-589	TBD	Parkinson disease	U.S.				
		Amyotrophic lateral sclerosis (ALS)	U.S.				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S. / Japan				
SEP-363856	TBD	Schizophrenia	U.S. / Japan				
DSP-3748	TBD	Cognitive Impairment Associated with Schizophrenia	U.S.				
DSP-1200	TBD	Treatment-resistant depression	U.S.				

※1 / A Phase II / III study completed, development strategy under consideration ※2 / Phase II / III study

Development Pipeline (2) (as of July 27, 2016)

Oncology Area (napabucasin, amcasertib)

Revisions since the previous announcement are in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
BBI608	napabucasin	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical trial)	U.S. / Canada / Japan, etc.				
		Colorectal cancer (Combination therapy) (Global clinical trial)	U.S.				
		Non-small cell lung cancer (Combination therapy) (Global clinical trial)	U.S.				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
		Solid tumors (Ovarian cancer, Breast cancer, Melanoma, etc.) (Combination therapy)	U.S. / Canada			※1	
		Malignant pleural mesothelioma (Combination therapy)	Japan			※1	
		Solid tumors (Combination therapy) ※ ³ Hematologic malignancies (Monotherapy / Combination therapy)	U.S. / Canada				
		Solid tumors (Combination therapy) ※ ⁴	Japan				
BBI503	amcasertib	Solid tumors (Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.) (Monotherapy)	U.S. / Canada			※1	
		Solid tumors (Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, etc.) (Monotherapy)	Canada				
		Ovarian Cancer (Monotherapy)	U.S.				
		Hepatocellular carcinoma (Combination therapy)	U.S.		※2		
		Solid tumors (Combination therapy)	U.S. / Canada				
		Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	Japan				
BBI608 + BBI503	-	Solid tumors (Combination therapy)	U.S.				

※1/Phase II of Phase I / II study ※2/Phase I of Phase I / II study

※3/A number of tumor type-specific studies (Gastrointestinal cancer, Hepatocellular carcinoma, Glioblastoma, Pancreatic cancer)

※4/A number of tumor type-specific studies (Hepatocellular carcinoma, Colorectal cancer)

Development Pipeline (3) (as of July 27, 2016)

Oncology Area (Excluding napabucasin, amcasertib)

No changes after the announcement of May 2016

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
DSP-7888	TBD	Myelodysplastic syndromes	Japan			※1	
		Solid tumors, Hematologic malignancies	U.S.				
		Pediatric malignant glioma	Japan		※2		
WT4869	TBD	Myelodysplastic syndromes	Japan		※2		
		Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies	U.S.				
		Solid tumors	Japan				

※1/Phase II of Phase I / II study

※2/Phase I of Phase I / II study

Respiratory Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
SUN-101	glycopyrronium bromide	Chronic obstructive pulmonary disease (COPD)	U.S.				

Other Areas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				

(Reference) Napabucasin CO.23 study results will be presented at the ESMO in October 9, 2016 by CCTG (Canadian Cancer Trials Group).

	Partnering	Region (planned)	Cell type	Schedule for practical use (Calendar year)					
				2016	2017	2018	2019	2020	
Chronic Stroke	SanBio	North America	Allo MSC	Ph2b		Ph3		Approval Target	
AMD (age-related macular degeneration)	Healios RIKEN	Japan	Allo iPS cell	Clinical research	※ Investigator or corporate initiated clinical study			Approval Target	
Parkinson's disease	Kyoto Univ CiRA	Global	Allo iPS cell	Clinical research or clinical study					
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell			Investigator initiated clinical study			
Spinal Cord Injury	Keio Univ Osaka National Hospital	Global	Allo iPS cell			Clinical research			

※Start of clinical studies originally scheduled in 2017 may be delayed due to changes in non-clinical study plans.

Appendices

Appendix (Clinical Development Status) Napabucasin – Clinical development progress

(as of July 27, 2016)



Revisions since the previous announcement are in red.

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase III	U.S. / Canada / Japan, etc.	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy)	paclitaxel	BRIGHTER (BBI608-336)	Aug. 2014
Phase III	U.S.	Colorectal cancer (Combination therapy)	FOLFIRI, FOLFIRI + bevacizumab	CanStem303C (BB608-303CRC)	June 2016
Phase III	U.S.	Non-small cell lung cancer (Combination therapy)	paclitaxel	CanStem43L	Oct. 2016
Phase II	U.S. / Canada	Colorectal cancer (Combination therapy)	cetuximab, panitumumab, capecitabine	BBI608-224	Mar. 2012
Phase II	U.S. / Canada	Solid tumors*1 (Combination therapy)	paclitaxel	BBI608-201	Apr. 2011
Phase II	Japan	Malignant pleural mesothelioma (Combination therapy)	cisplatin + pemetrexed	D8807005	Feb. 2015
Phase I	U.S. / Canada	Gastrointestinal cancer (Combination therapy)	FOLFOX, FOLFOX + bevacizumab, CAPOX, FOLFIRI, FOLFIRI + bevacizumab, regorafenib, irinotecan	BBI608-246	Jan. 2014
Phase I	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	Dec. 2014
Phase I	U.S.	Pancreatic cancer (Combination therapy)	gemcitabine + nab-paclitaxel, FOLFIRINOX, irinotecan liposome injection + fluorouracil + leucovorin	BBI608-118	Aug. 2014
Phase I	Canada	Glioblastoma (Combination therapy)	temozolomide	BBI608-251	Mar. 2015
Phase I	U.S.	Hematologic Malignancies (Monotherapy / Combination therapy)	dexamethasone, bortezomib, imatinib, ibrutinib	BBI608-103HEME	May 2015
Phase I	Japan	Hepatocellular carcinoma (Combination therapy)	sorafenib	D8808001	Feb. 2015
Phase I	U.S.	Solid tumors (Combination therapy)	iplimumab, pembrolizumab, nivolumab	BBI608-201CIT	Aug. 2015
Phase I	Japan	Colorectal cancer (Combination therapy)	FOLFIRI + bevacizumab	D8809001	Dec. 2015

*1 / Ovarian cancer, Breast cancer, Melanoma, etc.

Start date is based on ClinicalTrials.gov (as of July 27, 2016)

Amcasertib

No changes after the announcement of May 2016

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase II	U.S. / Canada	Solid tumors*1 (Monotherapy)	–	BBI503-101	Feb. 2012
Phase II	Canada	Renal cell carcinoma, Urothelial carcinoma (Monotherapy)	–	BBI503-205a	July 2016
Phase II	Canada	Hepatocellular carcinoma, Cholangiocarcinoma (Monotherapy)	–	BBI503-205b	Feb. 2015
Phase II	Canada	Gastrointestinal stromal tumor (Monotherapy)	–	BBI503-205c	July 2016
Phase II	U.S.	Ovarian cancer (Monotherapy)	–	BBI503-205GYN-M	June 2015
Phase I	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	Dec. 2014
Phase I	Japan	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	sorafenib	DA101003	Mar. 2015
Phase I	U.S. / Canada	Solid tumors (Combination therapy)	capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel, sunitinib	BBI503-201	Sep. 2015

*1 / Colorectal cancer, Head and neck cancer, Ovarian cancer, etc.

Napabucasin + Amcasertib

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase I	U.S.	Solid tumors (Combination therapy)	–	BBI401-101	Apr. 2015

Start date is based on Clinical Trials.gov
(as of July 27, 2016)

Target submission date of key late-stage pipeline

(Updated July 2016)

Area	Development	Submission target			
		FY2016	FY2017	FY2018	FY2019 or later
Psychiatry & Neurology	SEP-225289 <dasotraline> (Adult , Pediatric ADHD) U.S.		●		
	TRERIEF® <zonisamide> (Parkinsonism in Dementia with Lewy Bodies) Japan		●		
	SEP-225289 <dasotraline> (BED) U.S.			●	
	LONASEN® <blonanserin> (Schizophrenia / Transdermal patch) Japan			●	
	SM-13496 <lurasidone hydrochloride> (Schizophrenia / Bipolar I depression / Bipolar maintenance) Japan				●
Oncology	BBI608 <napabucasin> (Gastric and Gastro-esophageal junction adenocarcinoma / Combination therapy) U.S./ Japan		●		
	BBI608 <napabucasin> (Colorectal cancer / Combination therapy) U.S./ Japan				●
	BBI608 <napabucasin> (NSCLC /Combination therapy) U.S.				●
Respiratory	SUN-101 <glycopyrronium bromide> (Chronic obstructive pulmonary disease) U.S.	●			

New Chemical Entities

New Indication, etc.

Product Launch Plan (Updated July 2016)

Area	FY2016	FY2017	FY2018	FY2019	FY2020 - FY2022
Japan		napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma)	TRERIEF® (Parkinsonism in Dementia with Lewy Bodies)	LONASEN® (Schizophrenia / Transdermal patch) amcasertib (Solid tumors)	lurasidone (Schizophrenia / Bipolar I depression / Bipolar maintenance) napabucasin (Colorectal cancer, etc.) DSP-7888 (Solid tumors/ Hematologic cancer) obeticholic acid (NASH) DSP-6952 (IBS with constipation, Chronic idiopathic constipation) iPS cell-derived RPE cells (Age-related macular degeneration)
U.S.	New in-licensed product (In-license)	napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma) glycopyrronium bromide (COPD)	dasotraline (ADHD)	dasotraline (BED) amcasertib (Solid tumors)	SB623 (Chronic stroke) DSP-2230 (Neuropathic pain) SEP-363856 (Schizophrenia) napabucasin (Colorectal cancer, Pancreatic cancer, NSCLC) DSP-7888 (Solid tumors/ Hematologic cancer)
China		LONASEN® (Schizophrenia)	lurasidone (Schizophrenia)		

 / Psychiatry & Neurology
 / Oncology
 / Liver / Digestive
 / Respiratory

 New Chemical Entities
 New Indication, etc.

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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