Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Financial Results for Q2 FY2017
(April 1 to September 30, 2017)

October 31, 2017

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma

Financial Results for Q2 FY2017

Financial Results for Q2 FY2017

Billions of yen

	Q2 FY2016 Results	Q2 FY2017 Results	Change			Q2 FY2017 (Apr.-Sep.)		FY2017	
			Value	FX rate impact	%	Previous forecasts	Achieve-ment %	Previous forecasts	Progress %
Net sales	198.1	240.5	42.4	7.1	21.4	234.5	102.5	464.0	51.8
Cost of sales	47.9	60.5	12.6	* 5.1	26.4	57.5	105.3	117.0	51.7
Gross profit	150.2	179.9	29.7	1.9	19.8	177.0	101.7	347.0	51.9
SG&A expenses	123.5	132.7	9.2	4.5	7.5	136.0	97.6	282.0	47.1
SG&A expenses less R&D costs	85.7	92.3	6.6	3.1	7.7	95.5	96.7	194.0	47.6
R&D costs	37.7	40.4	2.6	1.3	7.0	40.5	99.7	88.0	45.9
Operating income	26.7	47.2	20.5	(2.5)	76.7	41.0	115.2	65.0	72.7
Ordinary income	23.9	48.4	24.5		102.6	41.0	118.0	65.0	74.5
Extraordinary income (loss)	(6.2)	–	6.2			–	–	(2.5)	
Net income attributable to owners of the parent	10.9	34.9	24.0		219.4	28.5	122.4	44.0	79.3
E B I T D A	33.1	58.1	25.0		75.4	50.5	115.0	85.0	68.3

* Includes an impact [¥4.2B] of change in FX rates on the unrealized profit of inventory

FX rates:
Q2 FY2016 Results : 1US$ = ¥ 105.2, 1RMB = ¥15.9
Q2 FY2017 Results : 1US$ = ¥ 111.1, 1RMB = ¥16.4
FY2017 Forecasts: 1US$ = ¥ 110.0, 1RMB = ¥16.5

Sales of Major Products in Japan

Billions of yen

	Q2 FY2016 Results	Q2 FY2017 Results	Change		Q2 FY2017 (Apr.-Sep.)	
			Value	%	Forecasts	Achievement %
AIMIX®	8.3	9.2	0.9	11.1	8.6	107.5
TRERIEF®	7.6	8.1	0.5	6.3	8.1	99.4
LONASEN®	6.7	6.5	(0.1)	(1.8)	6.7	97.5
METGLUCO®	5.7	5.6	(0.1)	(2.1)	5.6	99.5
REPLAGAL®	5.3	5.8	0.5	9.0	5.6	103.3
Trulicity® *	2.1	7.1	5.0	235.2	5.0	142.5
AVAPRO®	5.3	5.1	(0.2)	(4.0)	4.7	107.7
SUREPOST®	2.2	2.5	0.3	13.9	2.5	98.4
AmBisome®	2.2	2.2	(0.0)	(1.1)	2.2	99.6
Promoted products Total	45.3	52.0	6.7	14.8	49.0	106.2
AMLODIN®	6.7	6.0	(0.8)	(11.6)	5.6	106.4
PRORENAL®	3.5	2.9	(0.6)	(16.8)	2.8	103.1
GASMOTIN®	3.2	2.6	(0.6)	(18.8)	2.6	99.6
MEROPEN®	2.3	1.8	(0.5)	(23.2)	2.2	80.0
Others	9.5	7.6	(1.9)	(19.9)	8.4	90.7
Total	70.5	72.8	2.3	3.3	70.6	103.2

Note: Sales of each product above are shown on an invoice price basis (* Trulicity® is shown on NHI price basis).

Sales of Major Products in North America & China

	Q2 FY2016 Results	Q2 FY2017 Results	Change	Q2 FY2016 Results	Q2 FY2017 Results	Change			Q2 FY2017 (Apr.-Sep.)		
						Value	FX rate impact	%	Previous forecasts		Yen-based achievement
North America	Million $			Billion yen					Million $	Billion yen	%
LATUDA®	584	779	195	61.4	86.5	25.0	4.6	40.8	776	85.4	101.2
BROVANA®	153	147	(6)	16.1	16.4	0.3	0.9	1.7	156	17.2	95.2
APTIOM®	47	66	18	5.0	7.3	2.3	0.4	46.8	68	7.4	98.6
Ciclesonide	23	13	(10)	2.4	1.4	(1.0)	0.1	(40.0)	16	1.7	84.1
XOPENEX®	25	17	(8)	2.6	1.9	(0.8)	0.1	(28.9)	15	1.7	109.5
New COPD products *	–	2	2	–	0.2	0.2	–	–	4	0.5	38.8
Others	37	123	87	3.9	13.6	9.8	0.7	251.6	107	11.7	116.5
Total	868	1,146	278	91.4	127.3	35.9	6.7	39.3	1,142	125.6	101.4
China	Million RMB			Billion yen					Million RMB	Billion yen	%
MEROPEN®	505	610	106	8.0	10.0	2.0	0.3	24.7	518	8.5	113.9
Others	71	90	19	1.1	1.5	0.3	0.0	30.1	71	1.2	123.4
Total	576	701	124	9.2	11.5	2.3	0.4	25.4	589	9.7	118.6

* UTIBRON™, SEEBRI™, ARCAPTA®, SUN-101 (NDA filed)

FX rates:
Q2 FY2016 Results : 1US$ = ¥ 105.2, 1RMB = ¥15.9
Q2 FY2017 Results : 1US$ = ¥ 111.1, 1RMB = ¥16.4
FY2017 Forecasts: 1US$ = ¥ 110.0, 1RMB = ¥16.5

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Q2 FY2017 Results	Net sales (Sales to customers)	72.8	127.3	11.5	6.8	218.4	22.0	240.5
	Cost of sales	26.2	11.5	2.3	3.1	43.1	17.4	60.5
	Gross profit	46.7	115.8	9.2	3.7	175.4	4.6	179.9
	SG&A expenses less R&D costs	25.0	58.5	3.7	1.9	89.1	3.2	92.3
	Income (loss) of Segment	21.7	57.3	5.5	1.8	86.3	1.4	87.6
	R&D costs					39.9	0.5	40.4
	Operating income					46.4	0.8	47.2
Q2 FY2016 Results	Net sales (Sales to customers)	70.5	91.4	9.2	5.3	176.4	21.7	198.1
	Cost of sales	22.5	4.1	1.4	2.5	30.5	17.3	47.9
	Gross profit	48.1	87.2	7.8	2.7	145.8	4.4	150.2
	SG&A expenses less R&D costs	28.5	49.0	3.5	1.5	82.5	3.2	85.7
	Income (loss) of Segment	19.6	38.3	4.3	1.2	63.4	1.1	64.5
	R&D costs					37.3	0.5	37.7
	Operating income					26.1	0.6	26.7
Change	Net sales (Sales to customers)	2.3	35.9	2.3	1.5	42.1	0.3	42.4
	SG&A expenses less R&D costs	(3.5)	9.6	0.2	0.4	6.6	(0.0)	6.6
	Income (loss) of Segment	2.1	19.0	1.2	0.5	22.9	0.2	23.2
	R&D costs					2.6	0.1	2.6
	Operating income					20.3	0.2	20.5

FX rates:
Q2 FY2016 : 1US$ = ¥ 105.2, 1RMB = ¥15.9
Q2 FY2017 : 1US$ = ¥ 111.1, 1RMB = ¥16.4

Ordinary income & Net income attributable to owners of the parent

Billions of yen

	Q2 FY2016 Results	Q2 FY2017 Results	Change	
			Value	%
Operating Income	26.7	47.2	20.5	76.7
Non-operating income and expenses	(2.8)	1.2	4.0	
Ordinary income	23.9	48.4	24.5	102.6
Extraordinary income	3.8	–	(3.8)	
Gain on sales of investment securities	3.8	–		
Extraordinary loss	10.0	–	(10.0)	
Business structure improvement expenses	10.0	–		
Income taxes	6.8	13.5	6.7	
Net income attributable to owners of the parent	10.9	34.9	24.0	219.4

FX rates:
Q2 FY2016 : 1US$ = ¥ 105.2, 1RMB = ¥15.9
Q2 FY2017 : 1US$ = ¥ 111.1, 1RMB = ¥16.4

Financial Forecasts for FY2017

Financial Forecasts for FY2017

Billions of yen

	FY2016 Result (a)	FY2017 Previous forecasts (b)	FY2017 Revised forecasts (c)	Change from previous forecasts (c)-(b)	Change from FY2016 (c)-(a)		
					Value	FX rate impact	%
Net sales	411.6	464.0	474.0	10.0	62.4	4.3	15.1
Cost of sales	100.1	117.0	118.5	1.5	18.4	8.5	18.4
Gross profit	311.6	347.0	355.5	8.5	43.9	(4.2)	14.1
SG&A expenses	258.8	282.0	283.5	1.5	24.7	2.8	9.5
SG&A expenses less R & D costs	178.0	194.0	194.5	0.5	16.5	2.0	9.3
R&D costs	80.8	88.0	89.0	1.0	8.2	0.8	10.1
Operating income	52.8	65.0	72.0	7.0	19.2	(7.0)	36.5
Ordinary income	54.3	65.0	72.0	7.0	17.7		32.5
Extraordinary income (loss)	(7.1)	(2.5)	(2.5)	–	4.6		
Net income attributable to owners of the parent	29.0	44.0	47.0	3.0	18.0		62.1
EBITDA	72.8	85.0	92.0	7.0	19.2		26.3

FX rates:
FY2016 Result : 1US$ = ¥ 108.4, 1RMB = ¥16.1
FY2017 Forecast : 1US$ = ¥ 110.0, 1RMB = ¥16.5

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2017 Revised Forecasts	Net sales (Sales to customers)	141.6	251.8	19.7	15.9	429.0	45.0	474.0
	Cost of sales	51.0	21.4	3.8	6.4	82.6	35.9	118.5
	Gross profit	90.6	230.4	15.9	9.5	346.4	9.1	355.5
	SG&A expenses less R&D costs	52.0	124.2	7.8	3.7	187.7	6.8	194.5
	Income (loss) of Segment	38.6	106.2	8.1	5.8	158.7	2.3	161.0
	R&D costs					88.0	1.0	89.0
	Operating income					70.7	1.3	72.0
FY2017 Previous Forecasts	Net sales (Sales to customers)	139.2	245.6	18.3	15.9	419.0	45.0	464.0
	Cost of sales	48.4	22.5	3.8	6.4	81.1	35.9	117.0
	Gross profit	90.8	223.1	14.5	9.5	337.9	9.1	347.0
	SG&A expenses less R&D costs	53.0	122.7	7.8	3.7	187.2	6.8	194.0
	Income (loss) of Segment	37.8	100.4	6.7	5.8	150.7	2.3	153.0
	R&D costs					87.0	1.0	88.0
	Operating income					63.7	1.3	65.0
Change	Net sales (Sales to customers)	2.4	6.2	1.4	–	10.0	–	10.0
	SG&A expenses less R&D costs	(1.0)	1.5	–	–	0.5	–	0.5
	Income (loss) of Segment	0.8	5.8	1.4	–	8.0	–	8.0
	R&D costs					1.0	–	1.0
	Operating income					7.0	–	7.0

FX rates:
FY2017 Forecast : 1US$ = ¥ 110.0, 1RMB = ¥16.5

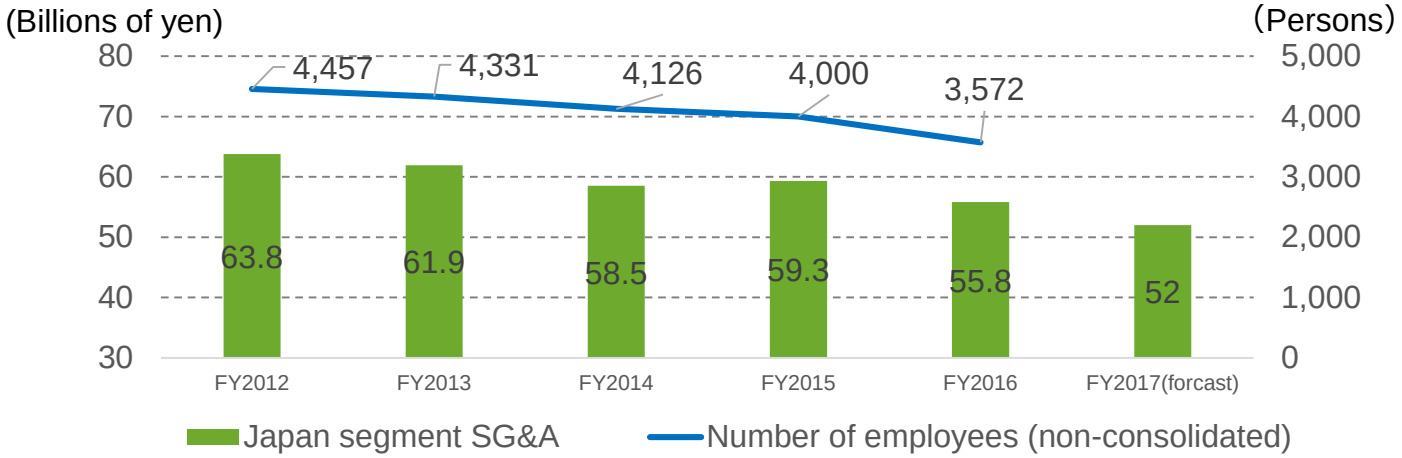
To strengthen robust revenue base

To strengthen robust revenue base

Pursue Operational Efficiency in Japan

➢ Reduce SG&A costs continuously

- FY2012: 63.8 billion yen ⇒ FY2016: 55.8 billion yen (down by 8.0 billion yen)
- FY2012: 4,457 employees ⇒ FY2016 : 3,572 employees (down by 885 persons)



- Optimize the number of employees of Manufacturing Division associated with the planned reorganization of production sites, by implementing an early retirement program at the end of FY2017

➢ Work Style Reforms

- Various efforts in 2017 as the first year for Work Style Reforms initiative

  Seminars for employees, training for middle management (“IkuBoss”), encouragement to take annual paid leave, Work Style Innovation Meetings (all divisions), expansion of scope of work from home system, etc.

→ Improve operational efficiency

Strengthen Robust Revenue Base in the U.S.

Establish efficient sales system for new products

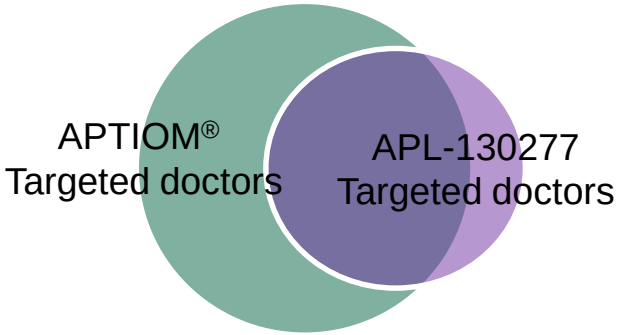
➢ Psychiatry & Neurology Area

- **Dasotraline**

  Developing efficient sales structure for dasotraline, utilizing LATUDA sales structure

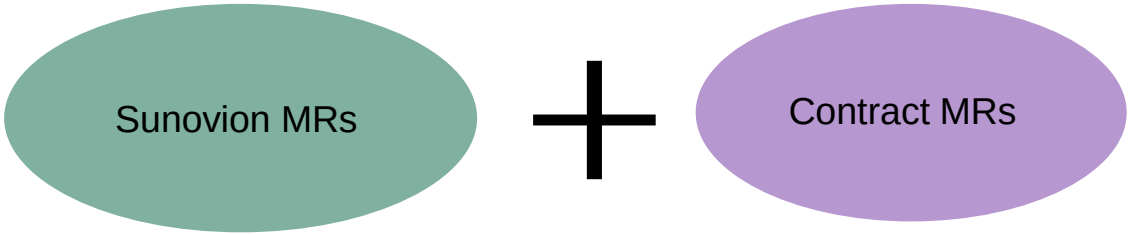
- **APL-130277**

  Covered by APTIOM® MRs



➢ Respiratory Area

BROVANA® + SUN-101, UTIBRON™, SEEBRI™, ARCAPTA®



Research & Clinical Development Status

Reorganization of Research Framework (October 2017)

Reorganization of Drug Research Division

- Organizational realignment in the research framework significantly to create more productive development pipeline
- Introduced "New Project-based Research Management System" aiming to strongly accelerate drug discovery research projects

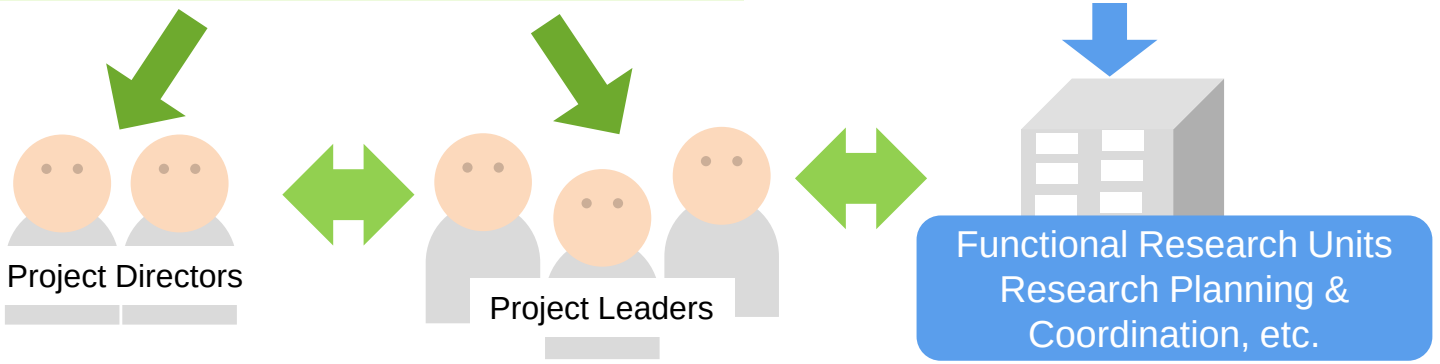
“New Project-based Research Management System"

- Project Leaders : Responsible for advancing projects, authorized to implement project budgets
- Project Directors : Responsible for strategic proposals from a holistic perspective and supporting Project Leaders

Drug Research Division

Senior Executive Research Director : Toru Kimura
Oversee the entire Drug Research Division

Executive Research Director : Hideyuki Harada
Direct control over Functional Research Units, etc.



Clinical Development Updates Psychiatry & Neurology Area

Dasotraline

- Pediatric/Adult ADHD： NDA submitted in August 2017 in the U.S.
- A new chemical entity that acts as a dual dopamine and norepinephrine reuptake inhibitor (DNRI) Extended half-life supports potential for stable plasma concentrations yielding a continuous therapeutic effect over 24-hour dosing interval
- The number of patients with ADHD (U.S.)：estimated 6.4 million※1 children ages 4 to 17 and 8 million※2 adults

TRERIEF®

- Parkinsonism in dementia with Lewy bodies (DLB)：Submitted in August 2017 in Japan

  If approved, would become the world's first drug to be indicated for parkinsonism in DLB
- DLB accounts for 4% to 15% of all cases of dementia

APTIOM®

- Partial onset seizures in children and adolescents ages 4 to 17： Approved in September 2017 in the U.S.
- The number of patients with epilepsy (U.S.)： estimated 470,000※1 children 17 years of age or younger, 3 million※1 (numbers include children <4 years and non-partial onset seizures)

Apomorphine (APL-130277)

- Phase 3 studies ongoing, plan to submit an NDA in FY2017 in the U.S.

Discontinued

- DSP-1200 (U.S.: Phase 1 study (Treatment-resistant depression))

※1: Center for Disease Control and Prevention ※2: Anxiety and Depression Association of America

Clinical Development Updates　Oncology Area

➢ Boost of development in Boston Biomedical, Inc.

- Hired the R&D head (CMO) and vice presidents in clinical development, R&D operations, and others

➢ Napabucasin

- Phase 3 studies ongoing
  - ✓ Colorectal cancer (combination therapy with FOLFIRI and bevacizumab)
  - ✓ Pancreatic cancer (combination therapy with gemcitabine and nab-paclitaxel)
- Unblinded study for Gastric and gastro-esophageal junction adenocarcinoma (BRIGHTER study) under analysis

➢ Alvocidib

- AML (Refractory or relapsed patients)
  - ✓ Stage 1 of Phase 2 study ongoing
    Plan to start Stage 2 of Phase 2 study in 2H of FY2017, in consultation with the FDA
    Aiming to submit an accelerated approval application in FY2018
- AML (Newly diagnosed patients)
  - ✓ New Phase 1 study (combination therapy with 7+3 standard therapy) started

※7+3 standard therapy : cytarabine, duanorubicin

➢ DSP-7888

- Phase 2 studies ongoing (Glioblastoma, Pediatric malignant glioma, MDS)
- New Phase 1 study started (Solid tumors combination therapy with immuno-checkpoint inhibitors)

Clinical Development Updates　Other Areas (Diabetes)

➢ New alliance: Exclusive license for Imeglimin from Poxel SA

- Licensed territory:　Japan, China, South Korea, Taiwan and 9 countries of South-east Asia
- Mode of action: Increasing insulin secretion in response to glucose and improving mitochondrial function (targeting the mitochondrial bioenergetics).
- Expected profile:
  - Imeglimin acts on all three key organs (the liver, muscle, and the pancreas) which play an important　role in the treatment of type 2 diabetes
    - ✓ Increase insulin secretion from pancreas in response to glucose
    - ✓ Improve insulin sensitivity in liver and muscles
    - ✓ Suppress gluconeogenesis in liver
  - Protecting β cell survival and function

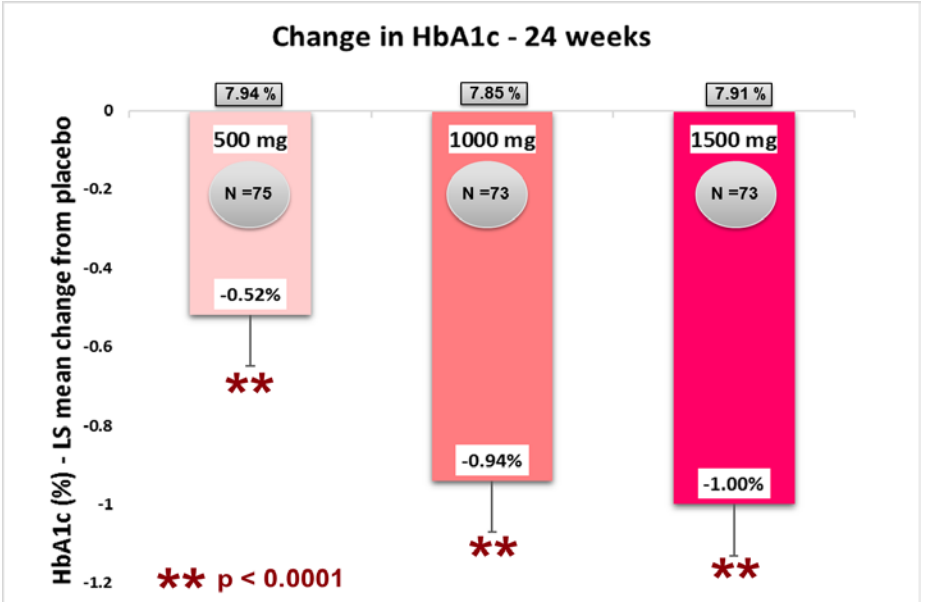
● Results of Phase 2b study in Japan

Study design：24 weeks, placebo-controlled, double-blind study, involving 299 Japanese type 2 diabetes

✓ Efficacy : Imeglimin demonstrated dose-dependent improvement vs placebo

✓ Safety : Imeglimin generally well tolerated

Plan to start Phase 3 study in 2017



J. Dubourg, EASD 2017 Session PS066 Novel approaches to glucose-lowering: 843

Strengthen product lineup in diabetes therapeutic area in Japan

Clinical Development Updates Regenerative Medicine/Cell Therapy

Regenerative Medicine/Cell Therapy

- **Chronic Stroke (SB623): Partnership with SanBio**
  - Phase 2b study progressing (estimated enrollment 156 in FY2017)

- **AMD (age-related macular degeneration): Partnership with Healios RIKEN**
  - Giving consideration to changing schedule for clinical study due to changes in non-clinical study plans (Start date of clinical study changed from 2017 to after 2018)

- **Parkinson's disease: Partnership with Kyoto University, CiRA**
  - Plan to start investigator-initiated clinical study in FY2018

- **Construction of a cell processing center (new CPC) is progressing steadily; operation planned to start in FY2017**

Reference (drug discovery using iPS cell)

Collaboration with Professor Toguchida (CiRA) : Succeeded in elucidating the mechanism of ectopic bone formation in FOP, sing iPS cells derived from patients with FOP, and identified a therapeutic drug candidate

→ Succeeded in conducting the world's first high-throughput screening to search for compounds using iPS cells derived from patients

Other topics

➢ Infectious disease area

- Joint drug discovery research with The Kitasato Institute :
  Aiming to create novel drugs for infections with Antimicrobial Resistance (AMR)

Japan Agency for Medical Research and Development（AMED）

Contract R&D

The Kitasato Institute

Drug discovery research is being conducted at Kitasato University
[approx. 30 scientists in total]

Dr. Omura's drug discovery group
World-class research team with anti-infective drug discovery system
+
Sumitomo Dainippon Pharma assigned researchers

Joint research

Chemical synthesis
（Drug discovery research, process chemistry）

Pharmacokinetics, safety studies

CMC＊ ＊ Chemistry, Manufacturing and Control

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Clinical studies (Japan and overseas)
Application for regulatory approval

Submission Target of Key Late-stage Pipeline

(as of October 2017)

Area	Products under Development	Submission target			
		FY2017	FY2018	FY2019	FY2020-2022
Psychiatry & Neurology	**SEP-225289 <dasotraline>** (Adult , Pediatric ADHD) U.S.	Submitted in Aug. 2017			
	TRERIEF® <zonisamide> (Parkinsonism in Dementia with Lewy Bodies) Japan	Submitted in Aug. 2017			
	APL-130277 <apomorphine > (Parkinson's disease) U.S.	●			
	SEP-225289 <dasotraline> (BED) U.S.		●		
	LONASEN® <blonanserin> (Schizophrenia / Transdermal patch) Japan		●		
	SM-13496 <lurasidone > (Schizophrenia / Bipolar I depression / Bipolar maintenance) Japan			●	
	SB623 (Chronic stroke) U.S.				●
Oncology	**alvocidib** (Acute myeloid leukemia (AML) / Combination therapy) U.S.		● ※		
	BBI608 <napabucasin> (Colorectal cancer / Combination therapy) U.S./ Japan				●
	BBI608 <napabucasin> (Pancreatic cancer / Combination therapy) U.S. / Japan				●

New Chemical Entities | New Indication, etc.

※Premised on the application of accelerated approval program (Plan to consult with the FDA)

Appendices

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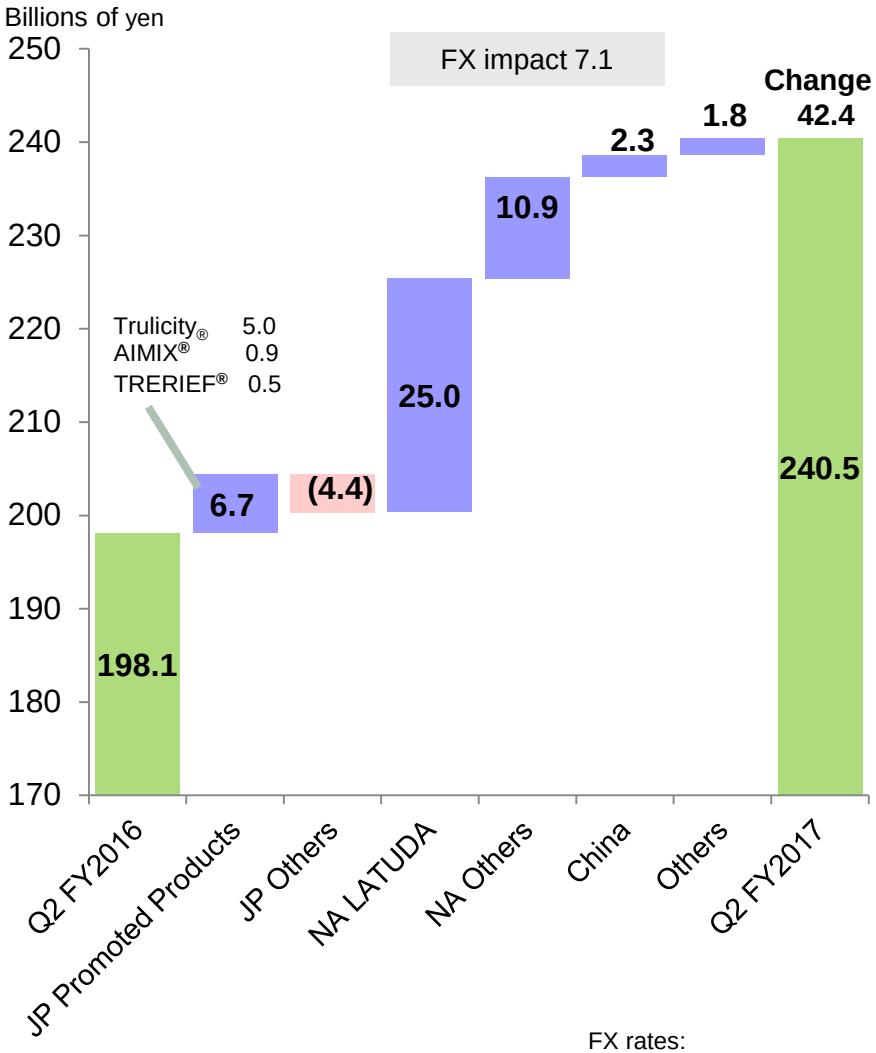
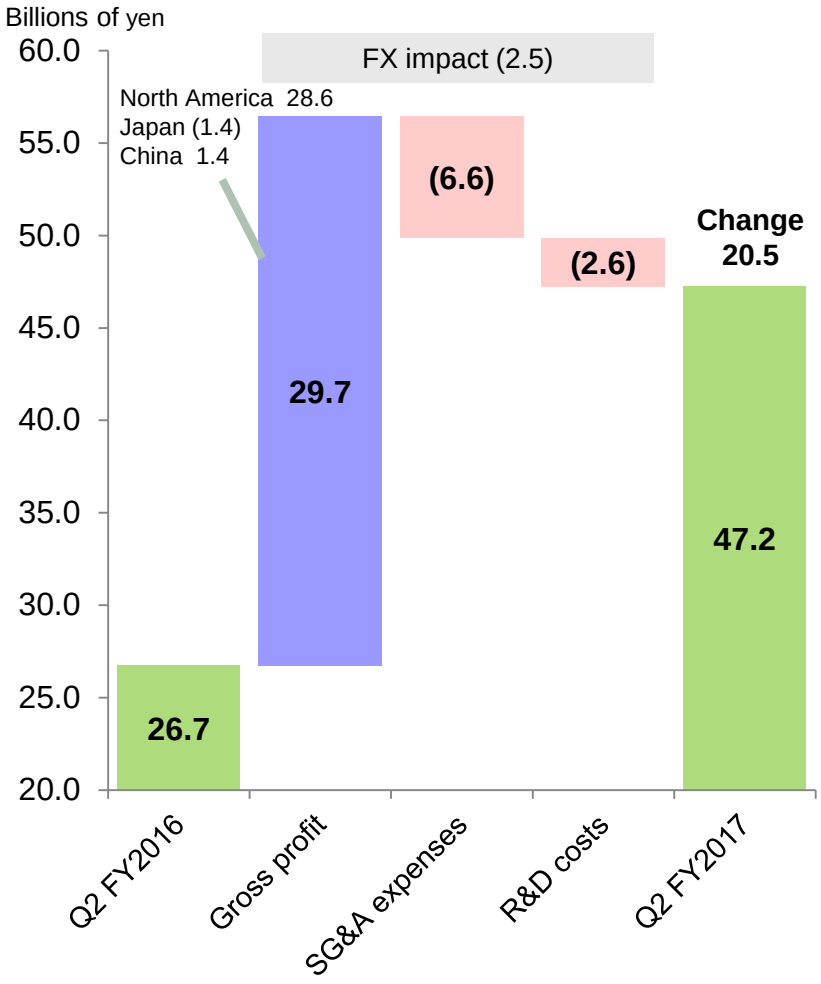
Changes from Q2 FY2016

Sales



Operating Income



FX rates:
Q2 FY2016 : 1US$ = ¥ 105.2, 1RMB = ¥15.9
Q2 FY2017 : 1US$ = ¥ 111.1, 1RMB = ¥16.4

Net Sales by Segment

Billions of yen

Changes +42.4 +21.4 %
Achievement 102.5 %

Japan ・Changes +2.3 +3.3 %
- Growth of Trulicity®, solid sales of AIMIX®, TRERIEF® ,decrease in long-listed products

・Achievement 103.2%

North America
・Changes +35.9 +39.3 %
- Driven by growth of LATUDA® and APTIOM®, divestiture of ciclesonide products

・Achievement 101.4%

China ・Changes +2.3 +25.4 %
- Strong sales of MEROPEN®

・Achievement 118.6%

Other Regions
・Changes +1.5 +28.1 %
- Increase in export of MEROPEN®

・Achievement 102.5%

Other Business
・Changes +0.3 +1.5 %

・Achievement 100.2%

FX rates:
Q2 FY2016 : 1US$ = ¥ 105.2, 1RMB = ¥15.9
Q2 FY2017 : 1US$ = ¥ 111.1, 1RMB = ¥16.4

※ Progress is % to 1H forecast

Financial Position / Cash Flows

Billions of yen

B/S	As of March 31, 2017	As of Sep. 30, 2017	Change
Assets	794.0	828.5	34.6
Current assets	376.5	406.2	29.8
Fixed assets	417.5	422.3	4.8
Liabilities	333.3	332.5	(0.7)
Current liabilities	228.4	236.3	7.8
Long-term liabilities	104.8	96.3	(8.6)
Net assets	460.7	496.0	35.4
Shareholders' equity ratio	58.0%	59.9%	

C/F	FY2016 Q2	FY2017 Q2	Change
Operating CF	13.5	44.8	31.2
Investment CF	31.6	(6.6)	(38.1)
Financial CF	(26.5)	(12.4)	14.2
Cash / Cash equivalents	140.4	132.2	(8.2)
Operating funds	153.9	146.8	(7.0)

【Assets】

Cash and time deposits	20.9
Notes and accounts receivable	7.3
Intangible assets	(3.7)
Investment securities	10.0

【Liabilities】

Income taxes payable	3.1
Reserve for sales allowance	7.2
Bond / Loan payable	(8.0)

(Reference)

Balance as of end of FY2016

Cash / CE	105.6
Operating funds	122.3

Sales of Major Products in Japan

Billions of yen

	FY2016	FY2017 Previous Forecasts	FY2017 Revised Forecasts	Change from Previous Forecasts
AIMIX®	17.1	17.5	17.5	–
TRERIEF®	15.1	16.0	16.0	–
LONASEN®	12.8	13.2	13.2	–
METGLUCO®	11.2	11.3	11.3	–
REPLAGAL®	10.7	11.3	11.3	–
Trulicity® *	6.8	11.0	14.5	3.5
AVAPRO®	10.3	8.0	8.0	–
SUREPOST®	4.3	5.3	5.3	–
AmBisome®	4.4	4.5	4.5	–
Promoted products Total	92.8	98.1	101.6	3.5
AMLODIN®	13.0	10.6	10.6	–
PRORENAL®	6.5	5.1	5.1	–
GASMOTIN®	6.0	5.0	5.0	–
MEROPEN®	4.3	4.1	3.3	(0.8)
Others	18.2	16.3	16.0	(0.3)
Total	140.8	139.2	141.6	2.4

Note: Sales of each product above are shown on an invoice price basis (* Trulicity® is shown on NHI price basis).

Sales of Major Products in North America & China

	FY2016	FY2017 Previous Forecasts	FY2017 Revised Forecasts	Change from Previous Forecasts	FY2016	FY2017 Previous Forecasts	FY2017 Revised Forecasts	Change from Previous Forecasts
North America	Million $				Billion yen			
LATUDA®	1,254	1,538	1,618	80	135.9	169.2	178.0	8.8
BROVANA®	305	313	313	–	33.1	34.4	34.4	–
APTIOM®	107	152	152	–	11.6	16.7	16.7	–
Ciclesonide	47	16	13	(3)	5.1	1.7	1.4	(0.3)
XOPENEX®	47	29	29	–	5.1	3.2	3.2	–
New COPD products *	0	37	6	(31)	0.0	4.1	0.7	(3.4)
Others	66	148	158	10	7.1	16.3	17.4	1.1
Total	1,826	2,233	2,289	56	197.9	245.6	251.8	6.2
China	Million RMB				Billion yen			
MEROPEN®	954	958	1,023	65	15.4	15.8	16.9	1.1
Others	141	151	171	20	2.3	2.5	2.8	0.3
Total	1,095	1,109	1,194	85	17.6	18.3	19.7	1.4

* UTIBRON™, SEEBRI™, ARCAPTA®, SUN-101 (NDA filed)

FX rates:
FY2016 Results : 1US$ = ¥ 108.4, 1RMB = ¥16.1
FY2017 Forecast : 1US$ = ¥ 110.0, 1RMB = ¥16.5

Segment Information FY2017 / FY2016

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2017 Revised Forecasts	Net sales (Sales to customers)	141.6	251.8	19.7	15.9	429.0	45.0	474.0
	Cost of sales	51.0	21.4	3.8	6.4	82.6	35.9	118.5
	Gross profit	90.6	230.4	15.9	9.5	346.4	9.1	355.5
	SG&A expenses less R&D costs	52.0	124.2	7.8	3.7	187.7	6.8	194.5
	Income (loss) of Segment	38.6	106.2	8.1	5.8	158.7	2.3	161.0
	R&D costs					88.0	1.0	89.0
	Operating income					70.7	1.3	72.0
FY2016 Results	Net sales (Sales to customers)	140.8	197.9	17.6	11.6	367.9	43.7	411.6
	Cost of sales	46.7	9.6	3.4	5.6	65.3	34.8	100.1
	Gross profit	94.1	188.3	14.3	5.9	302.7	8.9	311.6
	SG&A expenses less R&D costs	55.8	105.0	7.5	3.1	171.5	6.5	178.0
	Income (loss) of Segment	38.3	83.3	6.7	2.8	131.1	2.4	133.6
	R&D costs					79.9	1.0	80.8
	Operating income					51.3	1.5	52.8
Change	Net sales (Sales to customers)	0.8	53.9	2.1	4.3	61.1	1.3	62.4
	SG&A expenses less R&D costs	(3.8)	19.2	0.3	0.6	16.2	0.3	16.5
	Income (loss) of Segment	0.3	22.9	1.4	3.0	27.6	(0.1)	27.4
	R&D costs					8.1	0.0	8.2
	Operating income					19.4	(0.2)	19.2

FX rates:
FY2016 Results : 1US$ = ¥ 108.4, 1RMB = ¥16.1
FY2017 Forecast : 1US$ = ¥ 110.0, 1RMB = ¥16.5

Appendix (Clinical Development Status)

Development Pipeline (1) (Psychiatry & Neurology Area)

(as of October 30, 2017)

Sumitomo Dainippon Pharma

Revisions since the announcement of July 2017 are shown in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
APTIOM®	eslicarbazepine acetate	(New indication) Epilepsy- Monotherapy	Canada				
		(New usage :pediatric) Epilepsy- Monotherapy/ Adjunctive therapy	Canada				
LATUDA® （SM-13496）	lurasidone hydrochloride	Schizophrenia	China				
		(New usage :pediatric) Bipolar I depression	U.S. / Canada				
		Schizophrenia	Japan				
		Bipolar I depression, Bipolar maintenance	Japan				
SEP-225289	dasotraline	Adult, Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Binge eating disorder (BED)	U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism in dementia with Lewy bodies (DLB)	Japan				
LONASEN®	blonanserin	(New usage :pediatric) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
EPI-743	vatiquinone	Leigh syndrome	Japan				※1
APL-130277	apomorphine hydrochloride	OFF episodes associated with Parkinson's disease	U.S.				
EPI-589	TBD	Parkinson's disease	U.S.				
		Amyotrophic lateral sclerosis (ALS)	U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				
		Parkinson's disease psychosis	U.S.				
		Schizophrenia	Japan				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S. / Japan				
DSP-6745	TBD	Parkinson's disease psychosis	U.S.				
SEP-378608	TBD	Bipolar disorder	U.S.				

※1／A Phase 2 / 3 study completed, development strategy under consideration

Development Pipeline (2) (Oncology Area) (as of October 30, 2017)

Sumitomo Dainippon Pharma

No changes since the announcement of July 2017

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
BBI608	napabucasin	Colorectal cancer (Combination therapy) (Global clinical study)	U.S. / Canada / Japan				
		Pancreatic cancer (Combination therapy) (Global clinical study)	U.S. / Japan				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
		Solid tumors (Ovarian cancer, Breast cancer, Melanoma, Glioblastoma, etc.) (Combination therapy) ※3	U.S. / Canada			※1	
		Malignant pleural mesothelioma (Combination therapy)	Japan			※1	
		Solid tumors (Combination therapy) ※4 Hematologic malignancies (Monotherapy / Combination therapy)	U.S. / Canada ※5				
		Hepatocellular carcinoma (Combination therapy)	Japan				
BBI503	amcasertib	Solid tumors (Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.) (Monotherapy)	U.S. / Canada			※1	
		Solid tumors (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	napabucasin amcasertib	Solid tumors (Combination therapy)	U.S.				

※1／Phase 2 of Phase 1 / 2 study ※2／Phase 1 of Phase 1 / 2 study ※3／Glioblastoma's development is only Canada
※4／Multiple studies for different tumor types (Gastrointestinal cancer, Hepatocellular carcinoma, Pancreatic cancer)
※5／Clinical study for gastrointestinal cancer is conducted only in Canada

Appendix (Clinical Development Status)

Development Pipeline (3) (Oncology & Other Areas)

(as of October 30, 2017)

Sumitomo Dainippon Pharma

Oncology Area (Excluding napabucasin, amcasertib)

Revisions since the announcement of July 2017 are shown in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
DSP-7888	adegramotide/ nelatimotide	Myelodysplastic syndromes (Monotherapy)	Japan			※1	
		Pediatric malignant glioma (Monotherapy)	Japan			※1	
		Glioblastoma (Combination therapy)	U.S. / Canada / Japan, etc.				
		Solid tumors, Hematologic malignancies (Monotherapy / Combination therapy ※3)	U.S. / Canada				
alvocidib	alvocidib	Acute myeloid leukemia (AML) (Combination therapy / Refractory or relapsed patients)	U.S. / Canada, etc				
		Acute myeloid leukemia (AML) (Combination therapy / Newly diagnosed patients)	U.S.				
WT4869	TBD	Myelodysplastic syndromes (Monotherapy)	Japan		※2		
		Solid tumors (Monotherapy)	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies (Monotherapy)	U.S.				
		Solid tumors (Monotherapy)	Japan				
TP-0903	TBD	Solid tumors (Monotherapy)	U.S.				
DSP-1958 ※4	thiotepa	Conditioning treatment prior to hematopoietic cell transplantation (HPCT) (Monotherapy)	Japan				

※1／Phase 2 of Phase 1 / 2 study ※2／Phase 1 of Phase 1 / 2 study
※3／Combination therapy is only U.S. ※4／ Development for the use of unapproved or off-labeled drugs

Respiratory Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	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 1	Phase 2	Phase 3	Submitted
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				

Appendix (Clinical Development Status)

Napabucasin – Clinical development progress

(as of October 30, 2017)

Sumitomo Dainippon Pharma

No changes since the announcement of July 2017

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 3	U.S. / Canada / Japan	Colorectal cancer (Combination therapy)	FOLFIRI, FOLFIRI + bevacizumab	CanStem303C	June 2016
	U.S. / Japan	Pancreatic cancer (Combination therapy)	gemcitabine + nab-paclitaxel	CanStem111P	Dec. 2016
Phase 2	U.S. / Canada	Colorectal cancer (Combination therapy)	cetuximab, panitumumab, capecitabine	BBI608-224	Mar. 2012
	U.S. / Canada	Solid tumors*1 (Combination therapy)	paclitaxel	BBI608-201	Apr. 2011
	Japan	Malignant pleural mesothelioma (Combination therapy)	cisplatin + pemetrexed	D8807005	Feb. 2015
	Canada	Glioblastoma (Combination therapy)	temozolomide	BBI608-251	Mar. 2015
Phase 1	U.S. / Canada	Gastrointestinal cancer (Combination therapy)	FOLFOX, FOLFOX + bevacizumab, CAPOX, FOLFIRI, FOLFIRI + bevacizumab, regorafenib, irinotecan	BBI608-246	Jan. 2014
	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	Dec. 2014
	U.S.	Pancreatic cancer (Combination therapy)	gemcitabine + nab-paclitaxel, FOLFIRINOX, irinotecan liposome injection + fluorouracil + leucovorin	BBI608-118	Aug. 2014
	U.S.	Hematologic Malignancies (Monotherapy / Combination therapy)	dexamethasone, bortezomib, imatinib, ibrutinib	BBI608-103HEME	May 2015
	Japan	Hepatocellular carcinoma (Combination therapy)	sorafenib	D8808001	Feb. 2015
	U.S.	Solid tumors (Combination therapy)	iplimumab, pembrolizumab, nivolumab	BBI608-201CIT	Aug. 2015

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

Start date is based on Clinical Trials.gov (as of October 29, 2017)

Amcasertib, Napabucasin– Clinical development progress

(as of October 30, 2017)

Sumitomo Dainippon Pharma

No changes since the announcement of July 2017

Amcasertib

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 2	U.S. / Canada	Solid tumors*1 (Monotherapy)	–	BBI503-101	Feb. 2012
	Canada	Hepatocellular carcinoma, Cholangiocarcinoma (Monotherapy)	–	BBI503-205b	Feb. 2015
	Canada	Gastrointestinal stromal tumor (Monotherapy)	–	BBI503-205c	Mar. 2017
	U.S.	Ovarian cancer (Monotherapy)	–	BBI503-205GYN-M	June 2015
Phase 1	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	Dec. 2014
	Japan	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	sorafenib	DA101003	Mar. 2015
	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.

Amcasertib + Napabucasin

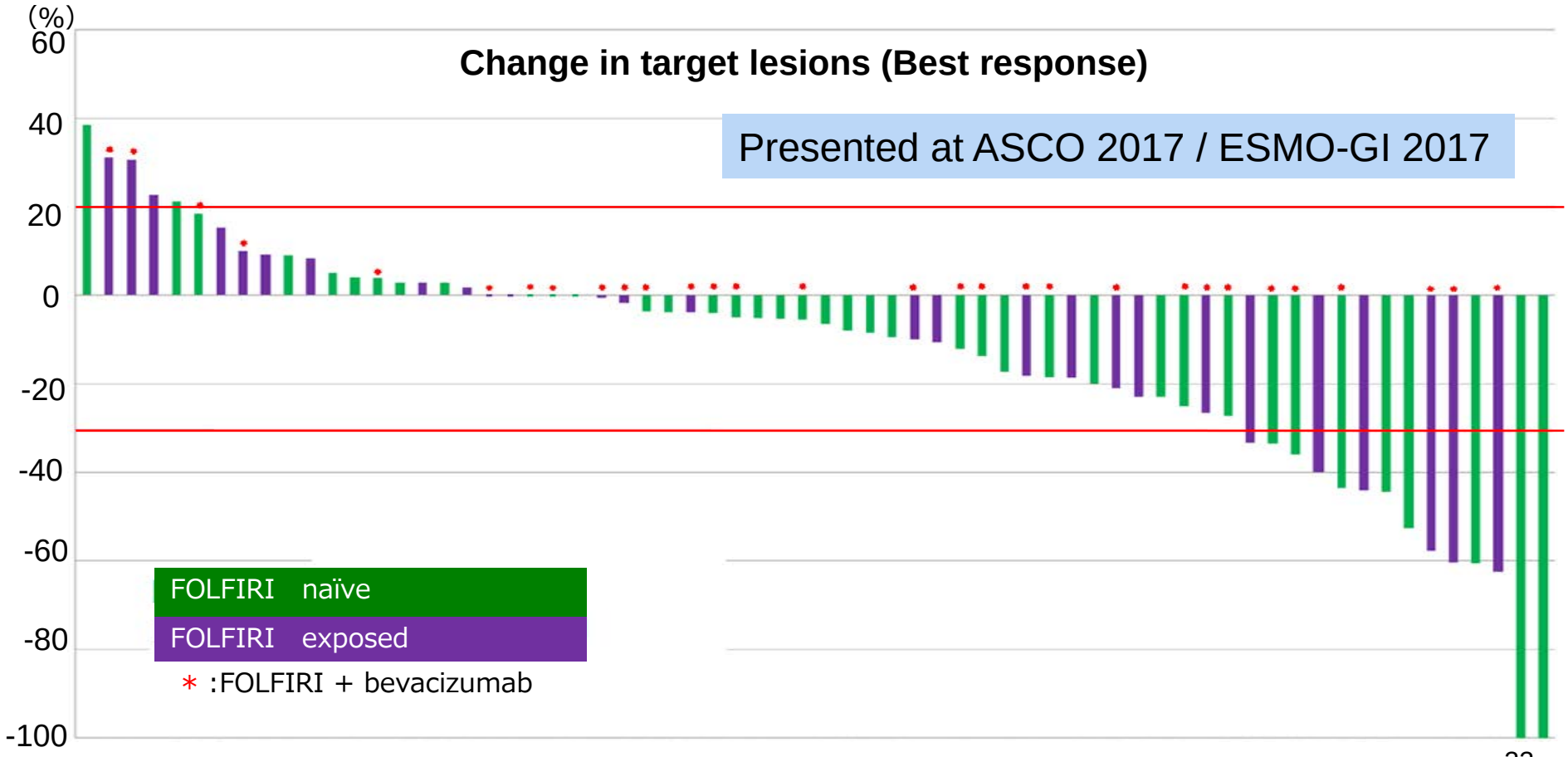
Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 1	U.S.	Solid tumors (Combination therapy)	–	BBI401-101	Apr. 2015

Start date is based on Clinical Trials.gov (as of October 29, 2017)

Napabucasin Phase 1b/2 study (Colorectal Cancer: 246 study)

- Colorectal Cancer (combination with FOLFIRI, or FOLFIRI and bevacizumab)
- Study design : open label, multi-center
- Endpoint Classification: safety, efficacy
- All patients: 82
- Total evaluated patients: 66 (DCR 83%, CR:1, PR:13)

Started Phase 3 study (CanStem303C study) based on the results of this study

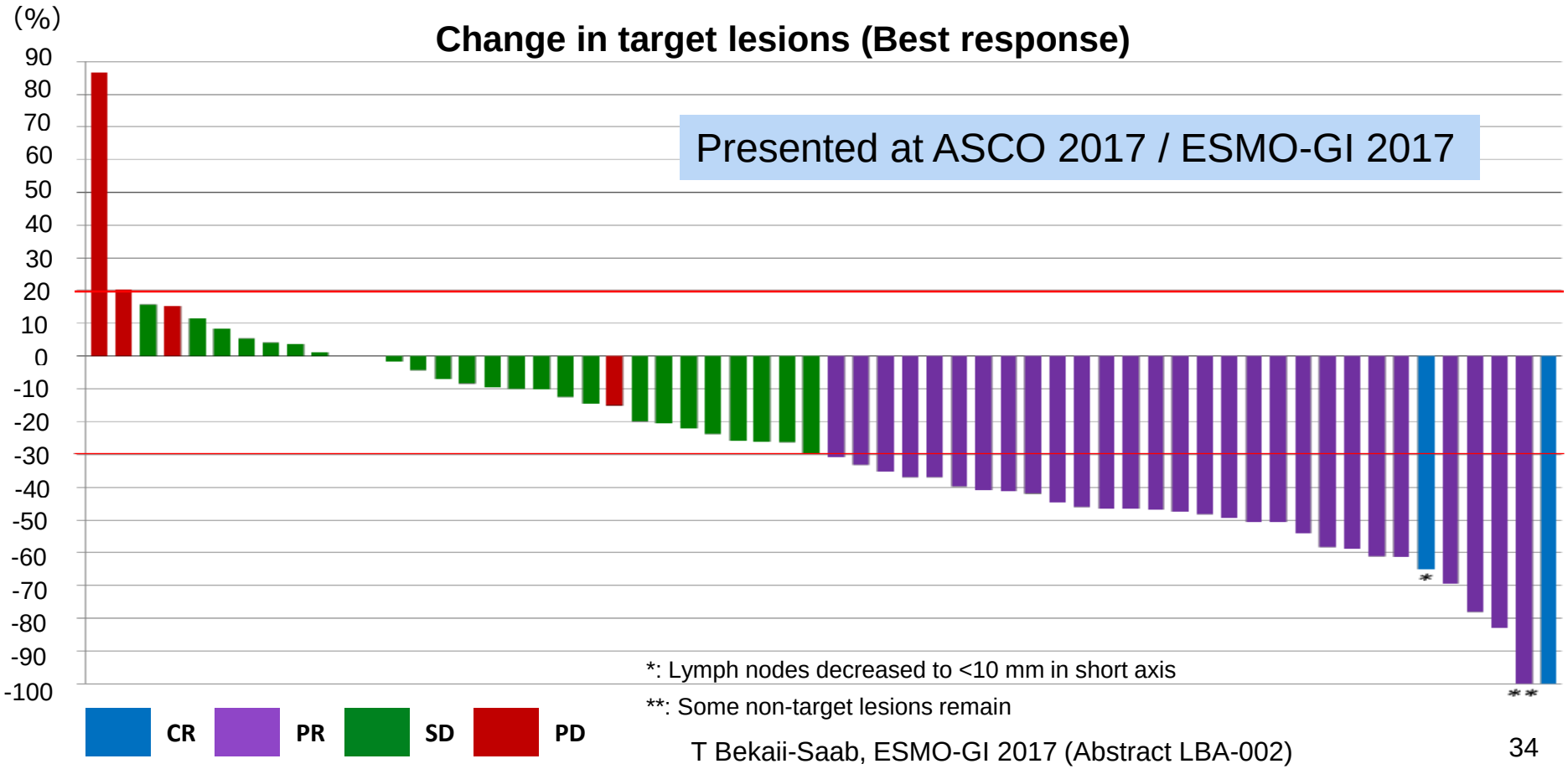


Johanna C. Bendell, et al. *J Clin Oncol 35, 2017,* ASCO 2017 (Abstract 3529)

Napabucasin Phase 1b/2 study (Pancreatic Cancer: 118 study)

- Pancreatic Cancer (combination with gemcitabine and nab-paclitaxel)
- Study design : open label, multi-center
- Endpoint Classification: safety, efficacy
- All patients: 66
- Total evaluated patients: 55 (DCR 93%, CR:2, PR:28)

Started Phase 3 study (CanStem111P study) based on the results of this study



T Bekaii-Saab, ESMO-GI 2017 (Abstract LBA-002)

LATUDA® (lurasidone) – Clinical development progress

(as of October 30, 2017)

Revisions since the announcement of July 2017 are shown in red.

Japan / China (In-house)

Indication, Proposed indication	Development location	Development status	Submission plan
Schizophrenia	China	Submitted	—
Schizophrenia	Japan	Phase 3	FY2019
Bipolar I depression , Bipolar maintenance		Phase 3	FY2019

Europe (In-house)

- The license agreement with Takeda for the joint development and exclusive commercialization in Europe was terminated on January 31st, 2016.
- The Marketing Authorization (MA) for LATUDA® in EU and Switzerland was transferred to Sunovion Pharmaceuticals Europe Ltd. (SPE) in February 2016.
  - ✓ SPE started commercializing LATUDA® in May 2016 in the countries where the product has already been launched.
  - ✓ For other countries, we will continuously seek a licensing partner.

  (Reference)

  MA Submitted in: Turkey

  Approved in: Russia

  Launched in: UK, Switzerland, Denmark, Norway, the Netherlands, Finland, and Sweden

Asia, South America, etc. (Partnering)

- MA Submitted in: Venezuela (submitted by Daiichi Sankyo)
- Approved in: Brazil (obtained by Daiichi Sankyo)
- Launched in: Australia (commercialization partnership with Servier Australia),
  Taiwan (commercialization partnership with Standard Chem. & Pharm.)
  Singapore, Thailand, Hong Kong (commercialization partnership with DKSH)

Product Launch Plan (as of October 2017)

Sumitomo Dainippon Pharma

Area	FY2017	FY2018	FY2019	FY2020 - FY2022	
Japan		TRERIEF® (Parkinsonism in Dementia with Lewy Bodies)	LONASEN® (Schizophrenia / Transdermal patch)	lurasidone (Schizophrenia / Bipolar I depression / Bipolar maintenance)	obeticholic acid (NASH)
		thiotepa (Conditioning treatment prior to HPCT)		napabucasin (Colorectal cancer, Pancreatic cancer)	DSP-6952 (IBS with constipation, Chronic idiopathic constipation)
				amcasertib (Solid tumors)	iPS cell-derived RPE cells (Age-related macular degeneration)
				DSP-7888 (Solid tumors/ Hematologic malignancies)	
U.S.	glycopyrronium (COPD)	dasotraline (ADHD)	dasotraline (BED)	SB623 (Chronic stroke)	napabucasin (Colorectal cancer, Pancreatic cancer)
	UTIBRON™, SEEBRI™ (COPD) (In-licensed)	apomorphine (Parkinson's disease)	alvocidib (Acute myeloid leukemia)	DSP-2230 (Neuropathic pain)	amcasertib (Solid tumors)
				SEP-363856 (Schizophrenia)	DSP-7888 (Solid tumors/ Hematologic malignancies)
China	LONASEN® (Schizophrenia) (Approved on Feb.2017)	lurasidone (Schizophrenia)			

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

New Chemical Entities | New Indication , etc.

Regenerative Medicine/Cell Therapy Business Plan

(as of October 2017)

Sumitomo Dainippon Pharma

	Partnering	Region (planned)	Cell type	Schedule for practical use (Calendar year)			
				2017	2018	2019	2020-2022
Chronic stroke	**SanBio**	North America	Allo MSC	**Phase 2b**		**Phase 3**	**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 (Designated as a "SAKIGAKE" Product in Feb. 2017)	**Kyoto Univ CiRA**	Global	Allo iPS cell		**Investigator-initiated clinical study**		
Retinitis pigmentosa	**RIKEN**	Global	Allo iPS cell		**Clinical research**		
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.

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.

Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.

Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows