Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Financial Results for FY2016
(Year ended March 31, 2017)

May 12, 2017

Masayo Tada, President and CEO

Sumitomo Dainippon Pharma Co., Ltd.

Main Achievements in FY2016

Topics by Region

Japan： Establishment of efficient business operation systems after implementing the Early Retirement Program

North America: Significant growth in revenue (dollar basis) thanks to LATUDA sales performance

Other regions: MEROPEN® business returned in Southeast Asia

M&A, In-licensing

Acquired Cynapsus: APL-130277 added to our pipeline (U.S.)

Acquired Tolero: Alvocidib and TP-0903 added to our pipeline (U.S.)

In-licensed from Novartis: Three COPD products (U.S.)

R&D

SUN-101： NDA filed for COPD (U.S.)

Dasotraline： Completed pivotal studies for ADHD (U.S.)

TRERIEF®： Completed Phase 3 study for additional indication (Japan)

Napabucasin： Started recruitment for new pivotal studies (colorectal / pancreatic cancer)

Financial Results for FY2016

Financial Results for FY2016

Billions of yen

	FY2015 Results	FY2016 Results	Change			FY2016	
			Value	FX rate impact	%	Forecasts	Achievement %
Net sales	403.2	411.6	8.4	(24.6)	2.1	404.0	101.9
Cost of sales	104.5	100.1	(4.4)	* (8.0)	(4.2)	98.5	101.6
Gross profit	298.7	311.6	12.8	(16.6)	4.3	305.5	102.0
SG&A expenses	261.8	258.8	(3.0)	(17.7)	(1.1)	259.5	99.7
SG&A expenses less R & D costs	179.8	178.0	(1.8)	(12.3)	(1.0)	178.5	99.7
R&D Costs	82.0	80.8	(1.2)	(5.4)	(1.5)	81.0	99.8
Operating income	36.9	52.8	15.8	1.1	42.9	46.0	114.7
Ordinary income	35.2	54.3	19.1		54.3	46.0	118.1
Extraordinary income (loss)	4.3	(7.1)	(11.5)			(5.0)	
Net income attributable to owners of the parent	24.7	29.0	4.3		17.4	26.0	111.5
EBITDA	55.8	72.8	17.1		30.6	65.5	

* Includes a downward impact (¥6.7B) on cost of sales from the unrealized profit of inventory on FY2015 FX rate realized in FY2016 with stronger yen

FX rates:
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 Results : 1US$ = ¥ 108.4, 1RMB = ¥16.1
FY2016 Forecasts: 1US$ = ¥ 108.0, 1RMB = ¥16.0

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
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
FY2015 Results	Net sales (Sales to customers)	146.5	184.9	18.4	11.2	360.9	42.3	403.2
	Cost of sales	45.8	16.0	2.8	6.1	70.6	33.8	104.5
	Gross profit	100.8	168.9	15.6	5.1	290.4	8.3	298.7
	SG&A expenses less R&D costs	59.3	103.8	7.6	2.6	173.3	6.5	179.8
	Income (loss) of Segment	41.5	65.2	8.0	2.4	117.1	1.8	119.0
	R&D costs					81.1	0.9	82.0
	Operating income					36.0	0.9	36.9
Change	Net sales (Sales to customers)	(5.6)	13.0	(0.7)	0.4	7.0	1.4	8.4
	SG&A expenses less R&D costs	(3.5)	1.3	(0.1)	0.5	(1.8)	(0.0)	(1.8)
	Income (loss) of Segment	(3.2)	18.1	(1.2)	0.4	14.0	0.6	14.6
	R&D costs					(1.3)	0.1	(1.2)
	Operating income					15.3	0.5	15.8

FX rates:
FY2015 : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 : 1US$ = ¥ 108.4, 1RMB = ¥16.1

Ordinary Income & Net Income Attributable to Owners of the Parent

Billions of yen

	FY2015 Results	FY2016 Results	Change	
			Value	%
Operating Income	36.9	52.8	15.8	42.9
Non-operating income and expenses	(1.7)	1.6	3.3	
Ordinary income	35.2	54.3	19.1	54.3
Extraordinary income	6.1	5.8	(0.4)	
Gain on sales of investment securities	6.1	5.8		
Extraordinary loss	1.8	12.9	11.1	
Business structure improvement expenses	0.6	10.9		
Loss on discontinuation of R&D programs	–	2.0		
Loss on disposal of property, plant and equipment	0.6	–		
Impairment loss	0.6	–		
Income taxes	14.9	18.2	3.4	
Net income attributable to owners of the parent	24.7	29.0	4.3	17.4

FX rates:
FY2015 : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 : 1US$ = ¥ 108.4, 1RMB = ¥16.1

Valuations and Accounting Procedures Following the Acquisition of Tolero

Valuation of assets and accounting procedures associated with the acquisition are as follows.

Millions of US$

	Before Purchase price allocation	After Purchase price Allocation	Valuation Differences	Accounting procedures (Amortization)
In-process R&D (Intangible assets)	–	526	526	Capitalize (amortize after launch)
Deferred tax liabilities (of the above)	–	(195)	(195)	–
Contingent consideration (Fair value)	–	(310)	(310)	–
Other assets & liabilities (Net)	(5)	10	16	–
Goodwill	–	163	163	Amortization for 20 years
Total acquisition cost	(5)	195	200	

Financial Forecasts for FY2017

Major Activities for FY2017

Japan

- Secure profits by efficient business operations
- Improve profitability through new in-licensing and alliances
- Improve productivity by work style reform
- Strengthen business foundations through continuous cost reduction

North America

- Further growth in sales of LATUDA® and APTIOM®
- Early sales growth of new COPD products in the market / synergy effect with BROVANA®
- Establish efficient sales system with a view to mid-term growth

New COPD products : UTIBRON™, SEEBRI™, ARCAPTA®, SUN-101 (NDA filed)

R&D activities

- Promote late-stage development
  (Psychiatry & Neurology / Oncology / Other areas)

Financial Forecasts for FY2017

Billions of yen

	FY2016 Result	FY2017 Forecasts	Change			(Ref.) FY2017 Revised MTBP	Change
			Value	FX rate impact	%		
Net sales	411.6	450.0	38.4	4.0	9.3	440.0	10.0
Cost of sales	100.1	116.0	15.9	* 8.5	15.9		
Gross profit	311.6	334.0	22.4	(4.5)	7.2		
SG&A expenses	258.8	279.0	20.2	2.7	7.8		
SG&A expenses less R&D costs	178.0	194.0	16.0	1.9	9.0		
R&D Costs	80.8	85.0	4.2	0.8	5.2	85.0	-
Operating income	52.8	55.0	2.2	(7.2)	4.2	50.0	5.0
Ordinary income	54.3	55.0	0.7		1.2		
Extraordinary income (loss)	(7.1)	(2.5)	4.6				
Net income attributable to owners of the parent	29.0	36.0	7.0		24.2		
E B I T D A	72.8	75.0	2.2		3.0	75.0	-

* Includes an impact (¥8.2B) of change in FX rates on the unrealized profit of inventory

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

We are making preparations for the adoption of IFRS (International Financial Reporting Standard) from the end of FY2017.

Sales of Major Products in Japan

Billions of yen

	FY2016 Results	FY2017 Forecasts	Change	
			Value	%
TRERIEF®	15.1	16.0	0.9	5.9
LONASEN®	12.8	13.2	0.4	3.0
REPLAGAL®	10.7	11.3	0.6	5.7
SUREPOST®	4.3	5.3	1.0	22.1
AIMIX®	17.1	17.5	0.4	2.3
AmBisome®	4.4	4.5	0.1	2.8
METGLUCO®	11.2	11.3	0.1	1.0
AVAPRO®	10.3	8.0	(2.3)	(22.7)
Promoting Products Total	86.0	87.1	1.1	1.3
AMLODIN®	13.0	10.6	(2.4)	(18.6)
PRORENAL®	6.5	5.1	(1.4)	(22.0)
GASMOTIN®	6.0	5.0	(1.0)	(17.0)
MEROPEN®	4.3	4.1	(0.2)	(3.6)
Others	25.0	27.3	2.3	9.1
Total	140.8	139.2	(1.6)	(1.2)

Note: Sales of each product above are shown on an invoice price basis.

Trulicity® (NHI price basis)	6.8	11.0	4.2	62.3

Sales of Major Products in North America & China

	FY2016 Results	FY2017 Forecasts	Change	FY2016 Results	FY2017 Forecasts	Change		
						Value	FX rate impact	%
North America	Million $			Billion yen				
LATUDA®	1,254	1,440	186	135.9	158.4	22.5	2.4	16.6
APTIOM®	107	152	45	11.6	16.7	5.1	0.2	44.4
BROVANA®	305	313	8	33.1	34.4	1.3	0.5	4.0
New COPD products *1	0	37	37	0.0	4.1	4.1	0.1	–
Ciclesonide	47	42	(5)	5.1	4.6	(0.5)	0.1	(10.2)
XOPENEX®	47	41	(6)	5.1	4.5	(0.6)	0.1	(11.8)
LUNESTA®	(5)	22	27	(0.5)	2.4	2.9	0.0	–
Others	71	59	(11)	7.7	6.5	(1.1)	0.1	(15.0)
Total	1,826	2,106	280	197.9	231.6	33.7	3.4	17.0
China	Million RMB			Billion yen				
MEROPEN®	954	958	4	15.4	15.8	0.4	0.4	2.9
Others	141	151	10	2.3	2.5	0.2	0.1	10.1
Total	1,095	1,109	14	17.6	18.3	0.7	0.4	3.8

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

Exchange rates:
FY2016 Results : 1US$ = ¥ 108.4, 1RMB = ¥16.1
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		
FY2017 Forecasts	Net sales (Sales to customers)	139.2	231.6	18.3	15.9	405.0	45.0	450.0
	Cost of sales	48.4	21.5	3.8	6.4	80.1	35.9	116.0
	Gross profit	90.8	210.1	14.5	9.5	324.9	9.1	334.0
	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	87.4	6.7	5.8	137.7	2.3	140.0
	R&D costs					84.0	1.0	85.0
	Operating income					53.7	1.3	55.0
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)	(1.6)	33.7	0.7	4.3	37.1	1.3	38.4
	SG&A expenses less R&D costs	(2.8)	17.7	0.3	0.6	15.7	0.3	16.0
	Income (loss) of Segment	(0.5)	4.1	0.0	3.0	6.6	(0.1)	6.4
	R&D costs					4.1	0.0	4.2
	Operating income					2.4	(0.2)	2.2

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

Investment Strategies / Dividend policy

Financial / Investment strategies

R&D investments （85 billion yen for FY2017）

New in-licensing / M&A （Focusing on domestic business）

Dividend Policy

- Maintain a consistent payment policy but also consider reflecting any improvement in the Company's performance in the dividend payment
- Annual dividend for FY2016 / FY2017 : ¥20 per share（Year-end :¥11）
  We propose a special dividend (¥2 per share) because operating income for FY2016/ FY2017 is expected to be higher than the 3rd Mid-term Business Plan target of 50 billion yen.

	FY2015 actual	FY2016 plan	FY2017 plan
Dividend per share(yen）	18.00	20.00	20.00
Payout ratio（%）	29.0	27.4	22.1
〈Reference〉			
Dividend on equity（%）	1.6	1.8	1.7
Return on Equity(ROE) (%)	5.5	6.4	7.6

Clinical Development Status

Clinical Development Status (Major Changes since January 27, 2017)

LATUDA®

- ✓ Approved for pediatric schizophrenia in the U.S. (January 2017)

Blonanserin

- ✓ Approved for schizophrenia in China (February 2017)

APTIOM®

- ✓ Submitted sNDA for pediatric epilepsy in the U.S. (March 2017)

Dasotraline

- ✓ Started Phase 3 study for binge eating disorder (BED) in the U.S.

DSP-7888

- ✓ Started Phase 2 study for glioblastoma (combination therapy) in the U.S.

Discontinued

- ✓ DSP-3748 (U.S.: Phase 1 study (cognitive impairment associated with schizophrenia))

Others (Regenerative Medicine / Cell Therapy)

- ✓ Started construction of a cell processing center (new CPC)
- ✓ Parkinson's disease: Designated for "SAKIGAKE Designation System" product

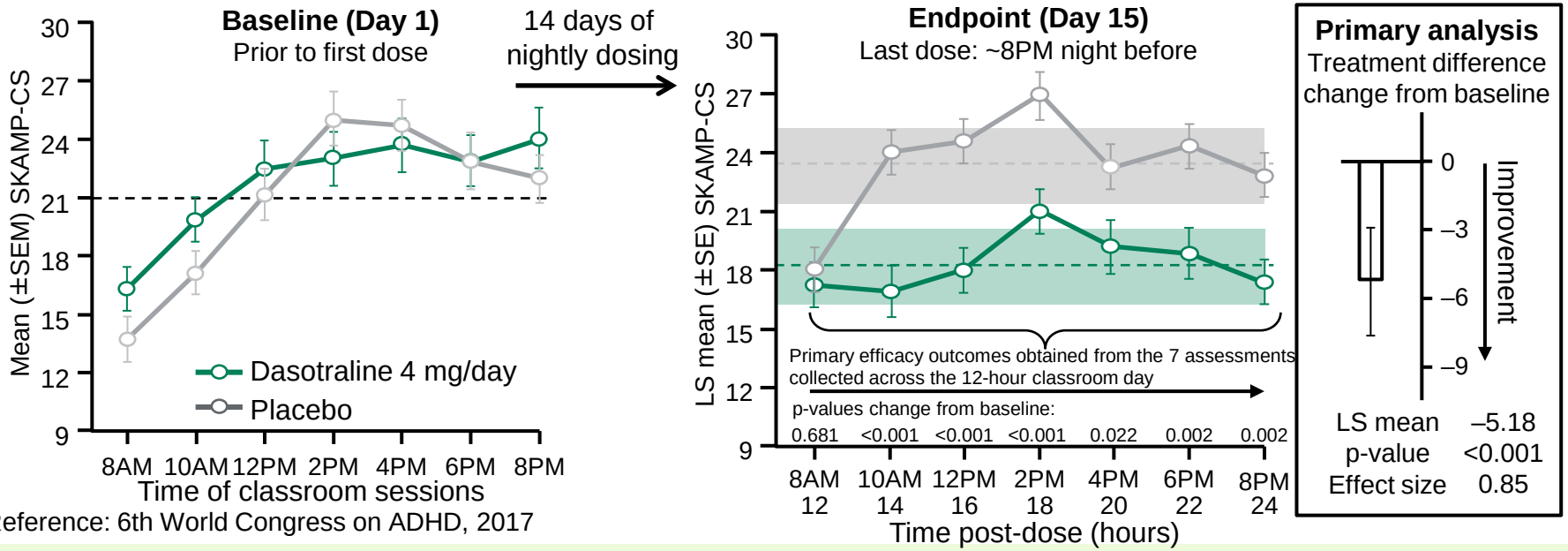
Psychiatry & Neurology Area : Dasotraline

NDA package for attention-deficit hyperactivity disorder (ADHD)

- Adult : Phase 2 study (201 study) : Met primary endpoint (8mg)
- Pediatric : Phase 2/3 study (202 study) : Met primary endpoint (4mg)
  Phase 3 study (305 study) : Met primary endpoint (4mg)

- **Pediatric ADHD Phase 3 study (305 study, 6-12 years in a laboratory classroom setting) topline results** **(announced by a press release on April 12, 2017)**
  - **Efficacy**: Dasotraline demonstrated statistically significant improvement vs placebo
  - **Safety**: Adverse events were consistent with previous studies

Primary endpoint: Change from Baseline in SKAMP-Combined scores at Day 15



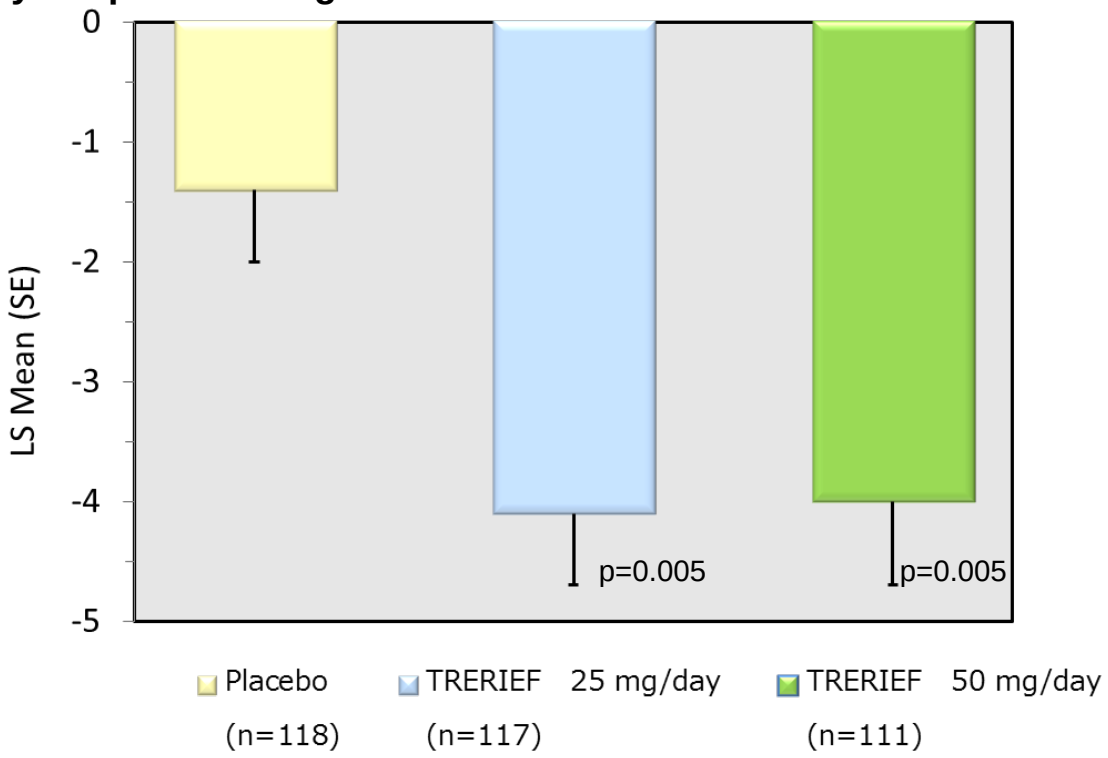
Reference: 6th World Congress on ADHD, 2017

- **ADHD : Plan to submit NDA for adult and pediatric ADHD in FY2017 in the U.S.**
- **BED : Promote Phase 3 study in the U.S.**

Psychiatry & Neurology Area : TRERIEF®

- **Top line results of a Phase 3 study for parkinsonism in dementia with Lewy bodies (DLB)** **(announced by a press release on April 6, 2017)**
  - **Efficacy:** TRERIEF® demonstrated statistically significant improvement vs placebo
  - **Safety :** Adverse events were consistent with previous studies

Primary endpoint: Change from baseline in UPDRS Part III total score at 12 weeks



- **sNDA under preparation based on the above results**
  Plan to submit sNDA for parkinsonism in DLB in FY2017 in Japan

Psychiatry & Neurology Area : APL-130277, Lurasidone

- **APL-130277**
  - Phase 3 study ongoing, expect to obtain top line results in FY2017

  ■ **Aim to submit NDA for OFF episodes associated with Parkinson's disease in FY2017 in the U.S.**

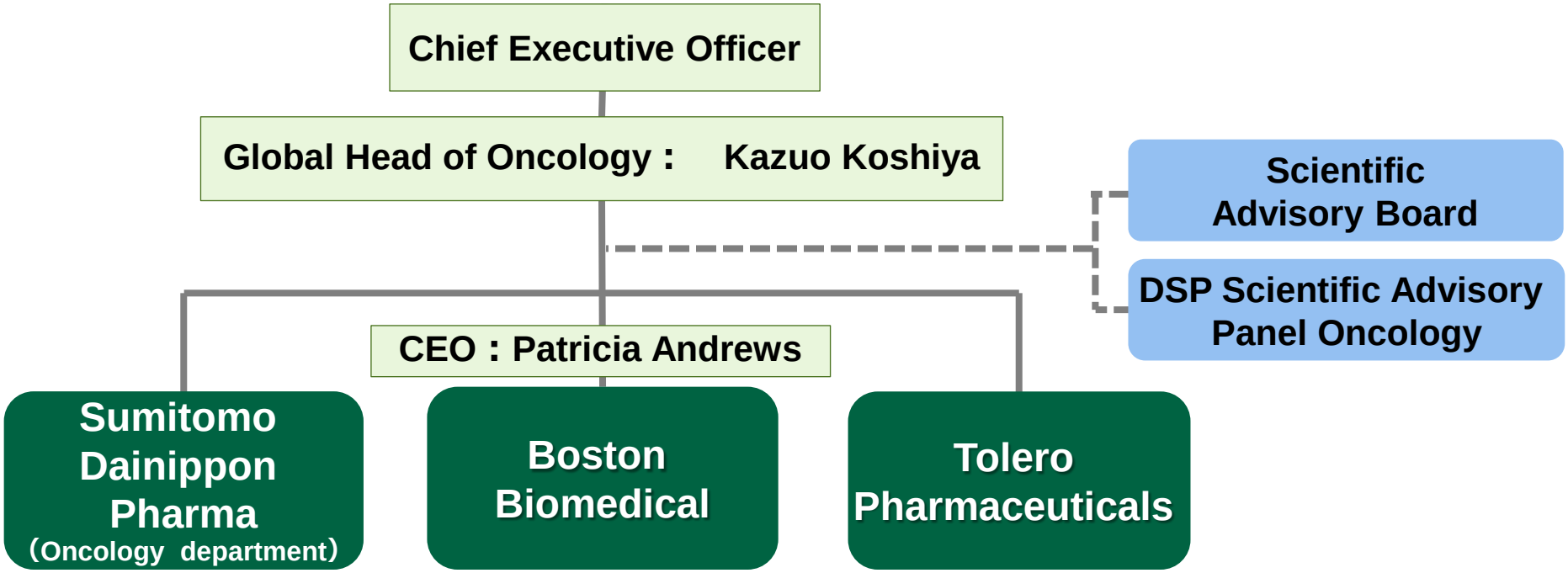
- **Lurasidone**
  - Schizophrenia: Phase 3 study ongoing, expect to complete in FY2018
  - Bipolar I depression: Completed dosing, under analysis
  - Bipolar maintenance: Phase 3 study ongoing, expect to complete in FY2018

  ■ **Aim to submit NDA for schizophrenia and bipolar disorder (depression and maintenance) in FY2019 in Japan**

New Global Oncology Organization (Changed April 2017)

- Establishment of Global Head of Oncology, change of Chief Executive Officer at Boston Biomedical, Inc.
- Under the leadership of Global Head of Oncology, Sumitomo Dainippon Pharma, Boston Biomedical and Tolero Pharmaceuticals will collaborate in oncology business deployment

New global oncology organization



Oncology Area : Napabucasin

- **Promote Phase 3 studies of napabucasin**
  - **Gastric and gastro-esophageal junction adenocarcinoma (combination therapy / BRIGHTER study)**
    - ✓ Completed enrollment of 700 patients (December 2016)
    - ✓ Interim analysis ongoing (Reached target number of events)
    - ✓ Full analysis to be executed with 566 events
  - **Colorectal cancer (combination therapy / CanStem303C study)**
    - ✓ Patient recruitment ongoing
  - **Pancreatic cancer (combination therapy / CanStem111P study)**
    - ✓ Patient recruitment ongoing

- **Aim to submit NDA for gastric and gastro-esophageal junction adenocarcinoma in FY2018 in the U.S. and Japan**
- **Aim to submit NDA for colorectal cancer in FY2020 in the U.S. and Japan**
- **Aim to submit NDA for pancreatic cancer in FY2021 in the U.S.**

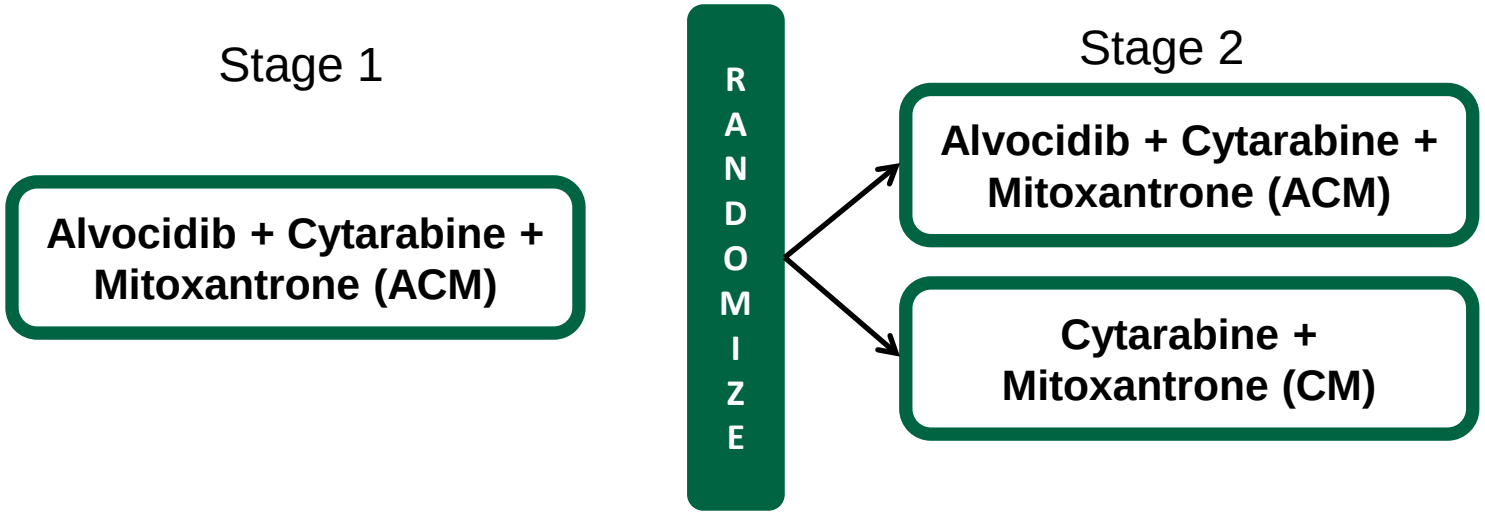
- **Plan for presentation at ASCO (American Society of Clinical Oncology) 2017**
  - **Results of Phase 1 and 2 studies (seven posters for colorectal cancer and pancreatic cancer, etc.)**
  - **Protocol of Phase 3 studies (colorectal cancer and pancreatic cancer)**
    - ✓ The abstracts will be published on May 17 (US time).

Oncology Area : Alvocidib

- **Promote Phase 2 study of acute myeloid leukemia (AML)**
  - Aim to complete Stage 1 of Phase 2 study in 1H of FY2017
  - Aim to start Stage 2 of Phase 2 study in 2H of FY2017

(Reference) Phase 2 study design

- Two-stage Phase 2 study; Open-label, randomized study to assess the clinical response to ACM compared to CM treatment in relapsed or refractory AML in MCL1 positive patients (18-65 years)
- Primary endpoint: Complete remission rate
- Secondary endpoint: Overall survival rate, etc.



- **Aim to submit NDA for AML in FY2018 in the U.S. based on the results of the above study**

Submission Target of Key Late-stage Pipeline

(as of May 2017)

Area	Development	Submission target			
		FY2017	FY2018	FY2019	FY2020-2022
Psychiatry & Neurology	**SEP-225289 <dasotraline>** (Adult , Pediatric ADHD) U.S.	●			
	APL-130277 <apomorphine > (Parkinson's disease) 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 > (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> (Pancreatic cancer / Combination therapy) U.S.				●

New Chemical Entities | New Indication, etc.

Appendices

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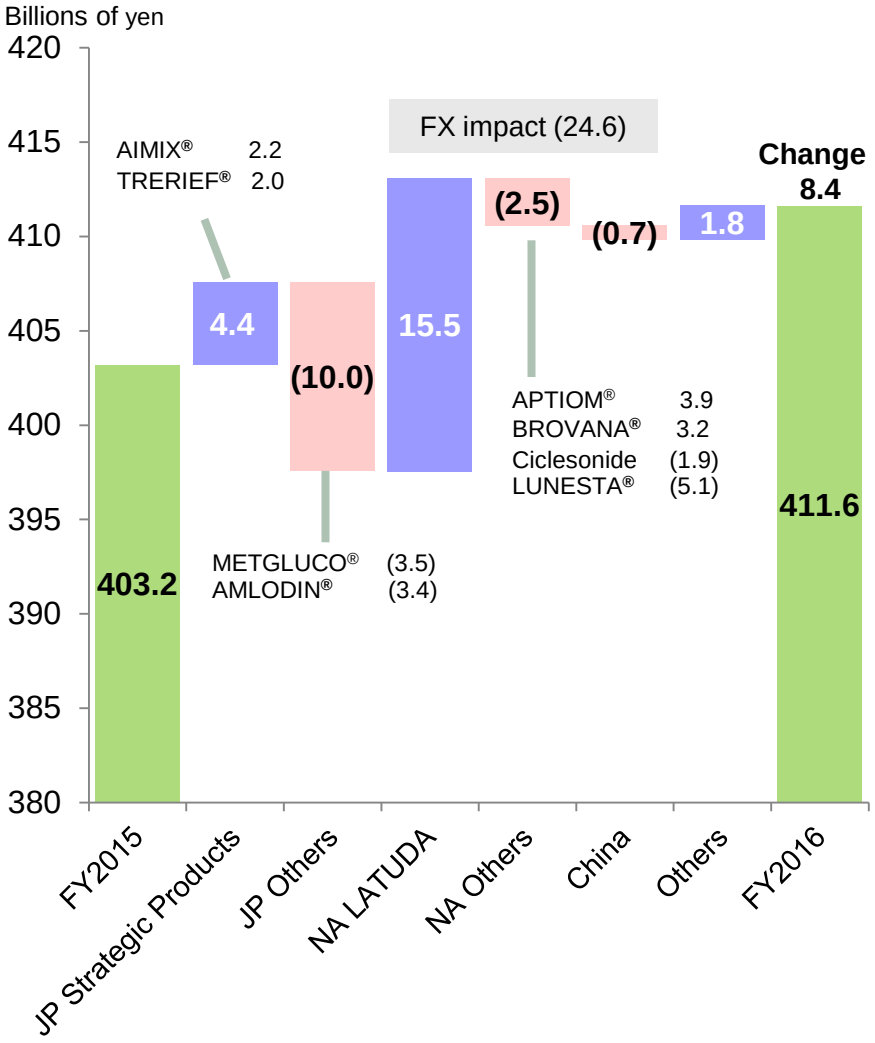
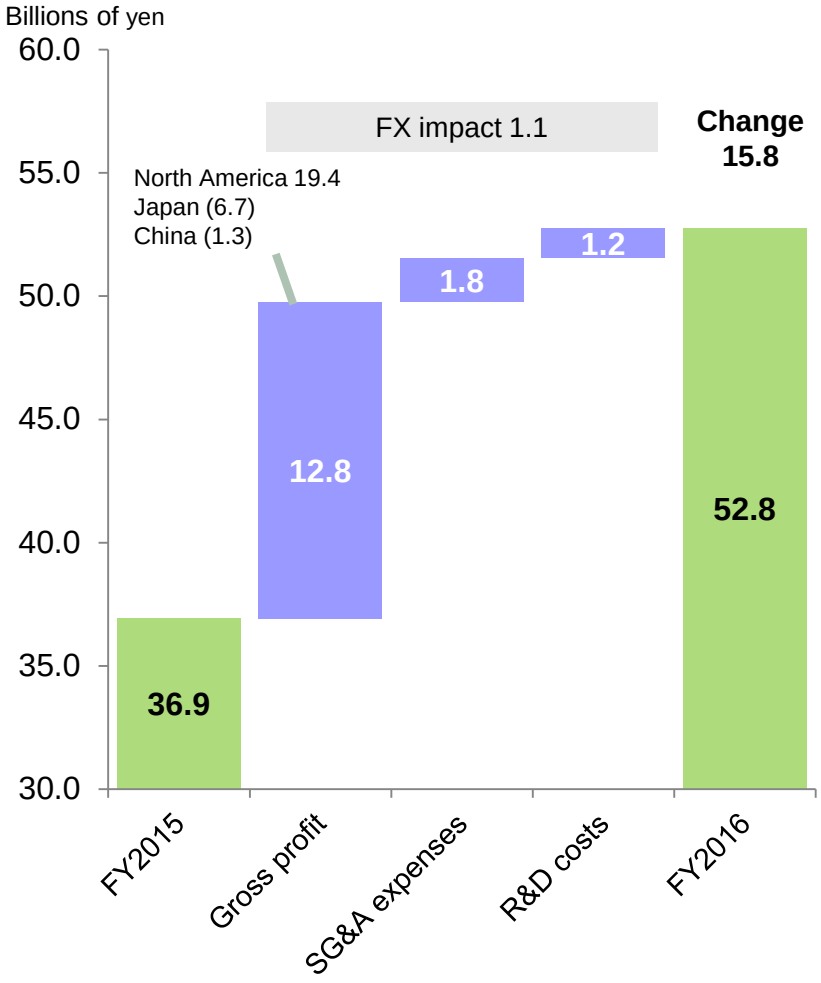
Changes from FY2015

Sales



Operating Income



FX rates:
FY2015 : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 : 1US$ = ¥ 108.4, 1RMB = ¥16.1

Net Sales by Segment

Billions of yen

Changes +8.4 +2.1 %
Achievement 101.9 %

Japan ・Changes (5.6) (3.9) %
- NHI drug price revision (7.6)
  Increase in strategic products and Trulicity®, decrease in long-listed products

North America
・Changes +13.0 +7.0 %
- Growth of LATUDA®, APTIOM® and BROVANA® offset impact of yen appreciation (21.5)

China ・Changes (0.7) (4.1) %
- Decrease due to FX impact (3.0) despite increase in MEROPEN®

Other Regions
・Changes +0.4 +3.4 %
- Increase in export of MEROPEN® and others

Other Business
・Changes +1.4 +3.4 %

FX rates:
FY2015 : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 : 1US$ = ¥ 108.4, 1RMB = ¥16.1

Sales of Major Products in Japan

Billions of yen

	FY2015 Results	FY2016 Results	Change	
			Value	%
AIMIX®	14.9	17.1	2.2	14.5
LONASEN®	12.6	12.8	0.2	1.6
TRERIEF®	13.1	15.1	2.0	15.3
Strategic Products Total	40.7	45.0	4.4	10.8
REPLAGAL®	10.2	10.7	0.5	4.7
AmBisome®	4.3	4.4	0.0	0.8
AVAPRO®	10.8	10.3	(0.5)	(4.6)
SUREPOST®	3.6	4.3	0.8	21.8
METGLUCO®	14.7	11.2	(3.5)	(23.9)
AMLODIN®	16.4	13.0	(3.4)	(20.8)
PRORENAL®	8.7	6.5	(2.2)	(24.9)
GASMOTIN®	8.4	6.0	(2.4)	(28.2)
MEROPEN®	6.2	4.3	(1.9)	(31.4)
Others	22.4	25.0	2.6	11.5
Other Products Total	105.8	95.8	(10.0)	(9.5)
Total	146.5	140.8	(5.6)	(3.9)

Note: Sales of each product above are shown are shown on an invoice price basis.

Trulicity® (NHI price basis)	0.7	6.8	6.0	812.3

Sales of Major Products in North America & China

	FY2015 Results	FY2016 Results	Change	FY2015 Results	FY2016 Results	Change		
						Value	FX rate impact	%
North America	Million $			Billion yen				
LATUDA®	1,002	1,254	252	120.4	135.9	15.5	(14.8)	12.9
APTIOM®	64	107	43	7.6	11.6	3.9	(1.3)	51.3
BROVANA®	249	305	56	29.9	33.1	3.2	(3.6)	10.6
Ciclesonide	58	47	(11)	7.0	5.1	(1.9)	(0.6)	(27.0)
XOPENEX®	56	47	(8)	6.7	5.1	(1.6)	(0.6)	(23.5)
LUNESTA®	38	(5)	(43)	4.6	(0.5)	(5.1)	0.1	–
Others	72	71	(1)	8.7	7.7	(1.0)	(0.8)	(11.5)
Total	1,539	1,826	288	184.9	197.9	13.0	(21.5)	7.0
China	Million RMB			Billion yen				
MEROPEN®	826	954	128	15.6	15.4	(0.2)	(2.6)	(1.4)
Others	148	141	(7)	2.8	2.3	(0.5)	(0.4)	(18.8)
Total	974	1,095	120	18.4	17.6	(0.7)	(3.0)	(4.1)

FX rates:
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 Results : 1US$ = ¥ 108.4, 1RMB = ¥16.1

Financial Position / Cash Flows

Billions of yen

B/S	As of March 31, 2016	As of March 31, 2017	Change
Assets	707.7	794.0	86.2
Current assets	421.6	376.5	(45.1)
Fixed assets	286.1	417.5	131.4
Liabilities	261.2	333.3	72.1
Current liabilities	179.7	228.4	48.7
Long-term liabilities	81.5	104.8	23.3
Net assets	446.5	460.7	14.2
Shareholders' equity ratio	63.1%	58.0%	

C/F	FY2015	FY2016	Change
Operating CF	49.4	21.6	(27.8)
Investment CF	15.9	(59.7)	(75.6)
Financial CF	(42.6)	9.9	52.5
Cash / Cash equivalents	135.6	105.6	(30.0)
Operating funds	184.4	122.3	(62.1)
(Ref.) FX rate (FY ending) $1=	¥112.6	¥112.2	

【Assets】

Cash and time deposits	16.5
Marketable securities	(46.8)
Short term loan receivable	(31.7)
Intangible assets	147.7

【Liabilities】

Income taxes payable	(17.5)
Short term loan payable	39.0
Reserve for sales allowance	16.4
Bond / Long term loan payable	(22.0)
Deferred tax asset (non current)	＊ 21.8
Contingent consideration (non current)	＊ 34.8

＊Increments thru Tolero acquisition

【Operating CF】

Increase of Income tax paid (29.9)

【Investment CF】

Cash out for acquisitions in FY2016 (84.3)

【Financial CF】

New borrowing of short term loan in FY2016 40.0

Appendix (Clinical Development Status)

Development Pipeline (1) (Psychiatry & Neurology Area)

(as of May 11, 2017)

Sumitomo Dainippon Pharma

Revisions since the previous announcement 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) Pediatric epilepsy- Monotherapy / adjunctive therapy	U.S.				
LONASEN®	blonanserin	(New usage :pediatric) 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.				
		Binge eating disorder (BED)	U.S.				
APL-130277	apomorphine hydrochloride	OFF episodes associated with Parkinson's disease	U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
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-1200	TBD	Treatment-resistant depression	U.S.				
DSP-6745	TBD	Parkinson's disease psychosis	U.S.				

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

Development Pipeline (2) (Oncology Area) (as of May 11, 2017)

Sumitomo Dainippon Pharma

Revisions since the previous announcement are shown in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
BBI608	napabucasin	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical study)	U.S. / Canada / Japan, etc.				
		Colorectal cancer (Combination therapy) (Global clinical study)	U.S. / Canada / Japan , etc.				
		Non-small cell lung cancer (Combination therapy) (Global clinical study)	U.S.				
		Pancreatic cancer (Combination therapy) (Global clinical study)	U.S.				
		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 (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	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 May 11, 2017)

Sumitomo Dainippon Pharma

Oncology Area (Excluding napabucasin, amcasertib)

Revisions since the previous announcement are shown in red.

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

※1／Phase 2 of Phase 1 / 2 study　※2／Phase 1 of Phase 1 / 2 study　※3／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 May 11, 2017)

Revisions since the previous announcement are shown in red.

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 3	U.S. / Canada / Japan, etc.	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy)	paclitaxel	BRIGHTER	Aug. 2014
	U.S. / Canada / Japan, etc	Colorectal cancer (Combination therapy)	FOLFIRI, FOLFIRI + bevacizumab	CanStem303C	June 2016
	U.S.	Pancreatic cancer (Combination therapy)	gemcitabine + nab-paclitaxel	CanStem111P	Dec. 2016
	U.S.	Non-small cell lung cancer (Combination therapy)	Paclitaxel	CanStem43L	Nov. 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 May 10, 2017)

Amcasertib, Napabucasin– Clinical development progress

(as of May 11, 2017)

Sumitomo Dainippon Pharma

Revisions since the previous announcement are shown in red.

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	Renal cell carcinoma, Urothelial carcinoma (Monotherapy)	–	BBI503-205a	Jan. 2017
	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.

Napabucasin + Amcasertib

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 May 10, 2017)

LATUDA® (lurasidone) – Clinical development progress

(as of May 11, 2017)

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

Product Launch Plan (as of May 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 (Gastric and Gastro-esophageal junction adenocarcinoma)	napabucasin (Colorectal cancer, etc.)	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)	napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma)	DSP-2230 (Neuropathic pain)	amcasertib (Solid tumors)
			alvocidib (Acute myeloid leukemia)	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 May 2017)

	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	**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.

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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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Innovation today, healthier tomorrows