Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Q1 FY2018 (April 1 to June 30, 2018) Conference Call

July 27, 2018

Sumitomo Dainippon Pharma Co., Ltd.

Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, targets, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties.
Accordingly, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.
Information concerning pharmaceuticals (including compounds under development) contained herein is not intended as advertising or as medical advice.

Financial Results for Q1 FY2018

Financial Results for Q1 FY2018 (Core Basis)

Billions of yen

	Q1 FY2017 Results	Q1 FY2018 Results	Change			Q2 FY2018 (Apr.-Sep.)		FY2018	
			Value	FX rate impact	%	Forecasts	Progress %	Forecasts	Progress %
Revenue	116.2	115.9	(0.3)	(0.8)	(0.2)	230.0	50.4	467.0	24.8
Cost of sales	27.5	28.9	1.4	(0.9)	5.2	53.5	54.0	110.0	26.3
Gross profit	88.7	87.0	(1.7)	0.1	(1.9)	176.5	49.3	357.0	24.4
SG&A expenses *1	44.2	47.8	3.5	(0.4)	8.0	94.5	50.5	195.0	24.5
R&D expenses	19.9	20.9	1.0	(0.2)	5.0	41.0	50.9	85.0	24.5
Other operating income and expenses *2 (Core basis)	0.2	0.0	(0.1)	(0.0)	(73.1)	–	–	–	–
Core operating profit	24.8	18.4	(6.3)	0.8	(25.6)	41.0	44.9	77.0	23.9
Changes in fair value of contingent consideration (negative number indicates loss)	7.1	(2.5)	(9.6)			(8.5)		(19.0)	
Other non-recurring items *3 (negative number indicates loss)	(0.2)	(0.1)	0.1			(0.5)		(5.0)	
Operating profit	31.6	15.8	(15.8)		(50.0)	32.0	49.4	53.0	29.8
Net profit attributable to owners of the parent	24.6	15.2	(9.4)		(38.1)	22.0	69.3	35.0	43.6

*1 Exclude non-recurring items (changes in fair value of contingent consideration, impairment losses, etc.)
*2 "P/L on business transfer" and "share of P/L of associates accounted for using equity method"
*3 Non-recurring items ("other operating income and expenses" except for *2 items, impairment losses, etc.)

FX rates: Q1FY2017 Results : 1US$ = ¥ 111.1, 1RMB = ¥16.2
Q1FY2018 Results : 1US$ = ¥ 109.1, 1RMB = ¥17.1
FY2018 Forecasts : 1US$ = ¥ 105.0, 1RMB = ¥16.5

Revenue of Major Products in Japan

Billions of yen

	Q1 FY2017 Results	Q1 FY2018 Results	Change		Q2 FY2018 (Apr.-Sep.)	
			Value	%	Forecasts	Progress %
Trulicity® *	3.4	5.2	1.9	55.2	10.8	48.6
TRERIEF®	4.1	4.2	0.1	1.8	7.2	57.8
LONASEN®	3.4	3.3	(0.0)	(1.1)	6.4	52.1
REPLAGAL®	2.9	3.2	0.3	10.7	6.2	52.2
METGLUCO®	2.9	2.6	(0.2)	(8.3)	5.6	47.0
AIMIX®	4.7	4.5	(0.2)	(4.6)	6.5	69.4
SUREPOST®	1.2	1.5	0.3	22.1	2.9	52.3
AmBisome®	1.1	0.9	(0.2)	(15.0)	2.2	42.2
Promoted products Total	23.7	25.6	1.9	7.9	47.8	53.5
AMLODIN®	3.1	2.5	(0.6)	(20.4)	4.8	51.6
PRORENAL®	1.5	1.1	(0.4)	(26.0)	2.3	48.5
AVAPRO®	2.6	0.8	(1.8)	(68.2)	2.2	37.8
GASMOTIN®	1.4	1.0	(0.3)	(22.9)	2.1	49.8
Others	4.8	4.3	(0.5)	(11.2)	8.8	48.6
Total	37.1	35.3	(1.8)	(4.8)	68.0	51.9

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

Trulicity® grew significantly.

TRERIEF® sales increased offsetting negative impact of NHI price revision.

Erosion by GEs of AIMIX® started in June 2018.

AVAPRO® decreased significantly after launch of GEs in December 2017.

Impact of NHI price revision was 2.5 billion yen.

Revenue of Major Products in North America & China

	Q1 FY2017 Results	Q1 FY2018 Results	Change	Q1 FY2017 Results	Q1 FY2018 Results	Change			Q2 FY2018 (Apr.-Sep.)		
						Value	FX rate impact	%	Forecasts		Yen-based progress
North America	Million $			Billion yen					Million $	Billion yen	%
LATUDA®	395	402	6	43.9	43.8	(0.1)	(0.8)	(0.3)	863	90.6	48.4
BROVANA®	75	75	(1)	8.4	8.2	(0.2)	(0.1)	(2.6)	156	16.4	49.8
APTIOM®	31	43	11	3.5	4.7	1.2	(0.1)	33.3	95	10.0	46.6
LONHALA® MAGNAIR®	–	3	3	–	0.3	0.3	–	–	10	1.0	30.8
Therapeutic agent for COPD (in-licensed 3 products) *	1	1	0	0.1	0.2	0.0	(0.0)	29.5	10	1.0	15.3
XOPENEX®	8	12	4	0.9	1.3	0.4	(0.0)	45.9	17	1.8	73.7
Others	28	20	(8)	3.1	2.2	(0.9)	0.0	(30.0)	37	3.9	56.5
Total	540	556	16	60.0	60.6	0.7	(1.1)	1.1	1,188	124.7	48.6
China	Million RMB			Billion yen					Million RMB	Billion yen	%
MEROPEN®	277	273	(4)	4.5	4.7	0.2	0.2	4.0	606	10.0	46.7
Others	44	45	1	0.7	0.8	0.1	0.0	8.5	91	1.5	51.2
Total	320	318	(3)	5.2	5.4	0.2	0.3	4.6	697	11.5	47.3

LATUDA® sales remained unchanged year on year. APTIOM® grew continuously.

LONHALA® MAGNAIR® started in line with the forecast.

* UTIBRON™, SEEBRI™, ARCAPTA®

FX rates: Q1FY2017 Results : 1US$ = ¥ 111.1, 1RMB = ¥16.2
Q1FY2018 Results : 1US$ = ¥ 109.1, 1RMB = ¥17.1

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total (Core basis)
		Japan	North America	China	Other Regions	Subtotal		
Q1 FY2018 Results	Revenue (Sales to customers)	35.3	60.6	5.4	4.7	106.1	9.8	115.9
	Cost of sales	13.6	4.6	1.1	2.1	21.3	7.6	28.9
	Gross profit	21.8	56.0	4.3	2.6	84.8	2.2	87.0
	SG&A expenses	12.4	31.0	2.1	0.9	46.4	1.4	47.8
	Core segment profit	9.4	25.0	2.3	1.7	38.4	0.8	39.2
	R&D expenses					20.6	0.2	20.9
	Other operating income/expenses					0.0	0.0	0.0
	Core operating profit					17.8	0.6	18.4
Q1 FY2017 Results	Revenue (Sales to customers)	37.1	60.0	5.2	2.6	104.9	11.3	116.2
	Cost of sales	13.0	3.1	1.2	1.3	18.6	8.9	27.5
	Gross profit	24.2	56.9	4.0	1.3	86.3	2.4	88.7
	SG&A expenses	12.3	27.8	1.7	0.8	42.6	1.6	44.2
	Core segment profit	11.9	29.1	2.2	0.5	43.7	0.8	44.5
	R&D expenses					19.7	0.2	19.9
	Other operating income/expenses					0.2	0.0	0.2
	Core operating profit					24.2	0.5	24.8
Change	Revenue (Sales to customers)	(1.8)	0.7	0.2	2.1	1.2	(1.5)	(0.3)
	SG&A expenses	0.1	3.3	0.4	0.1	3.8	(0.2)	3.5
	Core segment profit	(2.5)	(4.1)	0.0	1.2	(5.3)	0.1	(5.2)
	Core operating profit					(6.4)	0.0	(6.3)

Core segment profit in Japan decreased mainly due to NHI price revision.

Core segment profit in North America decreased due to increase in sales cost for new products, etc.

Core segment profit in Other Regions rose due to increased sales of MEROPEN® mainly for Southeast Asia.

Financial Results for Q1 FY2018 (Full Basis)

Billions of yen

	Q1 FY2017 Results	Q1 FY2018 Results	Change	
			Value	%
Revenue	116.2	115.9	(0.3)	(0.2)
Cost of sales	27.5	28.9	1.4	5.2
Gross profit	88.7	87.0	(1.7)	(1.9)
SG&A expenses	37.1	50.3	13.1	35.3
R&D expenses	19.9	20.9	1.0	5.0
Other operating income and expenses	(0.0)	(0.1)	(0.0)	
Operating profit	31.6	15.8	(15.8)	(50.0)
Finance income and costs	0.4	4.8	4.4	
Net profit attributable to owners of the parent	24.6	15.2	(9.4)	(38.1)

Financial Forecasts for FY2018

Financial Forecasts for FY2018 (Core Basis)

Billions of yen

	Q1 FY2018 Results	FY2018 Forecasts	Progress %
Revenue	115.9	467.0	24.8
Cost of sales	28.9	110.0	26.3
Gross profit	87.0	357.0	24.4
SG&A expenses	47.8	195.0	24.5
R&D expenses	20.9	85.0	24.5
Other operating income and expenses (Core basis)	0.0	–	–
Core operating profit	18.4	77.0	23.9
Changes in fair value of contingent consideration (negative number indicates loss)	(2.5)	(19.0)	
Other non-recurring items (negative number indicates loss)	(0.1)	(5.0)	
Operating profit	15.8	53.0	29.8
Net profit attributable to owners of the parent	15.2	35.0	43.7

FY2018 forecasts are unchanged.

Both revenue and expenses have been almost in line with the plan.

Expected that changes in fair value of contingent consideration are likely to decrease (increase in profit) due to the revised target of NDA submission for alvocidib, but this will not necessitate any revisions to FY2018 forecasts.

FX rates: Q1FY2018 Results : 1US$ = ¥ 109.1, 1RMB = ¥17.1
FY2018 Forecasts : 1US$ = ¥ 105.0, 1RMB = ¥16.5

Research and Development

Development Pipeline (as of July 2018)

: Psychiatry & Neurology : Oncology : Regenerative medicine / cell therapy : Others

Revisions since the announcement of May 2018 are shown in red.

Area	Phase 1		Phase 2	Phase 3	NDA submitted
Japan	**dasotraline** (ADHD) **SEP-363856** (Schizophrenia) **DSP-2230** (Neuropathic pain) **EPI-589** (ALS) **SEP-4199** (Bipolar I depression)	**alvocidib** (AML)	**amcasertib** (Solid tumors) **DSP-7888** (Solid tumors / Hematologic malignancies) **DSP-6952** (IBS with constipation / Chronic idiopathic constipation)	**lurasidone** (Schizophrenia / Bipolar I depression / Bipolar maintenance) **LONASEN®** (Schizophrenia / Transdermal patch / Pediatric) **EPI-743** (Leigh syndrome) **napabucasin** (Colorectal cancer / Pancreatic cancer) **imeglimin** (Type 2 diabetes)	**thiotepa** (Conditioning treatment prior to autologous HSCT for pediatric solid tumors)
U.S.	**DSP-2230** (Neuropathic pain) **DSP-6745** (Parkinson's disease psychosis) **SEP-378608** (Bipolar disorder) **DSP-3905** (Neuropathic pain)	**alvocidib** (AML / MDS) **TP-0903** (Solid tumors / Hematologic malignancies) **DSP-0509** (Solid tumors) **TP-0184** (Solid tumors) **DSP-0337** (Solid tumors)	**EPI-589** (Parkinson's disease / ALS) **SEP-363856** (Schizophrenia / (Parkinson's disease psychosis) **SEP-4199** (Bipolar I depression) **alvocidib** (r/r AML) **amcasertib** (Solid tumors) **DSP-7888** (Solid tumors / Hematologic malignancies) **SB623** (Chronic stroke)	**dasotraline** (BED) **napabucasin** (Colorectal cancer / Pancreatic cancer)	**dasotraline** (ADHD) **apomorphine** (OFF episodes associated with Parkinson's disease)

Clinical Development Status (Major Changes since May 11, 2018)

- **TRERIEF®**
  Japan: Approved for a new indication for Parkinsonism in dementia with Lewy bodies in July 2018
  ✓ World's first approval for the indication

- **Apomorphine (APL-130277)**
  U.S.: NDA accepted (expected action date by FDA: January 29, 2019)
  ✓ Plan to launch in Q1 FY2019
  ✓ Presented Phase 3 study data at the Pan American Parkinson's Disease and Movement Disorders Congress on June 23, 2018

- **Dasotraline**
  U.S.: Obtained topline results of the second pivotal study for binge eating disorder (BED)

- **Alvocidib**
  U.S.: Started Phase 1/2 study for myelodysplastic syndromes (MDS) (combination therapy)

- **TP-0903**
  U.S.: Started Phase 1/2 study for chronic lymphocytic leukemia (CLL) (monotherapy/combination therapy)

- **Thiotepa (Development for the use of unapproved or off-labeled drugs)**
  Japan : NDA submitted for conditioning treatment prior to autologous hematopoietic stem cell transplantation (HSCT) for pediatric solid tumors in July 2018

Dasotraline : BED Phase 3 Study Results (SEP360-321 study)

- **Study design:** 12-week, randomized, double-blind, placebo-controlled study in adults with BED (dasotraline 4mg/day and 6 mg/day)
- **Efficacy:** 6mg group met primary endpoint (Primary endpoint: Change from baseline in number of binge days per week at Week 12)
- **Safety:** Adverse events consistent with previous studies

Pivotal studies summary

Study	Study dose	Primary endpoint results
Phase 2/3 study (SEP360-221)	4-8mg/day flexible dose	Statistically significant improvement with 4-8mg group
Phase 3 study (SEP360-321)	4, 6mg/day fixed dose	Statistically significant improvement with 6mg group

- **sNDA under preparation based on these results**
- **Plan to submit sNDA for BED in FY2018 in the U.S.**

* Announced the topline data of SEP360-221 study in the press release on January 16, 2017
* Announced the topline data of SEP360-321 study in the press release on July 26, 2018

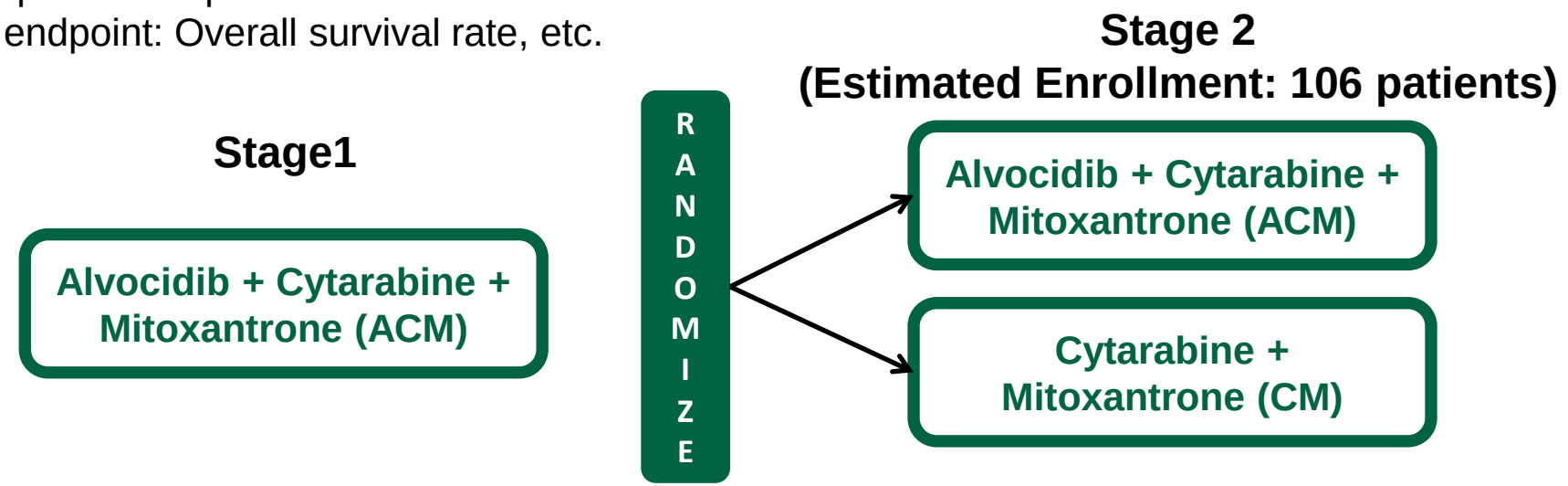
Alvocidib：Phase 2 Study Design & NDA Submission Target for AML

Revised target of NDA submission for AML

- Submission target: Changed from FY2018 to FY2019
  (Based on the assumption of NDA submission for accelerated approval with interim analysis data)
- Reason for change: Reviewed patients recruitment plan, etc.

Design of Phase 2 study (stage 2)

- Stage 2 of Phase 2 study; Open-label, randomized study to assess the clinical response to ACM compared to CM treatment in relapsed or refractory AML patients (18-65 years) with MCL-1 positive patients
- Primary endpoint: Complete remission rate
- Secondary endpoint: Overall survival rate, etc.



Status as of July 27, 2018	Completed	Started

Activities in FY2018 : Clinical Development Status

Area	Products	Proposed indication	Area	FY2018 target	Status as of July 27, 2018
Psychiatry & Neurology	TRERIEF®	Parkinsonism in dementia with Lewy bodies (DLB)	Japan	Approval	**Approved in July 2018**
	dasotraline	Attention-deficit hyperactivity disorder (ADHD)	U.S.	Approval and launch	**NDA submitted**
		Binge eating disorder (BED)	U.S.	sNDA submission	**Obtained Phase 3 topline results**
	apomorphine (APL-130277)	OFF episodes associated with Parkinson's disease	U.S.	Approval and launch	**Action date by FDA : Jan 29, 2019 Launch target changed from FY2018 to Q1 FY2019**
	LONASEN®	(New formulation: Transdermal patch) Schizophrenia	Japan	NDA submission	**Preparing NDA submission**
Oncology	alvocidib	Acute myeloid leukemia (AML) (Refractory or relapsed patients)	U.S.	NDA submission for accelerated approval	**Submission target changed from FY2018 to FY2019**
	napabucasin	Pancreatic cancer, Colorectal cancer	U.S., Japan	Promotion of Phase 3 studies	**Phase 3 study ongoing**
Regenerative medicine / Cell therapy	SB623	Chronic stroke	U.S.	Obtain Phase 2b study results in 1H 2019	**Phase 2b study ongoing**
	Allo iPS cell-derived products	AMD (age-related macular degeneration)	Japan	Start a clinical study (corporate-initiated)	**Preparing for start of clinical study**
	Allo iPS cell-derived products	Parkinson's disease	Japan	Start a clinical study (investigator-initiated)	**Preparing for start of clinical study**

Appendices

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Adjustments to Core Operating Profit

Q1FY2018 Results

Billions of yen

IFRS Full Basis		Adjusted amount
Revenue	115.9	
Cost of sales	28.9	
Gross profit	87.0	
SG&A expenses	50.3	(2.5)
R&D expenses	20.9	
Other operating income and expenses	(0.1)	0.1
Operating profit	15.8	2.6

IFRS Core Basis		Adjusted items
Revenue	115.9	
Cost of sales	28.9	
Gross profit	87.0	
SG&A expenses	47.8	Changes in fair value of contingent consideration (2.5)
R&D expenses	20.9	
Other operating income and expenses *1 (profit/loss on business transfer, share of profit/loss of associates accounted for using equity method)	0.0	
Core operating profit	18.4	
Changes in fair value of contingent consideration (Positive number indicates profit)	(2.5)	From SG&A expenses (2.5)
Other non-recurring items *2 (Negative number indicates loss)	(0.1)	

IFRS Full Basis : Each item is shown by original financial value under IFRS

IFRS Core Basis : Each item is shown by value after adjustment for calculating core operating profit

*1 "P/L on business transfer" and "share of P/L of associates accounted for using equity method" included in "other operating income and expenses" are used for calculation for core operating profit.

*2 Non-recurring items including "other operating income and expenses" except for *1 items, and impairment losses, etc.

Product Launch Target (as of July 2018)

Area	FY2018	FY2019	FY2020	FY2021	FY2022
Japan	**TRERIEF®** (Parkinsonism in dementia with Lewy bodies)	**LONASEN®** (Schizophrenia / Transdermal patch) **thiotepa** (Conditioning treatment prior to autologous HSCT for pediatric solid tumors)	**lurasidone** (Schizophrenia / Bipolar I depression /Bipolar maintenance)	**napabucasin** (Colorectal cancer / Pancreatic cancer) **imeglimin** (Type 2 diabetes) **DSP-6952** (IBS with constipation / Chronic idiopathic constipation)	**Allo iPS cell-derived products** *2 (AMD) **Allo iPS cell-derived products** *2 (Parkinson's disease) **DSP-7888** *1 (Solid tumors / Hematologic malignancies)
U.S.	**dasotraline** (ADHD)	**Apomorphine** (OFF episodes associated with Parkinson's disease) **dasotraline** (BED)	**alvocidib** *1 (AML)	**napabucasin** (Colorectal cancer / Pancreatic cancer) **DSP-7888** *1 (Solid tumors / Hematologic malignancies)	**SB623** *2 (Chronic stroke)

: Psychiatry & Neurology : Oncology
: Regenerative medicine / cell therapy : Others

Expect peak annual sales to be 50 billion yen or more (described in the first launch)

*1 Premise to utilize an application of accelerated approval program (Plan to consult with the FDA)

*2 Launch schedule is based on our goal pending agreement with partners.

Regenerative Medicine/Cell Therapy Business Plan (as of July 2018)

Proposed indication, etc.	Partnering	Region (planned)	Cell type	Clinical research	Clinical study
Chronic stroke (SB623)	SanBio	North America	Allo mesenchymal stem cell		In progress *2 (Phase 2b study)
AMD (age-related macular degeneration)	Healios RIKEN	Japan	Allo iPS cell-derived retinal pigment epithelium	In progress	Preparing for start
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto Univ CiRA	Global	Allo iPS cell-derived dopamine neural progenitor		Plan to start in FY2018 in Japan (Investigator-initiated)
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor	Preparing for start	
Spinal cord injury	Keio Univ Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	Preparing for start	

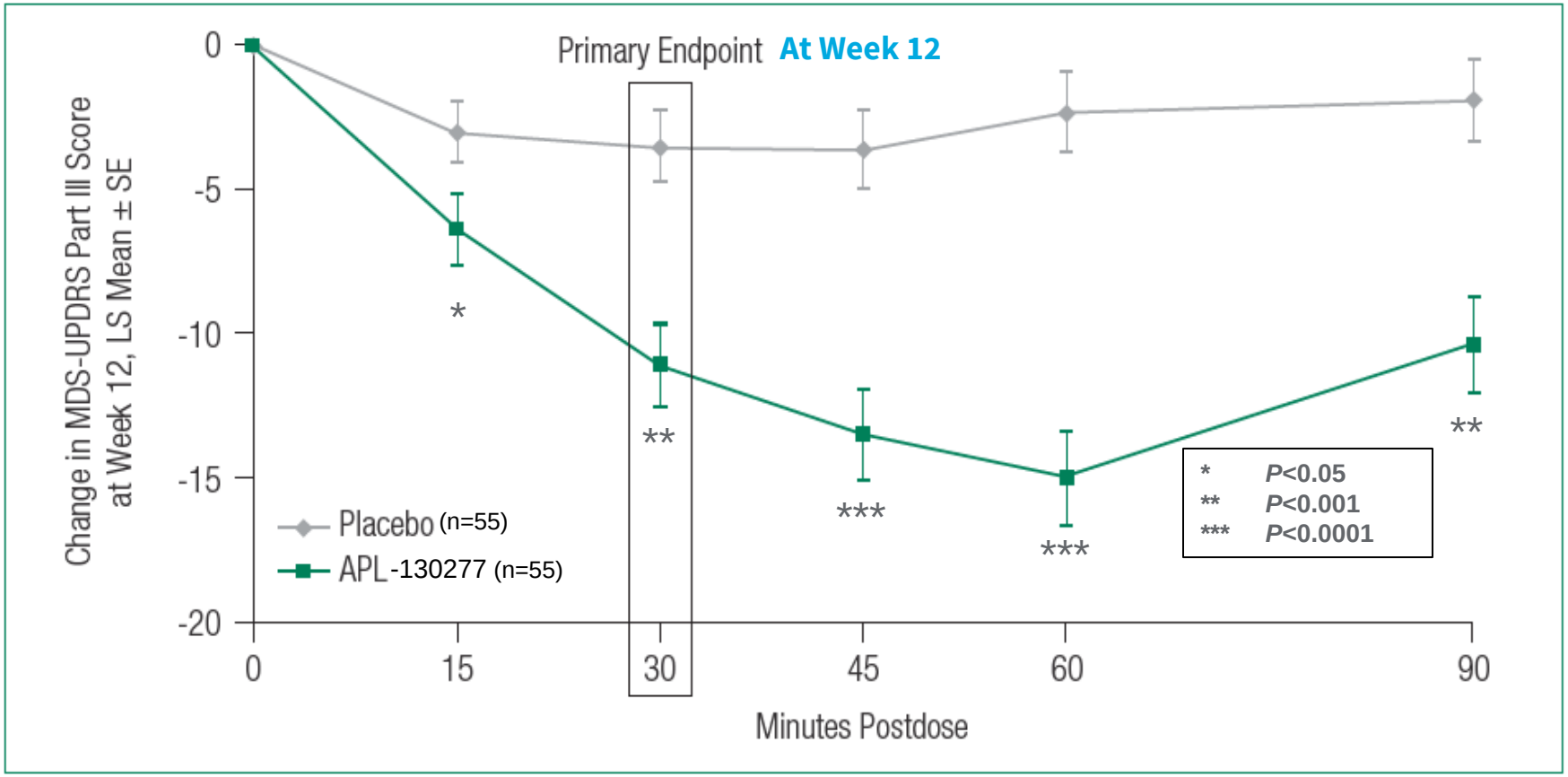
Aim to launch in FY2022*1

*1 Launch schedule is based on our goal that is not agreed with partners.
*2 Plan to conduct Phase 3 study, but aim to utilize the application of accelerated approval program depending on Phase 2b study result.

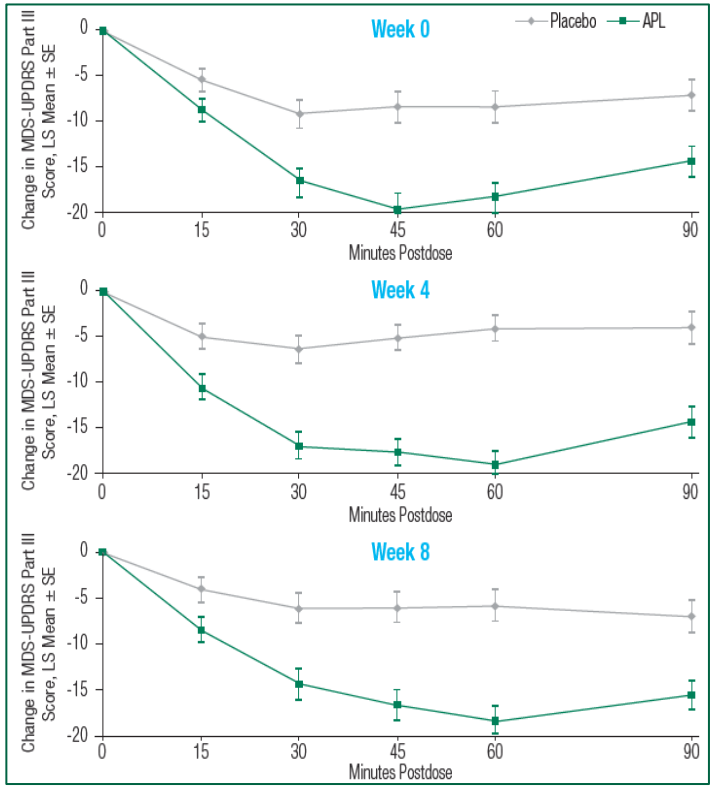
Psychiatry & Neurology : Apomorphine (Phase 3 study)

Pan American Parkinson's Disease and Movement Disorders Congress (MDS-PAS) (June 2018)

- Phase 3 study result for OFF episodes associated with Parkinson's disease (CTH-300 study)
  - ✓ Primary endpoint showed significant difference vs placebo.



<Reference>
Change From Predose in MDS-UPDRS Part III Motor Examination Score at Each Visit (mITT Population)

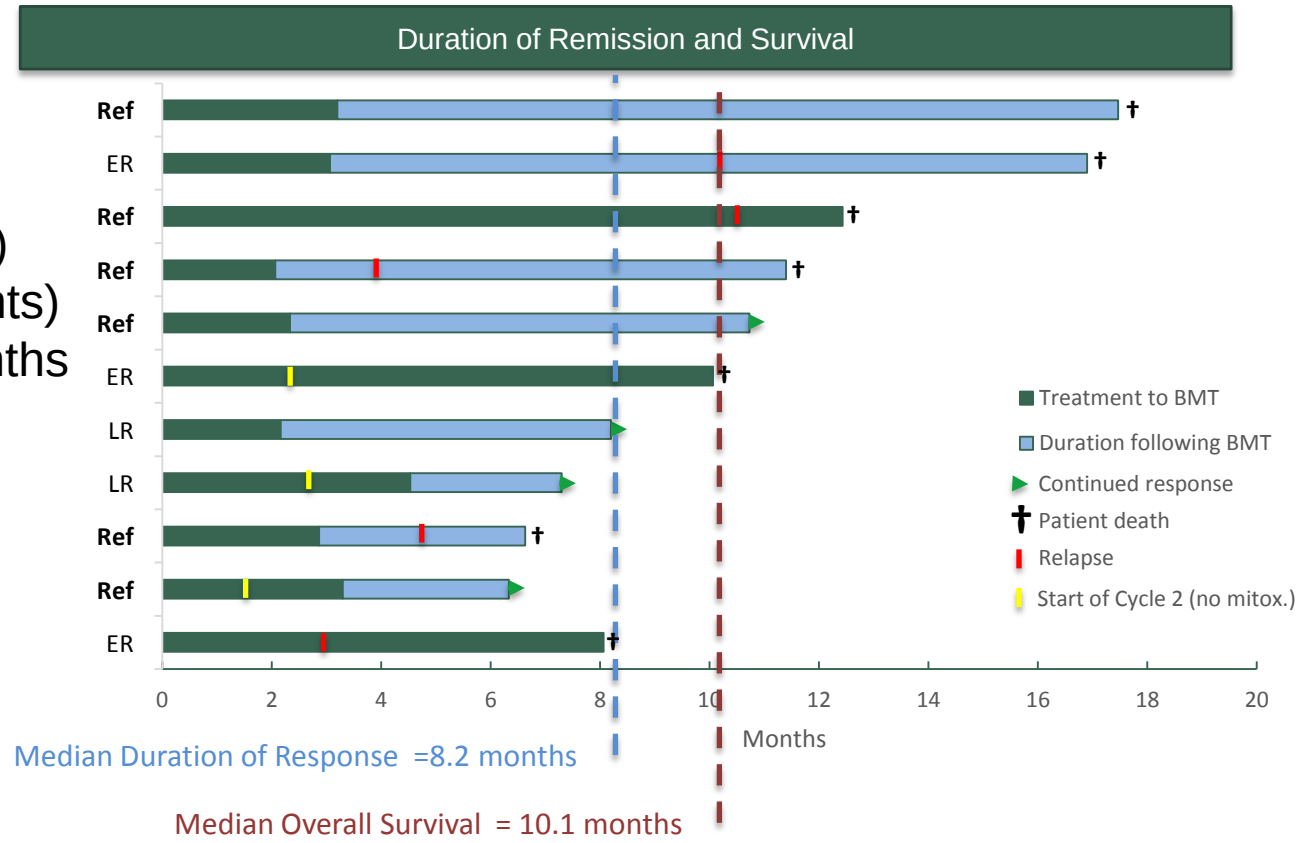


C. Warren Olanow, et al., The 2nd Pan American Parkinson's Disease and Movement Disorders Congress, Volume 33

* Announced the topline data in the press release on January 30, 2018

Oncology : Alvocidib (r/r AML Zella 201 study)

- **The 2018 European Hematology Association (EHA) Annual Meeting (EHA 2018) (June 2018)**
  - ➢ Phase 2 study's stage 1 for relapsed / refractory acute myeloid leukemia (AML) (Zella 201 study)
  - ✓ All patients : 21
  - ✓ Evaluated patients : 18
  - ✓ Overall complete remission (CR/CRi) : 61% (11 patients)
  - ✓ Overall response rate (ORR) : 67% (12 patients)
  - ✓ Proceeded to an allo SCT : 44% (8 patients)
  - ✓ Median overall survival (mOS) : 10.1 months

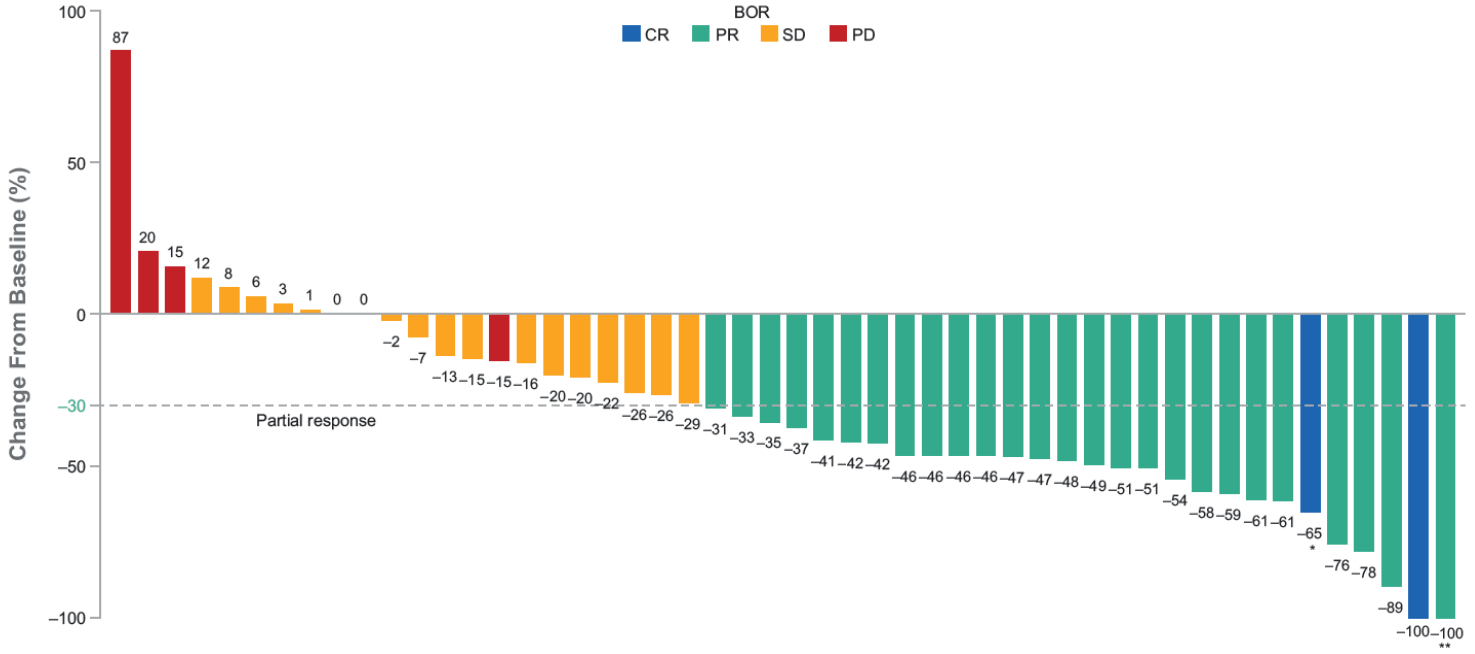


Ref : Refractory, ER : Early Relapse, LR : Late Relapse

Joshua F Zeidner, et al., EHA 2018 (Abstract PF243)

Oncology : Napabucasin (Pancreatic cancer 118 study)

- **The 2018 American Society of Clinical Oncology (ASCO) Annual Meeting (ASCO 2018) (June 2018)**
  - ➢ Phase 1/ 2 study results for pancreatic cancer (combination with gemcitabine and nab-paclitaxel) (118 study)
    - ✓ All patients : 59
    - ✓ Evaluated patients : 50
    - ✓ Disease control rate (DCR) : 92% (46 patients) (CR:2, PR:26)
    - ✓ Median progression-free survival (PFS) : 7.06 months
    - ✓ Median overall survival (mOS) : 9.59 months
    - ✓ Patients eligible for CanStem111P : 29
    - ✓ Evaluated patients : 26
    - ✓ Disease control rate (DCR) : 88.5% (23 patients) (CR:1, PR:13)
    - ✓ Median progression-free survival (PFS) : 7.10 months
    - ✓ Median overall survival (mOS) : 9.62 months



*Lymph nodes decreased to <10 mm in short axis. **Some non-target lesions remain

Tanios Bekaii-Saab, et al. J Clin Oncol 36, 2018, ASCO 2018 (Abstract 4110)

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Innovation today, healthier tomorrows