

## Summary of Conference Call for Q1 FY2021

Date/time: Thursday July 29, 2021; 17:00–17:45 (Q&A Session: 17:10 - approx. 35 minutes)

Attendees from Sumitomo Dainippon Pharma:

Hiroshi Nomura      Representative Director, President and CEO

Toru Kimura         Representative Director, Executive Vice President/Chief Scientific Officer

Hisayoshi Kashima    Senior Director, Finance & Accounting Department

Disclaimer:

This is a summary of the Q1 FY2021 call and clarifies certain information provided. Myovant Sciences Ltd. (“Myovant”) is listed on the New York Stock Exchange, and the Group holds approximately 53% of the outstanding shares of Myovant. As a result, Myovant is consolidated into the results. This material contains information about Myovant, which is based on information disclosed by Myovant. For more information on Myovant, please visit <https://www.myovant.com/>.

### Opening remarks

(Nomura) Thank you very much for joining us on the conference call concerning our financial results for the first quarter of the fiscal year ending March 31, 2022 (FY2021). I would like to take this opportunity to express my appreciation to you all for your interest in our business and your valuable comments. I imagine you want to know more about the numbers we announced earlier today, such as year-on-year comparisons and progress vis-à-vis our full-year forecasts. I am happy to answer questions you may have as long as our time permits.

### Presentation

(Kashima) It is my pleasure to be able to walk you through our financial results for the first quarter of fiscal 2021, as well as the clinical development status. Please refer to the presentation material.

## Financial Results for Q1 FY2021

### Financial Results for Q1 FY2021 (Core Basis)



	Billions of yen						
	Q1 FY2020 Results	Q1 FY2021 Results	Change			FY2021	
			Value	FX impact	%	May 12 forecasts	%
<b>Revenue</b>	133.9	<b>131.2</b>	(2.7)	2.0	(2.0)	578.0	22.7
Cost of sales	36.0	<b>38.5</b>	2.5	1.5	7.0	156.0	24.7
Gross profit	97.9	<b>92.7</b>	(5.2)	0.5	(5.3)	422.0	22.0
SG&A expenses	47.8	<b>62.0</b>	14.2	0.9	29.7	263.0	23.6
R&D expenses	25.7	<b>22.4</b>	(3.3)	0.3	(12.9)	95.0	23.6
<b>Core operating profit</b>	<b>24.4</b>	<b>8.5</b>	(15.8)	(0.7)	(65.0)	64.0	13.3
Changes in fair value of contingent consideration (negative number indicates loss)	(1.2)	<b>(0.1)</b>	1.2			(1.0)	
Other non-recurring items (negative number indicates loss)	0.1	<b>(0.1)</b>	(0.3)			(2.0)	
<b>Operating profit</b>	<b>23.3</b>	<b>8.3</b>	(15.0)		(64.3)	61.0	13.6
Profit before taxes	22.0	<b>8.0</b>	(14.0)		(63.8)		
Income tax expenses	6.4	<b>7.2</b>	0.7				
Net profit	15.6	<b>0.8</b>	(14.8)		(94.8)		
<b>Net profit attributable to owners of the parent</b>	<b>18.3</b>	<b>4.8</b>	(13.5)		(73.7)	41.0	11.7

#### The forecasts are not revised

- Expecting revenue from possible new alliance and sales growth of new products in North America

#### (Ref.) Earnings related to Sumitovant

	Billions of yen	
	Q1 FY20	Q1 FY21
<b>Revenue</b>	<b>3.7</b>	<b>5.8</b>
SG&A expenses *	6.4	19.9
R&D expenses	7.3	5.9
<b>Core operating profit</b>	<b>(10.0)</b>	<b>(20.7)</b>
<b>Operating profit</b>	<b>(10.0)</b>	<b>(20.7)</b>
Net profit	(10.2)	(21.0)
<b>Net profit attributable to owners of the parent</b>	<b>(7.5)</b>	<b>(17.0)</b>

The figures include intra-group transaction  
\* Include amortization of patent rights

FX rates:  
Q1FY2020 Results : 1US\$ = ¥107.6, 1RMB = ¥15.2  
Q1FY2021 Results : 1US\$ = ¥109.5, 1RMB = ¥17.0  
FY2021 forecasts : 1US\$ = ¥110.0, 1RMB = ¥16.5

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Please turn to Slide #3.

Here we have the IFRS financial results for the first quarter of fiscal 2021, which are calculated on the core basis. Revenue amounted to 131.2 billion yen, down by 2.7 billion yen year-on-year. While the China segment recorded revenue growth, revenue decreased in Japan, North America, and Other Regions segments.

SG&A expenses increased by 14.2 billion yen, primarily due to the start of full-scale marketing activities by Sumitovant Biopharma's subsidiaries and increased amortization of intangible assets.

Meanwhile, R&D expenses decreased, mainly because of a drop in the oncology area and spending by Myovant Sciences.

As a result, core operating profit was 8.5 billion yen, down by 15.8 billion yen year-on-year.

With no major increases/decreases in fair value of contingent consideration and other non-recurring items from the previous fiscal year, operating profit came in as 8.3 billion yen, down by 15.0 billion yen year-on-year.

Net profit attributable to owners of the parent, which reflects adjustment for the non-controlling interests in Myovant Sciences, dropped sharply by 13.5 billion yen to 4.8 billion yen.

Our revenue and profit on each level made a somewhat slow start in the first quarter, but we have not revised our original guidance for the full year as we currently expect additional revenue from a possible new alliance and sales expansion of new products in the North America segment.

## Financial Results for Q1 FY2021

### Revenue of Major Products in Japan



	Billions of yen					
	Q1 FY2020 Results	Q1 FY2021 Results	Change		FY2021	
			Value	%	May 12 forecasts	%
Equa®/EquMet®	10.3	9.8	(0.5)	(4.7)	37.4	26.3
Trulicity®*	8.4	8.8	0.4	5.3	38.2	23.1
TRERIEF®	4.3	4.3	0.1	1.4	17.9	24.1
REPLAGAL®	3.5	3.5	0.0	1.0	13.8	25.3
METGLUCO®	2.5	2.1	(0.4)	(14.7)	6.9	30.4
LATUDA®	0.5	1.4	0.9	167.1	6.7	20.7
LONASEN® Tape	0.3	0.5	0.2	78.5	2.5	18.6
AMLODIN®	1.7	1.5	(0.2)	(13.1)	5.0	29.8
AG products	1.9	2.4	0.5	27.6	10.1	24.0
Others	6.5	4.3	(2.2)	(33.6)	11.5	37.7
<b>Total</b>	<b>39.8</b>	<b>38.7</b>	<b>(1.1)</b>	<b>(2.8)</b>	<b>150.0</b>	<b>25.8</b>

■ Progress is almost as forecasted in the segment total

■ LATUDA® is on track  
Prescription days limit was lifted in June

Note: Sales of each product are shown by invoice price (\* Trulicity® is shown by NHI price)

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Please turn to Slide #4 for revenue of major products in Japan.

Revenue was 38.7 billion yen, down by 1.1 billion yen year-on-year.

Sales of LATUDA®, Trulicity®, and other products grew, but the segment total declined due to lower sales of Equa®/EquMet® on the back of the National Health Insurance (NHI) drug price revisions, and a decline in sales of long-listed drugs.

Progress versus the full-year forecasts for the segment was 25.8%, which is in line with our expectations.

## Financial Results for Q1 FY2021

### Revenue of Major Products in North America & China



	Q1 FY2020 Results	Q1 FY2021 Results	Change	Q1 FY2020 Results	Q1 FY2021 Results	Change			FY2021		
						Value	FX Impact	%	May 12 forecasts	Yen-basis %	
		Million \$			Billions of yen			Million \$	Million RMB	Billion yen	
<b>North America</b>	Million \$			Billions of yen			Million \$	Million RMB	Billion yen		
LATUDA®	493	469	(24)	53.0	51.4	(1.7)	0.9	(3.1)	2,004	220.4	23.3
APTIOM®	63	63	0	6.8	6.9	0.1	0.1	1.9	249	27.4	25.2
BROVANA®	72	51	(21)	7.8	5.6	(2.2)	0.1	(28.3)	106	11.7	47.6
KYNMOBI™	—	2	2	—	0.2	0.2	0.0	—	28	3.1	7.4
ORGOVYX™	—	11	11	—	1.2	1.2	0.0	—	—	—	—
MYFEMBREE®	—	1	1	—	0.1	0.1	0.0	—	792	87.1	8.4
GEMTESA®	—	7	7	—	0.8	0.8	0.0	—	—	—	—
Others	61	48	(13)	6.5	5.2	(1.3)	0.1	(20.4)	—	—	—
<b>Total</b>	<b>689</b>	<b>652</b>	<b>(37)</b>	<b>74.1</b>	<b>71.4</b>	<b>(2.7)</b>	<b>1.2</b>	<b>(3.7)</b>	<b>3,179</b>	<b>349.7</b>	<b>20.4</b>
<b>China</b>	Million RMB			Billions of yen			Million RMB	Million RMB	Billion yen		
MEROPEN®	260	392	132	3.9	6.6	2.7	0.7	67.6	1,364	22.5	29.4
Others	78	111	32	1.2	1.9	0.7	0.2	61.9	442	7.3	26.3
<b>Total</b>	<b>338</b>	<b>503</b>	<b>165</b>	<b>5.1</b>	<b>8.5</b>	<b>3.4</b>	<b>0.9</b>	<b>66.3</b>	<b>1,806</b>	<b>29.8</b>	<b>28.6</b>

■ **North America segment**  
Revenue dropped y-o-y, progress in line with full-year forecast  
■ LATUDA® dropped due to impact of high sellout in the last December  
■ BROVANA® decreased due to loss of exclusivity in June  
■ Launched MYFEMBREE® in June, GEMTESA® in April  
■ Revenue from possible new alliance included in full-year forecast has not incurred in Q1 yet

■ **China segment**  
Increased y-o-y since Q1 FY2020 sales dropped due to the effect of COVID-19.  
Progress is as forecasted.

FX rates:  
Q1 FY2020 Results : 1US\$ = ¥107.6, 1RMB = ¥15.2  
Q1 FY2021 Results : 1US\$ = ¥109.5, 1RMB = ¥17.0  
FY2021 forecasts : 1US\$ = ¥110.0, 1RMB = ¥16.5

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On Slide #5 is revenue of major products in the North America and China segments.

Segment sales in North America decreased by 2.7 billion yen year-on-year to 71.4 billion yen.

LATUDA<sup>®</sup> sales decreased by 3.1% year-on-year to 51.4 billion yen. This is primarily because channel inventory built up in response to high sell-out in December 2020, and lingering until May 2021. We believe that the inventory level had returned to normal by June 2021.

BROVANA<sup>®</sup> also saw a decline in sales as its exclusivity was lost in June 2021.

New product offerings from Sumitovant's subsidiaries, including Urovant Sciences and Myovant Sciences, include ORGOVYX<sup>™</sup>, a therapeutic agent for prostate cancer released in January 2021, GEMTESA<sup>®</sup>, a therapeutic agent for overactive bladder released in April 2021, and MYFEMBREE<sup>®</sup>, a therapeutic agent for uterine fibroids released in June 2021. GEMTESA<sup>®</sup> was released by Urovant Sciences and ORGOVYX<sup>™</sup> and MYFEMBREE<sup>®</sup> were released by Myovant Sciences. Myovant Sciences expects sales from ORGOVYX<sup>™</sup> and MYFEMBREE<sup>®</sup> to increase going forward, and we expect the same from GEMTESA<sup>®</sup>. Based on our internal forecasts and information from Myovant Sciences, the progress of these products in the first quarter versus the full-year forecasts is in line with our expectations. Further, lump-sum payments to Myovant Sciences resulting from its alliances for relugolix is reported under "Others."

Segment sales in China amounted to 8.5 billion yen, up by 66.3% year-on-year. This significant increase is a reaction to sluggish shipments due to COVID-19 in the corresponding period in the previous year. Progress versus the full-year forecasts is in line with our expectations.

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Q1 FY2021 Results	Revenue (Sales to customers)	38.7	71.4	8.5	2.7	121.3	9.9	131.2
	Cost of sales	20.0	8.0	1.6	1.3	30.9	7.6	38.5
	Gross profit	18.7	63.4	6.9	1.4	90.5	2.3	92.7
	SG&A expenses	11.9	45.3	2.7	0.8	60.7	1.3	62.0
	Core segment profit	6.7	18.1	4.3	0.6	29.8	1.0	30.8
	R&D expenses					22.3	0.2	22.4
	Core operating profit				7.7	0.9	8.5	
Q1 FY2020 Results	Revenue (Sales to customers)	39.7	74.1	5.1	5.5	124.5	9.3	133.9
	Cost of sales	20.4	5.4	0.8	2.4	29.0	7.0	36.0
	Gross profit	19.4	68.8	4.3	3.1	95.6	2.3	97.9
	SG&A expenses	11.4	32.9	1.6	0.7	46.5	1.2	47.8
	Core segment profit	8.0	35.9	2.7	2.4	49.0	1.1	50.1
	R&D expenses					25.6	0.2	25.7
	Core operating profit				23.4	0.9	24.4	
Change	Revenue (Sales to customers)	(1.1)	(2.7)	3.4	(2.8)	(3.2)	0.5	(2.7)
	SG&A expenses	0.6	12.4	1.1	0.1	14.2	0.0	14.2
	Core segment profit	(1.3)	(17.7)	1.6	(1.8)	(19.3)	(0.1)	(19.3)
	R&D expenses					(3.3)	(0.0)	(3.3)
	Core operating profit					(15.8)	(0.1)	(15.8)

Billions of yen

- **Japan:** Lower profit due to declined sales and increased expenses
- **North America:** Lower profit mainly due to incremental costs of Sumitovant in addition to lower revenue
- **China:** Profit increased mainly due to higher revenue
- **Other Regions:** Lower profit mainly due to decrease in export

Slide #6 shows financial results by segment.

In the Japan segment, core segment profit decreased by 1.3 billion yen to 6.7 billion yen. This is because there was a revenue decline as well as an increase in SG&A expenses as spending rebounded after being curbed in the corresponding period last year due to COVID-19.

In the North America segment, core segment profit decreased by 17.7 billion yen to 18.1 billion yen. This is primarily owing to an increase in expenses following the start of full-scale marketing activities by Myovant Sciences and Urovant Sciences and an increase in the amortization of intangible assets, in addition to a revenue decline.

In the China segment, core segment profit increased by 1.6 billion yen, as an increase in expenses was more than offset by revenue growth.

In the Other Regions segment, core segment profit decreased as a high level of sales in the corresponding period of the previous year was largely achieved as trading partners built up their inventories.

Research and Development					Sumitomo Dainippon Pharma
Development Pipeline (as of July 29, 2021)					
<span style="color: blue;">■</span> : Psychiatry & Neurology <span style="color: orange;">■</span> : Oncology <span style="color: green;">■</span> : Regenerative medicine / Cell therapy <span style="color: yellow;">■</span> : Others <span style="color: purple;">■</span> : Frontier business             Revisions since the announcement of May 2021 are shown in red					
Area	Phase 1	Phase 2	Phase 3	NDA/BLA submitted	
Japan	EPI-589 (ALS)	DSP-0390 (Solid tumors)	SEP-4199 (Bipolar I depression)	ulotaront (SEP-363856) (Schizophrenia)	
	DSP-1181 (Obsessive compulsive disorder)		Allo iPS cell-derived products (Parkinson's disease/ Investigator-initiated clinical study)	DSP-7888 (Glioblastoma)	
U.S.	DSP-6745 (Parkinson's disease psychosis)	guretolimod (DSP-0509) (Solid tumors)	EPI-589 (Parkinson's disease/ALS)	ulotaront (SEP-363856) (Schizophrenia)	RVT-802 (Pediatric congenital athymia) BLA resubmitted
	SEP-378608 (Bipolar disorder)	itacenosertib (TP-0184) (Hematologic malignancies)	ulotaront (SEP-363856) (Parkinson's disease psychosis)	DSP-7888 (Glioblastoma)	MYFEMBREE® (relugolix) (New indication: Endometriosis)
	DSP-3905 (Neuropathic pain)	TP-1287 (Solid tumors)	SEP-4199 (Bipolar I depression)	GEMTESA® (vibegron) (New indication: OAB in men with BPH)	
	SEP-378614 (Treatment resistant depression)	TP-3654 (Hematologic malignancies)	dubermatinib (TP-0903) (AML Research group- initiated clinical study)		
	SEP-380135 (Alzheimer's disease agitation)	TP-1454 (Solid tumors)	rodatristat ethyl (Pulmonary arterial hypertension)		
	DSP-0038 (Alzheimer's disease psychosis)	DSP-0390 (Solid tumors)	URO-902 (Overactive bladder)		
	DSP-5336 (Hematologic malignancies)				
China			LATUDA® (New indication: Bipolar I depression)		
			ulotaront (SEP-363856) (Schizophrenia)		
			lefamulin (Bacterial community-acquired pneumonia)		
Europe				relugolix (Prostate cancer)	8

Please skip to Slide #8.

Let me move on to talk about our development pipeline.

This table shows our development pipeline by stages.

Indicated in red are changes that have been made since May this year, which I will come back to on the next slide.

Also, SEP-363856 now has a generic name, ulotaront.

- **DSP-7888**  
Japan : Changed from Phase 2 study to Phase 3 study for glioblastoma
- **DSP-0390**  
Japan : Started Phase 1 study for solid tumors
- **DSP-5336**  
U.S. : Started Phase 1 study for hematologic malignancies
- **TWYMEEG® (imeglimin)**  
Japan : Approved for type 2 diabetes in June 2021 and planning to launch in September 2021
- **MYFEMBREE® (relugolix combination tablet)**  
U.S. : Approved for uterine fibroids in May 2021 and launched in June 2021  
U.S. : Submitted sNDA for endometriosis in July 2021
- **RYEQO® (relugolix combination tablet)**  
Europe : Approved for uterine fibroids in July 2021 and planning to launch sequentially in Gedeon Richter Plc.'s territory from the second half of 2021
- **Lefamulin**  
China : Acquired exclusive development and marketing rights from Sinovant in June 2021  
➤ In preparation to submit NDA based on positive Phase 3 study results for bacterial community-acquired pneumonia

Please turn to Slide #9. Here we have all the changes since this May.

In the oncology area, DSP-7888 has changed from Phase 2 to Phase 3 study in Japan.

We have commenced Phase 1 study of DSP-0390 in Japan, following one in the U.S. Speaking of the U.S., we have started Phase 1 study of DSP-5336 for hematologic malignancies. DSP-5336 is a new chemical entity jointly created with Kyoto University. Its profile can be found on Slide #15 in Appendix.

In the other therapeutic areas, TWYMEEG® was approved for type 2 diabetes in Japan this June and will be launched this September.

Relugolix combination tablets produced by Myovant Sciences are marketed as MYFEMBREE® in the U.S. and as RYEQO® in Europe. In the U.S., relugolix was approved for uterine fibroids in May and launched in June this year. Myovant Sciences also submitted an NDA for an additional indication of endometriosis to the FDA in July this year.

In Europe, on the other hand, relugolix was approved for uterine fibroids in July this year and will be launched sequentially in Gedeon Richter Plc's territories from the second half of 2021.

In June this year, we acquired the exclusive development and marketing rights of lefamulin in China from Sinovant, and have added it to our pipeline. Based on positive Phase 3 study results for bacterial community-acquired pneumonia, we are preparing to submit an NDA and aim to launch in China in fiscal 2023. Please see Slide #14 for the profile of lefamulin.

Lastly, I have an announcement to make on an upcoming R&D event. At 13:00 on September 8, 2021, we are planning to hold an online informational meeting on our Frontier business. I hope you can join us.

This concludes my comments. Thank you for your kind attention.

Q&A

Questioner 1

Q: Has there been any change to your explanations in May about the purpose and details of a possible new alliance currently under negotiation in the North America segment?

A: (Nomura) As I explained in the investors meeting in May, the purpose of the proposed alliance is to share development expenses and risks through partnering in anticipation of the challenges after LATUDA<sup>®</sup> has lost its exclusivity. At that time, I said that "we should soon be able to make an announcement concerning the alliance," but ironing out the details is taking longer than expected, and we now hope to close the deal by the end of this coming September. This will likely affect our numbers, as the delay in the signing means a delay in sharing development expenses, but we have not revised our financial forecasts because we do not believe it will have a material impact.

Q: Have patient registrations been completed for the Phase 3 study of ulotaront (SEP-363856)? When will its results be available?

A: (Kimura) Due to the COVID-19 pandemic, we are several months behind the original schedule. Patients are still being enrolled, and we expect to have the results sometime in the fiscal year ending March 31, 2023.

Questioner 2

Q: Am I correct in assuming that, other than the proposed alliance, sales of the three new products (ORGOVYX<sup>™</sup>, MYFEMBREE<sup>®</sup>, and GEMTESA<sup>®</sup>) can have a material impact on your full-year forecasts? Do you foresee a downward risk of LATUDA<sup>®</sup> sales in the U.S.?

A: (Nomura) The three new products will significantly impact our financial results for FY2021. Another key factor is the performance of LATUDA<sup>®</sup> in the U.S. Because its channel inventory was built up in response to high sell-out in the previous fiscal year, its sales were sluggish in April and May 2021. Things returned to normal by June, and I believe we can make up for the lagging sales. Yet, we believe the performance of LATUDA<sup>®</sup> is one of the factors that will affect our financial results. Our profit/loss will differ greatly if LATUDA<sup>®</sup> sales change by a matter of 10 to 20 billion yen.

Q: How do you think Sumitovant Biopharma's R&D expenses will trend going forward?

A: (Nomura) Sumitovant Biopharma has five subsidiaries under its umbrella, each of which has its own development pipeline involving expenses unique to it. Myovant Sciences has launched ORGOVYX<sup>™</sup> and MYFEMBREE<sup>®</sup>, but we need to conduct clinical studies to collect evidence, which will require additional R&D expenses for some time to come.

Q: When do you expect sales of the three new products to really take off?

A: (Nomura) The spread of COVID-19 infections is improving in the U.S., I was told that both Myovant Sciences and Pfizer had to do remote marketing mostly in April and May, and they finally began visiting medical institutions in June to promote their products. Partly because of this, it was admittedly a rather slow beginning, but we are optimistic that Myovant Sciences can achieve the plans laid out in its financial forecasts for FY2021. That said, it is hard to say when we will see their full-scale start-ups.

**Questioner 3**

Q: When Roivant Sciences goes public, what will Sumitomo Dainippon Pharma do about Roivant Sciences' stock? Do you intend to get involved in Roivant Sciences' business?

A: (Nomura) At present, Roivant Sciences' stock offers little liquidity. If we can increase liquidity by IPO, we will have a variety of options to take. As a stakeholder, we now have one outside director on their board, but we do not plan to get directly involved with Roivant Sciences' management.

Q: When do you expect the Phase 3 study for SEP-4199 to start? Do you have any ideas about mitigating the placebo effect and other events?

A: (Kimura) I believe that we can announce the start of the Phase 3 study for SEP-4199 soon. To minimize the placebo effect, we are planning studies that utilize various techniques and our proprietary know-how. We should be able to give you more details after the Phase 3 study has commenced.

**Questioner 4**

Q: Why is the first-quarter gross profit margin low for the North America segment? Also, the plan for the FY2021 gross profit margin appears to be low. Why is that?

A: (Kashima) In this first quarter, the cost of sales ratio in that segment was 11.1%, which is up by 3.9 percentage points year-on-year. This is chiefly attributable to the change in product mix: sales of low-cost LATUDA<sup>®</sup> decreased while those of high-cost products from Sumitovant Biopharma increased. Another factor that pushed up the cost of sales ratio is forex losses on unrealized profit on LATUDA<sup>®</sup>'s inventory. Also, some of it was losses on the liquidation of inventory. We expect the cost of sales ratio for FY2021 to grow year-on-year, due to an expected increase in revenue from the products of Sumitovant Biopharma's subsidiaries and Myovant Sciences' plans to record payments of shared profit with Pfizer as cost of sales.

Q: The tax rate for the first quarter seems high. Any reason for that? Will it be this high for the full



year?

A: (Kashima) The tax rate for pre-tax profit was seemingly very high at around 90% in the first quarter. Because we have yet to determine the tax effect for the Sumitovant Biopharma Group, whose pre-tax profit was negative, the tax rate appears to be high on a consolidated basis. The full-year tax rate may be a bit lower than what it is now, but we expect to see a similar trend nonetheless.

Q: GEMTESA<sup>®</sup>'s market is crowded with generics, on top of mirabegron. Do you have any competing products in mind that you target? If so, what is your strategy?

A: (Nomura) With regard to anticholinergic generics, we will stress GEMTESA<sup>®</sup>'s small effect of increasing the risk of dementia. For mirabegron, we have not conducted a head-to-head comparative study, but we believe that we can safely differentiate GEMTESA<sup>®</sup> through information provided on its label. Although it may not be easy to encourage a switch from generics because of the large disparity in prices, we could facilitate a switch from brand-name drugs, and so we will focus on differentiating GEMTESA<sup>®</sup> from mirabegron.

#### Questioner 5

Q: Why was a limit on the prescription period not imposed for RYEQO<sup>®</sup>, which has been approved for uterine fibroids in Europe?

A: (Nomura) According to information provided by Myovant Sciences, it is unclear why the prescription period was not limited, but we understand from Myovant Sciences that they took note of long-term safety data in the clinical study results. We shall see how the market reacts to the absence of the limit on the prescription period after its sales begin.

Q: It looks like ORGOVYX<sup>™</sup> has made a rather slow start. Is the switchover from in-house-prescribed injections going smoothly?

A: (Nomura) According to information provided by Myovant Sciences, leuprorelin for injection is primarily administered at medical institutions. Similarly, ORGOVYX<sup>™</sup> is prescribed at medical institutions. Because of this, signing a delivery contract with medical institutions is important, and we understand Myovant Sciences is doing well in this regard.

#### Questioner 6

Q: When you say the proposed alliance, do you mean the one in Europe between Myovant Sciences and Pfizer concerning relugolix for the oncology area?

A: (Nomura) After signing a development and commercialization agreement on relugolix between Myovant Sciences and Pfizer in 2020, Pfizer received an exclusive option to commercialize relugolix in oncology outside North America, excluding certain Asian countries. The new alliance

that is factored in our financial forecasts is a different one.

**Questioner 7**

Q: It seems that Medicaid enrollment has been on the increase in the U.S. since March 2020. Do you think that this will have any impact on LATUDA<sup>®</sup>'s payer mix or prices?

A: (Kashima) In the first quarter of FY2021, LATUDA<sup>®</sup>'s payer mix remained unchanged, including those on Medicaid. It doesn't seem as if its net prices have changed, either.

Q: What do you think are the competitive advantages of DSP-5336 over other menin-MLL inhibitors, which are in advanced development stages?

A: (Kimura) There are a few menin-MLL inhibitors ahead of DSP-5336, which are currently under clinical studies. We believe that our menin-MLL inhibitor offers a higher safety margin than its predecessors because of the difference in the chemical structural formula. If we can successfully prove this in clinical settings, we believe that we can increase its competitiveness, thus commencing clinical studies.

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