April 13, 2021

Summary of the Q&A Session at the Sumitovant Meeting

- Date/time: Tuesday March 23, 2021; am 10:00–pm 0:30
- Attendees:

Hiroshi Nomura: Representative Director, President and CEO
Toru Kimura: Member, Board of Directors, Senior Executive Officer and Chief Scientific Officer
Hiroyuki Baba: Senior Executive Officer, Global Data Design Office; IT Management & Digital Transformation
Satoru Tsuchiya: Senior Director, Global Data Design Office
Myrtle Potter: CEO of Sumitovant
Dan Rothman: Chief Information Officer of Sumitovant and Chief Digital Officer of Sumitomo Dainippon Pharma Group
Bill McMahon: Chief Algorithmic Analytics Officer of Sumitovant
Sam Azoulay: Chief Medical Officer, Head of Research & Development of Sumitovant
Adele Gulfo: Chief Business and Commercial Development Officer of Sumitovant
Yuichiro Haruyama: Executive Vice President, Finance & Corporate Strategy of Sumitovant

□ Questioner 1:

Q: As treatment for prostate cancer is long term, it seems that selecting a convenient modality is more important than for other cancers. With previous injectable GnRH receptor antagonists, it was convenient to be injected when going to a clinic for tests and it was painless. So, what kind of patient is targeted for taking Orgovyx once daily at home?

A: (Myrtle Potter) We believe that Orgovyx is an attractive drug for all patients with advanced prostate cancer.

(Adele Gulfo) The patient population for Orgovyx is broad as the drug is indicated for men with advanced prostate cancer. Types of advanced prostate cancer include, early stage, metastasis, resistance and receiving ADT (androgen deprivation therapy). I will note that men with advanced prostate cancer who also have cardiovascular disease are also ideal candidates for Orgovyx. So, the estimated 300k patients in the U.S. with advanced prostate cancer undergoing ADT would be candidates.

Q: Through the Strategic Alliance with Roivant, you have the option to acquire extra shares in the six companies up to 2024. How is that going? When will a decision be made to exercise the option?

A: (Nomura) Information regarding each of the companies has been given. We have not made a decision regarding the option yet but will do so by 2024. As we are currently focusing on robust launches for relugolix and vibegron and developing them into blockbusters to

succeed Latuda, a decision on exercising the option will be made a little later.

 Questioner 2:
Q: You said that orders for Orgovyx had been received from 10 of the 20 top priority accounts. What about progress with the remaining 10 accounts? Also, if coverage is going to be expanded from the second half of 2021, is it correct to think that sales will accelerate from the second half of 2021?
A: (Myrtle Potter) The 10 accounts we mentioned showed interest early on and we believe that the remaining accounts will follow suit. Coverage will be important for sales expansion.
(Adele Gulfo) Listing in Medicare Part D is very important for uptake. We plan to achieve wide coverage under both commercial and Medicare Part D by the end of 2021 and believe we will have broad Med Coverage from January 2022

Q: Is it correct that the plan for rodatristat ethyl is to complete the phase 2b study, carry out the phase 3 study and then submit for approval? Also, on ClinicalTrials.gov, the status of the ELEVATE1 (phase 2a study) study is “terminated.” Could you explain the reason for the termination and the background?
A: (Myrtle Potter) The phase 3 study will be carried out after the phase 2b study, which started this month.
(Sam Azoulay) The phase 2a study was terminated due to problems in the study design. The issues were combination therapy was not approved, the study was short, and there was no extension study. In the phase 2b study, improvements have been made to remedy these issues and ensure that enrollment went ahead. Also, the members of the team in charge of the clinical study have been changed to those with experience in PAH (pulmonary artery hypertension) and have a network with doctors who could be key investigators for the study. Since the phase 2b study is small in scale with 90 subjects, regulatory submitting will be after the phase 3 study.

Q: Regarding relugolix in the gynecology area, with previous products, companies have struggled to achieve the expected take up based on the anticipated market before launch. What do you see as the reason for this? And, what is different about relugolix that will make it a high seller?
A: (Myrtle Potter) The clinical study results for relugolix demonstrate the points of difference with other GnRH receptor antagonists.
(Adele Gulfo) In differentiating from previous drugs, the most important thing is efficacy. In the clinical study on uterine fibroids, the proportion of responders was close to 90%. Regarding safety, bone mineral density was maintained in a 52-week study, the incidence of hot flushes was similar to placebo and overall tolerability was favorable. Many women

complain of hot flushes with other therapies, and doctors see this as a huge challenge. In addition to compelling efficacy, maintenance of bone mineral density and low incidence of hot flushes, convenient, once daily oral dosing for both indications of uterine fibroids and endometriosis are differentiating factors. Another strength of relugolix-combination will be our patient support program at clinics. Commercial strategies for Orgovyx will be linked to those for the relugolix combination therapy.
(Myrtle Potter) The partnership with Pfizer will also be important. As Pfizer has great experience in the gynecology area, we are happy to have their collaboration.

 Questioner 3:
Q: The plan was to submit relugolix for approval for prostate cancer in Europe between January and March. Will you be able to meet this schedule?
A: (Sam Azoulay) We completed submitting on March 8.

Q: Regarding competition in prostate cancer medicines, in the U.S., there have been supply difficulties with Lupron and as a result, sales of Eligard have been increasing. Do you think the temporary drop in Lupron sales will be a plus for Orgovyx? Also, Lupron comes under part B and Orgovyx under part D. Will the difference in coverage affect marketing?
A: (Adele Gulfo) Supplies of Lupron were short in the second half of last year but that has been resolved. Regarding coverage, for the last 30 years injectables have been used for ADT under part B. The fact that Orgovyx is an oral agent coming under part D should be highly persuasive in marketing. Patients prefer oral medications and doctors want to use oral anticancer drugs.

Q: In addition to at Sumitovant, will DrugOME be incorporated in Sumitomo Dainippon Pharma’s R&D, to assess competitiveness and value in the process of carrying out development projects?
A: (Kimura) It has not been incorporated up to now. However, we consider DrugOME to be extremely effective and are examining how we can incorporate it in our R&D activities. We are equipped with some tools for searching for new targets and will use them to achieve efficiency and competitiveness in drug discovery.

 Questioner 4:
Q: Doctors have been making thousands of dollars from injections annually. What effect will the lack of this with Orgovyx have?
A: (Myrtle Potter) Myovant has been studying in-office dispensing agreements and considers that this will be not disadvantageous with respect to leuprolide.
(Adele Gulfo) It has been many years since the launch of leuprolide and the income per

injection for doctors has decreased over time. Also, as at least 50% of facilities practice in-office dispensing, Myovant's contracting agreements with these practices are designed so practices are not financially disincentivized by writing for Orgovyx.

Q: For relugolix, a phase 3 study on contraception has started. What impact will it have?
A: (Myrtle Potter) This is an important study for relugolix. If the results are positive, we believe that relugolix may be used in place of the barrier method.
(Adele Gulfo) In a phase 1 study that has already been carried out, relugolix combination therapy resulted in 100% ovulation inhibition, with 100% return to ovulation after discontinuation of treatment. Through the phase 3 study on contraception, we hope to verify that relugolix combination has a product profile that also allows it to be offered to women whose objective is contraception. Also, a market survey of patients and doctors revealed this to be a strong attribute and there is a desire for indication expansion, so we are hoping for positive results.

Q: It is a year since the regulatory filing for uterine fibroids in Europe in March 2020. When will approval be?
A: (Sam Azoulay) Examination by the EMA usually takes 12–15 months.

□ Questioner 5:
Q: Peak sales of relugolix are at least ¥100 billion. What proportion of sales will Orgovyx and the relugolix combination tablet account for at the time of peak sales? And, what about Gemtesa?

A: (Myrtle Potter) Relugolix is a drug that is either approved or filed for approval for prostate cancer and gynecological disorders, and there is the possibility for further indication expansion in gynecology. It is possible that it will be a blockbuster in prostate cancer and in gynecology. In a market that is greatly expanding, approval has been obtained with a label that clearly differentiates Gemtesa. Urovant will be selling together with specialists with excellent knowledge in this area.

Q: What about differentiation of Orgovyx and Gemtesa from previous products?
A: (Myrtle Potter) There are few incidences of Major Adverse Cardiovascular Events (MACE) with Orgovyx, so its safety profile is an advantage. An excellent feature of relugolix combination in gynecology diseases is that there are few hot flushes. For Gemtesa, we have obtained approval for a label that differentiates the product using the results of the phase 3 study.
(Adele Gulfo) For Orgovyx, we have received reports from doctors regarding patients' favorable evaluation of the lack of testosterone surge causing flare.

A factor in the differentiation of Gemtesa is efficacy with single dose and that the starting dose is the maintenance dose meaning no need for titration. The situation of many patients with previous drugs is that they have continued with a low dose without titrating to the more efficacious dose resulting in poor results. Another point of difference is that the symptoms of urge urinary incontinence and urgency frequency are listed in the label. In addition, with previous drugs, there are warnings about increases in blood pressure, which is a negative factor for both patients and doctors. There is no blood pressure warning for Gemtesa. Another important point is that there are no drug interactions relating to CYP2D6, which are common in combination use. We believe that these features and benefits will be convincing in differentiation.

Q: DrugOME seems to be a great system, but what you presented were just model applications. Are you thinking of disclosing actual examples and results externally; or will it only go as far as being an in-house technology?
A: (Baba) We are using DrugOME internally, but we feel it important to demonstrate its value to everyone.
(Bill McMahon) In an examination of the commercial positioning of DrugOME, we arrived at the conclusion that it was important for increasing our competitive advantage. In the future, it may be possible to sell DrugOME.
(Baba) While there will be competition and this will be a difficult point, we would like to show examples of the use of DrugOME and the results achieved.

 Questioner 6:
Q: For Orgovyx, you said that you were concluding agreements that avoid loss of income for doctors doing in-office dispensing. What is the content of such agreements?
A: (Myrtle Potter) In the U.S., doctors are supplied with drugs by distributors or pharmaceutical companies in their offices and bill for reimbursement based on the agreement. At the time of concluding agreements rates are set such that there is no disadvantage for the doctor.
(Adele Gulfo) First, there is a discount from the distributor for drugs purchased for in-office dispensing and the rebate increases in pace with the amount purchased. There is also a rebate at a discounted rate when billing for reimbursement, which is positive financially for doctors.

Q: What are the rates of discounts and rebates?
A: (Adele Gulfo) I can’t give specific figures, but they are significantly less than 30% or 50%.

Q: Are present patients targeted for Orgovyx switches from leuprolide or new patients?
A: (Myrtle Potter) New patients are an easy target, but there will also be some switches from injections. Doctors have an overall view of patients and are thinking of targeting several patient strata including those who are starting new treatment, those with a low frequency of visits, those who don't want to have injections, and those who have cardiovascular diseases.

 Questioner 7:
Q: What are the conditions for Gemtesa to become a blockbuster product with sales of at least ¥100 billion?
A: (Myrtle Potter) The market for Gemtesa is large, a lot of it is accounted for by branded products, and there will be competition in the same product class. We have validated the Gemtesa phase 3 data together with the FDA and urological associations and have obtained approval for a label that will enable differentiation from other β3 agonists. Sales reps will be able to use the differentiating features of Gemtesa in marketing. The single dose is also a feature.
(Adele Gulfo) With around 30 million patients with overactive bladder and 18 million prescriptions issued in 2020, the market in the U.S. is huge. While the market is not very large in terms of value because it is comprised of largely generics. Note that with many of the generics, there are concerns regarding potential dementia- and blood pressure- related adverse effects, while there are few adverse effects with Gemtesa. Gemtesa is the only drug with efficacy for urge urinary incontinence mentioned in the label, there is no warning about blood pressure, and there are no interactions with drugs metabolized by CYP2D6. In addition, due to the single dose, there will be no difference between the starting dose and the maintenance dose, which we consider will make marketing easy.

Q: With the strict subject enrollment criteria for rodatristat ethyl, subjects could not be recruited for the phase 2a study. How will it be for the phase 2b study?
A: (Sam Azoulay) As the period of the phase 2a study was short, there was little benefit for patients, and as we were in the COVID-19 pandemic at the start of the study, it was difficult to enroll patients. The period of the phase 2b study is six months, and as patients can enter the extension study providing treatment with the active drug, there will be the benefit of receiving treatment long term for patients, and they will be able to be enrolled with continuation of the previous treatment. In addition, a newly organized team that is building a powerful network will be in charge of the study, and they will be able to visit medical institutions to explain the study once COVID-19 abates. So, we think the phase 2b study will go according to plan.

 Questioner 8:

Q: What are the specific roles of each company in the alliance between Myovant and Pfizer for Orgovyx?

A: (Myrtle Potter) In the alliance for Orgovyx, both companies will formulate marketing strategies, Myovant will engage in activities related to lifecycle management and additional studies. Our expectations of Pfizer are not only in marketing but also regarding specialist knowledge accumulated in the prostate cancer market and expertise in direct-to-consumer activities.

(Adele Gulfo) We see Pfizer as a truly excellent partner not only with regard to sales and account management but also in various other aspects, including negotiations with payers.

Q: What are the specific roles of Urovant and Sunovion in the promotional alliance for Gemtesa?

A: (Myrtle Potter) Having experience in primary care, Sunovion will take charge of primary care-specific promotion for Gemtesa. Sunovion will also be responsible for contract management and other back office support tasks. We expect to see continuing synergies in the future.

 Questioner 9:

Q: In the presentation by Senior Executive Officer Kimura, what was meant by ‘We expect an impact on Sumitomo Dainippon Pharma’s culture?

A: (Kimura) The meaning of culture in this respect includes not only proceeding efficiently in R&D but also utilizing digital technologies and thinking rationally about daily tasks. However, we also expect the Sumitovant technologies presented today to speed up patient recruitment and allow clinical studies to proceed efficiently.

(Baba) The idea is that digitalization will make current operations more efficient, and we aim to use it to raise productivity to a high level. For this purpose, behavioral change will be necessary, and we want to pursue thorough reduction in waste and greater efficiency in various aspects of work procedures. For instance, just eliminating the 10 to 20 minutes taken to search for information companywide will improve efficiency. Utilizing Sumitovant’s advanced knowledge and digital tools in a culture with a changed mindset, we aim to work together as a united company.

(Dan Rothman): By ensuring transparency through the use of technology and using data in decision making, we will be able to act more efficiently and gain the time to think about new things. A change in behavior and culture will not just be achieved through promoting technology, education on how to utilize the data, tools, and information will also be needed.

□ Questioner 10:

Q: You said that Sumitovant products will provide for R&D expenditure for the next 10 years. Could you give a breakdown?

A: (Nomura) At present we have great expectations for the sales of two products, relugolix and vibegron.

Q: How will the use of digital technology be helpful in aspiring to be a Global Specialized Player in 2033?

A: (Baba) We are thinking of efficiently disseminating the expertise of the U.S. Sumitovant team to Japan and other areas and have established the Global Data Design Office as a global unit for this purpose. Though it is difficult to shorten the current drug development process, we will pursue efficiencies in various aspects including shortening the period of clinical studies and raising the probability of success in drug discovery, and use digital technology to expedite the achievement of results and profit increases needed up to 2033.

(Tsuchiya) We have made efforts toward digitalization in R&D and are making efforts to accelerate this using Sumitovant's expertise. This will not only involve utilizing AI, we also hope to disseminate this expertise from the viewpoints of design thinking and agility in the use to data. In the future, we hope to produce specific results not only through greater efficiency in operations but also through working on drug discovery that creates innovative pharmaceuticals as well as behavior changes.

Q: What kind of behavioral changes will there be in drug development?

A: (Kimura) Through the analysis of various data using digital technologies and by changing our previous way of thinking, Sumitomo Dainippon Pharma is aiming to create our new business structure. As there is plenty of room for improvement in the current situation where the probability of success in drug discovery is low, and spending 20% of sales on drug research and development costs may not create products, we want to achieve a major transformation in our way of thinking from the basics.

[Nomura's comments]

Sumitovant and Sumitomo Dainippon Pharma are sharing strategies for the differentiation from other drugs and marketing of relugolix and vibegron. This year, we will consider how to respond to the reaction of the market to our activities as a process for raising the potential of these products. Sumitovant's R&D is going ahead based on the results of discussions on governance relating to Sumitomo Dainippon Pharma Group R&D. Four key persons—Dan,

Bill, Baba and Tsuchiya—are examining how the DrugOME and Digital Innovation technologies will be used. Given that our top line is about ¥500 billion and that we use about ¥100 billion for R&D expenditure, we want to use DrugOME and Digital Innovation to enhance commercial aspects to improve the top line and reduce R&D expenses through greater efficiency in R&D and by doing this produce specific value.