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MYOV.N - Myovant Sciences Ltd and Pfizer Inc Collaboration To Develop and Commercialize Relugolix in Oncology and Women's Health Call

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by. And welcome to the Myovant Sciences conference call. Today's call is being recorded.

I would now like introduce your host for today's conference call, Mr. Ryan Crowe, Investor Relations at Myovant. You may begin.

Ryan Crowe - *Myovant Sciences Ltd. - VP of IR*

Thank you, Kevin. Good morning, and welcome to Myovant Sciences conference call to discuss the relugolix collaboration in oncology and women's health between Myovant and Pfizer. Our press release for today's announcement as well as the slides we will present are available on our Investor Relations website, investors.myovant.com.

Joining me for today's call are Dr. Lynn Seely, Myovant's Chief Executive Officer; Frank Karbe, President and Chief Financial Officer; and Adele Gulfo, Interim Chief Commercial Officer; and Dr. Juan Camilo Arjona, Chief Medical Officer.

During this conference call, we'll be making forward-looking statements. These include plans and expectations with respect to our collaboration agreement, product, product candidates, strategies, opportunities and financials, all of which involve certain assumptions of risks and uncertainties that are beyond our control and could cause actual results to differ materially from these statements. A discussion of these risks can be found in our latest SEC disclosure documents. In addition, Myovant does not undertake an obligation to update any forward-looking statements made during this call.

With that, I'll turn the call over to Dr. Lynn Seely, Myovant's Chief Executive Officer. Lynn?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Thank you, Ryan, and good morning, everyone. Today is truly a landmark day for Myovant Sciences as we announced a transformative collaboration with Pfizer for our relugolix franchise. Both Myovant and Pfizer believe ORGOVYX and relugolix combination tablet represent potential breakthrough medicine that can become the new standard of care in advanced prostate cancer as well as in uterine fibroids and endometriosis.

In Pfizer, we have found the ideal partner that will enable us to fully unlock the tremendous potential of relugolix, achieving more together than Myovant could alone. Pfizer's commercial and market access capabilities significantly strengthen our upcoming launches. With additional life cycle opportunities for relugolix and greatly increased financial resources, this collaboration will further enable Myovant to redefine care for women and for men.

Myovant and Pfizer have entered a broad collaboration to jointly develop and commercialize ORGOVYX and relugolix combination tablet in the United States and Canada. The companies will evenly share profits and certain expenses associated with relugolix development and commercialization with Myovant recording revenues. My event will remain responsible for regulatory interactions and drug supply and will continue to lead clinical development in the women's health indication, while development and oncology will be shared.

In exchange for these co-development and co-commercialization rights, Pfizer will pay Myovant up to $4.2 billion, including a $650 million upfront payment, $200 million of potential regulatory milestones as well as sales milestones. Additionally, Pfizer has an exclusive option to commercialize relugolix in oncology outside the United States and Canada, excluding certain Asian countries.

This collaboration dramatically enhances our ability to reach as many physicians and patients as possible. It also puts us in a very strong financial position and provides us with additional resources to further expand our pipeline. The commercial opportunity for relugolix is significant. And with Pfizer as a partner, we are better positioned to successfully execute the upcoming launches. Pfizer has strong relationships with health care providers in both prostate cancer and women's health as well as a proven track record of building blockbuster brands and creating leadership positions in competitive markets. Together, Myovant and Pfizer have the potential to significantly improve the launch trajectory and maximize the peak revenue potential for the relugolix franchise.

Pfizer is an established leader in prostate cancer, co-marketing the blockbuster drug, Xtandi, with Astellas Pharma in the U.S. despite the COVID pandemic, Pfizer alliance revenues of for Xtandi grew 25% in the U.S. in the first 9 months of this year. ORGOVYX is the first and only oral androgen deprivation therapy, or ADT. Importantly, Xtandi is an oral therapy like ORGOVYX and is used in combination with ADT. So we see great synergy in having the Pfizer sales force promote both products.

This collaboration will more than double the number of high-quality sales representatives detailing ORGOVYX from 100 to over 200. The combined field teams will initially target the 10,000 physicians who write the vast majority of ADT prescriptions and have the ability to quickly activate community urologists, oncologists and key opinion leaders to boost awareness of the differentiating features of ORGOVYX.

Pfizer also has a rich heritage in women's health and deep relationships with OB/GYNs formed by their sales force over many decades, and Pfizer is a well-known leader in direct-to-consumer promotion with tremendous media-buying power as well as deep expertise in data analytics and insights. These capabilities are a powerful combination that will help Myovant position relugolix combination tablet, if approved, as the best-in-class treatment for uterine fibroids and endometriosis.

As we discussed during our approval conference call, our launch priorities are focused on positioning ORGOVYX as the new standard of care in advanced prostate cancer. Myovant and Pfizer are fully aligned on these priorities as well as the overall approach to the upcoming launch. First, the Myovant and Pfizer sales teams will focus on educating urologists and oncologists on key ORGOVYX product attributes using materials developed by Myovant. The Myovant team will start detailing physicians in early January, and the Pfizer sales professionals will join us in the field as soon as they are fully trained, which is expected by February.

Second, Myovant and Pfizer will establish broad access to ORGOVYX by working with payers, supporting our specialty pharmacy distribution model and facilitating patient access through the ORGOVYX support program. Myovant and Pfizer national account managers will work together collaboratively to engage with payers.

Finally, once physician education and access milestones are met, we intend to activate patients and their care partners around the efficacy and safety of ORGOVYX while highlighting the convenience of its 1 pill, once-a-day dosing.

Now I'll turn it over to Frank to review the financial terms of the collaboration. Frank?

Frank L. Karbe - *Myovant Sciences Ltd. - Principal Financial & Accounting Officer*

Thank you, Lynn. The collaboration with Pfizer is truly transformational for Myovant, as it puts us in a very strong financial position with significantly more resources to advance our business, including expansion of our pipeline. The financial benefits of this collaboration include substantial payments from Pfizer, sharing of expenses and operational synergies. Myovant is eligible to receive up to $4.2 billion of payments from Pfizer, including an upfront payment of $650 million, $200 million of regulatory milestones split evenly upon the FDA approvals of relugolix combination tablet for uterine fibroids and for endometriosis as well as tiered milestones based on annual net sales for relugolix in oncology and the women's health indications.

Myovant will record revenues in the U.S. and Canada, and both companies will equally share profits and certain expenses associated with the development and commercialization of the relugolix franchise. Pfizer also has an exclusive option to commercialize relugolix in oncology outside the U.S. and Canada, excluding certain Asian territories. If the option is exercised, Pfizer will pay Myovant an additional $50 million and Myovant would receive double-digit royalty on net sales in these territories. The transaction immediately strengthens Myovant's financial position and has the potential to substantially enhance our near-, medium- and long-term cash flows. Collectively, the upfront payment of $650 million combined with cash on hand and the remaining committed financing from our majority shareholder, Sumitomo Dainippon Pharma, total approximately $900 million. In addition, Myovant benefits from expense sharing with Pfizer that will meaningfully reduce our cash burn for relugolix-associated expenses.

This transaction allows us to maximize the relugolix franchise and to accelerate the expansion of our pipeline through business development. While our near-term priorities remain launch execution and successful commercialization, we intend to leverage our proven development engine by pursuing life cycle opportunities for relugolix with Pfizer, continuing development of MVT-602, our novel oligopeptide kisspeptin-1 receptor agonist, and advancing new potential drug candidates.

In summary, our collaboration with Pfizer provides strong validation that ORGOVYX and relugolix combination tablet have the potential to be breakthrough medicines, bringing great value to patients and the broader health care system. The partnership will enable us to bring relugolix to more patients faster by significantly expanding our commercial and market access capabilities. It also fortifies our financial position and provides us with the resources to further invest in Myovant's pipeline, enabling us to continue to deliver on our commitment to redefine Care for women and for men.

Thank you for your attention. I will now turn it over to Ryan to begin the Q&A session.

Ryan Crowe - *Myovant Sciences Ltd. - VP of IR*

Thank you, Frank. Operator, can we now please poll for questions?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Jason Butler with JMP Securities.

Unidentified Analyst

Frank for Jason. I guess the first one, maybe Frank mentioned it, I missed it, but how does this change is for how you're going to use the funds available from Sumitomo? And does it change the Sunovion commercial infrastructure deal?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Thanks for the question, Frank.

Frank L. Karbe - *Myovant Sciences Ltd. - Principal Financial & Accounting Officer*

Yes, so 2 questions here. Let me take the first one first. We have remaining financing commitments available to us under the existing financing facility from Sumitomo Dainippon Pharma, and those amounts remain available to us. And whether or not we use them is at our discretion, and we'll see where we land there. But clearly, of course, our financial situation has been greatly enhanced, most notably through the $650 million upfront payment.

The second question was about how this impacts our relationship with Sunovion. And given the proximity of our launches, the relationship with Sunovion here is not impacted.

Unidentified Analyst

Okay. Great. And then a couple of extra ones. Do you have -- can you remind us if Takeda retains China or if you guys have disclosed that? And how you're going to recognize the $650 million upfront?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Frank?

Frank L. Karbe - *Myovant Sciences Ltd. - Principal Financial & Accounting Officer*

Yes. So I'll start with the second question first. So the $650 million upfront payment, I would say, in general, that the accounting treatment for the financial implication of these transactions are still being finalized. But we expect that the $650 million upfront payment is going to be recognized over the lifetime of the collaboration. With regards to China, this is part of the Takeda Asian territories.

Operator

The next question comes from Eric Joseph of JPMorgan.

Eric William Joseph - *JPMorgan Chase & Co, Research Division - VP & Senior Analyst*

Congrats on the deal. Lynn, you talked about -- given Pfizer's presence in the space with Xtandi, this partnership certainly broadens reach with ORGOVYX. I'm just wondering if you could elaborate a little bit more on the operational synergies or benefits to commercial margins for the product that you see with this -- in pairing up with Pfizer versus if Myovant were to launch the product on its own, and then I have a follow-up.

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Sure. Thanks, Eric. No, we're tremendously pleased with this collaboration and believe that the combination of the Myovant and Pfizer sales teams launching ORGOVYX is enormously valuable because this is a synergistic sale. I think when you think about Xtandi and its position as really a blockbuster prostate cancer drug, it is used in combination with ADT. And with ORGOVYX as the first and only oral androgen deprivation therapy, there's natural synergy there. So our team will be out fully focused on ORGOVYX, and then the Pfizer team will also be out. So we believe that's a tremendous and very powerful combination, which will allow us not only to build momentum in the launch with an accelerated trajectory but also achieve higher peak revenues.

Eric William Joseph - *JPMorgan Chase & Co, Research Division - VP & Senior Analyst*

Got it. And is there more that you can describe with potential life cycle management opportunities that you and Pfizer are considering? And how are they -- how are the funding of those efforts considered in this deal?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Sure. So that is something that is enormously exciting for us. With this collaboration, it gives us an opportunity to really take full advantage of the potential of the relugolix franchise. And we believe that there are significant life cycle management opportunities, both in prostate cancer, potentially more broadly in oncology as well as in women's health. So there are a number of opportunities under consideration, and we'll look forward to bringing you more information about that in the future. In terms of how these are going to be managed in terms of expenses, they'll be shared.

Operator

The next question comes from Paul Choi with Goldman Sachs.

Kyuwon Choi - *Goldman Sachs Group, Inc., Research Division - Equity Analyst*

Let me also offer my congratulations on the deal. I have 2 questions. First, with your new partner, can you maybe speak to -- do you have an updated view as to the potential pace of payer coverage, both on the private and public side versus your comments that you said on the approval call? And second, in terms of strategy, you will obviously have a fair amount of cash here available now post the deal. I was just curious, what is your -- any updated thoughts on business development or looking for potentially additional assets to develop or bring into the pipeline?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Sure. So Adele, why don't I let you take the question on market access?

Adele M. Gulfo - *Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director*

Sure. Yes, thanks for the question. You asked if we have any updated comments relative to market access reimbursement. I would say, just overall, generally speaking, the fact that we're going to have greater reach and frequency, so more physicians are going to be learning about ORGOVYX faster. This is going to create huge demand. So as that impacts how the payers think about reimbursement, all I could say is our plans remain the same in terms of when coverage will come online, the key commercial plans, will probably make their coverage decisions beginning in the first quarter of 2021. This could only help expedite their thinking and their actual committing to bringing those plans online. It is just how the payers think about it, and it will also help us as we think about on the Medicare side, the opportunity for medical exceptions by having more patients write this drug -- more physicians write the drug as more patients get on it, demand increases. That all has a very powerful effect. So I'm not changing what we had said initially. All I'm saying is it could actually enhance those quarter -- the timing within those quarters.

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Thanks, Adele. And I think with respect to business development opportunities, I mean, obviously, with this upfront payment, the potential regulatory milestones and other sales milestones that really provides us with an opportunity to not only support the launches, to invest in new life cycle management opportunities, which we discussed, but also to move forward MVT-602, which is another novel kisspeptin-1 receptor agonist in our pipeline that has been in Phase II for infertility, and then finally, to look outside and to bring in new opportunities. And I think you'll see us focusing, obviously, in the areas where we already are. We're committed to women's health, as you know, as well as to prostate cancer and oncology. And these are places where you will see us potentially looking for business development opportunities.

Operator

Our next question comes from Brian Skorney with Baird.

Brian Peter Skorney - *Robert W. Baird & Co. Incorporated, Research Division - Senior Research Analyst*

Congrats on a really great deal. Just one for me, really kind of looking for more insight in terms of maybe your thoughts, Lynn and Frank, on the business development opportunities that are before you now with the sort of ability to accelerate them. Obviously, you're in women's health, as you said, in cancer, as you said, gives you kind of like a kind of unique 2-sided focus. I was just wondering, when you kind of think across the development stage landscape, I mean, where do you kind of think your core competencies are? Is it sort of late-stage clinical? Is that sort of the area that we should be thinking about in those 2 fields that you would do BD? Or would you consider something much earlier stage or even commercial?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

I'm very proud to say, Brian, that we have built a very strong development engine, which is fully capable across the phases of development from very early phase. And obviously, I think we've proven our capability in late phase. And so we are going to be opportunistic and look for the best fits for Myovant. But I think you can see us looking across the spectrum.

Operator

Our next question comes from Phil Nadeau with Cowen and Company.

Philip M. Nadeau - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

Let me add my congratulations on the deal. First, just a couple of clarifying questions. I'm sorry if you mentioned this and I missed it. But in terms of Pfizer's rights to opt into prostate cancer ex U.S., what -- by when do they need to opt in? Are there certain milestones, after which they have a time-limited chance to strike a deal?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Yes. So we are scheduled to file the marketing authorization application for prostate cancer ex U.S. and Europe in the first half of this coming year. And once that's filed, they'll have the option, the exclusive option to opt in.

Philip M. Nadeau - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

And what about women's health? Is that being contemplated outside the U.S. at all? Or is Pfizer strictly interested in the U.S.?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

So women's health is partnered ex U.S. already with our partner, Gedeon Richter, for those territories not included in the original Takeda Asian territory. So we have Takeda in women's health for the Asian territories and then Gedeon Richter for other territories outside the U.S.

Philip M. Nadeau - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

All right. That's right. And then final question is, this is a substantial deal. At any point did you consider a merger with Pfizer and right job for this structure rather than a takeout?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Sure. So obviously, the details of the negotiations are confidential, but we are very pleased with the collaboration. It is something that we believe now we can bring together the strengths of the 2 companies to really optimize the value of the relugolix franchise. So we are absolutely thrilled with where we ended up with the collaboration.

Operator

Our last question comes from Ami Fadia with SVBL.

Ami Fadia - *SVB Leerink LLC, Research Division - MD of Biopharma & Generics and Senior Analyst*

Congratulations on the deal. A quick question from me on what do you intend to use the proceeds from this transaction to do going forward?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Thanks, Ami. So I think really, there are several things we're going to use the funds for. The first, of course, will be to support the launches. The second will be life cycle management support for the relugolix franchise, both prostate cancer and women's health. Thirdly, moving forward, MVT-602, which is in development, as you know. And then finally, for other business development opportunities to -- for the long-term growth of the company and building out our pipeline. So those are really the key areas.

Ami Fadia - *SVB Leerink LLC, Research Division - MD of Biopharma & Generics and Senior Analyst*

I was not clear whether you were going to participate in commercializing either of the prostate cancer or women's health indications in the U.S. at this point. Are you?

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Absolutely. So this is a co-promotion agreement in the U.S. So we will be -- we have hired and trained 100 sales professionals who will be launching ORGOVYX in early January, and then they will be joined by the Pfizer sales professionals once they're trained. And certainly the same in women's health that we will be building a sales force for women's health and will be joining the Pfizer OB/GYN sales professionals.

Operator

And I'm not showing any further question at this time. I'd like to turn the call back over to our host.

Lynn Seely - *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Thank you. Well, December has been a remarkable month for Myovant. Alongside the prostate cancer community, we celebrated the recent FDA approval of ORGOVYX in advanced prostate cancer, and now we have announced a landmark collaboration with Pfizer that will ensure the incredible

work of the Myovant team resulting even more potential benefits for women and for men. We look forward to advancing our relugolix collaboration with Pfizer starting with the ORGOVYX launch early next year. Happy New Year, and thank you for joining us today.

Operator

Ladies and gentlemen, this does conclude today's presentation. We thank you for your participation. You may now disconnect, and have a wonderful day.