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CEO & Director

Juan Camilo Arjona Ferreira
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ANALYSTS

Philip M. Nadeau
Cowen and Company, LLC,
Research Division

Presentation

Philip M. Nadeau
Cowen and Company, LLC, Research Division

Good morning, and welcome once again to Cowen's 42nd Annual Healthcare Conference. I'm Phil Nadeau, a biotech analyst here at Cowen, and it's my pleasure to moderate a fireside chat with Myovant Sciences. We have with us today a few executives from Myovant. We have Dave Marek, the CEO; Uneek Mehra, the CFO, and Juan Camilo Ferreira, the CMO; and Lauren Merendino, Chief Commercial Officer. Thanks for joining us today. We know you're all busy. These are very exciting times for my event in the midst of several launches.

Question and Answer

Philip M. Nadeau
Cowen and Company, LLC, Research Division

So Dave, maybe I'll turn it to you. Can you give a brief state of the company overview? Biggest strengths, biggest challenges? What needs to happen to drive outperformance in the next 12 to 24 months?

David C. Marek
CEO & Director

Well, thanks for having us, Bill. Look, Myovant continues its mission of redefining care for women and for men. And I think -- and when I go back to our first strength, it's really about our people. We have a highly experienced and accomplished leadership team and staff. And by the way, given today's International Women's Day, I'm proud to say that 60% of our team members are women, and they're a critical part of our 550 employees, all of whom are tremendously talented and dedicated to making a real difference through our science, through our differentiated medicines and importantly, through our education and advocacy efforts to close gaps and help equity.

When I think of one of our core strengths, of course, it's our brands. We launched 2 brands last year, ORGOVYX for men with advanced prostate cancer, and MYFEMBREE for women with uterine fibroids, and both with very strong differentiated clinical profiles in large markets with significant unmet needs.

Another key strength is our partnerships to maximize the commercial value of our brands. So that includes Pfizer, of course, in the U.S. for both ORGOVYX and MYFEMBREE, co-commercialization and codeveloping both of those brands with us. And we have Gedeon Richter for our international markets who's commercializing RYEQO for women's health. And these launches are off to a great start in 2021. And now we're looking for real growth as we enter 2022. So our primary focus right now, Phil, is really commercial execution.

We are aiming to broaden health care provider awareness, first, through our differentiated clinical profile, but also through the excellent payer coverage that we've already established. And we're also going to build engagement directly with patients throughout the year. So in addition to our commercial execution, we're already advancing what's next for Myovant.

So in the coming months, we expect to receive regulatory decisions for MYFEMBREE in endometriosis in the U.S. and ORGOVYX in the EU, where we believe that these potential approvals represent real significant opportunities to reach even more patients, and further unlock the commercial potential for each brand. So we intend to leverage our other key strength, which is our highly productive development expertise to really expand our pipeline as we look to further develop relugolix and MVT-602 as well as look for targeted investments and business development opportunities in the areas of women's health and on oncology. And we'll expect to detail out some of those plans later this year.

And then finally, we have a very strong balance sheet, and that provides us the flexibility to execute on our commercial plan while fully funding our pipeline aspiration. So we've got a lot going on, Phil. It's going to be a great year, and we're excited about it.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

That's great. Let's dive right into that commercial execution, starting with ORGOVYX in prostate cancer. Can you provide a brief update on the ORGOVYX launch? Specifically, you're satisfied with the pace of uptake, the level of reimbursement and the type of patients you're getting out there.

David C. Marek
CEO & Director

Yes. We're very excited about the launch momentum. Lauren, maybe you could detail out some of those topics for Phil.

Lauren Merendino
Chief Commercial Officer

Yes. Thanks for the question, Phil. First of all, we're very pleased with the uptake of ORGOVYX in over 11,000 patients treated in our first year. And in terms of access, of course, our coverage is excellent. So we have established 81% of commercial lives covered, and 99% of Part D lives covered as of January. And even more importantly, the quality of that coverage is really -- very good. The prior authorizations are not very onerous and there are no step edits required for the vast majority of covered patients.

So now that we have care coverage established and a strong base of prescribers. We really do believe that 2022 will be a year of growth for ORGOVYX with many more men benefiting from this important therapy. And since you asked about the patient mix, I'll just share a little bit there. We've seen ORGOVYX really being used across the spectrum of advanced prostate cancer patients. Based on our latest claims analysis, we see that ORGOVYX use closely resembled that of LUPRON with about 50% of patients having clinically localized disease and about 35% of patients with metastatic disease.

Additionally, over 60% of ORGOVYX patients treated to date were previously naive to ADT. So we're capturing patients early on who may likely stay on ORGOVYX for a significant portion of their treatment journey. From a physician mix perspective, we see about 60% of our ORGOVYX volume coming from urologists, and the remaining 40% coming from oncologists. And this mix is consistent with how we see advanced prostate cancer patients being treated with urology practices, seeing a higher volume of advanced prostate cancer patients and managing those patients for longer.

And then by the time a patient gets to an oncologist, they often are already on an ADT, and oncologists are focused more on the additional treatments as opposed to adjusting ADT therapy. So they often stay on the ADT therapy that they arrived at the practice on. So that gives you a little bit of a sense of our patient and physician mix. Hopefully, you found that helpful.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

That is very helpful. Maybe referencing some of the competitors that you just noted, how do you go about differentiating ORGOVYX from some of the entrenched standard of care agents?

David C. Marek
CEO & Director

Yes. Lauren?

Lauren Merendino
Chief Commercial Officer

Yes. So ORGOVYX is meaningfully differentiated from all of the current ADT therapies. First of all, ORGOVYX offers rapid and profound testosterone suppression, which is exactly what you're looking for from an ADT treatment. There's no hormonal surge that's seen with some of the other therapies. And if a patient discontinues therapy, they have a rapid testosterone recovery, which is really important to patients. Additionally, we're the only oral ADT. And so with 1 pill once a day, physicians are able to manage a patient's testosterone. And this is really important, especially to patients where 2 out of 3 patients have expressed a strong preference for oral therapies versus an injection. However, as you may be aware, there is an entrenched usage of LUPRON in this marketplace, leuprolide overall. And so our success is really about breaking the leuprolide habit. That's really the key to our launch.

So aside from clinical differentiation, it's important that we implemented contracts to offset the economic incentives that were in place to use leuprolide and to level that playing field. And so now that we've established a great payer coverage and built a strong base of prescribers, our next step really is to activate patients because we believe that many patients are not aware that an oral therapy and oral options for their ADT treatment. And so that's one of the things we look forward to dialing up in 2022.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

How is the cardiovascular data been perceived by the field? Is that a major factor in the decision to prescribe?

Lauren Merendino
Chief Commercial Officer

Yes. So this is an important topic of growing interest because about 1/3 of patients with advanced prostate cancer have cardiovascular comorbidities, and cardiovascular events are the leading cause of death for patients with prostate cancer. So there's an increasing interest to understand how to better manage cardiovascular risk in these patients.

The ORGOVYX cardiovascular data that you referenced from our HERO study is certainly a consideration and something that physicians have shown interest in. But based on our customer feedback and market research, the primary driver for ORGOVYX being selected is really the level of control of testosterone that it provides. So we believe the data generated in the HERO study is compelling, and has raised awareness among urologists and oncologists about cardiovascular risk in men with advanced prostate cancer. However, further data is needed in order to draw more definitive conclusions regarding the cardiovascular event rates in then receiving ORGOVYX versus other ADT.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

That's perfect. Turning to Europe, ORGOVYX recently received a positive CHMP opinion. Can you give an update on your current search for a commercialization partner in Europe? What criteria are you looking for and do you continue to be confident that you'll sign one before the EMA approval?

David C. Marek
CEO & Director

Uneek, why don't you take that one?

Uneek Mehra
Chief Financial & Business Officer

Yes. Absolutely. Thanks, Phil. First of all, we are really excited with the positive CHMP approval that we recently got. We have a formal process underway to evaluate potential partners for international rights to relugolix in oncology. We're seeking a partner, Phil, with an established commercial infrastructure in Europe, preferably with urology or oncology presence. As you know, Europe is, from a market and a patient perspective, very similar to U.S. in terms of patient numbers, although the pricing levels are much lower.

So we believe it's still a very attractive opportunity for the right partner with commercial capabilities in Europe. We are in discussion with multiple interested parties in the process currently, and we remain on track towards our goal of reaching an agreement with a partner by the anticipated European Commission approval in first half 2022.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

One more question on ORGOVYX before we move to MYFEMBREE, and this is about revenue. So current consensus calls for ORGOVYX revenue of $51 million in 2022 and $317 million in 2024. How do you feel about those estimates? Do they seem reasonable? And any sense when you could begin to provide ORGOVYX revenue guidance?

David C. Marek
CEO & Director

Uneek?

Uneek Mehra
Chief Financial & Business Officer

Yes. Thanks. So given the relatively early stages for [lodge], we've not provided revenue guidance for our ORGOVYX. It will not be hence, appropriate for me to comment on our expectations for revenues relative to consensus. What I will say, though, is that we continue to believe we can steadily go ORGOVYX' revenues, and establish it as a potential ADT standard of care over time.

When you step back and look at the overall size of this opportunity, 300,000 men on ADT in the U.S., 100,000 men to therapy every year. Even a modest share of this market sell would allow ORGOVYX to be a significant revenue contributor to our P&L.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

That's perfect. Moving to uterine fibroids. A similar question as we started the prostate cancer section with. Can you give us an update on the launch of MYFEMBREE uterine fibroids, and are you satisfied with the pace of uptake, level of reimbursement and type of patients you're getting on therapy.

David C. Marek
CEO & Director

Yes. We're very pleased with the uptake of MYFEMBREE, and the progress that we've made to date. As of December, which was only 6 months into our launch, we've already captured 45% of the new-to-brand prescription share among the GnRH antagonist that are approved for uterine fibroids. And we're continuing to see really sustained momentum into this year. So we're very happy with the progress we've made there. And this suggests that when physicians are given treatment options -- gynecologists are choosing MYFEMBREE as the awareness continues to grow. So we're very pleased with that momentum.

And regarding reimbursement, we've already established coverage for 83% of commercial lives as of January. And again, that's only 6 months into launch. So we're still in the early days, Phil, but we're off to what we think is a really good start, not only in terms of capturing share, but helping to expand the marketplace.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

Actually, on those 2 points, can you discuss your strategies for growing the market for GnRH [indiscernible], and how will you take or maintain share from the other GnRH inhibitors that are either on the market now or are likely to come?

David C. Marek
CEO & Director

Yes. Lauren, do you want to take that?

Lauren Merendino
Chief Commercial Officer

Sure. So first of all, just to take a moment to speak about uterine fibroids. So there are over 5 million women with symptomatic fibroid who seek treatment, and 3 million who are failed by their first line therapy. So this speaks to the ineffectiveness of the existing treatments. Additionally, about 250,000 hysterectomies are performed each year for women with uterine fibroids. And many of them felt that there was no other option to relieve them from their symptoms. So there's a huge unmet need here and an opportunity to really shift the paradigm so that women have better treatment for this condition.

So as we start thinking about how we expand the GnRH class is really a three-pronged strategy. So first of all, we need to show how MYFEMBREE better meets physician and patient needs. And it's been clear from the beginning that physicians want to stop the symptoms, minimize the side effects, and make it easy for their patients. And we believe that MYFEMBREE has the right clinical profile in order to do that.

Secondly, we needed to establish robust payer coverage. As you heard from Dave, we now have 83% of commercial coverage established within our first 6 months, and that was an important factor because GYNs are particularly sensitive to payer coverage. And then we'll want to activate patients as we move forward this year. Many women don't know that they have options. And now that we have a growing base of prescribers and strong coverage, we want to begin or increase our engagement with patients in order to educate them on their options so that they can have discussions with their physician. And so far, we've seen this strategy paying off. So we've seen a significant increase in awareness of the GnRH antagonist class in uterine fibroids.

We've seen an expansion of use of the class. So when we look at the 4-week moving average of total GnRH antagonist prescriptions for uterine fibroids, it increased 81% from our launch in June through the end of December. And then we've also seen an expansion in prescribers. So nearly 60% of our MYFEMBREE prescribers are first-time riders of the GnRH antagonist class. So this is the #1 factor in our success is really expanding the class.

And then when you ask about within the class, why choose MYFEMBREE? We believe the choice is clear. The clinical profile is really what makes MYFEMBREE the clear choice. We have efficacy in reducing the most challenging symptom, which is heavy menstrual bleeding, tolerability, particularly as it relates to hot flush, which is an important factor for many patients and physicians, and then the simplicity and convenience of 1 pill once a day.

So we are strong believers in the progress that we've made to date with the new-to-brand share that Dave mentioned of 45% in our first 6 months. And we're still early in our launch, but we're excited about the trajectory and the leading indicators that we're seeing, and we believe that MYFEMBREE has the potential to be a new standard of care in uterine fibroids.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

Maybe a couple of more questions on potential points of differentiation. First, on duration of therapy. How long do you expect women to stay on therapy? Have you submitted the 2-year data from the Phase III referral study? And could that result in a differentiated label with the removal of the limitation and duration of use from the MYFEMBREE label?

David C. Marek
CEO & Director

Juan Camilo, do you want to take that one?

Juan Camilo Arjona Ferreira
Chief Medical Officer

Yes. Absolutely. So Phil, as you know, uterine fibroids is a chronic condition. So we expect women to stay for a relatively longer time than other therapies, on treatment. With regards to our randomized withdrawal study, we should be submitting, as we've said before, that supplemental application in the next few weeks, and we're on track for that.

However, I would not want to speculate how FDA is going to interpret the data. We usually have engaged in a thorough conversation with the agency with regard to our data, and how it may or may not be reflected in the label, and we'll get to that when we get there and give you more details.

Maybe 1 more thing that I wanted to add based on what Lauren said, although the thing that's very important that has changed since over the last 6 to 8 months is that the ACOG guidelines were issued were updated. And there are 2 things that are very important that happened there. One is highlighting the importance of GnRH antagonist as a new option that should be made available to patients. And second, making clear that the importance of shared decision-making between physicians and patients, and ensuring that the voice of the patient and her preference for therapies or treatments that fit her life better should be taken to serious consideration. So I think that works very well for where we are today and at the time where we are with MYFEMBREE.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

Perfect. A second potential point of differentiation is on contraceptive use. Myovant's conduct a Phase III study to effect -- to assess MYFEMBREE's efficacy as a contraceptive. What are women doing today who are -- who you're having to approach birth control? And how could contraceptive labeling speed MYFEMBREE's uptake?

David C. Marek
CEO & Director

Yes. Juan Camilo?

Juan Camilo Arjona Ferreira
Chief Medical Officer

Yes. I think that's a super important point, Phil. Today, as you know, based on the label for the GnRH antagonists that are approved for uterine fibroids but the use of nonhormonal methods of contraception as required. And then there's the -- the use of hormonal methods is -- should not be -- like hormone methods should not be used because of the already hormones contained in the products. We believe that demonstrating prevential pregnancy with MYFEMBREE would be a pretty significant differentiator. Because women -- we're talking about premenopausal women that not only are seeking treatment for their bleed-heavy menstrual bleeding or other symptoms of uterine fibroids, but they also have to think of how they want to manage their fertility in providing a solution that takes care of that in a predictable way, as in [Australia], hopefully by this study, would put us really apart from everybody else in the class.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

Moving to MYFEMBREE endometriosis. How confident are you in the sNDA being approved around its May 6 PDUFA? And how do you think its approval in endometriosis could affect the launch in U.S.?

David C. Marek
CEO & Director

Yes. Well, we believe we are on track for the May 6 PDUFA date. I won't comment further on kind of the review itself. But we're very proud of the SPIRIT data, which demonstrated MYFEMBREE's efficacy and safety in the treatment of endometriosis-associated pain. So very proud of that data. And as we look at commercialization, should we get approved, there's a high overlap of the prescribers between endometriosis and uterine fibroids. Those are the same physicians that value the same things across both disease state.

So they're looking for efficacy. They're looking for safety. And importantly, with gynecologists are looking for simplicity. And I think across those, that's where we think MYFEMBREE can really deliver. We have experience across 2 potential indications that we think will build greater comfort and confidence across the prescriber base.

And I think one thing that's very important for MYFEMBREE, should we get that approval is with both indications, we would have 1 single brand, 1 dose, 1 pill once a day. And again, for gynecologists who really prefer options that are straightforward and simple. That's going to be a key differentiator for us in the marketplace across both of those therapeutic areas.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

I'm sure you've done a full post mortem on [Arles'] launch in endometriosis. Are there other barriers to uptake other than the complexity of the regimen that you find that you might be able to address through your own marketing efforts? So basically, what is your strategy for taking share, growing the market, specifically in endometriosis?

David C. Marek
CEO & Director

Lauren, do you want to take that?

Lauren Merendino
Chief Commercial Officer

Sure. So we believe that the current option forces physicians to choose between 2-dosing options that have different pros and cons, which can be challenging and unsatisfying. So really product profile matters, and we believe that MYFEMBREE efficacy and safety, along with the simplicity of the dosing of 1 dose, 1 pill once a day will make it the preferred choice by physicians over time. So many of the principles that apply to our uterine fibroid launch apply here to endometriosis as well.

So as Dave mentioned, the simplicity, also the importance of a positive first experience and best-in-class patient support and advocacy. So if approved, our strategy in endometriosis will be, first, to expand the class, so leveraging the strength of our data and clinical profile to expand the use of GnRH antagonist in the treatment of endometriosis. And with the high overlap of prescribers, the experience with MYFEMBREE in uterine fibroids will help to build comfort and confidence in trying the product in endometriosis.

Secondly, we need to rapidly establish payer coverage, which you've seen we've had success in uterine fibroids, and we plan to have a similar strategy in endometriosis. And we believe that the coverage we have established in U.S. may actually help us to accelerate coverage in endometriosis, and then really emphasizing the simplicity with 1 brand across both indications, 1 dose, 1 pill once a day. It really makes it simple for physicians to remember and to prescribe and simple for the patients to take.

And then the last piece at some point in the future, once we've established a prescriber base in endometriosis and established care coverage, this is also an area where we have interest in educating and activating patients as well. And we believe through all these strategies, we'll be able to have a successful entry of MYFEMBREE into endometriosis.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

Investors are debating how many women with endometriosis and uterine fibroids could be on GnRH antagonists, generally, but also MYFEMBREE specifically at peak. Does Myovant have any figures for what peak penetration could look like or maybe if not strict figures? Any color for how penetrated these massive markets could become?

David C. Marek
CEO & Director

Well, I think -- look, they're seeing what we see, which is when you look at women who are unfortunately afflicted by both uterine fibroids and/or endometriosis, you're looking at tens of millions of women. And even if we start with our initial focus, which are those women who've already been failed by first-line therapy. You're still at 3 million women with uterine fibroids, and 1 million women with endometriosis.

And so when we look at where we are now, we're very proud of the 1,400 women who've already been treated with MYFEMBREE, but the headroom in both of these markets is very significant. And we're seeing in uterine fibroids, our experience across a broad range of patient types. So while I don't have specific numbers for you, Phil. I can tell you there is significant potential in both of these therapeutic areas to really capture a significant share. And as Lauren said earlier, we believe there's no reason why we can't be a standard of care over time for both of these therapeutic areas.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

On Pfizer's commercialization efforts, I think you've been very clear on how your message is likely to differ from Pfizer's in some of the disease areas. How about structurally, are there any major differences in what Pfizer is going to do versus some of the competitors in terms of sales-force size or marketing muscle

direct-to-compete consumer? Any major differences in strategy Pfizer and Myovant compared to where you see your competition doing?

David C. Marek
CEO & Director

Yes. I'll let Lauren jump into that a little bit. But look, Pfizer is a tremendous partner for us, and gives us a lot of flexibility in our commercial approach. Lauren, do you want to detail that out a little bit?

Lauren Merendino
Chief Commercial Officer

Yes. Absolutely. So we and Pfizer are united in our approach to these disease states, and have worked very closely to leverage the strength of both companies in order to show up differently in these marketplaces. And so as we think about the differences -- so first of all, we have two field teams in the field that allows us some flexibility and nimbleness in order to get the breadth of coverage of customers that we need, but also double down on the highest volume customers and drive frequency. Also, through our partnership, we've seen success on establishing the payer coverage, as we mentioned earlier. And we also have leveraged samples from very early on in order to drive trial, which is something unique to the way that we've approached the market, and we've seen success with that. And then, of course, as I mentioned earlier, we do have plans to dial up our activation of patients later this year, which I think is a new approach in uterine fibroids. And then the simplicity that we mentioned of the same brand across both indications, pending FDA approval and endometriosis, and the simplicity of our dosing.

So in all those ways, we believe we show up differently. And the partnership with Pfizer has been very positive in helping us to execute those plans.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

Myovant's disclosed that you can earn up to you, I think, $1.75 billion in sales based milestones for each indication I don't believe that it's ever been disclosed where the breakpoints are. Cowen estimates you'll receive milestones of annual sales of $500 million, $1.5 billion to $2.5 billion. I guess, one, could you confirm whether we're correct with our estimates there? And two, I'm guessing you want to -- if not, give us some broad color. And how you achieve what the sales milestones are?

David C. Marek
CEO & Director

Yes. Uneek, why don't you take that one?

Uneek Mehra
Chief Financial & Business Officer

Yes. Sure. Phil, we have not provided the sales milestone, teasers nor financial guidance for either ORGOVYX and MYFEMBREE, and hence, it would not be appropriate for me to discuss feasibility of these milestones in detail. What we have said in the past and continue to believe today that some of the sales milestones for ORGOVYX and MYFEMBREE are achievable. We strongly believe in that while some of the higher tiers are relatively more aspirational, and I'll leave it at that.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

That's fair, sort of what we thought you were going to say. Maybe in the last minute, could you provide an update on your business development strategy? Could you characterize the types of acquisitions or licenses you'd be interested in? Can you give us some sense of the management and financial capacity that you feel you have today to do a deal on the pipeline?

David C. Marek
CEO & Director

Sure. I'll start, and then Uneek feel free to jump in. But Phil, it starts with our focus on planning for the future, and we really start with leveraging what we already have. We -- first of all, we have an outstanding and proven development engine led by Juan Camilo and his team. And so the first place we go is life cycle management. And we believe there are many more applications for relugolix and we also have MVT-602 in our pipeline. So that's the first place to really expand the future potential for Myovant.

And then when we look externally, we're looking at opportunities from a business development perspective with both the areas of women's health as well as in oncology, uro-oncology in particular. But those are 2 of the key areas that we're going to focus. And any asset or deal that we would look at would of course, go through the lens of what's right for us strategically, but also financially. And then I don't know if there's anything you want to add to that as well, Uneek?

Uneek Mehra
Chief Financial & Business Officer

No. I think you covered it all, and I believe we are probably at the sort of time point here, but nothing further to add to the thing.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

That's great. We are actually out of time. So thanks so much for a very interesting session. Congratulations on all that you've achieved over the last year.

Uneek Mehra
Chief Financial & Business Officer

Thank you so much, Phil.

David C. Marek
CEO & Director

Thank you so much.

Lauren Merendino
Chief Commercial Officer

Thank you.

Uneek Mehra
Chief Financial & Business Officer

Pleasure to be here. Thank you.

Philip M. Nadeau
Cowen and Company, LLC, Research Division
Thank you.