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Company Conference Presentation

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Table of Contents

Call Participants

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Chief Commercial Officer

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Presentation

Eric William Joseph
JPMorgan Chase & Co, Research Division

Okay. Good afternoon, and thanks again for joining the 40th Annual JPMorgan Healthcare Conference. I'm Eric Joseph, senior biotech analyst with the firm. Our next presenting company is Myovant Sciences. And it's my pleasure to welcome company's CEO, Dave Marek, to talk to us a little bit about the company. [Operator Instructions] With that, Dave, thanks so much for sharing some of your time with us this week.

David C. Marek
CEO & Director

Well, thank you, Eric, and good afternoon, everyone. I have to say that after leading Myovant for the past year, it's been great to be back here today presenting at the JPMorgan Healthcare Conference. So thank you for inviting us. And I'll briefly mention that our presentation today will include forward-looking statements. So please refer to the latest SEC disclosures for a discussion of the risks and uncertainties.

So Myovant's mission is to redefine care through purpose-driven science through empowering medicines and transformative advocacy. We now have 2 FDA-approved products. We have ORGOVYX for advanced prostate cancer and MYFEMBREE for the treatment of uterine fibroids as well as a European approval with RYEQO for uterine fibroids. And helping to enable our global development and commercialization strategies are several partners, particularly Pfizer, who is our co-development and co-commercialization partner for both or ORGOVYX and MYFEMBREE with us in the U.S. And we have Gedeon Richter, who is commercializing RYEQO in our international markets.

On Slide 4, we believe Myovant will be a category-leading company in the areas of both women's health and oncology. And our confidence stems from our differentiated therapies from our strategically leveraged partnerships from our strong balance sheet with high revenue growth potential and from our commitment to investing in our pipeline. And we have a proven development engine that has generated positive Phase III data in 5 pivotal studies leading to 3 approvals and 2 more pending decisions this year. We also have an incredibly strong executive team leading Myovant and we're supported by a deeply experienced Board that continues to guide the long-term vision for the company.

2021 was a busy year for Myovant with many notable achievements. And most importantly, we had a meaningful impact on thousands of patients. Over 11,000 men with advanced prostate cancer were treated with ORGOVYX last year and approximately 1,400 women with uterine fibroids were treated with MYFEMBREE. And RYEQO was also launched by Gedeon Richter in 11 countries. So this resulted in approximately $65 million of net product revenue. And from a clinical development standpoint, the results of the pivotal LIBERTY program in uterine fibroids were published in the New England Journal of Medicine. We presented positive results from the LIBERTY randomized withdrawal study, including bone mineral density data through 2 years as well as positive results from our SPIRIT long-term extension study. And we began enrolling in SERENE, our study to evaluate prevention of pregnancy in women with uterine fibroids or endometriosis.

And finally, in addition to our regulatory achievements, with 3 regulatory approvals last year, we also have the filings for MYFEMBREE and endometriosis in the U.S. and for relugolix in prostate cancer in the EU, both with decisions expected this year. So let's move to the objectives for 2022.

Slide 6. Our main focus remains on commercial execution. Building on the strong foundation we achieved last year, we expect to drive ORGOVYX growth by increasing depth and breadth of prescribing while increasing patient engagement. We intend to accelerate MYFEMBREE in uterine fibroids and pending FDA approval to launch MYFEMBREE for endometriosis where there's high prescriber overlap that would enable us to leverage the same brand, the same dose, the same 1 pill once-a-day approach that MYFEMBREE already brings to uterine fibroids patients today. And at the same time, we need to build for tomorrow by expanding our pipeline, and we plan to advance relugolix life cycle opportunities to advance MVT-602 clinical development and to announce an ORGOVYX international partnership.

And along with Gedeon Richter, we expect to file for EU approval for RYEQO in endometriosis. And finally, we'll also continue to look externally for additional opportunities, primarily in urology, oncology and women's health to add fuel to our clinical development engine and to complement our commercial capabilities.

So now I'd like to provide a focus on near and long-term commercial opportunities for ORGOVYX and then for MYFEMBREE. So on Slide 8, we really detail out that prostate cancer is the second most common cancer in men with 3 million men in the U.S. currently living with the disease. This year, approximately 300,000 men are projected to receive androgen deprivation therapy or ADT, which is the foundational treatment for prostate cancer with approximately 100,000 men initiating ADT for the first time this year.

In clinical practice, cardiovascular risk may be overlooked in prostate cancer patients despite 2 out of 3 men having cardiovascular disease risk and the urology and oncology communities are beginning to appreciate CV risk in their patients.

LHRH agonists such as leuprolide acetate have traditionally been the ADT standard of care, but are associated with known mechanism of action limitations, including an initial surge in testosterone levels that can exacerbate clinical symptoms. And because of this initial testosterone surge, it can take weeks to suppress testosterone to castration levels and to reduce PSA levels, the biomarker that's widely used to assess disease activity. Agonists are also associated with delayed testosterone recovery when discontinued due to their long-acting depot formulation.

And finally, hyperglycemia and diabetes as well as cardiovascular disease are required warnings across this agonist class. Importantly, all ADT therapies, except ORGOVYX have injectable administration, requiring office visits, which can be inconvenient for patients and a safety consideration during the COVID pandemic.

ORGOVYX is the first and only oral ADT for advanced prostate cancer. It offers men with advanced prostate cancer, rapid, profound and sustained testosterone suppression. And as an antagonist, its mechanism of action does not result in testosterone surge or flare. In the ORGOVYX pivotal trial, the majority of men in the subgroup analysis achieved testosterone recovery with just 90 days of treatment discontinuation. And we saw low incidence of MACE that was suggested by the HERO safety data. And finally, as I mentioned earlier, ORGOVYX provides an alternative to the injectable ADT options with a convenient 1 pill once-a-day dosing.

This differentiated clinical profile has led to notable commercial achievements since our launch last year. Now we aim to serve patients and we're proud that we've reached over 11,000 patients with ORGOVYX, which is an increase of more than 3,000 men since we last reported at the end of September.

We've also expanded our prescriber base now with over 1,800 treatment centers having prescribed ORGOVYX at least once, and that's an increase of 15 -- from the number of 1,500 that I reported in September. Payer coverage for ORGOVYX also continues to improve with over 250 million lives now covered for ORGOVYX across all channels, including approximately 80% of commercial lives and 99% of Part D lives.

In terms of net revenue, this translates to approximately $57 million in our first year on the market. And the fiscal third quarter revenues reflect 40% sequential volume growth for ORGOVYX compared to the fiscal second quarter. As volume growth was partially offset by a lower net price due to the expected increase in gross-to-net discounts in the quarter. And the gross-to-net discount for ORGOVYX in fiscal third quarter was in the low 40%, and we expect it to remain in the low to mid-40s for the foreseeable future. While our early achievements for ORGOVYX are notable, there is opportunity for substantial growth ahead. We're certainly proud of the 11,000 patients treated to date and with 300,000 patients receiving ADT annually, there are clearly many more patients who can benefit from ORGOVYX.

And we have many of the critical success factors that are already in place with our differentiated clinical profile, including oral administration, the excellent payer coverage we've established and our life cycle management plans. And our focus remains on establishing ORGOVYX as the ADT standard of care and capturing meaningful share in advanced prostate cancer.

So now shifting to MYFEMBREE, where there is also significant opportunity. Uterine fibroids is a very common disease with significant unmet need. And of the 5 million women who sought treatment for their uterine fibroid symptoms, 3 million have been failed by initial treatment. And even though 2 out of 3 women would prefer a medical option versus surgery, approximately 1.25 million women per year in the U.S. make the difficult decision to undergo a hysterectomy as a last resort. And historically, prescribers treating the symptoms of uterine fibroids, primarily OB/GYNs, has struggled with medical treatment because previous treatment options have been insufficient and didn't meet the needs of the market. The need such as stopping excessive menstrual bleeding or minimizing side effects, and accomplishing this in an easy and convenient manner.

We're motivated by the challenge of addressing this burdensome disease, and we believe that MYFEMBREE is the medical option that women and their providers have been seeking. In the LIBERTY Clinical program that we reported 70% of women treated with MYFEMBREE responded to therapy. On average, women who received MYFEMBREE had an 84% reduction in menstrual blood loss volume, more than 4x that of placebo.

And hot flash, a particularly bothersome side effect, occurred in less than 11% of MYFEMBREE patients, which was not meaningfully different than the 7% treated with placebo. And while duration of use is limited to 24 months due to risk of continued bone loss, the average decline in lumbar spine BMD at 12 months was under 1%. And finally, MYFEMBREE achieves all of this with 1 pill taken just once daily. So we're confident in MYFEMBREE's clinical profile. And we're encouraged by the prescriber receptivity that we've received since launch.

And one measure of early launch success is the percentage of new-to-brand prescription share or NBRx. And we're proud that in the first 6 months of launch, MYFEMBREE has been able to rapidly gain new-to-brand prescription share in the GnRH antagonist market for uterine fibroids. And despite limited insurance coverage for many of the early launch months, MYFEMBREE has already captured 45% new-to-brand share as of December. And we believe this rapid prescriber adoption reflects the desirable clinical profile and the simple once-a-day dosing advantage.

And while we're excited about capturing significant market share, we know that the full potential of MYFEMBREE will be realized by also growing the overall uterine fibroids market and the GnRH antagonist prescriber base. As awareness for MYFEMBREE continues to build providers are recognizing its differentiated clinical profile, reflected by the rapid increase in the number of prescribers every month where now we sit at over 800 unique prescribers of MYFEMBREE through mid-December. And we're also expanding the pool of GnRH antagonist prescribers, nearly 60% of MYFEMBREE prescribers chose to wait until MYFEMBREE became available before writing their first GnRH antagonist prescription for a uterine fibroid patient. So we are reaching new prescribers, and they are responding by prescribing MYFEMBREE.

And we've also seen market growth. The volume of GnRH antagonist prescriptions for uterine fibroids increased by 81% in the 6 months following the MYFEMBREE launch, demonstrating that this prescription market can be expanded with the right treatment option. Approximately 1,400 women were treated with MYFEMBREE through November, more than doubling the number of patients treated just 2 years prior. I mentioned over 800 different providers have prescribed MYFEMBREE since launch as we captured 45% NBRx share of the class in December. And all of this has been achieved despite coverage only recently reaching 83% of commercial lives.

So in terms of net revenue, this translates to approximately $4 million from launch through calendar year-end, including approximately $2.4 million in the most recent quarter. We expect to launch MYFEMBREE in endometriosis, pending FDA approval, by its PDUFA date in May, which we believe is a very significant opportunity with high unmet need.

Endometriosis is a debilitating disease that impacts approximately 8 million women in the U.S., of which 6 million experienced symptoms like pelvic pain, pain during intercourse and infertility that can significantly impact quality of life. And 1 million of these women are failed by their initial therapy. So there is significant prescriber overlap between uterine fibroids and endometriosis. So if approved, we expect gynecologists to already be familiar with MYFEMBREE, given, once again, it's the same brand, same dose, same 1 pill once-a-day approach, that's already approved today for uterine fibroids.

We also believe the process for establishing reimbursement should take less time for endometriosis. And these factors combined should help us to accelerate initial uptake in endometriosis should we get approval from the FDA. So the market opportunity in women's health is significant. There are approximately 5 million women in the U.S. with symptomatic uterine fibroids who are seeking treatment and 6 million women with symptomatic endometriosis. And combined, approximately 4 million of these women are failed by initial treatment for their condition. So this is the initial patient focus, with the opportunity to expand significantly as providers gain treatment experience and confidence in MYFEMBREE for uterine fibroids and if approved endometriosis. So even a small share of this 4 million patient market would result in significant revenues for MYFEMBREE.

And there's reason to be optimistic about MYFEMBREE over the longer term. It has a clinical profile that meets the needs of both prescribers and patients. Most women with uterine fibroids or endometriosis strongly prefer medical options to surgery and scientific societies recommend sharing clinical decision-making between doctors and their patients. And finally, we have quickly established broad payer coverage, minimizing patient out-of-pocket costs and we continue to work towards assessing other hurdles to prescribing. So changing in trends prescribing behavior takes time, but we're off to a great start with a differentiated product. And over time, we believe has a potential to have significant revenue opportunity.

So in closing, we are delivering on our mission to redefine care for many patients. We believe ORGOVYX's adoption will continue to build this year, reflecting increased patient and clinician demand for its differentiated clinical profile. In our first year on the market, we continue to believe that ORGOVYX is poised to become the ADT standard of care in advanced prostate cancer.

And MYFEMBREE has a potential to have a significant impact in the lives of many and to transform the treatment paradigm for symptoms associated with uterine fibroids and if approved for pain associated with endometriosis. And these represent substantial opportunities for growth. We're encouraged by our launch progress as we've been able to rapidly gain new-to-brand prescription share while simultaneously growing the market in uterine fibroids. So we have plans to expand our pipeline this year, by executing on relugolix life cycle opportunities by advancing MVT-602 and by pursuing business development, all made possible by the strong financial position we carry into the year with $528 million of cash as of December 31.

So we have an exciting year ahead. In addition to executing commercially, we expect to complete multiple regulatory filings. We expect to receive multiple regulatory decisions. We expect to read out important clinical data and we expect to initiate additional clinical studies. So I'm confident in our ability to deliver on our mission of redefining care for those who depend on us for our differentiated medicines. And I look forward to reporting our progress to you throughout the year.

So thank you, and I'll turn it back over to Eric now to facilitate the fireside chat. Eric?

Eric William Joseph
JPMorgan Chase & Co, Research Division

Great. Thanks for that, Dave. Maybe by way of getting started, I can have you to sort of introduce members of the Myovant team on the desk with you, and we'll proceed from there.

David C. Marek
CEO & Director
Sure. We're bringing on Uneek, our Chief Financial and Business Officer. We'll have Lauren Merendino, our Chief Commercial Officer; and Juan Camilo, who will join us as our Chief Medical Officer. So we're ready for your questions, Eric, and those from your audience.

Question and Answer

Eric William Joseph
JPMorgan Chase & Co, Research Division

Great. Thanks. Well, sure, maybe we can just start with ORGOVYX's performance in advanced prostate cancer so far. And one of the questions I've been getting of late is the rising gross-to-net trend and whether that's typical of products in the advanced prostate cancer's space that are reimbursed under Part D. I think it's caught someone in the Street a little bit by surprise. Your [signaling] stabilization at sort of the 40% range going forward, I guess, what gives you comfort in that essentially you have good line of sight and maybe just a little bit more characterization of the gross-to-net trend so far?

David C. Marek
CEO & Director

Yes, absolutely. I'll let Uneek take this just by way of introduction. We're going through the typical cycle of a new launch where early on in the first few months, you enjoy patients who might be treated, but yet are -- not yet under contracted with our payers. And then as we move through the year, of course, more of those lives come under the coverage that we've been able to establish. So that was a trend we expected to see. But I'll turn it over to Uneek to address that more specifically and where we see it going. Uneek?

Uneek Mehra
Chief Financial & Business Officer

Yes. Thanks, Dave. So consistent with the commentary that Dave gave, as our brand ORGOVYX continues to sort of go well into the launch year, we have established coverage for both Medicare Part D as well as commercial coverage. And as a function of that evolution, we believe as the coverage has now stabilized to almost excellent levels. The gross to net should now come into that stable range of the low 40s that Dave mentioned. And we expect that it will continue to be in the low to mid-40s in the foreseeable future.

Eric William Joseph
JPMorgan Chase & Co, Research Division

Okay. Okay. Great. And in terms of where you're seeing volume demand right now. I guess do you have a sense of how uptake is split between newly diagnosed versus or patients that are new to APCs versus those that are switching from an existing product? And then secondary to that, for newly-treated APC patients? Are physicians -- to what extent are physicians taking in a patient's baseline cardiac health in choosing an appropriate treatment option, right? Are they sort of -- how likely are they sort of to relegate relugolix use for those who have higher CV risk in addition to the APC?

David C. Marek
CEO & Director

Sure, Eric. I will let Lauren address the first part of the question in terms of the distribution of patients. I think we're enjoying a lot of treatment-naive patients to ADT. And then Juan Camilo, maybe you can address the consideration for cardiovascular. So let's start with Lauren.

Lauren Merendino
Chief Commercial Officer

Thanks, Dave. Yes, we're seeing the use of ORGOVYX across a broad range of patients, which is consistent with our label in advanced prostate cancer. And of those patients, 60% are ADT naive, which is important because many of them are early in their treatment journey. So we would expect them to be on ADT for longer. And then that means that 40% of our patients are also transitioning from another ADT. And this to us signals that there is a unique value proposition that ORGOVYX brings to the table even for patients who are already on an ADT.

David C. Marek

CEO & Director

And Juan Camilo regarding cardiovascular considerations?

Juan Camilo Arjona Ferreira
Chief Medical Officer

Yes. I think that, Eric, what we're seeing is that with the conversation about the data from our HERO study and an ongoing discussion about the safety profile of agonist versus antagonist, there has been a raise awareness of the existing risk of cardiovascular disease in patients with prostate cancer, where 2 out of 3 patients have significant risk factors and 1 out of 3 will have a prior history of cardiovascular disease. And therefore, this is becoming a component to the assessment of best treatment options. And I don't see it -- I don't think we see it as niching ORGOVYX for patients that have risk given that that's the majority of patients, they are actually reassessing their use of ADT having CV risk into consideration.

Eric William Joseph
JPMorgan Chase & Co, Research Division

Okay. Okay. And in terms of the mix between Part D coverage versus uptake under commercial insurance. Can you just sort of remind us where that stands currently? And how that is likely to trend through 2022 and beyond?

David C. Marek
CEO & Director

Yes. Yes. Sure. Lauren, would you like to take that?

Lauren Merendino
Chief Commercial Officer

Sure. So our patient population is roughly half commercial and half Medicare Part D.

Eric William Joseph
JPMorgan Chase & Co, Research Division

Okay. Okay. Right, right, right. But I mean, I guess, where you're seeing demand currently? Are you sort of indicating what the mix is today -- I mean currently, are you seeing uptake kind of equally split within those populations? And obviously, with what you just laid out there, you'd expect it to sort of arrive at that point, I guess, longer term, but I guess from where things stand today, you're seeing a roughly even split?

Lauren Merendino
Chief Commercial Officer

Yes. So just to clarify, in the advanced prostate cancer market overall, there is a higher percentage of Medicare Part D patients. However, the mix of ORGOVYX patients is roughly 50-50, which shows that we're having greater uptake on the commercial side relative to market.

Eric William Joseph
JPMorgan Chase & Co, Research Division

Okay. Okay. All right. Great. So submitted question here is the latest developments on your partnering activities are seeking a global partner -- an ex-U.S. partner with ORGOVYX. What are you looking for in a partner going for ORGOVYX -- sorry, what are you looking for in a suitable ex U.S. global partner for the product?

David C. Marek
CEO & Director

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

Uneek Mehra
Chief Financial & Business Officer

Yes. Thanks, Eric. So we have a formal process underway to evaluate partners for the international rights for elagolix in oncology for our ORGOVYX. We have multiple interested parties. And what we are seeking for in a partner is an established commercial infrastructure in Europe, but preferably with urology or oncology presence. And we remain confident that the partner will be named in the coming few months in advance of the EU approval decision on ORGOVYX, which we expect around mid-2022.

Eric William Joseph
JPMorgan Chase & Co, Research Division

Okay. Okay. So switching to MYFEMBREE. Who would be -- sorry. Questions are coming in from all over the place here. Okay. Great. So yes, switching to MYFEMBREE. Just curious to get a sense of where -- the type of patients where you're currently seeing the product being used, particularly as it relates to their prior treatment experience? Are you seeing update primarily in newly care-seeking patients or for those who might be experienced transitioning from something else. And then among physicians, the targeted physicians that you're detailing to, anything in the way of feedback in terms of their recognizing a difference in how the product is being received relative to the incumbents Orilissa, ORIAHNN.

David C. Marek
CEO & Director

Yes, certainly. Lauren?

Lauren Merendino
Chief Commercial Officer

Yes. So I'll answer the second part first, if you don't mind, Eric. So the response that we've received from physicians has been very positive in our product profile. They are confident in the efficacy that we've shown in our studies. They have a positive view of our safety profile, and they like the simplicity of 1 pill once a day, both for them and for their patients. So overall, we've had very positive feedback on our patient profile.

To the first part of your question, which is around the types of patients that are receiving MYFEMBREE today. So our physicians and our market research -- anecdotal feedback from our physicians as well as our market research confirms that they are utilizing MYFEMBREE in a broad set of urine fibroid patients today. And when we look at prior treatment, the large majority of these patients have been treated previously with an oral contraceptive. Now this isn't surprising. This is as expected because as you may know, that has been the primary first-line treatment for uterine fibroids for a long time. And there are some payers that do require use of oral contraceptives upfront. So the fact that the majority of our patients have received oral contraceptives is not surprising. A very low percentage of our patients have received ORIAHNN. And so we are, in many cases, the first GnRH antagonist that this patient is receiving.

Eric William Joseph
JPMorgan Chase & Co, Research Division

Okay. Okay. Great. And for the sake of us, modeling this out, can you just speak to, I guess, use of discounting gross to net as a tool for kind of providing access? And how you expect that to trend as the launch built?

David C. Marek
CEO & Director

Yes. Certainly, Lauren.

Lauren Merendino
Chief Commercial Officer

I believe for gross-to-net, Uneek, generally...

Uneek Mehra
Chief Financial & Business Officer

Is this -- I believe -- is this for MYFEMBREE?

Eric William Joseph
JPMorgan Chase & Co, Research Division

Yes. Correct. Yes. Gross to net on MYFEMBREE.

Uneek Mehra
Chief Financial & Business Officer

Yes, MYFEMBREE, of course, quite different from ORGOVYX. It has largely a commercial population. So we are contracting with payers. We are at the stage of the launch where the contracting and coverage decisions are happening as we speak right now. So we do expect the gross to net for MYFEMBREE to continue to increase as the coverage increases. And I think we are still some time away from stabilizing there given the nature and the timing of the launch at this point.

Eric William Joseph
JPMorgan Chase & Co, Research Division

Okay. Okay. Okay. Submitted question here. Looking for a little bit of an update with respect to MVT-602. And in addition to that, I guess, how should we be thinking about further life cycle opportunities with relugolix and opportunities for pipeline expansion.

David C. Marek
CEO & Director

Yes, certainly. Pipeline expansion is a key part of 2022 for us as the question outlined. It's really 3 categories of that. We think there is tremendous opportunity for life cycle management relugolix itself. We also see opportunities with MVT-602, and then, of course, supplementing that with business development efforts that will focus around women's health as well as oncology. I'll turn it over to Juan Camilo to give a little more detail on those areas that you asked more specifically. Juan Camilo?

Juan Camilo Arjona Ferreira
Chief Medical Officer

Yes. I think that for life cycle management opportunities, we look at 3 different categories. One is what additional data can we generate that would be meaningful and informative for patients and prescribers today within the indications that we have approval for. We also look at the potential new indications, and we have a list of options that we are triaging right now for both the monotherapy in ORGOVYX or the [indiscernible] combination of MYFEMBREE. And then the third thing is we are exploring any potential for additional combination with other products that are used in these or other populations. So it's a pretty broad net that we're casting to advance life cycle management.

The second pillar that Dave mentioned is MVT-602. As you know, it's a kisspeptin receptor agonist that has multiple potential indications. We've been working hard to define which of those we want to pursue, and we look forward to letting you know those details in the near future. And then working with Uneek and the business development team, who have been canvassing quite a vast net of assessment for what is available in the areas of interest. It's mainly urology, certain areas of oncology and women's health. And we are looking for the right opportunity so that we can continue to advance our pipeline.

Eric William Joseph
JPMorgan Chase & Co, Research Division

Okay. Great. Just coming back to MYFEMBREE a couple of things looking out for here, right? Both the label expansion for endometriosis and a longer follow-up and possible submission for an amendment with long-term durability -- sorry, longer-term dosing. Can you just talk about sort of the go-forward planning with respect to a supplemental finding for the 2-year bone mineral density data? And just your confidence level in kind of expanding allowed timeline of therapy for the product.

David C. Marek
CEO & Director

Sure. Juan Camilo?

Juan Camilo Arjona Ferreira
Chief Medical Officer

Yes. I think I'll start with the excitement about the potential for an approval for the endometrial syndication, as Dave and Lauren have commented. We are excited about the opportunity to bring to physicians a simple solution that has -- in a single label with the same brand, 1 dose and dosing regimen and 1 pill once a day for both uterine fibroids and endometriosis and provide all the data that we've already presented for that indication.

With regard to the submission of our randomized withdrawal study, as you may recall, we are very excited about having -- being the only brand that has 2-year data that provided evidence of persistence of efficacy as long as patients continue treatment, provide clarity on what happens when you discontinue therapy with a return of heavy menstrual bleeding around 5 to 6 weeks after and the option of retreatment with regaining of efficacy. But also, as you referred to the demonstration of stable bone density from week 52 to week 104, we are planning to submit, as we've said before, that information to the FDA in the next few weeks. We're finalizing our documentation for that purpose. But what I want to make clear is that what will -- how that data will be reflected in the label and how that may or not affect the duration of treatment is up to the FDA and their review. So I wouldn't want to speculate on what their assessment is going to be.

Eric William Joseph
JPMorgan Chase & Co, Research Division

Okay. Okay. All right. Great. Well, I think we will leave it there for time. Dave and team, I want to thank. And everybody at the Myovant team, I want to thank you for joining us this afternoon, and thanks, everybody, for tuning into this session.

David C. Marek
CEO & Director
Thank you, Eric, and thanks, everyone, for joining us today.