

# EDITED TRANSCRIPT

## MYOV – Myovant Sciences, Inc. LIBERTY Randomized Withdrawal Study Results Call

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### OVERVIEW:

Myovant Sciences presents results of LIBERTY Randomized Withdrawal study



## CORPORATE PARTICIPANTS

**David C. Marek** *Myovant Sciences Ltd. - Principal Executive Officer & Director*

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

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**Unidentified Analyst** -

## PRESENTATION

### Operator

Good day, everyone, and welcome to Myovant Sciences presentation of the Phase III LIBERTY randomized withdrawal study results. Today's call is being recorded. At this time, I would like to turn the call over to Ryan Crowe, Vice President of Investor Relations at Myovant. Please go ahead.

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

Thank you, Stephanie. Good morning, and thank you for joining us today to review the results of the LIBERTY randomized withdrawal study in women with uterine fibroids. Joining me for today's call are Dave Marek, Myovant's Chief Executive Officer and Dr. Juan Camilo Arjona, Chief Medical Officer. In addition to the press release issued earlier this morning, the slides that will be presented during today's webcast are available on our Investor Relations website, [investors.myovant.com](http://investors.myovant.com).

During the course of this conference call, we will be making forward-looking statements. These include plans and expectations with respect to our products, 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 SEC disclosure documents. In addition, Myovant does not undertake any obligation to update any forward-looking statements made during this call.

With that, I'll now turn the call over to Dave Marek, Myovant's Chief Executive Officer. Dave?

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### **David C. Marek** *Myovant Sciences Ltd. - Principal Executive Officer & Director*

Thank you, Ryan, and good morning, everyone. Before I ask Juan Camilo to review the detailed results of our randomized withdrawal study, I'll highlight the key takeaways from the study, the significant need that remains in the management of uterine fibroids, and why we believe relugolix combination tablet has the potential to redefine care for the millions of women who suffer from this debilitating disease.

We are very pleased with the results of the randomized withdrawal study. The primary endpoint was achieved with 78% of women receiving relugolix combination therapy, maintaining menstrual blood loss volume of less than 80 milliliters from week 52 to week 76 compared to 15% of women receiving placebo. All 3 key secondary endpoints were achieved, and the difference between groups was highly statistically significant. There were no new safety signals identified. And bone health was maintained for all women [both treatment groups] over the 1 year observation period.

Uterine fibroids are noncancerous tumors that develop in or on the mucosal walls of the uterus. They are among the most common gynecologic tumors in women. In addition to an individual's genetic predisposition, estrogens are well-known to play an important role in the regulation of fibroid growth. Although uterine fibroids are benign tumors, they can cause chronic debilitating symptoms such as heavy menstrual bleeding, which frequently results in anemia and fatigue, pelvic pain, urinary and gastrointestinal symptoms, constipation, pregnancy complications, and in some cases, infertility. These symptoms can also lead to loss of productivity at work, limitations and normal activities of daily living and social embarrassment.

Uterine fibroids are very common. More than 1 in 4 women globally of reproductive age have uterine fibroids with approximately one-quarter of them experiencing symptoms. In the U.S. alone, there are 5 million symptomatic women, with an estimated 3 million who are inadequately treated by current therapeutic options, primarily hormonal contraceptives. So there is clearly a need for new treatment alternatives. Importantly, nearly half of women with heavy menstrual bleeding, the most common symptom of uterine fibroids, have never consulted a doctor or sought treatment. And we believe there are likely many reasons for this, including social stigma, lack of access to care, feeling helpless or that medical options won't work, or they simply aren't aware that their perceived heavy menstrual bleeding could be improved.

At Myovant, we're motivated by the opportunity to empower these women to address this burdensome and condition that can have such a negative impact on their quality of life during some of their most productive years.

We believe that relugolix combination tablet has the potential to be a meaningful option for women with symptoms of uterine fibroids. Relugolix combination tablet combines 40 milligrams of relugolix, a unique GnRH antagonist, with 1 milligram of estradiol and 0.5 milligram of a progestin called norethindrone acetate. The LIBERTY program has demonstrated that relugolix combination therapy strikes the right balance by reducing estrogen levels to a range consistent with that observed in the early days of a natural menstrual cycle, thereby improving the heavy menstrual bleeding and pain associated with uterine fibroids while minimizing the side effects of low estrogen levels. And the relugolix potency and half-life allow for convenient, once-daily dosing.

Because uterine fibroids is a chronic disease, we designed our clinical program to develop relugolix combination tablet as a potential long-term treatment option for women with symptomatic uterine fibroids and as an alternative to surgery and other invasive procedures. Prescribers, primarily OB/GYNs, generally struggle to treat uterine fibroids medically because the options are limited, and therefore, would often resort to major invasive surgical procedures to relieve symptoms. When we ask OB/GYNs, their top priorities for medical treatment for uterine fibroids were clear and consistent. They want a medicine that reduces or stops the bleeding in pelvic pain with minimal side effects, including bone health, and with dosing that is clear and convenient for both the prescriber and the patient.

We believe relugolix combination tablet has a potential to address those treatment aspirations

based on the results generated from our LIBERTY clinical program. Symptom relief was rapid and dramatic. Relugolix combination tablet was generally well tolerated with bone health maintained. And finally, it's convenient -- one pill, once a day.

Before Juan Camilo reviews the detailed results of the randomized withdrawal study, let me highlight the goals of the study and the timing of these results relative to FDA's review of relugolix combination tablet for uterine fibroids. The randomized withdrawal study is the first and only study of a GnRH antagonist with results reported through 2 years in women with uterine fibroids. It was designed to establish durability of efficacy over 2 years to demonstrate predictable outcomes after discontinuing and then restarting relugolix combination therapy, and to assess safety, tolerability and maintenance of bone mineral density over a second year of treatment.

Given the timing of these results relative to the June 1<sup>st</sup> target action date for our U.S. NDA in uterine fibroids, these data have not been submitted as part of our application. However, we do believe these results offer additional support for the efficacy and safety profile demonstrated in our pivotal studies, and if relugolix combination tablet is approved by FDA, we do intend to submit these data in the future for potential inclusion in our label.

Now I'll turn the call over to Juan Camilo to review the design and results of the LIBERTY randomized withdrawal study. Juan Camilo?

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**Juan Camilo Arjona Ferreira Myovant Sciences Ltd. - Chief Medical Officer of Myovant Sciences, Inc.**

Thank you, Dave. Our LIBERTY clinical development program was designed to evaluate the long-term efficacy and safety of relugolix combination therapy in women with uterine fibroids. The randomized withdrawal study is the capstone of our LIBERTY program and builds on the results generated in prior studies. As you may recall, in 2019, we reported positive results for LIBERTY 1 and LIBERTY 2, our replicate Phase III pivotal studies. These results were also recently published in the New England Journal of Medicine. Last year, we reported positive results for our LIBERTY long-term extension study. These 3 studies support the regulatory submissions currently under review in the U.S. and EU.

The randomized withdrawal study that just completed was a 52-week double-blind placebo-controlled study in eligible women who completed LIBERTY 1 or LIBERTY 2 and the long-term extension study and who responded to treatment with relugolix combination therapy.

Let's briefly review the trial design for the studies in the LIBERTY program. LIBERTY 1 and 2 will replicate 24-week studies that evaluated women with heavy menstrual bleeding associated with uterine fibroids, who were randomized to receive placebo, relugolix combination therapy or relugolix 40-milligram monotherapy for 12 weeks, followed by 12 weeks of relugolix combination therapy. At the conclusion of these initial studies, women had the option to enroll into the 28-week long-term extension study in which all women received relugolix combination therapy regardless of the treatment they have received in LIBERTY 1 or 2.

Upon completing the long-term extension study, women who at week 48 had menstrual blood loss volume of less than 80 mL and a 50% or greater reduction from baseline were considered responders and were eligible to enroll into the 52-week randomized withdrawal study. A total of 229 responders enrolled in the randomized withdrawal study. These women were randomized 1:1 to receive either placebo or relugolix combination therapy for 52 weeks. All women were

provided rescue therapy with open-label relugolix combination therapy if their menstrual blood loss volume exceeded 80 mL. The primary endpoint for this study was a proportion of women who maintained menstrual blood loss volume of under 80 mL from week 52 through week 76. That is, through 24 weeks after re-randomization into the randomized withdrawal study.

Baseline characteristics were generally consistent across the relugolix combination therapy and placebo treatment groups and were also generally consistent with those of the overall population of women originally enrolled into the LIBERTY 1 and 2 studies.

This slide depicts baseline characteristics for women enrolled into the randomized withdrawal study, both prior to randomization into the LIBERTY 1 or LIBERTY 2 study and at week 52, following at least 28 weeks of active treatment with relugolix combination therapy and just prior to initiation of the randomized withdrawal study. BMI was essentially unchanged. As expected, menstrual blood loss volume was high at baseline or week 0 and very low at week 52 after treatment with relugolix combination therapy for after 1 year in the prior LIBERTY studies. As a consequence of this reduction in menstrual blood loss volume, there was a notable increase in hemoglobin and a decrease in the proportion of women who were anemic, defined as hemoglobin of less than 10.5 grams per deciliter. Women's distress associated with symptoms of uterine fibroids as explored on the bleeding and pelvic discomfort scale was also meaningfully improved from baseline to week 52, the start of the randomized withdrawal study.

The primary endpoint of the randomized withdrawal study was achieved with 78% of women receiving relugolix combination therapy maintaining menstrual blood loss volume of less than 80 ml from week 52 to week 76 compared to 15% of women receiving placebo. There were 3 key secondary endpoints that were evaluated: time to relapse defined as the first cycle in which menstrual blood loss exceeded 80 mL, the proportion of women maintaining menstrual blood loss volume of less than 80 mL from week 52 to week 104, and the rate of amenorrhea or lack menstruation at week 76 or end of treatment. All 3 key secondary endpoints were achieved and the differences between groups were highly statistically significant, all with p-values less than 0.0001.

The line graph on this slide depicts the cumulative number of women that relapse. As you can see from the gray line, heavy menstrual bleeding returned for most women randomized to placebo within 4 to 8 weeks following discontinuation of relugolix combination therapy with a median time to relapse of 5.9 weeks. The orange line indicates the cumulative relapses for women randomized through relugolix combination therapy. Given this small number of women who relapsed in this group, median time to relapse could not be calculated. Based on these data, over 52 weeks, women received relugolix combination therapy had an 87% lower risk of relapse compared to women receiving placebo, with return of heavy menstrual bleeding in most women within 1 to 2 menstrual cycles after discontinuation of treatment.

91 [92] women on placebo relapsed compared to 31 on relugolix combination therapy. Those women randomized to placebo who relapsed and who received retreatment, 98% responded, demonstrating that resumption of relugolix combination therapy reversed the heavy menstrual bleeding that followed treatment discontinuation. It is also important to note that of the women randomized to active treatment who received rescue therapy, 96% responded to retreatment, suggesting that the relapse was transient, was managed with continued treatment with relugolix combination therapy and did not represent a treatment failure, but rather a reflection of the variability of bleeding from one cycle to another.

The orange line on this graph depicts mean menstrual blood loss volume for women randomized to relugolix combination therapy regardless of retreatment. As you can see, over the entire 52-

week treatment period, mean blood loss remained well below the 80 ml threshold, indicated by the gray dotted line, demonstrating durability and consistency of effect. When we layer on in the gray line that indicate the mean menstrual blood loss volume for women randomized in placebo, also regardless of retreatment, there is a very sharp increase over the first 8 to 12 weeks of treatment, which is consistent with the cumulative incidence curves on the prior slide. This sharp increase in menstrual blood loss volume for women initially on placebo is quickly followed by a reduction of menstrual blood loss over the next 12 weeks as women initiated retreatment with open-label, relugolix combination therapy.

The number of women receiving rescue therapy are indicated by the bars of the chart. 59% of women randomized to placebo had started retreatment by week 68 or 16 weeks after treatment discontinuation. This corresponds with the decline in menstrual blood loss volume for women on placebo, which peaks at week 60. By week 76, 72% of women randomized in placebo had started retreatment and thereafter, mean menstrual blood loss volume for both groups remained similar to the end of the observation period.

Regarding safety, the adverse event profile in the relugolix combination therapy group was consistent with prior observations in the LIBERTY program. There were no new safety signals identified based on data from the randomized withdrawal study. The only adverse event reported in over 10% deployment was nasopharyngitis. It is important to note that most women randomized to placebo also received rescue relugolix combination therapy during the treatment period. Therefore, the adverse event profile in that group is reflective of the sequence of placebo followed by relugolix combination therapy, limiting comparison between groups for safety. There was 1 pregnancy reported in the women randomized to placebo while on placebo treatment. This woman did not receive active rescue treatment.

Bone mineral density data show -- shown in this slide reflects the effect of continuous treatment with relugolix combination therapy in orange and in gray, the effect of treatment with the sequence of placebo followed by open-label relugolix combination therapy in most women. During this second year of treatment, bone mineral density at the lumbar spine and to the hip remained stable in both treatment groups. I'll now turn it back over to Dave for some closing remarks. Dave?

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**David C. Marek *Myovant Sciences Ltd.* - Principal Executive Officer & Director**

Thank you, Juan Camilo. In summary, the LIBERTY randomized withdrawal study further supports our belief that relugolix combination therapy has the potential to become the new standard of care treatment option for women with uterine fibroids. The study demonstrated durability of efficacy over the second year of treatment and that discontinuation of therapy led to a rapid return of heavy menstrual bleeding. The study also demonstrated that retreatment with relugolix combination therapy is highly effective with nearly all women that received rescue therapy again becoming responders to relugolix combination therapy. Bone mineral density was maintained from week 52 to week 104, and the adverse event profile continues to be consistent with that observed in previously reported studies.

We have a very exciting set of upcoming near-term catalysts, which you can see listed on the right side of this slide, including the FDA's decision on our new drug application for relugolix combination therapy in women with uterine fibroids, which has a PDUFA date of June 1, and we continue to expect a decision for our EU filing in women with uterine fibroids in the middle of this year. We look forward to keeping you updated on our progress on all of these milestones.

So thank you for your time and attention, and I'll turn it over to Ryan to begin the Q&A session.

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## QUESTIONS AND ANSWERS

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

Thank you, Dave. Before we start the Q&A session, I ask that you please limit the scope of your questions to the results of the randomized withdrawal study or the commercial opportunity in women's health.

With that said, Stephanie, can we please now poll for questions?

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**Operator**

(Operator Instructions) And our first question is from the line of Eric Joseph with JPMorgan.

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**Unidentified Analyst -**

This is Hannah on for Eric. Just a few from us. So first, based on your market research, do you have a sense of what proportion of symptomatic women might be seeking long-term medical treatment for uterine fibroids as opposed to treatment as a prelude to surgical resection? And then I have another one after that.

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**David C. Marek *Myovant Sciences Ltd. - Principal Executive Officer & Director***

Yes. I think Juan Camilo, maybe you could address the patient perspective of treatment?

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**Juan Camilo Arjona Ferreira *Myovant Sciences Ltd. - Chief Medical Officer of Myovant Sciences, Inc.***

Yes, absolutely. Thank you, Dave, and thank you, Hannah for your question. We believe that there is a significant interest on the option for having medical treatment solution for women who have menstrual bleeding associated with uterine fibroids, which as of today, tend to go into surgical solutions like hysterectomy. That is not always the desired outcome for patients that either want fertility or simply don't want to undergo a major surgical procedure.

So I don't have specific numbers to how many patients would that be, but what we've heard from physicians and for patients that we talk is that this is highly expected option for treatment.

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**David C. Marek *Myovant Sciences Ltd. - Principal Executive Officer & Director***

And Hannah, you had a second question?

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**Unidentified Analyst -**

Yes. And just briefly, would you be able to give us an overview of your initial launch strategy? To what extent do you think the Pfizer collaboration will provide additional support for marketing and detailing efforts?

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**David C. Marek *Myovant Sciences Ltd. - Principal Executive Officer & Director***

Well, sure, Hannah. Well, we believe that the Pfizer partnership is ideal for us in women's health. So when we think about our launch strategy, of course, it begins with how we ensure that the prescriber base is fully educated and aware of what the clinical profile is for relugolix combination tablet. And we believe that process will, as we go through kind of the key criteria of what's important to clinicians. As mentioned, we believe our product profile very much aligns with what the treatment aspirations are in the treatment of uterine fibroids. So when you look at the high degree of efficacy that we've reported, when we look at the safety and tolerability profile, including the BMD data that we've discussed as well as the clear and straightforward dosing, not only what we would anticipate for uterine fibroids, but how that also translate eventually to endometriosis. So we believe that our clinical profile is ideal for meeting the needs of the marketplace.

As far as the Pfizer collaboration, we fully expect Pfizer to be co-commercializing this with us. So that includes field support in concert with our field efforts as well as the marketing and payer support as well. And notably, with this patient population, we believe that there's a significant opportunity for patient engagement and education. And clearly, Pfizer brings an outstanding capability of engaging patients in educational and informative way, and we would look to leverage that within the collaboration as well.

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**Operator**

Your next question is from the line of Paul Choi with Goldman Sachs.

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

Let me add my congratulations as well on the data. Maybe this question is best for Juan Camilo. But just as we look at the headline data for the responder rates at the various key time points, 24, 52, 76 and 104 weeks, 104 weeks. The data, I believe, indicate responder rates of 72%, 88%, 78% and 70%. So I was just wondering, recognizing that there are a couple of moving parts with regard to patient numbers and things like that, could you maybe just speak to the to the declining responder rate trend over the longer-term and longer follow-up period? Is this an adherence issue? Is it just a patient number issue? Any just sort of color or insight there would be helpful. And then I had a follow-up.

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**David C. Marek *Myovant Sciences Ltd. - Principal Executive Officer & Director***

Yes, go ahead, Juan Camilo.

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**Juan Camilo Arjona Ferreira *Myovant Sciences Ltd. - Chief Medical Officer of Myovant Sciences, Inc.***

Yes. Thanks, Dave. Yes, there is a reason, and I think it's very important to understand that there are differences in the definition of the responder. As you may recall, for the week 24 and the week 52 analysis, the patients -- the definition of responder was a menstrual blood loss volume of less than 80 ml and greater than -- 50% or greater reduction from baseline at that particular time point, and that was assessed over the last 35 days of treatment before the time point.

In this second year study, the endpoint is slightly different. This is a sustained bleeding reduction. So to be a responder at week 76, for example, patients have to remain less than 80 ml at every single month from week 52 to week 76, which is a higher hurdle. And the same for the assessment at week 104, they had to stay under 80 ml for the full 52-week period. So I think that this is not necessarily inconsistent with the prior results. It's just a slightly different measure in, as I mentioned, it's a higher hurdle, and then we're pretty satisfied with the numbers we've got of 78% and 70%.

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

Got it. That's a very helpful clarification. And then maybe for Dave, just on your preliminary or updated payer conversations now that you have the 2-year durability data with respect to both efficacy and safety. Could you maybe just sort of comment if there are any indications with regard to preferential positioning for relugolix here with respect to the uterine fibroid indication?

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**David C. Marek *Myovant Sciences Ltd. - Principal Executive Officer & Director***

Sure. Well, we certainly have engaged payers to first make sure that there's appropriate attention towards uterine fibroids and eventually endometriosis, and we're very pleased with those discussions. Of course, we have not yet put these data in front of payers, as they're just now being revealed. However, we are reviewing our complete value proposition for relugolix combination therapy. And I would say that as we look at the clinical profile as it is now published in the New England Journal of Medicine, what we're seeing there, certainly, the body of evidence continues to support a very strong clinical profile that aligns with the needs of the marketplace.

So we'll continue to have those discussions with payers. But to date, certainly our discussions around the therapeutic areas. And eventually, as we get more into clinical data as we approach the PDUFA date, we would anticipate continued excitement around the possibility of what we can bring to the marketplace.

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**Operator**

Your next question is from the line of Jason Butler with JMP Securities.

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**Unidentified Analyst -**

It's Roy for Jason. I guess a little curious on -- I think in Slide 22, the blood loss volume crossed over 104 weeks, I'm curious about the patient numbers. The placebo patient numbers dropped quite a bit, which would be expected, except the patients were given the opportunity to take relugolix, correct? So I'm just curious why the patients were dropping out, if they just -- were

given the choice decided to drop out or what the explanation is there?

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**David C. Marek *Myovant Sciences Ltd. - Principal Executive Officer & Director***

Sure. Yes, Juan Camilo?

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**Juan Camilo Arjona Ferreira *Myovant Sciences Ltd. - Chief Medical Officer of Myovant Sciences, Inc.***

Sorry. Thank you, Dave. So the explanation, and you will see -- we try to capture that in the footnote that once patients met the greater than 80 ml threshold and were eligible for retreatment and started retreatment, we continue to collect their bleeding for at least 2 cycles. But certainly, until they demonstrated response to treatment. So they had to meet less than 80 ml for 2 consecutive cycles before they could stop collecting their feminine products. This was a highly burdensome program for patients with collection of feminine products. So what you see at the bottom is the number of patients that we're collecting at that date, that visit, not necessarily that they were not continuing on treatment. And as you -- we've shown early on is that the majority of patients, more than 75% of patients in both groups stayed or around 75% of patients stayed on treatment for the duration of 104 weeks -- of 52 weeks in this study.

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**Operator**

Your next question is from the line of Phil Nadeau of Cowen & Company.

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

Congrats on the data. A question on how the FDA is likely to deal with the data. You suggested that you will submit a following approval to supplement the label. What do you think would be added to the label with inclusion of the data? I guess, specifically, I'm wondering about a limitation on the duration of use or has a limitation for less than 24 months of therapy because of bone mineral density loss. Your data seems to pretty clearly show that there's no bone mineral density loss with long term treatment. So is it possible if you do get that restriction in the initial label that this data could remove it?

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**David C. Marek *Myovant Sciences Ltd. - Principal Executive Officer & Director***

So Phil, certainly, as you know, we won't comment on the current ongoing discussions with the FDA regarding the label and any expected outcome that we might receive. Juan Camilo, I don't know if you want to address maybe perhaps not related to the label, but how do we see dissemination of these data in the public for scientific exchange?

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**Juan Camilo Arjona Ferreira Myovant Sciences Ltd. - Chief Medical Officer of Myovant Sciences, Inc.**

Yes. Thank you, Dave, and thank you, Phil. Yes, we expect to present this data. So this is data for presentation and in the second half of the year, there are multiple conferences that we could target and we're deciding where to go. And we will also send that for publication soon thereafter. So we are very excited to make this data visible to the scientific community. And as we pointed out in our presentation to submitted to FDA for their consideration, once -- if we get approved.

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

Maybe as a follow-up, are there particular elements of the data that you think will help differentiate versus what has been shown? Or any outstanding questions on its profile that have been answered by the study for relugolix?

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**David C. Marek Myovant Sciences Ltd. - Principal Executive Officer & Director**

Yes. Well, certainly, we are the only therapy in this class to show 2-year data across efficacy, tolerability, safety, including BMD. So certainly, we believe that these data are important to prescribers in making clinical decisions for their patients. And so we certainly see that in addition to the other data that has already been presented on this program, that these data add to the body of evidence around what we think is a very unique and differentiated clinical profile. In addition to our clear and concise prescribing and dosing recommendations across what we would hope to be consistent across both uterine fibroids and endometriosis as we think that is a clear point of difference in addition to the data.

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

Perfect. And congratulations again on the results.

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**Operator**

Your next question is from the line of Mohit Bansal of Citigroup.

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**Mohit Bansal Citigroup Inc. Exchange Research - Research Analyst**

And congrats on the data. Maybe a commercial question, but before that, I just wanted to follow-up on Paul's question. Do you see any changes in compliance and adherence rates compared to the first 24-week period versus the remainder of 1.5 years?

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**David C. Marek Myovant Sciences Ltd. - Principal Executive Officer & Director**

So Juan Camilo, I'll let you address the compliance rates.

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**Juan Camilo Arjona Ferreira Myovant Sciences Ltd. - Chief Medical Officer of Myovant Sciences, Inc.**

Yes. Thank you, Dave. Mohit, we didn't see a significant difference in compliance. As you can imagine, the women have been going through a whole year of treatment, where, as I mentioned before, had to collect their feminine products every cycle and send it to the site for quantification. So they are very motivated, and there were this group that entered the randomized study, where patients who responded to treatment. So they remained very satisfied with treatment and motivated to stay. So we saw not only a great retention of a whole second year of treatment, but also great compliance with study medication, which I believe is reflected in the data that we showed you this morning.

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**Mohit Bansal Citigroup Inc. Exchange Research - Research Analyst**

That's very great. And then on the commercial side, so I mean, as you are talking to the payers and preparing for the launch, can you talk a little bit more about the discussions in terms of how the pricing discussions are going? I know it is premature, but do you see, given your profile, there is a premium potential there? That's the first part.

Second part is in terms of potential prior auth and obstacles payers could come up with, how do you plan to navigate that? And is there a low-hanging fruit or go-to-market, which could be the initial adopter here?

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**David C. Marek Myovant Sciences Ltd. - Principal Executive Officer & Director**

Sure. Thank you for the question, Mohit. And yes, you're correct. We -- when it comes to the pricing decisions, first of all, we have not established the price and are not in the process of negotiating a specific price with payers. So we don't have anything to report on that front. Where we do focus in our discussions with payers is certainly around the significant unmet need that continues to remain despite currently available options. And we talk about making sure that there's a clear understanding around what are the value drivers for patients. And as mentioned, when you look at what is important to clinicians, tends to be very similar to what's important to payers around a high degree of efficacy, the safety and tolerability profile, including BMD, as well as then the attractiveness for prescribers and patients regarding our dosing. So the conversations with payers are moving along at the appropriate pace that we would expect, and we're very pleased with the discussions that we've had to date.

I think as far as low-hanging fruit from a patient profile perspective, again, we know that there are many, many patients with uterine fibroids, 5 million women who suffer from symptoms of uterine fibroids and 3 million who are inadequately treated by their current medical therapy, which is primarily hormonal contraceptives. So we believe that there are a significant number of patients who would benefit from a therapeutic option like relugolix combination therapy that we believe more closely aligns with what the market is telling us is important in treatment of uterine fibroids.

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**Operator**

And at this time, there are no further questions.

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**David C. Marek *Myovant Sciences Ltd. - Principal Executive Officer & Director***

Okay. So I want to thank everyone for joining us this morning. This is an exciting day for Myovant Sciences in terms of further building the body of evidence as it relates to results with the LIBERTY randomized withdrawal study. So thank you for joining us, and we hope you have a great day.

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**Operator**

Ladies and gentlemen, this concludes Myovant Sciences presentation of the LIBERTY randomized withdrawal study results. Thank you for your participation. You may now disconnect.

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