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Myovant Sciences Ltd and Pfizer Inc MYFEMBREE FDA sNDA Approval Call

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CORPORATE PARTICIPANTS

David C. Marek *Myovant Sciences Ltd. - CEO & Director*
Juan Camilo Arjona Ferreira *Myovant Sciences Ltd. - Chief Medical Officer*
Lauren Merendino *Myovant Sciences Ltd. - Chief Commercial Officer*
Uneek Mehra *Myovant Sciences Ltd. - Principal Financial Officer*

CONFERENCE CALL PARTICIPANTS

Gavin Clark-Gartner *Evercore ISI Institutional Equities, Research Division - Analyst*
Hannah Temiloluwa Adeoye *JPMorgan Chase & Co, Research Division - Research Analyst*
Philip M. Nadeau *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*
Roanna Clarissa H. Ruiz *SVB Securities LLC, Research Division - Director of Infectious Disease, Endocrine & Cardiovascular Disorders & Senior Research Analyst*

PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the MYFEMBREE FDA sNDA Approval Conference Call. (Operator Instructions). Please be advised that today's conference is being recorded.

I would now like to hand the conference over to your speaker today, Uneek Mehra, Chief Financial and Business Officer. Please go ahead.

Uneek Mehra ***Myovant Sciences Ltd. - Principal Financial Officer***

Thank you, operator. Good morning, and thank you for joining us today to discuss the exciting news of the FDA approval of MYFEMBREE for the management of moderate-to-severe pain associated with endometriosis in pre-menopausal women. Our press release as well as the slides that will be presented during today's webcast will be available on our Investor Relations website, investors.myovant.com.

Joining me for today's call are Dave Marek, Myovant's Chief Executive Officer; Lauren Merendino, Chief Commercial Officer; and Dr. Juan Camilo Arjona, our Chief Medical Officer.

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

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

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Thank you, Uneek. It's an exciting day for Myovant as we advance our mission to redefine care for women and the patients we serve. I'm proud to announce the FDA approval of MYFEMBREE as a one pill, once-a-day therapy for the management of moderate-to-severe pain associated with endometriosis in pre-menopausal women, with the treatment duration of up to 24 months.

The approval establishes MYFEMBREE as the first and only once-daily oral GnRH antagonist treatment with 2 indications. This marks our third FDA approval in less than 2 years, and this milestone is a strong statement of our team's commitment to redefine care for women.

MYFEMBREE's new indication serves as a catalyst for us to expand and to enhance our impact on the millions of women with uterine fibroids and endometriosis in the U.S. Nearly 1/4 of women with uterine fibroids and 80% of women with endometriosis experience symptoms, yet there's a high unmet need for new options to help these patients as the current treatment paradigm is limited, with many failed by their initial treatment or not being able to manage their symptoms.

We also know that physicians are seeking new treatments that provide meaningful pain relief, while enabling their patients to resume

daily activities, and this is why we're excited about MYFEMBREE's new indication and how we can fulfill this need.

The approval of MYFEMBREE in endometriosis contributes to our strong growth trajectory to deliver sustainable long-term value. MYFEMBREE brings a distinctive efficacy that delivers relief of commonly-reported pain associated with endometriosis, and has a tolerable safety profile in a simple one pill, once-a-day formulation that can be used up to 24 months.

We're accelerating our reach to patients and will execute an efficient launch for this new indication by leveraging the MYFEMBREE brand and promotional synergies across uterine fibroids and endometriosis. And the $100 million milestone payment from Pfizer will fuel our financial strength and long-term growth, while we work to advance our pipeline.

Now let me turn the call over to Juan Camilo, who will walk us through the MYFEMBREE prescribing information and the relevant Phase III SPIRIT program clinical data. Juan Camilo?

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

Thank you, Dave. The approval of this new indication for MYFEMBREE is a proud achievement for our team and most importantly, a significant milestone in our commitment to redefine care for women with endometriosis. I would like to take this opportunity to thank the patients, families, clinicians and advocacy groups, all of whom played a critical role in bringing us to this milestone. We are grateful for their commitment to our common cause, and we celebrate with them this significant achievement.

Endometriosis is a highly debilitating disease, characterized by the appearance of tissue similar to the urine lining, but growing outside of the urine cavity that can have a significant negative impact in the lives of women. In our research, women have shared that their endometriosis symptoms have limited their ability to participate in the activities they want, made them feel invisible to others when their symptoms were dismissed, and sometimes made them unrecognizable even to themselves due to the significant mental and emotional toll that these feelings and symptoms bring.

Over the last 20 years, we have learned a lot about this disease; however, there remains a significant need for better treatment options. Although endometriosis is a benign disease, it can be associated with debilitating symptoms, such as menstrual pain or dysmenorrhea in about 80% of women with endometriosis, non-menstrual pelvic pain in about 78% and pain with intercourse or dyspareunia in about 58%.

During market research, we learned from clinicians of their desire for medical treatment options that deliver relief from the pain associated with endometriosis and reduce the need for repeated surgical procedures, have a manageable tolerability profile, allow women to rely less on prescription medications to manage their pain and are affordable and easy to access. Women with endometriosis deserve better options, and we believe MYFEMBREE has the unique potential to help address those treatment needs.

Now let's take a look at the details of the updated label for MYFEMBREE. MYFEMBREE is indicated for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. And now it's also indicated for the management of moderate-to-severe pain associated with endometriosis. MYFEMBREE is the first and only once-daily oral treatment approved for these 2 indications. As has been the case for women with uterine fibroids, the indicated use of MYFEMBREE in women with endometriosis should be limited to 24 months due to the risk of [continued] bone loss, which may not be reversible. MYFEMBREE, as a once-daily pill, can be taken with or without food and should be taken at around the same time each day.

Because endometriosis is a chronic disease, we designed our SPIRIT clinical development program to evaluate the long-term efficacy and safety of MYFEMBREE. SPIRIT 1 and 2 will replicate 24-week studies that evaluated women with endometriosis, who have moderate-to-severe dysmenorrhea and non-menstrual pelvic pain. Women eligible to participate were randomized 1:1:1 to receive placebo or MYFEMBREE for 24 weeks, or relugolix 40 milligrams monotherapy for 12 weeks, followed by 12 weeks of MYFEMBREE. We are proud to have had the results of the SPIRIT 1 and 2 studies published in The Lancet in June.

SPIRIT 1 and 2 had 2 co-primary endpoints. The first was the dysmenorrhea responder rate and the second was the non-menstrual pelvic pain or NMPP responder rate, both evaluated at week 24. For each study to be successful, both co-primary endpoints have to be met.

Dysmenorrhea and NMPP were assessed using a daily 11-point Numerical Rating Scale, or NRS, in which 0 reflected no pain and 10 reflected pain as bad as you can imagine. Various secondary endpoints, including change in NRS score, improvement in the impact of pain on daily functions, improvement of dyspareunia and change in the use of opioids were also evaluated at week 24.

At the conclusion of SPIRIT 1 and 2, women have the option of enrolling into an 80-week long-term extension study, in which all women received MYFEMBREE regardless of the treatment they received in SPIRIT 1 or 2. The regulatory submission leading to this approval was based on 52-week data, including 24 weeks from SPIRIT 1 and 2 on the first 28 weeks of the extension study.

In July, we presented at the European Society of Human Reproduction and Embryology results of the second year of treatment in the extension study, represented here by the [hatch] light purple on the right. These data demonstrated durability of treatment effect, no new safety signals and no evidence of progression in mean BMD changes over 2 years. We plan to submit these results to FDA in the first half of 2023 for potential labeling updates.

MYFEMBREE met the first co-primary endpoint in both SPIRIT 1 and 2, achieving a dysmenorrhea response rate of about 75% in both studies at week 24. The difference between the MYFEMBREE and placebo groups were statistically significant with a p-value of less than 0.0001 in both studies. MYFEMBREE also met the second co-primary endpoint in both studies, with NMPP responder rates of 58.5% and 65.9% in SPIRIT 1 and SPIRIT 2, respectively, at week 24. The difference between the MYFEMBREE and placebo groups was statistically significant with a p-value of less than 0.0001 in both studies.

Now let's review how pain improved over time. In women treated with MYFEMBREE, mean dysmenorrhea NRS scores improved over the first 2 cycles, with near maximum efficacy achieved by week 8 and maintained through week 24. Results in both SPIRIT 1 and 2 were consistent, as shown by the nearly superimposable lines at the bottom, with a reduction from baseline of 74.1% with MYFEMBREE compared with 26.4% with placebo in pool data from the 2 studies. These observed reduction in mean NRS score is considered clinically meaningful since it represents a reduction from severe pain at baseline to mild pain at week 24.

Similarly, in women treated with MYFEMBREE, mean non-menstrual pelvic pain NRS score improved progressively over time through week 24. Results in both studies were again consistent with a reduction from baseline in mean NRS score of 49.7% with MYFEMBREE compared with 36% with placebo in pool data from the 2 studies.

Relative to dysmenorrhea, the pathophysiology of NMPP is more complex, tends to be multifactorial and is more challenging to treat. With this context, the observed improvement from baseline in NMPP is meaningful since it represents a reduction from moderate pain at baseline to mild pain at week 24.

To assess how pain improvement would reduce the impact that pain has in the life of women, we use the Endometriosis Health Profile-30, a validated tool developed by Oxford University. It is a health-related quality of life, patient self-report instrument used to measure the wide range of effects that endometriosis can have on women's lives.

In particular, we pre-defined as a key secondary endpoint the change from baseline in the pain domain of the EHP-30, which assesses the impact of endometriosis pain on the ability to perform daily activities, like sleeping, sitting, walking and doing work around the house.

As you can see on the slide, treatment with MYFEMBREE was associated with progressive and significant reduction from baseline in mean EHP-30 pain scores of 57.9% compared with 32.6% in the placebo group in the 2 studies pooled. These results show that by improving multiple facets of pain, treatment with MYFEMBREE led to a significant reduction in the impact pain has in the ability of women with endometriosis to perform daily activities.

In women who had painful intercourse or dyspareunia at baseline and who reported to be sexually active at baseline and at week 24, treatment with MYFEMBREE was associated with a statistically significant reduction in the dyspareunia NRS score compared with placebo, with a p-value of less than 0.05 in both studies. We believe these results are meaningful in dyspareunia has been shown in other studies to have a significant impact on the woman's psychological health, characterized by poor self-esteem and sense of

femininity with negative consequences of -- on intimate relationships.

In many women, management of pain associated with endometriosis requires use of opioids. In both SPIRIT 1 and SPIRIT 2, improvement of pain in women treated with MYFEMBREE led to a significant reduction in the use of opioids relative to those who received placebo. As shown on the left, of women who were taking opioids at baseline, more than 60% of those who received MYFEMBREE were opioid-free at week 24 in both studies compared with 32.1% and 40.4% of those who received placebo in SPIRIT 1 and 2, respectively. On the right, in women who were not on opioids at baseline, less than 4% of those who received MYFEMBREE were using opioid rescue at week 24 in both studies, relative to 7.7% and 11.3% of those who received placebo in SPIRIT 1 and 2, respectively.

Now let's look at safety. No meaningful updates were made to the MYFEMBREE safety highlights in the label. As you know, the MYFEMBREE prescribing information includes a boxed warning. MYFEMBREE may increase the risk of thromboembolic disorders and vascular events, including pulmonary embolism, deep vein thrombosis, heart attack or stroke. Women over 35 years of age who smoke, women with uncontrolled hypertension or with other risk factors are at a greater risk for these events. No changes were made to the MYFEMBREE contraindications, which are summarized on the slide.

As I've already noted, MYFEMBREE's label includes that it may cause a decrease in bone mineral density, or BMD, in some women that may not be completely reversible. Baseline and periodic BMD assessments are recommended for women with heavy menstrual bleeding associated with uterine fibroids. In women with moderate-to-severe pain associated with endometriosis, annual dual energy X-ray absorptiometry, or DEXA, is recommended while taking MYFEMBREE. A complete list of warnings and precautions can be found in the MYFEMBREE prescribing information.

The most common adverse reactions reported in at least 10% of women treated with MYFEMBREE and at an incidence greater than placebo in SPIRIT 1 and 2 included headache, vasomotor symptoms and mood disorders. Adverse reactions reported in at least 5% but less than 10% of women treated with MYFEMBREE and at an incidence greater than placebo were abnormal uterine bleeding, nausea and toothache. All other adverse drug reactions were reported in less than 5% of women treated with MYFEMBREE. Common adverse reactions in the SPIRIT extension study were similar to those observed in SPIRIT 1 and SPIRIT 2.

Serious adverse reaction rates were low and similar in both treatment groups. Discontinuation due to adverse reactions were reported in 4.9% of women treated with MYFEMBREE compared with 2.9% of women receiving placebo. The most common adverse reaction leading to discontinuation of MYFEMBREE was mood disorders reported in 1.7% of women. The effect of MYFEMBREE on BMD was assessed by DEXA. The mean percent change from baseline in lumbar spine BMD at month 6 in the SPIRIT studies was minus 0.72% for MYFEMBREE compared to 0.12% for placebo.

In addition to the SPIRIT program, Myovant conducted a separate concurrent prospective observational natural history study that enrolled 452 women with endometriosis, who were age-matched to participants of the SPIRIT studies. The women in this study, who did not receive treatment for endometriosis as part of the study, underwent DEXA scans at month 6 and month 12 to monitor for changes in BMD. As you can see in the graph at the top, the mean percent change from baseline in BMD is the lumbar spine at month 6 was 0.35% and at month 12 was 0.53%.

At the bottom of the slide is data from 6 and 12-month time points of the SPIRIT clinical program are presented. At month 6, the mean percent change from baseline in BMD at the lumbar spine was minus 0.91% and at month 12 was minus 0.81%. After an initial reduction of BMD through week 24, no evidence of progressive bone loss was observed with mean changes in BMD from baseline over 1 year remaining at less than minus 1%.

After 1 year, a decline in lumbar spine BMD of greater than 3% was observed in 19.7% of women who received MYFEMBREE in the SPIRIT extension study and in 9.1% of untreated women in the natural history study. A decline of greater than 7% to less than or equal to 8% was seen in less than 1% of women in each group, and no patients with loss greater than 8% were observed in either group.

In summary, the clinical profile of MYFEMBREE reflected in the label shows best-in-class efficacy results for improvement of dysmenorrhea, NMPP and dyspareunia in a product approved for up to 2 years of use. Those improvements in measures of pain

translated in significant reduction in the impact of pain and ability to perform daily activities as measured by the EHP-30 pain domain. They also translated into a reduction in the proportion of patients using opioids to manage their pain.

Treatment with MYFEMBREE was associated with vasomotor symptoms in 13.7% of women, and these symptoms were generally mild or moderate in severity and unlikely to lead to treatment discontinuation. After an initial reduction of BMD through week 24, no evidence of progressive bone loss was observed, with mean changes in BMD from baseline over 1 year remaining at less than minus 1%. We are proud of our data and the potential for MYFEMBREE to make a meaningful positive difference in patient lives.

I will now turn it over to Lauren to discuss MYFEMBREE endometriosis launch [readiness]. Lauren?

Lauren Merendino ***Myovant Sciences Ltd. - Chief Commercial Officer***

Thank you, Juan Camilo. This is truly an exciting time for Myovant and for women with endometriosis. We are thrilled to launch MYFEMBREE together with our partner, Pfizer, later this month and redefine care for women struggling with this disease. Today, I'll review the progress we've made in preparing for the launch of MYFEMBREE in endometriosis-associated pain.

MYFEMBREE brings a unique and compelling new option for women with endometriosis. It's the only treatment that delivers meaningful relief across the most commonly reported pain symptoms with a tolerable safety profile in a simple one dose, once-a-day pill formulation. And due to our bone mineral density data, MYFEMBREE can be used long term, for up to 2 years. MYFEMBREE is the only GnRH antagonist that delivers on this trifecta of efficacy, tolerability and simplicity, which is truly an advance in the care for women with this challenging disease.

In order to realize the potential of MYFEMBREE in this new indication, our launch strategy has a comprehensive focus across providers, payers and patients. With health care providers, we will discuss MYFEMBREE's ability to deliver meaningful efficacy across the most commonly reported symptoms and a tolerable safety profile with the simplicity of one pill once a day. With payers, we've already successfully established coverage in uterine fibroids for 94% of commercial lives, and we believe we can leverage these policies to quickly add coverage for this important new indication.

For patients, we will be extending our comprehensive patient support programs to support women with endometriosis. These programs are especially helpful during the time frame in which we are establishing coverage in order to ensure ease of access for patients and simplicity for physicians and their staff. Since medical treatment is used more extensively in the management of endometriosis, over the long term, this new indication will approximately double the market opportunity for MYFEMBREE.

Our existing women's health teams across both companies with approximately 200 sales professionals will be launching the endometriosis indication in August. As you can see from the diagram here, the large majority of our targets for both indications overlap. This means that our teams are already calling on these customers and have established relationships and knowledge of their practices, enabling accelerated opportunities to speak to our new indications. We have also prioritized the subset of our highest potential endometriosis targets for rapid engagement immediately after launch.

As we add this new indication to our brand, it's important that we also maintain momentum in uterine fibroids as well. For this reason, we've deployed a 2-pronged strategy. First, continuing HCP engagement with our sales teams promoting both indications on the majority of calls. And secondly, increasing patient engagement through our uterine fibroid direct-to-consumer campaign that launched in June that will prompt patients to initiate discussions with their physicians. Overall, there's a great deal of synergy between these 2 launches that we can leverage across many elements of our brand promotion to maximize the overall promotional and financial efficiency of this launch.

Similar to uterine fibroids, over 80% of women with endometriosis are commercially insured. It's unusual to have any coverage at the time of approval, but based on prior coverage decisions, MYFEMBREE and endometriosis has almost 20% of commercial lives covered at launch. This percentage will grow -- will continue to increase as we actively engage with payers who are in the process of making coverage decisions for this new indication.

It's not only the breadth of coverage that's important, but also the quality of that coverage. We have already held preliminary discussions with key commercial payers and believe we are well positioned to establish affordable access for endometriosis patients within 6 months. In uterine fibroids, between our payer coverage and our support programs, 75% of patients pay $5 or less out of pocket, and our goal will be to deliver similar support for women with endometriosis as well.

Our full suite of top-tier support services that have been used to help uterine fibroid patients will now be extended to support patients with endometriosis. These resources include benefits investigation, prior authorization and appeal support, bridge programs, co-pay support for commercially insured patients and patient assistance for qualifying uninsured patients. We also have samples on the shelf at many practices to enable physicians and patients to gain experience with MYFEMBREE prior to filling a prescription. These programs have been positively received by physicians and patients to date, and the familiarity with these programs should make supporting endometriosis patients even easier for physician practices.

As we look across indications, the simplicity of MYFEMBREE is a clear differentiator. It's simple for physicians with one brand and one dose across indications, and easy for patients with just one small pill once a day. This simplicity, coupled with the power of our efficacy data, the tolerability of our safety profile and the ability to stay on treatment for up to 2 years truly sets MYFEMBREE apart and paves the way for MYFEMBREE to become a future standard of care for both indications. We are incredibly excited to be launching MYFEMBREE in endometriosis and making a difference in the lives of more women who can benefit from this innovative therapy.

I'll now turn it over to Dave for some closing remarks.

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Thank you, Uneek, Juan Camilo and Lauren. Myovant is well positioned for strong commercial execution and sustainable growth. The approval of MYFEMBREE in endometriosis contributes to our growth trajectory to deliver long-term value. We believe MYFEMBREE can become a standard of care by delivering meaningful relief across the most commonly reported pain symptoms and offering a tolerable and simple option that most prescribers want in both endometriosis and uterine fibroids treatment, thereby fully unlocking the potential of this market.

With the approval of MYFEMBREE's 1-year data for endometriosis, we plan to build on this foundation and submit our 2-year data to the FDA in the first half of 2023.

Thank you for your attention, and I'll turn it over to the operator to begin the Q&A session.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question will come from Philip Nadeau of Cowen.

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

Congratulations on the approval. First, a question on insurance coverage. In your prepared remarks, you mentioned that it would take about 6 months, you think, to secure reimbursement. Is that process faster this time around because of the [UF] approvals and insurance there? Does that -- does the fact that you've already secured reimbursement for one indication to speed the process of getting reimbursement now for the second one in endometriosis?

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Yes, certainly. Lauren?

Lauren Merendino ***Myovant Sciences Ltd. - Chief Commercial Officer***

Yes. Thank you for the question. Of course, payer decisions are on their own timeline, so -- with that caveat. But what I will say is we do believe it accelerates the process to establish coverage because we already have coverage for MYFEMBREE in uterine fibroids. You may remember when we launched in uterine fibroids, we projected broad coverage to be established within a year. So in this case, we're saying that it will be a -- we expect it to be established within 6 months, so we do expect it to be faster.

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

That's helpful. And then second question is on the market dynamics. I think most people have been underwhelmed by ORILISSA'S uptake. What does your market research say has been a problem with that launch? What lessons can you learn from the slow launch of ORILISSA?

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Yes. Well, I think one of the areas that we have certainly learned from is the success that we've had in uterine fibroids and making sure that we're delivering what our gynecologists and patients are looking for.

Lauren, I'll turn it over to you for more specifics around how we believe that our efforts will compete effectively.

Lauren Merendino ***Myovant Sciences Ltd. - Chief Commercial Officer***

Yes. So first of all, our clinical profile, we believe in the strength of our clinical profile, right? Juan Camilo reviewed the compelling efficacy data that we have as well as the safety information, and the fact that you can use our product up to 24 months to achieve that efficacy and safety profile, plus the simplicity of one pill once a day. So we think we believe our profile is differentiating and compelling to physicians based on the research that we've done.

Additionally, having launched MYFEMBREE already in uterine fibroids, we already have prescribers with experience for the product and have built momentum as we've discussed in uterine fibroids. So we believe that sets us up for success as well. And you've seen the response we've had in uterine fibroids, and we expect to be able to translate that into this market as well.

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

Congratulations again.

Lauren Merendino ***Myovant Sciences Ltd. - Chief Commercial Officer***

Thank you.

Operator

Our next question will come from Hannah Adeoye of JPMorgan.

Hannah Temiloluwa Adeoye ***JPMorgan Chase & Co, Research Division - Research Analyst***

It's Hannah on for Eric Joseph. Just a few from us. So are you able to provide just any insight on the market expansion of the GnRH class we've observed since the launch of MYFEMBREE in uterine fibroids? I believe you said about 180% growth. And just from your market research, have there been any key characteristics of MYFEMBREE that physicians or patients themselves specifically highlighted as drawing them to try that specific drug as their first, GnRH antagonist? And what that might signal for the potential for similar competition in endometriosis?

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Yes. So we're really proud of not only capturing share within the GnRH antagonist marketplace, but as we've said from the beginning, it's less about just capturing share and more about ensuring that more women have access and are utilizing contemporary treatments, specifically around MYFEMBREE. So when we see growth rate of the class of 180-plus percent, it speaks to our strategy is working, the product profile is working, and we're gaining momentum.

Lauren, I'll turn it over to you for some of the rationale for why we believe that's happening.

Lauren Merendino ***Myovant Sciences Ltd. - Chief Commercial Officer***

Yes, so thank you. In uterine fibroids, we've seen tremendous uptake with MYFEMBREE. As we shared at our earnings call last week, we now have crossed the threshold where we are the market leader on both NBRx and TRx, as well as the market growth that you mentioned of 180%. This is really driven by our clinical profile, which is differentiated, as well as our field execution and our strategy overall. And response from physicians has been clear, we have -- the majority of our prescribers are new to writing an approved GnRH for uterine fibroids, and a lot of that is driven by the differentiated clinical profile and also the fact that it's one pill once a day. Many of these patients start on an oral contraceptive, and so it's an easy transition and a simple and easy-to-use product with it being once a day.

So we do expect the experience they've had in uterine fibroids to translate to endometriosis and expect to drive new use there as well, both from current prescribers as well as bringing new prescribers to the table.

Hannah Temiloluwa Adeoye ***JPMorgan Chase & Co, Research Division - Research Analyst***

Okay. Very helpful. Congrats on the approval.

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Thank you, Hannah.

Operator

One moment. And our next question will come from Madhu Kumar of Goldman Sachs.

Unidentified Analyst

This is Rob on for Madhu. Congratulations. I was just wondering how should we think about the operating margin impact of MYFEMBREE now being available in 2 indications? And is there anything you'll do differently from your marketing efforts to expand the GnRH market?

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Well, thanks, Rob. First, I think in the remarks, we are very focused on an efficient launch. Lauren certainly reviewed the vast majority of prescribers our prescribers were already calling on. More specifically, I'll turn it over to you, Uneek, to talk about any impact on margin.

Uneek Mehra ***Myovant Sciences Ltd. - Principal Financial Officer***

Yes. Thanks, Rob. I mean, in totality, we're very pleased with the approval of MYFEMBREE in endometriosis. Given what Lauren explained about the overlaps with the targets as well as on our commercial programs, we do expect a great amount of synergies in terms of how we spend, so our spend will be pretty effective across now both indications from MYFEMBREE. And that means we will benefit, as you can imagine, from the revenues without substantial investment on the OpEx side. So that should lead into a considerable margin improvement, not only just for the MYFEMBREE franchise in total, but also overall for Myovant.

Operator

(Operator Instructions) And our next question will come from Roanna Ruiz of SVB Securities.

Roanna Clarissa H. Ruiz ***SVB Securities LLC, Research Division - Director of Infectious Disease, Endocrine & Cardiovascular Disorders & Senior Research Analyst***

So I wanted to check in, and not sure if I missed this. In terms of your deficiency letter that you had a few months ago, is it safe to say that that's fully resolved? And any extra color that you might have on your FDA interactions around that would be super helpful. And I have a follow-up after that.

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Okay. Roanna, I'll let Juan Camilo address the interactions with FDA.

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

Yes. So Roanna, what I can say is that we're very pleased with the label we got. And we provided -- you recall the -- you referred to the deficiency letter we obtained. Remember after that, we got a request for information from the FDA, which we provided, and that led to moving into labeling negotiations, and now an approval with the label that is pretty good from our perspective. So although I do not want to speculate or try to address the question that the FDA should address, I believe that whatever was holding at the time, their ability to move forward was resolved because we are here with an approval.

Roanna Clarissa H. Ruiz ***SVB Securities LLC, Research Division - Director of Infectious Disease, Endocrine & Cardiovascular Disorders & Senior Research Analyst***

Got it. That helps. And I was also curious, maybe could you speak a little bit about the competitive dynamic that you might expect in endometriosis between MYFEMBREE and AbbVie's ORILISSA? I believe ORILISSA has done a bit better in endometriosis than ORIAHNN did in uterine fibroids, so I'm curious how you're thinking about that dynamic? And I know one of your goals is also to expand the overall class, so I think that's also really interesting. Any extra color there?

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Sure. Lauren?

Lauren Merendino ***Myovant Sciences Ltd. - Chief Commercial Officer***

Yes. Thank you for the question. So you're correct. ORILISSA's uptake in endometriosis is greater than ORIAHNN in uterine fibroids. As you know, ORILISSA has 2 dose formulations, a high dose and a low dose. The low dose is 80% of ORILISSA's use based on the research -- based on the data that we have. And when you -- and so the benefit of MYFEMBREE as we come into this market is that we can deliver the efficacy that is top of the class. So more similar to their higher dose, but with a one pill, once-a-day formulation and a tolerable safety profile. So we believe that we can deliver better on the overall profile of the product and set ourselves apart.

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

And maybe I can add to that. This is Juan Camilo. I think as a gynecologist and thinking from a practice perspective, having now the 2 indications in same label, same dose, same regimen and the profile of efficacy and safety, I think it's going to be really appealing to gynecologists. And the other piece that I want to remind you is that there is a large proportion, close to 25% of women that may have both uterine fibroids and endometriosis, and therefore, that would also bring simplicity for the practice.

Lauren Merendino ***Myovant Sciences Ltd. - Chief Commercial Officer***

But of course, we have no studies that are looking across both products. So we're -- they're independent studies, but that is our assessment.

Roanna Clarissa H. Ruiz ***SVB Securities LLC, Research Division - Director of Infectious Disease, Endocrine & Cardiovascular Disorders & Senior Research Analyst***

Got it. Helpful.

Operator

And our next question will come from Gavin Clark-Gartner of Evercore ISI.

Gavin Clark-Gartner ***Evercore ISI Institutional Equities, Research Division - Analyst***

Congrats on the approval. I'm just wondering, in the real-world setting, what do you think is the average duration of treatment for MYFEMBREE? And do we know what it is for ORIAHNN or ORILISSA also?

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Lauren?

Lauren Merendino ***Myovant Sciences Ltd. - Chief Commercial Officer***

So at this point, it's too early for us to speculate on the duration of therapy for MYFEMBREE. However, we do have the ability to be utilized for up to 2 years.

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Gavin, do you have a follow-up?

Gavin Clark-Gartner ***Evercore ISI Institutional Equities, Research Division - Analyst***

Do we know what the average duration of treatment is for ORIAHNN or ORILISSA, given that those have been on the market longer, or could we just not see it based on the available data?

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

I don't think we have data that we're ready to determine their average duration of therapy. As you know, you have the -- many times, it requires kind of claims data, et cetera, so we don't have a point of reference for you today.

Gavin Clark-Gartner ***Evercore ISI Institutional Equities, Research Division - Analyst***

Okay, got it.

Operator

And I'm now showing no further questions. I would now like to turn the conference to David Marek, Chief Executive Officer of Myovant for closing remarks.

David C. Marek ***Myovant Sciences Ltd. - CEO & Director***

Thank you. Well, as you can see, Myovant is at a very exciting time in our evolution, and we're well positioned both operationally and financially to deliver strong commercial execution and build sustainable long-term value. So thank you, and I look forward to keeping you updated on our progress.

Operator

Ladies and gentlemen, this concludes today's conference. Thank you for participating. You may now disconnect.