EDITED TRANSCRIPT

MYOV – ORGOVYX FDA Approval Conference Call

EVENT DATE / TIME: DECEMBER 21, 2020 / 8:30 AM ET

OVERVIEW:
FDA approval of ORGOVYX (relugolix 120 mg) for advanced prostate cancer.

CORPORATE PARTICIPANTS

Ryan Crowe; Myovant Sciences; Vice President of Investor Relations

Lynn Seely; Myovant Sciences; CEO

Adele Gulfo; Myovant Sciences; Interim Chief Commercial Officer

Frank Frabe; Myovant Sciences; President & CFO

Juan Camilo Arjona; Myovant Sciences; Chief Medical Officer

CONFERENCE CALL PARTICIPANTS

Phil Nadeau; Cowen and Company, LLC; Analyst

Josh Schimmer; Evercore Inc.; Analyst

Eric Joseph; JPMorgan Chase & Co.; Analyst

Ami Fadia; SVB Leerink; Analyst

Paul Choi; Goldman Sachs Group Inc.; Analyst

Mohit Bansal; Citigroup Inc.; Analyst

Brian Skorney; Robert W. Baird & Co.; Analyst

Jason Butler; JMP Securities LLC; Analyst

PRESENTATION

Operator

Good day, everyone and welcome to Myovant Sciences ORGOVYX FDA Approval Conference Call. Today's call is being recorded.

At this time, I would like to turn the call over to Mr. Ryan Crowe, Vice President of Investor Relations at Myovant. Please go ahead.

Ryan Crowe – Myovant Sciences, Inc. – VP of IR

Good morning and welcome to Myovant Sciences' conference call to discuss the FDA approval of ORGOVYX for advanced prostate cancer. Our press release as well as the slides that will be presented during today's webcast are available on our investor relations website, investors.myovant.com. Joining me for today's call are: Dr. Lynn Seely, Myovant's Chief Executive Officer; Frank Karbe, President and Chief Financial Officer; Adele Gulfo, Interim Chief Commercial Officer; and Dr. Juan Camilo Arjona, Chief Medical Officer.

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

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

Lynn Seely – Myovant Sciences, Inc. – CEO

I am very proud to announce that the FDA approved ORGOVYX, our oral relugolix monotherapy 120 mg tablet, for the treatment of adult patients with advanced prostate cancer. As the first and only approved oral gonadotropin-releasing hormone, or GnRH, receptor antagonist, ORGOVYX represents an important new treatment option for men with advanced prostate cancer.

ORGOVYX offers patients rapid, profound and sustained reduction in testosterone levels, the flexibility to reverse testosterone suppression after treatment discontinuation, and, as shown in the Phase 3 HERO study, a lower incidence of major adverse cardiovascular events compared to leuprolide injections, the current standard of care. And ORGOVYX can achieve all this as a convenient one-pill, once-a-day therapy.

Prostate cancer is the second most common type of cancer in men in the United States, with approximately 3 million men living with the disease. Of those, approximately 300 thousand patients are projected to receive androgen deprivation therapy, or ADT, in 2021. Of the 300 thousand patients, approximately 100 thousand will initiate ADT next year with about 200 thousand continuing their prostate cancer treatment journey on ADT. Importantly, due to advances in prostate cancer care and an aging population, the number of advanced prostate cancer patients in the U.S. is expected to increase by mid-single-digits annually over the medium term.

Two out of three men with prostate cancer have cardiovascular risk factors and an estimated 30 percent of prostate cancer patients have diagnosed cardiovascular disease. In fact, more men with prostate cancer die of cardiovascular disease rather than from prostate cancer. Notably, injectable LHRH agonists as well as other prostate cancer medicines may increase the risk of cardiovascular events. The urology and oncology communities are beginning to recognize this troubling reality and is one of the main reasons why the development and launch of ORGOVYX is so important for patients with advanced prostate cancer.

Prostate cancer is a disease driven by testosterone. Androgen deprivation therapy, which lowers testosterone to very low levels, is used as the first-line medical therapy for advanced prostate cancer. Prostate cancer is considered advanced when it has spread or come back after initial treatment and may include biochemical recurrence, indicated by a rising PSA in the absence of metastatic disease on imaging, locally advanced disease, or metastatic disease. As men progress from castration-sensitive to castration-resistant disease, ADT is continued and other therapies are added to this foundational treatment. As patients progress through their disease course, the treatment rate with ADT increases with worsening disease state.

Injectable LHRH agonists, such as leuprolide acetate, are the current ADT standard of care, but are associated with mechanism of action limitations, including an initial surge in testosterone levels that can exacerbate clinical symptoms, a side effect known as clinical or hormonal flare. Because of the testosterone surge, it can take weeks following the initial LHRH agonist injection to suppress testosterone and to reduce PSA levels, the biomarker widely used to assess disease activity. LHRH agonists are also associated with delayed testosterone recovery when discontinued due to their long-acting depot formulations. Finally, according to FDA prescribing information, there are several warnings and precautions associated with the use of LHRH agonists including: tumor flare; hyperglycemia and diabetes; cardiovascular diseases including increased risk of myocardial infarction, sudden cardiac death and stroke; as well as QT/QTc interval prolongation; and convulsions.

ORGOVYX is the first and only oral GnRH antagonist which offers men with advanced prostate cancer rapid, profound, and sustained testosterone suppression without hormonal flare, and testosterone recovery for the majority of patients within 90 days of treatment discontinuation. And men treated with ORGOVYX in the Phase 3 HERO study had a lower incidence of major adverse cardiovascular events,

including heart attacks, strokes, and death from any cause, compared to those receiving leuprolide injections, all with one pill once-a-day. With the FDA approval of ORGOVYX, men with advanced prostate cancer will soon have an alternative to the injections they currently receive, which require travel to the clinic or hospital for administration. This is particularly important during the COVID-19 pandemic.

Now let me now turn the call over to Juan Camilo who will walk us through the ORGOVYX label and clinical data. Juan Camilo?

Juan Camilo Arjona – Myovant Sciences – Chief Medical Officer

Thank you, Lynn. The approval of ORGOVYX is certainly a proud achievement for our team and, more importantly, a significant development for men with advanced prostate cancer. Before I begin, 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 the approval of ORGOVYX. We are grateful for their support and we jointly celebrate this achievement on behalf of patients with prostate cancer.

The FDA granted approval for ORGOVYX following a priority review. We believe this reflects the differentiated clinical benefits and safety profile demonstrated by ORGOVYX in the Phase 3 HERO study, which compared ORGOVYX to leuprolide acetate injections. ORGOVYX is indicated for the treatment of adult patients with advanced prostate cancer and is the first and only oral androgen deprivation therapy. Its once-daily film-coated tablet formulation has a diameter of about 1 centimeter, enabling easy ingestion, and can be taken with or without food. On Day 1 of treatment, a loading dose of 360 mg, composed of three 120-mg tablets, should be administered. Following that, one 120 mg tablet of ORGOVYX should be taken once daily.

The results of the HERO study, published in the New England Journal of Medicine earlier this year, supported our NDA filing and the FDA's approval of ORGOVYX. HERO was a multinational Phase 3 randomized, open-label, parallel group study to evaluate the safety and efficacy of ORGOVYX in men with advanced prostate cancer. Overall, 934 patients with advanced prostate cancer underwent 2:1 randomization and received 48 weeks of either: ORGOVYX 120 mg orally once daily after one-time 360 mg loading dose or a leuprolide injection every 3 months.

ORGOVYX met the primary endpoint of the HERO study, achieving a 96.7 percent response rate with sustained castration through week 48 compared to an 88.8 percent response rate for leuprolide. The FDA label describes the ORGOVYX and leuprolide response rates along with their non-overlapping 95% confidence intervals.

ORGOVYX achieved rapid and profound testosterone suppression compared to leuprolide acetate that was sustained through 48 weeks. As you can see on the left side of the graph, the decline in testosterone with ORGOVYX occurred by Day 4 after treatment initiation and ORGOVYX did not exhibit the surge in testosterone experienced by patients in the leuprolide group during the first few weeks following treatment initiation. By Day 15, ninety-nine percent of ORGOVYX-treated patients achieved castrate levels of testosterone vs. 12 percent of those receiving leuprolide injections.

The majority of men receiving ORGOVYX achieved testosterone suppression to castrate levels of less than 50 nanograms per deciliter on or before Day 4 compared with zero men on leuprolide. At Day 15, testosterone was suppressed to profound castrate levels of less than 20 nanograms per deciliter in 78 percent of men on ORGOVYX vs. 1 percent of men on leuprolide. And after only one month on therapy, PSA was reduced by 83 percent in men treated with ORGOVYX.

Also notable was testosterone recovery for patients in the ORGOVYX group, which you can see on this graph. A sub-study was conducted in 184 men eligible to discontinue ADT. Fifty-five percent of men achieved testosterone levels in the normal range or above baseline within 90 days after discontinuation of ORGOVYX, compared to 3 percent of men in the leuprolide group. This may be particularly important for patients who receive time-limited treatment courses and would benefit from a faster return to normal testosterone levels.

The Warnings and Precautions for ORGOVYX include QT interval prolongation, embryo-fetal toxicity, and laboratory testing. Similar warnings for QT interval prolongation appear across all androgen deprivation therapies, as does a laboratory testing warning that these therapies result in suppression of pituitary gonadal hormones. An embryo-fetal toxicity warning and precaution is also listed. The co-administration of ORGOVYX and P-glycoprotein inhibitors or combined P-gp and strong CYP3A inducers should be avoided. The prescribing information provides options for when co-administration is unavoidable. Atorvastatin, rosuvastatin, CYP3A inhibitors, acid reducing agents and enzalutamide may be co-administered with ORGOVYX.

The most common adverse reactions occurring in at least 10 percent of patients included hot flush, musculoskeletal pain, fatigue, constipation, and diarrhea. The incidence and severity of common adverse reactions were similar for ORGOVYX compared to leuprolide. The events of constipation and diarrhea were graded as mild or moderate and were generally short in duration. The most common laboratory abnormalities occurring in at least 15 percent of patients included glucose increased, triglycerides increased, hemoglobin decreased, alanine aminotransferase increased, and aspartate aminotransferase increased. The incidence and severity of these laboratory abnormalities were generally consistent across the ORGOVYX and leuprolide study groups.

In the FDA label for ORGOVYX, fatal and non-fatal myocardial infarction and stroke were reported in 2.7% of patients receiving ORGOVYX. In the HERO study, as published in the New England Journal of Medicine, the incidence of major adverse cardiovascular events -- defined as nonfatal myocardial infarction, nonfatal stroke, and death from any cause -- was 2.9% in the ORGOVYX group and 6.2% in the leuprolide group after 48 weeks of treatment. The graph displays the cumulative incidence of major adverse cardiovascular events with leuprolide in gray and ORGOVYX in yellow. Depending on the presence of cardiovascular risk factors, men with prostate cancer are estimated to have a yearly incidence of major adverse cardiovascular events of approximately 2% to 3%, similar to that observed in the ORGOVYX group in the HERO study.

I will now turn the call over to Adele to discuss the launch strategy, Adele?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Thank you, Juan Camilo. This is truly an exciting time for Myovant and for prostate cancer patients. We are thrilled to launch ORGOVYX, our first product, in the United States in January. Today, I'll review the progress we've made against our launch priorities, which we introduced to you on our second-quarter earnings call last month.

Our upcoming launch will focus on three priorities as we position ORGOVYX to become the new standard of care in advanced prostate cancer. First, we will focus on educating urologists and oncologists on key ORGOVYX product attributes. Second, we will work to establish broad access to Orgovyx, including continuing to work with payers, supporting our specialty pharmacy distribution model and facilitating patient access through the Orgovyx support program. Finally, once physician education and access milestones are met, we intend to activate patients and their care partners on the efficacy and safety of ORGOVYX, while highlighting the convenience of its one-pill, once-a-day dosing.

In terms of educating prescribers, we are starting with a strong foundation despite the COVID pandemic, which was built through our Medical Affairs team over the last several months. Physician awareness of ORGOVYX is high for a product that has yet to launch. Fifty-nine percent of urologists and medical oncologists surveyed earlier this year were aware of ORGOVYX, with half of those doctors already knowledgeable about the product profile. Additionally, in a separate survey, 60% of physicians indicated they are either extremely likely or very likely to prescribe ORGOVYX after learning about the target product profile.

We recently completed the hiring of our field force of 100 sales professionals and training is well underway so the team can launch ORGOVYX early in the new year. The diverse team was intentionally built with sales professionals selected based upon their urology and oncology experience and pre-existing relationships with key physicians. We've been planning for months for a virtual launch into a COVID pandemic, and so selection criteria also included being tech savvy, adept with virtual detailing, and enthusiastic about incorporating advanced analytics to drive results. Many of our sales professionals came to Myovant with endorsements from prostate cancer opinion leaders and have been previously recognized as top performers. Our sales team will initially target the 10 thousand physicians that write the vast majority of the ADT prescriptions.

Our sales professionals will be equipped with materials to educate physicians on the ORGOVYX profile and what differentiates it from other ADT treatment options. On the slide are two examples of these materials, including our core visual aid and our access leave-behind, which covers components of our patient support program. Another core educational aid for prescribers is the New England Journal of Medicine publication that details the results of the HERO study. We have developed a re-print carrier that summarizes these results and includes a full reprint of the publication as well as the ORGOVYX prescribing information.

Patient access is also an important priority for us at launch. We anticipate 50% of ORGOVYX patients will be commercially insured. 45% are expected to be covered by Medicare Part D, of which approximately half are anticipated to be supported by either Employer Group Waiver Programs or Low-Income Subsidies. Taken together, 75 percent of ORGOVYX patients are expected to have access support through either our commercial co-pay assistance program or plans with Part D subsidies. As a result of our pre-launch work with payers, we are well-positioned and expect key commercial plan decisions and coverage initiations to be implemented in the first half of 2021, with other commercial plans coming on later in the year. For Medicare, we will submit our bid for the 2022 plan year and expect a decision on Part D coverage in the first half of 2021. We expect some limited Part D adds in the second half of 2021. Regarding price, the ORGOVYX wholesale acquisition cost is approximately $2,300 dollars per month. Our decision on price took into careful consideration the value that ORGOVYX brings to patients and the broader healthcare system while balancing our goals of driving uptake and maintaining patient affordability.

Distribution is also an important part of establishing broad access. We will be distributing ORGOVYX through a specialty pharmacy network and working closely to support practices with in-office dispensing capabilities. We estimate approximately 60 percent of large group practices currently have in-office dispensing capabilities, and that proportion continues to grow year over year. We expect these practices will generate the majority of ORGOVYX volume. Practices that do not have in-office dispensing will be able to access ORGOVYX through our specialty pharmacy network.

Myovant is launching the ORGOVYX Patient Support Program, which provides benefits investigation, prior authorization and appeals support, free trial for up to 2 months of therapy, copay support for commercially-insured patients, and patient assistance for qualifying, uninsured patients. There will also be virtual reimbursement managers to help facilitate access and a nurse support hot-line for patient adherence.

We have worked hard to ensure accessing ORGOVYX will be as easy as possible for patients and physicians – whether initiating therapy or transitioning to ORGOVYX from other treatment options. Finally, once physician education and access milestones are met, we will deploy a highly targeted and focused education campaign to ensure that patients and their care partners are aware of this new oral treatment option.

Our market research indicates that a majority of patients are dissatisfied with the current standard of care injections, that they prefer a pill to a shot, and are willing to actively engage in their treatment decisions. We are ready to launch ORGOVYX in January as there is clearly a need for an oral ADT treatment option, especially during a pandemic.

We look forward to keeping you updated on our progress. I'll now turn it back to Lynn for some closing remarks.

Lynn Seely – Myovant Sciences, Inc. – CEO

Thanks Adele and Juan Camilo. As a reminder, ORGOVYX is not Myovant Science's only commercial opportunity. We are also in the process of expanding the relugolix franchise to potentially include a new product in women's health, our relugolix combination tablet that will be separately branded.

We have multiple clinical and regulatory milestones in women's health over the next 12 months. Our new drug application for uterine fibroids is currently under review by the FDA with a target action date of June 1, 2021 and is also under review by the European Medicines Agency with a decision expected next year. In endometriosis, we plan to file for regulatory approval in the U.S. in the first half of next year.

Our focus is squarely on successfully executing these launches and bringing these important therapeutic options to patients. We are in a strong financial position with approximately 460 million dollars of cash and committed financing as of September 30th to appropriately resource these upcoming product launches. Finally, Myovant maintains the full US rights for the relugolix franchise. Thank you for your attention.

I will now turn it over to Ryan to begin the Q&A session.

Ryan Crowe – Myovant Sciences, Inc. – VP of IR

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

QUESTIONS AND ANSWERS

Operator

Thank you. (Operator Instructions)

Our first question comes from Phil Nadeau from Cowen & Company.

Phil Nadeau; Cowen and Company, LLC; Analyst

Good morning, congratulations on the approval. It's great news. First, a couple of questions on marketing. Can you talk a little bit more about how you can market the CV benefit or the lack of cardiovascular disease warning in the label. I know you mentioned New England Journal of Medicine Paper. But how aggressive can you be at pointing out those differences between relugolix and leuprolide?

Lynn Seely – Myovant Sciences, Inc. – CEO

Thanks, Phil. Yes, we are absolutely ecstatic to get this approval. And why don't I let Adele answer your question.

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Sure, hi, thanks, everyone. With regard to the cardiovascular benefit, what I would say is, as we mentioned -- as I mentioned in my opening remarks, our sales representatives will have the New England Journal of Medicine reprint carrier as well as the full publication. The reprint carrier will highlight those key benefits and specific points that we are able to make as it relates to the cardiovascular benefits for ORGOVYX. So we're very confident they'll have the New England Journal reprint carrier and they'll have -- be able to give the physicians that full manuscript, the full publication.

Phil Nadeau; Cowen and Company, LLC; Analyst

And what about specifically on the lack of a cardiovascular disease warning on your label or as leuprolide has one. Can you point that out to physicians, specifically in try to move patients with cardiovascular disease on to relugolix?

Lynn Seely – Myovant Sciences, Inc. – CEO

So certainly, Phil, we will be talking and pointing out the important safety information for ORGOVYX. And I think we're very pleased with the overall profile and believe that the profile is going to be compelling to physicians, not only because of the benefit, the safety as well as the oral administration. And so we believe our sales representatives are going to be well positioned to provide physicians with the information they're going to need to make the decision.

Phil Nadeau; Cowen and Company, LLC; Analyst

Perfect. And then one question on price and reimbursement. Have you had discussions with commercial payers about your proposed price? And do you have any sense of whether they'll be tiering or prior auths necessary?

Lynn Seely – Myovant Sciences, Inc. – CEO

Sure. Thanks, Phil. No, we have been working with payers for months now, both doing payer research as well as having our national account directors out into the field. And so we were very carefully considered the price that we selected and to make sure that it brought the right balance for bringing the

value of ORGOVYX to patients and the broader health care system. And then, of course, also making sure that it could drive uptake and maintain patient affordability. So we believe we're well positioned, and we'll be working very hard to gain access as quickly as possible.

Phil Nadeau; Cowen and Company, LLC; Analyst

Great, congratulations again and thank you for taking my questions.

Operator

Thank you. Our next question comes from Josh Schimmer from Evercore ISI. Your line is open.

Josh Schimmer; Evercore, Inc.; Analyst

Thank you for taking my questions and my congrats as well. First, for the survey where the respondents indicated likelihood to prescribe. Did you get a sense for those who were not likely or very likely to prescribe what their rationale is and the extent that could be overcome for the rest of the population?

Second, the CYP3A inducers, how many patients in the Phase III were on CYP3A inducers? What are the most common examples? Just trying to get a sense as to whether that's something that will be a common phenomenon that needs to be avoided. And then last, the fetal tox language in the package insert. Can you discuss if that has any impact on the women's health indications or additional studies being done and will yield a different label for the women's health indications for relugolix? Thank you.

Lynn Seely – Myovant Sciences, Inc. – CEO

Thanks, Josh. So why don't I let Adele begin with a question on the survey.

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Right. Thank you. Actually, when you take into account what I highlighted that 60% was very or extremely. If you factor in the entire pool of physicians that we surveyed that would either be all the way through somewhat likely, it's actually 95%. So it wasn't like we had a large percent at all that was not interested. So I really wanted to just capture in my statistic, that 60% number. But Josh, to your point, 95% we're all-inclusive of the very likely or even somewhat likely to prescribe.

Lynn Seely – Myovant Sciences, Inc. – CEO

Juan Camilo, do you want to answer the question about the CYP3A inducers?

Juan Camilo Arjona; Myovant Sciences; Chief Medical Officer

Yes. Thank you. Thanks, Josh. So for DDI inducers, your question was about the number of patients participating HERO. Use of DDI P-gp inducers during the HERO trial was not allowed. So we didn't have many patients taking any of those. But the -- the clear example that we have, one example is apalutamide, which is the drug we expect to be used in combination with ORGOVYX and what we are

very pleased is that we have an option for how to use ORGOVYX by doubling the dose with P-gp inducers.

With regard to the embryo tox, the data is consistent with other drugs in class, right? This is driven by the mechanism of GnRH antagonism. And what it does is that women that are pregnant should not take relugolix. And if they get pregnant while taking relugolix they should not be -- they should not -- they should stop it immediately.

Lynn Seely – Myovant Sciences, Inc. – CEO

And that's, of course, very consistent. The GnRH antagonist for women's health currently on the market are contraindicated for pregnancy.

Josh Schimmer; Evercore, Inc.; Analyst

Got it, thanks very much and congrats again.

Operator

Thank you. Our next question comes from Eric Joseph from JP Morgan. Your line is open.

Eric Joseph; JPMorgan Chase & Co.; Analyst

Hi. Good morning, my congrats on approval, and thanks for taking the questions. With respect to Part D coverage. Do you have a sense of the amount of discounting that you would need to incur from WAC relative to commercial? And I guess in the early phase of the launch here, do you have a sense of the amount of -- will you providing sampling to physicians, do you have sense for the sampling that might be used? And will you also be allowing third-party data providers to share prescription information?

Lynn Seely – Myovant Sciences, Inc. – CEO

Sure. Why don't I start just with that last question first about third-party prescription data. So we are not going to be blocking data from the third-party providers. So it will be available. However, as you know, the data are always incomplete and particularly early in the launch, are a little bit difficult to interpret. And for example, we will be having this free trial program, which will not be showing up. So we'll be, as the launch progresses, providing you with updates, so you can have a better feel for how things are going, but I just want to be clear about that. Adele, maybe you can take the question about sampling and Part D coverage.

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Well, let me remind you that for ORGOVYX patient population, approximately half or 50% of our patients will be commercially insured, and the majority will pay no more than $10 a month out of pocket. For the 45% that are on Medicare, that have Medicare coverage. We know that about half of those patients have either employer group waiver plans or part of the low-income subsidy.

So that brings about another 25%, making total overall 75% of the overall ORGOVYX population are expected to either be commercially insured or eligible for a Part D subsidy, which means they're out-of-pocket costs will be much more affordable, as I said, either less than $10 for the commercial or part of those other plans. Relative to the discounting we're going to do and the gross to net there, we're not going to provide information on that.

Frank Karbe; Myovant Sciences; President and Chief Financial Officer

One thing I want to mention yes. I would just add to this, Eric. Keep in mind that ORGOVYX, as an oral therapy will be managed under the pharmacy benefit while Lupron and other injectable ADT therapies are managed under the medical benefit. The discounting dynamics between the two are quite different. And consequently, we expect the ORGOVYX gross to net discount on average to be significantly lower than what it is for LUPRON.

Eric Joseph; JPMorgan Chase & Co.; Analyst

Got it, that's helpful, thanks for taking the questions and congrats again.

Operator

Thank you. Our next question comes from Ami Fadia from SVB Leerink. Your line is open.

Ami Fadia; SVB Leerink; Analyst

Congratulations on the approval. With regards to the gross to net, the comment that you just had, for LUPRON, the gross to net is significantly high. Can you give us a little bit more color, is the gross to net for this product going to be more in line with sort of the industry standard for typical products, more in the 35% range, not? And then my second question is, where do you expect to see the initial adoption of the product? And beyond kind of the newly diagnosed patients, what are you going to be doing to drive adoption in patients who are already on androgen deprivation therapy or patients who've been on therapy but have high cardiovascular risk profile? And then lastly, are you willing to talk about sort of the peak sales potential in this indication?

Lynn Seely – Myovant Sciences, Inc. – CEO

I didn't -- Ami, I didn't hear the last question. Can you repeat the last part of it.

Ami Fadia; SVB Leerink; Analyst

The last question is just can you give us a sense of the peak revenue potential for the product?

Lynn Seely – Myovant Sciences, Inc. – CEO

Okay. So why don't -- there are many parts in that. So let's see if I can bring them out. So Frank, do you want to comment on the gross to net?

Frank Karbe – Myovant Sciences – President and Chief Financial Officer

Yes. Ami, we're not providing guidance on the gross to net discounting. Other than saying that the gross to net discounting for ORGOVYX, again, is expected to be significantly lower than what you typically see for LUPRON.

Lynn Seely – Myovant Sciences, Inc. – CEO

And I think, Ami, in terms of the initial adoption, I think you know the indication is broad for men with advanced prostate cancer, and we expect the initial adoption to be in a mix of patients, both men who are newly starting androgen deprivation therapy as well as those men who are continuing on their journey.

And we believe that the overall profile that is described in our label and that we will be able to educate physicians about is quite compelling with the benefit and the efficacy, the safety profile and the oral administration. And so this total package, we believe, is gives ORGOVYX the great potential to become the new standard of care. So we expect to see the initial adoption across a broad range of men with advanced prostate cancer. And then, of course, with respect to peak revenues, we're not giving guidance.

Operator

Thank you. Our next question comes from Paul Choi from Goldman Sachs. Your line is open.

Paul Choi; Goldman Sachs Group Inc.; Analyst

Hi, thank you. Good morning and let me add my congratulations as well. I want to maybe follow a little bit on the commercial coverage piece. And I think in prior calls, you had talked a little bit about the pace of coverage here. Now that you have your label here, can you maybe just talk about how you think about percentage of lives being covered over the course of calendar 2021? And just how you think about maybe what the exit rate in terms of percentage of lives covered might be by year-end next year?

Lynn Seely – Myovant Sciences, Inc. – CEO

Adele?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

The specificity, I might not have all of those details at my fingertips, but I think the way to think about it is when you have the key commercial plans will start making coverage decisions as early as first quarter of 2021. And those plan those plan decisions will go into effect very soon thereafter, either first quarter or early second quarter.

With regard to Medicare, those -- that is -- we are in the process of the 2022 bid cycle and decisions for that will take place around June of 2021 for the 2022 bid cycle. I will note that there will be some Part D adds that could come on as early as mid- to late 2021. But as you know, for Medicare Part D, realistically, the bid plans that we're making now will go into effect for the 2022 bid cycle.

Paul Choi; Goldman Sachs Group Inc.; Analyst

Okay. That's helpful context, thank you for that. And then I just want to maybe ask with regard to your launch preparations and how you think about the degree of virtual and versus in-person selling. Can you maybe just elaborate on that first part with regard to virtual selling, how you think about marketing ORGOVYX here in the near term? And just how you see the pace of in-person selling transitioning over the next 12 months as well? Thank you very much for taking our questions and congratulations.

Lynn Seely – Myovant Sciences, Inc. – CEO

Thank you, Paul, Adele?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Yes. We're becoming very adept as a country overall and lots of aspects, virtual selling and virtual educating. You could think about our medical affairs teams have been out educating physicians. Our payer teams have been out speaking to the payer community with the pre-approval information exchanges that they have been very well equipped to provide. So I'm very comfortable that we will translate the payer and the medical affairs schemes, and now we'll be able to have our sales professionals go out and educate our physicians on the compelling profile that ORGOVYX has to offer.

And I think in all of my experience, when you have a very compelling product profile, you will gain access to physicians, whether it's a video call, a phone call, whatever specific vehicle that is, we're very confident that our sales professionals will have access to those physicians and they will be interested in hearing about the profile. We also know that patients are going to be interested. As we know that many men prefer a pill to a shot. So we're going to have that dynamic playing to our favor as well.

Lynn Seely – Myovant Sciences, Inc. – CEO

And I'll just add, we've been preparing to launch into COVID pandemic for months now. We've had the advantage to know that this was going to be a reality we were going to have to be prepared for. So our sales team is fully prepared to interact virtually as needed or in-person as this pandemic gets under control. Hopefully, we'll start to see that as 2021 progresses. But we have specifically hired our representatives based upon their relationships and their ability to sell in the virtual environment. So as Adele said, and I just want to underscore, we are highly confident.

Operator

Thank you. Our next question comes from Mohit Bansal from Citigroup. Your line is open.

Mohit Bansal; Citigroup, Inc; Analyst

And many congratulations from my end as well. Maybe -- so a couple of questions. The first question is, so you matched last quarter call that the size of the patient the population is about 300,000 patients. Do we know what percentage them are newly diagnosed patients so that we understand the low-hanging fruit there? And the second part is the FDA label seems to be playing down the impact of rapid T

reduction in clinical benefit thereafter. Do we know why FDA did that? And would that have any impact on your marketing efforts?

Lynn Seely – Myovant Sciences, Inc. – CEO

So Adele, please comment on the size of the market and the patients.

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Yes, very large patient population, 300,000 patients today on androgen deprivation therapy. Of those patients, as Lynn mentioned, we are going to educate physicians on the treatment for the very broad majority of those patients who are eligible for ORGOVYX. There are about 100,000 that get initiated on therapy each year. So I would say that 100,000 is a very -- you asked for the low-hanging fruit, that's a very easy starting point because these patients are going to be new to therapy, and they could easily be started on ORGOVYX and I would say those would come on initially, and then we have that other large pool to tap into. I don't know if I can answer that in any other way then.

Mohit Bansal; Citigroup, Inc; Analyst

This is very helpful, thank you.

Lynn Seely – Myovant Sciences, Inc. – CEO

I want to -- I just want to underscore again that we believe that not only will we be seeing ORGOVYX prescribed to new patients, but also to men who are currently on treatment as they continue on that journey. So it's going to be a mix of new starts as well as patients who are already on treatment. And Mohit, I'm sorry, I'm not sure I understood the second question. Could you repeat that?

Mohit Bansal; Citigroup, Inc; Analyst

Sure. I think from the label, there was one, I think -- so the label kind of mentioned that the benefit of impact of rapid T suppression is unclear. The clinical benefit long-term is unclear. Do we know what -- like -- because, I mean, this is one of those benefits of GnRH antibodies. Do we know why FDA would add commentary like that in the label? And do you think it would impact your marketing efforts because the fast T suppression is one of those -- the benefits of ORGOVYX?

Lynn Seely – Myovant Sciences, Inc. – CEO

Yes, Juan Camilo?

Juan Camilo Arjona; Myovant Sciences; Chief Medical Officer

Yes. I think that you're referring to a comment about the significance of rapid PSA reduction.

Mohit Bansal; Citigroup, Inc; Analyst

Yes. Exactly, yes.

Juan Camilo Arjona; Myovant Sciences; Chief Medical Officer

Yes. I think the label clearly shows the importance of rapid testosterone suppression. We -- it actually has great table that shows how quickly the testosterone is reduced to castrate levels with relugolix, and it has a side-by-side with leuprolide and then similarly shows how rapid it gets to profound castration, which is becoming more and more relevant today. So we feel pretty confident that the rapidity of onset is clearly portrayed and highlighted in a very important way.

Mohit Bansal; Citigroup, Inc; Analyst

Very helpful. If I may squeeze in 1 more. Do -- so for your internal modeling purposes, or in your internal thinking, how you are thinking about compliance? So if any color you can provide there.

Lynn Seely – Myovant Sciences, Inc. – CEO

Adele?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Yes. I think with regard to compliance, first off, physicians are quite comfortable. There's many new prostate cancer drugs that are oral. So they're used to prescribing orals, and we have made a special attempt as part of our ORGOVYX patient support program to ensure we have built in adherence and support programs for our patients. There's, as I mentioned, a nurse support hotline, there's other things that I didn't go into detail around patient starter kit and all sorts of tools and tips that we will do to actually help those patients who might need a little extra help and remaining compliant. So overall, we feel we'll have a quite compliant patient population on ORGOVYX.

Mohit Bansal; Citigroup, Inc; Analyst

Very helpful. Thank you very much for clarifying all that. Thank you, appreciate it, and congrats.

Operator

Our next question comes from Brian Skorney from Baird.

Brian Skorney; Robert W. Baird & Co.; Analyst

Hey, good morning everyone and thank you for taking my questions. Maybe to start with Juan Camilo. Maybe I was hoping you could kind of give us an idea of how in practice CV monitoring is done when initiating and using LUPRON, how cumbersome that may be and how much it varies depending on the patient's underlying risk factors? And then for adult, does that represent any sort of value differential that you can quantify here in terms of cost of monitoring if at all with payers?

Lynn Seely – Myovant Sciences, Inc. – CEO

Yes. So let me just clarify your question. You're asking about the CV monitoring when patients start on Lupron. And I think, at this point in time, there's no mandated CV monitoring in the label. What's very interesting is we've done some economic analysis from our HERO data that was presented at the AMCP Nexus Conference that demonstrated that the number of men needed to treat with ORGOVYX to prevent one major adverse cardiovascular event as compared to leuprolide was 31, which is a very low number needed to treat. And I think something that's been very -- of great interest to payers as we present that.

So we do believe that this cardiovascular data is important both to prescribers, to patients as well as to payers, but there's not any mandated leuprolide cardiovascular monitoring in their label. I think the oncology and the urology communities are now becoming much more attuned to cardiovascular risk in men with prostate cancer because that's -- it's interesting and with the advent of new prostate cancer treatments men are dying more from cardiovascular disease now, men with prostate cancer dying more often from cardiovascular disease than they are, in fact, from prostate cancer. So I think that's important. And I don't know, Adele, if there's anything you wanted to add to the second part of the question.

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

No. I think you said it, Lynn, it's the economic benefits, that analysis, the 31 number needed to treat is something that resonates extremely well with the payer community.

Brian Skorney; Robert W. Baird & Co.; Analyst

Great. And then maybe if I could throw one question to Frank. With the 100-person sales build, how should we be thinking about the SG&A contribution from ORGOVYX next year? And assuming approval in uterine fibroids, what additional commercial resources are needed to build up for the women's health launch? Thanks.

Frank Karbe – Myovant Sciences – President and Chief Financial Officer

Yes. So you heard that the prostate cancer sales force has been fully hired in the course of this quarter. So there will obviously be an increase in our G&A expenses, commensurate with that. I think the cost per sales rep are sort of average with what you would see typically in our industry. And then with regards to preparations for the launch in women's health, we expect to execute our sort of pre-launch activities in a very similar way to what we've done in prostate cancer, where we expect to hire the majority of women health sales force shortly before the PDUFA date on June 1. And then again, of course, commensurate with that, you will see sort of a step increase in our G&A expense.

Lynn Seely – Myovant Sciences, Inc. – CEO

And we've guided that we expect about 200 sales representatives in women's health.

Operator

Our next question comes from Jason Butler from JMP Securities. Your line is open.

Jason Butler; JMP Securities LLC; Analyst

Hi. Thanks for taking the question and let me add my congrats on the approval. Just wondering if you had any perspectives on patients that are potentially not viewed as eligible or where physicians are less willing to prescribe leuprolide that could be -- have a different perspective for relugolix, i.e. more willing to prescribe? Obviously, there's the patients with underlying cardiovascular risk, but are there other populations where leuprolide is viewed by physicians is less attractive?

Lynn Seely – Myovant Sciences, Inc. – CEO

So it's interesting as we speak to physicians about this and what you see as they start to think about this, there are many different ways they think about it. So first and foremost, the new patient starts, I think there is this issue of the clinical or the hormonal flare where ORGOVYX, the LHRH agonist have which ORGOVYX does not. So I think for new starts, they really like this rapid suppression.

I think the issue of cardiovascular risk is very important. And what many people are now starting to realize is a very high proportion of men with advanced prostate cancer, have at least 1 or more cardiovascular risk factors. And in fact, in our HERO Phase III clinical trial, more than 90% of men had at least 1 cardiovascular risk factor, and many of them had more than one, such as diabetes and hypertension and others.

So and then, of course, there are men who are able to discontinue their treatment, and we've been able to show this rapid testosterone recovery into normal levels within 90 days in our HERO study in 55% of men. So each of these are advantages and different physicians start to think about different ones. And it really is they're educated about the data. And then finally, there's the convenience and of the oral and instead of the injection.

And we know, as Adele alluded to, that the vast majority of men prefer an oral treatment to an injection. And obviously, in this COVID-19 pandemic, that's more important than ever. And so we think different physicians look at the data and the patient in a different way, but for -- we believe ORGOVYX will become the standard of care has certainly has the potential to become the standard of care because of the many different attractive attributes.

Jason Butler; JMP Securities LLC; Analyst

Great. Really helpful. Thanks for taking the question and congrats again.

Operator

Thank you. And our last question comes from Josh Schimmer from Evercore ISI.

Josh Schimmer; Evercore Inc.; Analyst

Thanks for taking the follow-up questions. Sorry if you've touched upon these already, but they can be a little bit confusing topic. So I just want to ask first, your comments around formulary adoption for the commercial and Medicare population. Can you align that commentary with expectations for real-world adoption and patient access? Are there paths to reimbursement for the product before it's added to

formularies and how complex might that be? And then relatedly, if you could talk a little bit to the co-pay and the out-of-pocket dynamics for commercial versus Medicare and how that would contrast to the injectable therapies and then what able to offer those different populations in terms of co-pay support? Thank you.

Lynn Seely – Myovant Sciences, Inc. – CEO

Sure. It's -- yes. And Adele, why don't you start addressing that? Is the formulary adoption?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Yes. With regard to formulary adoption, we -- as I mentioned for commercial plans, we expect the decisions for formulary adoption to start as early as the first quarter. So with regard to patients that their insurance might not have yet picked up coverage we'll ensure that patients who are prescribed ORGOVYX will have access to ORGOVYX with our free trial program, which can go as long as 2 months.

So we feel that, that's going to give us ample time for their -- for the commercial insurance to pick up. That's the program that we have there. For Part D, we can't offer co-pay assistance, as you know. But what we have done is with our research, we've uncovered that a large portion or half of those patients have either employer group waiver plans or are part of the low-income subsidy, which enables them to have a very low co-pay out of pocket. So we feel those patients will be covered with that regard. I hope, Lynn, I didn't want to add anything else.

Lynn Seely – Myovant Sciences, Inc. – CEO

No. Did we answer your question, Josh?

Josh Schimmer; Evercore Inc.; Analyst

Yep. That's very good, thank you.

Operator

Thank you. And that does conclude our question-and-answer session for today's conference. I'd now like to turn the conference back over to Dr. Lynn Seely for any closing remarks.

Lynn Seely – Myovant Sciences, Inc. – CEO

I'd just like to close and say that I could not be more proud of our committed Myovant team for achieving FDA approval of ORGOVYX and preparing for commercial launch all during the COVID pandemic while working remotely. We look forward to bringing this new oral treatment option to physicians and men with advanced prostate cancer in January 2021. Thank you for joining today.

Operator

Ladies and gentlemen, this concludes Myovant Sciences' ORGOVYX FDA approval conference call. Thank you for your participation, and you may now disconnect.