EDITED TRANSCRIPT

MYOV – Myovant Sciences, Inc. at Evercore ISI 3rd Annual HealthCONx Virtual Conference

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Frank Karbe; Myovant Sciences, Inc.; President and CFO

CONFERENCE CALL PARTICIPANTS

Josh Schimmer; Evercore ISI; Analyst

PRESENTATION

Josh Schimmer – Evercore ISI – Analyst

All right. Welcome everyone. This is Josh Schimmer from the Evercore ISI biotech team.

Pleased to introduce from Myovant, we have Lynn Seely, Chief Executive Officer; Frank Karbe, President and Chief Financial Officer.

Some exciting updates ahead with relugolix PDUFA date for prostate cancers, maybe give us a snapshot of what you're looking for in relugolix label and how that will set the stage for your commercial efforts?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

Thanks, Josh. It's great to be here. And of course I have to begin by saying we will be making some forward-looking statements potentially. So please consult our disclosures on our website.

Yes, we are very excited and looking forward to our PDUFA date for prostate cancer drug relugolix. It's expected December 20th of this year. So we're – all eyes are on that date. And I think, obviously, we're very close to that date. So we can't really discuss our labeling negotiations or what we expect, but I can tell you that things have been moving forward as expected and we are on track and expectantly looking forward to the label.

Josh Schimmer – Evercore ISI – Analyst

So assuming approval and then move towards commercialization. As we've spoken to urologists, there's some interest in both starting patients with prostate cancer therapy, but also switching some of the agonists. How did they switch? Are there specific guidelines? Have you looked at this? What is the protocol for taking a patient who's on a Q three or Q six month injection and then switching them to a daily oral?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

Sure. Well, let's start with what we believe our indication statement will be, which is for men with advanced prostate cancer, which is a broad spectrum of patients really ranging from biochemical recurrence, i.e., rising PSA after definitive therapy, locally advanced disease, metastatic disease. And we think that in 2021, there'll be about 300,000 men who are treated with a drug to lower testosterone or androgen deprivation therapy. So of those about a 100,000 will be new starts and others will be continuing on their journey. And so as you talk about that, we think we have opportunities in our patient

mix those for patients starting relugolix as their first androgen deprivation therapy. And it's a great choice for them because it rapidly lowers testosterone, but also an opportunity [for] patients to transition.

And there are many reasons to transition, but one of them would be for example the risk reduction in major adverse cardiovascular events. We were able to show in our Phase 3 HERO study. So I think physicians in general would know when the next injection of LHRH agonist would be due. And we would anticipate that they, as they do, when they switch medicines frequently would then begin relugolix. And in the standard way that is, will be labeled, which we expect to be a single 360 milligram loading dose. And then after that 120 milligrams each day.

Josh Schimmer – Evercore ISI – Analyst

And it's nothing fancy in terms of converting from an agonist to the antagonist?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

No. And you think about even today, men are switched from relugolix to leuprolide, Lupron to Eligard. I think when the next injection is due typically that would be the time to make a change if one is needed.

Josh Schimmer – Evercore ISI – Analyst

How do we think about putting in place the pieces for broad access? I guess some oncology drugs, those seem to typically go pretty quickly on the other hand it's – there's already this entrenched agonist class that you're pumping up against. So, does that create any access headwinds and how do you navigate that?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

So I think, achieving broad access as quickly as possible is going to be a key component of a successful launch. And we have had our national account directors out there for months now talking to payers. So I don't expect anyone to be surprised by the approval of relugolix. We've done a great job, speaking to them introducing Myovant and introducing the data that came from the HERO study and it were published in the New England Journal.

But access doesn't pop up overnight. It takes time. We expect for us to see commercial payers to begin to cover in the first quarter and to continue from there throughout the year. So we don't see significant headwinds, but as always access takes time.

Josh Schimmer – Evercore ISI – Analyst

Got it. I guess again, having the GnRH agonists out there at, such heavily discounted prices, how do you think about making the value case for relugolix? First of all, are you kind of, as you think about the cancer benefit, right? There's cancer benefit, cardiovascular benefit, oral pill benefit, reversability benefit, have the GnRH agonist define the cancer benefit or is there an opportunity to reevaluate that because you've got a new molecule going down the path for reimbursement?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

I think, I'm not sure I 100% get that question, but I think there's so many opportunities with relugolix and maybe I'll start, and then Frank, you can jump in here. But I think we have so many ways to really differentiate relugolix as a treatment because it is more than just cancer. And I think one, relugolix is as an oral treatment. And now in the time of COVID more than ever, men would like an opportunity we hear from our market research to avoid trips to the hospital and the clinic and having an oral therapy. I think it gives more an opportunity for more precision control. And we showed in our Phase 3 HERO study, that's rapid onset. So testosterone suppression occurs very, very quickly within days, as opposed to a surge that you can see with the agonist. And it can take weeks to suppress testosterone.

And then importantly from on this whole concept that when, if you're able to stop treatment, you can get those testosterone recovery and much more quickly than with the depot injection. So there is a more precise testosterone control that's important for patients, but then it's beyond that.

It's beyond just controlling testosterone, because we were able to show this cardiovascular risk reduction with relugolix versus leuprolide in the Phase 3 study. And I think the whole field is beginning to understand that men with prostate cancer are dying more commonly today from cardiovascular disease, not from prostate cancer. And so there's a real need to think about yes, the cancer, but also the whole man and his cardiovascular risks. So I think there's a lot of issues going on there. And then there's this whole issue about access and reimbursement and maybe Frank, you can speak a little bit about that.

Frank Karbe – *Myovant Sciences, Inc. – President and CFO*

Yeah. Maybe to turn the corner to another part of your question, Josh, about pricing.

I mean, taking into account what Lynn just said about how relugolix is different from other options out there. We want to, of course, reflect the value of that relugolix provides to patients in our pricing decision. We're really aiming for as a, what we call a value-based price that at the same time also supports coverage and uptake. And we've provided a little bit of guidance on how we think about that. And by saying that we would expect that relugolix would be priced at a premium to the Lupron WAC price. And Lupron WAC price is currently at $1,664 a month. This price evolve continuously over the years. And we would expect it to be at around $1,800 a month in 2021.

Josh Schimmer – Evercore ISI – Analyst

So, many advantages that you highlight for relugolix. Some of them, I feel like we're a little bit more comfortable translating into pharmacoeconomic calculations. You've got the PCSK9 class and as we think about cardiovascular risk and opportunities with that. So many other ones, I feel like they're just harder to turn into an equation. Right. Kind of at the end of the day for a payer to be able to say, what yeah, that is good value. How do you think about that math and the inputs for an oral over an injectable for a rapid onset over a slow onset?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

Well, I mean, I think first of all, I think for oncology, payers don't manage that tiny rate. If there's a new approved treatment in oncology, generally it's covered. And I think that would be true here as well. And I think they look to things like the National Comprehensive Cancer Network guidelines. And I think

already relugolix as mentioned in the NCCN guidelines and even pre-approval. So this is something they look for.

But with respect to value, we recently presented at the AMCP Nexus Conference, an economic analysis that they do understand, to your point, of the number of men needed to treat with relugolix to prevent one major adverse cardiovascular event versus leuprolide. And it was only 31 -- and this number needed to treat is something that payers do understand because they understand the cost of these major adverse cardiovascular events like a heart attack or a stroke. So I think that's – we will also bring that value proposition to them.

Josh Schimmer – Evercore ISI – Analyst

Got it. How do we think about in this market who are late adopters – sorry, who are early adopters, who are the late adopters, who's a never adopter?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

Well, hopefully a very few of them. It's been very gratifying, I think, as we've done a lot of market research right now, the awareness among physicians, preapproval is quite high, higher than we might normally expect. And if you ask both urologists and medical oncologists if you show them a product profile like relugolix they say that they are very likely or extremely likely to prescribe 60% of them. And this, again pre-approval is a very high number. So I think that we find this both in community urologists, oncologists, academics but in general, we expect that early adopters to be the large urology group practices and in large multi-specialty clinics.

And fortunately for us, there's been so much innovation in this space and a lot of new drugs moving forward that urologists in particular, who really are the primary prescribers of androgen deprivation therapy, are open to trying new medicines now maybe more than they were in the past. And so I think that's a real opportunity for us. And also because of in-office dispensing, a lot of them are very comfortable prescribing new oral medicines.

Josh Schimmer – Evercore ISI – Analyst

So does this purpose specialist tend to participate in the oncology care market paradigm of value based pricing, or it feels like maybe that's such a small sliver of their overall practice that they don't enroll in the program.

Lynn Seely – *Myovant Sciences, Inc. – CEO*

So I think that it is still a relatively small program, mostly in oncology practices as opposed to urology practices. But when you think about this is where the practices are responsible for the overall care of the cost of care for the patient. Something like relugolix could be quite attractive because of this reduction in major adverse cardiovascular events that we were speaking about. But I think right now that this still constitutes a very small part of the urology practices in particular.

And I might add one thing that is going to be, I believe, important as we look at you are asking about adoption. And I think one is the prescriber, but another thing that we have to consider is men, and one of the things that we know is that men actually are dissatisfied with leuprolide injections, and that they really would prefer to have an oral medicine once-a-day than an injection.

And so I think as they start to understand that this oral medicine is out there, that's also going to help with adoption.

Josh Schimmer – Evercore ISI – Analyst

So previously when we were talking about the relationship with Sumitomo, they will access some of their commercial services, et cetera. It didn't mean a heck of a lot because they were really in the urology field, but that is changing that they're requiring Urovant all of a sudden they're going to have in theory, some very complimentary resources to Myovant. Do you see that as something that you'd be able to leverage going forward? And if so, how, or is that not really going to be a part of your strategy even if they are in urology offices?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

Well, maybe I'll comment a little bit about what we're doing for commercial preparation and Frank Karbe will comment about Urovant.

I would say that we are fully prepared to launch and commercialize with our salesforce, it is very much focused on prostate cancer in the urology and medical oncology space. So I don't think at this particular time we'll be looking to the Urovant salesforce for that. We have our own field team, but we do see some synergies and maybe Frank you can talk about that with respect to Sunovion.

Frank Karbe – *Myovant Sciences, Inc. – President and CFO*

Yes, I think the broader umbrella here is what is our relationship with Sumitomo Dainippon Pharma in general and there are really two main components to this. And I will say it has been a hugely beneficial relationship to Myovant. So on one hand DSP provided us this a very large, low cost loan facility. And they have given us an option to evaluate to what extent we want to leverage the existing commercial capabilities and infrastructure in the U.S. That infrastructure resides mainly within Sunovion, which is a hundred percent owned subsidiary of Sumitomo Dainippon Pharma here in the U.S.

And based on that we have announced earlier this year, a fee for service agreement with Sunovion, where we are contracting with Sunovion for a number of services, including contract services, market access services, order-to-cash services, government pricing services, and things like that. The benefit for us is that we are latching onto a very well-established infrastructure that has supported a blockbuster franchise for many years. And we don't have to build this ourselves. But importantly, it really is just a fee-for-service arrangement. So there are no other sort of economic ties at Sunovion or DSP, for that matter has to relugolix.

Josh Schimmer – Evercore ISI – Analyst

I was just – as we're talking about the benefits of relugolix on the cardiovascular health benefits just looked at Repatha. PCSK9 is selling more outside the U.S. than in the U.S., which to me is an indicator that ex-U.S. is equally happy to embrace cardiovascular benefits. So reimburse for cardiovascular benefits, how are you thinking about the ex-U.S. opportunity for Repatha?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

Yes, so we are planning to submit. We've already submitted our marketing authorization outside the U.S. for the women's health product in uterine fibroids. And we expect to promote for that next year 2021, we will be submitting the marketing authorization application for prostate cancer in the first half of next year.

Josh Schimmer – Evercore ISI – Analyst

And commercial strategy there?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

So we're still defining that whether we're going to do that ourselves or whether we're going to find a partner to help us with that. We are partnered currently on the women's health side with getting the vector outside the, U.S. and the Asian territory.

Josh Schimmer – Evercore ISI – Analyst

On the women's health side of the equation, ORILISSA and ORIAHNN have not been doing as well as I think most of us had hoped. To what extent are you confident that simply the ease of prescribing for relugolix can really succeed where that product has not?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

So certainly I would not limit the reasons to prescribe relugolix to ease of prescribing. It's much more than that. And I think the first thing to note is yes, ORILISSA and ORIAHNN launches have been disappointing, but we continue to believe as many other companies have also assessed and believed that this is a large marketplace. This isn't a failure of the marketplace. The market is out there. The women are suffering from heavy menstrual bleeding from uterine fibroids and pain from endometriosis, but we need to find the right product profile. And so what relugolix combination tablet intends to bring to the market is a drug which can and has been shown in four different Phase 3 clinical trials two in uterine fibroids and two in endometriosis to benefit the bleeding, to benefit the pain associated with these, without a lot of side effects.

And so we've – I mean uterine fibroids, we've shown a safety profile comparable to placebo, specifically with bone mineral density maintained, and we've presented recently one-year data on bone mineral density that shows this is a plateau and really maintenance of bone density. And then also with hot flashes, which are very important. And similarly in endometriosis benefit in the pain without sacrificing sort of tolerability.

And so with that, we have one brand, one dose, one pill, once-a-day. And this is this simplicity that you were referring to that is it has to – the drug has to benefit patients and their symptoms. It needs to be well tolerated. And this simplicity, we think makes a big difference because patients want to be, well, they don't want to have to take multiple pills multiple times a day, and doctors, the gynecologists, they're very busy and they want things that are straightforward to prescribe. And so that's our intent to bring that to those marketplace launching first and uterine fibroids, and then, which is a market with we think three million symptomatic women, large market, and then moving to endometriosis.

Josh Schimmer – Evercore ISI – Analyst

Excellent. We're looking forward to seeing what you can do in that market with a differentiated product. Maybe a last question as you think about managing a portfolio in men and women's health, it might be a little bit earlier to think about that stage of the company, but when is the right time to think about building out the pipeline and defining that strategy in those…

Lynn Seely – *Myovant Sciences, Inc. – CEO*

Now, is absolutely the right time where on the – we're very fortunate to be in the position to have two potential product launches, with PDUFA date in prostate cancer this month, and then a PDUFA date in uterine fibroids in June of next year. They're great catalysts. And then we need to build a pipeline from there. So we do already have a second asset, we're developing for infertility and we're looking to expand from there.

Josh Schimmer – Evercore ISI – Analyst

Excellent. We're looking forward to updates across the portfolio still this year, still some important news this year, and then into next.

Lynn Seely – *Myovant Sciences, Inc. – CEO*

All right.

Josh Schimmer – Evercore ISI – Analyst

Thanks Lynn. Frank, thank you so much for joining us.

Lynn Seely – *Myovant Sciences, Inc. – CEO*

I appreciate it.

Frank Karbe – *Myovant Sciences, Inc. – President and CFO*

Thank you. Bye-bye.

Lynn Seely – *Myovant Sciences, Inc. – CEO*

Bye.

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