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CORPORATE PARTICIPANTS

Ryan Crowe Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Christopher Fenimore Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

Andres Sirulnik Regeneron Pharmaceuticals Inc - Senior Vice President, Hematology Clinical Development Unit Head

CONFERENCE CALL PARTICIPANTS

Salveen Richter Goldman Sachs Group Inc - Analyst

PRESENTATION

Salveen Richter - Goldman Sachs Group Inc - Analyst

Good afternoon, everyone. Thank you so much for joining us. Really pleased to have with us the Regeneron team. Next to me is Chris Fenimore, CFO; Andres Sirulnik, SVP, Clinical Development Unit Head of Hematology and Ryan Crowe, IR and strategic analysis.

And Ryan, let me turn it over to you.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Just to get this out of the way. And Salveen, thank you very much for having us. Great to be back in Miami again to see a lot of familiar faces and excited to have this chat.

But first, let me get through this forward-looking statement disclaimer. I'd like to remind you that remarks made today may include forward-looking statements about Regeneron, and each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in such statements. A description of material risks and uncertainties can be found in Regeneron's SEC filings that are on our website.

And with that, Salveen, let's jump in.

QUESTIONS AND ANSWERS

Salveen Richter - Goldman Sachs Group Inc - Analyst

Great. Chris, to start here, Regeneron has been challenged recently on both the earnings front, driven by headwinds facing the EYLEA franchise. And on the pipeline, most recently for fianlimab Phase 3 failure.

In that context, how do you see the company positioned from here for second half of the year and into the end of the decade? And maybe touch on the key priorities for the company at this point.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

Thanks, Salveen, and I hope we have plenty of time for Andres because he's got a lot of exciting things to talk about.

So if you look at the Regeneron business, it's fundamentally strong, resilient, coupled with a balance sheet that provides us with a tremendous amount of flexibility to allocate capital in a way that we think will drive the most long-term value for our shareholders. If you look at the first quarter alone, we had strong double-digit growth, both on the top and bottom line, driven by our core franchises.

So continued strong performance from Dupixent. We basically saw Libtayo, which I have to say, our commercial team has done a remarkable job of really driving and executing on Libtayo since we took that product back from Sanofi in the middle of 2022. And it really just goes to show you that when we, as a management team, sort of put the execution behind it and the focus, what you can do with the brand in our hands.

And then lastly, continued strength and momentum that we're seeing in the EYLEA HD franchise following the approval of the enhancements to the label at the end of last year, in both retinal vein occlusion and every four-week dosing. So a lot of reasons to be excited about the current core business as well as what the future holds.

You mentioned fianlimab. Fianlimab is one of basically 50 things in our pipeline. We historically, and will continue to be very focused on driving what we think is a world-class pipeline. If you look at the perspective, it's always been multiple shots on goal, spreading those shots across multiple therapeutic areas and having opportunities where we think in the short, medium and long term, have significant commercial opportunities.

So we're very excited about what the pipeline will be able to deliver over the next few cycles.

If you look at the balance of the year, there's a few catalysts that we're also very, very focused on delivery. Some of them are regulatory catalysts. So we've got the approval for the prefilled syringe. We've got an approval for cemdisiran in myasthenia gravis, and then we've got the approval for garetosmab in FOP.

Looking at clinical catalysts, and I'm sure Andres will talk about these... we've got data coming in our complement franchise in both PNH and geographic atrophy. So a lot of catalysts coming in the second half of this year.

We're also, at the same time, laser-focused on commercial execution. So I touched upon, obviously, our three growth drivers. We will continue in the remainder of the year to really stay focused on driving that commercial execution and doing it, obviously, in as efficient way as possible and continuing to drive growth.

One thing not to forget about as well is the repayment of the Sanofi development balance, which will be repaid by the end of the second quarter, which will allow an inflection in our share of collaboration profits, basically in the second half of this year.

If you just think about other things that are there in the pipeline in terms of where we think we've got some exciting opportunities. I think Ryan and the IR team, coupled with members of management have done, I think, a very good job using the Regeneron Roundtables as an opportunity to highlight where we have exciting near-term opportunities with large commercial potential in areas like multiple myeloma, anticoagulation, complement mediated diseases and obesity. And those are just some of the nearer-term opportunities.

If you then turn and focus to a pipeline with 50 different sort of candidates in there, there are plenty of earlier stage opportunities that will eventually become mid- and late-stage opportunities as we continue to drive those forward in exciting areas like inflammatory and immunology, ophthalmology, cardiovascular, metabolic and even neuroscience.

So there's a lot going on at Regeneron and a lot to be excited about.

Salveen Richter - Goldman Sachs Group Inc - Analyst

Just touch on strategy here. It does seem like the company is increasingly open to larger M&A. Just speak to your view here regarding size of deal and modalities and therapeutic areas and stages of development. And you've also spoken to valuations in cases being prohibitive in the context of return on investment and acknowledge competitive dynamics amongst acquirers.

How do you think about all these factors when you put it together?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

Yes, it's a very good question, Salveen. I don't -- the way we view it, we're not limited by either the size of the transaction. As I said, we've got the balance sheet with an enormous amount of flexibility. We're not necessarily limited by therapeutic area. We really look at things and evaluate opportunities where we think the science really makes a lot of sense and that can translate into commercial opportunities where there's unmet medical need.

I think if you look historically, we've done more in the traditional collaboration sort of side of things and not necessarily traditional M&A. And those historically have been opportunities where they are complementary technologies or things that augment some of our capabilities as recently as in the past couple of months, we did a deal with Telix in radiopharmaceuticals.

We did a deal with Parabilis, using their Helicon technology, coupled with our ability to conjugate them to antibodies to allow potentially targeting those Helicons in interesting ways. And we will continue to do those sorts of things.

We are also very active looking at larger-scale M&A or even smaller types of transactions. You alluded to the fact that we've talked about being involved in some competitive processes as we've evaluated them and kicked the tires. What ends up happening in some of those situations are: you have companies that probably don't have necessarily the discipline or don't evaluate the opportunities the way we look at them that when you look at the value that was sort of where those deals actually transacted relative to what we saw as the opportunity on a risk-adjusted basis, we just couldn't get there.

But that doesn't mean we won't get there in the future. It really depends on the opportunities that present themselves. We have the ability to basically in a disciplined fashion execute if something makes sense, and we'll continue to evaluate things going forward.

Salveen Richter - Goldman Sachs Group Inc - Analyst

Great. Could we also touch on the Sanofi collaboration here from two standpoints, one from the IP, but also from the openness you've talked to about working with your partner to potentially add more assets into the collaboration.

Where do these efforts stand? And to what extent are you looking externally for assets to bring in? And what characteristics are you looking for in terms of these assets? And if I could just add, how long will this process take?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Maybe I could start with the Dupixent loss of exclusivity question. Clearly, that's of importance to investors given the impressive scale of the product and its continued very strong growth trajectory. Dupixent has a very broad and layered intellectual property estate that has expiries beginning in the early 2030s, including its composition of matter patent in March of 2031, but additional patents that go into the mid-2040s.

And these cover other facets of dupilumab, including its manufacturing, its formulation as well as its methods of treatment for various diseases, which really underscores the clinical work that's gone into this antibody that's now approved in nine distinct diseases. So this -- it's not -- there is no date certainty at this point.

I think it's important to consider all of these different patents when trying to figure out when eventually biosimilars could launch. So the most important for us is continuing to drive the growth along with Sanofi and then put up a vigorous defense of the patents that we do have and feel very strongly can extend the runway meaningfully beyond the composition of matter patent in 2031. Updates will probably come as we approach that date.

And as the patent challenges and litigation processes get underway. We're still a few years away from that really happening. So unfortunately, today, I can't tell you when biosimilars will launch, but I can assure you, we are going to mount a very vigorous defense of all of the intellectual property that we have to extend Dupixent's marketing exclusivity for as long as we can.

Salveen Richter - Goldman Sachs Group Inc - Analyst

And just on the maybe two aspects. One, the ability to expand upon the collaboration with Sanofi, but also on the life cycle front, the extended IL-13, when could we expect to see data from this agent or the other agents? And when could they enter the clinic?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

I'll take the collaboration aspects of it and I'll ask Ryan to speak to IL-13. I think if you look at what we and Sanofi have built with the Dupixent franchise, there's a tremendous amount of value that's been built there. If you just look at relationships with the provider community, relationships with the payer community, even just patients themselves in terms of the trust and confidence that they have in Dupixent in terms of what it's been able to do for them, in terms of, in a lot of instances, changing their lives, in terms of the therapeutic efficacy there.

Being able to leverage that is extremely valuable and it makes a lot of sense if we can do that. With that being said, it's got to make, obviously, strategic and financial sense for both parties. I will tell you with Sanofi's new CEO joining, we've had some initial conversations along those lines. And we'll have to see where those conversations evolve.

There are, I think you've alluded to it, a number of different opportunities that we basically have in the pipeline that we can bring as well as whatever Sanofi might be able to bring, as well as external opportunities. But we've got the long-acting IL-13, which Ryan will talk about, a long-acting IL-4, basically a Supi-Dupi, as we call it internally, as well as a bispecific. So there's a lot of opportunities to really grow and develop what's there in terms of from an I&I perspective.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Thanks. So Chris, thanks for that. And I think the long-acting IL-13 antibody is the first in a wave of Dupixent, I'll call them next-generation opportunities for us. The long-acting IL-13 antibody went into its first patient earlier this -- last month or earlier this month, the last couple of weeks. And so that will begin a Phase 1 study in normal healthy volunteers initially but then move into patients with varying degrees of atopic dermatitis where we hope to learn what the clinical activity looks like and what the durability profile is.

We think that this fully human VelocImmune-derived antibody has an opportunity to meaningfully extend the dosing interval that Dupixent currently has without reducing its efficacy and maintain a similar safety profile. So we're very excited to be in the clinic.

We're moving in as quickly as we can. We believe we have the expertise, the experience, the relationships, all the capabilities to run this program very efficiently start to finish. And to Chris' earlier point on the collaboration, this is an opportunity that Regeneron wholly owns.

And we intend to run this program to maximum effect and make sure we get it to the clinic or get it to patients commercially as quickly as possible and in a competitive time frame.

Salveen Richter - Goldman Sachs Group Inc - Analyst

Just switch before we go to the pipeline, just switching over to EYLEA HD. For the prefilled syringe, what are current expectations in the context of both sites?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

We don't really have an update to provide, really no change from the information we provided on our Q1 earnings call. We have two pending applications with the FDA, one with Catalent and another with an alternative vial filler for the prefilled syringe. We continue to expect a decision on one or both of those applications before the end of the second quarter.

But I'd say, importantly, the momentum for the product continues to be very strong in its current presentation. And the prefilled syringe is -- we're not dependent on a prefilled syringe to continue to drive growth for this franchise. It's becoming increasingly recognized as the best-in-class product.

The label enhancements that were added in November of last year only continue to add to the bolus of patients on therapy. So we're very excited about the revenue result in Q1 and then hope for a very strong 2026.

Salveen Richter - Goldman Sachs Group Inc - Analyst

And what are the scenarios from here, just given the observations at Catalent, but also the PDUFA being passed for the other site?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

So I'm sure Catalent is working very hard to resolve the observations that were noted during their April inspection, and we would expect them to continue the dialogue with the FDA in order to tick all the boxes required to get that facility back to VAI status.

In our alternate manufacturer, as you noted, the PDUFA date was in late April, the FDA opted not to act. There's been continued engagement between this manufacturer and the FDA, and hopefully, progress is being made, and they can approve that file at some point in the future.

Salveen Richter - Goldman Sachs Group Inc - Analyst

And just looking back at the first quarter sales for EYLEA HD, there was impact from pricing and inventory and seasonality. Maybe speak to which factors are specific to 1Q and how to think about that read-through to 2Q from them and beyond?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

So as you look at the performance in the first quarter, we talked about the underlying demand approaching basically 10% sequentially and as we talked about, obviously seeing continued momentum just based on the current product profile, as Ryan talked about.

The biggest factor that we saw was definitely attributable to inventory. Wholesaler inventory is something that's totally at the discretion of the wholesalers. It was at an elevated level at the end of Q4. They drew down those levels in Q1, which impacted the net sales relative to

the demand. There is pricing headwinds out there. It's a very competitive category, and we obviously are -- have to operate in that environment and do what we feel is necessary to maintain our competitive position out there in the marketplace.

So if you look at historical pricing and what you see in the class, we would expect similar competitive pricing pressure to continue going forward.

Salveen Richter - Goldman Sachs Group Inc - Analyst

As we pivot over to the pipeline here, you do have a lot of programs that are reading out over the next 12 months and beyond. Where do you have the most conviction in terms of those programs translating to meaningful revenue?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

I think a lot of them are actually being managed by Andres, and I can't wait to get into some of his programs. So certainly, C5, BCMA in myeloma are three and then obesity, which we can certainly talk about as not only about weight loss, but also about better managing, kind of, cardiovascular risk. So those are the three that I'm probably most -- three or four that I'm most excited about.

And hopefully, we can have Andres dive into a few.

Salveen Richter - Goldman Sachs Group Inc - Analyst

Perfect. Andres, I'll turn it over to you for any comments here, and we'll jump into some of the -- maybe we could start with the C5 pipeline here.

Andres Sirulnik - Regeneron Pharmaceuticals Inc - Senior Vice President, Hematology Clinical Development Unit Head

Great, Salveen. Thank you for having me and the opportunity to share what we are doing in hematology. Quite a lot going on, as was just said. So C5, we are very excited with the prospects of our C5 assets and the approach that we are taking in exploring how different degrees of C5 inhibition may translate in defined and clinical outcomes for patients.

We span indications from: in hematology, PNH, paroxysmal nocturnal hemoglobinuria, to myasthenia gravis and to geographic atrophy, diseases that are driven by complement dysregulation. And from the early on, we hypothesized that maximal C5 inhibition will be required, and tested that question, to benefit patients. And we have learned a lot throughout these programs.

I think the one that really the readout taught us a lot about how the degree of complement inhibition may translate or not in clinical benefit has been in myasthenia gravis. And maybe we can go a little bit into the results of our data in myasthenia gravis, which essentially is driving a launch at the end of the year in this disease. And this is where we tested either driving full complement inhibition by combining siRNA that inhibits the production of C5 with an antibody that inhibits the activation of whatever remaining C5 is in the circulation.

And what we learned in myasthenia is that you don't need full complement inhibition to actually benefit patients. Furthermore, the study -- the NIMBLE study demonstrated that single-agent siRNA benefits the vast majority of the patients in the trial. And this was done with what we call a potentially sweet spot. We observed a 70% inhibition of complement, while in PNH, we know that we want to drive 100% inhibition of complement to decrease hemolysis.

Here, we learned that in this disease that was not necessary. And we are very excited with the results of the clinical trial. We think that we have the potential for the best-in-class in terms of the C5 inhibition. We're looking across different studies where we observed a sustained benefit and improvement in symptomatology to patients.

This was -- and when I say sustained, why is this important? Because we observed the benefit throughout the dosing period from beginning to the next dose where patients sustained their symptomatic relief. And doing so with an administration that is very convenient to patients every three months, given subcutaneously, which we think will drive a lot of the future market opportunity for cemdisiran in this disease.

Importantly, also, when we look at the study, the safety was very manageable. And when we look at serious -- we have no serious adverse events in single-agent cemdisiran. We had no discontinuations throughout the study period when we reported the 24-week outcomes, which we think is very favorable within the class. So we think that there is a tremendous potential for cemdisiran there.

Salveen Richter - Goldman Sachs Group Inc - Analyst

Where do you see it being positioned versus the FcRns or Amgen's UPLIZNA?

Andres Sirulnik - Regeneron Pharmaceuticals Inc - Senior Vice President, Hematology Clinical Development Unit Head

So that's a great question. So let's start first with why it's different and what is the differentiation. One of the critical, I think, differentiation is, at first, a very efficacious drug, yes. We have comparable, if not better, to C5 inhibitors in terms of symptomatic improvement. When we look at the duration of that improvement vis-a-vis FcRns is sustained, it's not cyclical.

And even in C5 inhibition, it has been observed that you may see worsening of the symptoms as you get closer to the end of the dosing period. So sustained inhibition, and then convenience, of course. We are looking at subcutaneous administration, four doses a year, which I think, again, will be critical in terms of driving the success of this drug.

But I think that one aspect that sometimes goes unrecognized, and we should pay a lot of attention is about safety. We are hypothesizing and based on the data that we observed with minimal adverse events or not minimal, but with no cases of meningitis, with no SAEs throughout the treatment is the fact that potentially the sweet spot that we found where you don't necessarily need to drive full inhibition of complement allows for some remaining complement activity that may potentially help in fighting infections.

So we have to generate more data to demonstrate this point. But I think the data from the clinical trial already suggests based on infections, SAEs and so forth that there might be an advantage of cemdisiran. When you look at where FcRns are depleting all immunoglobulins with other potential for infections, viral infections and so forth, which you don't see with complement inhibition.

And when you look at the CD19 inhibitor targeting plasma cells, again, we think that the complement inhibition may be associated with less infections and so forth. And lastly, I want to highlight the rapid onset of benefit that we observe. We looked at symptomatic relief when we assessed this was at two weeks.

And in fact, the vast majority of patients already start experiencing symptomatic relief within 14 days of initiation of therapy. CD19s can take months. In fact, it takes half a year to get to that steady state of improvement. And as we know, FcRns and other C5s potentially delay a little bit vis-a-vis what we observed here, but with the problem of these losing of benefit towards the end of dosing.

Salveen Richter - Goldman Sachs Group Inc - Analyst

And in geographic atrophy, you're going to disclose 26-week data. Could you just discuss the desired clinical profile here and the differentiation that you need to see to support further development and the likelihood of this given it's systemically delivered?

Andres Sirulnik - Regeneron Pharmaceuticals Inc - Senior Vice President, Hematology Clinical Development Unit Head

Absolutely. And this is an excellent question. So what are we going to learn from the first 225 patients really? The first one is [does the] C5, systemic C5 inhibition have an effect on the slope of progression of the growth of the lesions in the eye. That's the first thing that we're going to learn.

Also, we're going to learn whether monotherapy or double inhibition with the antibody and siRNA is necessary in this disease. We learn in myasthenia, it's not. We know and we strongly believe that in PNH that's necessary, but we don't know yet in the eye. Those are the first two things that we're going to learn, but I think that the data that is going to emerge also is going to help us further refine the ongoing clinical program in GA.

Now moving to what is that we are looking for. So we're looking at the slope of growth of the lesion. But importantly, in this study, prospectively, we are going to be looking at -- as you know, that has not been done prospectively in any of the clinical trials with injected C5 or C3 inhibitors. So I want to point out, however, we are looking at 24 weeks.

It's a bit early. As you know, most of the benefits are observed longer term, but we're looking at the slope at 24 weeks, and we may get a hint on a potential benefit in terms of visual acuity. Those are the two important aspects that we're going to learn towards the end of the year, and we're going to be sharing with all of you as the data becomes available.

Of course, we're going to learn about safety, which is always very important. But we think that we will learn more towards the end of the year.

Salveen Richter - Goldman Sachs Group Inc - Analyst

Perfect. Ryan, you touched on obesity being a key focus for the team and we'll see some data by year-end. Maybe help us understand what proof of concept could play out with that data set and then the overall strategy for the obesity portfolio.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Yes. I mean, I think for the strategy, it's really about more than just weight loss. I think that's patient -- that has largely been solved, right? I think we're going to focus on other elements, including improving tolerability as well as addressing comorbid conditions and starting with cardiovascular disease.

So Hansoh, the company that we in-licensed olatorepatide from, disclosed earlier this year top-line data in their Chinese patients with obesity with weight loss on par with leading agents. But with the GI tolerability profile that was much more favorable than like-run studies in China were. So we're very encouraged by that, and we're in the process of enrolling a small Phase 2 study in the US to see if that GI tolerability profile can be replicated.

And should it be replicated, I think we will have an impressive competing agent within a category that has room for many, many therapies. Beyond just the monotherapy opportunity in obesity and type 2 diabetes, we're also in the process of co-formulating olatorepatide with our PCSK9 antibody, Praluent.

Of all the miracles that GLP/GIPs and GLPs have produced, one that it has not is lowering LDLs... in the pivotal studies for those agents, something like a placebo-adjusted decline in LDLs was only in the mid-single-digit percentile. So not really having much of an effect on lipids.

However, we think that about half of obese patients actually have elevated LDL levels and could benefit from being on a PCSK9 inhibitor like Praluent. So our approach is going to combine these into the same weekly injection that many patients are already used to.

And in addition to lowering their weight, we would also expect their LDL to lower on par with what we saw in the Praluent monotherapy studies, which were in the range of 50% to 60% at six months. So this is a way for us to enter the market, a large and growing market in a differentiated way.

We have other potential combinations to address other comorbidities of obesity that we will talk about at a later time. But certainly, we feel this could be a differentiated opportunity and make a nice -- take a nice part of a large market.

Salveen Richter - Goldman Sachs Group Inc - Analyst

And you announced collaborations on radiopharmaceutical therapies with your agreement with Telix and Antibody-Helicon Conjugates by your agreement with Parabilis. Can you discuss your interest in these technologies and how you envision integrating them into your platform?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Yes. I think this is, as Chris was talking about, opportunities that really complement Regeneron's core strength, which is antibody development as well as genetics, but in this case, primarily focused on antibodies. We're going to use these antibodies that we make with our platform to better direct these radioligands and these Helicons that Parabilis makes in an effort to, in the case of Parabilis, address intracellular pathways that antibody simply can't address.

So this is a way of kind of enhancing a core strength that Regeneron already has, but take us to places that we couldn't go with antibodies alone. So we're very excited to get started with both, a lot of work to do, but this could be a very important expansion of our capability set to address some of these different types of opportunities.

Salveen Richter - Goldman Sachs Group Inc - Analyst

Great. With that, thank you so much.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Thank you, Salveen.

Andres Sirulnik - Regeneron Pharmaceuticals Inc - Senior Vice President, Hematology Clinical Development Unit Head

Thank you, Salveen.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

Thanks, Salveen.
