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EDITED TRANSCRIPT

REGN.OQ - Regeneron Pharmaceuticals Inc at Leerink Partners Global Healthcare Conference

EVENT DATE/TIME: MARCH 11, 2025 / 12:00PM GMT

OVERVIEW:

Company Summary

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PRESENTATION

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

All right. So we're going to get started. Good morning, everybody. Thank you so much for joining the Regeneron session at the Leerink Global Healthcare Conference.

It's my pleasure to welcome Chris Fenimore, the company's CFO; and Ryan Crowe, who leads Investor Relations. Thank you again for coming this year. Last year, it was great to have you and I appreciate you coming to Miami again. So welcome, and let me turn it over to Ryan.

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

Never a chore to come to Miami in March Dave, so thanks for having us. Great attendance here. Excited to be here and let me just briefly read this forward-looking statement and we'll get started with some questions.

I would like to remind you that remarks made today may include forward-looking statements about Regeneron, and such forward-looking statements are 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 our SEC filings. Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Dave, back to you.

QUESTIONS AND ANSWERS

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Excellent. Well, I thought we'd jump right into it. And maybe Chris, at a high level, if we could kick off with the EYLEA franchise. So that's been a big fear factor for investors currently. Can you share management's views on how you see the EYLEA franchise, the risks associated with it? And then we'll go from there.

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

Thanks, Dave. It's been about a year that I've been in the CFO seat. This is one of the first conferences I did a year ago. So thanks for having us back, and it's always a pleasure to be at the conference. So as we look at the EYLEA franchise, we recognize that investors are focused on EYLEA and what it means for the business.

We are obviously laser-focused on doing all that we can to drive the uptake of EYLEA HD and then also preserve share of EYLEA in what is a competitive market. With that being said, the EYLEA franchise between EYLEA and EYLEA HD continues to be the market leader. We have about a combined 46% market share. And we are going to do everything that we can to make sure that EYLEA, which has been approved since 2011, and now EYLEA HD to continue to be that dominant force out there in the market.

With that being said, we recognize there are opportunities to increase and enhance the profile of the product and the competitiveness of the product. And we are doing all that we can on that front. There are three key areas that we have talked about that we are focused on. One is a

prefilled syringe for EYLEA HD. That is something that physicians have been looking for, and we are doing all that we can to bring that forward. We expect that to launch the middle of this year.

There is also dosing flexibility that patients are looking for, and that's every four week dosing. We expect that enhancement to the label second half of this year. And there is also RVO. So RVO is about 20% of the EYLEA business right now and having that incorporated into the label, we believe will provide physicians with a product that has the greatest breadth in terms of indications that are out there.

As well, one other thing I will mention is we have a PDUFA for two year data for EYLEA HD, which is in April coming up in April. And that will allow patients with two year data to go out to, I believe, it's 24 or 26 weeks. So with -- once all of those enhancements are on the label, we think EYLEA HD will be positioned to have all the indications that they're looking for as well as the highest level of dosing flexibility.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Excellent. Excellent. So I wanted to ask additional questions on EYLEA, but just to keep it high level to start. In terms of share repurchase, could you just comment on that? What does management see as underappreciated by the market?

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

Sure, Dave. So I mean, a few things. We view obviously, Regeneron is more than just the EYLEA company. I mean if you look at what else is there in terms of our in-line brands, we've got DUPIXENT, which continues to be a solid product, obviously, for us and our partners in Sanofi and continues to grow. We've got Libtayo that obviously has been, I think, underappreciated by the Street, and is now getting, I think, more attention as the product continues to do well, and we're seeing continued growth of Libtayo.

But I think most importantly, as we think about the longevity and the long-term aspects of the business, it's the pipeline. We were out at a competing conference at the beginning of the year, talking about the pipeline and how I think just 10 of the assets that are in the portfolio address about $220 billion of market potential. And that's just the tip of the iceberg as we like to say. So we roughly have, I think it's over 40 different molecules in clinical development. And we think that we're well positioned to -- for long-term growth.

So as we sat down and thought about our capital allocation strategy, it remains unchanged. We continue to prioritize internal investment, especially in research and development. We'll opportunistically look at business development opportunities where they make sense. But we also just initiated a dividend, which was the first time, obviously, for Regeneron. It's a modest dividend. It's about $400 million a year. It allows us to tap into a broader base of shareholders, which wouldn't have otherwise been able to invest in Regeneron before, which we think is really important.

But at the same time, we increased our commitment to returning capital to shareholders with the buyback, as you mentioned, added an incremental $3 billion of capacity that as of our earnings date in February brought total capacity to $4.5 billion, and we continue to think that will be our primary way of returning capital to shareholders.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Excellent. And just turning to the pipeline. So for this year, could you just touch on -- and we can go into maybe some details later, but just touch on some of the big pipeline cards turning over. I know you have several.

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

Sure. There's probably four that we can focus on. There's basically fianlimab, which is being studied in combination with Libtayo. We'll see data from first-line metastatic melanoma in the second half of this year. We'll also have interim Phase 2 data in non-small cell lung cancer that will be in the first half of this year.

We'll have data from our cemdisiran combo with pozelimab in myasthenia gravis. From our obesity franchise, we'll have Phase 2 data of trevogrumab, which is our myostatin antibody, which is being studied on top of semaglutide plus or minus garetosmab, which is an Activin A antibody. So we'll have that data in the second half of this year.

And then lastly, there's itepekimab, which I'm sure we'll talk about more in this discussion, where we'll have data -- pivotal data from our AERIFY program for itepekimab.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Excellent. Excellent. Great. In terms of EYLEA, one of the things that would be helpful to understand is just the key drivers in the near term. Clearly, you have one biosimilar competitor, you're going to have a full quarter of competition, right? And you had to compete on price.

So we'll see how the net sales shake out because obviously, you're losing both price and volume, and we'll see how that shakes out in the first quarter. But then beyond that, maybe you could just talk about the evolution. So you quickly this summer get into, hopefully, the prefilled syringe launch and that starts to turn the tide for the franchise effectively. But with respect to the state of play and defending volume share, could you provide a little more color on that for the 2 milligram?

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

Sure. So I mean, we touched on, obviously, the enhancements, Dave. And I think all three of those enhancements are important to physicians in terms of what they're looking for in terms of enhancing the competitiveness of EYLEA HD.

If you look at the prefilled syringe, Dave, something that physicians are looking for, there's an overhead in their practice right now. Where they actually have to take a vial, they have to draw up out of the vial into a syringe, they have to worry about sterility. And if you're injecting 100 patients a day, you multiply that by multiple physicians in practice, it's a lot of overhead.

So they're looking for that device. We've heard basically from anecdotal feedback as well as from focus groups as well as our colleagues, Bayer, who have basically gotten the same device approved in Europe that the device should be well received by the physician community. We just have to see how that goes.

Dosing flexibility, as we said, is important for physicians as well. It -- there's a small subset of patients that are difficult to treat. And physicians want to know that if they need to basically back down the dosing frequency that they have the ability to do that and the ability to get reimbursed and get paid. So that's really important. And then we touched on obviously the RVO indication and about the 20% sort of component that, that represents.

In terms of the competitiveness out there in the marketplace, it continues to be competitive. We're not going to specifically talk to what our pricing strategy is. I will tell you that for the first time in our history, we actually announced price increases for -- this was done in January, 2.5% for EYLEA and 2% for EYLEA HD. That's partially in response to some of the competitive pressures out there and trying to offset some of those pressures.

In terms of the specifics on what the dynamics look like in pricing, CMS publishes on a regular basis, ASP data that comes out quarterly, and that will give investors an idea of what the level of pricing pressures are out there in the marketplace.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Got it. Okay. Thank you. And just turning to physician customers, so we understand maybe get a little bit better sense for what percentage of the customer base is part of a group that is creating a lot of leverage to negotiate. How would you characterize the percentage mix of large group practice volume?

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

Sure. I don't think we're going to get into specifics on percentages, but maybe just give some qualitative background on what the market is like out there. Private equity has been very active in the retinal physician space, and they've been rolling up practices. Some of them are fairly sizable when you look at the number of physicians and the revenue opportunity there.

In addition, some of these private equity practices, they've been achieving some exits. So they've actually sold some of these roll-ups to what you would think of as traditional distributors. So that's an interesting dynamic, and we continue to watch that.

But even if you look at these large practices that you're talking about, some of the smaller practices belong to group purchasing organizations. And they are basically trying to -- as they look at the competition themselves and trying to run their practices in a most efficient way possible, they want to get the buying power that some of these larger physician groups have. So they join these group purchasing organizations, and that obviously puts pressure on pricing dynamics as well.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Got it. Okay. So then turning to Dupi. What can you tell us about the adoption of Dupi in COPD so far? When do you think it will start to meaningfully be reflected in revenue?

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

So it's early days, obviously, in the launch. We're encouraged by what we're hearing from the physician community. This is a group of respiratory specialists, pulmonologists that have used DUPIXENT for asthma. So this is obviously not a new therapy for them.

What we're hearing is they're encouraged. We've heard some anecdotal evidence of patients that have been difficult to treat and have had some initial good responses, which is great. We're seeing it in the NBRx data that we're -- if you look at the NBRx data for the launch and you sort of align that to other DUPIXENT launches compared to the respiratory launch for DUPIXENT historically doing better. So all good signs.

From a reimbursement perspective, I think we've got 85% of commercial lives covered. I think, it's 90% of Medicare lives covered. So all are good on the reimbursement front as well. So now it's just watching the launch and just ensuring that between ourselves and Sanofi that we're doing all possible to bring what we think is an innovative therapy of these patients.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Excellent. Yeah. And then turning to additional Dupi indications that are ahead. Could you remind us about those, including the potential timing of launches of those?

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

Sure. So we have two PDUFA dates that are upcoming. One is in CSU. I believe that's April 18. So that's chronic spontaneous urticaria. The approved therapy right now in that space is Xolair. Based on our understanding of the market research that we've done only about 15% to 20% of these patients are prescribed Xolair and somewhere in the neighborhood of 40% to 60% of those patients that are treated either have an inadequate response or no response.

So there's plenty of opportunity there to bring DUPIXENT to these patients where it could be a different alternative for both physicians and patients. So there's an opportunity there. I think the market research, there's roughly 300,000 potential patients in that market. So it's a pretty big opportunity.

The other opportunity is in bullous pemphigoid. I believe that's a June PDUFA date. That is a serious disease where a lot of these patients where there is no good treatment for them. The current sort of standard of care is topical corticosteroids or immunosuppressants. And those typically don't necessarily result in the best outcome for patients. So I think this is a great opportunity to bring an innovative therapy to those patients in need.

Not as large as some of the other opportunities, I think it's just north of 25,000 sort of applicable patients that are out there. But again, another example of additional growth for DUPIXENT and an example of it's literally a pipeline in itself and with multiple products and indications for DUPIXENT.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Excellent. And how does management feel the competitive threat from Lilly's Ebglyss, they had said on their fourth quarter call that they were going to be placed on two major formularies in March for AD. Could you comment on that?

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

Obviously, we continue to watch the space very closely with our partners at Sanofi. Right now, we haven't seen any notable sort of implications for the AD franchise. I think one thing to remember is, anytime there is a new entrant into the market, there will always be some trials that physicians will have with their patients.

But the way we look at it is, historically, when you have an entrant come into a marketplace it drives increased promotional spend. That gets the awareness out there with both patients and physicians and with DUPIXENT as the market leader in the space. We think that any expansion in the market will benefit DUPIXENT more so than might the competition.

I think the other thing that we should focus on is the mechanism of action, DUPIXENT clearly with its role in Type 2 diseases and how broadly applicable it is, a lot of these patients when they show up, either to their allergists or their dermatologist. They present with comorbid conditions, and DUPIXENT provides them with the offering that if you show up and you've got atopic dermatitis, but you also have asthma, you've got one stop shopping in DUPIXENT, so that's one of the key messages that we will make sure it gets out there with both physicians and patients.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

That makes a lot of sense. Great. So let's pivot to itepekimab. So the itepekimab Phase 3 COPD trials had passed an interim futility analysis back in 2023. Could you remind us about what you said on that specific interim analysis and then discuss what the study is powered to demonstrate this summer?

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

Sure. I would say not all of that information is available for me to talk about today, but I'll do my best. The interim analysis was performed after a certain proportion of patients had reached a certain time point in the study. And there was an efficacy bar that was evaluated by an independent data monitoring committee and us and Sanofi were notified that the trial should continue unchanged and it has, and we're now looking at a readout in the second half of this year. We did not disclose the bar and Sanofi and Regeneron are totally blinded to the data. So we're excited about that.

We think there's a good reason to believe that IL-33 and itepekimab could be a really important therapy in COPD. We not only have this past interim futility analysis, but we also have some very supportive Phase 2 data that we published, where in former smokers, which is the target population of the AERIFY study, itepekimab reduced annualized exacerbation rate by 42% and improved lung function by 90 ml's, which is an important thing because many had believed that COPD was a disease that was irreversible -- it caused irreversible damage to the lungs, and we are showing that with IL-33 itepekimab in the Phase 2 study as well as with Dupi, that's actually not true. And with the proper intervention, you can improve lung function over time.

So I think there's a -- we haven't provided the powering assumptions for the AERIFY program. They're similarly sized to the DUPIXENT COPD program around 1,000 patients each. There's a slightly more patients in the AERIFY-2 study as there is a small cohort of current smokers that were included. But those -- importantly, those patients will not count towards the primary analysis of the AERIFY-2 study was, regulatory request that we just -- we accommodated in. So there will be a small sliver of patients that are current smokers in AERIFY-2 study that we'll learn about but won't be in the primary analysis.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Okay. Thanks. That's very helpful color. Thank you. And the opportunity, and obviously, you're not providing explicit guidance, but the opportunity is for itepekimab to treat more patients than DUPIXENT. Could you just frame that out because clearly, that is something that my sense is that Regeneron sell siders haven't really possibly model appropriately, but would love to hear.

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

Yeah, I'd say that's correct. There's an actually only a minority of analysts are actually are modeling the itepekimab opportunity even today as we close in on the readout. So that's something we'll need to try and hopefully fix with positive data.

The addressable population for itepekimab is current -- is former smokers regardless of eosinophilic phenotype. And that in the G7 comprises around 1 million patients, half of which are in the US. DUPIXENT, on the other hand, is approved in patients, current or former smokers that have EOS at baseline above 300 microliters per unit.

And -- so there is an overlapping population that would be the former smokers with high EOS. There is a prespecified subset of patients in the AERIFY program that will look at annualized exacerbation rate reduction in those specific patients. And in fact, in Phase 2, we saw that they were better responders than patients that had lower eosinophils.

So we're excited to see that it could end up being itepekimab could be more effective in these patients with higher EOS, and we certainly would want physicians to learn about that and it will be part of the study in its readout. So overall, there is an overlapping population, but a bigger opportunity for itepekimab than for Dupi in COPD based on the target population.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

And have you disclosed the LOE for itepekimab?

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

We have not. I think we'll probably wait until -- certainly the readout possibly the approval before we get into patent life.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Okay. Great. So I wanted to pivot to Factor 11. Could you discuss at a high level what options Regeneron is considering for Phase 3 development and when you plan to update investors?

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

Sure. So our approach in Factor 11 is using two antibodies to create a tailored approach to anticoagulation. We have one antibody that targets the catalytic domain and really maximizes antithrombotic activity. We have another antibody that targets the A2 domain on Factor 11, which we think will reduce bleeding risk and still have adequate antithrombotic activity to compete with current standards of care in certain settings.

So our approach is really could one antibody where you want to maximize anticoagulation such as in a stroke prevention setting, this might be right for the catalytic domain antibody, where there are other settings that are, where they're not getting treatment. And we believe that DOAC's are only treating around half of the addressable population, where the A2 domain antibody 9933 may be more appropriate. So we're looking to improve the standard of care but also expand the market.

And we're going to do that hopefully through a combination of better safety and better efficacy in various indications. We haven't been specific and provided a road map for the development program as yet. We believe there is some competitive advantage to keeping that in-house. And as these programs get listed on clinicaltrials.gov, I'm sure people will notice, and then we'll begin to talk about them in more real time.

I'd say there are a few indications that are going to be smaller and will take shorter -- will be shorter trials to run and could lead to a faster path to market, while other opportunities are going to be in -- are going to require a large population in order to show stat sig improvement on the endpoints that we'll look at.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Excellent. All right. Great. And -- so have you said whether you're considering partnering for some of those large indications?

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

So we haven't said anything about partnering, Dave. I mean, obviously, we evaluate the merits of each of our programs. We look at the risk, and we look at what the commercial opportunity would -- and how to necessarily commercialize various assets. So as you look at Factor 11, we're going alone right now, but we're open to evaluating things if it makes sense as we go through and think about some of the risks and what some of the trade-offs might be in sharing economics that would be downstream.

One other factor as I alluded to as you're talking about a population that is a primary care population. And in addition to sharing the financial risks and rewards, it's also thinking about commercial execution, and what might be the most efficient way of reaching what is a fairly large physician population. So all things that we'll consider, but right now, we're going alone.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Got it. Okay. Very good. Then I wanted to touch on the oncology franchise and had a final question. So on the oncology franchise, could you just discuss the evolution of it over the next couple of years? Clearly, you have important new launches coming, which are going to leverage the infrastructure that you've invested in. But if you could discuss that in a little more in detail.

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

Sure. Maybe I'll look backwards before looking forward. Our efforts in oncology really centered around creating the best PD-1 antibody. And we think cemiplimab, Libtayo has its own on the brand side. We think we've achieved that with cemiplimab and it really is the cornerstone of our entire oncology strategy going forward, where we know that checkpoint inhibition is going to be an important mechanism and something that we can add to in hopes of modulating the immune system to better fight tumors.

So cemiplimab approved in 2018 has reached blockbuster status in 2024, did $1.2 billion and was growing at 40% last year. I'm excited to see that continue to grow in lung cancer and more recently with the adjuvant CSCC data that we toplined a couple of months ago, another opportunity to grow Libtayo in the future, we hope.

CD3 bispecifics are another cornerstone of our strategy, where in the hem-onc settings of myeloma and follicular lymphoma, we have two agents pending approval currently with midyear PDUFA dates for linvoseltamab in refractory myeloma and for odronextamab in relapsed refractory follicular lymphoma. And we think both of these agents are best-in-class in the late line settings, and that gives us confidence to look at them in earlier line settings, either as monotherapy or in very limited combinations.

And just to underscore that point, when we look at odronextamab in relapsed refractory follicular lymphoma, 80% response rate, 73% complete response rate on patients with multiple previous interventions. When we look at the standard of care in first-line follicular lymphoma, Rituxan plus a chemotherapy regimen known as CHOP. The historical complete response rate there is 67%. So you're looking at highly refractory patients that complete response of 73% versus frontline setting, standard of care, 67%. We think we can do better than that.

And in fact, in our pivotal study, Olympia 1, odronextamab monotherapy, we had a safety lead-in cohort of 12 patients, all of which had a complete response. We're very optimistic about odronextamab in earlier lines as we are with linvoseltamab. There's less data out there at this point on linvo in earlier-line settings. We hope to change that this year at some oncology meetings and begin to get people interested in what the ultimate opportunity for both of these are, the bigger opportunity is obviously in earlier lines where there's more patients and usually with longer duration of therapy.

Lastly, and this is really looking forward more so than in the past, is on our co-stimulatory bispecifics, which look to ramp up the immune system when paired with either a checkpoint inhibitor like cemiplimab or one of our CD3 antibodies. We have ongoing work in prostate cancer as well as in EGFR mutated tumors. There's a MUC16 costim that we're looking at in ovarian cancer. Those are earlier-stage studies. We've obviously had some issues with the PSMA by CD28 host in terms of getting the right safety profile, but that work continues and we're optimistic we can solve that problem.

So I think we're very optimistic about the oncology programs going forward. Like, again, with the backbone of Libtayo and building on that with fianlimab in LAG-3 in myeloma -- I'm sorry, in melanoma where we'll have pivotal data later this year. So a lot going on in oncology and hopefully a lot of good news to come.

David Risinger Leerink Partners – Senior MD & Senior Research Analyst

Excellent. Well, that's a great way to wrap up. Thanks so much for being here with us today. Really appreciate it.

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

Thanks for having us, Dave. Bye.
