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EDITED TRANSCRIPT

REGN.OQ - Regeneron Pharmaceuticals Inc at Jefferies London Healthcare Conference

EVENT DATE/TIME: NOVEMBER 19, 2024 / 11:00AM GMT

OVERVIEW:

Company Summary

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CONFERENCE CALL PARTICIPANTS

Akash Tewari Jefferies - Analyst

PRESENTATION

Akash Tewari - Jefferies - Analyst

Okay. Good morning, everyone. Thanks so much for joining us day one of our healthcare conference. My name is Akash Tewari. I'm a pharma and biotech analyst here at Jefferies.

This is the Regeneron management team. We have Ryan, Head of IR; and then Marion McCourt, Executive Vice President. Always a pleasure to have them in this conference.

Ryan, why don't I hand it off to you for some intro remarks, and then we'll get started?

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

Thanks, Akash. Great conference, as usual, very great meetings so far. And I'm just going to read this forward-looking statement, and we'll get started with your questions.

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.

The description of material risks and uncertainties can be found in Regeneron 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.

Back to you, Akash.

QUESTIONS AND ANSWERS

Akash Tewari - Jefferies - Analyst

All right. Thank you very much. So look, I wanted to start off maybe with high-dose Eylea because I think that's where we get the most amount of questions. And this is what I tell investors a lot. Everyone's like, oh, my god, the high-dose Eylea launch is disappointing.

And I point out to investors if you peg the launch of high-dose Eylea versus low-dose Eylea and Vabysmo it is still the best launch we've seen in wet AMD in history thus far. It's -- maybe it's slower than maybe investor expectations, but it's certainly not a bad launch.

But I do think on the Q3 call, you did say like, hey, there are some areas where we can improve and here's some things whether it's the prefilled syringe, whether it's getting monthly on the label, where we feel like we can really accelerate this.

So can you kind of frame how the launch is going in context early on? And what are some landmarks going into 2025 and beyond, that could lead to an inflection on that launch?

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Thanks, Akash, I'll take that. Good morning to everybody. So delighted to talk a bit about the Eylea HD launch and also the context of Eylea, where certainly we originally launched, I'd share with you, when we look at the quarters, we've reported for Eylea HD to date. They actually have been at the highest level in terms of net sales performance in the category, except for one product, and that product was Eylea. When Eylea launched 13 years ago, it had a more rapid uptake.

But in recent launches, and obviously, there have been several in the anti-VEGF category. Eylea HD is performing very, very well. Some of the specifics I'll give you that I mentioned in the third quarter for Eylea HD and Eylea.

We looked at net sales in the third quarter of $1.54 billion. That was a 3% increase year-over-year. We also talked about the $392 million in net sales for Eylea HD which also was a double-digit increase, I think, 20-some-odd percent over the prior quarter. So the launch is going well.

But I did want to be transparent in that call to talk about inventory levels. And also just share that as we go into next year, there are a number of elements that are going to further support the launch of Eylea HD that are really important.

One, for example, is that by midyear we hope to have an FDA approval for our prefilled syringe. That's an important convenience factor know that from our experience with Eylea, we wanted to share that.

Additionally, we don't have an indication for RVO in the Eylea HD label today. That's something also that we're progressing. We hope to see some data by the end of this year towards the very end of the year, the QUASAR data. And that also would enable a filing and potential indication approval as we get into the second portion of 2025.

So on balance, I'd share as well, we're very pleased with the efforts in market and the acknowledgment of the retina community on the factors of Eylea HD that make it a great choice for patients. Certainly, the clinical efficacy and the safety. We often hear the phraseology Eylea made better but really the most important differentiator is this level of durability that Eylea HD shows in the marketplace which is truly important for all patients for their caregivers, for their families, and for the physicians who are choosing meds for them.

Akash Tewari - Jefferies - Analyst

Understood. Now when you look at low dose Eylea, there's kind of three buckets. There's the 12 to 16-week kind of treat and extend patients. There's the -- that's the third -- maybe the two months and then the thirds the people who are very short in vitro half-life and they're going to be on monthly
dosing.

Going if -- logically, you would have thought the patients who are on monthly dosing, they're going to be the first ones to raise their hand and try to get on the high-dose Eylea product. Can you talk about not having monthly on your label for high-dose Eylea? Why is that maybe leading to that actual -- the lowest hanging fruit, I feel like biologically not maybe switching as fast as expected.

And then number two, you're generating data to get monthly dosing on your label. Can you talk about when that data comes out and then the possibility of an updated label as we get into 2026 or beyond?

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Sure. So first, let me talk a little bit about the profile of patients that are on Eylea HD. And very pleased to report that we have certainly naive patients who are being started on Eylea HD and remember, a significant portion of the marketplace is made up of Medicare fee-for-service. It's about 45% of the anti-VEGF category. There's freedom of prescribing there.

Obviously, commercial populations in Medicare Advantage may have utilization management or step-edit type approaches. But we're really pleased that we're having about 20%, 22% of our Eylea HD patients would be considered naive.

For the switch patients, not surprisingly, most of the switch patients come from Eylea. And as you know, Eylea and Eylea HD make up about 44% of the anti-VEGF category. So it makes sense that Eylea would be one of the largest sources of switching.

The second source of switching in terms of frequency is from faricimab patients, where the patient hasn't achieved what the physician was hoping for. And then probably third is Avastin. And as you talk about looking at the profile and some of the data and evidence we're generating, we hear very frequently that Eylea HD is the product that allows patients truly to extend their dosing, getting patients out.

If there are a switch patient out two, three weeks, sometimes more in terms of their ability to extend the patient. You know as well our clinical trials support even lengthier switches out of patients. And of course, the real world I would share with you the more physicians use Eylea HD in their practices, gain experience, the more comfortable they become with longer dosing intervals and a variety of patient types.

You mentioned the Q4 weekly dosing interval, and we are aware of that interest. I would share with you that the recalcitrant patients who potentially need that dosing interval or a smaller percentage of the market, but all patients are important to us. We will continue to generate clinical data, work with FDA, and see if that increment to the label as possible.

Akash Tewari - Jefferies - Analyst

Understood. And I was talking to Ryan about this post quarter, okay, you might get that monthly on the label, but it does seem like between that or the prefilled syringe. The prefilled syringe is probably the more important opportunity from a commercial inflection. Talk to me about why the prefilled syringe is important. And could we expect an inflection of uptake in the back half of next year as you get that online?

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Sure. So all of these factors, whether it's prefilled syringe, the RVO indication, these are going to be opportunities to get greater depth of use and greater experience of use. So it's all important. We do understand convenience for offices is an important factor. The prefilled syringe is significant.

And as an example for our Eylea utilization, over 90% is in the form of the prefilled syringe versus the vial today. So we do think that's a great opportunity. We'll work carefully with our clinical data and make sure we progress all of these items.

Akash Tewari - Jefferies - Analyst

Understood. Now I think the question we get a lot from investors is, okay, well, there's a potential for an Amgen biosimilar to enter the market now. Regeneron is really going to have to work on the switch. And in the back of my mind, I'm like what could they do differently?

You guys are already trying to switch as many patients as possible onto your next-gen formulation. I mean, is that perception correct? Now that you do likely anticipate a biosimilar to enter, what happens commercially the day after that news gets hit on the preliminary injunction that changes your commercial strategy on high-dose Eylea or is it nothing changed. We are switching patients as fast as possible.

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Sure. So our priority is that physicians have choice of medication, and we do believe that Eylea HD has the best profile for physicians and every aspect of ability to become a standard of care.

As it relates to other products just entering the marketplace, potentially, it's early days, potentially, there are legal uncertainties. But I think most important in the anti-VEGF category is realizing that products have to be used in the real-world setting.

As I mentioned, there's a lot of complexities in what's going on in the legal situation. But even beyond that, we've seen products that we may thought would make it to market that didn't because of clinical and safety issues. We've seen other products that did make it into the market in the anti-VEGF category. And then for a variety of reasons, either the clinical experience, what was not -- what was thought it would be or there was a safety issue. So I would just guide that it's early days.

The other thing that I've been educated by the physicians in the retina community and their offices have repeatedly is the importance of reimbursement certainty. And we're really in a really ideal situation today with Eylea HD. And of course, Eylea is a wonderful product in terms of being appropriate for certain patients. But reimbursement confidence is significant.

Today, in the payer environment, we have over 80% coverage for those portions of patients with Eylea HD, significantly as well. We are able to give patients the opportunity to continue therapy using a permanent J-code so for office staff. This notion for offices, I can be reimbursed for the product is significant. And as you know, it takes several quarters on the market before products move from a temporary code, which is very complicated for offices to a more permanent code.

Akash Tewari - Jefferies - Analyst

Understood. And just to put a finer point on that. To kind of what you're alluding to, any ophthalmologist should wait. I mean what happened with Beovu, what's happened with some of the GA products.

The Amgen biosimilar does look like it's a bufferless formulation. I mean just to be clear, do you feel like that will have any difference in terms of clinical profile or probably unlikely? It's more just these doctors are going to be conservative in terms of adopting anything.

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

Maybe it's -- maybe I'd start with -- I'm not sure we necessarily agree that it's a bufferless formulation. But putting that aside, there's limited data that they generated in their clinical studies. And what they did generate looks at basically every data point at every time point on the efficacy side to look like an inferior profile to that of Eylea and safety actually looks worse for the biosimilar.

So we'll see how that all plays out in the market. Obviously, the launch is very early along in its life cycle. But we're confident that Eylea is -- has been the gold standard and Eylea HD represents the future standard of care in the category.

Akash Tewari - Jefferies - Analyst

Understood. Yeah, I was -- this is a question that actually I've been starting to get more with investors on Avastin, and there's obviously been a shortage of Avastin in kind of the space, and it's just impossible for me to kind of track the compounding market because you just don't know what's getting used for oncology versus what's getting used in a compounding setting for wet AMD.

But has the supply disruption for Avastin somehow change either your patient mix or increase the opportunity for low dose Eylea to kind of take share as kind of that first treatment that you're putting patients on?

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Sure. So we are aware of the situation with Pine and their discontinuation of Avastin in the marketplace. It's early days. So I don't want to get ahead in terms of impacts. But certainly, both Eylea HD and Eylea are care alternatives.

And I think responsibly, payers have changed in many instances where maybe previously they would require an Avastin step edit to allow for more freedom of prescribing based on this situation. But early days, I certainly won't reassure all that our field forces are very active in offices and making sure that we're appropriately supporting information and things that might be helpful.

Akash Tewari - Jefferies - Analyst

Understood. Maybe stepping back and talking about Dupi in the COPD launch because I think there's a lot of interest there. I mean I think a lot of people don't understand. That's the third biggest killer of Americans in the United States.

You have the functional lung benefit, and you have a prescribing base, which is already educated in how to use and understand type 2 inflammation. I think we always get ahead of ourselves, but why wouldn't this launch -- just why wouldn't this launch be meaningfully better than what you saw in asthma with Dupixent? Any early thoughts there?

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

So all of the indications for Dupixent have been important and very proud of the team and our science in saying that for all the indications worldwide, we have seven approved indications for Dupixent sticks in the US and certainly, each has been very important in terms of transforming patient and physician lives.

For COPD, point very well taken, third leading cause of death, tremendous unmet need. First, biologic to help COPD patients with an asinophilic phenotype. Early days in the US, things are going well. It is a recent launch, but I think the teams are educating appropriately.

There's been a lot of interest from the pulmonology community in appropriate respiratory communities who already have experience with deficit now in the market for seven years approximately and a product that is approved for children down to the age of six months in atopic dermatitis and one year in eosinophilic esophagitis.

So the profile and the clinical data on COPD are quite compelling. And certainly, we'll work hard on the launch. As you all know, COPD Dupixent approval is now in 30 countries worldwide. The launch in Germany is ongoing. And certainly, all indicators are that this is going to be a meaningful product for appropriate COPD patients.

Akash Tewari - Jefferies - Analyst

Understood. And then maybe what you've seen in Europe and what you expect in the US? I mean you don't have a cutoff for 300 eosinophils, right? It's just basically -- because rarely do patients have sustained elevated eosinophils, you have a broader just elevated label.

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Yes. Just to clarify on that, in the US label, it is 300. The test for eosinophil level is a routine test. There's also a look-back period. So to your point, there can be variability in eosinophilic levels there's a period of months of look back generally that is within the window of opportunity.

The other thing that's really important to realize is COPD patients, when they do enter the emergency rooms and hospitals, often it's a lengthy stay. I mean I think we're aligned with the payer community and wanting to make sure that these patients are treated and aren't hospitalized for lengthy stays.

In contrast to never good, but an asthma patient, if they do end up in ER, usually, it's a hopefully, shorter visit. They go home, they're on their meds, things of that sort. COPD is a much more costly situation for the healthcare system, and it's great to have an alternative in care now with Dupixent.

Akash Tewari - Jefferies - Analyst

Understood. And I mean, I think the question becomes from a payer perspective and really where this market gets adopted, I feel like over time, it's going to just basically be generally T2 high. Maybe 150 will be the cutoff that actually gets used in clinical practice.

And then number two, you're not even waiting for patients to be on triple therapy. They might be on double therapy and you're like, look, if they need a clinical benefit, we're going to get them on something that's disease-modifying like Dupixent. What are the kind of access restrictions you've seen so far with COPD? And how do you think that may evolve over time?

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

So it's -- I think it's very favorable that the coverage to date is to label where we've seen determinations on payer coverage. There have been several. It's looking very good. The coverage is to label. And I would hear that very often the COPD patients have been on triple therapy. But the important thing is Dupixent is able to help them with a systemic therapy. And early days, the reports have been quite favorable.

Akash Tewari - Jefferies - Analyst

Understood. Maybe switching to atopic dermatitis. And this is obviously a major label for Dupixent. Lilly is entering, you have the OX-40s and Lilly's talked about, hey, we're going to not do the same mistake we did with Taltz where maybe we didn't discount out of the gate aggressively enough. But Dupixent is clearly standard of care there.

It's great payer access. How do you anticipate commercially handling the entry of a legitimate competitor like Lilly with the IL-13, which does also have comparable data. Do you expect to see any change in the market share or your uptake in atopic derm growth going into next year and beyond?

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

So I think there's a lot of confidence in Dupixent in atopic dermatitis. The product has performed very well now in the market across age groups, across geographies. The persistency levels are very, very high.

Often, the KOLs that I talk to speak of Dupixent as being first and best in category, I'd also share that we take all competitive readiness very, very seriously. And I think our team is always rise to the occasion. Competition is good in bringing out the best often in individuals education and clinical profile of drug. So we're confident in Dupixent's profile.

I also would share there is a competitive product in the anti-IL-13 on the market today that has largely disappointed in terms of comparison with Dupixent. The other item, I think that's important is there's still so much unmet need in the atopic dermatitis marketplace. We've probably penetrated only to the high teens in terms of percentage of moderate to severe patients to be held by Dupixent.

So some of the incremental attention to the category has been favorable for patients and physician interest as well. But we certainly are very proud of what Dupixent has done across the age groups.

Akash Tewari - Jefferies - Analyst

Understood. Now I remember meeting with [Lennon George] at the event at JPMorgan. I felt like there was increased confidence on the IP for Dupixent, where I think a lot of investors are like, okay, it probably goes off early 2030s. And your team was like, no, we see this going into the mid-2030s or potentially beyond. Can you talk to us about your confidence on the IP portfolio for Dupixent? What should investors be modeling as a base case and why?

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

That's a good question. I think our composition of matter patent expires in March of 2031 in the US, and I think that represents the strongest IP in the portfolio. That said, there are a number of other patents that cover formulation methods of treatment as well as manufacturing that we believe could extend marketing exclusivity into the early to mid-2040s. That would be some of the longer dated patents. Of course, we expect any and all of these patents to be challenged by biosimilar manufacturers, and we'll see how they hold up in court.

I'm not willing to handicap that right now. It would be unwise to do that given we don't even know who the competitors will be, what their formulations are going to look like, anything like that. So a little premature to try and speculate there.

I'd note also that in Europe, we have supplementary protection certificates that expire in 2033. And with longer dated patents covering formulation, et cetera, there as well. And then in Japan, expiry is in 2034. So we feel very good about the runway we have with Dupixent and are going to do everything we can to maintain its exclusivity in all of these markets for as long as possible.

Akash Tewari - Jefferies - Analyst

Understood. Now I mean, I know maybe I wasn't thrilled with the OX-40 data that maybe has initially come out. But I think a legitimate point, some people say is like Sanofi has done a better job than Regeneron thus far, elucidating what a life after Dupixent looks like.

And I think that's -- right now, it's probably true, right? You haven't really had next-gen I&I targets that you've announced yet, but I'm sure your team is working on it. Talk to me about what's the internal Regeneron plan for life after Dupixent? And can we think about new product candidates being announced and trials starting to occur in 2025. What's the strategy there?

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

Another great question. I think we view itepekimab which is our IL-33 antibody, that's also in the Sanofi antibody collaboration as a next-gen Dupi perhaps in certain respiratory indications, including COPD, where we're in a Phase III program that will read out next year. There's other potential respiratory indications we may pursue currently have a Phase II underway in non-cystic fibrosis bronchiectasis, and there's more opportunity there that we may explore with Sanofi down the road.

Beyond that, within the Regeneron pipeline, we do have a number of preclinical candidates that we're working on. I think a few of them may IND in 2025 and 2026. And they certainly will look to expand upon Dupi's treatment interval as well as its level of efficacy. So we are excited about these targets and look forward to bringing them to the clinic or we can talk more openly about them.

Akash Tewari - Jefferies - Analyst

Okay. Understood. Now maybe thinking about capital allocation. I mean you're approaching $20 billion cash on hand. And everyone is like, Regeneron doesn't like buying stuff. They have inventor syndrome. But you're at a different place in terms of your -- where you are as a company. You have a lot of flexibility with your balance sheet.

So talk to me about your appetite of share buybacks, dividends, things that can maybe open yourself up to a new shareholder base versus going out and doing a larger transaction, a $5 billion, $15 billion deal, where you feel like you can diversify away from Dupixent, Eylea.

I think you guys would probably agree right now the valuation is probably not even fully reflecting your base case on Dupi and Eylea. So where does BD fit in versus some of these other levers you can pull?

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

I think we are -- we view capital allocation as something that's important to balance, and we continue to prioritize internal R&D with our spend, and that has proven to be a very high return spend. So I think that's going to remain the priority.

We're also actively repurchasing shares. Now the valuation, we think, is significantly dislocated from our intrinsic valuation that we maintain internally. I'd also say we are considering a dividend. And I think the appropriate time that we may decide to initiate one will be after the development balance with Sanofi has paid down. Obviously, that's a decision that the Board will make in due time, but it's something we continue to look at very closely.

With BD, I think our lens is really not around dollar size of a deal. It's really about what can we bring to add value to the target. So far, most of those have taken the form of platforms where they're complementary to a Regeneron antibodies technology.

I think we'll continue to look at those types of opportunities, but we're never going to take anything off the table in terms of what we may look at with business development. So I wouldn't suggest that we're only going to look at platforms. But right now, that historically, that's been the priority.

Akash Tewari - Jefferies - Analyst

Understood. And look, maybe just on obesity. I feel like I would say the interest on your program and my stance in general for obesity, it's gone down, it's not gone up over the last year. And I think part of that point is why would you want to stay on a myostatin forever? You use it in a short period of time when you're buys in a catabolic state, you're eating away at your body as you're in a caloric deficit.

But then get off the myostatin and stay on the GLP-1. And I feel like when I talk to your team, it's the opposite. I want you to stay on the myostatin and get off the GLP-1. Why is that the right paradigm? And then number two, what do you feel like investors are maybe misunderstanding about your myostatin program right now?

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

I think the volume has turned down a little bit on myostatin programs in general, simply because there's not been any new data to talk about. So we will be reading out our primary endpoints for the myostatin/activin A COURAGE study in the second half of next year.

I think our view is -- and this is going to be the second half of COURAGE, is going to look at myostatin as a maintenance regimen. And we think that's the ideal approach, mainly because of the side effect profile. It's very benign relative to that of the GLPs, which have a lot of GI toxicities associated with them.

If you're able to lose your weight in the first 6 to 12 months, the induction phase as we'll call it, and then remove the GLP, stop feeling nauseous and having some other unpleasant side effects but stay on something that preserves your lean mass throughout that entire journey and you can keep all of your weight off. That's kind of the ideal regimen.

So first half of COURAGE, we'll look at weight loss inclusive of semaglutide on top of GDF8 and activin A. After six months, all patients will drop semaglutide and half will remain on myostatin. So we'll be able to see if maintaining the weight loss and maintaining the lean mass exists for the next 26 weeks. And that could be very informative for our Phase III plans.

So we have a very broad approach that we're taking. I think over the next couple of years, we're going to see a lot more from Regeneron in the obesity space, and we're excited to bring those things forward as quickly as possible.

Akash Tewari - Jefferies - Analyst

Understood. I know we're out of time. Thank you so much. Really appreciate it.

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Thank you.

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

Thanks, Akash.
