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EDITED TRANSCRIPT

REGN.OQ - Regeneron Pharmaceuticals Inc at RBC Capital Markets Global Healthcare Conference

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Brian Corey Abrahams RBC Capital Markets, Research Division - Senior Biotechnology Analyst

PRESENTATION

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

All right. Let's get started. Welcome, everyone. I'm Brian Abrahams, senior biotech analyst here at RBC Capital Markets. Really pleased to have Regeneron here, represented by the CFO, Chris Fenimore, and their SVP of IR, Ryan Crowe. Chris and Ryan, thank you guys so much for joining us.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Thanks, Brian. Great to be here at the RBC conference. Just going to read a quick forward-looking statement disclaimer.

I'd like to remind you that our remarks made today may include forward-looking statements about Regeneron. 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. Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. Brian, happy to jump right into your questions.

QUESTIONS AND ANSWERS

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Great. Thanks, Ryan. So there's a lot going on, so a lot to cover, but maybe let's start with the ophthalmology franchise and EYLEA. And maybe can you talk a little bit about what you're seeing on the ground. It's been a few weeks now since the permanent J-code for EYLEA HD. Can you talk about some of your early observations on the drug's uptake since the J-code and what you're seeing with respect to positioning versus other long-term agents?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure. Thanks, Brian. As Ryan said, thanks for having us. So EYLEA is the leader in the anti-VEGF category. If you look at combined market share between EYLEA and EYLEA HD, it was 45% in the first quarter. If you look at EYLEA HD in particular, the launch is progressing very nicely. Sequentially, growth was up 63% since Q4 to about $200 million in the first quarter.

We're seeing on HD, in particular, an increase in both depth and breadth of use. So as we think about depth, we're seeing existing customers post the effectiveness of the J-code on April 1, ordering more. And if you look in terms of breadth, we're seeing new customers ordering who haven't ordered before, which is -- it was -- which is great to see.

On top of that, as you look at the dynamics out there in terms of what we're seeing with market access, we have greater than 80% of covered lives have access to EYLEA HD, with that being, we are seeing that on the payer landscape, it's a much different landscape than it was basically over a

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decade ago when EYLEA launched, and we are seeing a little bit of an uptick in utilization management by some of the payers, but that's an issue for all branded agents and not just EYLEA or EYLEA HD.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

With regards to the IRA and its potential impact on the franchise, what's your latest thinking on Medicare Part B drug pricing negotiation? And I guess short of having Part B guidance, what's your latest codified? What are your latest views on when a biosimilar might need to come to the market in order for this franchise to avoid IRA discounting?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

So it's a very good question, one we wish we had better clarity on, quite frankly. But in the absence of the Part B guidance, as you mentioned, Brian, we're kind of left to assume maybe there's some read-through from the Part D guidance, where drugs with the same active moiety are aggregated for purposes of both selection and from exclusion from the negotiation process.

So if you were to use those Part D rules for Part B drugs and any biosimilar launches prior to the selection process beginning, all drugs with the same active moiety should be excluded from the process. So we're certainly keen to understand better how the CMS is going to interpret the law for Part B drugs. But absent that, we're kind of assuming it's going to follow a similar trend as the Part D guidance.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

And then speaking of biosimilars, it's obviously an important week this week with regards to the biosimilars in the LOE. And I know this is a scheduling conference for the recently consolidated lawsuit against multiple biosimilar -- biosimilar filers that's happening in just a couple of days.

Can you tell us a little bit more about what might be discussed there? And just any similarities to the earlier case, how should we be thinking overall about the standard dose EYLEA durability and LOE?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

It's another one that's tough for us to answer, Brian, but I think we had -- we obviously backing up a favorable decision that was issued at the end of 2023 with regard to a formulation patent for EYLEA, the 865 Patent, which was found to be valid and would be infringed by Biocon by a judge in the Northern District of West Virginia.

That same judge has asked that other parties that are involved in aflibercept litigation to come together on May 17, and that happens to be the last day of regulatory exclusivity for EYLEA. So I think he has a lot of options for that meeting. He certainly, I think, is considering how to best protect and defend aflibercept IP rights, which would be infringed by Biocon, while not neglecting others who haven't had their cases heard yet.

So he's got a delicate balance that he needs to find. We're certainly anxious to sit down with him and see what he's thinking for the days following and the weeks and months and years following regulatory exclusivity for EYLEA until these other cases can be heard.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Okay. Makes sense. We're looking forward to that. Maybe we shift gears to DUPIXENT. Obviously been a really strong performer for many years. First quarter always has its seasonal headwinds, which you experienced this quarter as well. But even your partner Sanofi is guiding for about $14 billion in global sales for the full year.

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So can you talk about maybe just, I guess, some of the onetime factors that may have impacted first quarter? And then how you guys are thinking about growth drivers for DUPI over the course of this year? And what's really driving you and your partners' confidence in the potential for this growth trajectory to really continue to be so strong?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Sure. So just one caveat Sanofi actually book the net sales for DUPIXENT, what we have heard from our partner, is that due to seasonality, there's a lot of insurance resets that happened, and this is something that happens in the normal course every quarter and we've seen it historically with DUPIXENT.

I think the most important thing is what you reiterated, which is that Sanofi basically had previously got to about EUR 13 billion, which is $14 billion. They reaffirmed that guidance on their most recent call.

In terms of growth drivers, if you look at DUPIXENT, we refer to it, obviously, as a pipeline within a brand, and it's -- if you look at across all of its approved indications, we are basically leaders with our colleagues at Sanofi and NBRxs, I think, in 4 of the 5 approved indications, we're in the #1 position in TRxs.

If you look at recent launches, both in EoE, eosinophilic esophagitis or PN prurigo nodularis. Those launches are progressing well. We most recently had an expansion on the EoE indications in pediatrics. So we're obviously excited about that opportunity to bring in DUPIXENT to such a young patient population where EoE is a fairly serious disease. And then we've got, obviously, PDUFA data upcoming with COPD and obviously, an exciting opportunity there in terms of bringing DUPIXENT into that patient population as well.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

We've heard a lot of enthusiasm on the part of pulmonologists for having a biologic like DUPI and COPD. Can you maybe talk a little bit more about the regulatory process there? I know the FDA requested some additional data. It sounds like that was primarily to ensure that efficacy wasn't being driven by any subgroups.

How far are you -- how far along are you with respect to gathering, analyzing, and providing this data and can you -- maybe elaborate a little bit more on the basis for -- what you think the basis was for the FDA's request. Is there -- I guess, is there any concern about whether certain subgroups females, patients with high based on exacerbations or lower IG, whether they might not perform as well? And what's kind of your hope for the ultimate breadth of this label expansion?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

That's a great question, and we're certainly working with the FDA to ensure that they're satisfied with the review and the quality of the data that we're providing to them as part of this process.

Recall, we filed for approval at the end of 2023, and we're giving the priority review. The PDUFA date is June 27, and we said on our most recent earnings call that an information had request -- an information request came from the FDA asking for all of these various subgroups. And I can tell you there are dozens of them that the FDA has asked about, and that includes some of the ones that you listed, everything as basic as ages and genders all the way down to history of emphysema.

There's all kinds of different types of analyses that they've requested. And so far, we've been able to perform them. We've already submitted our information request response. That was last week. So that's in front of the FDA now, and we continue with the process and continue to engage with them.

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And we're optimistic that an on-time decision can still be made. We were given a month to respond to the information request and we responded in a little over a week. So we're hopeful that with that promptness of response and responsiveness, the FDA will continue on track for an on-time of decision.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

And what's your level of confidence that the drug will have reasonably comparable efficacy across many of these subgroups. To the extent that...

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

We've seen very, very consistent, and clinically meaningful efficacy across every single subgroup that we looked at. So the FDA, I think, is just being very diligent in their review. Obviously, they had an experience a couple of years ago with a biologic that was seeking approval in COPD that was driven by asthma patients primarily. And that's obviously not the case here. We excluded asthma patients from our studies. And we are confident that this is not an approvability issue, but one rather of ensuring that all patients that we enrolled benefited from the drug.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Good. Great. So maybe let's shift gears and talk about the obesity platform. There's a lot of different ways that you guys can potentially compete in this emerging space, starting with your myostatin in Activin A Antibodies, where I know we just got some additional details on the healthy volunteer study that you guys have previously run.

What are your latest views as to where agents like that can fit into the treatment paradigm? And what aspects of the SAD and MAD data as well as Part A from the ongoing Phase II study, do you find most encouraging ahead of potentially moving into patients with obesity in combination with the GLP-1.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

There's a lot packed into that question. Maybe I'll start, and Chris can add to my answer. But I think the last question first, I think most encouraging from the single ascending dose data that we presented on Sunday was that we saw an increase in lean mass and a decrease in fat after just one dose of either durvalumab or garetosmab or the combination thereof very encouraging tolerability and safety profile as well. So it looks like these drugs are going to be pretty well tolerated.

Of course, we don't know their role yet because we need to run Part B of our Phase II study, which we'll layer on our anti-myostatin antibody with semaglutide with or without garetosmab or Activin A Antibody. This is a study that has a 26-week primary endpoint with the endpoints being weight loss as well as percentage of fat loss. And then there's another 26-week Part 2 of Part B that looks at maintenance where all arms will drop, semaglutide and we'll see what high dose trevogrumab, in maintenance setting looks like.

And perhaps that's where these agents play best. We know that weight loss plateaus on these agents somewhere in the 6- to 12-month range. And people drop therapy as a result of tolerability issues. If they're able to lose that weight in those -- in that same period, but then drop semaglutide and perhaps keep on a myostatin antibody and maintain that weight loss and the body composition, that might be the solution for a lot of these body composition issues and weight loss rebound issues that we're seeing in the real world today.

So we're very confident and optimistic about the outlook for both of these antibodies. We're anxious to get enrollment underway in the obese population next month, and still are on track for a readout sometime probably in the second half of next year.

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Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

What sort of read-throughs would you be looking for other Activin myostatin pathway targeted approaches, which maybe are not as nuanced as hitting the ligand and then more kind of receptor-based approaches. And I guess maybe along with that, how are you guys thinking about balancing the potential additional efficacy benefit from an Activin antibody with some of this potential side effect trade-offs that we've seen with the garetosmab antibody historically?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Yes. I think you're referring to bimagrumab, a study that Lilly is running in combination with semaglutide, and theirs is a Activin type 2 receptor blocker as opposed to blocking the individual ligands for GDF8, which trevogrumab does or Activin A like garetosmab does bimagrumab blocks the receptor, and that receptor binds to about 3 dozen different ligands, all of which have different biological manifestations.

So it's unclear exactly what that will mean from a tolerability or efficacy standpoint. I think we fully expect there to be incremental weight loss. This is a pretty well validated pathway. And the question will be on safety and tolerability, I think we're certainly anxious to see what those results look like.

Again, our study is we have a much more specific targeted approach, and we think that could result in a better tolerability profile, which is going to be very important for a very broad population like this. What we saw in the nonhuman primates and the interplay between trevogrumab and garetosmab was that trevogrumab was sufficient to preserve lean mass. Essentially, no lean mass was lost in the trevogrumab, semaglutide combination. It was all fat.

And the trevogrumab, semaglutide garetosmab arm on the other hand, we saw even more fat loss, but with some lean mass gains. So that might play a role in an elderly of this population that really could benefit from adding lean mass in the presence of a caloric restricted diet.

So we're -- it might be a more nuanced or a more niche indication, a more specific indication for garetosmab because it does have other safety concerns that trevogrumab does not appear to have. So we'll be watching all that and trying to figure out what makes the most sense for this market once we get more data.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

That makes a ton of sense. Maybe going back to Dupi, Chris, I find one of the areas that people are either confused about or don't have a full appreciation of is the step-down in collaboration expenses or the step-up in collaboration revenue through the partnership that you'd be expecting once the development balance is paid off. So can you maybe elaborate a little bit more on what we should be expecting? And what type of impacts we might see for margins and earnings once that happens?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure. So the development balance and for the first time, we actually, on a quarterly basis, have published what that development balance was, which was $2.2 billion as of the end of the first quarter. We will continue to do that going forward to help investors understand how that balance is being paid down.

We also stated on our earnings call that we expect the balance to be paid down by the end of 2026, and that's obviously subject to how well DUPIXENT does and how the margins evolve over the next couple of years. What we have historically said in terms of what that impact would look like is somewhere in the neighborhood of $600 million to $800 million of a step-up in collaboration profits or our share of those profits, which we would expect to see after that development balance is paid down.

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Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Got it. And as we think about -- let's just think longer term about life cycle, can you talk about some of the ongoing life cycle management work that you guys are undertaking? How far along those are? Are you -- are they mostly focused on sort of longer-acting versions or maybe incorporating additional improvements to IL-4 and IL-13 targeting?

Any sort of existing or additional formulations, just formulation patents that are out there that themselves could extend the exclusivity period for DUPI? How are you thinking about this franchise longer term? And where are we at with life cycle?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Great questions. We obviously are well aware of the composition of matter patent expiry for DUPIXENT in the U.S., which is in 2031. We're also very confident in the rest of the patent estate for DUPIXENT, which has much longer dated patents into the 2030s and even the late 2030s in some cases. And we're certainly along with Sanofi going to be defending them as vigorously as we need to defend them.

In terms of other approaches to address type 2 inflammatory diseases, and we have several different approaches in preclinical development, and we generally don't comment on mechanisms or things like that. But I will broadly say that there are some that are looking at kind of a longer-acting DUPIXENT as well as others that have -- other approaches that are kind of an adjacency to where DUPIXENT is today. And we'll certainly -- we're anxious to bring them to the clinic. And as soon as we do, we'll let you guys know.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

On the pipeline, on linvoseltamab, how are you thinking about that launch. That launch is going to be coming up relatively soon. It's going to be the second drug in this particular area, your first drug in heme-onc, what are some of the advantages that could enable broad uptake here? And maybe can you talk about some of the updated data we should be looking for at ASCO?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure. So if you look at linvoseltamab, we've got a PDUFA date upcoming in August. We're excited about the potential for linvoseltamab to potentially be best-in-class in that category.

If you look at where we see the product being differentiated, it's on an efficacy front. So again, you have to take cross-comparisons with a grain of salt. -- from an ORR perspective, we -- and again, comparing numerically to similar periods of follow-up, looking at other competing agents that are out there, but ORR is at a 71% rate.

If you look at complete responses, also looking very good at a 46% rate. So we're very encouraged that as we get to see more follow-up data that there's even a potential for those numbers to go up.

Beyond that, if you look at safety from CRS is sometimes an issue of some of these agents are rates, again, looking across studies at 46%, much lower than some of the other competing agents that are out there.

And then another area of differentiation is convenience for the patient. So from a hospitalization perspective, linvoseltamab is right now at about 2 days, and we're hoping to get that even lower. And the other competing agents is somewhere between 3 and 6 days. So we think there's really an opportunity to clearly differentiate linvoseltamab as a best-in-class agent.

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Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

And we won't have any more data at ASCO, Brian, but we do plan an update for EHA with a few more months of follow-up. I can see whether or not those CR or better rates continue to improve.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Yes. I meant to say. And then on the cancer portfolio as well, I know we'll see some additional data from fianlimab in lung cancer later this year. Obviously, a potentially large market. What should we be looking for out of this next cut of data? And then are you seeing anything from your initial clinical or preclinical data that might speak to a sub population of lung cancer patients who may be optimally responsive to LAG-3.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

So I'll start with -- maybe I'll start with melanoma, where we have a lot more clinical data, and we have shown, I think, a pretty significant differentiation across trial, of course, to either PD-1 monotherapies or other immuno-oncology IO-IO combination with response rates in the low 60s, that compares very favorably to 30%-ish for PD-1 monotherapies and a 43% response rate for Opdualag.

We are excited to show some more data later this year with continued follow-up of the same first-in-human patients, where we've seen with continued dosing, even deeper responses. So that data we'll share in the second half of this year, which gives us a lot of confidence on the melanoma tumor.

You may have recall -- you may recall from our conference call, we also said that we'll have the final Phase III data next year and not provide a Phase II interim look later this year as we had initially thought we would. So pushed out the timing for the next readout in melanoma, but it will be registration-enabling at that time.

In lung cancer, we only have a handful of patients. So it's unclear exactly how LAG-3 plus Libtayo will perform in lung. But we have, like, as I mentioned, in melanoma, such deep responses and broad responses that we're very optimistic that we can have a similar experience in lung, and we'll let the data inform that decision on whether to move forward in Phase III at some point later this year.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Okay. Chris, I'd be remiss if I didn't ask about capital deployment and R&D investment. How are you currently thinking about deploying your growing cash on the balance sheet? And can you tell us a little bit more about how your bigger picture approach in balancing R&D pipeline expansion versus additional share repurchases versus external opportunities?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure. I mean our capital allocation strategy has been consistent over the past couple of years, and I don't foresee that changing. First and foremost, we want to invest in George Yancopoulos and his team in terms of the pipeline that his team has brought forward, and we think there's ...

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Worked well so far.

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Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

It's worked well so far. And then we think that's the best way to invest our capital to deliver long-term returns for shareholders. When you look beyond the pipeline, we've got a business development group out there that's fairly Activin looking at complementary technologies we historically have done, for the most part, traditional collaboration deals, and you see that with the likes of arrangements we have with Intellia and Alnylam. We most recently announced a deal with Mammoth Biosciences as well.

And then the third pillar of that strategy is to be out buying our shares back. We finished the first quarter with about $1.2 billion remaining under an existing authorization and also announced an additional $3 billion authorization, which was new. So it will give us a lot of flexibility to continue to return capital to shareholders over time.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Good. Maybe just in the last 20 seconds. What do you guys' think is most misunderstood or underappreciated about the Regeneron story?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Maybe I'll go. I think the fundamental genetics work that we're doing, I think it's hard for people to understand the value that it brings to Regeneron because you can't put a number in a cell and then put it through your DCF models. It's something that -- but it is something that's ingrained throughout every decision we make at Regeneron. We had come up with a hypothesis and we go and say, "Well, what do genetics tell us? Does that make sense?" And the RGC has now sequenced over 2.5 million exomes, all linked to de-identified health records and the target identification engine continues to hum along.

It also is great for informing clinical trial design and also for diligence on BD opportunities. So we use it in all sorts of ways, and I think that's something that's probably underappreciated from an investor standpoint.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

And we were fortunate to have some of those members of that team at our conference last year...

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Correct.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Quite a limit...

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic & Analysis

Yes. Aris and Christos.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Great. Well, there's still so much more I'd love to cover. But unfortunately, we're out of time. So Chris, Ryan thank you guys so much.

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Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Thank you.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Thanks, Brian.

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