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OVERVIEW:

Company Summary

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CORPORATE PARTICIPANTS

Brook Jennings *Regeneron Pharmaceuticals, Inc. - VP of Commercial Dermatology*

Ryan Crowe *Regeneron Pharmaceuticals, Inc. - VP of IR*

PRESENTATION

Colin Bristow *UBS Biotech Analyst*

Good morning and welcome to the UBS BioPharma Conference. I'm Colin Bristow one of the biotech analysts here. It's my pleasure to have Regeneron Pharmaceuticals with us today. On behalf of the company, we have Brook Jennings, VP of Commercial Dermatology; and Ryan Crowe, Head of Investor Relations. Thank you both for being with us today. I'll turn it over to you guys now. I know you have some prepared remarks, and so I'll leave it to you. Thanks.

Ryan Crowe *- Regeneron Pharmaceuticals, Inc. - VP of IR*

Yes, we won't spend too much time on this, but let me first get the FLS disclosure out of the way. 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 on Regeneron's SEC filings. Regeneron does not undertake any obligation to update any forward-looking statements or as a result of new information, future events or otherwise.

With that out of the way, perhaps I'll just provide a brief recap of the third quarter, and then Brook can talk about DUPIXENT. He's responsible for the derm indications, but certainly knows the entire brand extremely well. Third quarter is very strong for Regeneron. We had a 15% top line growth, most of which dropped to the bottom line. We had a 4% EPS growth. But when you add back the $100 million IP R&D charge, EPS would have grown 11%. So very strong top and bottom-line performance for the company. EYLEA maintained market share and EYLEA HD is off to a great start posting $43 million of revenues.

LIBTAYO, now annualizing close to $1 billion and growing at 62% globally. It also is coming on strong. And of course, DUPIXENT with -- annualizing over $12 billion and growing at around 33% in terms of net product sales, just a great commercial performance overall for the company. On the pipeline front, a couple of updates. We obviously got the approval for EYLEA HD and presented data from both PHOTON and PULSAR in the last few months. The 2-year data, which showed a very high proportion of patients able to maintain dosing intervals of greater than 12 weeks with even more results and extended durations.

I think something like 78% in the wet AMD study, were able to be eligible for q16 dosing or greater. So it looks like a very paradigm-changing product, we're positioning it as the new standard of care for these retinal diseases, and the launch is off to a great start. I'm sure we'll talk more about it. We also reported that the odronextamab BLA was accepted and we'll have a March 31 PDUFA date. DUPIXENT for pediatric eosinophilic esophagitis also had an accepted sBLA with a January PDUFA date as well. So lastly, and this was part of an acquisition of Decibel DB-OTO, we had preliminary data that showed improvement in a single patient with congenital hearing loss related to the otoferlin gene.

So we're continuing to follow up with that patient and hopefully continuing to see improvements in their ability to hear, and also looking forward to dosing additional patients to further validate this platform. So really a great performance across the entire company in the third quarter. I'll let Brook get into some of the details of DUPIXENT in the most recent quarter and what the outlook for that brand looks like.

Brook Jennings

Thank you very much. And much like with Regeneron overall, I think DUPIXENT had a very strong third quarter. If you look at the overall sales and you mentioned it's now annualizing at over $12 billion. So $3.1 billion in sales in the quarter globally. And that is across each of the indications, all

of which are growing. That was a 33% growth year-over-year and almost 12% quarter-over-quarter growth from a dupilumab perspective. When you look at the indications, atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, EoE and prurigo nodularis, all of which are contributing meaningfully to the top line growth of the brand, which is great.

You look at what the future holds, both short and longer term from a dupilumab perspective as well. We have the ability to add roughly-speaking, another 650,000 patients to the potential patient population in the United States alone. When you think about the potential indications of chronic obstructive pulmonary disease, chronic spontaneous urticaria, bullous pemphigoid and the aforementioned EoE pediatric indications. So there is still meaningful growth there. And when we look at the brand itself specific to the markets in which we are currently indicated, those penetration rates also show that there is a significant opportunity for growth.

So the adult atopic dermatitis penetration rate is still about 12% overall. So there's a lot of upside that is left there in the asthma space, specifically for those that are biologic eligible. That number is still just over 20% penetration, and there are 6 different drugs in the marketplace for that currently. So clearly, as additional modalities come to the market, MOAs come to the market, we have an opportunity to meaningfully grow both penetration overall as well as the brand across every indication. So it is an exciting time for DUPIXENT.

QUESTIONS AND ANSWERS

Colin Bristow

That's great. Perfect intro. I mean, DUPI has been an incredible grower as you articulated. As we look at 2024, what are the key indications that will be driving that growth?

Brook Jennings

So certainly, we know that atopic dermatitis continues to be a monster in the marketplace. And we are continuing to invest heavily in growing that market overall, which has been great. And prurigo nodularis specific to dermatology is also off to an absolutely fast start. In fact, that was just named one of the best launches in dermatology based on both uptake as well as physician sentiment towards the indication. So I think that shows that there's a meaningful upside there as well.

But we look at what's happening in the overall market in respiratory. I think that there's a great story there that I'm not sure we tell very well. And specifically, we were the fifth biologic to market in asthma. And from an NBRx perspective, we are #1 and have been #1 now for an extended period of time, and we are closing in on the TRx lead overall. So I think that shows that there's tons of upside that are still available in that asthma space, which is clearly the most mature of the markets in which we compete. Nasal polyps continues to be #1 and certainly in prurigo nodularis and EoE, where we were the first products that have been indicated there, those continue to have an upside opportunity as well. So if we look across all 5 indications that we are currently indicated for, we do see that we are #1 in NBRx is in every indication in which we compete. So I think that there's a broad-based opportunity for growth continuing in '24 and beyond.

Colin Bristow

And then just from an indication standpoint, I think COPD and, I think, CSU as well is just very much on investor's radars. What would be subsequent indications that you think are potentially underappreciated will be coming subsequently that we should be paying attention to?

Brook Jennings

So as I mentioned earlier, there's about 650,000 potential patients that you can think about that could be added, they are the lion's share being COPD and CSU. But there are other indications in which we are currently investigating, all of which I think can be a meaningful contributor to overall growth, not the least of which is chronic pruritus of unknown origin, as well as some of the eosinophilic subtypes of different GI diseases. So I do

think that there are opportunities for us to have across each of the individual specialties that we are currently in, meaningful opportunities of growth in the future.

Colin Bristow

Switching to COPD. The notice interim should be later to this year, correct? And what should we expect to hear from you regarding the sort of the outcome and any detail around the interim? Let's start with that.

Ryan Crowe - *Regeneron Pharmaceuticals, Inc. - VP of IR*

Maybe I'll take that. Obviously, any disclosure around an interim analysis would have to involve our partner, Sanofi. So we -- and we haven't aligned on that just yet. But what we expect to do is do an interim analysis before the end of this year. This is from guidance that we have received from the FDA that would, in addition, if it were to be positive, in addition to the positive BOREAS results could support an sBLA for COPD of eosinophilic phenotype.

So when the interim analysis is performed, it's going to be done by an independent data monitoring committee. And they will either give us a thumbs up, you have met the prespecified efficacy threshold and the trial should be stopped or they will say, the trial should continue, you did not meet the prespecified threshold and the final readout will occur in mid-2024.

We've designed this protocol assessment in a way that will spare alpha so that we can preserve the ability to have a positive result should it continue to the primary analysis. Once we get our answer from the independent data monitoring committee, if it's positive, we'll read out the rest of the endpoints and provide an update once that statistical analysis is complete. If the response from the DMC is for the trial to continue, we would also indicate that.

Colin Bristow

Okay. Assuming a positive outcome that facilitates an sBLA filing, you're going to be in a position where you could potentially market DUPIXENT COPD next year. What are the -- how are you then thinking about additional sales and marketing build for that indication and what does that strategy look like?

Brook Jennings

Certainly from a sales perspective, our footprint right now, we are clearly covering the vast majority of folks that would think of advanced therapeutics to treat COPD. So we do have a sales force in allergy. We do have a sales force in pulmonology, which would cover the vast majority of those folks. So I would think that there would be a limited amount of additional capital needed to get the sales team up and running.

Certainly, we would have to invest in creating a brand-new marketplace where there's been no biologic and quite frankly, not a lot of breakthrough kind of opportunities in the near term. So we would have to educate very successfully the marketplace so they understand exactly what, in this case, DUPIXENT would have to offer for those patients that are suffering with COPD, but we've done that multiple times in different markets, and I'm confident we'll be able to do it again relatively quickly in COPD.

Colin Bristow

Do you have a sense of what percentage of COPD patients could potentially be getting DUPIXENT already just because they have some COPD overlap?

Brook Jennings

I could certainly tell you that once the data dropped from BOREAS, we did not see an appreciable gain in any of the of the Rx that we had seen from pulmonology or from the allergy community outside of what our baseline growth rate had already been. So I don't know if there's tons of overlap between them, give or take, about 20% between that ACOS group of COPD and asthma, but I don't think that we have meaningfully penetrated that market as of now.

Colin Bristow

And some commentary we've heard from some physician KOLs is that blood eosinophils are typically not measured in COPD, which feels like it would be an important point of a nurture for the launch. Can you speak to what you're hearing and how you sort of overcome that to part of the launch strategy?

Brook Jennings

Absolutely. I think the good news is blood eosinophils is literally a relatively straightforward blood test, and they're already doing it for asthma and the vast majority of the HCPs that we'll be treating for COPD are also treating for asthma. So I do not see that as something that is going to be an insurmountable hurdle. Certainly, it would be an additional step that they probably don't do today in COPD, but they already do it in asthma. So we don't expect that to be something that's going to be a rate-limiting step.

Ryan Crowe - *Regeneron Pharmaceuticals, Inc. - VP of IR*

I think the reason they don't is because there's no therapeutic option. What would they gain by running those tests today? So perhaps once a therapy is available for a subtype or a biomarker, they would begin to adopt that a lot more broadly.

Brook Jennings

Yes, that makes sense.

Colin Bristow

Do you have a breakdown of DUPIXENT use? And I guess, initial prescribing in terms of lung specialists versus in the primary care setting, in the asthma indication and how is that therapy typically initiated?

Brook Jennings

Yes. I think if we look at that market overall, the vast majority of our time, the vast majority of our resources are spent specifically in the specialists' offices, right, between the lung specialists and the allergists. So the amount of the Rxs that are being generated by primary care other than as follow-up because they were already put on that by one of the specialists is relatively minimal, and we will continue to, while educating the primary care folks spend a vast majority of resources on the lung specialists as well as the allergists.

Colin Bristow

Maybe switching to AD. You had very good growth in 3Q. And I think you said 12% in the adult population, which feels that you've got a lot of room to grow. What are some of the push pulls there, the challenges and the tailwinds that you're going to have in terms of moving that 12% up?

Brook Jennings

So I think back -- from the launch back in 2017 in adult atopic dermatitis, we were the only ones that were attempting to push that boulder up a hill. So first and foremost, I think that as you get additional competitive entries to the marketplace, that additional noise will benefit all of the players in the market. So that is first and foremost. Secondly, a lot of these patients had left specialty care or left care altogether because the choices they had 20 years ago were the same choices they had 7.5 years ago prior to the launch of DUPIXENT.

So I was going to get a tub of triamcinolone, I was going to get oral Kenalog injection or oral prednisone. These are the 3 choices. And if I wanted to, I could explore methotrexate, cyclosporine, azathioprine, mycophenolate. And those were the exact same set of choices for an extended period of time. So if you were suffering from atopic dermatitis, you realize that you weren't getting something new. You didn't have an opportunity to have a cutting-edge medication. And quite frankly, you know what the outcome is going to be, so you just decided to pass on that or you would go to an urgent care and get a Kenalog injection a couple of times a year.

So with the advent of DUPIXENT in the marketplace, we knew very early on that about half of this market had left specialty care, so we needed to reengage them. That was one of the reasons we started direct-to-consumer advertising. And while we have done a good job of trying to reengage and educate the consumers, we have a lot more work to do there. And again, as I think of the other competitors that have come to market, we know that Eli Lilly will likely do direct-to-consumer advertising. We know that Pfizer does. We know that AbbVie does. So all of that is going to help reengage those patients to have them come back into care. And as that happens, as the market leader, we will get a disproportionate number of those patients coming in our direction.

Colin Bristow

And just you touched on Lilly in terms of the competitive that you see in lebrikizumab, can you just characterize that for us?

Brook Jennings

Absolutely. So Lilly is clearly an experienced and rationale player in Dermatology with Taltz. And we know that they are a formidable competitor. They have their own issues they need to overcome to get to the marketplace. They will be the second of the IL-13s in the marketplace as tralokinumab has beaten into market already. So with that being said, we have a very differentiated profile. We don't think that IL-13 is a complete mechanism for these patients with atopic dermatitis. So we do know that the side effect profile looks relatively the same.

We know that tralokinumab on the market already has Q4 weekly dosing in their label. So we don't see that as a huge differentiating factor, and then it's going to come down to a safety and efficacy story. And while we have well over 750,000 patients globally across all indications currently on product, we've got a great story to tell. We just launched in the United States, our 5-year open-label extension data, which has been included in our label as well from a safety perspective in atopic dermatitis. So we've got a great story.

So will Lilly come to the market and make noise? Yes. Will that bring more patients? Yes. Are we confident in our profile and ability to differentiate our drug moving forward? Also, yes.

Colin Bristow

That's great. With obviously added competition, there's a consideration around pricing. Could you just talk about the gross to net evolution you're seeing with DUPIXENT and where you see that going? And are we going to see an acceleration of the discounting? Help us think through that?

Brook Jennings

Absolutely. So again, going back almost 7 years when the drug had originally launched in atopic dermatitis, we have seen a modest erosion of gross debt over time, but that also comes with access. So if I think of access specifically around atopic dermatitis, asthma and chronic rhinosinusitis with nasal polyposis, more than 99% of patients have commercial access to these drugs. Yes, there certainly could be hurdles they need to overcome or prior authorizations they need to overcome, but they have the ability to access the drug.

You throw on top of that EoE, which is now over 90%, prurigo nodularis now over 80% coverage. That is something that is great. But as you add additional indications and additional lives and as you get other competitors that come to marketplace, you also have to respond in a competitive manner. So I do believe that we'll be in a position where we continue to see a moderate erosion in GTN over time. But overall, I think it's a very positive picture.

Colin Bristow

That's great. Maybe let's switch to CSU. Recently you got the CRL. Study C is the same population versus study A. And so based on the discussions with the FDA, is -- would the data from study C be sufficient for potential approval?

Brook Jennings

Yes. And I'll take the first crack and Ryan, if there's more, please feel free. So based on our conversations, we know that they wanted to have 2 well-controlled, placebo-controlled trials that had positive outcomes. And we know that the CUPID A study was a treatment-naive population, and we have decided to do the exact replicate of that, to your point. So we do believe that in our conversations with the FDA that, that should be enough to satisfy the additional request for data that would allow us to move forward.

Ryan Crowe - *Regeneron Pharmaceuticals, Inc. - VP of IR*

Yes. I would just add that the approach in CSU is very similar to what the feedback we got on COPD when we approached them with the BOREAS study alone. FDA essentially indicated that they wanted to have data from a second controlled study, and that is NOTUS, and that's where we're at with this interim. So we may not like the answer, but at least they've been consistent. And we should have data from that study C in the biologic-naive CSU population towards the end of next year.

Colin Bristow

And CSU is a sizable population. And so how important is it that you get this to sort of meet your internal goals for DUPI growth?

Brook Jennings

Strangely, I think the good news is our internal goals were never factored in, including CSU. So I do believe that we are in a rather enviable position, if you will, that this is just another potential growth lever that we can pull moving forward. And you're exactly right. You have about 300,000 patients in the U.S. that would be appropriate for therapy. And we do know that Xolair has a meaningful portion of their business coming from CSU.

So it's a marketplace where the allergists spend most of the time doing advanced therapeutics for this population, and dermatology does tend to send those patients on to allergists to be treated. So there is an opportunity for us to continue to grow both in dermatology and allergy, and CSU would be a meaningful portion of that as we continue forward.

Colin Bristow

And just to round this out, just on the clinical trial pathway, the study B obviously failed in the Xolair refractory population. And just -- what's the rationale or hypothesis as to why you think that happened?

Brook Jennings

So we did, as you know, the interim analysis, which showed utility. And then ultimately, over time, we ended up being very close to hitting statistical significance towards the end. So I think that if you look at that population, Xolair, while not considered a type 2 drug clearly probably has an undue portion of their positive effect in a population that could be considered type 2. And by looking at folks that were already doing well on Xolair and removing them from the study, you probably limited your population and would likely need both a larger population in the trial as well as additional time to be able to show the same effect.

Colin Bristow

Great. So now let's switch to EYLEA, EYLEA HD. Good -- so a good start -- I think you were noting that there's patient switching or the growth is coming from naive and switches. And so what's the breakdown here in that initial quarter of launch?

Ryan Crowe - *Regeneron Pharmaceuticals, Inc. - VP of IR*

Yes. No, we've had a great launch. We, as I mentioned earlier, hit $43 million in the partial quarter where we launched, which compares quite favorably against competitive launches. In terms of where the EYLEA HD source of business is coming from, it's very early, but primarily coming from switch patients. I think EYLEA switches are certainly the majority of the patients on EYLEA HD today, and that makes a lot of sense to me.

But there are also switches from other brands in the category as well as from Avastin. And the early anecdotal feedback has been that this is a very exceptional clinical profile, the anatomical change that people have seen has been very impressive, and we're looking forward to more stories like that as it gets broader uptake. Naive use is very low, but I mentioned that this EYLEA source of business is only about 10% of revenues come from naive patients in a given period.

So it's really about a continuing patient, it's what's driving most of the revenues across this category. New patients are being introduced, but it's certainly a minority of the opportunity. We're excited to see naive patients getting an opportunity to get what we think is the best-in-class agent.

Colin Bristow

Did you see any VABYSMO switches?

Ryan Crowe - *Regeneron Pharmaceuticals, Inc. - VP of IR*

We have. We saw some patients that -- some physicians have reported that patients that were not being optimally treated with VABYSMO had switched to EYLEA HD. And after one injection showed dramatic improvement in their retinas. So obviously, a very encouraging early indicator that we have a very profound effect on these patients with wet AMD and DME.

Colin Bristow

What should we expect? Or what are you expecting in terms of guideline updates to take account of these new longer-acting agents?

Ryan Crowe - *Regeneron Pharmaceuticals, Inc. - VP of IR*

It's hard to predict exactly how those guidelines are going to play out. I'm not going to try and handicap it up here on stage. We'll kind of let those guys do their job. But we certainly envision EYLEA HD as being a prominent product in the treatment algorithm for these diseases.

Colin Bristow

So maybe we have just a little over a minute left, and I have to ask, but since Lilly are moving into your space with lebri, you potentially moving into their space with some early-stage pipeline work you're doing. So walk us through your -- what you've got going on in obesity, some of the broad time lines of disclosures and movements into the clinic? We're excited.

Ryan Crowe - *Regeneron Pharmaceuticals, Inc. - VP of IR*

We have a few irons in the fire in obesity that are very early, but promising. And I'll highlight a couple of them now. We presented some data at ADA that combine semaglutide with two of our antibodies, one, a myostatin antibody called trevogrumab, and another activin A antibody called garetsomab. And what we saw in these obese primates was actually better weight loss when combining trevogrumab with semaglutide. But really more importantly, the fat reduction was dramatically greater in that combination versus sema alone.

And the lean mass, you lost essentially no lean muscle in the trevogrumab, semaglutide combination versus a pretty decent amount of fat -- of muscle loss in the semaglutide mono arm. So that's also -- that there may be an advantage there because we see it in the data, patients have dramatic weight loss on the GLP-1s. But once they -- but a lot of it is fat, somewhere between 20% and 40% is muscle though. And when they rebound, they gain all of the weight back rather quickly, and it comes almost all in the form of fat, which could lead to longer-term negative health outcomes.

So we're going to explore a similar combination in man beginning next year. I'd also add, we have a leptin receptor agonist that we're excited about combining a GLP, potentially starting a trial next year as well. And finally, the genetic discovery from the Regeneron Genetics Center, GPR75, which we're attempting to target through various different ways, one of which a small molecule. We're collaborating with AstraZeneca on a chemically based molecule to target the gene.

We're also looking at an antibody approach that Regeneron is working on internally and then also working with our siRNA partner, Alnylam for an approach there using siRNA. So we'll see very early data, but we should have some progress to report sometime next year.

Colin Bristow

Fantastic. We'll stay tuned. So Ryan, Brook, thank you very much for your time. Thank you, everyone.

Ryan Crowe - *Regeneron Pharmaceuticals, Inc. - VP of IR*

Thank you, Dr. Colin.