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OVERVIEW:

Company Summary

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CONFERENCE CALL PARTICIPANTS

David Risinger Leerink Partners LLC - Analyst

PRESENTATION

David Risinger - Leerink Partners LLC - Analyst

So we'll kick it off here. Thanks for your patience. So I'm Dave Risinger. It's very much my pleasure to welcome members of the Regeneron management team. So with us is Marion McCourt, who's Executive Vice President of Commercial; and Ryan Crowe, Senior Vice President of Investor Relations and Strategy.

So thanks again for being here with us. I thought that maybe I'd turn it over to you to provide some just opening comments about the prospects for the business this year.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

Maybe I'll start, and we really truly appreciate the opportunity to be here, Dave. Leerink conference is always something we plan to attend every year and excited to be back. And today, we think we have a thoughtful discussion around the commercial momentum we have in our business as well as the deep, diverse and diversified pipeline and how we're executing all across that as well as our disciplined approach to capital allocation. But before we get to all those topics and before Marion gives kind of an overview, I need to read this forward-looking statement.

So I would like to remind you that remarks made today may include forward-looking statements about Regeneron, and each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in such statements. A description of material risks and uncertainties can be found in Regeneron's SEC filings. Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Marion?

David Risinger - Leerink Partners LLC - Analyst

That was double speed. Wow, that was impressive.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

I got a lot of practice doing it.

David Risinger - Leerink Partners LLC - Analyst

I think you've read that before.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

Just a few times.

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

And I'll go a little bit more slowly, but good morning to everybody. And just to give a little bit of an introduction to the year, I'll give that in context of our fourth quarter performance and obviously willing to continue the strength of our commercialization and the depth of our portfolio. But in fourth quarter, we shared with you our results on EYLEA HD. Certainly, strong numbers with $506 million in the quarter, that was 66% year-over-year growth for EYLEA HD.

And certainly, in the end of the year in the November, mid late November timeframe, we had the enhancements to the EYLEA HD label, which were long awaited but very important for Q4 weekly dosing and also the RVO indication. DUPIXENT, also a very strong performance, pleased to say, through the year and in the fourth quarter. We had in the fourth quarter specifically, $4.9 billion in sales for DUPIXENT. And that was obviously in our relationship, the alliance with Sanofi, with very strong performance across all indications with DUPIXENT, and that also was a significant growth in the fourth quarter number, which was up about 32% versus prior year.

And then also over to Libtayo, strong performance, $525 million. That was a year-over-year increase of about 13%; strength not only in our skin indications but also performance in lung cancer, and we had also recently launched into the adjuvant cutaneous squamous cell carcinoma setting. Other products certainly in our portfolio; but those would be the highlights and certainly the major brands, and I'm just sure you're interested in, in in-line commercialization as we go into the year.

QUESTIONS AND ANSWERS

David Risinger - Leerink Partners LLC - Analyst

Excellent. And so for this year, could you just talk about the pushes and pulls and what we should be focused on?

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

Sure. So I absolutely would continue to focus on. I'll start with our largest brand in DUPIXENT. Certainly, we have major established indications in the marketplace. But the exciting thing is even our first indication launch with atopic dermatitis is very much underpenetrated in the marketplace.

So the category is growing, competition is coming in, but DUPIXENT remains the leading product; is, the KOL community frequently reminds me, first and best product in the category. We continue to lead in asthma as well, in new-to-brand scripts and total scripts, also in nasal polyps, eosinophilic esophagitis; all major indications for DUPIXENT performing really well on an international basis. And then more recently, we've had the launches of COPD for DUPIXENT, performing quite well. CSU has been really important, chronic spontaneous urticaria. I'll remind us a patient population of about 300,000 patients as well in terms of potential.

And then more recently to the label enhancement, we've also had allergic fungal rhinosinusitis, which is really important for patients with a really significant condition of allergic fungal infection, often resulting in surgeries, but then having to repeat surgeries because frankly, it's not an effective means of treating that disease, which is chronic in nature.

So great things happening with DUPIXENT and certainly a lot of excitement for... I mentioned Libtayo performance and the indications. But we recently also last year, in the last months of the year, launched Lynozyfic and that has been an exciting launch certainly for later-line patients in terms of treatment. But early days, seeing a lot of very positive uptake in both academic and community setting based on the clinical profile

of efficacy, safety profile, lesser hospitalization, which is so important to those patients and their physicians. And also the ability to extend their dosing treatment interval more rapidly, also really important for patients being treated with multiple myeloma.

David Risinger - Leerink Partners LLC - Analyst

Excellent. And EYLEA?

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

So for EYLEA, certainly, the focus of my attention is now the expansion of EYLEA HD. We have some label extension, hopefully more to come with prefilled syringe but certainly strong performance in the last several quarters in terms of being actually the leading product in the anti-VEGF category for innovative brands in terms of growth and certainly a lot more potential for the product. EYLEA, I did mention in our most recent earnings call that we obviously had seen a double-digit decline on sequential quarters in EYLEA. We expect to continue to see that as we go into the first quarter.

At the same time, we commented on seeing growth in EYLEA HD. We talked about high single digits in terms of the EYLEA HD unit growth as we go into the first quarter. So again, declines in EYLEA not only because of growth of EYLEA HD, but also because of obvious biosimilar competition that we have in market. And I'll remind everybody in the second half of the year, our expectation would be to see additional biosimilar competition to EYLEA 2 milligram.

David Risinger - Leerink Partners LLC - Analyst

Excellent. And so you mentioned high single-digit unit growth for HD in the first quarter sequentially. But how should we think about net price sequentially?

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

Well, I think you have to think a little bit more carefully on that because we did share with you that we had some inventory build in the fourth quarter of last year. That's not unusual. We had a similar inventory build on EYLEA HD and EYLEA in the prior year. I think it has to do with patterns of buying at the wholesale level. But certainly, we continue to see robust demand with EYLEA HD.

And there has been very positive response to the enhancements to the label of the Q4 weekly dosing to give physicians confidence and flexibility prescribing as they want to use the drug. Even though they see with EYLEA HD great durability, there are occasionally patients, and they don't always know which ones, that when they see them, and they treat the patient, they want to use the shorter dosing interval for at least one or maybe a couple of more treatments.

David Risinger - Leerink Partners LLC - Analyst

And then how important is the prefilled syringe commercially? So meaning, is adoption by physicians really constrained by the lack of a prefilled syringe?

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

So it's important. I would say that from our demonstrated performance, EYLEA HD has been in market now for over two years. We launched in August of 2023. We've been -- we're a blockbuster brand. So I'm very proud of the team and what they've been able to accomplish.

It's really all about the science and the profile of the brand that allows that, but I'll share, even though we've done well with EYLEA HD, if I look at EYLEA as an example, 95% of use is with the prefilled syringe. So it's important to practices. It hasn't constrained use, it certainly will open use though in some practices where they may have been more hesitant.

David Risinger - Leerink Partners LLC - Analyst

Great. And since we just talked about your commercial presence across different therapeutic areas. Could you just talk a little bit about maybe this is more of a question for Ryan, but both of you can comment maybe, the opportunity to leverage Regeneron's infrastructure through M&A. Meaning obviously, the company wants to invest aggressively in R&D going forward. But I would think there's an opportunity to roll in products that leverage where you're already operating in specific therapeutic categories to drive even better financial returns to support that R&D growth in the future.

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

I'm happy to start, and then I'm sure Ryan will have comments as well. So absolutely, when we built the commercial organization over many years now, starting in ophthalmology and then broadening into immunology, oncology, hematology, rare disease; and having the infrastructure to allow for increment to the portfolio, we did so always with the future [in] mind, of being specialized in therapeutic areas, but being able to expand.

I'll give you a quick example of something that already is a byproduct of partnership. We have cemdisiran coming into the marketplace, fingers crossed with an approval, if not end of the year, early next year for generalized myasthenia gravis. We already are working towards the footprint and the build of a neurology business unit, for a product that we brought into the organization. Similarly as we look to the future of our own science and potentially partnered, or M&A, as you asked, types of opportunities, we have the infrastructure in place to be able to do that.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

I think Marion has it right. We certainly have the core infrastructure of commercial team that can support a number of products. And as you know, Dave, we have a very broad pipeline across many, many therapeutic areas. And as those advance into pivotal stages, the commercial team begins to get built around that.

I'd say in terms of bringing in outside opportunities, commercial synergies are unlikely to be the primary motivation there. We have done historically earlier-stage M&A and platform focused M&A. I think that's probably going to remain how we view the opportunities outside, but not ruling out something bigger and more late stage for sure. Just I don't think it would ever be commercial synergy-driven M&A.

David Risinger - Leerink Partners LLC - Analyst

Got it. So regarding the Sanofi alliance, can you talk a little bit about the strategic decision-making framework within Regeneron, specifically whether it makes sense to try to extend the duration of the alliance or not? Any high-level comment would be helpful.

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

Sure. So as a start, I think that the alliance with Sanofi has been very important for Regeneron, and we're incredibly proud of what we've created. And specifically, with DUPIXENT today, we have 1.4 million patients on DUPIXENT worldwide. It's been an amazing product, help so many patients, and then obviously really important to both organizations. As we have opportunities to look at strategic endeavors that make sense for both companies, absolutely that's the right thing to do.

I think, Ryan, perhaps you have some more detail on some of the elements of consideration.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

Yeah. I think DUPIXENT would not be the product it is today without both Regeneron and Sanofi. And I think it's in the best interest of both companies to maximize all of the progress that we've made together beyond maybe Dupixent. And we have plenty of next-wave opportunities within our own pipeline. Sanofi as well, and trying to leverage DUPIXENT to the max, I think, is in both sides' best interest.

There are certain assets that we've identified in our preclinical portfolio that also hit the IL-4 receptor alpha. They're already kind of by default in the collaboration, but there are others that do not, and are not currently in the collaboration. Whether that can change is a matter for us and Sanofi to figure out whether, A) it makes sense for both sides and B) at what terms.

So we're certainly interested in pursuing that. We've been great partners over the years, of course, with some disagreements along the way, but overall, a highly successful partnership that I think we should continue to try and maximize.

David Risinger - Leerink Partners LLC - Analyst

Excellent. And just remind us about what you had updated the Street in early January about which candidates are in the alliance, which candidates are out of the alliance. I think there was that one specific side where you had some of those details.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

Yeah, that's right, Dave. So it's not really that complicated. In fact, if it hits -- if an antibody or some other drug hits the IL-4 receptor alpha, which is the target of dupilumab, it's in the collaboration. That's a very bright line in the agreement. If it hits really any other target, it is not. So for some of the next generation assets that we are working on preclinically at the moment, including our long-acting IL-13 antibody, our long-acting IL-4 antibody, our long-acting IL-4 by IL-13 bispecific antibody, none of those are in the Sanofi collaboration.

So we are independently working on them. We have, I'd say, bespoke development plans around each of those assets. IL-13 long-acting will be the first of those opportunities to enter the clinic. We've said that, that would occur in the first half of this year, and that remains on track.

So we're looking forward to putting that into a human very soon. And the first indication that we'll be pursuing is in atopic dermatitis. So initially in healthy volunteers. And then we plan to follow an expedited development program to hopefully allow for registration and launch ahead of Dupixent's composition of matter patent expiry, which would be the earliest potential launch of a biosimilar. I think there's some opportunity to maybe extend that exclusivity runway beyond that date, though.

David Risinger - Leerink Partners LLC - Analyst

So is that what George referred to as Supi-Dupi or is that a different one?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

Supi-Dupi, I think George was talking about the long-acting fully human IL-4 receptor alpha antibody. So literally another version of DUPIXENT that can be dosed at longer intervals. So that is the Supi-Dupi. And then these other opportunities are kind of adjacent to that, all within the IL-4/IL-13 axis which we think is truly the underlying driver of all of these atopic inflammatory diseases.

David Risinger - Leerink Partners LLC - Analyst

Got it. Okay. That's great. And turning back to EYLEA. Could you just talk about sort of the commercial dynamics when a number of additional biosimilars launch later this year. Just how you manage this year ahead of that and next year after that? Obviously, I'm sure you want to convert as many patients as possible to HD but it would be just helpful to have you describe sort of your commercial positioning as you're operating it today.

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

Sure. So I think it's important to understand that when you look at the market today, even for years, there's always been a low-cost alternative with Avastin in the anti-VEGF category. So that one fact that remains. And certainly, as more biosimilars come into the marketplace, you would expect to see more price competition, things of that sort. Where today, the biosimilar use, aflibercept 2-milligram, has been limited to select practices as opposed to a widespread use in the marketplace.

Having said that, your point was spot on, and we're very fortunate to have EYLEA HD next-generation product. Retina specialists are a very sophisticated audience, both scientifically and from a business standpoint. Anything for them, it's really important to be using state-of-the-art care for their patients. The durability by EYLEA HD is very exciting in the market. We know the label enhancements have been important.

So the timing is really nice that we're bringing forward EYLEA HD to be all that it can be, hopefully, very quickly, so that we're in a really strong position to be the product in the marketplace and the innovative branded product in the marketplace that physicians see all the attributes of what's most important to them for the retina patients.

And then you would expect with more biosimilars, potentially, more elements of pricing actions and also physicians potentially always having the thought in retina because we inject into the eye, there's always the consideration as new products come into the marketplace, wanting to see them in the real world setting. It's not possible always to know, and this is true of all products, not just biosimilars, but even branded products; we've seen some products before [in] the market experienced fail because of safety, but we've seen others who we thought we were going to be highly effective in the marketplace, not succeed because of issues related to safety. So that, too, is something that always will be really important in this category.

David Risinger - Leerink Partners LLC - Analyst

Sorry. So thinking about that commercial infrastructure that you have for EYLEA. So could you just talk about leveraging that longer term and maybe also comment on pipeline candidates as well that could fit in.

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

Yeah. So very happy to. And there is a lot, obviously, in our various programs that potentially feed into the ophthalmology business unit for commercialization. So just to maybe mention a few that I've been incredibly impressed with is: we have a program for uveitis. We have a glaucoma program.

We have a geographic atrophy program. There may be others that we haven't commented on yet that Ryan can add to my comments, but really exciting. And Regeneron is a long respected company in the retina and ophthalmology community. So we're really excited. It's your point of building our business units that is an example. And I'll also share with you: I'm never hesitant to build a new business unit as we did for oncology or hematology or as I mentioned, neurology, as our science feeds in. But in this particular case, it's a therapeutic area where we have a footprint.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

Just we also have an opportunity in thyroid eye disease using a novel target. So a few of these are going to be first in human targets that we're excited about. And I think as they move along clinical development, the commercial team will be preparing.

David Risinger - Leerink Partners LLC - Analyst

Excellent. That's great. So maybe we could turn to a couple of other pipeline questions. So could you just talk about fianlimab? If you could provide an update. Obviously, the trial has been delayed. We're still awaiting the results. And I know that you've commented before... Obviously, there have been some investor concerns that maybe the pembro arm is performing dramatically better than anticipated. But, would love to hear the latest, please.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

Sure. certainly been a lot of scrutiny around this study and the readout has been delayed a couple of times, and we're now still on track for a first half readout as we await these final PFS events to come in. We don't believe we've enrolled a population that would result in an outsized pembrolizumab benefit of above and beyond its historical analogs of, call it, four to five months. Some of the inclusion criteria in some of the trials that have been recently conducted, I think, are slightly different than what we enrolled. And as a result, pembrolizumab perhaps did better in those trials than we would expect it to do here.

We don't know how pembrolizumab is doing in our study. We are totally blinded to the events and where they're occurring. We only know the total number and how they are accruing, the rate in which they're accruing. So we will see.

I think you can look at it from two different ways. On the negative side, pembrolizumab is doing something miraculous and amazing and it's going to have a much higher-than-anticipated median PFS. Or you could look at it and say, well, the active arms are actually doing quite well and are approaching the activity that we saw in the early human studies, where pooled median PFS across three independent cohorts was 24 months.

I'd add that we feel that we've conservatively powered the study and actually have assumed pembrolizumab performs at a median PFS of seven months, which is roughly 50% better than it has in first-line metastatic melanoma in past studies. And so based on that assumption and our assumption of at least relatlimab-nivolumab-like activity from our combination, we feel comfortable with the powering of the study even if pembro were to outperform its historical analogs.

David Risinger - Leerink Partners LLC - Analyst

That's very helpful. And can you talk about with respect to that enrollment, the mix of patients by PD-L1 status?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

Sure. We haven't stratified by PD-L1 status. There is no floor, there's no cap in enrollment. We are pursuing patients that are in the real world. So we would expect to enroll a roughly even split between expressers and non-expressers of PD-L1, but those baseline characteristics have not yet been disclosed.

David Risinger - Leerink Partners LLC - Analyst

Okay. Very helpful. So you have a new launch to prepare for in MG. Could you talk a little bit about that? And whether there's any possibility of launching earlier than the schedule for the first quarter of '27?

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

Yeah. Well, based on the filing and submission, we had been speaking about early portion of next year, January. There are scenarios where potentially you can move it late this year. We certainly will be launch-ready and we look forward to participating in this marketplace. The product profile is exciting from the standpoint of efficacy, safety, convenience of dosing.

There's still a lot of unmet need in myasthenia gravis marketplace. It's about a $5 billion marketplace today. By 2030, could be up to about $10 billion, a lot of potential, a lot of unmet need, obviously, a highly competitive marketplace as well. But one, we're excited in being able to participate in with an approved product.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

And I would just add, we do plan to present the full data from the NIMBLE study next month at AAN. So we'll show what the curves on MG-ADL look like. And I think what you'll see is rapid improvements in the activities of daily living and sustained across six months, with every three-month dosing, which is very differentiated from the medicines that are approved today for myasthenia gravis.

David Risinger - Leerink Partners LLC - Analyst

Yeah. And just given the evolution of the MG commercial market, could you just shine some light on exactly where you see the product being positioned and taking share?

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

I would say that we're looking at a variety of scenarios now based on the profile I mentioned related to efficacy, safety, dosing convenience and then the unmet need of patient population. I think it's early to give you specifics on the strategy because I'd like to have the final label and there are a number of different opportunities, all very exciting. So I just would request a little patience, stay tuned. And then as with all of our other launches, we've always held back on specific strategy of launch until the timelines. But delighted to share as we move along and the decisions being made.

David Risinger - Leerink Partners LLC - Analyst

Excellent.

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

I will share that as we've build a number of business units at Regeneron, it's always really been exciting. The level of talent that we've had from, in the industry, wanting to join Regeneron. And I can share with you that early days in our build-out with the neurology business unit, we're seeing that again.

David Risinger - Leerink Partners LLC - Analyst

Excellent. And so could you talk a little bit about label scenarios?

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

I think it's early. Candidly, Ryan, I'll always defer to you and the IR team of what you've been sharing or what you'd like to share. I would only comment that it relates to the notion of the mechanism of the product, the degree of inhibition, the level of efficacy you see the -- as Ryan was mentioning, the patient experience in terms of their activities of daily living really important; dosing frequency is always an element of convenience that is important to patients with a chronic disease like this, which is truly debilitating.

As you know, for women, it's usually an earlier age diagnosis, bimodal disease. Men, the diagnosis tends to be a little bit later, more often patients in their, 60-65 and up age range, but all these patient groups having similarities of need in terms of relief of symptoms, products that are convenient to use, safe and allow them to go about their lives. But the specifics, I'm going to wait until we get the label. I appreciate the question, though.

David Risinger - Leerink Partners LLC - Analyst

All right. Why don't we pivot to the GA readout that you have ahead? That's clearly a very exciting opportunity, very substantial. Could you just remind us about that and discuss the efficacy bar for success?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President of Investor Relations & Strategy

Sure. So this is an exciting one for us. And of course, we're doing this a little differently than the currently approved products for GA where we're approaching this with a systemic administration with both the combination of cemdisiran plus pozelimab, our antibody to C5 as well as cemdisiran monotherapy against placebo. We believe, while the actual cause of geographic atrophy is a little ambiguous, the key driver of the disease is complement mediated inflammation of the choroidal capillaries, along with some genetic and perhaps environmental factors.

And by completely blocking C5, which we we've demonstrated in multiple studies with the combination of cemdisiran and pozelimab, we can eliminate circulating C5 with pozelimab, and stop the liver from making more, with cemdisiran. So in the PNH, I'm sorry, the gMG study, we saw the combination reduced C5 levels in patients by 99%, at least 99%. So if you believe that complement drives this disease and you eliminate complement, you should see improvement in lesion growth -- deceleration in lesion growth, which is what our interim analysis is going to explore at the half year mark. So it's going to be an early look.

It's going to be a subset of patients, but it should give us an indication about whether or not the systemic approach for either the combination or the monotherapy is differentiated from a placebo. So we're looking forward to that. It's going to be towards the end of 2026, and that will inform our future plans for a second study in GA.

David Risinger - Leerink Partners LLC - Analyst

Excellent. Well, we're actually out of time. Thanks so much for joining us. Really appreciate you being here.

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

Thank you very much, everyone!
