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OVERVIEW:

Company Summary

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PRESENTATION

Eliana Merle - Barclays Services Corp - Analyst

Okay. I think we can get started. Good morning, everyone, and welcome to Miami. Very happy to have Regeneron here with us today to kick off the morning here at the Barclays Global Healthcare Conference. I'm Ellie Merle, one of the biotech analysts here at Barclays.

Very happy to have Marion McCourt here with us, the Head of Commercial; as well as Ryan Crowe, the Head of Investor Relations. Thank you both so much for joining us. Before we jump into questions, Ryan, I'll pass it to you for some opening remarks.

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

Thank you, Ellie, and thanks for having us, and welcome to the sell-side coverage of Regeneron. I wanted to start today kind of highlighting your initiation report from last week, which I thought hit on a lot of themes that we'll cover in our chat today, and really underpinning your buy rating was your argument that the stock is fundamentally mispriced on the durable cash flows.

And when you consider our valuation today really only reflecting the cash flows from DUPIXENT, the EYLEA franchise, and our cash on hand, if anything in our pipeline works, I would argue we are undervalued. And if a lot of things work in our pipeline, we are significantly undervalued. So I'm sure we'll get to a lot of the themes I'm about to highlight in our chat. I just wanted to go through a couple of areas to frame the discussion.

DUPIXENT momentum, really as a pipeline in a product, is well positioned to continue, with growth anticipated across all 9 of its FDA-approved indications, including more recently, the launches of chronic spontaneous urticaria, as well as COPD. It has a long runway and a lot of growth to come.

EYLEA HD, now approaching half of the revenues from the EYLEA franchise, and market share is poised to continue to expand with the label enhancements that were put on the FDA label late in 2025, and the hopeful approval next month for the prefilled syringe, which [would] really round out the profile.

And then you specifically highlighted in our report, LYNOZYFIC, which I think is a very underappreciated asset that's now approved in late-line myeloma, but with a significant commercial opportunity in earlier lines of myeloma as well as in precursor conditions, all of which are currently being evaluated in various clinical studies.

And finally, there's a lot of near-term catalysts that I think we'll talk about today, including Fianlimab plus LIBTAYO in metastatic melanoma, which has a near-term readout sometime in the first half of this year. And then we have some interesting data coming from our geographic atrophy program, likely in the second half of this year, as well as a pivotal readout in proximal nocturnal hemoglobinuria, or PNH, from the C5 combination of pozelimab and cemdisiran late this year.

So before we go any further though, I need to read this forward-looking statement disclosure, and we can jump straight into the questions. I'll do this as quickly as I can. 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. 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 result of new information, future events or otherwise.

New record time.

Eliana Merle - Barclays Services Corp - Analyst

That was very fast.

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

Anyway, I think -- I hope I framed the conversation well. Let's get into your questions.

QUESTIONS AND ANSWERS

Eliana Merle - Barclays Services Corp - Analyst

Awesome. Well, starting off with DUPIXENT, what are your expectations for some of the newer launches this year?

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

So Ellie, I'll jump in, and good morning to everybody. Very nice to be here. So certainly, DUPIXENT has been amazing as we reported to you most recently in our earnings call. Last year's sales, $17.8 billion; [fourth quarter sales] up 32% year-over-year. We have the established indications that are still growing based on patient unmet need like atopic dermatitis, like asthma, certainly been really excited by the recent launches as well.

COPD has been remarkable for patients who had such limited therapeutic choices previously. And then additionally, as Ryan was mentioning, as I go to some of the newer launches, with so many indications, I'll try to give you a quick comment on some of them, but I don't want to miss anybody either, but certainly CSU, chronic spontaneous urticaria, is off to a really strong start. A lot of unmet need for these patients where anti-histamine therapy alone just didn't give them the relief from the hives and the itching and the concerns that they had.

Bullous Pemphigoid for older patients, an amazing launch in that arena, smaller group of patients, but previously tremendous unmet need, really the only therapy that was used was chronic steroids, which isn't good for that age group of patients, worse still, it did not work. And certainly, across all the indications, most recently, we launched for allergic fungal rhinosinusitis, very difficult disease, often results in immune allergic fungal responses requiring surgery, but now with DUPIXENT, a tremendous opportunity for patients. So across geographies, indications, age groups, we continue to see growth and tremendous progress with DUPIXENT.

Eliana Merle - Barclays Services Corp - Analyst

Great. And COPD as well. I mean, I know it's approved a little bit earlier, but massive indication. Can you talk a little bit about some of the trends that you're seeing there and how we could think about that as contributing to the top line this year?

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

Sure. So very exciting indication, as I mentioned, tremendous unmet need. But now, with some time in the market with COPD, often, it's an older age group of patients. We've made tremendous progress in making sure that pathways are established where necessary, eosinophilic levels, biomarkers... payer coverage is robust. So there's a lot of enthusiasm with pulmonologists as we brought COPD into the marketplace.

Of course, they'd had experience often, or their institutions had, with DUPIXENT in asthma, surrounding out into COPD patients where there's so much unmet need, has really been amazing. Each phase of launch has gone on track. Our DUPIXENT organization, I think Regeneron overall, we're a bit of a launch machine, but certainly, each stage of launch has important parameters, goals, execution, delivery performance metrics that we look at, and COPD certainly has been living up to the opportunity it presents for patients and their prescribing physicians.

We've heard stories of patients coming back in for routine visits who had been on oxygen therapy. For any one of who has ever had a loved one on oxygen therapy, you know how incredibly difficult it is, even for transport. The patients coming back into the office, being able to be ambulatory, engaging not only in their physician visits, but life generally just makes such a tremendous difference in their care.

Eliana Merle - Barclays Services Corp - Analyst

Great. And turning to the atopic dermatitis side of things, there's a lot of compounds in development for atopic dermatitis. Obviously, DUPIXENT was the first. How are you thinking about life cycle management here, what you have in development and sort of the sustainability of the DUPIXENT revenues in light of some of this emerging competition?

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

Sure. So I'll take it as a two-step. Maybe I'll cover the market currently, and then Ryan will cover a little bit of the future for us. But one of the things that I hear most frequently at the KOL visits or major meetings like the upcoming American Academy of Dermatology meeting later this month:

The KOL community so often repeats one simple phrase to me, that DUPIXENT is first and best in atopic dermatitis. And the data, the clinical data, the market experience, the patient experience, really does seem to, at every turn, establish that dynamic. In other categories that many of us have worked in across our careers, the later compounds sometimes show improvement in differentiation. It's the opposite with DUPIXENT, and it's better that they describe it to me, and I repeat it to you. But it's the dual mode of action that you see with DUPIXENT. It's the tremendous market experience, it's the efficacy, it's the relief the patients feel.

So other products coming into the marketplace have actually been important from the standpoint of getting more education to the market, more consumer education, more physician education, and this actually is benefiting DUPIXENT as the product the patients and their physicians know now and reach for first. So we'll keep a close eye on competition.

Competition always makes you better. But in the case of DUPIXENT, all the aspects of our dosing convenience, mode of action, the fact that we have so many indications, and truly is the product that gets at comorbidities across the type 2 cascade, is highly differentiating.

It also really matters to physicians and patients that across any of the age groups and indications, you can say that DUPIXENT is approved for children as young as 6 months in atopic dermatitis, one year in eosinophilic esophagitis, which is a major indication that I didn't even talk about today. But these characteristics, this market experience, efficacy of the product and safety, really make it the first product that physicians and patients turn to.

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

So the bar that Dupi has set in the marketplace and in its clinical studies is very high, and we've seen many competitors try and reach that bar and fail to reach it. We have been thinking about life cycle management for DUPIXENT for a number of years, and I think we've built a robust approach to ultimately succeeding DUPIXENT with even better products. I would highlight a few that we've talked about in recent months that should be entering the clinic either later this year or into 2027, all of which have custom development plans, and we plan to expedite based on our experience, not only in the marketplace but also in conducting these studies.

So I'll start with the "Supi-Dupi" as our Chief Scientific Officer, George Yancopoulos, termed on our last earnings call. This is a long-acting, fully human, IL-4 receptor alpha antibody, that is the exact same target that DUPIXENT currently hits and would have that same dual mechanism of action that Marion mentioned. That one is part of the Sanofi collaboration by default as it targets the same receptor that's in our agreement, and we are looking forward to hopefully partnering with Sanofi on developing it once it is clinic-ready.

Beyond that, outside of the Sanofi collaboration, I would highlight the lead candidate being a long-acting fully human IL-13 antibody that will be entering the clinic within the next couple of months, we've said first half of this year. And we will be looking at the IL-13 antibody in atopic dermatitis initially. We believe we can reach, at minimum, every 3-month dosing with this antibody and would hope for even longer intervals with comparable efficacy to DUPIXENT. We think longer intervals are obviously more convenient for patients and would be well received in the marketplace.

Beyond that, we have other long-acting antibodies, including one for the IL-4 ligand, which would be outside of the Sanofi collaboration, as well as a bispecific that would target both IL-4 and IL-13. So a life cycle strategy that is certainly centrally focused on the IL-4/13 axis as we believe that is the fundamental underlying driver of all of these atopic diseases, and we look forward to keeping you updated on our progress across this important part of our pipeline.

Eliana Merle - Barclays Services Corp - Analyst

Great. A lot of exciting programs. So for EYLEA HD, the prefilled syringe approval is expected soon. I guess, what's been the feedback from the retinal clinics on the importance of prefilled syringe and operating their workflows? And I guess, how should we think about a potential inflection in the demand curve for EYLEA HD once the prefilled syringe is approved?

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

Sure. Thanks. So I'll reflect a little bit on the recent experience with label enhancements, as you know, is towards the end of November, where we were able to secure FDA approval for Q4 weekly dosing for EYLEA HD and also the RVO indication.

Also, just as a quick reminder, in the last quarter, we reported sales of $506 million, up 66% year-over-year for EYLEA HD. So certainly, progress being made. I was really proud of our commercial and medical affairs team on the education and promotion in the marketplace showing that EYLEA HD was actually the innovative branded product growing more than any other in the anti-VEGF category.

To the question of prefilled syringe, I very much look forward to that approval. I do think it will be important. As a point of reference for you, with EYLEA, about 95% of our business is with prefilled syringe. But certainly, I believe we have a very strong profile with EYLEA HD that we're working with right now and working on steadily in the marketplace, and obviously a very competitive anti-VEGF category.

But EYLEA HD is becoming known as the product with the broadest label in terms of dosing flexibility opportunities and the durability of that return is bearing out. So the phrase there that I hear most often is "EYLEA made better in EYLEA HD". So certainly, a lot of work underway and a lot of progress to be made, even before we have the prefilled syringe in the marketplace.

Eliana Merle - Barclays Services Corp - Analyst

And I guess, turning to sort of the implications for pricing, both for potentially EYLEA HD as well as EYLEA with the entrance of new biosimilars this year. How should we think about that in terms of the incentives of the practices to say, continue to stock both products and the implications for pricing?

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

So I think it's a number of factors. One is that the retina community and physicians like to choose the product that they're selecting for their patients. Many of them are highly academically oriented, have participated in clinical trials. And certainly, there are select practices, and it is select, it's not across the market, that have used biosimilars for financial reasons, that's not the totality of the marketplace, is something that we're well aware of. But I would think more broadly over time, consider that physicians want to make the selection of product that's best for their patients as they're treating blinding eye disease.

Having said that, we did want to be balanced, and I think I shared with everybody in the last earnings call, when you think of EYLEA, now I'm not talking about EYLEA HD, but EYLEA, we would expect to see declines quarter-over-quarter. I referenced double-digit types of sequential decline. That in part is because of coming biosimilar or current biosimilar competition, but it's also because we deliberately are making conversions not only of EYLEA, but other patients coming into the anti-VEGF category, naive patients or switch patients over to EYLEA HD.

Eliana Merle - Barclays Services Corp - Analyst

Great. Pivoting a little bit to the pipeline, you recently had some data in obesity. The question that we get from investors is obesity is a very crowded market. So where do you think Regeneron and your program fits into this?

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

That's a great question. And I'm pleased to share the information that was relayed via Hansoh -- the company from China that we've licensed our GLP/GIP receptor agonist from – a peptide called olatorepatide, which is a mouthful. But, the first pivotal data in China was generated and showed that olatorepatide was able to generate 19% weight loss, and over 95% of patients were able to achieve at least 5% of their weight reduction.

These are very similar to the in-market and market-leading GLP/GIP agonists that are out there. And I would add, perhaps differentiating about olatorepatide is its tolerability profile, particularly in GI tolerability, where Hansoh reported on average, under 10% incidence of nausea and under 5% incidence of vomiting, both of which would be about one-third of the incidents reported by the market-leading GLP/GIP agonist. So very excited about this encouraging data from China.

Our plan for US development and, I guess, ex-China development, which is where we have our rights in this license, is to begin our Phase III study later this year, initially enrolling patients outside the US. And by end of year or perhaps in early 2027, begin enrolling patients into these pivotal studies in the US.

In parallel, we are working on co-formulation of alirocumab or Praluent with olatorepatide, which we hope will eventually lead to a product that combines these two important products to one that can generate meaningful weight loss while also reducing LDL cholesterol, which is a need by about half of the market today that is currently not being served by in-market products, which only reduce LDLs by low to mid-single digits.

Praluent on the other hand has demonstrated in its clinical studies, at least 50% reduction in LDL, which I think could be very important for many patients [suffering] from hypercholesterolemia. So we're excited about the opportunity in obesity. We have other ideas around combining olatorepatide with other assets and pipeline opportunities in our pipeline. So look for more to come in terms of our approach in obesity.

Eliana Merle - Barclays Services Corp - Analyst

Great. Well, turning to LAG-3, which is certainly a lot of focus in the near term. Maybe for either the first-line metastatic melanoma trial, how are you thinking about what success looks like here from a competitive perspective? And what should we expect to see on OS?

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

Great questions and ones I wish I could answer today. But unfortunately, the data is still maturing. So we've been running a study in first-line advanced melanoma. We're looking at two different doses of Fianlimab, our LAG-3 antibody, in combination with LIBTAYO, our approved PD-1 inhibitor, compared to pembrolizumab, or KEYTRUDA.

So we -- the primary endpoint of the study is progression-free survival. And once we reach a certain number of events in this study, we'll be able to read out the data. So we're waiting on events to continue to accrue. And once we reach that magic number, we will lock the database and read out the data.

I think for differentiation, we've seen in the PD-1 class kind of mid-single digit, maybe low single-digit median PFS. We see combinations from Bristol with ipilimumab and nivolumab, hitting around 11 months of median PFS... And their LAG-3, Bristol's LAG-3 combination has generated around 10 months of median PFS. So while the study is powered against pembrolizumab, I think cross-trial comparisons will be made, and I think they'll be appropriate given the population we're enrolling is very similar to those in other pivotal studies. For differentiation there, I think low to mid-teens median PFS would put us clearly at the top of the board there and potentially practice changing.

In terms of OS, it's highly unlikely that that data will be mature at the time of the final PFS readout. Hopefully, we'll be able to have some initial trends in overall survival and there will be interim analyses. I think there's 4 interim OS analyses built into this clinical protocol before a final OS analysis will be made. So there's opportunity to have a clinically significant or statistically significant, clinically meaningful benefit on OS, where Opdualag has failed to do so in there. So that would really be another differentiator that we're hopeful for from this study.

Eliana Merle - Barclays Services Corp - Analyst

Great. Just in the interest of time, turning to LYNOZYFIC. Maybe starting first with sort of the fourth line plus opportunity. Marion, I guess how are you thinking about the size of this opportunity?

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

Sure. So very exciting launch in hematology with LYNOZYFIC this year, both US and select international markets. Early progress and early read on use has been that the differentiating characteristics of efficacy, potential for less hospitalization for patient on initiation of therapy, getting to extended dosing intervals more quickly, all has been really important.

Early use has been positive. I will just comment, it is a refractory patient population, fourth line plus. So patient population in the US about 3,000 to 4,000 patients. But certainly, we're making a lot of progress with pathways at the institutional level going through the REMS process of education and payer coverage.

So early days, really exciting, and perhaps most important of all, this early experience in later line certainly suggests that with clinical trial readout in earlier lines of therapy, we'll be able to participate more broadly in this $30 billion market, which is really significant and a potential

to help a lot more patients. But we're starting in the late line setting, and certainly we'll work hard there and then be ready to go into earlier line settings with the clinical data readout and approvals.

Eliana Merle - Barclays Services Corp - Analyst

And yeah, I guess how should we think about the cadence of the launch over the course of this year? And then as we pivot to thinking longer term, I mean, can you sort of help quantify a little bit how we should think about the size of the opportunity as you potentially move into the second line plus setting?

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

As you start moving earlier, and Ryan, maybe you can help me with some of the specific numbers. I know that the patient population, for example, in the US, about doubles as you go from fourth line plus the third line plus. As you go up into second line plus, it's a much bigger patient population. So we have aspirations to go into the earlier settings as quickly as we have the data readouts and the product profile is suggested that we really will be able to make a difference for these patients.

Ryan may wish to add more.

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

I mean, I think we've demonstrated best-in-class activity in the late-line settings. And as we are generating earlier line data, we're also seeing best-in-class activity in second line and in first-line myeloma with very limited combinations. So we're very excited about LYNOZYFIC as a differentiated BCMAxCD3 antibody. I think we can compete very effectively. And oftentimes, in oncology, the data will sell your product, and we're in the process, we think, of generating a very compelling data set for patients.

Eliana Merle - Barclays Services Corp - Analyst

Great. Well, you guys have a very rich pipeline, maybe in the last minute or so that we have, Ryan, can you sort of walk us through maybe what you think are the key catalysts for the pipeline over the next 12 to 18 months? And any programs that you think people should be paying more attention to?

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

Sure. I can walk through a few. We've already talked about LAG-3. That's clearly front of mind for many. I think in the second half of the year, we should have an interim readout for the C5 opportunity in geographic atrophy, which is a very meaningful opportunity and then in PNH towards the end of this year.

We also have Factor XI in the process of enrolling patients. And I think even by sometime in the first half of next year, get a readout in the VTE study following post knee replacement. So beginning to read out some pivotal data from Factor XI as early as early next year. So we're certainly excited about that. That program is huge and has a lot of opportunity.

I think there's also going to be read-throughs that we can make from competitive readouts that should be occurring in the second half of this year. So we'll be looking at those. Additionally, I think the obesity study start will be important for us as a milestone. And then I guess, ultimately, we're going to be looking for those LYNOZYFIC readouts beginning sometime in 2027.

Eliana Merle - Barclays Services Corp - Analyst

Great. Well, thank you both so much for joining us, and thank you for everyone for joining us in Miami.

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

Thank you. Thanks, everyone.

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

Thanks, Ellie.
