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OVERVIEW:

Company Summary

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PRESENTATION

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Thank you for joining us. Welcome back to the Bank of America Healthcare Conference. It's my pleasure to have with me our next presenting company, Regeneron Pharmaceuticals. Up here on stage with me are two members that we'll be talking to for the next 30 minutes, Marion McCourt, who is, of course, Executive Vice President, Commercial, as well as Ryan Crowe, who is Senior Vice President, Investor Relations. Guys, thanks for making the trip over from the East Coast *(technical difficulty)*

QUESTIONS AND ANSWERS

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

...the companies that made agreements or announced agreements before we did. So, we are going to lower prices for patients in the Medicaid channel for certain of our products. We are also committing to MFN pricing for certain future products. We have put Praluent, and made it available to patients through TrumpRx. And then lastly, and probably most important to us, is making our first gene therapy approved at Regeneron, Otarmeni, for profound hearing loss available for free for patients. So we certainly are excited about all of that.

In exchange, we are not going to be subject to future government pricing mandates, and we'll also have tariff relief through at least January of 2029. So, all in all, a very similar construct to the previous deals that were announced. Perhaps one detail that we've included in some of our disclosures is that this includes products that are wholly owned by Regeneron in the United States. So that excludes certain of our alliance products from this agreement.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Are those exclusions inclusive of EYLEA and DUPIXENT?

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

We have never made any comments about specific products and because of the confidentiality around these agreements, I can't name specific products. But what I will say is we wholly own EYLEA and EYLEA HD in the US, but we do not wholly own DUPIXENT in the US.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Okay. So you talked about this $27 billion plan to invest in R&D and manufacturing in the US. Can you talk to us over what time frame and how that's going to be invested?

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

Yeah, there's a little bit of mixing and matching of time frames and numbers and exactly what is what, but maybe I can just do a quick summary of that.

So we've committed to approximately $9 billion of capital investment through, at least the end of the decade, probably 2030, 2031, we expect that to all have been completed. That includes R&D facilities in our Tarrytown headquarters, expanding our R&D footprint in Upstate New York as well as with some contract manufacturers we're working with in the United States.

On top of that, so that's around a third of it. The other two-thirds are related to expenses for R&D that will be incurred in the US as well as for manufacturing expenses that will be incurred in the US through approximately the end of the decade as well.

So there's a bit of mixing and matching in terms of investment versus what we're going to spend. But all in all, I think very supportive of the US economy, which was one of the objectives of this deal.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Okay. So let's move on to DUPIXENT. Can you just talk about the evolution of the different indications? Rightly or wrongly focus remains on AD. What's your penetration in that indication? And how should we be thinking about uptake. We do our own survey work. We do a lot of checks with physicians. One thing that we've noted is a particular level of excitement, for example, around COPD. So we'd like to hear maybe, Marion, your thoughts on where you are and where you think it's going to go from here.

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

Sure, very happy to talk about DUPIXENT. I also thought really briefly just to share with you, Ryan talked about Otarmeni, the product that we're giving for free to patients in the US marketplace. It has been launched.

It's a small population of patients, babies that have this and young children, this profound hearing loss. Some of you may have seen in the report from the Oval Office as Len and George were talking about our MFN plan, but also sharing the story of young Travis who is there with his mom and for the first time hearing her words as she was able to share things like I love you to her son.

So I mentioned Otarmeni, fortunately, it's a very small number of patients, and families, but incredibly important that we can make a difference for them.

Over to DUPIXENT, which helps so many patients. So there are 1.4 million patients on therapy right now worldwide. We have nine indications in the US marketplace. I'll give you kind of a brief tour of a product that's at a run rate of about $20 billion a year right now. It's been an amazing journey. My time at Regeneron has been spent with all of our portfolio, but certainly launching DUPIXENT across indications, atopic dermatitis was the first blockbuster indication. Today we have four because in addition to atopic dermatitis, we also have asthma, nasal polyps, eosinophilic esophagitis, and then more recently we've launched five more indications.

I'll talk about the original launches. In every indication, we lead the market in new to brand prescriptions, total prescriptions. In some cases like asthma, we launched in to a very competitive market and quickly the physician experience and the patient experience with DUPIXENT was so remarkable that it became the leading product in category.

Atopic dermatitis, I come to you weeks off being at the American Academy of Dermatology and pretty much every KOL I met with, didn't -- well, they didn't always use the exact same words, but everyone had the same message is that DUPIXENT is first and best in category. Unlike so many other categories in our industry, sometimes follow-on products give improvements. In the case of DUPIXENT is seen as the standard of care, the gold standard, and has helped so many patients with atopic dermatitis.

Children as young as six months are being helped by the product in atopic dermatitis and children as young as a year of age eosinophilic esophagitis. So whether it's one of our established more blockbuster -- all the indications are growing or newer launches to your point in COPD or bullous pemphigoid, prurigo nodularis, CSU, in all these indications, it's so important that there's a product that's been so well experienced.

DUPIXENT, I'm pleased to share with you, is the leading biologic for allergists, pulmonologists, respiratory therapists and also for physicians who are treating eosinophilic esophagitis for that particular indication. But the product, in addition to helping the indication, which has brought the patient to see their physician. It also, helps across type 2 allergic conditions. And it's not uncommon, for example, that a patient that is suffering with asthma also has nasal polyps, or the atopic dermatitis patient who also has some other type of type 2 illness. So I hope I've gotten to answer all your questions.

Maybe just one more moment on COPD. The launch is going very well there. Obviously, first biologic to launch four COPD patients and we continue to see great reports from physicians, their patients, and continue to help those patients.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

So one question I'll throw in there since you mentioned COPD and it's in line with what we're hearing from physicians is that -- what do you think is the undermet need there? What are the therapies that are approved not addressing the patients? And what's particularly appealing that you're hearing from your field force and why docs want to try it.

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

Sure, and directly from physicians as well. I would say the first element for COPD is the unmet need in patients who are on triple therapies, but not getting the level of relief, the exacerbations, the difficulty of many patients having to be on oxygen therapy, which is really, really difficult for patient, family, and their caregivers.

We hear stories of patients coming back in to see their physicians after being on DUPIXENT for COPD and coming off their oxygen therapy, feeling better than they have in years in terms of dealing with their condition. And all the while, a product that is convenient to use and is safe to use, so it's made a remarkable difference in these patients.

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

If I could just add, the competing biologic in the market for COPD has never demonstrated any lung function improvement, whereas DUPIXENT and its pivotal studies demonstrated on approximately 80ML improvement in FEV1, which is the gold standard for measuring lung function. So these patients are not only exacerbating less, but they're feeling better. And I think that's probably what they notice the most. As Marion mentioned, a lot of patients are able to either discontinue or significantly reduce their reliance on oxygen.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

So you've been picking up a lot of real estate with all the different indications that you've launched on for DUPIXENT over the last several years. And so naturally, I think people are thinking two things. Number one, your partner Sanofi and extending the IP, which seems like it's largely in their court. But also, you as a company have talked about next generation, so what we affectionately called “Supi-Dupi”. So maybe you can quickly tell us what you think would be an attractive profile for a next generation drug.

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

Yeah, sure. I can probably start with that. I think we believe that DUPIXENT, as Marion mentioned, is first and best in class. But these next generation opportunities that we've developed in our pre-clinical pipeline are looking to at least improve on the dosing interval that DUPIXENT currently has, which is every two weeks in most indications.

So our goal is to extend on that and “Supi-Dupi” happens to hit the exact same receptor that DUPIXENT does. The issue with trying to put more drug in and just trying to get a longer dosing interval simply by adding more drug is receptor mediated clearance is something that happens with the IL-4 receptor, which means that you can put more drug into it, but it's unlikely to meaningfully extend the dosing interval.

So we've come up with a new approach using a new antibody that seeks to avoid or at least mitigate this target mediated clearance issue that the IL-4 receptor presents. We haven't discussed exactly how that approach works publicly yet, but I'm sure we'll get into that once we reach the clinic. And we do expect that antibody to be clinic ready by year end or perhaps in early 2027.

Perhaps in the, backing up in terms of what's in the collaboration with Sanofi versus what is not, that “Supi-Dupi”, the IL-4 receptor next generation opportunity is covered by this collaboration because it is the exact same target as dupilumab does today. Other opportunities like the long-acting IL-13, which is about to enter the clinic is not part of the collaboration. So we certainly are working collaboratively with Sanofi in certain areas, but then independently in others. So we look forward to continuing with that.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Would you want to do parallel development of both mechanisms at the same time?

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

Yeah, I think that's -- I think it's in both companies' best interest to maximize all the commercial infrastructure we built, all the commercial leverage that DUPIXENT has established. So and I'm sure there's discussions that have taken place and will take place about expanding the collaboration. But I think it's premature to get into exactly what form that takes.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Okay. Now, I think partly -- well, definitely because of the success of DUPIXENT, lots of other companies have tried to make tweaks, if you will, and make adjustments to this drug, whether it be, an oral version, or let's say or, an oral compound, or less frequently dosed. So as you think about the evolution of this market opportunity, knowing what you just said about moving into clinic in the nearer term, does it change the level of differentiation you think you need to achieve just because there might be other options coming around in the beginning part of the 2030s?

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

So let me start. I'm sure Ryan has some comments to and you had asked this before. When it comes to penetration in the market for atopic dermatitis, there's only about high-teens percentage penetration for patients who could and probably would benefit their lives if they were treated with DUPIXENT. So what we found is more products have come into the marketplace, it actually helps grow the market, educate the market, bring more patients into the treatment continuum.

Obviously, today DUPIXENT is incredibly highly held by physicians and patients. If we're able to bring additional enhancements to product profile in the future with Sanofi, as Regeneron, that will be incredibly important to the market as well, and I think we're in a good position to do that. We obviously understand the market very well. We have a really experienced [commercial and medical team in the marketplace. All of those are really powerful ingredients, coupled with our science.]

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

[With regard to some of the competitor approaches that are in development,] it's hard to imagine that there's going to be a differentiation on efficacy, at least in a meaningful way. Because when you think about the biologic cascade, it really starts at IL-4.

So even, STAT6 inhibition or degrading is further down the cascade. So perhaps an oral option will be desirable for some patients. But to think it's likely to outperform on skin clearance or itch seems unlikely to us biologically.

So, yes, there's going to be perhaps improvements on certain convenience properties or the convenience profile for some of these. But we believe that DUPIXENT, as Marion said, is kind of the top of the cascade, and it's going to be very difficult to beat if you're in the space.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Marion, maybe I wanted to ask you, what is the latest that you've heard about patients that are needle phobic, let's say, for AD?

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

So, it's interesting. The evolution of DUPIXENT across indications has demonstrated that for better efficacy, for safety, and for what is a very easy self-administration for most patients themselves or for family members with children, it has not been a barrier to care, as you can see evidenced in DUPIXENT performance. It's interesting in the world as well. I think injectables have become more a mainstay across so many different disease areas.

Having said that, if in the future, Regeneron is able to keep everything great about DUPIXENT and give other options for use, some patients actually now prefer injectables because it's not something they have to remember daily. Others potentially might be more drawn towards an oral therapy or the I think the number of pure needle phobics is probably not what it was in years past. But certainly, we want to be on the cutting edge of that delivery options for patients and doing the right thing.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Is that something that you'd be willing to try to acquire if you thought you found a good asset?

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

I don't think anything is off the table for us in terms of M&A. I don't want to speak to specific therapeutic areas or targets, but we certainly cast a broad net, look at everything that's going on out there and what we think is interesting scientifically and can be complementary to what Regeneron has. We'd certainly take a look.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Okay. Maybe let's do a couple of questions on EYLEA before we go on to LAG-3, which I get a couple of questions on here and there now. So the HD launch, I think going back a year ago, I think people were still of the view that with the biosimilar for 2mg EYLEA, it was unclear how that franchise in general would survive biosimilar launch. But it does look like from our work, and I'd love to hear your thoughts from your feedback from the field, that HD is something that's very appealing to physicians and patients. So maybe can you give us a little bit of color on that?

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

Without question, certainly, EYLEA HD has the profile of product to be standard of care as EYLEA has been in category. Together, they are the overall innovative branded franchise leaders I'm pleased to report that EYLEA HD is almost half of that in terms of net sales now. The product grew nicely in the last quarter based on demand increases that we shared with you. And certainly, the approval towards the end

of November of having Q4 weekly dosing in the label, the RVO indication and also dosing durability out to 20 weeks is really, really important to physicians in choosing the product that is best for their patients.

So we see good performance there, very solid performance and certainly look forward to potentially bringing prefilled syringe into the market as well.

But in spite of that, we still guided and I guided to you on the most recent earnings call that we expect to see in the coming quarter demand growth in the range of about that 10% as we produced prior quarter.

Similarly, we also guided that we would expect to see continued decline -- demand decline in EYLEA, the 2-milligram product in the range of the mid to high teens.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Okay. And as you think about the market moving forward, what do you think is the most attractive about the HD or even from your competitor, Vabysmo? Is it that it's more efficacious or is it the convenience of less frequent dosing?

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

So I'd say with EYLEA HD and EYLEA long now the standard of care. Physicians really like the profile of EYLEA HD. They trust the safety. They like the clinical efficacy in indications like RVO. EYLEA had always been the standard of care. There was never wavering of that and it was based on performance. We also see EYLEA HD referred to as the product that's got the greatest durability for patients who can have the extension of dosing. That coupled back to safety and efficacy are the ingredients that the retina community is most looking at.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

What on average is the dosing frequency are you hearing right now? It's early.

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

It really varies by patient, but I can share with you that, when we look at data, looking at durability, EYLEA HD is the product that can achieve the greatest durability for patients when you look at totality of care.

I like very much that we have the Q4 weekly dosing available now because physicians can't always determine after three loading doses on EYLEA HD. They can't always determine which patients can get out to a seven-week dosing interval which is required in most instances for payer coverage. They just didn't know. Now having this assuredness is really helpful. Additionally, having the indication for RVO, where they really wanted to use have been using EYLEA really wanted to use EYLEA HD. That certainly now is something that is available to them as well.

So EYLEA HD, if you look in totality, has the broadest label, greatest dosing flexibility of any product in the category.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

And based on what you said, you do think that when the PFS does come online, that would be meaningful improvement in terms of how doctors see it for patients.

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

We do think it's important. Physicians as you can see, want to use EYLEA HD, but we do think that flexibility of having the prefilled syringe will be important a reference point for you within EYLEA, about 95% of the use is with prefilled syringe opposite vials. I think what is also remarkable and very, very important is that EYLEA HD is highly held in the minds of physicians. So even though we've had the vial-only delivery physicians are using the product, they're having a great experience for patients. And you can imagine for blinding eye disease, efficacy, safety, and durability are key ingredients.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Okay. Perfect. So now let's move on to fianlimab, to the LAG-3 study. Maybe, Ryan, can you level set for us metastatic melanoma? What do you think is the rough total addressable market opportunity here? And how does that compare to the products that we just talked about, EYLEA, DUPIXENT for Regeneron?

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

We believe the global metastatic melanoma market opportunity is somewhere in the range of $2 billion to $3 billion. Obviously, there's standards of care, including PD-1 monotherapy, PD-1 plus CTLA-4 and the incumbent PD-1 LAG-3 product that's out there. With fianlimab, Libtayo, we believe that we have a potentially differentiated efficacy profile relative to that incumbent LAG-3 PD-1 product and we expect to get our data very near term.

We certainly were encouraged by the promising Phase I data that we generated across three independent cohorts that when pooled, generated a median PFS of about 24 months and a complete response rate of 25%. And those compare very favorably to the incumbent LAG 3 product that had around 10 months of median PFS and around 12% or 13% complete response.

And the differentiator against the CTLA-4 PD-1 combination, I think, is going to hopefully be efficacy as well. But certainly, on the safety side, we see a lot of toxicity with that combination. But at 11.7 months, the median PFS has set the highest bar for efficacy in this setting. So we're very encouraged. We are looking forward to getting this data and hopefully sharing with you guys shortly thereafter.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

And what level of top line information should we expect?

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

That's TBD, but I think Regeneron typically errors on the side of providing more detail in our top line press releases than most other companies. I think it's safe to assume we'll say more than positive study and see you at a medical conference in six months. I would think providing the medians across all arms would be an appropriate level of disclosure and perhaps more depending on the interim overall survival readout and the objective response rates. So we'll see exactly what we get from the DMC when the data reads out and put together a fulsome disclosure, I'm sure.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Okay. After that, I think all eyes will move on to the adjuvant setting. So I think we've all talked about this, but love to hear your updated thoughts on what do you think the read-through is going to be from the metastatic study onto the adjuvant study. And again, as a reminder, you are going to be taking interim looks -- another interim look before year-end?

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

The adjuvant setting is quite different. I mean, with Opdualag, the incumbent LAG-3 PD-1 combination product, that Bristol markets, obviously, they had a positive readout in advanced melanoma but an adjuvant generated a hazard ratio of 1.01 compared to nivolumab monotherapy. So literally, no efficacy whatsoever.

And the biologic rationale that their investigators came up with was that by resecting the tumor, you've essentially removed a lot of the T cells that you're looking to activate with LAG-3 blockade. So that biologically makes some sense to us, but we think that perhaps since we're able to dose much higher than relatlimab can be dosed in Opdualag maybe there will be residual T cells that we can block that will enable us to generate a positive readout in adjuvant.

I do think it's much higher risk than the advanced melanoma setting. We don't have any Phase I data to support this. But it did enroll very quickly, and we will have a second interim analysis early in the second half of this year, and if necessary, a final analysis before the end of 2026 for this adjuvant melanoma opportunity.

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

I'll just add, as Ryan was talking about future product. Just a quick reminder to everyone. We obviously have a very experienced oncology team in the marketplace today with Libtayo across our non-melanoma skin indications of basal cell carcinoma, cutaneous squamous cell carcinoma. Libtayo has been a really important product to Regeneron into the oncology community and patients.

There, we did recently secure the adjuvant CSCC indication, which has been launched, has been incredibly well received. And obviously, we've made a lot of progress in IO therapy in lung.

Second most frequently used product today with oncologists. So we look forward to future launches and certainly, potentially, we'll be ready if we have the clinical readout we hope for and an approval to follow.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Okay. And maybe we will wrap it up with this last question, which I think you might have gotten a couple of times in the last week or so. You did make that recent change to the statistical analysis plan. So that's going to now include all patients with at least six months of follow-up.

Len and George talked about this a little bit, but maybe can you just reiterate what the genesis of that was when it started? When the idea came and why you think it's important to have it be the case as you go into the readout that this change was made?

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

Yes. Thanks, Tazeen, for the question. I think there's certainly been some confusion out there about what actually happened, what the time lines for the decisions were. So let me kind of start from the beginning.

We ran this study with originally with two cohorts, a PFS cohort, which was to include the first 1,175 patients or so across four arms, and that was going to be the population that contributed to the primary analysis of progression-free survival.

Upon the 1,176th patient, we were going to begin enrolling a 360 patient cohort that was only going to contribute to the overall survival, secondary endpoint. And that enrollment ran from essentially January through late summer of 2025.

As we moved through 2025, we saw a very slow accumulation of PFS events in the PFS cohort, which went for several consecutive months into the second half of 2025. And we were beginning to get concerned about when exactly the readout would occur.

So what we decided to do, and this was in the fall of 2025 was to add the patients that were originally only going to contribute to the overall survival, secondary endpoint to the primary analysis, without changing the number of events required to trigger the readout.

We also added the requirement that every patient would have the opportunity for at least 6 months of follow-up. And we did that because we didn't want to drop in those patients from the old OS cohort and then immediately read out the data when some of those patients would have just begun treatment.

So all patients will have at least six months of treatment. We need to reach 399 events in high-dose fianlimab plus Libtayo plus pembro. That analysis, and then the low-dose fianlimab versus pembrolizumab. Each of those need to equal 399 and the last patient first dose needs to be at least six months beyond that first -- that last patient first dose in order for us to lock the database and read it out.

So it was done because of slow event rates, we made the protocol amendment towards the end of last year. I believe we submitted it to all the global regulatory authorities in November, December time frame. We had to wait until it was signed off by all of them before we began talking about it. And the EU member states that are involved in the study only approved this protocol amendment at the beginning -- towards the beginning of April, so only about a month ago. which is why it only became public then.

So we're now locked and loaded. As I mentioned, we're fast approaching this readout. We're really looking forward to it, certainly have high hopes for this data set and look forward to sharing it with you as soon as we can.

Tazeen Ahmad - Bofa Merrill Lynch Asset Holdings Inc - Analyst

Okay. With that, we're out of time. So thank you, guys, for making the trip over again, and thanks, everybody, for listening. Thank you.

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

Thank you.
