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EDITED TRANSCRIPT

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OVERVIEW:

Company Summary

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PRESENTATION

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Good morning. My name is Mohit Bansal. I'm one of the biopharma analysts here at Wells Fargo, and I'm very happy to start with Regeneron Pharmaceuticals today.

We have Marion McCourt, Head of Commercial at Regeneron, and Ryan Crowe, Head of Investor Relations. Thank you very much for joining us. Over to you, Ryan.

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

Thanks, Mohit, and it's great to be here. I always love coming to this conference. It's our second year in a row here, and I'm very excited to be here again.

I'd like to remind you that our remarks 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, whether as a result of new information, future events or otherwise. I think it's appropriate to reminisce on our last seat at this stage, Mohit, when we announced the results from the first year of the PHOTON and PULSAR studies of what's now known as EYLEA HD, at the time of aflibercept 8 milligrams. And clearly, that was a very exciting and pivotal day for Regeneron and for patients with wet AMD and DME.

Almost to the day, 1 year later, we sit with an approved product in 3 indications. So in addition to wet AMD and DME are also approved in diabetic retinopathy. And while the launch is in the early days, I believe it's business day 12, the early signals are very positive, and I'm sure we'll talk a lot about that. But in addition to the approval, we've also put out very strong 2-year data underscoring the clinical profile over a much longer period of time, showing that EYLEA HD is capable of putting a very high proportion of patients beyond even every 12-week dosing for both types of patients. So that's very exciting, all while maintaining the visual gains and the safety profile that EYLEA, the standard of care for a very long time was able to put forward.

So very excited about launching this product, and I'm sure we'll talk more about it.

Dupixent was another important -- there are a lot of important milestones achieved for Dupixent over the last year, including the approval of prurigo nodularis in the U.S. last September, as well as the readout for COPD in patients with type 2 inflammation, that was in March. We look forward to the NOTUS study, which will read out in the middle part of next year to facilitate a filing there.

And then lastly, more progress in the oncology pipeline with additional data for odronextamab, CD20xCD3 bispecific in lymphoma. And our BCMA by CD3 bispecific, linvoseltamab, in multiple myeloma. And then finally, fianlimab, we also made notable progress in both melanoma and lung cancer with pivotal trials now underway for both.

So lots of achievements. Obviously, the financials have continued to move along. Last quarter, revenues grew 11%, driven primarily by the Sanofi collaboration, including Dupixent, as well as Libtayo, which continues to make inroads in non-small cell lung cancer following its November 2022 approval. So a lot's happened in the last year, Mohit. I'm sure we can dive into all of those topics. Why don't we get started with the Q&A.

QUESTIONS AND ANSWERS

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Seriously, like, I mean, like in 15 years, this is the time you've been announcing so many new things so, an amazing time for you to be here, Marion..

So maybe let's just start with EYLEA here. There is high dose EYLEA specifically. How are you thinking of this launch versus the first EYLEA launch back in 2012? Is it the same playbook you are playing? And how important is J-code? Like what are the mechanisms wherein you can still get a share even without J-code? And how should we think about that?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

So Mohit, happy to -- and good morning to everybody. So as Ryan mentioned, we're on business day 12 in the EYLEA HD launch. So I can give you some recent insights. And the first part of your question is how is this similar or dissimilar from when we launched EYLEA.

Let me start with the similarity, and that is that the level of enthusiasm prior to launch is now moving into the same level of excitement albeit very early days for physicians as they now have the opportunity to evaluate EYLEA HD in the market. And the way we have spoken about EYLEA HD is that we're bringing a product into the marketplace that fulfills the tremendous need of durability and with that being the ability to meaningfully extend the dosing interval with EYLEA HD as we saw in some of the recent clinical data that went out to 2 years for wet AMD and diabetic eye disease, where you potentially can get patients out to 12 weeks, 16 weeks, that doesn't exist in the marketplace today. And at the same time with the confidence that you have the efficacy and safety that physicians have come to know with aflibercept. So the similarity is that level of enthusiasm and excitement of having something they haven't had before, and that transcends then into the market today with this enthusiasm for EYLEA HD, what it brings that hasn't been available in the market for the approved indications.

What I would say is dissimilar. It's a different market environment. And always, Here, we are 11, 12 years later. But I do think the sophistication of our teams, our medical team that's in the market today, our medical affairs team, our commercial organization, our reimbursement team are all working very, very well in the marketplace. And I'll add for all of you very quickly. It's always kind of fun to hear the stories from companies on when the product was approved. So our approval came as these things often do, late on a Friday evening in August. And with immediacy every team member across Regeneron and all functions got to work through the entire weekend 24/7, so that we could launch as promised on Monday and start actually having patients treated by the Wednesday of the first week of product being in the market, which meant it had to get to the wholesalers, be distributed, get into the marketplace, get into physician offices, and we're already having reports of early use, which is really, really exciting.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

That completely makes sense. And the importance of J-code?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Yes, that was the second part of your question. So you can certainly trust that we are doing everything required so that our submissions will be at CMS, and we would then be planning for, of course, the date we have to shoot for is by October 1 in terms of submission. That would result in a permanent J-code generally being achieved by April 1. In the window of time prior to the permanent J-code, we'll be working under a temporary J-code. Our retina specialist practice offices are quite sophisticated. They do know how to make certain that they check on coverage for patients.

We certainly do anticipate that there will be use of EYLEA HD before we have a permanent J-code. We look forward to that day. But certainly, there is opportunity for trial, evaluation and true practice-changing type of occurrences in offices where physicians deem that they would like to transition to EYLEA HD before we have the permanent J-code. So we believe there's an important opportunity in front of us immediately.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Can you do some level of sampling or those kind of strategies in the beginning so that...

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sampling is permitted. We do believe, though, at Regeneron, that it's very appropriate that we work through the channels in the marketplace, so the physicians are experiencing the product and also making certain that their patients will have enduring reimbursement and ability to use the product and have reimbursement and coverage for the products. So we do believe that that's very, very important.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Got it. That's super helpful. I have one question in my inbox, sorry Ryan, I have to direct it to you.

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

Quite all right.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

So I think this is a question for Ryan. So the question is how important it is to push off standard dose EYLEA by a similar lot to convert as many patients as you can? I mean -- and what should be the base case? And how should we think about the upcoming court case there?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

So maybe I'll make a quick comment on EYLEA HD and then over to Ryan to talk a little bit more about some of the other elements of your question. The one comment I wanted to make sure I share with you because it is early days of launch, and I promise to give you some early insights. One thing that's really interesting is that as physicians are starting to evaluate EYLEA HD with their patients, we're hearing stories of physicians not only trying EYLEA HD on what you might describe as recalcitrant patients. But we're also hearing stories and instances where physicians are saying they may have a product -- excuse me, a patient who's on -- for example, EYLEA, which obviously is a standard of care with about 46% of the market, but perhaps have a patient who's on a 7-week dosing interval.

And they're excited to be able to share with that patient that they now have an alternative that could allow the patient to come back in many more weeks over time. We're also hearing situations where a physician might have been trying a patient on another branded product. I'll use EYLEA again, but it could be another branded product. We just happen to have more of the branded market with about 70% of the category. But they might be instead of starting EYLEA, starting the patient on EYLEA HD from the start.

Patient transition from Avastin, a new patient. I share this because it is rather unique in this category to be hearing early use experience in a variety of patient types. So that also bodes well for the enthusiasm and product uptake.

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

I'll take the question about EYLEA biosimilars. I think most people are now aware that the regulatory exclusivity expires on May 17, 2024. So that's the next day, May 18th would be the first day that the FDA can approve a biosimilar version of aflibercept 2 milligram. We have -- we are currently litigating -- in litigation for 3 patents against Viatris and Biocon with a decision currently pending from the Northern District of West Virginia. We believe the decision could come any day, and we are optimistic but realistic with our expectations there.

I think the base case for people should remain biosimilar entry around the middle part of next year, with potential for upside, should we receive a favorable judgment there. We'll have to see what that looks like. So obviously, the longer you have without biosimilars, I think the longer the runway to convert patients -- appropriate patients to EYLEA HD, the better but the strategy doesn't change. The strategy has always been, let's move this market to what we believe is the new standard of care EYLEA HD. So that's how we think about it, and that's how I think you guys should think about it.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Got it. Got it. And bringing IRA into the discussion at this point. I mean how are you thinking about IRA/any potential settlement here?

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

Yes. IRA brings in another dimension to the calculus, (inaudible) I guess. We think we're in a pretty strong position with regard to IRA. We are awaiting Part B guidance. Right now, we only have Part D guidance, and there's been some potential for read through from Part D to Part B. But until we have it in hand and understand what it says, it's hard to make business decisions.

Should the FDA decide to aggregate products similar to how they're doing in Part D with the same active moiety we believe that so long as there is a biosimilar for aflibercept 2-milligram that -- then any aflibercept containing product would be not subject to negotiation.

On the other hand, should we -- should EYLEA HD be considered a new product, obviously, it would benefit from the 11-year shield from selection for negotiation. So we'll have to see what the guidance looks like. In either case, we think we're in a very strong position. And certainly, I believe that the retinal franchise, at Regeneron is one that will be enduring.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Got it. If you have any questions, please do let me know. So maybe moving on to the pricing because this is probably the first public forum for you after you announced the price. Can you talk a little bit about the thought process behind pricing high-dose EYLEA? And how has been the feedback from the payers/physician community so far?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure. So the pricing philosophy for EYLEA HD is very consistent with Regeneron's overall pricing philosophy, which is one of great responsibility, keeping the patient at the center of the thought process in terms of product opportunity for that patient in need. So that responsibility and that thoughtfulness. When you look at the pricing for EYLEA HD quite deliberately, if you do kind of the translation of durability, you're looking at a price point that is very consistent with EYLEA. In fact, you could even calculate that it's a little bit lower than EYLEA, but I would go more with consistent with EYLEA pricing.

And then also remind everyone that EYLEA never took a price increase since launched 12 years ago. And therefore, the thoughtfulness and being responsible with our pricing, but also recognizing that EYLEA HD brings in the opportunity for patients to have much greater durability while still benefiting from the confidence of aflibercept in terms of its efficacy and its safety.

So great -- I said something very quickly that the team's actually validated over months and years of work and making sure that our pricing was appropriate to the market. And to your comment of how has the external world reacted since we've launched, it's been quite favorable. The comments that I hear are as expected from Regeneron, fair pricing, equitable pricing, there always will be room for those who would have gone to a different price point. But there's been a very consistent message of support for the pricing and the responsibility that we've brought to the category.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Got it. This is super helpful. One last question on EYLEA from my side. How do you think about -- like how has been the uptick of biosimilar Lucentis so far? And there were some rumblings that -- or it probably happens already that there is like physicians are doing a little bit of -- experiencing a little bit of prior auths with Avastin. And so is it happening in a big way? So how should we look at biosimilar prior auths?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure. So the experience with biosimilars today, obviously, biosimilars to Lucentis has predominantly impacted the Lucentis product category in the market, which obviously, Lucentis is a smaller by market share and volume and by level of used product today. And that's primarily where the biosimilars have impacted, and we've started to see some early use.

Beyond that, I would say that there are step edits in the market today related to trial of most frequently, it's Avastin -- trial of an Avastin before moving on to a branded product. That's not the majority of the marketplace, but certainly that exists in the market today. And I think our physicians and practitioners are quite experienced with how to navigate a user trial of a less costly product before moving on to their branded selection product. They're very skilled with, how to do that and how to operate in the best interest of their patients.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Great. Well, this is super helpful. Thank you. Any more EYLEA questions? 50% time on EYLEA. So let's just talk about another small product you have called Dupixent. So help me understand from where -- in what innings you are in, in terms of launch because the product is still growing 5 -- more than 5 years after the launch, even in atopic dermatitis? So how should we think about growth in the areas, Dupixent is in right now versus the new launches that are coming up?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure. So Dupixent on a worldwide basis has been an absolutely remarkable product in terms of transforming the lives of patients and the physicians to treat them. The experience certainly in atopic dermatitis demonstrates not only in the U.S. but more broadly, the tremendous unmet need. And even today, we're only penetrating the atopic dermatitis marketplace in adults in the -- maybe perhaps now we're up to the high teens or so in terms of percentage of market of patient capture versus those that still are untreated. So there's tremendous opportunity, not only in atopic dermatitis but to Ryan's point, recent launches like prurigo nodularis which is an incredibly difficult disease for patients who have had really no meaningful alternative until Dupixent was launched.

And then we go into some of the other therapeutic or, I should say, indications where Dupixent is being used now. Biologic asthma has been an absolute godsend to so many patients in terms of making sure their lung function and exacerbations are brought under control, and they're minimizing the use of inhalers. Similarly, an eosinophilic esophagitis, when we launched, the gastroenterologist for the first time brought relief to patients who are suffering so terribly from that disease.

And I can go on with all the indications. It's not uncommon for patients who have nasal polyps to also suffer from asthma. So the other thing really important to think about with Dupixent is that it's treating Type 2 disease. Often, it's one indication that sends the patient to the physician like atopic dermatitis or asthma or EoE. But very often, these patients also have concomitant type 2 diseases, which are incredibly benefited by Dupixent.

So to the -- so the growth we see today, there's certainly tremendous future opportunity, and we very much look forward to future indication launches as well and helping more patients.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

That's amazing. Maybe talk a little bit about the upcoming competition with Dupixent. I mean we -- like I know we all -- every year, we talk about something as there was Jak inhibitor. But now it's lebri- seems like they have shown pretty much similar data to Dupixent so far in atopic dermatitis. And Lilly has a history of with taking some pricing tactics whenever they are a new player in a market where they don't have a place. So how are you thinking about the upcoming competition from lebrikizumab? And what are the points where Dupixent could differentiate?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure. So the first point of differentiation and what I was mentioning a moment ago, when you look at Dupixent in the treatment of type 2 disease, Dupixent has 5 indications. And the thing that's remarkable about that is in each of the indications, Dupixent is the product that has the highest rate of new brand prescriptions. That's across biologic asthma, nasal polyps, atopic dermatitis, EoE. All the indications where we have Dupixent in market, it's #1 in terms of new scripts. And in every indication except biologic asthma where we launched, I think, the fourth or fifth product into the marketplace, we're #1 in total prescriptions. And again, it's the treatment not only of the single indication, but it's the comorbidities often that come with type 2 disease.

But if I go specifically with atopic dermatitis, the other unique things that we hear from the specialist community and the key opinion leaders is that this dual mechanism of action of anti-IL-4, anti-IL-13 really is important. The Lilly product is an anti-IL-13. There is a product in the marketplace today that has that same mechanism of action. It hasn't been tremendously impactful to the market. We certainly always practice very, very thorough competitive readiness across all of our Regeneron teams. So certainly, we'll be ready as new entrants come into the marketplace, but I do think we hold a very distinctive profile in terms of Dupixent's efficacy, safety with indication down to patients as young as 6 months. These are very, very important characteristics of efficacy, safety, ease of use, reimbursement that are very important with Dupixent today.

The other thing I'll add is that, having additional competitors in the marketplace often is a good thing as well because it brings more attention to a disease category. So certainly, we'll be ready for any incremental competition and certainly feel very confident in the profile that Dupixent brings to patients today.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Got it. This is super helpful. So one thing we often hear from experts is that Dupixent's does better in real world than it did in clinical trials, so -- which is a rare comment. Do you think 5 years of head start and so many patients being on the treatment already, can it overcome any pricing tactic competitor plays here?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Yes. Well, I think that most important in selection of biologic is the efficacy that it brings to the patient. And I say that also, but on the sight of we've been very conscious of making sure that we have coverage and affordability for patients with Dupixent, and that exists across all of our indications, and it's very important in the real world setting that patients can actually access and use the medication. But most important is the efficacy.

And I'll share with you an anecdote, one of the key opinion leaders that I know well in the New York area taught me early days when I joined Regeneron that, if a patient doesn't respond to Dupixent, then they don't have atopic dermatologist (sic) [atopic dermatitis]. This is a world renowned dermatologist who shared this. The product is so incredibly efficacious. So I think that's probably the #1 thing.

By the side of that is safety, and it's really reassuring whether to an adult or to a parent to potentially has a child who's being started on Dupixent. Hearing that the product is approved down to the age of 6 months because the safety is so robust, is incredibly reassuring. Then you look at some of the elements of mechanism of action. It's not accidental that the Regeneron scientists and George Yancopolous has anti-IL-4 and anti-IL-13 together when you have half the mechanism of action is probably not going to do all that you get when you combine the dual mechanism of action, which is really important. But as I said, both stay really attuned to the market environment and competition actually coming into some of the categories where we have Dupixent in market has actually been helpful to growth of the overall category.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Great. This is helpful. Maybe moving on to COPD. So a question for you. As a commercial leader, the first trial was great. How important it is for the second trial to have a similar kind of effect when you talk to the prescribers? How are you thinking about the second trial and what is the bar now? I mean, sure the bar should have been raised now, so...

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Yes. So let's say -- and Ryan will comment on this as well, but I would say in terms of potentially having the opportunity to bring Dupixent into the market for COPD is a tremendous opportunity. There's such incredible unmet need on a worldwide basis that, that would be a remarkable opportunity. And certainly, our team would be ready for that upon completion of various trials, submission to FDA and having a product approval. Ryan, maybe to you and some of the most recent information on timing.

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

Yes. And I think the bar certainly has been raised when you can demonstrate a 30% reduction in exacerbations for patients that are already being maximally treated with inhaled triplet therapy. In addition to that, we also improved lung function or, I should say, Dupixent improved lung function in these patients by 80 milliliters -- 83 milliliters, placebo-adjusted, and their quality of life because of those endpoints also improved.

So a really impressive data set overall for the first COPD trial for Dupixent. And Mohit, to your point, the bar certainly has gone up in terms of what the sort of the standard is for this disease.

We hope that NOTUS can replicate the results. It is designed almost exactly the same. The readout is anticipated in mid-2024. And Sanofi and us are working together to try and expedite a filing to make that happen as quickly as possible. So we are very excited about COPD in getting this to patients. We think it represents an important breakthrough. And hopefully, we can move this forward quickly.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Great. Maybe one more question for you Ryan. I'm a little bit surprised that for IL-33, itepek -- it is taking some time, itepekimab. There are not many questions. There were not many questions on the call. Help me understand your level of confidence with this drug versus Dupixent in COPD because they have more data with this one. So how should we think about this?

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

Yes. Itepekimab, which is a mouthful to say -- it's an anti-IL-33. And this one, I think we have a pretty high level of confidence given the results that we have seen in Phase II, which in the former smoker population demonstrated a 42% reduction in acute exacerbations related to COPD. Obviously, that's a little, that's higher than Dupixent's 30%, but this doesn't have any kind of type 2 phenotype. These are all comers in the former smoker population. So we, a, have great Phase II data; b, we've got a lot of information from our genetics medicine center that suggests that anti-IL-33 should have effect in the COPD population. The IL-33 gene when it has loss of function, you see a much higher rates of patients with COPD. So therefore, blocking it should lead to very good outcomes. And that's what we've seen.

So the AERIFY-1 and AERIFY-2 studies are our Phase III studies we're working with Sanofi on. They recently passed an interim futility analysis, which is a good sign for moving forward to the final end point, the primary analysis, which is expected in 2025, which is another -- this is a population, you're talking about 1 million patients in the G7 that are former smokers regardless of type 2 phenotype. So a really large opportunity and we're very excited about it and hope to get to that readout as quickly as possible.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Awesome. Moving on to oncology. So with Libtayo, you have a product. I mean, like basically, the promise was that you will have the as close to Keytruda PD-1 as you can, and you have an antibody which is very similar to Keytruda albeit a few years later. Can you talk a little bit about the launch experience so far here? And then overall -- how are you thinking about making this as big a backbone of the team because you have (technical difficulty) coming up, so a commercial team, how are you thinking about leveraging on Libtayo?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure. Very important. And Libtayo is the backbone of our future oncology portfolio. And certainly, we very much look forward to some of those opportunities for the future, both oncology and hematology. But just to focus on today with Libtayo, the team obviously did a very good job in launching Libtayo initially for cutaneous squamous cell carcinoma and basal cell carcinoma. In both cases, Libtayo very quickly became the standard of care in those non-melanoma skin indications. Very importantly as well, we've seen an important uptick in use of Libtayo as we've launched as of last November, the chemo-combo indication in lung cancer. We previously, as you know, we had the mono indication, but having the chemo-combo indication truly is important for lung cancer patients and having that optionality of chemotherapy for patients who need it.

So we're very pleased with our uptake, we see growth in prescribers. We see growth in inclusion of Libtayo for lung cancer patients and standing order sets at academic institutions, also use in the community setting. So I think the team is doing a really nice job in the U.S. And as well, we now have expansion of Libtayo Regeneron teams in select markets internationally on a worldwide basis. And we also are bringing in some incredible talents to run that area of our business. So we'll be positioned well for the future, not only for Libtayo, but for future products as well.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Got it. And then how has been the interest in your LAG-3 so far now that you're prepping for that?

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

LAG-3, fianlimab as it is now known, has shown some really impressive data in Phase I in metastatic melanoma, where we've seen response rates in the low 60% and PFS of about 15%, median PFS were up 15 months, median PFS, which, when you look cross trial at PD-1 monotherapies, it's around triple median PFS of a monotherapy PD-1 and around double the response rate. And when you look across trial once again, at the end market LAG-3, PD-1 combination you still have significant benefit with mid-60s versus a low 40% ORR and a 15-month versus the 10-month median PFS. So we think we have a differentiated combination. The metastatic melanoma studies are currently enrolling. And we're also beginning the lung cancer studies which has a Phase II step in it, which we could see data for next year or into '25 with the ability to expand those cohorts to Phase III registration-enabling studies. So we're very excited about the anti-LAG-3 and not just in those 2 tumors. We're also exploring it in other tumors that have been sensitive to anti-PD-1 therapy. So more to come from the LAG-3 pipeline, I think.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Awesome. So my last question, which I ask every year. So next year, September 1st week, after Labor Day, I hope you are here. What would make you really happy about your -- when you look back 1 year, what will make you really happy about your accomplishments at Regeneron?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

I'll start, I'm sure Ryan will add to this. But -- so what would make me very excited, I'll start where we ended. I think the advancements in our oncology portfolio, both in-line product and future products is something that we'll be ideally talking with you about. I'm confident we will be next year.

Secondarily, I think we can expect to see Dupixent across approved indications perform incredibly well in the marketplace. And it's really been an amazing product like so many Regeneron products to be part of. And then obviously, we'll be talking, I would imagine we will start the conversation again next year, talking about the launch of EYLEA HD. And at that point, we'll be celebrating a 1-year birthday of time in marketplace and certainly look forward to showcasing those results with all of you.

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

I think that says -- Marion's answer covered a lot of ground. I think for me, obviously, continuing to see progress across oncology and potentially next year having 2 new products approved, odronextamab and linvoseltamab, we've previously signaled that we anticipate filings by the end of this year with approvals potentially next year. So maybe not all of them approved by this time next year, but hopefully by the end of next year. EYLEA HD and monitoring the launch progress there will obviously be of critical importance.

And then back to Dupixent and COPD, where we had hoped to at least be filed in that indication with another positive readout from NOTUS coming around the middle part of the year. So there's plenty of things to be excited about at Regeneron. I think the growth profile for the company has never looked better, and we're certainly all about execution on the commercial side as well as within the pipeline.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Awesome. On that note, thank you very much for joining us today.

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

Thank you, Mohit.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Thank you, Mohit. Thank you, everyone.
