REFINITIV STREETEVENTS

# EDITED TRANSCRIPT

REGN.OQ - Regeneron Pharmaceuticals Inc at Wells Fargo Healthcare Conference

EVENT DATE/TIME: SEPTEMBER 04, 2025 / 1:30PM GMT

**OVERVIEW:**

Company Summary





REFINITIV

## CORPORATE PARTICIPANTS

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

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

## CONFERENCE CALL PARTICIPANTS

**Mohit Bansal** Wells Fargo Securities LLC - Analyst

## PRESENTATION

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Awesome. Thank you very much for joining us today. Welcome to the -- welcome to my second session of the day. I'm Mohit Bansal, one of the biotech analyst here at Wells Fargo, and I'm joined by the Regeneron management team. So we have Marion McCourt, the Head of Commercial at Regeneron; and we have Ryan Crowe, he heads IR operations here. And Team Regeneron has been constant with us for the last four years. So thank you very much for being here today with us.

---

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

Thanks for having us, Mohit. It's always a pleasure to attend your conference. Great venue, always great, well attended, so outstanding.

I'll just read this forward-looking statement, we'll get right to your questions. I'd like to remind you that our remarks made today may include forward-looking statements about Regeneron. Each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in such statements.

A description of material risks and uncertainties can be found in Regeneron 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.

Back to you, Mohit.

---

## QUESTIONS AND ANSWERS

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Great. Awesome. So a lot to talk about. There's a lot of commercial execution going on, a lot coming up there. Great quarter with high-dose EYLEA.

So can you talk a little bit about the journey of high-dose EYLEA in the beginning and then obviously a lot changed with the charity thing earlier this year and then you are reinvesting in that. So there's a lot -- there are a lot of questions there, but just talk a little bit about the journey in the last six months and then the outlook as well here with the high-dose EYLEA.

---

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

Sure Mohit. Very happy to. Good morning to everyone. I'll cover the commercial aspects of EYLEA HD, EYLEA and then let Ryan talk a little bit more about some of the factors of affordability. But to start with EYLEA HD certainly, last quarter, we were very pleased with sharing with you our performance of EYLEA HD, having the strongest growth in the branded category within the anti-VEGF category.

We talked about demand growth in the quarter of about 16%. The prior quarter US, for a six-month view, if I go back a quarter for the first quarter was about 5%. As we think about EYLEA HD, the trajectory of the brand, I think the most important thing I share with you is that the retina community really likes EYLEA HD. They have confidence in Regeneron, even more importantly, experience with EYLEA. So frequently, we hear EYLEA HD is described as EYLEA made better because it really is the product that's showing that level of durability, the ability to elongate dosing intervals for patients, but still give them the efficacy and the safety that they've come to appreciate with EYLEA over 14 years now, and so many injections in the eye helping so many patients and across indications, giving them that ability to have confidence in their vision, their lives and their families.

What I'll share with you, though, is really exciting, and we're trying to be patient. We look forward to some enhancements to our label. We do and Ryan will talk a bit more about the timing and the expectation there. But consider that EYLEA HD performance in the category has been without a couple of key ingredients that we very much look forward to. Q4 weekly dosing is not something that every patient needs, but there's a portion of patients for some practices, it might be 5%, others 10% maybe 15%, 20%.

The fact is that the physicians don't know when they're administering product, which patients are going to be the ones that need the shorting dosing interval. So Q4 weekly dosing as an option in the label like we have with EYLEA -- nothing more than that. It's just the potential to use Q4 weekly dosing will be most helpful. Prefilled syringe is a tremendous convenience factor. Our busy retina practices are treating 50, 80 hundreds of patients sometimes across a practice in a given day. Prefilled syringe will be important.

And certainly, we look forward to the potential inclusion and potential approval also of the RVO indication. Of reference in 2024, that was a $1 billion indication for EYLEA. So those elements are important. I would say that the way I would think of it now is I'm seeing with my team a stable, steady growth of EYLEA HD, very strong performance in what is a very competitive category. A lot of different elements going on but a product profile that really has the opportunity to be the standard of care as we broaden the label.

---

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

And that growth is notwithstanding some of the challenges that the branded category has had due to some affordability issues that have been encountered this year. This -- wet AMD is a disease of the elderly, and a lot of these patients are on Medicare plans and Medicare Advantage plans that require large out-of-pocket costs. And historically, some patients have relied on charitable contributions to offset their out-of-pocket costs.

These charitable contributions are done by third-party foundations and the contributions this year have been significantly lower than in years past. To help ameliorate this, Regeneron has offered a potential solution to match donations from any other donor who would like to help these patients out. But -- and this was a program that launched this summer, but so far, we have yet to see any meaningful contributions that Regeneron could match.

So we continue to hope that there is going to be some donations made in the second half of this year that can help these patients get the drugs that they need because moving to Avastin is going to lead to worse visual outcomes for these patients. It's been shown time and time again that Avastin is an inferior product that requires more frequent injections and so these patients need the better drugs and need help with their financial -- supporting them financially, which we intend to do but with the help across the entire spectrum of potential donors.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

So is it fair to say that 2Q strength you have seen in high-dose EYLEA has not, like charity or the new contribution to foundation has not contributed to that yet. It is mostly the strength of the product at this point?

---

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

So maybe let me take a start on that. What I would share is that the market is -- it's complicated. It's a large market. So EYLEA HD is a product that's been in market now for about two years. It's probably less impacted by the affordability challenge as EYLEA, which is a bigger product.

However, I want to be candid, there's an interplay because EYLEA HD is a source of growth for -- EYLEA is a source of growth for EYLEA HD, as faricimab as is Avastin. So you really can't just dissect one away from affordability, but I also would say that a larger product is going to be appreciating a greater impact from the affordability situation right now. I hope that's helpful.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

No, that is helpful.

---

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

I also will share though that the overall franchise performance of being EYLEA and EYLEA HD 60% of the anti-VEGF branded category is very important, and it bodes well for the ability for EYLEA HD to continue to perform well in the market.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Got it. So I mean, how are you seeing the competition from biosimilars at this point. So I asked this because, I mean, like people do not appreciate that this category has been actively managed with Avastin anyway, right? It's not that starting this year, it hasn't been managed, right? I mean there have been prior auths before that as well. So are there are prior auths there with EYLEA biosimilar? Or like what -- how are you competing against EYLEA biosimilar, which is a very good product actually?

---

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

So I would say the market again see the complications in the market at this time, at this stage, payers have not gotten involved with utilization management favoring a biosimilar in the anti-VEGF category. And then within retina practice, there is selective interest. Some are not particularly enthusiastic about a biosimilar because they already have that product available in EYLEA or in some cases, they've already decided EYLEA-HD is going to be their go-to for all the reasons we mentioned with durability, better profile, next standard of care.

There may be situations where if financially motivations tie in, there may be some interest in using biosimilars episodically. That followed in prior biosimilar participation opposite Lucentis a couple of years ago in the marketplace. So we'll watch all of this carefully, and we'll stay true to Regeneron want to bring the best products in the marketplace and realizing the opportunity that's most exciting to us is helping patients and prescribers with a better product for their patients going into the future. And that's what we believe we have with EYLEA HD. And fortunately, many physicians, many practices feel the same way.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Got it, very helpful. And then let's just talk a little bit about the upcoming PDUFA files for some of those expansions. So first of all, how do you feel about this now that you've got the new PDUFA, new PDUFA number one. And number two, there are three different things like Q4 dosing, RVO and PFS pre-filled syringe approval. So can you just think about -- help us understand the importance of each of them.

---

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

You want to take the second question first.

---

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

The important each, I would say they're all important. So I'm working closely with our regulatory team and Ryan and across the business, all are important because they're different. So as we mentioned on the Q4 weekly dosing, that gives an opportunity for dosing flexibility that you don't need all the time, but you really like to have when you need it, and it gives you confidence for not only your patient care but also reimbursement.

Some practices, frankly, it doesn't stop at all because they see the durability in EYLEA HD, and they have the confidence. Others, they really like to have that safety being able to have the flexibility, it's important.

Prefilled syringe, convenience factor, busy practices. Again, I couldn't be more proud of how well EYLEA HD has performed in the marketplace for two years now not having a prefilled syringe. We know it is the preference, having it is going to be very attractive to many of our prescribers. And then, of course, the RVO indication where EYLEA really is the standard of care and then some -- the clinical data with EYLEA HD looks very exciting. We've got a lot of interest in the marketplace for that indication. We don't have the approval yet, but we look forward to that addition to the label.

---

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

Yeah. And with regard to the regulatory status of those applications, as we previewed on our second quarter earnings call, we had anticipated a delay in the decision from the FDA due to a manufacturing issue at Novo/ Catalent, who is the filler of EYLEA HD vials as well as the proposed filler for the prefilled syringe. There was an inspection conducted in June, concluded in July that resulted in observations.

Since the inspection concluded, Novo has provided a very comprehensive and robust response to the FDA. And on our PDUFA date for the RVO and Q4 dosing sBLA, we received a major amendment, which cited this response that Novo made regarding these manufacturing, which pushed out the PDUFA date into the fourth quarter.

So this was a good outcome for us. It was -- and it suggests that perhaps the FDA believes that these inspection-related issues can be resolved within a three-month window and hopefully Catalent is able to resolve it. We certainly are working closely with them, and they are working closely with the FDA. There's been a lot of back and forth between them, and we believe they're on the right track.

But a lot of this is out of our hands, unfortunately, but we're going to continue to support Catalent, along with working on backup options should Catalent not be able to fix their issues in a timely manner.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

All three of these submissions are -- like there are two submissions, right? So they all got delayed for the manufacturing reasons at this point.

---

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

Yes, exactly. The prefilled syringe submission is under a different pathway than the Q4 and RVO submission. The prefilled syringe is a manufacturing supplement and a normal course review for a manufacturing supplement is a four-month review. The extension is only two months for that application. So instead of a late August decision, we're now anticipating a late October decision. The sBLA for every four-week dosing and RVO, [a two-fer] if you will, is an efficacy supplement and that is a three-month extension.

So instead of a late August, it will be a late November, decision point. And we feel very confident about everything that we have submitted to the FDA with regard to all of those filings. And we believe that once these manufacturing issues at Catalent/ Novo are resolved that the FDA will approve these, and we'll be able to really hopefully reaccelerate EYLEA HD uptake in the US.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Got it. Very helpful. Do you expect a reinspection at this point? Because inspection already happened, right?

---

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

Unclear, and it would be totally up to the FDA, and I don't want to speculate on that.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Got it. Very helpful. I have to ask.

---

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

Fair enough.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

So okay, so awesome. So this is very helpful. Moving on to the other product you have, small product called Dupixent. So I mean, amazing that after so many years of launch, you are still growing at 20%-plus. So I mean I ask this question every year. Where would the next growth come from? So can you talk a little bit about that.

---

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

Well, I appreciate that question every year. So keep asking, but Dupixent has been remarkable, eight indications in the US for a blockbuster status. I look forward to growing that number -- most recently, we just launched CSU, early start with new-to-brand experience has been very favorable. We obviously have a lot of work to do.

COPD continues to perform very well in the marketplace, helping older patients with Dupixent in a way where there's been a meaningful unmet need, and we hear remarkable stories of patients that are having much better lung function, not relying on their medications, oxygen therapy, living fuller lives. The stories we get every day on atopic dermatitis patients go on, eosinophilic esophagitis has been an amazing indications for patients who are able to do something most of us take for granted, enjoying a meal with family or just every day interactions.

Remarkable and certainly in the very competitive asthma biologics category Dupixent like so many of the indications in fact, we lead now. I hate to be boastful, but I have to, in this case for you with Dupixent we lead across seven indications in the US, not only in new-to-brand scripts, but also total scripts.

So never want to get ahead of ourselves, but the growth story on Dupixent has been remarkable, helping children as young as six months now to older patients as well Across so many disease areas, which is such a differentiated product in terms of its mechanism of action, its tremendous efficacy across Type 2 disease, helping many patients who have concomitant disease as well. Nasal polyps has been a remarkable indication for patients who so suffered with basically feeling like they had a severe sinus infection and not being able to taste or smell every day to normal life.

For our team, for my commercial team, our medical teams, everyone touching Dupixent, it's really been an amazing product like EYLEA and EYLEA HD, life-changing for patients to participate. So I think the go-forward picture looks strong. We obviously have competition coming into many of our indication areas. Across all of our brands at Regeneron, we practice tremendous competitive readiness so that there's great understanding on where our product fits.

And I would share so far in the case of, for example, very strong competitors coming into atopic dermatitis. It's helped to grow the market, but because Dupixent is seen as the product with the go-to first profile, first and best is what I often hear from the KOL community. It probably is helping the growth trajectory of atopic dermatitis. Mohit to your point, we're now eight years in the market with that indication.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Yeah, I know my boss's -- Robin's kid was born on that day, that's why I remember the day. Yeah. Awesome. So great. So let's just talk about COPD a little bit. You have seen a very good traction in the beginning. In what inning we are in sport terminology at this point? I mean, you launched last year. So like how much more -- like I know the growth has been really rapid there, but I mean it's a big market. So how are you thinking about this?

---

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

Of course, so [COPD] is a big market. We launched as the only systemic biologic therapy in COPD. The uptake has been quite strong. We've also, I would say, what's very important in the COPD population, it's the one indication where there's not only a commercial population, but there's also the older Part D population.

The payer and PBM coverage for COPD is quite strong. And certainly, we're still early just coming into a year plus of launch. So we continue to see uptake in the indication -- but I would share with you, we've seen a steady growth. It's not like we had a lack of growth as we were getting payer coverage.

I give a lot of praise to the team and frankly, to the payer community for recognizing the importance of Dupixent in COPD as a game changer, it's actually really attractive to them because when COPD patients have exacerbations, they go in the hospital. They're not short stays like so often with asthma patients, it's ER and you go home. COPD patients go in and they're usually hospitalized for a long period of time, not good for them, not good for their payers. So there's been a lot of uptake and recognition of the importance of Dupixent for COPD.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Got it. So you've got a very broad label there, right? I mean, the label is not restricting on EO as such. So do you see usage beyond the -- beyond like below 300 as well here in the real world?

---

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

What I would share with you is that the level the 300 EO level is important -- but when you look at the COPD patients that there are the appropriate candidates for Dupixent therapy when their pulmonologists often look into the history of their data, the patients do have history of EOs at this level. So we have not seen -- we've seen the importance of education. We've seen the importance of making sure prescribers and offices understand they need to look at the patient history, not what the EO level is on triple therapy or on corticosteroids, which naturally lowers it. But as long as the patient shows in their history, EOs at that level. So we have seen a lot of understanding, common test, common language for both the prescribing physicians and the payers.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Got it.

---

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

What I would say is most important to them is the remarkable efficacy they see with Dupixent. And candidly, it's not unlike when we launched into, very different indication, but related specialty. When we launched into asthma, we were the fourth product coming into a crowded market. It's the efficacy, it's the safety. It was the results they got at Dupixent that has made it the leading product in the category. Similarly, in COPD, it's not a problem if you have competition as long as your product performs better.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Right. That's for sure. Very helpful. Thank you for that. So let's just talk about some of the competition out there. So I mean we have the IL-13 out in the market. I mean none of them look better than Dupi, and they -- at best, they look similar to Dupi's clinical trial, but Dupi works really well in real world as well. So are you seeing them as a challenger? Or are they -- like you are not seeing them --

---

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

So I would say, as I was making the comment, we do look at competitors always to make sure that our teams are prepared, our teams are educated so that if a competitive product comes up, they know how to respond, how to educate. But as I mentioned before, and we so often hear Dupixent is so often viewed first and best that growing the market because of competition coming in actually is quite favorable for patients, but certainly the profile of Dupixent is one we all can feel very confident and based on the results it's produced in the market.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Got it. Very helpful. Another interesting readout last week from myasthenia gravis. So congratulations first of all. Again, now you have a task at your hand, right? So trying to understand, like help us understand like how do you plan to position the product here? And I mean it is a crowded market, but then at the same time, it is a growing market as well. So how do you think about the market evolution there's a C5, the FcRn. So how do you position yourself?

---

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

So I think first and foremost, as you mentioned, we were very excited with the clinical data. And certainly, we are looking forward to planning for, being ready for an approval and then a launch into the marketplace. The data suggests we've got a really nice opportunity in the C5 portion of the marketplace based on what we're seeing so far and obviously more work to be done within the clinical profile of efficacy, safety and very important, in this case, the dosing convenience. So certainly look forward to preparing for a launch in this really important area for gMG patients where, as we all know, there still remains so much unmet need.

---

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

And maybe I'll just highlight some of the clinical data that we reported -- in terms of efficacy, the primary endpoint was the myasthenia gravis activities of daily living scale where the cemdisiran, C5 siRNA monotherapy resulted in a 2.3 point placebo-adjusted improvement in that scale, which would be the best among all the C5s at week 26. And is competitive with even the FcRns at a different time point.

But again, it's about the durability of this product and the convenience of the administration being a subcutaneous quarterly injection that ultimately will be self-administered, probably not at launch, but shortly thereafter, we intend to introduce a prefilled syringe for at home or HCP administration.

So this could be game changing, and you don't have the cycling on and cycling off of drug. You have sustained efficacy, and we look forward to presenting that data at an upcoming medical meeting where everyone can see the profound impact it has, not only over the duration of 26 weeks, but how quickly the onset is. So we're very excited about that as well.

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Got it. So this is a sales force you do not have at this point, right? So this is something you will have to build up.

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

We will have to put together the commercialization footprint. We look forward to that and I would share with you, over the last many years now as our portfolio and our in-line brands have grown, obviously, EYLEA was long ago established for ophthalmology and then similar footprint, combined footprint and expertise for EYLEA HD, but think across Dupixent, we've built out dermatology, gastroenterology, pulmonology, I won't name them all.

And certainly, you've also seen us build with success -- an oncology organization, now oncology and hematology. So we've deliberately in the commercial organization had talent at Regeneron or brought talent into the organization that has had experience across multiple therapeutic areas and also internationally, so that we're at the ready and thrilled as we have the opportunities to bring in products for more therapeutic areas. We'll always build out the commercialization, not only the headquarter strategy execution team, but the customer-facing model that matches the needs of that product.

In some places, we're able to take a portfolio approach like our market access payer teams, but then we'll also build specific to that specialty. So we make sure we make the most meaningful impact. I'll share as an example, when we built out our oncology team, we had some Regeneron colleagues who had depth of oncology experience. So they were potentially very strong candidates for roles if they were interested.

But then also, we brought in industry best. And fortunately, and I'm thrilled about this. We've had a lot of people who've wanted to join Regeneron because of the reputation, because of the science, because of the culture of the company. So I would expect that, that will continue as we go into neurology and other therapeutic areas in the future.

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

Yeah. Maybe last point on this. This is just the first of three potential indications with the C5 franchise. So we saw success in myasthenia gravis with not only the monotherapy, but also the combination of cemdisiran with pozelimab, which hit all of the primary and key secondary endpoints as well. The efficacy results weren't as impressive as cemdisiran monotherapy, but notwithstanding that, still showed efficacy. We have an ongoing Phase III study in PNH as well as in geographic atrophy.

And in geographic atrophy, we're looking at both the combination as well as the siRNA monotherapy. So there's a lot more opportunity here. And when we looked at Street numbers for C5 in 2030, there were like $225 million. And today, myasthenia gravis is something like a $5 billion market and expected to double between now and 2030. So it's an exceedingly low bar or Regeneron. I think even in just myasthenia gravis, to exceed that. And we're very excited about moving this forward and hopefully filing with the FDA by the first quarter of 2026.

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Got it. Great. I mean -- awesome. So let's just talk about two last topics before we conclude. So LAG-3, you have interesting data coming up later this year. So I mean, but you have a great LAG-3 and great PD-1 here, but you're comparing it against a PD-1, which is also a good PD-1. So can you talk a little bit about how you are thinking about what is meaningful here -- and yeah, just at this stage here?

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

Yeah. So we have fianlimab, which is our LAG-3 antibody combined with LIBTAYO in an ongoing Phase III study in first-line advanced melanoma with pembrolizumab or Keytruda as the comparable arm. Keytruda, historically, at least in its label, has performed somewhere around four to five

months of median PFS. We've seen some studies have a little more. Some studies have a little less. We don't really know what to expect from pembrolizumab beyond what the historical analogs are and that would probably put us somewhere in the mid- to high single-digit months.

Fianlimab plus LIBTAYO in three independent cohorts in Phase I when pooled had a median PFS of 24 months and a response rate in the upper 50s when pooled as opposed to response rates in the low 30s for pembrolizumab. So all of that is very encouraging. But of course, we need to get the results here. And I think for differentiation, you don't need to get into the 20s here. The bar kind of, I think, for us is somewhere in the low to mid-teens perhaps and anything above that would be exceedingly differentiated from the other approved advanced melanoma therapies in the market.

We announced on our second quarter earnings call that we expect this data in late '25 or potentially early 2026 due to a slowing of events. This is an event-driven study and we need a certain number of events in order to conduct the final analysis on progression-free survival. You can interpret a slowdown in event rate accrual in a couple of ways, whether it's outperformance by the comparable arm or whether patients that are responding to the active arm are having very long and durable responses, which is certainly what we hoped for.

We'll get our answer in a few months. I don't know how else to -- I'll let you guys speculate on what that's going to look like, but we're very excited about fianlimab and LAG-3 in melanoma.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

So uncertainty is the [sell side dream]. Awesome. So like this is very helpful. And then let's just step on [itepekimab] here as well. What are the next steps here? I'm sure you have -- you've seen a lot more data now after the top line. And then there's a partner as well, so you have to think about that as well. So how do you think about that?

---

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

Yeah, Sanofi have had a very hard look at the data, just to refresh everyone's memory, we had a highly successful AERIFY-1 study, where there was a roughly 27% reduction in annualized exacerbation rate in former smokers. But in AERIFY-2, we had a very underwhelming result and one that did not meet statistical significance, mainly because we saw an attenuation of effect in the second half of the AERIFY-2 study.

So we've been scratching our heads and looking very hard at what could have driven that. We have a few ideas, but I would say we're not ready to share them at this point. The next steps are for us to sit down with regulators, the FDA, the European regulators, other global regulatory authorities, explain the data set and understand what potential next steps would need to be taken to have a filing that could be approvable.

In the background, I'd say we are contemplating another Phase III study in terms of what that could look like, how to size it, how to power it, based on our learnings from AERIFY-1 and AERIFY-2. But no final decision on whether or not we're going to conduct that third Phase III has been made, and it will be a joint decision between Regeneron and Sanofi but probably not until we have those discussions with regulators.

I would expect this decision to be made certainly before the end of this year, but I don't have a more precise time line for you today, Mohit.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Got it. Very helpful. And one question on like, you have a very strong balance sheet. And I mean, Regeneron is a very innovative company. Any other company, people would be just clamoring for BD. But again, I'm sure you are getting those questions as well at this point. So has anything changed internally in terms of thought process around BD and use of cash in recent months, especially after itepekimab?

---

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

No. I mean I think one benefit we have at Regeneron is Len and George, they founded the company and have a long-term vision for where we're going. And there's not going to be a knee-jerk reaction because the second half of one study failed. So we continue to have that long-term view, but we also don't have blinders on about the innovation that's going on in the rest of biotech and pharma.

So I think we are -- we've always cast a pretty wide net. Historically, we have focused on earlier-stage opportunities and platforms that could complement our strengths in antibodies. I think we've seen a lot of good results from that, quite frankly between this latest result with the C5 siRNA that we in-licensed from Alnylam to the ongoing gene editing -- TTR gene editing opportunity at Intellia in TTR cardiomyopathy.

So we have a lot of, I think, successes to talk about with those earlier opportunities, but we also understand that there is sometimes more of a focus on later stage ones, and we don't discount them because they're past proof of concept. We just don't want to overpay for something that may not be truly differentiated. So we continue to look. We're very active, don't always see that activity because not all deals come to fruition. But trust me, there's a lot going on in the BD department at Regeneron.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Awesome. One last question I ask every year. One year down the line, I hope you are here. I hope I'm here, what would make you look back at the year and say it was a great year for us?

---

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

So I'll start. And of course, with Regeneron, I have so many choices, which is amazing, but I'll stay a little bit near-term focus. So I do think that the catalyst for EYLEA HD are very important, they're very near term. And we just recently have launched new indications in Dupixent, and we have many. We will continue to make those perform well.

We haven't talked about LIBTAYO today yet, but I do want to share that we thought the data for cutaneous squamous cell adjuvant therapy was very exciting and potentially an indication launch coming there next year. Beyond that, I would say Lynozyfic just launched in the marketplace for hematology patients, unique profile, efficacy, safety. We talked a little before, we're off to an early start just having launched within the last couple of months, but early days, strong indicators. And certainly, that is such a meaningful and large potential marketplace for the future.

---

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

And the next year for us, I think it's really about getting some of these regulatory issues fixed and hopefully, that can even happen in the next few months. But in addition to that, advancing the pipeline more broadly, whether it's fully launching the Factor XI program in [thrombosis], the obesity program, we hope to launch with the in-licensed asset from Hansoh. We look to read out the fiamlimab/LIBTAYO melanoma data as well as some maybe under the radar opportunities in allergy with birch and cat readouts coming in the near term as well as in the genetic medicine division, where we have [Otoferlin], which is our hearing -- rare disease for a genetic hearing loss. As well as some interesting opportunities in NASH and MASH.

So all of those, we hope to have some more data on in the near term, along with the hem/onc opportunities where we're enrolling earlier-stage studies in really large categories. So overall, there's a lot going on in Regeneron.

---

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

I would add to Ryan's comment and then kind of going back to one of your comments from a commercialization standpoint, in all these areas, we already have existing experience or new indications. We would be thrilled for cardiometabolic obesity, certainly commercialization opportunity

there. So whether a current therapeutic area or a future, we are very much prepared to bring that into the marketplace and successfully position ourselves for patients and our prescribers.

---

**Mohit Bansal** - Wells Fargo Securities LLC - Analyst

Awesome on that high note, thank you very much. Really appreciate it.

---

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

Thank you everyone. Good to see you.

---