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EDITED TRANSCRIPT

REGN.OQ - Regeneron Pharmaceuticals Inc at Evercore ISI
Healthcare Conference

EVENT DATE/TIME: DECEMBER 02, 2025 / 6:20PM GMT

OVERVIEW:

Company Summary

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

Cory Kasimov Evercore Inc - Analyst

PRESENTATION

Cory Kasimov - Evercore Inc - Analyst

Good afternoon, everybody. My name is Cory Kasimov, one of the senior biotech analysts here at Evercore ISI. And it's my pleasure to host our next discussion with Regeneron. We're fortunate to have both Marion McCourt, who heads up Commercial; as well as Ryan Crowe, SVP of IR and Strategic Analysis. And we have them for a full 45 minutes, which I'm sure you guys are thrilled about.

In all seriousness, thank you both very much for being here today. And Ryan, I guess let me hand it over to you first, read off your little thing, and then we'll get going.

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

I'll read my little thing. But first, I will say thank you, Cory, and to Evercore for having us here. Great conference, as always, and a lot of great meetings so far. So excited to do this fireside chat with you, even though it is an extended version of a typical fireside chat.

But without further ado, I would like to remind you that remarks made today may include forward-looking statements about Regeneron, and each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in such statements. A description of material risks and uncertainties can be found in Regeneron's SEC filings. Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

We're ready to go into questions, Cory.

QUESTIONS AND ANSWERS

Cory Kasimov - Evercore Inc - Analyst

All right. Perfect. So hard to believe we're already in December, but that is the case. And so given the timing, I'd love to start the discussion by asking you to reflect back on 2025 and talk about what you think are the company's biggest accomplishments this year, recognizing it's been quite a busy year for Regeneron.

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

Sure. Thanks, Cory, and good afternoon to everybody. Pleased to be here today. Very timely question as we kind of reflect on the year and get ready for 2026. But I would -- I'll start with some of our in-line product performance portfolio expansions and accelerations this year.

And I'll keep it really short, and then Ryan will cover some of the advances of great importance in our scientific platform that will be so important for the future. But I'll start with EYLEA HD. Certainly, in the past year, most recent quarter and quarter before, the growth we were able to show you on EYLEA HD is something we're very pleased to see.

We have a lot more work to do in certain the very recent news of label enhancements for EYLEA HD, the Q4 weekly dosing, and also the RVO indication are very important to the future. We certainly expect to see -- we're launch ready and in the process of launching and have launched those indications. But based on time of year and holiday season, we probably would reasonably expect more of the performance uptake associated with those two enhancements to happen next year. Similarly, we're really excited about Dupixent, the breadth of indications we have in the US marketplace, eight indications.

Certainly, international performance has been very, very strong as well. I do as a call out the recent indications, the most recent related to COPD, bullous pemphigoid, CSU, all very important to Dupixent, and we continue to see great expansion across geographies, age groups and indications.

Libtayo as well this year has been really exciting, I would say, for Regeneron overall, for all our teams, but certainly from my commercialization team. It's been a really exciting year. In Libtayo as well, we've had an expansion to our label most recently with adjuvant CSCC. We also see performance uptick and expansion in our lung cancer indication as well as our skin indications.

Like Dupixent, we have international commercialization and activities across Regeneron associated with these products in other markets, specifically cross functional activities related to Libtayo and now also our hematology program.

We launched Lynozyfic this year, as you know, very important patient population in its advanced treatment indication for Lynozyfic, but early days, we're seeing a lot of interest and uptake and advancements in the community. And certainly, in our ultra-rare disease portfolio, we've also seen a lot of exciting things happening. Today, that portfolio is Evkeeza for patients with HoFH, but very important that we have this capability in commercialization as we look at future products that fit into that area of unmet need of ultra-rare and rare disease.

Ryan, maybe over to you for some of the future.

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

Yeah. I mean, that's been a great year for advancing Regeneron's pipeline. So I'll just do a rapid fire across various therapeutic areas where we've seen advances, starting with immunology with Dupixent, we read out positive data in AFRS, which is a disease that is commonly associated with rhinosinusitis. This is allergic fungal version. So we hope to add that to the label with a PDUFA date in February, but an important top line data earlier this year.

We also had FDA approval for bullous pemphigoid for Dupixent and CSU in Europe. In oncology, we obviously read out positive data for Libtayo and adjuvant CSCC and then subsequently got that approved in the US and in Europe very recently. Marion mentioned Lynozyfic, US approval and very recently, European approval as well. And then also in Europe, odronextamab known as Ordspono was approved in Europe as well.

Moving to neurology, perhaps the most important readout we had this year was the Phase 3 data for cemdisiran in generalized myasthenia gravis, where we hope to enter a very competitive space with a differentiated product based on extended dosing intervals out to three months, which would be best in category. In allergy, we read out Phase 2 results for birch and cat allergies. These are allergen-specific programs, and we will be running second Phase 3s for each. That will begin either late this year or in the first half of 2026.

And then finally, as Marion mentioned, in rare disease, we read out additional positive data for DB-OTO, our otoferlin gene therapy, which is just looks like a miracle product there that's turning profoundly deaf children into being able to hear within weeks of therapy.

And lastly, garetosmab in FOP, a very rare disease that is of the muscular -- skeletal muscular system, where we saw a 99% reduction in ossification lesions. So a really important advance for the small community of patients that have this terrible disease. Maybe finally, in terms of looking back on 2025, the capital allocation achievements that we have made, we initiated a dividend this year. Now it's a very modest yield, but it was really intended to open up a new flank of potential investors, those that have a dividend remit as part of their fund rules. So we've been able to attract some dividend investors.

We also have stepped up our share repurchase from the year prior. In 2024, we repurchased approximately \$2.6 billion of shares. And this year, we look to step that up by around \$1 billion. So in total, in 2025, we anticipate returning approximately \$4 billion between the dividend and share repurchases this year. Lastly, domestic investment.

We committed earlier this year to deploying over \$7 billion to manufacturing and research capabilities in the United States, a very important priority for not only Regeneron, but the country as a whole. So we're very proud of all of the achievements that we've had across the commercial portfolio, the R&D pipeline as well as in the capital allocation space and looking forward to an even better 2026.

Cory Kasimov - Evercore Inc - Analyst

There's so much going on in hindsight. We needed more than 45 minutes. All right. So let's start as we go specifically into products with EYLEA HD and the recent FDA approvals of the monthly dosing and the RVO indication. As we've written in the past, you guys are kind of competing and competing effectively with one arm tied behind your back. How much do you expect these two label enhancements to impact uptake still without the prefilled syringe as part of that?

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

So every advancement, as we had mentioned when we were awaiting the label expansion is really, really important and certainly look forward to also getting approval in what we're seeing is likely the second quarter timeframe of next year for the prefilled syringe. I'm sure you'll have more questions on that. But in terms of the teams that are now launching just before Thanksgiving, we started the launches for Q4 weekly dosing, the RVO indication. I'll remind everybody that in the anti-VEGF category, the RVO indication is about 20% of the overall market, probably about 18% of EYLEA -- 17%, 18% of EYLEA's overall business. So this is an important indication, and it's one where EYLEA HD has excellent clinical data.

So there's a lot of enthusiasm for that indication and now physicians having the flexibility to treat more broadly with EYLEA HD. So we're excited about that. Q4 weekly dosing also very, very important because there were some patients where physicians wanted the security of knowing that the patient couldn't be extended out after loading doses to seven-week intervals plus or minus a week on label, which was 8, they would have that security of being able to do so. So these are important.

And certainly, when we round out prefilled syringe, that will be all the label enhancements. But as you know from the most recent quarterly performance update, second quarter, third quarter, our teams, both commercial teams and medical teams, customer-facing roles are incredibly active in the market.

I'm just amazed with how much progress we've made, but I know there's so much more work to be done, and that's exactly what the team members are embarking upon now. So good news certainly for the later portion of this year, but I think the uptake in terms of performance will be seen more thoroughly in 2026. I need more days in the year. I can't cancel holidays, don't want to do that, but we certainly couldn't be more excited about the label enhancements.

Cory Kasimov - Evercore Inc - Analyst

Okay. Great. And then as it relates to the prefilled syringe, in terms of where things stand on that front, maybe what are the pseudo bookends at this point as you see them? And are these at all impacted by the warning letter that was disclosed earlier today, I guess, it came last week for the Catalent facility.

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

Yeah. Maybe I'll take that one. Great question. To answer it very bluntly, the Catalent warning letter has nothing to do with the timing for when we anticipate bringing EYLEA HD's prefilled syringe to market. We're still on track to submit to the FDA our filing for prefilled syringe using an alternate prefilled syringe filler by January of 2026.

Upon submission, that would trigger a four-month FDA review. The warning letter itself is really a reiteration of some of the observations seen in the 483 that was issued back in July. Catalent has -- Novo, Catalent has notified us of their plan to temporarily pause production in that facility, which we disclosed this morning in our media statement.

We do not anticipate that this voluntary pause of production will have any impact on any Regeneron products that are in that facility. We believe we have adequate inventory to support demand for EYLEA, EYLEA HD going forward and look forward to adding the additional vial filler that we previously discussed by the late December PDUFA date that we've previously disclosed. So warning letter really doesn't change anything nor does this temporary pause in production. We're looking forward to getting prefilled syringe approved, hopefully by the second quarter of next year.

Cory Kasimov - Evercore Inc - Analyst

Okay. And then, Marion, with the PFS for EYLEA HD is already approved in Europe, and I recognize that's commercialized by your partner, Bayer. But what trends have you noticed there in Europe that maybe inform your expectations as you think about the impact the PFS could ultimately have here in the US.

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

Sure. So I would say that Bayer certainly has been an excellent partner. And as it's called overseas EYLEA 8-milligram, which is the terminology, as you know, for HD, I think they've done a nice job and certainly having prefilled syringe is positive, and it meets the needs of physicians administering product.

I'd say, Cory, to the question about how we look at the read-through, I'd say, in the US marketplace, which does have some dissimilarities from the international markets, we know from our own experience with EYLEA that when you have the opportunity for vial or prefilled syringe, and keep in mind, our team launched the prefilled syringe for EYLEA now more than a handful of years ago, but the uptake with proper training in the marketplace on the device was very, very well received.

And over time, it's over 95% of our utilization for EYLEA is with prefilled syringe. I think what I hear time and time again with EYLEA HD is the product is so differentiated from the standpoint of durability. It's the efficacy of EYLEA, the safety of EYLEA, things that people never take for granted because they're so important in every category, but in particular, the anti-VEGF category when you're injecting into a person's eye, but we look forward to bringing the alternative of prefilled syringe into the market as quickly as possible. We've done proper medical advisory panels with the device we intend to use. It's been very well received.

So we do -- once we get into actual promotion and launch and FDA approval, that obviously will give the opportunity for my commercial team to get involved and make sure physicians have the support they need. And we would anticipate that the uptake of prefilled syringe will be very, very well received.

Cory Kasimov - Evercore Inc - Analyst

Okay. Excellent. And then as it relates to the biosimilar impact on EYLEA 2-milligram -- how much more are you expecting as we move into '26? I mean, is the brunt of it done? Do you think you continue to see this persist into next year, especially as additional biosimilars come to market? How should we think about that dynamic?

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

I'll mention it in two ways, and I do want to get back to your comment of biosimilars in the future. What I'd share with you right now, I'm pleased, very pleased that more EYLEA business has gone to EYLEA HD. So as we planned for and our strategy has been, we wanted patients to have the advantage of durability. So EYLEA business has more dominantly shifted to EYLEA HD. Back to my comment before, we have more work to do.

The second most frequent source of business for EYLEA HD is faricimab. The third is Avastin. And then we also have patients who are started as naive patients on EYLEA HD. There have been -- I'll move now to your section of the question on biosimilars.

Certainly, there was some biosimilar uptake. It tends to be more episodic. Not all retina specialists and retina practices, frankly, are interested in biosimilars. Some prefer to focus their efforts in different places and not uptake biosimilars. Some do a bit more episodic.

It tends to be somewhat more financially motivated practices. And then, of course, as many of you know, the financial attractive of biosimilars is sometimes relatively short-lived. More biosimilars coming into the market potentially next year, perhaps one would think of the possibility in the second half of the year. That is always uncertain because we never know about FDA approvals. But certainly, that creates the opportunity for price pressure in the marketplace.

I also, though, applaud the retina community because I think there are a group of physicians that like to select the product for their patients. They're treating blinding eye disease. They're injecting a one's eye. They like the choice. They don't want others to potentially be guiding or blocking their use of product.

Obviously, in Medicare fee-for-service, there's more freedom of prescribing. In the Medicare Advantage segment of the marketplace where we see sometimes Avastin step edits, physicians, if they feel a patient should stay on Avastin, they would do that. But more frequently, they will move the patient on to EYLEA HD, EYLEA, another innovative branded product if they're not seeing the results that they would like. As you know, the market this year has been complicated by affordability issues. So that's been another factor in the overall scheme of things that has impacted brand selection in the case of uptick of Avastin, as you were, because it's a low-cost alternative, not because the quality of the product is there.

Cory Kasimov - Evercore Inc - Analyst

I'll refrain from asking about those affordability issues today. Last question, I guess, on the ophthalmology front is kind of looking into the future, multiple companies that are looking to bring bispecifics, multispecifics, depots into the market. I heard Merck was talking this up earlier today in their session. What do you make of the pending competition here? And are next-gen products something that are of interest to Regeneron --

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

Yeah. Well, I would say that our scientists led by George and his team are always looking very, very carefully at not only our future science, which Ryan will comment in a minute in ophthalmology, but also more broadly competitively. I would say, at present, as we monitor and certainly my team and I take a close look at potential future competition, probably most that we see right now that's being talked about is on similar targets to what we target today, some related to different kinds of implants, things of that sort. I think we'll have to wait and see how some of that bears out. But I would share my learning in retina over many years now has been no one assumes safety of any product in this category until it has real-world experience.

So whether a biosimilar or an innovative branded product, there's always the desire to see what actually happens in the real world to see how patients react from a clinical standpoint and a safety standpoint. And I would say going back to our focus for this year and next year

on EYLEA HD, we feel that we have a very, very competitive product profile, couldn't be more thrilled with the already existing label enhancements and more to come fairly early in the year. We think we can make some meaningful contributions.

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

And maybe I'll just provide some quick comments on our ophthalmology pipeline, which I find to be very exciting. But first, I'd just like to underscore that EYLEA HD has really set the bar extremely high for anyone to beat. And for a long time, there are many competitors that were trying to beat EYLEA and really nobody did. And the only one that did was Regeneron with EYLEA HD. So we look at all the different modalities that are out there, whether it be gene therapy or TKIs or bispecifics I really don't see anything really in the near term or even medium term that we view as a significant threat. Time will tell. We'll see some data perhaps next year from some of these agents. But for now, we're very comfortable with the profile and the market position that we have in the retinal space with EYLEA HD.

On the ophthalmology side, I think our focus is beyond the retina, and we're looking -- we introduced a new molecular entity that targets CD3 for non-infectious uveitis. That is going into man as we speak right now. And we also plan to bring to the clinic next year a couple of other opportunities. One we mentioned briefly on our last earnings call is an opportunity for -- to treat glaucoma, which is a very high unmet need that's treated by eye drops and steroids and things that don't really work. We have identified a distinct genetic marker that we will be targeting with this therapy and hope to bring that to the clinic next year, which I'm very excited about.

There's one other unidentified ophthalmology target we anticipate bringing to the clinic next year as well. So I think the early-stage pipeline is going to come into focus very much in the next few months into 2026. And we have many opportunities beyond EYLEA HD to continue, to participate in the ophthalmology space.

Cory Kasimov - Evercore Inc - Analyst

Okay. Excellent. So let's move on to Dupixent. And here's an area we keep tacking on additional indications. I think the count is eight now, maybe nine. So I guess curious how much of these newer indications contribute to Dupixent's trajectory at this point, especially, I mean, you have -- the product has now got line of sight on \$20 billion in sales pretty soon, maybe as early as next year.

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

So to comment on the recent indications and certainly, the foundation for the recent launches is based on many of the specialists that we're launching in new indications to already have experience with Dupixent. But to mention just a couple of the recent -- you're correct with eight indications and obviously, more to come. But most recently, COPD in the US, there's a patient population of about 300,000 patients who are eligible candidates. CSU, another potential 300,000 patients, bullous pemphigoid, 27,000 patients. So real opportunities to help patients with significant unmet need with Dupixent.

And as specialists are considering care with Dupixent, they already know as a product that's been extremely efficacious, incredibly safe with indications down to six months in the case of atopic dermatitis, one year in the case of eosinophilic esophagitis and then also profound efficacy across all indications from AD to asthma to nasal polyps.

And I won't list all eight, but you guys understand that as we launch incremental indications, it's with a product that is becoming very well-known and has a tremendous trajectory. But to your point, being able to bring a product forward for biologic, COPD has been incredibly important, very well received by pulmonologists, both in the academic and the community setting. We're still early days in that launch, but certainly, it is going well. The efficacy, the safety, the ease of use are all being commented on frequently. CSU, different kind of launch because there probably previously, Xolair was the standard of care, more frequently administered by allergists.

Now an alternative for CSU, which is incredibly debilitating to patients who suffer from that disease. We're seeing a lot of use from dermatologists, who obviously know Dupixent very well and allergists, which is terrific.

Only just getting started, but the launch is going very well. My teams have so many indications. They're competitive by nature in a very positive and appropriate way, but they would be clear in saying that probably COPD and CSU are amongst the third largest indications if I time align the trajectory of launch. So atopic dermatitis would be the largest understandably because of the size of the patient population. And we've only penetrated about 20% of eligible patients for atopic dermatitis in the US.

So back to a lot of work for my team. Biologic asthma, we're the leading product as well in terms of new scripts, total scripts. That experience translates beautifully as you start treating additional skin indications like bullous pemphigoid for where these older -- generally somewhat older, more elderly patients are coming off steroids, which have been ineffective, very difficult to take. And now you've got an alternative in a product that it really makes such a meaningful difference for their lives.

So I hope I got to the new indications. I always like to tag the new to the old because it's that synergy across type 2 disease areas that has made Dupixent such an amazing, remarkable top product in the world. Amazing science, dual mechanism of action, and helps patients not only with particular indications that we discussed, but many of these patients have comorbidities because type 2 cascade doesn't know it should only stay one place. You see overlap between asthma, nasal polyps, atopic dermatitis, asthma. So you really are helping the patients in a profound way.

It's very difficult for competitors coming into the category. So as I go to a lot of the industry meetings and talk to KOLs, the most frequent description I hear from them is Dupixent is first and best. And certainly, our scientists have worked hard to create this product that it truly is making an amazing difference for patients around the world.

Cory Kasimov - Evercore Inc - Analyst

So bottom line, Dupi has a lot of legs left to it. At the same time, you have talked in the past because it's inevitable, right? You have to think about life cycle management. What might Dupixent life cycle management look like? And would any follow-on molecules be subject to the Sanofi collaboration?

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

Maybe I'll take that one. We, of course, are looking at ways to have life cycle management around Dupixent. But it's challenging. I mean, Dupi has set a very high bar as we've seen many competitors try and beat and have failed to. I think there's a couple of different angles that we're taking here, some of which involve Sanofi, some of which do not, which is similar to what they're doing.

I think first and foremost, what would be included with Sanofi? Well, if the antibody or any other modality targets the IL-4 receptor alpha subunit, it would be considered part of the collaboration. That's what Dupi hits, and that's what's in the collaboration today.

If we were to figure out a way to extend the dosing interval for Dupi and it still hits that exact target, we would -- it would be part of the collaboration. If it hits any other receptors, then it would not. So we -- it's difficult to extend the dosing interval for Dupixent because of receptor-mediated clearance. IL-4 clears the drug very efficiently and quickly. So putting more in will not extend the dosing interval meaningfully.

So that's been a technical challenge that we have encountered and are trying to work around through various different mechanisms. I think we also are looking at adjacent pathways within the type 2 cascade. And of course, if it doesn't hit the IL-4 receptor subunit, then it would not be part of the collaboration. We hope to bring those opportunities to man in the next couple of months.

There are other I&I targets that we're looking at outside of type 2 inflammation that I'm also very excited about, and we hope to bring those to the clinic in 2026 as well. So in terms of life cycle, in terms of planning for after -- life after Dupi, as people like to talk about, I don't think there's going to be a single product that's going to replace a 2025, maybe even more \$1 billion peak annual revenue drug. That's not

guidance, but that's kind of what people are anticipating at this point, I think, for Dupixent, by the time the composition of matter patent expires in 2031 in the US. So we're going to take very much a basket approach.

We have a very broad pipeline of over 45 clinical candidates, many of which are in Phase 3 or entering Phase 3 in the near term that are addressing very large market opportunities, and they should be entering the market around the same time as the composition of matter patent expires.

And maybe a final note on the IP for Dupi. The composition of matter patent is obviously the strongest in the patent estate, but we have other patents that address the methods of treatment using dupilumab, the manufacturing of the antibody, the cell lines as well as the formulation for Dupixent that extend into the mid- to late 2030s and maybe even 2040. So we are going to certainly look to assert and defend those patents to the extent they're challenged for many biosimilar manufacturers that decide they want to make a biosimilar Dupixent.

Cory Kasimov - Evercore Inc - Analyst

Got it. All right. So let's move on to oncology and start with Libtayo. Curious how the adjuvant CSCC launch is progressing and how you think about the impact of this indication, be kind of immediate versus more gradual in nature?

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

Sure. So first, I'll just share that in commercializing for Libtayo, the adjuvant CSCC indication, the response from the KOL community when we announced the data was just overwhelmingly positive. In fact, at the presentation with the announcement, there was a standing ovation, and I think to a large extent, it is because we were the first and only product that's shown efficacy for this indication, which is a big deal. Launch has gone along very well. We still -- like all launches, they take time, but we certainly are seeing a lot of interest, a lot of uptake within the oncology community. Libtayo has done remarkable things for patients with CSCC and basal cell carcinoma.

Now to have the indication where we can help patients earlier up in the treatment paradigm, it's very, very important. We're investing appropriately to make sure that we're covering radiologists, Mohs surgeons, other physicians who are involved in the treatment of adjuvant CSCC patients earlier. And I think early days, things are going well. And at the same time, we're being very thoughtful about our leadership position in the other skin indications for more advanced disease and also in lung cancer. And that's something we're working on not only in the US marketplace, but as we get expansion of indications in the international markets because, as you know, as Regeneron, we now have full rights to Libtayo and are running the product on a worldwide basis, which has been really, really exciting.

Cory Kasimov - Evercore Inc - Analyst

Okay. And then with ASH around the corner -- around the corner meaning this weekend, I wanted to ask about Lynozyfic, your newly approved BCMA bispecific. And I guess the appropriate place to start is with the big news last week from Johnson & Johnson on their bispecific with the MajesTEC-3 trial. I guess, broadly, what do you think these results might mean for BCMA bispecifics in multiple myeloma? And then more specifically, what's the potential impact or read-through to Lynozyfic?

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

Sure. So let me give you a little bit of the latest on launch and then over to Ryan for a bit of the future, if that's okay. But what I would share is early days of the Lynozyfic launch, and I'll focus on the US marketplace with broader experience. We also, as Ryan mentioned, have launched Lynozyfic in Germany.

But in the US marketplace, things are going well, early days. We do have an indication that's for later line patients, more heavily pretreated patients, fourth line plus.

There's been use certainly in the academic setting, often, and this is a good sign coming first from physicians who had clinical trial experience. But more broadly, we also see pathway inclusion for Lynozytic. We see information related to formulary guidelines, including Lynozytic, payer coverage is developing well. Institutions or practices that needs to be REMS certified are going through that effort. All of these are really good signs for the launch of Lynozytic.

Perhaps most important of all, one of the most frequent questions I get is related to when we'll be able to move into earlier lines of treatment. So perhaps with that, Ryan, over to you to comment on some of the recent competitive data, but also a little bit of the life cycle management plan for Lynozytic.

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

We were very -- the teclistamab plus daratumumab data that we saw the abstract for that's going to be presented in full at ASH, certainly was a very impressive data set. I don't think there's any question about that. Looking forward to diving in a little deeper into what exactly the types of patients they enrolled were as well as what the safety profile looks like. And I think it's a clear positive for BCMA bispecifics in terms of their use earlier in the treatment algorithm for multiple myeloma, of which we fully anticipate participating.

Our strategy with linvoseltamab or Lynozytic, as it's now known, has always been about simplifying combinations and using differentiated combinations from our competitors. In second line, we currently are in the process of getting underway a Phase 3 study that combines linvoseltamab with carfilzomib, which is obviously different than daratumumab. And we hope that based on data we saw at ASCO earlier this year with a 90% response rate, a 76% complete response rate in second and third-line patients that we can have a competitive profile vis-a-vis the recently top line data from Janssen.

We also are looking at precursor conditions where we hope to even stave off advancing to the malignant setting through interventions in light chain amyloidosis and MGUS. So we're very excited about the profile, and I'll just throw a plug in for the upcoming Regeneron roundtable next week, which will be on December 10. Everyone tune in at 8:30 AM Eastern Time, and we'll unveil the vast development program we have planned there. And finally, our data at ASH, I think, is also -- is going to be pretty impressive to look at as well in newly diagnosed myeloma patients. So we anticipate having that data in an oral presentation this weekend as well.

Cory Kasimov - Evercore Inc - Analyst

We'll be tuning into that roundtable, and I'll give it a plug myself and say, I think it's a great idea you guys started this. So kudos to you for doing that. All right. So moving on to LAG-3. What do you believe you need to see in fianlimab? It's always been a mouthful. The frontline metastatic melanoma Phase 3 trial for this product some point next year to become a commercial success? I guess what's the ideal outcome here?

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

The ideal outcome would be replicating the data that we saw in the Phase 1 pooled cohorts where we had three independent cohorts that in total was around -- was 98 patients and produced a response rate of, I believe, 57% and a pooled median PFS of 24 months. That would be fantastic to replicate in a Phase 3 setting. I think the bar for being differentiated, of course, starts with beating pembrolizumab, which is the control arm of our Phase 3 study. But beyond that, looking across trial at the approved LAG-3 agent from Bristol, where the response rate was 43% and had a median PFS of 10 months. I think improvement from there would be potentially practice changing depending on the magnitude.

So we're clearly focusing on a result that not only beats pembro, but is competitive across the field and think that something in the low to mid-teens in terms of median PFS would achieve that. Of course, we aspire for more, but we'll get that data in the first half of 2026 and eagerly await those results along with you.

Cory Kasimov - Evercore Inc - Analyst

Okay. Excellent. So another area of active development for Regeneron, where there's been some big news of late is Factor XI. Bristol and Bayer have had recent updates, one positive, one negative in indications you're not initially pursuing. Nevertheless, how do those trials impact your confidence in your programs, if at all?

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

Great question. I think that the primary read-through for us from both the study in acute coronary syndrome for Milvexian, which failed at interim, as well as the data from Asundexian and Bayer in secondary stroke was on the safety side, where these Factor XI oral small molecules did not increase the risk of bleeding, which has always been kind of an underpinning of our entire Factor XI strategy, which we have two antibodies to address. So our antibodies, we are looking to -- we are targeting initially in venous clot indications, including venous thromboembolism following total knee replacement, cancer-associated thrombosis, peripheral inserted catheter thrombosis as well as in stroke prevention and atrial fibrillation in patients that are both candidates for daily oral anticoagulant therapy as well as those who are not due to the increased risk of bleeding.

And finally, in peripheral artery disease following revascularization. So we have a huge Phase 3 program that is underway, and we'll certainly be enrolling all of these programs next year, encompassing over 20,000 patients in total. The value proposition is having no increased risk of bleeding. And we believe that our antibodies, even in this Phase 1 data that we disclosed in our last Regeneron roundtable earlier in November showed that in a provoked bleeding study, in fact, when layer on top of aspirin, adding our antibodies did not increase the risk of bleeding while adding rivaroxaban on top of aspirin did.

So that was very encouraging in addition to these read-throughs from the competitor data sets that are out there. Once we see what the Bayer data for Asundexian is in secondary stroke, I think we'll take a hard look at that and consider whether or not it should be added to our Phase 3 development program. Until then, we're going to concentrate on getting these other Phase 3s that we already have disclosed off the ground and enrolling and take it from there.

Cory Kasimov - Evercore Inc - Analyst

All right. Makes sense. So next up on cemdisiran in gMG. Can you talk a little bit about how you see the unmet need there and the size of the commercial opportunity?

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

Sure. So substantial and very excited about moving our commercialization capability into neurology with this program. The early clinical data has been really compelling. To your question about the size of the market and the opportunity, so today, the generalized myasthenia gravis market is about a \$5 billion market, as you know, split somewhat between the C5s and the FcRns. Interestingly, the amount of unmet need and dynamic of patients coming into the market suggests that by five years from now, get to that 2030, that market size will about double to about a \$10 billion market.

So very exciting to have a program that is showing the early clinical attributes, safety, convenience of dosing, certainly would see strong competition in the C5 space, but also the opportunity within the FcRn market as it exists today as well.

We will use everything we have in Regeneron commercialization that we've learned from launching in so many other therapeutic areas that we've talked about today. So we will have neurology-specific talent and customer-facing model, but that also will be supported by our commercial organization that's quite experienced, for example, in market access and pricing and payer coverage commercial operations, other areas where we can share some of the learnings across this new team and build out in a very dynamic but also very focused and

effective way. So look forward to it. And the fact that we might have that more data and then potentially submission and approval, launching potentially in the beginning of not next year, but the year following in '27 is really exciting.

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

Maybe I'll just add how we think about complement. It's not simply in myasthenia gravis. We have ongoing Phase 3 work in PNH, where we've already shown that the combination of cemdisiran, the C5 siRNA plus pozelimab and C5 antibody has outperformed ravulizumab or Ultomiris in PNH patients in a small lead-in cohort, 96% of patients reached normalization of LDH with our combination versus around 80% of patients on ravulizumab. And of those patients that did not reach normalization on ravulizumab, we subsequently switched them to our combination and all but one was able to reach normalization within 12 weeks. So we think we are the only -- the combination of cemdisiran and pozelimab is the only one that can completely block complement.

And in the myasthenia gravis study, we showed that 99% of complement was blocked by this combination. That will lead to better outcomes in PNH and prevent breakthrough lysis. The other opportunity in complement that we are pursuing in Phase 3 is for geographic atrophy, a systemic approach to treating geographic atrophy. The currently approved products have had some safety issues and efficacy has not been demonstrated in terms of visual acuity on a prospective basis. We will have an interim readout for our geographic atrophy study, which is looking at both the cemdisiran monotherapy and the C5 combination I've mentioned in the second half of 2026, which will inform plans for a second Phase 3 study. So we're very excited about the C5 space. We think we can really transform with some differentiated agents and look forward to providing future updates.

Cory Kasimov - Evercore Inc - Analyst

Sounds great. Regarding the GIP/GLP you in-licensed from China, I'm curious how you think about the monotherapy potential of this asset. I mean, assuming this market is ultimately as large as everyone believes it will be, even a small single-digit percent share can quickly add up. So do you think about it this way at all? Or is it really just about the future combination potentials with some homegrown assets?

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

I think we think about it both ways, quite frankly. And your point is certainly well taken that even a small slice of a huge pie will be meaningful to Regeneron or any company for that matter. So in order for us to pursue combinations, we need to run monotherapy studies in both obesity and in type 2 diabetes. So we will be hopefully getting those Phase 3s underway next year.

And beyond that, we are looking at novel combinations, both in the muscle preservation space with our GDF8 antibody, trevogrumab, which we intend to learn more about next year with some readouts over a longer time period and at different doses as well as in combinations with other agents to treat comorbidities of obesity, of which there are many. We think that could be another differentiated approach to making an impact in this huge market and look forward to providing some more detail on what combinations we have in mind next year as well.

Cory Kasimov - Evercore Inc - Analyst

Okay. And then two questions left for you in our last two minutes. The first is on BD. Curious how business development priorities have evolved at Regeneron and how they might change going forward, especially given the amount of cash that products like Dupixent are going to be generating for you guys?

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

Yeah. I think we've always been active in business development. I think a lot of people kind of overlook the efforts that we make there. And even yesterday, we announced a deal, a small one, but \$150 million to collaborate with Tessera on an alpha-1 antitrypsin deficiency gene editing opportunity that should be in human by the end of this year. And I think we'll be able to get a pretty good read on what that can do fairly soon thereafter. So we're excited about that.

I think we continue to look at platform opportunities such as Tessera and such as Alnylam, which we did a long time ago and Intellia as well. But we do look at other larger opportunities. And certainly, continue to look for differentiated science, differentiated opportunities in across the biotech ecosystem. We do think it's an important part of the strategy. We don't have a non-invented-here syndrome at Regeneron despite what some people may say. We look forward to continuing to engage in finding good value out there, which we think is sometimes difficult.

Cory Kasimov - Evercore Inc - Analyst

Okay. And then as we wrap up, I recognize this last question is a tough one for you guys given how much you have going on. But asking for a little sneak peek into 2026 and sort of setting the stage for how you think about sort of the key objectives for Regeneron next year. You have 30 seconds to answer.

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

I'll do and more than 15 for Ryan. So I would say most immediate for my team is to optimize our in-line brands and the recent launches we have, products like Lynozytic indications across all of my products, EYLEA HD, we'll have hopefully more indications, but the focus will be on optimizing our in-line brands while preparing for the great science of the future.

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

Yes. I'll just follow that up with advancing the pipeline. That's what it's always about at Regeneron. I think we're excited to get the myasthenia gravis opportunity with cemdisiran filed in the first quarter and moving quickly with regulators there. We, of course, have that geographic atrophy interim as well as the fianlimab data in first-line melanoma in addition to lung cancer, which is a Phase 2 study that we anticipate results for in the first half of next year as well.

And then lastly, I'll just throw a little plug in for the MASH pipeline that we've been working on, which is composed primarily or solely of siRNAs that are beginning to generate some provocative data that I think we'll be able to share at some point next year.

Cory Kasimov - Evercore Inc - Analyst

It sounds like a lot of R&D roundtables to look forward to.

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

We got a full slate kind of in draft form right now. Looking forward to bringing that to investors at the appropriate time.

Cory Kasimov - Evercore Inc - Analyst

Excellent. We're out of time. Thank you guys very much.

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

Thank you, everyone.

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