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OVERVIEW:
Company Summary

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PRESENTATION

Tyler Van Buren - ***TD Cowen - Analyst***

Good morning, everyone. Tyler Van Buren here, senior biotech analyst at TD Cowen. Welcome again, and thank you very much for joining TD Cowen's 45th Annual Healthcare Conference.

For our next session, I'm very excited to have a fireside chat with Regeneron. And it's my pleasure to introduce Marion McCourt, Chief Commercial Officer; and Ryan Crowe, Senior Vice President and Investor Relations and Strategic Analysis for Regeneron.

So Ryan, Marion, thank you very much for joining me. I now go ahead and pass it over to you to read FLS.

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

Thanks, Tyler. It's great to be here. Always well attended, this year is no exception. Thanks for having us. I just will read this forward-looking statement disclaimer, and we'll get started.

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. That's a record time. Back to you, Tyler.

QUESTION AND ANSWER

Tyler Van Buren - ***TD Cowen - Analyst***

That was well done. Naturally, we'll start with EYLEA, Marion, what's the latest on the EYLEA franchise? And what do you view as the key catalysts in 2025 that are going to accelerate the growth of the franchise, obviously including HD.

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

Yes. So Tyler, I'm happy to be here, everyone. Good to see you and very happy to talk about EYLEA HD. So we absolutely believe that our EYLEA HD has the potential to be the new standard of care in the anti-VEGF category. And there are, as we've highlighted, both in our last earning calls and at JPMorgan, some of the catalysts in 2025 that we think are going to be most helpful.

I'll share as well that EYLEA HD, certainly, is getting a lot of experience, real-world experience in the marketplace since time of launch, and we do see an increase both in breadth and depth of prescribing. But specifically, some of the items that will be happening with FDA approvals in 2025 are important to our trajectory.

For one, the prefilled syringe, which we know physicians have a strong preference for is expected to launch by midyear. The RVO indication which is nearly 20% of EYLEA business is for the RVO indication. So another important factor.

We also look at that potentially being added into our label in the second half of the year. And then similarly, we also look forward to an increment to our label for every four-week dosing, which will help to simplify physician confidence in treatment for some subset of patients that have more of a burden of disease.

And that too is something that we would have as an enhancement to our label in the second half of the year. We think these factors are important. We do believe there's a lot of ongoing and now there's a lot of ongoing EYLEA HD prescribing in the marketplace today, but these factors will be important.

We also have a PDUFA date of April 20 for the addition of two-year data to the EYLEA HD label, and that will provide physicians with the opportunity to extend dosing intervals to every 24 weeks. Perhaps equally important, it gives physicians confidence in the durability that they're already experiencing seeing that in longer clinical trials.

So I do think that all these catalysts are achievable this year. Obviously, they depend upon FDA approvals. And with these increments to the label, EYLEA HD will have the broadest indication set and also the greatest dosing flexibility in the entire anti-VEGF category.

Tyler Van Buren - ***TD Cowen - Analyst***

Thank you for that. I know you guys don't comment too much on pricing, but I'm going to ask about it anyways. Roche with VABYSMO has been quite aggressive with their branded launch, way more aggressive than you guys have had to be historically.

And now we've got Amgen's PAVBLU, right, which is a somewhat different dynamic. And obviously, there's discounts that they can offer to where the physicians could make a little bit more money per injection certainly in the near term, but how that evolves over time as we think about what happened with Lucentis biosimilars is important to note.

So there's complex dynamics going on here with pricing. And I'm sure you guys are looking at it on a daily, monthly, quarterly basis. How do you think about it right now? And how do you put these all together? And how should we think about pricing?

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

Sure. So to your point, we don't give guidance on our pricing strategy. We do have a team, both market access and pricing that are very sophisticated in the marketplace, and they look at all the opportunities related to pricing product, payer dynamics, and I think they're quite sophisticated in that regard.

I'll hold off on comment but just share that over the course now of many years with EYLEA and now EYLEA HD, we have the product that has about 46% of category share. So the team has been pretty sophisticated.

I also would comment that certainly for EYLEA. As you know, we have seen incremental pricing pressure in the marketplace. And specifically, you can look at that through CMS-reported ASP pricing publications. As it relates to PAVBLU and strategy, Amgen will be in the best position to describe the factors that they're considering in product experience in the marketplace, which has been fairly limited to date.

I do think that real-world experience is important for all the products, and we will certainly make sure that we stay close to factors that allow for robust physician prescribing and also the clinical factors that are important for the benefits by EYLEA HD or where appropriate EYLEA for patients based on their clinical results, their safety, their product experience and confidence in the product.

I did want to share as you were talking about EYLEA that some of the things that I did want to mention related to going into the first quarter, as we previously said on the fourth quarter earnings call and at JPMorgan, there was significant EYLEA inventory build in the fourth quarter, and that did create a favorable impact for fourth quarter EYLEA results.

The inventory benefited EYLEA by approximately $120 million, and we expect this inventory build to be a headwind in the first quarter as it is absorbed. And obviously, demand has impacted that burn off of inventory.

Tyler Van Buren - ***TD Cowen - Analyst***

Okay. And that's primarily EYLEA 2 mg, right?

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

That was specifically EYLEA 2 milligram, another update to the market, though I do like to make mention of it this time of year. Quarter one does have a seasonality impact associated with it. And that, of course, includes the impact of reimbursement reauthorizations, which historically has negatively impacted EYLEA and benefited compound Avastin share, and we would expect that to be the case this quarter as well.

Tyler Van Buren - ***TD Cowen - Analyst***

Understood. So EYLEA 2 mg consensus has come down with the introduction of Pavblu. I think for this year, 2 mg is maybe down like 15%, if not 20% year-over-year. Given the potential biosimilar erosion of Pavblu, which is interesting. I mean, it continues to grow even with VABYSMO launching into this market.

So what are your latest thoughts on the potential for biosimilar erosion and what you've seen so far with Pavblu in the market?

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

So I'll comment on early days, probably the uptake of biosimilar has been limited. We certainly will keep close watch into all the factors I mentioned related to EYLEA HD and EYLEA. We've got a really busy year in terms of increments to the label, delivery system, more clinical data. It really is an exciting time for the launch of EYLEA HD.

Tyler Van Buren - ***TD Cowen - Analyst***

Great. Let's move to DUPIXENT. What's the KOL feedback or feedback in general been on the COPD launch? Do you guys still have confidence in that being a potential multibillion-dollar opportunity for DUPIXENT?

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

Well, we have a lot of confidence in DUPIXENT across all of its multiple indications. And certainly, the COPD launch was an exciting milestone for us as a company to bring COPD patients in alternative and care that hasn't existed previously, first biologic-treated, systemic approach. So it's exciting times. The early feedback from physicians has been very positive.

They've been very impressed with DUPIXENT's ability to reduce exacerbations for uncontrolled patients. Those patients generally on triple therapy. They've got really high unmet need. We've also heard a lot of reports from physicians on improvement that patients are seeing in lung function.

We had one prescriber who reported that a very severe COPD patient who previously had labored breathing that required that they were on an oxygen tank pretty much chronically had vastly improved after taking DUPIXENT and described the patient and shared this with us at Regeneron as back in the office, hopscotching through the office and smiling in a way that the office staff and physician had never seen before.

So that's an anecdotal report, but I can tell you broadly the uptake has been of high interest. We have a lot of work to do. It's early days in the launch. But certainly, it's an increment of great advance for patients with COPD who are appropriate for DUPIXENT therapy.

Tyler Van Buren - ***TD Cowen - Analyst***

That's great. In terms of prescribing and the EOS cutoff of 300, do physicians have to stick strictly to that cutoff or given the label of elevated eosinophils or eosinophilic phenotype, is it up to their discretion?

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

So we have seen generally that physician prescribing has been similar to our clinical trial data, and that is with a cutoff of 300 eosinophils level that generally is required from payers. There is some variation that we've heard of. It's also really important for physicians to understand that they're looking at the history of the patient.

So it is patients that have demonstrated a 300 eosinophils level in the history of their prescribing. That's meaningful to payers because those levels of eosinophils will vary and sometimes in response to steroid therapy, which alone is inadequate for the patient, they'll come down.

There'll be some variation in levels. But really pleased to report that at this time, we would share that probably over 40% of top-tier pulmonologists have already prescribed DUPIXENT to their eligible patients. So the indicators of launch uptake, always a lot of work to do, but certainly are very favorable at this time.

Tyler Van Buren - ***TD Cowen - Analyst***

Moving to the largest indication with DUPIXENT atopic dermatitis. Obviously, Lilly has gotten EBGLYSS approved and is launching that. Have you guys seen any early impact or pressures by EBGLYSS on the dupi franchise?

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

So we haven't seen a notable impact on the atopic dermatitis business from Lilly's launch certainly always, our team is very conscious of competitive readiness. In this particular case, certainly, we know that DUPIXENT benefits from extensive experience in the marketplace.

It is the go-to product in atopic dermatitis based on the great results that physicians have seen and patients have experienced across all age groups down to prescribing at six months of age. In addition, the combination of indications for type 2 disease is a big advantage that DUPIXENT alone has in the marketplace.

I also would share though that with the new entrant, we would expect trialing in some select patients. There's great knowledge on the part of dermatologists and KOLs that it's a different mechanism of action.

And the dual mechanism of action, or some would say the complete mechanism of action, with DUPIXENT is really important for atopic dermatitis patients. But certainly, we believe that increased promotional spend in the category is favorable and will bring more atopic dermatitis patients to physicians for the treatment that they need.

Tyler Van Buren - ***TD Cowen - Analyst***

Great. So CSU and bullous pemphigoid, which I'm pretty sure most of the audience hasn't done much work on yet. Potential approvals and launches later this year to sixth and seventh indications. Can you talk about those incremental opportunities and how significant they could be?

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

Sure. So we are very excited, and I'll start with the the CSU indication. The PDUFA date is April 18, a very important launch for DUPIXENT. We know in the US, there are about 300,000 patients that are underserved by existing agents. Xolair has been the only approved agent since 2014. But it's interesting that about only 15% to 20% of CSU patients are prescribed Xolair.

And many only have a partial or no response that's estimated to be about 60 to -- excuse me, 40% to 60% of the time, CSU patients don't respond to Xolair. So we're very excited about bringing this product into the marketplace. Usually, allergists treat CSU, and we'd be confident with an FDA approval.

They will in the case of DUPIXENT as well. But often referred by dermatologists, we do see an opportunity for dermatologists who are very familiar with -- and very experienced with DUPIXENT to keep these patients and help them more quickly and not have to refer them to another specialist. So that certainly will be exciting.

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

And for the record, it seventh and eighth US approvals.

Tyler Van Buren - ***TD Cowen - Analyst***

Losing track. Sorry about that. Okay. That's great. And DUPI life cycle management plans are underway, 31, 33 potential LOE, obviously, without any additional patents or extensions, which there are. But when will we learn more about your plan for life cycle extension or management?

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

Yes. So thanks for the question, Tyler. You listed the composition of matter patents. And obviously, there's a much broader estate of IP associated with DUPIXENT that we think could confer protection beyond those expiry dates. In terms of life cycle, we are working on a number of both novel and some fast-following approaches to a DUPI life cycle including extending the half-life of DUPI.

The other part -- the other point I'd like to make is itepekimab itself might be a life cycle opportunity for DUPIXENT. And we're obviously pursuing itepekimab or IL-33 antibody in COPD broader subset of patients, former smokers regardless of eosinophils, but we are also pursuing non-cystic fibrous bronchiectasis, which is not an approved indication for DUPIXENT, but some other overlapping indications include chronic rhinosinusitis with nasal polyps, for which we're starting a Phase 3 program imminently.

And then there are some other overlapping indications that I think certainly have genetic support for pursuing that may be gated by the results for the COPD study. And if we get a strong result there, I think you'll see other indications that DUPI is approved in the respiratory space primarily that could become the life cycle opportunity there.

Tyler Van Buren - ***TD Cowen - Analyst***

So the Phase 3 itepekimab COPD readout, it's a big readout coming later this year. Can you talk about -- or can you give us a little bit more precision as to when we may get that readout? And what would be a strong result that would encourage you all moving forward, what would you like to see?

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

Yes, great question. We officially say second half of the year for the readout of the itepekimab AERIFY studies. I'd also note that we, with a positive result, anticipate being able to file itepekimab with the FDA in the second half of the year.

So that suggests that it's -- the readout itself will be in the earlier part of the second half. So I have to be careful because Sanofi has -- have to be aligned on this.

So second half officially, but earlier part of the second half of the readout. In terms of what we're looking for, obviously, with DUPIXENT in the high EOS current and former smokers, we had a 30% reduction in exacerbations from the BOREAS study and 34% for the NOTUS study, so low 30s, obviously, a good result.

But we're hoping to replicate what we saw in Phase 2 with itepekimab in former smokers where we demonstrated a 42% reduction in exacerbation rate as well as a very strong improvement in FEV1 or lung function. So we're hoping to replicate those results. And should we do that, I think we'll be very excited about expanding the opportunity in COPD for both Regeneron and Sanofi.

Tyler Van Buren - ***TD Cowen - Analyst***

Talking about expanding the opportunity in COPD, how much larger of an opportunity could this be relative to DUPI in COPD?

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

So we estimate for the DUPI opportunity, which would be in current and former smokers with high EOs over 300 in the G7, that population is approximately 500,000. But for itepekimab in former smokers regardless of eosinophil levels, we estimate in the G7, there are 1 million patients.

So clearly, a much bigger opportunity and partially overlapping with DUPIXENT and the former smokers with high EOs, but I would note that in the Phase 2 study, once again, on a post-hoc analysis of patients greater than 250 eosinophils, we demonstrated a 53% reduction in annualized exacerbation rate.

So there's a potential for itepekimab to actually out-do DUPIXENT, which is something that a lot of people have been trying to do for a long time in various indications, but have not. So we're excited about the data set that's coming probably only a few months away. And when we get it, we'll be excited to share with you.

Tyler Van Buren - ***TD Cowen - Analyst***

Wonderful. Let's go ahead and round out the commercial franchises in Hem/Onc, Well, I guess we might get to Libtayo in a little bit too. But in Hem/Onc, bit excited about these bispecific launches, right? Linvo in particular, best-in-class CR rate. Unfortunately, you've had some delays with both of those launches.

So can you just talk about your commercial preparations for Linvo with the potential launch in July as well with odro in follicular lymphoma later in the year? And how prepared you are to compete against heavyweights like J&J?

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

Very good, Tyler, and happy to get back to Libtayo when you're ready as well because there's exciting news there. But certainly on Linvo, we're excited about the launch later this year.

As you mentioned, it's July 10, the actual PDUFA date certainly a nice opportunity to further establish Regeneron in the oncology space. This is what we've been planning for is incremental opportunities in oncology and now hematology. Our teams are working hard to prepare.

We have pre-launch activities underway. There is a nice synergy of effort between linvo and odronextamab as well. We believe that linvoseltamab really brings the potential of a differentiated product in terms of efficacy, safety and administration.

It's very exciting to see nearly double the complete response rates with other BCMA x CD3 bispecs at a similar follow-up time. We've seen to date lower rates of CRS with shorter median onset and duration, also the potential for less hospitalization burden and the potential to extend to Q4 dosing for certain responders is exciting.

So we know that this is a highly competitive market, but we know there's a very important opportunity for patients. And certainly recognize as well that we'll be launching in the later line indication so that as we do this in third line, it's about 8,000 patients in terms of incidence. And then over time, obviously, as the additional clinical studies are completed and we submit data to FDA, we would hope to move to earlier lines.

But in first line, the population is about 30,000. But very exciting that through the linvoseltamab potentially being able to bring a differentiated approach to patients, where there certainly is opportunity for improvement and a new standard of care for them.

You also mentioned with odronextamab, again, in follicular lymphoma. We're looking at the second half of the year. Here, we're going to have a busy summer at Regeneron because we're looking at a PDUFA date of July 30 here.

We would hope to launch shortly thereafter. We also believe here there is a potential for improvement based on the clinical data that we've seen in odronextamab, which is very, very exciting in the FL setting, with the highest response rates observed in the class with 80% overall response rate, 73% complete response.

So certainly exciting and important products that we bring to the marketplace. We do similarly acknowledge in this setting that we would also be starting in later line setting, which is a smaller patient population of about 2,000 patients versus – that's in third line versus in first line, it's about 11,000 patients.

But again, it's a start in the marketplace, and we're very excited about the clinical profile. Some of you probably recall, we reported at JPMorgan that in the lead-in portion of the Phase 3 OLYMPIA-1 study, 12 of 12 evaluable patients had a complete response to odro monotherapy. So very exciting that we bring these products to the marketplace, and we'll be ready.

Tyler Van Buren - ***TD Cowen - Analyst***

Tremendous. Now back to Libtayo. So Libtayo is annualizing well over $1 billion in annual sales. I'm not sure how many people actually realize that. But cutaneous squamous cell carcinoma earlier this year, you showed exciting adjuvant data.

Can you talk about what you see for the opportunity there, differentiation? And how quickly you could get something like that to market?

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

Yes. So the data was really exciting, and this is data that we announced in January, where we showed a 68% reduction in the risk of recurrence or death versus placebo with a p value, significant p-value of 0.0001 at the first interim analysis. We also were encouraged that we were the first immunotherapy to show a benefit in this setting, some will recall that Merck reported last year, that KEYTRUDA had a failed study in the adjuvant CSCC setting.

So we do think this could be a significant opportunity for Libtayo with approximately 10,000 addressable patients in the US potentially representing alone a blockbuster indication, and we certainly plan and look forward to filing to the FDA in the first half of this year.

Tyler Van Buren - ***TD Cowen - Analyst***

Also in the first half, we'll get Phase 2 Libtayo plus fianlimab-LAG-3 lung cancer data. What do you need to see from that Phase 2 to move it forward into pivotal development?

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

Yes. LAG-3 in lung cancer, we're probably trending towards the second quarter for a readout there. We have two ongoing studies now in the proof-of-concept Phase 2 realm. This will be our first look at the data set. We're calling it interim Phase 2 because it will not be mature.

These studies are not large, and they have three different arms. There's a high dose of fianlimab, a low-dose of fianlimab, and then there's the control.

And in the all-comer study, we're also layering on chemo. So there's not going to be -- and the *n's* for each study is only 150. So these are small studies, limited follow-up. What we hope to see is a strong response rate, and that's going to be the end point we're going to look at the most and lean on. We should have an interim -- an early trend on PFS at that time as well.

And I think for us promising data there would be great and continuing to follow those patients. But what we think probably unlocks the go/no-go decision is actually in melanoma where we'll get the data in the second half of the year.

And if we get a robust result that demonstrates a clear differentiation versus other products approved in metastatic melanoma that would give us confidence that the signal we're seeing in lung is likely also differentiated and can withstand the rigors of a larger pivotal study.

So with melanoma, as we've demonstrated in Phase 1 very robust response rates in the high 50% when pooled across three independent cohorts, a median PFS of 24 months, which compares quite favorably to PD-1 monotherapies which are in a mid-single-digit month range as well as against Opdualag, Bristol's LAG-3 combination, where they demonstrated a 10-month PFS, median PFS in their pivotal study.

So hopefully, we'll be able to replicate the data we've seen across these independent Phase 1 cohorts in the pivotal study. Should we -- I think that would unlock not only the lung opportunity but also some other solid tumors that have historically been responsive to PD-1 monotherapy.

Tyler Van Buren - ***TD Cowen - Analyst***

You could drive a truck through the difference in your Phase 2 data versus Opdualag data. So it should be positive. But -- as you think about that opportunity, how large do you think it is for Libtayo fianlimab in melanoma?

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

The metastatic melanoma opportunity, I think I would ballpark in the US, somewhere in the $2 billion to $3 billion range. We're also running a study in adjuvant melanoma, where Opdualag recently reported a failure. We believe that opportunity is likely about half the size of the metastatic population.

So in total, between adjuvant and metastatic melanoma, we're looking somewhere around $4 billion to $5 billion. And hopefully, if the data holds up, we could become a really strong player in that tumor.

Tyler Van Buren - ***TD Cowen - Analyst***

Obesity. There's a lot we could discuss there, but maybe we'll just -- for this discussion with 3.5 minutes left, focus on the myostatin, the lead program. Can you just describe when we should get that Phase 2 data, what we should expect from it and what you want to see to have confidence to move forward into Phase 3.

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

Yes, great question. I think we're anxiously waiting for this readout as well. And we've tagged it with the second half timing. We also noted that we had reached full enrollment by the end of 2024. The primary analysis is at 26 weeks.

So it's probably again on the earlier side of the second half. And we're going to be looking at these primary endpoints of percent weight loss and percent of fat loss.

And we're going to look at it, the combination of semaglutide plus trevogrumab, at a low and a high dose. -- separate arms against semaglutide monotherapy. And there's actually a fourth arm of this study that will look at a triplet with semaglutide, high-dose trevogrumab, and activin A antibody called garetosmab.

We hope that the non-human primate data that we reported at ADA in 2023 can be replicated where at 20 weeks, these monkeys demonstrated on the combination of trevogrumab plus semaglutide, greater weight loss and total preservation of lean mass. So all of the weight that was lost was fat versus semaglutide in these animals was a mix of fat and muscle.

So if we can show greater weight loss and the body composition is improved, I think that's a clear differentiator for the combination approach. I think that the FDA's recent guidance has put the bogey [at about 5%] incremental weight loss. So we would hope to see that or more. And we're, again, looking forward to those data in a few months.

Tyler Van Buren - ***TD Cowen - Analyst***

Is the larger goal there to move forward with the myostatin monotherapy or in combination or in the same molecule?

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

That's another great question that we debate a lot. I think for weight loss, certainly, we're going to need to layer on top of a GLP in order to achieve the weight loss. But after you reach the goal weight or begin to plateau, the second half of the Phase 2 study that we're running actually looks at trevogrumab maintenance -- trevogrumab monotherapy as a maintenance regimen.

So in the second 26-week interval of this Phase 2 COURAGE study, all patients are going to drop semaglutide and half will remain on high-dose trevogrumab, to see if the weight that's lost in those first six months can be retained by staying on myostatin monotherapy.

You would expect the placebo arms to begin to regain the weight post the semaglutide discontinuation. The hypothesis we're testing is whether or not preservation of this lean mask can also lead to preservation of the weight loss.

Tyler Van Buren - ***TD Cowen - Analyst***

Very interesting. I'm going to go to another pipeline program with a Phase 3 readout at the end of the year that I'm pretty sure most of the audience is not aware of the Phase 3 MG readout. Why should people be paying more attention about that readout? And what do you need to see to have the differentiation and compete commercially?

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

Yes. It's, I guess, under the radar for whatever reason, but we do have a second half readout, pivotal readout or our C5 combination approach that combines an siRNA, cemdisiran with our antibody, pozelimab. It's going to look at myasthenia activities of daily living at 24 weeks, and this is a scale, a patient-reported scale.

It's across eight categories with the highest -- higher numbers are bad, but a MAX score of 24. We're looking for something similar or better than the C5 inhibitors that are currently on the market and approved for myasthenia gravis, which range from somewhere in the 1.5 to 2-point range.

The FcRn inhibitors have demonstrated slightly better than that, somewhere in the 2s. So anything in the 2s, I think, would be a great result. And I think the differentiator here is our approach, which we think by knocking out the gene that makes C5 in the liver, which is where most of it is synthesized, as well as using pozelimab to remove any existing C5 that's in circulation will allow for rapid complete and uninterrupted inhibition of C5, which is a driver of this disease.

The other piece is convenience. So we're hoping to bring to market an every four-week subcutaneous injection, which would be much better than the IV is required for [ECU and RAV] antibody, C5 antibody treatments today.

And I guess lastly, this pivotal study includes a monotherapy arm to satisfy contribution of components with the FDA. So cemdisiran monotherapy which is being dosed every 12 weeks is going to also read out, and we'll see which arm wins. And we're very excited about this opportunity.

We've already seen in PNH that this approach can lead to better suppression of LDH into the normal range where RAV has only achieved that in about two out of three patients. So we're definitely excited and we want to see this data as soon as we can in the second half.

Tyler Van Buren - ***TD Cowen - Analyst***

That's great. We're out of time, and we're competing with lunch now. But to wrap up the conversation Marion, Ryan, what do you believe is the most underappreciated aspect of the Regeneron story by investors?

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

Well, I'll take it, and I'll give you a very quick answer, but it is the pipeline. Our commercial team can't wait to deal with the indications and the product launches to come this year, but totality of the pipeline isn't the thing to look at with Regeneron.

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

Yes. I would totally agree with that. I think we've got a lot coming in the middle part and the second half of this year. But even beyond that, this is just the tip of the iceberg. There's so much exciting science happening across a variety of different diseases, and we're going to be moving that pipeline forward and efficiently and look forward to sharing more details as these programs advance.

Tyler Van Buren - ***TD Cowen - Analyst***

Great. Marion, Ryan, thank you very much for your time.

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

Thanks, Tyler, and everybody.

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

Take care, guys.