

REFINITIV STREETEVENTS

# EDITED TRANSCRIPT

REGN.OQ - Regeneron Pharmaceuticals Inc at Goldman Sachs Global Healthcare Conference

EVENT DATE/TIME: JUNE 09, 2025 / 2:40PM GMT

## OVERVIEW:

Company Summary

## CORPORATE PARTICIPANTS

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

**Christopher Fenimore** Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

## CONFERENCE CALL PARTICIPANTS

**Salveen Richter** Goldman Sachs & Company, Inc. - Analyst

## PRESENTATION

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

Morning, everyone. Thank you for joining us. I'm Salveen Richter, biotechnology analyst at Goldman Sachs, and really pleased to be joined by the Regeneron team. Next to me is Chris Fenimore, Head of Finance and CFO; and Ryan Crowe, Head of IR and Strategic Analysis.

So to start here, actually, Ryan, let me turn it over to you, because I think you have some opening comments.

---

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

Just some forward-looking statement business to take care of here. I'd like to remind you that 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. 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.

With that, Salveen, let's get into the important part of the talk.

## QUESTIONS AND ANSWERS

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

Perfect. So to get started here, I think it would be helpful to frame for us how you see the company positioned today with the current EYLEA franchise dynamics, the Dupixent Outlook, and the late-stage pipeline, and where you are most focused from a strategy and execution standpoint over the next 12 to 18 months.

---

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

Sure, thanks Salveen. For us, as we execute on our strategy, there's two things that are core on that execution. One is obviously the focus on our inline brands. And as you look at both EYLEA and Libtayo, as well as Dupixent, you look at Libtayo and Dupixent, they're both growing.

We have Dupixent, where both from a TRX and an NBRX perspective, is leading in all of its indications with the exception of CSU, which was recently launched. The COPD launch is obviously underway and going well.

If you look at Libtayo, Libtayo recently became second in NBRXs. Obviously, it's behind the market leader, but we're very proud of the execution on Libtayo and most recently presented data in adjuvant C5CC, which we're also very optimistic about.

On the EYLEA front, again, it's all about execution. We need to get the prefilled syringe approved. We need to ensure that the label gets enhanced with every four week dosing and obviously the addition of the RVO indication, and we're laser focused on making sure all three of those components happen.

But the important thing about our strategy is all about the pipeline, and what's core to our strategy is investing in our science, our internal R&D capabilities. And we have 45, roughly 45 different assets in the pipeline. We've got readouts coming out in the second half of this year. We'll see metastatic melanoma data from a pivotal study, as well as data for myasthenia gravis, and those are just two assets in the portfolio with some near-term data. Most recently, disclosed some data on the obesity front as well, so there's a lot happening in the pipeline.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

Has the strategy changed in the context of the recent news flow, or is this just an even greater emphasis on the internal pipeline and R&D?

---

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

Len and George have been running the business north of 35 years since the founding, and the philosophy has not changed, the philosophy of investing in our internal R&D capabilities. We view some of the dynamics today as short term and we're really focused on what we believe is the best way to deliver long-term shareholder value -- continuing to invest in our own internal R&D capabilities.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

What is, in that context, your plan to enable long term growth via business development, given your balance sheet, so outside of the internal R&D? Particularly as we look to Dupixent LOEs in the early 2030s, could we see Regeneron step in to buy revenue or late-stage assets to supplement the product portfolio?

---

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

[We have] tremendous amount of flexibility with our balance sheet and the cash that we have on the balance sheet, so we can basically look at a lot of business development transactions. We've got a very active deal team that is constantly evaluating opportunities. I think historically, if you look at some of the transactions that we've done, they've been complimentary either to some of the assets in the portfolio or complimentary from a technology perspective. We'll continue to do transactions like that, but we wouldn't rule out bringing in assets to the portfolio that made sense, that may generate nearer term revenue opportunities, but we're constantly looking. We just haven't found the right opportunity yet, but as we view it, we clearly have the ability and the wherewithal, just based on the balance sheet, to have a lot of flexibility.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

And on the BD standpoint, can you just touch base on the 23andMe acquisition and the strategy behind that?

---

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

Sure. So 23andMe, there's an auction process. That process was recently reopened. I'll say it's a fairly complicated process. We're not sure what the ultimate outcome will be of the process, but we continue to stay engaged. From a strategy perspective, we clearly see the value of what 23andMe has built as an opportunity, first and foremost to enable our target identity and identification and validation perspective, and then there's a longer sort of range of views in terms of what the value is there, but we continue to stay engaged and we'll see how the process evolves.

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

Chris, can you just more broadly touch on capital allocation here and your share buyback strategy? Is this status quo with regard to what you're doing, or could you see an acceleration on that latter point with the buyback or even the Libtayo buydown?

---

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

Sure, so in terms of a capital allocation perspective, again, we haven't really changed our perspectives or priorities, but we're constantly evaluating it. If you look at over the past two quarters on average, we've bought back about \$1 billion worth of our shares. Our perspective has been to basically be out in the market and supporting the stock, and we feel that that has been working. But we're open minded. There are other vehicles out there, and we continue to evaluate those, whether it's an accelerated share repurchase or something like that. To date, we just have decided that that wasn't the right approach, but we're constantly evaluating and looking at it.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

Policy dynamics, acknowledging it is a fluid situation, could you touch on the current policy environment, in particular how you're thinking about potential impacts to your business via tariffs or any of the drug policy changes, and also speak to whether you have an understanding of what might play out with MFN announcements this week.

---

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

Yeah, it's obviously a very fluid situation. We have a policy group in Washington DC that's very active with the administration, as well as with those on the Hill. They keep us updated as to what they're hearing. And right now, we're monitoring the situation. The tariff situation right now, from what's currently been enacted, is not material to the business. If sectoral tariffs were to be enacted, we'll have to see exactly what those look like and what impact they might have on the business. But in the meantime, between ourselves and collaborators, we're obviously employing risk mitigation strategies in the event that they did come into play to minimize the impact on the business.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

And manufacturing, what is the plan here in the context of recent CRLs to ensure that these do not occur on the forward? So could you change your relationships with different organizations, I guess, would be one question. And then also speak to your new manufacturing and supply agreements that you've signed and some of the investments that you've announced that you're making.

---

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

Sure, in terms of the CRLs, we're clearly, from an execution perspective, not happy of the recent number of CRLs. I will say that if you look at the manufacturing capabilities that we have internally, the CRLs have been limited to, for the most part, external third parties, whether they're contract manufacturing organizations or component suppliers.

We view, whether it's those suppliers, those component manufacturers, as strategic partners to us. We value those relationships. With that being said, we took steps a couple of years ago to build out our own fill-finish facility in upstate New York. That process is underway and nearing completion. We actually hope to be able to produce some commercial quantities at that facility later this year.

We also recently, on the bulk manufacturing side, as you're alluding to, entered into a relationship with Fuji Diosynth, which basically nearly doubled our US capacity at the large scale manufacturing capabilities, so that gives us a tremendous amount of flexibility as we think about number 1, growth in the pipeline, enable to be able to manufacture quantities as we see additional assets coming through, but also, as we're talking about from our perspective of manufacturing more in the United States, it gives us the ability to mitigate some of that risk as well.

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

You touched on this earlier, but as we look to the second half of the year, or maybe even over the next 12 months, what are the key pipeline data sets that we should be focused on?

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

Thanks, Salveen. For EYLEA HD specifically, of course, we want to get the prefilled syringe application approved, and I'm happy to provide an update on that. We've resubmitted our application. The FDA has considered it a complete response, it's under review, and they've provided a decision date for this application in late August. We certainly hope it can be resolved sooner than that. The FDA is committed to reviewing our resubmission expeditiously, and so far, it seems to be unfolding that way, so we're optimistic about that.

I consider this a when, not an if scenario in terms of approval for prefilled syringe, because it is the same device with the same components and assembled by the same company as the prefilled syringe for EYLEA 8 milligram in Europe, which was approved and launched in September of last year. So, I'm hopeful that this can be resolved sooner than that, but we continue to work with the FDA and expect the review to be thorough.

On a couple of other enhancements to the HD profile that we feel will strengthen its competitiveness in the VEGF category, as Chris mentioned, we have sBLAs filed for retinal vein occlusion, which is a disease of the eye that is about 20% of the category. Last year with EYLEA, it was about \$1-billion contributor in the US alone, so a very meaningful expansion opportunity for EYLEA HD and potentially could be the only product approved with every 8 week dosing.

And lastly, every 4 week dosing is another label enhancement we hope to get. So dosing flexibility on the shorter end, we think that's important to give prescribers the confidence to use the product because what we found in the real world is not everyone can reach 8 week intervals after the initial monthly loads, so allowing patients to be more subtly extended after the loads would be helpful and allow the prescribers to be reimbursed, which is really the main problem that we're facing. So these three pieces, we think, can all be resolved before the end of summer and hopefully will lead to a significant inflection in HD prescribing as we exit 2025 and into 2026.

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

So jumping into the EYLEA franchise here, could you speak to the copay assistance programs and what you think will play out here on the forward? I mean, recognizing that you could have a situation where someone else provides funding and you match that amount. But A), I guess what are your thoughts of where it lies today and how we should think about it from a baseline perspective? And B), is there a way to pivot patients to a different opportunity, be it via their payers or some other aspect that could allow them to get this offset on the co-pay?

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

I think first and foremost, Salveen, we at Regeneron really believe that patients should have the ability to have access to the therapies that their physicians prescribe for them, and we have always supported patients and we want to continue to support patients.

We just realized, in the current environment, it's impossible for us to support the entire category. So we think we came up with what we think is an innovative solution, which is to have a matching program. We are very close in terms of finalizing that program with the charity that we've been discussing this with, and we expect to have that up and running in the next month or two. It's then up to others in the marketplace to hopefully be philanthropic and to basically contribute to the program, in which case we will match their contributions.

In terms of alternatives for patients, obviously if you're a commercial patient, we have the ability to provide co-pay assistance, so the restriction on copay assistance is with government-insured patients. And then in addition to that, there are opportunities through physician education and things like that, and their office staff, that if they're Medicare patients, they can procure supplemental coverage which would sit on top of their Medicare

B coverage which may allow them to be able to afford different therapies, obviously for an incremental premium. So those are all different things that could be available for patients.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

And then speak to your overall strategy for this franchise in response to rebates and discounts that are being -- or just overall economic incentives being offered by Amgen for their biosimilar and what might be playing out with Roche's drug as well.

---

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

Yeah, that's a great question. I think we're obviously monitoring very closely how PAVBLU is being positioned in the market. They are clearly leaning into physician economics. That's really the only differentiator they can provide to the marketplace, and there are some practices that are certainly interested in that.

We are working as hard as we can to try and stabilize EYLEA while at the same time accelerating EYLEA HD uptake, which I think I spoke to some of these issues in the previous response. Once the profile is fully rounded out, we can become a lot more competitive and accelerate the switch from EYLEA to EYLEA HD. So overall, we're going to do our best to maintain our share of the category and improve HD to drive uptake.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

I guess net, when we think about the low dose EYLEA franchise with regard to those two factors we talked about, but also your ability to change gross to net to kind of offset some of these dynamics, do you think that you've reached a floor here as we look to Q2 and beyond with this part of the business?

---

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

I think we don't want to talk about our pricing strategy going forward and how we may position these products in the future. It's obviously a very competitive space, and we're just going to keep that information to ourselves for now.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

On the high dose here, maybe you could just speak to the prefilled syringe, and in light of the FDA response there, to rectify that aspect and get that drug on the market, and how much of a lever that will be versus RVO and the every-four-week with an inflection in growth?

---

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

As I mentioned, we resubmitted the application. The resubmitted application was considered a complete response, and the FDA has assigned a late August decision date for that. So we hope it can be resolved sooner, and we continue to work with FDA on that.

I think in terms of increasing uptake, this will be more about a conversion from vial to prefilled syringe as opposed to maybe a vast expansion of HD prescribing. It'll certainly remove a barrier that we hear about in the marketplace, but I think adding RVO and adding every four week dosing are perhaps more expansionary than simply providing a new device, which once this profile is rounded out, I think we have a best-in-class product with the best-in-class device and it will allow prescribers to kind of have a single solution for all of their patients with these retinal diseases which currently HD cannot offer, per its label. So we're looking to strengthen the profile over the next few months, and everything seems to be going pretty well with the HD resubmission process.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

And any thought as to giving revenue guidance for this -- for EYLEA?

---

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

So we historically have not given revenue guidance. Our perspective on providing guidance is when there's information asymmetry, we will provide investors with that information that we have that they may not have too. So I don't think we're going to change from that perspective as of right now, but never say never.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

So pivoting over to Dupixent, could you elaborate on the early launch experience for Dupixent in COPD and how patients are actually switching onto the drug with regard to baseline eosinophil levels and then how your commercial strategy is evolving here, not only for COPD but atopic dermatitis, as you see these new entrants in the market.

---

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

So as we look at the launch, we're clearly seeing an uptake by pulmonologists, high prescribing pulmonologists in terms of their prescription writing. If you look at basically patient education and things like that, we started a DTC campaign. If you look at launch metrics in terms of how the launch has actually progressed, it's second to atopic dermatitis, and basically tracking a launch-aligned basis, basically better than the respiratory launches. So we're very encouraged about what we're seeing. And we're optimistic that the launch will continue and the uptake will continue.

We also see and hear from the field a lot of anecdotal feedback from the field of patients who historically had to deal with supplemental oxygen, and now they're out without oxygen and they're walking around and things like that. So obviously small numbers in terms of anecdotes, but very encouraging to hear that as well.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

And on atopic dermatitis with the new entrants?

---

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

Yeah, atopic dermatitis, we continue to obviously lead the category by a pretty wide margin. Some of these new entrants that have come along, I think, have probably been expanding the market, and because of that market expansion, Dupixent's probably been an outsized beneficiary of those efforts. Lebrikizumab, nemolizumab are now approved drugs in the US but so far have not taken meaningful share, and we continue to expect Dupixent to lead the category.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

And when will we have a sense of the life cycle management strategies that you're looking at with regard to the Dupixent franchise?

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

We're working on a variety of things. Unfortunately, none of them are in the clinic yet. We prefer to not comment on targets that we're looking at pre-clinically. But certainly, we're looking at an extended dosing interval for Dupixent as well as some other targets in adjacent type 2 inflammatory pathways with longer dosing intervals. So I'll leave it at that, but hopefully in the next six to nine months we'll have some new INDs to talk about with some more detail around them.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

And then with your partner Sanofi on the back of the recent Itepekimab data, could you remind us or just walk us through what next steps are here?

---

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

Sure, Itepekimab obviously had a disappointing second half of a second study which didn't read statistical significance in terms of its reductions in annualized exacerbation rates. I think as a broader context about both of the studies, the background exacerbation rate was well below what our powering assumptions were. And for that reason, I think we had a harder time reaching the statistically significant benefit.

In terms of next steps, we continue to look at this data and try and figure out exactly what happened in the second half of the second study. We have probably more questions at this point than answers, but we do have a couple of theories that we're operating under that we need to interrogate a little further before we can talk about. But once we have a better understanding of that, we will approach regulatory agencies, discuss the data set, discuss perhaps some of these reasons why we think the results ended the way they did, and we'll go from there.

Whether or not a Phase 3 study is going to be required, another Phase 3 study is going to be required or not, I think we're going to have that discussion with regulators and then it'll be up to Sanofi and Regeneron to determine whether or not they want to pursue that. But certainly, that decision has not yet been made, so we're hoping to get more clarity on that in the coming months and we'll share that as we learn.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

Ryan, you just touched on new programs and targets in the autoimmune side. You've also talked about some on ophthalmology. When do you think we'll start to -- or when will you provide an update on these targets, but also file these INDs?

---

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

I think we do this pretty consistently at Regeneron where once we IND and a trial goes to clinicaltrials.gov, we can then begin to discuss the target and why we think it could be differentiated and what its ultimate commercial opportunity could be. So it's really -- we're in the late innings in a couple of very novel ophthalmology targets for some diseases that have high unmet need. I mentioned some of the I&I INDs we expect to have in the next six to nine months. So as these are reaching man, I think we'll be much more flexible in how we communicate, but for now we want to be mum. We don't want to have competitors know what we're working on until we're in a clinical setting.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

On obesity, you recently announced Phase 2 data from your program where we saw additional weight loss with your triplet program over semaglutide monotherapy, and you are optimizing the benefit risk here with regard to tolerability. Can you just provide us additional insight on what you're trying to optimize now, the regulatory pathway for this program, and then also your rationale behind the acquisition of the asset from China?

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

Yeah, those are all great questions. I think for us, obesity, the narrative really needs to change. It's not about weight loss. It's about fat loss. And adiposity is what drives comorbidities and other cardiovascular-related diseases. And we think that preserving lean muscle mass in the presence of an incretin backbone is going to be critical to having long-term better outcomes.

So what we saw in the interim results from the COURAGE study that we topline last week, was when combining semaglutide with trevogrumab, or myostatin antibody, 50% less lean mass loss versus semaglutide alone. And when you add an activin A antibody called garetosmab to the semaglutide trevogrumab combination, something like 75% or 80% less lean mass loss, or mass preservation, if you will, including some incremental weight loss.

That came with some toxicities. They were on target and kind of expected from us. What we think we need to do is revisit how we're dosing the drug and perhaps a titration schedule. So we're going to be pursuing all of those things.

In terms of the Hansoh in-license, this is a GLP/GIP agonist that we attained the worldwide rights to, excluding China and a couple of other territories in Asia. This is to serve a couple of different strategies for us. One, we're going to pursue a monotherapy obesity strategy with this asset. When you look cross trial in Chinese obese patients with similar baseline characteristics, looks very similar to some market leaders. Also, we're going to pursue this Hansoh in-licensed asset in combination with our lean mass preservation agents. And then we have some thoughts on combining it with some other targets in our earlier stage pipeline and portfolio that could address other cardio metabolic diseases.

So this is an important backbone. It helps accelerate our strategy. To your earlier point on business development, it is Phase 3 ready. Hansoh will be launching a Phase 3 in China very soon, and we hope to be launching one in the US maybe sometime next year. So there's -- we have to wait for the deal to close, of course, and it is subject to antitrust clearance, but hopefully, that can be finished up in the next few weeks to months, and we can begin to execute on our strategy, which we think will differentiate us from current competition.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

And the team seems quite confident on LAG-3 with the outlook here in melanoma, and then we look to lung cancer next year, but help us understand the rationale behind the confidence here.

---

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

I think our confidence in melanoma really comes from the Phase 1 data that we've generated. So, to refresh everyone's memory, we ran three independent cohorts in advanced melanoma and had very consistent results across all three. Now, these are single arm studies, but they were investigator assessed and centrally reviewed data. The data has improved over time, and [as of] the latest update as of ESMO in 2024, we had a response rate approaching 60% and a median PFS across all three of these independent cohorts of 24 months, which compares very favorably to both PD1 monotherapies who have response rates in the low to mid-30% and a medium PFS in kind of the mid-single-digit months, as well as to the incumbent LAG-3 PD1 combination product from Bristol-Myers, which has a response rate in its FDA label of 43% and a medium PFS of 10 months.

So we think our Phase 3 data will readout in the second half of this year. The primary analysis is median PFS. So it's event-driven. I can't narrow the window for you today. We'll need to get an update from our data monitoring committee to understand event accrual rate. But we think -- if we can translate that Phase 1 data into Phase 3, we would feel very good about becoming the new standard of care there.

And even a median PFS bar of, call it, mid-teen months would represent a 50%-ish improvement over Opdualag. So we feel very good about our melanoma opportunity. Of course, we'll let the data speak for itself when it's read out.

Regarding lung cancer, we did an interim analysis earlier this year in lung. We could not make a conclusion based on the maturity of the data about advancing fianlimab-Libtayo into Phase 3. So we're allowing the data to mature some more, and we also will get an understanding of what

this advanced melanoma data looks like by the time that next readout occurs, which is ultimately a pretty important gating factor, as well as the data itself, to advancing the program.

So we're excited about LAG-3. We have an ongoing adjuvant melanoma study as well and we have some head and neck opportunities potentially down the line as well. So there's a potential big opportunity with LAG-3 and fianlimab plus Libtayo that we're going to explore.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

And you also have generalized myasthenia gravis data in the second half of this year. Help us understand the differentiation that could play out with this compound and then, where it would result in terms of the competitive dynamics where this could fit in?

---

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

Yes. So this is kind of, for some reason, a very under the radar trial, but I'm happy to speak about it. I think it represents a meaningful opportunity for Regeneron if the data supports it. So, C5 inhibitors in myasthenia gravis have produced a placebo-adjusted change in the myasthenia daily active living score of about 1.5 to 2 points with the FcRn agents producing somewhat more -- results somewhere maybe in the mid- to high 2% on a placebo-adjusted basis.

We will get our data in the second half of this year. I think we are optimistic because we have shown at least in PNH, another complement-mediated disease, that we can inhibit C5 much better than the C5 inhibitors alone. Our combination of an siRNA silences the gene in the liver that produces C5, while our antibody, which is used in combination with the siRNA, clears out any circulating C5.

So better suppression will lead to better results. We began to see that in some emerging data in PNH, and we look forward to seeing what it can do in myasthenia gravis. I'd add that we're looking at this across different doses and different dosing intervals and different combinations. So we, of course, have the siRNA monoclonal antibody combination arm. We also have an siRNA monotherapy arm, which would be dosed quarterly, which could be a very significant dosing advantage in this category. We'll have to see what that data looks like, and then balance it against safety.

Obviously, these -- all of these drugs have infection risk. I don't expect ours to be different, but hopefully, we can compete both on efficacy and having a comparable safety profile, and we shouldn't have to wait much longer to find that out.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

Chris, Ryan, a last question here. Maybe let us know if there's anything that you want to highlight that we haven't discussed with regard to the pipeline or commercial dynamics, but also touch on Linvo and Odro with those launches in light of the upcoming PDUFA's and how big that commercial opportunity could be.

---

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Executive Vice President - Finance, Chief Financial Officer

So for linvoseltamab, we have a July 10 PDUFA date. We're very encouraged. Obviously, it's later lines of therapy, but encouraged by the data that we produced. So we think relative to the competition, that's going to be competitive, both from an ORR and a complete response perspective.

We're basically 2x some of the competing therapies that are out there, lower hospitalization burden, and then potentially better dosing flexibility for those patients that qualify and the lowest CRS rates as well. So, very encouraged by the opportunity there, but the real excitement is to go into earlier lines of therapy. And if we can have the success we're having in these later lines, just think about the possibilities that could happen going into earlier lines of therapy.

Recently at ASCO, we provided some additional data with linvoseltamab in combination with some of the proteasome inhibitors. And again, seeing improvements in later-stage patients on top of monotherapy alone, where you're seeing 90% [overall] response rates and CRs in the mid-60s, I think it is. [Company correction: complete response (CR) was 76% in this setting.]

So again, very encouraging. On the odronextamab asset, where we've got a PDUFA date of July 30. Again -- later lines of therapy, but the excitement there is again going to earlier lines, so, very encouraging ORR and CR response rates. We recently, again, provided some data from our OLYMPIA 1 study, where looking at earlier patients where we actually saw 12 of 12 complete responses where the standard of care right now, R-CHOP has a response rate around 65% or 66% or something like that. So two assets that are probably overlooked right now, but prospective launches coming up in July.

---

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

I guess to round it out, I think we've got a very broad pipeline, over 45 programs here. We'll be launching our Phase 3 Factor XI program imminently. So we should have some clinical trials posting very soon. And that's another mega category that we hope to be a player in along with obesity, and some of the other opportunities that we mentioned like in melanoma and in oncology overall. So I think there's a lot of innovation going on at Regeneron, and we're excited about all of it, and we look forward to delivering on our pipeline.

---

**Salveen Richter** - Goldman Sachs & Company, Inc. - Analyst

Great. Thank you so much, Chris. Thank you, Ryan.

---

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

Thank you, Salveen.

---

**DISCLAIMER**

Refinitiv reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2025, Refinitiv. All Rights Reserved.