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REGN.OQ - Q3 2025 Regeneron Pharmaceuticals Inc Earnings Call

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OVERVIEW:

Company Summary

REFINITIV

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PRESENTATION

Operator

Welcome to the Regeneron Pharmaceuticals' third-quarter 2025 earnings conference call. My name is Shannon, and I'll be your operator for today's call. (Operator Instructions) Please note that this conference is being recorded.

I will now turn the call over to Ryan Crowe, Senior Vice President of Investor Relations. You may begin.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Thank you, Shannon. Good morning, good afternoon, and good evening to everyone listening around the world. Thank you for your interest in Regeneron and welcome to our third-quarter 2025 earnings conference call. An archive and transcript of this call will be available on the Regeneron Investor Relations website shortly after our call concludes.

Joining me on today's call are Dr. Leonard Schleifer, Board Co-Chair, Co-Founder, President, and Chief Executive Officer; Dr. George Yancopoulos, Board Co-Chair, Co-Founder, President, and Chief Scientific Officer; Marion McCourt, Executive and Vice President of Commercial; and Chris Fenimore, Executive Vice President and Chief Financial Officer. After our prepared remarks, the remaining time will be available for Q&A.

I would like to remind you that remarks made on today's call may include forward-looking statements about Regeneron. Such statements may include but are not limited to those related to Regeneron and its products in business; financial forecast and guidance; development programs and related anticipated milestones; collaborations, finances, regulatory matters, payer coverage and reimbursement, intellectual property, pending litigation and other proceedings; and competition. Each forward-looking statement is subject to risk and uncertainties that could cause actual results and events that differ materially from those projected in that statement.

A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2025, which was filed with the SEC this morning. Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

In addition, please note that GAAP and non-GAAP financial measures will be discussed on today's call. Information regarding our use of non-GAAP financial measures and a reconciliation of those measures to GAAP is available in our quarterly results press release and our corporate presentation, both of which can be found on the Investor Relations website. Once our call concludes, the IR team will be available to answer any further questions.

With that, let me turn the call over to our President and Chief Executive Officer, Dr. Leonard Schleifer. Len?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

Thanks, Ryan. Thanks to everyone for joining today's call. For my remarks today, I will summarize our third quarter top line performance, provide an update on EYLEA HD regulatory matters, briefly discuss our recent pipeline progress, and close with some comments regarding our discussions with the United States government to lower drug costs for American patients while preserving innovation.

I'll then hand the call over to George, who will provide more details on our pipeline progress. From there, Marion will review our commercial performance. And finally, Chris will detail our financial results and guidance.

Regeneron delivered a solid third quarter driven by double-digit net sales growth for three of our leading products. Compared to the third quarter of last year, worldwide net product sales for Dupixent increased by 26% and Libtayo by 24% at constant exchange rates, while EYLEA HD in the United States grew by 10%.

Regeneron had Dupixent global net sales for the third quarter [of] $4.9 billion as recorded by Sanofi with strong growth continuing across approved indications in geographic regions. In the United States, Dupixent net product sales grew 28% compared to the third quarter of last year while maintaining its leadership position in both new to brand prescription share and total prescription share across all indications approved prior to this year.

Dupixent is now approved in the United States to treat eight distinct diseases driven by underlying Type 2 inflammation, including diseases of the skin, gut, and respiratory system, spanning age groups from infants to the elderly, and with more than 1.3 million patients globally being actively treated. Dupixent is one of the most widely used biologic medicines. Dupixent's approved indications could potentially address more than 4 million patients in the United States alone, positioning it to remain a strong growth driver over the near, medium, and long-term.

Global Libtayo net product sales were $365 million, up 24% on a constant currency basis compared to the third quarter of last year. In the US, net product sales grew 12%, where Libtayo continues to be the market-leading immunotherapy for advanced non-melanoma skin cancers while building share in lung cancer.

Earlier this month, the FDA approved Libtayo in high-risk adjuvant cutaneous squamous cell carcinoma, making Libtayo the first and only PD-1 antibody indicated for this setting. While it only has been a few weeks since approval, our launch is already off to a great start, and we look forward to treating the up to 10,000 addressable patients in the United States who could benefit from this medicine.

Moving to EYLEA and EYLEA HD. Affordability issues continue to dampen branded anti-VEGF category growth. As announced in June, we initiated a matching program for up to $200 million in contributions to the Good Days Retinal vascular and Neovascular Disease Fund. But I am disappointed

to report that the matching of third quarter was under $1 million due to the lack of donations from other potential contributors. We remain committed to matching future donations to this fund through the end of the year.

Despite affordability headwinds, EYLEA HD had a strong performance in the third quarter, with US net product sales reaching $431 million, an all-time high, driven by robust physician unit demand growth, partially offset by a lower net price. We continue to believe that future product enhancements, such as a four-week dosing interval, the inclusion of macular edema following retinal vein occlusion or RVO, and a pre-filled syringe administration are needed to fully unlock EYLEA HD commercial potential.

Earlier this month, we were notified by Catalent Indiana LLC, an affiliate of Novo Nordisk, that the FDA classified their facility as official action indicated or OAI. And to date, the issues identified during the July 2025 inspection have not been completely resolved. On that basis, the FDA issued a complete response letter yesterday for the pre-filled syringe supplemental BLA with the sole approvability issue relating to unresolved inspection findings at Catalent.

We continue to execute on our previously announced plan to submit an application to add an alternate pre-filled syringe by January 2026 which would trigger a four-month FDA review.

We have also been diligently working with an alternate vial filler and have already submitted an application to include them in the EYLEA HD BLA with a PDUFA date in late December. This would provide an additional opportunity for the FDA to approve the sBLA for every-four-week dosing in RVO given we believe there are no other outstanding review issues for this application.

Moving briefly to our pipeline which George will soon discuss in more detail. We continue to make significant investments in R&D that have yielded notable progress across several key programs. In just the past three months, we have announced positive Phase 3 or registration-enabling data for six distinct programs spanning immunology, neurology, allergy, and rare diseases.

Over the next several months, we look forward to rapidly expanding pivotal programs in hematology, oncology, thrombosis, obesity, and other metabolic diseases, as well as allergies, all of which we believe represent an impressive next wave of innovative medicines discovered or developed by Regeneron.

Finally, I'd like to take a moment to address our ongoing progress toward reaching an agreement with the US government to help lower the cost of medicines for American patients. We are having constructive discussions with the administration, and I'm pleased to share that our priorities are closely aligned.

Both Regeneron and the administration are deeply committed to ensuring that American patients have timely and affordable access to ground-breaking medical breakthroughs. We likewise share the goal of preserving the United States' position as a global leader in biotech innovation and manufacturing.

For more than a decade, George and I have argued that foreign governments have benefited from American innovation without sharing the burden of its cost. We are hopeful the efforts of this administration can level the playing field and convince high GDP nations to contribute their fair share, rather than relying on the United States to shoulder the vast majority of this responsibility.

By addressing this imbalance, we can ensure a more equitable global system that supports continued advancements in medicine while improving affordability for US patients.

Furthermore, we agree that investing in US manufacturing is not only vital for creating jobs and strengthening our economy, but for safeguarding national security. In fact, in testimony before Congress in 2014, Regeneron highlighted the importance of prioritizing biotech manufacturing and innovation in the United States.

Regeneron has already made significant commitments in this area, including our plans to invest over $7 billion in infrastructure and manufacturing facilities in New York and North Carolina over the coming years.

We remain optimistic about finding common ground with the administration that strikes the right balance between achieving our shared priorities while advancing Regeneron's mission of harnessing the power of science to deliver life-changing medicine to patients.

In closing, Regeneron's business continues to perform well with impressive commercial execution, driving strong financial results in the third quarter. Our pipeline is poised to deliver scientific breakthroughs that can potentially help treat millions of patients and translate into meaningful commercial opportunities. The commercial team remains focused on maximizing growth drivers from our inline brands, while successfully launching new products and indications. Finally, we continue to prudently deploy capital with the goal of delivering long-term value to shareholders.

With that, I'll now turn the call over to George.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer, Co-Founder

Thank you, Len. Over the last few months, as Len just mentioned, we have delivered multiple important data readouts showcasing the strength of our robust pipeline and the potential to drive future growth with positive pivotal data for Dupixent, for our C5 program, our cat and birch allergy programs, as well as in our rare disease programs. I will also update progress in oncology, anticoagulation, and other programs.

Starting with immunology and inflammation. Dupixent continues to deliver remarkable outcomes in addressing indications driven by Type 2 inflammation, potentially adding to its existing approvals for eight diseases in the United States. We're anticipating the FDA's acceptance of our submission for allergic fungal rhinosinusitis or AFRS in patients age 6 years and older based on positive data that we plan to present shortly. This represents yet another potential opportunity for expanding Dupixent's label.

Moving to our IL-33 antibody, itepekimab, which was studied in COPD for which it met its primary endpoint in one of two replicate Phase 3 trials, we and Sanofi are contemplating another Phase 3 trial for itepekimab in COPD, pending feedback from regulators. Itepekimab development is also advancing other respiratory diseases, most notably our ongoing Phase 3 studies in chronic rhinosinusitis with nasal polyps, where our genetic evidence is compelling.

Moving to our innovative and multi-pronged allergy programs. As previously announced, our Phase 3 studies of our antibodies for cat allergy and for birch allergy have yielded statistically significant and clinically meaningful outcomes on primary and key secondary endpoints. These results represent the first proof of principle that targeting allergens with highly specific monoclonal antibody cocktails can achieve improvements in both ocular itch and redness.

Importantly, in prior clinical trials, our cat and birch allergy approaches have delivered impressive and durable therapeutic benefits across nasal, respiratory, and skin allergy symptoms. In the coming months, we plan to present these results at an upcoming medical meeting and initiate confirmatory Phase 3 studies for these programs. In the US alone, these therapies could help approximately 1.6 million people suffering from severe cat allergies and the approximately 1.4 million people suffering from severe birch allergies.

Regarding our innovative severe food allergy program, enrollment and dosing are progressing well in our small proof-of-concept trial combining linvoseltamab and Dupixent. The first three patients have responded remarkably with greater than 90% rapid reductions in the allergy-causing immunoglobulin E levels following a short course of linvoseltamab treatment which are then maintained and continue to decrease with ongoing Dupixent maintenance. Full enrollment of this small initial study is still expected over the next few months.

Based on insights gained from the programs so far, we are advancing the development of next-generation agents designed to specifically and safely deplete allergy-causing plasma cells, the first of which is expected to enter clinical trial next year, alongside several other promising novel candidates in immunology and inflammation.

Moving on to oncology and starting with Libtayo, which was recently FDA approved as the first and only immunotherapy for adjuvant treatment of high-risk cutaneous squamous cell carcinoma following surgery and radiation based on the only successful clinical trial in this setting, the C-POST trial data that showed a notable 68% reduction in risk of disease recurrence or death. This approval expands and extends Libtayo's leading position in non-melanoma skin cancers.

Moving to fianlimab, our LAG-3 antibody studied in combination with Libtayo, our pivotal trial in metastatic melanoma is ongoing with enrollment for our progression-free survival cohort completing last January. And results are now anticipated in the first half of the coming year due to slower rates of event accrual.

Lynozyfic, our BCMAxCD3 bispecific has been approved in the United States and the EU for relapse refractory multiple myeloma. Lynozyfic has the potential for best-in-class efficacy in this late line setting compared to the other approved BCMAxCD3 bispecifics, with almost double the rates of complete responses as reported in the respective label.

This is the basis for our enthusiasm for studying Lynozyfic in earlier lines of myeloma and even in precursor settings, as a monotherapy or in limited combinations.

Consistent with this, we've recently presented promising Phase 2 results in high-risk smoldering myeloma patients with Lynozyfic monotherapy, demonstrating a 100% objective response rates in 19 evaluable patients, with all six patients who have been followed for at least one year achieving a molecular complete response.

A Phase 3 head-to-head study against Darzalex is planned to start in the coming months with Darzalex having demonstrated a 9% complete response rate in this setting. In addition, we have observed rapid normalization with Lynozyfic monotherapy in previously-treated light chain amyloidosis patients, including patients who have previously received and failed the Darzalex-containing combination chemotherapy.

Finally, I would like to highlight that Lynozyfic has demonstrated an 83% overall response rate as a monotherapy in newly diagnosed multiple myeloma patients with responses deepening over time. Updated results will be reported at a medical meeting later this year. All together, these data give us confidence in terms of pursuing Lynozyfic as a monotherapy or in simplified combination in early line and precursor settings of myeloma.

Though I won't go into detail on odronextamab today, I want to highlight that our Phase 3 study evaluating odronextamab as first-line monotherapy against the standard of care in follicular lymphoma patients is fully enrolled. Similarly to Lynozyfic, odronextamab demonstrated potentially best-in-class efficacy in late-line patients, driving our enthusiasm for this approach in the earlier line settings.

I'd also like to remind you that in the lead-in cohort for this Phase 3 study in first line follicular lymphoma, odronextamab monotherapy demonstrated a 100% complete response rate, further reinforcing the potential of odronextamab in this setting.

Moving on to our C5 and complement inhibitor programs. Let me remind you that in paroxysmal nocturnal hemoglobinuria or PNH, where deep blockade of C5 seems critical to prevent breakthrough hemolysis and potentially catastrophic events, the lead-in cohort for our Phase 3 study demonstrated there are once-monthly subcutaneous regimen, combining a C5 antibody with a C5 siRNA, may provide the best-in-class disease control with the best-in-class convenience.

For PNH patients, we have also just initiated our first-in-human study of our siRNA targeting Complement Factor B, primarily intended for the 20% to 30% of patients who remain anemic despite optimal C5 therapy due to so-called extravascular hemolysis.

Moving on to our C5 program in generalized myasthenia gravis. In the third quarter, we announced positive Phase 3 results for our C5 siRNA, cemdisiran. This siRNA conveniently dosed subcutaneously every three months, showed statistically significant results for the primary endpoint, improvement in the MG-ADL score compared to placebo, and numerically better results compared to other C5 inhibitor therapies in cross-trial comparisons.

The convenience advantage for patients currently being treated with regular intravenous infusions, together with its efficacy and safety profile, positions cemdisiran as a potential best-in-class treatment option for this debilitating neuromuscular disorder. We are planning on submitting a US regulatory application for cemdisiran monotherapy in the first quarter of 2026, pending FDA discussions, with global submissions to follow.

Finally, for our C5 program, in terms of our efforts in ophthalmology, we are hoping to complete enrollment in the first quarter of 2026 for the lead-in cohort of our first Phase 3 study in geographic atrophy, with initial results expected by the end of 2026.

Additionally in ophthalmology, I'd like to note that we are initiating a clinical trial in active non-infectious uveitis of an intravitreally-delivered CD3 monoclonal antibody which is designed to locally block autoimmune T cell activity in the eye, marking the first in a new series of novel ophthalmology targets that we will be progressing to the clinic over the next year.

Turning to our anticoagulation efforts and in particular, to our Factor XI program involving two different antibodies designed to tailor anticoagulation therapy for each individual patient's needs. Pivotal studies in post-operative venous thromboembolism following total knee replacement surgery are in progress with data anticipated in 2027. Pivotal studies in other anticoagulation indications are set to launch in the coming months.

On November 10, we will kick off a new investor event series called, The Regeneron Roundtable, which will spotlight our various innovative pipeline programs, starting with our Factor XI story in which we will provide, for the first time, exciting new clinical data in trials exploring the Factor XI antibodies in catheter-associated thrombosis and a provoked subclinical GI bleeding study.

Upcoming Regeneron Roundtables will spotlight our opportunities in hematologic and solid tumor oncology, obesity, and other areas.

Moving to our growing siRNA portfolio, coming out of our research collaboration with Alnylam. I'd like to highlight our ongoing clinical studies, including our PNPLA3 and CIDEB siRNAs in NASH; our SOD and HTT siRNAs in amyotrophic lateral sclerosis and Huntington's disease; and in addition, we plan to begin clinical trials for alpha-synuclein siRNA for Parkinson's disease and our MAP-tau siRNA for Alzheimer's in the coming months.

Finally, I'd like to highlight our commitment to developing innovative new approaches in the ultra-rare disease space. In the third quarter, we announced unprecedented clinical benefit using garetosmab in our Phase 3 OPTIMA trial in fibrodysplasia ossificans progressiva or FOP. Individuals suffering from this tragic genetic disorder progressively replace their muscle and soft tissue with abnormal bone formation, encasing themselves in a horrific osseous cage.

Remarkably, in the OPTIMA trial, we're able to demonstrate a greater than 99% reduction in abnormal bone formation at 56 weeks, offering great hope for this ultra-rare genetic disorder. Regeneron plans a US regulatory submission by the end of 2025.

We are also providing new hope for children suffering from another ultra-rare genetic disorder in which absence of the OTOF gene results in profound genetic hearing loss. As we recently described in the New England Journal of Medicine, our novel gene therapy approach provided meaningful hearing gains in 11 out of 12 treated children, with several achieving normal hearing levels.

The FDA recently announced that this program was the first new molecular entity selected for a Commissioner's National Priority Voucher, and we are finalizing preparations for a US regulatory submission this year. This program highlights Regeneron's commitment to advancing the leading edge of biotechnology.

In summary, Regeneron has delivered a quarter filled with positive clinical readouts, advancing our pipeline and reinforcing our leadership and scientific innovation, from groundbreaking advances addressing some of the most common medical conditions, to transformative innovation in the ultra-rare disease space.

With that, let me turn it over to Marion.

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

Thanks, George. Our third quarter performance highlights the strength of Regeneron's commercial portfolio. Today's results demonstrate our ability to drive growth of inline brands and to accelerate launch opportunities, delivering our transformative medicines to even more patients.

Beginning with EYLEA HD and EYLEA, total combined third quarter US net sales were $1.11 billion, comparable on a sequential basis. As the decrease in EYLEA net sales was offset by an increase in EYLEA HD net sales, EYLEA HD net sales grew 10% quarter over quarter to $431 million, again growing faster than any other innovative medicine in the category.

EYLEA HD unit demand grew 18% quarter over quarter which was partially offset by ongoing competitive pricing pressures within the category. As EYLEA HD grew, EYLEA's third quarter US net sales decreased 10% quarter over quarter to $681 million reflecting a commensurate decline in unit demand driven by the ongoing conversion to EYLEA HD, patient affordability issues, and competitive dynamics. We expect a similar demand decline in the fourth quarter for EYLEA, along with ongoing pricing pressure.

Together, EYLEA HD and EYLEA lead the branded anti-VEGF category based on best-in-class efficacy, safety, and with EYLEA HD durability. And EYLEA HD now represents approximately 40% of Regeneron's US retina franchise.

Looking ahead to the fourth quarter for EYLEA HD, we anticipate sequential demand growth to moderate to high single-digits as we await label enhancements. Once approved, we believe these enhancements have the potential to generate a significant positive inflection in demand.

Now to Dupixent. Third quarter worldwide net sales reached $4.9 billion, growing 26% on a constant currency basis compared to the prior year. In the US, Dupixent's net sales reached $3.6 billion reflecting 28% year-over-year growth. Dupixent leads the market across all established indications including atopic dermatitis, asthma, nasal polyps, and eosinophilic esophagitis. In addition, Dupixent is the main beneficiary of competitor market growth efforts based on its proven efficacy, safety, ease of access, and ability to address unmet patient needs.

Our recent launches in COPD, chronic spontaneous urticaria, and bullous pemphigoid are progressing very well. Across all launches, Dupixent's differentiated clinical profile and growing physician experience are driving strong uptake. In COPD, prescribers see Dupixent's benefits across a range of appropriate patient types, and recent market research found pulmonologists expected to substantially increase their prescribing of Dupixent over the next 12 months.

[Additionally], there has been rapid uptake among chronic spontaneous urticaria patients as both dermatologists and allergists embrace Dupixent. In bullous pemphigoid, Dupixent is the first biologic medicine addressing a critical unmet need. Physicians are eager to transition elderly patients off steroid therapy, with Dupixent offering them a safer and more effective alternative.

In summary, Dupixent continues to transform the lives of patients across indications, geographies, and age groups from as young as 6 months. There are currently more than 1.3 million patients worldwide benefiting from Dupixent for multiple Type 2 diseases.

Turning to oncology and hematology, in the third quarter, Libtayo delivered $365 million worldwide net sales, growing 24% on a constant currency basis compared with the prior year. In the US, Libtayo net sales grew 12% year over year to $219 million based on strong demand across all approved indications.

In non-melanoma skin cancers, Libtayo's strong performance is based on established market leadership and ongoing category growth. We are making encouraging early progress with US launch in adjuvant CSCC where physicians are already embracing Libtayo as a new treatment option. We estimate that up to 10,000 eligible patients may benefit from Libtayo in this setting.

And now, in lung cancer, Libtayo is now the second most commonly prescribed immunotherapy for newly diagnosed patients. Physicians increasingly recognize Libtayo as an important treatment option based on clinical experience, versatility as a monotherapy or in combination with chemotherapy, and an increasing body of clinical evidence including recent five-year survival data.

Outside the US, Libtayo sales reached $146 million, growing 47% year over year on a constant currency basis, supported by sustained demand and ongoing launches in international markets.

Moving to our new hematology therapy, Lynozyfic, we've made strong early progress in commercializing this important bispecific for fifth line multiple myeloma patients. Positive launch indicators include physician feedback, formulary listings, pathway inclusions, completion of REMs

requirements, and payer coverage. While we expect modest revenue contribution in this heavily pre-treated population, Lynozyfic is an important therapeutic advance to the hematology community, and we look forward to additional clinical data supporting its potential use in earlier treatment settings.

In summary, in the third quarter, Regeneron delivered ongoing growth across EYLEA HD, Dupixent, and Libtayo, and made important progress in several launches. Our commercial portfolio is well-positioned to capitalize on many near-term growth opportunities, enabling us to deliver more treatments to more patients.

With that, I'll turn the call to Chris.

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

Thank you, Marion. My comments today on Regeneron's financial results and outlook will be on a non-GAAP basis unless otherwise noted.

Third-quarter 2025 total revenues of $3.8 billion grew 1% compared to the prior year, reflecting higher Sanofi collaboration revenue driven by strong Dupixent sales growth and continued growth in net sales of Libtayo globally and EYLEA HD in the US, partially offset by lower net sales of EYLEA in the US and lower Bayer collaboration revenue. Third quarter diluted net income per share was $11.83 on net income of $1.3 billion.

Beginning with the Sanofi collaboration, revenues were approximately $1.6 billion, of which, $1.5 billion related to our share of collaboration profits. Regeneron's share of profits grew 34% versus the prior year driven by volume growth for Dupixent and improving collaboration margins.

The Sanofi development balance was approximately $900 million at the end of the third quarter, reflecting a reduction of approximately $300 million since the end of the second quarter and approximately $730 million since the start of the year. Dupixent's continued strength has enabled a rapid reimbursement of the development balance in 2025. And we now expect this balance to be fully reimbursed by no later than the end of the third quarter of 2026.

Moving to Bayer. Third quarter net sales of EYLEA and EYLEA 8 mg outside the US were $854 million, inclusive of $232 million of EYLEA 8 mg sales. Total Bayer collaboration revenue was $345 million, of which, $312 million related to our share of net profits outside the US.

Other revenue in the third quarter was $198 million which included $165 million of profit share and royalties associated with license agreements. The increase from the prior year was driven by higher royalty income from Ilaris and growth in our share of profits from Arcalyst.

Now to our operating expenses. R&D expense was $1.3 billion in the third quarter, reflecting continued investments to support Regeneron's innovative late-stage pipeline, including our pivotal programs for Lynozyfic and Ordspono in earlier lines of myeloma and lymphoma, our Factor XI program in anticoagulation indications, and our ongoing efforts in other clinical programs.

Third quarter SG&A was $541 million down 12% from the prior year, primarily driven by lower charitable contributions to an independent non-profit patient assistance foundation. Third quarter 2025 gross margin on net product sales was 86%. The lower gross margin versus the prior year reflects a changing product mix and higher ongoing investments to support our manufacturing operations.

Regeneron generated $3.2 billion in free cash flow through the first nine months of 2025 and ended the quarter with cash and marketable securities, less debt, of approximately $16 billion. Through the first nine months of 2025, we have repurchased approximately $2.8 billion of our shares, the most ever allocated to open market repurchases in any full fiscal year in our history. We continue to be opportunistic buyers of our shares and anticipate returning approximately $4 billion to shareholders through dividends and repurchases in 2025.

Moving to guidance for 2025. We have updated and narrowed the ranges across our financial guidance which can be found in our press release issued earlier this morning. Finally, as we turn to 2026, we continue to make significant progress across our innovative pipeline and anticipate advancing multiple large registrational programs in myeloma, lymphoma, anticoagulation, obesity, and other hematology and solid tumor oncology programs, as well as several new assets into the clinic.

We believe investing in these programs can drive significant long-term value. And to support these efforts, we currently expect a mid-teens percentage increase in R&D expense in 2026 relative to 2025. We will provide details on 2026 guidance for other line items early next year.

In conclusion, Regeneron's third quarter results demonstrate the ongoing strength of our business and enable us to continue investing in our differentiated pipeline to deliver significant advances for patients and drive long-term value for shareholders.

With that, I'll pass the call back to Ryan.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Thank you, Chris. This concludes our prepared remarks. We will now open the call for Q&A. To ensure we are able to address as many questions as possible, we will answer one question from each caller before moving to the next. Shannon, can we please go to the first question, please?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Akash Tewari, Jefferies.

Akash Tewari - Jefferies - Analyst

Hey. Thanks so much. It seems like your team has retooled your commercial strategy on EYLEA and it seems related to kind of price. What are you doing on a ground level when it comes to volume-based discounts that's allowing you to take share from Roche and Amgen? And are you seeing more price erosion on EYLEA? Are we also seeing that discounting on high dose? And maybe just lastly, should we continue to see volume gains and revenue gains ahead of the label enhancement potentially midyear? Thanks so much.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

Well, I think you may have set the record for the number of questions we're not going to answer. Not because we don't want to, Marion would love to, but I think that there's so many competitive issues ongoing there in terms of our strategy on the ground, our rebates, and so forth. So I'm not sure we're able to really help you out there. Marion, I don't know if you want to add anything?

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

Well, I think I would just add that when we look at the EYLEA HD performance in the quarter, the [favorability] that we're seeing certainly is related to EYLEA HD, the product and the science. And retina specialists see the clinical efficacy, the safety, and now durability with EYLEA HD and that is making a big difference.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

We do see that until we get these enhancements in place, we can't, I think, see a significant upswing.

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

Len, if you like, I can highlight what I shared a moment ago, but just to answer the question a bit more completely, for EYLEA HD, I mentioned we anticipate to sequential demand growth to moderate to high single-digits as we await label enhancements. And we also made a comment on EYLEA that we anticipate similar levels of demand reduction in the coming quarter. And as I noted today, we saw a 10% reduction in EYLEA 2 milligrams, and that was in terms of the lower demand quarter over quarter. I hope that's helpful.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Okay. Thanks, Len and Marion. Let's move to the next question, please, Shannon.

Operator

Geoffrey Meacham, Citi.

Geoffrey Meacham - Citi - Analyst

Morning, guys. Thanks for the question. I guess for Chris or Len, on utilizing the balance sheet, you guys haven't historically done larger scale BD and it seems like that's going to be the case going forward. But in manufacturing, what's the appetite to further expand your plans that you've announced just so you own all elements of manufacturing? Obviously, that would be viewed pretty favorably by the Trump administration as well. Thank you.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

Yeah. Great question, Geoff. Just on whether or not we would use our balance sheet for large deals, we certainly have no allergy to doing that, if we saw the right opportunity. So it's not a question of philosophy there. It's really a question of what would make sense where we think we could create additional value.

In terms of investing further in manufacturing, and as I said during our [remarks], we've been talking about the need for domestic manufacturing since 2014, I think, in testimony before Congress. We mentioned the over $7 billion investment plan.

But I think you do highlight one piece of the whole puzzle that we do not have adequate positioning in is the filling. But I'm pleased to say that we would expect our filling plant to come, which we've invested quite a bit in, Geoff, it's now ready to go, and we expect it to come online during the coming year. So that's a great question, and it should help us sort of control all aspects of the standard biologics manufacturing.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Okay. Thanks, Len. Shannon, next question, please.

Operator

Chris Raymond, Raymond James.

Chris Raymond - Raymond James - Analyst

Thanks for taking the question. It's maybe a question on EYLEA HD, Marion, I think I've heard you talk a lot about the importance of the labeling enhancements and Len, I just heard your comment about share and how important they are. But I think we've come to understand maybe the

primary need here and the reason for these enhancements and why they're important is for certain clinics to have dosing flexibility so they can center their inventory around one drug. But just maybe, Marion, as you've seen this market evolve, can you talk about how that clinic inventory policies have evolved over time and especially how private equity in the space may be influencing this? Or is this really more of as you're looking for share with clinics that don't necessarily have relatively aggressive inventory policies.

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

Thanks. So Chris, my comment will be that the retina community and certainly, retina KOLs, look for the ability to select the right product for their patients. And I'm not an expert in inventory, but I can share with you that EYLEA HD is a newer branded product in the category two years in the market now, certainly, availability, not only inventory-wise, but payer coverage-wise.

And then as I mentioned a moment ago, the most important characteristics of the product is this element of profound clinical efficacy, safety that people really can count on. And then, of course, with EYLEA HD, they're getting, for appropriate patients, the ability to have durability that is very, very important for the patients and their caretakers.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Okay. Thanks, Marion. Next question, please.

Operator

Terence Flynn, Morgan Stanley.

Terence Flynn - Morgan Stanley - Analyst

Hi. Thanks for taking the question. George, you mentioned, it sounds like, likely, you and Sanofi are going to do another Phase 3 trial here for IL-33 in COPD. Can you just talk about any new insights you might have learned that drove the differential outcome in the prior two Phase 3 trials? And then what you think you can change or optimize in a third trial here to improve the likelihood of success? Thank you.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer, Co-Founder

Well, due to competitive issues, I'm not going to really comment on most of your questions there. And as you said, we're going to have a meeting with the FDA and that's going to help us decide on our strategy going forward.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Okay. Thanks so much, George. Next question, please.

Operator

Tyler Van Buren, TD Cowen.

Tyler Van Buren - TD Cowen - Analyst

Good morning. Congratulations on the quarter. Can you elaborate on the probability of the late December decision on the RVO and every-four-week dosing filing with the new filler resulting in an approval? And just a quick follow-up would be, is this the same alternate filler that you use for the recent Libtayo adjuvant cutaneous squamous cell carcinoma approval?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

No, it's a different filler. It's a complicated sort of timeline here. Because the new filler has to undergo its review and it probably in an inspection and review, and it's unclear when that would be done. Ideally, if that could get done before our November timeline for the approval, for the PDUFA date for the RVO/Q4, that would really be perfect, and we could get it all wrapped up in late November.

If it turns out that they have to go to December to get the filler approved, hopefully, that would be as far as they have to go. But of course, the FDA looks at all these things pretty carefully. This filler has a very good track record, but it's got to undergo the inspection and so forth. So I suspect that If they got through that in December, then we could rapidly resubmit or maybe the application would still be on file, we don't know exactly. We're going to have discussions with the FDA. But we believe that there is nothing left to do on that application other than to get the filler in place.

So we think we've had very good discussions about label and indications and all, that's fine. But it's not over until it's over, obviously.

But ideally, to summarize, if we could get the filler online before the late November date, it could all be wrapped up then. If not, we would expect and hope that that filler would get approved in December. And then rapidly, we would immediately resubmit and the FDA hopefully could act immediately. That's to-date that we can tell you.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Yes. Thanks, Len. Complicated situation. Let's move to the next question, please.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - BMO Capital Markets - Analyst

Hi, guys. Thank you so much for taking my question. Just taking a step back, can you walk me through some of the internal changes you've made with your regulatory manufacturing teams to prevent the CRLs that we've seen of recent and ensure that products that should be approved get approved and get the patients as quickly as possible? Thank you.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

Now that's a very pointed question. And I really want to address it head on. The issues that we have had have not been internal regulatory problems. We have a terrific relationship with the FDA. Our regulatory team includes people who used to work at the FDA or people who've been in the industry doing this for decades. There's no shortage of expertise or relationships on a regulatory front. We've certainly asked that question, the Board always ask that question, and there's no issue there.

On the manufacturing front, we recognize that it would be more ideal if we could have our own filling. We would have expected to have that by now, but we got delayed dramatically during COVID because of supply chain issues in manufacturing. As I said, we hope that filling will come online next year.

In terms of getting backups and what have you, it's a relatively complicated situation. We've been working on backups for quite a long time now. The problem, as you might imagine, is that, for good reason, the FDA is very finicky about showing where you make, going to make the product, literally, what equipment it's going to touch, and then you have to do stability testing, and quality testing. All of that for a given filler. And that takes quite a bit of time, quite a bit of resources.

So in summary, I don't want to sound [defensive] at all. We have looked at this. It is not a regulatory problem for us. It is, in some respects, a manufacturing issue in terms of getting online our own filling. Having backup fillers in place is complicated, we're trying to do that.

But our biggest problem, frankly, is the FDA has now paid quite a bit close attention. And I might point out that the biggest companies in the world have had the same issue with fillers where even with the same filler, and they've called us to know how's it going? But they just don't talk about the CRLs that they get, and we know that they're out there. So I'm not sure that we're worse off in that regard. But wherever we are, I'm not happy about it and we're not happy about it, and we're trying to rectify the situation. I hope that gives you a glimpse into our thinking.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Okay. Let's move to the next question, please.

Operator

Brian Abrahams, RBC Capital Markets.

Brian Abrahams - RBC Capital Markets - Analyst

Good morning. Thanks for taking my question. Just on the pipeline front on the Factor XI antibody program. I don't want you to front run your roundtable, but I know you guys recently started a large Phase 2 study for the antibodies in afib. So I'm just curious what you guys are looking for out of that study and maybe out of other Factor XIs in development to move into registrationals in that and other large indications and really accelerate that program? Thanks.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer, Co-Founder

Well, the Phase 2 study is a running study into what we anticipate to be our Phase 3 pivotal program there. And we are in pivotal programs in other settings where anticoagulation can be important. And of course, what are we looking at? We're trying to understand as well as we can the benefit risk ratio for our two distinct antibodies.

We think, in this program, it's all going to be about benefit risk. We think that frankly in some ways, decreases in bleeding risk are going to be frankly more important than, in some cases, the anticoagulation effect. As long as you have anticoagulant effect, but if you have really a safe way of achieving it, we think there's a plethora of settings where these two antibodies can respectively find their place. And particularly, in patients maybe even much larger than the [SPAF] indication where, right now, use of anticoagulants is very limited because of the bleeding concerns. That's what's really limiting the utilization of anticoagulants more widely across many, many, many more settings.

And so we think that our approach using two antibodies is going to allow us to really customize and tailorize how individual patients are treated, where we can optimize, we can pick the antibody perhaps with the least bleeding risk for the patients who are most concerned about that while providing a different antibody with maybe higher anticoagulation capability when that's needed.

So we think there's a lot of opportunities here beyond [SPAF]. We think that's where the major opportunity is today. We do not think that's where the major opportunity is going to be going forward in the future. We're going to where we think the future is not necessarily where the current is right now.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

And in the future, we'll be having a roundtable to tell him about that.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Correct. November 10. Thanks, George. Let's move to the next question, please.

Operator

Carter Gould, Cantor.

Carter Gould - Cantor Fitzgerald - Analyst

Good morning. Thanks for taking the question. Len, you highlighted the sort of the meager matching thus far with the foundation and I guess you framed it remaining committing to that funding until the end of the year, which I guess sort of allude to a potential terminus. At some point, maybe at the start of the year, does it warrant taking a different tact if you don't see any other people match your commitment?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

Yeah. I mean, I'd like not to tell people don't bother to make a commitment because we're going to take care of it. That's not our approach. Our approach will be that we will look at it fresh next year and see what the best strategy is to help patients. Good question though.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Thanks, Len. Let's move to the next question, Shannon.

Operator

Cory Kasimov, Evercore.

Cory Kasimov - Evercore ISI - Analyst

Good morning, guys. Thanks for taking the question. So on the heels of your positive Phase 3 data for cemdisiran, can you outline how you see the commercial opportunity evolving for gMG and what your plans are in Europe with this asset? Thank you.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

Before we get to that, maybe, George, could you just remind everybody what's out there and what the limitations of the current therapies are? Because I'm not sure everybody's on the same page on that.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer, Co-Founder

Well, right now, there are two major classes that are being utilized in this space. One, of course, is the C5 class. The other is the FcRn class. In terms of the C5 class, as we know, most of those are administered using these large intravenous infusions which are very inconvenient for the patients.

And in terms of the FCRN class, those are given via also intravenous infusions approaches right now or ultimately, they may move to large-volume subcutaneous approaches that are also somewhat difficult to self-administer. But in any case, the issues also have to do with safety and efficacy.

The thing that's exciting about our program is unlike the FcRns which, either when you use weekly treatment, you get less benefits, at least cross-studies, from these standard scores; or with the episodic treatment where you have a U-shaped curve where the patients respond deeply, but then, almost revert back to baseline before you give them their next dose.

The C5s allow you to have stable deep control through the entire dosing period. And cross-study comparison, our agent seems to have, in terms of the standard measure that is being used to evaluate these, the best cross-trial efficacy that's stable and continuous throughout the dosing period.

Now, one important feature of all of these agents, obviously, is they all work by suppressing the immune system through various degrees, either the FcRns or the C5 via their inhibition of the complement cascade, they both result potentially concerns with efficacy, in the case of the C5s mostly, meningococcal infections. As you've probably seen with the FcRn class, with longer usage, they've seen serious infections, for example, resurgence of EBV and even fatal EBV infections. So those are concerns with everything that's available in the class.

The thing that's exciting about our program is not only do we seem to have, at least, potentially best-in-class and stable efficacy with dosing using the most convenient dosing regimen which is subcutaneous once-every-three months. Nothing like that's ever been seen for this class delivering this sort of efficacy. But because we only partially inhibit the complement pathway, there is the potential which we will have to get data to support going forward that may offer certain safety benefits for patients.

So the exciting thing about the program is we certainly have the most convenient dosing regimen, we seem to have the most consistent efficacy with cross-study comparisons, the deepest control. And the fact that we don't completely inhibit the target in this class, there is the long-term opportunity that we may be able to show that we may have better safety for patients as well here.

So it's a very exciting profile, I think, potentially be able to deliver for this class of patients who are really needing better treatments in terms of convenience, in terms of efficacy, but also in terms of safety. Marion?

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

Sure. So everything we're doing in the launch strategy for commercialization is based on the very encouraging clinical profile that George is describing. So we're very excited about this opportunity. We will be launch-ready and we do feel for this really important category in patients with unmet need that we potentially have a very highly differentiated product to bring into the marketplace.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Thanks, George and Marion. Let's move to the next question, please, Shannon.

Operator

Simon Baker, Rothschild & Company Redburn.

Simon Baker - Rothschild & Co Redburn - Analyst

Thank you very much for taking my question. My first ever question on the call. I just wanted to go back to your comments, George, on intravitreally delivered CD3. You're trying it initially in uveitis. I just wonder what the scope of your ambition was in that setting given the role of T cell infiltration in glaucoma which is, obviously, a much bigger indication. Any thoughts on where this could go will be much appreciated. Thank you.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer, Co-Founder

I didn't hear what you said about glaucoma. What glaucoma?

Simon Baker - Rothschild & Co Redburn - Analyst

So there's some evidence that glaucoma is caused, greater or less part, by T cell infiltration in the eye. So I just wondered if using CD3 antibodies in this setting would potentially encompass that indication as well as uveitis.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer, Co-Founder

Yeah. We're very excited about our CD3 antibody program, as you mentioned. We believe that this is the world's first complete blocker of CD3 or T cell function that's ever been evaluated in the clinic. There have been partial blocker, partial agonist to-date. We think that going into the eye in uveitis which a lot of data suggests that most, if not all, of these uveitis are related to T cells.

If we can block the T cells locally without, because the doses that we're going to be using are very low, they're not going to be having systemic effects, you can have really profound benefits in this high unmet need without subjecting patients to any sort of global or systemic immunosuppression.

So we really think this is a very novel, very different approach to active non-infectious uveitis. We think it's the perfect setting to try our CD3 antibody.

We have been working a lot on glaucoma. I'm glad that you brought it up. I believe, based on our Regeneron Genetic Center, which are world leaders in understanding the genetic bases of disease, we've, I think uncovered the most important drivers genetically of glaucoma. And we will be rolling out in the very near future our strategy and our programs in a very near clinical program in glaucoma as well.

So I'm glad you brought it up. I'm glad you're interested in it. But these are going to be two very different distinct programs. We're going to have our CD3 program for non-infectious uveitis. And we're going to be rolling out a very special and very exciting program in glaucoma based entirely on our internally discovered genetics capabilities. We think that these programs really have the opportunity to create entirely new franchises in ophthalmology. The way we think about it, one could be the EYLEA for uveitis; the other could be the EYLEA for glaucoma. So stay tuned.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Thank you, George. Very exciting. I think we have time for three more questions, Shannon.

Operator

Alexandria Hammond, Wolfe Research.

Alexandria Hammond - Wolfe Research LLC - Analyst

Thanks for taking the question. On the upcoming Libtayo LAG-3 readout, it seems like the goal is to outperform Opdualag. But could you share your confidence in demonstrating a [stat-sig] benefit against Keytruda? And as a follow-up, can you tell us a little bit more about the open-label Phase 3 trial you have ongoing against Opdualag? Is it just another show of confidence that your combo can be more potent than the currently approved option?

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer, Co-Founder

A lot of questions in there. But first and most importantly, our study is ongoing. As you said, we are trying our combination versus Keytruda. Our hope is that the Keytruda will behave as it has more or less historically. And our hope is that, remember, we have two arms in the study, a low dose and the high dose, that the two arms, at least one of them, will behave better than the Keytruda arm.

The way we power the study is that we powered it to not only hit PFS and OS. And with the minimal expectation that if we have Opdualag-like activity, we've powered the study so that we can win in both PFS, but also where Opdualag failed in OS.

If, as you mentioned, we have better data than Opdualag, then obviously, we will significantly win even more than that. So we've powered the study for a minimal of Opdualag-like benefit, but so as to have a large enough OS signal so that we will win with comparable data there.

Of course, the data will speak for itself. We'll see whether or not we end up having better efficacy than Keytruda, better efficacy cross-study comparison than Opdualag, and so forth. But we continue to be excited obviously about this program. There's obviously a high need here. There was very exciting earlier trial data using our fianlimab antibody. And so we are anxious but excited about awaiting the data readout next year.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Yeah. First half of next year is the timing on that. Shannon, next question, please.

Operator

Chris Schott, J.P. Morgan.

Christopher Schott - JPMorgan - Analyst

Great. Thanks so much. Just a quick one on the launch of linvoseltamab. Just how's that progressing versus expectations? And can you just elaborate a bit on the timelines of when you could actually get this product into some of those earlier lines of therapy given the profile that seems to be shaping up here? Is there an ability to pull that forward or accelerate that all in terms of working with FDA, et cetera? Thank you.

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

So I can take the first portion on the launch and then I'm sure George will come in on the rest. But certainly, it's early days. But as I mentioned, the progress has been very, very good. We've seen the typical indicators when you have a successful launch ongoing. Physician feedback has been very favorable. Our formulary listings, pathway inclusion, REMS requirements, payer coverage. So we are pleased with that we're seeing so far. And certainly, the enthusiasm of the hematology community for Lynozyfic is high. Keeping in mind this is the fifth line setting for multiple myeloma patients, so a heavily pretreated population. But to George for earlier lines.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer, Co-Founder

Well, we believe that if one looks at the totality of the data, certainly, if it was me or somebody that I cared about, giving the late-stage patients any of these treatments, I think, Lynozyfic would be the choice based on all the available data out there.

And importantly, what this says, if it looks like it has the potential for impressively more benefit in the late-line patients, that of course suggests that it should have also the best benefit for the earlier-stage patients. Because of that, we've taken on a lot of very aggressive programs in the early stages, not only in first line myeloma and in second line myeloma, but in the pre-malignant settings. As I summarized, we now have data in most of these settings, either as monotherapy or in very limited combinations, most of which we've now presented to varying degrees.

And the data really is stunning and unprecedented. We're having a high rate of seeing molecular complete responses in smoldering in, amyloidosis which is a premalignant condition, but where the protein made by the abnormal cells can cause problems. Once again, unprecedented monotherapy activity in the first line setting, we've described that. And in later-line settings, with new combinations that we're also trying, unprecedented levels of activity.

So we think that this program really has the potential to change the face of treatment for these disease indications in all of its manifestations, whether it be premalignant precursor settings, whether it's early-line disease, whether it's second-line disease, or whether it's for the late-stage patients.

So I think this is an exciting time for the field. And I just want to remind you that in many ways, our odronextamab program is quite similar in that particular in follicular lymphoma where we look like we have the best late-line data, we're going aggressively in earlier-line disease. And once again, we've released the data-leading cohorts of Phase 3s as monotherapy and so forth. Once again, unprecedented efficacy in these small initial cohorts that we're looking at which really get us excited that these bispecifics really have the chance to really change the hematologic oncology space in their respective settings.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

Let me just say, before we go to the next question, one is I think inherent to what George is saying there is that all bispecifics are not created equal. The team spends an enormous amount of time with all the technology at hand to select and create bispecifics that we think are different, fundamentally different. And that's why we think we're seeing better data.

I just also want to emphasize, we're making a huge commitment here. We expect to conduct as many as 10 registration of trials for Lynozyfic including, as George outlined, a broad registration program in frontline or even earlier myeloma patients, both for transplant eligible and ineligible. This is a big space. It's a $30 billion market potential. Darzalex alone is annualizing at $15 billion. You saw some cross-study data that suggests that we can outperform. We've had some success where Darzalex has already failed in the IgA space. And we've had some success in cross-study comparisons in the smoldering.

So I think this is pretty exciting. As George outlined, it's a huge commitment. You expect us to spend a lot and go very -- as fast as we can. Somebody asked about can we accelerate with the FDA. We're certainly going to talk with the FDA and advise them that we think we have the best program, how can we work together?

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer, Co-Founder

You meant amyloidosis, not IgA.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Executive Officer, Co-Founder

Sorry. I meant amyloidosis. Thank you,

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Thank you, Len and George. We also look forward to having a Regeneron roundtable on Lynozyfic in December of this year. So let's move to our final question, Shannon.

Operator

Salveen Richter, Goldman Sachs.

Salveen Richter - Goldman Sachs - Analyst

Good morning. Thanks for taking my question. You spoke to novel targets here in I&I and ophthalmology, on the GA program in particular, can you speak to what the FDA may be looking for potential study designs, whether it's slowing [GA] lesion growth or vision improvements and whether you need to evaluate against current agents? And just remind us on the I&I side when we might hear about these novel targets. Thank you.

George Yancopoulos - Regeneron Pharmaceuticals Inc - Co-Chairman of the Board, President, Chief Scientific Officer, Co-Founder

Well, in terms of GA, we've already designed and planned our pivotal readout study for geographic atrophy. We are able to go against placebo. And we're primarily looking at slowing down of growth together with, of course, vision control. And as I said, we have data from the cohort A from our Phase 3 trial where we expect readout in the second half of 2026 which really will help inform whether this novel systemic approach, which can have a lot of advantages in terms of the issues of having to bilaterally inject two eyes multiple times as opposed to being able to systemically treat, we'll know whether there's a real opportunity there or not from that data.

I think that in terms of our I&I programs, I think you'll probably be hearing about one of the first one, additional ones, additionally to the CD3 program, which obviously are related I&I and ophthalmology program, you'll be hearing it roll out over the next couple of months with hopefully a new clinical program initiating next year.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President-Investor Relations

Okay. I appreciate everyone's patience, we went a little over time; and appreciate your interest in Regeneron. Apologies to those who remained in the Q&A queue who we did not have a chance to hear from today. As always, the Investor Relations team here at Regeneron is available to answer any remaining questions you may have. Thank you once again and have a great day.

Operator

This concludes today's conference call. Thank you for your participation. You may now disconnect.