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# EDITED TRANSCRIPT

REGN.OQ - Q4 2024 Regeneron Pharmaceuticals Inc Earnings Call

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

**OVERVIEW:**

Company Summary





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## CORPORATE PARTICIPANTS

**Ryan Crowe** Regeneron Pharmaceuticals Inc - Senior Vice President of IR & Strategic Analysis

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

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

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

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

## CONFERENCE CALL PARTICIPANTS

**Brian Abrahams** RBC Capital Markets - Analyst

**Tyler Van Buren** TD Cowen - Analyst

**Cory Kasimov** Evercore ISI - Analyst

**Salveen Richter** Goldman Sachs - Analyst

**Taylor Hanley** JP Morgan - Analyst

**Mohit Bansal** Wells Fargo - Analyst

**Alice Nettleton** Bank of America - Analyst

**Akash Tawari** Jeffries - Analyst

**William Pickering** Bernstein - Analyst

**David Risinger** Leerink Partners - Analyst

## PRESENTATION

**Operator**

Hello, and welcome to Regeneron Pharmaceuticals' fourth quarter 2024 earnings conference call. My name is Tawanda, and I will 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 Pre sident, Investor Relations.

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**Ryan Crowe** - Regeneron Pharmaceuticals Inc - Senior Vice President of IR & Strategic Analysis

Thank you, Tawanda. Good morning, good afternoon, and good evening to everyone listening around the world. Thank you for your interest in Regeneron , and welcome to our fourth quarter 2024 earnings conference call. An archive and transcript of this call will be available on the Regeneron Investor Relations website shortly after the call ends.

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 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 your questions. 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 and business, financial forecasting 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 risks and uncertainties that could cause actual results and events to 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-K for the year ended December 31, 2024, which we expect to file with the SEC tomorrow, February 5.

Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information at 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 accessed on the Regeneron Investor Relations website.

Once our call concludes, Chris and 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.

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

Thank you, Ryan, and thank you, everyone, for joining today's call. Regeneron capped 2024 with a strong fourth quarter, highlighted by 10% revenue growth, reflecting the strength and durability of our key franchises, primarily Dupixent, Libtayo, and EYLEA, and EYLEA HD. 2024 was also a year in which we made significant investments across our broad pipeline, which yielded notable progress across several key programs.

For my remarks today, I will review some of our key performance drivers, then briefly discuss a few of our more differentiated pipeline opportunities, and close with a few comments on capital allocation. After my remarks, George will provide further updates on our pipeline. Marion will then review our commercial performance, and finally, Chris will detail our financial results for the fourth quarter of 2024 and our guidance for the current year.

To start, I would like to share my perspective on the current state of Regeneron. From the beginning, our focus has been on science and innovation, developing cutting-edge technology platforms that repeatedly yield scientific breakthroughs. These efforts have led to 13 products that have been approved or authorized worldwide, several of which are driving revenue growth and hold significant future potential.

Our approach has already delivered five blockbuster drugs, a leading pipeline of approximately 40 product candidates across various therapeutic areas, and a world-class DNA sequence-linked healthcare database, providing us with unparalleled insights into key drivers of disease.

At the JPMorgan Conference last month, we detailed 10 differentiated mid- and late-pipeline opportunities that could collectively address a total market opportunity of over $220 billion. Given these opportunities, the strength of our early-stage pipeline, and our turnkey technology platforms, we have never been more confident in Regeneron's future, and we are incredibly excited about what lies ahead.

Moving to our quarterly results, Dupixent continues to be a transformative medicine, with over 1 million patients on treatment around the world across seven approved indications. In the US, Dupixent remains the leader in new-to-brand prescription share across all of its approved indications, and continues to be well-positioned for future growth, given the potential for further penetration in approved indications, the ongoing launch in COPD, and potential 2025 launches in chronic spontaneous urticaria and Bullous pemphigoid.

Regarding the ongoing launch in COPD, where Dupixent is the first and only biologic approved, we and our partner, Sanofi, have made great progress securing broad payer coverage and reimbursement, positioning us to drive uptake over the course of this year and beyond. EYLEA HD and EYLEA continue to lead the anti-VEGF category, and our commercial efforts remain focused on driving EYLEA HD uptake, while preserving share for EYLEA in an increasingly competitive category.

Over the course of this year, we expect continued competitive pressure on EYLEA, while strengthening the profile of EYLEA HD by offering it in a more convenient prefilled syringe administration, broadening its label to include macular edema following retinal vein occlusion, or RVO, and adding more dosing flexibility, including every four-week dosing, as well as extended dosing intervals of up to every 24 weeks for certain indications.

With these anticipated label enhancements, EYLEA HD will offer the broadest set of retinal disease indications with the greatest dosing flexibility of any product in the anti-VEGF category, positioning it to become the new standard of care in the category. And we anticipate these enhancements will lead to an acceleration in EYLEA HD uptake, starting in the second half of this year.

Libtayo became Regeneron's latest blockbuster product in 2024, and we are looking to build on that by expanding share in metastatic non-melanoma skin cancers, along with making further inroads in lung cancer. We also plan to seek regulatory approval for high-risk adjutant cutaneous squamous cell carcinoma, a setting in which Keytruda failed and over the longer term could represent a blockbuster opportunity globally in and of itself.

Moving to our pipeline and focusing on the upcoming year, we expect regulatory approvals for Linvoseltamab in relapsed refractory multiple myeloma, odronextamab in late-line follicular lymphoma, and the aforementioned Libtayo indication in adjuvant CSCC.

In addition, we expect to read out pivotal or proof-of-concept data this year from several other programs, including our pivotal AERIFY studies for Itepekimab, our IL-33 antibody, and former smokers with COPD. Pivotal data for the fianlimab Libtayo combination in first-line metastatic melanoma are also anticipated in 2024. We also expect pivotal data for our C5 antibody siRNA combination in generalized myasthenia gravis.

Finally, we expect to learn more about our potential opportunity to improve the quality of weight loss in obese patients on semaglutide by blocking myostatin and Activin A. George will soon discuss these programs in more detail and provide updates on many of the other programs in our broad and differentiated pipeline.

Finally, regarding capital allocation, this morning we were pleased to announce the initiation of a quarterly cash dividend program and an additional $3 billion share repurchase authorization, increasing our total current buyback capacity to approximately $4.5 billion. These decisions reflect our board and management's ongoing commitment to returning capital to shareholders, but this does not change the core of our capital allocation framework.

Importantly, our dividend will not impact the way we plan to heavily invest in our business and pipeline going forward, does not impair our ability to do business development in the future, and we anticipate that share repurchases will remain the primary means of returning capital to shareholders. However, initiating a dividend reflects our continued confidence in the future cash flows from our business, provides more balance to our approach to capital return, gives us flexibility in how we return capital in the future, and expands the pool of potential Regeneron shareholders to include funds with a dividend mandate.

In closing, Regeneron remains in a very strong position scientifically, commercially, and financially, enabling us to invest heavily in R&D and deliver tremendous innovation from our pipeline, maximize the growth opportunities from our inline brands, initiate a quarterly dividend, and significantly increase our capacity to repurchase shares. We look forward to keeping you updated in these innovations throughout 2025 and beyond.

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

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

Thank you, Len. At last month's JPMorgan Healthcare Conference, we showcased our robust R&D efforts and the promising opportunities within our pipeline that have the potential to revolutionize the practice of medicine across several different disease areas. This year holds the potential to be transformative for Regeneron, as we hope to capitalize on several of our scientific and technological breakthroughs. We anticipate reporting pivotal or proof-of-concept data from multiple programs across diverse therapeutic areas, including in oncology, COPD, and obesity, while also rapidly advancing our factor XI antibodies to multiple Phase 3 trials.

These programs represent significant opportunities for Regeneron to address substantial unmet needs across large commercial categories, positioning Regeneron for long-term growth. Let me highlight some of these opportunities and recent pipeline advancements.

Starting with EYLEA HD, in December, we and Bayer reported positive data from the Phase 3 quasar study in retinal vein occlusion, where EYLEA HD demonstrated non-inferior vision gains with an every eight-week dosing regimen, compared to the standard-of-care 2-milligram EYLEA dosed

every four weeks. Additionally, approximately 90% of EYLEA HD patients were able to maintain eight-week dosing intervals throughout the 36 weeks.

These data, together with our recently presented long-term follow-up data from the PULSAR and PHOTON studies in wAMD and DME, respectively, continue to support EYLEA HD's best-in-class clinical profile. We remain on track to submit a supplementary BLA for this indication later in the first quarter. We also plan to seek approval from the FDA to potentially include every four-week dosing, maximizing EYLEA HD's dosing flexibility for physicians.

Along with the submission for a pre-filled syringe and the potential FDA approval in April to extend dosing intervals to up to 24 weeks, the longest intervals in the category, EYLEA HD is set to provide the greatest dosing flexibility across the broadest indication set of any anti-VEGF therapy, all in a convenient pre-filled syringe.

Next, immunology and starting with Dupixent. In November, Dupixent was approved in Europe to treat Eosinophilic Esophagisits in children as young as one year old, making it the first and only medicine indicated for these young patients in the US and the European Union, and further highlighting Dupixent's exceptional safety profile. The supplementary BLA resubmission for chronic spontaneous urticaria was recently accepted by the FDA, with a target action date of April 18, potentially making it the first new target therapy for CSU in a decade.

Finally, a supplementary BLA was submitted for Bullous pemphigoid late last year, marking another first, as Dupixent is the only biologic to achieve significant improvements in disease remission and symptoms for this indication. While Marion will discuss the ongoing launch of Dupixent in COPD, I want to remind you of another potentially significant opportunity in COPD with itepekimab, our interleukin-33 antibody discovered by Regeneron. We anticipate reporting pivotal results in former smokers from the AERIFY program in the second half of this year, partially overlapping and distinct population from that treated with Dupixent.

As part of our long-term commitment to improving the lives of patients with allergic conditions, I would also like to highlight the compelling initial data from our ongoing Dupixent plus linvoseltamab trial for severe food allergy. These two agents have the potential to eliminate immunoglobulin E or IgE, the key driver of allergic reactions and prevent IgE for returning, thereby reversing severe allergies.

Last month, we shared initial clinical data from the first patient in our proof-of-concept study, which showed greater than 90% reductions in both total and food specific IgE levels following initial treatments at low doses. This trial is continuing to enroll patients, and we plan to provide updates throughout 2025.

Turning now to oncology, where we continue to break new ground. Last month, we announced positive data for Libtayo in high-risk adjuvant CSCC, becoming the first immunotherapy to show a benefit in this high-risk population. At the first prespecified interim analysis for disease-free survival adjuvant Libtayo demonstrated a 68% reduction in the risk of disease recurrence or death compared to placebo, with no new safety signals identified. This is the same setting in which Merck reported last year that KEYTRUDA had failed, highlighting that antibodies even within the same class, do not always produce the same treatment effect. We plan to submit these data to the FDA in the first half of 2025 and present these results at a medical meeting later this year. This data set reinforces our belief that Libtayo provides a best-in-class foundation for combinations with our other oncology assets.

Data from early clinical trials in melanoma suggests that [Fianlimab] our Lag-3 antibody, when combined with Libtayo might be the first combination to demonstrate meaningful additive benefit compared to PD-1 monotherapy without exacerbating safety. This combination is being studied in an ongoing randomized Phase 3 trial versus KEYTRUDA monotherapy in first-line metastatic melanoma, with results expected in the second half of this year. If these data confirm best-in-class activity in melanoma, it will increase our confidence for this combination in other cancer settings.

Turning to our CD3 bispecifics. We are pleased to announce that we have recently resubmitted the BLA for linvoseltamab, our BCMA by CD3 bispecific for relapsed refractory multiple myeloma following the resolution of third-party manufacturing issues. Linvoseltamab has the potential to be the best-in-class BCMA by CD3 bispecific due to its differentiated clinical profile, dosing and administration with nearly double the reported complete response rates at similar duration of follow-up.

Given the strength of the data in late lines of therapy, including the observed level of efficacy and favorable safety profile of linvoseltamab, we are pursuing a differentiated approach in earlier lines of therapy emphasizing monotherapy and novel limited combination approaches. For odronextamab, our CD20 x CD3 bispecific we are pleased to announce that we have resubmitted the BLA for relapsed refractory follicular lymphoma where odronextamab has also demonstrated potentially best-in-class efficacy, and we expect an FDA decision in the second half of 2025.

In December, at the American Society of Hematology meeting, we presented initial results from the safety lead-in portion of the confirmatory Phase 3 OLYMPIA trial. Odronextamab monotherapy delivered complete responses in all 12 patients evaluable for efficacy with previously untreated follicular lymphoma. As a reminder, the standard of care regimen in this setting, rituximab plus chemotherapy has historically achieved complete responses in approximately 67% of patients.

Based on this impressive monotherapy efficacy for odronextamab in both late line and first-line patients we are once again exploring a differentiated program in early lines of therapy, highlighted by our head-to-head evaluation of odronextamab monotherapy compared to Rituxan plus chemotherapy in our Phase 3 OLYMPIA 1 trial, which has already achieved over 40% enrollment.

Our CD28 costimulatory bispecifics for solid tumors are also progressing. We're working to mitigate safety concerns related to their combination with PD-1 blockade while prioritizing combination with CD3 bispecifics. The science suggests that this approach may enhance efficacy with fewer immune-mediated adverse events. We will provide updates on these innovative combinations later this year.

Moving now to a rapidly advancing Factor XI program. We're employing a two-pronged approach to anticoagulation that offers a potential for improved blood clot prevention and lower bleeding risk supported by genetic data from the Regeneron Genetics Center our approach has delivered two antibodies with unique profile to meet different market needs.

REGN7508, which targets the catalytic domain of Factor XI may provide improved efficacy compared to standard of care options. Offering patients who need significant anticoagulation activity, a potentially more effective option. On the other hand, REGN9933, which targets the A2 domain is expected to carry a lower risk of bleeding. Potentially making it a viable option for patients with the highest bleeding risk who would otherwise not be candidates for currently available anticoagulants.

Late [last] year, we reported positive proof-of-concept data with the prevention of venous thromboembolism following total knee replacement with both antibodies demonstrating robust antithrombotic effects, REGN7508 was superior to enoxaparin and non-inferior to apixaban, while REGN9933 was numerically better than [Enoxaparin]. These data support the advancement of both antibodies into broad pivotal programs across multiple indications and patient types with initial Phase 3 studies expected to begin enrolling this year.

Moving briefly to obesity, where we are progressing early clinical programs and an expansive pipeline of preclinical assets. Our muscle-sparing Phase 2 COURAGE study is investigating the addition of trevogrumab to semaglutide with and without garetosmab to improve the quality of weight loss and evaluate the maintenance of weight loss after discontinuing semaglutide. This trial is fully enrolled with data expected in the second half of the year.

Moving to our Regeneron Genetics medicine pipeline, starting with our differentiated siRNA plus antibody approach. We have a potential to address multiple complement-mediated diseases. In December, at the ASH Annual Meeting, we presented compelling updated results from an exploratory cohort in our Phase 3 program for paroxysmal nocturnal hemoglobinuria.

Our combination achieved greater disease control compared to the standard current of care, ravulizumab and only our combination lowered mean LDH levels to the normal range. When ravulizumab patients were switched to our combination, their mean LDH levels, which remained higher than normal, also became normalized. We are also evaluating this combination in generalized myasthenia gravis with pivotal results expected in the second half of this year.

In addition, we recently initiated our Phase 3 program exploring this combination in geographic atrophy in dry age-related macular degeneration where we believe our systemic approach has several advantages over currently approved intravitreal agents. For DB-OTO, our otoferlin gene

therapy program for genetic hearing loss, we announced data last month from the ongoing clinical program, DB-OTO is an AAV-based dual vector gene therapy delivered to the inner ear to enable hearing and children suffering from profound genetic hearing deficit.

We reported that 10 out of 11 treated children with at least one post-treatment assessment showed a notable increase in hearing with some reaching the normal range. We look forward to continuing to share additional data later this year.

Regarding our collaboration with Alnylam, we are advancing several new siRNA CNS programs, including synuclein for Parkinson's and tau for Alzheimer's and other neurodegenerative diseases with trials initiating later this year.

And finally, I would like to highlight two recent advances that extend our leadership position in the field of structured big data that will be necessary to allow computational approaches to revolutionize the health care industry. Over the past decade, we have become the leader in high-throughput human DNA sequencing, enabling us to create the world's largest DNA sequence-linked health care database, encompassing nearly 3 million individuals, all with DNA sequence linked to de-identified health care records. We are now emerging also as the leaders in high-throughput proteomics, as reflected by the selection of the Regeneron Genetic Center to generate the proteomics data for the UK Biobank pharma proteomics project, building on our previous selection to provide the sequence data for the UK Biobank.

Importantly, our new strategic collaboration with Truveta is expected to dramatically expand our database to include up to an additional 10 million individuals from Truveta's network of leading US health systems with the opportunity to generate both DNA sequence and proteomics information. While our leadership position in this big data space has already proven invaluable for our drug discovery and development efforts we believe it can ultimately help us contribute to revolutionizing the field of health care analytics and management.

In summary, I have never been more excited about the future of Regeneron and our potential to transform the practice of medicine and revolutionize the health care industry. Our pipeline is more innovative and exciting than ever, and we anticipate several pivotal or proof-of-concept data readouts throughout 2025, positioning Regeneron for long-term success. Let me now turn the call over to Marion.

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

Thank you, George. Regeneron's fourth quarter performance demonstrates our ongoing leadership across therapeutic categories. Our commercial team is well positioned to optimize our 2025 growth opportunities driven by new indications, new product enhancements and new product approvals.

Turning to fourth quarter results, starting with EYLEA HD and EYLEA. In January, we announced combined fourth quarter US net sales of $1.5 billion for EYLEA HD and EYLEA capturing over 46% of the total anti-VEGF category.

For the full year, net product sales grew by 1.4% to approximately $6 billion despite increasing competition in the category. EYLEA HD net sales were $305 million in the fourth quarter and $1.2 billion for the full year, representing 20% of the combined net sales for EYLEA HD and EYLEA. Fourth quarter net sales for EYLEA HD were affected by elevated wholesaler inventory levels at the end of Q3, which were absorbed over the course of the fourth quarter.

In 2025, our team is laser-focused on growing EYLEA HD adoption. Physicians tell us that EYLEA HD has the potential to be the new standard of care for retinal diseases and several catalysts occurring this year will put us in a position to grow our competitive share. The team is ready to launch the prefilled syringe and our two-year label updates, both of which are anticipated to occur in the second quarter.

Physicians easily await the prefilled syringe, which has been described as game-changing by clinical trial participants. Further, our two-year long-term follow-up data from the PULSAR & PHOTON studies in wAMD and DME, respectively, clearly illustrate EYLEA HD's ability to extend dosing beyond any other competitor in the anti-VEGF category.

Two other potential FDA approvals are also expected later this year, the RVO indication and additional dosing flexibility. In RVO clinical trials, EYLEA HD dosing could be extended to every 12 weeks following loading doses making it the only medicine with durability beyond 4 weeks and also the only medicine to show a numeric improvement in vision for RVO patients compared to EYLEA dosed every 4 weeks.

In terms of additional dosing flexibility across all of our approved indications, we look forward to the potential FDA approval of every 4-week dosing for the subset of patients who need it which would mean EYLEA HD has the most flexible dosing schedule of any anti-VEGF medicine. Fourth quarter EYLEA net sales were $1.2 billion, primarily driven by persistent physician demand in spite of a recent aflibercept 2-milligram biosimilar launch, wholesale inventory levels were elevated at the end of the fourth quarter, and we expect EYLEA net sales will be negatively impacted in the first quarter of 2025 as this increase in inventory is absorbed. We also expect ongoing market dynamics will put downward pressure on the EYLEA business.

We continue supporting existing and new patients who benefit from EYLEA while prioritizing uptake of EYLEA HD, which has the clinical profile to potentially become the new standard of care in the anti-VEGF category.

Turning now to Libtayo, which achieved blockbuster status in 2024 with global net sales of $1.2 billion. In the fourth quarter, global net sales grew by 50% year-over-year to $367 million with US net sales reaching $251 million. Libtayo's strong performance was based on growth in non-melanoma skin cancers and steady gains in lung cancer. Looking forward, we eagerly await the submission and potential approval of Libtayo in high-risk adjuvant CSCC beginning in the US, where we estimate there are approximately 10,000 patients who may benefit from treatment.

And next to Dupixent, which continues to deliver exceptional results in type 2 inflammatory diseases, approved in seven indications worldwide, more than 1 million patients are currently benefiting from Dupixent treatment. Three of these indications, atopic dermatitis, asthma and nasal polyps have achieved blockbuster status each generating over $1 billion in annual net sales.

In the fourth quarter, Dupixent worldwide net sales grew 15% year-over-year to $3.7 billion with increasing volume across all indications, age groups and geographies. In the US, net sales grew 10% year-over-year to $2.7 billion, driven by a 24% increase in total prescriptions including the recent COPD launch. As Sanofi noted, fourth quarter results were negatively impacted by one-time items. We continue to see broad growth across all blockbuster indications of atopic dermatitis, asthma and nasal polyps, despite new entrants and atopic dermatitis, Dupixent continues to be first choice for physicians who now understand that IL-4 and IL-13 are crucial drivers of type 2 inflammation.

Additionally, there is robust uptake in our recent US launches for eosinophilic esophagitis, prurigo nodularis with current trends suggesting that these indications will likely also achieve blockbuster status. We are off to a promising start in COPD, following approvals in more than 30 countries.

In the US, the FDA approved Dupixent in September of last year, and we are very encouraged by our progress in early market adoption Together with our partner, Sanofi, we've made significant strides in securing US access and reimbursement for commercial and Medicare patients. At the start of this year, nearly 85% of commercial patients and nearly 90% of Medicare patients had coverage.

Additionally, we are pleased that global GOLD treatment guidelines for COPD now include Dupixent as the only recommended biologic medicine for these patients. We look forward to accelerating the launch of this important indication and to make a significant difference in the lives of hundreds of thousands of COPD patients worldwide.

Our teams are also preparing for a potential April launch in chronic spontaneous urticaria pending FDA approval, we believe Dupixent offers a compelling treatment option and if approved, would be the first new targeted therapy in the US in over a decade for the estimated 300,000 CSU patients.

In conclusion, we continued to deliver solid performance across our commercial portfolio in the fourth quarter. We also see significant growth opportunities in 2025 and beyond with near and medium-term catalysts to drive growth.

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

**Christopher Fenimore** - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior 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. Regeneron ended 2024 with strong financial performance in the fourth quarter, delivering growth on both the top and bottom line. Total revenues grew 10% year-over-year to $3.8 billion, primarily reflecting higher Sanofi collaboration revenue driven by Dupixent growth and strong global net sales growth for Libtayo and modest growth for combined net sales of EYLEA HD and EYLEA in the US.

Fourth quarter diluted net income per share was $12.07 on net income of $1.4 billion, up 2% from the prior year. On a full year basis, total revenues were $14.2 billion, representing growth of 10% when excluding revenues from Ronapreve. 2024 earnings per share grew 4% from the prior year to $45.62.

Turning to collaboration revenue in the fourth quarter. Revenues from the Sanofi collaboration were $1.2 billion, of which $1 billion related to our share of collaboration profits. Regeneron's share of profits grew 18% versus the prior year driven by volume growth for Dupixent and higher collaboration margins. For the year, our share of profit, net of development balance reimbursement increased to the highest level since initiation of the collaboration, reaching approximately [27%] of total antibody net sales.

The Sanofi development balance was approximately $1.6 billion at the end of 2024, reflecting a reduction of approximately $175 million from the end of the third quarter and approximately $700 million from the end of 2023. We continue to expect this balance to be fully reimbursed by the end of 2026 which is expected to result in a significant increase in Sanofi collaboration revenue and cash flow thereafter.

Moving to Bayer. Fourth quarter ex US net sales of EYLEA and EYLEA 8-Mg were $888 million, up 2% on a constant currency basis versus the prior year. Total Bayer collaboration revenue was $377 million, of which $349 million related to our share of net profits outside the US. Now to our operating expenses. R&D expense was $1.2 billion in the fourth quarter. The increase in R&D expense versus the prior year was driven by cost to support advancement of Regeneron's broad clinical pipeline, including our C5 and Factor XI programs in hematology, certain oncology programs, itepekimab in COPD and our ongoing program in obesity.

Fourth quarter SG&A was $681 million, with growth from the prior year, primarily reflecting investments to support the launch of EYLEA HD and our international expansion. Fourth quarter 2024 gross margin on net product sales was 86%, up slightly from the prior year quarter.

Now to cash flow and the balance sheet. Regeneron generated approximately $3.7 billion in free cash flow in 2024 and ended the year with cash and marketable securities less debt of approximately $15.2 billion. In 2024, we deployed $2.6 billion towards share repurchases, including a meaningful step-up in the fourth quarter, during which we repurchased nearly $1 billion of our shares. Consistent with our capital allocation framework, we are investing heavily in our R&D capabilities to drive long-term growth, exploring business development opportunities and returning capital to shareholders. This morning, we announced an additional share repurchase authorization of $3 billion, increasing our capacity for repurchases to approximately $4.5 billion as of today.

In addition, we are enhancing our approach to returning capital to shareholders. As announced this morning, our Board of Directors has authorized the initiation of a quarterly dividend with the first dividend payable on March 20 and to shareholders of record as of February 20. The dividend will be $0.88 per share, equivalent to $3.52 per share on an annual basis. We are confident in the long-term growth of our business, our innovative R&D engine, our differentiated pipeline and the durability of our cash flows, all of which support the initiation of our first quarterly dividend and the announcement of an additional share repurchase authorization.

I'll conclude with a review of our 2025 financial guidance. We expect 2025 R&D spend to be in the range of $5 billion to $5.2 billion. The increase versus 2024 is driven by cost to support our expanding late-stage pipeline including Phase 3 programs for our Factor XI antibodies and heme-onc bispecifics as well as programs in obesity and genetic medicines and the advancement of multiple new assets into the clinic.

We expect 2025 SG&A to be in the range of $2.55 billion to $2.7 billion, representing 3% growth at the midpoint of this range versus 2024, driven by investments to support multiple potential oncology launches. We expect our gross margin on net product sales to be in the range of 87% to

88%. This guidance reflects a changing product mix as well as ongoing start-up costs for our new fill finish facility and investments to drive future efficiencies across our manufacturing network.

We expect cost of collaboration manufacturing to be in the range of $1 billion to $1.15 billion in 2025 and primarily driven by higher Dupixent volumes. Recall that we are reimbursed for these costs as revenue, making them generally neutral to net income. We expect 2025 capital expenditures to be in the range of $850 million to $975 million, primarily related to ongoing expansion of the R&D facilities at our Tarrytown headquarters and investments to increase both manufacturing capacity in the US and Ireland to support our expanding pipeline.

Finally, we expect our 2025 effective tax rate to be in the range of 11% to 13%. In summary, Regeneron delivered solid financial results in 2024 and our strong financial position and prudent capital allocation enables Regeneron to deliver long-term shareholder value.

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

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**Ryan Crowe** - Regeneron Pharmaceuticals Inc - Senior Vice President of IR & Strategic Analysis

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

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## QUESTIONS AND ANSWERS

**Operator**

(Operator Instructions) Our first question comes from the line of Brian Abrahams. Your line is open.

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**Brian Abrahams** - RBC Capital Markets - Analyst

Hey, guys. Good morning. Thanks for taking my question. Consensus numbers suggest expectations for annual sales erosion of about 7% annually over the next few years for the EYLEA franchise. Just given what you've been seeing on the ground and some of the dynamics you described, including competitive pressure, but a potential acceleration in HD with some of those approvals, do you think that these expectations look reasonable?

And I know you guys don't typically provide guidance, but I just -- I think any directionality might be helpful here. Just to understand whether folks are looking at dynamics here the right way or if expectations may be way off?

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

So as you pointed out, we don't give guidance. I wanted to give you a summary today of how we see the market and certainly, as it relates to EYLEA HD and the strengthening of the profile that we hope with additional FDA approvals this year related to delivery system with the prefilled syringe, indication with RVO, dosing flexibility and then also the clinical data that further cements EYLEA HD as the product with the greatest durability -- we believe that combination of factors for EYLEA HD and the fact that already in our year -- this past year in the market, EYLEA HD at $1.2 billion in net sales is a blockbuster product . We see that as a very compelling profile.

But I did want to be very realistic and my comments indicated, we do expect to see additional competitive pressure on EYLEA. Obviously, there's a biosimilar in the market today. So that is a factor that needs to be considered as well. But overall, we certainly believe we have a very strong position. I also noted today that our category share in the fourth quarter was at 46%. So obviously, we have a very strong position in the marketplace.

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**Operator**

Our next question comes from the line of Tyler Van Buren with TD Cowen.

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

Hey, guys. Good morning. Thank you very much for taking the question. So the dividend initiation is an exciting disclosure and earlier than some might have expected. So I'm curious why you guys decided to institute the dividend now as opposed to when the Sanofi development balance was paid off by the end of next year and whether you plan to increase it from these levels over time.

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

Thanks, Tyler. Thanks for the question. So obviously, we publicly were talking about initiating it at the end of the repayment of the Sanofi development balance. I think for a variety of reasons, we have a lot of confidence as we reiterated on the call today that, that would be paid down. It's also obviously a differentiation in our capital allocation strategy to sort of migrate a little bit away from share buybacks, although as Len indicated in his remarks, that it will be the primary purpose of returning capital to our shareholders but allowing us a little bit more flexibility of starting the dividend.

And it also opens up a larger base of shareholders. So there are a lot of funds out there that have a dividend mandate. And this will give them the opportunity to invest in Regeneron that they wouldn't have otherwise in the past been able to do.

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**Operator**

Our next question comes from the line of Cory Kasimov with Evercore.

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**Cory Kasimov** - Evercore ISI - Analyst

Hey, good morning, guys. I wanted to ask on the adjuvant CSCC Libtayo readout that you top lined in January. How critical is it that the product also hits an overall survival in addition to the DFS top line? And can you kind of comment as to how you see this as the opportunity here from a commercial perspective relative to the indications you already have?

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

Well, because these patients are relatively earlier stages of their disease, they tend to have long survival times from their initial surgeries and so forth. So there are very few survival events. That said, of course, the FDA will be looking at the data to make sure that at least numerically, things are not going in surprising or wrong directions. But we have confidence that the package is going to look pretty attractive.

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

And then just adding on the commercial perspective. As I noted, we obviously have a very capable and talented oncology, Libtayo team, the US and in key international markets. But for the US, we estimate there'd be about 10,000 patients who may benefit from the adjuvant CSCC indication.

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**Operator**

Our next question comes from the line of Salveen Richter with Goldman Sachs.

**Salveen Richter** - Goldman Sachs - Analyst

Good morning. Thanks for taking my question. Could you just speak to the magnitude of inventory impact on EYLEA HD that played out last quarter and also the dynamics that are happening in the marketplace with Pavblu, the biosimilar?

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

So Salveen, as we had noted last quarter, there had been a build an EYLEA HD inventory, and that obviously impacted fourth quarter for EYLEA HD burning off that inventory. As to the specific numbers, the range of impact in total would have been in the range of -- if we looked at the combined EYLEA HD and EYLEA net product sales for the fourth quarter, the favorable impact was predominantly to EYLEA, and that was about $85 million, and that was the result of higher wholesale inventory levels for EYLEA partially offset by lower wholesale inventory levels for EYLEA HD.

**Ryan Crowe** - Regeneron Pharmaceuticals Inc - Senior Vice President of IR & Strategic Analysis

Do you want to comment on Pavblu?

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

Well, it's Glenn, it's really difficult to comment on Pavblu. I will note one thing that very recently, we had some victories at the Federal Circuit Court of Appeals, which thus far is leading to the conclusion that there's only one competitor biosimilar. If that holds, that really changes the dynamic quite a bit in terms of pricing and things like that.

So having one competitor is quite different than having multiple competitors. So I encourage you to look at some of the recent wins we had at the Federal Circuit on the injunctions against other players. In terms of what's actually going in the market, I think maybe you'll be on Amgen's call this afternoon, maybe they can give you a more direct answer.

**Operator**

Our next question comes from the line of Chris Schott with JPMorgan.

**Taylor Hanley** - JP Morgan - Analyst

This is Taylor Hanley on for Chris Schott. I just had a question on how you're thinking about operating expenses going forward. So with numerous programs advancing to late-stage development. How are you thinking about balancing investments across the pipeline? And do you think that there would be the potential to partner any of these programs? Or should we think about Regeneron and keeping everything in-house going forward?

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

So I think it's important to note that our primary allocation of our capital is to our research and development efforts. We're in the midst of doing a little interesting exercise that if you compare our investment to other companies and you take into account equity investments and other upfronts and milestones that are essentially buying research and development, I think the data is going to show that we have an incredibly productive dollar to dollar pound for pound R&D capabilities in the industry.

In terms of whether or not we would partner, I think we have always been -- that is a financial partner, perhaps or a strategic partner in some program. We've always kept an open mind to see what is the best for the program and how can we best allocate our resources. So we don't manage

the business in any fixed allocation way. We don't say we're going to spend X percent. We look at what's worth spending our money on. We look at what the potential ways to fund our programs are and we try and make decisions that way rather than having some allocation quotas or the like.

That flexibility, I think, has served us well, and it will continue to serve well given that we have more than 40 programs in the clinic and many, many more heading towards the clinic.

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**Operator**

Our next question comes from the line of Christopher Raymond with Piper Sandler.

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**Unidentified Participant**

This is Sam on for Chris. On EYLEA, we noticed you had a modest price increase, which is the first time we've seen that for EYLEA. Meanwhile, we've seen Roche have more regular price increases for Vabysmo since they launched. Any comments on your pricing strategy for EYLEA going forward? Is the goal to stabilize average sale price over time?

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

No comment.

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

Okay. I was going to say no comment. I'll add. You mentioned a price increase for EYLEA. There is a modest price increase for EYLEA HD.

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**Operator**

Our next question comes from the line of Mohit Bansal with Wells Fargo.

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**Mohit Bansal** - Wells Fargo - Analyst

Great. Thank you very much for taking my question. Maybe, I just wanted to get a little bit more color on how you are thinking about the cadence of EYLEA HD of the year -- for the year because it seems like you're saying that you expect incremental conversion when pre-fill syringe and label expansion comes in. Could you help us understand? I mean, is it like -- is it going to be more incremental? Or do you think that there's an inflection primarily due to pre-filled given the market acceptability of that of that [formulation]? Thank you.

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

Mohit, I don't have additional comment at this time. I wanted to give the overall balance we see obviously opportunity for EYLEA HD to continue to grow. As you know, the market is probably about 10% naive patients, 90% switch patients going over to EYLEA HD and among those patients that are switching the source of business is often coming from EYLEA second faricimab and third Avastin. to the overall market dynamics, I don't have additional comments.

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

Yes. I mean I encourage you, obviously, to look beyond the hyperfocus on EYLEA. We have Dupixent launching away in COPD, we have pivotal data coming up with itepekimab in COPD. We have first-line melanoma, metastatic melanoma data coming up. Second part of this year. We've got data in myasthenia gravis coming up. We're starting a trial in geographic atrophy. And I could go on and on and on, and I would encourage you to work through those because our strategy is not to be solely dependent on any one thing, yet still optimize every single thing.

So we will do everything we can to optimize each of our programs, HD and so forth, but we don't want to become dependent on any one thing which is why we're so excited about the pipeline. So I would say it's the pipeline.

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**Operator**

Our next question comes from the line of Tim Anderson with Bank of America.

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**Alice Nettleton** - Bank of America - Analyst

This is Alice Nettleton on for Tim Anderson. Sorry, another one on EYLEA.

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

Why don't we come back to that question at the end, so we can get some non-EYLEA questions in. We'll put you at the end of the queue and we'll come back to you.

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**Operator**

Our next question comes from the line of Akash Tewari with Jefferies.

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**Akash Tawari** - Jeffries - Analyst

I'm not going to ask an EYLEA question. George, I'd love your take on Factor XI. We've seen both asundexian and some of the private mAb players show issues in preventing ischemic stroke events with the mAb also showing an inverse dose response on bleed prevention. That said, Regeneron is the only company that's shown an incremental benefit in a total knee replacement study versus Eliquis. So can you talk about your confidence on 7508 and some of the recent data sets in the space?

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

Yes. Our strategy from the beginning was take advantage of our understanding from the genetics to design and select two antibodies that have very complementary with different profiles can address different patients and allow physicians and patients to choose the best antibody for their needs. So our antibody that the 7508 that you mentioned that hits the catalytic domain in side-by-side comparisons is biochemically the strongest blocker and has the strongest anticoagulant activity of anything in this class. And that would be designed for the patients who need the most anticoagulant control.

And as you said, it performed very impressively in the initial proof-of-concept studies with regard to that functionality. The 9933, which affects the A2 domain is designed to be slightly gentler, and the genetic suggests it may have very little, if any bleeding risk but perhaps a little bit less anticoagulation activity. So that's designed to give alternatives or options for the patients and the physicians who are most concerned in that setting about bleeding risk.

So we think this is a very powerful optionality and flexibility to be able to offer both physicians and patients who struggle between solving the dilemma about how do I control anticoagulation without causing bleeding and all of those concerns that go with that. And in this way, we'll have data and we'll have comparative data in multiple settings to allow the physician and the patient to hopefully choose the best approach for their situation.

And we think that certainly, patients, the settings are really crying out for this sort of optionality and flexibility. This is why so many patients in so many indications, not only in atrial fibrillation, but across the entire spectrum of diseases in which thrombi and clots are a problem are left untreated or not maximally treated.

So we're hoping to address that huge unmet need by evaluating and getting data on these two genetically validated approaches.

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**Operator**

Our next question comes from the line of William Pickering with Bernstein.

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**William Pickering** - Bernstein - Analyst

Hi, thank you for taking my question. It's about your complement programs. So it seems like your antibody siRNA combo has potential to deliver really leading efficacy. But on safety, you've seen some grade 5 AE so far -- discuss how you see these combos fitting into the MG and GA treatment landscapes. And for GA specifically, anything about the design of the Phase 3 trial that would kind of minimize some of those safety events that you've seen so far?

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

Yes. So first of all, the safety events are consistent with what's been seen with the class in general. Right now, we don't really have evidence to suggest that it's different than the other approaches vis-a-vis safety. In terms of efficacy, it's an incremental benefit that is able to drive many more of the patients into the normal range. So the current drugs can achieve in some patients as deep complement inhibition as we're seeing but they don't do it for all the patients. We're doing it for a much higher percentage of patients.

So we're not really lowering complement to much lower levels, we're just driving more of the patients to the levels that are already being achieved. This is consistent with the safety profiles being analogous to what's already been seen with the class. But very importantly, it's the uncontrolled patients, which are causing the problems, whether it be in PNH or perhaps some of these other complement mediate diseases who are being suboptimally treated, which we hope we now have a solution for.

For those patients, roughly 30% of the population is even with the best standard of care who are left suboptimally treated. That said, complement inhibition for an elderly or older AMD patient is certainly a concern with any approach. And as you said, we are doing a variety of things that are somewhat standard for the class to try to choose first of all, enroll patients who are not as high risk to make sure, for example, they're vaccinated against the organisms of risk and, of course, monitoring them closely.

But we have to balance that, of course, with the concerns and the safety events that have been happening with the intravitreal approaches, I mean these are designed to slow down slowly progressing vision-threatening events yet the safety events can cause catastrophic immediate vision loss in patients. So that's a little bit of a dilemma. Do you take a prevention that can make you immediately blind to slow down your eventual blindness? We're hoping to offer another option for these patients that might not risk their vision. But as you said, we'll have to balance the safety infectious types of events which, as I said, are a class-specific type of problem.

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**Ryan Crowe** - Regeneron Pharmaceuticals Inc - Senior Vice President of IR & Strategic Analysis

Thanks, George. I think we have time for two more questions.

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**Operator**

Our next question comes from the line of Dave Risinger with Leerink.

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**David Risinger** - Leerink Partners - Analyst

Yes, thanks very much. So my question is on obesity. George, could you please discuss the need to combine myostatin with an Activin in blocker to treat obesity and optimized body composition. I ask because I'm curious about whether if the Activin doesn't have the right benefit risk profile, whether you could develop a myostatin as a stand-alone or not? Thanks very much.

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

Yes, you pretty much summarized exactly our strategy based on our previous data in humans, including in sarcopenic individuals, the combination can grow more muscle. However, we do have some concerns with the Activin A blockade. The GDF8 blockade now based on both genetics and what we've seen looks to be exceedingly safe in terms of all the early data. We don't have as much data with the Activin A, and so we're left with more concerns.

So we're testing the combination, but we can fall back on just single approaches which might have a little bit less efficacy in terms of muscle preservation but might be safer. So that's why we're exploring these individually, but also together.

So to understand the best benefit/risk profile I want to remind you that, for example, at Lilly, they're trying a receptor blocker that not only blocks these two growth factors but more than a dozen other related growth factors. So that may yield good efficacy, but the concerns there is not only you're blocking the myostatin and the Activin A, but a dozen other factors as well, and what are the potential side effects you'll see here.

That's why we like our program that we can actually target the two most important factors as we've shown preclinically and clinically for muscle preservation while also trying them individually. So that way, we'll have, once again, the most flexibility as a lot of our programs are designed to dissect and separate individual agents in various processes to understand best the benefit risk profile where you might trade efficacy for safety and vice versa.

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**Ryan Crowe** - Regeneron Pharmaceuticals Inc - Senior Vice President of IR & Strategic Analysis

Thanks, George. I don't see Bank of America in the queue. So we'll just go to the next question in the queue is our final question.

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**Operator**

Our final question comes from the line of Terence Flynn with Morgan Stanley.

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**Unidentified Participant**

This is Chris on for Terence. Just a question on your Lag-3 plus PD-1 combo in non-small cell lung cancer program. What is the efficacy bar on the duration of response or PFS that you need to see for you to advance that into a pivotal program?

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

Yes. As we've seen from the small data set with our friends at Bristol in terms of their combination, those data sets are very small, and they're hard to really make convincing conclusions on. That's why we are more focused on our melanoma data. If the melanoma data really deliver the sort of efficacy profile, safety and efficacy profile that we've seen in our proof-of-concept studies when we read out the Phase 3. I think that's going to generate enormous excitement both for the potential to really help first-line melanoma patients but also to extend this combination to a variety of other cancer settings, including potentially lung cancer.

So I think that the bigger data set in the Phase 3 study is going to provide the most insight and the most potential confidence as opposed to the smaller Phase 2 and proof-of-concept studies, which obviously can generate excitement, but they're not really definitive as we've seen from our own data, but also from our friends who have other related programs going on. So I really point to the pivotal melanoma data. If that really emerges as the new standard of care in melanoma, it's going to -- I think it's going to provide a lot of interest and excitement in other cancer settings as well.

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**Ryan Crowe** - Regeneron Pharmaceuticals Inc - Senior Vice President of IR & Strategic Analysis

I see Bank of America is back in the queue. So we will take our final question from them as promised.

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**Operator**

Our next question comes from the line of Tim Anderson with Bank of America.

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**Alice Nettleton** - Bank of America - Analyst

This is Alice on for Tim. So back to my question on EYLEA. We talked to one big purchaser of EYLEA recently, who said that Regeneron essentially hasn't sweetened the contract terms on standard dose in an effort to compete with Amgen's product yet. So can we infer from this that you are likely to hold the ground on price and pricing concessions with the goal being that doctors will start using high dose more once the label and product enhancements come through.

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

Alice, thank you for your patience. We don't comment on pricing strategy, but I certainly will complement our very talented market access and pricing team, but no comment.

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**Ryan Crowe** - Regeneron Pharmaceuticals Inc - Senior Vice President of IR & Strategic Analysis

With that, we will conclude the call. Thank you, and thanks to everyone who dialed in for today's call. We apologize for those remaining in the Q&A queue. We did not have enough time to hear from you. but we're always happy to follow up. We're available to answer any or any questions you may have. Thank you once again. Have a great day.

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**Operator**

Ladies and gentlemen, that concludes today's conference call. Thank you for your participation. You may now disconnect.

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