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EDITED TRANSCRIPT

REGN.OQ - Q1 2023 Regeneron Pharmaceuticals Inc Earnings Call

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OVERVIEW:

REGN reported 1Q23 total revenues of $3.2b, non-GAAP net income of $1.2b and non-GAAP diluted EPS of $10.09.

REFINITIV

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PRESENTATION

Operator

Welcome to the Regeneron Pharmaceuticals First Quarter 2023 Earnings Conference Call. My name is Josh, 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, Vice President, Investor Relations. You may begin.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thank you, Josh. Good morning, good afternoon and good evening to everyone listening around the world. Thank you for your interest in Regeneron and welcome to our first quarter 2023 earnings conference call. An archive of this webcast will be available on our Investor Relations website shortly after the call ends.

Joining me today are Dr. Leonard Schleifer, Co-Founder, President and Chief Executive Officer; Dr. George Yancopoulos, Co-Founder, President and Chief Scientific Officer; Marion McCourt, Executive Vice President and Head of Commercial; and Bob Landry, Executive Vice President and Chief Financial Officer. After our prepared remarks, we will open the call 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 and business, financial forecast and guidance, revenue diversification, development programs and related anticipated milestones, collaborations, finances, regulatory matters, payer coverage and reimbursement issues, 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-Q for the quarterly period ended March 31, 2023, 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 measures will be discussed in today's call. Information regarding our use of non-GAAP financial measures and a reconciliation of those measures to GAAP is available in our financial results press release and our corporate presentation, which can be accessed on our website. Once our call concludes, Bob Landry and the IR team will be available to answer further questions.

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

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Thank you, Ryan, and thank you to everyone joining today's call. Following our significant achievements in 2022, Regeneron is off to a good start in 2023, highlighted by important regulatory and pipeline advances, commercial execution and prudent capital allocation, all of which position better the company to deliver sustainable long-term growth and shareholder value over time.

George, Marion and Bob will cover details of our first quarter performance in a few moments. In the meantime, I would provide an update on our goal of continuing to grow our business while simultaneously diversifying our revenue and earnings streams, which is part of our long-term vision for Regeneron.

We have made substantial progress toward achieving that goal. Over the past 4 years, while total revenues have nearly doubled, EYLEA accounted for only 57% of total revenues in the first quarter of 2023 compared to 88% of total revenues for the year 2019. Driven primarily by the growth of Dupixent, our Sanofi collaboration accounted for 25% of our total revenues in the first quarter of 2023 compared to only 6% of our total revenues in 2019. We expect this trend of revenue growth, along with diversification to continue.

For example, assuming the approval and successful launch of aflibercept 8 milligrams, which has a June 27 PDUFA date, EYLEA 2 milligrams is expected to become a smaller share of our revenues, while aflibercept 8 milligrams is expected to contribute to overall revenue growth. In addition, Dupixent remains in a high-growth mode, with global net product sales up 40% on a constant currency basis compared to the prior year quarter, driven by growth across all 5 approved indications.

We believe the positive Phase III results for Dupixent in the subpopulation of COPD patients with evidence of type 2 inflammation, as well as the promising results for our IL-33 antibody, itepekimab, in former smokers represent additional significant opportunities to accelerate revenue growth as well as diversification.

Our oncology portfolio is also starting to make a meaningful contribution to our top line, with last year's acquisition of full global rights to Libtayo and the recent launch of Libtayo in combination with chemotherapy in advanced non-small cell lung cancer. Moreover, we believe that fianlimab, our LAG-3 antibody, in combination with Libtayo, has the potential to become an important therapy in both melanoma and non-small cell lung cancer, where we have already advanced to pivotal studies.

We are also quite excited about the emerging clinical profile for linvoseltamab, our BCMAxCD3 bispecific. Updated data for which will be presented at the upcoming ASCO Annual Meeting. We remain on track to submit a BLA seeking accelerated approval in late-stage myeloma later this year.

We continue to invest in our research and development engine and expect it will deliver new differentiated medicines that will drive organic growth over time. Our broad development pipeline of nearly 3 dozen programs spans many different therapeutic areas and modalities, notably our co-stimulatory bispecifics in cancer; our early pipeline in cardiovascular and metabolic diseases; as well as our collaborations with Alnylam, Intellia, Decibel and others are expected to drive medium- and long-term revenue growth, profitability and diversification.

Before handing over to George, I'd like to take a moment to recognize the contributions that Dr. Roy Vagelos has made to Regeneron over the nearly 3 decades that he has served as our Board Chair. Over the years, he has provided invaluable guidance and he continues to inspire us as we work to turn world-class science into medicines. Roy will retire from the Board after his current term ends next month. At that time, in addition to our current roles in the company, George and I will be appointed by the Board to serve as co-Chairs, and Christine Poon, a member of Regeneron's Board since 2010, will be appointed as the Board's Lead Independent Director.

With that, let me turn the call over to George.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Thank you, Len. The first quarter of 2023 delivered multiple significant milestones for Regeneron and for our collaborations, from the positive Dupixent Phase III COPD data, to progress in our oncology pipeline, as well as exciting new landmarks from our genetic medicines programs.

Starting with Dupixent. In March, together with our Sanofi collaborators, we announced that Dupixent was the first new mechanism of action treatment to produce statistically significant and clinically meaningful results in a Phase III trial for COPD in over a decade. Our BOREAS trial enrolled COPD patients with moderate to severe disease and evidence of type 2 inflammation.

Dupixent-treated patients demonstrated a clinically meaningful 30% reduction in exacerbations, a significant improvement in lung function as well as quality-of-life benefits, an impressive trifecta in a potential paradigm-changing treatment for this deadly disease. We are looking forward to presenting the detailed BOREAS results in a late-breaking presentation at the upcoming American Thoracic Society Meeting later this month. We also plan to discuss these exciting results with regulatory authorities and expect to report results mid next year for the replicate Phase III NOTUS study.

I would remind you that we are also trying to address an overlapping COPD population with our IL-33 antibody, which is in Phase III studies based on positive Phase II proof-of-concept data. This approach is further supported by genetic analysis from our Regeneron Genetics Center, which demonstrated association of loss of function in interleukin-33 with reduced COPD risk. Similar genetic analyses supported the role for a Dupixent benefit in COPD.

The BOREAS COPD data indicates that Dupixent can help even more patients beyond the 5 current FDA-approved indications and diseases caused or exacerbated by type 2 inflammation, including atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis and prurigo nodularis. We are also expecting an FDA decision for Dupixent for chronic spontaneous urticaria on October 22, 2023, and we are continuing to tailor Dupixent development to patients with other type 2 inflammatory diseases, most likely to be responsive to this method.

Moving to oncology. With the progress of our late and early stage pipeline, we are looking forward to several important milestones this year. Starting with Libtayo. In addition to expanded use in lung cancer, Libtayo was recently added to the NCCN guidelines for neoadjuvant treatment of CSCC. The Libtayo U.S. label was also recently updated with more mature CSCC and BCC data, supporting its differentiated clinical profile in these tumor settings and satisfying all post-marketing commitments that require full approval in these indications.

Regarding our exciting new combinations with Libtayo. Starting with fianlimab, our LAG-3 antibodies, for which we are planning a broad pivotal program spanning several cancer indications. These efforts were triggered by our robust and confirmed data in first-line metastatic melanoma patients, which will be presented in further detail at ASCO, suggesting that the fianlimab-Libtayo combination could produce about double the response rates with longer progression-free survival, the anti-PD monotherapy standard. Based on this, we have already initiated pivotal trials in metastatic and adjuvant melanoma, and we will start a study in perioperative melanoma in the second half of the year. In addition, based on

promising data in small patient cohorts, we started a seamless Phase II/III pivotal study for treatment of metastatic non-small cell lung cancer, and we will soon start a Phase II study in the perioperative setting.

Next to bispecifics for solid tumors, which are being investigated in combination with Libtayo. Earlier this year, at ASCO-GU, we presented initial positive first-in-human data for our PSMAxCD28 costimulatory bispecific in combination with Libtayo in advanced prostate cancer, a tumor type considered immunologically cold and largely unresponsive to anti-PD-1 therapy alone. Over the next 12 months we plan to present updated PSMAxCD28 data in more patients, some of which will have been prophylactically treated with our anti-IL-6 receptor antibody, sarilumab, to potentially reduce the severity of immune-mediated side effects while maintaining or improving antitumor activity. Also during this time frame, we plan to present data in advanced ovarian cancer for both our MUC16xCD3 bispecific and our MUC16xCD28 costimulatory bispecific as well as data in several tumor types from our EGFRxCD28 costimulatory bispecific, all in combination with Libtayo.

Our hematology oncology pipeline continues to advance. In an oral presentation at the upcoming ASCO Annual Meeting, we will present updated data for linvoseltamab, our BCMAxCD3 bispecific tested in late-line multiple myeloma. We believe these data will show that linvoseltamab has the best-in-class potential with differentiated efficacy, safety and a favorable dosing schedule in the competitive environment of relapsed/refractory multiple myeloma treatment candidates. We remain on track for a regulatory submission in the United States in the second half of this year for linvoseltamab.

For odronextamab, our CD20xCD3 bispecific, we are on track to complete U.S. and EU regulatory submissions for both relapsed or refractory follicular lymphoma and diffuse large B-cell lymphoma in the second half of this year. Odronextamab in late-line relapsed or refractory follicular lymphoma has a potential best-in-class efficacy profile, and our optimized step-up dosing regimen has improved odronextamab's safety profile without impacting efficacy. Also, we have initiated a first-in-human study of our CD22xCD28 costimulatory bispecific in combination with odronextamab in relapsed/refractory DLBCL, which we hope could further improve upon the anticancer benefit for these patients.

Now to genetics medicines. Starting with our collaboration with Alnylam in siRNA therapeutics. Just last week, we and Alnylam announced an important update for our Alnylam APP program in early onset Alzheimer's disease. For the first time, an RNAi therapeutic demonstrated sustained silencing of a pathological gene in the central nerve system in a clinical trial. In their earnings call this morning, our Alnylam collaborators provided additional details on these results. Our siRNA approach aims to prevent production of amyloid precursor protein as opposed to clearing existing amyloid plaques after they have already formed, providing a new way to potentially address Alzheimer's disease, which will still have a devastating impact on patients and their families even with the emergence of amyloid-clearing antibodies.

Patients treated with single doses of ALN-APP experienced dose-dependent, rapid and sustained reduction of up to 90% in APP production as assessed by biomarkers in cerebrospinal fluid. The safety and tolerability profile with single dosing is encouraging so far. While the multi-dose Part B portion of the study is on partial clinical hold in the United States due to findings observed in prior nonclinical chronic toxicology studies, Part B has already received regulatory approval to proceed in Canada, where the majority of the part A clinical trial patients had been enrolled.

Detailed results from the study will be presented in an upcoming medical meeting. We are looking forward to advancing additional development candidates for the many other neurodegenerative diseases that currently have few or no therapeutic options such as other targets for Alzheimer's, as well as for ALS or Lou Gehrig's disease, Parkinson's and Huntington's.

In addition to these exciting developments in central nervous system diseases, we are continuing our progress with liver targeted medicines, including our broad and multipronged approach to develop treatments for NASH, or nonalcoholic steatohepatitis. We're enrolling a Phase II study of ALN-HSD in NASH patients with genetic risk factors, continuing clinical development of ALN-PNP, and we are planning to progress additional more recently genetically-validated NASH targets as well.

Finally, I would like to highlight our recently announced collaboration with Sonoma Biotherapeutics' discover, develop and commercialize regulatory T cell therapies for autoimmune and inflammatory diseases. This collaboration will bring together our industry-leading technologies for the discovery and characterization of fully human antibodies and T cell receptors, as well as our additional biologics candidates with Sonoma's pioneering approach to developing and manufacturing gene modified Treg cell therapies.

In conclusion, Regeneron's R&D engine truly continues its productivity in both late and early-stage pipeline. Before turning the call over to Marion, I would also like to thank Roy Vagelos for serving as a role model for all of us at Regeneron as well as for so many others across the industry. I hope that we can continue to live up to the high standards that Roy has set over his distinguished career.

With that, I will turn the call over to Marion.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Thank you, George. Our first quarter performance demonstrates ongoing leadership across multiple therapeutic categories. Taken together, our in-market brands anticipated near-term launches and extensive development pipeline uniquely position Regeneron to expand our leadership across multiple disease areas.

First quarter EYLEA U.S. net product sales declined 6% year-over-year to $1.43 billion. On a sequential quarter basis, EYLEA U.S. net product sales decreased 4%, reflecting the favorable impact of higher demand volume, offset by lower sequential wholesaler inventory levels, higher sales-related deductions and increasing competitive pressure. EYLEA captured approximately 70% branded share in the first quarter.

Based on presentations at scientific meetings, the retina community has expressed increasing enthusiasm about Regeneron's portfolio with the aflibercept 8-milligram PDUFA date now 7 weeks away. EYLEA is the well-established gold standard anti-VEGF treatment and aflibercept 8-milligram has the potential to be as paradigm changing as EYLEA when it was introduced more than a decade ago.

In clinical trials, aflibercept 8-milligram demonstrated improvements in visual acuity with less frequent injections and a safety profile comparable to EYLEA, exactly what retina specialists have told us they need in a next-generation medicine. Launch preparations are well underway, and we look forward to bringing this important treatment option to patients following FDA approval.

On to Libtayo, which is foundational to Regeneron's oncology portfolio, first quarter global net product sales grew 49% on a constant currency basis, reaching $183 million, which includes $6 million from Sanofi transition sales in international markets. In the U.S., net sales grew 39% to $110 million. Libtayo continues to lead the market in both advanced CSCC and advanced BCC as demand volume increases.

Following last November's FDA approval of Libtayo in combination with chemotherapy for first-line advanced non-small cell lung cancer, new patient starts have accelerated as physicians of Libtayo has an important new treatment option. Initiatives to raise brand awareness and improve access have driven share gains in both the academic and community settings. Outside the U.S., Libtayo net sales grew 67% on a constant currency basis to $73 million, driven by steadily increasing demand and additional country launches. The European Commission recently approved Libtayo in combination with chemotherapy for PD-L1-positive lung cancer, and we are in the process of securing access and reimbursement for this new indication.

Turning to Dupixent. First quarter global net sales grew 40% on a constant currency basis to $2.49 billion. In the U.S., net sales grew 43% to $1.9 billion, with notable volume growth across all approved indications. Driven by its outstanding efficacy and safety profile, Dupixent is the #1 prescribed biologic for new patients in all 5 of its approved indications.

In atopic dermatitis, Dupixent is the leading systemic treatment based on its unique mechanism of action, clinical profile and real-world experience. Strong prescribing trends continue across moderate and severe disease and across approved age ranges. There's also significant opportunity to further increase market penetration as Dupixent is uniquely positioned to provide an effective, safe and convenient treatment for patients 6 months and older.

In prurigo nodularis, Dupixent is the only FDA-approved systemic treatment. Launch update is progressing well, and we anticipate ongoing growth as we leverage our dermatology commercialization capabilities for patients in need. Across the competitive asthma space, Dupixent continues to gain market share as naive and biologic switch patients are initiated on treatment. Dupixent also continues to capture the majority of market demand in nasal polyps with increased prescribing from allergists and ENTs.

Our eosinophilic esophagitis launch is exceeding expectations. In the first year following U.S. approval, more than 11,000 patients have initiated therapy, demonstrating extensive unmet patient need and our strong launch execution and collaboration with Sanofi. Both gastroenterologists and allergists have embraced Dupixent as the new standard of care setting meaningful improvements in disease symptoms and quality of life for those now on therapy. A new patient campaign is underway to raise awareness of the scientific advancements in treatment of eosinophilic esophagitis.

Outside the U.S., Dupixent net sales were $587 million, growing 30% on a constant currency basis, driven by growth across approved indications and launches in new geographies. Recent European approvals of eosinophilic esophagitis, prurigo nodularis and atopic dermatitis in young children are expected to contribute to Dupixent's ongoing growth.

In summary, our commercial portfolio continues to diversify across many serious medical conditions and delivered solid results in the quarter. Moving forward, we are well positioned to serve even more patients driven by the strength of our existing portfolio, coupled with anticipated launches that have the potential to advance standards of care.

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

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

Thank you, Marion. My comments today on Regeneron's financial results and outlook will be on a non-GAAP basis unless otherwise noted. Regeneron performed well in the first quarter of 2023 with solid financial results. First quarter total revenues increased 7% year-over-year to $3.2 billion as Dupixent and Libtayo contribute to increasingly diversified revenue and earning streams. First quarter diluted net income per share was $10.09 on net income of $1.2 billion, which included a previously announced $0.42 impact of acquired IPR&D.

Beginning with collaboration revenue and starting with Bayer. First quarter 2023 ex-U.S. EYLEA net product sales were $847 million, up 4% on a constant currency basis versus first quarter 2022. Total Bayer collaboration revenue was $357 million, of which $332 million related to our share of EYLEA net profits outside the U.S. Total Sanofi collaboration revenue was $798 million in the first quarter and grew 26% versus last year's first quarter, which included a $50 million sales milestone that did not recur this year.

Our share of profits from the commercialization of Dupixent and Kevzara was $637 million, an increase of 53% versus the prior year. We continue to see increasing profitability from our antibody collaboration and expect further margin expansion as we begin to realize drug substance yield improvements from a new Regeneron-developed manufacturing process for Dupixent. Finally, we recorded Roche collaboration revenue of $222 million in the first quarter for our share of gross profits from ex-U.S. sales of Ronapreve related to a previously signed contract. We do not expect to record any additional revenue from Ronapreve in 2023, absent a new contract.

Moving now to operating expenses. First quarter 2023 R&D expense increased 28% year-over-year to $960 million as we continue to invest in our pipeline to drive organic growth. The increase in R&D was primarily driven by higher headcount and related costs and funding of the company's growing pipeline, which now encompasses approximately 35 programs in clinical development in more than 15 ongoing late-stage studies with additional study starts expected this year. These late-stage programs include our expanding fianlimab development program, upcoming Phase III studies in earlier lines for our heme-onc assets, as well as ongoing development programs for Dupixent and itepekimab for which we now record our full 50% share of development costs as a result of the Libtayo transaction.

SG&A expense increased 32% year-over-year to $515 million due to higher contributions to an independent, not-for-profit patient assistance organization, higher headcount and related costs, and the impact of the Libtayo transaction. First quarter 2023 COGM was $249 million, up 26% versus last year, due to increases in shipments of ex-U.S. commercial supplies of Praluent to Sanofi and manufacturing costs for Dupixent. Reimbursements for these production costs are recorded as part of Other Revenue and Sanofi collaboration revenue, respectively.

Shifting now to cash flow and the balance sheet. In the first quarter of 2023, Regeneron generated $1.2 billion in free cash flow. We ended the first quarter with cash and marketable securities, less debt, of $12.3 billion. We have continued to strategically deploy our cash to deliver on our capital allocation priorities, which are focused on investing in innovation, both internal and external, as well as returning capital to shareholders.

We purchased nearly $700 million of our shares in the first quarter with $3.1 billion remaining under our existing authorizations as of March 31. Additionally, as George discussed, we announced the collaboration with Sonoma Biotherapeutics, investing $75 million through an upfront payment and equity investment to add a new approach to our scientific capabilities.

I'd like to conclude with some select updates to our financial guidance and outlook for 2023. We are updating 2023 COGM guidance to be in the range of $820 million to $880 million, an increase of $90 million at the midpoint, reflecting increased shipments of ex-U.S. commercial supplies for Praluent and Dupixent to Sanofi. Importantly, these anticipated incremental expenses will be reimbursed by Sanofi, generally resulting in a neutral impact to Regeneron's 2023 operating profit. Approximately half of the incremental $90 million of reimbursements from Sanofi are expected to be recorded as Sanofi collaboration revenue, with the balance recorded as Other Revenue.

As a result, we now expect 2023 other revenue to be higher than 2022 Other Revenue. For modeling purposes, second quarter 2023 Other Revenue is expected to be the lowest of the 2023 quarters, with the vast majority of the remaining Other Revenue to be recorded in the second half of this year. We are also updating our 2023 gross margin to be between 89% to 91%. The change in expected gross margin is primarily driven by an unfavorable change in product mix, as well as an increase in the start-up costs associated with our new fill/finish facility located in Upstate New York.

Finally, we are lowering our guidance for our effective tax rate to 10% to 12%, reflecting the benefit of higher than previously anticipated stock-based compensation deductions. In conclusion, Regeneron continued to deliver robust financial results in the first quarter of 2023, and the company remains well positioned to drive further growth in the remainder of the year and beyond.

With that, I will now pass the call back to Ryan.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thank you, Bob. Josh, that concludes our prepared remarks. We'd now like to 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. Please go ahead, Josh.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Mohit Bansal with Wells Fargo.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Great. Maybe, Marion, if you could elaborate a little bit on the EYLEA, or Vabysmo dynamic at this point a little bit. Given the weakness in the quarter, you did mention that Vabysmo is taking some share. So if you could elaborate on where the share is coming from? Is it more of a switch? Or do you think it is also some new patient starts? And your confidence level in terms of flipping this situation once high-dose EYLEA comes along.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure, very happy to comment. And as I noted, as we're reporting on the quarter performance on a sequential basis, we did see with EYLEA, if I look at a sequential quarterly basis, we did see with EYLEA a net product sales decrease of 4%. As I mentioned, it was driven by a number of factors. Certainly, competitive pressure is one, but we also reflected on while we had slightly higher demand volume. It was offset by lower sequential wholesaler inventory levels and overall higher sales-related deductions.

Specifically as it relates to competitive pressure, I would say that this is overall competitive dynamic in the anti-VEGF category, not something that we would necessarily identify with a particular product, more the totality of competition. I will comment that in the quarter, we certainly maintained a 70% branded share and over at approximately, I believe it was a 46% share in the overall anti-VEGF category. So certainly standard of care with EYLEA. And very importantly, we look forward to launching aflibercept 8 milligram, as I mentioned now, is about 7 weeks away.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks, Marion. Josh, next question, please.

Operator

Our next question comes from Robyn Karnauskas with Truist.

Robyn Kay Shelton Karnauskas - Truist Securities, Inc., Research Division - Research Analyst

Just some questions on LAG-3, and thinking about the first-line melanoma market and you're going to be having data relatively soon. So what -- I guess it's a multi-part question. What is the bar for success, do you think, for the combination to be competitive? And when you think about penetrating into ipi-nivo and checkpoint monotherapy buckets for first-line melanoma, can you help us understand how big these buckets are to actually model this opportunity better?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Well, as we've already reported, based on our 2 confirmatory cohorts, we are seeing remarkable overall response rate increases over the PD-1 standard alone, almost doubling with much longer PFS. If we get anywhere near these numbers along with a satisfactory safety profile, which we had seen a favorable safety profile in the small studies, but if we reproduce or come anywhere close to reproducing these results, we believe that this will establish an entirely new standard of care for this disease.

And as we all know, the first-line melanoma opportunity is very large, but we're also moving laterally and earlier and so forth into many additional applications within the melanoma opportunity itself. We're going -- we're already now in adjuvant and entering neoadjuvant studies. We'll also be going to other cancer settings, including lung cancer and so forth. So we consider this a major opportunity, and we can only help to -- if we approach the data that we've already seen in our earlier studies, it really has a chance to make a huge difference for these patients.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks, George. Josh, please move to the next question.

Operator

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

Tyler Martin Van Buren - TD Cowen, Research Division - MD & Senior Equity Research Analyst

For high-dose EYLEA, is there anything left to do on the regulatory front? And have you guys started labeling discussions yet? And forgive me for the follow-up, but just briefly for housekeeping and related to your response to the first question and prepared remarks, Marion, can you quantify the impact of the lower EYLEA inventory for the quarter?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

So on the regulatory update, we don't comment on ongoing stuff. I'd like to say we're looking forward, hopefully, to the action of the FDA on June 27 and the launch promptly thereafter. Marion, you can comment on the inventories.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure, Tyler. I can give you the detail there. So while still within the normal range of inventory related to your question on EYLEA in the quarter in the normal range is 5 to 10 days, our inventory levels were approximately 3 days lower at the end of the first quarter of 2023 compared to the end of the fourth quarter of 2022. And when you do the calculation on that, as I'm sure you all will do, that's a negative impact in the first quarter net sales of approximately $70 million.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks, Marion and Tyler. Moving to the next question please, Josh.

Operator

Our next question comes from Terence Flynn with Morgan Stanley.

Terence C. Flynn - Morgan Stanley, Research Division - Equity Analyst

I was just wondering on the commercial footprint for Dupixent here, given the potential for another indication with COPD. If you could talk about any additional footprint or spend that's required there. And again, maybe just how to think about leverage on the forward.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure, very happy to comment. And as we think of Dupixent and all the different therapeutic disease areas and specialists that we cover with some indications, there certainly is an amazing and wonderful synergy. And you give an example with COPD launch potentially. And obviously, today, we're in market with our asthma indication and with nasal polyps. As we look forward with COPD, it's a really important launch, an indication to help patients in a way potentially that, as George described, hasn't been achieved ever for this population.

So we have the opportunity to use our existing footprint, specifically in covering respiratory specialists, pulmonologists. But we'll also evaluate very closely with Sanofi, as you've seen us done in dermatology indications, where we might need some additional coverage and where the synergy is adequate, and we'll be very disciplined and very thoughtful about that. But you can be assured that we'll make certain that we appropriately give commercialization effort to such an important indication as COPD.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

And it's interesting, just to add a little bit to that, Marion, that the allergists seem to have really understood the concept of type 2 inflammation. And the fact that type 2 inflammation is not a collection of individual unrelated diseases, it's a collection of related diseases.

And I was speaking to an allergist the other day and said when you take an asthma patient, if you look carefully, many of them will have nasal polyps. And if you talk to dermatologists, they're beginning to understand that when they're treating atopic dermatitis, people who have concomitant asthma, for example, they get a benefit there.

So I think Dupixent really is kind of unique. And we are talking to the main doctors, including the allergists, the dermatologists and the pulmonologists, with some of the ENT, as Marion said. We're covering them all, and many of them are covering multiple diseases.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Yes. I'll add to the enthusiasm here too in COPD, the potential to have a second product following Dupixent as well. So this will be a very important future area for helping patients.

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

So with regards to your question on leverage, first off, welcome back. Nice to have you back on the team. You'll see with the issuance of our 10-Q this morning with regards to our share of the antibody alliance, we're going to pick up quarter year-over-year for the quarter, roughly 300 basis points. And again, that's half the economics on the transaction. So we're beginning to see really great leverage in to Marion's comment that should continue on with the COPD indication.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Obviously, we work very closely with Sanofi and all of these. And I believe it's fair to say they're equally excited about the potential for the future of Dupixent in all the current and, hopefully, future indications.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks, everyone. Next question please, Josh.

Operator

Our next question comes from Christopher Raymond with Piper Sandler.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Maybe another Dupixent question, if you don't mind. Len, I know you don't talk about regulatory interactions. But when you had the COPD data, I think the signal that I got from you guys that seemed to be pretty strong was that you were hoping to have some discussions with the agency on BOREAS alone.

Just kind of -- maybe can you map out how you anticipate communicating the results of that discussion with FDA once it happens? And then maybe a second part of that question is, our KOL checks have been pretty consistent when we asked them about this data. They're very impressed. But one of the things we've heard consistently is that this cutoff for eosinophils of greater than 300 is sort of arbitrary and that this drug would see and maybe add value to patients with eosinophil counts as low as 200 to 250. Just maybe your thoughts on this, and how you anticipate to sort of take advantage of that. Thanks.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Yes. Well, let me start with the regulatory aspect. The -- obviously, what we're all staring at is an incredibly positive study -- I mean a Phase III setting, where, as we've mentioned, that we not only improve people's exacerbations, but we also improved their lung functions and the lung function and their quality of life, and all these other measures that were also part of the statistical hierarchy.

So when you have a very robust study like that, and you have -- I don't know how many patients we currently have, but it's a huge number, a very large patient commercial database and so many indications, I think Sanofi and Regeneron concur, that this is something that we should be discussing with the FDA to see how they feel about whether or not there is a potential filing. We don't have any update for you, if it's something once we have that meeting, if it's something definitive, I'm sure Sanofi and Regeneron will figure out a way to properly communicate that.

In terms of cutoffs and what have you, I think it's a little bit premature to talk about that, other than to say you stick with what you brought to the trial, which is a cutoff of 300. And that's where you commercialize. But the future work one can look at in other studies, that's something obviously we'll think about. But I remind you as George and both Marion mentioned, our IL-33 antibody gives a larger, although somewhat overlapping population potentially. So we really could have cover many, many, many patients, a great opportunity to help people with what has been really a very unfortunate progressive loss of lung function.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Yes. Len to your comment, you were talking about numbers of patients. I can fill in there that as of March worldwide, we had over 600,000 patients on Dupixent in 57 countries.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Right. So that speaks a lot to the post-marketing experience of the product.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Absolutely. Next question, please.

Operator

Our next question comes from Brian Abrahams with RBC Capital Markets.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Shifting gears, you recently reported with your partner, APP data in Alzheimer's. I'm curious what this proof of principle potentially opens up beyond this indication? How quickly you can expand into some of the other neurodegenerative diseases that you mentioned, and your level of confidence overall in the safety of the program.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Well, we think that the data were really game changing. I mean this is the first time in human history that one has been able to use this very exciting siRNA technology within the brain and silence, to a very high degree, higher-than-expected levels an important pathological gene. Obviously, this could have important implications for Alzheimer's itself. But as you point out, the application goes way beyond that. To every neurodegenerative disease, there are also other types of CNS diseases as well. We have a number of programs that we're working with Alnylam. We have an exclusive relationship with them on all of these CNS targets.

And we're trying to expedite a lot of them based on the exciting results from this initial clinical work into the clinic. And we're also trying to expedite many of our programs that are behind as well. So we really think this opens up an entirely new way of addressing a whole assortment of brain diseases and neuropsychiatric diseases, not just neurodegenerative diseases.

We're in exciting times. We have to go cautiously. We have to hope that the initial results, in terms of the safety profile and so forth, hold up. We're all in the early days, and we don't know for sure. But the low doses with which we saw this very marked reduction in the target give us a lot of hope that we can have a sufficient therapeutic window that will be applicable to these large variety of diseases that could potentially be addressable by this modality.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

So I just wanted to add to that, 2 things: streaming on a different channel, I think you might find some further data being discussed by our friends at Alnylam, which will speak to not only impressive result, but the durability of the effect. And one of the other things I want to comment is really to echo something George said. The recent amyloid plaque clearing antibody results by Lilly, previously by Biogen, are really quite important. But as George said, even with the adjuvant, there's still going to be a tremendous burden of Alzheimer's disease.

But what the data seem to be speaking towards is that the process is ongoing, is that the pathologic role of amyloid is not over. And as George said, having another way, perhaps upstream, stopping the production of amyloid, maybe even a more advantageous way to deal with the ongoing process that amyloid seems to be generating, which is what the antibody data, I think, seems to be speaking to us.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Okay, thank you. Josh, next question please.

Operator

Our next question comes from Salveen Richter with Goldman Sachs.

Salveen Jaswal Richter - Goldman Sachs Group, Inc., Research Division - VP

So with regard to EYLEA high-dose becoming the larger share of revenue on the forward here, can you give us any color here on discussions with payers and how to think about formulary fit?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

So Salveen, we are actively involved in all aspects of launch preparation. And certainly, that includes all elements and levers associated with premarket activities and then getting ready for the launch activities. We do have in place a very sophisticated market access, payer and pricing team. And at the appropriate times, they most definitely will be involved with payers and other organized customers that will be important in our launch efforts. Additionally, this is a customer base that we know very well from our -- over a decade experience with EYLEA, so we look forward to potential FDA approval and launch activities and working with all of our customer stakeholders.

I'll also mention again the importance in the retinal space of the key opinion leaders and prescribers and the enthusiasm they have for a product that really can be a game changer for their patients in terms of visual acuity, duration and the safety profile they've come to know with EYLEA. So we're very enthusiastic and look forward to the launch opportunity, and we'll be ready.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Okay. Next question, please.

Operator

Our next question comes from Akash Tewari with Jefferies.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

So just to clarify the moving parts on U.S. EYLEA, there was a 5% market share loss, a $70 million inventory impact and then lower price. Any color on what the net price impact was on the quarter, and how it should evolve in the back half of '23? And additionally, should we expect EYLEA market share to hold at 70% going forward, or potentially start to grow again as high-dose EYLEA launches?

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

So let me take some of the items, and others may want to jump in here, too. But first, I would say that some of the calculation related to market share shift is not exactly correct. There was some decline in the quarter, but not to the height that you mentioned. When I look at market shares through the entirety of the first quarter period, then as described, it is a more competitive market, a variety of, obviously, competitors, very low cost and others. And overall, EYLEA performance is in a very strong situation as we look today to planning for our future portfolio and the aflibercept 8-milligram launch.

As to the specifics of pricing and calculation to the net, I can't give you specifics on that number. But I do think that we gave you some transparency on the overall item related to inventory, overall competitive pressures and then our preparation for our next launch in the category coming up shortly, we hope, following FDA approval.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Obviously, as Marion mentioned, on a sequential basis, demand was modestly up. So obviously, we were offset by the factors that Marion referred to.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

All right. Next question, please.

Operator

Our next question comes from Chris Schott with JPMorgan.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

I just had a question on the IL-33 in COPD. I guess just the success you've had with your kind of study design and results with Dupixent increase at all your confidence in that program. And just, I guess, maybe just elaborate little bit on, how you see kind of those 2 agents kind of interacting as we think about the space overall?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Yes. We are more optimistic, obviously, that all of our decisions, all of the data that led us to do the particular study and the particular population of patients in COPD with Dupixent was made based on a lot of factors. And we also had, from our Regeneron Genetics Center, very strong human genetic evidence suggesting that it would have activity particularly where we actually saw activity. And so all of that gives us confidence -- since

we use the same criteria, the same approaches and so forth to plan and design our IL-33 study, certainly, the fact that everything that went into one and it all worked so remarkably well gives us confidence that the same approaches will lead to success with the IL-33.

The results with Dupixent were really outstanding, as we've already mentioned. Not only a clinically meaningful reduction in exacerbations, but we hit all these other important endpoints, most importantly, improvement in lung function, as well as you rarely hit these quality-of-life improvements unless you have a really active agent that the patients can really feel the difference for their function and for their quality of life.

With IL-33, the genetics is very strong. We have a Phase II study in the subgroup that we're doing the Phase III study in. It was in that group. We have demonstrated a 42% reduction in exacerbations in the Phase II study. This will be an overlapping population with our Dupixent population. We think we already have a chance to really make a huge difference for this high unmet need population that really has had no new mechanism of action of drugs brought to help these patients for a very, very long time. We have one with Dupixent, and we're hoping to hit another one with IL-33. And this could make such a huge difference for these patients who have been suffering for so long without much hope. It could really make a big difference for this population.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

I just wanted to repeat, maybe George said it probably 2 or 3 times, but maybe it's worth saying a fourth time. In yesteryear, the way you did drug development is you identified a target based on some biology or what have you, you did your Phase I and Phase II, and you hope that Phase II was an indicator for how your Phase III was going to turn out. And obviously, that's how it is still done today. But what George mentioned is that we can layer on top of it in sort of a unique way our genetic insights and look and validate and say, is it reasonable to expect that if you block a certain target that you're going to have a beneficial effect? Is that target associated with the disease you're treating?

And I know George said it 3 times, but I think it's worth saying a fourth time. That really gives you added confidence that's uniquely Regeneron in many respects, how we can get this genetic information. People ask us a lot, if you think about the number of people that have been sequenced in the world, George can comment when I'm done, I know we've sequenced a large part of them and coupled that with all this medical, anonymized medical information. We use that in so many ways, not only to identify targets, but to validate the work we're doing in specific targets, specific diseases. George, how much have we done?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

We've seen about half of all the humans who have been sequenced.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

So I mean, that's a large database of millions. And I think that, that is what you're hearing is that that's why we had more confidence perhaps than others did with Dupixent and now with anti-IL-33.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Since Len expanded just a little bit, just let you know how it works. What we do is we identify genetic variations that mimic the blocking of a drug or exacerbation of this type 2 pathway. And what we showed for Dupixent, for the genetic variations that mimic Dupixent, those people were protected from COPD, particularly the type 2 COPD patients.

Whereas increased activity of the IL-4/13 path was associated with more disease. And obviously, that turned out to be the case. I mean it's human genetics. It's a very, very powerful predictor. And we've done the same thing, as Len said, with IL-33, where we have genetic variation at mimics blocking the pathway or exacerbating the pathway. And as I've said, this is one of the secrets to our ability to have high success rates in our studies is we use that as a criteria to make our decisions going forward.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Okay. Thank you. Next question please, Josh.

Operator

Our next question comes from Yatin Suneja with Guggenheim Securities.

Eddie Hickman - Guggenheim Securities, LLC, Research Division - Research Analyst

This is Eddie Hickman on for Yatin. I was wondering if you could talk about the draft guidance from the FDA on the anti-VEGF trial designs? And if that impacts your outlook on the high-dose program at all?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

I don't think that has any impact on us, on our program.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thank you, Len. Next question, please.

Operator

Our next question comes from David Risinger with SVB Securities.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Yes. And I guess I'll just go straight to the question. Len, you had mentioned in your opening remarks the ongoing diversification of the company's revenues away from EYLEA. Could you please discuss your expectations for EYLEA U.S. sales growth in the near term, including the total EYLEA franchise prospects after Regeneron launches the HD?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Let me go right to the answer since you ran right to the question. We don't give future guidance on specific quantitative measures of our sales. On a qualitative basis, Marion has said, that we're anticipating that the combination of EYLEA and 8 milligrams aflibercept will be a growth franchise over time for the company.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Okay, thank you. Next question, please.

Operator

Our next question comes from Hartaj Singh with Oppenheimer.

Hartaj Singh - Oppenheimer & Co. Inc., Research Division - Research Analyst

Just a quick question on linvoseltamab. At ASH, you presented a Phase I data, and these were your dose ranging, I guess, data. Really interesting data you present at ASH. At ASCO, what should we expect to see? Will it be dose expansion data? And then any duration also on the patients from ASH? And then what would FDA like to see before you can go ahead and submit the application?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Well, I think you're going to actually see an update on our pivotal Phase II data, the actual data that was a little bit more maturing, with a further update we will be hoping to submit to the FDA for our BLA. So the data will be very close. We think the data will even get better as it matures. Because as we all know, response rates and so forth get better with time as you follow these patients. But these data are going to show what we believe are the potential to have best-in-class efficacy, as well as safety in the favorable dosing schedule based on the results that we'll show from our pivotal study at the upcoming ASCO.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

All right. Thank you, George. I think we have time for 2 more questions.

Operator

Our next question comes from Carter Gould with Barclays.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Sorry to belabor EYLEA. I guess just simply, what's the pricing pressure that you guys highlighted in Q1. Was that a seasonal dynamic? Or would you characterize it as that? Or something more permanent around that market landscape going forward?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Before Marion answers that, I just want to come back to the BCMA story a little bit, because it's one that I'm particularly excited about. The bispecific field, which was initiated by Regeneron in terms of using bispecifics, I think we were the first to put a bispecific into patients, has obviously become a very crowded space and it's sometimes hard to differentiate what you've got compared to what the competition has and you look at somebody claiming one thing and you're claiming another and so on and so forth.

But if you take a dispassionate view, I think for the BCMAxCD3 program, you could really see a differentiated molecule and the potential to be best-in-class. Antibodies are not all created equal. Bispecifics are not all created equally. You do see differences. Clinical trial programs and not all created equally. This is one I'd really encourage you to think a very careful look at and compare. Now there was some question on EYLEA. Marion, you're going to answer that.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Sure. And Carter, getting back to your question on the competitive dynamic and pricing pressure. I think if you look at the anti-VEGF category and look at it over time, go back multiple quarters, there has been increasing competitive pressure. And that does then have a corollary to some extent on pricing dynamic, and that would go forward.

But I just want to share and remind all that in the category, in the VEGF category, what really is rewarded is product profile. And as we look at a product like EYLEA that launched and was a game changer in the category, that was its profile not being the least costly, right? There's been a low-cost alternative, very low-cost alternative for a very, very long time, but it was the product profile that made the difference for prescribers and patients.

So that will always be a very important dynamic to look at going forward, and certainly has strong interest for prescribers as we bring a new product into the marketplace following FDA approval with aflibercept 8 milligram. But to your point, pricing pressure will continue in this category. But what's most important is product profile and the clinical attributes that the patient experiences.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks. Last question, please.

Operator

Our last question comes from Evan Seigerman with BMO.

Evan David Seigerman - BMO Capital Markets Equity Research - MD & Senior BioPharma Research Analyst

I'd love to have you expand on some of the feedback you've been hearing from physicians regarding the 8-milligram dose. Maybe some color as to how they plan on using it and assuming approval comes in June.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

So of course, the updates on actual prescribing will be even more important as the product comes into the marketplace and physicians have an opportunity to use it and select patients. We obviously have done a lot of work with our medical team, looked at the clinical data with specialists. And to give you an early answer to your question, I think there's opportunity for a variety of patients that are deemed to be appropriate candidates. And there's a range. Certainly, when physicians are considering new patient starts, it's very attractive.

We obviously have a strong portion of patients that are naive to EYLEA today, but in the future, the question becomes, why wouldn't you start a new patient with a product that gives you all the visual acuity benefits and safety of EYLEA, but it also gives you that durability and duration? Because obviously, physicians know their patients are anxious and don't like to have more injections in the eye than they need to. Similarly, you might have a patient that's very well controlled on another product, maybe EYLEA, maybe another product in the anti-VEGF category. But you'd like to give them that opportunity for duration and, maybe in some cases, if the product is in another area of the anti-VEGF category, improved visual acuity and duration.

So I would say it's the combination of interest for patients who might be broadly anti-VEGF category switch patients, or the potential for new patients as well. I hope that helps, and I look forward to the day when we can give you specifics for market experience.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thank you, Marion, and thanks to everybody who dialed in, and for your interest in Regeneron. We apologize to those remaining in the queue that we did not have a chance to get to. As always, the IR team is available to answer any remaining questions that anyone may have. Thank you once again, and have a great day, everyone.

Operator

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