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A New Chapter for the Regeneron-Sanofi Alliance

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Presentation

Operator

Welcome to the Regeneron and Sanofi joint conference call announcing their expanded collaboration to include next-generation Type 2 medicines. My name is Michelle, and I'll be your operator for today's call. [Operator Instructions] Please note this call is being recorded. I would now like to turn the call over to Ryan Crowe, Senior Vice President, Investor Relations at Regeneron.

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

Thank you, Michelle. Good morning, good afternoon, and good evening to everyone listening around the world. Thank you for joining today's call to announce the expansion of the collaboration between Regeneron and Sanofi. We have members from the management teams from both Regeneron and Sanofi here today. But before we get started with introductions and our meeting agenda, both companies will read their forward-looking statements.

For Regeneron investors, 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, development programs and related anticipated milestones, collaborations, finances, regulatory matters, payer coverage and reimbursement, changes to drug pricing regulations and requirements and our drug pricing strategy, 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.

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François-Xavier Roger
Executive VP & CFO

For Sanofi investors, we would like to remind you that information presented in this call contains forward-looking statements, which are subject to substantial risks and uncertainties that may cause actual results to differ materially. We encourage you to read the disclaimer in the presentation, and we also refer you to our Form 20-F on file with the U.S. SEC on our French universal registration documents. Let me turn the call over to Ryan.

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

Thank you, François. Now moving to today's speakers and our agenda. Joining me on today's call are Dr. Leonard Schleifer, Regeneron's Co-Founder, Board Co-Chair, President and Chief Executive Officer; Dr. Belen Garijo, Sanofi's Chief Executive Officer; Dr. George Yancopoulos, Regeneron's Co-Founder, Board Co-Chair, President, Chief Scientific Officer; and perhaps most pertinent for this call, the visionary and principal inventor and developer of Dupixent as well as the technologies that have delivered not only Dupixent but all of the new assets being added to the alliance today. And finally, we also have François Roger, Executive Vice President, Chief Financial Officer at Sanofi.

For the presentation today, Len and Belen will begin with a high-level overview of the deal, its strategic rationale, highlight the productivity of the Regeneron-Sanofi collaboration over the past 2 decades as well as how the alliance intends to leverage the R&D engine and commercial platform the companies have jointly built over the years. Then, George will discuss the antibodies that the companies will now jointly develop as well as their development timelines.

Finally, François will review the key financial and operational terms for the transaction. After prepared remarks conclude, the remaining time will be available for Q&A. Additional members of the management teams from both Regeneron and Sanofi will also be made available to answer questions at that time.

With that, let me turn the call over to Len and Belen to begin today's discussion -- presentation.

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

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Thank you, Ryan, and thanks to everyone for joining our call today. It's an exciting day for Regeneron and Sanofi as we extend our highly successful collaboration by adding differentiated assets that have the potential to address Type 2 inflammatory diseases. For more than 2 decades, our alliance with Sanofi has been one of the most productive collaborations in the history of the bio-pharmaceutical industry. Together, we have developed and commercialized Dupixent, which redefined what was possible for the treatment of Type 2 inflammatory diseases. Like any long-standing partnership, our journey has not been without challenges, but we have worked through them and are now focused on the renewed momentum of our alliance and the opportunities ahead.

Today, we are opening a new chapter. Our agreement extends our shared leadership well beyond Dupixent. Regeneron is contributing four fully human, next-generation, long-acting antibodies. The lead candidate targets IL13 and is currently in the clinic for atopic dermatitis. Regeneron is also contributing three preclinical candidates, including an IL4/IL13 bispecific as well as antibodies to the IL4 receptor alpha and interleukin-4. These are also long-acting. George will provide more details on these opportunities later in his presentation.

Sanofi, in turn, is contributing an option for lunsekimig, their IL13/TSLP nanobody to potentially be added to the alliance at Regeneron's discretion pending Phase II results in chronic obstructive pulmonary disease.

Together, we are combining both companies' development capabilities to bring forward this next wave of innovation for Type 2 inflammatory diseases. Assuming successful development and regulatory approval, we will launch these medicines by leveraging our jointly built global commercial platform that currently serves more than 1.5 million Dupixent patients worldwide. The deal construct is also deliberately simple and aligns our shared motivations to advance the standard of care for Type 2 inflammatory diseases.

Regeneron and Sanofi will equally share development and commercialization costs while splitting any global profits 50-50. In addition, Regeneron will receive a $1 billion upfront payment from Sanofi, along with the opportunity to earn up to $7 billion in additional milestone payments upon the achievement of specified development, regulatory and commercial milestones.

Moving to Slide 7. Together, Regeneron and Sanofi have built something remarkable. What started nearly 20 years ago as a modest collaboration combining Regeneron's antibody platform with Sanofi's global development and commercial reach has become one of the most productive alliances in our industry. We now look forward to the next decade and beyond, building upon the success of Dupixent with the ambition to maintain our long-standing leadership within immunology.

Briefly to Dupixent, the standard of care for Type 2 inflammatory diseases, which is now one of the most widely used antibody medicines in the world, invented at Regeneron by George Yancopoulos and developed by George and his team in collaboration with Sanofi. Based on second quarter 2026 global net sales of EUR 5.2 billion as recorded by Sanofi, Dupixent is now annualizing above EUR 20 billion across 9 indications. In the U.S., Dupixent is the #1 biologic prescribed by dermatologists, pulmonologists, allergists and ENTs, and leads in total prescription share in 8 of its 9 approved indications.

As we look to the next generation of Type 2 medicines, extending the alliance beyond Dupixent is about more than simply adding new antibodies. It is about pairing these next-generation assets with a proven global development platform and a sophisticated commercial engine that has already established leadership in Type 2 inflammation and is well positioned to sustain that leadership into the future. Let me turn the call over now to Belen to further discuss how we will build on our strong commercial position in immunology.

Belen Garijo Lopez
CEO & Director

Thank you, Len, and hello, everyone. I am super excited with our announcement today since this is an important strategic step forward for both companies as we aim to sustain leadership in atopic dermatitis with a novel long-acting IL13 antibody, as well as the next-generation pipeline candidates. And let me tell you why we are so excited with the journey ahead.

First of all, is the market potential. While advanced therapy penetration has significantly grown over the last few years, thanks in large part to Dupixent, only about 20% of eligible U.S. patients are being treated on advanced therapy today. There are many opportunities for growth, and we expect the market to nearly double over the next 5 years. Despite the very successful development and commercialization of Dupixent, there is still a need for meaningfully longer dosing intervals without compromising efficacy or safety. And this is what we intend to address with our novel long-acting IL13. And we see an attractive opportunity here as we will leverage our established commercial footprint, the prescriber relationships that we have developed over many years as well as the patient support infrastructure to accelerate our next generation of alliance products.

Moving into Slide #10. Let's take a closer look at the atopic dermatitis market. AD is a large market with more than 2.5 million patients suffering from moderate to severe atopic dermatitis in the U.S. alone. We are projecting the U.S. market reaching

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approximately $20 billion in sales by 2032 and to continue to increase thereafter with advanced therapy penetration exceeding 50% by 2040, consistent with what we have seen in other mature immunological diseases such as rheumatoid arthritis or Crohn's disease.

AD is not a saturated market. It is a market in early stages of growth with a large untreated population and a significant growth trajectory ahead. Yet, there is a clear unmet need around treatment burden. For a chronic condition, this is the opportunity our long-acting IL13 program is designed to capture: superior dosing convenience without compromising efficacy or safety.

Let me now further elaborate on Slide #11, how we will continue to build on our successful development and commercial platforms, honing in on each partner's strengths. On R&D, Regeneron brings a pioneering, highly innovative antibody discovery platform. We will also leverage our leading immunology and atopic dermatitis development expertise across both companies. We have built deep and trusted relationships with health care providers across dermatology, allergy and pulmonology, just to name a few.

We operate a comprehensive patient services platform and have an industry-leading global supply and device capability that is serving patients across more than 60 countries. Our long-standing relationship with payers and our strong market access capabilities globally will serve as a competitive advantage and further support the acceleration of our next-generation medicines as part of this highly successful alliance.

Finally, on Slide 12, it is important to keep in mind something that Len already mentioned is that we have strengthened the governance of our expanded alliance and simplified the way we plan to operate this to further drive our successful collaboration. On development, Regeneron will hold final decision-making authority while both partners have aligned financial commitments to support that development. On commercial, Sanofi will continue to have final commercial decision rights, including access and pricing, while Regeneron will now have increased participation in key payer engagements.

I'm very pleased with the progress we have made to expand our collaborations with clear roles and clear accountability. This strengthened alliance setup will no doubt, better position us to bring these next-generation medicines to patients. And last but not least, mutual trust will be the guiding principle in this extended relationship.

Now let me pass it along the call over to George to discuss and build on these next-generation antibodies.

George D. Yancopoulos
Co-Founder, President, Chief Scientific Officer & Co-Chairman

Thanks, Belen. Let's move to the next slide. Before I discuss the new antibodies being added to the alliance, I'd like to briefly reflect on the incredible Dupixent development journey that Regeneron and Sanofi have jointly shared over the past decade plus. We used our VELOCIMMUNE platform to invent dupilumab, an interleukin-4 receptor alpha blocker, working from the hypothesis that interleukin-4 and interleukin-13 are the key regulators of Type 2 inflammation.

Over the years, we gathered more and more evidence that all these diseases share dysregulation of the same pathway. And in fact, it is the remarkable and consistent efficacy of Dupixent across all these diseases that has definitively proven that IL4 and IL13 are the key central and shared drivers of all of these interrelated diseases: from atopic dermatitis to asthma to eosinophilic esophagitis and beyond. Dupixent has indeed proved to be a breakthrough for so many of these patients, as I see every day with my own daughter.

It took not only great science and technology to bring this remarkable first-in-class and best-in-class drug to so many diseases and to so many patients, but an innovative and creative clinical development effort that broke new ground many times, addressing disease populations that, in many cases, had never been studied before at large scale. To do this, Regeneron and Sanofi joined forces and study by study, patient by patient, indication by indication, delivered a series of positive pivotal trials.

Dupixent is now FDA approved for nine distinct diseases spanning the skin, gut and respiratory systems, for patients ranging from infants as young as 6 months to the elderly. And in many of these indications and settings, Dupixent became the first and leading therapeutic. The clinical results across these nine distinct diseases and age ranges have strongly validated the key central role of IL4 and IL13 in the underlying Type 2 inflammation driving all these diseases. We will continue to apply these learnings and insights to design the next generation of medicines.

On Slide 15, you can see the four molecules Regeneron is contributing to the expanded alliance. All are fully human antibodies, naturally derived using the same VELOCIMMUNE technology that delivered Dupixent and more than a dozen other approved antibodies, and all are highly and specifically selected to meet the goal of increasing patient convenience by dramatically extending dosing intervals for Type 2 diseases. All programs are on an expedited development path. Our long-acting IL13 antibody is already in the clinic, where we have already confirmed its remarkable long-lived pharmacokinetic properties. It is now being tested in atopic dermatitis patients with registrational studies on track to begin in late 2027 or early 2028.

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Unlike Dupixent, our antibody to IL13 is a ligand blocker with a substantially prolonged half-life with a target dosing interval of at least every 3 to 6 months. Our proprietary VELOCIMMUNE technology enabled us to invent the only fully human, naturally-derived, non-heavily engineered IL13 antibody with a naturally strong target affinity and a favorable pharmacokinetic profile that supports an extended dosing interval, positioning it to be potentially best-in-class.

The three other programs are expected to be clinic-ready next year. The long-acting IL4/IL13 bispecific blocks both cytokines, and we believe it can produce a therapeutic effect similar to Dupixent in diseases requiring blockade of both. This bispecific was also uniquely enabled by our proprietary VELOCIMMUNE technology. This common approach, resulting in shared biopharmaceutical properties, greatly accelerates clinical development of this bispecific as well as of all of our related assets. The IL4 receptor antibody blocks the same target as Dupixent, but is expected to have a significantly longer dosing interval. The antibody to IL4 binds the ligands and may have distinct applications with extended dosing opportunities as well.

By targeting the IL4 and IL13 pathways at both the ligand and receptor levels and across monotherapy and combination approaches, we are building a highly versatile portfolio, providing flexibility to select the right molecule for the right disease while creating multiple opportunities for future clinical development and commercialization, and all were invented with the same VELOCIMMUNE platform, which we believe has proven that it produces the world's best fully human antibodies with the best biopharmaceutical properties.

Moving to the next slide. With these next-generation programs, we are building on the successful development model that Regeneron and Sanofi have built over the years. By combining our complementary capabilities and deep expertise in Type 2 inflammatory diseases, we intend to accelerate clinical development to potentially bring new treatment options to patients in the coming years.

Importantly, these programs will advance on parallel tracks. Learnings from each program will inform the others, allowing us to apply insights across these programs as data emerge. Moreover, Regeneron and Sanofi also bring a distinct advantage with our vast clinical experience and success that led to nine approved Dupixent indications across multiple age groups from infants and beyond. Our deep experience with these diseases, clinical endpoints, regulators and investigator networks gives us a meaningful advantage in designing and executing these programs efficiently.

Let me now turn the call over to François to review financial terms for the transaction. François?

François-Xavier Roger
Executive VP & CFO

Thank you, George, and hello, everyone. Moving to Slide 18. Let me share with you the main financial terms of this transaction. Sanofi may pay up to $8 billion of total considerations to Regeneron. That amount includes an upfront payment of $1 billion upon signing, as well as a certain number of milestone payments linked to development, regulatory and commercial achievements. The financial terms of this agreement reflect a genuine partnership of equals. Both R&D costs and global profits will be shared 50-50 between Regeneron and Sanofi for the new alliance medicines.

This means that there will not be any R&D development balance for the new antibodies since the R&D costs would be equally financed by both partners as they are incurred over time. That symmetry of the economics reflects a balanced partnership where both companies have aligned incentives around commercial success. Net sales will continue to be recorded as per our existing reporting practice, meaning that Sanofi will record net sales. The transaction will be reflected in both Regeneron and Sanofi fourth quarter 2026 financials.

Let me add one final important comment about the prior agreement that covers Dupixent. The terms of this original agreement remain unchanged, including the Dupixent profit sharing. Let me now hand over back to Belen and Len for their final remarks.

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

Thank you, François. Before I turn it over to Belen, let me offer just a few brief closing thoughts. We are excited about the future of Regeneron's strengthened alliance with Sanofi. First, it adds four Regeneron invented next-generation antibodies to the alliance that has developed and commercialized Dupixent. It also establishes a simple aligned framework for sharing risk and reward. Global profits will be split 50-50 with additional payments tied to development, regulatory and commercial milestones.

In summary, I am confident that this strengthened alliance gives our next-generation programs the best opportunity to move rapidly through development, reach patients around the world, extend our leadership in Type 2 inflammatory diseases for years to come. Let me now pass it along to Belen for a few additional closing remarks.

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Belen Garijo Lopez
CEO & Director

Len, thank you very much. I'm equally pleased and enthusiastic about the expanded alliance and the opportunities that we will be able to create together. This agreement brings a stronger and more durable framework for our alliance, clearer governance, greater transparency and the resolution of the litigation between our companies. It allows both organizations to move forward together and focus fully on advancing the science and importantly, delivering for patients.

Finally, this extended alliance positions both companies to sustain our leadership in immunology, capitalizing on Regeneron's next-generation science with the global development and commercial platform that we have built together over the years for Dupixent. And in relation to this, we have a very solid foundation to bring these potential new medicines to patients. This is also a first step into the transformation of Sanofi, and we are excited about the opportunities that lie ahead. We look forward to sharing the progress in the months and years ahead.

And with this, I would like to turn the call back to Ryan to begin the question-and-answer session. Ryan?

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

Thank you, Belen. This concludes our prepared remarks. We will now open the call for Q&A. Before we go to our first question, let me first introduce additional members of the Regeneron and Sanofi management teams that will also be available to answer questions. From Regeneron, joining Len and George are Marion McCourt, Executive Vice President, Commercial; Chris Fenimore, Executive Vice President, Finance and Chief Financial Officer; and Joseph LaRosa, Executive Vice President, General Counsel and Corporate Secretary. And from Sanofi, joining Belen and François are Manuela Buxo, Executive Vice President, Head of Specialty Care; Paulo Fontoura, Executive Vice President, Head of Research and Development; and Jamie Haney, Executive Vice President, General Counsel.
[Operator Instructions] Michelle, can we please go to the first question?

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Question and Answer

Operator

Our first question comes from Evan Seigerman with BMO Capital Markets.

Evan David Seigerman
BMO Capital Markets Equity Research

Congrats on the updated partnership. So a question for the Regeneron management team. So you clearly have a lot of cash on your balance sheet and adding $1 billion more only adds more to that. Why did you kind of accept the $1 billion upfront to kind of restructure this? Was there anything else that you could have done potentially to strengthen your position? I'd love for color on that.

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

Yes. Thanks for the question, Evan. Look, we do have a lot of money on the balance sheet. I like to say because we're lucky to have George as a genius inventing our molecules, so we don't have to throw out money on poor business development discussions. But we're always open-minded. And as far as the transaction with Sanofi, it was just a matter of creating a fair relationship, and that's what the payment was intended to be part of.

Operator

Our next question comes from Luisa Hector with Berenberg.

Luisa Caroline Hector
Joh. Berenberg, Gossler & Co. KG, Research Division

Congratulations. So my question is really on the sort of overlap in the mechanisms versus Dupixent and whether you considered other mechanisms, perhaps any thoughts on trispecifics and whether there was any attempt to add external assets as you were renegotiating? Or is this essentially you're tied to the original mechanism from Dupi and therefore, that's the reason for that persisting all the way through?

George D. Yancopoulos
Co-Founder, President, Chief Scientific Officer & Co-Chairman

Well, we have done an enormous amount of science, biology, human genetics based on our data -- our proprietary data set involving millions of humans that have been sequenced and characterized with multiomics and for their EHRs and medical records. And I think the overwhelming data demonstrates the critical central roles for IL4 and IL13 in all of these Type 2 diseases. And the evidence suggests that right now, there are not other pathways that are strongly driving or can supplement the remarkable efficacy and safety profiles that we've seen with Dupixent. So our goal was to build on what we've learned, but to create molecules that create and give more benefit to patients, particularly by maintaining the efficacy and safety, but providing more convenience.

By creating all of these molecules using the same format that doesn't depend on human engineering that invariably results in compromising the biopharmaceutical properties of molecules, increasing propensities for anti-drug antibodies and creating all sorts of other problems... By using the same uniform platform, but by creating agents that deliver much longer action, we think we really have an opportunity here to change the treatment landscape for already the diseases we've identified, as well as more potentially.

So I guess the bottom line is all the science suggests, and we're the ones who delivered it, that these are the central drivers. Everything else in the history of the science here does not support that adding other mechanisms is going to further enhance the efficacy without also hampering the safety profile. Let me remind you, the safety profile of addressing this mechanism through Dupixent is really essentially unprecedented.

Unlike almost any other biologics, we're not causing immunosuppression. We're actually, if anything, benefiting and correcting immune deficiencies or distractions that are seen in these patients. And so the science really supports exactly what we're doing, and we created the science. So we know it best.

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

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As far as adding any outside molecules, I think <if> the scientists feel that it makes sense. We, of course, are able to consider that.

Operator

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

Nicholas Lorusso
TD Cowen, Research Division

This is Nick on for Tyler. Congrats on the deal. $7 billion is a significant amount of downstream milestones, but I'm curious about the breakdown of the milestones over time. Could a significant portion of those be near term? Just a rough idea on timing for some of these would be great.

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

Yes. Those milestones are spread out over development, approvals, sales. I'm not going to go through all of them. The most near term we'll mention is start of Phase III. That will be the first $1 billion milestone. François, anything to add?

François-Xavier Roger
Executive VP & CFO

Nothing to add. I think that you got access to the details of the milestones is very transparent anyway, but I agree with what Len said.

Operator

Our next question comes from Victor Floch with BNP Paribas.

Victor Floch
BNP Paribas, Research Division

This is Victor Floch from BNP Paribas on behalf of Peter Welford. On lunsekimig, actually, it would be very nice if I can get Regeneron and Sanofi to comment on that. So first, for Regeneron, I was just wondering why was lunsekimig not entered into collaboration at this stage given the Phase II data that we've seen? And secondly, for Sanofi management, what are the development plans for lunsekimig in asthma and CRS moving forward?

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

I think we were very sensitive as an alliance not to create situations where we'll be competing with each other on our own additional assets outside of the alliance. The TSLP/IL13 bispecific or DuoBody technically that you referred to is in Phase III, and it does address one of the targets in the alliance. So there is an option for us to bring it into the alliance if the data suggests it's worth moving forward.

Manuela Buxo
Executive VP & Head of Specialty Care

Yes. And just to build on -- this is Manuela, Victor. Just to build on Len's point, we felt that in the interest of the partnership and with the COPD program being the one that is already in Phase III and the most advanced, to give an option to Regeneron to bring that into the partnership makes a lot of sense. And then for other programs, we will wait until we see the COPD data and then decide whether we continue for other indications as well.

But that will be a joint decision further down the road when we have more data. But we're excited about that potential, and we'll make that decision when we see the Phase III.

Operator

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

Kevin Meli
RBC Capital Markets, Research Division

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This is Kevin on for Brian. We just wanted to ask maybe if you can comment on -- for Regeneron management team. If you can comment on the kinds of targets that the agreement covers. I know you mentioned the IL4/IL13 pathway. But if you can comment perhaps on whether any upstream or downstream targets to the cytokine receptor interaction itself could perhaps make sense should any encouraging data be seen along the way?

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

Yes. We certainly can look beyond what the alliance is now focused on. But I think as George eloquently said, focusing on IL13, IL4 or the IL4 receptor is where our initial efforts will be. We will, of course, look at opportunities that could be complementary downstream, upstream or left stream, right stream. But right now, we're focused for the reasons George said.

George D. Yancopoulos
Co-Founder, President, Chief Scientific Officer & Co-Chairman

Well, if you're talking about targets upstream or downstream in the same pathway, for example, a STAT6 or so forth, I think what we have to understand is that we find those types of targets interesting and exciting, but they are not going to be delivering any better efficacy than blocking the actual target molecules themselves. And of course, there's always going to be safety concern with new modalities of action.

And I think that what we have to consider when we consider potentially bringing in or discussing those sorts of approaches in terms of -- really in terms of what's in the patient's interest, the medical health care system's interest and so forth and what is really more convenient, a twice a year subcutaneous injection or having to remember to take a daily pill, if, and it's a long way if, if it could possibly even be competitive in terms of both efficacy and safety.

So of course, we're thinking about all these things and so forth. But it's not as if we're talking about new targets that are going to somehow enhance efficacy and safety here. We're talking about alternative ways to somehow treat something that is now so elegantly and beautifully and safely and effectively treated with the existing approaches, but now with these new approaches that may enable a twice a year or even less intensive dosing interval. It's hard for me to imagine convenience regimens that are going to be able to compete against, I think, what we may have to offer going forward.

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

I should just add that while we're not at the moment thinking about new mechanisms, we do have some really interesting ideas about new indications and new approaches using the same molecules. We'll have more to say about that in the future.

Operator

Our next question comes from Florent Cespedes with ODDO BHF.

Florent Cespedes
ODDO BHF Corporate & Markets, Research Division

Florent Cespedes from ODDO BHF. A quick one on the long-acting IL4 combinations. Maybe -- I know it's early days, but could you share with us what you have in mind in terms of potential targets and diseases with this product?

George D. Yancopoulos
Co-Founder, President, Chief Scientific Officer & Co-Chairman

Well, as we all know and as our science has demonstrated that out of the nine diseases that we're already approved for, some of them might only need blockade of one ligand or another, while other ones require, for optimal efficacy and safety, blockade of both ligands. We have now put ourselves in the alliance in a position, as we outlined, to really specifically select and pick and put into the right position, the right reagents for the right diseases.

But because they're all generated from exactly the same platform, sharing very similar biopharmaceutical properties, in fact, they all share extensive sequence identity amongst themselves and so forth. This will greatly expedite clinical development programs when you're dealing with four molecules that can be chosen and picked correctly for the right setting and the right indication that in many other ways are very similar biopharmaceutically allowing us to really learn from one and apply to the other.

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I also want to add to what Len said in terms of the playbook that everybody else is following. Everybody else is essentially following the playbook that we've been writing together with Sanofi over the last 10 to 15 years. They're just trying to do what we've already done. As Len said, we wrote that playbook, and we have a lot of ideas about how we can rewrite the playbook going forward, particularly by having these very unique and special assets from which we can specifically pick and choose for the right setting and the right indication. So expect a lot more innovation going forward in this field from Regeneron and Sanofi.

Operator

Our next question comes from Akash Tewari with Jefferies.

Akash Tewari
Jefferies LLC, Research Division

So I think we're going to get -- we already saw some data with Zumi in asthma, where we did see some pretty robust FeNO reduction. And I think in the next couple of years, we're going to get asthma data with just a long-acting IL13. Let's say that looks in line with what we've seen with Dupixent. How does that change your team's view in terms of prioritizing these four assets if it becomes a bit more clear that IL13 alone would be sufficient in a lot of these Dupixent-like indications?

And just for the Sanofi team, the confidence for the bispecific going into COPD, given we've seen strong atopic dermatitis data from the Pfizer trispecific this morning, and we didn't necessarily see the same signal with your drug.

George D. Yancopoulos
Co-Founder, President, Chief Scientific Officer & Co-Chairman

Well, let me just say that you all have to remember that the newest IL13 blockers are essentially just reengineered, more highly engineered, which is more likely to cause problems as opposed to advantages than already existing IL13 antibodies. So the new IL13 antibody is just a rehumanized version of lebrikizumab or Ebglyss, which actually already failed in asthma and other respiratory indications.

So despite the possibility that it would have, which we know, partial activity in some of these respiratory indications, it is highly unlikely to match the unmatched efficacy profile and safety profile of Dupixent in these respiratory settings, whereas we think this is exactly why we endowed our pipeline and these assets with the particular ability for the right setting to block either one cytokine or both effectively together.

So people can take shots and hope that a new IL13 antibody that is just essentially a reengineered version with no different fundamental activities than an old version is going to behave differently or one can build the tried and true mechanistic understanding that we have convincingly delivered over the last 10 to 15 years.

Manuela Buxo
Executive VP & Head of Specialty Care

Paulo, can you comment on the lunsekimig question, please? We cannot hear you.

[Technical Difficulty]

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

We can't hear you, Paulo. Maybe when he gets back on, we can come back to him.

Operator

Our next question comes from Naresh Chouhan with Intron Health.

Naresh Chouhan
Intron Health Advisors Ltd

Just want to get some color on what the deal economics imply. I would have thought that, and presumably, this is a question for Belen and François, but I'm happy to hear from all of you. I would have thought that one of the key assumptions when you were agreeing the deal would have been around the Dupixent rebates and any kind of flexibility that might allow future commercialization of the new asset.

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On our analysis, the $8 billion total deal and the $1 billion upfront can only really be justified if you still got Dupixent without biosimilars when the new drugs launch. So should our base case given this deal now be that the Dupi LOE is now pushed towards mid-2030s?

François-Xavier Roger
Executive VP & CFO

I think we have consistently repeated what we have said, which is the LOE anyway is coming in March 2031 as far as the U.S. is concerned, anyways, the U.S. is what it matters. We are working actively in order to extend the LOE of Dupixent. There is no certainty at this stage, but we are reasonably confident on the fact that we should be able to extend it by a few years. And if you look at similar cases, I mean, on average, it has been extended by a few more years. Once again, there is no certainty at this point in time, but we are actively working to extend the LOE of Dupixent a few years behind the original LOE.

Belen Garijo Lopez
CEO & Director

And let me add to what François mentioned and what I said, during the introduction, this is a deliberate first step in the transformation of Sanofi and the alliance is now in a much stronger position to offer and progress a number -- of promising medicines, as George and Len were discussing. Obviously, this doesn't preclude that we are going to be moving our strategic road map moving forward. And without preannouncing anything, you will be hearing from us on how do we optimally prepare for the loss of exclusivity of Dupixent by 2031, 2032.

Paulo Fontoura
EVP, Global Head of Research & Development (Pharma)

Sorry. But can you hear me now?

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

Sorry. Paulo, we can hear you. Please go ahead and address that lunsekimig question.

Paulo Fontoura
EVP, Global Head of Research & Development (Pharma)

Yes, exactly. So really sorry about that. I was logged out and needed to log back in. Paulo Fontoura, Head of R&D at Sanofi. And just to comment on the lunsekimig question. What I think we -- our belief right now, and this is very much the spirit of the alliance that we want to make decisions based on data. Obviously, the data in the mild to moderate asthma is the only one in CRS with NP, the data that we have now. We still believe that the trial in COPD is worthwhile to pursue. These are Phase II/III design trials, very robustly powered and designed to really clearly demonstrate the signal there.

So at this point, it's not really about excitement. It's really about delivering the data that allow us to make a good decision. I think both mechanisms have shown in COPD that they have the potential to be beneficial for these patients. So again, our focus right now is really on delivering data for that experiment.

Operator

Our next question comes from Salveen Richter with Goldman Sachs.

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

Could you speak to the base case here for timing of market entry for these assets and how you could potentially accelerate development?

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

I would simply say -- just a couple of words on that, as soon as possible.

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

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Yes, we anticipate a pivotal study start for the long-acting IL13 either in late '27 or early '28. And obviously, we'll be moving as quickly as we can through that program to enable registration.

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

You have to recall, Salveen, the humor aside. The FDA understands what these molecules, based on what Dupixent has delivered. We understand through the work that we've done together this pathway better than anybody else. We know how to get the patients. We know what the endpoints are. We know what the trial designs should be. So we really do feel we can go very rapidly here, but the proof will be in the pudding.

George D. Yancopoulos
Co-Founder, President, Chief Scientific Officer & Co-Chairman

We have to remember, as Len said, I mean, we're the ones who identified and defined pharmacodynamic features, biomarkers, everything that you have to understand to best optimize dosing profiles and regimens to achieve optimal efficacy and safety as we've proven over and over and over again in our Phase III trials. All of those learnings are going into the expedited clinical development program. And thus, anybody should expect that the people who invented and created this entire field will know how to make sure that they take advantage of all of these learnings in terms of expediting things going forward.

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

Okay, Michelle, I think we have time for 3 more questions.

Operator

Our next question comes from Richard Vosser with JPMorgan.

Richard Vosser
JPMorgan Chase & Co, Research Division

Just wanted to go back to STAT6. It seems very clear that STAT6 is not a part of, or going to be a part of the collaboration. Just wanted to ask on Sanofi's STAT6, where this fits in, therefore, and how that could be commercialized within the framework or outside the framework of the collaboration. Just thoughts on that program.

Manuela Buxo
Executive VP & Head of Specialty Care

Thank you, Richard. This is Manuela. So I think on the -- first of all, as Belen said earlier, our immunology strategy is a core strategic focus area for us, both inside of the alliance as well as outside of the alliance. So this program that you mentioned and some of the other programs that we have ongoing, will continue and are not impacted by this. We are looking at several disease areas here. And the truth is also in immunology, there's so much unmet need and so many areas for opportunity that we're really looking at it very broadly and are committed to immunology, both, of course, with Regeneron in the alliance, but also outside of the alliance.

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

Thanks, Manuela.

Operator

Our next question comes from Alexandria Hammond with Wolfe Research.

Alexandria Janet Hammond
Wolfe Research, LLC

So you and your competitor showed some data this morning at EADV, and that drug is now moving into Phase III trials to demonstrate superiority over Dupixent. So I guess in this growing <competitive> environment, how are you thinking about putting these alliance drugs head-to-head versus Dupixent with the primary endpoint of showing superiority?

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

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I didn't quite understand the question. I heard you say that somebody is trying to take on Dupixent, and good luck. It's always great if patients can get something better than the remarkable safety and efficacy that Dupixent brings. But I didn't get the second part of your question.

Alexandria Janet Hammond
Wolfe Research, LLC

Just, will you run head-to-head trials with your new alliance drug?

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

I think George and the team will be unfolding the strategy fairly quickly. And so maybe you can just be a little patient there.

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

More to come on that, Alex. Let's move to our last question, please, Michelle.

Operator

Our last question comes from Graham Parry with Citi.

Graham Glyn Charles Parry
Citigroup Inc., Research Division

Just -- it's a commercial question really is what evidence you have or payer discussions you have that dosing interval would be sufficient to retain reimbursement and market share in a biosimilar Dupixent or dupilumab market. So the 50% of advanced therapies by 2040 that you're talking about, how much of that do you think would be dupilumab biosimilar and how much would be the non-dupilumab?

Manuela Buxo
Executive VP & Head of Specialty Care

Yes. So thanks, Graham. First of all, remember that the atopic dermatitis market, first of all, it's a highly heterogeneous market. It's a large market. And as Belen said earlier, you're talking right now about 20% advanced therapy penetration. So there's a lot of room for growth. We know that there -- for some patients, there's a preference for longer-dosing drugs. And this is what obviously, the IL13, the long-acting IL13 and potentially some of the other drugs we'll offer. And you also have to remember that the capabilities that we have built in the alliance around the commercial infrastructure, the deep relationships that we have with health care providers, but also capabilities around access and payer relationships, we will leverage those for any of the new assets that will hopefully come to fruition. And that is a real competitive advantage, we believe.

We'll also, as we discussed earlier, look at how do we design the programs, the trials in a way to drive that level of differentiation. But there's definitely opportunities given patient needs and different patient preferences for different products, whether it -- again, efficacy and safety is a must, right? But then some people will prefer longer dosing drugs, other people will prefer other things. It depends a little bit on patient preference, but there is a big opportunity in this market that is currently still to be unlocked, and we believe we have a real opportunity to do that within the alliance given what we have built collectively.

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

Thanks, Manuela. Len, do you have any closing thoughts?

Leonard S. Schleifer
Co-Founder, President, CEO & Co-Chairman

Well, so I just want to say that we've talked a lot about drugs. We've talked a lot about diseases. We've talked a lot about markets. I just want to say a few words about people. At Regeneron, we're particularly lucky to have the guy who invented all these technologies and these drugs. George Yancopoulos is here, who's going to continue to lead this development effort. So we're really fortunate and proud of that. And we are very pleased to welcome Belen to our alliance that I hope will continue to make a difference for the patients because it really is about making a difference for the patients.

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Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

Thanks, Len. And thank you, Michelle, our operator, and thanks to everyone who joined the call today. We apologize to the many folks who are in the queue. We don't have time to get to you today. But as always, the Investor Relations teams at Regeneron and Sanofi are available to answer any other questions that you may have. Thank you, everyone, and have a great day.

Operator
Thank you for your participation. You may now disconnect.

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