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REGN.OQ - Regeneron Pharmaceuticals Inc at Oppenheimer Healthcare Life Sciences Conference

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OVERVIEW:

Company Summary

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Ryan Crowe Regeneron Pharmaceuticals, Inc. - SVP of IR

CONFERENCE CALL PARTICIPANTS

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

PRESENTATION

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

Great. Thank you, everybody, for joining us on the second day here of this track of the Oppenheimer Healthcare Conference of 2024. Got David Snow, the SVP and the Global Head of Dupixent franchise and Ryan Crowe, the SVP of IR, joining us here giving us a presentation, which I'm really looking forward to. Regeneron has been always a constant supporter of ours at our healthcare conferences. Really appreciate having them back.

David will give us an update on DUPIXENT. And then from there, we can jump into our fireside chat or just an overall update on the franchise, and we can jump into the fireside chat after that. So please take it away.

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

Thank you, Hartaj and always great to be a part of the Oppenheimer Healthcare Conference, and Happy Valentine's Day to everybody out there.

Just do a quick forward-looking statement, and then I'll hand it over to David for some opening remarks before we get to Hartaj's questions. So I would like to remind you that remarks made today may include forward-looking statements about Regeneron, and each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in such statements. A description of material risks and uncertainties can be found in Regeneron's SEC filings.

Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. David take it away.

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

Thanks, Ryan. It's great to be a part of this today. Always excited to talk about DUPIXENT. It's a remarkable brand. It's transformed hundreds of thousands of lives, since our first launch in 2017 in atopic dermatitis in the U.S. It's continued to grow quite quickly. As we add new age groups, new indications, I think it's a multidimensional growth opportunity still. And I've been in the industry for 30 years, and I've never seen anything like it. And it's been a lot of fun to be a part of this over the last 5 years.

So just to give you a quick snapshot in 2023, if we look back with our collaboration partners at Sanofi, we had a very good year. We almost got to \$12 billion, \$11.6 billion in net sales. That's a 33% growth rate. We also continue to improve our profitability. We added like, as I said, we added new indications and age groups. We have AD PEDS in Europe and Japan, EoE Adults in Europe, Prurigo Nodularis in Japan. And not just talking about 2023 and 2024 in the U.S., we've already improved the label in hand and foot atopic dermatitis and in EOE pediatrics, which is an incredible indication we're really glad to have that.

As you know, last year, we announced some groundbreaking data in COPD. With both the BOREAS and the NOTUS studies could not be more excited about what that means for us, and we subsequently filed both in the U.S. and Europe. We have 5 very distinct type 2 inflammatory disease indications. We are #1 in each of those in the U.S. and NBRx, in new prescriptions. And we are #1 in total prescriptions and 4 out of 5, and I expect we'll get to the fifth one before too long.





So AD has, continues to be our largest overall opportunity, and we had -- continue to have very strong growth overall -- the AD biologic penetration rate is in the teens, glad to see this approach the teens, get there. And certainly, the younger age groups are contributing to that overall growth rate.

Second to AD is the asthma business. And despite the fact when we launched, we had 5 competitors, biologic competitors in the market. There are 6 now. We are driving to achieve the #1 position overall. We already have that in NBRx, as we expect to surpass Xolair shortly and achieve that in TRx's. Nasal polyps is just another amazing story of growth. We are the first-line option there. We continue to have a very high overall market share. It is a blockbuster indication by itself, just an incredible opportunity. And the transformations for patients and what they're able to smell with this group has just been really powerful, and we certainly continue to see a great growth opportunity there.

If you'll bear with me, there's more indications. Eosinophilic esophagitis itself is another amazing indication. We're the first there. Talk about transformations for patients and their families. We've got 25,000 patients on therapy right now. We just added, as I mentioned, the pediatric indication they are down to -- amazingly down to 1 year of age. We have some added benefits in terms of weight gain within the labeling, symptomatic improvement, really helpful, very excited about EoE.

We have another dermatological indication we launched recently, prurigo nodularis. It's off to a great start as well. We already have about 11,000 TRx's there, really impressive to see what's going on in that indication as well as kind of an additional opportunity for us in dermatology, kind of the -- an embarrassment of opportunities, I think, when I look at overall and then we've got COPD that's coming around the corner, and we look forward to having that and other indications like BP down the road, there's a few others that we're looking at.

But overall, look, we've benefited hundreds of thousands of patients around the world. It's a mega blockbuster brand. We still think there's significant growth opportunities, as I mentioned, across markets and age ranges and just continuing to penetrate the markets. So we look forward to continuing that.

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

David, that's fantastic. And by the way, when Ryan read that initial statement, whenever I hear that, I'm like, if I was in your shoes, David, I'd be like, I'm not saying anything after that. And just -- now I'm just kind of scary. No, I'm just kidding.

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

I don't want to scare anybody. Sorry about that.

David Snow Regeneron Pharmaceuticals, Inc. – SVP and Global Head, Dupixent Franchise

I've been around Hartaj, I'm good with it. I understood.

QUESTIONS AND ANSWERS

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

Yes, it's good to be a little bit scared. It keeps us honest. But -- but David, before we just talk a little bit about COPD, and we want to spend time really there. You said something really interesting. You've got high teens presentation or some are teens penetration in atopic dermatitis. Biologics have -- other than asthma have not really had a lot of penetration into indications. Can you just kind of give us -- what do you think is still the delta? Like where you're at? And where do you think biologic penetration could get into the various indications?

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David Snow Regeneron Pharmaceuticals, Inc. – SVP and Global Head, Dupixent Franchise

I certainly think it has much more room to grow. If we look at other biologic benchmarks in psoriasis and RA that have been out longer, but they also have a lot of players there. I think you could safely say that getting into the 25% to 30% range is certainly should be something we ultimately get to overall as in these indications. There's certainly that need. There are lots and lots of patients out there that continue to -- they need the benefits that we can provide with DUPIXENT. I would expect that we should see that.

And you're right, I think in asthma it's probably 25% already. And again, I think there's still a lot of room to grow in asthma alone.

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

Yes. It's interesting on that point, when we've spoken with a couple of KOLs about 3 or 4 years ago, they definitely mentioned that there were some folks that were forward-thinking allergists and treaters, pulmonologists that would take biologics up very quickly and others were a little bit more cautious and maybe need to get experience with that. Are you still experiencing that in the various indications?

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

We have seen really robust growth among prescribers and obviously, in areas where -- we are newer, like in GIs, where we just started with eosinophilic esophagitis. We're seeing month-over-month improvement in the number of physicians who are prescribing DUPIXENT. And then we're seeing an added depth of prescribing among those that have comfort with that.

So again, in areas like allergy where we have multiple indications, we have lots of multiple indication writers, depth of prescribing is very strong. It's probably the strongest in dermatology, where we've been out the longest. So we're seeing great growth across the existing pool of physicians, and we're always looking to bring more in.

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

Yes. No, that's a great sign. You're seeing patient penetration could increase and that the physicians also seem to be kind of like jumping on board over time. Now maybe you can just go to COPD. Assuming you get approval sometime in the next few months, the middle part of the year or maybe somewhere around there, what could the COPD launch cadence look like David?

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

Yes. So I think we announced -- I think our Sanofi partners mentioned that we had filed in December. We expect to get some feedback shortly on breakthrough designation. Well, we got breakthrough designation on BOREAS. And so we expect to find if we're going to get accelerated review. If we do that, then we could be launching towards the end of June -- at the earliest, and I think even if we had a normal cycle on that, which I can't imagine would happen given the data results, that would be towards the end of October.

The great thing is -- Hartaj is, we already have a very strong pulmonology team that's out there. So many of the prescribers or the HCPs that would be writing for COPD patients, we already reach on asthma -- and certainly, there's a few more out there that might be more focused on COPD, but we'll have those within the mix, and we're really excited about that team being able to bring COPD forward should we get approved.

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

And one of the things we've done, again, a call in COPD with physicians, and they said that there are some patients that exhibit even with these high eosinophilic patients, some comorbidity with asthma. How are you thinking about that, David? Like do you think the patient population is fairly well prescribed for the kind of patients you'll be looking for, assuming you get approval for launch?



David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

Yes. So the work that we've done and often Hartaj, the case is our epidemiology is probably on the low side. We've seen really nice growth in areas like EoE, where it may not have been as quite as accurate. And then PN is also another one, where we're very pleased with the results we're getting. COPD, we think there's at least 300,000 bio-eligible patients out there, who could benefit from the higher EOS Group. But you're right, with the asthma medication, and we know that there's these ACOS patients out there. There are probably some other patients as well that could benefit from DUPIXENT, depending on how they get at that.

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

Yes. And then how -- what's the overlap in terms of the patient allergist, immunologist I imagine the asthma, would you have to be going out there to additional doctors for COPD? Or is it pretty much close to 100%?

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

We have very strong overlap overall. There's a few that are COPD, more COPD specific that we'll pick up. We're in the process of making sure we have that coverage now, working to make sure we have that group covered. So it's not a massive lift on our part. We also, as you know, a big focus for us is mitigating as much disruption as possible. So we're able to accomplish that and be prepared for launch whenever it comes.

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

Yes. Got it. And then can you just talk to a little bit about assuming you get approval whether in June and October, David, what's sort of the next steps? I mean, is it -- I know with EYLEA, we've now gotten condition to that temporary versus permanent J code. Are there any kind of specialties to the reimbursement landscape here that we should be aware of -- assuming launch again in COPD?

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

So because DUPIXENT has such a robust payer footprint right now across our various indications have been out for years. We have a very good standing with the payers and access, and that includes both commercial and Medicare. So we have a very good position right now. So don't foresee that folding COPD into that is a huge lift for us. So we'll certainly are doing all the work now to make sure we're prepared for that.

And again, like I said, we've already got that footprint in place. So our launch sequences, obviously is to get our final label to understand what that is to get our promotional materials out there. Our payer group will be out there working ahead of us just trying to make sure that we've got everything in place. That will build over time. And with Medicare, as you know, it's usually a 1-year cycle and to get started towards the summer for the next year. So we're already in for the '24, '25 framework and then we'll have to build in the future, they'll have to think about what the implications are of having COPD with a biologic.

The last piece is, we're a pharmacy benefit. We're not really a J code. That's a medical benefit. So again, the ease of the safety profile, the ease of use, the auto-injector we've got should easily be able to accommodate the vast majority of patients with at-home administration, which the payers also like...

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

Yes. No, no, which I'm liking more and more, as I'm listening to you. So just on that note, the other thought that I would have is, if you don't mind just giving us some sense of what's the breakdown between allergists and immunologists. Is it similar to asthma, which I imagine would be all



pulmonologist, sorry, all pulmonologist. So in COPD, would you basically just detailing to all pulmonology or would there be some allergists or other kind of physicians there?

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

Yes. There are some other specialists who kind of consider COPD, but it really is most of the patients end up with a pulmonologist seeing them. And again, remember, we're talking about GOLD 3 to 4, more serious patients that are having exacerbations that are already on triple therapy. Most of those are going to end up with the pulmonologist. And that's -- again, that's a great sweet spot for us.

Primary care, they do like to treat these patients. But obviously, once they start to have some difficulty on a triple or they've had a breakthrough single exacerbation, they're probably going to get referred to the pulmonologists. And since we're already covering the vast majority of those, that's really going to help us in terms of being able to get the message out there.

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

Yes, it's kind of amazing that on this background therapy of the triple that you're getting such good reductions in exacerbations. I used to cover COPD, when the pharma companies were tackling it about 5 or 10 years ago, when they were coming up with triple therapies. And this is -- I think the exacerbation data is pretty -- in COPD is really something special.

What do you think -- David, is there anything with the COPD launch that, for lack of a better term, keeps you up late at night, -- like are there things that you think are important to sort of focus on or think about?

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

I get that question a fair amount, you can imagine. DUPIXENT is -- like I said, it's been the most unique brand I've ever worked with. It's incredible. What gives me a lot of comfort really -- they don't really have that much that keeps me up at night. The comfort that I've got is that our biggest indications in terms of AD asthma, nasal polyps continue to grow quite quickly. They're there.

COPD is an incredible opportunity for us -- it's another blockbuster potential indication. There's a lot of patients out there, we're excited about that. But we have so many great indications that are still in the steep part of their growth curve. They continue to grow at an amazing rate. It's just trying to make sure that we balance the overall opportunities we've got that.

We don't over-index on one that we're actually trying to pull all of those through. That's probably the biggest challenge we've got, but there's not really much that keeps me up. I think from a competitive standpoint, we've been able to withstand a lot that's come at us, and we expect that there will be more in the future. There's always going to be payer pressures or payer pressures 20 years ago. There'll be payer pressures in 10 years. But when you have a therapy like DUPIXENT with the efficacy, with the safety profile, with the comfort that physicians have and the transformations that you see with patients -- I can't -- it's not really a lot that I'm concerned about.

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

Yes. That's good to hear. And really nice. I just want to mention online, somebody just asked again, who are the presenters so I'll just mention that again, David Snow, the SVP of Global Head, DUPIXENT Franchise; and Ryan Crowe, the SVP of Investor Relations. And again, Hartaj Singh, I'm one of the analysts here at Oppenheimer. So just as an FYI. I think in our own world, we get so caught up in the details. Sometimes, it's -- it's nice to get these questions.

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David, a question that we had sort of that was maybe a little bit more kind of like analyst-like question. And it's important for us, how much more incremental sales and marketing expense would you want to need to have on your team? Would it be mostly all marketing expense? Or do you need some sales in medical liaison type of people, too?

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

Now you're going to get me in trouble with Ryan. No, actually, I think we're probably not going to share a lot with that. But I think the comfort is, again, we have a very strong pulmonology team. We're covering a large subset of the market out there. We know what that looks like. Look at the data we've got, that's incredibly encouraging. It is pretty much -- and we've been launching Hartaj indications almost every year, 1 or 2 -- so we really know the sequence here. The team is well experienced in how do we step through those paces. And again, I don't foresee this as a big lift for us in terms of the operational standpoint.

Obviously, you're entering into a new category, where you're first in market, we've done that a few times already. I think we've got a good track record of understanding how do we lay out the Type 2 story, how do we present the biologic option here, where it hasn't really been before. We know how to do that. We've got a very good platform in terms of PSP, in terms of how we pull patients through when the prescription gets written.

So all those are pretty familiar to us. And for those who don't know me, I'm the Regeneron partner to Sanofi. So we have a partner with Sanofi globally. I'm the commercial lead for Regeneron working with Sanofi been on the DUPIXENT brand for about 5 years across many of these launches, not all of them. And so again, just trying to make sure we get right.

Certainly, a big focus in the U.S. as the first launch market, our largest market, and then -- but we also have great penetration in many of the large markets around the world working with our Sanofi counterparts.

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

Yes. Well said. I can see, Ryan, kind of visibly relaxed and smiling as you were giving that answer. He was like, Dave is doing a good job. Don't give into these Wall Street analysts. And then just -- maybe we can just switch a little bit to itepekimab, itepekimab, right? It was kind of interesting why I bring that up. Last year, we had 2 folks from Regeneron, right?

Ryan and I believe 1 was a lady who was, I believe, Head of the IL-33 franchise, and she said, Hartaj, don't sleep on itepekimab. I'm kind of paraphrasing what she was saying. So we've got to spend some time there. Maybe if you can just give us a quick update, David, as to where that program is right now and then how you think about it from a commercial perspective?

David Snow Regeneron Pharmaceuticals, Inc. – SVP and Global Head, Dupixent Franchise

Ryan, do you want to give the -- I'll give a perspective on it, if you want to give an update on where we are in terms of the program and what the (inaudible)?

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

Sure. And that lady last year was Jamie Orengo, she's on the Inflammation Immunology Research Function and has been integrally involved in the development of both DUPIXENT and itepekimab as well as various other exciting l&I targets that we have in our preclinical portfolio.

On itepekimab, Sanofi and Regeneron are conducting 2 pivotal studies, AERIFY-1, AERIFY-2. There is not much difference between them. I guess AERIFY-2 has a small cohort of current smokers, but the primary analysis for both will be reduction in the annualized rate of COPD exacerbations among nonsmokers or former smokers. So those that have previously smoked greater than 10 years of smoking -- and so we are looking at specifically at former smokers in these studies.

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These studies passed futility assessment last year, and we expect to fully enroll both studies mid-to-second half of 2024 with pivotal data expected about a year later. So in 2025, -- so IL-33 is an interesting genetic marker. We've seen with pretty high correlation that loss of function of IL-33 is associated with the reduced risk of COPD. We've published these genetic results, along with the results of the Phase II study for itepekimab in the Lancet respiratory medicine publication in last year, July -- I'm sorry, 2021 in July, not last year. We're a couple of years beyond that.

So this study looked in all comers. They looked at both current and former smokers and did not hit its primary endpoint. It was not significant. But when we did an analysis of a prespecified analysis of current and former smokers, we found there was no benefit on current smokers. But in former smokers, there was a highly statistically significant, 42% reduction in annualized exacerbations, which obviously would be even better than the data that we saw with DUPIXENT, where we saw a 30% reduction in annualized exacerbation rate in BOREAS and a 34% reduction in the NOTUS study.

So the populations are slightly different as well. with DUPIXENT, which is a drug that we are now -- this would be the 6th disease that has a type 2 inflammation signature we had at baseline, measured eosinophil count and they had to exceed 300 at baseline. Itepekimab looks at basically everyone, every former smoker that is, regardless of their eosinophil count.

So I think the programs are pretty similar, but with some key differences in terms of the similarities there -- they're both 52-week studies. They both have the same primary endpoint, annualized reduction, moderate to severe COPD exacerbations, same key secondary endpoint, which is FEV1, which is a lung function measure. The timing is slightly different. I think we did the secondary endpoint for BOREAS and NOTUS was at 12 weeks in AERIFY program, it's at 24 weeks. But same endpoint.

All patients in both programs were on background maximum inhaled triplet therapy, and it excludes patients with an asthma diagnosis, which is very important to note for both DUPIXENT and for itepekimab. So like I mentioned, the key difference is that -- we're only enrolling former smokers in the IL-33 AERIFY program. You don't need to have a minimum count for eosinophils at baseline. And for itepekimab we're looking at both a -- every 2-week regimen and an every 4-week regimen. So some differences, but more alike than different, I would say, in terms of the programs and how we're looking at COPD.

And once we get the data, like I said sometime in probably the second half of '25, we'll see what we have and how it might fit into David's commercial organization. This is a very large population, even larger than that with which DUPIXENT can address, nearly 1 million patients, we believe, are former smokers and regardless of eosinophil count in the G7 markets, versus about 500,000 current or former smokers with eosinophils above 300.

So an incremental opportunity, some of it overlaps. And I think once we get the data, we'll be able to figure out what works best for those patients with the higher eosinophils, but in general, this would broaden the respiratory franchise at Regeneron in a very meaningful way, assuming we get results similar to what we saw in Phase II.

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

Yes. Ryan, that helps a lot. David, I mean, in terms of -- just from a competitive dynamic, I guess, when I worked in the industry for a little while now that long, having more products in the bag always help, right? I mean you get you potentially get another product in the bag on top of DUPI, does that help you? Or you just think DUPIXENT with all its indications, especially getting COPD approval is just going to be so far ahead that it's going to be difficult for folks to catch up?

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

I don't see any challenge with that, and I've been through my career in several situations, where we had multiple brands within the same therapeutic area. In this case, what I found really interesting was when I was reading up on itepekimab last year, some of the basic biology around IL-33 was clear and more well elucidated than it was for IL-4 and 13, -- so we've -- now we've got this great BOREAS and NOTUS data. And now we're trying to bring itepekimab along. You heard Ryan, it's patient population could be twice that. HCPs are these target pulmonologist are not concerned about former smokers. They think that's an ideal target for us to go for.



But overall, we've already got a framework about how we would put both of these in the market. We certainly will leverage our own expertise that we're building respiratory across the board. But I think these actually will fit very nicely together, and I'm excited about having both options out there. I mean given that higher EOS -- that's a select target. That's a big target. We're really happy to have that with DUPIXENT, but it's really nice to be able to think about those lower EOS patients and being able to maybe have something for them.

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

Yes. That's a really good point. I mean I never smoked in my life, but I have friends, who have and family members who have -- and I think, if you're a former smoker, there's always that sort of the sword of Damocles hanging over your head, right? Whether it's exacerbations, lung function, some effect on lung function or maybe something even further down the line. So I would imagine that the unmet need here, David, is it's not straightforward to see, but I imagine it's pretty high because these people do think about their future, right, or their current state affairs with their lungs.

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

Yes. And again, it's been over 10 years. We've had a number of combination steroid therapies, triples, et cetera. This is the advent of biologics. It's a really big opportunity for us in a disease category that kills many Americans, many people around the world where we haven't had a lot of innovation. So it's really exciting to think about having 2 of the first ones in the market to begin with.

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

Yes. And that's -- so that's our COPD discussion. David, since you're the head of DUPIXENT I guess what we're -- kind of we've got about 2, maybe 3 minutes left. What we'll kind of end with is just sort of what do you see in the future? I mean, is it all DUPI? Are you -- of course, itepekimab if it's successful, as like a global head, I imagine you think out 5 and 10 years out also, how are you thinking about DUPI and then sort of what's next?

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

It has been an incredible experience working within Regeneron that looks at development and discovery much differently. And you've heard from Jamie Orengo last year, she's very impressive in what she's bringing forward for us -- had been a part of the organization, when they brought forward their REGEN-COV and how quickly they can bring that forward and put that in the market just gives you an idea of what Regeneron is capable of.

So from an l&l standpoint, we're going to be very busy with DUPIXENT. We have a lot more indications. We have a lot more growth. We've just begun. We're kind of through the end of the beginning with DUPIXENT. And then somewhere in the next 2 or 3 years, we're going to bring itepekimab forward, hopefully. That's going to keep us quite busy, but then I have no concerns around what Regeneron thinks of the future, and how quickly they can bring things forward. And hopefully, we'll have a much more robust l&l opportunity over the next 5 to 10 years.

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

Yes. And then this would have to be kind of a Ryan question for basically the last minute left. Ryan, if you can just remind us what are the key kind of -- key catalysts and important things to watch out for with DUPIXENT and itepekimab over 2024?

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

Obviously, we hope to get our BLA -- SBLA accepted for Dupixent by the end of this month. So in a couple of weeks, we'll find out if we got priority review or not. We are optimistic on that and potentially launching in late-June, early-July of this year. So that's probably the next one.

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Obviously, the PDUFA date itself and the launch would be in the second half and something to watch. The CSU, which we got a CRL for last October, we have another study ongoing Study C, which is looking at a biologic-naive population. That study should read out in the fourth quarter of this year. And assuming a success like we saw in Study A in the same population, we'd expect to be able to file or resubmit, I should say, our sBLA for that indication, either late this year or in the first quarter of '25.

And then bullous pemphigoid, I believe, also has a readout in the second half of this year, which is a smaller indication, but 1 that, nonetheless, we think has a decent probability of success and is certainly a market that is in need of novel therapies.

So itepekimab. I mentioned enrollment complete sometime in the second half of this year. And then is a 52-week study, we'd expect to get results in the second half of next year, which would then hopefully support a filing by the end of '25. So that's pretty much it across DUPIXENT and itepekimab for the next, call it 18 to 24 months.

Did I forget anything, David?

David Snow Regeneron Pharmaceuticals, Inc. - SVP and Global Head, Dupixent Franchise

No, that's great. I mean CSU and BP are both exciting opportunities and CSU is probably as big as the COPD in terms of the number of patients that are out there that could benefit them.

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

Yes. No, I'm writing furiously here, David, because you were talking about EoE and PN, some of the changes we've made, updates you've made there over time, and I actually think we might have to put that in our model. So that's going to be a priority now for going forward, when I talk with my associate. But thank you both so very much. This was really -- I mean, we could I just kept on talking.

Thank you for taking the time, David. I know these are not easy to interact with the Wall Street people and Ryan. Thanks for making David available, who are always really thankful Regeneron for being part of our conference.

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

And we're thankful to you, Hartaj. Thanks for having us and look forward to speaking again soon.

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

Same here. Give our best to the team. Thank you, David.

David Snow Regeneron Pharmaceuticals, Inc. – SVP and Global Head, Dupixent Franchise

Thank you.

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