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REGN.OQ - Regeneron Pharmaceuticals Inc at Truist BioPharma Symposium

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## CORPORATE PARTICIPANTS

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

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

## CONFERENCE CALL PARTICIPANTS

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

## PRESENTATION

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

Good morning, everyone. What a delight to have Dr. Len Schleifer here today. I think I've known Len since I was a baby analyst. A really bad one, but much better now. And with him, we also have Ryan Crowe from Investor Relations as well. So thank you so much. Before we begin, both of us have to disclosures. So here are mine, because this is being webcast. So don't scream anything out, it's going to be transcribed and live. This call is arranged by Truist Securities Research for institutional investors and issuer clients only as defined by FINRA. If you're not an institutional investor or issuer, please disconnect this time. For required disclosures, please see our website at [truistsecurities.com](https://truistsecurities.com) or equity research library. So with that, I'll turn it over to you.

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

Now it's my turn. Thank you, Robyn, for hosting us here at Truist. Great to be here. I'd like to remind you that our remarks made today may include forward-looking statements about Regeneron. 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. Len, do you want us to have a couple of minutes to open, and then...

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

You want to read your disclosure, Len?

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

No. My only disclosure would be that there are very few people associated with Regeneron and almost as long as George Yancopoulos and myself, and that would be Robyn. I think she -- we checked. Robyn is the single longest uninterrupted analysts covering Regeneron that we're aware of.

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

It started when I was 15.

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

Yes. It's been great to watch us both develop, so to speak.

## QUESTIONS AND ANSWERS

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

Well, so I'll kick it off first. So there's a lot of near-term focus on high-dose EYLEA, DUPIXENT, where do you see Regeneron in 5 years? Because I do think that investors in this space are very myopic and how they think about stocks.

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

Yes, that's a fair point. We have tried to ignore what the market is doing at any given moment and what investors are doing at this second and try to focus on the long-term for Regeneron, and always keep looking at the long term. Where do we see ourselves?

We're following the path that science takes us. We're not married to any particular field of interest, whether it be -- are we in diabetes, or are we in cardiovascular, we're in immunology, we're in oncology. It doesn't really matter. We go where the science takes us. In 5 years, I think we're going to obviously be continuing down a very productive road with DUPIXENT, a molecule, which invented at Regeneron, and we developed and commercialized with Sanofi. And that's taken us into many different areas: dermatology with atopic dermatitis; prurigo nodularis; allergic diseases, such as allergic asthma, taking us to pulmonary diseases; eosinophilic esophagitis, gastrointestinal, nasal polyps, taking us to the ENT community.

So even just one molecule in COPD, we hope. It's one molecule has taken us down quite a path. EYLEA, of course, we've stayed focused on the retinal community. But I see us continuing to diversify because that's where I see where our science is pointing us. A lot of those directionals are at oncology. And we have a very big oncology program, which we can get into and talk about a little bit further. So I hope by the end of the decade, you continue to see us with strength in retinal diseases, strength in all of our Dupi areas of interest, but a leader, I hope, in thinking oncology.

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

Don't go anywhere, but I had to ask this question. I got approved by Ryan. How is Regeneron thinking about succession planning? Because your analysts would be terrified to ask on the quarter call. I'm going to ask.

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

Yes, there's nothing wrong with it. It's a question we ask all time. Our Board takes succession planning very seriously as does the management team. Look, we are in the midst of a succession right now, an orderly succession with Bob Landry, who has been our CFO and will continue into the signing of the 10-K in February and to be succeeded by Chris Fenimore, who's been a long-standing great participant in the company. So we have a plan. I don't -- personally, if you're asking me about me, I don't have any plans to leave. When I leave, if the stock goes up dramatically, I probably stayed too long. And if it goes down dramatically, maybe I should have stayed a little longer.

But as long as I can be productive, and I know George Yancopoulos who he and I have been doing this together for 3.5 decades. He has the same feeling. We love what we do. It's a privilege to be able to work every day where you really can make a difference in people's lives. We touch so many lives. We've saved lives. There's some lives that people tell me I shouldn't have saved, but I won't get into that. But we've -- I think we've touched many, many lives in a very productive way. And we're very proud of that, and we continue to want to do that. So -- but succession is something we're always thinking about.

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

All right. So I always feel like there's been obsession with EYLEA. So I kind of you don't even want to ask the question about that today. And maybe you can point to a few things outside of DUPIXENT. Two places in your portfolio that you think investors should really focus on?

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

Well, you can't escape -- you can escape.

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

Tell them where they're wrong.

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

Well, you can escape EYLEA, but you can't escape high-dose EYLEA.

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

No.

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

Which we're in the middle of launching. I don't think you can ignore DUPIXENT. I think there's a lot of mistake about how to think about DUPIXENT. People think about it as a single drug and put a single number on it. But when you think about it, it's -- you've been in this business long enough to know that in the aughts, maybe in the '90s, people talked about pipelines in drugs, if you remember that.

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

Yes, a pipeline in a drug.

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

Remember that thing.

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

Yes, it still a thing.

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

Well, people talk about it, but Humira may be one of the few examples where they done that exceedingly well. Certainly, KEYTRUDA has done that in the cancer space. But I would say, DUPIXENT, it truly is a pipeline of a drug. And so we're looking at asthma, prurigo nodularis, atopic dermatitis, eosinophilic esophagitis, nasal polyps and hopefully, COPD. In all sorts of geographies, in all sorts of age groups as young as 6 months. So I don't think people fully appreciate the power of that drug because what we've done there is take really a vestigial part of the immune system, which is the allergic IgE-type part of the immune system and tamed it. And that is just amazing, and you can do that.

And we have -- approaching towards 1 million patients, I think, on the drug or many more have used the drug and the safety profile that's unbelievable, and that it has been not the immune suppressive agent that people think of when they think of biologics. And that, I think, is a bit of a mistake. This is more just basically shifting you away from that type 2 phenotype. So I think that people might underestimate DUPIXENT. I think people don't understand just how much progress we've made in our cancer work because people do tend to look at the -- where are the sales.

LIBTAYO is approaching \$1 billion-run rate. But the real remarkable thing is we have validated multiple different types of pathways. And that's sort of the methodical way that George and the team go about our science. It's not the rush to get one thing across the finish line no matter what -- satisfy tomorrow's sales.

So how do we conquer oncology the way we conquer type 2 inflammation? And the way you do that is you have to be able to approach many different aspects. So think about it. So -- and many other companies are in this field, but most of them only attack one of these spaces. You might have a company that's attacking checkpoint inhibitors. Well, we've got 2 checkpoint inhibitors. You might have another company that works on CD3 bispecific. Well, we got one of those already submitted it for approval, another one going to be submitted. You might have another company that's trying to look at co-stimulatory pathways. We've already validated those.

And now we're mixing and matching or AD -- an ADC, for example. We have all of these under one roof. And I think people are going to be surprised about how productive one can be in this space when you control so many different pathways because the rule is really, in cancer, is trying to get multiple pathways going and covered. And so I think that's something that people are underestimating. I think people might be underestimating our efforts in genetic medicine. We believed in genetics a long, long time ago. And when we couldn't conquer human genetics, we conquered mouse genetics with our special mice.

And -- but then we -- when you can conquer human genetics, there's probably been about 6 million people who have had their DNA sequenced, and Regeneron's probably sequenced half of them. We have all -- millions of people sequenced coupled with their medical records, we're able to do all sorts of interesting things. I think people are underestimating the power of that. And now that we've got these -- a variety of both internal and collaboration-based efforts in genetic medicine, whether it be in siRNA with Alnylam, whether it be our gene editing with CRISPR and Sonoma and others. I mean, we really feel with our genetic database and these new technologies that we will emerge as a major player in genetics-based medicines.

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

That's fair and helpful. So I guess I'll ask the high dose EYLEA question first. I asked you on the call, what's your special sauce? How are you able to do \$43 million when your competitors did not have a great launch and you don't have the permanent code? And I guess, a more specific question would be in the physician community, is there pent-up demand waiting for this, and they're just waiting to get comfortable to use it when you get the code? Or do you think it will be a continued sort of progression of sales, because you did something, amazing.

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

Sort of yes and yes.

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

Some color.

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

Yes, let me give you a little background here. So when you launch a new product in this space, the first thing that the doctors want to know is this safe? And this community has been burnt by drugs that have been launched that have been purported to be safe in clinical trials and have not been safe in regular patient use. And they've resulted in disastrous results for both the drug company and for patients and for the doctors. So I think safety is really #1 in this community. And sometimes, safety isn't known until late. I mean one of our competitors just got in their label, a fair warning about occlusive vasculitis, which is one of the big fears that patients and doctors have when injecting things into patients' eyes. So safety is very important. And we're building on the scores of millions, I can't remember, maybe Ryan...

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

70 million injections.

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

70 million EYLEA injections. Try doing something 70 million times. That's -- and doing it well and doing it safely. So people have a lot of confidence in EYLEA and now EYLEA HD, which is the same molecule, but at a really improved formulation and really kind of a unique way to get a higher dose. I think people do have confidence. It is the highest dose of an anti-VEGF that the FDA has approved. And they approved it based on the strength of our data. So people -- for a drug launch to be successful, people have to have confidence in your drug, I think they do. They have to be confident in the company bringing the drug. I think we have a reputation over a decade of being straightforward with the retinal community when we've had -- when we launched EYLEA, you probably remember this, we launched...

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

You keep reminding me of my age.

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

Ageless. In 2011, the end of the year, we launched the product. And in the beginning of 2012, we had a little cluster of inflammation. And we were totally transparent with the community. They didn't believe that we would actually show them our FDA submissions, which we did, and we worked through it. And we developed a reputation, I think, of being scientifically driven and totally transparent. So people have confidence in us when we bring something out there in this space. So I think that helped with the initial launch.

Of course, the data, I think, were quite spectacular and sort of unprecedented in terms of the duration of -- the interval, people wanted less frequent injections in your eye. And this was -- the data were really quite unanticipated. I remember 1 analyst, not you, who was saying that he was very negative on the company, who said if we got 25% of the people who could go for every 12 weeks, maybe we'd be lucky. And we got something like 80%. So I think that the data were really quite a surprise how good they were to everybody. I think that you still have mechanics that have to happen in a launch, people have to get the drug, there has to be samples. And then there has to be reimbursement, as you alluded to.

We've worked our tails off on reimbursement, and I really think we're way ahead of the curve. We've gotten -- the business is sort of roughly divided half in terms of the Medicare business, half between the conventional fee-for-service Medicare and a little more than half in the Medicare Advantage. We've gotten in the Medicare and the fee-for-service. We've gotten claims paid in every single part of the country. So people look towards that. And we're making great progress in the Medicare Advantage with wins coming on a regular basis in terms of the kind of coverage we want.

Obviously, a J code, which we expect, I think, around April 1 would be a big boost because the doctors -- remember this. As you know, some of your clients might not know, this is a buy-and, what we call buy and bill. So the doctors actually have to buy the product and they have to bill an insurance company, and they don't want to get stuck buying a product that they won't get reimbursed, which is why these launches do tend to be a little bit slow going out the gate. I think -- but for all the reasons I just tried to elucidate, we had a much better launch than other recent launches in this space.

So I think it bodes well. I went through one of the retinal conferences a few weeks ago. And it reminded me exactly the kind of stuff we were hearing with EYLEA, which is people were coming up to us and saying, "Hey, I tried a patient who would blah, blah, blah, couldn't -- was taking this." I won't use names, of other products, but they were taking this and they couldn't get dry or they had to get it so frequently, and I gave him a shot of HD, and it was amazing. This community...

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

It will perpetuate itself. That's what happened with Avastin.

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

Well, that's what happened with EYLEA. I would say.

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

EYLEA taking over Avastin.

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

Yes, EYLEA taking over Avastin that people see it. This is something they can see with their eyes what's going on in their patient's eyes. And so they really rely heavily on their individual experience and as they try it, and if it's safe and then they start to see good, this does become an accelerating process.

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

So I want to touch next on IL-33. I know there's a lot of talk about DUPIXENT for COPD, but IL-33 doesn't get a lot of attention. And I guess I thought the best way to ask it is, could this be a product a pipeline in a product beyond COPD? Where else do you see it going?

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

Yes. We haven't talked about other places where that might go. It's something Sanofi and Regeneron are discussing. But I do think that it could be an important product in the COPD space. Fingers crossed that, we passed an interim futility analysis, which had a high bar, and we're hopeful that our studies will read out positively. So I think that, that one for now in the near term is sort of focused more primarily on the COPD space.

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

Got it. Turning to oncology, one of my favorite things to talk about. So like Regeneron's had lots of bispecifics. You've done that in oncology, but where do you see that going in immunology? And are you starting any programs there?

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

It's a fair question. We have focused on the oncology space right now, where we're trying to soup up the immune system. In the immunology space, we've had other approaches. We do have some preclinical data, which we really just don't talk about because it's early going. But for now, we've really focused mainly on the souping up of the immune system to fight cancer.

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

All right. So then I'll get to my favorite question. And I don't think a lot of clients know this because every time I talk about it, they're like, "What?" You're doing a combination of LIBTAYO with LAG-3 in melanoma and then for lung. And in lung, I believe I'm correct, there's actually a KEYTRUDA arm, a pembro arm. How important is that? What could the impact of having a head-to-head for the first time of your checkpoint inhibitor with the standard of care be, is it just to help reimbursement? And what's the impact of that?

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

Well, if the data were positive, the impact could be very...

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

Well, no one's done it yet though. People just don't show the different components...

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

People tend not to do head-to-head trials in this space because they tend to be harder. Obviously, if you are adding an active agent, KEYTRUDA is an active agent, then you've got to be that much better versus if you're going against background of low activity. I mean, if you take a look at our data, the cross-study comparisons in melanoma, okay? You see the single-agent KEYTRUDA activity is for -- just looking at ORR sort of a proxy and mind you, these are cross-study comparisons of investigational agents. So you can't take this to the bank yet. But it's a sort of a beginnings look, you look at KEYTRUDA, it has response rates in the 30s, okay? About 1/3, let's say, of patients. If you look at the combination of Bristol's PD-1 inhibitor plus, their LAG-3, you're in the 40s, let's say. Our data in multiple cohorts was in the 60s.

I mean this was rather striking to our team and to the experts we showed this to. So we're busy trying to outdo, Opdualag. We're in a study -- our comparator is KEYTRUDA in the metastatic melanoma space, and we're trying to do the same thing in the first-line lung. We're more ahead in terms of just how the trials are going much further, along in the metastatic melanoma. But that's -- I was just looking up before I came down here today that Opdualag is doing pretty well. It's not quite at \$1 billion run rate.

But if we have significantly better data, that's going to be a big space for us. And as you know, we're already in the skin cancer business with our data in cutaneous squamous cell carcinoma, which we've launched and as well as basal cell carcinoma.

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

What happens if LIBTAYO looks meaningfully better than pembro on the broader landscape, like you're already selling the drug so...

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

I mean I think it could, for sure, we hope it would. But this is still a fragmented market, Robyn. So that we need to deliver results, and where we deliver results, we can get share. It's hard to -- doctors don't use these drugs off-label. They don't get reimbursed. We don't promote them. So I think that -- but in these settings where we test it, yes, it could be very meaningful. And of course, the biggest opportunity is non-small cell lung cancer.

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

Do you -- we get questions a lot, I didn't have this on the list, so you don't have to answer. But we got questions a lot about LAG-3, given that you have a much more potent molecule than Bristol. Whether or not the safety will hold up and how it will compare to TIGIT. Do you have another thoughts there? And forget about the Roche TIGIT program the combos that are better.

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

Well, it's tough to compare the safety cross trial. But thus far, in our 2 cohorts that we've looked at it, it looks pretty darn good. We're seeing the efficacy we're looking for without really any noticeable increase in the toxicity. So I think we have to wait for the data, but fingers crossed. I think this -- it's just an example of how Regeneron when we have both of these together, and it just gives us a little advantage.

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

Okay. And switching a little bit to -- you have CDs, you have LIBTAYO, you have the costims. Costims are so cool and really interesting data, but there were some tox. Can you talk a little bit about the nuances of dosing and titrating? Doses between the 3 different immune mechanisms that you're using? Like what are the nuances and how do you get through it?

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

If you've got some answers, we've got some questions.

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

Hold on. Here's my resume.

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

It's complicated. Look, take the CD28 costim that we combined initially with, our PSMA in prostate cancer with LIBTAYO or cemiplimab. We had unprecedented data, truly dramatic data. But we saw quite a bit of toxicity that immune-mediated toxicity. So we probably were exaggerating the immune toxicity of cemiplimab by this activation of these T cells with our costim. And so it's something that we have to maybe back off a little bit of and maybe we don't need or use a full dose. We're looking at this right now at much lower doses. This is not like lowering cholesterol, where you can give the drug and you pretty much lower it, nothing else happens other than your cholesterol coming down, and you can test it 10 patients and know whether it works, that sort of thing.

This is complex. And you're right to ask the question, there are a lot of nuances, but we haven't figured out the rules yet. So we're working to it. But we haven't figured out exactly how much do you have to decrease this if you add a CD3, we think a -- that CD3 costim might be less of a problem than CD28. It's -- these are -- these are...

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

When do you think you'll have it figured out, you've got a lot of data coming in the next year...

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

Yes, I think over the next year or 2, we should have a much better idea of what the heck we're really doing here and how to get these things across the finish line. We do have a lot of data coming. And I think that, hopefully, we'll have it figured out when -- it's interesting, in our CD28-PSMA plus cemiplimab study in prostate cancer, where we -- these people, unfortunately, had metastatic prostate cancer, lesions all over the place, less than a year on average expected to live. We saw these dramatic, dramatic results that the prostate cancer doctors are begging us to just move this along as fast as we possibly can. But we have to be careful, and we can't just rush blindly. This is why we take the long view. We got to get this right. And because we're now looking at CD28 by EGF receptor. We're looking at MUC16. We're looking at a whole bunch of these. And so we got to understand the rules. I'm pretty confident that George and the team are going to figure out these rules, but we haven't got them all figured out just yet.

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

In talking to George, it seems like it's very possible that each cancer could have a different combination. And that makes it more -- even more challenging.

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

Makes it even more challenging. Absolutely.

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

And then when do you think -- given that the -- all the concerns -- I've asked this question before around CD28, the spookiness. When are the FDA can be like, "All right, you guys figured this out, you can go full steam ahead." Do they need like enough data next year for that?

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

I think the FDA has a lot of confidence in what Regeneron Science is. And they respect that we just aren't going forward and ignoring patient safety. And so I think we have a pretty good relationship with them. And I think that when we feel confident about it, I feel confident we'll be able to convince them that it's time to really go ahead full [bore]. So it's a collaborative interaction. And these interactions are really are dependent on how much they trust you and your science. And I think we do have some good reputation down at the agency, and we respect them, and they respect us. And so I think it will be productive.

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

Moving on to MET ADCs. Can you talk about the opportunity there? I think that's underestimated by the Street. What is the benchmark for these lung patients? And what would you expect to see in terms of response rate? What should be the bar?

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

Well, the bar with the MET ADCs, I think, is responses in the 20s or 30s or something in that nature. I don't know if I have that about right. So -- and I think -- so that's kind of what the bar is. We've seen some nice responses in our MET by MET, but we think we need to add more to that. And so we're now going MET by MET with our own ADC platform as well. And so we -- that's kind of what the bar is, and we want to see more than that. We think we will, but that's why you have to do the experiment.

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

And when do we get the data next year? Have you set early or late?

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

We haven't narrowed it but it will be just next year.

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

Okay. As a side note, I've been asking Ryan and every IR person that's worked for you. For all these years, when would you ever do like a deep R&D Day? When would that be necessary?

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

I always -- a lot of people ask us to do that. And a lot of them work for other drug companies.

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

So that the answer is like no because...

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

I don't -- like we're doing one tomorrow, except we're doing it for our technology committee. We have a technology committee that has, I don't know, let's say, 1, 2, 3, 4, or 5, something like that members of the National Academy of Sciences, 2 Nobel laureates. I mean -- and we are doing an R&D Day for them. But that's internal...

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

Not webcast.

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

But not being webcast, not attended. Somehow, I feel these R&D days are -- we don't get credit for the long-term stuff that we talk about. So all I'd feel is sometimes, it's George educating the rest of the world on his great ideas. Not that we don't do that anyway, but I just assume we do it internally and so I don't think we have any real plans for...

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

No. And we provide updates around medical meetings about how the oncology...

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

Yes, would be ASH and all those. Yes.

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

So turning to the costim CD3 combo in ovarian. As you can imagine, all of us are going to be comparing whatever data is available from the 3 immune permutations. What differences do you expect between LIBTAYO costim? Let's predict the future here, LIBTAYO plus CD3, costim plus CD3, what differences do you think you'll see? What are the pros and cons, too, of those approaches? I think you already addressed some of these...

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

Well, some of this is -- as I said, it's empiric, but I think the CD3s will be less prone to broader immune responses rather than combining it with, let's say, LIBTAYO. So I'm anxious to see those data. We know we've got an active set of molecules there. I can't recall when do you think we might...

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

We'll have some preliminary dose escalation data actually later this year. And then next year, we'll have additional data combining ubamatamab, the MUC16 by CD3 with the MUC16 costim.

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

Ryan is absolutely amazing.

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

Does he have a photographic memory?

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

That's why he was voted #3. I don't know who the other 2...

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

My guys, Bill over there. He knows everything.

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

Ryan knows everything, every program, every molecule, every date. Some has sort of a memory or...

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

Stop please.

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

He's really good.

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

Ryan, what has Len said about dividends?

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

We've done a lot of homework on dividends, and I think it's a fair question given the state of the balance sheet and the state of what I think our future cash flows are going to look like. And we've been getting the question more and more from some of our larger investors about how are we going to allocate capital in the future because continuing to accumulate cash is probably not necessary, given the \$15 billion we have on the balance sheet. So -- we are looking at it. I think it remains as part of the opportunity set, but not now is kind of the answer that we have for that.

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

When you think about BD, you talked about you can do anything. Do you still want to stay in your wheelhouse? Or do you think you could do something completely out of what you've done?

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

We don't -- we like to think we don't exactly have a wheelhouse there. But that's where the science sort of took us. There were a lot of people who didn't believe in eye diseases. So they -- we were hunting around. We had no money. I remember going to places, and they had EYLEA rights, so they gave them back to us or they paid us to take it back or things like that. I mean because they weren't in the eye business.

And so we try not to be -- think of ourselves as too smart to figure out where to go with everything. We really do try and let the science push us to the direction we're heading. And if it takes us into some strange disease, we'll be there. If it takes us into solving the problem of muscle mass loss in obesity, we'll go there. Wherever it takes us, we're prepared to go.

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

Are you sick about hearing obesity?

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

No. I think it's a big problem. And I think that what people aren't realizing and we had some very interesting monkey data in this and there's some human data that when you lose weight with these new -- like the ones that are maybe just approved today, you lose them -- you don't lose just fat, you lose a mixture of fat and some muscle. Our data suggests in primates that -- and I think there may be data in humans now, but I'm not positive about that -- maybe not. But no, in terms of when you gain the weight back, you gain the way back, you gain fat back. So if you -- just to make up numbers, if you lost 100 units and 70 were fat and 30 were muscle and you gained 100 back in fat, that doesn't sound like a good trade. It might be a good trade for the wedding or the beach, but not necessarily for the long-term health. And so I do think that somebody has got to solve that problem. And we've got some pretty cool nonhuman primate data that suggests a way to solve that problem.

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

So you hinted on last quarter call, maybe Ryan can refresh my memory, since he remembers everything.

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

He refreshes mine every day.

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

That's good. For next generation of DUPIXENT, not -- that's probably not the right word. But for life cycle management of DUPIXENT, which is a massive, massive drug, that's a big drug to sort of replace. Like how are you thinking about leveraging that sales force to develop something?

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

The same way we thought about "replacing" EYLEA, that is -- the rumors of EYLEA's demise were greatly exaggerated. And I think that there's a lot of length left in DUPIXENT. Think about -- if we get across the finish line in COPD, I mean that's an untapped market that's really attractive. So I think there's a lot of growth left in DUPIXENT. The life cycle management that we've had with Sanofi on this has been very effective in that we have increased the number of indications, particularly where we get there first or we get there best.

We have increased the geographies. China, has been a big opportunity for DUPIXENT. And then we increase the ages, the age groups where you can now have DUPIXENT approved as young as 6 months. We talked in the beginning of the conversation about how safe this product was. You don't get a product approved in 6 month-olds unless it's really safe, especially something that is "modifying" the immune system like DUPIXENT is. But life cycle management -- I think we've got some really interesting ideas where we could perhaps cure allergy.

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

Okay, go deep there.

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

Well, it involves DUPIXENT and a few other things. I'll say not much more about it, but there are some cool things that we can certainly understand -- I'm talking about, let's say, the severe allergies where people have to carry an EpiPen or something like that. We think that -- we have a path forward. I don't know how much we've talked about this publicly.

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

Not much.

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

Not much. So we won't to say much. Maybe that's all we should say.

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

Could we go deeper? Okay. Last question, then I'll let you say one line about whatever you think I missed or how annoyed you were with my questions. Regeneron's collaborations are beginning to bear fruit from a data standpoint, you've got C5. You might see that soon. What about the opportunity in PNH and MG? How are you thinking about these new indications?

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

Right, right. So like everything we do, we love the concept of a platform that is something that can be repeated more and more frequently in other settings. And the C5 data, which I don't believe we've released just yet, but we're pretty excited about, combining an siRNA with an antibody, we think that's a whole new platform idea. And there are certain settings, and we think in C5-related diseases where you really need complete control of C5 because of this hair-trigger mechanism of the complement activation system.

We're very excited about the combination of knocking down the production with an siRNA, not enough to treat the disease but enough so that now you can get a much better knockdown with an antibody and a much less frequent dosing. And we think something like that is kind of cool. You'll see some data, when will they see some data on that?

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

Soon.

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

Soon. That's what the man -- the man who controls.

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

I wish I had that control.

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

The man who controls the spout -- says soon.

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

So helpful.

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

Yes. So that's kind of cool. So in the last 30 seconds, I would say the industry -- you talked a little bit about BD. The industry is an interesting point where very exciting times where so many companies were formed, many more than the financial markets can now absorb. And so we're seeing good ideas out there that are going unfunded. So I think there's some opportunity for -- when people have a strong balance sheet like we do, to pick off technologies, and you ask me, "Would we do something far afield?"

We tend to stick to adjacent stuff. But if we saw something really exciting that we could add value to, we're not shy either. Right now, I think that the company is as exciting a place to be as it's ever been. We've got, what, close to 3 dozen things in the clinic.

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

In the clinic.

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

We're putting more in every year. I think that the way to solve the problem in this business of having very successful drugs is to have more successful drugs. And that's what we're aiming for.

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

Well, I'd like to thank you, appreciate it for coming and taking your time. I know you have better things to do like curing people or not curing them. And then we have Ryan and Bill and my team, I want to thank you both for making me not look like an idiot up here, and doing hours and hours of work over the last 6 months.

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

It's been a pleasure Robyn, thirty-odd years of you asking me questions, keeping me on my toes. Very much appreciate it.

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

Thanks a lot. Thanks, everyone.

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

Okay. Thank you.

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

Thanks, Robyn.

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