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PRESENTATION

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

All right. Good morning, and welcome to the Barclays Global Healthcare Conference. My name is Carter Gould, covering large cap biopharma here at Barclays. Welcome everyone.

I am pleased to welcome Regeneron Pharmaceuticals to the stage. Joining us, Chris Fenimore, newly minted CFO and Ryan Crowe who heads IR. Ryan's going to make some opening comments, and then we'll launch into Q&A.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Just some quick forward-looking statements 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. Carter?

QUESTIONS AND ANSWERS

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

All right. I'm pretty sure you can do that in your sleep now, Ryan. Chris, so -- I think we're just talking about a month into the new role. Your predecessor was there for a decade plus in that role. As we think now about you taking on this role, do you think about any shifts in priorities or shifts in your view on capital allocation?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure, and thanks for the opportunity to be here and have us. So I've been with Regeneron for 20 years. I started out -- I ran our financial planning and analysis function and then about seven years ago, our former CFO tapped me on the shoulder and said, just from a career development perspective, I thought it would be good for me to get some controller-ship experience. So I've been the Corporate Controller up until appointment as CFO for the past 7 years. I've worked closely with Len and George for these past 20 years. I understand their philosophy is -- how they like to manage the business. So I don't expect to see any significant changes in terms of my perspective, sitting in the seat as the CFO.

From a capital allocation perspective, I think you'll find that the messaging will be fairly similar. Our prioritization is effectively to ensure that we're investing in our own internal R&D engine and making sure that we're making obviously wise decisions as we allocate capital to those initiatives. We've been fairly active on the BD front. And by BD, historically, we've done a lot of partnering transactions. You'll see that we'll continue to do a

few of those a year where we find complementary technologies and platforms with other businesses that we think mesh well with what we want to get done from a strategic perspective.

Most recently, we started to do some acquisitions. You saw that with Checkmate Pharmaceuticals. You saw that with Decibel Therapeutics. And most recently, we announced the acquisition of the R&D programs of 2seventy Therapeutics. So those have been fairly modest in terms of size from an acquisition perspective. We have the ability with our balance sheet, obviously, to do things that are larger. We haven't found anything to date that we've thought was interesting, but we have the flexibility with our balance sheet and obviously, our cash flow to do things if it makes sense.

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

Okay. Maybe sort of the question that naturally follows now is that despite increase -- robust increases in R&D sort of year-on-year, the growing cash position even in spite of those investments, the question around potentially paying a dividend does come up. We've seen other large cap companies, albeit outside of biotech, sort of rerate with the introduction of dividend, bring in new investors, obviously, with Meta. How are you guys sort of grappling with that question, if at all, at this point?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

So we -- internally, we did an analysis in 2023 about whether not it made sense for us to initiate a dividend. We actually brought in some outside firms to help us with that. Analysis and the conclusion of sorting through that was it just wasn't the right time in 2023 to think about starting a dividend, but I think the emphasis is at that point in time, it was not the right thing to do.

We'll continue to evaluate it and see whether or not it makes sense. We've talked pretty openly about this development balance that we have with Sanofi. The balance as of the end of the year was $2.3 billion, we paid down just over $500 million over the course of 2023. We will continue to pay that down over the next couple of years. And a potential inflection point for thinking about a dividend might be once that balance is paid off. So we'll continue to monitor and see what the right thing to do is.

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

Okay. There are a few things give me as excited as Sanofi collaboration accounting. But we can -- and I'm serious, but maybe to circle back on this question, though, is Regeneron's pace in R&D growth has been pretty substantial -- the R&D expense is almost 2x kind of what it was at the start of the decade. Is there just like a natural limit on how much you can kind of continue to inflect in R&D growth going forward, given there's only one of George and Len?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure. So if you look at our guidance for 2024, it's about a 12% increase year-over-year when you look at the at the midpoint. We obviously have a fairly rigorous process in terms of what we decide to invest in and what we want to take forward. That increase is reflective of just an advancement of the portfolio. So if you look at a lot of our assets are moving into Phase III or already are in Phase III such as fianlimab, our hem onc, our portfolio assets. We're advancing our Regeneron genetic medicine portfolio with our partners at Alnylam and Intellia, and we're just starting to obviously bring forward a lot of things in the -- into Phase II this year and the likes of obesity and Factor XI and things like that.

We -- one of the things in our business and the portfolio is of that size is obviously the spend is spread over years in a lot of these programs and things kind of roll off of being advanced in late stage and things roll on. So we can manage it that way. And as we look at some of the other things in the portfolio as they advance, we're not necessarily averse to looking at partnership opportunities for commercialization and/or development expenses, that might be of a size or a risk profile that we might want to look to the outside and help fund some of those things. But we'll continue to obviously actively manage the growth and make sure we're investing and allocating the capital wisely.

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

Maybe switching to the product side a little bit. Obviously, the high-dose EYLEA launch is ongoing. We actually -- we were just in the midst of our retinal panel that -- I walked from here, and heard encouraging commentary in terms of (inaudible), your vantage point, how the launch is going? And to the extent you can frame for folks sort of the impact from the J-code coming shorty?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

I'm going to turn it over to Ryan. I mean, I think the initial response is -- the launch is going exceedingly well, but I don't know if you want to talk about some of the specifics.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Yes, I think that's right. I think our view is it's going really well, and it certainly compares favorably to the competitor launches that have occurred in the recent past. Probably as exciting as the revenue has been the enthusiasm in the market around the profile of the product where retinal specialists and patients are seeing efficacy and the safety in line with EYLEA, but with longer dosing intervals, which has always been the goal of this program and what we saw in the clinical studies.

So when you have a profile like that, I think that immediately is a draw to patients and prescribers. I'd add that recently, we've passed the 100 [thousand]-vial threshold for orders, and that is a significant milestone for some prescribers who want to see real-world safety in the marketplace. So that's something we recently surpassed and I think, further solidifies the profile that is comparable to what we saw in the trials.

I guess lastly, the J-code, which will come in just a few weeks now, we think will reinforce the confidence to prescribe because reimbursement risk is seemingly eliminated once that goes into place. So that's the next inflection for -- with ongoing launch here of HD, and we're very excited to see it advance.

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

And maybe where you sort of sit with the prefilled syringe, timeline wise? And how maybe -- if you have a view on how that compares to your most relevant competitor in the marketplace today?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Yes. So prefilled syringe, obviously, is preferred by our prescribers. I think over 90% of EYLEA administrations are done with the prefilled syringe today. So prefilled syringe for HD is a very high priority for us. We're working on it. We don't have a launch timing prepared today, but we're certainly focused on getting it to market as quickly as possible.

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

And after 4Q, there was a number of questions around just how the pricing headwinds for the class as a whole is facing, it's no surprise here that rebates are relevant to the commercial landscape. Any comments there, Ryan?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

I think the competitiveness of the market really ramped up a couple of years ago with the introduction of faricimab and then ranibizumab biosimilars, and with it came pressures on price. You can see that reflected in the ASP data that CMS publishes every quarter, and we've seen anywhere between 50 to 150 basis points sequential declines in price over that period.

So that's sort of been the trend. We don't want to forecast what that could look like in the future for competitive reasons, but that's -- that's sort of the environment that we're operating in, and we certainly want to remove any disincentives from using aflibercept products in the market vis-à-vis others.

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

Okay. We're not going to get out of here -- facing one IRA question. In a CFO role, when you think about just the uncertainty that comes with the IRA landscape around when you try to make decisions around advancing a pipeline in those investments, how you sort of grapple with that? Where do you anchor when there's so much uncertainty over what implementation will look like? I know the rulemaking has given you some clarity on what things look like at the same time, EYLEA is a big line item for CMS.

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

It is. And obviously, we're paying attention very closely to what's going on. There -- even State of the Union addressed this. It's obviously top of mind for a lot of folks in Washington. We have to run the business and obviously do what we can to make sure that, that future revenue growth and opportunities for our shareholders are there. And we're obviously following things very closely. I don't know, Ryan, if you want to sort of talk about the specifics with IRA.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Yes. Currently we have the statute, and we have Part D guidance. What's missing is Part B guidance, which would be applicable EYLEA HD and many other products. And the guidance with Part D seemed to be a bit of a departure from what -- how the statute reads. So we're interested in the interpretation that the CMS has of the statute for Part B products. We certainly are preparing for multiple different scenarios -- but to Chris' point, we've got a business to run and a brand to manage -- 2 brands to manage -- and we're focused on that right now.

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

Okay. Great. Maybe we'll switch gears to DUPI, and I was only modestly joking when -- joking about Sanofi collaboration accounting, but the margin improvement has been pretty impressive. And part of those COGS, part of that scale. But on the COGS side, kind of help frame what inning you are on that -- the improvement, on that side of the equation?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure. If you look at what we book in terms of our Sanofi collaboration profits, that margin increased about 300 basis points in 2023. That was largely attributable to a new manufacturing process for DUPIXENT, which is a higher yielding manufacturing process, had a significant improvement on COGS. The bulk of that phase-in happened for the most part in 2023. There's a few markets where that phase-in will continue in 2024. So we might see some incremental improvement in 2024, but I think it will be fairly modest.

And then as you think prospectively about the brand and the profitability, obviously, just as the sales increase, we also hope to get just sort of leverage of the operating expenses relative to increasing sales.

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

There's only so many DUPI commercials...

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Yes, exactly.

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

Okay. One of the questions we get all the time is sort of life cycle planning around DUPI and I think if you guys rolled out a once-a-month dosing option, I think the Street would rejoice. I haven't seen any really any details on that sort of -- that sort of effort. You guys have talked about the opportunity in severe allergies, but Chris, in your role as you think about planning for potentially life after DUPI 1.0. How do you -- how are you thinking about that today? How is the team internally thinking about that?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

I think this on a number of fronts. And obviously, the internal R&D team is actively working on what might potentially be sort of life cycle management for DUPIXENT. And obviously, looking at the portfolio as a whole, you mentioned sort of the allergy side of things which George Yancopoulos is particularly excited about and really has been a focus of our internal R&D efforts. I don't know if you want to maybe talk a little bit about it Ryan.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Sure. I think we have a number of opportunities preclinically now that will expand upon DUPIXENT, which blocks the IL-4 receptor alpha as well as other, I'll call it, adjacent targets in the type 2 cascade, all of which are being expedited and we're trying to bring them to the clinic as quickly as we can.

On allergy, that's a huge opportunity, something around 10%, 11% of people in the U.S. have allergies and around half of those people have severe allergies. So we're talking somewhere in the neighborhood of 15 million to 20 million people. It will be interesting to see the early clinical data that we generate with the BCMAxCD3 followed by DUPI regimen. We expect to dose first patients within the next couple of months.

And the initial cohort is going to be very small, maybe a half dozen patients. But we should get our answer pretty quickly. And if you're testing, once you're in the maintenance phase of this, and you're not seeing IgEs expressed, then you can be pretty confident that your IgE-mediated allergies have been reversed. So that's what we'll be looking for. And then if we are successful in this very early small study, we'll certainly be looking to rapidly expand it -- bring it to patients quickly.

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

Okay. And Ryan, maybe a follow up on that. To what extent is sort of Xolair's new approval in that setting, in -- a proxy for maybe the opportunity you're facing. That's just blocking, it's not depleting -- the Xolair approach might be viewed as (inaudible) from actual standpoint.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Yes. I mean Xolair's mechanism essentially obliterate all IgEs, and it does it transiently, so they do end up coming back. So you're not blocking the production of them. You're just eliminating them once they're created. And if you look at the data, I think it was something around 2 out of 3

patients who are able to at least have a couple of peanuts or whatever their food allergen was. It was hardly a cure, which is what we're seeking to do.

So when you swing big, you can make really important advances for patients, it does carry a risk. But I think the biologic rationale here where we're ablating plasma and B cells and allowing them to be essentially, call it, reconstituted under the setting of a DUPIXENT, which doesn't allow for IgG to IgE class switching to occur. Biologically, it makes sense. So we're going to really interrogate this hypothesis that we've had for a number of years, and we've seen actually replicated in some animal models, see if it manifests in people because I think while an advance, Xolair is hardly the solution to allergies.

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

Okay. maybe switching gears or sort of moving over sideways to your IL-33 program itepekimab. And I guess, first off let's -- when we think about this and kind of how this will sit within the Sanofi collaboration, will this just sort of be another layering on kind of a (inaudible) DUPIXENT and Kevzara. And maybe talk to -- maybe Ryan or yourself can talk a little bit around how you see that (inaudible) to DUPI and COPD?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure. So to answer your question, that is just another asset that's part of that Sanofi collaboration. So the accounting and the treatment of it will be identical to what we do for DUPIXENT and Kevzara. So just think of it as aggregating the profits and the sales and the expenses of all 3 of those assets together. And that will then obviously lead to repayment of development balance to the extent -- at a faster rate to the extent there are incremental profits as well.

In terms of one thing that we'd have to think about is if the data is positive from the studies as they come out and we think about incremental R&D expenses, that's something that we have to factor into what the incremental spend would look like on the R&D front, but that -- we now fund in real time, 50% of the R&D expenses on the Sanofi collaboration. So to the extent that there were incremental expenses that would have to be factored.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

And in terms of the products potentially co-existing, obviously, we have dupilumab in the type 2 COPD setting, which has an sBLA pending decision in August -- no it's June, sorry. The PDUFA is in June for DUPI for COPD, my apologies. But that's -- it's a current and former smoker population with eosinophils above 300 at baseline. And we estimate that population is around 0.5 million patients across the G7, around 300,000 in the U.S.

For IL-33, we're looking at it in a slightly different set of patients. So -- we're not looking at it in current smokers at all. We didn't see any signal in the Phase II study, what we did see was a very compelling signal in former smokers regardless of eosinophil count at baseline. So in the Phase II data set, we saw a 42% reduction in annualized exacerbation rate among former smokers regardless of eosinophils. And that's where we think itepekimab can play, if it's successful in its Phase III studies, which we'll have data next year. That population is around 1 million patients across the G7. So there is an intersection of type 2 former smokers that both dupilumab and itepekimab could potentially treat.

I think it will be interesting to see a prespecified population in these AERIFY studies of itepekimab, those patients with high eosinophils, how did their -- how did the exacerbation rate look? How do the long improvement look? If I'm doing a cross-trial comparison and perhaps with DUPI in that same cohort of patients from the NOTUS and BOREAS studies.

So in the end, I think it rounds out a very nice respiratory portfolio, fingers crossed for success in Phase III, we should complete enrollment later this year and then hopefully have the data about a year after that.

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

Okay. I want to get to obesity. But one last question on the IL-33 study in bronchiectasis -- to what extent should investors read through from that to – your confidence on the COPD studies and generally. These studies were always viewed as somewhat higher risk relative to a lot of former immunology -- what you've done, any color there?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

So kudos to you, I did notice your report came out basically in real time for when that trial got posted to clinicaltrials.gov. And yes, bronchiectasis, we launched a Phase II study largely on the belief of that the symptomatology is very similar to COPD, and we have some in-house preclinical mouse data that block IL-33, ameliorates or eliminates that symptomatology, which is why we've decided to move forward with this rather large 300-patient, Phase II study, and we're going to look at 2 doses for itepekimab against placebo. We're unclear exactly when that data will read out. But again, this would be another 1 million patients that will be addressed at G7 in this indication (inaudible) -- non-cystic fibrosis bronchiectasis.

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

Maybe making that transition to obesity here. It seemed like a little bit more of an execution year for Regeneron in the obesity side. We did see that you moved the program into Phase II, which I would assume means the high-dose trevogrumab data in healthy volunteers, looks okay. Maybe just help frame for folks what kind of time frame you should expect updates on obesity if anything that we should expect this year?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Yes. So Carter mentions the high-dose trevogrumab cohort. We're actually enrolling that study right now. It's a very small cohort. I think it's only 2 dozen patients that are only followed for 7 weeks. So that's data we think we can generate pretty rapidly, allowing us to initiate Part B of the study, which will be a 4-arm study including semaglutide with trevogrumab, plus or minus garetosmab, around the middle part of this year. The primary endpoint is 26 weeks weight loss as well as fat loss, those are co-primary endpoints at week 26. Assuming enrollment is relatively quick, we could expect data sometime in the first half or towards the middle part of 2025.

There is a part C to this study, which will look at the maintenance phase, where all patients are discontinued on semaglutide and roughly half will continue on high-dose trevogrumab to see if the weight can stay off that's achieved in the first 26 week of the study with the semaglutide on top of the muscle preservation agents.

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

Okay. And last question for Chris. Regeneron looks at obesity. Is it determined to be in obesity? Or is it just going to sort of take its shot with its assets in development? How critical obesity is for Regeneron as we think going forward?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

I think the study Ryan talked about is important. Once we see the data from that study that will really drive kind of how we take the strategy forward from there. It's obviously a large market opportunity. It will inform for us whether or not you've got something there. And then if, hopefully, it's positive, we'll figure out how to best kind of roll forward from what our commitment looks like to obesity.

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

Okay. So you answered so efficiently. I'm going to squeeze 1 more in. how critical to that effort is having your own GLP-1 as part of the equation?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

I think there's arguments for both sides. Of course, you'd love to control the cocktail, but is it better to be kind of a free agent so to speak and be able to augment or improve the body composition of existing therapies out there, across all of them. And that's -- so we're considering both options. We have our own internal preclinical GLP-1 program. And in parallel to this important proof-of-concept study, we'll be advancing efforts to come up with a unimolecular solution from Regeneron, while allowing the optionality to potentially partner with others -- multiple others or a single partner if that's the most appropriate strategy.

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

That's perfect. We'll have to leave it there. Chris and Ryan, thank you very much.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Thank you, Carter.