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CORPORATE PARTICIPANTS

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

Ryan Crowe Regeneron Pharmaceuticals, Inc. - VP of IR

CONFERENCE CALL PARTICIPANTS

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

PRESENTATION

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

Good morning. Welcome to Day 2 of Barclays Global Healthcare Conference. My name is Carter Gould, senior biopharma analyst here at Barclays. I'm pleased to welcome Regeneron Pharmaceuticals to the stage to help us kick off the day.

Joining me on stage, Robert Landry, CFO of Regeneron; as well as Ryan Crowe, VP of IR. Before we get started on the Q&A, Ryan is going to appease the lawyers, and then Bob can make some opening comments.

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

Thank you, Carter. Just very quickly, I'd like to remind you that remarks made today may include forward-looking statements about Regeneron. Any 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. Bob?

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

Great. Thanks, Ryan. And good morning, Carter. Thanks for having us here. We always look forward to coming to this conference. So I was going to open it up maybe 3 minutes of just kind of what's happened in the quarter-to-date, and then we'll talk about kind of a couple of catalysts that are coming. And then I'm sure Ryan -- Carter will dig a little deeper into those items.

So we did get acceptance of our filing with regards to the 8 mg aflibercept. That came -- and it came with a June -- end of June PDUFA date, which was obviously very positive on our end with regards to that, fast approaching.

With regards to Bayer, so we do collaborate EYLEA with Bayer ex U.S. So Bayer has made the submissions with regards to the EU on the 8 mg. And then they also just did the Japanese filing. And again, Japan is a fairly large market for us on the ex U.S. market on that front.

With regards to Dupixent, there is always something happening with Dupixent. So again, we got our sBLA accepted by the FDA in CSU indication.

And then in Europe, they approved EoE in the first quarter, which was a positive. And we continue to wait. We do have CHMP approval with regards to the tiniest kids. These are the 6-month old, which talks to the safety of Dupixent, all the way up to 5 years in AD. So we're going to -- we expect to get that by the end of the month.

And then with regards to Libtayo in our non-small cell lung cancer, we did in Europe get CHMP approval for PD-L1 positive indication on that. That should be coming shortly on that. So again, a pretty busy, pretty positive first kind of 2.5 months.

With regards to catalysts. So -- and again, I know Carter will dig deep. The biggest catalyst has to be the BOREAS trial, which is coming with regards to COPD. It's a gigantic indication. We're hoping it's a Type 2 disease that we can cure with COPD and with Dupixent, and we'll find that out shortly.

We also have bispecific information coming with our bispec platform. That's going to be with PSMA drug. We did show some prostate information at ASCO earlier. So again, we look forward for further readouts on that.

With regards to hem/onc, so we have our CD20, CD3 in non-Hodgkin's lymphoma, and then we have in multiple myeloma our BCMA. So we're going to have -- continue to press those forward and hope to have readouts on that.

We are in collaboration with Alnylam. And again, I believe Alnylam is here with regards to APP. And again, we're hoping in the first half of the year that we get a readout in terms of whether or not siRNA can make any head roads into CNS, which would really kind of open up a ton of opportunities.

And probably last but not least, again, we'll be the hopefully successful launch of 8-mg aflibercept on June 27, pending FDA approval. So again, a lot of kind of near-term catalysts on the horizon. Okay. Carter, next to you.

QUESTIONS AND ANSWERS

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

Perfect. Great. So before we get into all the juicy margin questions, we're going to test you on your pulmonology boards here. So maybe first, coming back to BOREAS. And I think when you guys talked about the Phase II interim portion of it, you talked about the high bar you set given the outlay you're going to need for the Phase III. So can you help frame how we should think about the hurdle you set there? I know you're not going to get into specifics or at least you haven't to date, but maybe just help kind of put some color on that for us.

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

So again, what Carter is talking to, in June of 2020, we did get interim data on the first trial, the BOREAS trial for COPD. And again, these are being run by Sanofi in the Alliance, and it was kind of a no-go assessment. And they decided -- again, they were blinded to the information. It was an independent data monitoring committee that came back, and based upon the thresholds that were there, basically gave both parties the thumbs up to go. When that happened, we immediately launched, I would say, at risk trial #2 Phase III, which is the NOTUS trial. And then, Ryan, maybe touch upon what -- between the futility and the analysis we saw.

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

So we started BOREAS without the benefit of knowing what Dupixent would do in Type 2 COPD. We didn't run a Phase I or Phase II study in the population. We've used a comorbid nasal polyp population to kind of see a signal, move quickly into Phase III. So that's why this interim analysis is very important. And before we began BOREAS, we've set a prespecified threshold, whereby we would either achieve it and move forward with the second Phase III or stop the study.

So it was -- I would put the bar somewhere between a futility analysis, which was kind of the bare minimum you would need to move forward. And on the other end, a positive Phase II. We think we set the bar sufficiently high such that it would warrant further investment in the large Phase III study. And with that blinded decision by the DMC, we moved forward with NOTUS.

I'd add that there was no stopping criteria as part of this interim analysis, so there was no way that we would have known -- we don't know what the bar -- we don't know how much we achieved the bar by, and it wouldn't have stopped regardless. It was going to move forward and run to the full 52 weeks.

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

Okay. So the data came out in shortly right after the world changed. And we've seen additional data come out of the COPD population thereafter that we saw exacerbation rates dropped during COVID as presumably a lot of these patients were sort of fighting out in their homes. How does that complicate the Phase IIIs? I'm sure you made assumptions around event rates, and there's a reason to believe they're going to be meaningfully lower. It should affect both arms. But in terms of just teasing out that signal, how does that complicate or not the odds here?

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

Yes. It's well documented, as you said, Carter, that COPD exacerbation rates were depressed during the lockdown periods of the pandemic. We saw that as everybody else has. But I think we are confident that the studies are adequately powered to detect a treatment effect. And to your point about placebo arm, it should also affect the placebo arm in the same way that it would the Dupixent arm. So my belief is that if there is really any disease-modifying activity with Dupixent, that it will be demonstrated despite potentially a lower-than-assumed exacerbation rate for the overall population.

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

Okay. And when we think about -- when we get this press release, historically, you guys have done a pretty good job of putting in data into these press releases for us to evaluate. This seems a little bit different in that you have NOTUS going on in the background. Is that reason why we may get less data than usual given the similarities in trial design?

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

I think to your -- I think we have a reputation of being very transparent and allowing all readers to kind of assess the strength of the data in a press release form and then obviously moving forward with scientific presentations to give the full detail. But we tend to provide more detail than less. With this trial, obviously, we're partnered with Sanofi. And obviously, the details of the press release are still being determined. But I would think at a minimum, we would at least provide the magnitude of the reduction in exacerbations, the primary endpoint for the study and potentially more. And I don't think that NOTUS ongoing, and it's still enrolling patients, but I don't think that will really impact our decision on the level of detail. The patients, obviously, are blinded. The investigator will be blinded. All site personnel are blinded. So I think maintaining that blind in NOTUS will be sufficient to make sure we don't bias the study even with the BOREAS results.

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

Okay. And should we still think that both of these studies will be required for approval? I know the guidance documents leave the door open to potentially filing on a single study if the results are robust.

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

Carter, our base case is that you're going to need both. I mean if we're pleasantly surprised, well, that would be great. But we are assuming we're going to need both to file.

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

Okay. Last question on the pulmonology side here. What should we -- what's the potential read-through from BOREAS and NOTUS to the IL-33 studies? Different populations, but relative to underlying assumptions or any other sort of mechanistic read-through that may or may not apply here.

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

Yes, the different and broader population, Carter, obviously, the Dupixent focusing only on the type 2 phenotype versus IL-33, at least our studies, AERIFY-1 and AERIFY-2, which are focusing on both type 2 and non-type 2 patients. I think probably more important than any readthrough from BOREAS and NOTUS is actually the Phase II data that we've already generated for itepekimab, which I believe we published in 2021, which showed in nonsmokers a 42% reduction in exacerbation, which is a huge result. There was not that same treatment effect in current smokers, though. And in that Phase II study informed how we designed AERIFY-1 and 2. We are only looking at nonsmokers or former smokers. And of course, we'll look at both type 2 and non-type 2 patients in that study. And data is expected, I believe, next year. And then with the potential filing, assuming supportive data, in '25.

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

Okay. Great. Maybe we'll pivot here to some of the other topics. Certainly no shortage of topics here. Maybe -- so Bob and I have a bit of a routine on when we go through the earnings notes. It's like where does EYLEA print? Where does Dupi print? And my third thing I always look at is where are Dupi margins. And inevitably, they outperformed our expectations. And then I asked Bob, what does this mean about going forward? And he cautions me a little bit, and then they blow them out again the next quarter. So in 4Q, I think if you just look kind of the evolution of Dupi margins relative to, say, the start of 2021, a meaningful expansion there. And this is even before we get sort of the -- sort of process improvement. So can you maybe -- to what extent to that fair or kind of stable base today to think about that expansion? And any additional color as we think about Dupi margins going forward?

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

I think what Carter didn't say after each call, I get an attaboy with the margins going up, being able to meet his models. Yes. The first couple of years in the -- with the Alliance launch, it was just difficult with regards to kind of show leverage. It just wasn't there. And then as you know, we did kind of DTC for the first time. It was a big kind of flood of DTC across asthma and AD within the U.S. markets, and the margins weren't just popping as much as we thought. But I think within the last -- certainly, within the last 18 months, we've had really good progression with regards to margins.

I think in Q4 quarterly -- year-over-year for Q4, it was like a 900-basis-point margin improvement, which, again, which is showing the leverage that we have, right? We have the necessary sales forces. We're in the necessary countries, and we're just kind of laying on new indications. Like I said, we just got the EoE indication approved in the first quarter in Europe. And again, that's proven to be a much bigger indication in the U.S. than we ever thought it was going to be. So I think that we are at steady state, and I would love for the margins, and I expect the margins to continue to improve year-over-year.

Now we've also been saying that on top of that, on top of the normal course, we've done something that we normally do with our antibodies in which we try to look for yield improvement. Can we get better cell lines than we currently have? So we launched a product with Sanofi with a C2 cell line, but that didn't stop the group in Tarrytown. So we have a group specifically designed for this to try to get yield improvement. So we have. We have come up with a C3 cell line, and it's been approved by both the FDA and in Europe. And again, we're getting it approved throughout the other countries in the world.

And what this does compared to the C2 line with regards to bulk drug, we get 3x better yield with regards to active proteins in the number of doses per batch, right? So the same cost per batch, C2 versus C3, but now getting 3x as many doses as a result of that. Now you'll begin to see some of that kind of come through in the second quarter of 2023 as we kind of start to make this switch from the C2 cell line to the C3 with regards to the bulk drug. And probably by the end of the year, if things go right, hopefully, 50% of the products of what we sold will be through the C3. So again, 2024 will be the big driver, but you'll begin to see hints certainly in the second half of the year with regards to cost of goods sold.

And the other beautiful thing that it does, particularly because of the volume that Dupixent is creating under the C2, it really helps with regards to capital expenditures, right? We don't need to put in more 10,000 capacity with regards to production because we're getting 3x as better yield

out of the same 10,000 capacity. So it's really, really been a bonus for us. And again, Sanofi and Regeneron look forward to the fruits of that with regards to margin expansion going forward.

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

Okay. Great. Maybe moving on to high-dose EYLEA. You touched on -- at the start sort of a shorter turnaround time on the review. Can you talk through the implications of that for the launch, potential J-code coming earlier and as well as just sort of the importance or, I guess, the relative importance of J-code during that initial couple of months?

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

Let me touch upon the beginning, and then Ryan will take the back half of that. So as we mentioned, right, we filed at the end of December. We got it accepted, the filing, in end of February. We were expecting kind of a late August launch with regards to the time frame. And we are using a priority review voucher that we got from Inmazeb, which is our Ebola drug when that was approved.

And we were very pleased to see that upon the letter that came back to us that they were looking at the 8 mg as kind of a non-new molecular entity, which basically had a 10-month review time. You put on the 4-month PVV shortening and then you get 6 months, right? So you go from end of December to end of June, which was really kind of was positive news. We felt we could have the possibility, but it was fantastic that it was kind of cemented with the FDA letter.

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

In addition to reaching patients faster, which is always our goal at Regeneron, I'd add that it does allow us to potentially get our permanent J-code a little sooner. The way the process works for obtaining a new J-code, they have certain deadlines set at the beginning of every calendar quarter. And with a June 27 PDUFA, that now allows us to go to CMS with our application for a permanent J-code by July 1, which would then make aflibercept 8 milligram eligible for and we would hope to receive a permanent J-code by January 1. Had we received approval at the end of August as we had originally signaled, that was going to be unlikely and probably more in the line of getting a permanent J-code on April 1. So we get an additional -- hopefully, get an additional 3 months with a permanent J-code.

But I'd end my remarks on this question with we don't think we need a permanent J-code to really begin to meaningfully convert this market. I think KOLs and we certainly believe that aflibercept 8 milligram is a meaningful improvement and could become the new standard of care in the anti-VEGF space. And we've heard a lot of excitement in the retinal community about using the product. So a temporary J-code would certainly allow that to happen. That should be issued within days of approval and would enable prescribers to obtain reimbursement for the product pretty much right out of the gate. So we certainly will not be waiting for the permanent J-code because I think that the launch can get a lot of traction right away.

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

Okay. And just a level of confidence. You'll be able to turn that around in that sort of weak time frame between PDUFA data and the deadline?

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

We do. I mean, Marion's got a very strong team, and they know what's coming. So it's not like it will be a surprise, and they've made commitments to the company that they will turn it around by July 1.

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

Okay. And in the past, you've talked about the -- just on high-dose EYLEA pricing. I know you're not going to get into specifics. But just sort of conceptually, how should we think about that relative to standard dose and the drivers of that discussion?

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

I started off by saying we have a lot of catalysts this year. We also have a lot of kind of major decisions, and this would rank as one of our probably top decisions in terms of just trying to price it right. I think when you hear Regeneron or I would hope that when you hear Regeneron, you think of us as kind of responsible pricers based upon the history that we've done in terms of launching and pricing drugs. And there should be no change with regards to the 8 mg.

Again, it'd be great to kind of see where the real-world usage is. I mean we're not going to really have the maintenance data. The 2-year data is not going to really come until August. So we're going to have to kind of hit the road out there with the KOLs in thinking about and triangulate all the market access and research information that we have to kind of deliver a really on-point price that's obviously fair to everyone.

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

Okay. As we think about these 2 key decisions and the impact they have on your growth trajectory over the next -- I mean Dupi is going to grow regardless of COPD but sort of turbocharge that growth. But when we think about -- and you're already spitting up a lot of cash. If we didn't think about overlaying that with these 2 drivers in addition, how does that start to shift the capital allocation strategy? This is not the Regeneron of a decade ago. You guys are buying back your stock now, things we never would have thought in the past. Does that start to shift you even more buybacks, additional M&A? How do you think about that? And how do these drivers kind of fit in?

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

So again, for those that don't follow, Regeneron has an $11.6 billion kind of net cash position as of the end of the year on our balance sheet. And we get the question on capital allocation a lot. So our answers are pretty simpler -- simple. First and foremost, above everything else, is we're going to continue to invest in R&D. Now secondly, we're going to complement that with partnerships and collaborations, the Decibels, the Alnylams, the Intellias. We did CytomX not that long ago. Those things will continue. And then thirdly, third on the list is a return of cash to shareholders, and we've been doing that in the form of a thoughtful buyback.

Now to Carter's question, to the extent that we see the COPD data and now that 8 mg, and it appears that our cash flow and earnings are going to be stickier kind of going out forward. We're not -- we don't think we're going to kind of change that path. If you look at what we did in 2022, we basically -- we went out, we brought back the rights for Libtayo. We did checkmate roughly $1.3 billion in kind of BD stuff. We did $2.1 billion of buybacks. And then we put a healthy amount of money into R&D. I think we grew year-on-year with something like 24.5%, which is a big number.

But again, we have a lot of things to invest in. We have a lot of assets, something like -- with regards to new clinical trials and INDs in new therapeutic areas, something like 10 of them are happening in 2023. So we need to keep the innovation going. So our 2022 pattern, Carter, is like exactly. That's what I'd like to do in the company going forward, just as you saw us do in this past year, a little bit of everything.

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

Okay. And when we think about sort of that pace of R&D growth going forward, clearly, it was sort of a transitional period here. COVID numbers were coming down. But when we think about the pace of R&D growth relative to the pace of revenue growth, particularly over the next couple of years, how should we sort of balance those R&D growth? It has been robust as you highlighted.

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

It has. I mean we did surprise, I think, the Street a little bit with regards to our consensus. It was a little bit higher than what they were expecting. But then again, when you hear the innovation that's coming from us, particularly what's happening in 2023 is our collaborations that we did years ago are now kind of coming to fruition with regards to where we are with Alnylam, what we're going to see on Decibel, where we are in the unveiling of kind of new Intellia data, that stuff is starting to really move through the pipeline. And then we've made no bones about it. We're going to be in oncology. We obviously bought back the rights of Libtayo. We're going to be in hem/onc with regards to CD20, CD3. So we think we have a lot of things to invest in. And we've done well in the past with regards to just making sure that R&D and that our pipeline is totally fueled with regards to the necessary support. And again, it's within our kind of capital allocation rule #1, make sure we continue to fund R&D.

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

Okay. You touched on the early-stage pipeline and specifically some of those partnership opportunities. We've seen larger biopharma companies go broad with a whole array of partnerships in the past. Your approach does lean pretty heavily on the RGC platform. Can you -- I mean that does seem like a pretty distinct potential advantage there. Can you talk about that distinction a little bit more? What insight RGC gives you? And maybe just -- I don't know if there are lessons you guys have taken away from some of the past BD strategies we've seen larger biopharmas follow maybe like during the last decade.

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

Yes. I think RGC is a very unique tool, distinct to Regeneron, that helps us identify targets and accelerate development of antibodies when that's the appropriate modality, but also figuring out maybe if antibodies aren't right, what the right partner could be. And certainly, we've leveraged the world's largest database of exomes, over 2 million at this point, that are all connected to health records, which provides us with a very rich database to find targets and address diseases that previously haven't been able to be.

So we are able to identify new targets. We've discovered the HSD17B13 gene in NASH, CIDEB was another NASH discovery, target discovery from RGC. And I guess the other was GPR75, which is an obesity gene that we're collaborating with AstraZeneca on. So we're very -- we've had a lot of success with leveraging that database. It also helps inform trial design for us and looking at the right population for a particular antibody. So I think it is a unique tool. It's one that we're going to continue to lean on and probably even more so develop our own capabilities in this space so that we can take those discoveries and develop products around them.

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

Okay. Maybe with just the last minute, I wanted to come back and touch on some of the oncology portfolio. You mentioned -- one of the things that I think we were excited to see was sort of the broadening of the LAG3 portfolio. You've announced sort of certainly, I guess, the initial start of a Phase III program in melanoma and lung. Can you talk through kind of where else that could potentially go and if sort of that's on the table for 2023? It does seem -- I mean your competitor clearly is taking a much broader approach there. They have first-mover advantage as well, but your melanoma data was pretty compelling.

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

Yes. LAG3 Fianlimab, as we now call it, in combination with Libtayo really has generated some very, I think, differentiated melanoma data, especially when compared to the combination from Bristol. When you look at PFS in a PD-1 naive setting, our fianlimab-Libtayo combination, 2 cohorts pooled, had a PFS of 24 months versus the data on label for Opdualag at 10 months, the response rates for the fianlimab combination were in the mid- to high 60s in 2 distinct populations, the response rate for Opdualag was 43%. So really, I think, a lot more activity, and that might be attributable to our ability to dose a little higher while maintaining good efficacy and safety.

So differentiated LAG3, we think a differentiated PD-1 backbone, has led to what we think is differentiated efficacy in melanoma. You mentioned lung. We are about to initiate Phase III studies in an all-comers population as well as one in a PD-1 high-expressing population. And yes, we do have our eyes on certain other solid tumors. We haven't announced any new clinical studies or programs yet. But I think we probably are in line to do that at some point this year. So definitely stay tuned on that.

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

Perfect. So we're out of time, Bob, Ryan.

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

Great, Carter. Thank you.

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

Thank you very much.

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

Thank you.
