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EDITED TRANSCRIPT

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OVERVIEW:

Company Summary

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PRESENTATION

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

Good morning, everybody. My name is Alex Hammond, and I'm the senior biopharma analyst here at Wolfe Research. Thanks for joining. With me, I have Regeneron, Justin Holko, Global Oncology and Hematology Commercial Business Unit Lead; as well as Izzy Lowy, Clinical Development Unit Head. Thank you guys, and obviously Mark Hudson from IR as well. Thank you guys so much for joining us.

Thanks, Justin. Oh no, Mark has something to start off.

Mark Hudson - Regeneron Pharmaceuticals Inc - Investor Relations

Yes, and thanks for having us, Alex. It's good to see everyone here too.

So let me start off with our forward-looking statements as we always begin our presentation with that. I'd like to remind you that remarks made today may include forward-looking statements about Regeneron, and each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in such statements. The 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 statement, whether as a result of new information, future events, or otherwise.

Alex, take it away.

QUESTIONS AND ANSWERS

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

So I guess, looking forward, we think one of the most important readouts for you guys is your PD-1 and LAG-3 in melanoma. Can you walk us through the confidence there from a trial readout perspective?

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

Sure. Thank you. And first of all, thank you for having us, and it's a pleasure to be here. And before I start, it's really exciting for us at Regeneron to be, I think, now comfortably viewed as a serious oncology company. It wasn't always the case that I think with the development of Libtayo and its success in a number of different indications, more recent success with some of our bispecifics in hematologic malignancies and as we believe it will be a next big thing for us will be the readout of our LAG-3, PD-1 combination study.

So when we set out to develop our LAG-3 antibody did a number of clinical trials in first in human studies. And we're struck to find a very high response rate in cohort of naive -- of PD-1 naive patients. And so we repeated it twice. And we basically -- it is at the end of the day, it's a single arm three-part cohort of 98 patients enrolled separately.

And that over time, what we've seen was a superior response rate and coming up to close to 60% with a PFS that over time, as we've continued to follow, has certainly outperformed what the competition that was available. So we decided to embark on a Phase 3 study to actually really test it. And the study is designed to be testing two different doses as part of our obligation to satisfy the Optimus requirement of the FDA to demonstrate contribution of dosing.

And since cemiplimab, Libtayo is not approved as a monotherapy in melanoma, we needed to go up against another one, and we chose pembrolizumab because, basically, it was a QW3 regimen fit basically with our study and would facilitate blinding across the study, so we could do it properly. So it also -- the study contains a calibrator on for cemiplimab, so that we know -- so we can demonstrate contribution of components. And it's basically testing two different doses of fianlimab, 1,600 milligrams every 3 weeks, 400 milligrams every 3 weeks, both of them in combination with cemiplimab, Libtayo versus pembrolizumab, KEYTRUDA at the standard dose.

When I've seen a lot of stuff percolating out in the literature review saying, oh, they're worried that there might be an unexpectedly long PFS for the control arm. And basically, what we can tell you is that although the label for the PFS for pembrolizumab is in the order of four to five months, and that was the expectation across multiple different trials. And certainly, that was also the area of how nivolumab performed in the relativity study, we took a conservative approach and it set up our study so that we are actually powered to win if Pembro surprises and it's in the high mid-single digits in terms of PFS.

We do believe that certainly compared to nivolumab we are very well poised to beat what we saw and what we're seeing in that study. And I think there also, I'll just proactively comment that I've seen some comments about recent studies where the PFS on pembrolizumab was in the teens. But I'd point out that, that study, the IO biotech study, in particular, was one in which we feel that the patients were very cherrypicked. They had a much lower, for example, rate of brain metastases and adverse base characteristics compared to what is in our study compared to what was in RELATIVITY-47, and compared to what was in actually the most recent study conducted, which was the LEAP study, which was a trial of pembrolizumab and lenvatinib versus pembrolizumab where the blinded independent review of PFS for pembro was 4.5 months, 4.6 months, something like that.

So we are waiting for events to come in. We believe that this is because the test arms are performing well. But we won't know until we know. So we think that the way the events are coming in now, we should get a readout by the end of the first half of next year. And what is also important about our study is that when we set it up, we set it up so that we could also get a survival readout in this that would be powered for that even if we were just relatlimab like.

So we think we are in as strong a position as possible within the realm of dice of clinical trials to be set up for success. And we are just adjusting to events as they come in. It's not the first time studies have had slow amounts of -- slowing of events that ultimately prove to be a good sign. And so that's kind of where we stand. I don't know if there's other specific questions you want me to address on it.

I mean, why we --

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

You've covered a lot of ground.

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

Yeah, I did. I usually do. I would also just say why do we think -- People ask us also, why do we think fianlimab is different, okay?

So one thing is that we were able -- there are differences in terms of the molecule in that our molecule does have a FC that was engineered to be inactive in terms of engaging antibody-dependent cellulose cytotoxicity and cellular phagocytosis. And we've seen preclinically that there are clear differences between that and the competition. Whether or not this has -- we've also noticed that we've been able to dose higher doses, particularly in combination with chemotherapy, which is particularly important in some of the other indications we're testing and not encounter toxicity.

So is that the reason -- I'm not 100% sure, but it is a phenomenon that we're seeing. And as it turns out because the timing is such that we will probably read out in the first half of next year. We also expect to have a potential for a substantial readout in our adjuvant study. During that period of time as well. It will be an interim analysis, may not be mature enough, but we will certainly have some initial analyses.

So we -- I can't -- it's like a pregnancy. I can't make it go any faster. But we'll -- we're sticking with it and trying to get through to the end and cautiously optimistic.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

If there's anything I've learned from Regeneron, it's pretty much not all monoclonal antibodies may (be created equal)

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

Correct. I would grant you that.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

So I guess what is the bar of clinical success here? Recently, management talked about this high teens, but it seems to have changed maybe more mid-teens now. So how are you thinking about this from a PFS perspective.

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

You mean in terms of the success of the fianlimab arm.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

Yes.

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

Right. Well, as I said, even if our data -- well, we even if our data is not that -- there's a surprise and it's not that differentiated from relatlimab, we expect to have OS data in our to be part -- could be part of the study. So to achieve that, we're powered with -- and to achieve that as -- And that's important also. Yes, over time, with five-year follow-up, et cetera, you start to see the OS emerging as well. But unfortunately, it doesn't end up getting into the label because it wasn't something that they were able to achieve at the primary readout. And it's also important in other jurisdictions like Europe, for example, as well. So we think that even mid-teens will be good because it will be superior and because we will -- we expect to have OS with it.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

You don't expect to update the initial readout in the second half or so.

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

We will be having an interim analysis of OS at the readout of PFS, so it's possible we'll have it then, but it may require a little more time to mature.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

A little more seasoning. Got it. Thank you. How should we think about the commercial opportunity as well, assuming that you hit on OS, particularly as you can likely market in Europe as compared to some other assets?

Justin Holko - Regeneron Pharmaceuticals Inc - Senior Vice President, Global Oncology/Hematology Commercial Business Unit

Sure. Strictly speaking, the metastatic melanoma market is probably around $4 billion to $5 billion globally within the metastatic space. It's a pretty fractionated market these days. You have some monotherapy utilization, you have immuno-oncology combinations, some of which come with a little more toxicity, and then the aforementioned LAG-3 and PD-1 combination. So if we do see that differentiated PFS come in and potentially even OS, that's a significant opportunity for us.

And if you'll recall, we're already the global leader in non-melanoma skin cancers, so to be able to add melanoma to this portfolio would really be a significant opportunity for us across the vast majority of skin cancers. So we're really excited to see this readout, just as excited as everybody else is, and if we see something that looks like what we saw in Phase 2, it's going to be a really exciting opportunity for patients globally.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

Yeah, no, we're very excited. I guess any last comments on the combination before you maybe move to just Libtayo as a monotherapy.

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

I would add that one of the things we set out to develop when we got into immuno-oncology quite a while ago was to be able to have a toolbox of agents that we can combine. And we have other agents in clinical development that we think could ultimately combine with a Libtayo-fianlimab combination. So to be honest, when we started as a segue way to Libtayo, we decided we needed a PD-1 to enable our entire strategy, and we made sure that that PD-1 would stand tall and be second to no one. And as you've seen, that's been true and that's the case.

And it's actually commercially doing reasonably well and probably surprising some of the people who originally said, do you really want to get another PD-1? So with fianlimab it's the same story. We have another combination, but we're not done. We have other things behind it. So these things will come in waves, so we're always building for the future.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

And I guess with that one follow-up. You also have a Phase 2 in non-small cell lung cancer that's supposed to read out in the first half of '26. So I believe George has said lung is a tough nut to crack. But how should we think about lung and other potential indications in the future?

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

So lung is a tough nut to crack. We took an early look, very early look, last year and weren't convinced that we had strong enough data to launch into Phase 3. And so what we're doing is letting the data mature and read out to see what the PFS as well as response rate looks like, and we'll take a hard look at that. And I really -- it's interesting that we're in this situation. I don't think -- we like to be convinced that we have a really potent agent to bring forward to help patients before we launch into Phase 3.

And so I think actually the first half of the coming year is going to be telling because we will find out about our melanoma studies, and we'll be reading out the maturing of our lung studies, as well as in addition to advanced lung cancer with and without chemotherapy on top of the combination, we also have some early looks at neoadjuvant perioperative studies in both melanoma and in lung cancer that we'll also be providing information. So it will be a very data-rich path.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

Looking forward to it. I guess on commercial, obviously Libtayo just got approval in adjuvant CSCC. I think the company has said that is around a 10,000-patient opportunity. How should we think about that halo effect in CSCC and what a ramp might look like?

Justin Holko - Regeneron Pharmaceuticals Inc - Senior Vice President, Global Oncology/Hematology Commercial Business Unit

Yeah, it's a great question. So we unveiled a pretty remarkable clinical trial result about a year ago, and that was presented at ASCO this year, showing that patients who are resectable and undergo adjuvant treatment with Libtayo have about a 68% reduction of their risk for the disease coming back. And this, according to our customers, what we have been told is certainly practice-changing. It's the first and the only treatment along these lines to be able to read out a successful study in this setting.

And so what really helps us as we think about helping more patients globally is that we are already the leader in the metastatic space. What this now allows us to do is talk to treaters in earlier settings, and what this is going to involve is involving many more specialties such as your surgical oncologists, radiation oncologists, dermatologists, many of which have limited familiarity with immuno-oncology. And so the benefit here obviously is to be able to help patients who have that surgery to have a better outcome longer-term, but we also see, as you mentioned, the halo effect, the opportunity to have more of these metastatic patients come into the mix earlier on.

What we see is that by the time a medical oncologist is ultimately involved in a treatment decision, these patients are very, very far progressed, and we know there's a lot of patients out there who are still being seen by specialties who could be referred to a medical oncologist. So I see this opportunity working hand in glove with the metastatic business that we already have today.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

And from a commercial perspective, the amount of work that it takes to go into that, do you see that more as like a second half lift? Or do you think that you could kind of see some of the benefits in the first half as well?

Justin Holko - Regeneron Pharmaceuticals Inc - Senior Vice President, Global Oncology/Hematology Commercial Business Unit

We're already seeing utilization within the adjuvant space. When you couple the study results from C-POST, NCCN guideline inclusion, Category 1 preferred, and again, our customer familiarity with Libtayo in this setting, we're already hearing about guideline additions, patients being treated. It is more of a lift as we do have to get to a broader range of these treating specialties. But my expectation is that we see this opportunity advance pretty quickly.

It's the only one in the space, and with the risk reduction we've seen within that C-POST study, it makes for a very compelling opportunity to educate both physicians as well as patients how to get to a better outcome.

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

Talk about nail biting. We were very worried about this study for a long time. It took a long -- We started it in 2018 or so, I think. Yeah, it was -- 1788 is the number, so technically the protocol was written in 2017, and it struggled through COVID because bringing people back. We were nervous about competition, but we stuck through it and it delivered beautifully, and people are thrilled with the results.

We had a standing ovation at ASCO, which was like, wow, that was nice. And people have really said you guys nailed it, and they're embracing it. And we are not stopping there. We have also cooperative group study, looking at neoadjuvant settings as well to formalize the Phase 2 results that we had a couple of years ago.

We also have efforts underway in other approaches and even earlier stages of CSCC to try and intralesional treatments. So we are -- And this is, of course, the earlier practitioners, not the advanced medical oncologists, that are going to be seeing it. So we think, this is -- from a time point from when we started in this field, there were a lot of skeptics that weren't even convinced that CSCC was a real disease. And we can go back that. So we've really staked out this area, defined it, performed beautifully in it, and had delivered great value to patients.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

And see not all monoclonal are made equally.

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

Right.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

And I guess, Justin, how should we think about the commercial opportunity here, particularly if we go beyond just adjuvant?

Justin Holko - Regeneron Pharmaceuticals Inc - Senior Vice President, Global Oncology/Hematology Commercial Business Unit

Well, we're currently annualizing at about $1.2 billion in terms of global Libtayo sales. I would say 60% or so are coming from the non-melanoma skin cancer business with the balance being in lung cancer and certainly happy and excited to talk about our progress there as well. But adjuvant CSCC does represent a pretty material addition to the non-melanoma skin cancer business to the oncologist. But there's also importance of educating on how it's important for patients to complete the full adjuvant treatment which is about 48 weeks.

We oftentimes see in market analogs that patients may only get out to six, seven, eight months, and it could be for a variety of reasons. But the study was run for patients to receive 48 weeks worth of treatment, and we want to make sure that all those patients have the best potential outcome of not having their disease come back.

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

We also, I would add, in the study provided patients with the option after their first four doses of Libtayo administered standard every three weeks to switch to a Q6-week dosing regimen. And the approval that we got is for either. They could either do 48 weeks at Q3 weeks throughout, or they could do the total of 48 weeks with the first 4 doses being given every 3 weeks and subsequently every 6 weeks. So we've demonstrated in this study that Q6-week dosing of Libtayo 700mg QW6 as opposed to 350mg QW3 is effective.

Comparison between those arms in the study who got straight QW3 versus QW3 switching to QW6 showed maybe even a little better outcome, although it wasn't really powered for that, but certainly no degradation. And certainly, I'm sure patients preferred coming in every six weeks. So we think it's a patient-friendly regimen now. after that, so that should help also.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

How do you make sure that patients go out to the 48 weeks of treatment, like what strategies will you have in place to push that narrative?

Justin Holko - Regeneron Pharmaceuticals Inc - Senior Vice President, Global Oncology/Hematology Commercial Business Unit

Again, it just goes back to that's how our study was written. We don't know what a shorter course could mean ultimately to the outcome. So it's upon us to educate the various specialties within the surgical and prescribing community and then as patients as well as appropriate.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

Perfect. And I guess, non-small cell lung cancer. You touched on it a little bit. How is that progress? Is it just more so now grinding away? How should we think about it?

Justin Holko - Regeneron Pharmaceuticals Inc - Senior Vice President, Global Oncology/Hematology Commercial Business Unit

Great question. Yeah, it's been a grind since the beginning. And as my colleague, Izzy says, I think there were a lot of skeptics wondering if we could even compete in that space. And I think what we've shown is that we can. First of all, it helps to have great data. We are NCCN Category 1 preferred in the indications where we are prescribed. And we've been able to really show that this drug is also foundational to a lot of the other things that we are doing.

But I would point out that in the US now, we have become number two prescribed. We're at about 15% new patient share. Outside of the US, we have as much as 25% to 40% new patient share in the high-expressing cohort, where we see a lot of strength.

If you look at our clinical data, we don't have studies versus some of the other market leaders, but you can see that our squamous data stands out very strongly. And our thought leaders do view squamous disease as one of the more high unmet medical needs. A lot of former smokers, challenges with longer-term outcomes.

And so we are, as Izzy said earlier, beginning to show up as a more legitimate player within the cancer space, but that also applies to lung cancer. As our data continues to stand out. And obviously, we have significant investment with Libtayo as well as the pipeline in lung cancer going forward.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

Very helpful. I guess, Izzy, I wanted to ask, what is your favorite child when it comes to the pipeline?

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

People ask me that all the time, and I don't have a favorite child. I mean, I love all my children.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

You love them all equally though.

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

I have to say I do. Well, look, at the end of the day, you like -- we bring things into the clinic that we think have very compelling preclinical rationale and supporting data. But then at the end of the day, when you go into the clinic, you find out that things don't -- we don't run a mouse clinic. What determines success in the clinic is sometimes a surprise.

So I would say we have a number of things that are cooking that are exciting. One thing that we have is we have a whole co-stimulatory bispecific panel of agents where we've been the pioneer. It's been -- it's conceptually really elegant, and we've seen different types of efficacy in different settings. In the prostate cancer field, we saw really promising efficacy, but some problematic immune-related adverse events.

We are continuing to move forward in that area, looking at combinations with PSMA by CD28, that can widen that therapeutic window and allow us to actually continue to deliver some of the striking responses we've had. We have a MUC16xCD28. We have an EGFR xCD28. Those so far have been relatively modest in terms of delivering clear-cut benefit, which I think speaks more to the lack of understanding we have about how to optimally develop this area.

But we are pushing forward. And as I said at the beginning, we do this with the idea of having conceptually appealing combinations. We have -- in terms of new agents that we have -- in terms of xCD3s, in addition to the hematologic space, which I don't manage, but we also have some promising data in ovarian cancer that people are MUC16x CD3 has delivered very durable, well-tolerated responses in women with advanced platinum-resistant ovarian cancer.

And I'm aware that there's a whole flood of ADCs entering the ovarian cancer space. But this is a non-chemotherapy option that actually when patients actually -- with very minimal CRS at the outset that when they get through that is extremely well tolerated and provides durability of response beyond the time of their actual life expectancy from when they came in. And then we have some newer agents that are in the clinic.

We have a PD-1 directed IL-2 to actually deliver cytokines to the tumor macro environment that is currently in dose escalation, showing well that it's tolerated well and delivering some early signs of responses in a number of different tumor types. Hopefully, in the next year or so, we'll be able to present more.

We also have developed -- while we are focused on immunotherapy, we have excellent chemists who have come up with a novel approach, we think a novel approach, developing topoisomerase payloads, and we have a novel met by met antibody that is actually extremely well internalized.

And so it was a great vector for delivering such antibody drug conjugate that actually will have -- we think will have efficacy across a number of tumor types: lung, colorectal, others that don't necessarily have to have super high expression on met but can work further.

So those are just sort of a smattering.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

That's an amazing overview. Clearly, a lot cooking. I guess in the last minute, Justin, do you have any closing remarks on the commercial portfolio?

Justin Holko - Regeneron Pharmaceuticals Inc - Senior Vice President, Global Oncology/Hematology Commercial Business Unit

Just thrilled to be leading this great organization. We've recruited hundreds of colleagues from around the world who have worked on market-leading treatments. The portfolio continues to grow. As you say, we are currently launching Lynozyfic in relapsed/refractory multiple myeloma. That launch is going extremely well.

That's a significant investment that we're making clinically. I think up to 10 Phase 3 studies. We look forward to hopefully moving treatment into earlier line settings. We really do believe that, like Libtayo, Linozyfic could be a powerful backbone opportunity for all lines of myeloma and perhaps even some precursor conditions.

So hopefully, more to come about that in the coming years, but couldn't be happier to be doing what we're doing here at Regeneron.

Alexandria Hammond - Wolfe Research LLC - Equity Analyst

Thank you guys so much for joining us. We're very much looking forward to the first half of 2026. Very data heavy.

Israel Lowy - Regeneron Pharmaceuticals Inc - Senior Vice President, Oncology Clinical Development Unit Head

Thank you.
