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OVERVIEW:

Company Summary

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PRESENTATION

Chris Raymond - Piper Sandler - Analyst

Okay. Let's go ahead and get started. Thanks, everybody, for being here. My name is Chris Raymond. I'm one of the senior biotech analysts here at Piper Sandler.

Very pleased to introduce our next presenting company, which is Regeneron Pharmaceuticals. Today, we have the CFO, Chris Fenimore, who's joining us and also Ryan Crowe, who is the Vice President of Investor Relations, up here on the stage. So very pleased to have you guys with us here.

Just a little bit of housekeeping. This is a fireside chat format. It's meant to be very informal. So if anybody has any questions from the audience, just raise your hand. I'll make sure it gets asked and answered.

One would argue, Regeneron needs no introduction, but I think you guys have some introductory comments, maybe some safe harbor statements. But maybe after that, if you could maybe provide a little bit of an overview for a few investors who might not know the story.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations

Sure. And maybe I'll kick it off with this forward-looking statement disclosure. And thank you for having us, Chris, we're very pleased to be here and love this conference. Great attendance as always.

I would like to remind you that remarks made today may include forward-looking statements about Regeneron, and each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in such statements. A description of material risks and uncertainties can be found in Regeneron's SEC filings. Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

And I think instead of opening remarks, we'd rather just jump right into the questions. I know there's a lot of focus on EYLEA lately, so maybe we could start there.

QUESTIONS AND ANSWERS

Chris Raymond - Piper Sandler - Analyst

All right. Let's do that. Okay. Cool. Yes.

Why don't we just jump right into conversion from the 2-milligram to EYLEA HD. This is top of mind with everyone. We've done a decent amount of survey work. I think others probably have as well. But we've had some recent KOL feedback around the mix for EYLEA 2-milligram versus HD and there's the survey work and then you get these one-off KOLs that have their own opinion.

And I think maybe what this illustrates is there's a big diversity, I guess, of use, of opinion, of projections. But one of the things that I think kind of caught our attention is we're starting to get more feedback that EYLEA 2-milligram might be a bit more sticky over the long range. And I'm not just talking about like what you've seen last quarter in the next coming couple of quarters. But ultimately, there is a -- you're not going to ever convert everybody from 2-milligram to HD. Maybe just talk a little bit about that dynamic.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

Sure. Thanks, Chris. And Ryan and I are very pleased to be here. I mean if you look at the EYLEA franchise in total between combined EYLEA and EYLEA HD. We had a remarkable Q3 in terms of the combined brands grew 3% year-over-year, did approximately $1.54 billion, maintained share about 44%.

So the franchise is doing incredibly well. In terms of EYLEA itself, clearly the market leader out there. It's very trusted brand among retinal physicians.

I mean as you said, Chris, it's a little bit stickier than we would like, and we're obviously out there doing our best to drive the conversion from EYLEA 2 mg to Eylea HD. It's an increasingly competitive environment out there, and we can acknowledge that there's a recent aflibercept 2 mg biosimilar launch. There's a recent prefilled syringe launch of a branded competitor. So those are obviously dynamics that we're dealing with, but we are incredibly focused on driving the conversion of HD.

There are some aspects of the label that I'm sure we'll get into that we are also very diligently working on, and it's something that we're very focused.

Chris Raymond - Piper Sandler - Analyst

Yes. Let's maybe talk about the label, right? There's been -- this has come up in a lot of our work that a Q4-week dose would be a very important thing for Eylea HD. Just talk about that effort.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

Sure. So we have been in contact and dialogue with the FDA and continue to have that dialogue. And as time lines become available, we will make sure we communicate out those time lines. I think as you look at the need for every 4-week dosing and you look at the clinical data between PULSAR and PHOTON it's really only a very small percentage of patients that require less frequent dosing. So with that being said, the retinal community does like flexibility and dosing flexibility. They're operating in a treat and extend type of dynamic.

So we are doing all that we can, obviously, to get that into the label. We also -- I mean, one thing to point is the physician community likes to have real-world experience and real-world evidence. And obviously, as they're out using HD more and more, our expectation is they'll get a little bit more comfortable in terms of how their patients are doing and using HD, and this should, over time, become less of an issue.

We recently started as well a Q4 dosing trial that is opened. That data obviously will be very helpful in conversations with the FDA as well as with payers as an example. So as I said, we are very focused on doing all we can to give physicians and what they are looking for in terms of dosing flexibility.

Chris Raymond - Piper Sandler - Analyst

Okay. And another issue, I guess, that we've heard from a couple of one-off maybe conversations with KOLs is that -- and this is new, actually, to me, is that there's a bit more ambivalence I guess, around extended dosing believing really don't care as much. And maybe this is a factor of how folks have sort of evolved their practices over time. There are a lot of practices that are focused on doing injections. You guys have been following or I should say you've been driving this market for years. You understand this better than anyone.

Has that maybe evolved over time where perhaps it used to be early on in the availability of VEGF that folks wanted the longer, the better. But now the things that maybe evolved where maybe that's not the top of mind?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

I think it's hard to say. And I think to your point, there's a tremendous amount of variability. It's going to vary from physician to physician. I think it's going to vary even within a given the physician from patient to patient in terms of how they want to treat their patients. What we do know is that physicians obviously want the best product for their patients and the best outcomes for their patients.

We do hear from a lot of physicians that getting their patients out from a dosing perspective is very important.

But we also do hear that dosing flexibility is also something that's important. And as you say, we're focused on both, obviously.

Chris Raymond - Piper Sandler - Analyst

So, obviously a very dynamic market, lots of stuff, a lot of, moving parts or cross winds if you will. But, you, you've got a competitor Vabysmo that's been, you know, a formidable competitor. And I guess it's interesting, we asked docs, across a ton of different attributes, what do you like about which, which, option and it's been pretty consistent, Docs favor Eylea HD in terms of, overall efficacy, Vabysmo does better on access, which, that obviously will change over time. It just takes time for reimbursement and access to the perceptions to change. But one of the hooks, I guess that the Vabysmo consistently wins with is with those recalcitrant patients, those that are, tough to dry.

And EYLEA HD doesn't really have that perceived attribute at this point, maybe just talk about this issue and how big of a deal is that and, is this something that, is a focus or am I just hearing this from physicians that are again in a minority?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

So I mean, to point to reimbursement for one second, Chris I think it's -- we have roughly 80% of covered lives out there for EYLEA HD. So we made significant progress on that front on the reimbursement front. In terms of what you're talking about from a drying perspective, I mean, ultimately, what really matters is visual acuity gains and clinical outcomes for patients, and I think physicians realize that.

We recently presented some data at AAO where there was a switch component of one of the studies where patients after two years were switched from EYLEA to EYLEA HD. And when you saw the data at the end of year three, that there was actually slower fluid reaccumulation for those patients when they switched to HD versus when you looked and you observed at fluid reaccumulation while they were on EYLEA.

So we are seeing trends of improvement in drying.

Chris Raymond - Piper Sandler - Analyst

Okay. Good. And so maybe just another sort of cross-wind or dynamic that's going on in this market is the potential for an Avastin shortage we got some KOL feedback that indeed -- and then we followed this up with a survey that indicated yes, it's a relatively wide -- somewhat widespread that physicians are starting to hear from their compounders that they're no longer willing to supply. Pine is a major supplier that's decided definitively to get out of the business, and it seems like there are others. Just give us a sense, we've seen supply issues with Avastin over time.

There have been a couple of different waves over the last several years where you've seen quality issues and other supply shocks. -- give us a sense maybe of how this particular instance sort of fits in with what we've seen in the past. Is this different maybe than others?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

So in terms of broader than Pine, it's hard to say what's happening out there in the broader compounding marketplace. But in -- this situation with Pine is clearly different. In the past, where Pine has had some issues. It was a temporary type of situation that they were able to get resolved. -- they have decided to exit the market.

They're roughly latest data that I've seen somewhere between 40% and 45% of the Avastin supply comes from Pine. So they are clearly a meaningful supplier that has exited the market. It's too early to tell in terms of what impact that will have on the branded marketplace. It's one thing that's, I think, helpful is if you think about the availability of Avastin, -- that availability was driven by patients a lot of times didn't have a lot of cost flexibility, and were restricted in their ability in terms of what they could pay with this Avastin shortage going away, it's really unclear how that need is going to be satisfied for those patients that are in need of that type of drug.

The other thing that I would also add is that CMS has recently sent out letters to a lot of the Medicare Advantage plans and basically have encouraged them to either not have pre authorizations because of this potential Avastin shortage or step edits. So that's obviously encouraging news, and we hope would be obviously a benefit for Eylea and Eylea HD.

Chris Raymond - Piper Sandler - Analyst

Any sense as to timing. It -- we keep asking, it seems like at this point in time, right, December of 2024, there's a lot of anticipation that going to happen, but I haven't really seen, especially in some of the pulse survey work that we've done that has really moved the market that much at this point. That's too granular.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

So when we first heard about Pine exiting the market, they had communicated to their customer base. They had about 2 weeks of supply. That was several weeks ago. So presumably, they are no longer in the marketplace, but we don't really have any confirmation of what those levels look like. And like I said, it's a little too early to tell as to what the impact might be.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations

Okay. And I'd just add that the compounding market is a little murky, and you never really have a clear read on who's manufacturing how much and can they step up and fill that void, other compounders, can they fill that void or not. What we've heard from the field is that so far, as you mentioned, Chris, the so far, there hasn't really been a noticeable shortage and people are able to find Avastin when needed.

Chris Raymond - Piper Sandler - Analyst

Okay. All right. Great. So let's maybe talk a little bit about the other news item or dynamic, which is the potential for the biosimilar aflibercept launch with Amgen launching Pavblu with a prefilled syringe. We got some pretty interesting feedback.

It seems the awareness of this was a lot higher than I would have thought and willingness to prescribe the drug once launched, was a bit higher than I thought.

I know you guys are making progress in front of this with the conversion, obviously, but you also have the prefilled syringe of EYLEA HD coming by midyear of next year. And you're also going to have a permanent J code around April or so, but just heading into the new year, maybe just share some perspective and how should we be thinking about this dynamic on this looming launch here?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

So we've obviously been planning for potential biosimilar competition for quite a while. Our commercial organization has a variety of strategies as to how to address a new entrant such as this biosimilar coming in the marketplace, we can obviously speak about what some of those strategies are. We are just doing as much as we can to convert the marketplace as much as possible from EYLEA 2mg to EYLEA HD, talking about some of the enhancements that you mentioned, Chris.

In addition to the two that you mentioned, there's also an opportunity for retinal vein occlusion. Right now, that is also not in the label for HD. Bayer is running a study called the QUASAR study. We're expecting data from that study by the end of the year. And based on conversations with the FDA and other global regulatory authorities, we believe that, that the data is positive from that study will form the basis for global regulatory filings. So that will also be forthcoming in terms of a competitive profile.

Chris Raymond - Piper Sandler - Analyst

Okay. All right. Let me ask a CFO question. So capital allocation, I know this comes up all the time. But maybe your latest thoughts, maybe, Chris, on capital allocation, whether it's a mix of M&A, share repurchase, you already have shown an appetite for that, maybe internal R&D investments sort of -- this question with respect to a dividend also comes up, any thoughts that might be new here with respect to capital allocation.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

Yeah. No, thanks for the question, Chris. So I mean our capital allocation strategy is not changed. It's -- we're very consistent in terms of how we allocate capital. First and foremost, we think we have one of the most innovative pipelines out there in the industry, and we continue to allocate capital towards driving what we think is the best use of that capital. And I'm sure you'll have plenty of questions on the pipeline and Ryan can sort of go into a lot of detail on that.

As you mentioned, we've done some M&A in the past. They have historically been what I would describe as relatively modest ancillary acquisitions, but that's not to say that we couldn't do anything larger. We clearly have the flexibility with our balance sheet if the right thing came across our plate that we have the flexibility to do that. In terms of share repurchases, we repurchased through the first nine months of this year, about $1.6 billion worth of our stock.

We ended the quarter with about $2.9 billion of capacity in terms of an authorization. And in the fourth quarter, we have meaningfully stepped up our repurchase activity. And you mentioned dividends. We continue to message to the world and a possible inflection point for that would be on a development balance with Sanofi for our antibody alliance when that is fully repaid which we expect to be by the end of 2026 that that will be an opportune time to consider paying a dividend. But we have to get there and obviously continue to evaluate that.

Chris Raymond - Piper Sandler - Analyst

Okay. All right. So let's maybe jump into the development pipeline. So maybe first, the geographic atrophy program, it feels like this is widely ignored still by investors, you're extending your C5 siRNA plus antibody approach into the ophthalmology space. You've got this pozelimab, cemdisiran combo.

Maybe just talk about this program. This is unique, right? You're jumping right into Phase III without patient data I'd love to get a sense of the premise there in GA, we know from some of the launches that have come already in that space, if there's a large unmet need or at least a large market opportunity, but the unmet need is pretty big. So maybe talk about that.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations

Sure. That's a great question. And we are just getting underway with our pivotal C5 program for geographic atrophy. As you mentioned, it involves an antibody called pozelimab as well as siRNA called cemdisiran. And we think that's the right approach, and it will be a systemically administered therapy instead of intravitreal, which are at the two approved agents in the US currently are dosed as.

We think this is a better approach because, A) it will get you complete knockdown of C5, which is important for a complement-mediated disease like geographic atrophy, and it also shouldn't carry the same risks of retinal vasculitis that have been widely documented with the existing approved FDA therapies.

There's other side effects that we need to be concerned about with our approach, I think, primarily with infections, but we're doing with our trial, doing the best we can to mitigate that risk with a screening period that will require either documentation of vaccination for meningitis, pneumonia and flu or a vaccination during that screening period.

We're also going to exclude patients that are on -- that have had an organ transplant or on any kind of immunosuppressive drugs. So we're really going to try and do the right thing on patient selection and to make sure this is safely conducted before we enroll any patients. We're encouraged by the progress that we've made in our PNH and myasthenia gravis programs.

We actually have an upcoming data presentation this weekend at ASH that will highlight this approach in PNH and show that versus ravulizumab, the current standard of care, we actually can accomplish better disease control and actually for patients that are uncontrolled on ravulizumab can actually get under the upper limit of normal when they're switched to our combination.

So very encouraged by what we've seen in other complement-mediated diseases believe that will translate to geographic atrophy and we're excited to have started the study a couple of weeks ago.

Chris Raymond - Piper Sandler - Analyst

And just noticing in clinic trials, I know this is not a perfect sort of guide, but the completion date is noted as July 2027. Is that just sort of a placeholder? Or do you really think the enrollment would take that long?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations

Well, I don't -- I think we -- anytime we put a date up there, it's kind of put your finger in the air, best guess at that time. Obviously, a big part of the readout is going to be contingent on enrolling the study. We think that our heritage in ophthalmology as well as the experience with this combination in other complemented diseases will get us and Izervay being a C5 inhibitor itself paves the road for us to get enrollment at an adequate pace.

But the date that we have up there reflects what we think the pace of the enrollment will be. And it's a 52-week study that will be similarly designed to the currently approved FDA -- the FDA approved agents, where we'll look at lesion -- the rate of lesion growth over a 52-week period, but we'll also add in some prespecified visual acuity secondary endpoints to hopefully demonstrate a functional vision improvement at 52 and 104 weeks.

Chris Raymond - Piper Sandler - Analyst

All right. So let's talk about the IL-33 in non-type 2 COPD. Last quarter, you guys shared you completed enrollment in your two Phase III studies, both passed interim futility in 2023. And I think results are you're guiding to second half of next year. Remind us of that maybe, if you will, Ryan, the positive data you shared from the Phase II and what we should expect to see from the readouts in Phase III?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations

Sure. IL-33 or itepekimab AERIFY programs, as you mentioned, did fully enroll. We announced that in -- at our third quarter call. And basically, they'll read out sometime in the second half of next year. This is going to look at a former smoker population.

The reason for that is because what we saw in Phase II showed that among former smokers in a post hoc analysis we were able to demonstrate a 42% reduction in annualized exacerbation rate among those patients, which is obviously a very efficacious drug.

We saw no effect in current smokers, which is why they've been excluded from the AERIFY program. This would address a bigger population than DUPIXENT, which will only look at patients with eosinophils greater than 300. This will be regardless of your eosinophilic count at baseline. So we're optimistic that this can actually improve the standard of care for COPD even in those high EOS patients. We actually saw that in our Phase II results as well for patients with over 250 eosinophil count at baseline achieved a 53% reduction in annualized exacerbation rate.

So once we get these results, hopefully, they're positive. We'll know kind of what the right drug for the right patient is for those with COPD. And again, we expect those results sometime second half of next year.

Chris Raymond - Piper Sandler - Analyst

Okay. Last, maybe pipeline question. You guys are always eager, George especially, to talk about your oncology efforts. It seems like you don't get enough attention as much as maybe you'd like on the oncology efforts. If there's maybe one or two programs, your LAG-3, I think, is top of mind and don't want to lead the witness -- what would you sort of highlight that maybe people are not paying enough attention to on the oncology side?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations

I think we've definitely been progressing our oncology pipeline over the years, and I think we're going to have a big year next year. we'll talk about LAG-3 in a second. But before we do, I wanted to put a plug in for our ASH data where we're going to have some very interesting monotherapy data for odronextamab in previously untreated follicular lymphoma patients. We're going to have some more odronextamab data in CAR-T refractory DLBCL, which is a very high unmet need. And we'll also have our first data in heavily pretreated patients with marginal zone lymphoma.

So those are all of our presentations, we're excited to have at ASH. LAG-3, as you mentioned, is kind of the lead in terms of the oncology assets we have in the pipeline, currently in Phase III in melanoma with a KEYTRUDA comparator.

That data is expected next year. In Phase I across three independent cohorts we demonstrated objective response rates in the low 60s, pooled I think, came into a high 57%, which compares very favorably to a PD-1 monotherapy, which I think for KEYTRUDA was around 33%. And median PFS for the pooled results in Phase I across these three independent cohorts was 24 months versus about four or five months for PD-1 monotherapy. So we think we've got a very good opportunity in melanoma, especially with LAG-3. We also presented data at ASCO this year in head and neck cancer, which is also very encouraging.

And we have two ongoing Phase II studies in lung cancer that we now expect will read out in the first quarter of next year.

So LAG-3, I think we'll have an exciting 2025. I'd also add that we have additional data coming from our CD28 co-stimulatory bispecific programs. So we'll have some more PSMA by CD28 data in the early part of 2025 and probably some in the later part of '25 and then EGFR by CD28 is in dose expansion across various different solid tumors, and we hope to have some more data for you in those indications.

And lastly, linvoseltamab, which we think is a best-in-class BCMA by CD3, we continue to enroll earlier-stage studies and including in precursor conditions. And we think that ultimately, this could be a solution for myeloma -- upstream of myeloma and potentially even prevented from metastasizing. So exciting across the board. We also have some other preclinical assets we hope to bring and IND in the next year. So oncology continues to crank along and we're excited about providing updates in 2025.

Chris Raymond - Piper Sandler - Analyst

Okay. Awesome. Well, this happens every year. I'm about halfway through my questions, and we're unfortunately out of time. So -- but thanks so much, guys.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations

Thanks. Really appreciate it.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Senior Vice President - Finance

Thank you.