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PRESENTATION

Terence Flynn - Morgan Stanley - Analyst

Great. Thanks for joining us, everybody. I'm Terence Flynn, US biopharma analyst at Morgan Stanley. We are pleased to be hosting Regeneron today.

I'll just read my disclosures, and then I'll turn it over to Ryan to read his disclosures. Please see the Morgan Stanley research disclosure website at www.morganstanley.com/researchdisclosures.

And again, pleased to be hosting Chris Fenimore, the company's CFO; and Ryan Crowe, Head of Investor Relations.

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

Thanks, Terence. Great to be back at Morgan Stanley. I'll just briefly go through our forward-looking statement. 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. 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. With that, Terence?

QUESTIONS AND ANSWERS

Terence Flynn - Morgan Stanley - Analyst

Thanks, Ryan. You win the award for the longest disclosures.

Well, Chris, I thought we'd start first with you. It's been about a year since you're announced as the company's CFO. Maybe just talk to us about your top three priorities here since assuming that position and what you're focused on the forward?

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

Sure. Thanks, Terence. And as Ryan said, thank you for having us. We're excited to be here. So it's been roughly a year since it was announced that I'd be the CFO.

I've only been in the seat since the first week of February, so a little more than six months at this point. My predecessor, Bob Landry, was in the seat for about a decade and really set up the finance function and me stepping into that role in a phenomenal fashion. So there's really not a heck of a lot I need to do in terms of what Bob left me with, and he sort of turned over the keys to the seat in very good shape.

In terms of priorities for me personally, one thing is I want to make sure I'm out with the investment community meeting the sell-side and buy-side analysts. We started sort of trend of trying to be as transparent as we can from a disclosure perspective.

So any time that we see there are things that are material that the Street needs to be aware of, I will continue with that of making sure that we're as transparent as possible. We get a lot of questions shifting to capital allocation about the balance sheet and our cash balance. So I'm laser focused on executing on our capital allocation strategy. We have three pillars of our capital allocation strategy. Most recently, in April, as you look at that, one of -- the third pillar of our capital allocation strategy is repurchasing our shares.

We basically got a reauthorization of an additional $3 billion of capacity for our share repurchases, which obviously goes a long way in terms of anchoring on that portion of our capital allocation strategy. And then the last piece I'm focused on is obviously making sure we're managing our investments wisely and efficiently on a number of fronts. So if you look at what we have coming up in terms of commercial launches, we've got a launch for COPD that will be forthcoming. We've got launches for our hematology programs that will be upcoming. So making sure we're doing that in the most efficient way possible.

Obviously, and then on the R&D front, we've got multiple shots on goal and just managing the investments that we're making and making sure we're doing those in a prudent fashion.

Terence Flynn - Morgan Stanley - Analyst

Yes. Okay. Great. There is more on the strategy side. But I think Regeneron, at least in the large-cap universe, you're still one of the few companies that doesn't give revenue guidance on an annual basis.

Just any thoughts on that now that you're in the CFO seat in terms of kind of the pros and cons? And would you make that change at some point in the future?

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

Yes. I've been at the company over 20 years. So if you look at the launch of Eylea and then obviously Dupixent that followed and many of the other products, our philosophy is not to provide revenue guidance. The rationale behind that is where there's information asymmetry, we want to be as transparent as possible.

But when there's a lot of access to data that allows analysts to effectively model out what the top line looks like, we'll rely on those data sources to obviously allow the Street to utilize that to build their models.

With that being said, we obviously watch where consensus is. And if we think there's any disconnects where we might be versus where the Street is, we'll do our best to, as I said, be as transparent as possible along those lines.

One area where we are -- we might not necessarily get formal revenue guidance, but in areas where it's not necessarily product revenue related, but it might be related to Sanofi collaboration revenue or other revenue, we will take those opportunities because those are areas where there probably is some information asymmetry and be a little more forthcoming with either the level of what we might expect or the timing of what we might expect.

Terence Flynn - Morgan Stanley - Analyst

Yes. Okay. Great. You alluded to this in your opening remarks, just on capital allocation and cash has been building on the balance sheet. And I know the preference has been internal investment, obviously, a lot on the pipeline on the R&D side.

And also select business development more earlier stage and talking to Len and George. Historically, it's always platforms where maybe you guys don't have as big of a presence.

And so I guess the big picture question first is just at some point, would you consider a dividend? And then how do you think about a starting point for any kind of payout ratio?

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

Yes. So we've -- if you look at last year, we did a pretty exhaustive analysis, brought in some outside advisers to help us analyze whether or not it made sense to initiate a dividend at that point. We concluded that '23, '24 was not the right time. With that being said, we've spoken publicly about the Sanofi development balance is a possible inflection point, which we've communicated we expect to have fully paid down by the end of 2026. That might be an opportune time to initiate a dividend.

So we'll have to wait and see, and we'll continue to evaluate it. In terms of payout ratio, what that level might be, we really haven't given it much thought. So I think it's a little too premature to comment.

Terence Flynn - Morgan Stanley - Analyst

Yes. Okay. In terms of the business development front, from a framework, anything that's shifting or changing in terms of some of those comments I made before in terms of how you're approaching that? And what are you seeing out there right now from kind of like a partnership appetite perspective?

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

Yes. I mean we have a very active business development group. They're regularly out there talking with other companies. From a strategic perspective, they sit down with Len, they sit down with George, look at areas where we might be interested where there might be opportunities for us.

And to your point, we look at opportunities where the technologies are complementary or synergistic with things that we have. And we think it will allow us to do more things in terms of investing in our R&D pipeline. And the decision at that point is whether or not we enter into a traditional collaboration or we decide that it makes more sense to own the asset or the platform.

Historically, we have not done much on the outright M&A front. We've done some fairly modest acquisitions. We've done three of them now and just -- the first one was roughly, I think, two or three years ago. So we're relatively new to the M&A space.

But that doesn't mean we won't be more active in the future. It really depends on what the opportunity looks like. We clearly, with the balance sheet that we have tremendous flexibility. So we don't necessarily feel that we have any constraints in terms of size or at least the size that we might necessarily play in.

We don't necessarily have an interest in single product types of opportunities. We think that space is relatively competitive, and we're better suited finding, as I said, opportunities where there's a little more depth and breadth that can bring longer-term value to shareholders.

Terence Flynn - Morgan Stanley - Analyst

Okay. Got it. And what's the opportunity set look like right now? I guess more on the partnership front, I mean, obviously, some of the mid-cap biotech companies, the financing window has been pretty tight. Does that create an opportunity for you guys to find more partnerships right now?

Or is it more kind of need dependent?

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

I mean it depends. To your point, there are companies that have had trouble raising capital and they knock on the door and say, hey, are you interested? And we look at those opportunities.

But we're clearly driven by where we think is what makes the most sense for us and not necessarily what makes the most sense for the other, the other party in terms of timing of a transaction or even entering into a transaction. So it's hard to say what we're interested in, we're just constantly out there looking and evaluating.

Terence Flynn - Morgan Stanley - Analyst

Okay. Okay. Great. Maybe just moving on to some of the products now. Maybe just any update on progress with high-dose Eylea conversion in the US?

I guess, as we step back, very attractive product profile, a space you guys know very well. So I guess is there a reason why you couldn't get over 90% conversion from low-dose as you think over the longer term?

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

Maybe I'll jump in since Chris has been talking a lot lately. So first, let me say this. The launch of Eylea HD is not about just converting from Eylea to HD. It's about really becoming the new standard of care in the category. Of course, the category right now, the biggest player is Eylea, and that's the primary source of business for HD.

And I think the conversion so far has been going well. But we're not satisfied with only converting from Eylea to HD. We certainly have been focusing on other branded products as well as compounded Avastin. And over time, we do anticipate Eylea HD becoming the largest player. We're not ready to make a target and put a target out there in terms of conversion of Eylea to HD, but we are confident in the product's profile.

We know that the prescribers like it. And as patients dosing interval extends, they're going to like it. So we're very happy with the launch so far. It's been about a year. And last quarter, we did just over $300 million. So we're excited to build from there.

Terence Flynn - Morgan Stanley - Analyst

And largest players, is that when you think about both branded and unbranded, somewhere on volume when we think about largest player on a volume basis?

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

Yes. I mean our share of the market between Eylea and Eylea HD was 45% of the category as of second quarter of last year -- of 2024. So that is -- and Eylea is obviously much larger than Eylea HD at this time. I'd say probably around 40% of the market at that second quarter time point. But Eylea HD continues to build not only from Eylea conversions, but from other brand products such as Vabysmo and others.

Terence Flynn - Morgan Stanley - Analyst

Yes. And what -- how do you think about the -- maybe coverage dynamics? I mean that's one question we get in terms of like fail first on Avastin. I mean, is that likely to remain steady state here? Or are there any other changes as we think about 2025 that we need to consider?

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

I don't think so. Right now, the way the coverage works, around 40%, 45% of the anti-VEGF category is managed by -- it's basically Medicare Part B standard beneficiaries, and there's no managed formulary for those patients. So they have first-line access to Eylea or Eylea HD.

The other, call it, 50%, 55% of the market is nearly evenly split between commercial and managed Medicare. And a lot of those formularies do require a single step that is oftentimes through compounded Avastin.

But that's a very normal treatment algorithm that our prescribers are very familiar with. Oftentimes, a patient on their first visit will come in. They'll be diagnosed. They'll receive Avastin -- compounded Avastin at that time. And then legwork around reimbursement will take place over the ensuing couple of weeks.

They'll come back, hopefully, have authorization to receive Eylea or Eylea HD, and they will begin that regimen. So I think not really anything changing there. We're very pleased to have over 80% coverage for Eylea HD a year into the launch, which is an excellent coverage outcome for the access team.

Terence Flynn - Morgan Stanley - Analyst

And maybe just remind us on the prefilled syringe. I know it's something else that helped accelerate the launch of low-dose Eylea. I know VABYSMO has one, they might already have it out in the market. You guys are working on it, but what's the time frame there?

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

We mentioned this on our earnings call. Our time line for Eylea HD prefilled syringes to launch in early 2025. Certainly, we see a lot of -- over 90% of Eylea usage comes from the prefilled syringe. So we know that it's certainly preferred by prescribers. I think it helps with their throughput of patients.

They don't need staff to prepare it. So it's clearly preferred. The Vabysmo prefilled syringe is launched -- I think, is basically happening right now. We did see that their prefilled syringe does require a filter needle, which would be the first time for that because of non-visible particulate. So it will be interesting to see how prescribers react to that requirement. Our goal is to bring a prefilled syringe that would not require a filter needle.

Terence Flynn - Morgan Stanley - Analyst

So is that more like an incremental step or cost? Or what's the hurdle to the filter needles? Is it more the perception of safety, which of those?

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

I think that's it. There's a perception of safety and you must use the filter needle provided in the kit. If you don't, then you're putting patients at risk, and there's a potential for that filter needle become nonsterile then the prefilled syringe is not usable. So there's some potential roadblocks or hang ups to the launch there.

Terence Flynn - Morgan Stanley - Analyst

Okay. Okay. We'll stay tuned. The -- I guess the other question we get is around high-dose formulation such as an Eylea, how that will be treated under IRA. And so as you think about that dynamic, maybe any considerations to think about?

Obviously, we had the first round. That was only for the Part D drugs. Part B is next up in a couple of years. But how do you see -- how does the company see this playing out? It's maybe one of the bigger picture questions we get oftentimes.

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

Yes. Certainly, a question we get quite a bit, too. But unfortunately, CMS has not been very forthcoming with how they're going to interpret the statute for Part B drugs. We still lack guidance in how the law will be implemented for Part D drug -- Part B drugs. We obviously have the guidance on Part D.

The selection process has taken place. The negotiation outcome has been announced and we'll see those prices implemented in January, but we are at least two years behind for Part B drugs and therefore, don't have great clarity into how CMS will handle it. If we are to use Part D as our guide for Part B, we would expect that should there be any biosimilars for any aflibercept product, including Eylea or Eylea HD, that all products using that same active moiety would be excluded from the negotiation process.

But once again, we need that clarity from CMS from their guidance to make a more certain claim there. And we look forward to that, but we have no -- we have not received any time frame for when to expect it from them.

Terence Flynn - Morgan Stanley - Analyst

So no even like bookends in terms of when we might hear something from them, if you have to take a guess?

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

My expectation is that it will follow a similar time frame to Part D. They put out the Part D guidance six months ahead of the selection date for Part D drugs. The first Part B selection date is February 1, 2026. So if we back out six months from there, we're talking around this time next year.

Terence Flynn - Morgan Stanley - Analyst

Okay. So Morgan Stanley Conference 2025.

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

We'll see. We'd love to get it earlier.

Terence Flynn - Morgan Stanley - Analyst

Yes. Okay. And then what -- just again, to close the loop on that before you go to Dupixent, remind us of what is the earliest low-dose biosimilar could enter the US market right now.

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

So we have a judgment against Biocon that is after a trial where we asserted a formulation patent for Eylea. There are other biosimilar manufacturers that we have also sued who are awaiting their trial and are currently enjoined from launching their product. We have another injunction decision pending against Amgen, which we expect a decision to come in the coming weeks.

And there's -- another defendant has entered the litigation very recently, Sandoz, whose biosimilar aflibrocept was approved last month, and we recently initiated litigation with them. So in total, there are six companies that we are trying to keep off the market by asserting this intellectual property for the formulation of the '865 patent, which expires in June of 2027.

And -- so we have -- and we believe that it will be the first opportunity for a biosimilar to come to market, and we will defend our IP against all of these other biosimilar players.

Terence Flynn - Morgan Stanley - Analyst

Okay. Great. Moving on to Dupixent, again, one of the other important growth drivers here of the company. I think the breadth of label has been a big part of the story here. And so maybe as we think about the indications, you could just kind of give us an overview of like relative size.

I'm assuming atopic derm is still at the top because that was the first indication. But as you go through some of these other indications, maybe how do those stack up as we think about the opportunity set here?

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

So you're right, atopic dermatitis is definitely the majority of sales for Dupixent. But if you look at both NBRxs and TRxs, the other indications outside of AD, NBRxs are roughly 40% and TRxs is roughly 33%, say, a third. So obviously, getting a lot of traction in these other indications outside of AD.

If you look at the three indications of basically AD, asthma and nasal polyposis, we classify those as basically being a blockbuster status, each of those indications. So sizable performance out there in the market.

Two of them were recent launches. So if you look at eosinophilic esophagitis, there's about 90,000 patients in the addressable population. To date for the launch, we've had about 30,000 NBRxs. So quite a significant penetration in that marketplace. And then prurigo nodularis where we've seen about 18,000 NBRxs to date with the launch, I mean, that addressable population is about 75,000 patients.

So again, sizable penetration. And then obviously, with COPD coming up next in the U.S. alone, we think the target population is roughly 300,000 subjects in the U.S. So clearly, as we described, Dupixent, it's a brand that's got multiple brands within a single brand.

Terence Flynn - Morgan Stanley - Analyst

Yes. Okay. Maybe you can unpack a little bit of this. Atopic derm, a question we get is just there's obviously other competitors potentially coming here, lebrikizumab, the OX40, Rinvoq is -- has been relegated to second-line setting given the label. But just how do you think about maintaining that kind of first-line position given some of these other biologics that could be coming to the market in atopic derm?

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

I think for Dupixent, it's been on the market now for seven years. For a while, it was the only approved biologic for atopic dermatitis. And it has a very large share of the market, but it's very underpenetrated. So as new products come to market, we think that will help to grow the pie, so to speak. And as they continue to promote behind these brands, these competitive brands, Dupixent will be the outsized beneficiary of that.

I think the last check, the adult penetration in atopic derm was only around 20% in the US And when you look across all age groups in the US, penetration somewhere in the low to mid-teens. So a lot of patients have not even come to be addressed with Dupixent. We think there's a lot of opportunity there. And competition, as Marion McCourt, our Chief Commercial Officer likes to say, will make us stronger.

We're certainly prepared for these competitive entrants, not only from lebrikizumab but from the OX40s and from the IL-31s that are all seeking to come to market. We believe that Dupixent's efficacy and safety profile has been proven. It is the first choice among dermatologists, and I don't see that changing with any of these new agents.

Terence Flynn - Morgan Stanley - Analyst

Does that become disruptive from a pricing standpoint at all? Or again, because you guys have the breadth of label, that really gives you an advantage in terms of that formulary positioning?

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

I don't think it will have a dramatic impact on price. These new competitors are going to fight for share and probably do some things with price. But I don't think Dupixent needs to get into that game.

Terence Flynn - Morgan Stanley - Analyst

Okay. Got it. The other, obviously, interesting area that people are focused on is COPD. You alluded to this, Chris, you have a PDUFA date later this month. Maybe just talk to us high level about some of the commercial preparations and anything different about the ramp in this indication versus some of the other disease areas we've been watching, atopic derm, asthma and nasal polyps that make us more optimistic about a quicker ramp or we should have a more measured view of kind of that trajectory out of the gates in COPD?

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

Yes. I think that the data with over 30% reduction in annualized exacerbation rates across two studies, a pre bronchodilator FEV1 improvement among patients is very compelling to prescribers. And I know that there's a lot of enthusiasm in the KOL communities to get access to this drug. We're working with the FDA on our pending application there, and we're working towards a decision by the September 27 PDUFA date.

I think with this population, it is primarily an older population, and it will fall into Medicare Part D if they're over the age of 65. And that's not the payer mix of most of the other indications for Dupixent. So upon approval, we'll need to go through the contracting payer process.

But over time, as we get those formulary positions in place, I think we'll have a very meaningful and exciting launch on our hands. The sales force is certainly ready, us and Sanofi have been partnering on how to position the drug in the market. And now we're just waiting for a decision by the FDA.

Terence Flynn - Morgan Stanley - Analyst

Yes. That contracting process, can you just remind us like is that a six-month process, approximately longer than that, shorter?

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

It always kind of depends, but I think we're looking at it in terms of a few months.

Terence Flynn - Morgan Stanley - Analyst

Few months. Okay. Got it. Okay. Okay. Great. And then any -- the other one is a geographic basis, anything like US versus ex-US that's notable about COPD? Or nothing to call out?

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

I think that there's -- in the US, we've identified around 300,000 patients that will be eligible for Dupixent treatment, and that would be patients with eosinophils at an elevated level above 300 cells per microliter. And it would encompass both former smokers and current smokers.

In the G7, which would include Europe and Japan and Canada. I think there's around 500,000 in total. So the US, EU and Japan would be around 500,000 in total. I think China is another big opportunity that will be primarily handled by Sanofi, but obviously, a large population there and with air quality issues.

Terence Flynn - Morgan Stanley - Analyst

Yes. Okay. Great. The other question is just the margin profile of the Dupixent JV. So Chris, this is probably more one for you.

There's obviously some incremental spend on the COPD launch that we're just talking about. Directionally, how should we think about that margin opportunity on the JV here with COPD coming online?

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

Sure. So I mean if you look at COPD, and particularly, we clearly, with the asthma indication, we have a respiratory sales force that's out there. With that being said, we want to make sure both Sanofi and ourselves that we're resourcing the launch properly and putting some incremental resources behind the launch to ensure success. So there'll be some incremental investment on that front. But at the same time, getting some synergies with the respiratory sales force that we have in place.

If you look at the margins on the Sanofi collaboration and as you called it, the JV, there has been some opportunities over the past couple of years to see some margin improvements. Originally, we phased in a new manufacturing process, which significantly impacted COGS. That was largely phased in, I would say, by the end of last year.

We continue with Sanofi to phase it in some other markets over the course of '24 and '25. But for the most part, a lot of that benefit was already realized last year and will come through a little bit this year as well.

If you look beyond that, as the product continues to grow and we get past the COPD launch and the launches are more mature, we definitely expect to get additional leverage as the expense base kind of normalizes and revenue continues to grow.

Terence Flynn - Morgan Stanley - Analyst

Yes. Okay. Okay. Great. And then the last one on Dupixent for you, some of the pipeline is a question we get somewhat frequently is just IP and how to think about that.

Obviously, we've seen the Eylea strategy and how that's played out. Maybe just any high-level commentary on how to think about Dupixent IP in the US?

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

I'll take that one. I'm not an attorney, but I've been handling all the patent questions. I'll just keep going. Full disclaimer. The composition of matter pf patent, which is typically the strongest patent in a patent estate is for dupilumab expires in March of 2031.

Now we have several other pending and issued patents that span formulations, methods of treatment using dupilumab and even manufacturing that reach into the early to mid-2040s. And we're certainly going to assert those and defend those patents that we would expect them to be litigated.

So we'll have to see on their defensibility and whether or not they can be upheld and whether or not the biosimilars infringe them. So I think March of 2031 is probably the earliest potential entry, but we are very focused on trying to defend all of this IP and extending the period of US exclusivity beyond that.

In Europe, we have a little bit longer runway. I think the supplemental protection certificates for dupilumab there expire in March of 2033. So a couple of years beyond the US exclusivity window for the composition of matter patent. And then in Japan, it's even beyond that, October of 2034.

So we have a pretty long time to really build Dupixent into -- and then let it realize its full potential and address as many patients as possible.

Terence Flynn - Morgan Stanley - Analyst

Okay. Great. Maybe just in the last few minutes, shifting over to the pipeline. I think one of the near-term data sets is your LAG-3 in combination with LIBTAYO Phase 2 data for lung cancer.

Again, maybe just high level of the design of those two trials? And then how much data we're actually going to get from this initial cut versus maybe another more mature cut down the road?

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

Yes, it's a great question. Certainly, I'll read out that I'm excited about. And we've shown a lot of early data in melanoma, which looks very promising for the combination of fianlimab and LIBTAYO in that advanced melanoma setting.

This will be a more substantive readout in a different solid tumor lung cancer. There, we're enrolling two Phase 2/3 studies. The first study is in an all-comers population, and we'll look at the combination fianlimab, cemiplimab and chemotherapy versus cemiplimab plus chemo. And we'll -- the second study will just look at patients that are greater than 50% expression of PD-1, PD-L1, and that is going to leave the chemo piece will fall off of those two arms.

The Phase 2 cohorts for each study are going to be 150 patients. So at the end of -- towards the end of this year, November, December timeframe, I'd expect us to -- take a look at the objective response rates for each of these populations that we're studying. I think it's going to be like kind of an interim Phase 2.

We're certainly not going to get much in the way of a read on PFS and certainly not for overall survival. But it will give us an indication about whether patients are responding at a greater rate when we add in LAG-3 to these more established regimens in lung cancer.

So we're excited about the potential there, along with other solid tumors for the fianlimab franchise.

Terence Flynn - Morgan Stanley - Analyst

And is that -- is this data going to be enough to make a Phase 3 go no go? Is that the trigger to expand into Phase 3? Or do you need to see that PFS, OS data to then pull the trigger on expanding into the Phase 3 portion? Or how does that work?

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

I think the goal would be to get that answer with this interim Phase 2 readout and then continue to follow those patients longer while potentially launching a Phase 3 in parallel. But we'll have to see if there's some degree of uncertainty there. We may decide to wait to pull the trigger on the Phase 3 start.

We're also interested in watching and seeing the magnitude of the treatment effect from the Bristol LAG-3 data that we expect them to present at ESMO. We noticed that they have initiated a Phase 3 study in patients expressing between 1% and 49% PD-L1. So that is apparently a population that they saw a signal in what we'll be looking for a similar signal across our studies as well.

Terence Flynn - Morgan Stanley - Analyst

Yes. Do you guys -- but are you more confident in that population? Or are you still confident in just the all-comer population?

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

I don't think that we have a view on confidence at this point. We ran a very small Phase 1 study of 15 patients. So this is really going to dictate whether or not we have a future in lung cancer or not.

Terence Flynn - Morgan Stanley - Analyst

Okay. Maybe just last minute, linvoseltamab. You have the CRL just next BCMA for multiple myeloma, for those that don't know. Maybe just next steps here post the CRL that we got in August?

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

Sure. So on our second quarter call, which happened in early August, we basically communicated to the investment community that based on discussions with the FDA at the time that we thought it was likely there would be a delay that happened. We got a CRL, as you said, on August 20.

It was related to a third-party fill/finish manufacturer that had some pre-approval inspection findings on another company's product, but that then prevented their ability to approve the product at the PDUFA date. Based on our conversations with the FDA, they said a reinspection is required, that inspection has been scheduled, and we expect to have it resolved in the coming months.

This third party has basically told us that they believe all the findings have been resolved. So it's really up to the FDA when they come in for that reinspection to agree with that third party's findings.

Terence Flynn - Morgan Stanley - Analyst

And then how long post that would the action be? Like would -- is there anything else procedurally you guys need to do as Regeneron or it's just getting that inspection clearance and then the FDA would act on your application?

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

I think we'll -- I think there are additional steps beyond that, but I don't know that there's anything that necessarily is problematic with it. It's all just part of the process of getting a drug approved with the FDA.

Terence Flynn - Morgan Stanley - Analyst

Okay. And does this impact at all like the -- any of the commercial plans or anything? Or is it just kind of pushed out a little bit, but anything like steps you're taking to kind of mitigate that delay?

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

The team is in place and they're ready to go. So once we get the approval, we'll be able to hit the ground running.

Terence Flynn - Morgan Stanley - Analyst

Okay. All right. Well, thank you so much, Chris, Ryan, really appreciate the time today.

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

Thanks, Terence.

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

Thanks.

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

Yes, appreciate it.
