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OVERVIEW:

Company Summary

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PRESENTATION

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Hey, the Citi Global Healthcare Conference. My name's Geoff Meacham. I'm the senior biopharma analyst here. We're thrilled today to have Regeneron. And speaking of behalf of Regeneron, we have CFO, Chris Fenimore, and we also have Ryan Crowe from the IR Team. So welcome, guys.

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

Thank you for having us.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Ryan's going to do a forward-looking and then we'll get right into it.

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

Yeah, thanks, Geoff. Great. Great conference you're running down here and we're really excited to do this fireside with you. I just need to read this forward-looking statement, and we'll jump right in.

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 that differ materially from those rejected 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, let's jump in.

QUESTIONS AND ANSWERS

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

All right. Okay. So Chris, let's first focus on maybe on the policy and the macro. We've had a lot of announcements from some pharma companies on manufacturing and tariffs and that kind of stuff.

Give us kind of an update of where you guys are with respect to either -- I know you've made some announcements on manufacturing, but on MFN, price negotiations. Just kind of the state of the world from a policy context.

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

Sure, and again, Geoff, thanks for having us. So just to recap in terms of our commitment to domestic manufacturing and fostering employment in the US, we announced earlier this year about a $7 billion commitment in terms of both expansion of our R&D capabilities as well as domestic manufacturing. So some of that is tied up with a relationship with FujiDiosynth in terms of a contract manufacturing arrangement.

We're expanding our headquarters in Tarrytown, New York, which will enhance our own internal R&D capabilities. Most recently, the Governor's office in New York announced that we are expanding our manufacturing capabilities in Saratoga, New York as well to allow us to continue to fulfill our abilities to meet the demands of our growing pipeline.

And in addition, we also have a fill-finish facility that we've been constructing for the past few years that is also going to allow us to diversify in terms of risk on the supply chain and bring new capabilities to Regeneron in terms of doing fill-finish which historically we had outsourced to third-party manufacturers.

On the MFN front, we were one of 17 recipients of a letter from the administration on them in terms of what they'd like to accomplish with drug pricing in the US. We're in active negotiations with the administration. I think if you look at the contents of those letters as well as some of the deals that have been publicly announced, the administration has a couple of goals in mind.

Many of those goals were very much aligned with and we've been vocal over the years in terms of what needs to happen in terms of fostering innovation in the United States, allowing companies to make investments, but at the same time get rewarded for making those investments with innovation. But also seeing that countries in the rest of the world that can afford to pay for those medicines are paying their fair share.

So we're very aligned with the administration in terms of those goals and those in terms of what they're looking to accomplish. But the other thing that's very clear is they value the industry. They want to reward innovation and we're very much focused on investing where we think is appropriate. And we see -- as we look at our pipeline a lot of opportunities to drive long-term shareholder value by investing in the pipeline investing here in the US.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay, that's super helpful. I guess, Chris, you just stick with more sort of a type of financial questions at the onset. You guys have a very substantial cash balance and you've initiated a dividend. You've done some buybacks. But you historically haven't done a lot of M&A or BD deals sort of of size. I guess and you -- and most companies that have done that have needed to do that to fill their pipeline so I think that's a good sort of scorecard on like where you are from a pipeline perspective.

But is that something that you're thinking about differently looking to say '26 or '27? Are there, say tools or technologies or indications that maybe you could be more aggressive with the cash? I mean, I guess the question is, it burning a hole in your pocket or is it not?

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

So in terms of our capital allocation priorities, first and foremost, Geoff, it's investing in our internal capabilities, and we will continue to do that. I think as you look at external opportunities, you saw on Monday we announced a relationship with Tessera. We will continue to look at external opportunities where we think it makes sense. I think historically, our focus has been on more traditional collaboration type arrangements where we think there's a complementary technology or a target of interest where it's complementary to things that we have ongoing.

With that being said, we are very much open to looking at external opportunities from an M&A perspective. We've got a fairly active business development group that evaluates things that are out there, that are available. The challenge is companies are all looking for the same

thing. They're looking for late-stage opportunities that are either have proof of concept data or in Phase III, that have the ability to drive near term revenue in multiples of billions of dollars, and the evaluations of some of those opportunities can be fairly high.

With that being said, if it's the right one and we think it makes sense and the science makes sense and the commercial opportunity makes sense, we definitely have the balance sheet and the wherewithal to make the appropriate investment if we think it's the right opportunity and we're not shy to do that.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

And how would you sort of tier that? Would it be sort of unmet need? New verticals, new therapeutic areas, or would it be just sort of staged? Like is there a way to think about kind of how you would prioritize something on the BD external front?

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

I think we evaluate internal and external opportunities the same. It's -- what does the science look like? Do we think there's a reasonable probability of success that the opportunity will result in, obviously, an approval in a commercial opportunity? What do we think the commercial opportunity looks like?

Do we necessarily have some complimentary resources on the sales and marketing front where it would make sense? But at the end of the day, the lens that we evaluate those opportunities is really no different between whether it's an internal or an external opportunity. It's got the same rigorous process.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay, that makes sense. And just to follow-up on the cutbacks on the commercial investments you're making in the US, I guess is the intermediate to long-term goal to manufacture products in the US for the US market and Europe for the European market. Is that kind of how you would think would ultimately end up steady state wise?

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

You know, managing a supply chain is a fairly complex way of bringing products to market. Ideally, that would be sort of the framework in terms of the way it would work. With that being said, things don't always necessarily work out as cleanly as you're describing and obviously, you have to match the capacity that you have with the demands of the products and sometimes, they don't necessarily match up the way you're describing.

But we're firmly committed to basically -- for domestic manufacturing, doing all that we can to increase those skills and capabilities, and we will always have a need to satisfy the demands of markets outside the US and we've got manufacturing capabilities outside the US that's very important and we will continue to obviously manufacture outside the US as well.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

That's helpful. Well, let's switch to some of the commercial markets. So we'll start with Eylea. In terms of Eylea HD enhancements, just got approval of RVO and the Q4 dosing. Maybe talk about when these could start to play out in the commercial setting? Is this maybe more of a '26 kind of inflection for Eylea HD? How should we think about the timing of the impact of those?

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

So we were very excited to get those approvals just before Thanksgiving. Our commercial team, immediately upon approval was getting trained. Is out there obviously talking to practices to get the word out on both every four-week dosing as well as RVO.

As we talked about the enhancements to the profile of the product, that's two of the three. So we're still waiting on the pre-filled syringe. In terms of the impact, because we're entering the holiday season and they're just getting the word out, it's really not a 2025 impact. But we are really encouraged about what it means for the brand starting in 2026.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay. Yeah, and the third one on the pre-filled syringe maybe help us with kind of what are approximate timelines? What's been the gating factor, and how should we think about that as being kind of the third of the approval to really see a bit of a tipping point?

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

Yeah. That's a great question and certainly would round out the profile for Eylea HD which I think is differentiated in all of its approved indications but needs that pre-filled syringe to really, I think, set it apart from the other competitors.

We are on track to submit a filing with the FDA to get the pre-filled syringe approved sometime in the second quarter. I think we've committed to a submission by January. This will be with an alternate, pre-filled syringe filler, that's not Catalent. So we are still on track for that and would anticipate that approval to come probably in the second quarter.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay, that's helpful. And guys, looking at the overall franchise, I know over this year, you've had some payer or foundation issues with regard to Eylea, Eylea HD. There's been a lot of nuances in the market. Would you say, by middle part of next year, a lot of these things will normalize, assuming that you have the pre-filled syringe? Do you expect maybe a return to sort of franchise growth for the combined Eylea and Eylea HD?

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

So I mean there's a few questions in there, Geoff. One is the affordability issue. It's obviously something that we follow very, very closely. We initiated a matching program in the middle of this year where we recognize that the need is out there and we want patients to get the therapy that their clinicians believe they should be prescribed. But we realized that we couldn't do it alone. So we initiated the program with the goal of matching dollar-for-dollar up to $200 million to the end of 2025.

Unfortunately, we didn't have a significant amount of participation, at least in the third quarter, and that was less than a $1 million. So we're really looking for other participants out there to help us and patients for that matter in terms of addressing the patient affordability issues. In terms of the franchise and the brand, our goal is obviously, especially now with these two enhancements to get out and convert as many Eylea 2 mg patients to Eylea HD.

We believe HD is really the best product for patients out there in terms of the clinical profile and the durability, and I assure you that our commercial team will be out there in full force trying to do that as rapidly as possible.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay. Yeah, that's helpful. And when you think though, Chris or Ryan, about the competition, so maybe help us with the Regeneron response to -- have biosimilars been impactful thus far? I know it's fairly early days. And then, help us with kind of how you're thinking about the Vabysmo looking to next year as a competition? Just thinking at a high level, like kind of price and volume strategies.

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

Yeah. I mean biosimilars present a formidable challenge, especially for the 2 mg. But I would say, anyone who is converted to a biosimilar still remains an excellent candidate to be switched to Eylea HD, which we view to be the best product in the category with unprecedented durability across wet AMD, DME, and now RVO. The dosing flexibility issue has been addressed with the label update.

And on RVO specifically, we are the only product in the category that's approved for every 8-week intervals and we have an uncapped dosing period. So I think we've got a differentiated label in RVO, and I think the two-year data that we've presented really underscores how efficacious, safe, and durable this product is.

So we continue to compete and of course our competitors are out there doing the same. But we view that the best product will win and we're really looking forward to completing the profile with this pre-filled syringe approval in a few months.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay. And last one, just on the sort of on the policy front. I know we've seen some announcements on MFN and on, at least for GLP-1s new Medicare, Medicaid access. Are there any Eylea-specific policy kind of data points that we should focus on looking to, say '26 or new shifts, new emphasis on wet AMD markets in particular, for example?

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

I guess we're still waiting to see what the first round of Part-B IRA drug selections are. We would think that because Eylea faces biosimilar competition. It would be excluded. But until we get that list from the CMS, we will continue to watch. So I don't envision there being any impact from a negotiated price. We do believe that the active Moiety Rule, meaning any drug with the same active moiety will be bundled for purposes of selection as well as exclusion, would then exclude Eylea HD from potential selection down the road.

But we, again want to see kind of where the CMS lands on its initial round of Part B drug selections, and that is due by February 1, 2026. So it could come anytime from now between now and then.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay, that makes sense. Eylea HD is outside of those conversations?

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

We -- so like I said, if you have a biosimilar for one, it should exclude the bundle based on the active Moiety Role that's been defined in the guidance documents that CMS has issued.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay. That makes sense. That's helpful. Well, Dupi still is, wouldn't ever call a drug on autopilot, but it's still growing up and to the right, pretty robustly, and the core markets in the case of AD and asthma are still growing as well.

Maybe let's focus on just those two indications. So help us with kind of the growth drivers going forward? Biologics are still very low penetration in AD, talk about kind of what activities you guys have done commercially to continue to invest in that as a brand.

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

Yeah, I mean, Dupi is an incredible product. It now is actively treating over 1.3 million patients globally. Its lead indication is atopic dermatitis was approved in the US in 2017 and really has set the standard for atopic dermatitis treatment, moderate to severe atopic dermatitis. So I think we continue to benefit from our own commercialization strategy that we collaborate with Sanofi on. Obviously out in the field, very actively detailing dermatologists. We have active DTC as well.

Obviously, there's been some competition that have launched in the last couple of years. What we've seen is, they've also invested in those launches and that has driven patients to dermatology practices. But it's been really market expanding. And as the market leader, I feel that Dupixent has been a disproportionate beneficiary of that market expansion which is driving a lot of the growth there.

That said, atopic dermatitis is very under penetrated, especially when you look across other derm indicator, other dermatological diseases such as psoriasis. Dupixent and other biologics for atopic derm have only penetrated the adult market by 20%, 25%. When you look at an analog like psoriasis, biologic penetration is something around 40%. So we still have quite a bit of runway in just atopic dermatitis.

Within asthma, we continue to lead in both new to brand share as well as total prescription share, really underscoring the efficacy profile that we've demonstrated there. And obviously with the COPD launch, we've been seeing a lot of pulmonologists more frequently and certainly underscoring the value proposition that asthma brings to patients.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Talk a little bit about the COPD launch, Ryan. When you think about eosinophil testing, I know initially that was thought to be an uncertainty with regard to patient identification and adoption. Has that become a more normalized like commercial situation?

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

Yeah, I think so. There -- we ran our studies, BOREAS and NOTUS in patients that had eosinophils greater than 300 cells per microliter and that is essentially what our clinical data and the label says, and what most payers have adopted as their prior authorization requirement.

There is oftentimes a look back period so that patients that have been tested for eosinophils, say for six months ago or three months ago or a year ago. And they exceed 300 would be considered a high eosinophil patient and therefore, eligible for reimbursement with Dupixent. So we haven't really run into a lot of issues with patients getting the drug.

And I think what we saw was around a 30%, 35% reduction in annualized exacerbation rate in our clinical data, which compared to the other approved biologic for COPD at around high teens, maybe up to 20%, is just dramatically different. That's greater than 50% improvement on that while not head-to-head, of course. So we think that the drug itself, it works better.

It also has demonstrated an FEV1 improvement, lung function improvement, I should say, versus our competitor which demonstrated actually a detriment in lung functional improvement. So patients feel better, they're exacerbating less. We hear anecdotes where patients that have

been on oxygen therapy for years are all of a sudden able to walk up the stairs without a tank. Really remarkable patient stories that we've heard in this launch, which is now only about 15 months in. So there's a lot of runway there.

In terms of its trajectory, it's the best-performing respiratory launch for Dupixent, and second best overall, trailing only atopic dermatitis in terms of new to brand share. So very excited about the momentum we have generated in COPD and really think there's a lot more work to do to get it to more patients.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Yes. And in terms of the future one runway, so CSU, BP are new line extensions and you have AFRS as the next, kind of line up. So talk a little bit about how you think about this as a kind of commercial investment. Do you redeploy a lot of the sales professionals to new indications? Are you growing overall the commercial effort? I just want to -- how do you maximize as you add more line extensions?

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

The beauty of all these new indications is that they kind of fall within the same spaces and practice, specialty areas that the existing indications do. Like for CSU, which is chronic spontaneous urticaria, a spontaneous breaking out of itchy hives. This is obviously a skin condition, and dermatologists historically have referred a lot of CSU patients to allergists, and allergists have been treating them with Xolair because it was the only approved product for this.

Now, when a patient presents at a dermatology clinic with chronic spontaneous urticaria, first option can be dupilumab after failure of antihistamines. So we've seen a lot of uptake in the derm community. They certainly want to retain those patients in their practice, and they're seeing great results with Dupixent. So, while the sales reps are in there detailing on atopic dermatitis, they're also certainly going through the clinical data for CSU as well.

Bullous Pemphigoid, similarly, a dermatological condition. This is a blistering, a very painful blistering of the skin, often in elderly patients, and there was no approved therapy before Dupixent. And now there is, and these patients are seeing very dramatic results right out of the gate. So very complimentary additional indications to where we are already entrenched with Dupixent.

And with AFRS, we have a pending decision from the FDA, I believe, it's in late February. This is a respiratory indication, almost a subset of chronic rhinosinusitis with nasal polyps. So I think that would again fit very nicely into the respiratory sales force's detail.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay, that's helpful. Well, let's switch gears to a pipeline. We can talk about Libtayo too. But, for LAG-3, the -- maybe just remind us of the timing of when we could see that data? What was, what does, in you guys' view, kind of a win look like in terms of clinical differentiation and maybe just remind folks the assumptions of the study?

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

Sure. We're conducting a Phase III study that combines fianlimab with Libtayo in first line advanced melanoma, and we are using Keytruda, or pembrolizumab, as our control arm. This study completed the PFS cohort enrollment in January and we are awaiting enough events to read out the final endpoint, the primary endpoint, which is median PFS.

We've pushed out the timing of this readout to the first half of 2026 due to a slowing of event rates, so we continue to wait for events to accrue, and once we reach the number that has been dictated in our trial protocol, we'll complete the study. We have a lot of hope and confidence that fianlimab plus Libtayo can generate a meaningful differentiation against current standards of care.

We look at PD-1 monotherapies, median PFS is range is sort of in the mid-single digits, four months or so for pembrolizumab, around five months for nivolumab, and clearly this study powered against Keytruda, you want to have a statistically significant result first and foremost. But when we look at other competing first-line melanoma therapies such as Opdualag from Bristol-Myers, which is another LAG-3 PD-1 combination product, they were able to generate a 43% response rate and a 10-month median PFS with no benefit to overall survival.

In our Phase 1/2 studies where we studied fianlimab plus Libtayo in three independent cohorts, on a pooled basis of about 100 patients, the response rate was 57% and the median PFS was around 24 months. So, should we be able to even approach replicating that result I think we'd have a very meaningful advance for first-line advanced melanoma. So we're excited about the data and hope that we can read it out in the next few months.

I'd add beyond first-line advanced melanoma, we're also studying this combination in adjuvant melanoma, which is a study that we fully enrolled and would anticipate first interim analysis to perhaps be conducted next year, depending, of course, on event rate accrual.

Beyond that and beyond skin cancer, we also are looking at this combination in lung cancer where we will read out some Phase II results in all-comers population as well as in a high expressing PDL-1 high expressing population sometime in the first half of next year as well.

But I think it all comes down to this first-line melanoma study, showing that we truly have a differentiated combination here relative to not only pembrolizumab but other standards of care in the setting, and we look forward to the results.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Thank for that, Ryan. And then I guess the follow-up would be in lung and maybe other indications. Could you go, right, I'm assuming you have Phase II success in lung. Could you go right into a Phase III? Would you do more of a basket trial? Like what would you say would be the, maybe the next steps outside of melanoma?

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

Yeah. Obviously, the Phase II results are going to inform what we do in lung. We are running that study as I mentioned, in all-comers population at two different doses of fianlimab, 1600 mg, which is the dose that we tested in Phase 1/2 as well as 400 mg to see if there's any differentiation on/or have a dose response. And we're comparing it to cemiplimab every three weeks. It's approved indication.

We combine in the all-comer study all arms with chemotherapy, and in the high expressing population, they are -- there is no chemotherapy component. So once we get that data and we'll be looking at different histologies, different PDL-1 expression levels to perhaps inform how we may design our Phase III program, we need the data though, to inform that, and we're looking especially at progression free survival, and potentially, likely immature but overall survival as well.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay. And when you think commercially in LAG-3 and melanoma, what are lessons to be learned from Opdualag and this adding in a next gen combo therapy on top of an already, pretty well-established market? Is there something you guys can take away that as an opportunity in melanoma?

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

I don't know that there's a lot of lessons learned. I think, in oncology, data sells your product. We hope to come to market with a very differentiated combination potentially with a benefit in overall survival, which Opdualag lacks, and we think that would be the key to unlocking the European market, especially.

But even really converting the PD-1 monotherapy holdouts that are continuing to use that as opposed to these more advanced products would likely come if you're able to show that you can generate a statistically significant overall survival benefit. So I think that's probably the biggest thing. But in general, I think really the data itself is the best way to market an oncology product.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

And looking to the core Libtayo franchise, maybe give us a bit of an update in terms of the future growth drivers? Obviously not including LAG-3, but, if you had the derm indications versus lung? Like what's been the trend over the past couple quarters and maybe what gives you, perhaps optimism looking to '26?

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

We have a lot of optimism about Libtayo. It's doing well over a billion dollars and growing at almost 30%, and that's not -- we think that the momentum there is going to continue. We were approved in October for another potential blockbuster indication in adjuvant cutaneous squamous cell carcinoma, where Libtayo was previously approved in the metastatic setting for that same non-melanoma skin cancer. So a lot of opportunity there and I think the halo effect of this differentiated data set will only help us in the metastatic setting as well.

In lung cancer, we've made a lot of progress and are currently second in new to brand share in the US in lung cancer. The data there stacks up quite well compared to the market leader Keytruda. When you look at the five-year overall survival benefits that we presented at World Lung this year, very comparable to what has been generated by Keytruda at the same time point. So, continue to make a lot of progress with lung cancer as well, and I think we'll continue to see great growth out of Libtayo going forward.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

I guess the bigger question is how are you guys thinking about the Keytruda and the Opdivo LOE sort of an indirect effect? I don't know if you guys have really felt this effect. It's not happening with Dupi and maybe Eylea just recently had sort of biosimilars. But is this something that you guys can sort of manage going into that -- your competitors LOEs? I know you have some differentiation obviously on the labels with respect to CSCC and Basal cell.

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

Yeah. I mean, we're kind of the standard of care in cutaneous squamous cell carcinoma, and Keytruda's also approved in that indication, but I think our data's better, and that's why it's getting used more. And so a biosimilar for Keytruda, I don't think it is going to impact the momentum we have in the non-melanoma skin space.

In lung cancer, I think that remains to be seen. We'll see the impact of biosimilars in oncology. I think oftentimes, it's the brand that has the biosimilar itself that is the most impacted, but there's likely to be some ripple effects of that across the category, especially in highly competitive spaces.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay. Let's switch gears to Lynozyfic.

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

Lynozyfic, it's very terrific.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Doing terrific. So talk a little bit about the myeloma kind of backdrop there from maybe a commercial kind of context? How you guys are thinking about this in a -- it's a crowded market, but it's also a big TAM that's growing still pretty nicely.

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

Yeah, crowded and complicated is how I would describe the treatment landscape within myeloma, I think for Lynozyfic in the late line settings. So, where we are now approved, I think it was in June or July of this year in the US at least we were approved, and then more recently in Europe. We were able to generate best-in-class data among the BCMA bispecifics in terms of efficacy with response rates around 70% and complete response rates around 50% comparing that to inferior results from both the Janssen antibody as well as Pfizer's. In terms of safety. It has the lowest and least severe CRS profile among the class.

It has the least amount of hospitalization burden. And it has the best dosing interval where you can go to every two weeks sooner and every four weeks sooner than either of the competing products. So we have a very compelling value proposition for patients and for payers, and I think we're beginning to see a lot of traction at some of these hematology clinics with uptake.

It's a smaller population. It's obviously highly competitive. The bigger opportunity is in earlier lines of therapy where we're beginning to generate early data that also looks compelling, especially when compared to other standards of care. So we will be presenting at ASH initial data from our newly diagnosed multiple myeloma program, where I think we'll see some pretty impressive response rates and complete response rates.

We also have some early data in smoldering myeloma that compares quite favorably cross trial to daratumumab, which was recently approved in the US and Europe. So we think we've got a best-in-class antibody. Our goal is to simplify the treatment algorithm in myeloma, where today you see quadruplets, quintuplet therapies with a lot of toxicity. We think we can achieve the same or better efficacy results with either monotherapy or very limited combinations.

And I'll throw in a plug for our upcoming investor event on December 10, the Regeneron Roundtable that will cover Lynozyfic, all of the data that we've generated to date, as well as what our plans for in both earlier lines of therapy and in precursor conditions. So that's something to look forward to just following the ASH conference.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Yeah. I guess you're bispecific platform you have in both oncology and hematology, you have a ton of stuff going on. Is there -- we talked about LAG-3, we talked about Lyno. Is there maybe looking to next year, like a Phase II or Phase III data set that you want to highlight that we may get sort of mature data that could be a new narrative to the story? I know there's -- when I look at your chart, for instance, there's a lot going on, right, in the pipeline.

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

Yeah, we continue to work on CD3 bipecifics and solid tumors. We have a MUC16 by CD3 antibody that has shown some efficacy in ovarian cancer, and I think we'll be moving that forward in a specific type of ovarian cancer. More to come on that probably next year. We also continue to work on our Costim platform, the CD28 bispecifics, where I expect us to present some data from EGFR by CD28 Costim next year as well in various EGFR mutated tumors. So that's a basket study that's been ongoing.

We've been in dose escalation for a while. I think we've finally reached dose expansion phase and we're beginning to generate some data there that hopefully begins to show some positive results. We will see that though in a few months.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay. And then, outside of oncology, hematology, the obesity asset, Myostatin, plus GLP-1. Talk a little bit about Regeneron's strategy going forward? There's obviously been a ton of deals. There's been a lot of commercial kind of news with respect to Lilly and Novo. So how are you guys thinking about being different in this indication?

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

So we in-licensed a GIP/GLP molecule from Hansoh, and the reason we did that was we thought it was going to be important as a backbone for our plans in obesity and, in George's sort of development strategy, he's got plans for a bunch of unique combinations.

We haven't really talked about what those combinations look like, but you could imagine a variety of different indications whether it's metabolic or cardiovascular or muscle preservation that there are unique opportunities to bring those forward and differentiate from some of the other offerings that are going to be out there in obesity. So I think you'll hear more about that story as things evolve over the course of 2026.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Okay. And then on the Myostatin, on the muscle preservation side, I think that's probably one of the bigger points of differentiation. How are you guys thinking about that from a maybe a commercial backdrop? I think there you'd have to get obviously paid for that component to it. So I wasn't sure if there's a different way to think about that in terms of the risks of current patients on a GLP-1 or GIP/GLP in terms of what muscle loss that the -- what sort of consequences of that really are.

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

Yeah. I think that the challenge that we face with the Myostatin combination is that the FDA guidance for filing requires incremental weight loss of 5% or more, and in our Phase II program, after 26 weeks, we didn't see incremental weight loss with Myostatin. We did see a pretty dramatic reduction in the lean muscle mass loss compared to semaglutide monotherapy when we layered on our Myostatin antibodies. But the weight loss, total weight loss was virtually unchanged.

I do think there are some subpopulations that we have not revealed that have even more compelling weight loss than the entire population generated, and perhaps we'll share more on that at another time. But I think the next steps for Myostatin are what does it look like in a weight maintenance setting? So the second half of this COURAGE study that we ran, all patients will drop semaglutide and half of the patients will remain on high dose Myostatin for 26 weeks.

And our hypothesis is that by preserving or better preserving lean muscle mass, you'll better be able to preserve the weight that you lose during the weight loss induction phase, the first 26 weeks of the study. So we should get those results in the first half of this year. Additionally, we are running a longer duration study at different doses of Myostatin. So instead of cutting off the data at 26 weeks, where even with GIP/GLPs, you're still seeing weight loss, we're running a study that combines semaglutide with Myostatin over 52 weeks. So perhaps out a little further, you'll begin to see some of the incremental weight loss that we would need in order to file as well as some of the cardio metabolic benefits that we think lean muscle preservation can warrant.

So there's a lot to learn about Myostatin. Chris mentioned some other combinations that we have kind of -- we're working on and with the Hansoh GIP/GLP backbone. We're very excited about obesity, obviously a very large space. I still think there's a lot of unmet need there and there's a lot of comorbidities that we think some of these combinations can effectively address.

Geoffrey Meacham - Citi Infrastructure Investments LLC - Analyst

Fantastic, Chris, Ryan, thank you so much guys.

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

Thank you.

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

Thanks, Geoff.
