LSEG STREETEVENTS

EDITED TRANSCRIPT

MRK.N - Merck & Co Inc at Citi Global Healthcare Conference

EVENT DATE/TIME: DECEMBER 03, 2025 / 6:00PM GMT

OVERVIEW:

Company Summary

LSEG DATA & ANALYTICS

CORPORATE PARTICIPANTS

Eliav Barr *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Chirfi Guindo *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

CONFERENCE CALL PARTICIPANTS

Geoffrey Meacham *Citibank Cameroon SA (Douala Branch) - Analyst*

Mary-Kate Davis *Citibank - Analyst*

PRESENTATION

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Second day of the Citi Global Healthcare Conference. So my name is Geoff Meacham. I'm the senior biopharma analyst, I have Mary-Kate Davis with me as well from my team here on stage. So we're thrilled to have Merck in this session, and we have Eliav Barr, who was SVP Head of Global Clinical Development and CMO; and then Chirfi Guindo, Chief Marketing Officer. So Eliav, good to see you guys.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

So here as well. Thank you for having us.

QUESTIONS AND ANSWERS

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Thanks for the time. So maybe we'll start with the -- first, with the Cidara deal, right? So maybe just give us some kind of context for the thought process that went into this. I mean I'm assuming it's more than just kind of economics and to try to manage the LOE. This is a real growth opportunity.

It's a real unmet need. It's very different in terms of the platform technology, I want to get kind of your insights into that.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Well maybe I can start with the medical side and then we can -- I'll ask Chirfi to speak about the commercial opportunity. Influenza is a pretty bad disease. Estimated around 110 million people in a season will get -- will have a medically attended illness. And so I think it's a pretty bad disease.

The current flu vaccines are reasonable, but not -- but oftentimes, they're off and they're not particularly as effective. Moreover there, they tend not to be effective in those individuals who are most likely to get sick from flu, the immunocompromised, those with comorbidities and so on, where immune response may not be quite as robust.

And then, of course, year-to-year, there's straight variability. What's great about CD388 is that it's a drug that has - that's strain agnostic is able to be efficacious across populations, 76% efficacy in the dose chosen for Phase III, and that's better than even the best of the flu vaccines.

And as I mentioned, being able to use it in all variety of different kinds of patients. So I think there's a high unmet medical need. It fits perfectly into our concepts around prophylaxis. We have both chemoprophylaxis and, of course, vaccines in our pipeline. We have got a lot of other drugs in respiratory that are important.

And so there's a lot of overlap there. And so -- and I think the commercial opportunity is great, and I'll ask Chirfi to speak.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

No, no, absolutely. I mean the fact that you are going to be able to protect especially those high-risk individuals and immunocompromised individuals who often do not respond well to the traditional flu vaccine, it really is a big deal.

And so as you think about it commercially, by the time we come to market towards the end of the decade, we anticipate that there will be about 110 million people in the United States who would be candidates for this treatment.

Once again, it's not a vaccine, -- it's an antiviral that you take once at the beginning of the season, and then you will give full protection to the population for the whole duration of the season, right, irrespective of the strain of influenza that you're talking about, and so that is really the attractiveness from a public health standpoint of CD388.

So from $110 million that we anticipate about $85 million fit the category of high risk or immunocompromised. These are people cancer survivors, people who live with COPD, atherosclerotic cardiovascular disease, PAH and so on and people who just have a weak immune response.

And then you have about 25 million or so who are older adults who are not even a immunocompromised or who do not have those co-morbid conditions that we talked about. So that is the pool of individuals that we anticipate coming into being candidates for protection with CD388. So very, very attractive.

Just to a couple more numbers that I could give you for context. In the United States last year, there were 1.6 million hospitalizations due to influenza, right, in the last season. And this season panning out to be a tough one as well.

So if you can provide protection to those individuals at high risk, I think the value proposition will be really, really compelling. So we look forward to really commercializing this, and we've announced greater than $5 billion commercial opportunity starting at the end of the decade and escalating into the early 2030s.

So a really meaningful opportunity.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

I guess let me follow up to that, Chirfi. I think when you -- you can see the differentiation, the fact that it's not a vaccine, it's an antiviral. I guess the biggest uncertainty, I would imagine would be the payer context, right? So you'll have to have, obviously, Phase III data, you'll have to have maybe pharmacoeconomic data that shows what is the -- maybe the commercial approach to go after the highest risk patients for -- that may have not gotten a vaccine anyway to try to make payers sort of understand the differential value proposition.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Yes. I'll provide a couple of insights on this, how we're looking at this. First of all, in the Phase III program, we would will have people who have been vaccinated and people who have not been vaccinated, right? So in terms of launch, in terms of commercial approach, we would consider the unvaccinated or the previously vaccinated as candidates equally, provided the high risk, right? So that's really, really important.

Cidara did some payer research. We had opportunities to review some of that in diligence and so forth. And in that research, payers in the US, again indicated that a price point between $500 and $600 per dose would actually present good value if you're talking about those high-risk individuals that I indicated. And so we will do our own research when we come to it once we progress. But the value proposition, we believe, is going to be compelling.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

And then Eliav, just a final one on this program. When you look at the development path you mean potential for an interim analysis, so there -- is there anything that you can build into the pivotal program that could maybe help you with the market opportunity, the downstream, just to try to further separate out the differentiation.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

So the population of the ANCHOR study is greater than 65-year-old patients. So it's in the right target population. The question is -- obviously, the way it works in clinical trials is that you're power towards your primary end points, which obviously is medically attended flu with symptoms and so on. But there will be opportunities for things like hospitalizations.

As Chirfi noted, there's a lot of these and then measures of severity even more than that. I think the ENFLONSIA program is kind of similar to that. We had medically attended lower respiratory infections, and then we had hospitalizations, ICU admissions and ultimately, those data were very important.

So we want to make sure that the study is large enough to be able to have all those critical endpoints. And once we have access to the drug and the company, which we hope will be soon, we'll be able to take a look and make sure that the study is properly sized for longer-term outcomes. Not longer term, but more rare outcomes. It certainly is well designed for the outcomes that it's currently evaluating.

Mary-Kate Davis - *Citibank - Analyst*

Great. I guess moving to another deal that you guys have closed this year, Verona. So that's recently closed, and you're bringing in OHTUVAYRE into your commercial portfolio for the treatment of COPD. Could you maybe talk about that opportunity and how you're looking at that product?

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

So first of all, we're really proud of the work. We're really pleased with the work that the Verona team has done a really impressive work in launching this -- developing the asset, first of all -- and launching it in the United States. So far, the feedback has been excellent as far as we've been able to determine.

And so the opportunity for OHTUVAYRE is for us to really bring the commercial engine that we have as Merck to really scale the work -- the good work that Verona has started. And so the feedback is excellent from customers.

And we believe that there's a huge opportunity for us to apply this engine and to reach more patients and create the value. We've announced significant opportunity in this space. And that's where I think the excitement is coming from. The feedback so far from the market research that we have conducted is excellent. And we believe that this is going to be transformative agent.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

So by the way, just to remind ourselves, the placement of OHTUVAYRE in the GOLD guidelines is really quite favorable. And it's fairly broad across different kinds of COPD. It's the first kind of nonsteroidal anti-inflammatory agent and I think that's very important, particularly because as we all know, steroid inhalers predisposed patients towards pneumonia and other and fungal -- local fungal infections.

So I think it has great opportunities. We're looking at it also for non-cystic fibrosis bronchiectasis. And so I think that there's enormous potential within the sphere of chronic pulmonary diseases to improve outcomes for patients.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

From a commercial perspective, you guys will have a pretty substantial respiratory portfolio was OHTUVAYRE , the incremental investment in commercial and in marketing, was it sort of nominal in addition to what you're doing already in PAH? Or is it going to be a substantial sort of add-on to the commercial efforts.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Yes. We certainly have an engine, right, that we can apply to scale and augment the good work that the Verona team has started to do. And so that is really the opportunity that we see -- we have, obviously, digital capabilities. We are going to reinforce the MSL capabilities, the commercial capabilities more broadly. And so this is really going to be a nice opportunity for us to create value.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

And let's move to WINREVAIR, so congrats on the Cadence trial in -- heart disease. So that's -- we did a session at the Cleveland Clinic this past April, and there was significant enthusiasm for this in terms of unmet need. Where do we kind of go from here when you think about the next steps into a Phase III, is there a potential to -- is this a fileable trial? I know it's not really usually the Merck way, but this clearly is a substantial trial in an unmet need.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Right. So first of all, we agree that the unmet need is substantial in this pre and post capillary pulmonary hypertension patients with HFpEF. It's a population that's enormously underserved. There's nothing there for them, and they have a pretty high mortality rate. The cadence trial is designed as a proof-of-concept study.

It had a lot of measurements, both from the pressures and heart function point of view and other elements, which we'll share in due course. But we are very happy that the PVR data were very clear and associated with all the other data that we collected in the study we think that there's a really good opportunity for patients.

In the field now, there's really not much for patients. And I understand the enthusiasm that people might have for this to become some sort of filing study. The truth is, it's a proof-of-concept trial. And the primary endpoint was not a filing end point. We'll talk to FDA about the design of Phase III trials.

And more than -- and I think that, that's something that we'll be doing and we're going to start Phase III next year. The field is a -- it's an unknown area. It's an area that doesn't have regulatory guidance. So we'll have to figure out the best way to design the trial and go forward.

I think that the other -- the reason why we would anyway want to do a Phase III trial is from a payer point of view, they probably want to make sure that they're seeing the right kind of value to be able to gain and give access to patients.

So my net-net is we'll look at the data, we'll have the presentation in 2026 at an important medical meeting will allow people to -- will have a really good consultation with all of our scientific leaders. We've already done that. We'll present FDA with the data and our plans and we'll go from there.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

It does seem like given we had Marty yesterday at a session that he's thinking about in terms of unmet need, there is maybe streamlined approaches. This seems like as good a candidate as any, but I guess you have to have the FDA discussions.

Yes. We present data and they present us with their ideas of see how enthusiastic they are. And again, I think that the studies are -- that the study was pretty clear, and gives us an opportunity with -- to improve outcomes, not just in pulmonary, but also cardiac function.

Mary-Kate Davis - *Citibank - Analyst*

Maybe looking at the opportunity in PAH, you've presented a lot of data kind of building, have you seen this translate into higher usage from physicians?

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Pulmonary arterial hypertension. Yes, it's a simple answer.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

From a durability perspective, have there been -- has that been better than you thought when you initially did the Acceleron deal?

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Yes. So The feedback has been tremendous, right? So WINREVAIR in PAH is meeting all of our high expectations, right? So what I would say is, just give me a second here, you just bring my thoughts together for a second here. In PAH, what we're experiencing really is the feedback has been tremendous, right? And so the data is planning it out and we're seeing continuous positive feedback from the overall community. So maybe, Eliav, you can provide that --

---

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Sure. Yes. So I think if you look about it overall for the SOTERIA study, when we look at the durability of the response, and now we have people several years out, safety profile is pretty much the same, efficacy remains very good, and patients are sticking on trial.

The things that I think are moving the needle in the marketplace is that we've had some terrific guidelines placement. And we're also really interested and we're also seeing a lot of use, both in people with three drugs. And now we're moving towards those on a background of two drugs.

Right now, with three studies that we've shown, we've taken the spectrum from newly diagnosed patients in all the way to those who are advanced and close to lung transplant or having to have hospice care. So I think we're -- we have all the data out there. And from an update point of view, things have been going very well.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

What I would add is really that you have the triple what we're seeing is certainly in the US where we are really -- we have most experienced so far. We're seeing really uptake in the triple segment of the population. We continue to be very encouraged by the adoption in that category that represents about a third of the patients. Another third is in the dual -- the so-called dual category.

And so we're seeing now the opportunity with the new data we have is to begin to really have greater penetration in the dual category of patient population. But the feedback has been tremendous. And so the data will pan out. But the real-world experience continues to be very encouraging as we continue to on the launch trajectory for WINREVAIR.

Mary-Kate Davis - *Citibank - Analyst*

That's excellent. I guess how are you looking at the OUS opportunity for one your as well?

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Yes. So we just started in Japan, really, really encouraging start in the Japanese environment. And in Europe, we also have -- we are going through the reimbursement process from country to country. But the overall feedback is really consistent with what we have seen also in the US in terms of physician and patient experience. And so we look forward to really realizing the value there as well. And so, yes.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

I guess the question PAH is you want patients to be healthy enough that they're on drug or the other or doublet or a triplet for an extended period. But they also are probably not going to take an injectable if they're Class 1, right? Maybe some class.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Well, I mean, I think it's important to -- it's important to understand that sotatercept has I think has been showing that across the different segments of patients, whether you're newly diagnosed, that's Hyperion; whether you've been on drug for quite some time and have worsening mostly on three drugs, that's stellar; or whether you're in pretty advanced state, that's Zenith, that you have similar benefits in time to clinical worsening and in hard endpoints like hospitalization or death.

The point I think -- I think the way people get on drug is on therapy is they usually take -- have the two generics together, right? So that's kind of the base point. And then the question is, what's your next drug? What I think we've shown throughout the trial program and with incredible consistency regardless of where you are in the disease journey is that sotatercept improves hard outcomes, along with all the good stuff that happens when you can walk around more and have a better exercise tolerance.

So I think physicians now got used to the three-drug regimen, the drug, how to administer all the things that have to happen in a practice -- and I think we'll move to the second -- to the two-drug regimen. One thing that we will have next year that's going to be very important is the auto-injector. And these are -- that might say, oh, it's not how sexy is that. It's very sexy, if you're a patient that needs to fiddle around with the dosing regimen and now you can have at home kind of nice single shot.

So I think that's going to make it easier for patients and I think what we've done, both with guidelines and with the work that we have both with our commercial and medical affairs team is to help people just reduce the kind of barriers, some of them are artificial. Some of them don't know to use it in my practice or how is it all going to work, all of that so that we can have adoption. And I think that's translated into the really nice trajectory that we've seen so far with the use.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Yes. And convenience is a huge factor, especially with the prostacyclins, and those are -- can be a little clunky there.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Yes. And so I think this is a good -- and again, patients don't want to come into the hospital to -- or into the office to get their injection. So once we have the auto-injector, I think we'll get a lot more ease of use.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

So let's switch gears to the oral PCSK9 program and the injectable PCSK9s have had very good commercial success. I think it took a couple of years for them to get the price and volume and aligned with payers. So you do have, obviously, the dosing convenience. But as you think about the profile. How are you thinking about going into the market? Is it more switches? Are there new patients that you think are particularly suited for an oral modality?

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Yes. What I would say is just coming out of the AHA, where the data was presented. I mean, really, the opportunity we have here really is to provide the full benefit of PCSK9 because so far, it's a great modality, but it has really not had the impact that one would have hoped.

And so I think the scientific community was so ecstatic when they saw our data, right, with enlicitide presented. And the reason why they saw that is, this is something that could finally reach more patients, right, and really make a difference in the lives of patients and so forth.

So the data is really compelling. When you think about the efficacy data as compared to the injectable. And so I like to simplify it as you're getting a robust, you're getting a robust effect, right? So 60%, I would say, 60%, 50%, 50%, 30%, you have to simplify the math for a moment, right?

So you're getting the, you're getting the robust 60% LDL lowering, right? And so you're getting the 50% basically lowering of the other parameters, right? And then you get your -- finally, you get 30%, right?

So you put it all together, the profile of enlicitide is going to be unmatched by any oral agents, right? And so this is what's giving the community confidence or excitement rather, that this is really going to be a game changer in the practice of cardiovascular medicine. And so we're talking about addressing the CV epidemic because now we are going to have a tool that is going to allow us to do just that going forward.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

So if you look at -- if you -- so the problem that the current cholesterol regime, so to speak, has is that actual goals that people need to get to are not very easily achievable with statins. So the current situation with regard to things that people can access, which are pills. Was that -- you just go ahead and start a statin. I think that with injectable PCSK9s, of course, the efficacy is terrific with regards to cholesterol lowering, but access has just been dismal.

When you think about the large number of patients who actually need these drugs. And because of that, I don't think there's been very much impetus for guidelines to be much more prescriptive and very specific about which LDL levels you need to get to reach your goal.

Now with an oral medicine that's just very easy to use, very easy to prescribe, will be priced both for access and for value and have the same kind of mindset for the treating physicians who tends to be a general practitioner, nurse practitioner, et cetera, in a community center.

Those guys can -- the ease of access will be very good. And now there's going to be an impetus to be able to change guidelines to be more prescriptive. And I think that's where both ACC and AHA are looking to do the less what scientific leaders have you normally told us so that we can actually reach focused people on reaching a goal break the current inertia, which is I got you on a statin, I'm done with your LDL cholesterol, not really thinking about it anymore, but now focusing on what's the target, what's the goal?

The statins will get you a certain part of the way there. Unfortunately, they can't get you all the way there. Now these days, we really want to have very low LDL-cholesterol level. So we think that having an oral PCSK9 that could be easily used doesn't create any address experiences, no new drug-drug interactions and can be available without a lot of paperwork -- will allow that movement. And hopefully, that will impact the rates of disease and death from cardiovascular disease.

So we'll see.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Is it reasonable to assume, let's say, in the next couple of years, guidelines will evolve to everyone's on a statin and then you have sort of verticals who needs a PCSK9 oral or injectable who needs a CETP who may need an Lp(a). I just don't know how it's going to all shake out.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

I'll tell you, the enemy -- so at this point in time, the enemy of being able to move things so that patients actually benefit is complexity. I think that the first position, the easiest one will be who -- what is the level of LDL cholesterol you need to get to?

And my hope is that there's just going to be one number, but it's possible that they'll maybe have two, the two numbers being those people who don't have clear evidence of atherosclerotic cardiovascular disease but have risk factors and those people who already declared themselves. And that's something like 70 and 55. So all in all, if we can get that done, and that's simple, simple and then we could do PCSK9.

The Lp(a) stuff is going to be very, very important as well. However, there's a lot of education that's going to be needed around that especially like what's the right test to use, to measure Lp(a), what level you need to get to. So I see that as being a slower uptake. Eventually, it's going to be very important.

But I look at the LDL cholesterol, as people understand what it is but they really need to be forced to a goal. And if you could get that as a quality measure, then all of a sudden, physicians are actually thinking I need to get them to that goal, not I just need to put them on a statin.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Can you capture that in the label? I wasn't sure the regulatory kind of discussions are --

---

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Well, we never -- we can't talk about -- we don't know what -- the label is up to the FDA to ultimately agree to, who can say is what patients we studied in the clinical trials program, which included primary prevention patients and secondary prevention patients. So we anticipate that those kind of patients would be in the product circular, we don't know. That's something that FDA needs to opine on, yes.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Okay. All right. So let's switch gears to the -- there's a lot to go over the vaccine space. So on GARDASIL, just sort of the one stock question on that. I mean you guys have talked about recovery unlikely this year or maybe the end of next year?

Kind of give us a catch-up maybe on a global basis, like in one year's time, do you think you'll be -- have a lot of the headwinds behind you? Or do you think this is more of a longer lasting?

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Yes, we think that we've really reached the point where we are going to continue to drive modest growth going forward at this point. And obviously, the China situation was a problem. But at this point in time, it represents less than 1%, right, of the revenue.

So -- on a going forward basis, we are looking forward to continuing to drive modest single-digit growth going forward or for GARDASIL. We still have work to do. We're proud of the work we've done really in providing protection around the world.

So this is something that our company is extremely proud of and that work must continue going forward.

Mary-Kate Davis - *Citibank - Analyst*

For beyond GARDASIL, looking at your -- the rest of your vaccine portfolio and some of the newer launches, can you maybe talk about how those are going and your expectations there?

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

The respiratory?

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

The launches of CAPVAXIVE, ENFLONSIA.

Yes, so CAPVAXIVE is going really well. So it's meeting our high expectations. So really -- we look forward to bringing it globally, right? So that's still early days from that perspective. ENFLONSIA it's also early days. We are just in the starting phase in the United States. And both, we believe, are well differentiated assets, and we look forward to really scaling and executing the launch as we go forward.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Let's switch gears again to immunology. Again, there's quick hits on everything. It's a good thing, though, because I mean you guys have quite a diverse portfolio -- TL1A, so on the back of the Prometheus deal. So your first major readout could be next year.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Next year. Yes, it is.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

That's highly anticipated that I think consensus numbers for WINREVAIR, we're $1 billion at peak and maybe now it's like more than $5 billion. For this one, I guess it has not really moved because we haven't seen a lot of new information. So help us maybe frame kind of how you're looking at this opportunity in terms of your investments, like just it does seem like you could go after a number of different immune indications pretty quickly.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

So we have -- so first of all, the TL1A mechanism was attractive to us because it was both anti-inflammatory and anti-fibrotic. So it provides a dual point of action for diseases that have a lot of these problems. Of course, the whole field was discovered on the basis of inflammatory bowel disease.

And that was where we went first. The UC data are going to be available. The induction study will be available next year and then induction maintenance thereafter. And Crohn's disease will also be first in that.

Aside from that, we've got about four other indications that I think are going to be very important, some of which will have Phase II readouts, which will tell the tale in the 2026 time frame. The first of these is systemic sclerosis-associated ILD. So this is interstitial lung disease caused by scleroderma. This is a mixed inflammatory fibrotic disease. It's a sweet spot for a drug like tulisokibart.

The Phase II study is pretty large, large enough that I think we'll be able to see a good signal. That's going to come in the April time frame. And then later on in the year, we'll have a study in hidradenitis Artiva HS which is, again, in dermatologic disease, inflammatory, and fibrotic that I think we will be able to see.

We also have a trial in Axial SpA so, spondyloarthropathy. As well as rheumatoid arthritis and other indications that we're looking to start soon. So we're taking a page from the success stories in the immunology space. Humira had multiple, multiple indications and a lot of the other drugs the same.

Our focus is on inflammatory plus fibrosis. And I think we have the right readouts coming through they will be able to validate why the Prometheus acquisition was such a good thing. And then we have got, of course, other Prometheus drugs in Phase I on that I think will be -- also have an important role to play.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Is a basket approach, though, for ATLAS is that -- should -- is the best approach sort of to go linearly and have a Phase III and figure out the next trials? Or do you --

---

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

We're going to see -- this is why we're doing a bunch of Phase IIs in parallel now. I mean I think that the key was to get ulcerative colitis to get the base understanding of what the drug does by itself in ulcerative colitis and Crohn's. That's necessary, and it's necessary both from a biologic point of view, but also most importantly, to tell physicians, patients, payers, and regulators what this drug's capability is.

We now have started with multiple Phase II studies there'll be more coming next year, and that's in the mono space. We're very interested in combination therapies. My -- I'm not an oncologist, but most of my time at Merck has been in oncology for a good reason. But we -- so we -- that's a world of combinations, and we need to be able to do that here as well.

But it has to be rational combinations. And I think once we read the induction data, then we'll start a whole bunch of other studies. So this is -- we're at the point of an inflection in the clinical trial field of broadening this drug up quite a bit. We see a lot of potential here.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

And we can move to oncology. I can't believe with five minutes to go that's its the first question on KEYTRUDA. So let's talk about QLEX. So the Sub-Q I know early days for the launch. But give us some context for how you're thinking about the wave of patients that are more

likely to go on this versus KEYTRUDA with the consideration, obviously, the biosimilars down the road are going to be eroding. Is it mostly preadjuvant like premetastatic?

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

So obviously, QLEX is off to really good starts. We are really enthusiastic about the early feedback that we're getting here in the US. We just got the good news also from a European perspective on that formulation, KEYTRUDA Sub-Q -- so we believe that this will be really a good option for patients in the earlier stages of disease.

And so we are gearing up for that. We have resourced the launch appropriately. For us, this is a launch, right? And so there's an opportunity here to impact earlier stages of cancer. So that's kind of how we are thinking about the opportunity.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Can you force that through with payers through discounting or rebates or whatever to try to maybe narrow the initial adoption or -- is that just how it's going to work out in the.

Chirfi Guindo - *Merck & Co Inc - Senior Vice President, Chief Marketing Officer - Human Health*

Well, at this stage, you have at this stage where you have mono use where you have combination use with in the earlier stages. This is where the adoption is anticipated initially. And so, so far, again, it's early days. We believe that KEYTRUDA QLEX is going to be adopted in that segment.

What we've indicated is an adoption rate in the initial 18 to 24 months are about 30% to 40% of QLEX in the United States. And so obviously, the first six months might be slower. Because obviously, we have to get the whole reimbursement system going and adoption will then kick in with that sort of magnitude.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

For oncology for the ADC. So I think you have a couple of ADCs that are going to turn the card over in 12 to 18 months from now. Talk a little bit about the funding of the TROP2. I wanted to get maybe your perspective on that?

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Well, so we have -- so first of all, we think the TROP2 ADC is going to be -- sac-TMT is a really differentiated molecule with a program that's really quite different from what has been used -- done for the other ADCs. So I think that's -- we have a lot of confidence in it. We're very pleased that Blackstone was able to saw the data, and were willing to plunk down quite a bit of money to help us.

The reason -- what we need to be able to do is -- as you see, we're just now talking about oncology, we've got this breadth of opportunity that's gargantuan -- a lot of things are moving in the right direction, knock on wood, no wood here, but anyway, so we're hoping that things are going to be -- are going to expand even further. We've got these acquisitions that now need to be fully funded.

We've got launches that need to be fully funded. And so I think as a company, we were -- we wanted to make sure that the short-term P&L profile was appropriate for the expectations of shareholders. And so we thought this was going to be a really good deal.

They put $700 million against our R&D spend in 2026 in exchange for a low to mid-single-digit royalties after the approval of -- after the readout and approval of sac-TMT for a particular study that's in triple-negative breast cancer.

So overall, we thought that the deal was really good, and it helps in ensuring that we're able to apply all of our resources to the extraordinary opportunities that we have. This is also in the context, of course, our multiyear optimization where the company has chosen that they're going to work to streamline and to focus attention on the things that really will move the needle on behalf of patients and there for the company.

So I see this as a great opportunity from the R&D point of view. From my shop, it gives me a lot of breathing room.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Is that approach to use Blackstone or others to help fund the development a good model for other ADCs in the pipeline?

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Well, we -- the other ADCs are partnered, and so they're a little -- it's a little bit more complex. There are other -- and then there are some ADCs that are still within our group. I don't -- I don't see this is a model that I'm going to -- that we're going to use every time. But this particular opportunity because sac-TMT is such a large part of our spend and our future and what we believe in, we thought that this would be -- we're very, very confident in this program.

And so that's why we allowed them to look in and see what we thought. And I'm such that they actually really -- they agreed with us that this is a tremendous opportunity. I don't know that it's going to be something we do every time -- but it's when the opportunity arose, it was a good one.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Awesome -- thank you very much.

Eliav Barr - *Merck & Co Inc - SVP Head of Global Clinical Development and CMO*

Thank you for your time.
