LSEG STREETEVENTS

EDITED TRANSCRIPT

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OVERVIEW:

Company Summary

LSEG DATA & ANALYTICS

CORPORATE PARTICIPANTS

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CONFERENCE CALL PARTICIPANTS

Terence Flynn *Morgan Stanley - Analyst*

PRESENTATION

Terence Flynn - *Morgan Stanley - Analyst*

All right. We're going to get started here. Thanks so much for joining us. I'm Terence Flynn, Morgan Stanley's US biopharma analyst. For important disclosures, please see the Morgan Stanley Research Disclosure website at www.morganstanley.com/researchdisclosures. If you have any questions, please reach out to your Morgan Stanley sales representative.

I'm very pleased to be hosting Merck this afternoon. Joining us from the company, we have Rob Davis, the company's chairman and CEO; and Dean Li, who's Executive Vice President and President of Merck Research Labs. Thank you both so much for taking time out of your day to join us. Really appreciate it.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Great. Well, thank you for having us. Appreciate it.

Terence Flynn - *Morgan Stanley - Analyst*

I thought first I'd turn it over to you, Rob, just to frame the discussion for us, and then we'll launch into Q&A.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah, no, appreciate it and happy to do it. And good afternoon, everyone. I mean, obviously -- already, 2026 has been a very eventful year for us. I would say, and I think it will frame the discussion we'll get into, our transformation is underway. Whether it's the product launches we have going, which are all the first waves that are coming, all going well.

But equally, if not more importantly, the fact that we're getting and seeing continued important data readouts that have all pretty much turned over positive, and many at a pace much faster than we expected, just gives us a lot of confidence in where we are. We have more to come.

Importantly, while those catalysts have been important, we have more catalysts yet to see this year, both in terms of other data readouts as well as potential filing. So as you look in the near term, a lot of continued excitement in what is ahead of us.

And then on top of that, business development, what we've done recently with the Terns deal, we'll get into, I'm sure, at some point. Animal health, our animal health business is performing at best-in-industry levels. We continue to have strong confidence that business can more than double in the next 10 years on the back of a product portfolio growth, very much in line with what you're seeing on our human health business.

And we have the capital, the resources, and the capability to add more. So whether you look at it as launches, as clinical readouts, as business development, I think we're really hitting on all cylinders. So I feel very good about where we are. More to do. You never say you're done, but I feel very good about where we're standing at the moment.

So maybe with that, I'll turn it over if you want to jump into any of those areas.

QUESTIONS AND ANSWERS

Terence Flynn - *Morgan Stanley - Analyst*

Yeah, absolutely. I think we'll get through a lot of that. The first I wanted to start on is just on the policy front. Obviously, you guys are very plugged into DC. You have the midterms coming up here. But just anything that's on your radar here that we need to be cognizant of?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. Obviously, it's going to be interesting to see how this plays out and what happens in both the House and, interestingly now, the Senate probably is going to be more interesting to watch than even the House. But whether it's Democratic or Republican, however you want to look at it, as an industry group and as Merck, where we're focused is continuing on what we see as the two biggest challenges we continue to have.

How do we make drugs more affordable for patients at the pharmacy counter? And how do we ensure access to all of these new meds in a world where we have an ecosystem that continues to reward for the innovation we're bringing? And if you look at those aspects of affordability and access, clearly, we continue to believe the challenge is the fact that the innovator, the manufacturer, still only gets $0.50 of every $1.

We have to address what happens with all of the $0.50 in the middle. That really is about PBM reform. That's about 340B reform. And I'm happy to say that there's growing momentum. You've seen a lot of movement with legislation in the PBM front. We continue to think there's more to do there. But importantly, you're seeing movement on the 340B front as well.

So we're going to continue as an industry and as Merck to push that. But really, with an added emphasis on this notion of access, the fact that you're seeing insurers and PBMs use utilization management to either delay or deny access to new medicines, whether it's through formularies, how they do formulary management through step editing or through prior authorizations, we think that is another element of this broader system that needs to be addressed. And we've spent a lot of time with members of Congress and the administration trying to bring greater focus on that.

Terence Flynn - *Morgan Stanley - Analyst*

Okay, great. Maybe the other one on the policy side is just 340B. It's been -- I think, front and center for a lot of folks here after second quarter results. So as you think about that going into 2027, how are you thinking about the impact to your business?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah, so if you look at 340B, we're very supportive. I think it's important -- a couple of points. One, as Merck, we very much support the initial and original intentions of what 340B was about, which is how do you support the most vulnerable members of society to ensure they have access to good healthcare and good hospitals and clinics.

The program has been perverted away from that and has grown and morphed in directions that were not in the initial intent, and we need to get back to that original intention. And so as we think about '27, you are seeing momentum, as I mentioned. There is some bipartisan legislation now moving both in the House and the Senate. There's actually, I think, a bill in the House called the Rx ACCESS Act. But maybe also not only from what the legislation is having, from a congressional perspective, you're seeing the administration themselves starting to make movements.

I just highlight the fact that we have HRSA running a demonstration project with the rebate model, which we think is very important. So we're very supportive of all those moves. As we look at our own business, those will create potential tailwinds. If they evolve, but they're not material to us, frankly. It's more of how do we set the right policy environment to get out some of these more fundamental issues that we have in our system.

Terence Flynn - *Morgan Stanley - Analyst*

Okay, great. The other one, you mentioned in your remarks, Rob, is that you guys have had a lot of success on some of the BD deals translating through to positive pipeline wins here. And so I think now you can say, like, all right, a lot of these have been ROI positive for the company.

And so maybe just what worked? Like, what was it that you guys changed when you came into CEO that you think has given you the ability to generate ROI on some of these BD deals? So I think there's this historical perception, again, probably rightly so, where a lot of the legacy deals that maybe -- you, your peers have done were being more challenged on the ROI side. So what was it about some of the changes that you guys made on the BD side?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Well, I give all credit to Dean, frankly. My superpower was just listening to Dean. So that's I think my mom raised me well in that regard. But in seriousness, what we have done is really, a lot of people talk about it, I think we've actually tried to both live it and institutionalize it in the way we operate, is treat the pipeline as one pipeline, whether it's internal or external, and make sure that we always are trying to look for the best science. We always start with the science.

I've never gone to Dean or to our business development folks and said, get me an asset in a space. I think that's dangerous, because they'll give you the best asset, but that might not be the best asset that's out there. You don't limit them in that way. You can't limit the science. The science has to dictate.

So we always start with the science, but then once we do that, we're willing to look at whether it's an internal asset or an external asset. We evaluate them always the same. We use the same financial measures. We use the same operational rigor. The teams that do the due diligence are our scientists, so it's not like a separate group. When we go into due diligence, it's our scientists on the ground with them. We leverage our statisticians to be able to make sure that we're understanding the probabilized risks and returns.

So it's that model we followed, and one of the things we did to organizationally align that is when I became CEO, we moved business development underneath, so all corporate development now sits underneath Dean, and I think that has also allowed for that ecosystem to thrive.

The other thing we do is we have, with each of our discovery centers, BD is embedded. So all of our search is done side by side with our scientists. So I think it's that culture combined with now institutionalizing processes around it that has allowed us to do well. And as I said, it's credit to our scientists. They've made scientific bets based on their expertise, and I think the fact that we have depth of expertise has allowed them to make the right bets.

Terence Flynn - *Morgan Stanley - Analyst*

Okay, great. Maybe the first one of those I want to talk about is obviously the INT program, which is partnered with Moderna. Some recent data there on the Phase 3 side, so congratulations. Very exciting.

I guess, Dean, maybe just help us think about framing what we're hoping to see. I know you can't say ESMO, but again, a conference this fall, and what it would mean for other tumor types, because I think that's the question we're all trying to get our head around, is not necessarily if the melanoma data is good, not good.

We know it's good because it hit at an interim, but what does this mean for other tumor types that you and Moderna are exploring? So can this be a platform, I guess, is the question.

Dean Li - *Merck & Co Inc - Executive Vice President and President, Merck Research Laboratories*

So the first thing is, I think one of the most important pieces of data actually didn't come out in August. It came out during ASCO, where we together presented the five years from the Phase 2. The big concern that I had about this -- I mean, the Phase 2 that was run was robust. But as many people know, there's been a concern that RNA-based sort of trying to use that to immunize can be short-lived.

And what was really interesting in that data is that we demonstrated that the people who responded who were cancer-free at one year remained largely so at three years, largely so at five years. So when people see that data when it comes out at the conference, I think people will immediately see the Phase 3 and extrapolate to five, seven, nine years. And that's a really important point.

The second issue is in that data -- there's a small sample size. There's always some imbalance. But what you're hoping in your Phase 3 is to be in the ballpark of that. And if you are in that ballpark of that, I think it will increase your likelihood of being successful in adjacencies. And what do I mean by adjacencies?

We have a relatively conservative plan right now in relationship to INT. We prioritize those tumors that have a high TMB and or where IO or checkpoint inhibitors have worked and or where KEYTRUDA itself has laid out in early stage.

So I think the louder the signal comes in for melanoma, I think it will somewhat de-risk that relatively conservative plan. What we have not done is we haven't gone in metastatic. We haven't gone in tumors that are not IO-sensitive or where a PD-1 doesn't work. And the reason we haven't done it isn't that we think it's a silly idea, we're very glad that other people are doing it. But if that should hit, we will change and expand our program dramatically if that should happen.

The issue for me is to hit and hit fast because this is unlike a T-cell engager, unlike a small molecule, unlike an antibody. I think the first mover advantage here in being able to commercialize in melanoma will teach you, give you all the repetition that you need. And that in itself will create a lot of information for both Moderna and Merck and give us an advantage. So that's why, quote, unquote, we have a relatively conservative plan scientifically, but the concept is to move fast and to move fast.

Terence Flynn - *Morgan Stanley - Analyst*

And so as you think about maybe the next couple of readouts, you've got muscle-invasive bladder cancer and RCC, how to think about likelihood of success in those tumor types, where those fall in the spectrum of --

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Dean Li - *Merck & Co Inc - Executive Vice President and President, Merck Research Laboratories*

Yeah, so they fall in around that conservative plan. You would say that for MIBC or for bladder cancer, the tumor mutation load is higher. But you also have to look at RCC, where RCC, the tumor mutation burden, is not that different than MSS mCRC.

But in RCC, how many immuno-oncology agents work? I mean, how many checkpoint inhibitor cytokines work? So I think both of them are good examples, but they will give us a general sense of bookends in relationship to our conservative plan, and we will act accordingly as we see that.

And we will open other trials, depending on what the sort of -- if MIBC hits it or something like this, we'll start thinking IO, higher tumor mutations. If it's RCC, it's IO-sensitive, checkpoint-sensitive, but a lower TMB.

Terence Flynn - *Morgan Stanley - Analyst*

Okay. Maybe, Rob, one for you. I know you guys had guided to over $70 billion in recent launches pipeline by mid-2030s, and you had a number of different buckets in here. Oncology was one of those. It looks like over $25 billion. I think from what I remember, INT was fairly minimal in that. And so, number one, I guess, am I remembering that correctly? And number two, is it fair to assume that there could be upside now as a result of this new data that we got on a top-line basis?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Well, maybe speaking broadly to the $70 billion, and we can unpack the comments, but I think, yes, you should assume we see upside to the $70 billion, and I'll give some reasons why. But it is specific to how did INT fit.

So, if you recall, we had $70 billion made up from 20 assets. 10 of those assets, we said, would make up 70% of the $70 billion, and those are the ones that we thought would have readouts, really, in the next couple of years. We initially expected INT, just based on primary completion date, which is what we use as the way we guide, was beyond that. It was in 2029. So, obviously, pulling it forward to the interim, it was not in the initial 10. It was in the 20, so it is in there.

But if you look at more broadly, what do we see as far as this opportunity? The other thing is not in that $70 billion. The Terns acquisition, the asset, the TKI, we brought in with that, which we see itself as a multibillion-dollar opportunity. That was not in the $70 billion. Importantly, and this will come up, I'm sure, in a moment MK-2010 which is our PD-1 VEGF, was not in the $70 billion. And as you know, we are starting multiple studies with MK-2010.

So those two assets alone are new, they're upsides. And then on top of that, I would say, while we did have INT in there, just given now the fact that we are -- if you assume technical regulatory success, because that's what we always assume, but then you look at what is the commercial opportunity, I do think it's safe to say that the broad commercial opportunity probably could be bigger now, given what we've learned and what we'll continue to see as the data flows out. So all of those things are why we have a lot of confidence that you're going to see us raise that number. We just have to decide when is the right time to do that.

Terence Flynn - *Morgan Stanley - Analyst*

Okay. Is that a this-year event or a next-year event?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Raising the number? To be determined in the near term. It is coming. Last year we laid it out at the beginning of the year. We'll think about whether or not probably that'd be the timing we'd think about again.

Terence Flynn - *Morgan Stanley - Analyst*

Okay. Fair enough. Just in the interest of time, I want to keep going here because there's a lot going on. But sac-TMT, another more recent de-risking pipeline asset for you guys.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Also came much earlier than expected.

Terence Flynn - *Morgan Stanley - Analyst*

Okay. Another driver of upside to the $70 billion.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Check.

Terence Flynn - *Morgan Stanley - Analyst*

But I guess the question is just, the one thing that I think we've been getting some questions on is differentiation still versus the competitive landscape. And so I know you guys have a strong view on this. We're going to get some data from AstraZeneca for Dato from their AVANZAR study, which we haven't seen yet.

There was some data for Trodelvy, another TROP2 over the weekend at World Lung. So maybe just level set us on kind of where you see differentiation versus those other TROP2s given some data over the weekend, but also in the event of the AVANZAR data and what that means for sac-TMT.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah, maybe I'll make some high-level comments and then Dean can get into specifics. If you just recall, we have 17 Phase 3s we're running. 13 of those are in tumor types where we think will be first in class. So most of those, they're outside of lung and they're outside of breast. But they are meaningful tumor types. So it's important that in alone, the fact that we can be first in class is fairly important.

As you look at the more competitive spaces, especially around lung cancer, Dean can get into why we think we have a unique asset. But the one thing I would add to that -- I think is not appreciated is going forward, the number of potential additional combination studies we could think to with sac-TMT, whether it's in combination with MK-2010, which as you've seen is now on ClinicalTrials.gov, other assets we have, is unique because we have such a broad portfolio.

We have a lot of different combination assets we can bring. A lot of those studies aren't reflected yet. And there are studies we're still -- some are spooling now and more we're continuing to look at. So that in and of itself is something that's underappreciated.

And then I think your specific question is, well, what about, what differentiates us in the more competitive spaces? And I'll let Dean take that.

Dean Li - *Merck & Co Inc - Executive Vice President and President, Merck Research Laboratories*

Yeah, so as Rob said, the linchpin of the whole thing is that we thought the molecule, when we looked at the molecule, was different than the previous two. And because it was differentiated, we decided to do two things. One is to race the indications where the other two weren't playing.

We were actually surprised that they didn't move it forward. And you see with the endometrial data, there is a chance that we can be first in lots of these indications that are outside lung and breast. And we intend to do that.

The other thing that's important about that data is that we had gotten signals in China. And so when we got signals in China, there's always this question of, would you get that signal in a global study? And the endometrial study de-risks that to us to some degree.

In relationship to lung and breast, we've already had one that's not going to make it into first line, one of the competitors. We'll have to see where the second one ends up. But we feel very good, based on the Chinese data, that this is an important ADC. We intend -- initially, we were very thoughtful of trying to be differentiated. But with the data that we've done with Kelun and with other data, we're extremely confident across PD-L1 that we could play with sac-TMT. The question is, when do you play with it with KEYTRUDA and when do you play with it with [MK-2010]?

Terence Flynn - *Morgan Stanley - Analyst*

And when will you guys make that decision? Like what other pieces are you waiting for to make that decision?

Dean Li - *Merck & Co Inc - Executive Vice President and President, Merck Research Laboratories*

Well, those studies are already ongoing. They're on ClinicalTrials.gov, and I think moving them from Phase 2 to Phase 3 potentially as the data evolves will happen in the next year and 1.5 years. But they're already actively going in Phase 2.

Terence Flynn - *Morgan Stanley - Analyst*

Okay. One other related one from AVANZAR is the biomarker population. Their data, there's an opportunity for them to show ITT or just the biomarker positive or outright failure. As you think about that spectrum of outcomes, what does that mean for your sac-TMT program in the event that, let's say, the biomarker population only is positive?

Dean Li - *Merck & Co Inc - Executive Vice President and President, Merck Research Laboratories*

If the situation where their biomarker is only positive, we would look very deeply as to whether or not what our results in a non-biomarker selected would look like. I think the -- that is something that we would gauge, but we'll see as the data advances. And I also think that the other sort of thing is -- we always have biomarkers available for our ADCs, whether we actually use them in the clinical sort of labeling sort of thing is one that's built on what the data suggests.

Terence Flynn - *Morgan Stanley - Analyst*

Okay. Maybe just, again, moving on to another important more recent approval and product for you is enlicitide, and I know there's been a lot of focus on kind of the early launch and access. We've got, I don't know, five weeks of prescription data, so I won't ask you to comment on that.

But again, just talk to us about maybe the importance of the label and some of the language in there on cardiovascular outcomes. And then what that means for guidelines and then how you guys are thinking about the access equation here, rest of this year into '27?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. And maybe I'll just start with the, kind of, broadly where do we see access and then I'll let Dean speak specifically to the kind of the label and what some of that stuff means. But if you look at the strategy, we've always said we were going to bring. It was we wanted to have an asset that we could price at a competitive price, a low price such that we could democratize care and drive the volume to all the patients that need this.

If you look today in the United States, 30 million people in the United States are on lipid lowering therapies today, not at goal. 30 million people. Number one killer in the United States is cardiovascular disease, and impacts from arteriosclerosis is a leading cause. So you have a silent killer that is affecting huge populations of our citizens that have an option to lower their LDL further up to 60% on this medicine who aren't on it today.

So a lot of the conversation is, well -- and we get this all the time, how are you going to do? Do you think you're going to take share from the existing injectable PCSK9s? Let's be clear, that is not the goal. My goal is not to have 5% of people on PCSK9, which is roughly where it is today. It's to say, how do we get to 50% or more of the population who would be eligible on PCSK9s. Everyone who is on a lipid-lowering agent not at goal should be on -- with an add-on therapy. And we think we are best positioned with the oral LIPFENDRA, which is the brand name that we have.

So knowing that we wanted to make sure we price this in a way that would maximize access. And we've done that. I will tell you what we're hearing from the payer community. They recognize and appreciate the differentiated characteristics of LIPFENDRA, we're actually hearing that. And we have not seen anything other than the ordinary restrictions that you'd see with the new drug.

So I think we've been successful in getting broad access, and we're on a path. As you look forward, we think we'll have full commercial coverage to the majority of lives by the time we get to the end of '27. We expect to have Medicare coverage by 2028. Chance to pull that forward. We're working hard to do that.

So as it sits here today, I feel very good from an access perspective. I think the profile of the drug and to your point, the label is extremely positive and we are very bullish about this, but maybe you can comment on the questions around the CVOT and what the --

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Dean Li - *Merck & Co Inc - Executive Vice President and President, Merck Research Laboratories*

Yes. So the bottom line is we have a CVOT proceeding, but I do think the FDA understood that this molecule was designed to do what the antibodies did in relationship to biomarkers. And if you look at the biomarkers of ours, and you look at the antibodies, they, kind of, look like they're all in the ballpark.

I think the second thing that the FDA understood is, although we talk about PCSK9 generally, if you look at, for example, the PCSK9 siRNAs or other sort of things, they're not in the 60% range, they're in the 50% range.

So I thought it was interesting what the FDA did. They reminded people that we don't have an outcomes trial, but they recognize that this drug should be done in addition with a statin. So they say statins have cardiovascular outcomes in our label. And they also reminded everyone that although we don't have cardiovascular outcomes, we were designed to be like an antibody, and they remind everyone that the antibodies have cardiovascular outcomes. So we view that as all positive movement.

Terence Flynn - *Morgan Stanley - Analyst*

And what does that mean for guidelines? Before you have your own CVOT data, is there a chance that you get kind of parity with the antibodies from a guideline perspective? Or do you have to wait for your own CVOT data? Just trying to think through any implications for guidelines.

Dean Li - *Merck & Co Inc - Executive Vice President and President, Merck Research Laboratories*

So if you're talking about AHA/ACC guidelines, I think always, there's going to be some, sort of, question as to -- until you have the cardiovascular outcomes and how do you think through it. But I think the larger question for AHA and ACC is two things.

The first one is they finally have LDL. The second thing is for those patients who have secondary ASCVD, I think many people believe that their guidelines of less than 70 is not sufficient, it should be less than 55 and 40. I think that's the major issue.

And then the third issue that comes from guidelines is that CMS has never had a quality metric in relationship to LDL, which is shocking. And the question is whether the CMS will begin to do it. That to me is where all of our competitors and us should be pushing for.

Terence Flynn - *Morgan Stanley - Analyst*

And how should we think about the out-of-pocket channel here? I mean, is that a real opportunity? Or is it a function of, look, I mean, most people have commercial Medicare coverage with cardiovascular disease. So it's likely going to be fairly small as we've seen with, kind of, the antibodies? Or is there more of an opportunity for the out-of-pocket channel?

And then maybe even step back more broadly, like how are you guys as a company thinking about leveraging an out-of-pocket channel or footprint, given some of the success we've seen for some other companies.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. So I do think the growing acceptance of direct-to-patient is something to take note of. And I do think you're going to see more of it and it's something that we are looking at doing aggressively not only in the cardiovascular space, but more broadly, it is very asset specific. So not all drugs are -- will meet that space in the right way. KEYTRUDA would never be in that, for example, but there are a lot of opportunities. And I do think it's an important way to continue to get directly to the patient at prices that often can be cutting out what's in the middle.

So we are looking to do that with LIPFENDRA. We are -- we have already announced intentions and we had it as part of our MFN agreement to put this on TrumpRx.gov. We're looking to do that as we move to the back half of this year. It's -- to that extent, it's immaterial as you think about 2026, and probably, it's going to take some while to ramp, but it is a channel that we are going to take advantage of. And as I said, not only here, but as we bring new assets, it will be something we'll look at each asset and ask because it's something that should also sit in that channel.

Terence Flynn - *Morgan Stanley - Analyst*

Okay. And any -- last one, any early feedback from kind of your sales reps out there in the field? I know you mentioned some of the payer feedback, but anything on the patient side you're hearing from your reps?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

The short answer, it's all positive. The amount of press this has received, it frankly exceeded my expectations, the understanding of what we have is probably broader than we thought. So I would say early days, but everything is quite positive.

Terence Flynn - *Morgan Stanley - Analyst*

Okay. Great. Maybe moving on to tulisokibart, your TL1A antibody for IBD. Maybe just again, any update on when we might see that first set of full Phase 3 data? Is this something that we could see at the UEGW conference?

And then maybe just help us think through that second Phase 3 trial that you guys have ongoing in terms of timelines for data and anything to call in terms of similarities or differences versus that first data set?

Dean Li - *Merck & Co Inc - Executive Vice President and President, Merck Research Laboratories*

Yeah. If I could reframe the question a little bit, which is our interest in tulisokibart is not IBD. Our interest in tulisokibart is to be a major node, a major cytokine node across indications. That's why we're doing GI, IBD. That's why we're doing derm like HS.

That's why we're doing rheum. And our hope is that this node and this antibody can be one of the best, if not the best biologic in each one of those indications and be one of the safest, if not the safest. Because if we're in that situation for each one of them, that will be great. And in that situation, your comparator changes.

In IBD, you think of IL-23 in HS, you'd think of IL-17AF. So our ambition is broad in relationship to that. Specifically to your question, we need two Phase 3s to be able to file. We should be getting some of that data this fall. I don't know that I will have all the data for any conference this year, but more likely the beginning of next year.

Terence Flynn - *Morgan Stanley - Analyst*

Okay. And then Rob, what does that mean more broadly? Again, if this is a cornerstone for an immunology franchise, again, I've seen some of your peer companies kind of struggle to scale in immunology because of, again, that kind of -- maybe they've got one asset, but maybe it's not like a best-in-class, first-in-class or later, and they don't have enough other assets around it. So how do you think strategically around what TL1A is for the company and your presence in immunology?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Well, I would start by saying we are committed to playing in immunology as an important therapeutic area. And if you look at what we have, both with our TL1A with Tulisokibart, but also what we have, which hasn't been fully disclosed, but in our -- we have a lot in actually our Phase 1 pipeline moving into Phase 2, which as we move over the next year to two years, you'll start to see increasing cards turn over. And I think our strategy will become more clear.

But as Dean said, whether it's in rheumatology, whether it's in dermatology, in IBD, we are covering the landscape with the studies we have going. I think the important point you raised is, do you have a drug which is best-in-class, first-in-class? We need to see the clinical data. We need to get the final outcome. If it plays as we hope and we believe it could, and we do have something which is a best-in-class, a new mechanism, as Dean has pointed out, I think that's a different situation from a competitive landscape, it's hard for people to close you out if you have a drug that brings unique characteristics.

So we need to know that. But beyond that, how do we build around it with a portfolio of assets? As I said, many we have internally. We also continue to be open to adding through business development. So this is an area where if we see interesting science, we will move opportunistically because we do think that this is an area we want to be in for the long term.

Terence Flynn - *Morgan Stanley - Analyst*

Okay. Maybe just a couple of quick hits here in the last minutes. One is just on China. I know that has been a source of innovation for you guys, Kelun, LaNova. Again, maybe another asset that I'm missing. But I guess the question we get sometimes is there a risk that either the US government or the Chinese government tries to stop these kind of cross-border deals. I mean what's your take on that?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. I don't want to get -- I don't want to try to speculate on what the US government will or won't do. What I will say is the conversations we're having with Washington is really around respecting and understanding the concerns around national security and making sure that we don't take that lightly, but also recognizing that there's innovation happening in China that should be available. We want to have available -- made available to US patients, to European patients and others.

And the real focus needs to be on how do we keep our competitive edge. We are the leader as the United States today. We need to focus on continuing to maintain that. The area where we see the greatest opportunity continues to be in how do we modernize, how we run clinical studies in the United States, primarily as you think about early Phase 1 first-in-human studies, that's an area where China has a significant advantage in both time and cost.

If you look at the TrialBlazer program being run right now by the FDA, we're very supportive of that. So let's focus on getting the best system in the United States to keep our lead. Let's put guardrails to ensure that we don't trip into national security concerns. And then other than that, let's let the market work and have access to those assets. But to be clear, as Merck, we look at China as an opportunity, but we look globally.

We don't source only from China. We source from around the world. There's great science all over the place, including what we're doing in our own discovery. So we're investing in all of those areas to make sure that we have the breadth, regardless of what happens geopolitically.

Terence Flynn - *Morgan Stanley - Analyst*

Last one is AI. I had to squeeze one in here. Just what's one nonobvious current use case you've seen at the company at any part of the organization?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. I would say I think people assume that we're using AI a lot, you hear a lot of discussion about target identification and this notion of how can I go in silico, find a target and bring it through. We continue to believe you're never going to go straight from a virtual study into humans and ultimately through development, we think that you need the combination of the wet lab with the dry lab, if you will.

But that said, where we have seen meaningful benefits it's, frankly, when we talk about the fact that we're seeing above average PTRS, including especially as we look at our Phase 1 pipeline, a lot of that is driven by what we have been able to already do with AI, which is how do you think about molecular design and molecular design optimization.

And if you can do that early, you can start to get out a lot of the safety issues. You can get to an optimized molecule. That increases your probabilities it makes it through. It allows you to move faster to get to the optimized target, which brings lower cost. And we actually are

benefiting from that and actually are building those savings into our budgets today. So that's something I think is fully -- not fully appreciated is around how you think about molecular design.

Terence Flynn - *Morgan Stanley - Analyst*

Great. Well, I think we're up against time. But Rob, Dean, really appreciate it.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Thank you all.

Dean Li - *Merck & Co Inc - Executive Vice President and President, Merck Research Laboratories*

Thank you.
