

REFINITIV STREETEVENTS

EDITED TRANSCRIPT

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

EVENT DATE/TIME: SEPTEMBER 08, 2025 / 6:35PM GMT

OVERVIEW:

Company Summary

CORPORATE PARTICIPANTS

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

Eliav Barr *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

CONFERENCE CALL PARTICIPANTS

Terence Flynn *Morgan Stanley & Co Ltd - Analyst*

PRESENTATION

Terence Flynn - *Morgan Stanley & Co Ltd - Analyst*

Everybody, we're going to get started here. But I'm Terence Flynn, Morgan Stanley's US biopharma analyst. I'm very pleased to be hosting Merck this afternoon. From the company, we have Rob Davis, the company's Chairman and CEO; and Dr. Eliav Barr, who is the company's Head of Global Clinical Development and also CMO. Thank you both so much for joining us today this afternoon. Look forward to chatting.

Just quickly, 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. With that, I'm going to turn over to Rob for some opening remarks, and then we'll dive into it.

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

Great. Well, Terence, thank you. Thank you for having us, and thank you for everyone participating. Maybe just a few thoughts to kind of set the stage before we jump in. If you look at where we are as Merck right now, I would say we're really in a transformation. We're moving from being historically the Keytruda company to increasingly really on a precipice of a wave of launches you're going to see coming, to becoming a launch company and a much more diversified company, which are things we've been very focused on.

If you look, we've communicated over \$50 billion of commercial opportunity by the mid-2030s, and that doesn't even include some of the more recent deals we've done, like the recent deal we did for Verona or the deal for EyeBio, which -- each of those are a multi-billion dollar opportunity.

So as we sit here today, we feel good about the pipeline we're building, the commercial potential we have. We have to realize it. We have to add to it, so we're going to continue to invest in, augment, and accelerate our internal pipeline. And we're going to continue to look to do business development.

So we're not slowing down across any of those fronts. But importantly, with the fact that we now have 20-plus real new molecular entities that we're going to be bringing to market, almost all of which have blockbuster potential, our focus is about how do we launch all of these opportunities successfully, how do we do them in a way that delivers for the patients. And then ultimately, as the way we think of Merck, if we take care of the patient, ultimately we will take care of all of you, the shareholders.

So that's our focus. I feel very good. We've talked about the hill versus the cliff of the Keytruda LOE. That continues to be the case. My confidence in our ability to have sustainable growth long term continues to grow. And I'm sure we'll touch upon all that in our discussion that we go forward from here.

QUESTIONS AND ANSWERS

Terence Flynn - *Morgan Stanley & Co Ltd - Analyst*

Absolutely. Well, thanks so much, Rob, for framing that out. Before we get into all the more exciting stuff, I mean that's the question that I don't think anyone has the answer to, but just set the stage, latest perspective on tariffs and MFN, kind of where we stand because I think that is still top of mind for a lot of investors here and a lot of uncertainty, but just what are you hearing? How are your conversations with the administration going on those two topics?

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

Maybe start with the tariffs, and then we can move into the MFN. On a tariff front, we've done a lot to prepare ourselves, and we are now very well positioned through both the way we've managed the inventory across the company, but most importantly, as we started to shift our manufacturing footprints and have in place plans to really do US production for US sales.

So I would say, as well as you can be prepared, we are prepared depending on how the tariff situation evolves. Still unclear. We still have to see the outcome of the 232 investigation, so that is still out there, and we'll see how that plays itself out.

As it relates to MFN, probably as you've heard from others, there are several areas where I would say, on principle, we agree with the administration, and we're willing to work with the administration. And in fact, we've been having ongoing dialogues with them.

The question is really how do we think about taking what are principles we agree to, like, for instance, we agree we have to find a way to get foreign prices up and not to enrich the industry, but frankly, to allow us to bring prices in the US down. We agree that we have to find a way to make sure that the out-of-pocket cost for patients is lower.

Our belief the best way to do that is to go after the \$0.50 of every dollar that sits in the middle. You've heard of the industry say that in the past. For every \$1 of price you see, only half, actually less than half comes to us as the innovator, the developer, and the manufacturer.

If we could just capture that other \$0.50 and bring that to the patient, you could cut costs in half. We continue to believe that's one of the best things we could do as an industry. Direct to consumers may be a path to do that, and that's something we're open to. But beyond that, I think it's really going to have to -- we're going to have to see how it plays out and where the conversations go over the next coming weeks and months.

Terence Flynn - *Morgan Stanley & Co Ltd - Analyst*

One thing a recent cabinet meeting highlighted was potentially a linkage between tariffs and MFN is that something that you're hearing, and hence, as a result, is this going to -- the tariff situation is going to carry on further because there's this linkage. And so resolution of all this might be -- maybe longer than we expect versus it being two independent parallel processes?

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

Well, the short answer is I saw the same cabinet discussion. Beyond that, I really can't speculate because we've had no conversations in that regard. But I did see the same thing you're referring to, and we'll have to see how that plays out -- how that really plays out in practice, unclear yet.

Terence Flynn - *Morgan Stanley & Co Ltd - Analyst*

And then on the DTC side, that's something again a lot of your peer companies have talked about as well. Are there any areas that you see, as you think about this forward pipeline for the company? You have probably one of the broadest upcoming launch product sets in the industry. Are there certain areas that you would point to that are more amenable for DTC versus others that maybe aren't?

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

Well, as you look at the direct-to-consumer, the conversations so far have been more with existing products than it is forward-looking products. And today our portfolio is more Part B focused. I think what lends itself best to direct-to-consumer is really drugs that are in the pharmacy benefit, largely Part D drugs.

That said, we're open to it with some of the products we have, some HIV drugs, diabetes drugs, others we could consider. And then if it would become something on a forward-looking basis, there are opportunities that we would look to do it there as well. So we need to see, though, how it defines out before I would say specifically which products we would be looking to do that with.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

Okay. Makes sense. One of your peer companies, Lilly, announced it was raising the price of Mounjaro in the UK. You talked about this price alignment, but there are obviously -- there're certain hurdles, challenges across the portfolio. But are there certain areas that are easier to accomplish that in versus others maybe as you think about it? Or I guess the derivative question is again, new product launches, how does the company think about the strategy for new product launches because maybe that's a little bit easier to address existing product?

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

Exactly. So if you look at what Lilly did, one, I would say, you know, it's very product specific. But if you look more broadly at the way we've been thinking about this in Merck, and I think you hit upon it, we're at a point of transition with our pipeline. So we are going to be launching multiple new drugs into the market. The best time and place to effect the price imbalance between the United States and the rest of the world is with the launch of the new product. It's much harder to go back for products that already have established presences in the space to do that.

So as we look forward, I can tell you, we already have changed our approach with the way we think about pricing and are actively considering how can we get prices up outside the United States and how do we engage in those discussions.

And more broadly, as an industry, we've had a lot of conversations with the UK, with the European Union, and other governments to start to express to them an understanding that we need to see the disparity addressed. And we'll see how it plays out. But it is already changing our strategy as we look forward. And I think our pipeline positions us in a place, frankly, to be in some ways better positioned than many in that regard.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

Do you -- from those initial conversations, do you think that European Union is amenable to that, or how open are they, or what's going to be the pushback from them, do you think?

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

I would say generally in all the conversations I've been involved with and probably more at a country level than at the Europe level, we have had conversations with EU broadly. But at a country level, no one is challenging the principles upon what we're talking about. It really comes down to the practical, often budgetary pressures that everyone faces, and then how do you judge relative value.

And so I think that that is going to be the bigger challenge, how do we align on what is value? And then once we align on that, how do you translate that into something that they can absorb from a budget perspective?

And that's why I think this is going to take time. It's taken us 50 years to get to where we are, really, actually longer than that, post World War II. It's going to take some time to transition, but we're committed to trying to work on that path to bringing equalization to make sure that we bring full value for the innovation we bring to the marketplace.

Terence Flynn - *Morgan Stanley & Co Ltd - Analyst*

Okay, great. Maybe we'll just pivot over to strategy. Again, you talked about this a little bit, but just as you think about it, you guys have leaned in on the BD side, doing more of the kind of pre -- I'd say pre-Phase 3, pre-commercialization type deals.

You mentioned Verona, EyeBio as two examples. You also have the TL1A that you brought in, obviously, WINREVAIR as well. So been pretty active there.

I mean as you think about entering this period where you do have a high percentage of LOEs, does the calculus change at all in terms of the types of assets you consider? I mean I think a lot of investors look at AbbVie and how they kind of navigate this period. They ultimately acquired a big company, Allergan, they had two mega blockbuster launches, gave trough EPS guidance, and then came out the other side.

But how do you think about that as you get into this period? Is it still just execute the plan that we've laid out in terms of these kind of \$10 billion, \$15 billion deals? Or is there to become a time period where maybe you need to reconsider how to approach that?

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

If you look at the, I'd say, the common theme, and we've done some earlier-stage stuff, and as you pointed out, we've done some late-stage stuff. And even with commercialized assets, obviously, most recently with Verona. But there's a consistent theme. There's a science-driven narrative around it. There is a situation where we see usually a new mechanism of action, either first-in-class, best-in-class or both, and one where we think there continues to be a significant unmet need. And then lastly, one where it's not just that deal, but then what can it lead to?

So we like to talk about first best next. And the next is how can I think about combination therapy? How do I think about continuing to evolve in that space once I'm there, once I have a beachhead? So that's been kind of a consistent theme.

As I sit here today, I feel like we've done a good job. We've moved with urgency. We've invested over \$50 billion into business development since I've become CEO. And I think about the multibillion-dollar opportunities, think about it, when we talked to you last year, we have two more Ohtuvayre and what we have with EyeBio that we didn't have last year and with pretty much everything we had last year continuing forward. So those two, for instance, aren't even in the \$50 billion-plus.

So I think we need a few more of those. And I think if we can do that, continue to drive our pipeline, we're well positioned. But if we don't find those, I'm not opposed to doing a commercial deal, but it has to be one that still comes down to the basis of science.

I think doing something just to solve a short-term problem is the wrong answer. It has to be sustainable, which is then based on the science and how does it fit within the overall portfolio. So the \$1 billion to \$15 billion that we've been following continues to be our preferred area, but we remain open to others if the parameters of value, science come together in the right way.

Terence Flynn - *Morgan Stanley & Co Ltd - Analyst*

Okay. Great. The other area that's, I think, garnering increased focus is just the opportunity set in China. You guys have announced several deals there, oral GLP, PD-1, VEGF, Lp(a). So you've obviously been fairly active.

But as you think about that, is there opportunity for that to expand further into other therapeutic areas? And how do you think about making those kind of decisions vis-a-vis maybe some of the US biotech opportunities?

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

Yeah. So we go for the best science wherever it is. I wouldn't look to the fact that it just happened to be that the opportunities in China presented themselves around the same time frame. It was not a pivot in our strategy. Because since then, you look, we did Verona, that wasn't a Chinese-based asset. We did EyeBio, that's not a Chinese-based asset.

So we go to where the best science is. We continue to think the US offers as good a science, if not the best science in the world. But we're not limiting ourselves there. We will go to wherever that is. And China is an area where there's some interesting things.

But I wouldn't say it's also therapeutic area specific. It's broad-based in what we would look to do there. So there and the US as the opportunities present themselves will be where you're seeing us focused.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

Okay. Great. Maybe we'll move on to one of your key new product launches, just WINREVAIR, obviously, it's off to a strong start. Maybe just talk to us about kind of the dynamics that you're seeing kind of US, rest of world, and how to think about the cadence into '26.

And then the other kind of question we get more frequently now is just the impact from this upcoming label expansion decision, which could move into slightly earlier patients.

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

Yeah. Maybe I'll start with kind of where the commercial market is and I'll let Eliav speak to the label and how we think that could expand. The high-level answer is we continue to be very pleased with how the launch is going. Everything continues to perform.

Access is strong. Number of physicians prescribing continues to grow. Patients on therapy is growing. And our ability to see increasingly patients move from later lines, so from the people going on triple therapy and even some on dual therapy, everything is moving as you would expect.

And then as you look beyond the United States, we're still early actually in the approvals. As you know, as you get approvals in Europe, it's more about getting the reimbursement. So as we move into the back half 2025, you're going to see more major markets start to have reimbursement in Europe. We just launched in Japan, which is a very important market, a very big market for this drug. So as you get into '26, really, you're going to start to see that international piece take off.

But the early days of what we've seen in markets like Germany where we are in the market, it's moving very similar to what we've seen in the US. So I think the US as a proxy for you start with the sickest patients, you test and you learn how to manage the drug. And then as you get comfortable, you start to expand into earlier-stage disease and into broader patient populations. That's what's happening here and that's what we're seeing globally. But maybe you can speak to HYPERION and ZENITH.

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

Sure. So the ZENITH trial, as read out earlier in the year and was -- we submitted for regulatory approval. In the United States, we have a very, very broad label. So the ZENITH trial is already within the label. In Europe, this is very important for reimbursement because ZENITH, as you recall, the late-stage patients, patients with very severe functional Class III and IV disease. And by being able to demonstrate the efficacy of sotatercept against hard endpoints in this population, not only do we expand the label, but we also have the opportunity for a proper reimbursement decision.

Nevertheless, being that it is important in the United States because these -- it does continue to demonstrate over and over again the extraordinary benefit that sotatercept gives to patients across the spectrum.

We just announced a few -- a little while ago that the HYPERION study is positive, and it will be presented at the ERS meetings later on this month. HYPERION is very different than ZENITH. It's early patients within a year of diagnosis, mostly on two-drug regimens, so not on three-drug regimens. A lot more connective tissue disease, a broader age range. And so this represents the entry level, the people who are recently diagnosed with PAH.

The results of the study were really terrific and consistent with what we've seen with all of the other studies. And I think this will fill a really important gap right at the time that physicians are thinking, I'm feeling a lot more comfortable with WINREVAIR, now I really want to try to get to my earlier patients, the patients that are just starting to have symptoms from PAH, are on two drugs. And now I want to start them on something that will help them improve outcomes over the long term.

So this is going to be a really important study as well, and you will be able to see the benefit just being consistently seen whether it's STELLAR, ZENITH, HYPERION, and that kind of covers the spectrum of PAH.

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

One thing just you might clarify because you didn't mention it specifically, but the mortality benefits from ZENITH.

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

Sure. So in the ZENITH trial, you have hard endpoints, including mortality benefit. And again, that's the reason why European agencies, I think, would be particularly -- reimbursement agencies, reimbursement authorities, will be particularly interested in this data set because they have that bar to reimburse.

So I think we see this time to clinical worsening in STELLAR study, the hard endpoints including mortality benefit in ZENITH. We see again time to clinical worsening better in HYPERION, and you'll see those data soon. And I think that this is a really compelling data set, including a very clear and well-understood safety profile. So very exciting data, and I think it's going to be very important for the field.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

And the SBLA PDUFA date for ZENITH is October 25.

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

That's correct.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

HYPERION, I'm assuming now that you have other study, will be a separate SBLA filing?

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

That's correct. Yeah. But again, it's -- these are pretty very clear.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

And is there an opportunity to do -- I think maybe the company has talked about it before, but like a combined analysis of mortality across these studies almost, like on a post hoc basis?

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

We're going to be doing a lot of those analyses. That's going to be very important. Mortality is an important endpoint. We're going to look at also transplants and other really severe outcomes for the patients. Those data are going to be coming over the next few months.

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

Yeah. The other thing is there were some initial questions always on safety just given what this drug has done. And I think it's STELLAR with Stellar and then using the STELLAR data plus what we have from these studies, and then our ongoing follow-up study, we have SOTERIA, I think you're also going to see us focus on bringing real-world evidence to give confidence to the fact that the safety profile of this drug is quite, quite good.

Our confidence of that is quite high. We want to make sure that we have the data to back it up. So that's also another area where we're focusing a lot of our data aggregation to be able to give people the same confidence we have.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

Is that something that you think that maybe the community docs who treat PAH are still focused on, or do you think that's more of a Wall Street issue, the safety question?

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

Well, I think patients are -- I mean, doctors, physicians are always interested in balancing benefit-risk. I think that the safety profile of sotatercept is well known, it's really quite good. We haven't seen any new safety signals. And I think that all the clinical trials have been really good at defining how you reduce doses for hemoglobin and some of the bleeding elements and so on.

What's really important with the SOTERIA study, which is now really quite a large study with patients on drug for five, seven years now, is long-term outcomes. People want to know, well, what happens if things got worse over time, things get better over time, is the efficacy the same?

What we're seeing is the efficacy patients are -- the efficacy findings continue to be really good. The safety profile, again, quite manageable. There's no accumulation of problems, worsening. And so these data, I think, are very important because now we have patients who are in the real world and will be on this drug for a quite substantial period of time.

They're feeling better. They're doing better. We just don't have to be able to share what the data are. And we will have every 6 to 12-month update so that docs are comfortable with that.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

Great. Maybe just the last one on sotatercept is there's obviously a Phase 2 data from the CADENCE study that you guys are expecting later this year. So maybe first part of the question is just frame for us kind of what you guys are looking for to move that into a Phase 3 study.

And then the one that we frequently get is how to size the number of people that would be eligible for this therapy vis-a-vis the current PAH population, because I see a lot of different estimates out there. But how is the company thinking about eligibility in the patients that you enrolled in the study?

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

Yeah, maybe I'll let you start and if I can add anything.

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

Sure. So just to start with the end first. These patients are patients with heart failure with preserved ejection fraction that have high blood pressure in both the pulmonary veins and arteries. So it's a particular subset of what's called HFpEF. The TAM, the total addressable market, is roughly the size of PAH, we believe.

The difference versus PAH is that, because there's never been anything for these patients, they're somewhat less diagnosed. Now what we did with the CADENCE study is a Phase 2 trial that looked at two doses of sotatercept against placebo on a BRCA on the standard medicines in these patients, and we'll have the results.

The primary endpoint is blood pressure in the pulmonary vasculature, so-called pulmonary vascular resistance. And you have secondary endpoints, including the classic, the standard six-minute walking distance. And we'll see what those results are.

It's our expectation that those data will be available later on this year. And should the data look robust, then we would move into a Phase 3 program. But I think that the -- looking at enrollment rates in the study, at the beginning, they were pretty slow. But as people began to understand what sotatercept can do, and they recognize that there's potentially some hope with these patients, our enrollment rate went really quickly up. So I think that there's going to be a lot of enthusiasm should the data turn out to be supportive of use of sotatercept.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

Can you remind us what you think are clinically meaningful -- the result would be on PVR? I mean I remember a lot of the PVR data from PAH, but in this setting, is it similar to --

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

It's going to be something similar to that. I think this patient population in general is similar to HYPERION's, and so what's -- in terms of age and comorbidities and so on. But that gives me some confidence in the sense that HYPERION was such a great result, so I hope that will replicate. It's a different disease, so I don't have any data. But we're hoping to get the data later on this year.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

Okay. Great. Is that a press release opportunity? I mean this might be a question for Peter. Is that a medical conference presentation, or what's kind of for a Phase 2, remind us like Merck's standard disclosure for this kind of things?

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

Yeah. So we'll have to wait and see what the data is. But our expectation is we see the data near the end of this year, likely it would be for a conference, probably sometime early next year. But obviously, a lot of it depends on what the data is.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

Yeah. Okay. Great. I just want to kind of drill down to the pipeline a little bit further here. I think you guys have talked about this a lot, most recently on earnings, you reaffirmed this over \$50 billion opportunity. You mentioned it again here. I think oncology is one area where maybe, if I look at

consensus versus how you guys are thinking about it, you say over \$25 billion, I would guess there's not that much in Street models really that much. So when you look at your opportunity set in oncology, beyond KEYTRUDA, what do you think the biggest disconnects are that people are missing that you're excited about?

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

Yeah. Well, maybe I would just start and say one of the things I think in general when we speak to what are the things underappreciated, and I'll speak to oncology, is the overall breadth of our pipeline. We have now 80 Phase 3 clinical studies underway, 60 in oncology, all of which could be registration-enabling. So that's a massive Phase 3 pipeline.

And as we said, that's driving 20-plus assets that are unique assets that we think almost all of which have blockbuster potential. So I'll just lay that out there. But within oncology specifically, if you take the \$25 billion, we talked about that there's over \$25 billion from our oncology assets. And what is that made up of? It's made up of our antibody drug conjugate portfolio. It's made up of our small molecule portfolio, mainly precision molecular targeting agents, our individualized neoantigen therapy with what we're doing with Moderna and our recently acquired T cell engager that we have as well.

So that kind of is what's in that. It excludes the subcutaneous KEYTRUDA, excludes other assets. If you look at the \$25 billion, almost, I guess, a little over half of that \$25 billion would be just the ADCs. And within that, I would point to probably the one that we think is underappreciated, is sac-TMT. Sac-TMT currently has 14 Phase 3 studies underway, nine of which we think will be basically first-in-class indication. The other five could be potentially best-in-class.

So we think that in and of itself is a highly differentiated asset, top two that we're going to continue to pursue. And obviously, we invest behind the 14 Phase 3s based on our understanding of the oncology space and our confidence in what that could be.

Not to mention in the precision molecular space what we have with our KRAS G12C would be one. Maybe you can hit on the --

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

Our CYP11A1 inhibitor and our medicine bomedemstat for various proliferative diseases like essential thrombocythemia. So a very large pipeline, very diverse pipeline, new entry into the hematology space. Sac-TMT, I think, is a real workhorse medicine that will help both in maintenance settings in GYN and women's cancers, certain kinds of lung cancer.

A lot of these assets are biomarker defined so that we have deep and defined responses in specific patient populations. So overall, KEYTRUDA has helped us a lot. We are focused on areas where KEYTRUDA is foundational. But we're not limited to that as hematology points out. And with that, I think oncology is a huge opportunity.

I think it is undervalued by investors simply because, we will show you the data in due course, but I think that the result, the ADCs are terrific as are the targeted agents and combinations of those agents as well.

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

And maybe if you just allow me because we have so much. So going beyond oncology.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

That's one (multiple speakers)

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

Yeah, go ahead.

Terence Flynn - Morgan Stanley & Co Ltd - Analyst

On TROP2 because I think there's kind of two follow-up questions. Number one is I think investors have maybe become a little less optimistic because of some of the data on the lung cancer side. And so maybe you guys could just speak to what gives you confidence because, again, if I'm assuming half of this \$25 billion is for -- a big chunk of that that's probably lung cancer. What gives you the confidence in the lung setting here with the TROP2?

And then the related question is that biomarker question, which Eliav alluded to, is like how critical is the biomarker in unlocking this big opportunity for TROP2? Because I think that's the other thing investors kind of wax and wane on, is like, do you need a biomarker, do you not? And so maybe just elaborate.

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

We are very committed to the biomarker approach, but maybe I'll let Eliav can address this.

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

Sure. So I'll start with TROP2 and then I'll start with lung cancer there like this, overlap and then that completely. With TROP2, I think that the difference -- so if you look at the different TROP2 agents, each has some issue that I don't think we have with TROP2. ILD on the one side, and on the other side, some really significant diarrhea and problems with potency.

It hasn't -- so our program -- our drug, first of all, from an AE profile is much more of a traditional chemotherapy kind of AE, neutropenia, and so on, but not such an extent that it causes a lot of discontinuation. So first of all, well-tolerated drug with strong efficacy. That's step one.

Step two is where we're going. Merck has traditionally, with KEYTRUDA, been heavily focused in GYN and triple-negative breast cancer. And we also have, of course, HR-positive breast cancer studies going on. In any event, in GYN cancers, strong opportunity for Sac-TMT. We also see that in specific segments of lung cancer, where people are -- the biggest differentiator between our program and other's program is that we're not going up against the big-gun chemotherapies because those drugs are well-entrenched, they are quite effective.

What these drugs can't do, like a platinum doublet, can't do is give you -- allow for long-term anticancer effect. You get through it, you're done, and then you hope. Whereas sac-TMT has a long, long on long, long tail, which enables us to have maintenance therapies.

And so instead of going up against the first line, we have a lot of maintenance studies. And that as a concept that's not been exploited too much. But when it has been, the effects have been really quite good in terms of overall survival. So that's that.

Biomarkers is really important because all of these ADCs do have some enrichment, but not for every cancer. And so we have invested quite a bit in a lot of biomarker work, digital pathology, AI, all the kind of whiz-bang sort of stuff. And we've come up with the kind of markers that I think will make the right drug go to the right person at the right time.

That's why we have such a big suite of ADCs. We have sac-TMT; we've got three Daiichi compounds; we've got a hem ADC and we've got others in the pipeline. They're not going to cannibalize each other. They're each for that patient and that patient and that patient. And so you'll see that in lung cancer, we have some studies with sac-TMT.

We've got our B7-H3 in small cell. And in other cancers, in GYN cancers, we've got sac-TMT, but we also have our ovarian RDX with Daiichi. Overall, we cover a huge number of cancers with really groundbreaking efficacy specific biomarker-defined populations. KEYTRUDA data help us get there. And I think it's going to be -- these drugs are going to be quite transformational in health care.

Terence Flynn - *Morgan Stanley & Co Ltd - Analyst*

Rob, I know you want to talk broadly.

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

Yeah. Well, the problem is we have so many things, we're going to not have enough time to cover them. But no, if you look at a few others, I think, underappreciated HIV, we recently had an investor event where we went into a deep guide. But if you look, we have interesting opportunities in -- with islatravir and doravirine and daily treatment. We have weekly treatment in combination with lenacapavir.

We have our own weekly treatment coming in a combination of islatravir with ULO, which we're excited about. We think it's a very interesting next-generation agent. But probably the thing we're most excited about, MK-8527, which is our once-monthly prep. So we have a whole suite of opportunities. We now see with over \$5 billion of opportunity there and more coming in that space.

So I think that's one that it's going to take time for people to get comfortable with. But I think as they do, they will come to appreciate the power we're going to have in that space.

And then the other one is ophthalmology. We have -- through the acquisition of EyeBio, we have accelerated that program two years. So we're coming two years faster than the market than what was originally anticipated. And we have two assets, not just one.

We have, importantly, MK-3000, which is currently in Phase 3. That's we're looking starting first in DME, but looking then to move into to AMD. But then we also have another asset called Tyspectus, which we think is as meaningful as what MK-3000 is. And so that also is a multibillion-dollar opportunity, so we feel very excited about those.

And then the last one is Animal Health. Our Animal Health business, we're going to more than double it by the time we get out to the mid-2030s. And it's on a story that's very similar to the human health business. It's driven by new product innovation in both the Companion Animal and the Production Animal space.

In the Companion Animal space, we have a next-generation JAK inhibitor for atopic dermatitis, NUMELVI, that is launching outside the US. It will hopefully launch here in the US, get approval later this year, maybe early next year.

We just launched our annual -- once per year injectable BRAVECTO, long-acting BRAVECTO in the United States. We have that outside. We have a whole suite of next-generation vaccines for animals. And then we have a technology business. That business is going to grow faster than the market, and I think will surprise people with the strength of the growth that we'll bring.

So we're very excited about what we have. And the next time we're together, we'll go through some others. But if you wanted to know, that's a few areas, I'd say, if you haven't looked, open your book and look a little bit because I think you'll see there's more there than you probably originally expected.

Terence Flynn - *Morgan Stanley & Co Ltd - Analyst*

Great. Well, thank you so much, Rob. Eliav. Really appreciate the time today.

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

Thank you.

Eliav Barr - Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer

Thanks so much for having us.

DISCLAIMER

Refinitiv reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2025, Refinitiv. All Rights Reserved.