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EDITED TRANSCRIPT

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OVERVIEW:

Company Summary

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CONFERENCE CALL PARTICIPANTS

Steve Scala TD Cowen - Analyst

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PRESENTATION

Steve Scala - TD Cowen - Analyst

(technical difficulty) sixth annual health care conference. We are absolutely delighted to have Merck senior leadership here with us today. Representing the company, Caroline Litchfield, who is Executive Vice President and Chief Financial Officer; and Dr. Dean Li, who is President of Merck Research Labs, lots to talk about, both in the pipeline as well as the current operations. But to set the stage, Caroline, I'll turn it to you.

Caroline Litchfield - Merck & Co Inc - Chief Financial Officer, Executive Vice President

Thank you, Steve. So good afternoon, all. Thank you for being here and thank you for your support and interest in Merck. Our company is transforming its portfolio. We're launching many new products including WINREVAIR, OHTUVAYRE, CAPVAXIVE Enflonsia, and QLEX. We're in the midst of having more than 20 new growth drivers in our Human Health business.

Every one of these products has the promise of advancing patient care and almost every product has blockbuster potential. And we've highlighted that there's more than \$70 billion of commercial opportunity from those 20-plus products. And it's not just human health.

Our Animal Health business is also launching many products, and we expect to more than double the revenues of our Animal Health business by the mid-2030s. And so, we're increasingly confident in our future. And that future also includes a robust early-stage pipeline that will continue to evolve and hopefully yield Phase II, Phase III programs in the coming months and years that will equally drive revenues and patient impact in the 2030s.

So we're confident as a team that we can navigate the KEYTRUDA loss of exclusivity. And we talk about it as being more of a hill than a cliff as we expect our revenues to have a shallow dip before quickly turning to strong growth within a few years.

And we will continue as a team to execute: execute on our launches, execute on our pipeline, and continuing to augment this pipeline with scientifically focused value-creating business development so we can drive impact for patients and long-term growth for our company.

So with that, we look forward to talking about anything and everything that's going on at Merck.

QUESTIONS AND ANSWERS

Steve Scala - TD Cowen - Analyst

Great. So let's start with the pipeline. So Dean, you have six late-stage pipeline readouts in '26 and '27 and I'd like to ask you to rank them by clinical risk and let me just go through them for the sake of the audience, islatravir/lenacapavir, MK-3000, tulisokibart, sac-TMT, the Cidara antibody and I-DXd.

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

So I'm going to list them by what they mean to us as a pipeline. And so I would sit there and say sac-TMT and I-Dxd are very important. They are all based on really important in most cases, Phase II. But actually, in the case of sac-TMT, they're often based on Phase IIIs from China. So that is our pivot of KEYTRUDA and chemo going to next-gen chemo.

In terms of new molecular mechanisms of actions, I think the MK-3000, the first new MOA for diabetic macular edema, and neovascular AMD and clearly to the tulisokibart, where there is a possibility that this TL1A node could potentially become equivalent to the node of TNF and IL-23.

In relationship to sort of infectious disease, we're launching islatravir/doravirine, but the first time that someone could achieve a weekly treatment is a islatravir and lenacapavir. And I think that will increased -- we already have a lot of confidence in this pathway with islatravir, doravirine so is islatravir and lenacapavir. And clearly, MK-1406 in relationship to, in some sense, a pre-exposure prophylaxis for influenza. So I think all of them are important in different ways.

And so that's how I would sort of lay out the importance and relationship to our pipeline.

Steve Scala - TD Cowen - Analyst

Okay. Great. I should have mentioned at the outset, should anyone have a question anywhere along the line, please raise your hand, and we will call on you. Lots to dig in on those products alone. But maybe we could start with MK-3000, a very exciting drug.

What is the ideal target patient population for this asset? And what do you strive for in a clinical profile?

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

Yeah. So if one looks at diabetic macular edema and neovascular AMD, that field has been transformed over the last two decades by anti-vascular endothelial growth factor molecules. And they've all come in maybe 6 to 10 years after each other. So you have Lucentis, you have Eylea, then you have Vabysmo.

In every one of those situations, each one of them kind of took over the lead of the other ones using a non-inferior clinical trial. But all of them were based on vascular endothelial growth factor. This mechanism of MK-3000 is a totally different mechanism. It's based on Wnt agonism and so our hope is that we would do a clinical trial similar to the other ones that have been done.

But the critical point for us is it will be important for anyone with diabetic macular edema or anyone with neovascular AMD, but critically important is around -- up to 40% of individuals don't respond to anti-VEGF or anti-vascular endothelial growth factor. So we believe that that will be really important because it will be the first brand-new mechanism in decades for those diseases. And so that could be really exciting for the field.

Steve Scala - TD Cowen - Analyst

And are the patients enrolled in the BRUNELLO trial, are these patients who failed VEGF?

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

No. So we're going to treat the trial no differently in relationship to all of the other trials, which is you basically take all comers. But essentially, you already know in those all comers, maybe 30% to 40% of the patients won't respond to anti-VEGF. So, we will not be limited to those people who didn't respond. But in some sense, we will be enriched by the people who don't respond to anti-VEGF.

Steve Scala - TD Cowen - Analyst

I see. Very exciting asset. Also on the list is Islatravir. And we're intrigued by this ISLEND-1 and 2 trials. And curious, I guess, a risk with this modality could be that patients may forget a dose. So how is the trial designed? Is it patients who -- or do you exclude patients who have had trouble in trials with FAS or in the before, are you -- how are you gauging adherence?

And how are you enriching the trial to assure regulators that there will not be a dosing issue with this molecule?

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

Yeah. So these are people living with HIV. And the patients that we're doing are not patients who have virologic failures. So there's no enrichment. So this is going to be no different than any other sort of HIV study. What you've seen in our Phase II that this involves two important mechanisms, the nucleoside analog with translocation as well as the HIV capsid of our partner, Gilead.

And in that trial, what you saw is you saw greater than 90% adherence and greater than 90% efficacy and we will count clearly adherence through pill count, but we believe that this once-weekly option, which will be the only once-weekly oral option for treatment will be something very important for certain patients living with HIV.

Steve Scala - TD Cowen - Analyst

Okay. Maybe moving to another asset on the list, that being sac-TMT. What would be -- you point to as the strongest evidence that sac-TMT is better than the currently approved Trop ADCs, TROP2 ADCs in lung and breast cancer?

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

Yeah. So first of all, we have a TROP2 ADC that is different. We would look at the other ADCs, one could potentially say that in one of them, the linker is a little bit loose. So you see this hematologic sort of adverse effect. The other one is quite tight.

So you see the adverse effect of interstitial lung disease. So, we think this is a differentiated molecules. Not all ADCs are the same. Enhertu is not the same thing as Kadcyla. And we are advancing sac-TMT in a whole series of trials, 17 trials. I think 13 of them are first movers, four of them are differentiated. And so we're moving in endometrial gastric, if positive, we can be the first mover of TROP2.

You specifically asked me about lung and breast. I can tell you all the theoretical, but we have a great partner in Kelun, and they have already shown Phase III trials in China that suggest that in non-small cell lung cancer in those patients with PD-L1 greater than 1, that, that would be a really important molecule. They've also done it in EGFR mutant.

Again, that data is out there. And then the third place is HR positive, HER2 negative. And in each case of that, we have taken that lead and that information and formulated global trials that fit in the global setting based on those studies. And the data for those, I think many people have said they've been compelling in their differentiation in lung and in breast.

Michael Nedelcovych - TD Cowen - Analyst

If sac-TMT does turn out to be differentiated relative to other Trop-2 ADCs, do you think the linker might be the key reason from an MOA perspective? Or are there other elements of the molecule that are --

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

I would say, generally, the antibody is basically saying the payload is slightly different, but I do think it's all 3 combinations of the antibody, the linker and the payload. So I would say from a molecular standpoint, it could be more related to the linker.

But I also think the concept that we were driving this in so many indications and tissue types that the other didn't even go into. So then you're not differentiated. You're just going there because you think your molecule has the tolerability and the durability to stay in for those cancers.

Steve Scala - TD Cowen - Analyst

Questions from the audience? Moving to the Cidara assets. So can you just give us an update on the ANCHOR trial and your level of confidence that you are still on track to read out the trial in mid-2026?

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

So that trial did recruit extremely well in the Northern Hemisphere. We are definitely going to the Southern Hemisphere. We -- and I should just recount what this is, this is essentially an antiviral conjugated to a biologic backbone such that it has a long half-life and the concept is this would be a way to really reduce the chances of giving influenza, especially for those patients who are immunosuppressed, who have substantial comorbidities.

We want to make sure that we are recruiting in the Southern Hemisphere because we think that it's very important to have a strain agnostic preventative in that patient population. And I'll remind everyone that the flu vaccine does around 20% to 40% in us. But in patients who are immunosuppressed, it doesn't do that great. And in that patient population, the chances of something bad happening or a bad outcome is high.

So we think this is a really important medicine for the world, but I would also just state that I'm going to imagine that the rate of vaccination in this country for flu will not necessarily increase over the next three to four years. So I think this molecule could be really important. But Caroline, did you want to touch any of that?

Caroline Litchfield - Merck & Co Inc - Chief Financial Officer, Executive Vice President

So we're very excited about the promise that MK-1406 has. To Dean's point, we think this can be really impactful for people who have immunocompromised conditions or people over the age of 65. As we sized this opportunity, there's about 110 million people here in the United States.

85 million immunocompromised or with other comorbidities, a further 25 million who are over the age of 65. So what we're trying to do in our clinical program is really have a data set that will help see the impact that this protection could provide in helping stop getting the flu.

And so we're progressing with our study. We have expanded and in the process of expanding in the Southern Hemisphere and would expect to read out during the early part of 2027.

Steve Scala - TD Cowen - Analyst

Okay. A few products that aren't on that initial list though, which we discussed earlier, but are still very important, of course, first, the oral PCSK9. We had a cardiology panel yesterday here at the conference. Part of it was on lipids and the doctor believes that oral therapies are going to catalyze this market like we haven't seen in a long time.

And the Merck product was front and center, albeit there was good attention on your competitor as well. But in addition to having the oral therapy, guideline changes were very much a part of the doctor's view what's going to catalyze growth in those markets.

So how are you viewing that? And do you also think it's a catalyst? And also, can you include in the answer why you feel you can win in this market against what should be a pretty tough competitor?

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

So I would just say that I think many people don't realize that in 2013, in the American Heart Association, ACC guidelines, they took out any goal for LDL in 2013. I mean -- and in other places like Europe, they kept it. And that, I think, has done a disservice to the field and so over a decade, there hasn't been LDL levels.

I believe that the American Heart Association and ACC will change that. They will drive that guidelines after more than a decade, they'll have some level for LDL, but I also think, increasingly, they look at other fields such as ASCO or oncology.

I bet you they're going to not just lay a guideline but they're going to update their guidelines more effectively and more frequently. The reason why that became so important is that a competitor or a colleague or however you want to put it, Amgen with Repatha show the VESALIUS trial.

And essentially, if you had an LDL of 90 to 100, that's oftentimes your doctor says, well, that's kind of okay. If they could drive the LDL to 45, they got a 25% cardiovascular outcome benefit. So I think the AHA and ACC realize there's a lot of movement in that space. And I think that if you get the guidelines, then you can get quality metrics than the hospitals care because if you're a hospital administrator, you don't care if it ain't in the guidelines.

And I think it will catalyze the field. In relationship to our molecule, essentially, I talked about VESALIUS. In some sense, what we try to do, and I should just highlight Repatha, which is the basis of VESALIUS was an Amgen product that Roger Perlmutter developed. We essentially had in our mind that we were going to make a biologic, a Repatha in a pill.

So our molecule does exactly the interaction biochemically is exactly like Repatha. And the reason I say it is that the data that we've shown suggests that, but that makes it the most potent LDL cholesterol-lowering medicine that has ever been provided once it gets accepted.

I believe that with the guidelines potentially coming in at 70 with some patient populations with 55 and increasingly drive it, a standalone will not do it. You will need a stand and the next most important low LDL cholesterol-lowering molecule that you possibly can get. And that's what we hope to provide to patients and to people throughout the United States and the world.

Caroline Litchfield - Merck & Co Inc - Chief Financial Officer, Executive Vice President

And so what we have with enlicitide is very strong compelling clinical data. The United States have given us a commissioner national priority voucher. So we will be imminently filing enlicitide and an ordinary timeline would take us to a Q1 '27 launch. We're hopeful, subject to that review process that we'll be launching in the nearer term.

Steve Scala - TD Cowen - Analyst

Of course, approvals tend to reflect clinical trial design. And I imagine when this trial was designed 5, 6, 7, 8 years ago, the food dynamic was embedded in the trial design for whatever reason. But roll forward this number of years, it could be that maybe the fasting requirement is excessive, maybe it doesn't have to be that much.

Is Merck doing any work to look at exactly in the contemporary world, how long that food effect has to be? Could it be shortened? Are you doing work to shorten it?

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

So I would answer it two ways. The answer is yes. But I would just recount that I understand that you're referring to someone else's where I don't have their Phase III, but their Phase II clearly is less LDL-cholesterol lowering. So if you take ours properly and you take theirs properly, ours is substantially more reduction in LDL.

I don't know where their number is going to end up, but I suspect that even if you had a full English breakfast with ours than ours -- I still think it will be hard for people to be above ours. So ours, if you take it, you took it, you went to bed, you woke up, you took your medicine, you could have water, tea, coffee or like this for 30 minutes.

If you do this, you'll get the most potent LDL-cholesterol-lowering medicine. If you sneak in a piece of bacon or something like this or a donut in there, I still think that you will have effective LDL-cholesterol but you won't have it at the level of the most potent LDL cholesterol lowering.

Steve Scala - TD Cowen - Analyst

The question actually wasn't intended to infuse a competitor into -- it's more that your product could be -- it's a great product now, it could be even better if food restriction wasn't quite what it was. So is Merck doing studies to say, it doesn't have to be eight hours, it could be one?

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

15 minutes? Is it 20 minutes? Those sort of things. Yes.

Steve Scala - TD Cowen - Analyst

So you're doing that?

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

Yes. But I think the critical thing is we know that even if you did eat, where you would end up.

Caroline Litchfield - Merck & Co Inc - Chief Financial Officer, Executive Vice President

And knowing that this medicine, you will get up in the morning, you will take it with the other pills that you take. You can drink water, tea, coffee, you shouldn't eat for 30 minutes, and in our clinical program, 96%, 97% of the patients on the program were compliant without us having to tell them what to do, they were naturally compliant with doing so.

Steve Scala - TD Cowen - Analyst

Questions from the audience? You probably don't get a lot of BTK questions, but nemtabruta -- nemtabrutinib is a product that Merck seems to be maybe chatting about a little more about. Why is this an exciting molecule in a very competitive market?

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

It is a competitive market. I mean so this is CLL and -- there was a great drug that started the whole thing with Ibrutinib. But those are covalent inhibitors. And now the question is whether non-covalence can come in and go into first line. So we're really eager to see that but it's also we're talking about it not just because we're talking about nemtabrutinib.

We talked about diversifying oncology. We had KEYTRUDA and they were going to diversify, and we're going to use what we knew about KEYTRUDA to get into the ADCs that we've just talked about to get into precision targeted, such as WELIREG and KRAS. But the other sort of thing is KEYTRUDA didn't have that big impact in heme malignancy. And so we have a series of compounds. It's nemtabrutinib.

It's also our ROR-1 ADC. It's also our T cell engager, MK-1045 and then in the nonheme malignancies space, we have bomedemstat. So we're talking about nemta, but we're talking about four programs that will have readout in the next one, two, three years that is four products in the heme space.

Steve Scala - TD Cowen - Analyst

Okay. One more product or a pipeline-related question then we'll get some to some business questions. But V940, will we get to Phase III cutaneous squamous cell carcinoma data this year? And if so, what should be our expectation?

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

Yeah. So just to remind, this is the collaboration of the individualized neoantigen therapy, or some people say the cancer vaccine for melanoma. That is in Phase III. We have two other Phase IIIs in non-small cell lung cancer, and we have a series of Phase IIs just peaking out ready to go into Phase III, depending on what we see with the Phase IIIs that we have out.

And so the melanoma readout is based on a Phase II where you added the INT or the cancer vaccine on top of KEYTRUDA, and you saw an impressive reduction in disease relapse-free survival. The other important thing is over five years, that was a durable response.

So we're very eager to see what that Phase III is because not only it will -- if it's successful, will it be important for melanoma, but it will trigger even more investment in these other tumor types. In relationship to the PCD data, I think the PCD date is [2029] (corrected by company after the call), and there's always chances of having interim analysis that read out early.

Michael Nedelcovych - TD Cowen - Analyst

Okay. Can I ask about KRAS? You mentioned your KRAS inhibitor. Obviously, especially at the outset, an enormous amount of fanfare around the G12C inhibitors. I think it's fair to say that it's taking a little bit longer to see substantial impact on patients than perhaps had been hoped or at least implied by investor expectations. Where do you see the KRAS target going from here?

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

So I would tell you that KRAS G12C as a molecule and as a target is critically important in lung. And so this is an important lesson that we constantly learn, which is if you want to go in lung, and you can't move first line with a PD-1, you will not have an impact. The impact of KEYTRUDA or other PD-1s in lung is so profound that you have to be added to that.

And the first-generation molecules could not do that. I don't think it will take time for those molecules. If you cannot combine with a PD-1 effectively and be at par of KEYNOTE-189 and better, I think it won't take on. Our 1084, we are enthusiastic. We're moving it in lung because we believe that it can -- here's a pill, you give subcu pembro, early, late, right?

That's something that could be really important, both in the early stage, but in the first line. The same thing is true if you want to move it in CRC. If you're going to move it in colorectal cancer, it's fine to have a signal in second line, third line. But if you cannot combine it within EGFR or cetuximab, you will not have the full impact. So there was a lot of excitement because you got a signal .

But in order to move these things, you need to be able to put it in first line, and you have to have a clear understanding of what it needs to combine with because if it does not combine, you will knock it in first line. If you do not get into first line, you will not have that impact.

Steve Scala - TD Cowen - Analyst

Maybe going to a product that's just rolling out now and that's KEYTRUDA subcu or QLEX. So how -- what can -- other than sales, what metrics can investors monitor to see how you're progressing against that goal of 30% to 40% penetration of the KEYTRUDA molecule in a few years?

Caroline Litchfield - Merck & Co Inc - Chief Financial Officer, Executive Vice President

Yeah. So we're really excited about QLEX, our subcutaneous formulation of pembrolizumab and the benefits it can provide patients as Dean just demonstrated in just a very short duration shot, you have been given your treatment for cancer. So what we have with this is a sales level of around \$35 million in the fourth quarter of 2025.

We expect sales to grow modestly in the first quarter this year before we'll see the permanent J code that we expect at the beginning of April. What we're hearing from both the health care providers as well as patients is in line with our expectations. That is, this is a tremendous innovation.

It's an innovation that they need to work through their own operating processes and systems to ensure that it has the relevant formulary decisions. It's also on the electronic health record so that it can be utilized. But we're seeing early utilization already in predominantly patients who are on KEYTRUDA monotherapy or KEYTRUDA in combination with another oral agent. So that's the majority of the current use.

We are, however, also seeing use with IV chemotherapy. And that's largely in the early cancer setting. So the indications we're having thus far is the importance of this innovation the importance, especially when the patients are monotherapy or in combination with an oral agent and the importance in the early-stage cancer setting.

So we expect still and have confidence in the 30% to 40% penetration of our overall KEYTRUDA business with adoption here for that patient group. And we will continue to provide insights to our investors as we see this unfold over the coming months and quarters.

Steve Scala - TD Cowen - Analyst

GARDASIL, should we expect any major change in trends in 2026?

Caroline Litchfield - Merck & Co Inc - Chief Financial Officer, Executive Vice President

So we are very proud of the impact GARDASIL is having for the world in helping prevent HPV-related cancers. What we have stated for 2026 is we expect revenues to be roughly stable compared with where we were in 2025. And that's as we continue to really advance the vaccine, especially in the mid adult segment.

While we do see in the adolescent segment, some maturation of where we've had penetration in the U.S. and outside of the U.S. So we see this as an important product for the world, an important contributor to Merck's revenue but not a driver of growth.

Steve Scala - TD Cowen - Analyst

And we're down to only a few seconds left in the panel. So let me close by asking you each a question, same question, and that is, what do you anticipate will be the biggest change or surprise at Merck in the next decade? Maybe not a surprise to you, but it's a surprise to us.

Caroline Litchfield - Merck & Co Inc - Chief Financial Officer, Executive Vice President

So maybe where we started, our company really is transforming. And I think what you'll see in this next decade is our company transforming from a position where KEYTRUDA, GARDASIL, and Animal Health were the dominant parts of our business to instead be a company that has a diverse set of products, products that are either first-in-class, they're best-in-class or we've innovated around them to bring the next innovation in those therapeutic areas.

And as a result, we'll have made a difference in this world, we'll have driven strong growth for our company and returns for our shareholders.

Steve Scala - TD Cowen - Analyst

And in Merck Research Labs?

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

To deliver on that promise.

Steve Scala - TD Cowen - Analyst

Okay. That's a tall order. Well, thank you so much. This has been a very interesting conversation.

Caroline Litchfield - Merck & Co Inc - Chief Financial Officer, Executive Vice President

Thank you so much, Steve.

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