REFINITIV STREETEVENTS

EDITED TRANSCRIPT

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

EVENT DATE/TIME: NOVEMBER 20, 2025 / 2:30PM GMT

OVERVIEW:

Company Summary

REFINITIV

CORPORATE PARTICIPANTS

Peter Dannenbaum *Merck & Co Inc - Senior Vice President - Investor Relations*

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

Marjorie Green *Merck & Co Inc - Senior Vice President, Head of Oncology Clinical Development*

CONFERENCE CALL PARTICIPANTS

Akash Tewari *Jefferies LLC - Analyst*

PRESENTATION

Akash Tewari - *Jefferies LLC - Analyst*

Last day. This has been a great conference. I can't tell you how grateful I am for everyone for joining. My name's Akash Tewari. I'm a pharma and biotech analyst here at Jefferies. We have Merck, also goes by the alias MSD when they're not on that side of the Atlantic.

Peter, why don't I hand it off to you for some intro remarks and we'll get started.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President - Investor Relations*

Thank you all for being here. Appreciate your time and your interest. Akash, thanks for hosting us. With me is Chirfi Guindo, our Chief Marketing Officer; and Marjorie Green, who leads clinical development for oncology.

QUESTIONS AND ANSWERS

Akash Tewari - *Jefferies LLC - Analyst*

Understood. So I'll start off with, I think obviously, your team's been very active on the BD front recently, and there was another major acquisition that your team consummated in Cidara. And this is kind of a theme that we're starting to see emerge of how do you build a vaccine business but kind of almost make it vaccine adjacent, right? Talk to me about what you saw in Cidara and why the flu market really needed a long-acting antiviral to maybe build that market out.

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

Yes. No, thank you for the question, and thank you all for giving us the opportunity to tell the story of our fantastic company. For those of you who just -- if you haven't been paying attention, we had a phenomenal week. And Cidara was just one of a number of milestones announced just this past week.

We announced the good news on HIV, right, in the naive population with islatravir/doravirine, basically Phase 3, so really, really exciting. We announced the WINREVAIR CADENCE Phase 2 readout, also very, very exciting. KEYTRUDA sub-Q approved in Europe yesterday. So a lot happening in our company. And Cidara, indeed, represents a significant opportunity, first and foremost, for the protection of many, many people around the world who have high risk of complications from influenza infection or who are immunocompromised.

So I'll talk a little bit about the rationale for Cidara and how we see value creation with this particular acquisition. So traditional vaccines have limited efficacy in certain populations. If you're immunocompromised, obviously, you're going to continue to have risks. If you have COPD, HIV -- if you have had an event, atherosclerotic, cardiovascular disease patients, and the list goes on and on, these are all populations who are at high risk.

As we look at the opportunity, we've looked at the US just as an example, there are about 110 million people who really could benefit from this long-acting antiviral, which by the way, really, I should say this, is really strain agnostic. So you take it once at the beginning of the season, and you get protection through the whole season. And so whether you've been vaccinated before or you've not been vaccinated, you can benefit from this long-acting antiviral.

What we've seen in the Phase 2 data is 76% efficacy in protecting against influenza infection, independent of the strain of the influenza infection. So from 110 million people in the United States, 85 million of them are people with underlying disease, right? So immunocompromised, cancer survivors, HIV patients, COPD patients, and so on and so forth. And 25 million are people who are 65 or older without comorbid conditions who also really could get additional protection from this long-acting antiviral. So we believe that by bringing this to market, we have the opportunity to really help many, many patients.

Clinical benefit is clear, as I described, but there's also a huge economic benefit. In the last season, as an example, there were up to 1.6 million hospitalizations due to influenza in the United States alone. So obviously last year was a really tough one, a big one, but this season is also proving to be very challenging. There are new strains that are being talked about here in the UK, in Canada, in Japan. And so we see this as a real opportunity to protect millions of people around the world and to really create value for our company and for our shareholders.

Akash Tewari - *Jefferies LLC - Analyst*

Understood. Your answer also, I think, when it comes to infectious disease, a lot about product uptake is also about patient education, but also kind of getting the governments behind recognizing the value of certain products. I think we certainly saw that with COVID-19. But even if you think about the long-term story on GARDASIL.

We're in a different FDA. And I think there has been an increase in vaccine hesitancy, not just say what you will about the FDA, but really at the ground level. Americans are more hesitant to use vaccines in a way that we haven't seen historically. As you think about a long-acting antiviral like Cidara's drug and think about the importance maybe to the US government and nationally, do you feel like there might be alignment with how, let's say, the FDA and the Trump administration values that product and how Merck does?

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

So we believe that there is going to be alignment. In fact, the FDA has asked Cidara to expand the patient population for the Phase 3 program to include 65-year-olds and above who do not have comorbid conditions. It just goes to show the level of interest that exists within the FDA and the US government more generally.

We believe that CD388, which is the asset that we're talking about, will be really attractive also in terms of government policy, public health policy, and pandemic prevention in the US, but also in Europe, importantly. So BARDA might be interested in this as a strategy for prevention of future pandemics. I think this is aligned with government strategy.

Akash Tewari - *Jefferies LLC - Analyst*

So just two quick points on that. A, sometimes we'll see you have to put out an initial efficacy data set to kind of prove that the product works. But then you start to get, certainly with vaccines, expedited routes to market after that. Is that a framework we could potentially think about for a long-acting antiviral like Cidara, where let's say you have the new strains and you can show that this is completely neutralizing them?

Is that type of pragmatism potentially applied to your product with the FDA. And then number two, as we think about the national priority review voucher, a pathway that's now suddenly available, is this product potentially something that Merck could pursue?

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

So we will pursue all options. What I can tell you, really, is there's a high level of interest. The fact that this is strain agnostic makes it uniquely important in terms of public health. And we will continue to engage both with the FDA and the administration more broadly to make this available as early as we can. So we're in Phase 3. Whether you're vaccinated or not vaccinated, you're going to be a candidate for Phase 3 enrollment, and for the high-risk populations that I'm talking about, just to be clear. We are looking forward to generating the data that will really motivate public health to adopt this prevention.

Akash Tewari - *Jefferies LLC - Analyst*

Understood. Now maybe hitting on WINREVAIR, and you had mentioned the CADENCE that had come out. You have to give credit to your team. If I look at the report card of the Acceleron acquisition, if we knew ZENITH would hit, HYPERION would hit, CADENCE would hit, the drug would launch well. You think about the value that Acceleron would be at right now.

A couple things. Number one, now that you have HYPERION, ZENITH, really data to support the use of sotatercept broadly in PAH, should we expect a corresponding increase in patient starts in 2026? And then number two, the CADENCE data came out. I think the issue for a lot of investors, and we're struggling as well, is it doesn't seem to be a clear relationship between PvO2 and the endpoints we've traditionally seen in this population, like six-minute walk. Why should we feel confident that this drug will gain regulatory approval ultimately in Phase 3?

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

So the first point is we're really pleased with the uptake so far in the launch of WINREVAIR in PAH. It has been transformative. I mean, PAH is a really terrible disease, a disease of young women. Most of the patients are women in their 30s and 40s. And the survival rate at five years is less than 50%. So it's a really, really terrible disease. And before these patients die, unfortunately, they have a terrible quality of life.

And what we've seen in the clinical program, but also in the real world since the launch, is really, really the benefit that WINREVAIR brings to these patients and to the community. And you're right in saying that all of the studies have been positive. We have a world of data now around WINREVAIR, right? And so in the advanced patients on triple, but also with HYPERION, we now have data, convincing data, in the dual therapy-treated patients, which really is giving confidence to the community to begin to adopt WINREVAIR to a broader base of patients, right?

So far, most of the prescriptions are still in the more advanced triple therapy-treated patients, but we're beginning to see uptake moving to earlier stages and more of the dual-therapy patients. So that's what I will say. We have about 500 or so patients that are initiated every month on an ongoing basis in the United States. We're beginning to see uptake in Japan, in Germany, in France, and other parts of the world. So we are really bullish about the PAH opportunity going forward.

As far as CADENCE, this is a different patient population. This is Group 2 PAH. In fact, it's a subset of Group 2 PAH, the CpcPH. You could think about that as a rare disease also with a similar size to PAH, roughly 40,000 to 50,000 patients in the United States, similar to the PAH population. But the diagnosis rate is very low in this case. So the Phase 2 data is very promising. You saw the press release. The level of excitement is high because there's no treatment for these patients with CpcPH.

Now we're getting into Phase 3. We're really excited about the opportunity to advance the program. We believe we do have to do a Phase 3 program. Our team is working with the FDA to define the parameters of the Phase 3 and the endpoints, whether it's functional endpoints, or to your question, all of that will be determined in the coming periods. So stay tuned for the Phase 2 presentation that will be delivered early in the new year. And then for the Phase 3, we'll keep you updated as well. But it's really exciting and hope for those patients who really have no options to speak of as of today.

Akash Tewari - *Jefferies LLC - Analyst*

Yes, that's a good point. So maybe just jumping to a couple other products that your team is consistently pointing out, ex-oncology is important to you. Talk to me a bit about EyeBio, that deal. You have a tri-specific, a new mechanism of action in a quite mature market. And I think a lot of investors say, well, there's going to be biosimilar Eylea. There's biosimilar Lucentis. ASPs have been just in secular decline. Why is Merck interested in this opportunity? What makes your asset different in what's becoming a pretty mature marketplace?

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

So this is another exciting part of our portfolio that we believe is under-appreciated, frankly. The acquisition of EyeBio is really motivated by the great science, unmet medical need, and value opportunity. And why do we think there's unmet medical need? Because the anti-VEGFs that have now been adopted broadly have done a really, really nice job in helping many, many patients. You're talking millions of patients.

Again, for context, in the United States, there are about 1.5 million people who live with diabetic macular edema and a similar number who live with neovascular or wet AMD. So these are big numbers of patients. 40% of these patients who are treated continue to have issues. They're either not responding, or they do not respond adequately to the anti-VEGFs. So there's an unmet medical need, and there's a need for a new MOA. And that is what the EyeBio portfolio brings us, right?

So you have the Wnt pathway, which is the MK-3000, right? And then you have the bispecific of Tie2 and VEGF, which we have with our Tiespectus assets. So two assets that we have acquired as part of the EyeBio acquisition that are responding to an unmet medical need in this patient population. So it's a large pool of patients who are treated, but 40% of them are not treated adequately. So this is the opportunity, right?

And so as we come to market, we believe that we're going to create value. We're going to have rapid adoption in this patient population. And so -- and the data so far is really, really encouraging. The program is advancing, in fact, accelerating, which is always an indication. When you have acceleration of clinical trial enrollment, it is an early indicator of adoption at a later stage.

And so next year, look out for the Phase 3 readout for DME for MK-3000. So that's going to happen next year. Last October, we presented data on Tiespectus, which is really, really encouraging. It's early Phase 1b data presented at the Orlando meeting, the American Academy of Ophthalmology. But all this to say that we are really looking forward to bringing these two drugs to market to augment, right, the anti-VEGFs and to provide additional value for patients. And this is a multi-billion-dollar opportunity, by the way. So stay tuned on that.

Akash Tewari - *Jefferies LLC - Analyst*

Oral PCSK9, really robust data. I mean, you're getting biologic-like efficacy. I think there's two questions. A, food effect, is this going to be problematic? But I think there's another one, too, which is Dean's mention for outcomes. You're designing a study, and you're going to be patient. You're looking for greater than 20% risk reduction. That seems to be important.

But that also means that you're going to have to wait several years for outcomes to read out. You can't have your cake and eat it, too. It kind of brings an interesting question, which is, without outcomes data, maybe for a bit, how is Merck thinking about access and uptake here to allow this drug to be commercially viable without the outcomes data out of the gate? How are you thinking about that challenge?

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

Yes, so I mean, we are really excited about enlicitide. This is really our, I would say, chemistry masterpiece, if I can put it this way. And the reason why I say this is our chemists have been working for a number of years to try to deliver a biologic in a pill. And they have succeeded in doing that. It's really -- I invite you to read up on the story and the molecule of enlicitide itself. When it was presented a few weeks ago at the American Heart Association Conference, it blew the field away because it's able to deliver the potency and the efficacy of the antibodies.

So just to summarize it a little bit, you get 60%, approximately 60% reduction in LDL cholesterol on top of the statin. You get 50% reduction in non-HDL cholesterol, 50% reduction in apoB, and 30% reduction in Lp(a), right? And so that is what you get in this one simple tablet that you take in the morning, 30 minutes before your breakfast right? So the so-called food effect really was not an issue in the clinical trial program. In fact, 97% or more of the patients had no problems following the regimen of the morning intake 30 minutes before meals.

So we look forward to bringing it to market. We have a large -- we have experience in the space. The data is celebrated. We look forward to guidelines now being updated in the US. So experts are now talking about needing to update those guidelines in the context of the VESALIUS data that was presented from Amgen, again, excellent data.

And our data, there's now reason for them to begin to think about updating those guidelines, so we can have those conversations with payers. We do intend to think about broad access, right? So our strategy is going to be price to value and price to access for enlicitide, very important. We think Dean has used the concept of democratizing access to PCSK9, and that is very much what we're going to be doing.

And we believe there will be uptake prior to the CV outcome data that you referenced because of the mechanistic way in which enlicitide works. It really works similar to the antibodies and very different than the traditional small molecules, right? And so we believe that there is going to be recognition for that in the guidelines, which will then help us with the payers. Obviously, the pricing strategy will also help with early adoption.

Akash Tewari - *Jefferies LLC - Analyst*

Right. Understood. Marjorie, maybe turning to you. We had lunch early. You described sac-TMT in a way that I think is -- I've not heard an ADC describe before. You think of Enhertu and you say, okay, if you have breast cancer -- and clearly, even if it's HER2 low or nonexistent, apparently, there's a clinical effect.

But there's a segment of people who take Enhertu. If you take PADCEV, your urologists are likely looking at that. You described sac-TMT as a drug that might be useful for community oncologists. Can you talk about what that means? Because I don't think we've thought about ADCs with that framework before.

Marjorie Green - *Merck & Co Inc - Senior Vice President, Head of Oncology Clinical Development*

Thanks for the question. Ultimately, what we hope to see with sac-TMT is efficacy across multiple diseases. And we have a great partnership with Kelun. A lot of data has been generated in China, some of which you all have seen at ESMO recently in hormone receptor-positive breast cancer, EGFR-mutated non-small cell lung cancer. There have been other Phase 2 data sets, and there's more that haven't been publicly presented. And that led to our 15 registration studies that are currently ongoing across multiple tumor types, including gynecologic tumors, lung cancer, breast cancer, and many more.

And so thinking about drugs, ultimately, we want a drug that is highly active and really does change the standard, and not only for the academic oncologist out there. But also thinking about in the United States, 80% of oncology care is given in the community. And often, these are physicians who see people who have multiple different tumor types.

There are some practices where people are sub-specialized. I'm a breast oncologist by training, and all I saw was breast cancer patients in the academic world. And so a person can see a patient with lung cancer. They could see a person who has endometrial cancer. They could see someone who has gastric cancer.

And by having a drug with potent efficacy and what we hope we will see in the global Phase 3 studies is really good tolerability, that ability to keep people on drugs, it becomes the choice then. I have someone who has non-small cell lung cancer, and I want to give a TROP2 ADC and KEYTRUDA. Well, okay, there's data with sac-TMT. My next patient has endometrial cancer. I have sac-TMT.

And so it's the workhorse ADC because it's got -- we think, again, I've described this for those who know the Goldilocks and the Three Bears kind of analogy. It's just right. It's really potent, but that tolerability comes out. ADCs are not identical at all. And that's where I think this really is for the community oncologist, something that we would be able to provide great value through the clinical efficacy and the broad utility across multiple indications.

Akash Tewari - *Jefferies LLC - Analyst*

Understood. And you talk a lot about tolerability. But one of the things that we saw certainly at ESMO, you have similar response rates to some of the early TROP2 ADCs when you had your Phase 1/2 data. And I think that's what I think a lot of the field saw. What we're starting to see is that on overall survival, there seems to be a very different shape curve than when I look at TRODELVY or I look at DATROWAY.

So talk to me about how tolerability plays a role into overall survival and what I would say is also when you think about -- 15 Phase 3 trials, that's a lot of investment. What do you want to see on OS for this to be needle moving and kind of the workhorse product for Merck in the way that KEYTRUDA is?

Marjorie Green - *Merck & Co Inc - Senior Vice President, Head of Oncology Clinical Development*

Multiple sort of aspects of that question. So again, we need to see what the global data looks like. I think that the Phase 3 studies that Kelun has done have been really impressive, and you're seeing consistent data across multiple different kind of diseases with sac-TMT and the Phase 3 data that Kelun has generated.

The survival is interesting. I think we have all gotten a little spoiled in oncology with the checkpoint inhibitors. And I think I don't want to discount that PFS is still an important endpoint in oncology. So it's clinically meaningful because patients don't always, or people with cancer don't always make it to the next therapy.

And if it's a large enough number and they can't get to subsequent therapy, then you start seeing overall survival. So there are different aspects that go into overall survival. Can people make it to their next therapy? Can people stay on therapy a long period of time like you see in the progression-free survival? And that's where I think the ability to stay on therapy becomes a part of the equation.

Cancer is smart. It develops resistance to therapies, and unfortunately for people that many of their cancers will develop resistance and progress, but it's that long-term ability to have disease control that we think can impact the overall survival. Every disease indication and segment is a little different about what kind of survival advantage is clinically meaningful. I still believe that progression-free survival is a clinically meaningful endpoint, and so I'm very excited about the upcoming Phase 3 readouts.

Akash Tewari - *Jefferies LLC - Analyst*

Okay, understood. Now maybe towards the end here, let's touch a bit on HIV. And again, another product your team talks about, Street maybe not be paying enough attention to. And I think even when we do talk about it, it's about PrEP, right? It's about the monthly PrEP. And I want you to talk about, A, the importance of a two-drug regimen that could compete against Biktarvy in the antiviral side. And what do you think about that product opportunity? And then separately, what do you think about the impact of a monthly PrEP option as well?

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

Yes. Thank you for the question. So we announced this week, as I mentioned earlier, the naïve data for islatravir/doravirine. This is our daily two-drug regimen that basically is indistinguishable or non-inferior to Biktarvy in terms of efficacy. So this one will be -- the PDUFA on this one is going to be April next year. Next year, we also have two important treatment readouts in Phase 3, and that is a weekly oral, islatravir with lenacapavir, and so just to paint the picture a little bit. And the PrEP one will come later in 2027 in terms of readout.

So coming back to the treatment, daily treatment, why is there a need for a two-drug regimen that does not contain integrase inhibitor? For a number of years, the field has been looking for options, a new anchor treatment, right? Integrase inhibitor is the current anchor treatment. And Biktarvy is the standard of care. No question about that.

Now as you get older on your treatment, physicians are looking for options to save or to preserve, if you want, the integrase inhibitor. For the first time, we have data now that suggests that with islatravir as anchor, you can have the same efficacy as Biktarvy. And potentially, you can avoid some of the liabilities of integrase inhibition over time, cardiometabolic toxicity over time.

And so this is really appealing part of this two-drug regimen. You get less drug and you have the cardiometabolic issues that you don't have to worry about as the patients get older on their treatment. So that is really the compelling case with the two-drug regimen.

Akash Tewari - *Jefferies LLC - Analyst*

Can you maybe just define what of the antiviral opportunity would be those patients who really want to try a non-integrase option?

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

What is the -- sorry?

Akash Tewari - *Jefferies LLC - Analyst*

As in the market you're alluding to for people who would explore that new option, how big of that -- what subset of that is of the antivirals as a whole?

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

So as we talk to clinicians -- again, we've done a lot of market research on this. We ask them this question, so which patients are you going to be prioritizing for this regimen? I mean, if you think about diabetic patients, think about patients with obesity and other cardiometabolic issues, maybe some patients with renal issues. So those are the types of patients that are most likely to be prioritized for this type of regimen. And that is the insight that we're getting from clinicians.

Akash Tewari - *Jefferies LLC - Analyst*

It's very helpful. And then maybe also for the monthly PrEP?

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

Yes, for the monthly PrEP, so this one is going to be also really important for the field. Because I have to say, first of all, that the injectables have been really, really impressive in terms of protecting people against HIV infection, whether you're talking about the twice-yearly injection, once-yearly injection soon, or even every three to four months injection. So those are all very effective drugs at preventing HIV infection.

But what we hear from people who are at risk is that they do prefer to have a long-acting oral option. About a third of the people that we've surveyed tell us that if there's a long-acting oral option, especially a monthly oral option, they would prefer that to having to go to the doctor, get an injection.

And with the oral option, you can get it in the privacy of your home. You get it sent to you. You don't have to go see the doctor. And you get effective protection with a single pill that you take. And it starts working within 30 minutes. And then you get protection for the whole month,

right? So that is the compelling case for our PrEP option. We look forward to bringing that one also to market. Collectively, you're talking about a multi-billion dollar opportunity for HIV, which we think has been underappreciated.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President - Investor Relations*

And just for perfect clarity, the PDUFA date in April is for the islatravir/doravirine switch.

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

The daily, yes.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President - Investor Relations*

Yes. What we read out this week, top line, was the treatment naive. But it's for the same regimen, just in a different setting.

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

Yes. Thanks for the clarification.

Akash Tewari - *Jefferies LLC - Analyst*

We're going to call it here. There's a lot more that's worth talking about. And I do encourage investors to really dig into their pipeline. So appreciate your time. Thank you so much.

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

Thank you so much.

Marjorie Green - *Merck & Co Inc - Senior Vice President, Head of Oncology Clinical Development*

Thank you. Thank you all.
