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PRESENTATION

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. Good afternoon, and welcome to Day 2 of the Barclays Global Healthcare Conference. My name is Carter Gould, senior biopharma analyst here at Barclays, and I'm pleased to welcome Merck to the stage.

Merck has been one of our top-ranked names for a bit here and certainly came -- coming off a pretty stellar 2022, followed that up with a solid start to 2023 with PAH data, which we're going to touch on.

Joining us from the company, President of Merck Human Health, Jannie Oosthuizen, as well as Peter Dannenbaum from the IR team. Peter, Jannie, thank you very much for joining us today.

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Well, thank you for having us.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

So we can hop into Q&A unless you wanted to make any opening comments.

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

No, I was actually going to say, Merck is coming off a great '22, but you said that. And we had a really exciting start with some of the data releases and our KEYNOTE-091 launch, but I'm sure that's material for a good discussion now. So looking forward to talk to you.

QUESTIONS AND ANSWERS

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Right. So we just spent time, I think about 10 days ago now. Maybe not even. Yes, I think around 10 days since we were in New Orleans there on the back of the sotatercept Phase III data. And I guess the -- I'll open it up with a relatively broad question, which is, when we think about sotatercept's potential integration into the treatment paradigm in PAH, how do you see that playing out on the back of this initial data?



Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes. As you said, it's really been a very, very strong data set. We were able to (inaudible) the conclusion of the STELLAR trial. We believe that, based on the data, that sotatercept will change the way that PAH is treated. Our aspiration is that sotatercept will become a foundational treatment in PAH.

So as we know, this is a very specialized treatment community. [PAH experts] are mostly pulmonologists and cardiologists with a keen interest in this disease treating most of these patients in highly specialized treatment centers. There's about 150 of these throughout the country.

And I think the feedback we're hearing is really positive in terms of the scientific leaders but increasingly the broader treatment community. So we think we're going to see really strong uptake of sotatercept as a treatment in the space as we move forward.

There's more to learn over the next few weeks in terms of just how it physicians are thinking in terms of where to use it. There's this population in STELLAR that is very similar to what you find out in the market. These patients have been diagnosed for 8 to 9 years in the trial. They've been maybe 40% on the doublet, 60% on triple therapy, so highly treated patients. And so we think it's going to be very much an applicable data set as physicians think of the existing patients that set out in the market.

But I think it's going to be interesting to see how they think about how soon to introduce sotatercept with -- for these patients.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

And when we think about like what part of that population is going to be dynamic versus a patient who maybe is a little bit closer to stable, do PAH docs think about it like that? Or is it just going to be, "Hey, this is a new foundational treatment and you're clearly seeing gains, so you should adopt it?"

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes. And I think -- so STELLAR is obviously 1 data set. We've got another trial, HYPERION, I think, that is really answering the question, how soon after diagnosis should you introduce sotatercept? We've heard some physicians saying that as soon as the patient is stable on doublet vasodilators, they will think of introducing sotatercept. But I think the trial is really going to help us to figure that out. And then obviously, the STELLAR population is continuing in that area, so there's also going to be an opportunity to continue to see how they do.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. So while the hazard ratio was outstanding, there was a bleeding risk associated with the drug. Let's -- first, I guess, maybe let's start off at a high level. Can you talk about the bleeding risk and how you think that may or may not impact commercial adoption?

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

So epistaxis the bleeding that we saw in the trial were mostly gum and nosebleeds. And they were mild. There were no discontinuations as a result of that. And I think the additional good news is that none of that were gastrointestinal or intracranial bleeds. So it was mild, it was manageable and didn't lead to any discontinuation.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. On that point, I just -- so there were no GI bleeds?



Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

No GI bleeds.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. And when you think about just the uncertainty that maybe comes to mind in these docs, is that going to -- just the uncertainty around bleeds, is that going to have an impact in any way, you think?

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes. I think in general, in PAH, side effects is something that physicians think about a lot in terms of the currently available treatments. I think when there's known side effects like this, everybody is going to be thinking about it. But I think the efficacy signal was so strong that we believe the benefit/risk profile is really strong in favor of sotatercept.

And then as I said, with SOTERIA, we're going to be able to continue to monitor. There's been some other side effects that will receive the same attention, so nobody is dismissing it. But I think to date, we feel really good about the benefit/risk profile and the fact that we have opportunity to continue to monitor how this is continuing to play out.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. And when we think about the go-to-market strategy here, is this going to require additional sales force above and beyond kind of what's already being used for your existing [for riociguat] or the Adempas?

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes. So we obviously have a legacy cardiovascular with some current heart failure products in the market in the U.S. But this is a slightly different treatment population. It's really focused on PAH. As I said, it's a fairly tight, small community. Most patients are sitting in these 150 centers in the U.S. So -- and our commitment is to really stand up a world-class rare disease operating model that can cater for this treatment community and the stakeholders involved in PAH. So that's in the U.S.

So it's going to be, I think, a very efficient sales force that we will put out, and we're going to highly augment it with some of our digital capabilities in terms of reaching this community also through different channels, and leveraging just how connected this community is in terms of scientifically, this understanding of the data, of getting interest in this area and every development that happens today.

If you want outside the U.S., we have an Adempas footprint, the product in collaboration with Bayer, that we can leverage. In Europe, there's about 115 of these centers, so again, fairly concentrated, 45 of them in Germany and about 20 to 25 in France. So we think we can have a significant pace of reach through these highly concentrated engagement.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. Maybe one last point on sotatercept, and that is, I think it's lost on some people that you do have CADENCE data not too far in the horizon. And what success in left heart disease might do for an asset like sotatercept? And just what that might mean commercially?



Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes, that's right. I mean, as we look at this exciting data in pulmonary arterial hypertension, so if you look to the right heart, the question is when you look at the unloading that sotatercept bring on the right heart, we see it through reduction in pro -- NT-proBNP, what could that mean for pulmonary hypertension associated with left heart disease?

And that's an area where there's really nothing for these patients today. So a huge unmet need. Even diagnosis is low. So we believe this could be a meaningful opportunity where we can make a significant difference for these patients, but really add a significant opportunity to sotatercept overall.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

And just thinking about patient numbers, can you help give us some context, left heart...

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes. I mean, right now, the [epi] is really low because there's really nothing, there's very poor diagnosis, but we know this exists. So this is work, as CADENCE lays out, that we will continue to do to really inform ourselves how big this could be.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay, perfect. Let's go to the other kind of darling of ACC, and that was the PCSK9 data. Merck has kind of framed this really about democratizing PCSK9 access with an oral. What gives you, I guess, confidence that this is really an oral/access issue, and not a larger issue of just patient inertia around a generally asymptomatic disease?

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

So I think starting with the last one. We know that there's really broad, high-volume statin use already for a lot of these patients, right? So even though it's asymptomatic, there is a sense of urgency to treat, and a lot of patients are attempting to get their LDL cholesterol to a reasonable target. But we know it's really difficult to get these patients to target, right?

So if you start with just the unmet need, we know about 85% of cardiovascular disease results from ASCVD, so that is out there. Despite that, only 5% of patients today -- or let me rather start, with only 70% -- or only 70% of patients are [not] managed to goal, right? So we know that with statins, it's really difficult to get patients to the right dose, to keep them on the right dose, and really bring those lipid levels down. So today, only [less than] 5% of [ASCVD] patients are accessing an injectable PCSK9.(added by company after the call)

So when you look at all this, there's no doubt a significant opportunity, significant unmet need. We know part of the issue with the injectable PCSK9 is clearly the payer restrictions due to where they started from a pricing perspective, how it's being managed. But it's also the setting where patients need to access this.

So if we bring that into the offering solution in a tablet where we can really look at a price point and looking at innovative payer agreements where we can open access from a payer perspective, that makes us available in a primary care setting, where patients can get is from their primary care physician, we believe that we can make a very meaningful difference and really broaden access, not just in the U.S., but also outside of the U.S.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Do you think you can see that meaningful adoption even ahead of formal CVOT data?



Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes. I mean, CVOT data will open this up, we will pursue that, as you know. But we believe there's a meaningful opportunity. I mean, if you just look at the [CVD] prevention market, [40 million] patients around the world where there is a higher sense of urgency. We think there will also be a reference to some of the existing outcome data that could help. So we think we can pursue a meaningful opportunity.

We obviously need to open up payer access, that we just talked about. So we will pursue innovative ways of creating that. That will help with guideline updates. That will help with policy shifts. So I think it's really creating all these positive aspects, including ultimately outcomes that will further expand access, especially in some of the more restricted [markets].

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. I think the #1 negative pushback to PCSK9 data was the [fasting], and to what extent you think that's going to limit adoption. I guess the 8-hour fasting ahead of time, I guess, [acceptable]. I was of the view it probably didn't make -- wouldn't probably going to be that big of a hindrance if people are taking it right in the morning. But maybe there's some nuance I'm missing and you think about it, how it's going to impact the commercial adoption.

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes, that's right. I think a lot of patients that take their chronic medication is used to taking in the morning. That would probably be the right thing to advise patients off. And then at a 30-minute wait before food intake, which is very similar to what the statins have to do today. So we don't see that as a barrier. I think it's very easy for patients to incorporate that approach into their daily life.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. And then maybe just to wrap up on the CV portfolio. Now you've got good momentum on the back of sotatercept and PCSK9. Can you maybe help -- you have some other additional assets beyond that, but just that momentum and kind of getting those foundational kind of linchpin to the franchise. What that -- how that sets you up for the broader franchise and drives synergies across the entire CV org.

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes. I mean, from a CV perspective, we have some others. We also have inhaled sGC right, that will come into PAH. So certainly, we will continue to build in this space. But I also think we will continue to be, in a way, agnostic to therapeutic area. I think Merck's approach has always been to pursue the best science, really look at unmet patient need.

Clearly, we wanted to have a fit with some of our internal capabilities because that makes us the advantage owner of everything that we bring in, and we can really develop for a differentiated patient impact ultimately that really drives the long-term value.

And we've done some of that recently. You've seen the collaboration with Kelun on some of the ADCs, the recent agreement with Moderna on the personalized cancer vaccine. So we see this in terms of the areas that we will continue to pursue.

But no doubt, these internal capabilities, coupled with the scientific developments that happens outside of Merck's walls, is something that we see as beneficial in how we approach this all.



Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. And maybe ask an initial question on just sort of business development. How does that success within a portfolio then potentially then drive additional focus in BD within CV, now that you have that kind of foothold in the space? And does Merck think about it like that in terms of like that portfolio approach? Or is it more agnostic?

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

I think it is more agnostic. I mean, again, certainly, once you have a presence, it help if you build it out, we've seen that in oncology over the last few years. But we have never restricted ourselves to just stay within those areas. I think it truly is about identifying cutting-edge science, couple it with capability to assess and decide, can we do something differentiated with this?

And we've also continued to build capability, right? We look at immunology, we brought in a lot of external capability. We've learned a lot from immuno-oncology that we're applying into immunology. So it's also dynamic in a way. But I think it benefits us to have an agnostic approach to this.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. Going to bring Peter in here real quick. Just maybe you could outline kind of what you guys have framed in terms of how big you think CV could be, and over kind of what time frame.

Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Yes. So a year ago, we hosted a deep dive event focused on our cardiovascular pipeline. And since that time, obviously, based on the discussions, some positive things have happened.

So at that time, we had said, on non-risk adjusted basis, we saw greater than \$10 billion of commercial revenue potential by the mid-2030s. And as we've had some derisking events, we've now been saying we have even greater confidence that, that can occur.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. So we're 15 minutes into the presentation. We have not said the KEYTRUDA at all, which I don't think have happened any time in the prior 5 years. So maybe let's talk about some of the drivers on KEYTRUDA. 2022 was a solid year for KEYTRUDA on the back of a number of label extensions. As we think about '23, are those drivers still going to be meaningful, even if sort of those approvals kind of anniversary?

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes. I think exactly. I mean, we continue to hold a very strong position in IO and continue to increase share, new patients as well as overall share. So I think this is a really strong foundation. We continue to see good momentum growth across almost all of the tumor types. Certainly holding a very strong position in lung, which is a significant portion of KEYTRUDA, but also very meaningful expansion into the earlier stage cancers, right?

And really, what we saw in 2022 was a triple-negative breast adjuvant, triple -- neo-adjuvant, adjuvant triple-negative breast; adjuvant melanoma; adjuvant RCC driving significant growth, and a lot of that is continuing in 2023.

And obviously, we continue to go further in terms of KEYNOTE-091. We've got a PDUFA on KEYNOTE-671. So the early stage indications, it's going to continue to be a strong driver of growth. We expect that it will be about 50% of our growth between now and 2025, at least that would make up about 25% of KEYTRUDA revenue by 2025. So I think we're in a good place in terms of the drivers playing out.



Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

So I want to come back to the 091 data. Pretty sure it was me who asked the question on the call, and I think Rob tried to level-set expectations in terms of adoption based on the 091 data, but then you followed up with 671 data way ahead of expectations, and now you've got a PDUFA date. Does that potentially accelerate that adoption? Should we be thinking about that on a faster scale than maybe kind of how it [said on the call?]

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes. And I think there's 2 things. So I think the data, there's no issue with the data. We feel very strong about in KEYNOTE-091 in Stage IB, II and IIIA; with 671 in Stage II, IIIA and IIIB, right, to some of that. The data, no question about the data.

I think what Rob was trying to take across is that, if you look at 2 significant tumor areas, like lung and triple-negative breast, or lung and breast, almost equal in terms of the number of patients. But in breast, we see a high level of screening, we see a high level of diagnosis, we see a high level of treatment pre-and-post surgery, right? Because most of those patients are young, they're healthy, and get [these treatments].

Whereas in lung cancer, what we see is really low screening rates in the U.S., around 6%. Only about 44% of patients are diagnosed. And then what we also see is that significant number of patients are not eligible for surgery, right? So you have a little bit of a different drop-off in the early stage lung setting that is very different from breast. From that perspective, we will see an uptake, but it's not going to be -- it's probably not going to be as we saw it in [triple negative breast.]

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. That's good context. Maybe moving to subcutaneous KEYTRUDA. For the person running the commercial franchise, this was tremendous opportunity but also a number of kind of issues to kind of potentially navigate here. Maybe you can help, first off, frame how your patients and clinicians will think about subcutaneous KEYTRUDA kind of in a world in which we have biosimilar IV. Well, maybe start there.

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

First of all, I mean, we continue to drive these innovations to make the significant difference in terms of patient outcomes, whether its higher efficacy. In this case, much greater convenience, right? So that's really why we continue to innovate in this form. And KEYTRUDA subcutaneous certainly will be a big time saver in terms of how patients get the drug administered.

So the way we think about is that, if you think of the early stage, the patients are typically on longer treatment cycles, and it might be in most of the adjuvant settings, KEYTRUDA only. Subcutaneous will be a very convenient way to deliver KEYTRUDA, both for the patient as well as for the offices where it gets a administered, right? It's a very different logistical setup and it saves a lot of time and it equates to a lot of efficiency.

The other place is where KEYTRUDA is used on its own, this is a place where the subcutaneous could easily slot in, as well as in combination with oral treatments, so Lenvima, Lynparza, etc. So that is roughly, it's going to be by '28, about 50% of where the KEYTRUDA volume sit, is in a space where a subcutaneous KEYTRUDA can bring a lot of patient convenience as well as efficiency for the -- for the practices where it's being administered.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. And when the added wrinkle here is IRA impact and how that -- sort of when would the clock start for a subcutaneous KEYTRUDA?



Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

That is the question. I mean, one of the things with the IRA, we don't know exactly how they look at these different formulations. This will be a unique co-formulation, right? So from that perspective, it will be unique. It will be novel. It will bring significant treatment and patient value.

We are looking closely at how we think the IRA is going to treat these, and that's something we will hopefully get increasingly more clarity on as we work with CMS on rules and execution, implementation of how the negotiation ultimately will happen.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. And maybe for Peter here, just how we think about the 2 formulations. And you talked about prioritizing the second formulation. Where -- kind of what happens with the first formulation? Is that still potentially coming to market? Or just sort of...

Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Yes, the Phase III on the initial subcutaneous program will read out this year and will help inform our broader efforts with subcu. But we've said that we are likely to prioritize the second program, which is in combination with hyaluronidase, in part because of the efficiency with which it delivers the drug into the body, fewer injection site reactions, and the ability to potentially dose every 6 weeks, which when you're thinking about early stage patients, that's a real benefit.

And Jannie mentioned convenience, but it's really -- we like to say, it's an access issue for many of these patients, particularly in early stage, or for patients that live far away from infusion centers, to be able to access at their local physician's office.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. Maybe coming back to lung for a second, focus on TIGIT. We had Gilead here earlier. We had Roche yesterday, as I recall. Just given sort of KEYTRUDA's strong position in lung today, when you think about what it would take to really move the needle in first-line lung, how do you think about that?

It seems on some level, it would take a pretty overwhelming kind of hazard ratio or survival benefit to kind of move the needle. But you also have your own program. So kind of how you think about the balance there and the competitive drugs.

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Yes. Well, first of all, I think when we move the needle in that setting, it will be great news for patients, right? So that's why I think we will continue to try and do that because a lot of patients are benefiting. But we never forget that there are still patients who are not benefiting from current standard of care. So that will be a good thing the day when it happens. And we hope it could be us.

In terms of our TIGIT program within our KEYVIBE program, we have 9 trials ongoing, of which, 5 are in basically right now in non-small cell, 1 in small cell and recently announced adjuvant study melanoma. Obviously, we don't compare head-to-head on the TIGIT assets, but we do believe we have an asset that is very clean, high affinity for when it binds. It has performed well in the models and in human cells.

And we also have the opportunity to obviously combine it with KEYTRUDA, right, which others are not able to do. So we hope that we can show a differentiated effect. And the data will inform us. We continue to look at -- not just what's happening within our own set of studies and data sets, but also what's happening externally, to better inform where we go next and how do we continue to develop this co-formulation.



Peter Dannenbaum - Merck & Co., Inc. - VP of IR

And as you know, we have a strong position in lung based on really strong overall survival results in a variety of different settings in lung. So whether it's us or competitors, you need to show meaningful benefit over what's already been achieved, [KEYTRUDA].

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

If we have enough time to ask the deeper question, but how do we know the melanoma data with Moderna is going to be at AACR? Can you maybe just kind of help frame the path forward there? There's been a lot of talk about potentially filing on that data. Just the latest from Merck there.

Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Yes, we look forward to Moderna's presentation of that data, and it's very exciting, [at least] from the top line release. We have always said it's a relatively small Phase II trial in a novel setting, and we look forward to proceeding as quickly as we can into Phase III. We'll have to see how those discussions with the regulators turn out. We always are open to the idea of filing on Phase II, but we're looking forward to the Phase III trials.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Fair enough. And we're out of time. All right, Jannie, Peter, thank you very much for your time.

Jannie Oosthuizen - Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health

Thank you so much for having us.

Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Great. Thank you, Carter.

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