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

EVENT DATE/TIME: MARCH 12, 2024 / 7:05PM GMT

OVERVIEW:

Company Summary

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PRESENTATION

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

Good afternoon and welcome to Day 1 of the Barclays Global Healthcare Conference. My name is Carter Gould, covering U.S. biopharma. I'm pleased to welcome Merck to the stage. Merck is one of our top picks to start the year. And it's been a good year for Merck.

Joining us from the company, Jannie Oosthuizen, President, Human Health U.S.; as well as Peter Griffith (sic) from the IR team. Welcome, Merck. Thank you very much for joining us.

Maybe before we get to start. We can just jump into Q&A. If you want to make some opening comments. But I think we were just going to jump in as we discussed, yes?

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

Well, I mean, I can just make a few comments. But thank you for having us, Carter. It's good to be back. You said it, I think it's an exciting time to be at Merck. We're benefiting from strong execution across our clinical program, across our commercial organization. And we continue to anticipate good growth as we move forward, driven by our key oncology vaccines. But also very exciting this year to launch [sotatercept], V116, but those we'll get into.

And then we're also starting to see our pipeline maturing. We're getting line of sight of significant areas opening up, continue to be in oncology, immunology, cardiometabolic, vaccines and the infectives. So really, a good place to be.

QUESTIONS AND ANSWERS

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

Great. Well, looking forward to talking with Peter Dannenbaum as well, so thank you for that. Maybe let's start with sotatercept because we got the PDUFA right around the corner, and sotatercept's been one of our favorite molecules since its Acceleron days. Maybe start first -- and Merck has been sort of very positive on the commercial opportunity here. Just kind of your level of enthusiasm around this becoming a foundational asset in PAH going forward.

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

Yes. Absolutely. So as I said, this is really one of the exciting launches this year. It's pretty soon. PDUFA is at the end of March. And we're really excited for 2 reasons. The one is it's -- really, it's a new area for Merck to move into. So a lot of excitement as we move into a rare disease space. But also, if you think about PAH, there's really been no significant innovation in the last 10 years. And we know this is a patient population with significant unmet needs. So we're really excited to bring a meaningful therapy to market.

And I think since we've seen the data at ACC in 2023, there's just been really strong excitement within the treatment community. We know, as physicians started to think through what sotatercept is bringing, their patient population, they -- a lot of them have specific patients in mind that they think should receive this therapy as soon as possible.

So -- and the majority of patients are treated by highly specialized PAH specialists in the centers of excellence, there's about 150 in the U.S. treating half the patient population, and PAH experts outside of CoEs. And this is a close-knit community, so we know that there's going to be strong uptake of this.

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

So I think when we spoke last year, we talked a little on the back end of ACC. There was some chatter around the bleeding risk. We've now seen some longer-term update data earlier in the year with larger follow-up, and there were some additional bleeds. Maybe just talk about your confidence in that profile and potential for REMS or some other kind of troublesome language, and how that impacts the commercial opportunity, which you still seem to be very positive about.

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

Yes. That's right. So we have seen, with the ongoing SOTERIA study, which is the open-label ongoing longer-term study following STELLAR, we've seen more patient observations. So there has been some differentiated outcomes with some of those additional patients coming in.

But I have to say, from a results perspective, we continue to see lasting clinical benefit. We do not see discontinuations as a result of bleeding. And we've also observed that most of the more serious bleeding is associated with other conditions, whether it's low platelets, use of anticoagulants, steroid use or maybe even prostacyclin. So certainly something that we will continue to monitor. We take this very seriously. And we will continue to report on what's observed.

In terms of REMS, this is really -- it's a decision in the hands of the FDA. So we'll have to wait and see how they think about this. But we feel very confident about the profile and how we think we're going to bring this to market.

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

Okay. And as we think about that launch, is that something that Merck is going to make easy for us to follow? Or are we going to see those scripts as they kind of hit on a weekly basis, et cetera?

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

Yes. I think we're working through what are the data sets going to look like. I think we would like to see the number of patients that we make an impact to. And if we have, I would say, credible data sources, we will like to report out on that as much as possible.

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

Okay. And then maybe just last one on that side in terms of expanding the field force and being in a position ready to go out of the gates here in a couple of weeks.

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

We are very ready. We were preparing to be ready for any early positive surprise in terms of an approval. As I said, this is a really small treatment community. So we've built a rare disease model through which we can really reach these centers effectively and give the best support to patients and physicians who's already navigating a fairly complicated journey and make sure that we make it as easy as possible for them to access and get sotatercept.

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

Okay. So you've had some other positive kind of updates here in the past 2 weeks. You had what we thought was a very positive ACIP meeting for V116. It didn't seem to get as much attention from The Street. But can you talk through sort of your takeaways from that meeting? And specifically touching on the potential expansion of that standard-risk population down to 50 years old?

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

Right. Yes, I agree. I think it was a very positive ACIP meeting. And what we were really encouraged about was the recognition by the committee of the population-specific vaccine that we bring forward and the value of being population-specific, right?

So we've often talked about serotypes. V116 is 21 serotypes, it is 1 more than PCV20. But the importance is really the disease coverage that comes about because of the serotype composition. And that's where we're encouraged about conversation within ACIP to bring down that age recommendation to 50 to 64.

If you just think about it, there's 120 million people in the United States over the age of 50. 60 million is sitting in this population of 50 to 64, and 60 million -- so basically 50-50 in that 50 to 64 and 65-plus. So this is really a significant patient population. We also believe that an age-based recommendation is much more effective in terms of getting segments vaccinated versus a risk-based, which is what it is today. And it's also good from a health equity perspective to make it age-based rather than risk-based.

So that lowering of the age recommendation is [really positive] in terms of the conversation. And we know that V116, because of the serotype composition, is about an 83% coverage, residual disease coverage for adults, which is a good 30% higher than what PCV20 is providing today. So really huge incremental benefit for patients both at a lower age as well as potential revaccination over the age of 65.

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

One of the things I think -- and there's obviously some new data cuts at ACIP that we hadn't seen before. But I think one of the things that still take to investors is those patients that maybe have already been vaccinated with Prevnar, or at least have the first dose with Prevnar, and then going in and potentially retreating with V116. How do you -- any expectation on how the ACIP and the guideline-making bodies will sort of respond to that?

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

Yes. So that's a population that we studied in STRIDE-6 in terms of revaccinating everybody that's been vaccinated more than 12 months before with another pneumococcal vaccine.

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

Right. It was sort of a bucket cohort.

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

Right. And so in that population, we saw the immunogenicity in that expansion from 53% disease coverage to 83%. So that's where we will continue to have an exchange with the ACIP and hopefully get to that discussion to open up that revaccination above the age of 65.

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

Okay. And sort of this encouraging data you've seen with V116, sort of what does this then portend for your effort in the pediatric opportunity? You talked about a second program to go after pediatrics. Is that still the game plan? Or does the positive data here sort of change that plan in any way?

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

No. There's a few things we're doing. There's at-risk children and teenagers who could benefit from a V116 vaccination. So we studied that in STRIDE-13. But we will continue to work on V117, which is a further expansion of our current VAXNEUVANCE serotype profile. So that is still early stage, but we will continue to develop population-specific vaccines, including for pediatrics, moving forward.

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

So I think, Rob, on the last earnings call, he talked about a \$3 billion TAM for V116. And when we think about that, was that sort of the adult population as you kind of outlined it there? Or is the younger -- the expansion down to the 50-year-old cohort, that additional? Does that include the pediatric opportunities you just talked about with V116 for at-risk? Kind of what's in, what's out there?

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

That's focused on the adult opportunity, both in terms of lowering the age recommendation as well as that revaccination over the age of 65.

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

Okay. So that's two pretty compelling launches in -- against the backdrop of, frankly, you've had a lot of KEYTRUDA line extensions in your past. That's got to be exciting to sort of have this new dynamic kind of...

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

It really is. It really is, yes.

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

And maybe one thing that also has kind of gotten lost in the mix was you're going to potentially have an oncology launch summer, too, with the Daiichi asset. Can you talk about how you see that playing out and where that -- what fits in the paradigm?

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

Yes. So a big part of our business development focus has been to expand outside of oncology but also to diversify within oncology. And we signed a fairly significant collaboration agreement with Daiichi Sankyo towards the end of 2023 that includes three ADCs.

The first one is the PDUFA at the end of June. It's a HER3 ADC that we will launch in later-stage metastatic, EGFR-mutated non-small cell lung cancer. So really an exciting launch. It's a small indication, but really [excited for] launch as we get this collaboration and partnership going with our partner, Daiichi Sankyo.

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

And maybe the -- you also just closed the Harpoon deal. And small cell has been sort of that -- maybe calling it a white whale isn't totally appropriate here, but it's been the one thing that sort of has been a bit of a challenge for Merck despite KEYTRUDA winning in a number of other places. Can you talk about how that fits in? Is that an opportunity to bring back KEYTRUDA in small cell? Or is that -- is it really just sort of living on its own merits with the asset in question here?

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

So one of the ADCs within the deal with Daiichi Sankyo is the B7-H3, which is really the one that we're looking at for small cell. You're right, small cell has been the most elusive -- one of the most elusive parts of the lung cancer space that we've explored. So hopefully, we can crack it with B7-H3. And the DLL-3 is pretty much going to play a role within this investigation.

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

Okay. But at this point, no real sense in how they're going to kind of coexist? Or...

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

I don't know. That's a bigger question...

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

Let the data play it out. Okay.

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

That's right.

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

Okay. Maybe it's a good segue to focus back to KEYTRUDA in sort of these early stage lung approvals and how that part of the launch is going. It was a very big part of the narrative. In '23, you told us it would take time, but it was clearly helping the sales trajectory. Now with sort of a little bit more time, maybe an update on that front.

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

Yes. So I think, Carter, you're right. If you go back, I think we talked about 25% of KEYTRUDA sales will come from early stage by 2025. In fact, in '24, about 27%, 28% of KEYTRUDA sales will be related or driven by the early stage indications. And over the past few years, we've launched in early stage melanoma, early stage renal cell carcinoma, early stage triple-negative breast, and these have been strong growth drivers.

And in early 2023, we launched our first early stage lung indication with KEYNOTE-091, which is KEYTRUDA in the adjuvant setting. And towards the end of last year, we launched KEYNOTE-671, which is the perioperative presurgery followed by surgery and then KEYTRUDA in the adjuvant phase with 671. And it's really going really well. Early stage is driving close to 60% of our oncology growth right now, yes.

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

Okay. And so when you think about sort of what's the next step to drive that inflection of adoption of KEYTRUDA here, is it just more awareness, better testing, better screening? At this point, kind of where does it sit?

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

I think we feel really good. We've taken a strong share leadership position already in the early stage with KEYNOTE-091. We continue to expand that with 671.

The treatment rate, there are really 2 big drivers if you look at early stage. The one is diagnosis in that early stage. You need to be diagnosed, obviously. And in lung cancer, that is still a big challenge. The screening rates are low. So there's a lot of work needed to further increase lung cancer screening.

And then the treatment rate itself. When we launched with the KEYNOTE-091, treatment rate was sitting at around 35%. We've been able to bring that up to 60% right now. So we're making meaningful progress in terms of having diagnosed patients treated, but the other thing we need to do is we need to get more patients diagnosed in the early stage so that they can be treated.

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

Okay. That's probably a good segue to the subcutaneous KEYTRUDA and how that fits in here. And to the extent that it can help accelerate things into an earlier adoption of KEYTRUDA in the adjuvant setting, I mean, I think there's always a focus on sort of potentially extending the life of KEYTRUDA. But maybe that's too simplistic way of thinking about it, and there is sort of a broader opportunity in growing the pie.

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

Yes. I mean, subcu has really been a focus to innovate for patients, right, in terms of bringing a level of convenience in a difficult disease where you have to come back frequently for an infusion, right? So the one aspect is to really address people who will be longer term on an infused product like KEYTRUDA. And the second one is there's also a significant efficiency for the practices administering these medications.

So we are developing Q3 weekly formulation of subcu KEYTRUDA as well as a Q6W. We see the -- although the subcus can be used for any one of the KEYTRUDA indications in combination with any medication that is in label, we see it really as of particular value where KEYTRUDA is used either as a monotherapy. And that could be in some -- still some metastatic settings. But in particular, in the early stage, if you think about the adjuvant phase where patients came back for almost a year, if they can get just a subcu injection every 6 weeks in a few minutes, that's a very convenient way.

And then where KEYTRUDA is used in combination with oral anticancer treatments, right? So really, you don't need to sit in an infusion chair. It's an easy way of administering it. But again, as I said, physicians can obviously use it in combination with infused treatments as well.

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

Okay. And we're still going to get that data, hopefully, by second half of this year. And that will support...

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

Yes. That's right. Yes, for September -- I think in September this year that we'll see the data.

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

And then when you think about how much of the opportunity subcu might be able to let you hold on to, certainly, your competitors have put out different bogeys in terms of what they think. Would love to hear the updated Merck line.

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

Yes. So that optimal place where we think subcu can provide the most value for patients and practices. We project that to be more or less 50% of the KEYTRUDA volume by '27-2028. So we would say that 50% of the volume, that would be a good place to use subcu KEYTRUDA.

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

And then any initial thoughts on sort of how you might think about the pricing there relative to IV KEYTRUDA and just how you might manage that?

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

Yes. We would definitely -- pre-LOE of the IV, we would definitely price subcu to make sure that patients can access it. So it doesn't need to be at a premium to the IV, for instance. I mean, we could, but we're definitely going to be sensible to make sure that patients have access. This really should benefit patients in a significant way.

And as we think about biosimilars coming into the market, the same thing. We will need to be cognizant of biosimilar pricing. We can probably get, I would say, some premium versus biosimilar pembrolizumab. But again, we would be very much focused on making sure that patients have access to subcu in that treatment scene.

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

Okay. As we were talking a minute ago, you talked about KEYTRUDA in early stage renal cell. Renal cell is clearly a place where you guys have had a lot of success. You've been expanding upon that now with WELIREG. Had a positive data last year. Scripts got off to a fantastic start to the year. In your view, kind of what drove that inflection? And maybe just talk about your enthusiasm for WELIREG as you see that playing out going forward.

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

Yes. WELIREG has been probably an understated launch within our oncology portfolio when we first came in for a rare disease, VHL-related renal cell as well as hemangioblastomas, PNET, [PNS]. But it really has made a significant role in that population where there really was no treatment. And we got to about \$219 million of sales in 2023. We grew 77% from '22, so there's really been strong uptake within that setting. And I think we can still do more within VHL-related disease.

And then with the data coming through that is from LITESPARK-005, we are now able to push into advanced renal cell carcinoma in the second, third line-plus saving following I-O and TKI. And we're seeing some really strong uptake. That's a heavily treated population, but additions are really what they're seeing with the data.

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

And given sort of the safety profile of the asset, I guess, is this something ultimately you'd see more as sort of like a frontline metastatic drug or an adjuvant setting drug? It seems like as an oral, with pretty tolerable, that would be well positioned in the adjuvant setting.

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

Well said. I think given the profile of WELIREG, it's a HIF2 alpha inhibitor, we see that as we move into the adjuvant setting in combination with KEYTRUDA, as we see it in the frontline setting at first line as a triplet in combination with KEYTRUDA as well as LENVIMA. And in the second-line setting, we can combine it. I think it's in combination with lenvatinib in the second line as well.

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

LENVIMA as well?

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

Yes. LENVIMA, yes.

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

Okay. Maybe if we can switch gears to -- back to cardiovascular a bit. It was certainly something that dominated the conversation last year coming on the back of ACC and sotatercept data, the updates on PCSK9. And you came up with new, bold kind of target for how you see the CD part of the portfolio progressing over the next foreseeable future.

The PCSK9 part is a little bit more execution mode. But how you -- at this point, how you see an oral fitting into the broader opportunity given all the other dynamics we've seen in the space, sort of fits and starts with the injectables. They seem to be on a better trajectory now. But just sort of your level of confidence in an oral in this opportunity...

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

Yes. When we look at -- as a company, when we look at oral PCSK9, and we said it, I think, last year at the ACC, aspiration is really to democratize the most potent LDL cholesterol-lowering agent around the world, right? So the ability to take an injectable PCSK9 into a tablet, there's just endless opportunity to get this to every part of the world and make sure that patients benefit broadly.

When you look at the United States, 85% of cardiovascular disease is still driven by atherosclerotic disease, right? So that's still high. We know that 70% of high-risk patients are not [control] standards today and only about 5% of the U.S. population have access to an injectable PCSK9. So when you bring all those things together, and there's going to be some hard work to bring that together and make sure that we get the right policies in place and treatment guidelines and standards, but I think that does spell that there's a huge need and this product can make a meaningful difference in how we manage cardiovascular disease moving forward.

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

Okay. So outside the U.S., completely aligned. I think we get that. In the U.S., it's tough to think of a better example where sort of the challenges with IRA are going to be sort of put to the test in terms of how you think about a launch strategy here. So how important is having that CVOT data when you go to market here with an oral?

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

Yes. I mean, I would say it's always better to have it rather than not. Are we going hold back?

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

When push comes to shove here, are you going to hold back? Yes.

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

I mean, if our Phase III plays out and is registrationable, we will bring this product forward to patients. We've seen increasingly cardiovascular outcomes data with the injectable PCSK9s. We believe that physicians will infer their class affect as well. but we will bring this forward to market in advance of a CVOT, and we will continue to develop our CVOT later.

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

Okay. As we go back, I'm sure I'm getting pinged in that I didn't ask a question on sotatercept's sort of value, right? So clearly, again, with approval just sort of weeks away, I know you're not going to reveal pricing here. But at least when ICER did their pricing analysis, they threw out a \$400,000 sort of assumption per year. Any sort of immediate reaction to that? Is that a fair assumption? Totally off the wall?

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

I mean, we will -- Merck, as we always do, we will price to the value of the medication, the value to the system, the value to the patient, right? It is -- yes. So hopefully, soon, we can reveal that price. But we think that we are asking a fair price for what value sotatercept will bring to these patients.

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

Okay. Maybe a broader question, and I'd love to get Peter to chime in here. Just given all the chatter around IRA and sort of how that changes the calculus going forward, you've had some lawsuits with like -- lawsuit with the government. And at this point, kind of what's the message in terms of expectation around pricing negotiations and how you -- when you have to make your internal assumptions and anchor around the view of the world going forward, how are you doing that in this sort of ever-changing world? I gave Peter the easy question, yes.

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

So we're in negotiations on JANUVIA, as you know. And when we have something more to say around how those negotiations are going, we'll communicate that.

More broadly on our lawsuit, we've -- the District Court judge has heard both sides, and we're awaiting the District Court judgment in that case.

Big picture on IRA. It doesn't change our company strategy or approach. We will remain an innovation-driven company. And while we don't agree with the price negotiation component of the IRA, and we think it has adverse effects on the industry longer term, we think we can still -- if we bring the right innovation to patients and to the market long term, we can still do well as a company.

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

Okay. Great. We'll have to wrap it up there. But 2 weeks to sotatercept PDUFA. Best of luck. Thank you.

Johannes J. Oosthuizen - *Merck & Co., Inc. - Senior VP & President Merck U.S. Human Health*

Thank you so much.

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

Thank you, Carter.

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