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

EVENT DATE/TIME: SEPTEMBER 15, 2020 / 1:30PM GMT

## CORPORATE PARTICIPANTS

**Kenneth C. Frazier** *Merck & Co., Inc. - Chairman, President & CEO*

**Roger M. Perlmutter** *Merck Research Laboratories - President*

## CONFERENCE CALL PARTICIPANTS

**David Reed Risinger** *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

## PRESENTATION

**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Pleasure to introduce the session with Merck. I need to refer you to disclaimers at [www.morganstanley.com/researchdisclosures](http://www.morganstanley.com/researchdisclosures). And it's very much my pleasure to welcome the Chairman and CEO, Ken Frazier; and also the Head of R&D, Dr. Roger Perlmutter with us. As you know, these 2 individuals are leading the company's mission and vision to lead Merck to continue to be the premier biopharmaceutical research company in the world. Congratulations on your recent progress and momentum. Ken, let me turn it over to you for prepared remarks, and then we'll go from there.

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**Kenneth C. Frazier** - *Merck & Co., Inc. - Chairman, President & CEO*

Thanks, David. Thanks for having us today. I would just start by saying -- start where you just left off, which is at Merck, we will consistently focus on science as core to our strategy. Our view is that we should always look to follow wherever the science leads us and prioritize our investment in R&D, and that means both our internal R&D, and we're very pleased to have built out our discovery operation under Roger's leadership.

But we also continue to search for business opportunities, business development opportunities to bring in the best external research to actually help complement our internal pipeline. Over the next 5 years, we expect strong revenue growth based on demand for our innovative, derisked and visible in-line products.

And when we look out to 2024, we still believe our revenue growth is underappreciated. We have tremendous opportunities to grow based on KEYTRUDA, GARDASIL, LYNPARZA and LENVIMA. As we look beyond 2024, our strong mid- and late-stage pipeline will continue to drive continued success, and Roger could talk more about these particular items. But we look at V114, islatravir, gefapixant, various vaccines. They all represent significant medical opportunities. And longer term, as I mentioned before, we've reinvigorated our discovery research to help generate breakthroughs going forward. I mentioned also that we're going to continue to complement that with business development.

So we continue to see improving business momentum as a company. This year, obviously, we were hindered to some degree by the severe social distancing measures required by COVID-19. But we still expect revenue growth of 3% to 6%, ex foreign exchange, despite these pandemic headwinds. And over the next 12 to 18 months, we see numerous upcoming clinical and regulatory events that will enhance our growth, including our earlier-stage trials for KEYTRUDA, the continued rollout of the V114 program, et cetera. So as we look forward, we're very much confident in our ability to grow the company in the short, intermediate and longer term. And so with that, I'll turn it over to you.

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## QUESTIONS AND ANSWERS

**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Great. Thanks very much, Ken. So obviously, KEYTRUDA has been a phenomenal success. I thought it would be helpful for you to just provide a little bit more color and perspective on the KEYTRUDA growth drivers and also the prospects in the face of greater competition.

**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, President & CEO

Well, let me start by saying that we continue to be pleased with how well KEYTRUDA is performing in its key areas. So for example, we continue to see that we're getting 8 out of 10 are newly diagnosed eligible lung cancer patients. There's a lot of competition out there, but we see the competition is not making inroads. And we've seen -- speaking of lung, we see continued growth ahead in lung. As you know, we're still launching sort of our lung indications, including 189 around the world, and so we see additional growth potential there.

As I look over the longer term, and I would say that I still see KEYTRUDA as still very much in the middle innings when it comes to its growth opportunities. We have opportunities which Roger can discuss in more detail, but I'd say they fall into a number of large categories. One is expanding the utility across different tumor types that -- which we're working on. The second one is going into earlier lines of therapy. And the third one is the work that we're doing with various combinations. So we see tremendous growth opportunities for our KEYTRUDA going forward.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Excellent. And maybe you could speak to -- and I'm not sure if you're going to have Roger comment here as well. But this is more of kind of a high-level strategic question. How should we think about adjuvant as a commercial opportunity for KEYTRUDA? The vast majority of KEYTRUDA sales are in metastatic.

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, President & CEO

Are in metastatic.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Exactly. And so that's got to be over a \$12 billion run rate today. I think it's actually tracking -- the total franchise would probably do about \$14 billion roughly on an annualized basis. So how should one think about adjuvant as an opportunity relative to metastatic?

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, President & CEO

Well, I'll let Roger get specific. But to answer your question, we see a very large opportunity moving into earlier lines of therapy. As you know, there's a significant burden of disease in the early lines of therapy. The majority of patients and a large number of tumor types present with earlier stage disease. So by bringing treatment earlier in the overall continuum, we have a great opportunity to save more lives and we see the opportunity as additive to the metastatic opportunity. We'll be able to maintain our metastatic business while also benefiting patients in the earlier lines of care.

So when we think about the breadth of the data that we're generating, we expect to have a comparable wall of data in the early lines of therapy as to -- compared to what we've been able to generate in metastatic disease. And so with that, why don't I turn it over to Roger who can talk about the opportunities that we have going forward? Obviously, we're currently approved in adjuvant melanoma based on KEYNOTE-054 in early-stage breast cancer -- bladder cancer rather, based on KEYNOTE-057 and cutaneous squamous cell carcinoma based on KEYNOTE-629, and Roger could talk about where we go from here.

Roger, it seems like you're on mute.

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Yes, let me just unmute this. Well, I'm just going to make just a few points. What I would say is -- the first thing just is, as Ken mentioned, is that as we have explored monotherapy, we have advanced into new tumor types and advanced into earlier lines of therapy. And if you just look at this

time in 2020 alone, we've had 5 new KEYTRUDA approvals, including the approval in nonmuscle-invasive bladder cancer, which is an early line of therapy. And as well, we are gaining approvals in -- with new dosing regimens, for example, the Q 6-week dosing, which has been very important for gaining broader access.

But as you look still further, there's a lot of reason to believe, just on first principles, that if you can get to cancer patients early on in the journey and treat the tumor at a time when it's small and it hasn't yet spread, there's a better chance to have a treatment effect. And the reason to believe that, of course, is that -- the fundamentals of how KEYTRUDA actually works. So KEYTRUDA reveals the preexisting immunity directed against the tumor. We don't know exactly when that immunity developed. But you can think of it as sort of a balance between, on the one hand, tumor growth as the tumor is selected for improved -- that is improved from the tumor's point of view, growth characteristics, versus the immune response.

When the immune response, for whatever reason, is depressed and the balance shifts in favor of the tumor, that's a time when we would like to be able to apply KEYTRUDA to readdress that balance and to eliminate the tumor, if at all possible. It was that kind of thinking, of course, that drove the KEYNOTE-054 melanoma study where adjuvant melanoma, in the adjuvant setting, treating melanoma has a dramatic effect, and we'll have a chance to provide updated data on that at the European Society for Medical Oncology meetings coming up a little bit later this week.

And it has similarly driven over 100 early-stage programs. We have now something on the order of 30 with registrational intent. So you'll be seeing more and more of these studies coming forward. Obviously, we've already reported the neoadjuvant and adjuvant 520 -- KEYNOTE-522 in triple-negative breast cancer currently under review at the FDA. But we also have studies in non-small cell lung cancer, in head and neck cancer, where the -- I think the effect will be quite powerful and in a variety of other settings. Just imagine, local control in head and neck setting and the neoadjuvant experience where, as a result of the administration of KEYTRUDA, I believe surgeons will have much, much better ability to perform complete tumor resection. So there's a great opportunity for KEYTRUDA going forward in these early treatment settings.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

That's very helpful, Roger. So could you add a little bit more color on head and neck, including potential timing of readouts ahead? And then also, if you could just discuss the KEYNOTE-091 adjuvant lung trial. I believe the primary completion is in August of 2021, but I would assume that there could be an interim look soon. If you could comment on that as well, that would be much appreciated.

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Yes. I mean I would just say, first of all, that the KEYNOTE-048 study in head and neck demonstrating both monotherapy and chemo combination in individuals with locally advanced or metastatic head and neck cancer has had a big effect. And KEYTRUDA is broadly used in the head and neck cancer setting, frankly, that those data are enormously powerful, and they are seen that way.

But as I indicated in head and neck cancer, there's every reason to believe there is typically a long time frame in development of those tumors. There's every reason to believe that if we can get in earlier and reassert the balance between immune response and tumor growth that we can have a meaningful effect, and we can improve the ability of surgeons to gain control because we know local resection is very important.

We're going to have a chance to look at chemoradiation data in 2021 from the KEYNOTE-412 study in head and neck cancer, and then there will be other studies in addition. So we are very interested in this. And I would say anecdotally, and this has been true for a long time, head and neck surgeons have approached me with statements about what they are seeing not outside of the clinical trial setting, and that's very encouraging. And of course, these are anecdotal reports. So you can't rely on them completely, but I think it is encouraging.

The same thing applies in terms of our lung cancer programs, and we will see initial readouts in 2021 as well. As far as interim analyses are concerned, of course, there's always an opportunity to have interim analyses. You don't specifically comment on those. We also -- of course, remember, these are event-driven studies, and they're under the supervision of the Data Monitoring Board. So at any point, we could -- they'd be informed in one way or another by the Data Monitoring Board. But that's just the beginning of a whole set of studies that will read out over the next 5 years.

I guess I should say that the label for KEYTRUDA is now nearly 100 pages long. And at the current pace of approvals, in essence, we're creating sort of a textbook of medical oncology based entirely on the use of KEYTRUDA in broad, broad settings. It's quite extraordinary.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Excellent. Truly phenomenal progress. So maybe we could step back to a couple of strategic questions for Ken. So Ken, GARDASIL's demand outstrips supply. Could you discuss the current capacity constraints for GARDASIL and whether Merck can increase production volumes in the near term ahead of the planned tripling of capacity in 2023?

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, President & CEO

So let me start by just pointing out that over the last couple of years, we've been able to double our production by focusing on expanding and maximizing our existing facilities. We're also working with certain contract manufacturers to alleviate certain bottlenecks in the process. And all of this should allow us to achieve year-over-year growth in both 2020 as well as going forward over the next several years.

The main thing for us, though, is that we are working on constructing 2 new bulk manufacturing plants, which are expected to come online around 2023. And that should allow for much greater increased ability to meet the global demand, which is fabulous right now. And it's going to go on for many, many years as people around the world see this as a cancer-preventing vaccine as it's now being used in males as well as females around the world. So we look forward to that. But in the meantime, we continue to see growth in the interim.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

That's great. And the current penetration is less than 5%? Is that correct?

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, President & CEO

Yes.

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**Roger M. Perlmutter** - Merck Research Laboratories - President

That's right, globally, of the indicated age cohorts. And David, just to correct something in your question, our capacity expansion will double our overall GARDASIL capacity in 2023, not triple.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Got it. Okay. And turning to M&A. Why don't we start with the very encouraging transaction that you announced yesterday, wasn't a merger or an acquisition, but instead a partnership with Seattle Genetics. If you could provide some comments on that and then I wanted to ask another question more broadly about M&A.

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, President & CEO

So let me start, and then Roger can fill in the details because it obviously was his colleagues who found this as the best scientific opportunity that we could acquire. But stepping back, I think the way to think about this is it certainly demonstrates our continuing focus on finding new innovative medicines, including in oncology. We're very committed, in particular, to finding early-stage assets. And we think that, that's how you can create much more value as to find those early-stage assets. And this helps obviously broaden our oncology portfolio by adding breadth and depth to the pipeline, which is key to us.

And from my perspective, one of the challenges that we face in business development, and you saw that with respect to at least another transaction yesterday, is that the prices for acquisitions right now are rather sky high. And we have to ask ourselves how we can acquire useful assets, medically important assets but acquire them in a way where, in our hands, they create value for our shareholders. And we have found that these kinds of partnerships like we have with Seattle Genetics, like we have with AstraZeneca and Eisai and others are one way of doing it in a fairly derided manner.

Roger, do you want to make any more comments about that?

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Yes. I mean, if I could, I would just say, with respect to Seattle Genetics and the broader field of antibody drug conjugates, this is a field that we have followed for some time. The underlying logic is straightforward, is to improve the benefit/risk of active drugs by targeting them more specifically to the areas where they can do the most good, finding the right way of doing that, both in terms of which drug warhead to use, how to couple it to an antibody that would bring it to the right place and how to link the 2 together so that there's maximum effect, has taken a long time.

And Seattle Genetics has clearly been a leader in that area over the past couple of decades. We had the opportunity to work with them on PADCEV with -- also with the vedotin warhead and demonstrated a dramatic improvement in outcomes in terms of response rate and urothelial malignancy when you combine that antibody with a conjugate, with KEYTRUDA. And it has driven, in our thinking and also in the thinking of Seattle Genetics, a view about immunogenic cell death, that the death of tumors that is provoked by cytotoxic therapy targeted using antibody-drug conjugates is pro-inflammatory and can be amplified still further with the presence of KEYTRUDA.

And so we have collaborated with them on the further elaboration of that with PADCEV. But as we looked at the opportunity with LV, we will use that shorthand as easily. We saw this was a place where, at an early point, we could work together to rapidly expand the exploration of that compound, both by itself and in combination with KEYTRUDA in breast cancer (inaudible), starting in triple-negative breast cancer.

Their Phase Ib studies are already going on in that setting, but as well in non-small cell lung cancer, small cell lung cancer, esophageal cancer, gastroesophageal malignancy, where signal finding studies already give us reason to hope that a combination of LV plus KEYTRUDA would be effective. So it represents a further amplification of our ability to harness the power of immune manipulation to improve outcomes in patients with malignant disease.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

That's very helpful. And just to follow on, Roger, do you see other opportunities to pursue additional external ADC candidates? And then could you speak more broadly about Merck's focus on M&A in the near term?

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Yes. I'll take both of them, but Ken should also speak to the M&A -- the breadth of M&A question. First of all, with respect to ADCs, the field is rapidly advancing. I don't think anyone believes that we have fully -- that we, the scientific community, have fully identified the best possible warheads or the best way to deliver those warheads to tumors. And that includes targeting immune manipulation as well. And so when you think about that, you think about using different oncolytic viral warheads, as an example, to broaden the spectrum as well as redirected lysis, something which I was involved in years ago. So all of those things, I think, with the background of better immune manipulation, provide hope that we can gain further benefit in treating patients with cancer. So that looks very promising.

If we now elevate just a little bit and ask, "Well, what does that mean in terms of the M&A landscape?" I'd just say, first of all, that I think that Merck prospers moats, does the best thing for the world, for the patients whom we serve and of course, for those who invest in us as well when we get in early in these opportunities because we can use our considerable scientific strength as well as our ability to [execute] clinical trials around the world to rapidly identify and capture major therapeutic insights.

And so we're usually trying to look fairly early on. I think that for us, the idea of going in and purchasing already registered drugs that are generating revenue, while we may be able to promote those more effectively because of the reach of our commercial organization, we have less leverage there. So we tend to want to work at the vanguard. That's generally how we think about M&A. And if you look at what we've done with our acquisition of Peloton, for example, in the HIF-2 alpha program, which is moving along extremely effectively, or what we've been able to do with noncovalent BTK inhibitor from ArQule, which we call MK-1026, it gives you a feel for the kinds of what would be called bolt-on acquisitions that we can perform that -- where our scientific strength and our ability to impose clinical discipline on a development program really gives us an opportunity to make a big difference for the patients whom we serve.

Ken, you might want to add to that.

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, President & CEO

So I would just add to that, that, as you know, this is an environment where assets go, are richly valued, in my opinion. Biotech has outperformed the general market, both last year and so far this year. And so when you're thinking about buying targets, you know that you're buying into a very rich environment.

Now we are willing to pay full valuation. And I think if you just look at Peloton as an example, that shows that we're willing to pay full valuation. But we have to believe that we're acquiring an asset, as Roger just said, that we can -- with our own scientific ability, we can create value with that asset in our hands over and above what the market has already valued it.

So we want the best science because we understand, in the long term, the value of the company really comes down to the value of its pipeline more than anything else. But at the same time, while we have a strong balance sheet and the ability to look across the full spectrum of opportunities, we still believe it's important to remain disciplined and to acquire assets that will create sustainable value for our shareholders consistent with our overall strategy.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Very good. Well, I wanted to say that we're going to extend the time to speak for another 5 minutes simply because we got started a little bit late. I did want to cover pipeline opportunities. So I thought it would be appropriate to discuss MK-4482, the Ridgeback oral antiviral. Just a couple of questions, please, Roger. First, when should we expect the Phase II data? I'm assuming that you'll want to publish that to be able to ensure rapid enrollment once you kick off Phase III.

And then second, I noticed that there were some ClinicalTrials.gov changes just in the last few days. I believe that one study took out the high dose. Any color that you can provide to help us understand where you are and how you'd like to characterize that product opportunity?

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Yes. David, thank you. So I'm very enthusiastic about MK-4482. I think in the near term, we all recognize that if there were potent antiviral drugs directed against SARS-CoV-2, COVID-19 after all is a viral-mediated disease. To get rid of the virus, early enough anyway, you get rid of the disease. So that offers great promise provided you can get in early enough with something that people can take.

I think that the challenge thus far with, for example, remdesivir, is, okay, the drug has to be given intravenously. Obviously, that's in a hospitalized setting. It tends to be given late. We know from prior experience that, and just from first principles, that if you're going to treat a viral-mediated disease, you'd like to get in from the earliest moment of infection. Or indeed, from a prophylactic point of view, even that would be better.

4482 is an analog of ribonucleotide. It is incorporated into the RNA that is produced by the unique viral enzyme, the RNA-dependent RNA polymerase. And that is part of the replication of the virus that enables the virus to make more of itself. When it is incorporated, it, as a result, causes errors in the genetic code of the virus. And those errors accumulate, and the phenomenon is called error catastrophe. It's not the first drug that works by

this mechanism, but it's a very powerful mechanism because there's -- with appropriate drug levels, it's just more and more misincorporation. And you fairly rapidly see viral copies disappear because they're not functional anymore. They don't encode the virus as it's supposed to be.

And that's effective when you look in cell lines, and it's effective when you look in animals. And our Phase I studies, which were, of course, initiated by Ridgeback, and we then acquired our interest in this, our Phase I studies have demonstrated that the compound can be administered in a 5-day course. It is well tolerated, and we achieved levels of drug that should be associated with inhibition of the replication of the virus through this mechanism.

There are ongoing Phase II studies in the eastern seaboard of the United States and also in the U.K. And those studies are -- were small studies, again, designed by Ridgeback to take doses based on Phase I and see, both in the outpatient and inpatient setting, whether you could block viral replication. So those studies are going on. Data are being accrued. They're measuring viral production by repeated swabs and looking at the actual nucleic acid sequence of the virus. So we'll learn something from that.

But the big Phase II studies and Phase III studies are just beginning. So very soon, you'll see posted the large Phase II and then Phase III programs, which we will be initiating globally, and that will be happening within the next few weeks.

I expect enrollment will be fairly rapid because, unfortunately, COVID-19 is very widespread. And so they'll be both in the inpatient and outpatient settings. Individuals with symptoms are eligible for treatment. We believe we have some understanding of where we need to be with respect to the dose. It is a 5-day course of treatment. And the key question will be, number one, do you knock down the virus so that there's less of it? Number two, is that associated with clinical benefit? That should be visible fairly quickly.

We have been in discussions with regulatory agencies, particularly with the FDA on the design of these studies. We've agreed on how they will work and how Phase II leads to Phase III. The initial studies will enroll on the order of 2,000 or more subjects. So we'll get a lot of data, and the data will be extremely informative.

And in the meantime, because we have a lot of confidence in the mechanism, we've secured manufacturing capability to produce tens of millions of doses by the end of the year. So that's -- we're in a position to do a lot of good. I think it stands to reason that if we can say to the world that we can reduce the likelihood -- if you were infected, we can reduce the likelihood that you would be hospitalized or certainly end up in an intensive care unit.

That would have a big effect on the psyche of the world, certainly in the United States but elsewhere as well. We've had a devastating experience here in the United States and for a whole variety of reasons. And we're eager to make inroads into the process, whereby we regain control of our health by preventing people from getting desperately ill from SARS-CoV-2 infection. 4482 is one part of that, so we're enthusiastic about it. We hope those studies are very effective.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Excellent. Let me just ask one final question on the pipeline, and I'm sorry that we are running out of time here. But obviously, Merck is very enthusiastic about its HIV candidate, 8591, given its potential for monthly oral dosing. But true transformation will require co-administration. And could you talk about your level of confidence that you can develop a combination agent that can also be once monthly?

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Well, I have high confidence that we can. But I think we first have to distinguish between the 2 (inaudible) active HIV infection with islatravir as opposed to the prophylaxis indication, right? So I think that the -- we have already begun our combination studies for once-daily treatment with doravirine. We believe that we can go to much longer intervals -- treatment intervals in the treatment setting, and there are other candidates that we can use for those longer intervals.

In the prophylaxis setting, once monthly oral, we think, is easy to achieve as a monotherapy in prophylaxis. And long-duration oral, as we've demonstrated with our implantable, including up to once yearly, is also possible. Islatravir has very special properties. And I should mention that we do have internal candidates that we believe we can combine, but we're also willing to combine with long-acting drugs from others. All of that is being explored, and I think there's a great opportunity there.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Excellent. Wonderful. Well, we should wrap it up there. Thank you very much, Ken and Roger. Really appreciate you joining us today, and we look forward to your continued good progress and updates. Thank you again. You can close out the call.

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**Roger M. Perlmutter** - Merck Research Laboratories - President

No, David, thank you. Thank you.

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