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PRESENTATION

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

So we'll get started with the Merck session. We're delighted to have Merck here, which the company management went through tremendous efforts to be with us here due to weather and elevators and all kinds of stuff. So we deeply appreciate you being with us. Representing the company is Roger Dansey, Senior Vice President of Clinical Research and Oncology; and Teri Loxam, who heads up the Investor Relations effort at Merck.

Of course, Merck is now a leader in immuno-oncology. And if you look at our immuno-oncology model, which we've published many, many times over the last year or 2, we think Merck will be a major player in this market going forward. And more so perhaps, they are secretly becoming a major player in the adjuvant setting. So I hope you don't mind I said that. I think it's true. But that is an opportunity which I think none of us fully understand.

QUESTIONS AND ANSWERS

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

So with that, let's head right into questions, and we'll start out with KEYNOTE-189. So at some point this year, we're going to get the results of both PFS and OS. And help us calibrate our expectations for that data. How would you like us positioned heading into this data readout?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

So thanks, Stephen. Just as a commentary here, and maybe we have to stay a little bit longer than we had planned. So I think we're excited about KEYNOTE-189. It will be presented at AACR. I think titles will be available tomorrow, so the timing will also become available tomorrow. So KEYNOTE-189 is a reprise of 021G. 021G, a small Phase II trial but adequately powered, we believe, the outcome of PFS, which showed over time not just the PFS outcome but a maturing OS signal. And so our hopes, our aspirations around KEYNOTE-189, despite the crossover design, which has potentially the ability to confuse an OS outcome, we have indeed hit on both PFS and OS at the interim. So we're excited with the results. This is an all-comer trial. The results will be presented at AACR. And we believe that these results confirm and extend the observations that were made in 021G.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

So as you say, the results are not only obviously statistically significant but also clinically relevant and that doctors will be impressed by this and use the combination to an even greater extent?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

I think that's our expectation. One of the points, I think we've made multiple times, is we believe this will set a new bar for efficacy.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Okay. Let's chat biomarkers. So we're very familiar with the PD-L1 biomarker. And then, of course, a competitor, Bristol-Myers Squibb, introduced the TMB biomarker. It wasn't a new concept, but it was new to us that it would be in such a high-profile trial. So how are you approaching TMB, and how are you using it in your clinical development front?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

Right. So just to step back a little and give the framework under which KEYTRUDA has been developed. If you look back at the program, you'll note that we have taken the view that monotherapy is something very important to evaluate, and so we have prosecuted a broad monotherapy program to see where single-agent KEYTRUDA can make a difference and beat standard of care will be available. And in that regard, if you've not noticed it this morning, we released that we have had the file acceptance for advanced cervical cancer using pembrolizumab monotherapy. In the monotherapy environment, because of the need to beat the standard of care, and standard of care -- standards of care are standards of care because they work. The requirement or the lack of requirement to be able to enrich the monotherapy outcome such that we can get to a level with a monotherapy that will beat standard of care is something that we've looked at very carefully. And the best example, that is KEYNOTE-024, where we took a high biomarker cut points and we beat a very active chemotherapy combination in frontline lung cancer and not only for PFS and OS but for OR as well, so all 3 endpoints were consistently positive. So from a biomarker perspective, a lot of our assets have been focused on the monotherapy. And with regard to TMB, I think we have evaluated a TMB-like stage, which is MSI high, which is based on the same sort of mechanistic principle of high mutational burden, very high in MSI high, circumstance resulting in increase in the antigen expression. So obviously, from a scientific perspective, we see this validity, and MSI high is already the sort of entrée into that. I think the question that will need to be answered is the clinical utility. And so that will require an evaluation of the data that's presented and a comparison of different trials. Even though indirect comparisons are not necessarily the easiest things to do, they are generally what's available. And again, I would just come back to our 189 approach, which is truthful almost all of our combinations, where we focused in a combination environment on an all-comer population. Where as in the monotherapy environment, we've used the biomarker to try and elevate the responses.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Okay. If there's questions from the audience at any point, please just raise your hand and we'll call

(technical difficulty)

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

trials are being conducted by cooperative groups. We have head and neck efforts. We have gastric cancer. So I think you can get a sense that we are committed to the sort of adjuvant -- in the adjuvant space across multiple tumors.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Okay. Let's move to IDO and talk about ECHO-301. So what gives Merck confidence that ECHO-301 is going to be a successful product?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

So I think that the decision to proceed with Phase III trials using epacadostat in collaboration with Incyte was based on data that was generated in a single-arm fashion but very encouraging. So if you look at the melanoma data, the response rates were in the order of, I think, 57-or-so percent. That's enough to trigger a desire to answer the question formally in a randomized trial. And I think -- I don't think our position has changed. The

data generated to support the Phase III remains at that level, and we will just have to wait for the Phase III readout. Obviously, biologically and mechanistically and from a tolerability perspective, this is a very attractive combination.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

If this study were to fall short of expectations for any sort of reason, what does that mean for the IDO target? Is it still a target that Merck will continue on clinical development in other settings and other tumors? Or would it be a target that you might wish to leave aside and move on to other things?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

I think that's really difficult to speculate beyond seeing the data. So I'm not sure I have an answer. Obviously, if the target turned out not to be clinically relevant, it would be hard to move forward. But ahead of seeing any form of randomized study, it's really hard to speculate what actions we would take or not.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Okay. Recently, Merck started the clinical development of its own IDO1 inhibitor, MK-7162. How is this molecule different than epacadostat?

Teri Loxam - *Merck & Co., Inc. - SVP of IR & Global Communications*

(inaudible)

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

Yes, I don't think we've disclosed any details around our IDO.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Okay. But safe to say there are some aspects to it that you early on view as differentiating, or else you obviously...

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

I think we're interested in the pathway and prosecuting our own trial. So okay, that's what our IDO program represents.

Teri Loxam - *Merck & Co., Inc. - SVP of IR & Global Communications*

And we -- so we acquired a whole host of IDOs, TDOs, IDO/TDO combos as part of our IOmet acquisition a couple of years ago now. And so we've been looking at a whole suite of products that we're looking at moving forward depending on the different needs.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Okay. And what other novel targets -- immuno-oncology novel targets would you say the top 2 or 3 in your eyes right now within your portfolio beyond IDO? What are they?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

Yes. So just to sort of step back a little bit again. If you look at the late-phase development program we have, we have placed multiple efforts around chemotherapy in multiple diseases. So that's the sort of first wave of possible combination readout. And then we have the IDO program. We had just these 2 recent collaborations with both AstraZeneca with the PARP inhibitor and now with Eisai with the VEGF TKI, lenvatinib. I think we're excited by both of those pathways because mechanistically, we believe that they are both relevant in an I-O environment. We think we have the opportunity to prosecute our PARP -- our pembrolizumab program, which is currently in planning. Similarly with lenvatinib, so VEGF TKI, and these are 2 approved agents. Nevertheless, they may result in quite powerful outcomes if we can come up with the right development plans and execute the trials. Then beyond that, in our own internal program, it has really blossomed and increased significantly in size. We now have 20 assets. A couple of them, just to call out by name, I think we're excited by the STING asset, things like LAG-3 and TIGIT. In general, intratumoral approaches look like they're very interesting, not only with our molecules but, for example, with TLR9 as a mechanism. So there's a lot going on. There's a lot of potential opportunity with novel targets. But of course, again, as our late-development program executes, we will set the bar for ourselves as well as everyone else as we're successful or if we're successful with the late-phase program.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Speaking of the STING agonist, when will we see mono and combo data? And how would you think you're positioned versus your chief competition, which appears to be Novartis?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

There is a STING release at AACR, and I think it's preclinical.

Teri Loxam - *Merck & Co., Inc. - SVP of IR & Global Communications*

Yes. Maybe preclinical. Some of the later data, the clinical data is probably a little bit later, but the early data at least is exciting.

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

Yes. I think we're in a good position. We have -- we're in the clinic. I think with our track record, we've demonstrated we can move programs forward quickly. And if we -- if the signal is strong enough, we will execute on that signal.

Teri Loxam - *Merck & Co., Inc. - SVP of IR & Global Communications*

And this is one where we actually leapfrogged the competition. So we were very, very early on, and we're able to get to the clinic very quickly with the STING agonist, and one that we're very excited about.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Okay. Questions from the audience? If we could chat about the collaboration with AstraZeneca for LYNPARZA. Maybe you could tell us first how it's going. And well, why don't we answer that question first and then we'll move on to the next one?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

I think it's going great. So firstly, AstraZeneca has done a fantastic job developing olaparib. Multiple approvals in ovarian cancer and breast cancer. They are obviously deeply embedded in the whole sort of DNA damage repair science, and we are coming up to speed. We see it as exciting. Again, mechanistically, DNA damage is sort of central to cancer biology. And the possibility of either impeding that, for example, with a PARP inhibitor,

or inducing it with chemotherapy and then following with a PARP inhibitor and then combining with pembrolizumab is very exciting. And so I think our approach to developing olaparib with pembrolizumab is to look for opportunities where pembrolizumab may not necessarily have a major development program in place or look for opportunities to follow it or to interleave a PARP inhibitor approach together with pembrolizumab. So you could imagine a situation where in a platinum-sensitive tumor, which is at least in ovarian cancer, where PARP inhibitors have clearly, as olaparib has shown, very high activity. There are multiple different cancers that are platinum-sensitive. It turned out that this is a generalizable phenomenon, that PARP maintenance could work in cancers like bladder and lung and head and neck and so on. You could envision a development plan that would encompass both the PARP inhibitor and pembrolizumab in that disease.

Teri Loxam - *Merck & Co., Inc. - SVP of IR & Global Communications*

And the approach, I would say, you can talk a little bit more about the Eisai deal as well. But from just a deal structure perspective, both the AstraZeneca collaboration as well as Eisai is a way for us to have a very derisked approach to gaining access to commercialized assets that can also above and beyond our monotherapy opportunities can then be combined with KEYTRUDA and that we can participate globally both in the revenues but then also help influence some of the development. And so these were both very structured in very similar ways, with the approach of being able to have the majority of the milestones tied to commercial success and sales success. And that gives us an opportunity to build that over time and really pay for success.

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

Maybe just one more comment, if I may. Look -- I mean, we see KEYTRUDA as an anchor treatment. It's foundational. And so all of our -- if you look back at our development plans, I think we build on our observation. So I think our expectations are that we will build development plans around the PARP inhibitor and build development plans around the VEGF TKI that fit well in the construct of pembrolizumab.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

When you think about the development of the combination of LYNPARZA plus KEYTRUDA, do you think about it more in terms of tumor by tumor or are you more focused on the settings within tumors? Or perhaps the answer is all of the above?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

I think it's probably all of the above because there are 2 components -- the development of PARP inhibitors is focused on biomarkers, things like the BRCA -- the BRCA [uses] and then by extension, other types of DNA damage repair signatures, whether it's DRD or HRRm. So that's one way to go with the treatment approach. And one could imagine combining an I-O together with a PARP inhibitor. But there's also this whole concept of platinum sensitivity and the use of a PARP inhibitor post chemotherapy, which is a very broad -- has very broad potential. So I think we see both of those. And those are -- the biomarkers are sort of cross-tumors and the platinum sensitivity would be within-tumor.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

One novel target I don't think you mentioned, but perhaps you did and I missed it, is CSF-1R. You're working on this, of course, also with MEK inhibition. How excited are you about this particular target?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

I think we are -- they're in the clinic, and I think we are obviously interested in the outcomes. I think it would be difficult to characterize levels of excitement, but we are asking the questions and we'll see if we have a signal we will move forward. Again, if you look at our approach, we really are agnostic as to partner. As long as the combination with KEYTRUDA produces clinically meaningful results, we'll move forward. And the biology

and the science behind these types of combinations is really quite clear. I mean, selumetinib is a MEK, which is obviously something that we now own half of. We are very interested in trying to work out what the role of a MEK inhibitor would be in immuno-oncology, and that's currently under development.

Teri Loxam - *Merck & Co., Inc. - SVP of IR & Global Communications*

And just more broadly, so we have over 400 combinations that we're studying with KEYTRUDA. And we do a lot of work early on in Phase I to identify signals in a setting that is shorter, less costly in the Phase I setting so that we know what to move forward into the larger pivotal trial. And so as we see signals, we are very quick to move forward as we have with some of the other ones that we've talked about. But in the early Phase I setting, it's really difficult, to Roger's point, for us to say one is better than the other until we see that data. And we've always taken a very scientific data approach.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Questions from the audience? So Merck has a multitude of readouts in 2018 in a variety of areas. We talked about just a couple of them, most notably 189. What other ones kind of rise to the top that you think investors should be focused upon?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

Sure. So our lung cancer program has 2 other trials that we believe are key. One is KEYNOTE-407. It's the companion protocol to KEYNOTE-189. This is in squamous carcinoma of the lung. The design elements are essentially the same. This is a crossover design. And the trial is, we believe, adequately powerful, both the PFS and OS readout, and that should be occurring in this calendar year. We have the other trial in lung cancer, KEYNOTE-042, which is a monotherapy approach, which essentially has the opportunity to extend the observations of KEYNOTE-024 down into lower cut points. We haven't discussed what those cut points are, but it is a biomarker-positive trial. And it's a good example of what I was indicating earlier, which is our monotherapy program built in the biomarker at the beginning. There are other cancers. So for example, our head and neck program, KEYNOTE-048, which is a frontline trial, which is a 3-arm comparison of pembro plus chemo versus the extreme regimen versus pembro monotherapy. We'll have a readout. We have esophageal cancer, a monotherapy readout that should be quite proximal. Hepatocellular carcinoma, bladder cancer. And obviously, we have the IDO combination, which we mentioned, which is going to read out in the near term. So we have a lot going on, a lot of trials that potentially could result in pivotal outcomes this year across multiple tumor types.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

I should have asked at the outset, you had mentioned that KEYNOTE-189 will be at AACR and that the abstracts are coming tomorrow. Will there be...

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

Titles tomorrow.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Titles tomorrow. Okay, so there will be no data tomorrow. Okay, okay. So we've talked about a lot of assets in a relatively short amount of time. I'm sure we've missed some in the oncology portfolio of Merck. What assets within the portfolio do you not get asked about that you feel that investors really should be watching, and they very likely could be outside of immuno-oncology? So what would meet that criteria?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

So again, there are 20 molecules in the pipeline. Not to go through all of them. We have a very nice personalized vaccine cancer program in partnership with Moderna. We have our own CTLA-4 molecule, which we have the capacity and the capability to develop further if we should so choose. I do think maybe what I've already tried to say, I think maybe it's a little underappreciated just how much work we're doing, and it's both early and late, how many cancers we are taking on to try and improve an outcome and the sort of the wealth of our development program and the time lines for readout. As I'm sure you can all appreciate, the world is accelerating, and we're part of that acceleration effort. And so it's really just getting an understanding of what our trajectory will look like over the next year is perhaps something that's a little underappreciated.

Teri Loxam - *Merck & Co., Inc. - SVP of IR & Global Communications*

And then beyond oncology, well, Roger Dansey obviously runs the clinical program on the oncology side. Beyond oncology, there's a lot work going on across a number of areas. Vaccines is one that we've been talking about a lot more. We obviously have a workhorse in GARDASIL that has just done terrific globally. Beyond that, though, we've gotten pneumococcal -- our next-generation pneumococcal vaccines moving forward. V114 is the next one up there that we said is going to be going into Phase III. We also have broad programs in RSV and CMV and dengue and others. And so we've got a really rich early pipeline in vaccines that we're moving forward very quickly, and we'll continue to work our way through until late development in those as well. And then beyond that, we've also talked a lot about our infectious disease portfolio, and in particular, our next-generation HIV portfolio that we've become even more excited about. We've got a novel mechanism that has just gone into Phase II. It's MK-8591. It's in combination with doravirine, which we have also just recently filed. And that is -- those are building blocks from which we believe we can build in long-acting HIV regimens and potentially get to a very long-acting combination of products in the HIV space. So there's -- and those are just a few of the pipeline. We've got work underway in a lot of different areas. So while there's a lot of focus near term, obviously, on KEYTRUDA and the oncology portfolio, we continue to build out the other aspects of Merck's portfolio as well.

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

If I may, I'll add one more comment. It's not just breadth of late-development programs. It's breadth of signal finding. If there's a target out there, you can be pretty sure we're evaluating it with someone, whether it's in a collaboration or whether we're doing it ourselves or whether an investigator is evaluating it. So I think our signal detection program is really quite remarkable, and that will feed into the late-development program over time.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Questions from the audience? So CTLA-4 is a controversial target in pharma. What will be the decision -- what does the decision tree look like for you to go ahead and develop your own?

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

Well, we've already decided to proceed with an ipilimumab-pembrolizumab combination in high-expressing lung cancer. And we do want to answer the question definitively, in this biomarker, in which populations can pembrolizumab plus the addition of CTLA-4 improve the outcome? As you know, we've generated data with ipilimumab in melanoma, so we're clearly interested in the target. It's been -- it's clinically validated. How to fit it in and how to develop it further in our hands, I think, is still a work in progress, but we have begun, at least in lung cancer, some of that effort with ipilimumab. And obviously, our own molecule is moving through the clinic, and that is -- would be readily fit into our general CTLA-4 plan.

Teri Loxam - *Merck & Co., Inc. - SVP of IR & Global Communications*

And to Roger's earlier point, I think all of our efforts are now looking at the bar that we have set. And especially, as we have the Phase III lung cancer trial reading out with KEYNOTE-189 in the chemo combo, all of the trials and all of our decision-making is relative to the new bars.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

We are actually out of time. So I'd like to thank you both for a very nice discussion, and we'll move on to the next session. So thank you so much.

Roger Dansey - *Merck & Co., Inc. - SVP of Clinical Research - Oncology*

Thank you.

Teri Loxam - *Merck & Co., Inc. - SVP of IR & Global Communications*

Thank you.