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MRK - Merck & Co Inc at Morgan Stanley Global Healthcare Conference

EVENT DATE/TIME: SEPTEMBER 12, 2016 / 5:05PM GMT

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QUESTIONS AND ANSWERS

David Risinger - *Morgan Stanley - Analyst*

All right. So, thanks, everybody for joining us for our session with Merck. I do need to refer you to disclosures, including personal holdings mentions, at www.morganstanley.com/researchdisclosures.

It's very much my pleasure to welcome the CEO of Merck, Ken Frazier, and the head of R&D, Roger Perlmutter. We appreciate you both taking the time with us today.

I thought that I would just start out with a high level question for you, Ken, regarding your vision for Merck and what you think investors may under appreciate about the Company's prospects.

Ken Frazier - *Merck & Co., Inc. - Chairman, CEO*

Okay. Well, first of all, thanks for having us here. And I want to thank all the people in the audience for showing up to listen to us.

When people ask me about my vision for Merck, I have to say the Company's 125 years old. And it has always had the same mission and the same purpose, which is to be among the very best research-based pharmaceutical companies addressing unmet medical needs.

And so, what we try to do is to make sure that we are focusing in those areas where we can make the greatest contributions. Our hope is to have a broad and differentiated portfolio. And we think that, going forward, we are in a position to do that.

You asked what do I think investors under appreciate. I think -- first of all, I think the opportunity in front of us for immuno-oncology is immense. I think people all agree with that, but I think it's bigger than what most people think it will be over time.

I think another thing that I frequently see is that people underestimate the importance of Merck being a global company and the strength of this Company in markets outside the US. People tend to be very US focused.

And then I think the last thing I would say is that there are some great opportunities coming along. I would just exemplify that by talking about Alzheimer's and the fact that we believe our BACE program is going to give us some very important information at some point about the dominant hypothesis.

So, I think we have a good pipeline. I think we're a globally strong Company. And in particular, I think the immuno-oncology opportunity that's imminent is an important one.

David Risinger - *Morgan Stanley - Analyst*

That's great. And before we dive into immuno-oncology, obviously Merck has significantly reengineered its cost structure in recent years. But you also have opportunities for additional efficiencies, if you could talk about those and how we should think about those opportunities looking forward.

Ken Frazier - *Merck & Co., Inc. - Chairman, CEO*

Okay. So, I think we've done a very good job over the past three years. We've taken about $2.5 billion out of our cost base. We're ahead of where we said we would be as it relates to that.

As I see the next few years, I would say that while we're going to continue to try to improve on our efficiency, what's really important is to make sure that we take advantage of the opportunities in front of us.

And so, with respect to, for example, KEYTRUDA and the multiple tumor types that we're talking about, I would expect that we will continue to reallocate resources to those areas of growth. But I think the challenges that we're living with today, in terms of the costs associated with a once in a lifetime opportunity like KEYTRUDA, are probably going to put a little bit more pressure on us in terms of the cost of developing a drug like KEYTRUDA.

So, I see us as a Company that's going to continue to be focused on continuous improvement. We've committed to a leveraged P&L. But at the same time, I think it would be remiss of us not to take advantage of the opportunity that's right in front of us with KEYTRUDA by fully investing in that opportunity.

And I would also say that I think -- again, coming back to what I said before, I think the long term opportunity associated with that molecule and that class is still underestimated.

David Risinger - *Morgan Stanley - Analyst*

That's very helpful. Roger, well, first of all to both of you, congrats on the success of KEYNOTE-024. Could you just talk about your -- how you would frame the outlook in both first line lung cancer and also second line lung cancer over time, and how you see that data specifically sort of supercharging Merck in lung cancer?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Well, David, first of all, I think everyone recognizes the opportunity that exists in lung cancer. We designed the KEYNOTE-024 study to position KEYTRUDA to show what it could do in the best possible circumstance, namely that we had learned that, in individuals who already had an ongoing immune response directed against tumor as judge by the expression of the PD-L1 biomarker, that we could improve responses in that population.

We'd learned from our second line data. We've published data that showed that there was a dose response relationship between PD-L1 expression and outcomes in the second line setting. So, naturally it was best to look in the first line setting in those individuals who were expressing the highest levels of PD-L1, which for our assay was those above 50%.

The fact that we were able to do a study that had only 300 patients in it and get a very significant result, not just with respect to progression-free survival but also with respect to overall survival, gives you a sense of the significance of the actual finding.

And that's -- obviously, I can't discuss the data. We're going to have a chance to see the data all together at ESMO in a little less than a month, and there will be also a publication describing these data.

But the data are very powerful. And I think that the result of that will be that oncologists, once they have a chance to look at the data and think about them, will be eager to use KEYTRUDA in the first line lung cancer setting.

I also think that, because oncologists will test for PD-L1 in first line, that this will be -- will tend to generalize testing more than it has to this point in second line, and provides an opportunity for enhanced KEYTRUDA use in the second line. Keep in mind that we will have -- we expect US approval for our 010 data coming forward in October for KEYTRUDA in the second line non-small cell lung cancer setting.

So, I think broadly speaking in lung cancer, there is a big opportunity for us to do a lot of good. And of course, that will enhance the commercial presence of the Company, actually throughout oncology but certainly with respect to KEYTRUDA in lung.

David Risinger - *Morgan Stanley - Analyst*

Got it. And historically I think investors have thought of Merck as being behind in combination development because you don't own certain assets. But it seems to me that you have some flexibility to pursue combinations, and you're not beholden to specific assets or dosing them the way maybe the originator would choose to dose them. So, could you speak to opportunities to potentially add, for example, Yervoy lines in clinical trials or at different doses than potentially Bristol would add, or to start new trials looking at CTLA-4 combinations?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

I'm happy to do so. First of all, I think everyone recognizes that experience tells us that over time combination therapy is going to be extremely important in cancer patients. It always has been. It will be. And in fact, combination therapy is common throughout the spectrum of serious illness. Why wouldn't it be?

The key is to manage the benefit-risk ratio. You want to have maximal benefit and minimize the risk. All drugs have adverse experiences associated with them. We want to minimize that as much as possible.

But what we know from preclinical work is that PD-1 blockade in a preclinical setting works well in combination with virtually every other kind of cancer therapy that has previously been studied. So, that includes cytotoxic chemotherapy. That includes radiotherapy. That includes targeted therapy. That includes other immune mechanisms.

And we are finding out in the clinic that the same thing may well be true. We have demonstrated with KEYTRUDA that one can see responses that look somewhat better in combination with, for example, the Incyte IDO1 inhibitor where we have Phase III studies ongoing; with TVEC, the oncolytic virus that Amgen has developed and registered.

But in addition, with traditional cytotoxic chemotherapy, and of course there's also data from us, and even more data from our colleagues at Bristol-Myers showing a combination with ipilimumab, the question is which ones of these different therapies are going to be best.

For example, if you look at cytotoxic chemotherapy, we presented at ASCO in June data from our non-small cell lunge cancer setting in the first line showing a 70% response rate in combination with Alimta and platinum doublet therapy in patients in first line.

Now, that's really quite powerful. That's an amazing result, KEYTRUDA in combination with traditional chemotherapy, but of course it was just 24 patients. Time will tell whether or not that result is generalizable and whether response rates actually translate into progression attenuation and improved survival.

But it suggests that there's a lot of work to describe how best to pursue KEYTRUDA in combination with other therapies. We have enormous flexibility to do that. And beyond that flexibility with respect to known agents, we also have our own experimental agents.

So, we have GITR directed agonist antibody. We have, in addition, a LAG-3 antibody in clinical trials, a CEACAM antibody in clinical trials. We have a number of approaches that we've taken where we say there might be an opportunity here for a combined immuno-oncology approach to benefit patients who don't have enough response with PD-1 alone.

In the future, there will be combination therapies. The question is which one is the right one and how best to bring those benefits to patients. And I do think we are in a very good position.

I guess the last thing I should say is, if you look at Clinicaltrials.gov, you see that there are more than 100 clinicals trials that we have currently underway in various different combinations. It's an astonishing array of important studies.

And they're yielding data, and we're going to have a chance to present these data just as we did at ASCO in June. We'll have a chance to present these data going forward at upcoming scientific meetings. So, I think there's a lot to learn.

David Risinger - *Morgan Stanley - Analyst*

And just to follow up briefly, so you mentioned GITR, LAG-3, CEACAM. Are any of these close to moving into registrational studies?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Well, they're all close. All they have to do is show us that they work, right? As soon as we see that, we're ready to move on registrational studies.

David Risinger - *Morgan Stanley - Analyst*

And what's the timing for seeing that or not seeing it?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

It is not expected, for most of these agents, that you'll see single agent activity. So, you really don't have a chance until you have the opportunity to first demonstrate that the single agent is safe by itself, and then secondly that you can use it in combination, which requires some adjustments of dose and schedule.

For the GITR antibody, for example, we are already in combination studies with KEYTRUDA. The others are coming along. So, we don't have -- I mean we're all eager to see this advance still more rapidly, but we don't have long to wait.

David Risinger - *Morgan Stanley - Analyst*

Got it. Let me pause there and see if there are questions from the audience.

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

I think they like your questioning style, David.

David Risinger - *Morgan Stanley - Analyst*

So, I wanted to transition back to you, Ken. You were recently the Head of PhRMA, the trade group. There's been a lot of pricing noise and scrutiny recently. For those that pay attention to Merck closely, they can see that Merck has not been as aggressive as many peers, many of your compatriots within the pharma group. And obviously your focus on R&D is critical here. Your focus is to bring new value to medicines and to society.

But maybe you could still -- so, it's not really a Merck problem or a specific issue associated with Merck, but if you could just talk about the pricing environment, what you see going forward. And then if you could weave in any comments on how you're thinking about the threat from the Part B demo at Merck, how you're thinking about the potential threat from IPAB, etc., that would be great.

Ken Frazier - *Merck & Co., Inc. - Chairman, CEO*

Okay. Well, thanks for the question. It's a very broad one, but a very important one.

So, let me start by saying we're right now in a season, a pretty heated rhetoric period in presidential campaign. And it's not unusual that, when there are newspaper headlines like we got recently with respect to the EpiPen, that people jump on that.

So, I think the rhetoric is very hot right now. My sense of it is that there are a lot of people in Washington, lawmakers and others, who do see the importance of those companies that are investing significant amounts of money in R&D in the hopes of doing something about some of the biggest health problems that we have, like Alzheimer's, which will cost society over $1 trillion in two or three decades if we don't have a disease altering mechanism. So, I think that we have to put the rhetoric over here.

But the reality of the world is that there will continue to be pricing pressures. And I'm glad that you are able to see and acknowledge that Merck has always taken a little bit of a different approach going way back. And we've always tried to say, well, what's the right value-based approach that we can take? What's a responsible approach?

We look at each drug and we say, okay, what is the unique therapeutic benefit that that drug provides? What's the benefit to patients? And we've tried to take, for example, a measured approach. You saw with the hepatitis C we took a different approach than maybe some other people did with respect to the pricing of their drug.

So, I think we've tried to be responsible. What makes me somewhat optimistic is that, when Secretary Clinton put out her comments about pricing recently and her plans around pricing, she was careful to distinguish between those companies that buy products, jack up the prices, and those companies that actually invest in R&D.

And we've tried to have communications with her campaign, and we've tried to impress that distinction on her. And to see that come through in her policy statements gives me some reason to be encouraged going forward.

I would say the other couple of things that I would say real quickly are we continue to work with our customers in this area, the large managed care plans, with respect to value-based approaches where we can both use drugs in a way that benefit patients as well as show a greater efficiency in terms of how those plans spend their money.

So, I'll use diabetes as an example. We are working with a number of customers now on approaches that would reward us for the number of patients who actually get to their goals, their HbA1c goals. And I think those are things that in the future will actually be beneficial not only to our Company, because we have a drug like Januvia that is actually very helpful in that context, but it also will be helpful to our patients.

Now, you asked a couple of quick questions at the end about the demo -- the Part B demo as well as IPAB. I think on the Part B demo what I would say is that a lot of patient groups, prominent patient groups, have been very outspoken about the fact that this is bad policy from the standpoint of restricting access to the sickest of all patients.

We join in that. We support that point of view. I think a lot of us also think the concept of a demo is not consistent with having 49 states in a mandatory program.

And so, we continue to work with our supporters in Washington to help them challenge the approach that's being taken around the Part B Demo. I think there have been a lot of criticisms. It will remain to be seen what the administration does with those criticisms.

And on IPAB, fortunately it wasn't triggered yet. It may be triggered in the next couple of years. Again, if you look at where healthcare expenditures are, it's not that drugs are driving the overall healthcare budget up.

And I think we've got to really work with lawmakers and regulators to help them understand that, if we're really going to get the healthcare spend under control, drugs can actually be a positive contributor to that, reducing things like hospitalization costs and things of that nature.

So, we'll continue to work to do the best that we can to help lawmakers and regulators think about better ways of preserving and expanding our healthcare expenditures without doing things like IPAB.

David Risinger - *Morgan Stanley - Analyst*

Got it. Thank you. Maybe since you mentioned Alzheimer's, it would be helpful for you, Roger, to talk about the BACE trial that's reporting next year. Obviously, it was designed in a fashion to enroll all-comers. It isn't screening out patients that may lack plaque on their brain.

I don't know if you have any estimate of what percentage of patients might be enrolled that have dementia rather than Alzheimer's. And the trial is also enrolling both mild and moderate patients. The field has been migrating towards studying more mild patients, if you could comment on that as well. And then finally, if solanezumab were to unfortunately fail later this year, would that influence your level of optimism about the BACE or not?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Let me I guess start with the last question because it's the simplest. And that is that solanezumab has failed twice already in Phase III, so obviously I'm proceeding anyway. And the results with solanezumab doesn't actually affect my thinking too much because of the way in which that was -- that program was developed.

What they're hoping for in their study is, just as you say, if we can get to patients earlier on before there has been substantial neuronal damage, loss of neuronal connectivity and loss of the ability to actually process thoughts, that we can preserve more of the neuronal infrastructure and hence preserve cognitive performance.

That just seems so sensible and straightforward one has to believe that that's true. Indeed, the genetic data with respect to BACE, as I've said to many of you in other settings, are -- just couldn't be stronger. Individuals who have a higher level of BACE activity, predicted by virtue of the sequence variation in BACE and beta-secretase, have a higher risk of developing dementia at some point in their life. Those that have been activity have less risk.

And my general feeling is that with a BACE inhibitor, if it's safe enough and can be administered well enough, that administering that drug will lower the risk of dementia for everyone. It will attenuate that risk. It will slow down that process provided that I can get in early enough. If I could get a BACE inhibitor in, well, the genetic data would say at the time of conception, then it should be better for all of us.

Of course, we can't do that experiment. We have to start with individuals who could actually gain some tangible benefit from therapy, and that's why we start with mild to moderate studies. We also have a study going on in an earlier population, those with minimal cognitive impairment in which there's a prior PET scan demonstrating the existence of plaque and that sort of thing.

I think the field is advancing. We continue to learn more. But right now the evidence that we have supports the view that a-beta peptide is in fact toxic, does play a role in the progression of Alzheimer's dementia, and indeed if you believe the genetic data, dementia of all-cause, and therefore the BACE inhibitor should be effective over time.

Whether it will be effective enough in the mild to moderate setting, I think we'll just have to wait and see. But we'll find out next year, and I've got my fingers crossed. I hope you do too.

David Risinger - *Morgan Stanley - Analyst*

Thank you. And then one more question on the pipeline. Could you just talk about other agents in the pipeline that you think investors should be focusing on in the next couple of years?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Well, I think it depends on your time horizon, but we have a very large pipeline and some things to be really excited about. Must of this is lost in the discussion, of course, about immuno-oncology. Even those late stage programs like our collaboration with Pfizer on ertugliflozin, which is -- we'll be filing before the end of the year and which will add dimension -- further dimension to our diabetes program.

But going forward, if you look at what we're doing in infectious disease as we attack the extended spectrum beta-lactamases and provide additional benefit to individuals suffering from bacterial infection, the work we're doing in CMV with letermovir, the really extraordinary new data that we're generating in the HIV setting, first of all with doravirine, which is in Phase III and which has properties very much like efavirenz, we believe, but a substantially better safety profile which could lead it to be one of the dominant agents used in HIV treatment and the treatment of that chronic infection, but beyond that some earlier stage molecules that look very exciting that we're very enthusiastic about.

And then there's our vaccine portfolio. And the early development in vaccines I think is really quite powerful, including not just our own efforts with respect to traditional carbohydrate or carbohydrate-protein conjugate vaccines, but as well the work that we have been doing with Moderna to develop novel vaccine approaches for a variety of different infections. We'll have a chance to present some of that data I hope relatively soon. It's really very exciting and I think could be transformational for the vaccine world.

So, as I always say in these formats, I love all my children. I'd like all of them to go to college. We're eager to support them. Some of them go on time. Some of them have to be red shirted. And some of the go to elite centers and others may end up going to trade school. But we are intending to develop the entire portfolio of programs.

David Risinger - *Morgan Stanley - Analyst*

Great. And actually one more R&D related question. Could you just talk about your PD-L1 assay and compare and contrast it with Bristol's?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Sure.

David Risinger - *Morgan Stanley - Analyst*

There are some questions about the quality of Bristol's assay and whether that may or may not have played a role in their trial failure.

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

I certainly can't comment about that. What I can say is that we have developed a PD-L1 immunohistochemistry assay. The key -- the immunohistochemistry really is fairly straightforward, the detection of the PD-L1 protein.

It's more a question of how to decide what represents positive. So, whether it's our assay or the Bristol-Myers' assay, the Roche assay, or AstraZeneca assays, the question is which cells do you look at? Are they the tumor cells, the inflammatory cells, some combination of them, cells that are infiltrating other cells, and what percentage of them are positive and how you decide where the cut point is.

There is a project now going on, because I think all of us recognized that it would be better to have one gold standard assay. There is a project going on to try and reconcile how these assays perform, one compared to another. This is being conducted. All of us are participating, but it's an independent group.

And we're beginning to get some information on the behavior of the different assays. It won't take terribly long until we'll have something like a Rosetta Stone that permits us to translate one assay results into another. The evidence that we have seen certainly indicate that the Bristol-Myers assay performs very similarly to our own assay.

David Risinger - *Morgan Stanley - Analyst*

Okay, thank you. Ken, could you discuss your business development strategy? It seems that this year you have been a little bit more optimistic about deals and the potential for deal related activity, but would love to hear it from you directly.

Ken Frazier - *Merck & Co., Inc. - Chairman, CEO*

So, let me start by saying that's the critical aspect of our overall strategy, our innovation strategy. We think a company like Merck can't expect to be successful without being very effective in finding the best external science. And so, we're actively involved.

A senior committee of myself, our CFO, Rob Davis, our Head of Commercial, Adam Schechter, Roger, and I meet regularly to scan the universe with the help of our professionals to look at the best scientific opportunities out there.

I'm excited by the fact that so much good science is going on out in the outside world. I'm a little bit pleased that some of the valuations have come back closer to what I would think to be normal, although they still are expensive.

Things out there are expensive, and particularly late stage things. There are no undervalued late stage assets. Some of the recent deals that got publicized and the prices that were paid were pretty eye-popping prices.

So, I would say that we're continuing to scan the universe for the best scientific opportunities. We've always said we're going to be financial disciplined. We're going to do deals in a way that can create value for our shareholders.

And just keep watching this space, because we have a strong balance sheet. We can do deals across the entire spectrum of development. We can do deals across spectrum of size. And we'll do those deals that are good at enhancing our pipeline.

We've said we're not in favor of doing deals that are simple cost synergy deals because that doesn't help us scientifically. But we're eager to get the deals done but, at the same time, disciplined.

David Risinger - *Morgan Stanley - Analyst*

Great. Well, is there a final question from the audience? If not, we are out of time. All right, we should probably wrap it up there so the next speakers can get started on time as well. Thanks so much for joining us today.

Ken Frazier - *Merck & Co., Inc. - Chairman, CEO*

Thank you.

David Risinger - *Morgan Stanley - Analyst*

We appreciate it. Thanks.
