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EDITED TRANSCRIPT

MRK - Merck & Co Inc at Morgan Stanley Healthcare Conference

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CORPORATE PARTICIPANTS

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

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*

All right. Busy times for Merck, so we're getting started a few minutes late, but we very much appreciate the Merck management team being here today. So I just need to refer you to disclaimers at www.morganstanley.com/researchdisclosures.

It's my pleasure to welcome Ken Frazier and Roger Perlmutter. Ken serves as the President and CEO. He originally joined Merck in 1992 as General Counsel and Secretary of the Astra-Merck joint venture. Took on positions of increasing responsibility and was named CEO of Merck in 2011.

Roger has served as Executive Vice President and President of Merck Research Labs since 2013. He rejoined Merck after serving as Head of R&D at Amgen from 2001 to 2012. And thanks again both for joining us today.

QUESTIONS AND ANSWERS

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

I thought it would be great, Ken, to just start out with asking you to talk about your vision for Merck and how you want to develop the company going forward.

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

So thank you, Dave, for having us, and thank you for your interest to the audience.

When I think about my vision of Merck, it's really sort of the heritage of Merck, which ultimately comes down to being focused on translating cutting-edge science in the medically important products. And that is what we've done consistently well to be a company that's 126 years old now. And as I move forward, that's what I think about.

And so what does that mean in practical terms? So first of all, I think a company like Merck is only going to be successful if it can continue to recruit and retain the very best scientists. And under Roger's leadership, a lot has been done to both streamline and rejuvenate our R&D organization in such a way that I am very confident over the long term that we will be able to continue to invent important products.

I'll just say that I had the opportunity to visit some of the new discovery hubs, which we've put up in the last couple of years in Cambridge, Massachusetts as well as South San Francisco. And when you're in there, it's a beehive of activity of really, really smart young people who are really engaged in doing important work, and they know that the company stands behind that. So that's something that I think people don't get to hear about very often when people talk about their company.

Then going forward from that, let's just talk about the things that are nearer term, right. So I'm very excited by our oncology franchise. And I just have to say, going back to my first comment about the importance of a company that's focused on doing science in the right areas and the right

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way, and I don't want to sound immodest, I don't think there are many people who 3 years ago would have thought Merck would be where it is in oncology at all. I mean, the reality of the world is, it's a very tough field. We had some very formidable competitors who we respect very much, but it really does go to show that you can translate that scientific ability into a success. And that's not the only time. I mean, if you look at JANUVIA, our biggest product now, we never were in diabetes before that. But it's the ability to look at those scientific opportunities, to put those resources behind them and then go after. GARDASIL is another example.

So I'm very excited about our oncology franchise, and Roger can talk about that. It's not just the fact that we now have 10 indications in 5 tumor types for KEYTRUDA. It's also the excitement that we have with the deal that we did with AstraZeneca to bring in 50% of LYNPARZA, another tremendous opportunity in the PARP field going forward. It's the molecules that are behind KEYTRUDA and immuno-oncology. But it's also outside the context of oncology, excitement in areas like vaccines, which has been a traditional field for Merck and an area where we've got some really exciting programs going in addition to GARDASIL 9, which continues to grow strongly. I'm very excited about the work that we're doing in HIV, another area that continues to be a very important area for the world going forward with some very exciting programs.

And then I think a very underappreciated aspect of Merck is the work that's going on in Animal Health, which, if we treated that like one product, it would be a very important growth driver for the company.

So all in all, I mean, if you ask me about my vision for Merck, it feels a little bit like I shouldn't be talking about Ken Frazier's vision for a company that's been around for 125 years, and it's made a made huge impact on human health. I hope that during our period together, we can do what little we can to make sure that the company can sustainably innovate in a way that makes a difference to humanity.

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

That's great. And maybe we can just translate that to the numbers a little bit and...

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

Okay. Numbers are important, too.

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

Be helpful for you to talk about how you see revenue growth prospects and margin enhancement potential at Merck.

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

So let me just say that I think, coming back to KEYTRUDA, I think there's a tremendous opportunity in that field alone to continue to drive revenue going forward. As it relates to margins, we're very much focused over the long term on having a leveraged P&L. But at the same time, KEYTRUDA is an unprecedented opportunity for us. And Roger refers to it often as a pipeline and a product. They're -- all of these indications that we can pursue through our clinical development organization. There're the commercial opportunities that come along as a result of the successes in the clinical operation, and we feel it's our obligation to invest both in the R&D side of that and the commercialization side of that in the short term. I think in this field -- as you think about the field going forward, it's going to be really important for us to take advantage of the leadership position that we think that we have, particularly in the lung indication going forward. And so I would not say in the short term, we're likely to produce the kind of leverage in our P&L that we want to over the long term, but I think it makes sense for us to invest and invest carefully. As the senior management team, we look at every other expenditure in the company, and we say, now how can we take money that we're spending only here and move it over here so that we can actually have the best financial picture as well as having the right kind of investment in those areas of growth going forward?

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

Okay, that's very helpful. So maybe, Roger, we could transition to KEYTRUDA. And it'd be helpful for you to maybe peel back the onion a little bit, talk about recent developments, and then we could transition to the near-term news flow that's forthcoming.

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

Right. Thanks, David. I mean, first of all, it's worthwhile emphasizing that we are still at a very early point in the development of KEYTRUDA and, more broadly, the immuno-oncology field. If you think back, KEYTRUDA was the first PD-1-directed therapy registered in the United States, and it was just 3 years ago in September of 2014 and 3 years later, as Ken says, this very large set of indications that have resulted from a very focused and committed development program for KEYTRUDA. I've said previously that the first and most important thing we needed to understand was how well did KEYTRUDA behave as a monotherapy after we had our initial demonstration of its value in treating advanced malignant melanoma. And it was only with that understanding of monotherapy that we'd be able to go out and begin to explore combinations in a sensible way, taking advantage of an increasing mechanistic understanding that we're developing at our research hubs, which, frankly, are a ferment of exciting scientific progress, as Ken mentioned. So we can say now that we've made a lot of progress on monotherapy. And we understand more or less how KEYTRUDA behaves in a whole variety of settings, whether that's in melanoma, in PD-L1-positive lung cancer, in head and neck cancer, in urothelial cancer, in classic Hodgkin lymphoma and, interestingly, in this patient population of -- involving in a whole broad range of tumor types in which there is evidence of microsatellite instability and, hence, a, we presume, a presentation of a set of recognition targets for T lymphocytes that have been unleashed by virtue of the action of KEYTRUDA. But going forward, the combinations look very, very powerful. If you look at the data that we presented just at the recent European Society for Medical Oncology meetings this past weekend, the 021 G data, we previously gained registration for this in the United States, under review in Europe, demonstrates that a combination of classical chemotherapy, including pemetrexed in the non-small cell lung cancer setting, in the first-line setting, gives really spectacular results with chemotherapy. And people have been concerned about the overall survival result, but I think we could see, as time goes on, how with 18 months of follow-up exactly how that -- how good that is. But we can see combinations with targeted therapies. For example, axitinib or lenvatinib in renal cell carcinoma, we see combinations with oncolytic viruses, the TVEC data, for example, which were represented. Combinations with IDO1 inhibitors. More or less, KEYTRUDA can partner with almost any kind of therapy that either directly kills tumor cells or improves immune function to yield a better result in cancer therapy. And we are in the process of defining exactly which patients benefit most from which combinations. And over the next few years, we're going to see that play out to a dramatic extent.

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

That's very helpful. And with respect to 189, so the near-term read-out, maybe you could talk about the bar that 021G has set not only actually for 189 but for competitors that are set to report our first-line lung results soon.

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

Right. So the 021G study was a very small, randomized study that compared roughly 60 patients per arm, looking at traditional chemotherapy with pemetrexed either by itself or in combination with KEYTRUDA. And the question was asked, does KEYTRUDA provide additional benefit to patients receiving chemotherapy? The primary endpoint was progression-free survival, and the results were very impressive, with a hazard ratio of 0.5, meaning that you were twice as likely to proceed without progression if you were receiving KEYTRUDA as compared to not receiving KEYTRUDA. The initial data were presented at ASCO last year, at which time overall survival data were quite immature. Now with 18 months of follow-up, we can say that overall survival is certainly trending in the right direction, with evidence that there could be a survival effect. We no longer have statistical power to show that because the study has been going on for a while. But it's important to emphasize that with a very small study, just around 60 patients per group, we had this dramatic effect that was easily recognizable and had a very strong p-value. The 189 study was designed really before we had these data as a confirmatory study of much larger size. But the actual design of the study is exactly the same as 021G. Our expectation was really that we would not see a hazard ratio of 0.5 but something closer to 0.7. So the study is powered more for that kind of result. And it will support, we believe, the 021G study. Where the numbers will fall out, we don't know exactly. But I think it does emphasize that in any combination going forward, one needs to see this kind of treatment effect and to see this treatment effect under circumstances where the adverse

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experience profile represents, at worst, what we know from a combination of chemotherapy plus KEYTRUDA, 2 sets of adverse experiences, which, at this point in time, oncologists have quite a lot of confidence in managing. So that's sort of a floor position for any future combinations that one would look at in the non-small cell lung cancer setting in first-line treatment of patients with advanced malignancy. Over time, we'll learn about how best to treat patients, for example, in the adjuvant setting and in other circumstances as we become better at diagnosing early cancer because we have, frankly, better treatments.

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

And the trial should be wrapping up now. Do you have enough events?

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

We don't yet, but we're sort of following it all the time. The 189 study is an event-driven trial, as you suggest. And as the events finally reach the right tipping point, then the study will go to statistical analysis, database cleaning and all the rest of it, and then we'll be able to read out the results. Should be fairly soon.

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

And could you just comment on crossover and how investors should think about the risk of crossover in 189?

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

Yes. Yes. I think that we recognize -- I think everyone recognizes in the current circumstance, where we've demonstrated that KEYTRUDA therapy adds enormous value in the treatment of patients with advanced malignancy, certainly advanced malignancy in the lung, that anyone who is randomized to therapy that doesn't include KEYTRUDA and progresses will likely cross over to KEYTRUDA therapy. They would do so no matter what. And if it were not KEYTRUDA therapy, then they would seek some other PD-1 or PD-L1 therapy. So crossover is a reality. If you look at the 021G study, at this point, about 75% of those patients who could cross over based on their original assignment have crossed over to additional therapy. And that's fairly typical for what we've seen in other studies. Nevertheless, the treatment effect, as we judge it now, seems robust. It is moving out, it's a small study, of course, but it is moving out very much in the right direction, which suggests, at least at this level of magnification, that having KEYTRUDA and chemotherapy at the first possible instance is better than KEYTRUDA therapy as a second-line treatment in people who have already received chemotherapy. So that gives us some confidence that although there will be substantial crossover in the 189 study given its heft, given the size of the study, that we have a good opportunity, if we look at the follow-up for long enough, to see a meaningful effect on overall survival.

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

Great. I want to say congrats on the AstraZeneca deal but look ahead and say, what's next? How do you think about external deal opportunities? Clearly, Merck has the balance sheet to do a lot more.

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

So we do have the firepower to do more. But I do think that the AstraZeneca deal was a terrific deal for us. I mean, it gives us access to a PARP inhibitor that is already filed and, as Roger will say, AstraZeneca has done a lot of very excellent scientific work for. And so we're able to get into that and at a 50% share value with paying essentially $1.5 billion up front. We -- the whole deal could be worth $8 billion, but it's important to recognize that we only paid 3/4 of that. In effect, it's a success. There's approval milestones. There's sales milestones. And sales milestones are by far the most important milestones in a deal. So if we end up paying that money, it will be because it's a really large drug. And we think this is the

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kind of drug that can have a real impact on a company, a significant impact, particularly in that period where JANUVIA is going off-patent. Having said that, you don't get these opportunities every day and have that kind of partnership. And so we're going to continue to look at bolt-on opportunities, and we're looking for things particularly to augment our early Phase II pipeline. We have to say it's challenging to find high-quality assets. And when you do find high-quality assets, it tends to be a bidding war often for those things, and we want to make sure that we are not overly conservative in how we think about these things financially. And we want to make sure that we put through a portfolio of opportunities for us to continue to grow the company. Those are really important aspects for us. But at the same time, there are a lot of people out there competing for a scarce number of assets, and we have to just make sure that we're financially disciplined as well as focused on our long-term growth.

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

Great, that's very helpful. Let me pause and see if there are any questions from the audience.

Yes?

Unidentified Analyst

Roger, I'd love your take on the competitive landscape in I-O. For example, Regeneron was in the room a few hours ago, saying they're excited about their PD-1 and they think they could get in the game even though they're pretty late and they'll -- I think they look at you and Bristol and say, look how fast fortunes can change. Like in 5 years, maybe we could be a big player, too. I mean, I guess the question is, how real is your first-mover advantage when we see other players trying to get in at this point? What's your take on how likely it is that they could put it in, in KEYTRUDA?

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

Well, it's very hard to handicap that. I think that there is -- it's always been the case that for practitioners generally and certainly for oncologists, they're very data driven, but they become used to managing patients in a particular way by virtue of the fact that we have been in the market for some time. We were the first to the market in this field, and we have, by far and away, the largest program with something on the order of 550 trials on ClinicalTrials.gov. But there's an awful lot of patient data around the world that has accrued with respect to the use of KEYTRUDA in the major malignancies, particularly in non-small cell lung cancer. That doesn't mean it's impossible for someone else to penetrate the market, but you'd like to hope. I mean, I just -- on behalf of patients everywhere, I'd like to hope that people are going to come to the market with something better and not come to the market with something where they hope in one way or another they can manage to gain penetration. So I'd like to know what's the distinguishing feature of any new therapy that's brought forward. Our goal within Merck is to use KEYTRUDA as a platform to build ever-better strategies for intervening in patients who suffer from malignant disease. And my goal is to take those kinds of response rates that we see, which are very impressive but typically on the order of 20% to 30% response rates and maybe 50% disease control rates and get them up double or more. I mean, sure, we'd like to be controlling 99%. And what does it take to do that? And I don't think what it takes to do that at this point is bringing forward another antibody directed against PD-1 or PD-L1. I think it takes something much more profound than that, and it takes kind of an intimate and detailed understanding of how these molecules work, which we have been developing over time.

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

Other questions from the audience?

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

Well, I'll just say I think, picking up from what Roger was saying, I think the fact that we have such a broad set of studies will actually create sort of a barrier to entry for people coming in. I mean, they'll have to decide whether or not they want to study these kinds of drugs and prove that they

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have some benefit over and above what we've now established. And I think that's not an easy thing to do when you have to compare yourself to a regimen that people know is an effective regimen like KEYTRUDA and chemotherapy. It's not as easy to come in as it is with a blank slate.

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

Maybe if we could just transition to the commercial side. It'd be helpful to get your perspective on the payer landscape. So payer pressures persist. Payers are increasingly trying to constrain access and extract greater rebates. Could you talk about Merck's recent experience and the outlook for 2018 and whether we should expect any formulary changes of note?

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

So let me start by saying from a strategic standpoint, that situation that you're talking about with payers continuing to constrain access and to press down on -- in terms of pricing pressure is the reason why we have our strategies for going after innovative things that actually make a difference. Because to the extent that you actually are focused on those things that make a difference, you're going to feel a lot less pressure. And you find you'll face a category for which there are multiple drugs that are proven to be useful. So we see the greatest amount of pressure, for example, with respect to DULERA and JANUVIA because there are multiple drugs that can be substituted for those drugs. As we look to 2018, we find ourselves in a situation where we continue to have very good, broad formulary access. But incrementally, we have to pay a little bit more for that formulary access in terms of rebates and discounts. And so with JANUVIA, which is our biggest drug, what we're seeing is we have volume growth that essentially has offset the pricing up until now. As I look forward in the next couple of years, I see that as a franchise where that dynamic will lead to stability for JANUVIA. And I see JANUVIA as a very strong platform on which we can have growth from KEYTRUDA and other molecules going forward. So to answer your question, I think we'll be fine as it relates to access. I think in some areas like JANUVIA and DULERA, we'll pay incrementally more. But in areas like KEYTRUDA, because we have these benefits, we won't pay nearly as much for formulary access.

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

That's helpful. And following along, biosimilars have been a hot topic. There's been a lot of interest in the U.S. in biosimilars, yet biosimilar REMICADE has struggled to garner any adoption because the price isn't low enough. The payers basically say, we're pretty happy with our branded REMICADE rebates, and the patients that are on therapy -- or existing -- or the existing patients are grandfathered such that we'd have to wait a significant amount of time for the patients to turn over to be on biosimilars over time. So maybe if you could just comment on that and what your strategy is with your biosimilar REMICADE and how you're thinking about biosimilars going forward.

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

So at a very high level, I come back to my first comment all the time, which is that we're focused on innovation as a company. And the reason why we did this particular strategy was because we see our colleagues at Samsung being willing to make the investment in research in formulation, and we see this as an opportunity to use our commercial infrastructure to run those products through them. So this is not, frankly, the kind of strategy that Merck does end to end. This is an opportunity to use our commercial infrastructure, for example, in the Lantus deal. We're already in those doctors' offices with sitagliptin. So if we have a product that we can put in the bag, that's a great thing. And it doesn't cost us very much. Not a lot of distraction from the part of the company that I care most about, which is mainly our R&D organization. So having said that, I think the experience in the U.S. with biosimilars is very early on. We saw in Europe at the very beginning there were those same kinds of challenges around getting the biosimilars accepted. I think over time, I think people will get more used to using biosimilars here in the U.S. As you know, we have 2 that have been approved, I think, for the insulin glargine as well as the REMICADE thing. And we're prepared to go forward soon and launch the REMICADE thing, and we'll see how well that does in the marketplace. But I want to come back to the fact that I see that as a short-term opportunity for a company like Merck. I don't see it as the main event at Merck. The main event will continue to be to come forward with medically important, innovative products like a KEYTRUDA.

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

Great. And we should probably finish up on the innovative side. So Roger, could you talk about the vaccines that you're most enthused about in development? And specifically, comment on B114 if you could, please?

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

Yes. And thank you for that. I mean, it shouldn't escape anyone's attention that in a few days, Doug Lowy and John Schiller are going to earn the Lasker Award for the HPV -- for their observations that led to the HPV vaccine. Those observations, which stimulated our efforts at Merck going back now 25 years, have resulted in GARDASIL and GARDASIL 9 that together are so dramatically reducing papilloma virus infection in young women and in boys as well that we can look forward to a time when we need to be very really unconcerned about cervical cancer. It's the first cancer preventative vaccine, an extraordinary accomplishment, and we feel very proud of that. We're certainly very proud of the fact that that we were able to make use of the published information that came from Drs. Lowy and Schiller to do that work. But it just points to our long-term commitment to this area. And in the vaccine area, we have made important progress in developing new polyvalent and pneumococcal conjugate vaccines. We already have Pneumovax. We also have exciting vaccine initiatives in the area of cytomegalovirus, which is an important cause of birth defects. We're making great progress in respiratory syncytial virus infection both in the pediatric and at-risk elderly adult population but also in healthy adults. And we've made progress in rare or infectious diseases that nevertheless have important impact, Ebola virus being one example. We've also done some work in other areas. So we're making a lot of progress with our colleagues at Moderna using RNA immunization as a way of moving vaccines forward. And we see an opportunity to use the same kinds of techniques that we've developed over the last 75 years or so to bring important preventative vaccines to adult populations and pediatric populations around the world, which will have a major public health impact.

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

Great. Well, we are out of time. Thank you so much both for joining us and we appreciate you being here.

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

Thank you. Thank you.

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

Thank you. Thank you.

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