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# EDITED TRANSCRIPT

MRK - Merck & Co Inc at JPMorgan Global Healthcare Conference

EVENT DATE/TIME: JANUARY 08, 2019 / 12:30AM GMT



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## CORPORATE PARTICIPANTS

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

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

## CONFERENCE CALL PARTICIPANTS

**Christopher Thomas Schott** *JP Morgan Chase & Co, Research Division - Senior Analyst*

## PRESENTATION

**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Good afternoon, everybody. I'm Chris Schott from JPMorgan. And it's my pleasure to be hosting a fireside chat with the Merck management team this afternoon.

From the company, we have the Chairman and CEO, Ken Frazier; as well as Roger Perlmutter who heads Merck's R&D.

As a housekeeping item before we start, we're not going to be hosting a breakout session after this, so we'll just do the fireside. But with that, I'd like just to kick off the session maybe first question to Ken with your thoughts on 2019. Merck's coming off of a very strong 2018, stock significantly outperforming its peers. What should investors be focused on as we think about Merck in the new year?

## QUESTIONS AND ANSWERS

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

So first of all, thanks, Chris, for having us. I do think 2018 was a very exciting year, and I think we have a lot of momentum coming into 2019. We're very pleased with the way our 4 important growth pillars are performing: oncology, Animal Health, Hospital and Specialty products, and vaccines. We continue to see the way that the health care environment is developing, the landscape is developing, it's more and more important to be innovative and to have differentiated products. And we believe that we have them in our current portfolio. We're very excited by our pipeline opportunities, so it's a good time to be at Merck. It's exciting time to be at Merck.

**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Absolutely. KEYTRUDA was obviously a huge success story for Merck over the past few years. Maybe first just on the commercial opportunity. Can you just update us in terms of where we stand with the ramp in first-line lung in the U.S.? Where are we with penetration now? Where do you think penetration can go over time?

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

So right now. I think if you look at the non-squamous population for newly diagnosed patients, we're getting over 70% of those people, which is a very positive thing. That compares very favorably to where we were before the 189 trial was unveiled last spring. I think as you look beyond the non-squamous population with 407 and the outcomes that we have with 407 in the United States, we really do believe that, that's another great opportunity for us. If you look outside the United States, at the third quarter, the ex U.S. market share was around 40%. But in September, as you know, 189 was approved in the EU. Just very recently, 189, along with a number of other studies, 407 and others, were approved in Japan. So we see ourselves as having a great opportunity outside the United States. Just with 189, it triples the addressable population we have in the EU. So we're just getting started with melanoma in China, so there's a great opportunity across all those markets.

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**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Yes. So on the international side, if I can just get a little more color. Some of those markets have -- maybe have a lag between the approval and when we actually see the commercial ramp. How do we think about something like KEYTRUDA, where the evidence seems to be so strong, is that something that could be a little different in terms of faster uptake or is it just you have to go through these procedures and these processes?

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

I think you have to go through the procedures. There are certain countries, like Germany, pretty quick, and there are other countries like to take a year, 16 months or 18 months. So it all depends on the market. But we're very excited because I think what you're saying is true. I think the data is so striking and the outcomes data, in particular, in terms of overall survival is so compelling that hopefully people will streamline the reimbursement process.

**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Okay. So talking about '19 and the international side of the KEYTRUDA business is something -- simply, that should be a pretty healthy growth driver for the company.

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

I think it is. Again, I want to come back to the beginning. I think '19 is a very exciting year. We've got these growth drivers, including oncology. I think we need to acknowledge, though, at the same time there's some challenges, okay. I mean, obviously, pricing is a challenge not just for Merck but across the industry. And again, it underscores why being an innovative company is so important. We're going to face more headwinds as it relates to ForEx. Last year, we had to overcome about \$800 million worth of foreign exchange. There will be challenges with respect to the more mature and the LOE part of our portfolio with SIMPONI in Europe, for example, having to deal with generic HUMIRA. Within the United States, JANUVIA facing additional problems with respect to the doughnut hole calculation. So there are challenges that we will face. I also think it's important to acknowledge that we are facing unprecedented opportunities that Roger and his colleagues, I think, have done a fantastic job developing KEYTRUDA, putting KEYTRUDA in a place with unquestioned leadership in lung. But we have a number of other opportunities coming behind us with KEYTRUDA as well as with Lenvima and Lynparza in our oncology franchise. If you look beyond our oncology franchise, and Roger could talk about this in greater detail, we've never had a stronger vaccine pipeline than we have right now. So I say that all to say that in addition to the challenges that I just talked about, this is a period where we have to invest because there's never been this kind of opportunity for us. It's unprecedented in terms of the scope. As you know, KEYTRUDA is approved today in 10 tumor types, including lung. We've shown activity in 25 tumor types. So there's a huge amount of investment that's necessary both in monotherapy as well as in combinations across all the different lines of therapy.

**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Great. So maybe before we turn to the pipeline, one last question, just you mentioned investment. One question we get is just how we think about the margin expansion opportunity for Merck over time? It seems that on one hand, you've been highlighting you need to invest properly to support this very interesting pipeline. At the same time, as KEYTRUDA keeps ramping, it seems like it's reached a point where it's just hard to spend away the type of growth that we'd expect from that asset. So help us just frame out how we should be thinking about the margin story at Merck, not so much in '19, but just the way to think about the next few years.



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

Okay. So what we've said is that we're committed over the long term to leverage P&L, and that we're committed over the long term to driving greater margin expansion, driven by, first of all, revenue growth for things like KEYTRUDA, but also the mix shift that we anticipate as well as additional efficiencies. But as you think about the timing of that in the near term, again, we have so many great opportunities to invest in. So I would say nearer term, the emphasis will be on investing to continue to maintain our lead in areas like oncology, to expand in other areas like vaccines to hospital specialty, where we have opportunities with the Afferent compound, opportunities with HIV pipeline and other things, animal health. We want to make sure that we invest properly in the short term. So I see the margin expansion is being driven largely, over the longer term, by the kind of revenue growth and mix shift that we expect.

**Christopher Thomas Schott** - JP Morgan Chase & Co, Research Division - Senior Analyst

Great. So bringing Roger into the conversation. Maybe first one, KEYTRUDA. A lot of focus has been on lung, but there's so many other indications that seems to be developed -- you're developing over time. Can you just maybe talk a little bit about the additional indications beyond lung we should be focusing on and some of the readouts that we should be watching on the non-lung side?

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

Right, Chris. So as you say, a huge number, and Ken already spoke a little bit about this. The reality is that there is -- has never been a broad spectrum antineoplastic agent like KEYTRUDA just based on its current approvals. And we mounted an effort starting now 5 years ago to explore the full use of the molecule in monotherapy. We're getting to the point where most of that monotherapy work has been done with the recognition of its activity in hepatocellular carcinoma, primary B-cell mediastinal lymphoma, with the Merkel cell approval that we got at the end of the year and a few others. Moving forward, there will be additional data, for example, in esophageal cancer. But I think what we've also seen, and you alluded to it before, is that the effectiveness of the combinations, particularly chemotherapeutic combinations. So with KEYNOTE-189 and 407 in lung cancer, that really expands the utility of KEYTRUDA. We're going to see a similar kind of chemo combo utilization in squamous cell carcinoma of the head and neck. The KEYNOTE-048 data, which we presented at ESMO, I think everyone recognized these as practice changing. Clearly, they will be under review at regulatory authorities around the world as we move forward. We've top lined the data for the combination of axitinib and KEYTRUDA in the KEYNOTE-426 study in renal cell carcinoma. Those data, too, very impressive, will be presented at ASCO GU. And looking forward, you're going to see additional data in esophageal cancer and non-muscle invasive bladder cancer, just to give a couple of examples. And we'll also have the opportunity to see data from some of our adjuvant and neoadjuvant studies. For example, the KEYNOTE-522 study neoadjuvant breast cancer and triple negative breast, those data, we had a chance to look at interim data recently, which were quite encouraging. FDA is eager to see a longer-term study because of the fact that these diseases tend to be more indolent and one wants to see the effect over time. But we are encouraged by what we've seen to this point. And as you can tell, it's obviously a very, very broad spectrum anti-malignant drug.

**Christopher Thomas Schott** - JP Morgan Chase & Co, Research Division - Senior Analyst

On the triple negative breast, what's the next time line we should think about of when we could hear another update from you on that update -- on the triple breast?

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

There will be an update on the 522 program later in the year, and exactly when depends a little bit on how the data accrue. But in addition, there are other programs that we're looking at in breast cancer that look in the adjuvant setting. So you'll have a chance to see quite a bit of data towards the end of this year and first part of next year.



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**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

And one other question, I was just thinking about the IO landscape, it seems like you've had real success either with chemo combo or TKI combos. The one area that I think there was a lot of enthusiasm a few years ago that so far hasn't necessarily panned out has been the IO/IO combos more broadly. What's your latest thinking in terms of the role that -- beyond CTLA-4, other I/O agents may play with PD-1 as you think about the different directions that the market can move over time?

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

Well, as I've said in this forum before, I try to think it at a high altitude about why it is that patients don't respond to KEYTRUDA, because the responses are so fantastic when we see them. I mean, if you look in the melanoma case, the image to have in mind is former President Jimmy Carter, at age 91, receiving KEYTRUDA at a time when we had advanced melanoma with liver, pulmonary and intracerebral metastases. And all of that goes away, and he's still very much with us and very active, now, 4 years later. That's quite a remarkable effect and not like anything anyone has ever seen before. When we look at that more broadly at KEYTRUDA, you would expect that we ought be able to see more responses like that. And the reasons why we wouldn't are either, first of all, because the tumor is not recognizable by any immune system, in which case, we have to tag it in some way. Or it's recognizable by some immune systems, just not that patient's immune system, in which case, immunization seems like it might be a good approach to expand a precursor frequency reactive with the tumor. Or it's possible that there are cells that are reactive that, that person's immune system can see the tumor, but there's some other checkpoint. I think all of us who are working in this field are trying to understand which one of those buckets will be most effective. We have 20 new agents that influence the immune axes in various ways that are currently in Phase I programs looking at combination studies, asking whether we can tease apart these fundamental mechanisms related to antitumor responses. And I'm optimistic that over the next year or 2, we'll see some exciting results.

**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Great. And then maybe one on the pipeline just beyond KEYTRUDA, maybe touch on some of these. But can you just tell us what you are most excited about the pipeline beyond KEYTRUDA?

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

Well, I think Ken made reference to the fact that we've never had a more exciting vaccine portfolio at Merck than we have right now. And I can speak across nearly 25 years of experience with the Merck vaccine portfolio. That includes the opportunity with GARDASIL, which is extraordinary, as public health authorities around the world are thinking much more seriously about actually eliminating HPV infection as a source of human disease. The magnitude of that task, where at a 2-dose regimen, if you want to immunize the entire birth cohort of the world, is more than 200 million doses a year, not to mention the catch-up with the extended approval that we have in an older population here in the United States and elsewhere. That's an enormous opportunity to do a lot of good, and of course, a huge opportunity for the company. In addition, we have our pneumococcal conjugate vaccine, the B114 program, 8 Phase III studies currently underway that we'll be reading out this year or towards the beginning of next year, should be very exciting data, very important data for preventing invasive pneumococcal disease. So that's really quite interesting first, in adults, and then pediatric populations later. We have a really interesting CMV vaccine, and we have our dengue vaccine program. We recently announced our collaboration with the Instituto Butantan to develop that vaccine which, with global warming, I hate to say, could become more and more important for the United States as well as for equatorial populations. So the vaccine program looks terrific. Our anti-infective programs are remarkable, including the HIV program with MK-8591, sort of the bell of the ball, the most exciting new anti-HIV agent, because it works by a novel mechanism which is blocking translocation of the reverse transcriptase. And we'll have a chance this year to see some data, and we'll, of course, share it with all of you, from the Phase II program with Doravirine, our new non-nucleoside reverse transcriptase inhibitor, in combination with 8591. That's just a small glimpse of the data that's going to come out. We have other data in metabolic disease, cardiovascular disease. It's really going to be a terrific year for us.



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**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Great. Great to hear. Maybe Ken, a question on -- building on those pipeline questions, how do you think about diversification within Merck? It's obviously a diversified business, but KEYTRUDA seems to be rapidly becoming one of the largest products I think we've ever seen. It's a good problem to have. But how do you ensure that Merck's growth doesn't become overly dependent on one asset and you kind of keep a balanced growth profile for the overall organization?

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

So obviously, we want to have a diverse pipeline coming forward, and Roger just gave you some of the things that make us excited. The other aspect of that, obviously, is business development. And we continue to focus on opportunities to develop new molecules through business development that are actually going to be differentiated and make a big difference. We talk about oncology, everybody focuses on KEYTRUDA. But I think if you look at the assets that we got in our deals with Eisai and AstraZeneca, respectively, Lenvima and Lynparza, we think those as monotherapy as well as in combination with KEYTRUDA will be very significant contributors beyond just KEYTRUDA. And of course, Roger mentioned the 20 other unique types of molecules that we have in development in our oncology field. So I would say the way to think about this is, first of all, I like the fact that we're diversified today. It's good to have a vaccine business. It's good to have an animal health business. In another context, people will often say, "How do you feel about the pricing pressure on the industry?" Well, those are 2 very significant growth pillars that are not largely subject to that kind of pricing pressure. And they provide a lot of steady cash flow. So diversification is an important thing as long as you're bringing forward the kinds of products that have that kind of differentiation meeting unmet medical need that the health care environment will pay for.

**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Great. And you mentioned business development, and that's been a focus for the organization. You've brought assets in. But can you just maybe talk a little bit about the environment you're seeing right now for business development? Certainly, 2019 started out as a pretty active year for some of your competitors. Has the market pullback created some opportunities that you can maybe look towards either larger acquisitions or more broadly than you were able to look before? Maybe just any color you have on what you see out there as you look to augment the internal pipeline with?

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

So at a very high elevation, I think it's helpful that valuations have begun to come down. We continue to look for those assets that we believe can create value for our shareholders, and I think it becomes more possible with more recent valuations. We're very active. I think the fact that you haven't seen a large deal coming out of Merck recently is not a reflection of the fact that we're not looking at those. When I say large, I mean, an important deal, not necessarily large from a size standpoint. We are active. We've actually tried to consummate some deals. They haven't worked because we haven't had a willing seller or the asset was too robustly competitive because it was a late-stage asset. But broadly speaking, I think with the valuations coming down, it creates more possibilities.

**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Great. Another topic you mentioned is Animal Health and a source of diversification. Maybe first question on Animal Health. Can you just comment on the recent acquisition of Antelliq and what that adds to the franchise?

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

So right now, in the Animal Health business, the fastest-growing areas have to do with identification and monitoring, and Antelliq is the market leader in those areas. And as we move forward into a more digital environment and people become much more concerned about, for example,

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on the production side, what's the source of the protein that they're eating, the ability to identify and monitor, trace it back, detect, predict, all those things become more important. And so this gives us a completely different growth platform. That's actually the fastest-growing part of Animal Health right now is this detection area. Over and above the pharmaceuticals and vaccines that we provide to our customers, we are able to provide a set of solutions that they value very much.

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**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

And I know you're asked this all the time, in terms of is Merck the right owner for the Animal Health business. I appreciate the diversification it brings. But when you balance that against some of the multiples we're seeing for some of the stand-alone Animal Health companies, how do you -- can you just help us with how do you think about that balance and how you evaluate whether it's -- does it make sense to keep that within the Merck family?

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

So I'll start by -- with your first question about whether Merck is a good owner of that business. I think the answer to that question can be looked at because the Animal Health business is, in fact, the market leader when it comes to growth, when it comes to profit margins. So that business has not suffered being a part of Merck. To the contrary, it's actually the market leader. There's no other business that's quite as good as that business. And obviously, it provides us the growth, the cash flow, the diversification. I think as we look beyond that, we have to ask ourselves questions like what are the synergies associated with having unfettered access to our human health R&D, and we've continued to believe that those are extremely valuable. So we see ourselves as not a disadvantaged owner but an advantaged owner of that business as we sit here today. But I also want to say that as we think about it, we constantly challenge ourselves about how our pipeline -- excuse me, how our portfolio ought to evolve. So we're not, I guess, I would say, stubbornly focused on maintaining that as a part of Merck. As we sit here today, we think it makes sense for all the reasons we've said for it to be a part of Merck, but we have to constantly challenge ourselves and make sure that we are thinking about it from the standpoint of what's best for the long-term health of the company and what's best from the standpoint of long-term shareholder value creation.

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**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Great. Last few minutes here. I guess first one I was wondering about was on capital deployment-absent deals. We saw with 3Q, obviously, announcement of a dividend a step-up and a share repo. Absent more meaningful transactions, can we expect more of that from Merck on a go-forward basis?

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

Well, our priorities are obviously -- again, going back to what we said a little while ago, we have unprecedented opportunities to invest in our current pipeline. We've never had the opportunities like we have just for oncology with KEYTRUDA, Lenvima and Lynparza. So those are actually very substantial opportunities to reinvest. And then there's business development, which we think is critical going forward. And we believe that the steps that we took with the ASR as well as the steps that we took with the 15% increase in our dividend are actually showing our confidence in the growth of our business going forward because we don't think they in any way inhibit our ability to do business development. So at the end of the day, we want to reinvest in our business what we have in our current portfolio as well as bringing new things into our portfolio. And then, obviously, with respect to excess cash, we want to return it to shareholders in a cost-effective way.

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**Christopher Thomas Schott** - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Okay. Roger, can I ask about one of your pipeline products in the vaccine side, the V114, the pneumococcal vaccine? Maybe just help us provide some perspective in terms of the additional coverage that, that offers relative to Prevnar and what you see that bringing to market?

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

Right. I think there has been a tendency among some, looking at it from a distance, to say it's really just a function of counting up the different specificities, whether you have 13 or 15 or 20 or 25. I mean, that's sort of what matters. We've got a lot of experience in this business having marketed Pneumovax for a long time. And we know from the experience that our colleagues at Pfizer have had with Prevnar that what happens over time is that the epidemiology of pneumococcal disease does change in specific markets. And it becomes more important to ensure that you have appropriate immunity directed against particular serotypes. So I think the thing to watch, in addition to the number, is what is the extent of protection that really is achieved using immunogenicity as a surrogate for each one of those serotypes, and particularly the ones that are emerging and being, in essence, selected for by virtue of prevalent immunity for immunization. So that's the important issue. We've taken great pains in developing V114 to ensure that the most important serotypes are actually highly immunogenic in that conjugate, and that will have big advantages. We'll see how the data play out over time. But certainly, we're extremely encouraged, not only by our adult data, but also our pediatric data and that the serotypes that are important are different in those 2 different populations. So there's a lot to look at here, and it's not just numerical exercise.

**Christopher Thomas Schott** - JP Morgan Chase & Co, Research Division - Senior Analyst

That's helpful. I think we're just about out of time. Sounds like very exciting year ahead for the company, and thanks so much for joining us today.

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

We're very excited. Thank you for having us.

**Christopher Thomas Schott** - JP Morgan Chase & Co, Research Division - Senior Analyst

Thanks.

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