THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

MRK - Merck & Co Inc at Morgan Stanley Healthcare Conference

EVENT DATE/TIME: SEPTEMBER 09, 2019 / 2:30PM GMT

CORPORATE PARTICIPANTS

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

Roger M. Perlmutter *Merck Research Laboratories - President*

CONFERENCE CALL PARTICIPANTS

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

PRESENTATION

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

So I will sit down in just a moment to join Merck. But it's very much my pleasure to welcome both Ken Frazier and Roger Perlmutter. I need to start off with the disclaimers. We need to refer you to the disclaimers at www.morganstanley.com/researchdisclosures.

And as you know, Ken serves as President and CEO of Merck. He originally joined the company in 1992 and was named CEO of Merck in 2011. And Roger has served as Executive Vice President and President of Merck Research Labs since 2013. He originally joined Merck in 1997 and then served as Head of R&D at Amgen from 2001 to 2012 before returning to Merck. So we're fortunate to have both of you with us today. Thanks for being here.

QUESTIONS AND ANSWERS

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

Maybe, Ken, I could just hand it over to you. First, congrats on the phenomenal execution in recent years. Maybe given all of the company's success, could you talk about your vision for continuing to drive Merck forward? And then we'll take it from there.

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

Okay. So first of all, thank you all for being here. Whenever I get asked questions like what's my vision for Merck, I always realize that I'm not nearly great enough to have a vision for a company like Merck that's been around for 130 years. So I'm simply going to say my vision is the vision that Merck has had for a long time, which is that if we continue to focus on cutting-edge science, if we hire the right kinds of scientists, if we create an environment where really good science can happen on a consistent basis, then we're more likely than not to be successful and not just because of chance, because obviously, there's a lot of timing and serendipity in success in this industry. But those companies like Merck that have been capable of repeatable success over the years have done so because they remained focused on important innovation.

I think right now, we have tremendous momentum inside the company. And as we look forward to 2023, over the next 5 years or so, we think we have in hand tremendous tangible assets that will drive sustainable growth over the next few years and then beyond that. We're also very excited by what's happening in our laboratories in terms of sustainable long-term growth. So we're very excited. It's a very exciting time to be at Merck.

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

And since you mentioned 2023, obviously, that will be the year that you take the hit from JANUVIA. Could you just talk about the power of the numbers outside of JANUVIA to be able to bridge that period?

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

Yes. So we've been very clear that we see ourselves growing each year up until that point and then also in 2023. And we believe, in 2023, I'll be so blunt as to say I think our ability to grow in that year of maximum exposure to JANUVIA patent expiry is actually underappreciated right now. And I think it's driven by a number of things. So first of all, obviously, KEYTRUDA, and Roger can talk in more detail, but the opportunities that we have across additional tumor types, across earlier lines of therapy in adjuvant and neoadjuvant going forward; an opportunity like China, where we're just bringing that product to that market, which is a huge market, particularly in areas like lung cancer; the opportunities that we have with Lenvima and Lynparza; the opportunities we have in our vaccine business, with GARDASIL, for example, where countries all around the world are very much focused on eliminating papillomavirus infections. And less than 5% of people in the world have been treated with GARDASIL -- or immunized with GARDASIL. So we see those as great opportunities. Our Animal Health business. We have tremendous opportunities in our hospital and specialty business. So we think we have, again, I'll stress again, a lot in hand. We have a huge opportunity to invest in the assets that we have in our hand to drive growth.

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

Excellent. Roger, maybe we could pivot to you to talk about KEYTRUDA. So obviously, the way that you've executed on continuing to develop KEYTRUDA has been unparalleled in the industry. Could you talk about some of the biggest levers looking forward? Obviously, lung cancer is being rolled out currently. But it would be helpful for you to frame what some of the important indications are to watch, let's say, in the next year or so that are going to be reading out and then the levers longer term. And as you speak to adjuvant, obviously, Roy had commented on adjuvant at your Investor Day and said that, effectively, Merck sees that as all incremental, which I think was a bit surprising and, obviously, quite encouraging. But if you could recap that for the audience, that would be very helpful.

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

Right. Well, thanks for the question. KEYTRUDA and the description of where we're going with KEYTRUDA could take an awfully long time, but I'll try and squeeze it down to just a relatively few words. The reality is that when you think about KEYTRUDA, you should recognize that we're treating not the cancer per se, but treating the host. And so we're improving immune activity and revealing the pre-existing immune activity directed against the tumor. It's already there. We're just revealing it or unshackling it, if you will. And that can be done across the very broad spectrum of different tumor types. We currently have more than 20 indications, 15 different tumor types. And our expectation is that, that will more than double in the next few years and, of course, across all lines of therapy. It is the case with KEYTRUDA that because of its relatively favorable benefit-risk profile, you have the opportunity to go much earlier in the patients who are less grievously affected, and that means adjuvant and neoadjuvant settings.

The first adjuvant data, of course, were the ECOG 054 study in melanoma, which -- for which we've already gained approval in the United States, and approval will come in many -- in all parts of the world, ultimately. And they demonstrate -- those data demonstrate the power of the adjuvant approach. And in addition, we'll have the opportunity to see at ESMO the neoadjuvant data from triple-negative breast cancer, the KEYNOTE-522 study, which, of course, is a study that is still going on, and we'll continue to follow the outcome in patients who have unfortunately been diagnosed with this disease and who are undergoing a resection.

The opportunity in adjuvant and neoadjuvant is enormous because an enormous number of people are unfortunately afflicted with cancer. And it spans a very broad set of tumor types, not just tumors like melanoma that are extremely visible or breast cancer that are often discovered incidentally, but as well the whole variety of tumors, epithelial tumors, including head and neck cancer, potentially lung cancer and many others. We have more than 100 studies going on in adjuvant therapy, and we see that as a very large opportunity.

But it is important to recognize that the patient populations are quite different. There's a very large patient population that, in principle, can be addressed with adjuvant or neoadjuvant therapy. There's a smaller but incredibly important patient population that presents with advanced disease. And that patient population that presents with advanced disease is the patient population that, largely, we're treating now. That's the majority of the patients that we're treating now. So to speak for Roy, when he was talking about that at Investor Day, he was pointing out that these populations, while they overlap, have many characteristics that are sort of disjoint.

As you look forward, you'll be seeing data in the next year or 2 that relate, of course, to the triple-negative breast cancer population, to other breast cancer populations, to earlier stages in bladder cancer. You'll have an opportunity to see data, adjuvant data, looking forward a little bit further in the lung cancer setting and, of course, in the head and neck cancer setting, where a neoadjuvant approach also is very attractive.

So that just gives you a sense of it. It is an enormous program. More than 1,000 studies on ClinicalTrials.gov and a terrific opportunity to make a big difference for people around the world.

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

Very helpful. And maybe each of you can talk a little bit about moving the company forward to the point of broadening the organization. So obviously, KEYTRUDA is an exceptional growth driver and will continue to be for many years, but that won't always be the case. And obviously, you're working to broaden the pipeline. So maybe each of you could speak to that, maybe a little bit how you're thinking about it internally and then from an M&A vantage point as well.

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

Well, I'll just start by saying that, as I was saying before, I've never seen this many important opportunities in the internal pipeline. And a couple of times this morning, I was asked the question about margins, what are you doing about margins. And I said one of the most important things for investors to understand about current Merck is we have tremendous opportunities to invest in our internal pipeline right now, and we would be remiss if we didn't do that. We think there will be opportunities for meaningful margin expansion starting in 2021. But right now, when you hear Roger say 1,000 pending studies with KEYTRUDA, that's -- we're not doing that without being very thoughtful about what the opportunities are. So we have a great opportunity to invest in our current pipeline. What comes after KEYTRUDA, Lenvima, Lynparza, the other molecules that we have in oncology, a very broad vaccine pipeline and portfolio, our hospital and specialty business. And at the same time, I think we have to be cognizant of the fact that most of the great science is happening outside our 4 walls. The vast majority of great science is happening outside our 4 walls. But we have to look for those value-creating opportunities in terms of business development, where we can get our hands on the best forthcoming science at a time and in a way that we can actually create value by adding it to our portfolio. So business development is another opportunity for us to expand beyond what we have today.

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

Ken said the important thing, which is that this is a very special time for Merck Research Laboratories. Most of you know I've been doing this for a long time and at different companies and in a variety of different settings. This is a very special time for us. If you look at the -- if I may, I'll just put it in buckets. When you look at where we are in terms of oncology, of course, KEYTRUDA is a gigantic and very important product, but beyond that, as Ken mentioned, we have our partnerships with AstraZeneca and Eisai on Lynparza and lenvatinib, which are very important drugs and very important in combination with KEYTRUDA as well. Beyond those combinations, we have more than 20 new molecules that we're advancing in our own program. And the fact that we have those 20 didn't stop us from gaining access to other things on the outside, most recently the Peloton transaction, because of our increasing emphasis on renal cell carcinoma, where we already have spectacular data that enabled us to get early registration. But in addition, we are marching forward to try to make sure that we can bring the benefits of KEYTRUDA combinations to all patients who, unfortunately, have renal cell carcinoma.

If you look at the oncology profile, then it's very large. But in addition, we have enormous progress in our vaccine program with Phase III studies ongoing in our pneumococcal conjugate vaccine program and multiple pneumococcal conjugate vaccines that will differentiate between the pediatric and adult populations. Our cytomegalovirus vaccine program, dengue vaccine program, these are going to turn out to be extremely important as well as our programs in respiratory syncytial virus.

Outside of the vaccine programs, we also have enormous activity in infectious diseases and recently registered yet another new antibiotic. We have enormous activity in antivirals, and islatra, which is our MK-8591 for HIV, is the first of a novel class and a very important class of long-acting

drugs directed against the polymerase of HIV that are useful not only in a treatment paradigm but also in a prophylaxis paradigm. And we presented data on both of those in Mexico City a couple of months ago.

And then if you go outside of the infectious disease area, we also have very important programs in metabolic disease. We have very important programs in neuroscience. And these programs are going to become more and more visible to all of you. So we see great opportunities for us to invest, to bring forward important new medicines over the next half dozen years.

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

Great. And then just going back to M&A briefly. So obviously, you've gotten the question over the years, but interested how you're being -- and thinking about the M&A environment today. On the one hand, you have more desperate competitors that are more needy than Merck that may be willing to overpay for certain larger transactions. On the other hand, given the leverage you're going to have from KEYTRUDA, you could potentially pursue, let's call it, a midsized pipeline-type acquisition and absorb that in a manner that maybe your peers can't because they have earnings pressures that they need to grapple with. So maybe you can just comment on your view of the M&A landscape and Merck's opportunity to further leverage its competitive advantage that it's working with today.

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

So in posing the question, you just gave both sides of the coin. To one extent, we do have an opportunity. Our balance sheet allows us to do transactions of very substantial sizes and natures. We are very eager to find those opportunities where we believe we're pushing on the envelope of science in a way that we can create value. You mentioned the environment. I will say -- you used the word desperate competitors. What I will say is just a few years ago, you could look out, and you saw opportunities in the marketplace. You could take advantage of them in premiums of, let's say, around 30%. Now you're looking at premiums that are almost always above 50%, and the valuations are very high.

So if you looked at it just from a financial standpoint, you might reach the conclusion that this is not a great environment with the market being where it is. With capital being made available to small companies, they don't feel the need to sell. But from our perspective, the first and the most important hurdle is the science hurdle. If our scientists see something that they think can make a huge difference going forward, then we are really interested in it. And if you think about it, in terms of overpaying or not overpaying, if you're picking the right asset and they have a big impact, then that's actually going to create value because, obviously, if it works, it has a lot of value. If it doesn't work, it doesn't have a lot of value.

So I just want to stress that we are very interested in business development. We're focused primarily on the future of science. I will say that I don't think very large transactions are the right thing for Merck right now given all the things that Roger described. I think they would disrupt our organization in a way that I think we would lose the value on the things that we're working on internally.

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

Very helpful. Let me pause there and see if anyone has a question from the audience before -- just hold on for the mic, please.

Unidentified Analyst

Roger, you have a lot of data coming out at ESMO at the end of the month. We saw the press release. What are the 2 most important things we should focus on coming out that's really going to be game-changing with respect to [it]?

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

Well, the 3, I think, that are included in the presidential symposia are the KEYNOTE-522 data in triple-negative breast cancer neoadjuvant, which I think are really interesting and important data. I think the data that we have with Lynparza as well from the [PALO 1] study and also from the

PROfound study in prostate cancer, these are really very important data. And I would also say, since you bring it up, ESMO this year will be among the most robust scientific meetings that we have ever attended in terms of what we're presenting. So there's a lot going on there, and I know many of you would like to take a trip to Barcelona, so see you there.

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

Any other questions? Yes, one upfront here.

Unidentified Analyst

I just want to hear your views on the drug pricing in U.S. as we head into election year next year because in the past, usually, ahead of the election, we see many biopharma companies hold back on price increases. So I'm wondering if you think next year will be any different. And if so, why do you think so?

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

Well, let me start by saying I think that the ability of people to pay for medicines is a real problem in the United States. I think that the industry has a responsibility to contribute to the solution to that problem. I happen to believe that the main problem is that while we pay substantial rebates, they don't get passed on to the patients at the counter. And I think the solution to the biggest problems we have involves that. I was disappointed when the administration withdrew the rebate rule because I thought it was a very good solution to these out-of-pocket costs we're paying at Merck. Roughly 45% of our revenue goes back into the supply chain. And if that's not finding its way to the individuals at the pharmacy counter, no matter what we do outside that, we won't have fixed, I think, the fundamental problem that we're facing in our country.

If you ask what's going to come out of this discussion, the Senate Finance voted out a package. House is going to be working on a package. President has his own ideas. Some of those ideas are ideas that I think are not going to be good for patients in the long run, for example, IPI. I can't predict what will happen. I think we're going through a period where, frankly, there's not a lot of bipartisan cooperation in Washington. But we will continue to push forward to try to come up with solutions that both help patients afford today's medicines without preventing us from being able to invent the medicines that we need going forward. This is an important issue for us as a company.

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

Great. Maybe we can just pivot to China. So obviously, that's an explosive growth driver for the company. If you could put that into some context, talk about where Merck China is today with KEYTRUDA and then the opportunity to potentially add KEYTRUDA to the government reimbursement list.

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

So China is a great opportunity for Merck. If you look at last quarter, we grew about $750 million in the quarter. About 51% ex exchange growth. The important thing about Merck's China business is it's based on our innovative products. A lot of other companies are selling older products in China. KEYTRUDA, GARDASIL, JANUVIA, which has been added to the NRDL, are the principal drivers of our growth going forward.

With respect to KEYTRUDA, it's a huge opportunity in China. If you look at just the size of the population, the fact that people are moving into urban areas, the fact that the Chinese government has become much more receptive to innovation in terms of approving things through the approval process, the reimbursement system becoming much clearer and better going forward, I think it's a huge opportunity. Just the size of the population, the incidence of lung cancer in China make it a great opportunity. Now if we have to get it listed on -- where we have an opportunity to get it listed on the drug list, that will obviously have some trade-offs in terms of volume versus price. But it's a tremendous opportunity to do a lot of good for a lot of people.

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

Great.

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

And if I could, I would say that this -- the harmonization of the Chinese regulatory environment with the rest of the world is a very powerful driving force, and it has changed things dramatically there. And as some of you know, we spent, Ken, I think probably close to a decade getting GARDASIL approved in China. GARDASIL 9 -- so 10 years. GARDASIL 9 got approved in less than 10 days. That's a pretty big difference, and that's the kind of responsiveness, I mean not 10 days, but that's the kind of responsiveness we're seeing in China now from a regulatory point of view. They're extremely keen to work with us to bring advanced medicines to the Chinese population.

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

And Roger, could you talk a little bit more about vaccines, the pipeline at Merck and what the products are with the biggest commercial potential?

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

Right. Well, of course, the product that, well, has the dominant near-term commercial potential is, as Ken said, GARDASIL 9. And there, the issue is primarily a manufacturing one, is that we had not expected that the demand would rise so suddenly as public health authorities around the world recognize that -- and this is largely based on data that came from the early adopters, particularly the Australian immunization program, that demonstrated that, in fact, by immunizing with GARDASIL, you can potentially actually eradicate cervical cancer. You can eradicate papillomavirus infection with the relevant strains of papillomavirus. And so as a result, as people have taken us on board, the question that's asked, and you see editorials on this almost every day in one newspaper and other around the world, why aren't we doing more? And the pressure, therefore, is on us, having now a 9-valent papillomavirus vaccine, to make enough vaccine to immunize the entire birth cohort of the world, which a 2-dose immunization protocol is around 200 million doses, much more than we planned for. To that end, Ken and I and our colleagues on EC have said that we're going to invest billions of dollars on building additional manufacturing capability for GARDASIL.

But beyond that, if we look at the pipeline going forward, I mentioned the pneumococcal conjugate vaccines, V114, which is currently completing its Phase III program. We'll start to see Phase III data at the end of this year, and the bulk of it will be coming through next year, which is a 15-valent pneumococcal conjugate vaccine that has breakthrough designation in both adults and in the pediatric population; V116, coming behind it, which also has an enormously broad reach; and additional pneumococcal conjugate vaccines, which, just to go to philosophy, demonstrate our focus on the fact that there are actually different populations based on age and distribution that benefit from different pneumococcal conjugate vaccines, and that's the path that we're pursuing. More to come on that, but it's a very advanced program.

We also have a -- pioneering a cytomegalovirus vaccine. As some of you know, congenital cytomegalovirus infection is the principal cause of infectious congenital birth defects in the world. And this is an extremely important program. There has never been a vaccine for it. We think we have one that will work, and we're deep in the midst of developing that program.

We also have what we think will be a leading dengue virus vaccine, which will become even more important as the temperature of the world warms and as dengue virus begins to spread because of vector spread. So that's very important. We also have a very large program in the respiratory syncytial virus, both as an active vaccine and also a passive vaccine.

So these are very important programs that address major needs around the world, and I expect that we're going to have a lot of success there.

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

Excellent. Maybe we can just finish up on your P2X3 candidate. It's quite interesting in that it could be a pipeline within a product, but it's also obviously hitting the central nervous system. And there's still some questions about its side effect profile and utility across some of the diseases that you're pursuing. So can you just paint a picture for that product in chronic cough and then the other potential therapeutic indications?

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

Yes, gefapixant P2X3 antagonist is designed to interrupt a problem of neuronal hypersensitization. All of us are aware that on the one hand, repetitive stimulation and repetitive painful stimuli can cause you to down-regulate the nervous impulses and to become inured to that stimulation. You can see that effect if you touch yourself repetitively on the knee. Eventually, you can't feel it very well anymore.

On the other hand, repetitive painful stimulation can also cause what -- something which is termed allodynia, a hypersensitivity to light touch. And that same kind of hypersensitization goes on in a whole variety of different areas. The area that we're approaching first is the chronic cough area with gefapixant, but there are many, many other areas that are approachable. Now keep in mind that chronic cough, number one, we've already demonstrated in the Phase II program that gefapixant is active in that setting. Gefapixant is -- was well tolerated in that setting, and the principal adverse effect is an effect on taste.

Chronic cough is incredibly common. It is one of the most common presenting complaints for people and their primary physicians. So there's a very large opportunity here to interdict the hypersensitivity that leads to chronic cough. But beyond that, we also have opportunities in endometriosis. We have opportunities in sleep apnea and a variety of other hypersensitization syndromes. So we'll learn more as the Phase III data become available, which will happen relatively soon.

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

Excellent. But we're out of time. Thank you both for joining us. Really appreciate you being here.

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

Thank you for having us.

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

Thanks, Dave.
