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MRK - Merck & Co Inc at Morgan Stanley Healthcare Conference

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Roger M. Perlmutter *Merck Research Laboratories - President*

CONFERENCE CALL PARTICIPANTS

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PRESENTATION

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

So thanks, everybody for joining us for the Merck session. I just need to refer you to disclaimers at www.morganstanley.com/researchdisclosures. It's very much my pleasure to welcome Ken Frazier and Roger Perlmutter.

Ken, as you know, serves as President and CEO of Merck. He originally joined the company in 1992 as Vice President and General Counsel, or General Counsel and Secretary of the Astra Merck Group and was named CEO of Merck in 2011. And Roger has served as Executive Vice President and President of Merck Research Laboratories since 2013. He originally joined Merck in 1997 as a Senior Vice President before serving as Head of R&D at Amgen from 2001 to 2012. So we're fortunate to have them with us today.

Congrats on the company's progress and the improving outlook for the business and the pipeline. Ken, I thought I'd ask you to maybe start off at a high level on the prospects for the business. I don't know, if you have any opening remarks, and then we'll go into the Q&A.

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

Thanks for having us. Let me just start with saying that I'm very excited by the prospects for the business. I think there are great opportunities in front of us. I've been in this job now, 8 years. And when I look at the opportunities that we have in our pipeline, with oncology, not just with KEYTRUDA, although KEYTRUDA is a formidable opportunity for us, but with LYNPARZA and LENVIMA as well as with a number of other proprietary, earlier stage assets that we have in the pipeline, you look at that and you look at our vaccines portfolio, this portfolio is the strongest portfolio I've ever seen inside Merck, anchored by GARDASIL, which is of course not a new vaccine but is looked at through new eyes by public health authorities around the world in terms of gender neutrality, in terms of eliminating HPV disease and all the things that come along, including cervical cancer, the opportunities Roger can describe in greater detail for a next generation pneumococcal vaccine, an RSV vaccine, a CMV vaccine a dengue vaccine, among others.

When we look at our hospital and specialty business, the growth of BRIDION has been fantastic but beyond that, our opportunity with the AFRIN compound which could also perhaps be used in endometrial pain, the opportunities that we have with HIV, which Roger can talk about in greater detail. Our Animal Health business, which is, I think the best animal health business that there is in the world in terms of its profitability, in terms of its growth, strong contributor to what we're doing as a company and then the early stage pipeline. So it's a very exciting time inside Merck, with a lot of opportunities to invest internally.

QUESTIONS AND ANSWERS

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

Excellent. And on the first quarter call you had stated that you viewed Merck's long-term revenue prospects as underappreciated, could you expand on that view?

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

Well you know, often people ask us what are you going to do about the (inaudible) patent expiry, because that's coming up. When I look again at the opportunities that we have with our KEYTRUDA franchise and that's across multiple tumor types, when I look at LENVIMA and LYNPARZA, I think they are underappreciated assets in terms of what they can be going forward. I think those were good deals for Merck to do, and I think those are 2 medicines that can grow a lot going forward. And as I mentioned, I think GARDASIL will be a tremendous opportunity for us. We -- as this vaccine is viewed completely differently than it was, 5 or 6 years ago, as people begin to say we've got to eliminate HPV disease. So it's all of the things I just finished talking about a few minutes ago. Across that entire portfolio, I think there's tremendous opportunities for growth in Vaccines, Hospital and Specialty Animal Health and I just -- I'm very excited by that.

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

And how do you think about that period? So including the pediatric extension, JANUVIA, will face generics in January of 2023. So obviously the business is going to grow a lot between now and then, the pipeline's going to evolve. I'm sure you'll be pursuing additional external transactions. So how do you see the business evolving to that point and then through that JANUVIA cliff period?

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

Well the good news is, I think that the assets that we have will go a long way towards dealing with the JANUVIA patent expiration. But you're right, we're going to continue to look for opportunities to augment our pipeline through business development, and as I, without giving any guidance over the next few years, I actually am extremely optimistic and confident about our ability to grow the top line going into that patent expiration and then out of that patent expiration.

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

And then, maybe you could comment then, you mentioned you're obviously not issuing new guidance here at our conference, although if you change your mind, you can feel free to do so.

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

I'll let you know.

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

But maybe you could provide some more perspective on when we should we expect a longer term view for Merck. And I'll also tie in another question I had, which is, investors have heard management talk about the opportunity to drive leverage, but investors have also said, well I've heard some mixed messages, because on the last call the company has been emphasizing its need to spend against the growth and reinvest. And so maybe you can provide some additional clarity on that message on leverage as you respond.

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

So let me start with the leverage point. Our goal is to provide a leverage P&L and we believe with the opportunities that we have in front of us that we're going to be able to drive margin improvement over the longer term. And for a number of reasons, first of all, I keep coming back to the fact that I think the growth of these assets is underappreciated. I think as KEYTRUDA grows, I think while some people are concerned about how important KEYTRUDA is to Merck, the flip side of that is, that the mix shift actually works in our favor for those kinds of things. As you look forward, the kinds of milestone payments that we have to make for LYNPARZA and (inaudible) will begin to move, they've receded to the past. I think that

we'll be able to drive margin improvement from the operating efficiencies that we continue to drive inside the company. So I would say without equivocation, we look forward to really substantial and meaningful margin improvement over the long term. The other side of that is we have such great opportunities to invest in things like KEYTRUDA in the short run, that we feel like it will be irresponsible for us to not make those investments because the most important thing to driving the margins is obviously the growth of the top line. And that sort of gets me to the whole issue around long-term guidance. You might remember, when I became CEO, we did have in place long-term guidance, we had 3 more years to run. And we made a decision 25 days in, that, that was not the right thing for Merck, given the opportunities that we thought that we had. So I'm just going to say about long-term guidance, we hadn't decided to do it or not to do it. But I sometimes worry, when there is that kind of guidance in place, does management focus more on the guidance than it does the real opportunities? And the same thing I will say with margin. I would love my margins to grow immediately. I'd love to get more money to the bottom line, but I want to make sure that I take advantage of the unprecedented opportunities, at least in my experience at Merck that we have with KEYTRUDA and other things to drive their long-term growth, because we can see that when you get to a particular tumor type first, with compelling data like survival data, you actually have a very strong position, it's hard to dislodge. So for our -- from our standpoint, it's growing the top line that I'm really mostly focused on, while not forgetting about the bottom line and efficiency.

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

Great. So maybe we could pivot to Roger. So Roger, since you only get questions on lung cancer, I'll actually start on a broader topic. And by the way, congratulations on the approval in Europe. It's about time patients have access to the combination with ALIMTA. Could you discuss the growth drivers for KEYTRUDA beyond lung cancer? And specifically, what additional indications you expect over the next year or so.

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

Well I think everyone recognizes that KEYTRUDA is the broadest spectrum antineoplastic agent introduced into clinical practice, probably since radiotherapy. And it has such a broad spectrum of activity that it has -- it causes problems in terms of prioritization. We've taken the position that we need first to enter those areas where we think we can do the most good for immunologically responsive tumors. We begin with salvage studies and advance into first line and ultimately, into adjuvant and neoadjuvant. Lung cancer, clearly is the most important cause of cancer death. It's an obvious place in which to pursue KEYTRUDA activity and we've had 5 major studies, demonstrating improvements in overall survival, including as you point out, the combination with platinum agents and pemetrexed, in which the KEYNOTE-189 study, which had a hazard ratio for overall survival of 0.49, that's quite remarkable and having a big impact in the United States and Europe and elsewhere. But beyond that, we have already 13 indications in 8 different tumor types, including 1 broad indication for patients with microsatellite instability. And currently under review, 5 major indications that include the expansion out of nonsquamous into squamous cell carcinoma in combination with the KEYNOTE-407 study which has a PDUFA date coming up next month. We have the monotherapy data 042, which also is a Priority Review. Coming up, we have the Merkel Cell data, not a large tumor population, but a very impressive treatment result coming up. We have additional data coming up from head and neck cancer, from the KEYNOTE-040 and KEYNOTE-048. First line, I would point out, which we top lined recently. So the spectrum is very large, hepatocellular carcinoma is coming along and the combination studies as well. I think everybody in this audience knows that if you look at clinicaltrials.gov, there is more than 850 studies that are using KEYTRUDA and more being added every single day. So the breadth is enormous. And even tumors that previously seem to have relatively little activity with KEYTRUDA that includes visceral tumors, microsized -- microsatellite stable colorectal cancer, prostate cancer, pancreatic cancer, others, we're beginning to get a sense that it would be possible to gain access to those tumors because additional pro-inflammatory stimuli, when added to KEYTRUDA, can add benefit. That's just a partial tour, but it gives you a sense of the spectrum of opportunities that exist to improve human health with KEYTRUDA.

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

That's very helpful. And obviously, KEYTRUDA has had extraordinary news flow and has drawn a lot of attention. But some say a little too much attention and ask the question, well what else is Merck doing outside of oncology? So could you talk a little bit about the R&D efforts outside of oncology and what some of the areas are that investors might be underappreciating?

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

Right. So clearly, oncology is -- a lot of our effort goes into the oncology space, KEYTRUDA and beyond. But our company has a long history of discovery and development in primary care medicine and in other areas. We start first with the vaccine portfolio. As Ken mentioned, GARDASIL, not a new vaccine, I was involved in the studies going back to my first tour of duty at Merck for what became Gardasil-4, and at the time, which is again as Ken mentioned, as a concern in the population was, is that in some way or other, the availability of a papillomavirus vaccine would stimulate promiscuity in the teenage population. That concern has evaporated and instead what you hear now from all the major advocacy groups, all the cancer societies, ACS, NCCN in the United States and from governments in Europe is we are interested in the idea of using GARDASIL and now GARDASIL 9, which we were able to register a few years ago, the 9-valent papillomavirus vaccine, we're interested in using that to try and eliminate papilloma virus infection in the human population. Older individuals still benefit from papillomavirus vaccination as we've shown, and that's currently under review in the United States. And in addition, we, to the extent we can gain access to both boys and girls early on, we, in principle, could eliminate that reservoir. And that could have a very profound effect, not just on cervical cancer but on a variety of other solid tumors, and approximately 50% of head and neck cancers are caused by papillomavirus infection. We've not shown that the advent of papillomavirus immunization reduces that number, but the expectation certainly is that, that would happen because papillomavirus is essential for the tumor.

Beyond GARDASIL, we have a very broad spectrum of programs in pneumococcal conjugate vaccines, where we already have a big presence from Pnumovax 23 and we're deeply engaged in this [NRV] 114 programs in Phase III, with many other programs behind it to address both adult and neonatal immunization, childhood immunization, neonascent toddlers. In addition beyond that, cytomegalovirus vaccine. When I go to academic centers, the pediatricians there are most interested in talking with me about cytomegalovirus vaccine because it is in essence, the rubella of our era, and responsible for a very substantial percentage of congenital abnormalities in the developed and developing world. Something that we think we're going to able to do something about our CMV vaccine in Phase II, we have a very broad program in respiratory syncytial virus and related pulmonary viruses. We also have programs in dengue. I think all of you are familiar with what we were able to do with Ebola virus vaccine, though that just takes advantage of our enormous strength in vaccines, that's not a commercial opportunity per se, but something we felt was important to do for the world. That's just the vaccine piece.

If you look at our hospital and Specialty Care programs, enormous opportunities there as well. We spent some time talking today in small groups about our P2X3 inhibitor, which is being developed in Phase III for chronic cough. The outcome of those studies from an efficacy point of view is in no sense in doubt, we've already published our Phase I and Phase II data. The question is durability over a 48-week period and the adverse experience profiles. But I think most of you recognize that cough is the most common complaint in the general practice environment that patients bring to their primary care physicians. So that's an area where we can, I think, do a lot of good, over time. And that the hyperstimulation effect that's caused by illegitimate stimulation of the P2X3 receptors, or rather, the damping down that we can achieve with 7264, that is a great opportunity in other areas besides chronic cough, including pain associated with endometriosis, most likely in several other settings as well. And beyond that, we get into our whole infectious disease program, which includes very broadly our HIV therapies. We just registered doravirine, the second-generation non-nucleoside reverse transcriptase inhibitor, building on a, many, many years ago foundation of Efavirenz and we're now adding to of NKD-591, the long acting nucleoside polymerase inhibitor, which has the unique character of being a translocation inhibitor as well, the first of its class, and it's very long acting. All of these have enormous possibilities. And we still are active in the antibacterial area. We just announced our success in Phase III for ZERBAXA, which is a broad spectrum antibiotic to be used for resistant organisms, and we'll be filing soon, relebactam to complement imipenem, an antibiotic that we developed 30 years ago, that remains very important in -- around the world. So we have a lot of activity there. And then there's cancer.

There's a lot there, too.

So when Ken talks about the breadth of opportunities that exist now, I mean this is the season, ladies and gentlemen, where we're engaged in prioritization. When we in the company, Ken and I, sit down and try to figure out how can we deploy the resources that we have, based on the revenue that we have and maintain a balance between top and bottom line, because we always want to get leverage on the bottom line, and the issue is we have such a large set of opportunities to invest in and they're so important. It's a struggle and a bigger challenge now, as Ken said, than at any time certainly in our tenure together.

Which is a long time by the way.

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

That's very helpful. Maybe we can talk a little bit more about the P2X3 inhibitor. The data was published, I don't know, a few years ago, maybe it wasn't that long ago.

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

Two different sets. One a few years ago, and one more recently.

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

But it didn't really catch a lot of attention at the time. So what do you think, let's say the market underappreciated about the profile of that product in chronic cough?

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

Gosh, I don't know. I think that the fact of the matter is that chronic cough is extremely common, I think that the epidemiologic studies that have been done probably exaggerate to some extent the prevalence of it, because people talk about 10% of the population having chronic cough, which is kind of absurd, but chronic cough is very common. It's a common complaint. And to the extent that you can interfere with what we believe is the underlying pathology, it improves people's performance quite a lot. It -- people find it quite disruptive to be coughing all the time, I'm listening in this audience, as I do now in every audience, where I have the privilege of being able to see a lot of people in one space, and you can hear people coughing. There are people in the room who are coughing. And some of those people have been coughing for months. The distraction factor is pretty large. So if you have a drug that's safe and well tolerated, then that can reduce that. I think there's going to be a large market for it.

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

And then, maybe this is too simplistic a question, but how concerned will the FDA about -- be about potentially masking underlying health issues, right? I mean, whether it be reflux that's causing the chronic cough, whether it be, I don't know, lung issues, et cetera, et cetera, I mean how do you study the drug and ensure to the FDA that you're not maybe repressing a symptom of something that could be more concerning to patient's health?

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

I don't actually think that's going to be a major concern for the agency, because we're not really giving an analgesic or a cough suppressant per se, but dealing with a, what is kind of an exaggerated feedback loop. So I don't -- I mean, longer-term studies would be required to see if there are individuals, who for one reason or another, failed to recognize some greater, more morbid condition as a result of this. But I think it's unlikely. I think there are other -- I mean the biggest concern with the P2X3 antagonist is there is a mechanism based adverse effect on taste sensation. And for some people, actual abrogation of taste, for others, a metallic taste, for some, it's unpleasant. I think what impressed me when I -- we licensed this compound from AFRIN, what impressed me in looking at the data, that was early on, was that even in the face of meaningful taste disturbances, at higher doses than we are using in our Phase III study, people stay on the drug. They would rather have the cough eliminated and suffer a taste disturbance. So it clearly is interfering in their life in some important way. And we will see how that plays out in the larger studies.

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

Let me pause and see if there any questions from the audience? Yes, there is one up here. Just bear with us for a minute, right up here, please.

Unidentified Analyst

I just have a question related to the branded drug pricing. So as we understand, like the distribution payments that kind of tie to the gross prices, and over the years, the gross price inflated, so the distribution payments are -- have increased as well. So I wonder, in your perspective, do you feel like the distributors' current payment levels reflect the value that distributors provide?

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

So the answer to your question is no. I think, when you look at the current situation in the U.S. and I assume you're talking about U.S. largely, and you're looking at for example a company like Merck, where across our entire U.S. portfolio, the aggregate rebate for discounts are now 50%. I'm not so sure that system makes a lot of sense when you have such a huge disparity between list price and net price. I think the president is very much focused on that. He's very much focused on that because frankly, it drives a lot of the out-of-pocket problems that consumers have. So there's a whole discussion about the price of the drug over here, and then there's a separate and I think more important issue, which is what does the patient actually pay out of pocket? And I think the good news is that they are very much focused on where those rebates go, and how come none of that seems to be providing any relief at the actual pharmacy counter for consumers.

Unidentified Analyst

And also a follow up question, maybe it's more direct, you think there should be direct payments from drug manufacturers to PBMs?

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

Well, that's sort of a similar question, too. I think there should be direct payments from drug manufacturers to PBMs. Well that's part of the current system, where people make those payments in order to position their dugs on formularies for PBMs. That has always been the case. I think Merck owned a PBM in '90s called Medco. And I think if we'd known that we could these kinds of rebates, we might have made different decision about spinning it out.

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

But one -- a point that Ken often makes, is that we don't want to be in a situation where the sick are subsidizing the well in terms of the payment scheme. And in many ways, we ended up there and clearly, that's something that should be addressed.

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

Maybe we could pivot to Merck's M&A strategy. So obviously, you've done some pretty compelling deals for LYNPARZA and LENVIMA, but investors still want more. And so if you could comment on, maybe can you comment at a high level, and then Roger, if you could just talk about the deal environment as you see it. Obviously, your team is assessing all sorts of opportunities all the time, but most transactions don't -- consider transactions do not happen, is there any reason for us to think that maybe your pace of activity will increase in the next year or two?

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

So at a high level, I would say we're very much focused on business development and augmenting our pipeline. The challenge is right now, assets are very richly priced in the environment, and the question becomes how do we acquire things at a reasonable price so that we can create value over the long term. Particularly 2 of later stage assets and for us historically, the real sweet spot has been acquiring something very early, where we can bring forward our clinical expertise, and I think KEYTRUDA's an example of that. Pembrolizumab is a good drug, but let's not underestimate how the drug was studied and the value that was created there.

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

So just as you say, Dave, we are constantly surveying the world for good opportunities, and there are many interesting opportunities out there. But to Ken's point, the pricing environment doesn't always work for us. I do want to emphasize that we're quite active in business development. And so we acquire small companies and we acquire compounds, we just talked about the AFRIN compound as one example. A very substantial proportion, in fact the majority of our developed pipeline in one way or another, came from the outside, which is very healthy. It's very healthy even for a large pharmaceutical company like Merck, which is very resourceful and has a very distinguished cadre of researchers, very capable. Nevertheless, we are few and they are many, and you should expect that a lot of the discoveries are going to come from the outside. And most recently, we acquired a small company called Viralytics in Australia for -- in order to gain access to their modified Coxsackievirus, it's an oncolytic virus to be used in combination with KEYTRUDA, has very interesting properties by itself. There's going to be a lot of interesting information coming out of that over time. We have a lot of expertise in the generation of viruses that have biological activity and can be used in humans. And of course, we have KEYTRUDA, that combination makes a lot of sense. In other circumstances, we found things that we were interested in, but you couldn't make the value work because in the current environment, they're just -- the prices are very, very high, and our expectation is that those will normalize in one way or another over a period of time. We'll see.

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

One final question, so obviously, we talked about your view that investors may underappreciate the longer-term growth drivers of the company. Are there any plans to shed any more light on the pipeline? Or provide some more clarity on how you see that playing out?

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

Yes. So one of the things that we discuss all the time is, when might be the right time to provide more insight and transparency into what's happening in the scientific enterprise, just stay tuned, that's something that we're thinking about.

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

Excellent. All righty, well, thank you very much for joining, appreciate you being here, Ken and Roger.

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

Thank you.

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

Thank you.