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MRK - Merck & Co Inc at JPMorgan Healthcare Conference

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Good afternoon, everybody. I'm Chris Schott from JPMorgan. I'm very pleased to be hosting Merck today. From the company, we have Ken Frazier, Chairman and CEO; as well as Roger Perlmutter, President of Merck Research Labs.

First of all, Happy New Year, and thanks for joining us.

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

Happy New Year to you, Chris, and thanks for having us.

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

Yes, we're going to be doing a fireside chat format. And like prior years, we're not going to be doing a breakout afterwards, so we'll just do the chat and then break from there. So maybe Ken to open up and just help us set the stage for the conversation. Can you talk a little bit about how you see Merck positioned as we enter into 2020?

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

Well, let me say that it's an exciting time at the company right now. Last year, 2019, was an exceptional year from the standpoint of execution and focus and results. Those results, I think, give us the opportunity to continue to reinvest in our internal pipeline, which, from our perspective, gives us more internal opportunity to invest in organic growth than we've had in a long, long time.

Also, it gives us the opportunities to think about bringing in the best external science. We're also very much focused on the external environment for pharmaceutical companies. So we're very much focused around the idea of seeing how we can use this opportunity to make sure our operating model is more productive and more focused going forward. But the bottom line is it's a great time to be at Merck. And I think the most recent results are something that we're very proud of.

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

Absolutely, yes. So KEYTRUDA has been quite a story, and even beyond KEYTRUDA, a lot of nice opportunities.
KEYTRUDA, obviously, though, is a key focal point of the story. And the sense I get from talking to investors is there still is a lot of struggle of just trying to get our hands around how large of an opportunity this can be for the company. So just your sense of what inning we are in terms of the commercial ramp of this asset as we think about kind of -- there's a lot of indications to come. Just any comp -- color there would be appreciated.

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

So I would say we're in the early middle innings with KEYTRUDA. That's how, you know...

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

Fourth inning? Fifth inning?

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

Maybe the beginning of the fourth inning. But remember, every inning is different, and a lot more runs get scored in some innings than other. And we think there are a lot of runs left to be scored in this particular situation. So obviously, KEYTRUDA has been an example of unprecedented commercial and clinical execution for Merck. And the good news is that we have a leadership position in a lot of important areas, including lung. We continue to think that there's opportunities to grow lung here in the United States. But there's also opportunities outside the United States to grow that really formidable indication.

But beyond just that, we have opportunities to grow other indications. We have 23 indications now in the United States and 15 tumor types. So there are lots of great opportunities in front of us.

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

And just as we think about KEYTRUDA growth drivers in 2020, I think you mentioned lung. Just elaborate a little bit more on the key indications we should be watching as we think about the ramp?

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

We're very pleased by what we've seen recently with renal cell carcinoma, first line. We are very excited by what we're seeing in head and neck and adjuvant melanoma. They're are wonderful opportunities to grow the drug this year.

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

Okay. Another one, I guess, we talked about is China and -- both KEYTRUDA and GARDASIL. Can you just talk a little bit about that market? Because it seemed like that was a real standout performance for Merck in '19. How sustainable do you think growth is in the China market with your portfolio?

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

We think we have a long runway ahead of us in China. First of all, I think one of the things about our business in China is that we were able to pivot to innovation. And so as you mentioned, GARDASIL and KEYTRUDA are driving our growth, and that's a very positive thing. It's a market where the self-pay market is a very substantial one. If you're thinking about -- we talk about, for example, 189 in lung. If you look at the number of newly diagnosed people with lung cancer in China every year, it's a huge number. So there are great opportunities. GARDASIL 9 continues to be something that people stand in line for in China. So there's a lot of opportunity in China.
Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Great. The NDRL, is that an important piece of the strategy in China? Or absent that listing, is there still an attractive commercial market to pursue?

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

I think there’s still very much an attractive commercial market in China on the self-pay standpoint in the emerging insurance market in China. So I think there’s a great opportunity in the private market from -- for both GARDASIL as well as KEYTRUDA.

I think getting it on the national reimbursement drug list is an important thing over time. But I don’t think it’s necessary for us right now to drive the kind of growth we want. And obviously, the challenge around those kinds of things is a price/volume trade-off. And we had to make the right decision, not only for the Chinese market, but as we think about pricing globally.

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

Okay. That makes sense.

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

And I would hope that in the future, there will be other opportunities to have discussions with the Chinese government.

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

Yes, that makes sense. Adjuvant for KEYTRUDA, it seems like the next major set of clinical readouts that we’re going to be paying attention to. What are you most focused on? How are you thinking kind of broadly about adjuvant as a growth driver for the PD-1 space?

Roger M. Perlmutter - Merck Research Laboratories - President

Well, I mean, the reality is that we’re already in the adjuvant market as far as we have approval in melanoma as adjuvant and doing quite well there. I think the next really important piece of information is in the breast cancer setting.

Now in triple-negative breast cancer, we announced the results of KEYNOTE-522 at the ESMO meeting last fall. But those results related to the neoadjuvant component of that study. That study enrolls patients with triple-negative breast cancer in the first-line setting first with neoadjuvant therapy that is prior to surgical reduction of the tumor, and then subsequently with adjuvant therapy.

The neoadjuvant results are terrific and offer great promise for improved health for that patient population because the pathologic complete response rate was remarkably increased. That -- we know from prior studies, the pathologic complete response correlates with good outcomes. But the next piece of it will be a deeper look at event-free survival in that patient population. And I’m optimistic that, that’s going to be very positive, and that leads to another set of adjuvant studies in other tumors. So I think we have a great opportunity there to do a lot of good for patients around the world.

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

Great. That event-free survival data, just rough time lines of when we could expect an update there?
Roger M. Perlmutter - Merck Research Laboratories - President

Well, I'm guessing that we'll have additional event-free survival data sometime in the second half of the year. But of course, it is an event-driven analysis.

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

And then beyond triple-negative breast, what are the other indications that we should be most focused on for Merck's adjuvant strategy?

Roger M. Perlmutter - Merck Research Laboratories - President

Well, there's a very large set of adjuvant studies. And those adjuvant studies will read out over a period of time, not so many of them in the 2020 time frame, but more thereafter.

Remember that adjuvant, people ask often about adjuvant in the lung cancer setting, just as one example. But most patients with lung cancer present with a very advanced disease under circumstances where resection is not really an option. So you have to look at tumors that have a more indolent course. Of course, we're very interested in neoadjuvant and adjuvant in the setting of, for example, head and neck cancer, which is such an accessible tumor. And although our data in KEYNOTE-048, which is being rolled out around the world, which is combination -- either monotherapy or combination therapy in the first-line setting in squamous cell carcinoma of the head and neck, there's an opportunity in adjuvant -- neoadjuvant, which I think will be realized relatively soon.

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

Interesting. Shifting gears to GARDASIL, this has been a significant growth driver in the last few years. It sounds like we're running into some capacity constraints in the near term. Can you just address your efforts to build out capacity there and when we should expect that to be complete?

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

So first of all, the demand for GARDASIL in recent years has been incredible. As the world has now started to look at data from Australia, U.S. and other places and realizing the impact that it could have on reducing, perhaps eliminating cervical cancer in certain markets, the impact that it could have on head and neck cancer, which has led to more of a gender-neutral approach.

So the fact of the matter is the demand has skyrocketed over the past few years. And in response to that, we have worked hard inside Merck to increase our capacity. In fact, we've doubled our capacity in the last couple of years from our existing facilities. There are challenges associated with it. It's an extremely complex vaccine to manufacture. We're doing everything we can with our existing facilities and with some -- use of some qualified contract manufacturers in certain areas where we think there might be bottlenecks in our current process to increase those dosages -- the doses that are available.

I think where you will see a real inflection point because we're going to bring on 2 new bulk manufacturing facilities in the 2023 time frame. And I think as we think about that, we'll be able to address much more of the world's needs. But right now, we're seeing an unprecedented expansion. As I was saying, you have now gender-neutral approaches that are being taken, you're getting greater vaccination rates in the traditional cohorts, you're getting greater geographic expansion around the world. And so we see a long runway in terms of our opportunity to address the issues around cervical cancer, head and neck cancer and other issues.

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

Once those 2 facilities are online, do you expect there'll be any capacity constraints? Or will that take care of the problem for the most part?
Kenneth C. Frazier - Merck & Co., Inc. - Chairman, President & CEO

I think it will take care of the problem for the most part. And again, we see this as a long-life opportunity. We think this is going to be in front of us for a long time. It’s a great thing about having a complicated opportunity like GARDASIL 4 and GARDASIL 9 is that it’s a very difficult vaccine to make for us, and we’ve been making for a long time. And so as we think about the durability of that, we think that’s a great opportunity for an awful long time.

Christopher Thomas Schott - J.P. Morgan Chase & Co, Research Division - Senior Analyst

Yes. Excellent. Pivoting to R&D question for...

Roger M. Perlmutter - Merck Research Laboratories - President

I would just say with respect to that, you should recognize that in an ideal circumstance, you really like to immunize the entire birth cohort of the world with 2 doses, which is 200 million doses to begin with, without considering the catch-up for all of those people who are post-adolescent but up to age 45 in women, and that’s without considering the head and neck issue. And we know at least 50% of head and neck cancer is HPV-related. So we don’t expect we’re going to be able to reach those kind of vaccination numbers, but the demand is really very substantial.

Christopher Thomas Schott - J.P. Morgan Chase & Co, Research Division - Senior Analyst

Maybe on the R&D side, it seems like there’s been such success with KEYTRUDA. And that’s been the complete focus of The Street, for better or for worse, over the last few years. The most common question I get is perception of is there enough else in the pipeline that could be significant enough to deliver to eventually diversify the company as we think about an LOE for KEYTRUDA over time? I guess where is The Street getting it wrong in terms of the pipeline right now and the perception that maybe we don’t have that -- those kind of mega blockbusters that we need to offset KEYTRUDA?

Roger M. Perlmutter - Merck Research Laboratories - President

Well, it is fair, and everyone recognizes that KEYTRUDA is no ordinary drug, and it is changing practice everywhere, has grown enormously and grew last year from a very high base at a remarkable rate, such that it’s annualizing at over $1 billion a month. And so it’s a very large drug. And it’s not like you will pick other drugs and reach that kind of sales milestone in a short period of time.

But look at the set of assets that we’re currently developing. So beyond that, first of all, we have other oncology assets that are very significant, Lynparza and Lenvima from our collaborations with AstraZeneca and with Eisai. Those are very very important, very big drugs that are doing a lot of good. Look at the same time at what we’re doing with our pneumococcal conjugate vaccine, V114, the Phase III program of which will deliver results this year, it represents an enormously large vaccine market, which we know very well because, after all, we’ve marketed Pneumovax for a very long time. And beyond that, we have other conjugate vaccines because we believe there are important segments of this market that can be addressed differently, and each one of those is a very significant drug.

Returning to oncology, but at a somewhat earlier stage, we have the Peloton renal cell carcinoma drug, HIF-2 alpha inhibitor, that drug has demonstrated activity. It will go on to demonstrate activity in the rare setting of Von Hippel-Lindau syndrome, but as well in renal cell carcinoma. And this is an area that we’ve made substantial inroads into because of our combination data in renal cell carcinoma. So a great opportunity there.

Also, we acquired, towards the end of the year, a novel, noncovalent BTK inhibitor from ArQule that will be very important, and we have a lot of internal oncology assets. In fact, more than 20 that have already advanced into the clinic, some of which are showing exciting early data. So there’s an awful lot going forward there. I haven’t even mentioned to you our P2X3 molecule for chronic cough. The fact that we had a positive study for vericiguat, the Phase III study in heart failure which -- the data for which will be presented at upcoming scientific meetings. So there’s a great
opportunity there. And looking earlier in the pipeline, still more opportunities in cardiovascular medicine and as well in vaccines. So we've got an extremely broad pipeline...

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

HIV.

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

And in HIV as well. So Ken says, from his experience in the company, which overlaps mine in large respect, although I left for a little while. But what Ken says is that he's never seen a time when the internal pipeline was more deserving an investment, and I agree with that. I think it's quite extraordinary.

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

Digging into a couple those. V114. Just your latest thoughts about how you see that product fitting in the marketplace relative to not just Prevnar, but potential 20 valent product that your competitor is developing? Just your perspective on how that landscape evolves over time.

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

Yes. I think that it's important to recognize that the pneumococcal vaccine market is going to change dramatically because every time you introduce a new vaccine, you change the set of pneumococcal species or subspecies, that is those defined by their carbohydrate serotypes, that is responsible for the bulk of invasive pneumococcal disease. If you're immunizing in the pediatric population with a certain set of serotypes, you can expect that immunity will be durable for those serotypes, and other serotypes will come to up to inhabit those niches for invasive pneumococcal disease. So that means that you want a different set of vaccines for an adult population as compared to a pediatric population.

We've done a lot of work to define the epidemiology of those serotypes and to design ideal interventions in the pediatric versus the adult population. That's why we're doing V114, V116 and now most recently, V117, which we used to call V11X, and we creatively chose the next number, V117.

So I mean, that's a big portfolio, but we know how to make these vaccines, and they will address important populations.

You could take the perspective of what one vaccine ought to just serve everyone, and we have colleagues/competitors at other companies who are taking that view. Our view is that a more focused approach to this will be more important.

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

And just the latest on the timing on 114. Is that data we should be expecting in...

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

Right, the V114 data, as I said, are coming this year, Phase III data. And we have a very large, very comprehensive program for V114. So we do expect that we'll have the opportunity to have a robust filing package, ideally, by the end of the year.
Okay, great. Question for Ken. Merck’s maintained a more diversified business than many of its competitors. And we’ve seen — it seems throughout the space, we’re seeing a continued trend of spinning or selling kind of nontraditional bio formats.

Yes. We’ll see how that works out over time. I guess the question I have here is, when I think about the momentum you have in your core business, is there a rationale to consider splitting off a portfolio of older, slower growing assets? Maybe not in the same structure we saw one of your competitors do last year. But is there a rationale in your view to do that? Is it something that you would evaluate?

So let me start by saying I think if you look at the recent performance of Merck, a lot of that is based on our making a decision a few years ago to put a great deal of focus around our growth drivers: oncology, vaccines, Animal Health, as well as certain parts of our hospital portfolio.

As we move forward, we see even greater opportunities for focus on those growth drivers. So happens, right now, in our human health portfolio, we have over 160 drugs. So our strategy was to articulate as prioritize the assets in the organization around the greatest growth opportunities and optimize everything else. There comes a point in time where you have to challenge yourself and see whether or not that optimization really makes sense. We continuously evaluate the whole human health portfolio, and we continuously ask ourselves how we can put those assets to best use, both on the perspective of public health, but also from the perspective of shareholder value.

So while we’ve made no decision, I will tell you that we continuously evaluate that portfolio. And the flip side of what we said earlier, which is that we’ve never seen an opportunity internally to invest around growth in our current asset set does make us ask the question about how do we manage the entire portfolio for the benefit of, again, public health as well as shareholders.

So as that – the success you’ve had in that core business maybe pushes you a little bit harder on that portfolio?

I think it pushes us harder to continue to reprioritize around the best opportunities for growth.

Okay. Great. Another kind of core topic has been business development. And I just would be interested in your latest thoughts on the landscape here. It just seems like The Street is generally supportive of Merck building out its pipeline and portfolio. And I was just interested right now what you see the sweet spot is for Merck as we think about commercial versus clinical, as we think about broader platforms versus maybe single product companies.
Kenneth C. Frazier - Merck & Co., Inc. - Chairman, President & CEO

So let me start by saying that we think that business development will remain for us a very big imperative going forward. And the reason we think about that is because we’ve always been a science-led company. And we always know that there are great opportunities on the outside. So I would say that the way we think about it is what’s the next great opportunity in science and how can we get a hold of it in a way that creates value for shareholders.

What we’ve said is we’re not particularly interested in doing a large consolidation-type merger or synergy-driven merger because that doesn’t help us over the long term be more effective in innovation. But as we think about bolt-on transactions, we don’t really discriminate on the basis of size. We ask ourselves where the next great scientific opportunity is coming from. And we are looking for those, again, in a financially disciplined way, but we’re very much focused on them. And last year, we did over 80 transactions. If you include the ArQule transaction, we’ve spent about $8 billion on those 80-plus transactions. And we’re going to continue to be active.

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

It seems like you’ve also had some success with these partnership type of arrangements? Is there a robust pipeline of opportunities to pursue like that?

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

Well, I have to say that they come along. I think what those opportunities reflect is the flip side of the conversation we have about concentration risk, which is because KEYTRUDA is so foundational, lots of people who are developing lots of other things come to Merck because they’re asking the question of whether or not those particular assets are best put in combination with KEYTRUDA. So those are 2 opportunities that came our way, frankly, because people were looking to see whether or not there was a joint development plan with their molecule and our molecule. And we continue to see these opportunities all the time. Roger and his colleagues field lots of requests from people to think about investigating a particular compound or candidate with KEYTRUDA.

Roger M. Perlmutter - Merck Research Laboratories - President

And I would also say that credit to our business development team who are very clever in thinking about, “Gee, how can we expand our impact through these partnership arrangements?” And we’re very pleased with what we’ve been able to do with our colleagues at AstraZeneca and at Eisai. Both Lynparza and Lenvima are doing terrifically well and will do terrifically well in combination with KEYTRUDA.

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

Last question is just I know in the past you’ve talked about valuation being a challenge for some of the transactions you look at. What latest state of the land, where are we today with valuation? Is it [everything] at this point? Or is it still balancing?

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

Everything is fully valued out there from everything that we can see. But we have a lot of strength in our balance sheet. We can do transactions as we take the long view. Again, the sweet spot for us has always been the kinds of transactions that are at a stage where we think that we can use our own internal scientific, our development prowess, our commercial prowess, to make those have more value than they do in the hands the people that have them now. And we’ll continue to look at them. Even though they’re fully valued, that doesn’t necessarily scare us away.
Okay. Great. Maybe in the last couple of minutes here, just pivoting a little bit to affordability because it seems like that's the bigger and bigger challenge across the space. How do you address patient out-of-pocket? Because it seems like that's been one of the challenges that this space is facing, that -- the patients absorbing a lot more of the cost of medication than the past. What should we be watching on that front as you try to kind of take on that challenge?

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

So I think that is the fundamental issue that we have in our industry right now, is the combination of the challenge associated with the amount of rebates that are being paid into the supply chain and the incentives that, that creates. Some of them are incentives that are not necessarily positive from the perspective of patients, and the fact that patients at the pharmacy counter are paying, in essence, 12% of the list cost under many insurance policies. And so for us, we think that we have a role to play in terms of affordability. I don't think the industry can walk away from the challenges around pricing. But I also think that if we don't come up with comprehensive solutions that include helping to get more of those rebates into the hands of the people who are actually filling prescriptions at the pharmacy counter. The other challenge is, how much of that is upfront at the beginning of every year. I mean we all know in this country that some -- a substantial number of people in this country cannot deal with an emergency that requires $500 worth of cash. So you think about people who are paying thousands of dollars in upfront payments because that's the way their policies work. We want to spread that. I think we have to put a cap on what people pay for -- out of their pockets. But I have to say, as I look forward to that, I continue to be optimistic that when we get around to creating policy solutions, people will take into consideration the fact that this industry is coming forward with more innovation than it's ever had before, that there are great opportunities in the future. And that we've got to find ways of helping people to pay for these drugs.

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

Great. Well, thanks very much, but we're out of time. But I appreciate the comments today.

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

Thank you, Chris. Thanks.

Roger M. Perlmutter - Merck Research Laboratories - President

That's great. Thank you so much.