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MRK - Merck & Co Inc at JPMorgan Healthcare Conference

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QUESTIONS AND ANSWERS

Chris Schott - *JPMorgan - Analyst*

Good afternoon, everybody. I'm Chris Schott, pharmaceutical analyst at JPMorgan and very pleased today to be introducing Merck and a fireside chat with Merck. From the Company, we have Ken Frazier, the Company's Chairman and CEO, as well as Roger Perlmutter, President of Merck Research Labs. So, welcome, and happy New Year.

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

Thank you, Chris. Good to be here.

Chris Schott - *JPMorgan - Analyst*

Yes, excellent. So, Ken, why don't we just start out? Obviously, 2016, very successful year for the Company. As we kind of turn the page to 2017, can you just talk through some of your priorities for the organization, what you're most focused on, really what we should be thinking about for the Company going forward?

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

So, the exciting thing for us, as we're entering into a very important time of new product introduction, both launches of drugs like Keytruda for first-line non-small cell lung cancer, Zepatier around the world, and we're also seeing the progress of our pipeline. So, it's a very exciting time. Our primary responsibility is to execute on the opportunities in front of us, balancing the short term and the long term.

Chris Schott - *JPMorgan - Analyst*

Excellent. One of the topics that you had discussed in 2016 was accelerated business development activity. And it was about a year ago we started hearing this from Merck in a much greater extent. I think the market's been a bit surprised we haven't seen maybe more transactions for the Company. So, maybe just as we enter this year, can you just update us where we stand in terms of capital deployment? What's the market look like out there for the opportunities you're pursuing? What are you most focused on?

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

So, business development remains extremely important for us, particularly augmenting our Phase 2 and earlier pipeline because we see the opportunities to create value earlier in the space.

We also will look at all kinds of transactions across the spectrum. In terms of the progress that we made, we did a lot of smaller deals, a lot of earlier stage deals. I think when you say the market was surprised, they probably mean we didn't do a lot of large transactions.

Chris Schott - *JPMorgan - Analyst*

Yes.

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

And there, I think it really comes down to taking a disciplined approach. We want to find the right assets at the right valuation. And that continues to be our goal. And so, we look at everything. We're particularly interested in bolt-on acquisitions that will help augment our pipeline. As I said, we're interested in products that we can bring to market. But, it has to be, again, the right product, the right assets at the right valuation.

Chris Schott - *JPMorgan - Analyst*

Does that -- those metrics, do larger acquisitions fit into that, or should we really be thinking about this as smaller transactions?

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

Well, I think we think about them as being bolt-on acquisitions. We don't really segregate them based on size. We worry about whether or not we're getting great assets that can actually help drive our innovation strategy. And then the larger they are, obviously, we have to start to think about the complexity of doing an actual transaction and whether that's going to be disruptive to a program like we have with Keytruda.

Chris Schott - *JPMorgan - Analyst*

Sure. Tax reform and repatriation seems like a big topic with this new administration. And maybe dovetailing a little bit into business development, what are your thoughts on tax reform? What will that mean for Merck in terms of cash flow, in terms of business development priorities?

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

So, obviously, we're very much in favor of comprehensive tax reform. We think it's important for US-based companies to be on an equal footing with our foreign competitors. And that has to do with everything having to do with, for example, acquiring things in the M&A context.

With respect to repatriation, I think that, if that happens, that's a positive thing. But, the most important thing is that we actually do comprehensive tax reform going forward. We're very pleased by what the Paul Ryan blueprint would say for us going forward.

But, in terms of linking it back to M&A, I don't think something like repatriation would drive specific deal activity. We would still look at deals the way that we look at them. That is to say, are we getting great assets, and we're getting it at a good valuation?

Chris Schott - *JPMorgan - Analyst*

Okay. Great.

Roger Perlmutter - *Merck Research Laboratories - President*

Over time, Chris, and I think many in the audience recognize this that a tax reform that invoked a territorial kind of system would reduce business complexity dramatically because, inevitably, we're driven in a lot of decision making by the current tax policy. And that results in some pretty complex supply chains.

Chris Schott - *JPMorgan - Analyst*

A couple more high-level ones, then we can dig into specific business. Drug pricing, hot topic right now, how are you thinking about drug pricing 2017 and beyond? And I think Merck's had a little different approach to pricing than some of its peers. That said, it seems like it's an issue that's kind of engulfed the whole industry. So --

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

Well, I think from reputation standpoint, it has harmed the industry greatly. Merck has always tried to take, as I think you were implying, a more responsible, somewhat disciplined approach to pricing.

We've always tried to think about it through the lens of value. What's the value to individual patients? What's the value to the overall healthcare system? We try to optimize access on the one hand and also profitability to see if we can put ourselves in that sweet spot where patients have access to our drugs, but we're also getting the kinds of return on investment that will incentivize future capital investment in our industry. So, that's how we've tried to look at it.

I think one of the things that's really important is that the industry not be looked at as just one uniform industry. A lot of the issues, as you know, have arisen with generic companies. They've arisen with some specialty pharma companies that have bought assets and paid a premium and then have marked up their drugs in order to cover that premium.

I think, when you look at a drug like Keytruda, you will hear some commentary about the price. But, we haven't gotten a lot of pushback on that drug because the value is clearly there. It is a life-changing drug. We tried to study it in a way with biomarkers that allow us to in a more sensible way figure out how to stratify patients. And so, I think we've gotten the right kind of reception, even though the sticker price might be high.

Chris Schott - *JPMorgan - Analyst*

Yes, diabetes has been I think a market similarly on pricing where there's been a lot of volatility. And there's been some pressures. How -- what's your outlook on that market, where there does seem to be quite a bit of competition? It seems like payers are more aggressive than they maybe have been historically in terms of narrowing formularies, etc. How do you think about the longer-term outlook for the diabetes segment?

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

Well, I'll speak to the business that we have, which is we've done very well with Januvia, in the United States and outside the United States. We're seeing good growth of Januvia right now. We're seeing great formulary access.

And so, in the United States, we see TRx growth that I think probably balances out some of the price pressures. Outside the United States, we're seeing great growth. So, if you put them together, that's actually a pretty good opportunity that we have.

We also are looking forward to the next generation of medicines. Our combination with our SGLT2 with Pfizer gives us an opportunity, assuming that those medicines prove out to have cardiovascular benefit, to put it together with the market leader.

So, we're very excited by the future of our diabetes franchise. Obviously, we have our once-daily product in Japan, where the drug is being sold first line. And we also have our insulin glargine business coming forward. So, we're very excited by it. And I think, again, some of the pressures that you might see in the insulin side of the business don't necessarily translate to the DPP-4 business.

Chris Schott - *JPMorgan - Analyst*

Okay. Great. Shifting to Keytruda, it was obviously a very exciting 2000 -- few years, but particularly very exciting 2016. Maybe just first starting with the frontline launch, I now it's early. Any experience you can -- or takeaways that you can share from reception thus far with the product?

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

It is early days. We just got the indication in October. But, I would say all indications are positive. One indication is that we're seeing about two-thirds of first-line patients are now being tested.

Chris Schott - *JPMorgan - Analyst*

Great. Yes.

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

And I think that portends well. But, obviously, there's no big bolus of patients that come through right away. I think that's a positive thing. And the second-line indication, obviously, we now have the indication going down below 50, all the way down to one. And we actually are seeing some testing spill over to that population, which I think is a positive thing for us.

So, all things considered, if you just look at the ramp of the testing, I think that gives us great confidence that doctors are looking for the right patients to treat with this. We're seeing the majority of the patients now being treated at 50 or above. But, we think that's a very positive sign for us, both in first line as well as in second line.

Roger Perlmutter - *Merck Research Laboratories - President*

And I should point out that we did have a favorable review in Europe by CHMP, which we hope will be ratified by the European Union this month. And we also did achieve registration in first line in Japan at the end of the year. So, again, 2016 was a spectacular year for Keytruda.

Chris Schott - *JPMorgan - Analyst*

Yes, absolutely. The drug is right now indicated in patients expressing greater than 50% PD-L1. How are physicians grappling with this issue where you've got a patient who's maybe close to 50%, but not quite there? Are you seeing it used really in the labeled indication, or are you seeing an ability to maybe move away from that a bit?

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

So far, what we're seeing is the majority of patients are within the labeled indication. I'm not sure that we can cut it so fine as to what's 47% versus 50%. But, the majority of patients we are seeing are within the label indication. And we're not hearing that there are big obstacles for physicians who want to use it for patients generally.

Chris Schott - *JPMorgan - Analyst*

Yes. The Company I would say has a tremendous position in lung right now. What are you doing to ensure you maintain this leadership position you have in frontline, given what we're seeing with competitors kind of hot on your trail I guess, and a lot of studies in the next 12 to 18 months? So, how do you think about maintaining this -- you got to market first; you've got a nice ramp ahead of you, but making sure you kind of hold that position over time?

Roger Perlmutter - *Merck Research Laboratories - President*

Well, I guess I would say that the profile of our clinical study speaks for itself. Log into clinicaltrials.gov. And you see that we have in excess of 400 studies currently going on with Keytruda.

More than 100 of those studies are accommodation studies. Not all of them are completely funded by us. Many of those are studies that are investigator initiated, but nothing wrong with that. Many important and interesting ideas have come from those investigator-initiated studies.

If you look at the totality of the work for Keytruda as monotherapy, for Keytruda in combination with a whole set of interesting programs, including radiation therapy, of course, classical chemotherapy, targeted chemotherapy, additional checkpoint inhibitors, oncolytic viruses, and of course, recently, and just announced this morning, the work that we're doing together with our colleagues at Incyte on the IDO1 antagonist, we have an extremely broad clinical portfolio.

And our expectation is, over time, what we all will learn, we all together throughout the industry and those in clinical practice, is that it's not a one-size-fits-all marketplace. There won't be one combination that takes over the entire program. What we know is that Keytruda will be foundational in cancer therapy for some long time to come. Many other things will be used in combination in a whole variety of different tumor settings.

Chris Schott - *JPMorgan - Analyst*

Since you mentioned it, can you elaborate on the announcement this morning in terms of Keytruda with the IDO, just data that led to those decisions? How excited are you about that opportunity relative to some other companies?

Roger Perlmutter - *Merck Research Laboratories - President*

Sure. We, again, are pursuing a whole variety of different combination studies. We had initiated a combination quite early on in the melanoma setting with Incyte using their IDO1 molecule, epacadostat.

And the combination of epacadostat and Keytruda together was intriguing enough, especially in terms of the depth of responses seen in the melanoma population, where again Keytruda monotherapy is extremely effective, that we wanted to pursue that further.

Keep in mind also that the adverse effect profile that has been seen thus far for epacadostat is very favorable. So, in the face of improved breadth but in particular depth of response and a favorable adverse effect profile in combination, we naturally looked and asked: Well, can we see anything else in single-arm studies in a variety of different settings that ought to have similar characteristics that includes non-small cell lung cancer? It's squamous cell carcinoma, the head and neck, and a variety of visceral tumors.

Over a set of four different indications, what we found was very similar kinds of results. And in looking over those data at the end of last year, we together with our colleagues at Incyte said: This is something we really need to pursue together. It was that announcement that came out this morning.

Chris Schott - *JPMorgan - Analyst*

How do you view PD-1 IDO relative to either PD-1 chemo or PD-1 CTLA4 just as you think about the various combos that are now moving into late-stage development?

Roger Perlmutter - *Merck Research Laboratories - President*

Again, I think that each one of these combinations is worth evaluating for its own merits. What we've shown, for example, in the 021 cohort G study is the value of traditional platinum-based chemotherapy in combination with Keytruda in a first-line non-small cell lung cancer setting. Those data are very impressive.

Of course, platinum-based chemotherapy is not without adverse effects. And not every patient is going to be appropriate for that kind of intervention. If one can achieve those kinds of improvements in response with other agents, then that would be a good thing to do.

Data that we have and, of course, data that comes from our colleagues at other companies says that CTLA4 can be used in combination. CTLA4-directed therapy, ipilimumab in particular, can be used in combination with PD-1-directed therapy. Over time, we will learn about the relative value of chemotherapy, CTLA4-directed therapy, IDO1-directed therapy, and a whole variety of other things.

Again, we and others have shown that the combination of T-Vec, the Amgen marketed oncolytic virus, in combination with PD-1 therapy also provides value in the melanoma setting, likely in other settings. And we're pursuing that, of course, in head and neck. So, there'll be a lot of different combinations.

And the question is, in which patients do you achieve the best balance of efficacy and safety? What is the benefit-risk profile? And I suspect that we will find over time that there will quite a lot of individualization of therapy.

Chris Schott - *JPMorgan - Analyst*

When you think about all these combos and very exciting science playing out here, do you see a role for monotherapy longer term, or do you ultimately see this being mostly a combo business?

Roger Perlmutter - *Merck Research Laboratories - President*

It's hard to predict, but I think that we still have not fully explored the totality of impact of monotherapy in certain settings. For example, the data that we presented at ASH on classical Hodgkin lymphoma, which is currently under review by the FDA with a PDUFA date in early March, those data are really quite spectacular in terms of response rate and the degree of tumor regression in patients who have failed other therapies.

We've seen other similar kinds of data in different settings. In aggregate, more than 30 different tumor types are being studied. And more than 20 of them, we've seen really meaningful monotherapy responses.

I've always taken the position that we must first understand how well monotherapy behaves before we can sensibly pick combinations. And we're still in the midst of that. There are going to be many patients, depending upon comorbidities and performance status, who will benefit most from a monotherapy intervention.

Chris Schott - *JPMorgan - Analyst*

There's been a lot of debate I think with a number of Phase 3 studies reporting over the next year or so of chemo combo versus CTLA4 in lung cancer. Can you just elaborate a little bit more on your views of, as you think about those two specific opportunities where we'll be -- we're going to be seeing Phase 3 data, how you think about the relative profiles of the two combos?

Roger Perlmutter - *Merck Research Laboratories - President*

Again, I think it's not an either-or. And there will be different tumor types in which different combinations are used. One of the things to keep in mind is that there is an established platform and understanding about how to use traditional chemotherapy and how to manage the adverse effects of that.

So, it is not so difficult, as long as the data support it, to add Keytruda to traditional chemotherapy. And we know the benefit that results because we've already demonstrated it in a controlled trial in the 021 cohort G. And additional studies exploring that benefit will be coming out later this year, for example, the KEYNOTE-189 study. So, chemotherapy clearly is something that's going to benefit from additional exploration. And it's something that already is being tested.

With respect to the combination of ipilimumab and Keytruda or other PD-1-directed therapies, there, there's already an indication in the melanoma setting. And the question is, how broadly can this be exploited? And which patients really benefit from it because, as everyone knows, the adverse effect profile of the combination is meaningfully worse than monotherapy with PD-1-directed therapy?

And that's just scratching the surface because, as I say, there are many other adjunctive therapies to be used in combination. And things like epacadostat may turn out to have similar benefit when we finally study all the aspects of it and have a much, much less serious adverse effect profile.

Chris Schott - *JPMorgan - Analyst*

How do you think about pricing ultimately if we go towards novel kind of IO-IO combos? Can this be a situation where one plus one is two, or is that going to be such that the system just can't support that type of cost per patient?

Roger Perlmutter - *Merck Research Laboratories - President*

Well, pricing is always going to be a function of value. And the value is determined by the benefits that inure to patients in terms of particularly overall survival and quality of life.

Until we have a better feel for that, I don't think we can really say. My hope, of course, is that combinations of Keytruda with other agents, some of which are already generic and relatively cheap, will yield very profound benefits in overall survival and quality of life and not require that there be a substantial additional investment by society in these improvements. But, we'll see.

Chris Schott - *JPMorgan - Analyst*

Maybe just in the last few minutes here, kind of shifting beyond immuno-oncology, can you talk about the pipeline more broadly? What are you most excited about? And what should we be watching in the non-IO part of Merck's pipeline?

Roger Perlmutter - *Merck Research Laboratories - President*

Well, there's a huge amount coming forward. Ken has already mentioned the fact that we have our own SGLT2 molecule that's in collaboration with Pfizer. That is a very, very large program. We had promised that we would file this in 2016, and we did achieve that. So, we're moving forward with that program.

Beyond that program, which I think will benefit from our presence in diabetes and the impact that Januvia and Janumet have had over time -- beyond that program, there are a number of things to look at.

First of all, we've made tremendous progress in the infectious disease arena, both for antimicrobials, traditional antimicrobials, and also antivirals. We top-lined data from the letermovir study in patients who have CMV -- that are at risk of CMV reactivation in a transplant setting. Those are very exciting data that we'll have an opportunity to share in scientific meetings.

Beyond that, we also have a novel nonnucleosidal reverse transcriptase inhibitor doravirine. We've presented Phase 2 data, in which we've talked about the improved characteristics of that molecule versus the existing molecule efavirenz, which we registered many, many years ago.

And beyond that, we have a very large portfolio of HIV-directed therapies which look extremely promising.

If you go to the vaccine arena, we've got an enormous amount of work going on, part of which is the interaction that we chartered years ago with Moderna, some of which they will be describing here at this meeting, using mRNAs to stimulate immune responses as subunit vaccines. Now, those data look really quite exciting and promise to change the entire world of vaccines. We'll be seeing some of those data this year. It's extremely promising.

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

And then (inaudible) in areas like cholesterol and in Alzheimer's, which are also important.

Roger Perlmutter - *Merck Research Laboratories - President*

Oh, that.

Chris Schott - *JPMorgan - Analyst*

Minor things. On Alzheimer's, maybe just our last question here, following the failure of the EXPEDITION 3 study, what should we read or not read into Merck's BACE program on the back of that dataset?

Roger Perlmutter - *Merck Research Laboratories - President*

I don't think that the EXPEDITION results have much impact in terms of thinking about our BACE inhibitor program. The genetic data associating increased BACE activity based on substitutions in the gene in coding beta-secretase, increased beta-secretase activity with a higher likelihood of progression to dementia over time, are very powerful.

And more importantly, if you inherit alleles of the beta-secretase gene that have lower BACE activity, there's a less likelihood of progressing to dementia, all cause, over time. And what that says is that, if I can introduce a safe, effective beta-secretase inhibitor that lowers BACE activity, in essence phenocopying the genetic mutation, I should delay the time to progression of Alzheimer's disease or dementia of all cause.

The problem is I don't know when to administer that. Now, exactly what happens when you put an antibody in and try to remove A-beta or remove amyloid plaque, that's a different mechanism. What we're doing here is reducing production of A-beta. And we're doing so by a genetically validated mechanism.

So, in that sense, I'm not sure EXPEDITION reads on our probability of success. My concern is that, in order to do these studies correctly, we need to start early. It always is better to treat disease early in its progression.

And if one studies patients too late in the process, where neuronal loss takes place, you're not probably going to be able to affect that too much. Time will tell. The first readout of our mild-to-moderate Alzheimer's study will take place this year. The 017 study will probably read out in the third

quarter. That's what we believe at this point. We also now have fully enrolled our prodromal study, the 019 study. And that study will read out in a couple more years.

Assuming that one can intervene early enough, there really should be a beneficial effect. Touch wood, we'll see it in the 017 study. Stay tuned. Third quarter isn't that far away.

Chris Schott - *JPMorgan - Analyst*

Great. Well, I think we're just out of time. Pretty exciting couple of years ahead here for Merck. So, we'll continue the discussion across the way in the breakout. But, Ken and Roger, thanks so much.

Roger Perlmutter - *Merck Research Laboratories - President*

Thank you.

Ken Frazier - *Merck & Co Inc - Chairman & CEO*

Thanks, Chris.
