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MRK - Merck & Co Inc at Bank of America Merrill Lynch Healthcare Conference (Virtual)

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## CORPORATE PARTICIPANTS

**Franklin K. Clyburn** *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

## CONFERENCE CALL PARTICIPANTS

**Geoffrey Christopher Meacham** *BofA Merrill Lynch, Research Division - Research Analyst*

## PRESENTATION

**Geoffrey Christopher Meacham** - *BofA Merrill Lynch, Research Division - Research Analyst*

Okay. Good afternoon, everyone, and welcome to the first day of the afternoon session for the BofA Virtual Vegas Conference. My name is Geoff Meacham. I'm the senior biopharma analyst here at BofA, and Olivia Brayer from my team is also on the line.

And we're thrilled to have Merck present this afternoon, and we have with us Frank Clyburn, who's Executive Vice President and Chief Commercial Officer, Frank you there?

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**Franklin K. Clyburn** - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

I am, Geoff. Can you hear me?

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**Geoffrey Christopher Meacham** - *BofA Merrill Lynch, Research Division - Research Analyst*

Yes. Perfect.

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**Franklin K. Clyburn** - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Okay. Good.

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**Geoffrey Christopher Meacham** - *BofA Merrill Lynch, Research Division - Research Analyst*

And we also have Peter Dannenbaum from the Investor Relations team as well. So the format is we'll do some questions here with Frank and the team. There is an availability to queue in electronically with some questions, which we can ask as well.

## QUESTIONS AND ANSWERS

**Geoffrey Christopher Meacham** - *BofA Merrill Lynch, Research Division - Research Analyst*

So with that, Frank, I'll just get right into it. So maybe probably the more topical questions that we've gotten just post the earnings call is when you think about the outlook, just help us with maybe the cadence of growth through the rest of the year. As we go through the COVID-19 crisis, maybe how has your learnings -- how have your learning has kind of affected maybe the commercial response outlook into the second half of the year?

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**Franklin K. Clyburn** - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes, Geoff, thanks for the question. Also thanks, everyone, for joining. A couple of things I'll want to mention, Geoff, is, first, if you look at coming off of 2019, we had exceptional growth in 2019 of 13% growth on the top line, 21% growth from an EPS perspective, if you would exclude exchange.



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And then when you look at 2020, Geoff, we feel very good. We got off to a great start, 13% growth on the top line and 26% EPS growth, excluding exchange.

So the first message I really wanted to reiterate is that the fundamentals of our business are very strong. We feel very good about our growth pillars that we have highlighted. And as we headed into the pandemic, in particular, in China, we did see some impact in China with regards to hospital visits and patients not being able to access the health care system. And despite that, we did show strong growth in the first quarter.

As we head into the second quarter, you saw the pandemic really starting to impact the U.S. and Europe. And what we are seeing is that hospital procedures, in particular, elective surgeries have declined approximately 70% to 80% in the U.S., and I think that's been well documented. And that does have an impact on a product such as BRIDION in some of our hospital portfolio.

We also see vaccines. A strength for us is our broad portfolio in vaccines. We do see well visits and patients, in particular, infants having their vaccinations delayed because of stay-at-home orders and social distancing. So we do anticipate in the second quarter an impact to our vaccine franchise.

We also highlighted we have a very important women's health franchise, and that portfolio, both fertility and contraception, we have an implantable contraceptive product, NEXPLANON, that women are deferring or not getting implantables right now because of stay-at-home orders.

And then in oncology, we think oncology is very resilient. We have tremendous strength in oncology, and KEYTRUDA grew very significantly over the first quarter. But we are seeing some new patient visit declines for cancer treatments in the U.S. We think that will have some impact in the second quarter. But as you head to the third and fourth quarter, we do expect for the health care systems, in particular, with cancer just to prioritize and make sure cancer patients get seen.

So the way we look at it is, Q2, we do think we'll see an impact, and we messaged that on our call. But as you head to Q3 and then back into the fourth quarter, we made the assumption that you'll have patients being able to access health care systems. Clearly, they'll want to prioritize vaccinations and cancer treatments as well as we do think as you head into the fourth quarter, hospitals will want to continue to try to get elective surgeries scheduled, which we think will have an impact on products like BRIDION as you get to the back half of the year, Geoff.

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**Geoffrey Christopher Meacham** - BofA Merrill Lynch, Research Division - Research Analyst

That's helpful, Frank. When you think about KEYTRUDA and the impact from COVID, I imagine that you have some best practices for centers that were able to appropriately sort of reflect social distancing guidelines and protection and things like that. So are there lessons to be learned when you think about the commercial implications, not just in the U.S. but more broadly?

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**Franklin K. Clyburn** - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes, we do. And what we're seeing is, clearly, we're engaging with customers around the world, Geoff, remotely to make sure that we're sharing not only our data and a lot of our new launches and indications around the world, but also doing everything we can to educate the importance of continuing care for cancer patients. That's really important.

And I think many hospitals, many clinics around the world are doing everything they can, in particular, for cancer types such as lung, Geoff, head and neck cancer, also ovarian cancer because many of those cancer types are diagnosed at a very late stage of disease. So it's really important to make sure those patients do not see interruption to their treatment.

So we've been working with a lot of customers to make sure that they are doing everything they can. And we've seen a lot of really good examples of bringing patients in, making sure they are socially distant and also helping them to navigate the health care system so that they can have a continuity of care.



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We are seeing some that are just delaying new cancer maybe diagnosis of treatments in cancer types such as maybe prostate and breast cancer, but we anticipate that they're going to want to get those patients in as quickly as possible. It's clearly an effort, not only from us, but also many of the associations, Geoff, are focused on getting cancer patients treated.

The other thing I would highlight, we just recently got an approval for Q6week regimen for KEYTRUDA. And we do think that, that will also help having a more flexible dosing schedule and regimen, especially during the pandemic. So those are some of the activities that we've been involved in.

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**Geoffrey Christopher Meacham** - *BofA Merrill Lynch, Research Division - Research Analyst*

Okay. That's helpful. Frank, you mentioned first-line lung. And obviously, that's going to be a pretty topical market and a pretty topical indication. This week, when you have TIGIT, and you have a lot of competitive data from TIGIT to 9LA to Poseidon. I want to get a perspective from you. Clearly, first-line lung is a huge share -- market share for KEYTRUDA and the data, including 024, including 189, are pretty robust. But just help us with how you think about this indication from a competitive standpoint? Is there sort of an offensive or defensive strategy that you can use maybe to in advance or following the data that help protect share from a commercial perspective?

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**Franklin K. Clyburn** - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Sure. And it's, I think, important to really look at what's developed in lung cancer, Geoff, and the position that we do have, in particular, nonsmall cell lung cancer. As you mentioned, we have 5 approvals in lung cancer, and we have very strong overall survival in monotherapy based off of KEYNOTE-024 and KEYNOTE-042 as well as in combination therapies with 189 and also KEYNOTE-407 in the squamous cell carcinoma population.

And the first thing I would emphasize is that the strength of our data, we think, has built a pretty high hurdle. You recall that our hazard ratios are 0.49 with 189 and 0.60 with KEYNOTE-407. So the first thing is we've seen a significant magnitude of effect and benefit of KEYTRUDA in lung. And we believe that of the current data as well as the experience that oncologists have had around the world in treating lung cancer with KEYTRUDA is very significant.

We will obviously want to see some of the data readouts that you mentioned from competitors. We'll have to see what the magnitude of effect size is with the competitive data sets. We feel, as I mentioned, confident in where we are positioned as a first mover.

If you think about outside the U.S., not only do we have regulatory approvals in lung, but we have now reimbursement which is really important in markets like Europe for KEYNOTE-189. And we have a chance to really establish our combination regimen in Europe here based on those recent reimbursement approvals.

And then lastly, I would say, we are also very interested in some of the new data. We have our own TIGIT molecule that we have spoken about, and we're actively investigating TIGIT as well as other agents and other combinations. So we continue with the breadth of our program. We're looking at all of these combinations to see if there is sufficient evidence to bring forward those combinations, and we've shown the ability to move very rapidly with our clinical development team when we see signals that really show a benefit.

So we're pursuing not only the combinations in the metastatic setting, but we also are moving forward, for instance, along with KEYNOTE-091 in the adjuvant setting as well. So moving into earlier lines of therapy.

So clearly, lung is important to us. We feel good about our position. We feel good about our combinations that we're working on in lung in addition to our position and then moving into earlier lines of therapy.

And then the last thing I will just add, Geoff, is that while lung is a very significant portion of our business, clearly, with the growth you're seeing, we're seeing very strong uptake in renal cell carcinoma, adjuvant melanoma. We're launching in the U.S. nonmuscle-invasive bladder cancer.



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So we've 23 indications for KEYTRUDA right now in the U.S. So the breadth of our program, 1,200 studies, greater than 600 combination trials. So while lung's important, clearly, we believe that the breadth of our program, and we have a lot of additional indications, and there'll be a lot of data coming up at ASCO as well.

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**Geoffrey Christopher Meacham** - *BofA Merrill Lynch, Research Division - Research Analyst*

Yes, you're leading me a little bit into the next indication, which is renal cell carcinoma. And just to maybe get an update from you as you look at some of the competitive data set and with what you have with KEYTRUDA and Inlyta, it looks pretty robust. And the share you guys have gained has been pretty dramatic over the past 12 months or so. But looking forward, what's your sense for how things could trend out? Is there room for multiple IO players in this indication? And maybe is there a strategy, for example, to -- does it matter if one is in sort of first-line share versus second line?

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**Franklin K. Clyburn** - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. And Geoff, so I think that it does matter. Frontline is a bigger opportunity than later lines of therapy. And the way we see RCC evolving, so clearly, we're very pleased with having the first IO TKI combination with axitinib. As you mentioned, we have approval across all 3 subrisk categories: intermediate, favorable and poor. And we have a very broad label across all of those categories and have shown very strong data. And we've seen an uptake in each patient segment. So we feel as though we're very well positioned in RCC based off of 426.

We'll have to see the whole data set from our competitors that have now top line their IO TKI combination. We'll have to see how that evolves in the marketplace. We also have the combination of KEYTRUDA plus Lenvima, which is a different TKI and VEGF receptor. And we know these behave differently, Geoff.

So having an additional offering, if we do see success with that trial, we think, will be helpful because oncologists do like to sometimes use different TKIs. And so having another TKI combination with KEYTRUDA, we think, will be beneficial.

So we feel as though we're well positioned in RCC. We're rolling out RCC now in Europe and in other markets around the world. So having the first IO TKI combination and being able to establish that in markets around the world, we think, is important as well.

But it will be competitive as we've said. There's opportunities also where in many markets, you have still TKI monotherapy. And I do think you're going to see greater penetration with the combination of KEYTRUDA in those settings as well. So we see RCC as a really important growth opportunity not only in the near term, but as we look over the next several years.

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**Geoffrey Christopher Meacham** - *BofA Merrill Lynch, Research Division - Research Analyst*

Great. Thanks. Maybe to ask a couple of questions as well on KEYTRUDA. Ari?

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**Unidentified Analyst**

Frank, you touched on this earlier a little bit, but you guys obviously have some really exciting data coming out at ASCO later this month and even some initial data tomorrow with the abstract. So can you just help us with how you think about those opportunities? Which are the readouts and really the indications that you're most excited about?

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**Franklin K. Clyburn** - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Sure. So let me highlight some of our data, and we have, of course, a lot of data at ASCO this year as we had last year. And I think what you're going to really see is the continued breadth of our program and how foundational KEYTRUDA is really becoming.



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The ones I would highlight is KEYNOTE-355, which is the study of KEYTRUDA plus chemotherapy in metastatic triple-negative breast cancer. There's an oral presentation, KEYNOTE-204, which is KEYTRUDA versus brentuximab or Adcetris in relapsed/refractory classical Hodgkin's lymphoma. We think -- I think that's an important data set.

KEYNOTE-177, I also think, is a very important data set. This is first-line therapy of KEYTRUDA versus the standard of care and MSI-high metastatic colorectal cancer. And we have established KEYTRUDA in later lines of therapy for MSI-high as you're well aware in the U.S., but this is a really important data set.

Also KEYNOTE-048, some additional data from -- and there will be an oral presentation with regards to head and neck, squamous cell carcinoma, so 048's an important data set. And then also I would highlight you'll get a chance to seek Merck 6482, which is our Phase II study of the oral HIF-2 alpha for Von Hippel-Lindau disease associated renal cell carcinoma. So this, you'll recall is a recent asset that we brought in through our BD efforts. So we're excited about that molecule as well. So those would be some of the ones I would highlight.

And then there's a number of abstracts and posters. And I think you're going to see just the significant breadth that we have with the KEYTRUDA program as we head into ASCO.

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#### Unidentified Analyst

Okay. Perfect. That's helpful. And you mentioned KEYNOTE-355 in first-line TNBC. Obviously, we saw that positive top line readout from the trial with regards to the PFS. So can you just give us a sense of is there any sort of overall survival update that we should be expecting at ASCO? Or is the focus at this point more on the PFS data and really the top line readouts that we've already seen?

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#### Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes. I think you're going to see additional PFS data. I'll let the data at ASCO -- you'll get a chance to see it here soon. And we're also -- obviously, we top lined our 522 data. We had mentioned that as well, which is in the neoadjuvant/adjuvant setting.

So when you take a look at both of those trials, we're excited about, obviously, the opportunity for the future in TNBC.

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#### Geoffrey Christopher Meacham - BofA Merrill Lynch, Research Division - Research Analyst

Yes, Frank, let me just switch gears. You mentioned in the beginning the vaccines business as a growth driver. And I'd say most investors, most of my conversations are mostly on IO, but on V114, a pretty important Phase III program. Just give us a sense for the timing of top line readouts, what trials from an adult setting are really needed that are critical for your year-end '20 filing?

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#### Franklin K. Clyburn - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes, Geoff, thanks for the question on 114. So a couple of things with respect to our 15-valent molecule for invasive pneumococcal disease. We believe it's important to continue to suppress the disease and maintain public health gains, but also maintaining immune response is really important and maintaining response level across all 13 serotypes.

After first accomplishing this criteria, we've been focused on really preventing additional disease by adding disease-causing serotypes 22F, 33F and improving performance for serotypes that persist, in particular serotype 3. We expect, and I think you heard Roger mention that we will see a lot of data here, Geoff, over this next second half of this year. We have over 15 Phase III trials in both adult and pediatric patient population. So we'll have a lot of data readouts coming this year. And then as the data readouts come, we usually top line those, and then we'll provide some additional clarity at that point in time. But we are encouraged by not only V114, but we've also mentioned that we're focused on broadening out our portfolio



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of pneumococcal assets, not only 114, but also 116 and 117 as well. So we're looking at how do you really address this disease for both adults and pediatrics going forward. And there'll be a lot of data readouts, as I mentioned, in the second half of the year.

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**Geoffrey Christopher Meacham** - *BofA Merrill Lynch, Research Division - Research Analyst*

And that kind of informs the next kind of conversation, which is, as you guys are marching towards the spinout of the women's health business, you have vaccines, you have IO as a growth driver. How much of a priority would you say it is at the executive level to further diversify the therapeutic areas or the assets when you think about either BD or what to move up in terms of the top clinical priorities for the balance of the year and going into next?

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**Franklin K. Clyburn** - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. So as you think about the spin, Geoff, we actually think this will allow us to even provide greater focus on the innovative portfolio. And we actually look at it from a couple of different lenses.

Clearly, business development remains an important priority for us at Merck in the Executive Committee. And Roger and Rob and Mike and Ken and all of us are focused on continuing to look for the best science and innovations that'll enhance our pipeline. And building a best-in-class pipeline has been our focus. And we think, ultimately, that's what generates long-term growth and value for our shareholders. So that's going to continue to be a focus area for us as we move forward.

We're also very confident in our growth, Geoff, in particular, over the next 5 years. We talked about the assets that we have in hand. They're very durable. And as we've mentioned, oncology and vaccines, our hospital and specialty business as well as our animal health business. Some of the examples that we are focused on as well, if you think about the opportunity we have with Lynparza and Lenvima, those are 2 examples of BD plans or I should say, BD programs that we now have executed upon. And we're seeing really good growth with those assets as well as an opportunity to broaden those products in combination with KEYTRUDA. And we have a very broad development program with both of those products that we are now working on with AstraZeneca and Eisai.

And then lastly, I would say that often, we hear about concentration and concentration around KEYTRUDA. We actually see that as an important strength of ours, and we leverage the insights that we get with KEYTRUDA and the understanding of the biology and the significant clinical program we have to really identify new targets, identify good combinations, which led to the Peloton acquisition. It led to what we have done with ArQule. It's led to really informing us of even the Lenvima program that I mentioned.

So we see that as a very significant opportunity, taking the data that we're gaining from that program and leveraging and understanding the biology to determine opportunities for the future. And then lastly is our internal pipeline. As we've mentioned, it's not just oncology. It's HIV with islatravir. It's gefapixant, and then also we've talked about the significant program that we have in vaccine with our pneumococcal program but also RSV, CMV, dengue and others.

So BD is a clear priority and focus for us. But also continuing to move forward with our internal assets is a major focus in executing on our clinical program as well, which is why we're excited about the next 5 years.

And then the last thing I'll say, Geoff, is that we have reinvigorated our discovery efforts at Merck. We've opened up 3 new discovery hubs, which we think is really important and making the investment there in the future. So we also feel really good about the leadership and the talent we're bringing in into our discovery hubs.

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**Geoffrey Christopher Meacham** - *BofA Merrill Lynch, Research Division - Research Analyst*

Great perspective, Frank. One of the questions that we've been asking management teams for the whole BofA health care team is some border play type of questions. But just going back to COVID-19 and maybe how you guys think about what is the risks, and what are the lessons learned



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from this wave should we have sort of wave 2 and beyond? Are there more permanent solutions or ramifications of that in Merck's business to try to maybe be more proactive for -- should that wave 2 happen?

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**Franklin K. Clyburn** - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Yes. I would say there's a couple of things, Geoff, and one, I think we have been very well prepared from an overall operational perspective. Our supply chain and our colleagues and our Merck manufacturing division have done a great job. So we've had very limited, Geoff, supply disruption. In fact, no supply disruption. So supply has been very good, and we've had to move certain assets and products around the world.

Our clinical team is continuing to execute very well, and our clinical operations has just done a tremendous job of making sure that we're continuing even to enroll new patients in the clinical program. So I think that's something that clearly has -- we've done very well.

And as I mentioned in the commercial space, a lot of our digital and remote efforts have gone well. We're clearly looking at that now, Geoff, to think about how will customers want to engage in the future, and do we need to invest even in greater capabilities from a digital and remote perspective. So I would say that would be an area that we're clearly looking at and thinking about for the future.

And then also, I do believe that we're going to have to see how policymakers and payers around the world think about coming post a pandemic. I think we have a unique opportunity, Geoff, to really have health care systems and payers and policymakers recognize the value we bring. And this is why we do feel very good about our vaccine portfolio because what we are hearing is that I think governments around the world are going to want to make sure that their populations are vaccinated. So that's clearly something we are looking at and thinking about as well.

But overall, I think we were prepared as much as one could be across the areas that I mentioned, but we are clearly thinking about what's going to be required for the future and if there are any new capabilities that we need to build and take some of the learnings from the pandemic. But overall, we feel we're in a good place.

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**Geoffrey Christopher Meacham** - BofA Merrill Lynch, Research Division - Research Analyst

Okay. Well, with that, I think we're out of time. So Frank, really appreciate your time. And hopefully, next time around, we can do live Vegas and not virtual Vegas.

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**Franklin K. Clyburn** - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

I would look forward to that, Geoff. Thanks, everyone, for your interest in Merck. Really appreciate it, and have a good rest of the day.

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**Geoffrey Christopher Meacham** - BofA Merrill Lynch, Research Division - Research Analyst

All right. Take care, Frank. Stay safe.

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**Franklin K. Clyburn** - Merck & Co., Inc. - Chief Commercial Officer & Executive VP

Thank you. Bye-bye.

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