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PRESENTATION

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Okay. Well, thank you all for being here. Pleasure to have Merck management join us. Mike, pleasure to have you; Peter, pleasure to have you guys join.

Before we get going, perhaps turning it over to you guys just to kick things off, what's on top of your minds, the biggest priorities, and we'll jump right into it.

QUESTIONS AND ANSWERS

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Great. Yes. Well, thank you very much, Umer. Thanks to the team for having us today.

2019 has been a good year for us, right? I think we have the business performing well on multiple fronts. Clearly, we continue to experience success with our oncology portfolio, led by KEYTRUDA, which the momentum continues to grow strong. We've obviously seen a few key opportunities. We've been able to capitalize on KEYTRUDA's opportunity among cancer where in the United States today, about 8 out of every 10 patients in its indication are now receiving KEYTRUDA in the first-line setting. If you go beyond lung, though, we're starting to see a number of the other indications start to pile on. We're seeing good momentum with renal cell carcinoma. We're seeing a good momentum in head and neck cancer. We're seeing opportunities with adjuvant melanoma. And so I think the story for KEYTRUDA is really great momentum. Clearly, the indications that are driving the growth are going to start to evolve as we go forward, which is a good thing.

Beyond KEYTRUDA, though, the whole business, vaccines are growing strongly. GARDASIL continues to perform very well. Clearly, we're managing and balancing some constraints on the capacity side, but we're seeing really good growth from our vaccine business. The specialty business continues to do well. Our Animal Health business is performing well. And I think that's maybe [why we have] a really strong 2019.

As we look to 2020, we see continued opportunity. The cancer will continue to drive a lot of growth. There'll be a bit more constraints on the vaccine side. We see pricing headwinds as we go into '20. And our margins overall will be continued discipline on the SG&A side and -- while we continue to invest in the next round of indications for future (inaudible). And so net-net, on balance here or past 2020, we think the R&D spend will start to abate a bit, where the rate of growth will start to slow. And so hopefully, we'll see more margin expansion in '21.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

You took it right to my second question. So I think in covering a lot of various companies across the large-cap therapeutics universe, I find some are more conservative than others. Merck to me seems like on the more conservative end as it relates to guidance but also in terms of where the expectations have been managed. Do we need to turn on?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

No.

Peter Dannenbaum - *Merck & Co., Inc. - VP of IR*

No.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

I'll just confirm that. There we go.

So is it -- so I guess the question for me has been, and I know this came up very prominently on the 3Q call, the operating margin reported in 3Q '19 was higher than what consensus has for 2020 and 2021. So maybe just to repose that question again, how do you describe that? And we have a few more follow-ups to that.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. Well, I think the operating margin this year has been largely driven by really, really strong top line growth. And within that top line growth, you're still seeing really robust investment in R&D. The challenge we're facing is every study that we look at with KEYTRUDA right now continues to show a really strong positive ROI. And so while we're balancing this kind of financial discipline, that opportunity still continues to present. SG&A has been tightly managed for a number of years. And so -- and then on the gross margin line, when you net things out, product costs are roughly staying in a comparable range. There are some bumpiness in terms of royalties that hit that line. So the key to operating margin expansion is either we drive faster top line growth, which then obviously benefits us, but in the longer term, we think as R&D costs start to slow below sales, you'll start to see even broader margin expansion.

In the third quarter, I think it was a perfect storm where you had this robust top line growth probably beyond what we think is a really truly sustainable double -- mid double-digit growth with a more moderate spending in that period.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. We'll bring [Bo] into the conversation on some of the Asia price changes that have been happening. But in the context of perhaps first, can you lay out for us some of the conservatism on margin expectations you've laid out? And what have you assumed on ex U.S. pricing beyond 2019?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. Well, the ex U.S. pricing environment has been deflationary for a long time, right? If you go across Europe, we've always been facing a deflationary price environment; Japan with the biannual decreases and now moving to a new pricing format where what we'll see in 2020 is KEYTRUDA hitting thresholds that create a huge seller discount, which will pressure prices; and then within China, there are a series of different mechanisms that are being put in place, whether it be the GQCE mechanisms or NRDL mechanisms that are challenging price. And so from us, we kind of have a, I think, a very realistic view that pricing will continue to be under pressure ex U.S. going forward.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Why don't you take...

Unidentified Analyst

China? Sure.

So maybe one question on the China KEYTRUDA status. Now we know that KEYTRUDA does not enter a deal for 2020, do you expect ongoing negotiation with the government with probably the first-line VOD indication and a future indication expansion?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. The NRDL process in China is something that we just kind of recently concluded. The reality is we had a very strong understanding of what value was in China based on all of the health economic modeling that we do. And we have a clear threshold in which we weren't willing to make a price/volume trade-off for the Chinese market. The important thing to recognize here is that the -- there's a huge opportunity within China in the private market, and we've already been seeing that opportunity. And there are different mechanisms that we have at our disposal, including different patient access programs, that allow us to still reach a sizable portion of the Chinese cancer market. So exactly right.

The benefit of NRDL ultimately is usually, it provides a subsidy that allows you to lower that affordability threshold to a certain portion of the market. What's critical here, though, is since KEYTRUDA was launched and as new entrants in the 3 different Chinese PD-1s have also launched, you've already started to see a market that is spread on price, where there is a certain portion of the market that is willing to pay a premium for the branded agents with robust datasets in these different tumor types, and then there's a more cost-sensitive portion of the market. And so as we go forward, what we -- what we're trying to figure out is how do we create the right patient access scheme to provide as broad an access as we possibly can while making sure that we retain the value that we have within KEYTRUDA given the data that we have in (inaudible).

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Before we move on from this topic over, perhaps, Peter, could you please clarify for us? I know on the earnings call [where] China and KEYTRUDA came up several times as a key growth driver. Should we continue to expect China to be a growth market into next year just on self-pay market alone? Or did NRDL have to happen for the continued growth?

Peter Dannenbaum - *Merck & Co., Inc. - VP of IR*

No. The self-pay opportunity, as Mike said, we think, is significant. We think we can continue to grow KEYTRUDA sales based on that.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. Got it. So it was not contingent on the reimbursement list?

Peter Dannenbaum - *Merck & Co., Inc. - VP of IR*

No. No.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

No.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Okay. My question exactly. Let's move on from ex U.S. pricing and (inaudible) dynamics and talk a little bit more about data and where the market moves, U.S. and EU. I think I-O obviously has generated a ton of data recently, and we just got Checkmate-9LA hitting with an OS benefit at their interim. The first-line lung cancer market is set to get a little bit more complicated. How do you think about the commercial approach in -- moving into '20 as things start to get a little bit more competitive?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. So I think, first, we feel pretty privileged to have had as much time as the sole entrant in the first-line lung market that we have had. I mean if you asked us a couple of years ago, we would have expected competition earlier. The reality is, is that the 5 different datasets in which KEYTRUDA has demonstrated an OS benefit and a significant OS benefit both across monotherapy as well as combination therapy create a real high barrier to entry. And I think when you look at where we are today, again 8 out of 10 new patients are starting on KEYTRUDA if you exclude the ALK and EGFR mutations. And so when we look at this market, clearly we've expected competition. Clearly, we think our datasets will hold up very well against that competition. We have to see what the 9LA data actually says. But the hazard ratios that we were able to post with the different KEYTRUDA studies create a very big barrier to entry.

Unidentified Analyst

Mike, is it...

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

There's no change in plans and the kind of the commercial (inaudible)?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Okay. Keep going.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Yes. On the flip side, I guess, in melanoma adjuvant (sic) [adjuvant melanoma] and RCC, you've gained a lot of ground against entrenched competition. So how much more progress can you make in those indications as we move forward with data as it stands?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. Well, again, at least in our view, cancer is a very data-driven market. The OS data that we showed in KEYNOTE-426 in renal cell carcinoma was outstanding. Hazard ratio of 0.53 and positive across all subgroups. That provides a really strong foundation and a strong rationale for physicians in renal cell carcinoma. In melanoma, that market has been probably one of the more competitive markets. The datasets are more comparable in that space. I think what you've seen over time is different dosing regimens being introduced that have benefit as you go forward. But we think, again, one of the real benefits that we have through the KEYTRUDA program is it's becoming standard of care across so many different tumor types that physicians have a brand recognition and the comfort in using KEYTRUDA, whether that be in melanoma, whether that be in lung, whether it be in renal cell carcinoma. And that helps them a lot in the community settings.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Mike, there's been a thesis that's been often vetted on The Street, which has been whether the perception in clinician community on Opdivo is actually very different than Wall Street perception of Opdivo in a sense that clinicians think of Opdivo as being fairly equivalent in melanoma, renal and in lung versus KEYTRUDA. Is that true? And if that's the case, do you see that disrupting KEYTRUDA momentum once Opdivo possibly gets on market?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Again, the -- cancer is a life or death condition. And the reality is, is that there has been a tremendous amount of heterogeneity in the dataset in these different indications. And so oftentimes, patients have a single choice to make. And I think when it comes down to it, you -- we can debate whether the molecules, the different PD-1s, are the same. In cancer, we'll never know that answer. What we do know is that the datasets have been different. And I think in many cases, in facing these sort of conditions, people make a choice, based on the data that sits in front of them, that this will give them the best chance of survival.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. So we want to switch to adjuvant. But before we ask a specific question on 522, question I had was broadly speaking, how do you guys internally think of adjuvant opportunity relative to metastatic, just broadly speaking, across indications? Is it half as big? Is it about the same? How do you think about that, well, in aggregate?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Well, we see it as a huge, huge, opportunity. I mean it's still to -- a lot of it is still to play for, but the reality is, is that treating patients earlier helps people survive. And with most of the tumors in which we're participating, more than half of the diagnoses occurs in earlier-stage settings. And so as we look across the different tumor types, the adjuvant, neoadjuvant and just earlier-stage treatment is a huge, huge opportunity for us. And so it's going to expand the population assuming there's comparable data to what we've seen in the metastatic setting. But the reality is that oftentimes, in those earlier stages, the patients' immune systems are more robust. And so immunotherapy actually plays well in that earlier-stage setting.

Unidentified Analyst

Yes. So one specific question on KEYNOTE-522, the neoadjuvant and adjuvant with TNBC. So we see that -- the pathological complete response rate. Is that -- is -- the delta is pretty small with the node-negative patients. Is the pCR rate driven by the node-positive patients? And previously, you mentioned there were some sophisticated statistics to determine what fraction of the patients would benefit from adjuvant setting. And -- but we haven't seen that at ESMO. Should we expect some update at [San Antonio] breast or in the future?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Well, I think it's important to note that within the 522 study, we're still in the relatively early phases. 29% of the events have occurred in the dataset that happened at ESMO.

To the specific question on node positive and node negative, the reality is, is that was one of the stratification factors for the trial. The absolute response in both the KEYTRUDA arms was almost on top of each other. It was 64.9% and 64.8%. It was the control arms that you saw a difference. And within that, the confidence intervals overlap. So to be honest with you, we can't say that definitively, this is this driven by one or the other. The reality is, is that the absolute response in both the treatment arms with KEYTRUDA was in that 64.9%, 64.8% range. And so for us, we show benefit across the entirety of the population. And we obviously -- what we're clearly looking for is based on the stratification.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

So obviously, the 522 data is still in its early stages.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Somehow, it looks very supportive. Meanwhile, KEYNOTE, I guess, 119, 11-9...

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

1-1-9.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

...1-19 failed in the metastatic setting and the same indication in triple-negative breast. So I obviously, there's a clear difference there. You just mentioned something I want to touch more on, that the patients might have a healthier immune system in the earlier setting. Is there something more that we can read into the difference there between the metastatic and the adjuvant and neoadjuvant?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Well, I think there are -- I think you hit on one of the really key important differences, is 522, obviously, was in the neoadjuvant and adjuvant setting, healthy immune systems. The other difference is in 522, you're adding KEYTRUDA on top of chemotherapy in the neoadjuvant setting, whereas in 119, it was a monotherapy study alone. We have another study, KEYNOTE-355, that's due to read out in the near future. And 355 will actually tell us, in the metastatic setting, do we see benefit of KEYTRUDA plus chemo...

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

(inaudible)?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

In triple-negative -- yes.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. And it's actually a good segue into possibly what other trials would you flag for us as key inflection points in KEYTRUDA coming up or the 355? Peter, is there anything that you get a lot more questions on?

Peter Dannenbaum - *Merck & Co., Inc. - VP of IR*

Well, so 604 is coming up as well. That's a big one.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. Now as we think about broader adjuvant opportunity, those will start to -- those are -- those trials are due to start coming in a little more slowly really starting in '21 and '22. How should we think about that flow of data relative to the broader adjuvant space and your competitor trials also coming out at the same time?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. I think when you look at the breadth of the adjuvant program, and we'll tell you neoadjuvant, adjuvant and early-stage settings, there are over 100 trials investigating KEYTRUDA right now across 11 different tumor types. As you say, those are all starting to -- are due to read out sequentially over the next few years. Right now, we kind of will stand by a final analysis date. Obviously, if we see a material effect, it could come a lot sooner. And so we think there's a huge opportunity in that setting across a number of these different tumor types, and we think KEYTRUDA is pretty well positioned across that whole space to really provide benefit.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. So Mike's very proficient across topics. Although technically, we should really be focusing on vaccines since he's head of vaccines. So Mike, let's talk vaccines for a minute. And my first question is -- and it's a question we've debated a lot and will dig into it a little more. You obviously have pnemococcal Phase III coming up. But the way this market is going to play out is the market's graduated from Prevnar 7 to Prevnar 13. And Merck will have a 15-valent with a 2-year lead time over Pfizer, and then Pfizer comes in with a 20-valent. The question I have is based on some other vaccine precedents we've seen, sometimes the switch from one to the next could be almost sudden and immediate. Do you expect that? Do you see the market switching completely from Prevnar to Merck for 2 years on infant and then possibly back to Pfizer and then possibly back to Merck? Do you see that happening?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. It's really hard to say. The -- as you look across different vaccine markets, what you find is that in cases where there's radically different efficacy across vaccines, you see those sudden switches even without recommendations. So in the case of HPV, GARDASIL garnered the whole market with the quadrivalent, and there was 0 -- almost -- [FLUCELVAX] ultimately withdrew from the U.S. market.

In the case of RotaTeq and rotavirus, you see a much more balanced picture within the market where there's 2 vaccines competing with more comparable efficacy profiles. We saw the opposite with -- in shingles, where the SHINGRIX actually had a very strong portfolio -- or profile.

In pneumococcal, I think the key here is the current standard of care, Prevnar 13, provides a robust immune response across all 13 serotypes in which it protects. What the -- what public health agencies don't want to do is they don't want to compromise that base level of protection as they introduce new vaccines, and then they want to broaden coverage for new serotypes. And so what we've been able to show with V114 is that we have a comparable immune response across all 13 Prevnar 13 serotypes, but we also add 22 F and 33 F.

What we don't know from Pfizer in the pediatric market is what is the profile of their PCV20. And we'll have to wait and see what that data suggests.

So there's a dimension that broader is important. But ultimately, you want to maintain protection. And what we've seen as we've moved from Prevnar 7 to 13 is there has been some breakthrough of certain serotypes. serotype 3 has started to return back. And so it's not just in the number, but it's also the level of protection against different serotypes.

Unidentified Analyst

So I guess how would you position your V114 against the competition? Do you want to highlight serotype 3 as maybe a unique character for your vaccine? And to add another layer to this discussion, how would you expect the impact on your Pneumovax 23 vaccine? Because now, it's like the recommendation is 2 shots, first the Prevnar 13 and then Pneumovax in adults. But going forward, the next-generation PCV, they may remove the necessity of Pneumovax.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

So the CDC, at their -- one of their recent meetings, actually withdrew the the 1 plus 1 recommendation. Prevnar 13 is now not recommended as a mandatory vaccination. Pneumovax 23 continues to be a CDC mandatory vaccination for 65-plus. How that evolves over time -- plus our approach in pneumococcal disease has been a portfolio-based approach. We've had Pnumovax 23 for 37 years. V114 will be our first pneumococcal conjugate vaccine. We have 2 other programs under way. One, a specific pneumococcal program focused on adult disease that's called V116. It was just posted in Phase I/II in August of this past year. That is really looking at the different epidemiology in the adult market. So the drivers of disease in adults is different than the drivers of disease in pediatric. That's why we think a tailored vaccine approach is required.

We also have another...

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

That's the $15 billion? The...

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

We haven't specified the number of serotypes, but it covers the majority of adult disease.

Unidentified Analyst

Have you commented on how different it is? You've mentioned that you think a tailored vaccine for the adult versus the infant population. How much overlap is there? How different is it from your infant program?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

What we've seen is that based on the epidemiology right now, that you're seeing protection up to 80% of that market or beyond.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it.

Peter Dannenbaum - *Merck & Co., Inc. - VP of IR*

And they just post this to ct.gov recently.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. Right. And then the thinking is over time, now that we have the complete polysaccharide library and we have a capability to conjugate all of these different types, we can continue to improve pediatric vaccines without undermining the protection that's already conferred. And so over time, we think we'll have multiple different efforts to compete effectively in the pneumococcal market.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

So you're saying you don't necessarily want the 24 serotypes, you want to have 13 plus 2 of these, 13 plus 2 of that, 13 plus 4 of these?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

It could be 24. It could be 15. It could be 21. It could be -- I mean, I think ultimately, what you want to do is create the optimal constructs to protect as much of the population against the disease. You don't want to compromise what we've already accomplished with the existing vector.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. So for generalist investors then, like maybe sort of as a summary of this pneumococcal conversation, it's a $6 billion market today. Do you think that's underrepresented because of lack of activity? And then thus, what do you think the bigger market size is? And do you see Merck as being a meaningful player?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. We see -- Prevnar's around a $6 billion product, and Pneumovax is about $800 million, $900 million and [FLORAX] is probably another $800 million. So we think the opportunity is probably somewhere in that $7 billion to $10 billion range. What's important is that the adult market, which is really underdeveloped, it's largely driven by the United States. There are only 27 national immunization programs in adults. There are 130 in pediatrics. And this is the nature of vaccine development. The adult pathway is radically underdeveloped. And so over time, as you have better adult vaccines, we think there's a real opportunity to continue to grow that market in the adult space.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. Jon, who's got a cough, has got a question. He's on the cough drug.

Jonathan Miller - *Evercore ISI Institutional Equities, Research Division - Associate*

I wanted them to -- yes, we can talk about it halfway into it if you like. I don't need to be on that clinical trial. Look, I do have a question on something you said just a minute ago about seeing that serotype 3 coverage seemed to dip a little bit in Pfizer's next-gen data, which I think is a meaningful point that a lot of investors have also picked up on. But despite the fact that they see that -- what appears to be a small dip, it still rises above the threshold of what would be considered effective coverage. So my question is how linear is that scale? How continuous is that scale? Does it dip as long as it meets that bar effect, in your opinion, the actual quality of the coverage?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

It's really hard to say. What we've seen to date is the adult data. We haven't seen the pediatric data. And you will generate different immune responses across the different populations.

Again, this is -- to us, this is a long-term play. We think, with the portfolio of vaccines we'll ultimately be able to construct, we'll be a meaningful player in the pneumococcal market.

How Pfizer perform -- Pfizer is going to be a formidable competitor. We're under no illusion that they won't be.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

I heard they're pushing.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

The reality of it is -- what that?

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

I said I heard they're pushing.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. The reality is, is I think as time goes on, we'll have really good alternatives across V114, 116 and the next-generation pediatric vaccine to be -- really make a meaningful difference to public health.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. I think we're ready to move on to GARDASIL. I do have a couple of questions on that one...

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Okay. Yes, we'll see where...

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

while we're on vaccines. You bought what CDC stockpiled this quarter to keep up with especially international demand, as you flagged this quarter. Are you likely to have to borrow more near term? And when will you have the capacity to refill that?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. So we borrowed -- we will technically borrow $120 million worth of GARDASIL in the fourth quarter of this year. We announced this as part of our third quarter sales and earnings. The reality is what we've seen with GARDASIL is as time has gone on, there has been this overarching push to migrate from the quadrivalent vaccine to 9-valent vaccine, from male- -- or female-only programs to gender-neutral programs. And in doing so, it's created a surge of demand. When you couple that with some unexpected regulatory approvals, most notably in China, which occurred in 9 days, the GARDASIL demand has spiked. And the lead times in terms of production can last as much as 4 years from seed to finished product in certain markets.

And so what we've been trying to do is how do you optimize a supply chain while you are capacity constrained in the short term. And so what you're seeing right now is across the world, the borrowing really was based on the surge in demand in the third quarter that accompanies the back-to-school cohort. We're working to try and optimize and maximize the cycle times or production for GARDASIL in the existing facilities. At the same time, we're building 2 new facilities to supply more GARDASIL in the long term.

The real question is how much process improvement can we make in the short term to increase production. And that's something that we kind of work on a daily basis, but it isn't a pure linear process. Every little tweak can add a few doses, and that ultimately can help us alleviate those bottlenecks.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

You said this brand-new capacity with these new plants you're building won't likely be online until 2023. But you've also said at various points that some parts of the work can be done by CMOs in the meanwhile. How far can you stretch current production while we wait for new capacity? And what proportion of that capacity can you get from CMS?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. So historically, the first bottleneck with GARDASIL was actually drug products. So fill and filling. And we've gone to 2 new CMOs to actually increase our yields there. We're now at a bottleneck at drug substance. And drug substance is something that we do internally, and that's what's reliant upon the new facilities or process improvements in the meantime.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Okay. Great. The other thing that you mentioned is the surge in demand in China, very rapid approval. And something you had mentioned in the past couple of calls and at your Investor Day was that the demand was really intense in that market. Given that pent-up demand and your supply constraints, what's the risk that you're going to lose some portion of that market share to local players before you have the opportunity to get in there?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Making a non-valent vaccine is not an easy thing. What we've seen historically is vaccines have a very durable effect on a market. There are usually 1 or 2 players that have the capability to do it. Over time, you'll see multiple entrants in different parts of the world. But the reality is, is that GARDASIL 9 is a very complex vaccine. And for anyone coming into the market, the capacity that you invest in, the lead times for a new facility are in the 3- to 5-year time horizon. And so the capacity that you're going to build is going to be gated based on the likelihood of success. But also, when you look at the China market, there are 100 million to 150 million women in the indicated age range with the ability to pay. And so the opportunity -- and right now, the recommendation in China is for 3 doses. So the opportunity in China is huge. And even if there is competition, there will continue to be a sizable opportunity for GARDASIL in China.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Fair enough. Okay.

Unidentified Analyst

So maybe a quick question and switch topic to HIV on the MK-8591, the long acting. You have monthly injection and also potentially an annual implant. So what drugs are you going to pair with that? Are you open to potentially external partnership?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. So MK-8591 is a first-in-class molecule that has some tremendous properties around the potency, the half-life around the barriers to resistant -- or the ability to prevent resistance. And so we're studying it in a number of different settings. The first setting will be in partnership with doravirine. And so we believe that, that will be the fastest route to market for the treated segment. It will be a daily pill, a daily fixed-dose combination. Beyond that, we're looking very carefully around integrase-based combinations. Again, the key is finding the partner molecule with the right properties to actually have this extended duration of treatment. And so you can imagine in treatment getting out to a weekly pill with the current potency of this molecule. And so we feel really good about that. I think -- but what I think we're talking about is the PrEP space. In PrEP, we think there will likely be an option for either a monthly pill or an annual implant. And in the PrEP space, based on the data we've seen to date, it's not clear that you need a partner molecule.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. Excellent. I want to move on to some strategic questions towards the end. But should we finish that off, Jon with -- do you want to do AFRIN before we...

Jonathan Miller - *Evercore ISI Institutional Equities, Research Division - Associate*

Yes. We should talk about AFRIN because it is an interesting program. It's something that you hit on in the Investor Day quite strongly.

In the chronic cough indication, where there's clearly a pretty substantial unmet need, the taste disturbance, which has really captured everybody's imagination, it doesn't seem to have been much of an issue. I think you've commented many times that the drop out rate was very low.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

That's right.

Jonathan Miller - *Evercore ISI Institutional Equities, Research Division - Associate*

But as you look into other indications of the long list that you said were potentially relevant there, how many of those indications will have similar robustness to such a widespread adverse event? How many of those patients are willing to suck it up and not having taste?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

It's hard to say, Jon. The reality is, is that those trials are still in the very early days, the sleep apnea trials, some of the endometrial pain trials. Ultimately, those are areas of significant unmet needs. By figuring out the right dosing in an area like sleep apnea, taste disturbance isn't a big issue in your sleep, right? And so depending upon how you monitor the dose and what the half-life is, you can find the chemical properties to, I think, thread those needles appropriately. We'll have to wait and see what the data suggests in terms of the dose as well as the efficacy as well as the side effect profile to see whether or not it is a meaningful roadblock. I think what we've said very clearly is for cough, we think between the 15-milligram dose and the 45-milligram dose, we have 2 really great alternatives that provide benefit. And we don't see people dropping out of the trial because of any sort of adverse event.

Jonathan Miller - *Evercore ISI Institutional Equities, Research Division - Associate*

And meanwhile, though, there are some competitors coming to market with what they claim to be more selective molecules that won't carry with it that taste disturbance. Obviously, none of them are as advanced as your compound is, but how do you view this potential competition coming down the pipe behind you?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Again, I think it's all going to be driven by the data. The reality is, is that what we don't know is do you compromise efficacy and getting that -- that's a benefit, right? So, I mean, the reality is let's see what the data says. We think we have a really good program. We think we have a really positive effect. We'll have to see what the data from the competitors say.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

So in the last 5 minutes or so, there's a few high-level and strategy-level questions I wanted to discuss. First one, I can't ask you, so I'll ask Peter instead. Peter, where do we stand on the status of the new CEO? I'm not looking at them.

Peter Dannenbaum - *Merck & Co., Inc. - VP of IR*

No change. So the mandatory CEO retirement policy was taken away last year. Ken has agreed to stay on. The Board, it's -- among their top priorities is succession broadly for Merck at our leadership levels, and they have said there are several candidates internally that they're-- we have a broad and deep pipeline of talented individuals. And when the Board is ready to make a decision, they will announce it.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Is there an expectation that we'll get an announcement in first half or so?

Peter Dannenbaum - *Merck & Co., Inc. - VP of IR*

There's no time line.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

No time line. Okay. So that was first. And now I can come back to you.

The second one is as we -- Mike, perhaps your vision of Merck and where Merck's priorities are right now. Do you see Animal Health as being a core part of Merck, especially considering all the success others have had but also considering all the operating profit contribution coming from KEYTRUDA? So the need for diversification internally as well.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. We go on -- we undergo a robust portfolio prioritization process every year. And we look at which portions of our portfolio do we think perform according to our expectations and which portions of our portfolio do we feel like we're privileged owners of.

The Animal Health portfolio, when we digest what that is, what we see is industry-leading growth and margins, and we see real synergies across our R&D organization. And so we feel really strongly that this is a business that fits well within Merck.

We often get this question around concentration. Animal Health is a very durable business that provides great diversification but also these best-in-class properties. And so we feel like it's a really good fit within Merck.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. Got it. So in terms of M&A opportunities, is there a -- I know you guys have been very consistent in saying you're looking for small organizations but agnostic to dollar size. Is there a more updated thought based on having looked at various opportunities available? Should we -- should the market be bracing more for a sub-$10 billion deal or bigger than that? Because it seems that the market reaction to a sub-$10 billion versus above $10 billion has been very different lately.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Again, we're not driven by the price of a deal. We have been very, very clear that we don't see the strategic benefits of large-scale M&A, especially where our business is today. The disruption that occurs within the research labs is something that -- given our momentum and our productivity right now, it's not something that we're really -- we have a big appetite for.

Beyond that, the dollar threshold isn't the primary thought process. Obviously, just the raw numbers tell you that there are a lot more sub-$10 billion deals than there are over $10 billion deals. We did over 60 transactions last year. Most of them are in areas where we see an ability to apply Merck's differentiating capabilities, which I think is taking in early science and applying robust clinical trial execution, registration capabilities, where we're able to really lean into these programs and do things that other companies perhaps can't do based on scale, based on competency. And so for us, we're trying to find those spots where there is those value-creating opportunities, and we look at everything. And we're not confined to a therapeutic area. We're not confined to a size. It's where we think we can provide value and create value for our shareholders.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. Any questions from the audience while we're on M&A and the broader topics? Because half the questions I get on Merck is always on this. They keep asking me to guess.

Is there interest perhaps, as we -- as you look at possible M&A opportunities, to stick to oncology? There's been very specific questions from investors on whether Merck has particular interest in antibody drug conjugates.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Yes. I think the benefit of looking at oncology right now is that as KEYTRUDA becomes the standard of care for so many different tumor types, if you're able to find the right combination partner, you will not only benefit from the sale of that asset, but it has a spillover effect to KEYTRUDA in developing with KEYTRUDA. So there is a natural synergy for the right combinations in oncology.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

So combinations in oncology is...

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Given -- well, it's not a core focus. I'm saying it's an attractive space.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

The core focus is wherever there's great science at Merck, things that can create value.

To your question on antibody drug conjugates, we've seen some good data in that space. And I think that's what fuels a lot of the talk that you're referring to. I mean the data that we showed at ESMO in bladder cancer was really good. And so the -- one of the things that we look at is time -- is this the time where antibody drug conjugates are now showing an ability to manage toxicity with clear clinical benefit. And in certain cases, that may be the case.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. Any last-minute thing before we move on?

Jonathan Miller - *Evercore ISI Institutional Equities, Research Division - Associate*

Peter, probably -- I was going to stay on that topic of which therapeutic areas you're most interested in. Umer asked specifically about ADCs. But broader than that, there are a number of modalities, next-gen modalities, that other folks have really invested heavily in that Merck has been very shy to adopt, things like gene therapy or other nucleotide-based therapies, cell therapies, those sorts of areas. What's driving your approach to those next-gen modalities? And why have you stayed out of the fray when others have to do it?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

I don't think that -- I think the -- part of that is true, I think part of it is not. We've had a long-standing interest in RNA-based therapies. We've got a deal with Moderna for a number of years in both cancer and in vaccines. The reality is, is when we look at selling gene therapies right now, scalability is an issue. And what we constantly ask ourselves is, is this asset better off in the hands of Merck than it is in someone else's hands. For one-off procedures, we have a hard time saying, Merck had disproportionate value than a biotech. And then, if we don't add disproportionate value, how do you justify the premium that's being afforded to those assets? Those scalability challenges are going to be solved at some point. And so what we're acutely focused on, when those scalability challenges are solved or if there are barriers to entry that emerge that by getting in early, you preclude the opportunity for others to get in later. Right now, we don't see the barriers, and the scalability challenges haven't solved themselves. And at today's valuation, that's a difficult equation for us to make worth. Perhaps others see it differently.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Got it. Peter, anything that comes up in your conversations a lot that we didn't bring up? Or any particular program? Or anything...

Peter Dannenbaum - *Merck & Co., Inc. - VP of IR*

No. I think you hit on it. You hit on those questions earlier. Certainly, we get asked a lot about margin expansion. I think we described that pretty well. 2021 is the year where we see the more meaningful inflection. But no, I think we largely hit on the main topics.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Excellent. Well, thank you for joining.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Thanks, Umer. Thanks, guys.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Great seeing you.