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CORPORATE PARTICIPANTS

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

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

CONFERENCE CALL PARTICIPANTS

Carter Lewis Gould Barclays Bank PLC, Research Division - Senior Analyst

PRESENTATION

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. Great. We are live. Good afternoon and welcome to the Barclays Global Healthcare Conference. Next up, we are pleased to welcome Merck to a fireside chat today. Joining us from the company is Michael Nally, Chief Marketing Officer, and Peter Dannenbaum is also joining from the IR team. Michael, Peter, thank you very much for the time today.

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

Thank you, Carter.

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

Thanks, Carter.

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

Great to be here.

QUESTIONS AND ANSWERS

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Right. So I'm looking forward to the conversation. Before we touch on all the individual product opportunities that everybody wants to hear about, I want to ask a few kind of overarching questions given sort of where we are in sort of the pandemic, specifically, now we've seen cases fall quite dramatically. Vaccination rates are picking up. And as you -- Michael, as you think about sort of this reopening dynamic, can you just give us a sense for kind of where we are today? How that's kind of changed in the recent weeks and how you see that playing out over the rest of 2021?

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

Thanks, Carter. It's something we follow, obviously, closely, given the portfolio of medicines we have in vaccines. As we look at it, what we've seen is the rising cases over the course of the winter. Obviously, it's had a continued impact on the health care system. We've seen a material impact in markets like Germany, Japan, the U.S. But as you note, there's real reasons for hope and optimism on the horizon. The fact that in the United States now, north of 55% of the over 65 population has received the vaccine. The rollout continues to gain pace, not only in the U.S. but around the world. I think we start to see real potential for a broader reopening and broader mobilization of society. And obviously, that has a knock-on effect to the health care system. As we look at our business, the part of the business that has been disproportionately affected by the pandemic has been our

vaccine business. Clearly, having healthy individuals access the health care system at a time of a pandemic has been a challenge. And the health care system has rightly prioritized other conditions over protecting individuals from unknown threats at a given point in time.

And so as we think about this year, the first quarter -- in the first half, we see a more profound impact from the course of the pandemic. As the second half of the year rolls around, we think things will open up. And we provided our guidance. We thought overall, we have a really strong underlying healthy business with roughly 10% growth prospects when you look at the midpoint of our guidance from point to point. And we said COVID would have about a 2% impact on our business, and it would be disproportionately in that first half of the year.

From a portfolio perspective, again, the vaccines will be disproportionately affected. The first quarter, I think we have to be thoughtful about the comparison because a year ago, we actually did not see a COVID impact, whereas in this -- in the comparator year, now we will see a COVID impact. A product like Bridion for anesthesia reversal is another product that disproportionately is affected. And we've seen stops and starts in the oncology market with new patient diagnosis lagging a bit from time to time. And so those are the things that we watch really, really carefully, really, really closely. We see -- we watch the pandemic go from market to market. But the health care system at large is better prepared than ever before. And I think when we think about our business, we feel really good about the underlying health. It's just navigating this current situation that gives us a reason to do -- carefully inspect different parts of our business and make sure we have the right tactics in place to help facilitate access wherever possible.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Great. Since you brought it up. I wanted to go into the vaccine business. I mean, it's usually one of the more, let's call it, interesting things to model given sort of seasonality dynamics. But now given the COVID and the potential for either catch-ups or maybe disruption to that seasonality. I'm not asking you to guide by quarter. But just roughly, at a high level, when you think about those traditional dynamics that we typically kind of associate with, say, like a GARDASIL, how should we think about that in this -- given all these moving pieces?

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

Yes. As we look at it, right, I think the GARDASIL product, in particular, is 1 that has a tremendous seasonality. The back-to-school season is extraordinarily important for it because the routine recommendation is for 11 and 12-year olds to be vaccinated. And the times that 11 and 12-year olds go and access the health care system is usually in their back-to-school checkups. And so as we think about this year, one of the phenomenon that we're going to watch carefully is both how does the vaccine roll out? And when does it reach that adolescent population? How does that potentially impact vaccination rates? But also, we know that the Biden administration and broader public health authorities are going to really push hard to ensure kids are back-to-school next fall.

I think any parent can attest that we're all ready for our kids to go back full time. And so for us, watching those sort of dynamics clearly play a role, you noted, I mean, the vaccine business is a lumpy business by its nature. Timings of shipments and purchases from government procurement agencies have an impact on quarter-to-quarter trends. I think when we look at our vaccine business at large, we feel like it's in a really healthy place. I think as we think about the first half of this year, again, with the vaccine rollout in the U.S., one of the things we are watching is CDC guidelines that are talking about, if you receive the COVID vaccine, to not be vaccinated with another product within 14 days of that. So clearly, that has an impact on some of our elderly vaccines, right?

And so all of these different dynamics are going to create some pushes and pulls throughout the year, I would assume it will probably be a lumpier year than normal. But the underlying health of the business, the underlying demand, we feel really good about. And it's a question of when not if for most of our vaccines. And for a lot of them, there will be a catch-up opportunity. It's just a question of when.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

One of the things that I wanted to ask you about is just sort of the longer-term impacts of just sort of working from home or Salesforce going digital kind of dynamics. And as you think about sort of the tangible longer-term impacts that has on the commercial infrastructure, to what extent you

incorporate those things or if that becomes sort of the status quo going forward? How do you think about that? I guess, what parts do you expect to be stickiest? And do we end up in a hybrid model in 2 to 3 years? Or is it just back to business once we get a little bit of distance between us and the pandemic?

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

I think there's no doubt we are changed forever. The reality is, we've been on the digital transformation journey for a number of years within Merck. We've kind of gone to a common CRM platform around the world. And within that, it's given us the tools and capabilities to really engage with our customers through our digital medium. There had been some hesitation in reservations within our own sales force. Some of our customers also shared some of those reservations around adopting these sort of interactive models.

The pandemic has changed our behavior in a fundamental way. Just look at this interaction case in point. We never would have done these sort of conferences remotely, and we found an effective way to get these messages out through technology. And I think as we look at our sales force, inevitably, we will leverage technology in a fundamentally different way than ever before. The -- I think the important part from our side is, it's not just the technology, but it's actually what the technology enables, that's really critical for our future commercial model. We have invested heavily in data and analytics. And so because we're leveraging this underlying technology platform, because these interactions are being captured in a fundamentally different way, we're able both to analyze those interactions and ultimately make better decisions around resource allocation, around messaging, around activating both patients and physicians where appropriate. And so we think, in many respects, our model will be a lot smarter going forward. It has an opportunity to be a lot more efficient going forward. And technology will underpin that. And I think that the pandemic has been an accelerant of many of those trends.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Clearly, the Organon spin is upcoming. And I think Peter and the team have done a really very good job of finding out the financial implications of all that. But I wanted to ask you a question just in terms of your tangible day-to-day and sort of as you manage -- work through the commercial infrastructure, what will -- how does that -- I don't know if simplification is the right word. But how does that -- sort of going to manifest and maybe make your life easier or simplify some of the complexity?

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

Well, I think the biggest thing is it enhances focus. When we look at the Organon portfolio, it is 15% of our revenue, 25% of our manufacturing sites, 50% of our products and 60% of our SKUs. And so as we think about our commercial model, we know where we want our teams focus. We know we've got to focus on continuing to compete effectively with KEYTRUDA, continue to properly communicate the tremendous clinical data that we have for a product like that. We want to make sure we're doing everything we can to help the health care system orient itself so that GARDASIL can be appropriately administered to patients around the world. The reality is, is that by spinning off the Organon portfolio, it enhances our focus on the areas of greatest opportunity. And when we're talking about 50% of our products and 60% of our SKUs, that's a huge difference for each of our commercial leaders. And it helps us make better resource allocation decisions. So that not only can we focus better on the Merck core products, but the Organon team will be able to give the care and attention to that portfolio that it hasn't been receiving within Merck.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Maybe we can move on to some of the products now. With the story going on in the background, I figured it was a good time to ask around the HIV franchise. Clearly, I feel like you've got a pretty good product in Islatravir. But maybe just taking a step back, as you think about sort of the unmet need in the PrEP market, is getting out to a once a month lead type product enough of an innovation leap or do we really need to get out to every 3 months, 6 months? Just kind of would love to hear your high-level thoughts to think about sort of like a target product profile in this segment.

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

Yes. It's a great question, Carter, and something that we've stared at long and hard and been in active consultation with public health authorities on. The reality is the PrEP market is underpenetrated. When you look at the CDC recommended guidelines, they estimate that about 1.1 million people are at risk. And ultimately, right now, it's about 20% penetrated.

So the current alternatives and the current public health infrastructure isn't serving the market need well enough. When we talk to the leading thought leaders in this space, they see the benefits of moving toward a once a month oral pill as a huge advantage over a daily to reach a population that at times, there are portions of it that are living chaotic lifestyles, there are portions of it that are going to need these longer-acting increments. And not only are we focused on the oral delivery, but we're also focused on new implantable technologies. The data that was presented yesterday at CROI showed we can get out to 12 months in the implant that we use for Nexplanon. And so an opportunity to have an oral pill as 1 alternative that extends the dosing regimen. But also an implant that could get out to a year, really changes the whole PrEP landscape, and we think will help fuel broader adoption because in many respects, we don't view the primary competition as the current alternatives. The real challenge in front of us in PrEP is how do we expand this market and reach more of that 1.1 million people in the U.S. in a similar proportion ex-U.S. with these sort of innovations. And we think with these 2 alternatives, we can do that well.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Kind of leading into my next question, I guess, that part of the market that's already gone to a generic product, you feel like that could convert back to kind of on brand kind of product offering in the coming years?

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

Well, in the PrEP space, I think the challenge oftentimes is, if you're taking a daily pill with a number of potential side effects associated with it. One of the great things about Islatravir is it's a single pill, and it's got a very benign side effect profile. And so we think there's a real value proposition for everyone in the PrEP market. But I think the -- if you said, where is your primary orientation? It's on market expansion rather than purely displacing the current alternatives.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. Perfect. Maybe we can move to the Pneumococcal segment here with V114. I guess the overarching question we get from investors all the time is sort of what would success look like from a commercial perspective here, given sort of the competitive dynamics and the push and pull between you and Pfizer. You've clearly shown good data thus far. But I guess maybe just kind of walk through how you think about your ability to compete there. And to whatever extent you can define, what commercial success would look like?

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

So it's a great question, Carter. When we look at the market, up until COVID, this was the single largest vaccine market, right? And today, it's about a little over \$8 billion. It will grow to a little over \$11 billion by our estimates. When we think about what the opportunity is, we look at this opportunity across 4 different products. So we have Pneumovax 23, which is our long-standing polysaccharide vaccine oriented toward the adult market. It is the broadest coverage adult vaccine and is favored in the majority of national immunization programs around the world today.

We're going to enter in with V114, which is our first conjugated offering. It's a 15-valent vaccine. That confers benefit in both the adult population, but also within a pediatric population, which is actually the bigger of the 2 markets today. And so when you think about V114 and how it fits, we think there will be benefit in the adult population. We think there will be an opportunity to help protect those most at risk in the adult population. In some cases, you've seen sequential recommendations in different parts of the world where you start with a conjugate and go to a polysaccharide or vice versa. And we think more broadly, what V114 represents is a paradigm that we think is really critical. First, as you bring in innovation in this

market, how do you do no harm over the existing serotypes? So if you look at the burden of disease of pneumococcal over time, the vast majority of disease that was seen on the Earth for pneumococcal was prevented by PCV7 and PCV13. So you don't want to see reemergence of those original serotypes, which were the primary causes of disease historically.

And what we've done with V114 is we've shown a comparable immune response across all 13 shared serotypes, with a potential benefit on Serotype 3. And then we've added on to additional serotypes. And this is really, really important because what you've seen historically is, as you add new serotypes, you see a degradation in the immune response. If you go from PCV7 to PCV13, you saw a degradation. And what the public health authorities have seen now is breakthrough disease. And so from our side, we think V114 will be a very meaningful product. We think it will compete effectively. We think the primary market will be the pediatric market. And then we have 2 follow-on vaccines, V116 and V117.

V116 is a product that is specifically targeting adult disease. So what are the most common serotypes that cause adult disease based on epidemiological data and creating a special vaccine for that adult population. And V117 will be an expanded serotype pediatric vaccine that follows those same principles. And so across the portfolio, we feel like we have a very competitive offering in the pneumococcal market over the long term.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Okay. Great. That's helpful color. We're 17 minutes in and we haven't mentioned the K word yet. So I'm going to move into KEYTRUDA, and I'm going to I'm going to temp the gods here and talk about renal, even though it was a topic that I think we all got bludgeoned with over late January, early February. I guess at this point, when you look at the renal market, I guess, as you think then about KEYTRUDA plus Lenvima down the road, how should we think about what the message to clinicians will be in terms of how to sort out sequencing or slotting of these agents in what's clearly a very competitive environment?

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

Yes. So I'd actually start, Carter, with the KEYNOTE-426 data set, the KEYTRUDA plus axitinib data set. It was a real profound advance, right? I mean a hazard ratio, an OS of 0.53, really remarkable result. What shows that this IO-TKI combination is a very meaningful contributor across all subgroups, right, all IMDC subgroups. And so for us, we knew there was activity with these combinations.

We also believe that the different VEGF receptors have different implications. And so having another combination with KEYTRUDA plus Lenvima would be beneficial for patients. And what we saw on the data was just really stellar data across all parameters, whether it be PFS, OS, response rate. This data set was, in many respects, groundbreaking. And so for us, we think we have 2 really, really great alternatives in the renal cell carcinoma market that's relevant across all subgroups.

We'll work with the clinicians in proper to articulate that data. But we feel like it gives us a great competitive offering going forward. And actually, the points of differentiation across those different subcategories become really germane to the conversations with clinicians.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Right. Okay. And then one of the things that we got most excited about coming out of ASCO GU was really, it sort of a global coming out party for your HIF-2 alpha. And we've seen over the previous months, really like a broadening of the clinical development plan there. How do you then see that existing alongside some of these other efforts?

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

Yes. So I think, obviously, the first indication is in an orphan disease, von Hippel-Lindau disease. But the reality is that this has broad utility and we've initiated a series of different combination studies in combination with Lenvima and in combination with KEYTRUDA and Lenvima. And we think, ultimately, it could play a broader role in earlier stage RCC.

And we'll have to wait and see. One of the real nice things about the HIF-2 alpha data was it was a relatively clean side effect profile in oncology. And you saw a great durability in the data as well. And so as we look at it, we think this is just another tool in the tool box, to ultimately address residual disease and RCC and can be used across a whole host of settings, and it makes it a very nice combination molecule as well.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

One of the things we heard Ken bring up earlier this year, I think with maybe greater emphasis or at least in a higher profile setting than we heard previously with around some of these KEYTRUDA life cycle management efforts, specifically around I guess, the tangible blocking back line of combinations or extending IP or co-formulation, et cetera. It's not something we've heard a ton about historically and clearly, everybody is very focused on 2028. Just kind of outline these efforts or how you see them? Or how -- maybe how investors should think about them sort of maturing over the next 12 to 24 in 0 months?

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

Yes. So as we look at it, KEYTRUDA is establishing itself in such a broad array of tumors. It's becoming foundational in so many different settings. We think there are nearly about 30 different tumors where we've shown activity. We've got 28 indications to date. The 1,400 trials that have either been conducted or underway is creating such an immense foundation for future oncology treatment.

It's natural that as we think about the future, we think about what works best with KEYTRUDA. And there are a host of different IO-based molecules that combine well with KEYTRUDA. And so in many of these cases, the single-agent activity isn't overly profound, but there's synergistic activity with KEYTRUDA. And whether it be TIGIT, whether it be ILT4, whether it be LAG-3, whether it be CTLA-4, each of these have the potential and we are actively co-formulating them with KEYTRUDA as we think about the future. The 3 of them, TIGIT, LAG-3 and CTLA-4 will start Phase III trials this year. We're working across all of them in different umbrella studies to determine where the best utility is, finding the specific tumor types. And as we see real activity, we're ready to really launch into those studies.

And so as we look at the future of KEYTRUDA, we're oriented around how do we add patient and system benefit. Some of that will be through different formulations. You saw the Q6 weekly formulation, which has really bolstered the franchise. We'll look at different subcutaneous options. We'll look at different co-formulation and options. And each of those have different IP associated with them. And we're adding distinct patient and system value, we'll pursue that IP appropriately. And so I think our view of the KEYTRUDA question is while many see it as a KEYTRUDA cliff, we think through a whole host of these different strategies, the longer-term curve could be altered.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

All right. We only have about 90 seconds left, so I'll ask you 1 question just around a recent approval, Verquvo, which you got approved. At this point, how do you -- how should investors think about your cardiometabolic franchise, clearly there's some patent cliffs. Verquvo doesn't seem to be like a huge product. Just trying to gauge your level of conviction in this franchise going forward and if it's core to the Merck strategy?

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

Yes. So I think with Verquvo vericiguat, what we see in the data is this is a really great option for patients with heart failure with worsening symptoms. And the unmet need here is really profound. Obviously, as we interpreted the different data from the clinical program, the Victoria study in particular, we realize there's potentially even broader utility. And so we've got to decide what the right life cycle management is, but we see this real near-term opportunity given that the consequences of heart failure being so profound. That there's a real unmet need, and we think it will fill it well. More broadly in cardiometabolic, we still see huge unmet need. And so our research program has a number of different potential candidates that could further advance cardiovascular care and address the broad -- a huge amount of the residual risk that's associated with many of the different cardiovascular diseases.

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

Okay. Let's leave it there. We're at the end of our time. Mike, thank you very much. Peter, thanks for joining as well. Thank you guys for your attendance today, and have a great day.

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

Thanks, Carter.

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

Yes. Thank you, Carter.

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