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EDITED TRANSCRIPT

MRK - Merck & Co Inc at UBS Global Healthcare Conference (Virtual)

EVENT DATE/TIME: MAY 18, 2020 / 3:40PM GMT



CORPORATE PARTICIPANTS

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

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

CONFERENCE CALL PARTICIPANTS

Navin Cyriac Jacob UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

PRESENTATION

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

Hello. Welcome to the UBS Global Healthcare Conference. It's the day 1. Our next presentation or fireside chat is with Merck & Co. I'm very happy to have with me today, EVP and Chief Marketing Officer, Mike Nally; as well as Head of Investor Relations, Peter Dannenbaum. Mike, Peter, thank you so much for joining us today.

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

Thanks, Navin. We appreciate the opportunity.

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

Thanks, Navin.

QUESTIONS AND ANSWERS

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

Great. So we -- we're just going to jump into questions here. We can't escape COVID, obviously, and so maybe I'll just start off with a couple of high-level questions around COVID-19. Merck was, I think, a little bit more levered towards the impact of COVID-19 than some of your peers, given that your portfolio is levered a little bit more towards physician-administered drugs and the fact that you have an Animal Health business as well. Any updates since the Q1 call and the impact you're seeing as the country now starts to open up? Are you starting to see physicians' offices opening up? What's the impact in vaccines? Any kind of color would be helpful.

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

Yes. Thanks a lot, Navin, and thanks, everyone, for the opportunity. I hope everyone is staying safe and healthy during this turbulent period.

I think when you think about COVID, you think about the impact that we cited on our first quarter call. The reality is our underlying business has great strength. When we looked at 2019, we showed double-digit top and bottom line growth. As we entered into 1Q, we were able to deliver top line growth of 11%, bottom line growth of 23%. And I think that's a good signal of the underlying strength of the business and the demand for our products.

The near-term impact that we see, especially in our Human Health business, is a real function of the reduced patient access to hospitals and other clinics as well as a major reduction in well visits as well as elective surgeries. As you noted, Navin, our portfolio is a bit skewed, where 2/3 of our

products are physician-administered products. And we think as a result of that and a result of the major patient access challenges that has occurred in the April time frame, we will have the most profound impact on our business in the second quarter.

If I kind of take it a click below that, our vaccines portfolio has been affected by the lack of access for routine wellness visits, where we've seen about a reduction of 70%, and this is despite the fact that the CDC and the American Academy of Pediatrics has been prioritizing infant immunization. Despite all of those recommendations, we're seeing patients -- parents and children with real trepidation in accessing the health care system, and that's been something that's been consistent in April. And hopefully, as the economy starts to open up, we'll see a rebound. I know it will be a big priority for all public health officials as, certainly, no one wants to lose the gains that we've made against vaccine-preventable disease in those populations.

Our adolescent vaccines have also seen an impact of these well visits as well as some of the adult vaccinations. We do believe as we get into the third quarter and into the fourth quarter, we'll return to normalcy. So the impact will be most acute in the second quarter. There will be an opportunity for some catch-up in the vaccines portfolio toward the back half of the year. And obviously, that's all predicated on kind of an avoidance of a second wave in the fall.

Our hospital products, and I'll focus here, most notably on BRIDION, have also been affected. Elective surgeries have plummeted, a similar reduction of around 70%. And because most of the surgeries that are reversed with BRIDION are elective, we've seen a disproportionate impact to that product. For KEYTRUDA, which is obviously a major focal point for all of us, we see real great underlying demand. In the first quarter, we showed 46% year-over-year growth.

But what we have seen is that oncologists are delaying appointments and procedures and then are prioritizing based on the severity of disease and the immediate needs of different tumor types. And so within that, partially because of our portfolio and partially because of the indications that are most meaningful, the lung indication is a little bit less affected. Earlier disease is a little bit more affected. New patient starts is a little bit more affected. But ultimately, we've seen new patient visits decline by approximately 10% to 20% depending upon the indication. Lung cancer has fared a little bit better than that. And importantly, I think the recent approval of our Q6 formulation should help, provide a less burdensome access to the health system for patients on KEYTRUDA.

The other area of our business that I think has been affected is in the women's health portfolio. Clearly, fertility starts have languished as well as implants for NEXPLANON. And so those are all pieces of the business that have been affected.

As you noted, Navin, roughly half of the impact that we cited in our guidance was in the Human Health portfolio. A major portion of it was foreign exchange. And then our Animal Health business has also been affected as the demand for Animal Health products, while it was strong in the first quarter, has been hit as, certainly companion animals, we've seen reduced access and trips to the vet. And our livestock business, we've seen lower demand for protein and milk as restaurants and schools have been affected.

Over the long term, we don't think any of the fundamentals of our business have been affected. We see these as timing and patient access challenges. Clearly, we're closely evaluating the longer-term economic impact including kind of trends unemployment, which are harder to assess. But one of the things within the Merck portfolio, given the fact that the majority of our business is physician-administered, we may be a little bit less exposed to certain payment types that are affected by the economy. And over the long term, I think we do think that the fundamentals are intact, that we should be able to return to a strong demand profile, assuming we do get back to a degree of normalcy as we kind of enter the third quarter and into the fourth quarter.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutical

And is there -- this may be a little bit early to ask this, but in your discussions with public health officials or your own market research as you're thinking over the very long term, is there actually potential for a benefit here when you think about the awareness that -- towards public health about the importance of vaccinations and vaccines to prevent diseases? Is there any kind of long-term implications here?



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

Well, I think it's a great question. I'd be -- in my own opinion, the -- this is going to be one of the great litmus test for our industry. This is a once in a lifetime public health challenge. And the innovative industry either will rise to the challenge, or we'll not and ultimately have huge reputational impact to the industry. I have a great degree of confidence that given the underlying science that we're seeing within our labs and we're seeing across the industry that we're going to be able to help in a meaningful way, both on the treatment as well as on the prophylactic side to help address this challenge. And we'll do so in a way that's responsible, where we prioritize broad equitable access to these innovations. The biggest challenge, I think, that's going to confront us will be ultimately scale-up. But I do think given the heightened focus and given the awareness, there's also potential longer-term ramifications for how people view the industry and the technologies we bring, including our vaccines. And certainly, we started seeing some of that, even with Pneumovax in the early days of the pandemic, where patients were prioritizing health systems, we're prioritizing protecting respiratory health in the face of COVID challenges.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutical

You -- Merck announced on the Q1 call that you have a vaccine program underway for COVID-19. There are various different vaccine modalities being explored. Just today, Moderna announced some Phase I data and some preclinical data. There's a DNA approach. Merck is taking a more traditional approach. But wondering how you think about your approach relative to some of the more novel approaches. Roger on the call, on the Q1 call, highlighted perhaps a need for multiple different vaccines for COVID-19. When you guys think about the reason why multiple vaccines may be required, is that because of different baseline demographics? Or what is the thought process behind why multiple vaccines may be needed for COVID-19?

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

Well, I think in many respects, Navin, when we've looked at this, right, one of the things that we've been very thoughtful about in our approach has been we really don't understand this virus at all. And the virus was initially sequenced in kind of the mid-January time frame, right? And our understanding of the implications of the virus continue to evolve on a daily basis. We've all kind of seen the evolution around the cytokine storms, around clotting, around risk in children. We've also kind of had a -- it's taken us some time, and we're still in somewhat the early days on understanding the fundamental transmission dynamics as well as durability of antibody protection. And so for us, and you've seen this in some of the announcements that we've made, we're trying to understand the nature of this virus. We've got a partnership with institute -- the systems biology to really try and understand the nature of the virus to kind of ultimately formulate the best approach for both treatment and vaccination.

When I think -- we look at the different approaches that are being taken. Things that we ask ourselves are: How immunogenic do you want the vaccine to be? Is there an opportunity for using a single dose? Or are you going to need 2 doses? How safe is the profile in populations like children? How durable is the response in the elderly? And different platforms will provide different answers to each of those different questions. And obviously, part of it is dependent upon, not only the platform, but also antigen selection. And so as we understand the virus, there's certainly a need for rapid intervention. And I think you're seeing that with some of the early programs that have announced, first initiating clinical trials, but also now we're starting to see the first-in-human data.

But as we think about the longer term, there's a high likelihood that this virus is with us for a while. And we may be in a -- not only a pandemic phase but an endemic phase of disease, and there may be different approaches that are warranted in those different phases. And look, we hope everyone that's pursuing a vaccine is successful. Obviously, that's the best thing for the world. It's the best thing for health. But as we've seen in the course of the vaccine market, the first intervention ultimately is not always the best intervention. And while the first intervention may have a meaningful impact on humanity, there's still an opportunity to continue to improve. And so we've prioritized some of the technologies that we know well to try and create the ideal contract and think about where Merck can uniquely contribute to the pandemic.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

We can't escape Merck without talking about KEYTRUDA. ASCO is coming up. We've seen the abstracts now, and 2 competitive datasets that folks are focused on are Bristol-Myers' Checkmate-9LA and Roche's TIGIT tiragolumab. I just learned how to pronounce that. So with 9LA, the first data set that we've seen here, sort of mostly in line with expectations, perhaps on the lower end of expectations. But with I-O/I-O, there's a thought that further along you go, we may get efficacy that gets better over time. Any thoughts on 9LA? We'll start with that and then move on to TIGIT.

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

So I think when we look at the lung cancer market, we feel really good about our competitive positioning across the 5 different trials that we've read out with overall survival benefits. We think we're well positioned both in the high expressors and the monotherapy and the combination therapy with our chemo combo data across squamous and non-squamous cancer. And so overall, while we kind of said never imagined that we would have the first-line lung cancer market to ourselves as far as long as we have. We knew there would be competitors in the market. The data sets that you cite, again, we feel like we're very well positioned to compete effectively. Then I think the first, I guess, Bristol got approval for the 227 data set on Friday. We've obviously looked at that carefully, and we think we have again -- overall survival is the gold standard, and we think we're well positioned there. On 9LA, again, the data, to a large extent, was in line with what we thought. And again, we'll feel good about how we compete in the first-line lung cancer market.

Right now, we're currently getting about 8 out of 10 patients in the first-line lung cancer market where we're indicated, and the opportunity for us continues to be in the non-expresser, and we're working hard with the health care system for people to understand the 189 data set in that context. And so while we see competitors on the horizon, we feel good about the position we have.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

And then with regards to TIGIT, you have your own program, tiragolumab, certainly in combination with TECENTRIQ seems to show what appears to be better data, at least on response rate and on hazard ratio and particularly in the PD-L1 high, but the comparison is tough to make relative to KEYTRUDA plus chemo, just different comparators, different baseline characteristics. But wondering if the data that you've seen with tiragolumab is going to accelerate your own program, and remind us where you are with your TIGIT. I believe you have a triple combination of TIGIT plus KEYTRUDA plus chemo running in non-small cell lung cancer. But do you have any other programs expected? And any kind of color would be helpful.

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

Yes. So the data that -- from Roche's Phase II trial is really scientifically interesting. We think the addition of TIGIT clearly increased response rates, as you rightly point out, especially in the PD-1, P-L1 high expressors.

One of the things that we did take note of is that the atezo control arm seem to underperform certainly other I-O therapies in that setting. And so it's really, in some ways, hard to interpret, especially given the fact that it is a small data set. But I think, clearly, there is promise. It's why we've been interested in the mechanism. We'll have to see how the larger Phase III study plays out to better determine the combination value. And I think for our own program, we're focused on 2 different umbrella studies with a series of novel mechanisms, one in melanoma, one in non-small cell lung cancer. That includes our own TIGIT program that has about 90 patients across the 2 different studies that allow us to move very, very quickly if we see compelling signals in the data. And so we're really looking toward those data sets to tell us which populations can move forward and which combinations.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

And then with regards to the commercial landscape, there was some pricing pressure in Japan and EU in Q4 and Q1. Do you feel that that's starting to ease now? And can we actually start seeing some of the beats that we've -- not beats, won't use that term. But should we see the volume overemphasized now as part of the driver as opposed to pricing pressure, which seems to have been a little bit of a drag over the last few months?

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

Well, I think you point out kind of -- as KEYNOTE-189 was approved around the world, it had a huge impact on the relevant patient population. In places like Europe, it tripled potentially the number of eligible patients, right? So as we went through the HTA process, there were the typical negotiations that you would see. And it's one of the -- lung cancer being one of the biggest indications, obviously, those negotiations take on an extra level of importance. So when you couple that with the fact that we saw approvals toward the end of last year in major markets like France, like Spain, like Italy, we saw some pricing pressure as we made the right long-term approach for the broader population that could be protected with KEYTRUDA. We've also seen an impact in Japan, and this is just predicated on the success we've seen in Japan, given some of the rules they have around pricing and as there's repricing events as you hit certain sales thresholds.

And so clearly, this is one of those things, given the unique nature of KEYTRUDA, given the number of indications that we're pursuing in the size of the population, these are events that we'll continue to have to work through with HTA authorities around the world with different government payers. And I think as we look forward, the 189 was a major milestone, but we hope there will also be other major milestones as we go into other sizable tumor types like triple-negative breast, like prostate and in early-stage disease that will obviously force us to have further conversation. But overall, I think we think the value proposition for KEYTRUDA is holding pretty well.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

And speaking of early-stage disease, there's several adjuvant trials that will read out over the next 12 to 24 months. Can you just remind us of some of the key readouts? And then particularly for something like lung or triple-negative breast, could you provide some context for -- on a relative basis, how we think about that adjuvant opportunity versus first-line met? And is there cannibalization that happens when you enter into -- or not cannibalization, but a deterioration or taking away from the first-line lung -- first-line market as you penetrate into adjuvant?

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

Yes. So it's a great question, Navin. One of the things that we've spent a lot of time looking at is we have a very broad adjuvant program with about 20 registration-enabling trials across -- in 100 trials, in total across most of the major tumor types, and we feel like we're really well positioned across the breadth of the first-line opportunity.

Clearly, you've seen some of the data start to emerge. We've presented the adjuvant melanoma data. We've presented the nonmuscle-invasive bladder cancer data. You've seen some of the data in triple-negative breast cancer with 522. And the abstract for 799 was part of the ASCO abstract in non-small cell stage 3 disease. So when we think about the data coming out, we're starting to see that, that early data across the KEYTRUDA program start to read out.

When we look at the patient opportunity, we have the potential to have 40% of the aggregate patients indicated in the early stage of disease relative to metastatic disease. And so the opportunity is really profound, assuming we can succeed across the different tumor types. Some of the upcoming trials that will continue to read out are things like 522, where we've shown the PCR data, and we're continuing to wait for EFS. KEYNOTE-091, our non-small cell lung cancer adjuvant trial, which we've got a date of 2021; KEYNOTE-412, which is our head and neck adjuvant trial, similar time line in '21. But as you know, all of these different trials are predicated on a series of different assumptions about interim analyses and so forth. And we're providing the same level of focus, rigor, execution on these trials as -- that we've had in the metastatic setting. So we see this as a really, really meaningful opportunity. The opportunity is further enhanced as we saw in melanoma. As you have viable alternatives, you start to see treatment

rates increase. And when you couple that with opportunities to also enhance diagnosis in certain tumor types, the early stage opportunity will be profound.

In terms of how that then affects the downstream metastatic opportunity, for the first few years, it will be largely incremental. Over time, it has a chance to erode, but most of that erosion will occur very late in KEYTRUDA's life cycle up through LOE. Really, the initial orientation will be this is incremental. And as -- hopefully, as we achieve more cures in that early setting, there's a downstream impact, but that'll take years to transpire.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

With regard to one of the newer assets that we started seeing data for at ASCO, MK-6482 alpha. You showed some data in treatment-naive non-metastatic clear cell renal cell carcinoma with VHL. Pretty interesting data, 30% ORR, 98% PFS rate at 1 year and pretty clean. How do we -- how should we be thinking about this data set? What is the comparison that we should be making relative to what else is out there and particularly in this setting? And then associated with that, what's the development plan for this molecule? I mean this is one that doesn't seem to get a lot of attention. Could this be used broadly in RCC with KEYTRUDA. You also have KEYTRUDA plus Lenvima? Should we think about this as a triple therapy potential? Any kind of color would be very helpful.

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

Yes. So we're excited about the data we've seen in von Hippel-Lindau disease, which, obviously, as a stand-alone is an extraordinarily small market with about 200,000 patients worldwide and less than 10,000 in the U.S. But as you point out, both on the ORR side as well as 87% of patients having a decrease in tumor burden, we think the data is pretty profound. And it's part of why we were so excited about the Peloton acquisition when we made it midyear last year.

As we think going forward, clearly, the initial path to registration will be in VHL, but we also have an ongoing Phase III study in renal cell carcinoma, and we're exploring it across a host of other tumors and in different lines of therapy because we do see the potential and the activity in the monotherapy setting to have potential impact much more broadly. And we think the asset has longer-term blockbuster potential. This is just a starting point, and we now need to do the work to kind of figure out where and what lines of therapy does this most appropriately hit. And clearly, renal cell carcinoma was an obvious follow-on, given the connection with von Hippel-Lindau.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

And so just in renal cell alone, just to be clear, are you thinking there's broader scope beyond just VHL? And does this place beyond VHL within renal cell? Or is the broad opportunity for 6482 in other tumor types associated with VHL?

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

Both. Both. Yes, we currently have a Phase III trial in advanced renal cell carcinoma with patients who have progressed on PD-1 and VEGF therapies, and that's underway, but we do see broader utility in renal cell carcinoma across different lines of therapies as well as in other tumors.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

Is it -- does this have the potential to be a multibillion-dollar drug? I ask because, I mean, there's literally no expectations built into consensus estimates.

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

I think we think it has the potential to be a blockbuster asset.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

Another key area within your pipeline that you're focused on is the pneumococcal vaccine market. V114 is competing in time lines with Pfizer's PREVNAR 20. Pfizer recently top lined data for their adult indication. What's -- how do we think about V114 in the context of the 20-valent vaccine? Obviously, a 15-valent vaccine on surface relative to a 20-valent vaccine, you can understand why folks would immediately gravitate towards something that has 20 serotypes associated with it. How do we think about this? How are you thinking about this, understanding that you also have V116 a little bit behind as well?

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

Yes. It's a great question, Navin. I think the first thing that we look at is the evolution of the pneumococcal market. And when you think about the gains that have been achieved, a huge -- the vast majority of disease has been addressed with the introduction of PCV7 and PCV13. Now there's still a real profound amount of residual disease, but a huge step change was achieved through the introduction of conjugated pneumococcal vaccines.

And so as we've thought about developing any new pneumococcal conjugate vaccine, the first order of priority has been to do no harm across the existing serotypes in the existing vaccines. And with our program, what we've been able to show with V114 is that in the 13 shared serotypes, we have a comparable immune response to PCV13. And this is really important because if you go back and you look at the data and the progression from PCV7 to PCV13, as you added more serotypes, you saw a reduction in the immune response of some of the shared serotypes. And what happens and what we've started to see in the epidemiology is you have a potential. And again, this has to be borne out in the data, but you have a potential to see breakthrough of disease where coverage and the immune response is less robust. And we've seen some of that with serotype 3 and some of the disease surveillance done by organizations like the CDC. And so for us, in our 15-valent approach, that first order priority was to do no harm. And then once you've been able to establish that, it's around how you add on additional disease-causing serotypes to provide broader protection. And I think with the V114 program, we've amply demonstrated the ability to do no harm, to actually show numerically higher benefit in key serotypes like serotype 3 and add in 22F and 33F.

But I think when you think about the totality of our vaccine program for pneumococcal disease, we've had a long-standing play with Pneumovax 23 in adult disease. And Pneumovax 23 contains 23 serotypes for protection in adults. It is a very broad-spectrum pneumococcal vaccine and is currently widely recommended in the majority of adult programs around the world.

As we think -- as the market evolves, our approach was actually to create a different vaccine for the adult market, V116, which is tailored based on the underlying unique epidemiology in adults. Because disease has been halted by the introduction of PCV7 and PCV13 in pediatrics, the disease circulation in adult has changed over time. And by having a tailor-made vaccine, we think we can protect against the majority of adult serotype with a tailor-made vaccine in adults. And then we have a subsequent program, V117, which would be more targeted again toward the pediatric space, where you would again try to build on the framework of the existing vaccines without compromising protection and then add on additional serotypes.

And so between the 4 different assets, Pneumovax 23, V114, V116 and V117, we think we ultimately will have very well-tailored options across both the pediatric and adult markets in what's a meaningful commercial opportunity because the current pneumococcal market is nearing \$8 billion a year. You have the potential for growth as you expand adult immunization programs. There's somewhere between 130 and 140 national immunization programs for pediatrics, whereas in the adults, there's probably somewhere between 30 and 40 ongoing programs. And so as you have better options for adults, we believe there will be a huge opportunity to continue to grow that market, and we think the portfolio will serve us well from a competitive standpoint.



Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

You also have several other assets that you've highlighted in the vaccines pipeline that you highlighted at your Investor Day last year: RSV, CMV, dengue. What is the latest on these? And of these, which ones are you most optimistic or excited about?

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

Wow. I mean the -- I think if I were to step back, the vaccine that I continue to be extraordinarily excited about is GARDASIL, just given the fact that there's so much more to be done with that. As we expand production capacity, we're still just scratching the surface in terms of global coverage. So that remains a huge opportunity.

But if I go beyond GARDASIL and PCV, I think what you see is you've got real opportunities. CMV has been a target the industry has struggled with for a long time. We have one of the best approaches. Certainly, the -- an approach that basically in the Phase I data came very close to mimicking natural immunity, and so this is one of those things that we think has a great shot.

Dengue, the construct that we've licensed from the NIH is a very well balanced construct across all 4 dengue serotypes. And given that almost roughly half the world's population lives in dengue-endemic regions, it's a huge opportunity going forward.

RSV has been, I think, the market that, from a commercial perspective, has a huge potential. The challenge has been finding a valid RSV construct. We obviously have long-acting monoclonals that have benefited in the pediatric space, but we haven't found the right approach from a vaccine perspective. We think the partnership we have with Moderna, coupled with the monoclonal that we're working on, has the potential to have benefit in RSV. And so both -- all 3 of those are great opportunities for the future.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

On GARDASIL, while clearly, the demand exists, Merck's been having challenges feeding that demand. You're obviously working on expanding capacity. The time line you've stated in the past is doubling capacity by 2023. Is there any update on those time lines? Is there any means of accelerating beyond 2023? And conversely, has there been any impact from COVID? Has that slowed any of the progression to expanding that capacity by '23?

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

Yes. So the capacity expansion plans, regardless that they started 3, 4 years ago, we started by, first, kind of reducing cycle times within our own operations, right? And so how do you just get more out of the existing footprint? We've coupled that with some partnerships and leveraging of CMOs for form sale activity, and those partnerships have helped us continuing to show steady increases year-over-year of supply for GARDASIL. We've been able to more than double the supply of GARDASIL to the market based on those sort of techniques. The next big step-up now is to alleviate the drug substance bottleneck, and that's through the addition of the 2 new facilities. And we continue to do everything we can to accelerate that time line as fast as we can.

The COVID piece, because we kind of have our drug substance as part of our internal network, we don't see a material impact of kind of COVID vaccination work on those assets. Those are projects that we will run in parallel with any sort of COVID effort that we make or others make, and those plans are well underway.

But as you point out, the real goal for GARDASIL and the way we've constructed the network is with an ideal situation where at some point, we have an opportunity to vaccinate the world birth cohort with GARDASIL. And that's the kind of capacity that we've been targeting. And we think given the investments we're making, we have an opportunity to execute on that over the next few years.



Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

As -- given the challenges of expanding coverage -- or rather, capacity with GARDASIL, how do we -- how do investors think about COVID vaccines? I mean Merck is one of the leaders in vaccine production and had obviously an existing franchise in GARDASIL and has had challenges expanding capacity there. Is this piece of vaccine production not fully appreciated by either Wall Street or general public as it relates to COVID vaccines?

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

Well, I think you're hitting on an important point, Navin. The -- in our estimation, scale-up will be as profound a challenge as the science, right, to come up with a valid construct. Now the difference with some of the COVID platforms is there's existing capacity that can be leveraged for those assets and also, the constructs may be more amenable to the existing facilities. The complexity of GARDASIL oftentimes comes in the fact that you're really combining 9 different vaccines. The 9 different serotypes in GARDASIL 9 makes it a very complex construct. And in doing that, it's far more complex than the constructs that we've seen to date for COVID. Usually, you're talking a single antigen-based approach, leveraging an existing platform that can leverage existing capacity. I think what you're going to see in the COVID response, the initial capacity build-out will leverage existing facilities. The -- a lot of the challenges will come on the form fill side because this is a challenge across the industry. It will depend on whether or not lyophilization capacity is required. And depending upon which vaccines are successful, how do you quickly shift capacity because we're going to need to band together across the spectrum, whether it be industry or CMOs, to try and support the most promising technologies going forward. But you also have -- within the time line, in the GARDASIL time line, we're moving at a breakneck pace. But even within that, things like permits and regulatory cycles are more traditionally-oriented. COVID will have, as we've seen with all the clinical work, unprecedented time lines on some of those things that can condense in these time lines a bit even as you're building new capacity.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

Well, with that, we're at our time limit. I sincerely want to thank Mike Nally, Chief Marketing Officer at Merck; as well as Peter Dannenbaum, Head of Investor Relations. Thank you both for joining us today for this interesting conversation.

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

Thanks, Navin. Take care.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

Take care. Bye-bye.

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

Thank you, Navin.

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