Q3 2020 Earnings Call

Company Participants

- Frank Clyburn, Chief Commercial Officer
- Kenneth C. Frazier, Chairman and Chief Executive Officer
- Mike Nally, Chief Marketing Officer
- Peter Dannenbaum, Vice President of Investor Relations
- Robert M. Davis, Chief Financial Officer
- Roger M. Perlmutter, President of Merck Research Labs

Other Participants

- Chris Schott, Analyst, JP Morgan
- David Risinger, Analyst, Morgan Stanley
- Geoff Meacham, Analyst, Bank of America
- Gregg Gilbert, Analyst, Truist Securities
- Mara Goldstein, Analyst, Mizuho Securities
- Navin Jacob, Analyst, UBS
- Seamus Fernandez, Analyst, Guggenheim Securities.
- Steve Scala, Analyst, Cowen & Co.
- Terence Flynn, Analyst, Goldman Sachs
- Tim Anderson, Analyst, Wolfe Research
- Umer Raffat, Analyst, Evercore

Presentation

Operator

Good morning. My name is Lara, and I will be your conference operator today. At this time, I would like to welcome everyone to the Merck & Co. Q3 Sales and Earnings Conference Call. All lines have been placed on mute to prevent any background noise. After your speakers' remarks, there will be a question-and-answer session. (Operator Instructions) Thank you.

I would now like to turn the call over to your host today, Peter Dannenbaum, Vice President, Investor Relations. Please go ahead.

Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Lara, and good morning. Welcome to Merck's third quarter 2020 conference call. Today, I'm joined by Ken Frazier, our Chairman and Chief Executive

Officer; Rob Davis, our Chief Financial Officer; Dr. Roger Perlmutter, President of Merck Research Labs; Frank Clyburn, our Chief Commercial Officer; Mike Nally, our Chief Marketing Officer; and Dr. Dean Lee, Head of Discovery Research.

Before we get started, I'd like to point out a few items. You will see that we have items in our GAAP results, such as acquisition-related charges, restructuring costs, and certain other items. You should note that we have excluded these from our non-GAAP results and provide a reconciliation in our press release. We've also provided a table in our press release to help you understand the sales in the quarter for the business units and products.

I would also like to remind you that some of the statements that we make during today's call may be considered forward-looking statements within the meaning of the Safe Harbor provision of the US Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs of Merck's management and are subject to significant risks and uncertainties. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Our SEC filings, including Item 1A in the 2019 10-K identify certain risk factors and cautionary statements that could cause the company's actual results to differ materially from those projected in any of our forward-looking statements made this morning. Merck undertakes no obligation to publicly update any forward-looking statements. Our SEC filings, today's earnings release, and an investor presentation with highlights of our results are all posted on merck.com.

With that, I'd like to turn the call over to Ken.

Kenneth C. Frazier {BIO 1391636 <GO>}

Thank you, Peter. Good morning, and thank you all for joining today's call. I want to start by acknowledging the extraordinary efforts of scientific experts across the biopharmaceutical industry who are rising to the challenge and working tirelessly to find solutions to help end the pandemic. We remain confident that science will prevail over COVID-19, and Merck is committed to contributing its scientific expertise and resources in support of these worldwide efforts. The momentum[ph] in the development of medicines and vaccines to address the pandemic is a testament to the societal value of our industry is continuing investments in science and to the women and men who are working with urgency and dedication to make it happen.

Merck has a special responsibility to apply its expertise given its long and productive history in antiviral and vaccine research, and we are advancing our vaccine and antiviral programs through focused investment of effort and resources. We have made significant progress over the last few months across our COVID program and our learnings we enforce are confident that the approaches we've selected are among the most promising.

We are moving forward with dispatch and diligence, designing our clinical studies in a manner that is successful, will provide physicians and patients confidence that our candidates are safe, effective, simple to administer and distribute and capable of being used, not just in millions but billions of people. While we understand the importance of moving expeditiously in light of the pandemic, our experience with the natural history of other pandemic and epidemic viral diseases castles[ph] us to seek enduring solution that can be deployed globally now and for future generations.

It is an exciting time at Merck and I am encouraged by our scientists' enthusiasm for the innovative research happening in our lab, not just on the COVID front, but across our broad pipeline of promising medicines and vaccines that we are continuing to invest in. Our deep pipeline and the team of world-class scientists at Merck Research Lab is a result of the stellar leadership and many meaningful contributions made by Dr. Roger Perlmutter, who will be stepping down from his current role at the end of this year.

I'm grateful for the extraordinary contributions Roger has made to science, medicine, and the health and well-being of people around the world, as well as to all of us here at Merck. Roger leaves behind a strong legacy of historic breakthrough in immuno-oncology and many other fields of medicine that had transformed clinical practice and improved patient outcome. Under his leadership, the company has received more than 100 regulatory approvals for its medicines and vaccines globally, and he has revitalized the future R&D of Merck.

Dr. Dean Li, currently Senior Vice President of Discovery Sciences and Translational Medicine, has been appointed to succeed Roger as Head of Merck Research Laboratories effective January 1, and I look forward to welcoming him to Merck's senior leadership team. I am confident that Dean's knowledge, energy and experience, and his purposeful pursuit of new technologies in transformational discovery will help Merck sustain the successful execution of our broad portfolio during this important time, advance our scientific strategy, and build on the strong momentum in our pipeline.

Now, moving to our third quarter performance. We continued executing on our strategic priorities, while once again delivering year-over-year growth in revenue despite some ongoing impacts of the pandemic and very strong EPS growth. Importantly, we exited the quarter with continuing business momentum. We are performing at a high level with production, supply, and distribution of our medicines, vaccines, and animal health products and clinical trials moving forward with minimal disruption. The underlying demand for our products remains robust globally as evidenced by the growth we achieved in Oncology and Animal Health. We are also encouraged by the recovery we are seeing in vaccine and those parts of the portfolio most affected by the pandemic impact on healthcare delivery.

We are executing well in the marketplace to drive growth across our existing portfolio and in our lab by advancing our innovative research program. Meaningful new data that we've recently disclosed in several areas of research, including

oncology, vaccine, HIV, and others increases the confidence we have in our ability to introduce new innovations to the market and sustain strong long-term growth. And our financial strength also allows us to execute on our capital allocation priorities, including our ongoing investments in both internal R&D and external business development, such as the recent oncology collaborations with Seagen.

At the same time, we are advancing our plans to spin off Organon, which is on track for completion in the second quarter of 2021. We remain confident in our decision to create two more focused companies devoted to their respective strengths and portfolio and better positioned to navigate an evolving healthcare landscape and enhanced value for patients and shareholders. We continue to hire talented and experienced leaders, who will help drive Organon success as an independent company.

Let me conclude by expressing my confidence in the business and our ability to advance our pipeline despite the challenges posed by the pandemic. Additionally, I express my sincere gratitude to the frontline healthcare workers and our employees who worked around the clock to help patients affected by COVID-19. Their dedication inspires all of us at Merck to remain committed to our mission and relentlessly pursue innovative science to help prepare for the greatest health threats, both now and in the future.

And with that, I'll now pass the call on to Rob to review the details of our performance and our outlook.

Robert M. Davis {BIO 6955931 <GO>}

Thanks, Ken, and good morning, everyone. As Ken noted, we continued to be encouraged by the strength and resiliency of our business as we once again delivered year-over-year growth despite ongoing impacts from the pandemic. Merck employees across the organization are continuing their important work, progressing the pipeline and ensuring patients have access to our portfolio of medically important medicines and vaccines while contributing to industry-wide efforts to develop solutions to the pandemic.

In the quarter, we saw a strong recovery in our performance and the underlying demand for products across our key growth pillars, setting us up for a strong close to the year, as reflected in our updated guidance. We continue to execute on our long-term strategy, including our capital allocation priorities. We are investing behind our deep pipeline including our COVID candidates that have been active on the business development front.

Of note, this quarter, we successfully entered into a strategic collaboration agreement with Seagen to gain access to two oncology assets to further augment our pipeline. We are committed to investing in our business for the long term and we will continue to do so in line with our mission of following the science to solve unmet needs of patients around the world.

Now, turning to our third quarter results. Total company revenues were $12.6 billion, an increase of 1% year-over-year or 2% excluding the negative impact from foreign currency. The pandemic negatively impacted our third quarter Human Health results by approximately $475 million, mostly in our vaccines portfolio. There was a minimal impact to Animal Health. Our revenue growth, excluding this estimated impact would have been approximately 5% or 6% ex-exchange.

The remainder of my comments will be focused on the underlying performance of our key growth drivers and near-term trends and will be on an exchange basis. Our Human Health revenues increased 2%. In Oncology, KEYTRUDA sales grew 21% year-over-year, reaching $3.7 billion.

In the United States, growth in KEYTRUDA usage across all key tumor types remain strong and KEYTRUDA continues to be the leader in lung cancer by a widening margin. We are strengthening our leadership in IO across a broadening array of indications outside of lung cancer, notably in melanoma, bladder and head and neck cancers with momentum from launches in renal cell and endometrial carcinomas.

It's worth noting that indications outside of lung now represent roughly 50% of our sales in the United States and we will continue to grow over time and we further penetrate these indications. They continue to add new indications going forward.

Uptake following the launch of our Q6 weekly adult dosing regimen helped to offset the impact of reduced new patient starts caused by the pandemic.

Outside of the United States, lung cancer indications remain the driver of KEYTRUDA growth. In the EU, growth continues to be driven by the uptake of KEYNOTE-189 and KEYNOTE-407 in the first-line setting, where we continued to see strong penetration. In Japan, the combined impact of the two huge seller pricing adjustments in the first half of the year more than offset underlying volume growth. Lynparza and Lenvima continue to demonstrate strong growth and remain meaningful contributors to our broader oncology portfolio, growing 58% and 29% respectively year-over-year.

Lynparza's performance in the quarter continues to reflect strong growth and leadership in the PARP class in the US despite increasing competition, with incremental contributions from an expanded indication in ovarian cancer and early launch uptake in prostate cancer. Lenvima maintains market leadership in first-line hepatocellular carcinoma, and the combination with KEYTRUDA in endometrial carcinoma is now the leading regimen in the metastatic setting in the United States.

Turning to vaccines. As mentioned, while our vaccines portfolio made a strong recovery from the second quarter, year-over-year comparisons were negatively impacted by continued below-normal levels of wellness visits, particularly in the United States. GARDASIL sales declined 10% year-over-year as growth in ex-US markets was more than offset by pandemic driven impacts in the United States.

Volumes in the key back-to-school season were below normal, particularly among adolescence. Sales were also impacted by delayed public sector purchases. Ex-US growth was driven by continued strong volume in China and the expansion of general neutral vaccination programs in Europe, partially offset by reduced demand in Hong Kong.

PNEUMOVAX delivered 58% growth due to heightened awareness of the importance of protection against pneumococcal disease amidst the pandemic and heading into the flu season, partially offsetting the GARDASIL decline. While our vaccines business, and in particular GARDASIL, is always subject to quarter-over-quarter variability, the longer-term trends for underlying demand continued to strengthen. We remain confident in the future growth prospects for GARDASIL due to growing global recognition of its important role in preventing certain cancers reinforced by recent data published out at Sweden. Our hospital performance also improved from second quarter levels. Most notably, the recovery in elective surgical procedures benefited BRIDION, which grew 13% year-over-year. Our ongoing PREVYMIS launch also contributed favorably growing 69%.

Our Human Health business had a stand-out quarter, achieving sales of $1.2 billion and delivering 12% growth year-over-year. Companion animal grew 18%, reflecting underlying demand for the BRAVECTO line of products and strength from our portfolio of companion animal vaccines. Livestock grew 8%, reflecting contributions across our ruminants, swine and poultry products, as well as growth from our technology products. We are encouraged by the resilience of our Animal Health business, which has outperformed our expectations in this challenging environment.

Turning to the rest of our P&L, my comments will be on a non-GAAP basis. Gross margin was 74.8% in the quarter, a decrease of 110 basis points due to a combination of pricing pressure, inventory write-offs, collaboration amortization, and foreign exchange, offset in part by product mix. Operating expenses decreased 6% year-over-year to $4.5 billion. In total, COVID favorably impacted spending by approximately $115 million driven largely by lower promotional, selling and administrative costs along with lower laboratory, travel and meeting expenses, partially offset by increased spending to advance our COVID-19 antiviral and vaccines research programs.

The significant year-over-year increase in other income was driven by unrealized gains in our security holdings, primarily reflecting our direct and indirect investments in Moderna. The effective tax rate for the quarter was 14.8% and was driven by a lower assumed full-year effective tax rate as a result of favorable earnings mix. Taken together, we earned $1.74 per share, an increase of 18% reflecting strong operational performance that more than overcame COVID headwinds as well as contributions from our other income.

Now, turning to the guidance. Our updated guidance reflects our confidence in the underlying strength of our business. We now expect revenues of $47.6 billion to $48.6 billion, which reflects an increase of $150 million from our previous midpoint. Our guidance assumes roughly $2.35 billion of COVID headwind for the year, an

increase from our prior assumption of $1.95 billion. We now assume a negative impact from foreign exchange of roughly 1.5 percentage points using mid-October rates. Overall, our guidance implies 3% to 5% growth in revenues for the full year, excluding the impact of exchange. Excluding the impact of the pandemic, our guidance range implies year-over-year growth of 8% to 10%, reflecting continued strong underlying demand for our products.

Broadly, we're encouraged by the recovery of our business, which has been largely consistent with our original expectations with GARDASIL being the primary exception. GARDASIL is trending in the right direction, but the phasing of the recovery is slower than we anticipated, largely due to the impact of the pandemic on the back-to-school season, particularly in the United States. We are also seeing some residual negative impacts of the pandemic extend into the fourth quarter in some parts of the world, primarily in Europe and certain emerging markets. Most importantly, our operational performance remains strong and has enabled us to offset the impact from the pandemic.

As we end the year and head into 2021, our confidence is further reinforced by the ability of the healthcare systems around the world to adapt and deliver care and by the value of our medically important products' delivery to patients. As a result, we continue to believe in our long-term growth prospects, which remain underestimated by the Street.

We continue to expect gross margin to be roughly 75%. Operating expenses are now expected to decline at a low single digit rate year-over-year driven by reduced spending due to the pandemic and strong expense management. We now expect our full year tax rate to be 15.5%, reflecting improved earnings mix.

We now expect other income of roughly $750 million reflecting higher income from investments in equity securities. We continue to anticipate 2.54 billion shares outstanding. Taken together, we now expect our non-GAAP EPS be between $5.91 to $6.01, which reflects an increase of $0.25 from our previous midpoint. This range includes a negative impact from foreign exchange of roughly 2.5 percentage points.

Our results continue to benefit from an improved tax rate and higher other income due to gains from our equity holdings. That said, our operational strength continues to drive the leverage in the P&L through robust revenue growth and expense management, allowing for meaningful investments in our pipeline while at the same time delivering margin expansion.

We continued to make progress on our strategy to evolve our operating model in order to drive efficiency and productivity throughout the organization. This is occurring through process improvements and the leveraging of new digital capabilities, which have become increasingly important as we find new ways to engage with patients and physicians in this pandemic.

Our balance sheet remains strong and we are well positioned to execute on our capital allocation priorities. Fully investing in our key growth drivers and pipeline remains our top priority and we are committed to growing the dividend and to driving value-enhancing business development that will help position Merck for long-term success.

To conclude, the swift recovery we experienced in the third quarter serves as an indicator of the true value our products provide to patients around the world and our ability to execute. We remain confident in the fundamental strength of our business and the significant runway for growth that our de-risk portfolio of assets provides.

Further, the spin-off of Organon in the second quarter will enable us to realize the growth potential of its portfolio of medically important products and will allow us to focus our attention in investments more fully on our key growth drivers and robust pipeline to deliver innovative medicines and vaccines to patients around the world now and long into the future.

Before I close, I'd like to also personally thank Roger for his many contributions to Merck, which will benefit our company and the patients we serve for many years to come. It's been a pleasure working alongside you and learning from you.

With that, I'd like to turn the call over to Roger.

Roger M. Perlmutter {BIO 3077183 <GO>}

Thank you very much, Rob.

During the third quarter, our laboratories made important advances on many fronts, including regulatory approvals, filing of New Drug Applications, obtaining meaningful new clinical data, advancing new product opportunities into development, and forging new R&D alliances.

Our press release tabulates many of these accomplishments, but cannot convey the rapid pace at which these programs are advancing. As an example, during the third quarter, in the United States Food and Drug Administration approved an expanded label for KEYTRUDA in the setting of relapsed or refractory classical Hodgkin lymphoma based on our KEYNOTE-204 study that compared KEYTRUDA monotherapy to treatment with brentuximab vedotin, a standard therapy. But note that approval of this indication was received just three months after acceptance of the file, a reflection of the high quality of the underlying work by our clinical development and regulatory colleagues.

KEYTRUDA is also under review for the first-line treatment in combination with chemotherapy of previously untreated, locally recurrent, inoperable or metastatic triple-negative breast cancer, with tumors expressing PD-L1 with a combined proportion score of 10 or greater based on the results of our KEYNOTE-355 study

with a PDUFA date of November 28. And also for the neoadjuvant and adjuvant treatment of triple-negative breast cancer, based on the results of our KEYNOTE-522 study, with the PDUFA date of March 29, 2021. Results from these studies have been previously presented.

In Europe, the Committee for Medicinal Products for Human Use or CHMP adopted positive recommendations for Lynparza as monotherapy in the treatment of patients with metastatic, BRCA mutant, castrate-resistant prostate cancer, who have progressed following treatment with the modern[ph] androgen blocking agent. Lynparza also received a favorable opinion for the first-line maintenance treatment in combination with bevacizumab of advanced homologous recombination deficient ovarian cancer based on the results of the PAOLA-1 Phase 3 study.

Meanwhile, in Japan, we obtained approval for KEYTRUDA in the second-line treatment of PD-L1 positive esophageal cancer based on data from our KEYNOTE-181 study. We also received approval in Japan for the 400 milligram every six weeks regimen for KEYTRUDA across all adult indications and approach already adopted in Europe and in the United States.

I mentioned each of these approvals, because they document the continued progress of our broad-based registration programs for KEYTRUDA and for our partnership with AstraZeneca on Lynparza just conducted around the world despite the challenges imposed by the COVID-19 pandemic.

At the European Society for Medical Oncology meetings in early September, we highlighted long-term data demonstrating the durable impact of KEYTRUDA in the treatment of malignant disease. For example, data from our KEYNOTE-024 study in the first-line treatment of non-small cell lung cancer in patients whose tumors expressed PD-L1 on at least 50% tumor cells showed that after five years, overall survival nearly doubled in the KEYTRUDA treated group as compared with those who received traditional chemotherapy, this despite a high rate of crossover to KEYTRUDA in the chemotherapy on.

Similarly, a combination of chemotherapy plus KEYTRUDA as compared with chemotherapy alone meaningfully improved overall survival of four years in squamous cell carcinoma of the head and neck, especially in those whose tumors had a combined proportion scores for PD-L1 expression of greater than 1 based on our KEYNOTE-048 study.

And in the adjuvant treatment of melanoma following surgical resection, long-term data showed a 40% reduction in the risk of distant metastases in the KEYTRUDA treated population as opposed to those who did not receive adjuvant therapy. Together, these data speak to the durable improvement in outcomes that tends[ph] in the use of KEYTRUDA in otherwise difficult to manage malignancies.

At ESMO 2020, we also presented data regarding potential new cancer therapies, including vibostolimab, our anti-TIGIT antibody, which we hope may improve

treatment responses when combined with KEYTRUDA in non-small cell lung cancer patients whose tumors express low levels of PD-L1, including in patients who have progressed on prior checkpoint inhibitor therapy.

Vibostolimab is one of three new agents that we have prioritized for combined therapy with KEYTRUDA, and we will advance this agent's pivotal trials in 2021. We also presented data for MK-4830, an ILT4 antibody that acts to block immune suppression imposed by elements of the tumor microenvironment. MK-4830 showed promising activity in multiple tumor types, including in patients whose tumors have progressed on PD-1 therapy. Ongoing expansion cohorts will explore the activity of MK-4830 in pancreatic adenocarcinoma, glioblastoma, head and neck cancer, advanced non-small cell lung cancer, and gastric cancer.

More recently at the North American Conference on Lung Cancer, we presented data on the combination of quavonlimab, our novel CTLA-4 directed therapy at a dose of 25 milligrams every six weeks in combination with KEYTRUDA in the first-line treatment of non-small cell lung cancer. Data obtained after 16.9 months of median follow-up showed an overall response rate of 37.5% and the median overall survival of 18.1 months. Importantly, the median duration of response in the responding population was not great[ph]. A registration enabling study testing quavonlimab co-formulated with KEYTRUDA is planned for 2021.

The third quarter gave us the opportunity to advance many other new drug candidates in a variety of other therapeutic areas. For example, we presented additional data on the activity of MK-6482, our HIF-2 alpha inhibitor for the treatment of von Hippel-Lindau disease, documenting shrinkage of tumors with MK-6482 therapy in the kidney, but the overall response rate including only confirmed responses was 36.1% for pancreatic lesions in this disease, the confirmed overall response rate was 63.9% and hemangioblastomas of the central nervous system, the confirmed overall response rate was 30.2%. These are meaningful responses, especially since current therapy for von Hippel-Lindau disease requires surgical extirpation of tumors often involving dozens of procedures extending over many years.

In the infectious disease area, we continue to advance islatravir, our novel non-nucleoside reverse transcriptase translocation inhibitor for daily administration in combination with Pifeltro. Phase 2b 96-week data presented at the HIV Glasgow meeting demonstrated sustained viral suppression in treatment-naive patients, which augurs well for the future of this regimen. Phase 3 studies will begin in February of this year -- I'm sorry, began in February of this year.

We also advanced MK-8507, a new long-acting non-nucleoside reverse transcriptase inhibitor, which we believe will partner well with islatravir in extended dose regimens. Meanwhile, we announced positive immunogenicity results for four additional Phase 3 studies of V114, our 15-valent pneumococcal conjugate vaccine when dosed in adults. These data helped to complete the entire set of adult registration studies, which will be filed before the end of the year. Finally, during the third quarter, we made substantial progress in our COVID-19 directed programs.

Turning first to molnupiravir, formerly known as MK-4482, which is a direct-acting orally bio available antiviral drug that we are developing in partnership with Ridgeback Biotherapeutics. Phase 1 studies completed during the first quarter provided evidence that the compound is well tolerated as monotherapy in single doses as high as 1.6 grams and in multiple doses of 800 milligrams twice per day for five days. We believe that the concentration of the active mortality[ph] that were achieved should be more than sufficient to terminate virus production.

Three relatively small Phase 2 dose escalation studies evaluating the antiviral effect of molnupiravir in COVID-19 patients were initiated by our colleagues at Ridgeback, and data from these studies will soon become available. Meanwhile, we have initiated two large global Phase 2/3 studies, one in hospitalized patients and the second in outpatients. Together, these studies will enroll more than 2700 patients and we'll examine clinical outcomes, including both efficacy and safety.

Based on its mechanism of action, we are hopeful that this new therapy, which is administered orally in capsule form will meaningfully reduce morbidity and mortality in COVID-19 patients. Along with this progress in clinical development, we have secured resources to produce millions of doses at molnupiravir before the end of 2020, with an even greater supply becoming available early in 2021. It should be mentioned that in preclinical studies, molnupiravir is active against numerous coronavirus species, including those responsible for SARS and MERS as well as a wide variety of RNA viruses, including the influenza virus. Hence, molnupiravir could prove to be a useful antiviral agent in a variety of settings.

Our COVID-19 directed vaccine candidates will also advance into clinical trials during the third quarter. As Ken mentioned, in developing a vaccine against COVID-19, we have pursued proven platforms focusing in particular on replicating virus vectors that could provide durable protection following a single administration.

Our first vaccine candidate developed in partnership with the Institut Pasteur in Paris employs a modified measles virus vaccine that has been engineered to express the major surface protein, SARS-CoV-2. During the third quarter, this vaccine candidate, V591 was advanced into two Phase 1 clinical studies involving nearly 300 healthy volunteers. The five V591 Phase 1 studies have enrolled well such that immunogenicity data should become available before the end of the year. A second vaccine candidate V590 developed in collaboration with the International AIDS Vaccine Initiative or IAVI make use of a vesicular stomatitis virus vector, which is the same vector system that we used to develop EBOV, the first successful vaccine for the prevention of Ebola virus disease.

The Phase 1 program for V590 is proceeding in much the same pattern as that for V591 albeit offset by several weeks. Here again, we are optimistic that the candidate vaccine will list durable immune responses to the SARS-CoV-2 spike protein following a single dose and then it will be safe and well tolerated. For both V590 and V591, we are developing facilities that will enable us to produce many millions of vaccine doses in the near term and hundreds of millions of doses should those be required in the longer term. Our expectation is that these vaccines will be made

available in a format that permits global distribution with appropriate cold chain management ideally and refrigerated temperatures.

Our prior experience in developing vaccines against many other viral diseases gives us some confidence that we will succeed in producing an effective agent for prophylaxis against COVID-19. In this context, I would call your attention to new data from a study published in the New England Journal of Medicine at the beginning of October that made use of Swedish demographic and health registries which captured health data on the entire population of Sweden. The study included 1.67 million girls and women, 10 to 30 years of age, evaluated during the period 2006 to 2017. In that group, after adjustment for oncovirus [ph], there was an 88% reduction in the risk of cervical cancer as a result of immunization with GARDASIL before the age of 17. These new data offer hope for the potential eradication of this disease, which according to the World Health Organization, claims the lives of more than 300,000 women each year. The new Swedish study adds further impetus to our efforts to expand production of GARDASIL 9 with the goal of producing enough of this vaccine about 200 million doses per year to permit girls and boys around the world to be successfully vaccinated.

Finally, I wish to express my gratitude to my colleagues throughout Merck and especially to those in the Merck Research Laboratories with whom I have worked on and off since 1996. It has been my privilege to join you in translating breakthrough research into medicines that improve and extend lives. Your success in developing new vaccines, like GARDASIL 9, novel antibiotics, new antiviral drugs, new drugs that battle cancer, drugs that improve outcomes in heart failure. and others that offer hope for those suffering from metabolic diseases and chronic debilitating syndromes. Your success has not only improved and extended life, but has inspired the world.

As I plan to assume an advisory role at Merck, I'm confident that Dean Li, who will succeed me as President, is well prepared to lead MRL to even greater achievements. We have orchestrated an orderly transition in leadership, pledging to ensure in the words of George W. Merck that human life will earn still greater freedom from suffering and disease.

I'll now turn the call over to Peter.

Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Roger. Lara, if you could assemble the queue for questions, please. And I'd like to ask the analysts today to limit themselves to one question. We're going to try to end right at 9:00, because I know there's other call that you're looking to get on.

Questions And Answers

Operator

Thank you, sir. (Operator Instructions). Beginning the Q&A, we have your first question coming from the line of Steve Scala from Cowen. Your line is now live. Go ahead, please.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you, and it's tough to limit to one question, but I'll comply. Ken, Merck has profoundly transformed under your leadership in the wake of Dr. Perlmutter's retirement. I wanted to note that I believe two years ago, Ken you agreed to stay on beyond 2019. May I ask whether or not you will stay on as CEO of Merck beyond 2021 to see this further transformation that the company is undertaking? Thank you.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Thank you, Steve. The Board will continue to evaluate the timing of CEO succession. Right now, there is no specified timeframe for CEO retirement. What I will say is that I am confident that we have internally strong candidates to take this job, and I look forward to working with the Board to actively review our leadership and succession planning and to ensure that we have an orderly transfer when the Board deems it appropriate.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Steve. Next question, please.

Operator

Thanks, Steve. Your next question will come from the line of David Risinger from Morgan Stanley. Your line is now live. Go ahead, please.

Q - David Risinger {BIO 1504228 <GO>}

Yes, thanks very much. So I wanted to say congratulations to you, Roger, and thank you for all of your contributions, including transforming cancer treatment for patients worldwide, and your contributions will be missed. So my question is with respect to the Phase 2 oral antiviral data from Ridgeback. Could you provide some more color on how you expect that data to be communicated and you would focus us on? Thank you.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Thanks very much, David. Yes, the Phase 2 studies carried on in the United States and the UK are relatively small studies that are focusing on neurological endpoints, that is understanding reductions in viral load and reductions in virus infectivity from patient samples. So these data, I'm hopeful that as the studies complete enrollment and their dose escalation studies, that these studies will provide data over the next couple of months. And as -- once those data are looked at and there is enough data that have accrued, then presumably we would provide a top line statement about those data. But of course, the full scientific results will be published shortly thereafter. We will certainly move expeditiously because of course we know the world is very interested in this as we ourselves.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, David. Next question please.

Operator

Your next question will come from the line of Tim Anderson from Wolfe Research. Your line is now live. Go ahead please.

Q - Tim Anderson {BIO 3271630 <GO>}

Well, thank you. I have a question on KEYTRUDA and adjuvant. Previously, Astra announced a delay in the readout of their adjuvant lung trial because of the ADAURA results that necessitated a design adjustment for EGFR positive patients on TAGRISSO. And I'm guessing that's going to impact other company to use adjuvant lung trials as well. Can you comment on the timing of us seeing your first lung adjuvant readout and more broadly neoadjuvant[ph], what's the timing of the next adjuvant readout for you? Thank you.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

All right. (Multiple Speakers) (inaudible) I'm sorry?

A - Peter Dannenbaum {BIO 20569031 <GO>}

Yes, go ahead, Roger, please.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Yes. So our adjuvant studies in non-small cell lung cancer are proceeding as planned. We are not at the moment undertaking any reevaluation of those studies. Again, it's difficult to comment on exactly when the studies will read out because of course we're accruing events, but we are anticipating that the first of an adjuvant lung study will be available sometime later next year and that's our hope, but time will tell.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Tim. Next question, please.

Operator

Thank you. Your next question will come from the line of Chris Schott from JPMorgan. Your line is now live. Go ahead please.

Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks very much. And Roger, best of luck with everything and congrats on all the success over the years. My question was on GARDASIL in the US. What do you think it's going to take to normalize results here? I guess my question is, do we need to wait until we get another back-to-school season for this to normalize? Or do you

think that trends can start to get back to normal even in a COVID environment, like we're operating today? And I guess, when things normalize, should we think about there being some sort of catch-up bolus for the patients who missed their vaccination this year? Or is this going to go back to just kind of a normal cadence of what we've historically seen with that vaccine? Thanks so much.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Frank?

A - Frank Clyburn {BIO 20654315 <GO>}

Yes. Hi, this is Frank. With regards to GARDASIL in the US, I think I'll take the second part of your question first, with regards to the catch-up. Our hope is that we will see some catch-up over time in particular, as we put more commercial efforts, making sure that the adolescent cohort in particular well aware of the importance of getting vaccinated with GARDASIL. So that was our plan.

With regards to looking at the timing, I think back-to-school as you head into '21 will be an important time frame. I'm just to give you some additional color or what's happening in the US. Well visits were down in the adolescent cohort about 30% compared to three-year historical averages.

As Rob mentioned, we are seeing a more positive trend, although not what we expected. So we'll have to see here over the next several quarters how things evolve, but we're still very confident in GARDASIL growth in the US as well as globally.

To Roger's point, the Sweden data is very important data, which I think reinforces the importance of the chance to prevent cervical cancer for girls and boys around the world. We also saw significant growth continue in China as well as Germany and many of our ex-US market. So I would say, we're going to look over obviously the next couple of quarters, but our confidence in GARDASIL, both mid and long term is still very strong. We still feel very strong about the overall demand prospects for the product.

Q - Chris Schott {BIO 6299911 <GO>}

Thank you.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Chris. Next question, please.

Operator

Your next question will come from the line of Mara Goldstein from Mizuho Securities. Your line is now live. Go ahead, please.

Q - Mara Goldstein {BIO 2458369 <GO>}

Great, thanks so much for taking the question. I just wanted to ask on the COVID vaccine program. Maybe if you could just discuss the clinical program in the context of the pending readouts from other vaccines and contingency plans to make sure that you're able to fully enroll those trials on a timely basis.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Right. Thanks, Mara. Of course, it's very difficult to speculate on what the results of other studies will be like everyone else, where we're hopeful that there will be many vaccines that yield positive readouts in terms of reduction in morbidity and ideally mortality associated with COVID-19 infection that time will tell, but in reality, we'll be sitting at the end of the year with what we hope will be quite strong, single dose immunogenicity data and we have well designed Phase 2/3 protocols that we can begin at that point. Those are global protocols. And my expectation -- unfortunately, given the very large impact of the pandemic, my expectation is that it would not be difficult to enroll those studies in a relatively short period of time. Justice has happened for the other studies that have been conducted using, for example, the mRNA vaccines or the adenovirus vaccines. So I'm not sure that there is anything there to respond to accept that we're eager to see the data just as everyone else is and we hope very much that there will be efficacy and a good safety profile.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Mara. Next question, please.

Operator

Your next question will come from the line of Umer Raffat from Evercore. Your line is now live. Go ahead, please.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, thanks so much for taking my question. Roger, I noticed for the COVID antiviral, there was a dedicated Phase 1, Phase 2 trial evaluating viral clearance. However, heading into the two Phase 3s we're seeing online, it doesn't look like a viral clearance of the primary endpoint or even a secondary endpoint, at least not on clinical trials. And I also noted you mentioned good safety. So just wanted to understand, are you expecting a viral clearance benefit? And how do you see the efficacy look different or similar relative to what we've seen in remdesivir so far?

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Right. Thanks very much for the question. To be honest, I am expecting to see viral clearance improve and that's based on a whole variety of inputs and the fundamental mechanism of the drug. I do think that in terms of reduction of viral burden that it is very likely that monlupiravir will be superior to remdesivir based on preclinical studies. Of course, that has to be demonstrated in the clinic, but we will have quite a lot of Phase 2 virologic data based on the Ridgeback studies, which of course were intimately involved with the dose escalation studies.

From a certain perspective, (inaudible) this is a virally mediated disease. If you get rid of the virus, you should get rid of the disease. The question is can you get in early enough? And is the effect strong enough? The good news is that this is an orally administered drug. It could in principle be given to individuals who at least[ph] are symptomatic or who have been in contact with virally infected people. But in order to broaden the use, we need to understand both preclinically and clinically that the drug is safe to administer to people who are otherwise healthy and just at risk.

So when we speak about safety, that's really what we're concerned about, and we are waiting for additional data from more subjects who have been treated with the drug. The drug has been used, it's in a five-day regimen and across now several hundred people seems to be extremely well tolerated, we're not aware of any safety signals at all with the drug right at the moment, so we'll just wait and see. I mean that's the important information that we need to have.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Umer. Next question, please.

Operator

Your next question will come from the line of Gregg Gilbert from Truist. Your line is now live. Go ahead, please.

Q - Gregg Gilbert {BIO 3565226 <GO>}

Thank you, and best of luck to you, Roger and Dean for what's next. I have a question on V114, sort of a -- maybe an R&D and marketing question. Other than any timing advantage as you might have versus Pfizer, particularly on the pediatric side, how do you envision having a meaningful share of this market over time if Pfizer successfully develops it's 20-valent product? Investors tend to view this as a winner-take-all type of market. I think you've made some comments to the contrary. Maybe you can put some more details on how that could be achieved. Thank you.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Mike Nally?

A - Mike Nally {BIO 20888689 <GO>}

So, thank you for the question. When we look at the market, the first and foremost area that we're looking at is making sure that we actually confer protection across the 13 shared serotypes with PCV 13, and I think what we've been able to demonstrate in the Phase 2 results that you've seen in the pediatric population is that you see a robust immune response across those 13 shared serotypes and that's after dose 3, which I think is also an important factor, because the primary series completion is really an important timepoint.

When you think about what's next, then it's about how do we add to those 13 shared serotypes, and for our program, we've been able to show a robust immune response

on 22F and 33F as well as a really robust response on serotype 3, which is a key contributing factor to residual disease. And so, I think when we look at the real effort on V114, it's always been about making sure that we provide the relevant level of protection in the core serotypes, but then add out their serotypes to it.

I think the question on the first year of life will be an important one as well and we're looking forward to see more data from both our program as well as Pfizer's program.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thanks, Gregg. Next question, please.

Operator

Your next question will come from the line of Navin Jacob from UBS. Your line is now live. Go ahead please.

Q - Navin Jacob {BIO 20931208 <GO>}

Hi, thanks for taking my question. My congrats as well to Roger. Roger, wondering if you think it's feasible for a COVID vaccine and specifically yours, but also just generally to achieve sterilizing immunity, obviously the focus of most of the trials currently are -- is reduction in symptoms, but given the discussion around herd immunity and the importance of herd immunity for opening the economy fully back open, what does that mean if vaccines aren't able to achieve a significant amount of reduction in infection?

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Right, okay. Thanks for the question. I think first and foremost, of course, what we want out of a vaccine is to prevent clinical disease. I don't think any of us would care that much if people were infected but been develop any diseases that we can guarantee that that would always be the case, of course provided that enough people can be immunized.

I think sterilizing immunity will be difficult. Just in the nature of things in these respiratory infections, it is difficult to prevent any viral colonization that will be challenging. Frankly, we are still in the early phases of understanding COVID-19 and SARS-CoV-2, the causative agent. So, we really don't understand a lot about the viral dynamics here, the state of the immune response in the natural infection setting, and the durability of that immunity either from natural infection or what we hope will see after immunization. There's a lot, yes, that we need to study.

It is clear that at least in rare circumstances, individuals who have been infected and cleared the infection can be re-infected and that should be a cautionary note for all of us, over time that this could evolve in a fashion that re-administration of the vaccine is required in order to prevent recrudescence of disease after exposure to (Technical Difficulty) or it may be the case that we are able to control it with single administration, which is of course what we hope for. I just think we don't have that

information right now, and we'll learn a great deal over the next few months as additional data become available.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Navin. Next question, please.

Operator

Your next question will come from the line of Geoff Meacham from Bank of America. Your line is now live. Go ahead please.

Q - Geoff Meacham {BIO 21252662 <GO>}

Good morning, guys. Thanks for the question. Roger, congrats on the retirement, it's been great working with you both at Merck and your time at Amgen. A question on monlupiravir. I just wanted to see if I can get more details from the Phase 1 such as common AEs or SAEs? And given that it's an oral, it does seem ideally suited for newly infected but mild patients. I want to get your perspective on that. Thank you.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Right, Geoff. Thanks very much. Yeah, monlupiravir from again a small number of subjects who have received the drug in Phase 1 studies and now in Phase 2 studies, it seems to be extremely well tolerated in a 5-day course BID doses that are well above what we believe is required to suppress viral replication or actually result in error catastrophe in essentially the elimination of the virus. So all of that looks quite good as you say, because it's an orally administered drug in principle, I mean all of the things being equal, it could be administered even prophylactically in individuals at high risk.

At the moment, we are waiting for additional data, because I point out that the drug is Ames positive and vector [ph] genesis assay, and although the drug did not score in eukaryotic micronucleus assays and there are other reasons to believe that that won't be a problem, nevertheless we're performing a whole variety of studies to explore immunogenicity. Assuming that those studies are negative, then I think we could think much more broadly about prophylactic administration.

At the moment, we're thinking mainly about the place where benefit risk is clearly the strongest and that is in individuals who are infected, particularly symptomatic individuals early in the course of the disease, an ideal place for an orally administered drug to attenuate the effects of that infection.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Geoff. Next question, please.

Operator

Your next question will come from the line of Terence Flynn from Goldman Sachs. Your line is now live. Go ahead please.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks for taking the question and best of luck, Roger. Thank you for everything you've done for the field. You guys are advancing a co-formulation of KEYTRUDA and your CTLA-4 into Phase 3 for lung cancer. Just wondering how broad your co-formulation strategy is, and if it's also possible, you could co-formulate KEYTRUDA with your anti-TIGIT. Thanks.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Right. Well, the reality is we've been working on checkpoint inhibitors for a long time now as with many others. And KEYTRUDA in particular, PD-1 directed therapies more generally have very dramatic effects and are easy to see. We hope to find something that would be even better than KEYTRUDA, but neither we nor anyone else has found such a thing. We are pleased that our agents have activity when administered by themselves, but the activity is modest, it's not KEYTRUDA like activity. And where we see the greatest effect is in combination with KEYTRUDA, so it makes sense that these things should be administered with KEYTRUDA, that's the place where you're going to see the biggest benefit and where co-formulation is possible, that's kind of the ideal. That's what we would do, because then with the single administration, get both drugs, assuming that you don't add a substantial safety burden. So we've conducted our studies and looking at those kinds of questions clearly for CTLA-4 directed therapy, that makes a lot of sense, but it makes a lot of sense for all of the agents that we're looking at, and we are looking both at the physical compatibility for co-formulation and as well whether that makes sense from a clinical perspective. Where it does, it's kind of the right thing to do for patients.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great, thank you, Terence. Next question please.

Operator

Your next question will come from the line of Seamus Fernandez from Guggenheim Securities. Your line is now live. Go ahead please.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Thanks very much. And Roger, best of luck and it's been great working with you over the last many years. I wanted to ask a commercial question. We're starting to see a lot of promotional efforts by other pharmaceutical companies to kind of drive a return to growth and a return to physicians' offices, as it relates to primary care visits and obviously impacting diagnosis of disease. I'm just wondering what Merck is doing on the commercial side and believe this is necessary to really kind of get us back on the right track in 2021. How much of that are you seeing in your business? And what are you doing to drive growth in '21? Thanks.

A - Frank Clyburn {BIO 20654315 <GO>}

Yeah. Hi, Seamus. This is Frank. I think that's really important and we're putting a lot of efforts. As you can imagine, a lot of those activities right now are still virtually being done, especially in certain markets around the world. But if you look at what we're doing in particular in the vaccine area, I think you maybe have seen some of our non-branded commercial activities to raise awareness about the importance of HPV vaccination. You can see that we are continuing to put a lot of effort behind KEYTRUDA with healthcare professionals as well as with our consumer campaigns and activities.

And we also are in many markets around the world continuing to engage in educational programs to make sure that physicians are well aware of a lot of the new data that you heard Roger speak about here this morning. So we have significant efforts around the world and that's why we're confident in our overall growth profile as we look towards not only the rest of this year as we head into 2021.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Seamus. And thank you all for limiting yourselves to one question. Great questions. I'd like to turn it over to Ken for closing comments.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Thanks, Peter. As you've heard, we remain extremely confident in our strategy, and we are highly motivated by the opportunities before us. We believe our ongoing scientific leadership, promising pipeline, upcoming launches, and track record of solid commercial execution will drive long-term growth. We remain committed to bringing Merck's mission to life by sharpening our focus on R&D and being at the forefront of life-saving research that will be essential to solving for this pandemic as well as other healthcare challenges.

So, thank you for joining us today. I hope that you and your families stay safe and healthy.

Operator

Thank you so much, presenters. And again, thank you everyone for participating. This concludes today's conference. You may now disconnect. Stay safe, and have a lovely day.