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## 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. Q2 Sales and Earnings Conference Call. (Operator Instructions) Thank you.

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

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

Thank you, Lara, and good morning. Welcome to Merck's Second 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; and Mike Nally, our Chief Marketing Officer.

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 U.S. Private 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](http://merck.com).

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

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, President & CEO

Thank you, Peter. Good morning, and thank you all for joining today's call. I want to start by thanking our employees around the world for demonstrating resiliency and diligence through this difficult time. As a result of their tireless work, we continue to make progress on our strategic priorities, and we exited the quarter with accelerating business momentum.

While the pandemic has brought challenges that few of us could have imagined even 6 months ago, it has also demonstrated the critical importance of organizations that are focused on breakthrough science. Our scientists are highly focused on this effort, and we are incredibly energized by this mission. Simply put, this is why Merck exists.

Throughout the quarter, Merck executed well both operationally in support of our existing portfolio and by advancing our innovative research program. We continue to perform at a very high level without significant disruption to the production, supply and distribution of our medicines, vaccines and animal health products or our clinical trials. As expected, social distancing measures in many regions negatively impacted second quarter volume for many of our products. However, customer access to care is steadily improving, including in our portfolio of vaccines, which was hit particularly hard this quarter. We remain confident that our innovative portfolio will drive strong long-term growth.

Our financial strength also allows us to execute on our capital allocation priorities, including continuing to invest in internal R&D and business development. In addition to advancing our strategic priorities, we also achieved significant progress on our plans to spin-off Organon & Co., which remains on track to be completed in the first half of 2021. We remain confident that creating 2 more focused companies will result in each being stronger and better positioned in an evolving health care landscape, which will benefit the patients we serve and our shareholders. We recently announced appointments of several talented and experienced leaders from outside the company to the strong leadership team, and they are already deeply engaged in driving the various work streams underway to set up the stand-alone company for success.

Before Roger provides more detail, I'd like to say a few words on the multiple efforts underway within Merck on the COVID-19 front. COVID-19 represents a tremendous challenge to the biopharmaceutical research community, and Merck is moving with urgency to apply our deep expertise in vaccines and infectious diseases toward potential solutions. During the quarter, we announced 2 vaccine development efforts, one through a collaboration with IAVI and the other through our now completed acquisition of Themis. We selected these candidates because they are based on proven platforms that we anticipate will lead to safe, effective and broadly deployable vaccine with the promise of single dosage. Both vaccine candidates will soon enter the clinic, and we have begun investing to facilitate our ability to manufacture hundreds of millions of doses. We also announced a program to develop a novel orally available antiviral candidate through a collaboration with Ridgeback Bio. This compound has advanced into Phase II clinical trials.

We are optimistic about the prospects for these 3 programs, and if successful, Merck is committed to working with others to create broad, affordable and equitable global access. These programs illustrate our continued commitment to supplementing internal capabilities with innovative external science. Roger will provide more details on the significant progress being made in our research activities elsewhere.

More broadly, the biopharmaceutical industry's response to COVID-19 had been extraordinary. Our industry is uniquely positioned to address this public health challenge on a global scale. Collaboration across the scientific, public health and biopharmaceutical industry community will be key to successfully finding solutions for this pandemic and to help ensure that we are adequately prepared for the next. We are confident that science will ultimately prevail over COVID-19 with new medicines and vaccines.



Let me conclude by expressing our gratitude to the frontline health care workers as well as to our own employees who have worked to help patients affected by COVID-19. Their dedication inspires us. It makes us even more resolute in our commitment to bring forward new tools to help end this pandemic. The value of our industry to society is underscored by this crisis as is the need for companies like Merck to continue to invest in research and development to address the greatest health threats both now and in the future.

And with that, I'll pass it over to my colleague, Rob Davis to review the details of our performance and our outlook.

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**Robert M. Davis** - Merck & Co., Inc. - Executive VP of Global Services & CFO

Thanks, Ken, and good morning, everyone. As Ken highlighted, our business performed well in an unprecedented environment. While we saw a meaningful impact from the COVID pandemic in the quarter, particularly in April and May, overall, the business fared well.

Within our human health business, the impact was largely as expected while within Animal Health, the impact was less than anticipated. That said, we were able to deliver better-than-expected results in both human health and Animal Health due to our underlying operational strength, combined with our execution in the face of the pandemic. Based on our ability to drive improved and accelerating operational momentum, we now expect to see stronger performance in the second half of the year.

As a point of reference, if we adjust for the impact of COVID in the quarter, Merck's underlying sales growth would have been 6% nominally and 9% excluding exchange, reflecting strong demand for our key growth pillars. We continue to operate from a position of financial and operational strength, which allowed us to execute on our capital allocation priorities. Investments behind our extensive pipeline of research programs remain robust, and we also successfully completed 2 collaborations and an acquisition to bring in-house promising vaccine and antiviral candidates to address the COVID-19 pandemic, as Ken referenced. All of this is in support of our goal of advancing science to fulfill unmet medical needs, the core of Merck's mission.

Now turning to our second quarter results. Total company revenues were \$10.9 billion, a decrease of 8% year-over-year or 5% excluding the negative impact from foreign currency. The pandemic negatively impacted our second quarter results by \$1.6 billion, reflecting approximately \$1.5 billion in human health and approximately \$100 million in Animal Health. In the human health business, the impact to sales was spread to varying degrees across our vaccines, hospital, women's health and oncology products due to access limitations from social distancing orders and prioritization of coronavirus patients in hospitals.

Within the Animal Health segment, livestock product sales were impacted by a change in protein demand due to restaurant closures and regional outbreaks while companion animal product sales reflected decreased visits to veterinarian offices. It's worth noting that despite the short-term headwinds experienced in the quarter, the underlying strength and demand for our products enabled first half growth of 4% excluding 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 ex-change basis. Our human health revenues declined 6%. In oncology, KEYTRUDA sales grew 31% year-over-year, reaching \$3.4 billion in the quarter.

In the U.S., KEYTRUDA demonstrated strong growth across all key tumor types. We continue to strengthen our leadership in IO, including in lung, in the face of recent competitor launches. We benefited from continued strength in melanoma, bladder and head and neck cancers and strong momentum from launches in renal cell and endometrial carcinomas. We received FDA approval for a 6-week dosing regimen across all adult indications, which enabled greater patient access and contributed to growth.

Outside the U.S., lung cancer indications remains a driver of KEYTRUDA growth. In the EU, growth continues to be driven by the uptake of KEYNOTE-189, with reimbursement secured across all major markets. In Japan, the combined impact of delayed new patient starts, reduced frequency of existing patients and the huge seller price adjustments from February and April more than offset volume growth in new indications. We saw COVID-related impact to KEYTRUDA in April and May across all tumor types but not to the degree we expected. We are encouraged by the recovery we saw in June, particularly in the United States and Europe, and this trend has continued in the third quarter.



Strong growth from LYNPARZA and LENVIMA continued to bolster our oncology performance as both products experienced limited pandemic impacts due to their oral formulations. LYNPARZA's performance in the quarter continues to reflect growth and leadership in the PARP class in the United States, and the recent launches of the PAOLA-1 in ovarian cancer and PROfound in prostate cancer provide opportunities for future growth. LENVIMA maintains market leadership in first-line hepatocellular carcinoma, and the combination with KEYTRUDA in endometrial carcinoma is now the leading treatment regimen in the second-line setting in the United States.

Turning now to vaccines. Our vaccines portfolio was negatively impacted by a reduction of patient visits to physicians' offices, in line with our expectations. GARDASIL sales declined 24% year-over-year, driven by stay-at-home orders in the United States and most European markets, partially offset by continued demand-driven core strength in China. In the United States, we were encouraged to see significant increase in wellness visits beginning in late April for children and in late June for adults and anticipate this trend will lead to a recovery in our vaccines business in the back half of the year.

Our hospital business was impacted by delays and cancellations of elective surgeries and prioritization of coronavirus patients in hospitals. This impacted sales of BRIDION, which declined 18% year-over-year. Reduced wholesaler inventories also contributed to the decline. We remain confident in the underlying demand for BRIDION and are encouraged by the ongoing recovery in overall surgical procedure volumes. Partially offsetting the decline in our hospital portfolio was the growth in PREVYMIS.

Animal Health revenue increased 3% this quarter to \$1.1 billion. Livestock grew 3% due to contributions from an acquisition in our Animal Health intelligence product line, and companion animal also grew 3%, reflecting strong growth of the BRAVECTO line of products. Visits to veterinarian offices were negatively impacted early in the quarter, but offices opened earlier than expected, which benefited volumes.

Turning to the rest of our P&L. My comments will be on a non-GAAP basis. Gross margin was 73.8% in the quarter, a decrease of 160 basis points, driven largely by catch-up amortization booked for expected milestone achievements for our collaborations on LYNPARZA and LENVIMA.

Operating expenses decreased 9% year-over-year to \$4.4 billion. In total, COVID resulted in reduced spending of approximately \$325 million, driven largely by lower promotional, selling and administrative costs, along with lower laboratory, travel and meeting expenses. The significant year-over-year increase in other income was driven by unrealized equity gains from our security holdings, predominantly reflecting our investments in Moderna and NGM.

Effective tax rate for the quarter of 15% was driven by lower assumed full year effective tax rate as a result of favorable earnings mix. Taken together, we earned \$1.37 per share, an increase of 9% excluding exchange.

Now turning to our outlook for the remainder of the year. As expected, April was a particularly challenging month in the human health business. As we moved through May and particularly through June, however, we saw a meaningful increase in patient wellness visits to providers and in elective surgeries at hospitals, and our oncology business was particularly resilient due to the strength and breadth of our offerings.

Business conditions have clearly improved. And despite increased outbreaks and inflection rates that are impacting the phasing of our recovery, we believe the health care system is better positioned to provide patient access as we move through the balance of the year. The improved underlying operational strength we are seeing across several parts of our portfolio will help to more than offset the impact from COVID-19 and lead to stronger expected second half growth.

In addition, we are benefiting from our prior investments in digital capabilities to interact with our patients, providers and payers and allowing us to continue to address medical inquiries and promote our products effectively. This gives us further confidence in our ability to drive efficiencies in our business as we adapt to a post-COVID world through our continuing digital and other transformation efforts.

On the Animal Health side, as mentioned, veterinarian offices opened earlier than initially expected, which benefits our companion animal products, and stay-at-home restrictions lifted sooner than anticipated, which positively impacts our livestock products. These favorable trends contributed to our better-than-expected second quarter results and favorably impact our outlook for the full year. We will continue to monitor regional outbreaks, restaurant and school openings and any potential impacts to demand for our livestock products.



Now turning to guidance. Our updated guidance reflects continued confidence in the underlying strength of our business, a more limited COVID impact than previously expected across our business as a whole and a more favorable FX environment. Our assumptions regarding the progression of the COVID impact remain unchanged. We assume that the largest impact from COVID occurred in the second quarter, with recovery having begun during the second quarter that will continue through the third quarter before a return to normal operating levels in the fourth quarter.

We now expect revenues of \$47.2 billion to \$48.7 billion, which reflects an increase of \$850 million from our previous midpoint. Our guidance now assumes roughly \$1.95 billion of COVID headwind for the year. This is a reduction from our prior assumption of \$2.1 billion with human health roughly in line with and Animal Health below our prior estimates. We now assume a negative impact from foreign exchange of roughly 2 percentage points using mid-July rates.

Overall, our guidance implies 3% to 6% growth in revenue for the full year excluding the impact of exchange, reflecting strong underlying demand for our products. The one area we are watching is vaccines and GARDASIL in particular for a potentially extended recovery time line. However, this risk has been fully considered within our guidance range and more than offset by the overall strength we expect to see across the rest of our portfolio.

We continue to expect gross margin to be roughly 75%. Operating expenses are now expected to be roughly flat year-over-year, reflecting increased R&D spend, offset by reduced SG&A costs. The increase in our OpEx assumptions versus previous guidance reflects spending in R&D associated with the acceleration of our COVID-19 programs. This guidance still implies operating margin expansion of approximately 100 basis points for the year.

We now expect our full year tax rate to be in the range of 16% to 16.5%, reflecting improved earnings mix. We now expect other income of roughly \$550 million, reflecting higher unrealized gains in our equity securities portfolio based on June 30 valuations.

We continue to anticipate 2.54 billion shares outstanding. Taken together, we now expect our non-GAAP EPS to be between \$5.63 to \$5.78, which reflects an increase of \$0.44 from our previous midpoint. This range includes a negative impact from foreign exchange of roughly 3 percentage points.

Our results are benefiting from an improved tax rate and higher other income due to gains from our equity holdings. Excluding these benefits, however, we continue to drive operational leverage in the P&L. Revenue growth, coupled with continued expense management while we invest in R&D, including our COVID-19 candidates, and capacity expansion is expected to drive operating margin expansion for the full year. Our cash flow generation and access to capital, both are strong, and we remain well positioned to continue with our capital allocation priorities, including full investment behind our key growth drivers and pipeline, continued commitment to the dividend and strategic value-enhancing business development to enhance our pipeline and long-term growth potential.

To conclude, we remain confident in the fundamentals of the business and the meaningful growth opportunities that lie ahead despite the near-term impact from the pandemic. The favorable recovery trends that we saw through the quarter positions our company for accelerating business momentum as we head into the back half of the year. The underlying health of the business and demand for our innovative portfolio of medicines and vaccines remain strong. This, combined with our strong clinical execution across the portfolio and our expanding indications, which Roger will highlight in a moment, continues to reinforce our confidence in the sustainability and strength of our revenue growth.

During these challenging times, we are leveraging our operational and financial strength not only to weather the storm but also to execute meaningfully on our strategy of innovation and our mission to bring new medicines to patients. We continue to believe this best positions Merck for success and value creation long into the future.

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



**Roger M. Perlmutter** - Merck Research Laboratories - President

Thank you, Rob. During the second quarter, we were able to expand laboratory operations beyond the essential production of materials for clinical trials such that we are now once again selecting new chemical entities in discovery research and advancing these materials in preclinical testing. As our laboratories reopen, our priorities remain: first, ensuring the safety of our employees; and second, ensuring that patients in our clinical trials receive their treatments and are managed appropriately; and finally, we are once again applying our skills to identify new medicines and vaccines.

Many programs that I highlighted in my remarks during our first quarter earnings call have made substantial progress. For example, in May, we received FDA approval for LYNPARZA, developed in collaboration with our colleagues at AstraZeneca, when used in combination with bevacizumab for the first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who have sustained a complete or partial response to first-line platinum-based chemotherapy and whose tumors demonstrate deficiency in homologous recombination based on results from an FDA-approved diagnostic test. This approval referenced a biomarker subgroup analysis of the Phase III PAOLA-1 trial, in which LYNPARZA plus bevacizumab improved median progression-free survival by more than twofold to 37.2 months.

LYNPARZA also received FDA approval in May for the treatment of patients with metastatic castration-resistant prostate cancer whose tumors have progressed following prior treatment with enzalutamide or abiraterone and also contain deleterious or suspected deleterious germline or somatic homologous recombination repair gene mutations. This approval was based on results of our Phase III PROfound study. We estimate that approximately 20% to 30% of men with metastatic castrate prostate cancer have tumors containing these kinds of mutations.

Also during the quarter, LYNPARZA gained a positive opinion from the CHMP for use in the first-line maintenance treatment of patients with metastatic pancreatic cancer whose tumors contain germline BRCA mutations based on the POLO study. This recommendation was ratified by the European Commission early in July.

KEYTRUDA was the subject of numerous important regulatory actions in the second quarter such that the FDA label is now nearly 100 pages in length and tabulates nearly 30 explicit approvals. I will not enumerate all of the regulatory activity associated with KEYTRUDA filings today, but I will note that the second quarter began with the approval by the FDA of an extended dosing interval, 400 milligrams every 6 weeks, for all adult indications. Though previously registered in Europe, approval of this new dosing schedule in the United States offers physicians an option to reduce the number of clinic visits that patients must attend to at a time when they have implemented important social-distancing measures.

In June, the FDA granted 3 additional approvals for KEYTRUDA: first, for the treatment of recurrent or metastatic cutaneous squamous cell carcinoma that cannot be cured by surgery or radiation therapy; second, for the first-line treatment of patients with unresectable or metastatic colorectal cancer in patients whose tumors show evidence of mismanaged repair deficiency or MSI high; and third, for the second-line treatment of adult and pediatric patients with unresectable or metastatic solid tumors whose tumors have progressed following prior treatment and who have no satisfactory treatment options, provided that the tumors show a high mutational burden of at least 10 mutations per megabase of DNA. I wish to note here that this is the second tumor-agnostic indication for KEYTRUDA.

We received the very first such indication in the history of oncology therapeutics in 2017 with the accelerated approval of our MSI-high indication for KEYTRUDA in adults with solid tumors. As I just mentioned, this approach was extended still further in June with the approval for first-line treatment of MSI-high colorectal cancer based on our KEYNOTE-177 trial. FDA approval for the second-line treatment of patients whose tumors show a high tumor mutational burden represents the second time that KEYTRUDA has received an indication based on the molecular characteristics of the tumors themselves rather than the cell or organ from which these tumors are believed to have originated.

Two other FDA approvals from the second quarter deserve special mention. GARDASIL 9 was approved for the prevention of human papillomavirus-related oropharyngeal and other head and neck cancers. This was an accelerated approval based on the effectiveness of GARDASIL 9 in preventing papillomavirus-related anogenital disease and was supported by studies showing clearance of persistent oropharyngeal HPV infection in vaccinees. A recent analysis by the U.S. Centers for Disease Control demonstrated that HPV-attributable oropharyngeal cancer has now surpassed cervical cancer as the most prevalent form of HPV-related cancer in the United States. Approval in the head and neck cancer setting was the result of decades of investigation pursued by Merck Research Laboratories.

We also received FDA approval for RECARBRIO for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia caused by susceptible organisms. As COVID-19 hospitalizations increase, the risk of secondary bacterial pneumonia becomes more profound. RECARBRIO provides an important new antibiotic that would be especially helpful in treating infections due to *Pseudomonas* species.

Beyond these regulatory approvals, we continue to support -- to submit important new files. For example, during the second quarter, we filed the results of the VICTORIA study, conducted in partnership with Bayer, which demonstrated that vericiguat, our novel orally administered soluble guanylate cyclase activator, reduced the risk of cardiovascular death and heart failure hospitalization when added to standard therapy in patients with symptomatic chronic heart failure following a worsening event. These data were previously presented at the American College of Cardiology meetings in the spring, and the FDA has granted priority review to this application, reflecting the significant unmet need for new therapies in the heart failure population.

In the oncology area, we also submitted for review our data from the KEYNOTE-355 and KEYNOTE-522 studies, which document the activity of KEYTRUDA in triple-negative breast cancer, either as second-line treatment in combination with chemotherapy, that in KEYNOTE-355; or as an adjunct to surgery in the neoadjuvant setting in combination with chemotherapy, followed by monotherapy KEYTRUDA in the adjuvant setting, that is the KEYNOTE-522 study. We announced yesterday the acceptance of both files for review by the FDA. And here as well, the KEYNOTE-355 filing was granted priority review. This week, we also announced that the FDA had granted breakthrough designation to MK-6482, our novel HIF-2 alpha inhibitor, for the treatment of certain patients with von Hippel-Lindau disease-associated renal cell carcinoma based on data that we presented at the American Society for Clinical Oncology meetings in June.

Finally, our broad portfolio of activities in cardiovascular medicine, oncology and in infectious diseases now includes 3 new programs directed at interdicting the COVID-19 pandemic. As you are aware, during the second quarter, we forged a partnership with Ridgeback Biotherapeutics to develop MK-4482, a nucleoside analog that disrupts the faithful replication of the SARS-CoV-2 viral genome. MK-4482 has now been studied at ascending dose protocols and has been shown to be well tolerated during 5-day oral administration, achieving drug levels that we would expect would be more than sufficient to block viral replication. The compound is currently under study in 3 different Phase II programs in outpatients as well as in inpatients here in the United States and in the United Kingdom.

Based partially on the results of these studies, we expect to initiate 2 large pivotal trials, one in outpatients and the second in hospitalized COVID-19 patients beginning in September. We are also in discussions with the ACTIV consortium to begin a large Phase II outpatient study conducted under the supervision of the National Institute of Allergy and Infectious Diseases.

MK-4482 has demonstrated a strong barrier to resistance when studied in vitro, which was to be expected based on its mechanism of action. It is, for example, active against viruses that have acquired mutations, rendering them resistant to remdesivir. In light of the profound medical need for an orally active treatment to reduce the impact of COVID-19, we have mounted a very aggressive clinical program as I described. And we have secured manufacturing capability to produce many millions of doses of the drug before the end of this year.

At the same time, we are advancing 2 important new vaccines directed against SARS-CoV-2. These vaccine approaches were selected for 3 reasons, as Ken mentioned. First, they make use of proven vaccine platforms that have been used in human studies, demonstrating both efficacy and safety. Second, they are replicating viral vaccines, which means that they provide a very potent immune stimulus that could offer the promise of single-dose administration. In dealing with an aggressive, globally dispersed disease like COVID-19, we believe that it is wise to lower the barrier to vaccination as much as possible, for example, by launching a vaccine that is effective with just a single administration.

Third, since we believe that there may well be a need for different vaccines in different populations, we chose 2 well-characterized vaccine platforms that have quite different properties: a measles virus recombinant that was invented by Institut Pasteur in Paris and which we acquired through the purchase of Themis Bioscience; and a vesicular stomatitis virus recombinant first developed by Health Canada, which we're advancing in partnership with the International AIDS Vaccine Initiative, IAVI, as this construct utilizes the same virus platform that we employed to develop our successful Ebola virus vaccine, which was registered in the United States earlier this year. In preclinical studies, both of these COVID-19 vaccine constructs have now been shown to stimulate neutralizing antibody production following a single intramuscular administration.

Our program using the measles virus vaccine platform, which we call V591, has now completed clinical manufacturing, and we plan to begin clinical studies performed in collaboration with the Institut Pasteur later this quarter. Meanwhile, we've been manufacturing clinical doses of the VSV-based COVID-19 vaccine, which we call V590 in our facilities in Pennsylvania. We also expect to begin clinical studies with V590 in the next few months.

Planning for large global clinical trials involving both V590 and V591 is now nearly complete. These trials will initiate as soon as we have supportive data regarding immunogenicity. Finally, I note that one additional advantage of V590 is that it may be active when administered orally via a swish-and-swallow protocol. And again, this will help lower the barrier to vaccination, should it be effective.

It should be plain that Merck Research Laboratories continues to advance development of new drugs and vaccines across many fronts. In this context, I wish specifically to commend the dedication of more than 10,000 MRL employees around the globe whose supererogatory efforts have again brought us hope that the world can gain greater freedom from grievous illness. Reviewing the progress that we have made in developing MK-4482 and both of our COVID-19 vaccines, I am optimistic that we will be able to reduce the impact of this devastating pandemic.

And now I'll turn the call back to Peter.

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

Lara, if you could put the Q&A order in place, please. (Operator Instructions)

We have a lot of questioners in the queue, and we are prepared to extend a bit past 9 to try to get to as many as we can. A couple of our speakers today are remote, so I'll do the best I can to quarterback those questions when they come in. Lara?

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## QUESTIONS AND ANSWERS

### Operator

Let me go ahead and begin with your first question for today, which is going to be coming from Mr. Andrew Baum of Citi.

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**Andrew Simon Baum** - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

Two questions. First one, we can see from your clinical trials that there is significant cohort expansion going on in some of your programs, (inaudible) one that's been spoken about, but also (inaudible) and there's a number of others, which suggests that you're seeing signs of promising activity. Can you give us some sense, just because the market is so very focused on the importance of KEYTRUDA, when you may be in a position to share some of that emerging Phase II data, maybe extending to cardiology as well? That would be the first question, timing of sharing. And I'm not expecting you to give me which conference and when, but as much as you can.

And then second, given the perceived competitor drug to KEYTRUDA, particularly in non-small cell, you have an ongoing trial with LYNPARZA in the maintenance setting. So perhaps, Roger, you could talk to your optimism in that because you're obviously (inaudible) that in other indications, in platinum-sensitive disease? And particularly whether you could address -- do you think you need to select for patients who have [virulent loss] of HR genes or whether you think there's concomitant use together with (inaudible), which are platinum-sensitive insufficient? So those are the 2 questions.

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

Roger, I think those are both for you. If you could take both of them.

**Roger M. Perlmutter** - Merck Research Laboratories - President

Yes. Andrew, thank you for the questions. I think that in some sense, the questions are related, if I caught them correctly. And I apologize for the fact that I'm remote, and so the connection is perhaps not as clear as I would like it to be.

But with respect to the expansion of clinical trials for a whole variety of new agents, we're seeing some interesting activity. Some of these data we'll, we hope, be able to present at the European Society for Medical Oncology meetings, which are coming up in September. And we'll have additional opportunities, we hope, through towards the end of the year to talk about these data. And these data go precisely to the issue that you raised with non-small cell lung cancer.

Now first, I should mention that, as you know, we have an extremely strong data set in non-small cell lung cancer. KEYTRUDA is very active in that setting and active in combination with chemotherapy as we've shown. And that remains a hugely important intervention, the dominant intervention in the treatment of non-small cell lung cancer, either as monotherapy in the PD-L1-high population or in combination therapy.

That said, you're also looking at activity of these new agents directed at a whole variety of different checkpoints in multiple cellular compartment as well as looking at the issue of mismatch repair deficiency in combination with KEYTRUDA. We're optimistic that we will begin to segregate non-small cell lung cancer patients still further on the basis of the fundamental properties of the tumors, and this goes precisely to our efforts in both MSI-high and tumor mutational burden in order to achieve still better results in the non-small cell lung cancer setting. So suffice it to say, we're extremely active in this area and generating a lot of very interesting data and hope to have a chance to present it to you very soon.

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**Operator**

Your next question will come from the line of Umer Raffat from Evercore ISI.

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

My question is on COVID with 2 parts, if I may. Roger, you've probably been seeing a lot of the first round of COVID vaccine data so far. And without really commenting on any single company, I'm curious how you view the data in totality to date of all the clinical data on COVID vaccines, perhaps specifically on whether you think the neutralizing titers that various players have shown are good enough. Or do you see a lot of room for improvement and your take on the T cell data?

And also on your small molecule for COVID, do you think you can show an antiviral benefit? Because that's something remdesivir was never able to achieve. But then there's also this school of thought that there's no large viremia in COVID so you may not be able to show that in the first place. So I'd really appreciate your thoughts there.

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

Roger?

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Yes. Thank you, Umer. The -- so first of all, with respect to the COVID vaccine data, we have to say that from our starting position, knowing very little about SARS-CoV-2 at the beginning, the results that we've seen thus far from a variety of early studies, Phase I studies are as good as one could hope for really. There was no guarantee that the spike protein of SARS-CoV-2 would prove to be as immunogenic as it is, so immune response, broadly speaking, across the population of vaccinees are quite good.

The question you asked is, is there enough neutralizing antibody and how well would that perform clinically. And unfortunately, we can't really know that until we've looked at Phase III studies. But I guess I would say first that, as has been discussed by others, most of the vaccines look as if



they are going to be -- require a boost in order to produce high-titer neutralizing activity against the spike protein. That seems clear. We don't know for sure, and maybe things will go better, which we can all hope for. With time, we'll see more of that.

The second question, of course, is, is the production of immune response against the spike protein sufficient by itself or is it necessary to generate responses against other components of the virus, particularly the nuclear protein. And then, of course, there is the question of what contribution is made by T cell immunity. And a little bit, that goes to the question of what we're actually trying to achieve. Finally, in the background is the question of whether the immune stimulation that we are producing could, in fact, contribute to adverse effects since it is widely believed that the severe pulmonary complications of SARS-CoV-2 infection include an overexuberant immune response that results in tissue destruction.

So those are all open questions that can only be answered by large Phase III studies that extend for a considerable period of time. Those studies at least have begun now in a couple of cases. More will begin soon. And we'll have a chance to see exactly how these vaccines perform. I don't think, at the moment, we can handicap it except to say that it is certainly a favorable finding that the spike protein in its various different forms, typically as a prefusion form or it's hoped it's a prefusion form, seems to be quite immunogenic, and there are reasonable titers of antibodies being produced. So that should give us considerable optimism.

I should also say, I -- we -- the broader industry is collaborating and thinking about these problems and how to make sufficient doses available. And I think the community at large should be very encouraged by the enormous numbers of vaccine doses that are being planned for manufacturing, particularly as we get into 2021 and beyond. If these vaccines are effective, I think the industry is going to be able to produce enough material, ultimately, to provide vaccination for a substantial fraction of the world's population.

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

Roger, I think there's a second question on 4482.

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Right. So the second question is would we see an antiviral benefit with MK-4482. It's important to note here that MK-4482 differs in mechanism quite a lot from remdesivir. Remdesivir, of course, is an RNA -- dependent RNA polymerase inhibitor. It causes termination. Whereas, MK-4482 is a cytosine analog that is incorporated and as a result, causes misincorporation of bases into the nascent RNA. Those RNAs are produced, but they contain many, many errors, and the result is something called error catastrophe, which is a very powerful means of preventing production of functional virus.

So those are 2 quite different mechanisms. The expectation is that there would be production of virus at least for a period of time, but that virus would not be able to replicate. I think from a variety of in-vitro studies, it is possible to measure a dramatic reduction in virus production. And we may see the same thing in our clinical studies.

We are, of course, looking for it. The Phase II studies are underway. So it won't take too long until we have a chance to see that. We are, of course, as well measuring clinical outcomes.

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**Operator**

Your next question will come from the line of Terence Flynn from Goldman Sachs.

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**Terence C. Flynn** - Goldman Sachs Group, Inc., Research Division - MD

Maybe 2 for me. Just one follow-up on the oral antiviral for CoV-2. I was just wondering if you can comment on when we might expect to see some of the initial Phase II data and then how you're defining success on that front.



And then the second question I had was for Rob. Just wondering, the outlook for capital allocation for the rest of the year, if the share repo program is still on hold and if that -- as a result, you're intending to be more active on the business development front here over the near term.

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

Roger?

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Right. For MK-4482, I think that we -- I don't really want to dribble out data on this. As we acquire meaningful data from the Phase II program, we'll, of course, let you know. But I should point out that we will be embarking probably in September on very large pivotal studies, and so those are going to be the important ones. And here, the goal has to be that with this orally active drug, that we can both reduce the duration of symptoms, but more importantly, keep people who are symptomatic from becoming sick enough that they require hospitalization or if hospitalized, that they require intensive care unit hospitalization.

The good news about MK-4482 is that it -- because it is an oral drug given in capsules, it can be easily administered from the time that people have symptoms. And so that, I think, could mean that we could have a meaningful effect on the clinical outcomes. And that, of course, has to be the goal of therapy.

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

And Rob, on capital allocation.

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**Robert M. Davis** - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes. So as you pointed out, we did stop the share repurchase after the first quarter, and you'll recall we did that really out of an abundance of caution because we weren't sure how the year would progress. I'm happy to report, and as I mentioned in the prepared comments, our cash flow actually remains very strong, and our access to capital is also very strong. And I think we demonstrated that in the recent debt offering at record low rates. So from that position, we're in a good position.

As we think about share repurchase for the remainder of the year, we continue to evaluate it. Business development is very important to us. So I obviously put a priority on making sure we have the capital necessary for business development to fund the business itself and the meaningful capital expansion underway as well as all of the important programs that we've talked about. So we're looking at all of that and continuing to evaluate whether or not we will restart in the remainder of the year.

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**Operator**

Your next question comes from the line of Louise Chen from Cantor.

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**Louise Alesandra Chen** - Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD

So first question I had here is, in light of the pandemic and ahead of the 2020 presidential election, how did the environment for M&A look? How are valuations? And what is the willingness of sellers?

And the second question I had for you is, assuming you get approval of V114 and the rest of your PCV portfolio, how do you see Merck fitting into the treatment paradigm for PCV? Is this a winner-take-all market? And will things change if these PCV 24s actually make it to market?

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, President & CEO

So I'll start off with the business development question, Louise. Thanks for the question. As Rob said, business development remains a really important priority for us now and going forward. Right now, I think the environment which we are in is still a tough one in the sense that as you look at the first half of the year, the biotech IPO market has outpaced last year, despite all the challenges associated with COVID, despite all the concerns that might happen with respect to the election. And of course, established biotech has also performed very well this year.

So I think the challenge for us is to find the best scientific capability in a way that's value-creating for our shareholders. And right now, I think seller expectations are very high, notwithstanding the issues around the political landscape, the executive orders and everything else. So I think at the end of the day, we still have to continue to search for the best science commensurate with the need to create value for our shareholders. And I don't think the election is a critical factor here.

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

Great. And Mike Nally on V114?

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

Louise, on V114, I think what's really important here is for any future PCV vaccine, the first and foremost, continue to suppress -- or continue to generate an immune response across all the 13 shared serotypes with the current PCV13 vaccine and then add on additional serotypes. What we've seen with V114 is we've been very successful in doing so in both the adult and pediatric segment.

As we look forward, we think there's room for multiple options within the PCV market. I think you can look at -- a market like rotavirus is a good analog, where despite having different profiles and different coverage profiles, we have basically a shared market with both Rotarix and with RotaTeq. And so as we look forward, we think there's a big unmet need still in this market. We think V114 will play a major role in that, and we continue to look at alternate options in the future with both V116 as well as V117.

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**Operator**

Your next question will come from the line of David Risinger from Morgan Stanley.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

I have 2 questions for Roger, please. First, regarding the Ridgeback Bio oral antiviral, what is your view on the risk of immunogenicity? And how do you plan to demonstrate to FDA that it has acceptable safety with respect to the action of the drug?

And second, Merck has very sophisticated understanding of mRNA vaccines. Could you please discuss why Merck chose not to pursue mRNA vaccine development for COVID? And I know you touched on that a little bit, but just a little more color on that would be helpful. And between the 2 Merck candidates, maybe you could just highlight for us which one we should be more focused on.

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

Roger?

**Roger M. Perlmutter** - Merck Research Laboratories - President

Well, thank you, David. First of all, for the MK-4482, as you know, the compound is Ames positive. That's, in a way, not unexpected given its mechanism of action. It is a cytosine analog so that -- one could expect to see those kinds of things. The question is, does the compound have mutagenic activity that's meaningful in mammalian cells and what do we want to do about this. Ordinarily, of course, we don't want to take mutagens forward into clinical practice, although it has been done where the benefit/risk profile makes sense.

With respect to this compound, we should note that in other tests, for example, the in vitro and in vivo micronucleus test, the compound is negative. We're doing other in-vivo tests for immunogenesis in mammalian systems. And we'll do the usual kinds of preclinical evaluations that are conducted in such settings, which includes developmental and reproductive toxicology studies and, of course, accelerated carcinogenicity studies in rodents.

Those are the things that one customarily does. And my expectation is that when you look at the totality of data, the benefit/risk profile for a short-term course in treating an acute pulmonary infection will be favorable. And of course, that has been seen before. So it is something that we pay a lot of attention to. But on the other hand, I think it's something that we can overcome.

With respect to mRNA vaccines, you're right, we have quite a bit of experience, which we've gained from working with colleagues at Moderna, in looking at mRNA vaccination. And I think there are some great strengths to mRNA vaccination. In particular, it's quite fast. As both Moderna and BioNTech now working with Pfizer have demonstrated, one can move very quickly from knowing the sequence -- the genetic sequence of a potential target to developing an immunogen.

On the other hand, our concern from the beginning was that this was going to be a pandemic. We felt that way long before WHO declared it a pandemic. We had no idea it would be as severe and as widely dispersed as it has proved to be and is a threat to the entire world. And we -- none of us are safe until we're all safe as everyone says. And with that in mind, the need will be to mount effective vaccination for a large fraction of the human population.

There are several aspects of that, that are important to emphasize. The first, of course, as I've said, is it is nice to have a single-dose vaccine. It would also be nice to have a vaccine that could be administered orally in the way that, for example, not that this is directly relevant, the Sabin oral vaccine came to replace the original polio vaccine.

And in addition, we should recognize that there are many different populations who are infected. Of course, everyone is ultimately infected. But we have an elderly population at extremely high risk, particularly those who have underlying cardiovascular disease. And those individuals, the elderly population, tend not to respond as well. So under those circumstances, one wants an especially potent immunogen, and that was a reason for wanting to choose a replicating viral platform in addition to our desire to have a single dose.

We also have children and adolescents and those in their decade of life who are currently being infected in very high numbers. And we have a lot of people in a robust early adulthood who are ending up in the intensive care unit. Those people have extremely potent immune responses, but it's important to get neutralization mounted quite early, I believe, in that population. So that could be a different kind of virus, maybe not the same one you would use in the adult population as a vaccine, a different kind of viral vaccine.

And the answer to the question of which one of these should we pay attention to, I think I'm paying attention to both. We will get information from the measles platform earlier. And of course, the measles platform -- the measles vaccine has been used successfully in billions of people. So we have a lot of confidence in the way that will behave. We just need to see immunogenicity data. And I would say, preclinically, it looks terrific.

And then, of course, we have a lot of confidence in the VSV platform, which we've investigated extensively through the course of our registration program for a Ebola virus vaccine. So I watch them both, and I think that they're potentially quite important.

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**Operator**

Your next question will come from the line of Seamus Fernandez from Guggenheim.



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**Seamus Christopher Fernandez** - *Guggenheim Securities, LLC, Research Division - Senior Analyst of Global Pharmaceuticals*

So Roger, I did want to just follow up on EIDD2801 or the Merck new number, 4482 but more so as a potential treatment for other respiratory retroviruses. Can you just maybe help us understand if you believe that this is a potential treatment in those settings and if there's broader potential for this particular mechanism?

And then second, I did want to ask actually about your HIV program, 8591. I believe Merck was hoping to have another agent to marry the 8591 to optimize the treatment opportunity. Would you mind just maybe updating us on that in the context of identifying a longer-acting treatment regimen? And then separately, just on the robustness of the data for some other agents in the PrEP regimen. Maybe you could just update us on your thoughts around 8591 as a potential best-in-class treatment choice for PrEP.

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

Thank you, Seamus. Roger?

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**Roger M. Perlmutter** - *Merck Research Laboratories - President*

Yes. Seamus, thanks for the questions. For 4482, you're right -- you're completely right. Because of its mechanism of action, that is that it resembles a nucleoside base, in fact, just a derivatized version of a cytosine, it can be incorporated into any nascent RNA strand that is made by an appropriate virus. It's just a function of how well the viral polymerase is willing to accept a modified base. And just as one expects, a virus is built for speed. Typically, viruses, there aren't -- polymerases for RNA viruses are more accommodating of different structures than our mammalian DNA-dependent RNA polymerases involved in making messenger RNA, for example. And so it has good selectivity and good properties in that regard and should work very well for a whole variety of RNA viruses. In vitro, it does exactly that.

So a whole set of RNA viruses could potentially be treated, including, broadly speaking, coronavirus that we haven't yet made the acquaintance of, and we don't really want to make the acquaintance of these. But our expectation is that this is not our last pandemic and probably not the last pandemic caused by coronavirus. So 4482 has broad activity and is potentially useful in a variety of different settings. Let's first see how it does with respect to SARS-CoV-2.

Regarding islatravir, we have -- of course, we remain enormously enthusiastic about islatravir. Phase III studies are ongoing for the first set of combinations for islatravir for treatment of HIV-infected individuals. And we've also, as you say, been looking for compounds to partner with islatravir, and we have such compounds. One of them moving forward right now is 8507. And we also have a group of others. So we believe that we're in a good place with respect to those, but we're moving forward in a variety of different directions.

And then with respect to pre-exposure prophylaxis, yes, the long durability of islatravir as a potential for a once-monthly oral, in particular, which could be used anywhere in the world, I think is extremely attractive. But beyond that, as we've shown, islatravir can be formulated in implantable form, which is a polymer that is positioned underneath the skin and can be active for potentially a year.

And that provides just about as close -- it's a perfect chemoprophylaxis as one can get. It's nearly vaccine-like. So we're pursuing that as well, and we're optimistic about the ability of islatravir to make a big change in terms of the prevalence of HIV-mediated disease and the incidence of HIV infection.

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**Operator**

Your next question will come from the line of Daina Graybosch from SVB Leerink.

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**Daina Michelle Graybosch** - *SVB Leerink LLC, Research Division - MD & Senior Research Analyst*

Two for me. I wonder why you're so confident in both your COVID vaccine candidates that they could be a single dose, when, let's say, the chimp adenoviral vector, which I think we also thought to be a single dose, looks much better with 2 doses in the early clinical data?

And a second question, a bit following up on one from earlier, is are you looking to choose between the 2 vaccine programs after you get clinical data? Or do you expect to bring both of them all the way through to registration, maybe finding different places for them in the market?

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

Roger?

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**Roger M. Perlmutter** - *Merck Research Laboratories - President*

Yes. Thanks for those questions. So we have a lot of confidence in the single-dose activity of both vaccines because these are replicating vaccines so they replicate in you. They're very potent immunogens. And they have single-dose activity -- single-administration activity in other settings.

So of course, with V590, that's the vesicular stomatitis virus vaccine, that has been demonstrated for Ebola virus disease very effectively. A single dose provides, in the field, in the setting of civil strife of a large magnitude, a greater than 97.5% efficacy in a single dose. Now I can't tell you that that's exactly how it will behave when we put a different gene, in this case, SARS-CoV-2 spike protein-encoding nucleic acids into the construct.

But the interesting thing about the VSV platform is that this is actually a vaccine in which the spike protein becomes part of the vaccine. The replication of the virus is completely dependent upon the spike protein. It becomes the envelope protein of the vaccine, which is different from simply expressing the protein wherever one expresses it. So that has big effects. And preclinically, the magnitude of the response following single administration is very impressive. Similarly, the measles platform has been shown in a variety of different settings, most recently with respect to the Chikungunya administration, to be a very potent immunogen. So we have a lot of confidence in that.

And with respect to why 2, as I've said, there's reason to believe that multiple different vaccines will be required in order to manage this extraordinary global pandemic, in particular when one thinks about the heterogeneity of the population that we want to vaccinate, those with extremely robust immune responses, for example, teenagers or those in their 20s; those in the elderly population, the greatest risk but who have poor immune responses, just to give a couple of examples. There is also reason in terms of just the ability to deliver the vaccine to different parts of the globe and to administer it successfully as part of a huge global vaccination program. So our intention at the moment is not to choose but to instead examine the special properties of each of these very good platforms and then to see which one needs to be taken forward first and in which population and which perhaps second, although both could be advanced simultaneously.

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

Thank you, Daina. We're going to take one more question, and apologies to those of you that we didn't get to today.

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**Operator**

Your next question will come from the line of Chris Schott from JPMorgan.

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**Christopher Thomas Schott** - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Just a couple of ones here. First, on KEYTRUDA, are you seeing fairly normalized new patient starts in major markets at this point? Or is there still some disruptions there? And maybe as part of that answer, can you just give us a quick update in terms of where kind of market share and penetration stands in front-line lung?

And then my second question was on the vaccine business and wellness visits. Are we also kind of at normalized levels as we move through July at this point? And are you anticipating any catch-up as we go later in the year for some of the missed vaccinations from 2Q?

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

Frank?

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

Yes. Chris, for KEYTRUDA, we are very encouraged, especially over the last month. We are seeing new patient starts get back to where they were almost pre COVID. If you look at what happened in the quarter, Chris, April and May, new patient starts were down somewhere in the range of about 5% to 10% depending on the cancer type, but that has improved. And we're seeing that pretty much around the world, where oncologists are now figuring out ways to be able to get patients into their practices.

That's going to vary by geographies. There will be some up and downs around that. But all in all, oncology has been very resilient. And probably most importantly, what we're encouraged about is the continued strong momentum not only in non-small cell lung cancer. We still are seeing in the U.S., Chris, about 80% of the eligible patients receiving KEYTRUDA. But we're also very excited about all the other indications that Roger mentioned, and we're seeing really good growth in head and neck, bladder, adjuvant melanoma and some of the other newer indications. So all in all, we feel very confident in KEYTRUDA not only in the near term but as we've continued to state, long term.

With regards to vaccines, you heard from Rob's comments upfront that April and May, wellness visits were down very significantly, in particular in the U.S. market, approximately 70% in the month of April. They started to improve as you got to June. And we really saw some encouraging pickup with wellness visits for our pediatric portfolio and for the pediatric patient population.

Adolescents are lagging a little bit behind, which is why we mentioned we're keeping an eye on GARDASIL. But we are seeing encouraging signs there with wellness visits picking up as well, which gives us the confidence not only near term for GARDASIL, but as we mentioned, the strong demand that we continue to believe will come through for GARDASIL not only in the U.S. but clearly outside the U.S., in markets such as China. So very confident in that outlook as well, Chris.

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

Great. Thank you, Chris. I'll turn it to Ken for concluding comments.

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**Kenneth C. Frazier** - *Merck & Co., Inc. - Chairman, President & CEO*

Thanks, Peter. As you've heard today, we remain confident in our strategy, our execution and our prospects for strong, long-term growth. We remain committed also to bringing Merck's mission to life by advocating for innovative approaches and partnerships that will be essential to bring an end to this pandemic while also investing behind our promising pipeline. I want to thank you all for joining us today, and 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.

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