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Energy & Commerce Committee, Oversight & Investigations Subcommittee
"Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"
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Chairwoman DeGette, Ranking Member Guthrie, and other members of the Committee, thank you for holding this important discussion and for the opportunity to appear today. The SARS-CoV-2 pandemic has already had an unprecedented impact on humanity, both in terms of lives lost and broader societal impact. While we continue to confront these unprecedented challenges, we are also seeing momentum that is a testament to scientific innovation and the men and women behind the initiatives to develop the effective vaccines and therapies that will be required to ultimately end the pandemic. The speed of these efforts has truly been astounding, as is the level of cooperation across the industry.

Merck is a premier biopharmaceutical company that leverages cutting-edge science to address important unmet medical needs. As such, we are contributing our experience and expertise to help solve the SARS-CoV-2 pandemic in the same way we have responded to past health emergencies like widespread measles outbreaks, the HIV pandemic, and the African Ebola virus outbreaks – and with speed made possible by sustained scientific progress in research and development and investments made at risk.

Experts have predicted for years that a pandemic of this magnitude would occur, and significant progress has been made over the last two decades in increasing our preparedness. Now that we are in the midst of responding to the current crisis, we can clearly see the vulnerabilities in our system that remain. Even as we work to manage the current pandemic, we must strengthen our ability to preempt, detect, contain, and mitigate the broad spectrum of future threats we may face. One of the most important pillars of our preparedness is the development of countermeasures – medicines and vaccines that target these threats. To assure ongoing research and development of these products, we must sustain a robust market for innovation and encourage collaboration, partnership, and strategic investments across the public-private continuum. At Merck, with our track record of innovative antivirals, antibiotics, and vaccines, both in human and animal health, we hope to be able to contribute to that readiness.

As one of the very few companies that have continued to invest in both vaccines and infectious disease medicines, at Merck we know we have a special responsibility to apply our experience and expertise to help advance both vaccine and antiviral therapies as part of our overall SARS-CoV-2 pandemic response. Since the earliest days of the pandemic, we have been contributing to the scientific underpinnings of therapeutic and vaccine approaches, working to understand the nature of the new virus and formulate the best approaches. One initial step we took was to establish a significant research collaboration with the Institute for Systems Biology to probe the basic biology of this virus and how it interacts with the immune system, to help formulate our approaches. Progress is accelerating through these and many other efforts, but there is still much to learn about this virus and how it can cause such a broad range of health effects.

Our long history of developing vital medicines and vaccines has shown us that durable scientific solutions take time, expertise, and experience to discover and deliver to the people and communities who so desperately need them. Our initial focus is on vaccine platforms that have proven track records and where Merck can apply its special capabilities and experience in development, formulation, and manufacturing. If approaches developed by others ultimately are proven superior to those being pursued by Merck, we will work to support those efforts for the benefit of global health during the pandemic.

None of us can do this alone. Merck has been leveraging existing partnerships and building new ones within industry and across sectors toward a common goal: ending this pandemic. Today, we are advancing three programs – two vaccines and one antiviral medicine – with a strong sense of urgency and the necessary investment of effort and resources. The vaccine candidate we are developing with the International AIDS and Vaccine Initiative (IAVI) uses a recombinant vesicular stomatitis virus platform, which is the same approach that was used for our Ebola virus vaccine (ERBEVO). Our vaccine candidate that came through our acquisition of Themis is based on a measles virus platform, the same measles virus that has been used in billions of people. The antiviral we are developing with Ridgeback is orally available – which has obvious potential benefits in terms of ease of administration.

We believe the approaches we have selected are among the most promising, and we intend to pursue a rigorous assessment of their safety and efficacy prior to being administered to a broad population. Speed is important, but we will not compromise scientific efficacy, quality, and above all, safety, despite the sense of urgency we all feel.

Once a vaccine is developed and approved for use, it will need to be produced at a scale never seen before. Under normal circumstances, manufacturing and distributing a vaccine is exceedingly complex, requiring hundreds of steps and thousands of complex tests, all validated to ensure that every single vial has the identical high quality and safety. When we think about what will be needed to address this pandemic, we are talking about orders of magnitude beyond what we as an industry are currently doing.

In order to meet this need, we must all appreciate that the biopharmaceutical collaborators are working at risk. In other words, we are making considerable investments in key elements such as manufacturing capacity before we typically would, before we know whether we even have a successful product – in many cases building a manufacturing facility before we have fully developed the process at a smaller scale. As a result, we must think carefully about how these decisions will impact other development programs and allocation of investments, including considering the inevitable opportunity costs.

This unprecedented experience really underscores the need for ingenuity, partnership, and advanced planning as we consider our manufacturing plans. It's also important that we consider the impact that the product profile will have on manufacturing. As discussed above, we are focusing on approaches using proven platforms such as the rVSV and measles platforms, as well as innovations that give us the potential for a single dose vaccine. A single-dose vaccine allows you to vaccinate twice as many people with the same number of doses – an important consideration given the scale that will be necessary to address the global pandemic.

We all hope the first approved vaccine will be transformational in terms of changing the way we fight this disease. However, it may not be the best or final approved vaccine. Novel vaccines will have different characteristics and may vary in the degree to which they have utility in certain populations and settings. Dosing regimens, storage requirements, and contra-indications are a few of the characteristics that will need to be considered when developing guidelines for use of these vaccines. That's why the work being done under the ACT-Accelerator and by technical advisory groups like the Advisory Committee for Immunization Practices (ACIP) in the United States to develop policies and normative guidance for deployment of SARS-CoV-2 vaccines will be so critical – to ensure that all vaccines doses can be deployed to maximize their public health impact.

Currently, the global vaccine industry is already operating close to full capacity – not only is there not a lot of excess capacity available, but it is not always easily transferable from making one vaccine to another. In order to meet anticipated global demand for SARS-CoV-2 vaccines, the industry will need to approximately double its current manufacturing capacity. At Merck, we are investing billions of dollars in new capacity for our current and pipeline vaccines – and that was before this pandemic. Now we are gearing up for hundreds of millions of doses of our SARS-CoV-2 vaccine candidates. In the short-term, one solution is typically to retrofit existing facilities. In the mid-term, construction of additional capacity for SARS-CoV-2 vaccines is necessary. But there is still a need to ensure long-term capacity for better preparation for future pandemic-response capability.

At the end of the day, whatever vaccines are finally approved will not be helpful unless people can access them – and are willing to do so. Merck has a long track record of making our vaccines and medicines accessible and affordable globally, and we will do that for any eventual SARS-CoV-2 vaccines and medicines as well. Our goal is to ensure that we can make these vaccines available to whomever needs them and to prioritize groups based on risk and medical need.

While we are all working tirelessly to bring new vaccines to people who need them, at Merck we are also deeply concerned that routine pediatric, adolescent, and adult immunization rates have fallen all over the world as patients are visiting their doctors' offices and other health care settings less. It's important that as we work to solve the SARS-CoV-2 pandemic we do not allow other diseases for which we do have vaccines to gain ground and overwhelm the already stressed health care system. We must do everything we can to ensure ongoing access to vaccines across the life-course, especially in hard to reach and traditionally underserved communities.

We urge strengthening of the systems that support routine immunization systems and preparing now to adapt them to mobilize for mass vaccination programs once pandemic vaccines are available. We need to apply the same ingenuity to creating innovative access and delivery mechanisms that we are applying to the development of vaccines. This includes strengthening mechanisms for global cooperation, designing innovative local vaccination campaigns, and identifying creative solutions to facilitate convenient access at the local level.

We also need to start now to build trust in the new vaccines and address escalating levels of misinformation related to the pandemic. We are dismayed by the ongoing dissemination of information that is inaccurate and/or misguided. We have also seen the erosion of trust in governments and the health care workers who will be conducting vaccination programs. Ultimately this misinformation threatens a dangerous reduction in people choosing to receive vaccines, which could extend the duration of this global threat. We are already seeing the result of this here in the U.S. A recent AP-NORC poll reported that 20% of Americans would refuse a SARS-CoV-2 vaccine and 31% were unsure whether they would choose to be vaccinated.[1] That more than half of Americans may not accept a vaccine is a troubling indicator of the impact of this misinformation campaign.

Partnerships have already been critical in establishing the current programs and even greater collaboration will be needed to ensure that vaccines and therapeutics are produced and deployed at scale. We believe a range of medicines and vaccines will be needed to end the pandemic, and we will continue to pursue the science along multiple pathways in collaboration with public and private partners. Merck stands ready to assist governments, organizations, and companies as we work together to solve this public health crisis.

[1] AP-NORC, Expectations for a COVID-19 Vaccine, accessible at https://apnorc.org/projects/expectations-for-a-covid-19-vaccine/.