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Chairwoman DeGette, Ranking Member Guthrie and Members of the Subcommittee, thank you for the opportunity to discuss Johnson & Johnson's efforts to research, develop, produce, and distribute a vaccine that will provide and make available safe, durable, and protective immunity against SARS-CoV-2, the virus that causes COVID-19.

I am Dr. Macaya Douoguih, and I am the Head of Clinical Development and Medical Affairs for Vaccines and Prevention for the Janssen Pharmaceutical Companies of Johnson & Johnson. I am speaking to you today from near our research facility, where I oversee clinical development of the company's vaccines portfolio, including the COVID-19 program. I have been engaged in discussions with authorities globally, including several U.S. government agencies, regarding the rigorous development strategy for our COVID-19 vaccine to support emergency use and licensure. The physicians in my organization lead the effort to develop the clinical studies and oversee their implementation.

Johnson & Johnson is the world's largest and most broadly based healthcare company, and we are committed to using our full breadth and depth to improve health outcomes around the world. Throughout our more than 130-year history, our company has supported local and global communities during times of crisis, from hurricane response efforts to our recent efforts to combat Ebola. Consistent with the Johnson & Johnson Credo, crafted by Robert Wood Johnson nearly 80 years ago as a mission statement that guides the company's decision making, the needs of patients come first. Therefore, we have a responsibility to invest in solutions for global public health crises.

Since January 2020, Johnson & Johnson has been working directly with governments, health authorities and other partners around the world to help end this fast-moving COVID-19 pandemic. I would like to outline our efforts to develop a vaccine and our public commitment to provide more than one billion doses of our vaccine at a not-for-profit price for emergency pandemic use. I will highlight the progress and the partnerships, both public and private, we continue to secure to deliver on these commitments.

Developing a Johnson & Johnson Vaccine

Working closely with health authorities, Johnson & Johnson is pursuing an accelerated approach that allows us to progress our program significantly faster than normal development timelines, which typically takes between five and seven years. There are several ways we are accelerating the development of our vaccine candidate given the ongoing health emergency, including conducting Phase 1 and Phase 2 clinical trials simultaneously, and beginning large scale manufacturing to support pivotal efficacy clinical trials and potential wider-scale distribution if authorized by health authorities.

In order to develop and supply a safe and effective vaccine, Johnson & Johnson combines deep scientific expertise and know-how with substantial investment in the technology platform, R&D and manufacturing. We also have formed an important partnership to assist in R&D funding with the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services. Under our current contract with BARDA, Johnson & Johnson will receive approximately $500 million for vaccine research and development.

Our agreement with BARDA supports the co-funding of vaccine research and development efforts, including preclinical, clinical development, and the production of clinical trial material.

Early research and manufacturing have progressed at a rapid pace. On March 30, 2020, Johnson & Johnson announced the selection of our SARS-CoV-2 vaccine candidate, Ad26.COV2.S, recombinant, from the constructs our scientists had been working on since January 2020.

We have completed a critical preclinical study of our vaccine candidate in non-human primates, in partnership with Dan Barouch, M.D., Ph.D., Director of the Center for Virology and Vaccine Research at the Beth Israel Deaconess Medical Center at Harvard Medical School and the Ragon Institute, his team and others. We have submitted the results of this study to a peer-reviewed scientific journal and are looking forward to their publication in the near future.

As we continue to move forward at a rapid and responsible pace, I am pleased to share with the Subcommittee that we expect to dose our first participant with Ad26.COV2.S, recombinant, in late July 2020 as we begin our Phase 1/2a "first-in-human" trial. This trial will be conducted in the United States and Belgium, and will involve more than 1,000 healthy adults aged 18 to 55 years, and adults aged 65 years and older. We expect to have preliminary results from this trial in September 2020.

If preliminary results are positive, we then plan to initiate our global Phase 3 randomized, controlled, multi-center trial in September 2020. We will design this study to evaluate the efficacy, safety and durability of protection of our vaccine candidate against COVID-19, the disease caused by SARS-CoV-2. The design of this rigorous, complex trial is ongoing, and we are working with the U.S. Food and Drug Administration (FDA), the National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIAID), BARDA, the U.S. Department of Defense (DoD), the European Medicines Agency and other experts on its design.

As we have seen, it will be a challenge to reliably predict disease incidence rates for the timeframe for which this study is planned. We are using available data sources and, in partnership with the Massachusetts Institute of Technology, have constructed a predictive model to determine where best to set up our trial sites globally so that they are in the areas of highest viral infection when we begin the Phase 3 trials, and to identify whom to enroll in the trials considering occupational, environmental, socioeconomic, and demographic risk factors. We have also incorporated all recommendations from the recent FDA guidance related to the development and licensure of COVID-19 vaccines into our development plan.

The AdVac® Technology Underpinning Our Vaccine

Our AdVac® technology is the foundation of our COVID-19 vaccine candidate. We have employed the same AdVac® technology to develop our Ebola vaccine regimen, which received European Commission authorization for use in adults and children on July 1, 2020, and to construct our vaccine candidates for HIV, respiratory syncytial virus (RSV) and Zika. Clinical experience with our AdVac®-based vaccine and vaccine candidates (with more than 75,000 individuals vaccinated to date, including adults, people over 65 years of age, infants, children, HIV-positive adults, and pregnant women) suggest these could be well-tolerated in studied populations.

To develop our COVID-19 vaccine candidate, we combined DNA that codes for the coronavirus spike protein – the protein that is used by the coronavirus to enter human cells – and our AdVac® technology. The AdVac® technology works by using a non-replicating inactivated

adenovirus, the type of virus that causes respiratory syndromes such as the common cold, as a carrier (also called a vector). This vector cannot cause a cold and the protein it produces cannot cause harm either.

Antigens (or, components of a pathogen, e.g., the spike protein of the coronavirus) are then produced to mimic the pathogen, without causing disease. The resulting combination viral vector-DNA encoding the antigen creates our vaccine candidate, which mimics components of the pathogen to trigger the immune system while not leading to infection. When the body encounters the antigen, the immune system will induce both a humoral and a cellular immune response against the antigen, by producing antibodies and immune cells.

Then, if the body later encounters the actual pathogen that causes COVID-19, the body will be able to respond faster and more effectively, as immune cells and antibodies specific to the pathogen will be rapidly produced in the body to prevent the pathogen from inducing disease.

Safety, Efficacy, and Development

I would like to share with you the steps Johnson & Johnson is taking to generate the necessary safety, immunogenicity, efficacy, and durability data of our vaccine candidate. We believe that we can both accelerate vaccine development and ensure safety. We trust that all those engaged in response to the COVID-19 pandemic are committed to developing solutions as rapidly as possible, and the multiple vaccine technologies being employed allow for varying paces of development at different phases.

At Johnson & Johnson, our fundamental responsibility is to provide patients, consumers and healthcare providers with products that are effective and safe. Guided by Our Credo, we put patient and consumer well-being first and foremost in all of our decision making and actions.

Starting in late July, we will initiate our Phase 1/2a study of Ad26.COV2.S, recombinant, in which the safety of our vaccine will first be assessed in a small cohort (or, sentinel group) of human volunteers. If no safety issues are identified, enrollment will be expanded to larger cohorts to further evaluate safety and immunogenicity of the vaccine. Generation of adequate safety and immunogenicity data on participants in this Phase 1/2a study will support further study of safety and efficacy in a larger population in a Phase 3 trial.

As we progress, we will continue to work with the FDA, NIAID, BARDA, DoD and other global authorities to prepare for our Phase 3 trial. Our goal is to complete the Phase 3 trial and have results in-hand in early 2021. Based upon the safety, efficacy, and immunogenicity data from

this trial and the cumulative data generated from our other trials, we would then enter into discussions with the FDA and other health authorities regarding regulatory authorizations for emergency use and licensure.

Pricing of Johnson & Johnson's COVID-19 Vaccine

Johnson & Johnson is committed to bringing an affordable COVID-19 vaccine to the public on a not-for-profit basis for emergency pandemic use. This is rooted in Our Credo and recognizes our commitment to all our stakeholders. We are committed to one price globally, regardless of country or income tier. The not-for-profit price will be for the emergency pandemic period.

Our not-for-profit framework is consistent with established vaccine costing methodologies. Our price will be determined based on one cost structure, with all appropriate costs included. We are pursuing external validation of our not-for-profit calculation approach and external audit / certification of not-for-profit price.

Ensuring Diversity and Inclusion in Our COVID-19 Clinical Trials

Johnson & Johnson is committed to robust representation of diverse populations in our studies. This is a major initiative within our Janssen Pharmaceutical Companies, and vaccine development is just one of the areas where it is paramount. It's well known that people from different ethnic, age, genders or socio-economic groups can respond differently to vaccines and medications. Understanding these variations is an important part of any clinical development program.

We are still in the process of designing our COVID-19 Phase 3 trials. However, ensuring diversity and inclusion is a key consideration balanced with the need to conduct the trial in areas of highest disease incidence. We face several challenges here, in that pandemic hotspots – and therefore the location of study populations we seek to enroll – change rapidly. As a result, it is difficult today to predict where the rates of viral infection will be later this year. Further, because a number of the companies here today will likely be pursuing Phase 3 trials before or at the same time as Johnson & Johnson, we will plan to enroll the study in different geographic regions, including those outside the United States.

As we seek to enroll our future Phase 3 trials in the United States, we will strive to ensure significant representation of populations have been disproportionately impacted by the pandemic, including Blacks, Hispanic/Latinx and participants over 65 years of age. To achieve recruitment of people from highly affected communities, we plan to implement a focused digital and community outreach plan to provide resources and opportunities to encourage

participation in our clinical trials. We will evaluate ways to reduce operational barriers and participant burden within clinical trial sites, and apply lessons learned from previous efforts with underserved and underrepresented populations.

We recognize the critical need to understand health impacts on diverse populations. Thus, we have created a new partnership with Johns Hopkins Bloomberg School of Public Health to generate deeper, more granular insights to better capture data more effectively and understand how the COVID-19 crisis is affecting different communities in the United States. We also have joined a number of coalition calls directed to congressional leaders for increased and improved COVID-19 demographic collection and dissemination, including funding for the U.S. Centers for Disease Control and Prevention's Surveillance for Emerging Threats to Mothers and Babies program.

On a global scale, our Johnson & Johnson Center for Health Worker Innovation is partnering with national governments and partners – like AMREF (formerly known as the African Medical and Research Foundation, Inc.) and the Aga Khan University in Kenya and Comprehensive Community Based Rehabilitation in Tanzania – to engage community health workers in the prevention, detection, and response efforts and to ensure delivery of primary health services in vulnerable and underserved communities.

Building on our commitment, we would like to take this opportunity to urge further collaboration by government, including bipartisan congressional engagement, industry, academia, and community partners to ensure late-stage clinical trials supporting the development of vaccines and therapeutic biopharmaceuticals include demographically and socio-economically representative participants, specific to the disease areas being studied. These data should be shared appropriately with the scientific and medical community.

Building Global Manufacturing Capacity for the Johnson & Johnson Vaccine Candidate

As a result of our own manufacturing capacity and through new U.S. vaccine manufacturing partnerships, we will have the capability to produce over 1 billion vaccine doses in 2021. At least four hundred million of these doses will be manufactured in the United States. We are in the process of identifying manufacturing capacity for the balance of the promised one billion doses.

We have begun preparations for clinical vaccine production at our campus in Leiden, the Netherlands, to support our Phase 1/2a first-in-human clinical trial. At this same campus, we developed our Ebola vaccine regimen and our HIV, RSV and Zika vaccine candidates.

In order to produce the vaccine necessary for wide-scale distribution, we continue our discussions with the U.S. government and other governments worldwide, other companies, global organizations, and other stakeholders as we establish a supply network able to meet, or exceed, our manufacturing goal. We select manufacturing partners based on critical criteria, including capabilities needed, partner experience, quality and safety, and geographic location. The need to ensure a diverse and resilient supply chain to meet manufacturing needs is always a consideration.

For example, we have established partnerships with Emergent BioSolutions, Inc. and Catalent Biologics. Both Emergent and Catalent will reserve operations capacity to potentially support commercial manufacturing of Ad26.COV2.S, recombinant, leveraging our AdVac® technology, beginning in 2021.

Manufacturing of the active ingredient for our vaccine candidate, otherwise known as drug substance, will be completed at Emergent's Baltimore Bayview facility, one of three Centers for Innovation in Advanced Development and Manufacturing (CIADM) in the United States. These centers have been designated by the U.S. Department of Health and Human Services as being designed for the rapid manufacturing of vaccines and treatments in large quantities during public health emergencies. In addition, Catalent will manufacture drug product and refine that into the final vaccine, including filling and finishing vials for distribution, at its Bloomington, Indiana facility, one of its global manufacturing locations.

We also have entered into an agreement with Vibalogics GmbH and IDT GmbH, a global contract development and manufacturing organization that specializes in the production of virotherapy products, to manufacture additional drug product for Ad26.COV2.S, recombinant.

Availability of Johnson & Johnson's Vaccine Candidate

Johnson & Johnson is committed to providing a safe and effective vaccine to healthcare workers around the world. As we progress with the clinical development of our SARS-CoV-2 vaccine candidate, Ad26.COV2.S, recombinant, we are in active discussions with global partners to support worldwide access.

We will continue to work with local and international health authorities, government organizations, regulators and non-government organizations to help ensure that, if development is successful and products are authorized by health authorities, we will provide broad and timely access to our vaccine.

In Summary

This is a critical moment for society, and we at Johnson & Johnson are devoting our global scale, proven success, experience, energy, and resources to swiftly develop a safe and effective vaccine to prevent COVID-19. We are committed to developing, producing, and making available a vaccine as quickly as possible while staying true to our commitment to safety, efficacy, and scientific integrity.

We are not alone in this effort. Global bodies, national governments, non-governmental organizations, academia and private industry all are devoting unprecedented effort to finding solutions to this pandemic.

At Johnson & Johnson, we believe that industry should engage in a collective effort to save lives. It is our sincere wish that multiple vaccines and treatments are identified and deployed, offering the world's population safety, confidence, efficacy, and security so that COVID-19 suffering and loss are ended and normal life may resume. Johnson & Johnson will continue to advance our vaccine research and development and other COVID-19 efforts rapidly and responsibly, reflecting the values of Our Credo, which places the lives of the patients we serve first.

Thank you for the opportunity to speak with you today and to have this critical and timely dialogue. I look forward to your questions and to providing any additional information you may need.

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