Statement of

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before the

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Chairwoman DeGette, Ranking Member Griffith, and Members of the Subcommittee, thank you for the opportunity to discuss Johnson & Johnson's efforts to develop, produce, and distribute a vaccine to protect against the virus that causes COVID-19. As you know, my colleague Dr. Macaya Douoguih testified before the Subcommittee last year about our research and development efforts for the vaccine. I am pleased to have the opportunity to update you today on the remarkable progress that we have achieved over the past several months, which has allowed us to request emergency use authorization (EUA) from the Food and Drug Administration (FDA) less than three weeks ago. Although we are cautious not to prejudge the outcome of the ongoing FDA review process, we believe that our single-dose COVID-19 vaccine will be a critical tool for fighting this global pandemic.

Johnson & Johnson is the world's largest and most broadly based healthcare company. We are committed to using the full breadth of our expertise and experience to improving health outcomes around the world. A century ago, Johnson & Johnson played a leading role in combatting the 1918 flu pandemic, and our history of confronting global healthcare challenges continues to the present day, including with the European approval of our Ebola vaccine last year.

We brought this same approach to the COVID-19 pandemic when, in January 2020, we launched a major research and development effort for a vaccine. The pace of development over the past year was extraordinary. We conducted an intensive evaluation of vaccine candidates, culminating in the selection of a candidate for a single-dose regimen. We began initial human clinical trials in July, launched our large-scale pivotal clinical trial in September, released topline interim results last month, and sought an EUA on February 4.

Even with this accelerated timeline, Johnson & Johnson adhered to our principles of putting patients first by committing to high-quality Phase 3 studies, taking extra steps for safety oversight, seeking diverse populations for our clinical trials, and performing rigorous scientific examinations of the trial data. As an infectious disease physician, I have decades of experience fighting challenging diseases around the globe. Johnson & Johnson's work to date, along with others in the industry, has been remarkable. I am pleased to provide an update on our efforts.

Trials, Results, and FDA Application

During last summer's hearing before the Subcommittee, Johnson & Johnson was on the cusp of initiating our first trials in humans after observing positive results in non-human primates. In July 2020, we began a Phase 1/2a first-in-human clinical trial in healthy volunteers in the United States and Belgium. We also launched a Phase 1 study in Japan, and a Phase 2a study in the Netherlands, Spain, and Germany. Interim results from the Phase 1/2a trials demonstrated the safety profile and immunogenicity of the vaccine after a single dose.

In September 2020, Johnson & Johnson launched ENSEMBLE, a large-scale, randomized, Phase 3 clinical study. We used sophisticated predictive models to recruit diverse participants, including from sites where new variants of COVID-19 have emerged. Ultimately, the trial included nearly 45,000 participants from eight countries across three continents, including a diverse and broad population in the United States, Central and South America, and South Africa. In January 2021, we announced that our single-dose vaccine met the study's primary and key secondary endpoints.

The study showed that our single-dose vaccine addresses the most important healthcare need in the pandemic: the prevention of COVID-19 related hospitalization and death. Importantly, this result was achieved across emerging variants, including the virulent B.1.351 variant first observed in South Africa, and the P2 variant first observed in Brazil. Specifically, the study showed the following outcomes, twenty-eight days after vaccination:

- The vaccine provided complete protection against COVID-19 related hospitalization and death, as compared to those study participants who received a placebo.

- The vaccine demonstrated 85% effectiveness overall in preventing severe disease, including across countries with newly emerging variants.

- The vaccine demonstrated 72% effectiveness in the United States (and 66% effectiveness overall) at preventing moderate to severe disease.

Based on these clinical trial data, Johnson & Johnson earlier this month submitted an application to the FDA for emergency use authorization for the vaccine. The FDA subsequently announced that the agency's Vaccines and Related Biological Products Advisory Committee will meet to review the vaccine this week, on Friday, February 26. We are working with the FDA to ensure that the agency has the information necessary to reach a decision based on the data relating to the safety, efficacy, and quality of the vaccine.

Production and Distribution

We are working around the clock to develop and broadly scale our manufacturing capabilities to supply the United States, and we are appreciative of the ongoing and extensive collaboration and partnership with the U.S. government. Assuming necessary regulatory approvals relating to our manufacturing processes, our plan is to begin shipping immediately upon emergency use authorization, and deliver enough single-doses by the end of March to enable the vaccination of more than 20 million Americans. We are confident in our plans to

deliver 100 million single-dose vaccines to the United States during the first half of 2021, and we are continuing to partner with the U.S. government to explore all options to accelerate delivery.

We are working with urgency, in collaboration with the government and others, to continue to increase production significantly throughout the year. To that end, we have been working to expand our own manufacturing capacity and to contract with established third-party vaccine manufacturers for additional production. Our current manufacturing plans are designed to meet our objective, which we announced last year, to produce the vaccine at a rate of one billion doses globally by the end of 2021.

Throughout the pandemic, Johnson & Johnson has focused on building a global supply network in parallel with the research and development of our vaccine. We began preparing for clinical vaccine production in our facility in the Netherlands in July 2020. Since then, we have increased manufacturing capacity significantly and continue to activate new manufacturing sites as quickly as possible, subject to approvals by the relevant health authorities. Our goal is to have seven COVID-19 vaccine manufacturing sites active by midyear. We have entered into agreements to expand our manufacturing capability, including by collaborating with established manufacturers in the industry, and we continue to pursue opportunities to expand our manufacturing capabilities with additional production sources.

The production of our vaccine is a highly complex process that requires very particular capabilities and experiences. As a result, there are significant challenges inherent in scaling manufacturing output and accelerating the timeline needed for a COVID-19 vaccine.

Over the past several months, we assessed nearly 100 different potential production sites, and we selected eight sites that were able to support an accelerated timeline. Three sites have produced process performance qualification batches of the vaccine, and we expect additional capacity to become available in the second quarter of 2021.

The production of the vaccine generally consists of two separate processes – the manufacturing of the drug substance and the manufacturing of the drug product. Attached to my testimony is a fact sheet on our vaccine production and distribution process.

The production of the drug substance takes about two months, due to the time necessary to grow the required biological cells and then purify the active vaccine. Our current plans call for the production of drug substance at sites in the United States, Europe, and Asia. The site in the United States is in Maryland. Production will occur both on existing production equipment and on new specialized equipment being activated for our vaccine.

The manufacturing of the drug product takes about five to six weeks to produce, test, and release. The necessary production timeline is also driven by the time required for cellular growth and sterility. Our plan is to manufacture drug product at sites in the United States, Europe, Asia, and Africa. In the United States, the drug product production sites are in Indiana, Michigan, and Pennsylvania. As with the drug substance, the production of the drug product will occur both on existing production equipment and new specialized equipment. Regulatory inspections and approvals for these sites are ongoing.

In the event that the FDA grants our request for an emergency use authorization, we have doses ready to ship immediately upon authorization. In the United States, Johnson & Johnson will distribute our vaccine through an agreement with the U.S. government for the production of 100 million vaccine doses. Pursuant to our agreement with the government, Johnson & Johnson will deliver the vaccine to a distributor that will create a vaccination kit containing our vaccine and the necessary ancillary equipment, such as syringes and personal protective equipment.

In addition to our commitment to provide millions of vaccine doses in the United States, Johnson & Johnson recognizes the global nature of the pandemic and the need for broad access to COVID-19 vaccines. We have therefore pledged to provide vaccine doses to lower income countries beginning this year. We committed to provide vaccine doses to COVAX, the initiative led by the Global Alliance for Vaccines and Immunization, the World Health Organization, and others, to provide equitable access to COVID-19 vaccines.

Importantly, the characteristics of our vaccine permit it to be distributed using the existing cold supply chains that we use to transport other medicines today. We estimate that the vaccine will remain stable for up to two years at -20° Celsius, and at least three months at routine refrigeration temperatures between 2° and 8° Celsius. Because the vaccine is compatible with standard vaccine distribution channels, it does not require new infrastructure for its distribution. We believe our current distribution channels include enough temperature-controlled trucks, containers, and planes to deliver the vaccine as needed. In addition, each vaccine pallet will include tracking technologies that will give us real-time location, temperature, and other information needed to maintain the quality and integrity of the vaccine.

Vaccine Technology

Johnson & Johnson's AdVac technology is the foundation of our COVID-19 vaccine. We have employed the same AdVac technology to develop our Ebola vaccine, which received European Commission approval last year, and to construct our vaccine candidates for HIV, respiratory syncytial virus, and Zika. We have significant clinical experience with vaccines based on the AdVac technology. Vaccines based on this technology have been administered for more than a decade to a wide variety of populations, such as adults, people over age 65, infants, children, and pregnant women.

To develop the COVID-19 vaccine, we combine DNA that codes for the coronavirus spike protein and the AdVac technology that uses a nonreplicating adenovirus as a carrier. The resulting combination mimics components of the COVID-19 pathogen and triggers the immune system while not leading to infection. When the body encounters this antigen, it produces antibodies and T cells. If the body later encounters the actual COVID-19 pathogen, the body will be able to respond faster and more effectively, as immune cells and antibodies specific to the pathogen are produced rapidly in the body to prevent the pathogen from inducing disease.

Vaccine Safety, Transparency, and Diverse Populations

In September 2020, Johnson & Johnson joined with eight other companies working on COVID-19 vaccines to reiterate our commitment to develop and test potential vaccines in accordance with high ethical standards and sound scientific principles regarding the conduct of

clinical trials and the rigor of manufacturing processes. The companies pledged to make the safety and well-being of vaccinated individuals the top priority, as well as to work to ensure a sufficient supply and range of vaccine options, including those suitable for global access. The companies also pledged to submit the vaccines for regulatory approval or emergency use authorization only after demonstrating safety and efficacy through a Phase 3 clinical study consistent with the requirements of expert regulatory authorities.

For Johnson & Johnson's Phase 3 COVID-19 vaccine studies, we established independent expert vaccine Safety Advisory Boards to consult and advise on safety risk management. In addition, independent Data and Safety Monitoring Boards oversee the safety of the entire clinical program. These measures are in addition to our standard oversight of safety during the course of our studies.

Johnson & Johnson is committed to disclosing the trial data on external public registries, such as ClinicalTrials.gov and the EU Clinical Trials Register. We expeditiously seek publication of all results from clinical trials in patients in peer-reviewed medical journals and will do the same for our vaccine trials. To that end, our preclinical studies were published in scientific papers, and our Phase 1/2a study data were published in the New England Journal of Medicine. For our Phase 3 COVID-19 vaccine studies, the Clinical Study Reports and clinical trial participant data will be made available for sharing through the Yale University Open Data Access Project after regulatory approval.

Johnson & Johnson has led efforts to ensure that clinical trials include a wide variety of populations, including historically underrepresented communities. In our COVID-19 vaccine trials, we employed an engagement strategy to reach underserved and underrepresented communities. The ENSEMBLE study of 45,000 participants included diverse and broad populations. Among the participants worldwide, 45% were Hispanic or Latinx, 19% were Black or African American, 9% were Native American, and 3% were Asian. More than one-third of participants were over age 60. For participants in the United States, 15% were Hispanic or Latinx, 13% were Black or African American, 6% were Asian, and 1% were Native American.

Pricing and Government Support

As my colleague indicated last year, Johnson & Johnson committed to making our COVID-19 vaccine available on a not-for-profit basis for emergency pandemic use. The not-for-profit price will be determined based on one cost structure, with all appropriate costs included. In addition, we have committed to one price globally.

Finally, I want to note that the U.S. government's support has been an important contributor to Johnson & Johnson's ability to develop our vaccine on an accelerated pace. Last year, the Biomedical Advanced Research and Development Authority provided a total of approximately $900 million to support Johnson & Johnson's vaccine research and development. Along with our own investment of approximately $800 million, building on our significant prior investment in our vaccine platform over the past decade, the government's support was an important contributor to our ability to conduct Phase 1 and Phase 2 clinical trials and to conduct the Phase 3 ENSEMBLE studies. In addition, last summer, the government and Janssen entered into an agreement for the demonstration of large-scale manufacturing and delivery of up to 100

million doses of the vaccine by June 30, 2021. This commitment to purchase our vaccine, if authorized by the FDA, was important for our ability to invest in the increased production capacity that will enable us to bring millions of vaccine doses to Americans in the coming months. In addition, Johnson & Johnson has committed more than $1.5 billion to develop and secure manufacturing capacity for the vaccine.

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Thank you for the opportunity to provide this update regarding our efforts to develop, produce, and distribute a vaccine against COVID-19. I would be happy to answer any questions that you may have.

Johnson & Johnson

Janssen Supply Chain

COVID-19 Vaccine Manufacturing

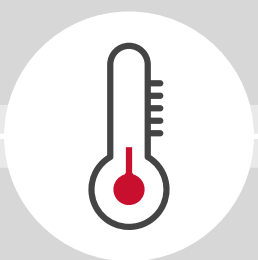
At Johnson & Johnson (J&J), we take seriously our responsibility to supply our COVID-19 vaccine candidate around the world upon approval, and are confident we have the capabilities, collaborations, and rigorous safety and quality standards to do so.

Vaccine Production and Distribution Process

1

In the production process, **cells are grown** and replicated in a controlled environment to generate "drug substance."

Quality control: Collect samples and perform testing.



2

The drug substance is **frozen at -60 °C** in bottles to preserve stability before drug product manufacturing.

3

Those bottles are **transported at -70 °C to production/ fill-finish sites,** often in a different country.

6

Those vials are frozen at -20 °C, and **shipped to J&J warehouses** for storage and distribution.

5

The vials are then **filled and finished with labels, then packaged**.

4

The drug substance is **thawed and diluted** into the vaccine formulation.

7

Following regulatory authorization, J&J will ship the vaccine for distribution using the **same cold chain technologies** we use today to transport other innovative medicines.

With Janssen's AdVac® technology platform, the vaccine **is estimated to remain stable for two years at -20 °C (-4 °F)**, three months of which can be at temperatures of 2-8 °C (36-46 °F).

Each pallet of our vaccine will include **track-and-trace technologies** that will provide real-time location, temperature and other information needed to maintain the vaccine's quality.

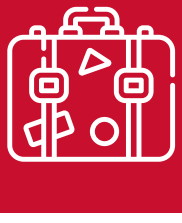
The general timeframe to produce a batch of vaccine, from drug substance to fill and finish, is **60–70 days, plus 18–22 days** for final product quality testing and release.

Global Manufacturing Collaborations

Given the unprecedented nature of the pandemic, Johnson & Johnson is expanding its global manufacturing capacity. We have established new U.S. vaccine manufacturing capabilities and are scaling up capacity in other countries.

In addition to our existing manufacturing capacity in Leiden, the Netherlands, we have entered into multiple agreements to expand our manufacturing capability of our COVID-19 vaccine candidate.

Manufacturing Partners



Due to the global interconnectivity of our production and supply chain processes, one batch of the J&J COVID-19 vaccine **will likely visit multiple countries** through the course of various manufacturing stages in its journey from drug substance to a finished vial for injection.

For more information on Johnson & Johnson's approach to help combat COVID-19, **visit www.jnj.com/coronavirus**.