Testimony of John Young, Chief Business Officer, Pfizer
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Chairwoman DeGette, Ranking Member Guthrie and Members of the Subcommittee, thank you for inviting me to testify today and I am honored to be part of this panel. My name is John Young and I am the Chief Business Officer at Pfizer. I completed a Bachelor of Science degree in Biology at the University of Glasgow, followed by post graduate research in Immunology at the University of Strathclyde prior to joining Pfizer, for whom I have worked for over 30 years.

At Pfizer, our purpose is: Breakthroughs that change patients' lives. In the face of COVID-19, we recognize that this need is more urgent than ever, and we have harnessed the full breadth and depth of our colleagues and their expertise from across our organization to help address this global pandemic. We know that safe and effective vaccines are pivotal to defeating this pandemic and providing protection from the threat of infection. We are committed to bringing our deep heritage and experience in vaccine development, which spans more than 130 years, our reach and scale, and our financial capital to serve the billions of people around the world impacted by this devastating illness and its consequences for their lives and livelihoods.

I am extremely proud of how Pfizer colleagues are applying our decades of scientific expertise in pioneering vaccine discovery, development and manufacturing, along with our partners, BioNTech, to respond to this global health crisis.

It is both a great privilege and responsibility for all Pfizer colleagues and we are focused every day knowing we are all working towards a common objective — to defeat this virus.

Pfizer has made decisions during this pandemic based on three clear priorities:

- First, ensuring the safety and well-being of our colleagues.

- Second, ensuring the continued supply of our medicines and vaccines to patients around the world.

- Finally, continuing our commitment to collaborate and play our part in discovering breakthrough therapies and vaccines to fight this crisis.

The COVID-19 global pandemic represents an unparalleled moment in the history of modern science. While there are important data on the safety and effectiveness of our potential COVID-19 vaccine still to be generated, if our studies are successful, and our plans to rapidly scale

manufacturing go according to plan, we have a path to submit our clinical trial data in a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) as early as October. According to recently published FDA guidelines, dependent on the data from our studies on the safety and effectiveness of our potential vaccine, that could allow the agency to consider Emergency Use Authorization if the agency determines that the clinical evidence sufficiently meets its guidelines, while it fully reviews our BLA submission.

On March 13, 2020, Pfizer's Chairman and CEO Albert Bourla announced Pfizer's five-point plan to help scientists and companies across the biotechnology ecosystem bring forward potential therapies and vaccines for COVID-19 and prepare the industry to respond more effectively to future health crises.

First, sharing tools and insights: As the scientific community continues to learn more about the virus, many are working in parallel to develop cell-based assays, viral screening tools, serological assays, and translational models to test potential therapies and vaccines. Pfizer is committed to making the tools and data we generate available on an appropriate open source platform to the broader scientific community and to sharing the data and learnings gained with other companies and academics in real time to help rapidly advance therapies and vaccines to patients.

Second, marshalling our people: Human capital is our most valuable resource. Pfizer has created a rapid response team composed of some of our leading virologists, biologists, chemists, clinicians, epidemiologists, vaccine experts, pharmaceutical scientists and other key experts to focus solely on addressing this pandemic. Pfizer's rapid response team is applying their passion, commitment and expertise to a single focus of accelerating the discovery and development process that will deliver therapies and vaccines to patients as soon as possible.

Third, applying our drug development expertise: Many smaller biotech companies are screening compounds or existing therapies for activity against the virus causing COVID-19, but some lack the experience in late stage development and navigating the complex regulatory requirements. Pfizer is committed to sharing our clinical development and regulatory expertise to support the most promising candidates these companies bring forward.

Fourth, offering our manufacturing capabilities: If a therapy or vaccine is approved it will need to be rapidly scaled and deployed around the world to help put an end to this pandemic. As one of the largest manufacturers of vaccines and therapeutics globally, Pfizer is committed to using excess manufacturing capacity that is not required for other important and life-saving medicines to support other companies to ensure new COVID-19 treatments get to patients as quickly as possible.

And, lastly, improving future rapid response: To address future global health threats, Pfizer is working with federal agencies including the National Institutes of Health, the National Institute of Allergy and Infectious Diseases and the Centers for Disease Control and Prevention to help participate in a rapid response team of scientists, clinicians and technicians that can move into action immediately when future epidemics surface.

These guiding principles have provided a consistent framework for all our subsequent work and elicited around 500 unique enquiries from academic institutions, small and medium sized biotech companies, and some industry peers.

As part of these efforts, we have developed a focused plan to develop both a potential vaccine and antiviral treatments for COVID-19, and we are leveraging expertise from across our organization in trying to rapidly progress these efforts.

As we pursue a potential vaccine for COVID-19, between funding both research and development and scaling up manufacturing capacity at risk to be able to quickly supply a vaccine at scale if we are successful, we expect to invest about $1 billion during 2020. To date, we have not accepted any federal government funding for this vaccine development program as we recognize that we are uniquely positioned with the scientific expertise and experience, manufacturing scale and financial resources to have the potential to deliver a potential vaccine without funding from the federal government. If our clinical trials progress well, and we receive regulatory approval, we hope to be able to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses in 2021 globally, subject to final dose selection from our clinical trial.

Pfizer's Rich History in Vaccines

Vaccines are among the greatest public health advancements of all time. For more than 130 years, Pfizer has played a pivotal role in helping to reduce the threat of deadly infectious diseases by developing and selling novel vaccines based on new delivery systems and technologies. And Pfizer's legacy continues to underscore our deep commitment to safety and efficacy.

- In 1906, the diphtheria antitoxin became the first FDA-licensed product manufactured at the company's Pearl River, New York, facility.

- In 1948, the company introduced a combined vaccine for preventing diphtheria, tetanus and pertussis in young children.

- In 1968, Pfizer was the first to develop a bifurcated needle which subsequently revolutionized delivery of the smallpox vaccine and led to its worldwide eradication.

- In 2000, Pfizer was the first to license a 7-valent pneumococcal conjugate vaccine for infants and young children.

- In 2010-2011, we were the first to license a 13-valent pneumococcal conjugate vaccine (PCV13) for infants and young children and, in 2011, for adults 50 years and older.

This history illustrates Pfizer's legacy in researching, developing and manufacturing safe and effective vaccines to help prevent many devastating diseases.

We operate one of the most sophisticated supply chain systems in the industry with over 40 Pfizer-owned global sites and have approximately 10,000 U.S.-based manufacturing colleagues. Pfizer manufactures 23 billion medication doses per year in-house, including over 200 million vaccine doses, and is one of the largest U.S. sterile injectables suppliers, producing approximately 1 billion sterile units in the U.S. per year.

Collaboration with BioNTech and Our mRNA Vaccines

Pfizer initially partnered with BioNTech in 2018 to research and develop an mRNA vaccine for influenza. Both companies recognized early in the pandemic that this technology had the potential to be successfully applied to COVID-19, and so we extended our partnership with the BNT162 COVID-19 vaccine program.

The vaccine candidates are based on BioNTech's proprietary mRNA vaccine platforms. The collaboration leverages Pfizer's expertise in vaccine research and development, regulatory capabilities, and global manufacturing and distribution network.

mRNA vaccines are a new approach to vaccination and work by conveying genetic instructions (the mRNA) to human cells that then use their cellular machinery to "translate" or make the spike protein antigen specific for the COVID-19 virus that is displayed on the surface of the cell.

The thesis is that the antigen is recognized by the immune system of the vaccinated individual, generating an antibody response to inactivate (neutralize) the SARS-CoV-2 virus and so prevent, or lessen the symptoms of, COVID-19.

The novel design of the clinical trial program has enabled Pfizer and BioNTech to evaluate up to four different potential vaccines with combinations of two different antigens and three different mRNA formats to enable us to select and advance the optimal vaccine candidate efficiently with the goal of identifying a potential COVID-19 vaccine for further evaluation, in a Phase 2b/3 safety and efficacy study that is subject to regulatory approval.

This approach of testing multiple vaccine candidates allows us to collect clinical data on the safety and effectiveness of each potential vaccine at multiple dose levels in each age group (older and younger adults) to inform our decision-making earlier in the development process.

Clinical Trials – Pfizer and BioNTech Development Plan

Pfizer and BioNTech are currently running two trials in parallel with Pfizer leading the U.S. trials and BioNTech leading the EU trials. The clinical trials in the U.S. and EU have been designed to test the same candidates.

The first stage of the U.S. study began in early May and is taking place at four sites across the U.S. These initial sites include: NYU School of Medicine; University of Maryland School of Medicine; University of Rochester School of Medicine; and Cincinnati Children's Hospital.

Diversity in Clinical Trials

Diversity in clinical trials is a priority for Pfizer and is critical given that COVID-19 disproportionately impacts communities of color in the U.S. We understand the importance of developing vaccines and potential treatments that are safe, effective and easily available to people of color. To that end, ensuring that our COVID-19 clinical trials are inclusive of diverse populations is a key priority.

Our COVID-19 clinical trials include understandable patient-focused materials in multiple languages to educate and inform prospective participants about the disease and explain what they can expect when participating in the clinical trial. Our goal is to recruit participants in alignment with the epidemiology data that has been produced by the Centers for Disease Control and Prevention. We know conducting studies in locations with diverse communities will be instrumental in recruiting minority participants and study staff.

We have developed a dashboard with data from Johns Hopkins University and the U.S. Census Bureau by county, including percent distribution of individuals in the population by race, ethnicity and other demographics, along with the incidence of new cases of COVID-19. This dashboard will aid the investigator site identification process and help us identify areas of opportunity for study placement in communities of color and in locations that have seen higher rates of COVID-19 infection.

Early Positive Phase 1/2 U.S. Data

On July 13, 2020, we announced that we have reached another milestone: two of our four investigational vaccine candidates have received fast track designation from the FDA. These two are the most advanced vaccine candidates in the BNT162 program.

Previously, we shared preliminary topline data from the most advanced of our investigational vaccine candidates, known as BNT162b1, from the mRNA-based vaccine program. Overall, the data are encouraging and showed that this candidate could be administered in a dose that was well tolerated, and generated dose-dependent immunogenicity, as measured by RBD-binding IgG concentrations and SARS-CoV-2 neutralizing antibody titers.

Early positive data show that BNT162b1 administered in doses between 10 ug to 30 ug provided neutralizing titers at or above a panel of human convalescent serum as early as 28 days; 7 days after the second dose of the vaccine.

Local reactions and systemic events after immunization with 10 µg and 30 µg of BNT162b1 were dose-dependent, generally mild to moderate, and transient. No serious adverse events were reported.

Data from the ongoing Phase 1/2 clinical trial will enable selection of a single lead candidate and identification of the optimal dose level for a large, global Phase 2b/3 safety and efficacy study of up to 30,000 participants that may begin later this month, subject to FDA approval.

The preliminary clinical data from this ongoing study have been submitted for potential publication in a peer-reviewed journal and we made this immediately available on an online preprint manuscript server.

Timelines for Approval

We are working with closely with regulatory authorities, including the FDA, to accelerate our program while ensuring that safety is our top priority. We are maintaining the highest standards in our development process. However, in order to reduce the normal time taken for such a development program, we are doing steps in parallel rather than sequentially, which requires more financial capital to be deployed at risk but is the only way to cut significant time from the development program while maintaining safety as the key priority.

We are sharing data from our COVID-19 vaccine clinical trials with the FDA in real time so the agency can evaluate at the earliest possible time whether the safety and efficacy threshold has been met that would enable us to continue our development and proceed to the necessary larger Phase 2b/3 clinical trials.

Manufacturing

Pfizer is dedicating its best-in-class global resources to ensure we can respond rapidly to the COVID-19 pandemic, including rapid development of a supply chain for the new potential vaccine while ensuring the necessary standards of quality and safety are achieved.

In the event our clinical development program is successful, we have already begun the work to scale up production for global supply. We have announced that our Pfizer facilities in St. Louis, Missouri; Andover, Massachusetts; and Kalamazoo, Michigan, will be the sites in our U.S. supply chain and we are currently scaling up to prepare for production. In parallel, we are working with our partners BioNTech to develop an EU supply chain. We are investing significant financial capital at risk to procure necessary raw materials, glass, and stoppers as well as making capital investments in new manufacturing suites and processes for this sophisticated new technology.

Volume

mRNA vaccines are an extremely innovative new technology that require the rapid development and scale-up of novel manufacturing technologies. As part of our capacity planning for a COVID-19 vaccine candidate, we identified that producing the volume of doses that we have committed to, in addition to our existing medicines and vaccines, will make significant demands on our current manufacturing network. We are leveraging redundant supply capacity as well as pulling forward production of other important medicines in our network to create capacity for vaccine manufacture to begin in the fall.

Next Steps

Pfizer's manufacturing and supply chain professionals have been taking several steps to accelerate the scale-up and manufacture of the most promising vaccine leads, including:

- Working with internal and external partners to exchange technology and to enable rapid facility, equipment and process design plans.

- Ordering materials and starting to manufacture multiple vaccine variants in parallel with initial clinical trials knowing that only one of the variants will be selected to move forward.

- Hiring and training staff in select sites to give our operations the support and flexibility needed.

- Shouldering the financial risk to do what it will take to bring as many doses of a vaccine forward as quickly as possible. Pfizer anticipates making additional investments over time.

In conclusion, I believe the probability is high that the biopharmaceutical industry will be able to develop one or more safe and effective vaccines, effective antiviral treatments, and targeted immune-modulators that patients and the world at large so desperately need. But we must also remain vigilant and be prepared to respond to potential new strains of the virus or future threats. We should learn from this unprecedented global crisis and ensure that the world has vaccine platforms capable of rapid development and deployment to prevent the human and economic tragedy of COVID-19 from ever happening again.

I have great confidence that our industry can prevail in the ultimate outcome of our battle against COVID-19 — and that Science Will Win.