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The Honorable Dick Durbin
United States Senate
Washington, DC 20510

Dear Senator Durbin:

Thank you for your September 3, 2020, letter regarding public confidence in the integrity of the vaccine approval process. I am responding on Albert Bourla's behalf.

Pfizer has a rich history in vaccine research and development. For more than 130 years, we have played a pivotal role in helping to reduce the threat of deadly infectious diseases like smallpox and polio globally. As a vaccine manufacturer, manufacturing 200 million doses a year, we understand how to develop and manufacture safe and effective vaccines on a large scale.

Our legacy in researching, developing and manufacturing safe and effective vaccines illustrates Pfizer's commitment to safety and efficacy. This commitment guides our work toward a potential mRNA vaccine candidate and a potential antiviral candidate for COVID-19. We will not cut corners in this pursuit. Patient safety is our highest priority, and Pfizer will not bring a vaccine to market without adequate evidence of safety and efficacy.

To this end, on September 8, Pfizer along with AstraZeneca, BioNTech, GlaxoSmithKline, Johnson & Johnson, Merck, Moderna, Novavax, and Sanofi announced a joint pledge outlining a united commitment to uphold the integrity of the scientific process as we all work toward potential global regulatory filings and approvals of the first COVID-19 vaccines.[1] Our intent is that this pledge will help ensure public confidence in the rigorous scientific and regulatory process by which COVID-19 vaccines are evaluated and authorized or approved. In addition, Pfizer has made the full protocol for its self-funded COVID-19 vaccine pivotal study available to reinforce Pfizer's longstanding commitment to scientific and regulatory rigor that benefits patients. For reference, Pfizer traditionally has not shared the full in-depth study protocol for any of its programs until the publication of the pivotal trial data to preserve the integrity of individual studies. We recognize, however, that the COVID-19 pandemic is a unique circumstance and the need for transparency is clear. As our actions have demonstrated, we want to make clear our commitment to developing and testing potential vaccines for COVID-19 according to scientific principles, *and not politics.*

[1] *Pledge available via Pfizer's press release here: https://www.pfizer.com/news/press-release/press-release-detail/biopharma-leaders-unite-stand-science*

We have been and continue to coordinate with the U.S. government and regulatory authorities, including working with the FDA to accelerate our program while ensuring safety as our top priority. The FDA has been proactive and transparent about the criteria they have laid out for both safety and effectiveness in their guidelines published on June 30, 2020. The FDA's guidance should instill confidence that any vaccine that is approved will meet the appropriately high standards for safety and effectiveness. FDA advisory committees, including the Vaccine and Related Biological Products Advisory Committee (VRBPAC), are important forums for evaluating scientific, technical, or policy questions and providing the Agency independent advice, and Pfizer will be attending the October 22 VRBPAC meeting.

Clinical Trials

Regarding our clinical work, safety is our number one priority in all clinical trials. Pfizer and BioNTech started global Phase 2/3 safety and efficacy clinical studies for the Pfizer-BioNTech COVID-19 vaccine candidate on July 27, 2020. The Phase 2/3 study protocol follows all the U.S. Food and Drug Administration (FDA) guidance on clinical trial design for COVID-19 vaccine studies. As of September 14, 2020, the Phase 2/3 trial had enrolled more than 29,012 people of the up to 30,000 participants globally. (*See* Pfizer's website for updated enrollment available at https://www.pfizer.com/science/coronavirus/vaccine .) Pfizer recently announced the submission of an amended protocol to FDA to expand enrollment of our Phase 3 pivotal COVID-19 vaccine trial to up to approximately 44,000 participants which also allows for the enrollment of new populations.

Timelines

Based on current infection rates, Pfizer and BioNTech continue to expect that a conclusive read-out on efficacy is likely by the end of October; neither Pfizer nor the FDA can move faster than the data we are generating through our clinical trial. According to FDA published guidelines, dependent on the data from our studies on the safety and effectiveness of our potential vaccine, the FDA could consider Emergency Use Authorization if the FDA determines that the clinical evidence sufficiently meets its guidelines, while it fully reviews our BLA submission. If all goes as expected during our clinical work and regulatory authorization or approval is obtained, we currently plan to supply up to 100 million doses worldwide by the end of 2020 and approximately 1.3 billion doses worldwide by the end of 2021.

Federal Funding

To date our COVID-19 vaccine research and development and scale-up costs have been self-funded and Pfizer expects to invest more than $1 billion dollars at-risk in this effort this year.

Given our track record for developing vaccines, for testing in large scale trials, and for manufacturing and distribution on a global scale, we felt uniquely positioned to leverage our existing partnership around mRNA and make these investments on our own to maintain our high standards in vaccines while proceeding with maximum speed, rather than risking potential delay while seeking financial assistance from governments. While to date Pfizer has not accepted government funding for our vaccine development program, we continue to work closely with U.S. health care authorities to ensure access to our potential vaccine, subject to regulatory approval or authorization. For example, on July 22, Pfizer and BioNTech announced the execution of an agreement with the Department of Health and Human Services and the Department of Defense where the U.S. government will receive 100 million doses of the Pfizer-

BioNTech COVID-19 vaccine candidate *after* Pfizer obtains approval or emergency use authorization from FDA and successfully manufactures vaccine doses.

Pfizer has not sought or received government funds for the discovery, research, development, or production scaling of our COVID-19 vaccine candidate. As of September 18, BioNTech has a patent licensing agreement with the National Institutes of Health (NIH), in which royalties are payable to the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH. In addition, BioNTech has separate licensing agreements with private third parties for patents originally filed by or jointly with The Trustees of the University of Pennsylvania. The University's patent (and patent application(s)) states that their inventions were made with government support awarded by the NIH. Royalties are payable by BioNTech to the private third parties for licenses to the University's patents. However, the University has not been involved in the research and development of the Pfizer-BioNTech COVID-19 vaccine candidate. None of these patent licenses involve receipt of government funds by Pfizer for the discovery, research, development, or production scaling of our COVID-19 vaccine candidate.

At Pfizer, our purpose is: Breakthroughs that change patients' lives. In the face of COVID-19, 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 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. We have great confidence that our industry can prevail in the ultimate outcome of our battle against COVID-19 — and that Science Will Win.

Sincerely,

Robert W. Jones

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