Johnson & Johnson

*Office of the Chief Medical Officer*

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Dear Senator Durbin:

On behalf of Johnson & Johnson and the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), I am pleased to respond to your September 3, 2020, letter seeking information regarding Janssen's development of a COVID-19 vaccine and our efforts to bring a vaccine to the public in a manner that maintains scientific standards for safety and efficacy. Janssen appreciates the opportunity to respond to your letter.

As noted in your letter, Janssen has devoted significant expertise and resources, in collaboration with the U.S. government, to developing a preventive vaccine candidate for COVID-19. Our scientists began working on a vaccine candidate in the earliest days of the pandemic. In March, we announced that we had selected a vaccine candidate, called Ad26.COV2.S, for further testing. After demonstrating favorable immune response in non-human primates, we began a Phase 1/2a "first-in-human" trial in July. Interim data from this study are anticipated this month, and pending the results, a Phase 3 study is planned to commence soon thereafter. We anticipate the first batches of the vaccine to be available for emergency use in early 2021. Notably, in March, Johnson & Johnson committed to working to bring an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use.

As you know, Janssen and other companies are pursuing an accelerated approach to the development of effective vaccines that allows us to progress our program significantly faster than normal development timelines, which typically take between five and seven years, while still ensuring safety. There are several ways that Janssen has accelerated 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 earlier.

Janssen believes that we can both accelerate vaccine development and ensure safety. Our vaccine development efforts are built on our AdVac® technology, which we have used in the development of prior vaccine candidates for Ebola, HIV, respiratory syncytial virus (RSV), and Zika. Our clinical experience with the AdVac-based vaccine and vaccine candidates supports safety, with more than 90,000 individuals vaccinated to date, including adults, people over 65 years of age, infants, children, HIV-positive adults, and pregnant women.

Even as we seek to develop a vaccine with the potential to end the global pandemic, we recognize that we will only be successful if the public has confidence in the rigorous scientific and regulatory process by which a COVID-19 vaccine is evaluated and may ultimately be approved. Janssen is committed to seeking regulatory authorization or approval from the U.S. Food and Drug Administration (FDA) only when we have sufficient scientific data that demonstrate our potential vaccine candidate is safe and effective, consistent with the expectations established by FDA.

For that reason, Johnson & Johnson was pleased this month to join with other companies seeking to develop a COVID-19 vaccine in an historic pledge that outlined our united commitment to upholding the integrity of the scientific process as we all work toward potential global regulatory filings and approvals of the first COVID-19 vaccines. Johnson & Johnson joined eight other companies in making the following commitments:

- Always make the safety and well-being of vaccinated individuals our top priority;
- Continue to adhere to high scientific and ethical standards regarding the conduct of clinical trials and the rigor of manufacturing processes;
- Only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is

designed and conducted to meet requirements of expert regulatory authorities, such as the FDA; and

- Work to ensure a sufficient supply and range of vaccine options, including those suitable for global access.

The following addresses the specific questions in your letter. First, you asked about the anticipated timeline for the availability of a vaccine. As noted above, Janssen aims to have our first COVID-19 vaccine batches available for potential emergency use in early 2021. The specific availability of our vaccine will ultimately be determined by the availability of sufficient data that demonstrate the safety and effectiveness of the vaccine, consistent with the expectations established by FDA.

Your second question asked about potential communications with representatives of the White House. Given the importance of confronting the pandemic, Johnson & Johnson has provided periodic updates to a variety of officials in the U.S. government, including White House officials. Because the U.S. government, through BARDA, is providing significant funds in support of our efforts, we believe these updates are an important part of our collaboration with the U.S. government. Our communications with the U.S. government have been focused on our shared interest in developing a safe and effective vaccine on an accelerated, but scientifically responsible, timeline.

Question three asked about pursuing applications for approval or emergency use authorization (EUA). To date, Janssen has not submitted an application for approval or EUA. We anticipate further guidance from the FDA in the near future regarding the EUA process and we will pursue an EUA only if sufficient data from our pending Phase 3 studies demonstrate safety and efficacy data that are consistent with the expectations established by FDA. We will continue to assess safety and efficacy as the pending Phase 3 trials continue and additional data are gathered over the next several years.

Question four asked about Phase 3 trials. As noted above, we expect to begin Phase 3 trials later this month. We anticipate the first trial, called ENSEMBLE, will include up to 60,000 people, and the final number of participants will be based on endorsement by FDA and our predictions of epidemiology (which could be affected by the recruitment of participants for other companies' COVID-19 vaccine clinical trials, as well as the potential

approval or authorization of other companies' COVID-19 vaccines). Our goal is to deliver a vaccine for emergency pandemic use by early 2021. You also asked whether Janssen will "cut any corners in adherence to the research, development, submission, or regulatory review process required under the Federal Food, Drug, and Cosmetic Act or Public Health Service Act for your vaccine candidate." We will not.

Question five inquired about potential emergency use authorizations before the end of Phase 3 trials. As we are focused on developing the vaccine and demonstrating its safety and efficacy in a pivotal Phase 3 trial, this question is premature. As discussed above, we anticipate further guidance from the FDA in the near future regarding the emergency use authorization process. We will pursue an EUA only if sufficient data demonstrate the safety and effectiveness of the vaccine, consistent with the expectations established by FDA. We will continue to assess safety and efficacy as the pending Phase 3 trial continues and additional data are gathered over the next several years. The question also asked about inclusion of data from outside the U.S. The FDA regularly considers clinical data from outside the U.S. as part of the agency's review, and we expect to include such data in our anticipated submission to the agency.

In question six, you asked whether Janssen plans to participate in an upcoming meeting of the Vaccine and Related Biological Products Advisory Committee. At present, Janssen plans to submit public comments and may seek additional participation in the meeting. Question seven asked about perceptions about the vaccine development process, the effect on uptake, and confidence in the approval process. As discussed above, Janssen recognizes that public confidence in a vaccine is essential to its success and for that reason publicly committed to adhering to scientific principles and regulatory standards in the development of a vaccine, even as we seek to develop a vaccine more quickly than has been done in the past. We believe that the U.S. government can bolster public confidence in vaccines and the approval process by ensuring the public understands the strong commitment that biopharmaceutical companies are making to develop and test potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles.

The U.S. government can also communicate the ongoing and well-established commitment of the FDA to ensure that its regulatory process is being followed for the development of COVID-19 vaccines. This includes establishing clear criteria for the potential authorization or approval in the United States based on scientific and medical principles and clear demonstration of safety and efficacy. The U.S. government should consider amplifying these messages to broad and diverse populations, especially those communities disproportionately impacted by COVID-19 and with limited access to healthcare information.

Finally, question eight asks about federal funding and intellectual property. As discussed above, federal funding has contributed to our ability to develop a potential COVID-19 vaccine on an accelerated timeline. Federal funding is provided pursuant to a cost-sharing agreement with BARDA (OTA No. HHSO100201700018C). Based on this innovative work, Janssen has filed patent applications that are considered to be subject inventions under the agreement, including our Ad26.COV2.S vaccine candidate. In addition, Janssen entered into an agreement with the U.S. government under the U.S. government's Medical CBRN Defense Consortium (agreement No. W15QKN-16-9-1002) for demonstration of the large scale domestic manufacturing and delivery of 100 million doses of the Ad26.COV2.S vaccine candidate for use in the United States and at embassies, military installations, and similar locations abroad following licensure or issuance of an emergency use authorization by the FDA. For our COVID-19 program, at the present time, we have not licensed patents held by the U.S. government.

Thank you for the opportunity to share critical and timely information about Janssen's development of a COVID-19 vaccine and our efforts to bring a vaccine to the public in a manner that maintains scientific standards for safety and efficacy.

Sincerely,

Joanne Waldstreicher, M.D.
Chief Medical Officer
Johnson & Johnson