September 21, 2020

Senator Richard Durbin
United States Senate
711 Hart Senate Office Building
Washington, DC 20510-1304

Dear Senator Durbin:

On behalf of AstraZeneca, we would like to thank you for your letter and express our sincere appreciation for your commitment and the commitment of the U.S. government to progress potential vaccine candidates with the goal of developing and distributing a safe and effective COVID-19 vaccine. Responses to your questions have been provided in the Attachment to this letter.

AstraZeneca is committed to the highest safety standards and the broad and equitable access around the world for our COVID-19 vaccine AZD1222. Sound science and patient safety and health are, and will continue to remain our top priorities. We are moving quickly but without cutting corners, and we fully support the mission of regulatory agencies, such as the FDA to ensure our vaccine is determined safe and effective before receiving approval or emergency use authorization.

Along with several other companies, AstraZeneca has publicly committed to only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase III clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA.

Addressing this pandemic is an urgent priority for our company. We come to work every day focusing on the goal that our efforts will save lives and alleviate the devastating humanitarian, social, and economic consequences of the ongoing pandemic around the world. We will remain true to our values as we continue our efforts to bring this vaccine broadly and equitably to billions of people around world.

Sincerely,

Christie Bloomquist

Vice President, US Corporate Affairs, AstraZeneca

ATTACHMENT

1. **How do you reconcile the inconsistency between the projected timeline promoted by President Trump and the timeline projected by our officials at NIH, BARDA, and FDA for a COVID-19 vaccine candidate?**

   AstraZeneca has committed to 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 and only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase III clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA.

2. **Separate from your direct engagement with our federal health agencies (e.g. NIH, BARDA, FDA), have employees or representatives of the White House communicated with your company regarding your COVID-19 vaccine candidate? If so, please provide a copy of all such correspondence between employees or representatives of your company and the White House.**

   We can confirm that we have not spoken to the White House. Our most senior level engagements have been with Ambassador Birx and Secretary Azar.

   a. **Has your company received any political pressure or incentive, outside of your contract agreements, regarding your vaccine candidate?**

   We are pleased the government has moved with speed to advance an agreement with AstraZeneca with the goal of developing and distributing a proven coronavirus vaccine as soon as possible. Our collaboration is going well, and AstraZeneca has been in regular communication with HHS and DoD as we scale up manufacturing and the vaccine candidate undergoes clinical trials.

3. **In a recent interview with the Financial Times, FDA Commissioner Hahn stated, "it is up to the sponsor to apply for authorization or approval, and we make an adjudication of their application. If they do that before the end of Phase Three, we may find that appropriate."**
   a. **Is your company pursuing an application for approval or for emergency use authorization (EUA) of your COVID-19 vaccine candidate?**
      i. **If you are unable to answer by September 17, do you expect to have an answer to that question by October 1 or October 15?**

      It would be premature to speculate on the possibility of EUA for AZD1222.

4. **In a recent interview with Reuters, NIAID Director Dr. Tony Fauci stated that, "The one thing that you would not want to see with a vaccine is getting an EUA before you**

have a signal of efficacy. One of the potential dangers if you prematurely let a vaccine out is that it would make it difficult, if not impossible, for the other vaccines to enroll people in their trial."

a. When did your vaccine candidate begin enrollment on its phase 3 trial in the United States?

The Phase III clinical trial initiated vaccination on 28 August 2020.

b. When did, or when do you project, your vaccine candidate to reach 30,000 enrolled patients in its phase 3 trial in the United States?

We do not have a projection at this time.

c. When do you predict you will have a signal of efficacy from the phase 3 trial of your COVID-19 candidate in the United States?

We expect to have the first data from the Phase III trial in the U.S. by the end of 2020.

d. Will your company 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 are putting science and the interest of society at the heart of our work. We are moving quickly but without cutting corners, and regulators have clear and stringent efficacy and safety standards for the approval of any new medicine, and that includes this potential COVD-19 vaccine. We will remain true to our values as we continue our efforts to bring this vaccine broadly and equitably to billions of people around world.

e. If the FDA issues an EUA for another COVID-19 vaccine candidate which is not your company's vaccine candidate, how would that impact your research, development, and approval process timeline?

We would plan to continue our Phase III clinical trial in the U.S. This is not a competition between vaccine candidates but one against the SARS-CoV-2 virus. Society may need more than one vaccine to help combat COVID-19.

5. A recent New York Times report indicated that Trump Administration officials told congressional leaders that they could give emergency approval to a coronavirus vaccine before the end of phase 3 clinical trials in the U.S., perhaps as early as late September.

a. Are you aware of this potential timing?

We are not familiar with that projected timing.

b. Would it be possible for the FDA to issue an EUA or approval based upon data from clinical trials in foreign countries? Do you support the inclusion of data from outside of the U.S. in the regulatory review of COVID-19 vaccines?

Along with several other companies, AstraZeneca has committed to only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase III clinical study that is designed and conducted to meet requirements of regulatory authorities. It would be up to FDA to decide whether to issue an EUA or approval based on data from clinical trials in other countries.

6. The FDA recently announced a convening of the Vaccine and Related Biological Products Advisory Committee on October 22. Does your company plan to present or directly participate in this event?

We are still evaluating whether we will participate in the Vaccine and Related Biological Products Advisory Committee on October 22nd.

7. Are you concerned that the perception within certain populations of cutting corners or having political interference in the approval process will reduce vaccine uptake? If so, how can HHS bolster public confidence in the approval process?

We share concerns with many that inaccurate public perceptions could lead to vaccine hesitancy. We believe that there will need to be appropriate communications to ensure that the American people understand the rigorous standards that are being applied to the vaccine by regulators such as FDA.

8. Has federal funding contributed to the discovery, research, development, or production scaling of your vaccine candidate? If so, please provide a list of all such federal funding disaggregated by the specific patent and/or stage of the vaccine development process.

We thank the U.S. government for their commitment to accelerating multiple potential vaccine candidates with the goal of developing and distributing a proven coronavirus vaccine as soon as possible. AstraZeneca's agreement with BARDA, which has now been transitioned to the Department of Defense (DOD), for over $1 billion is for the development, production and delivery of 300 million doses of the vaccine to the U.S. should it prove effective and well tolerated. The development program includes a Phase III clinical trial with 30,000 participants and a pediatric trial. We made from the outset the decision to provide our vaccine at no profit during the pandemic and therefore needed to partner with governments to ensure early manufacturing at risk since we have no profit to justify the investment required to develop and manufacture the vaccine at risk. We appreciate the willingness of the government to partner for the development and manufacture of this vaccine. The majority of the government funding is going to the procurement of the 300 million doses of vaccine manufactured at no profit to AstraZeneca during the pandemic period.

a. **If any patent related to your vaccine candidate is held by the federal government, please list the patent(s) and provide a copy of the licensing agreement.**
N/A

b. **If any patent related to your vaccine candidate is held by the federal government, please explain how your company plans to make the benefit of the invention "available to the public on reasonable terms," as required by 35 USC 201.**
N/A