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The Honorable Richard Durbin
711 Hart Senate Building
Washington, DC, 20510

Dear Senator Durbin,

Thank you for your letter dated September 3, 2020 expressing concerns about the potential for premature regulatory approval of COVID-19 vaccines. I am responding on behalf of Emma Walmsley.

GSK is a science-led company with technologies that we believe hold great promise to catalyze global pandemic preparedness and response. Our broad portfolio and innovative pipeline of vaccines help to protect people throughout life. We deliver over two million vaccine doses per day to people living in over 160 countries, illustrating our robust supply chain and demonstrated track record for developing safe and effective vaccines to improve public health at scale.

At GSK we are closely monitoring the COVID-19 pandemic and actively working on solutions to support the global efforts to tackle the virus. We are delighted to see so many companies and institutions making major commitments; we will only beat this virus with collaboration, cooperation and funding across industry, governments supranational organizations and NGO's.

We believe that a global multi-stakeholder effort will be needed to meet the challenge to further accelerate development, scale up of manufacturing, and equitable distribution of COVID-19 vaccines to the world. We are collaborating with companies and research groups across the world working on promising COVID-19 vaccine candidates through the use of our innovative pandemic adjuvant technology.[1] We believe using an adjuvanted vaccine is a promising approach that has shown to be successful in the past for pandemic flu – due to the dose-sparing impact of the adjuvant and higher efficacy delivered.

To date, we have formed several collaborations, including with scientific partners in North America, Europe and China, to develop vaccines. Discussions with potential partners on further collaborations are ongoing. We hope that there will be several successful vaccines developed, including vaccines using our pandemic adjuvant technology. Over the next few months we expect to see data from these collaborations.

Recently, our collaboration with Sanofi reached an important milestone with the start of the Phase 1/2 clinical trial of the GSK/Sanofi adjuvanted COVID-19 vaccine candidate. We hope to see data from these studies by the end of the year. Provided that these data are sufficiently robust to meet the requirements of a regulatory license, we plan to file a licensing application, and to request regulatory approval sometime in the first half of 2021. Sanofi is leading the clinical development and registration of the COVID-19 vaccine and would be the marketing authorization holder of the licensed adjuvanted vaccine. We are committed to follow the science and determine whether pursuit of an Emergency Use Authorization (EUA) from FDA is appropriate only when we have gathered the data and examined it in order to make a science-based determination on the filing.

[1] The U.S. Government does not hold any patents on this technology.

GSK is committed to developing and testing potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles. We recently joined Sanofi and other leading manufacturers as signatories, pledging:

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

We are engaging with BARDA and other officials associated with Operation Warp Speed on a regular basis regarding our adjuvant procurement contract and we have not been approached by the Administration outside of this official capacity. Several representatives from GSK plan to attend the upcoming FDA Vaccine and Related Biological Products Advisory Committee (VRBPAC) meeting but we do not plan to make a presentation.

We are confident that stakeholders, working together, can conquer this pandemic. Thank you again for your commitment to ensuring the delivery of safe and effective vaccines.

Sincerely,