September 17, 2020

The Honorable Richard J. Durbin
711 Hart Senate Office Building
United States Senate
Washington, DC 20510

Dear Senator Durbin:

On behalf of our CEO, Paul Hudson, and my colleagues, I am pleased to respond to your September 3, 2020 letter regarding Sanofi's Coronavirus Disease 2019 (COVID-19) vaccine candidates. Below please find general information regarding our COVID-19 vaccine candidate development efforts and responses to each of your specific questions.

Sanofi Pasteur, the global vaccines business unit of Sanofi S.A., has a legacy of scientific discovery and experience with vaccine development, licensure, and manufacturing that positions us well to respond to emerging public health threats such as COVID-19.[1] While developing a vaccine usually takes years, we are leveraging existing technologies and what we have learned from previous development efforts to potentially shorten the development timeline while maintaining the highest scientific standards with respect to establishing safety and efficacy. Sanofi currently is evaluating two COVID-19 vaccine candidates.

First, with support from the Biomedical Advanced Research and Development Authority ("BARDA"), Sanofi is leveraging its existing egg-free, recombinant DNA platform, together with an adjuvant, to produce a recombinant vaccine candidate.[2] The recombinant technology produces an exact genetic match to proteins found on the surface of the coronavirus, and Sanofi uses this technology now to produce Sanofi's seasonal influenza vaccine, Flublok®.

Sanofi and GlaxoSmithKline ("GSK") are partnering to test the use of GSK's proven pandemic adjuvant, ASO3[3] with our recombinant technology. The combination of a protein-based antigen together with an adjuvant is well-established and used in several common vaccines available today.[4] An adjuvant is added to some vaccines to enhance the immune response and has been shown to create a

[1] For simplicity, we will refer generally to "Sanofi" in discussing the vaccine development activities
[2] *See* https://www.hhs.gov/about/news/2020/02/18/hhs-engages-sanofis-recombinant-technology-for-2019-novel-coronavirus-vaccine.html.
[3] Sanofi, Press Release, Sanofi and GSK Initiate Phase 1/2 Clinical Trial of COVID-19 Adjuvanted Recombinant Protein-Based Vaccine Candidate (Sept. 3, 2020), *available at* https://www.sanofi.com/en/media-room/press-releases/2020/2020-09-03-07-00-00.
[4] For example, Daptacel (to prevent diphtheria, tetanus, and pertussis in infants and children), Prevnar 13 (to prevent pneumococcal disease), Recombivax HB (to prevent infections caused by hepatitis B virus), and Gardasil 9 (to prevent cancers caused by certain types of Human Papillomavirus ("HPV")) are all vaccines that contain adjuvants. *See, also,* CDC, Adjuvants and Vaccines, *available at* https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html.

stronger and longer-lasting immunity against infections than the vaccine alone. Use of an adjuvant also can improve the prospects for delivering an effective vaccine that can be manufactured at scale because it may reduce the amount of vaccine protein required per dose.

We initiated Phase 1/2 clinical trials on September 3, 2020.[5] Pending positive results from those trials, we aim to initiate Phase 3 trials in December 2020. The recombinant vaccine candidate is included in Operation Warp Speed.

Separately, Sanofi is collaborating with Translate Bio, a clinical-stage messenger RNA (mRNA) therapeutics company, to develop a novel mRNA vaccine candidate for COVID-19.[6] We intend to start Phase 1/2 clinical trials by the end of 2020. This vaccine candidate currently is not part of Operation Warp Speed, and Sanofi has not received any federal funding related to this vaccine candidate.

Our responses below focus on our recombinant vaccine candidate because it is our lead candidate and the only Sanofi vaccine candidate that is part of Operation Warp Speed.

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?**

Sanofi does not have any insight into the basis for the timelines that you reference in your letter. As noted above, Sanofi initiated Phase 1/2 clinical trials for its recombinant vaccine candidate on September 3, 2020. Pending positive results in those trials, Sanofi aims to initiate Phase 3 trials in December 2020, with Phase 3 results possible in the second quarter of 2021. As with all our research and development efforts, our COVID-19 vaccine development timeline is subject to change based on the data we receive during each clinical trial phase and will always be driven by science and the best interest of patients.

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.**

On March 2, 2020, John Shiver, Senior Vice President, Vaccines Global R&D at Sanofi participated in a roundtable with President Trump, the Coronavirus Task Force, and representatives from other pharmaceutical manufacturers.[7]

In early August 2020, the Office of Public Liaison at the White House contacted Sanofi regarding a possible White House meeting to discuss COVID-19 treatment and vaccine development activities and

[5] *Id.*

[6] *See* https://www.sanofi.com/en/media-room/press-releases/2020/2020-03-27-07-00-00.

[7] A recording of the meeting is available at https://www.youtube.com/watch?v=4mzSlaA2Td0. *See, also,* White House, Transcript, Remarks by President Trump and the Members of the Coronavirus Task Force in Meeting with Pharmaceutical Companies (March 2, 2020), *available at* https://www.whitehouse.gov/briefings-statements/remarks-president-trump-members-coronavirus-task-force-meeting-pharmaceutical-companies/.

progress. Sanofi was not able to participate at the proposed time and to our knowledge the meeting did not take place.

Other than correspondence regarding the scheduling and logistics of the above referenced meetings, we are not aware of any other communications between employees or representatives of the White House and Sanofi.

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

No. Sanofi has not received any political pressure or incentives related to our COVID-19 vaccine candidates.

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?

Given the early stage of the clinical trials for our vaccine candidates, it is premature for Sanofi to make a determination regarding whether, when, and in what form we will seek approval or emergency use authorization from the FDA. That decision will be driven by the scientific evidence obtained from our Phase 3 studies.

i. If you are unable to answer by September 17, do you expect to have an answer to that by October 1 or October 15?

We do not expect to have an answer to this question by October 15. Sanofi will not make a determination regarding whether, when, and in what form it would seek approval or emergency use authorization from the FDA until it has gathered, reviewed, and assessed the data from clinical trials.

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?

Sanofi has not yet begun enrollment for its Phase 3 clinical trials. Subject to results of its Phase 1/2 studies, Sanofi aims to begin enrollment for its Phase 3 clinical trial for its recombinant vaccine candidate in December 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?

Given that Sanofi has not yet begun Phase 3 clinical trials, we are unable to project when we will reach 30,000 enrolled patients.

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?

Given that Sanofi has not yet begun Phase 3 clinical trials, we are unable to predict when we may have a signal of efficacy from our Phase 3 clinical trials.

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?

No. Sanofi is committed to developing and testing potential vaccines for COVID-19 in accordance with the highest ethical standards and sound scientific principles. Sanofi has joined with other vaccine manufacturers in a pledge to:

- 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.[8]

e. If the FDA issues a 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?

It is possible that FDA's issuance of an EUA for another COVID-19 vaccine candidate could impact Sanofi's research and development process and timeline, depending on the timing and nature of the EUA and the status of Sanofi's vaccine development efforts at the time. Sanofi will be monitoring developments in this critically important initiative in order to minimize any impact on its clinical trials.

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?

Sanofi does not have any information regarding this potential timing. As described above, this does not align with our anticipated timeline for Sanofi's development of its vaccine candidate.

[8] *See* Press Release, Biopharma Leaders Unite to Stand with Science, *available at* https://www.businesswire.com/news/home/20200908005282/en/Biopharma-Leaders-Unite-Stand-Science.

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 the U.S. in the regulatory review of COVID-19 vaccines?

FDA routinely approves biologic products, including vaccines, based upon data from clinical trials in foreign countries, and Sanofi supports inclusion of data from clinical trials outside the U.S in its database supporting COVID-19 vaccines. Diversity in geographies helps researchers assess the safety and efficacy of a vaccine candidate across different populations. Of course, all such data must be developed in accordance with good clinical practices. Sanofi will collect all of its clinical trial data, regardless of trial site location, pursuant to clinical trial protocols submitted to the FDA as part of an Investigational New Drug (IND) application. Sanofi will share information regarding study locations on clinicaltrials.gov.

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?

Sanofi does not currently plan to participate in this meeting; however, Sanofi would participate if the FDA requests us to do so.

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 believe that HHS and the FDA should emphasize and reinforce the continued scientific rigor of the approval process. FDA has established clear guidance for the development of COVID-19 vaccines and clear criteria for authorization or approval of a COVID-19 vaccine in the US. FDA's guidance and criteria are based on the scientific and medical principles necessary to demonstrate the safety and efficacy of potential COVID-19 vaccines. More specifically, the agency requires that scientific evidence for regulatory approval must come from large, high quality clinical trials that are randomized and observer-blinded, with an expectation of appropriately designed studies with significant numbers of participants across diverse populations.

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 state of the vaccine development process.

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.

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.

Pursuant to its contract with the Biomedical Advanced Research and Development Authority ("BARDA") to support development including Phase 3 clinical trials and large-scale manufacturing of Sanofi's recombinant vaccine candidate, Sanofi has given the U.S. Government unlimited rights to all data generated from clinical trials funded through the contract. In other words, the U.S. Government has full and unrestricted access to use any data generated from Sanofi activities under the contract in

any way it sees fit. Sanofi also has agreed that the U.S. Government may grant patent licenses to other parties to manufacture our vaccine should the U.S. Government determine that such action is necessary to address public health and safety needs.

* * *

This fight is personal for us as many of our Sanofi colleagues have been directly impacted by this horrible disease, including one colleague who lost his battle with COVID-19. Our company is fully dedicated to finding and delivering safe and effective solutions to this public health emergency. We will not stop in our efforts until this pandemic is resolved and COVID-19 is defeated. If you have any additional questions, please feel free to contact me directly.

Sincerely,

Adam Gluck, Senior Vice President
U.S. and Sanofi Genzyme Corporate Affairs