moderna

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September 17, 2020

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

Dear Senator Durbin:

Thank you for your inquiry regarding Moderna's efforts to develop a vaccine for COVID-19. We deeply appreciate your support for our efforts, and those of our peer companies, to develop safe and effective vaccines for COVID-19.

Your letter raises important issues. We agree with you that our society has a compelling interest in developing COVID-19 vaccines rapidly in order to save lives and facilitate a return to normalcy. We also agree with you—strongly—that vaccines developed for COVID-19 must be safe, effective, and trusted by the public, particularly those groups who have been disproportionately harmed by the pandemic.

Moderna has pursued a vaccine for COVID-19 with unprecedented speed. We began work on our vaccine candidate, mRNA-1273, immediately after the genetic sequence of the novel coronavirus was released on January 11, 2020. Only 25 days later, on February 7, 2020, Moderna completed its first clinical batch of mRNA-1273. The Phase 1 study, led by the National Institutes of Health ("NIH"), dosed its first participant on March 16, 2020. The first participants in our Phase 2 study were dosed on May 29, 2020. Our Phase 3 study began on July 27, 2020, and the enrollment of 30,000 participants is on track to be completed in September 2020.

The Director of the National Institute of Allergy and Infectious Disease ("NIAID"), Anthony S. Fauci, M.D., described the progress of mRNA-1273 in a statement at the time our Phase 3 study launched:

> "[W]e urgently need a safe and effective preventive vaccine to ultimately control this pandemic. Results from early-stage clinical testing indicate the investigational mRNA-1273 vaccine is safe and immunogenic, supporting the initiation of a Phase 3 clinical trial. This scientifically rigorous, randomized, placebo-controlled trial is designed to determine if the vaccine can prevent COVID-19 and for how long such protection may last.[1]

The rapid development of mRNA-1273 has been possible because our mRNA technology platform is flexible and quickly adaptable. That platform is the product of years of research and investment that have put Moderna in a position to help address this pandemic. Rapid development of vaccine candidates for COVID-19 has also been made possible by the willingness of participants in this process—biopharmaceutical companies, their investors, the federal government, and nonprofits—to accept and share the financial risk of developing, testing, and manufacturing vaccine candidates that may never be approved.

[1] National Institutes of Health, *Phase 3 clinical trial of investigational vaccine for COVID-19 begins* (July 27, 2020), available at: https://www.nih.gov/news-events/news-releases/phase-3-clinical-trial-investigational-vaccine-covid-19-begins.

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While we have pursued the development of mRNA-1273 with speed, we have been—and remain committed to—prioritizing safety and effectiveness. We are working closely with NIH on the clinical studies for mRNA-1273, and those studies will be driven by the science and the data. We have also taken time to address important interests, such as harmonizing Phase 3 protocols across the vaccine-makers participating in Operation Warp Speed and slowing enrollment in our Phase 3 study to ensure minority representation. Consistent with its goals from the start of the Phase 3 study, Moderna has been diligently working to recruit participants that are representative of the communities at highest risk for COVID-19 and of our diverse society. As of September 17, 2020, approximately 28% of all Phase 3 participants are from diverse communities.[2] To build trust, we also recently published the clinical study protocol for our Phase 3 study online.[3]

We are also one of nine biopharmaceutical companies working on COVID-19 vaccines that united together in an unprecedented pledge to uphold the integrity of the scientific process. That pledge speaks directly to your concerns. It reads in full:

> *We, the undersigned biopharmaceutical companies, want to make clear our on-going commitment to developing and testing potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles.*
>
> *The safety and efficacy of vaccines, including any potential vaccine for COVID-19, is reviewed and determined by expert regulatory agencies around the world, such as the United States Food and Drug Administration (FDA). FDA has established clear guidance for the development of COVID-19 vaccines and clear criteria for their potential authorization or approval in the US. FDA's guidance and criteria are based on the scientific and medical principles necessary to clearly 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.*
>
> *Following guidance from expert regulatory authorities such as FDA regarding the development of COVID-19 vaccines, consistent with existing standards and practices, and in the interest of public health, we 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.*

[2] For the most up-to-date information on representation in Modern's Phase 3 Study, *see* https://www.modernatx.com/cove-study.

[3] *See* A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older (amended Aug. 20, 2020), *available at* https://www.modernatx.com/sites/default/files/mRNA-1273-P301-Protocol.pdf.

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

We believe this pledge will help ensure public confidence in the rigorous scientific and regulatory process by which COVID-19 vaccines are evaluated and may ultimately be approved.

We greatly appreciate your interest in these issues, your support of efforts to develop safe and effective vaccines for COVID-19, and your defense of scientific and regulatory integrity. Please let us know if we can be of further assistance on this issue.

Best regards,

/s/ John Lepore

John Lepore