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To: Participants Enrolled in the Study Protocol C4591001

Dear Study Participant,

We are grateful for your participation in the Pfizer BioNTech COVID-19 vaccine study. While the study will continue in a blinded fashion in the near term to collect longer term data on the safety and effectiveness of the investigational vaccine, the Vaccine Transition Option enables you to learn whether you received the investigational vaccine or placebo and, if you received the placebo, to have the option to receive the investigational vaccine within the trial. Every participant 16 and older in the placebo group has two doses of the investigational vaccine reserved for them that they can receive at the appropriate time during the trial.

We began implementation of the Vaccine Transition Option by first offering the investigational vaccine to those participants who are healthcare personnel and residents of long-term care facilities, following the national guidance issued by the U.S. Centers for Disease Control and Prevention (CDC). To date, over 2,000 study participants who were in the placebo group have already received their first dose of BNT162b2 via the Vaccine Transition Option.

I am now pleased to share that Pfizer and BioNTech have worked in close consultation with the U.S. Food and Drug Administration to ensure that there is a consistent approach to offering investigational vaccine to placebo participants across the different COVID-19 vaccine trials and to make changes to the program so that participants who received the placebo can be offered BNT162b2 as soon as possible.

The Vaccine Transition Option is now being offered to all participants 16 years and older in a prioritized manner following the guidance from the CDC guidance. The previous requirement for participants who do not fall into a prioritized group to wait six months after their second injection has been removed.
Our aim is that all participants 16 years and older who received the placebo and want to receive the investigational vaccine will be able to receive their first dose by no later than March 1, 2021. Please be assured that we are working as quickly as possible to meet the unique needs of each participant.

What to Expect:

- If you are in a group that has been prioritized by the CDC guidance or have received a request from your personal doctor or local vaccination center to set up a vaccination appointment, please contact us to begin the Vaccine Transition Option now.
- If you are interested in the Vaccine Transition Option but are not in a group that has been prioritized by the CDC or Commonwealth of Virginia guidance, we will contact you over the coming weeks to see if you are interested in the Vaccine Transition Option. If you would like to choose this option, we will schedule a phone visit for you to be unblinded (to learn whether you were in the vaccine or placebo group).
- If you learn that you were in the placebo group and would like to receive the investigational vaccine, you will have an in-person visit during which you will be provided with a new informed consent document that we will review with you before you sign it. Then, you will receive your first dose of BNT162b2.
- After you receive your first dose of BNT162b2, you will have a second dose about 21 days later and follow an updated study schedule that includes follow-up and illness visits.
- If you do not wish to choose the Vaccine Transition Option, you can remain blinded and continue with your planned study activities.

We thank you for volunteering to help fight this pandemic and for your continued participation in this study. By choosing to continue in the study, you are making an important scientific contribution and helping us learn more about how the investigational vaccine can prevent COVID-19. Should you have any questions about the Vaccine Transition Option or any other study related topic, please do not hesitate to contact us.

Sincerely,

Donald Poretz, M.D.

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