Neda,

The clinical team has three questions for Pfizer – see below. Please respond by COB Monday, August 16, 2021.

1. Please complete the following table to describe follow-up time for the efficacy population.

**Table. Blinded Follow-up Time after Dose 2, Phase 2/3 Participants 16 Years of Age and Older, Evaluable Efficacy Population**

<table>
<thead>
<tr>
<th></th>
<th>Vaccine Group (as Randomized)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>BNT162b2 N³=21047</td>
<td>Placebo N³=21210</td>
<td>Total N³=42257</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n^b (%)</td>
<td>n^b (%)</td>
<td>n^b (%)</td>
</tr>
<tr>
<td>Evaluable efficacy (7 days) population</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥2 Months to &lt;4 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥4 Months to &lt;6 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥6 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: HIV-positive participants are not included in this summary because they are not included in the efficacy analyses.

a. N = number of participants in the analysis population for the primary efficacy endpoints (evaluable participants with and without evidence of prior infection). This value is the denominator for the percentage calculations.

b. n = Number of subjects with the specified characteristic.
2. Please provide the number of participants, by age cohort, who received placebo originally and opted not to receive BNT162b2 after unblinding.

3. Please provide a breakdown of the subjects by age cohorts (young adults and older adults) who have ≥6 months of follow-up from Dose 2 to the earlier of discontinuation or the cutoff date, separately for the Safety and Evaluable Efficacy Populations. Please also provide a breakdown of these subjects, number of doses received and time of follow up after last dose.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

Mike Smith, Ph.D.
Captain, USPHS
Senior Regulatory Review Officer
Food and Drug Administration
Center for Biologics Evaluation & Research
Office of Vaccines Research & Review
Division of Vaccines and Related Products Applications
Tel: 301-796-2640
michael.smith2@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.