Vaccines and Related Biological Products Advisory Committee Meeting

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BNT162B2

PFIZER-BIONTECH COVID-19 VACCINE

PFIZER BRIEFING MATERIALS ADDENDUM

FOR JUNE 14 - 15, 2022

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

SARS-COV-2 NEUTRALIZING RESPONSES – PHASE 2/3 – OMICRON VARIANT

An additional descriptive immunogenicity analysis was performed for pediatric participants 6 months of age and 2 to <5 years of age who received a three-dose series of BNT162b2 3-µg in Phase 2/3 Study C4591007, compared with a subset of adults 18 to 50 years of age in Phase 3 Study C4591017 (lot consistency study) who had received a two-dose primary series followed by a booster (third) dose of BNT162b2 30-µg. At 1-month post-Dose 3, the FFRNT assay (as described in the Briefing Document immunogenicity methods) was used to measure 50% neutralizing antibody titers against a recombinant Omicron variant of SARS-CoV-2 in the pediatric and adult age groups. Serological evidence of prior infection with SARS-CoV-2 was determined by an N-binding assay, and virological evidence of active infection with SARS-CoV 2 was determined by PCR.

Results

Dosing Intervals

Omicron neutralizing titers 1-month post-Dose 3 were compared between the two pediatric age groups and adults 18 to 50 years of age. The adult comparator group in this analysis had a similar interval between BNT162b2 Dose 2 and Dose 3 (median 13.0 weeks) as the pediatric participants (median 10.6 weeks for children 2 to <5 years of age and median 12.9 weeks for children 6 months to <2 years).

Omicron Neutralizing Titers

Neutralizing titers against Omicron at 1-month post-Dose 3 in pediatric and adult participants without evidence of prior or active SARS-CoV-2 infection are shown in Figure S1 and summarized for each age group below.

Children 2 to <5 Years of Age

Among 37 children 2 to <5 years of age without evidence of prior SARS-CoV-2 infection who received three doses of BNT162b2 3-µg, neutralizing GMTs were 113 at 1-month post-Dose 3.

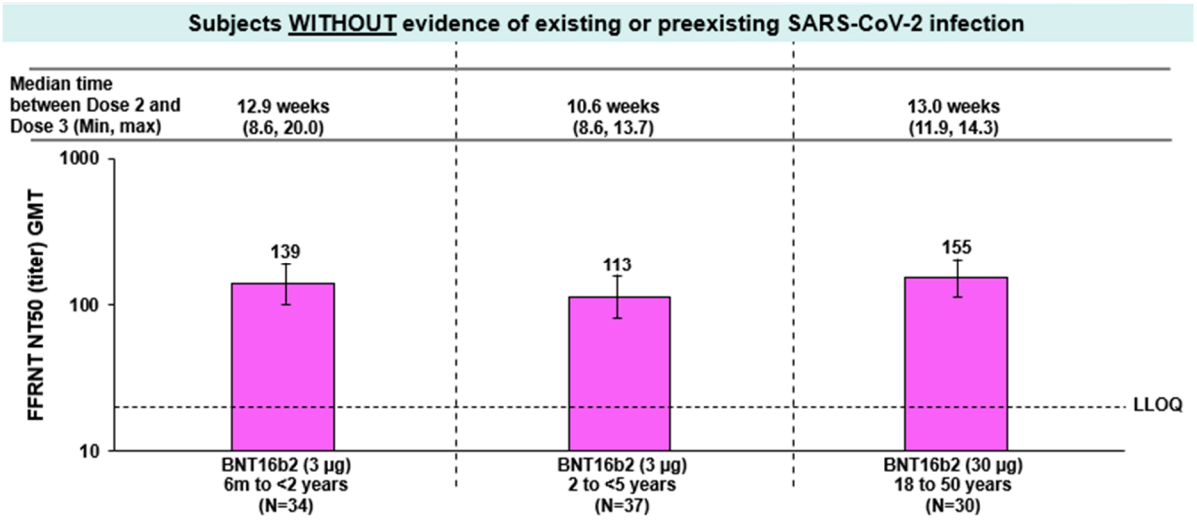
Children 6 Months to <2 Years of Age

Among 34 children 6 months to <2 years of age without evidence of prior SARS-CoV-2 infection who received three doses of BNT162b2 3-µg, Omicron neutralizing GMTs were 139 at 1-month post-Dose 3.

Adults 18 to 50 Years of Age

Among 30 adults 18 to 50 years of age from the C4591017 lot consistency study without evidence of prior SARS-CoV-2 infection who received three doses of BNT162b2 30-µg, Omicron neutralizing GMTs were 155 at 1-month post-Dose 3.

Figure S1. Omicron Neutralizing Titers at 1 Month After Dose 3 of BNT162b2 in Pediatric (C4591007) and Adult (C4591017) Participants Without Evidence of Prior or Active SARS-CoV-2 Infection



Omicron Immunogenicity Conclusions

These data show that for populations who received three doses of BNT162b2 at the age appropriate dose level and administered at a comparable dosing interval, the Omicron specific neutralization titers are very similar across pediatric age groups (6 months to <5 years of age) and an adult comparator group (18 to 50 years of age) for whom high efficacy was observed.

Document Approval Record

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