1. TABULAR LISTING OF CLINICAL STUDIES INCLUDED IN THE SUBMISSION

Information is provided for the clinical study included in the present supplemental submission data for COMIRNATY (BNT162b2).

Details provided in the table include study objectives, brief description of the design of the study, dose regimens, number of participants vaccinated, a brief description of the study population, and the type of Clinical Study Report (CSR). Data are included for adolescents 12 through 15 years of age.

Prior C4591001 clinical study reports relevant to adolescents 12-15 years of age have been submitted, including the following (synopses linked):

- Module 5.3.5.1 C4591001 Final Analysis Interim CSR Synopsis
- Module 5.3.5.1 C4591001 Adolescent Interim CSR Synopsis
- Module 5.3.5.1 C4591001 6-Month Update Interim CSR Synopsis

Table 1. Listing of All Clinical Studies Included in This Submission

Protocol No. Phase (Country)	Sponsor (Agent)	Study Design and Objective(s)[a]	Treatment Groups	No. of Participants	Demographics (by Phase)	Study Start/ Status	Study Synopsis
C4591001 Phase 3 (United States)	BioNTech (Pfizer)	**Phase 3 Objectives:** • **Efficacy:** To describe the efficacy of prophylactic BNT162b2 against confirmed COVID 19 occurring from 7 days after the second dose through the blinded follow-up period in participants without, and with and without, evidence of infection before vaccination • **Immunogenicity** To demonstrate the noninferiority of the immune response to prophylactic BNT162b2 in participants 12 to 15 years of age compared to participants 16 to 25 years of age • **Safety:** To define the safety profile of prophylactic BNT162b2 in participants 12 to 15 years of age in Phase 3	**Phase 3:** **BNT162b2** (30 µg) Placebo[b]	**Phase 3:** 2260 (12-15 years of age) randomized 1:1	**Phase 3[c]** **Participants 12-15 years of age:** ***BNT162b2 Group*:** **Sex:** Male: 567 Female: 564 **Age (years)**: **Mean/median**: 13.6/14.0 **Min, max:** 12, 15 **Race:** White: 970 Black or African American: 52 American Indian or Alaska native: 4 Asian: 72 Native Hawaiian or other Pacific Islander: 3 Multiracial: 24 Not reported: 6 **Racial Designation:** Japanese: 5	**Start Date:** April 2020 (ongoing)	Adolescent 6-Month Update CSR Synopsis

Table 1. Listing of All Clinical Studies Included in This Submission

Protocol No. Phase (Country)	Sponsor (Agent)	Study Design and Objective(s)[a]	Treatment Groups	No. of Participants	Demographics (by Phase)	Study Start/ Status	Study Synopsis
					Placebo Group: **Sex:** Male: 585 Female: 544 **Age (years)**: **Mean/median**: 13.6/14.0 **Min, max:** 12, 15 **Race:** White: 962 Black or African American: 57 American Indian or Alaska native: 3 Asian: 71 Native Hawaiian or other Pacific Islander: 0 Multiracial: 29 Not reported: 7 **Racial Designation:** Japanese: 2 **Phase 2/3 Immunobridging Subset 12-15 years of age[d]:**		

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Protocol No. Phase (Country)	Sponsor (Agent)	Study Design and Objective(s)[a]	Treatment Groups	No. of Participants	Demographics (by Phase)	Study Start/ Status	Study Synopsis
					BNT162b2 Group*:** **Sex:** Male: 106 Female: 103 **Age (years)**: **Mean/median**: 13.5/14.0 **Min, max:** 12, 15 **Race:** White: 184 Black or African American: 16 American Indian or Alaska native: 1 Asian: 5 Native Hawaiian or other Pacific Islander: 0 Multiracial: 3 Not reported: 0 **Racial Designation:** Japanese: 1 ***Placebo Group: **Sex:** Male: 21 Female: 15		

Table 1. Listing of All Clinical Studies Included in This Submission

Protocol No. Phase (Country)	Sponsor (Agent)	Study Design and Objective(s)[a]	Treatment Groups	No. of Participants	Demographics (by Phase)	Study Start/ Status	Study Synopsis
					Age (years): **Mean/median**: 13.4/13.0 **Min, max:** 12, 15 **Race:** White: 31 Black or African American: 3 American Indian or Alaska native: 0 Asian: 1 Native Hawaiian or other Pacific Islander: 0 Multiracial: 1 Not reported: 0 **Racial Designation:** Japanese: 0 **Phase 2/3 Immunobridging Subset 16-25 years of age[d]:** ***BNT162b2 Group*:** **Sex:** Male: 92 Female: 94		

Table 1. Listing of All Clinical Studies Included in This Submission

Protocol No. Phase (Country)	Sponsor (Agent)	Study Design and Objective(s)[a]	Treatment Groups	No. of Participants	Demographics (by Phase)	Study Start/ Status	Study Synopsis
					Age (years): **Mean/median**: 20.6/21.0 **Min, max:** 16, 25 **Race:** White: 147 Black or African American: 15 American Indian or Alaska native: 3 Asian: 10 Native Hawaiian or other Pacific Islander: 3 Multiracial: 6 Not reported: 2 **Racial Designation:** Japanese: 0 ***Placebo Group:*** **Sex:** Male: 14 Female: 18 **Age (years)**: **Mean/median**: 20.3/19.5 **Min, max:** 16, 25		

Table 1. Listing of All Clinical Studies Included in This Submission

Protocol No. Phase (Country)	Sponsor (Agent)	Study Design and Objective(s)[a]	Treatment Groups	No. of Participants	Demographics (by Phase)	Study Start/ Status	Study Synopsis
					Race: White: 28 Black or African American: 2 American Indian or Alaska native: 1 Asian: 1 Native Hawaiian or other Pacific Islander: 0 Multiracial: 0 Not reported: 0 **Racial Designation:** Japanese: 0		

a. Primary study objectives specific to the analyses for the interim 6-month update adolescent CSR.
b. Participants 12-15 years of age who originally received placebo and became eligible for receipt of BNT162b2 had an opportunity to receive BNT162b2 as part of the study.
c. C4591001 safety population, cutoff date: 02 September 2021.
d. C4591001 Dose 2 evaluable immunogenicity population, cutoff date: 13 March 2021.

Document Approval Record

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Signed By:	Date(GMT)	Signing Capacity
Perez, John	09-Dec-2021 20:16:45	Final Approval