1. TABULAR LISTING OF CLINICAL STUDIES INCLUDED IN THE MARKETING AUTHORIZATION APPLICATION

Information is provided for the clinical study included in the present Type II Variation for Comirnaty (BNT162b2).

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

Data are included from the 16 through 25 years of age and the 16 through 55 years of age strata for comparative purposes.

Study information and data for participants >55 years of age are not in scope for the present submission and are not presented here.

Table 1. Section 5.2. Listing of All Clinical Studies

Protocol No. Phase (Country)	Sponsor	Study Design and Objective(s)[a]	Treatment Groups	No. of Subjects	Demographics (by Phase)	Study Start/ Status	Study Synopsis
C4591001 Phase 1/2/3 (United States, Argentina, Brazil, Turkey, South Africa, Germany)	BioNTech (Pfizer)	**Phase 2/3 Primary Objectives:** • **Efficacy:** To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID 19 occurring from 7 days after the second dose in participants without evidence of infection before vaccination • **Efficacy:** To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants with and without evidence of infection before vaccination • **Safety:** To define the safety profile of prophylactic BNT162b2 in <u>all participants</u> randomized in Phase 2/3	**Phase 2/3: BNT162b2** (30 µg) Placebo[b]	**Phase 3:** 2260 (12-15 years of age) randomized 1:1 **Phase 2/3:** 3770 (16-25 years of age) randomized 1:1 26,164 (16-55 years of age) randomized 1:1 (within each dose/age group) (includes 360 in Phase 2)	**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: 971 Black: 52 American Indian or Alaska native: 4 Asian: 72 Native Hawaiian or other Pacific Islander: 3 Multiracial: 23 Not reported: 6 **Racial Designation:** Japanese: 5 ***Placebo Group:*** **Sex:**	**Start Date:** April 2020 (ongoing)	Interim CSR-Adolescents Synopsis

Table 1. Section 5.2. Listing of All Clinical Studies

Protocol No. Phase (Country)	Sponsor	Study Design and Objective(s)[a]	Treatment Groups	No. of Subjects	Demographics (by Phase)	Study Start/ Status	Study Synopsis
		• **Safety:** To define the safety profile of prophylactic BNT162b2 in participants 12 to 15 years of age in Phase 3			Male: 585 Female: 544 **Age (years):** **Mean/median:** 13.6/14.0 **Min, max:** 12, 15 **Race:** White: 962 Black: 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 Participants 16-25 years of age:** ***BNT162b2 Group:*** **Sex:** Male: 921 Female: 946		

Table 1. Section 5.2. Listing of All Clinical Studies

Protocol No. Phase (Country)	Sponsor	Study Design and Objective(s)[a]	Treatment Groups	No. of Subjects	Demographics (by Phase)	Study Start/ Status	Study Synopsis
					Age (years): Mean/median: 21.0/22.0 **Min, max:** 16, 25 **Race:** White: 1443 Black: 189 American Indian or Alaska native: 32 Asian: 108 Native Hawaiian or other Pacific Islander: 10 Multiracial: 76 Not reported: 9 **Racial Designation:** Japanese: 3 ***Placebo Group:*** **Sex:** Male: 882 Female: 1021 **Age (years): Mean/median:** 21.0/21.0 **Min, max:** 16, 25		

Table 1. Section 5.2. Listing of All Clinical Studies

Protocol No. Phase (Country)	Sponsor	Study Design and Objective(s)[a]	Treatment Groups	No. of Subjects	Demographics (by Phase)	Study Start/ Status	Study Synopsis
					Race: White: 1510 Black: 179 American Indian or Alaska native: 18 Asian: 108 Native Hawaiian or other Pacific Islander: 3 Multiracial: 74 Not reported: 11 **Racial Designation:** Japanese: 6 **Phase 2/3[c] Participants 16-55 years of age (totals):** **Sex:** Male: 13,052 Female: 13,112 **Age (years):** **Mean/median:** 38.9/40.0 **Min, max:** 16, 55 **Race:** White: 20,472		

Table 1. Section 5.2. Listing of All Clinical Studies

Protocol No. Phase (Country)	Sponsor	Study Design and Objective(s)[a]	Treatment Groups	No. of Subjects	Demographics (by Phase)	Study Start/ Status	Study Synopsis
					Black: 2865 American Indian or Alaska native: 318 Asian: 1415 Native Hawaiian or other Pacific Islander: 64 Multiracial: 875 Not reported: 155 **Racial Designation:** Japanese: 80		

a. Primary study objectives specific to the analyses for the interim adolescents CSR.
b. Participants ≥16 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: 13 March 2020.