1. TABULAR LISTING OF CLINICAL STUDIES INCLUDED IN THE BIOLOGICS LICENSE APPLICATION

Information is provided for each of the clinical studies included in the Biologics License Application (BLA) for 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 BLA.

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
BNT162-01 Phase 1 (Germany)	BioNTech	**Primary Objective:** • To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after Dose 1 only or after both Dose 1 and Dose 2 **Secondary Objective:** • To describe the immune response in healthy adults after Dose 1 only or after Dose 1 and Dose 2 measured by a functional antibody titer, eg, virus neutralization test (VNT) or an equivalent assay available by the time of study conduct **Exploratory Objectives**: • To describe the immune response in healthy adults after Dose 1 only or after Dose 1 and Dose 2 measured by an	**BNT162b1** (1, 3, 10, 20, 30, 50, and 60 µg)	**Phase 1**: 120 **BNT162b1** **Phase 1**: 96 **BNT162b2**	**Phase 1 BNT162b1: Participants 18 – 55 years of age: Sex:** Male: 44 Female: 40 **Age (years): Mean/median**: 38.30/36.29 **Min, max:** 19.9, 55.8 **Race:** White: 81 Black: 1 Asian: 2 **Participants 56 – 85 years of age: Sex:** Male: 13 Female: 23 **Age (years): Mean/median**: 65.71/67.21 **Min, max:** 56.1, 76.8	**Start Date:** April 2020 (ongoing)	BNT162-01 Interim CSR Synopsis

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Protocol No. Phase (Country)	Sponsor	Study Design and Objective(s)[a]	Treatment Groups	No. of Subjects	Demographics (by Phase)	Study Start/ Status	Study Synopsis
		antibody binding assay, eg, enzyme-linked immunosorbent assay (ELISA) or an equivalent assay available by the time of study conduct. • To describe the cell-mediated immune (CMI) responses, eg, by enzyme-linked immunosorbent-spot (ELISpot) and intracellular cytokine staining (ICS).	**BNT162b2** (1, 3, 10, 20, and 30 µg)		**Race:** All participants were White **Phase 1 BNT162b2: Participants 18 – 55 years of age: Sex:** Male: 26 Female: 34 **Age (years): Mean/median:** 40.26/41.50 **Min, max:** 19.0, 55.8 **Race:** All participants were White. **Participants 56 – 85 years of age: Sex:** Male: 18 Female: 18 **Age (years): Mean/median:** 65.06/65.29 **Min, max:** 56.8, 84.0		

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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: All participants were White.		
C4591001 Phase 1/2/3 (United States, Argentina, Brazil, Turkey, South Africa, Germany)	BioNTech (Pfizer)	**Phase 1** **Primary Objective:** • To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses[g] **Secondary Objective:** • To describe the immune responses elicited by prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses[g]	**Phase 1:** **BNT162b1** (10, 20, 30, and 100 µg) Placebo[b]	**Phase 1**: 105 randomized 4:1 (within each dose/age group)	**Phase 1:**[c] **18-55 year group, 100 µg & placebo** **Sex:** Male: 6 Female: 9 **Age (years):** **Mean/median:** 37.1/35.0 **Min, max:** 19, 53 **Race:** White: 14 Black: 0 Asian: 1 **Phase 1:**[c] **18-55 year group, 10, 20, 30 µg & placebo** **Sex:** Male: 28 Female: 17	**Start Date:** April 2020 (ongoing)	C4591001 Final Analysis Interim CSR 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
					Age (years): Mean/median: 36.9/35.0 **Min, max:** 22, 54 **Race:** White: 37 Black: 2 Asian: 6 **Phase 1:**[c] **65-85 year group 10, 20, 30 µg & placebo: Sex:** Male: 13 Female: 32 **Age (years): Mean/median:** 69.7/69.0 **Min, max:** 65, 82 **Race:** White: 42 Black: 1 Asian: 2		
			Phase 1: BNT162b2 (10, 20, and 30 µg)	**Phase 1**: 90 randomized 4:1 (within each dose/age group)	**Phase 1:** [c] **18-55 year group, 100 µg & placebo**		

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
			Placebo[b]		**Sex:** Male: 28 Female: 17 **Age (years):** **Mean/median:** 36.9/35.0 **Min, max:** 22, 54 **Race:** White:37 Black: 2 Asian: 6 **Phase 1:**[c] **18-55 year group:** **Sex:** Male: 19 Female: 26 **Age (years):** **Mean/median:** 36.7/37.0 **Min, max:** 19,54 **Race:** White: 39 Black: 3 Asian: 3 **Phase 1:**[c] **65-85 year group:**		

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
					Sex: Male: 17 Female: 28 **Age (years):** **Mean/median:** 69.3/68.0 **Min, max:** 65, 81 **Race:** All participants were White.		
		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[g] • **Efficacy:** To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose	**Phase 2:** **BNT162b2** (30 µg) Placebo[b]	**Phase 2**: 360 randomized 1:1	**Phase 2**[d] **18-85 year group:** **Sex:** Male: 190 Female: 170 **Age (years):** **Mean/median:** 52.6/56.0 **Min, max:** 18, 85 **Race:** White: 309 Black: 33 American Indian or Alaska native: 2 Asian: 9 Multiracial: 3 Not reported: 4		

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
		in participants with and without evidence of infection before vaccination[g] • **Safety:** To define the safety profile of prophylactic BNT162b2 in the first 360 participants randomized (Phase 2)[h] • **Safety:** To define the safety profile of prophylactic BNT162b2 in all participants randomized in Phase 2/3[g] **Phase 2/3 Secondary Objectives:** • **Efficacy:** To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants without evidence of infection before vaccination[i]	**Phase 2/3:** **BNT162b2** (30 µg) Placebo[b]	**Phase 2/3:** 43,448 randomized 1:1 (includes 360 in Phase 2)	**Phase 2/3**[e] **Sex:** Male: 22,125 Female: 21,323 **Age (years):** **Mean/median:** 50.0/51.0 **Min, max:** 16, 91 **Race:** White: 35,696 Black: 4198 American Indian or Alaska native: 319 Asian: 1864 Native Hawaiian or other Pacific Islander: 88 Multiracial: 1050 Not reported: 233		
C4591001 Phase 1/2/3 (United States, Argentina, Brazil, Turkey, South Africa, Germany)				**Phase 2/3:** 44,047 randomized 1:1 (includes 360 in Phase 2)	**Phase 2/3**[f] **Participants ≥16 years of age:** **Sex:** Male: 22,420 Female: 21,627 **Age (years):** **Mean/median:**		Interim CSR – 6-Month Update Synopsis

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Protocol No. Phase (Country)	Sponsor	Study Design and Objective(s)[a]	Treatment Groups	No. of Subjects	Demographics (by Phase)	Study Start/ Status	Study Synopsis
		• **Efficacy:** To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination[j] • **Efficacy:** To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination[i] • **Efficacy:** To describe the efficacy of prophylactic			49.7/51.0 **Min, max:** 16, 91 **Race:** White: 36,120 Black: 4216 American Indian or Alaska native: 438 Asian: 1894 Native Hawaiian or other Pacific Islander: 90 Multiracial: 1083 Not reported: 206 Racial designation: Japanese: 156		

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Protocol No. Phase (Country)	Sponsor	Study Design and Objective(s)[a]	Treatment Groups	No. of Subjects	Demographics (by Phase)	Study Start/ Status	Study Synopsis
		BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination[i] • **Exploratory Objectives:** To evaluate the immune response over time to prophylactic BNT162b2 and persistence of immune response in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination[h] • To describe the safety, immunogenicity, and efficacy of prophylactic					

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Protocol No. Phase (Country)	Sponsor	Study Design and Objective(s)[a]	Treatment Groups	No. of Subjects	Demographics (by Phase)	Study Start/ Status	Study Synopsis
		BNT162b2 in individuals with confirmed stable HIV disease[k]					

a. Includes only the objectives addressed in the submission.
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: 24 August 2020
d. C4591001 safety population, cutoff date: 02 September 2020.
e. C4591001 safety population, cutoff date: 14 November 2020.
f. C4591001 safety population, cutoff date: 13 March 2021.
g. Reported in the final analysis interim CSR with updated data reported in the interim CSR - 6-month update.
h. Interim data are reported in the final analysis interim CSR.
i. Prespecified complete efficacy data reported in final analysis interim CSR.
j. Prespecified complete efficacy data reported in final analysis interim CSR with updated efficacy data (for 7 days after second dose only) reported in the interim CSR – 6-month update.
k. Safety data only in participants with confirmed stable HIV disease are reported in the interim CSR – 6-month update.

Document Approval Record

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Signed By:	Date(GMT)	Signing Capacity
Perez, John	29-Apr-2021 20:25:55	Final Approval