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.

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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
C4591001	BioNTech	Phase 2/3 Primary	Phase 2/3:	Phase 3:	Phase 3 ^c	Start	Interim CSR-
Phase 1/2/3	(Pfizer)	Objectives:	BNT162b2	2260 (12-15	Participants 12-15	Date:	Adolescents
(United States,		• Efficacy: To	(30 µg)	years of age)	years of age:	April 2020	Synopsis
Argentina,		evaluate the efficacy	Placebo ^b	randomized 1:1		(ongoing)	
Brazil, Turkey,		of prophylactic			BNT162b2 Group:		
South Africa,		BNT162b2 against		Phase 2/3:	Sex:	3	
Germany)		confirmed COVID 19		3770 (16-25	Male: 567	1. A.	4 6 2 7 8
		occurring from 7 days		years of age)	Female: 564		
		after the second dose		randomized 1:1			12. 11
		in participants without			Age (years):	1 2 1 2 3	이야 같이 가 있다.
		evidence of infection		26,164 (16-55	Mean/median:		
		before vaccination		years of age)	13.6/14.0	B 22.7	12 E 11 E
				randomized 1:1	Min, max:	- 6 3	
		• Efficacy: To		(within each	12, 15	1. 2. 2. 3	
		evaluate the efficacy		dose/age group)		1.4	
		of prophylactic		(includes 360	Race:		18 A P
		BNT162b2 against		in Phase 2)	White: 971		
		confirmed COVID-19			Black: 52		
		occurring from 7 days			American Indian or	-12 8.2	S. S
		after the second dose			Alaska native: 4	18 2 2	
		in participants with			Asian: 72		(영향 : 문)
		and without evidence			Native Hawaiian or	1.134 E.c.	A CONTRACTOR
		of infection before			other Pacific		
		vaccination			Islander: 3	- 7 - · E/S	사람을 가지 않는
					Multiracial: 23		122 - 21
		• Safety: To define the			Not reported: 6		
		safety profile of					
		prophylactic			Racial		
		BNT162b2 in <u>all</u>			Designation:		
		participants			Japanese: 5		
		randomized in Phase					N 9 / 6 E
		2/3			Placebo Group:		8-2 8 f
					Sex:	1.0	

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			Male: 585 Female: 544		
		BNT162b2 in participants 12 to 15			Age (years): Mean/median:		
		years of age in Phase 3			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:		
					<i>BNT162b2 Group:</i> Sex:		
Contractor "		essilvepetion.			Male: 921 Female: 946	2040	

Table 1. Section 5.2. Listing of All Clinical Studies

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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
					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 <i>Placebo Group:</i> Sex: Male: 882		
					Female: 1021 Age (years): Mean/median: 21.0/21.0		
1000000		conferencess,			Min, max: 16, 25		

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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: 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:		
and a second s	le Les Ferres de	En equencies registration		a setue de const	Japanese: 6	atternate	
					Phase 2/3° 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		
		concertio.			Race: White: 20,472	School States	

 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		Contraction in the second
					Alaska native: 318		
					Asian: 1415		
					Native Hawaiian or		
1.1.1.1.1.1.1.1.1					other Pacific		
					Islander: 64		
					Multiracial: 875		
					Not reported: 155		
					Racial		
					Designation:		
				and the second second	Japanese: 80		
. Primary stuc	ly objectives s	pecific to the analyses for	the interim adoles	cents CSR.			
		ge who originally receive			pt of BNT162b2 had ar	n opportunity	to receive BNT162
s part of the stu				-	anthones a local second		
C4591001 s	afety populatio	on, cutoff date: 13 March	2020				

Table 1. Section 5.2. Listing of All Clinical Studies