BNT162b2 (COMIRNATY)

BLA STN 125742/0

Response to CBER 20 August Information Request –

Study C4591001 Frequency of Adverse Events by Age Group and Overall By Study Period in Blinded Follow-up

20 August 2021

1. INTRODUCTION

Reference is made to BLA STN 125742/0 for COVID-19 mRNA Vaccine (COMIRNATY), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age and to CBER's Information Request received via email on 20 August 2021.

CBER requests are presented in ***bold italics*** followed by Pfizer-BioNTech response in plain text.

2. REQESTS

2.1. Request 1

Please complete the following table to summarize the numbers and percentages of BNT162b2 and placebo recipients, by age group and study period, who reported the indicated categories of unsolicited adverse events during blinded follow-up in study C4591001. Please use denominators of the corresponding population in each column and please do not report percentages in 100/PY.

Response

The requested table is provided as Table 1.

Table 1. Number (%) of Subjects Reporting at Least 1 Adverse Event After Dose 1 - Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	BNT162b2 (30 µg)			Placebo		
	≥16-55 Years (N^a=12995)	>55 Years (N^a=8931)	Total (N^a=21926)	≥16-55 Years (N^a=13026)	>55 Years (N^a=8895)	Total (N^a=21921)
Adverse Event	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**
From Dose 1 through 1 Month after Dose 2						
Any unsolicited adverse event	4233 (32.6)	2384 (26.7)	6617 (30.2)	1871 (14.4)	1177 (13.2)	3048 (13.9)
Unsolicited non-serious adverse events	4207 (32.4)	2350 (26.3)	6557 (29.9)	1855 (14.2)	1141 (12.8)	2996 (13.7)
Serious adverse events	52 (0.4)	75 (0.8)	127 (0.6)	49 (0.4)	67 (0.8)	116 (0.5)
Withdrawal due to unsolicited adverse events	19 (0.1)	13 (0.1)	32 (0.1)	20 (0.2)	16 (0.2)	36 (0.2)
Death	0 (0.0)	3 (0.0)	3 (0.0)	2 (0.0)	3 (0.0)	5 (0.0)
From Dose 1 to cutoff date or participant unblinding (whichever is earlier)[c]						
Any unsolicited adverse event	4396 (33.8)	2551 (28.6)	6947 (31.7)	2136 (16.4)	1432 (16.1)	3568 (16.3)
Unsolicited non-serious adverse events	4347 (33.5)	2471 (27.7)	6818 (31.1)	2086 (16.0)	1347 (15.1)	3433 (15.7)
Serious adverse events	103 (0.8)	165 (1.8)	268 (1.2)	117 (0.9)	151 (1.7)	268 (1.2)
Withdrawal due to unsolicited adverse events	22 (0.2)	23 (0.3)	45 (0.21)	28 (0.2)	23 (0.3)	51 (0.2)
Death	3 (0.0)	12 (0.1)	15 (0.1)	4 (0.0)	10 (0.1)	14 (0.1)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Cutoff date: 13 March 2021; unblinding date varied depending on subject contact date for unblinding.

Document Approval Record

Document Name:	COVID-19 vaccine Response to FDA - AE frequency table 16+ - 20 August 2021
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Signed By:	Date(GMT)	Signing Capacity
Perez, John	20-Aug-2021 22:26:42	Final Approval