COVID-19 Vaccine (BNT162, PF-07302048; COMIRNATY)

BLA STN 125742/45

Response to CBER IR Regarding Cumulative Analysis of Post-Authorization Adverse Event Reports in Individuals Aged Between 12 and 15 Year of Age Received 23 February 2022

01 March 2022

1. INTRODUCTION

Reference is made to the sBLA to extend licensure of COMIRNATY to adolescents 12 through 15 years of age submitted to FDA on 16 Dec 2021 (Sequence number 0211).

On 23 February 202, Pfizer/BioNTech received the following request from the FDA regarding BLA 125742/45, Module 5.3. from Captain Mike Smith, PhD (CBER).

The FDA's request is presented in ***bold italics*** followed by Pfizer/BioNTech's response in plain text.

2. FDA INFORMATION REQUEST

We are reviewing the Cumulative Analysis of Post-Authorization Adverse Event Reports in Individuals Aged Between 12 and 15 Year of Age (BLA 125742/45, Module 5.3.6, dated December 1, 2021; received December 16, 2021) and have the following information requests.

2.1. Item 1

The cumulative analysis shows 18 adverse events reports with fatal outcomes among individuals 12-15 years of age. Please provide preferred terms and narratives for each of these fatal reports and indicate how many and which of the reports were U.S. vs foreign.

Response:

Out of the 3,320 case reports involving individuals 12-15 years of age, there were 18 case reports (45 events) with a fatal outcome. Narratives of the 5 case reports originated from the United States (US) are presented in Appendix 1 and those related to the 13 case reports from foreign countries excluding US are presented in Appendix 2.

The Preferred Terms (PTs) coded in these fatal cases included: Death (9), Sudden death (4), Pyrexia, Respiratory failure and Septic shock (2 each), Anuria, Asthenia, Blood creatinine increased, Brain death, Brain hypoxia, Cardiac arrest, Cardiomegaly, Cardio-respiratory arrest, Circulatory collapse, Coma, Disseminated intravascular coagulation, Dyspnoea, Headache, Hepatic failure, Inappropriate schedule of product administration, Intra-abdominal haemorrhage, Malaise, Multiple organ dysfunction syndrome, Pain in extremity, Pericardial effusion, Platelet count decreased, Pulmonary haemorrhage, Pulmonary oedema, Status epilepticus, Thoracic haemorrhage, Urinary bladder haemorrhage (1 each). A fatal clinical outcome was reported for the PTs Death (9), Sudden death (4), Septic shock (2), Brain hypoxia, Cardiac arrest, Cardiomegaly, Cardio-respiratory arrest, Circulatory collapse, Disseminated intravascular coagulation, Multiple organ dysfunction syndrome, Pericardial effusion, Pulmonary haemorrhage, Pulmonary oedema, Pyrexia, Respiratory failure, and Thoracic haemorrhage (1 each).

2.2. Item 2

The cumulative analysis indicates that 1,215 serious reports were received for individuals 12-15 years of age. Please provide the number of serious reports that were U.S. vs. foreign.

Response:

Out of the 1,215 serious case reports, there were 259 case reports originated from the US and 956 case reports originated from foreign countries excluding US.

3. APPENDICES

Appendix 1. Summary of Post-authorization or Post-approval AE Report: BNT162b2 12-15 Years of Age with a fatal Outcome (01 December 2020 through 30 September 2021) - United States

Appendix 2. Summary of Post-authorization or Post-approval AE Report: BNT162b2 12-15 Years of Age with a fatal Outcome (01 December 2020 through 30 September 2021) - Foreign Countries (Excluding US)

Document Approval Record

Document Name:	COVID-19 Vaccine: Response to CBER IR Regarding Cumulative Analysis of Post-Authorization Adverse Event Reports in Individuals Aged Between 12 and 15 Year of Age
Document Title:	COVID-19 Vaccine: Response to CBER IR Regarding Cumulative Analysis of Post-Authorization Adverse Event Reports in Individuals Aged Between 12 and 15 Year of Age

Signed By:	Date(GMT)	Signing Capacity
Maroko, Robert T	01-Mar-2022 14:45:53	Business Line Approver
Webber, Chris	01-Mar-2022 16:03:05	Final Approval