Approval Date: December 11, 2020

Product: Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY (EU Name)

Proper Name: COVID-19 mRNA vaccine (nucleoside-modified)

Manufacturer: Pfizer Inc.

Indication: The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 16 years of age and older.

Description: The active substance consists of a single-stranded, 5'-capped mRNA that is translated into a codon-optimized sequence encoding the spike antigen of SARS-CoV-2. The vaccine is based on the spike glycoprotein (S) of SARS-CoV-2.

BLA:

Regulatory Milestone:

On November 20, 2020, the Sponsor (Pfizer, on behalf of Pfizer and BioNTech) submitted an Emergency Use Authorization (EUA) request to FDA for an investigational COVID-19 vaccine (BNT162b2). A meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) was convened on December 10, 2020.

PDUFA Goal Date: -

EMA approval: December 21, 2020

Package Insert: Comirnaty : EPAR - Product Information

Summary Basis for Regulatory Approval:

European Public Assessment Report: Comirnaty: EPAR - Public assessment report

Manufacturing Platform:

PARAMETER	DATA	REFERENCE
Manufacturer	Pfizer Inc.	
Transgene	-	
Indication	Comirnaty is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older.	3
Virus and Serotype	mRNA	2
Cell Substrate	-	
Manufacturing platform	The RNA is synthesized from linear DNA via an in vitro transcription (IVT) step. The IVT step is followed by a number of purification and filtration steps. Lastly, the RNA undergoes a final filtration before being dispensed and stored frozen.	3
Dose in vial/final container	One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution. 1 dose (0.3 mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).	1
Dose / patient	30 µg of RNA in 0.3 mL	1

1. Package insert: Comirnaty: EPAR - Product Information
2. EPAR full: Comirnaty: COVID-19 mRNA vaccine (nucleoside-modified)
3. EPAR quality: Comirnaty: EPAR - Public assessment report

Advisory Committee:

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) convened on December 10, 2020, to discuss Pfizer's EUA request. The committee discussed potential implications of loss of blinded, placebo-controlled follow-up in ongoing trials including how this may impact availability of safety data to support a biologics license application. Some pointed out the importance of long-term safety data for the PfizerBioNTech COVID-19 Vaccine as it is made using a technology not used in previously licensed vaccines. The committee voted in favor of a determination that based on the totality of scientific evidence available, the benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its risks for use in individuals 16 years of age and older.

Safety:

NCT Numbers:

NCT	TITLE	COUNTRIES
NCT04368728	Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals	United States, Argentina, Brazil, Germany, South Africa, Turkey
NCT04380701	A Trial Investigating the Safety and Effects of Four BNT162 Vaccines Against COVID-2019 in Healthy Adults	Germany

EudraCT Numbers:

Publications: