Approval Date: December 18, 2020

Product: Moderna COVID-19 Vaccine

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

Manufacturer: ModernaTX, Inc.

Indication: COVID-19 Vaccine Moderna is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. The use of this vaccine should be in accordance with official recommendations.

Description: Single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

BLA:

Regulatory Milestone:

November 30, 2020, ModernaTX (the Sponsor, also referred to as Moderna) submitted an Emergency Use Authorization (EUA) request to FDA for an investigational COVID-19 vaccine.

PDUFA Goal Date:

EMA Approval:

Package Insert: COVID-19 Vaccine Moderna: EPAR - Product information

Summary Basis for Regulatory Approval:

European Public Assessment Report: COVID-19 Vaccine Moderna : EPAR - Public assessment report

Manufacturing Platform:

PARAMETER	DATA	REFERENCE
Manufacturer	ModernaTX, Inc.	
Transgene	-	
Indication	COVID-19 Vaccine Moderna is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. The use of this vaccine should be in accordance with official recommendations.	3
Virus and Serotype	mRNA	2
Cell Substrate	-	
Manufacturing platform	The uncapped mRNA is transcribed from linear DNA utilizing an in vitro transcription (IVT) reaction followed by purification and filtration steps. Next, mRNA is enzymatically capped followed by additional purification and filtration steps. Finally, CX-214414 mRNA is filtered, dispensed, and stored.	3
Dose in vial/final container	each vial contains sufficient volume to extract 10 doses of 0.5 mL each. One dose (0.5 mL) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles).	1
Dose / patient	two 0.5 mL doses. Second dose administered 28 days after the first dose.	1

1. Package insert: COVID-19 Vaccine Moderna: EPAR - Product information
2. EPAR full: COVID-19 Vaccine Moderna
3. EPAR quality: COVID-19 Vaccine Moderna : EPAR - Public assessment report

Advisory Committee:

A meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) was convened on December 17, 2020. Following a discussion of the data presented, the VRBPAC voted 20-1 (with 1 abstention) in favor of the determination that based on the totality of scientific evidence available, the benefits of the Moderna COVID-19 Vaccine outweigh its risks for use in individuals 18 years of age and older. The review team therefore recommends issuance of an EUA for use of the Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

Safety:

Clinical Trials:

NCT	TRIAL PHASE	SUBJECTS ENROLLED	TITLE	COUNTRIES
NCT04405076	2	600	Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 COVID-19 Vaccine in Adults Aged 18 Years and Older	United States
NCT04470427	3	30000	A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19	United States
NCT04649151	2, 3	3000	A Study to Evaluate the Safety, Reactogenicity, and Effectiveness of mRNA-1273 Vaccine in Adolescents 12 to <18 Years Old to Prevent COVID-19 (TeenCove)	United States

EudraCT Numbers:

Publications: