CLINICAL UPDATE

Brand Name	Comirnaty®
Generic Name	covid-19 Vaccine, mRNA
Drug Manufacturer	Pfizer Inc.

Clinical Update

TYPE OF CLINICAL UPDATE

New Brand

FDA APPROVAL DATE

August 23, 2021

LAUNCH DATE

August 25, 2021

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Biologics License Application (BLA)

DISPENSING RESTRICTIONS

Open distribution

Overview

INDICATION(S) FOR USE

Comirnaty® is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

MECHANISMS OF ACTION

The nucleoside-modified mRNA in Comirnaty® is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

DOSAGE FORM(S) AND STRENGTH(S)

Suspension for injection. After preparation, a single dose is 0.3 mL.

DOSE & ADMINISTRATION

- For intramuscular injection only.
- Comirnaty® is administered intramuscularly as a series of 2 doses (0.3 mL each) 3 weeks apart.

CLINICAL UPDATE

EFFICACY

Table 1. Comirnaty® Studies 1 and 2 Summary

Study 1	Study 2

• Phase 2
• 2-part, dose-escalation trial
• Participants were 18–55 years of age (n = 60) and 56–85 years of age (n = 36)
• Conducted in Germany
	• Ongoing Phase ½/3 multicenter, multinational, randomized, saline placebo–controlled, double-blinded (Phase 2/3), dose-finding, vaccine candidate–selection and efficacy study
	• 44,047 participants (22,026 Comirnaty®; 22,021 placebo)
	• Participants 16 years of age or older who received Comirnaty® or placebo, respectively.
	  ○ Male: 51.4% or 50.3%
	  ○ Female: 48.6% or 49.7%
	  ○ 16–64 years of age: 79.1% or 79.2%
	  ○ 65 years of age and older: 20.9% or 20.8%
	  ○ White: 81.9% or 82.1%
	  ○ Black/African American: 9.5% or 9.6%
	  ○ American Indian or Alaska Native: 1.0% or 0.9%
	  ○ Asian: 4.4% or 4.3%
	  ○ Native Hawaiian/Pacific Islander: 0.3% or 0.2%
	  ○ Hispanic/Latino: 25.6% or 25.4%
	  ○ Non-Hispanic/Latino: 73.9% or 74.1%
	  ○ No ethnicity reported: 0.5% or 0.5%
	  ○ Comorbidities: 46.0% or 45.7%
	  ○ Mean age at vaccination: 49.8 or 49.7 years
	  ○ Median age: 51.0 years (both groups)
	• 200 participants with confirmed stable* HIV infection were also included†
	• Upon issuance of the EUA for Comirnaty®, participants were unblinded in a phased manner over a period of months to offer placebo participants Comirnaty®
	• Conducted in the United States, Argentina, Brazil, Turkey, South Africa, and Germany
	• **Key exclusion criteria:** participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19 were excluded.

Interventions	Study 2 will continue until participants are followed for up to 24 months, for assessments of safety and efficacy against COVID-19

<table>
<tr><td>Endpoints</td><td>First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection</td></tr>
<tr><td colspan="2">Table 1. Comirnaty® Studies 1 and 2 Summary</td></tr>
<tr><td>Study 1</td><td>Study 2</td></tr>
<tr><td>Efficacy Results</td><td>
<table>
<tr><th colspan="4">Vaccine Efficacy: First COVID-19 Occurrence from 7 Days After Dose 2 in Participants with or Without Evidence of Prior SARS-CoV-2 Infection</th></tr>
<tr><th>Subgroup</th><th>Comirnaty® (n = 21,047)</th><th>Placebo (n = 21,210)</th><th>Vaccine Efficacy %</th></tr>
<tr><td>All participants</td><td>81 cases</td><td>854 cases</td><td>90.9%</td></tr>
<tr><td>16–64 years of age</td><td>74 cases</td><td>726 cases</td><td>90.2%</td></tr>
<tr><td>≥65 years of age</td><td>7 cases</td><td>128 cases</td><td>94.7%</td></tr>
</table>
<table>
<tr><th colspan="4">Vaccine Efficacy: First Severe COVID-19‡ Occurrence</th></tr>
<tr><th></th><th>Comirnaty® Cases</th><th>Placebo Cases</th><th>Vaccine Efficacy %</th></tr>
<tr><td>7 days after Dose 2</td><td>1</td><td>21</td><td>95.3%</td></tr>
<tr><th colspan="4">Vaccine Efficacy: First Severe COVID-19‡ Occurrence Based on CDC Definition</th></tr>
<tr><td>7 days after Dose 2</td><td>0</td><td>31</td><td>100%</td></tr>
</table>
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Abbreviations: BMI, body mass index; CDC, Centers for Disease Control and Prevention; EUA, emergency use authorization; HIV, human immunodeficiency virus

*Confirmed stable HIV infection was defined as documented viral load <50 copies/mL and CD4 count >200 cells/mm^3 within 6 months before enrollment, and on stable antiretroviral therapy for at least 6 months.

†HIV-positive participants are included in safety population disposition but are summarized separately in safety analyses.

Overall, Comirnaty® efficacy was 90.9% versus placebo; the subgroup analyses did not show any meaningful differences in efficacy across gender, ethnic groups, geographies, or for participants with obesity or medical comorbidities associated with high risk of severe COVID-19. Vaccine efficacy for severe COVID-19 ranged between 95.3% and 100% based on protocol or CDC definition from 6 days after Dose 2. Although data from the study were collected prior to the delta variant becoming the dominant strain in the United States.