Transcript Details

This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/the-drug-report/another-covid-19-vaccine-milestone-reached/12119/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Another COVID-19 Vaccine Milestone Reached

Announcer:
You're listening to The Drug Report on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to The Drug Report. December 18, 2020 marked another important milestone in the worldwide battle against the invisible enemy of COVID-19. The U.S. Food and Drug Administration determined that the statutory criteria have been met for the Moderna COVID-19 Vaccine and issued an emergency use authorization to allow its distribution in the U.S. for use in individuals age 18 years and older. This is the second vaccine that has achieved the EUA designation for the prevention of the coronavirus disease 2019 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

FDA Commissioner Stephen M. Hahn, M.D. stated, “Through the FDA’s open and transparent scientific review process, two COVID-19 vaccines have been authorized in an expedited timeframe while adhering to the rigorous standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization that the American people have come to expect from the FDA.The FDA also announced, “The totality of the available data provides clear evidence that the Moderna COVID-19 Vaccine may be effective in preventing COVID-19.”

Both efficacy and safety data were carefully evaluated.

The determination of vaccine effectiveness was based upon analysis of 28,207 participants in the ongoing randomized, placebo-controlled U.S. study of individuals who did not have evidence of SARS-CoV-2 infection prior to the first dose of vaccine. 14,134 participants received the vaccine and 14,073 received placebo. The vaccine was 94.1% effective in preventing COVID-19 disease among these clinical trial participants with 11 cases of COVID-19 in the vaccine group and 185 in the placebo group, with none in the vaccine group and 30 in the placebo group classified as severe. After the analysis of these 196 cases was completed, one severe case in the vaccine group was identified and is awaiting confirmation. At this time, data are not available to determine how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each) 1 month apart.

Vaccine safety data used to justify issuance of the EUA was based on an analysis of 30,351 participants enrolled in an ongoing randomized, placebo-controlled study conducted in the U.S. These participants, 15,185 of whom received the vaccine and 15,166 of whom received saline placebo, were followed for a median of more than two months after receiving the second dose. The most commonly reported side effects, which typically lasted several days, were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, swollen lymph nodes in the same arm as the injection, nausea and vomiting, and fever. These side effects were experienced more often after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose.

ModernaTX, Inc. and vaccination providers will be required to report the following to the Vaccine Adverse Event Reporting System (VAERS) for Moderna COVID-19 Vaccine: all vaccine administration errors, serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death.

© 2023 ReachMD

ModernaTX, Inc. has submitted a pharmacovigilance plan to FDA to monitor the safety of Moderna COVID-19 Vaccine. The pharmacovigilance plan includes a plan to complete longer-term safety follow-up for participants enrolled in ongoing clinical trials. The pharmacovigilance plan also includes other activities aimed at monitoring the safety profile of the Moderna COVID-19 vaccine and ensuring that any safety concerns are identified and evaluated in a timely manner.

There are a few differences between the Pfizer-BioNTech and Moderna vaccines including storage requirements and spacing of the first and second dose. For more information check out the company websites along with that of the FDA. You will find information for healthcare professionals administering the vaccine including a Fact Sheet for Healthcare Providers and one for recipients and caregivers.

V-safe, the new CDC smart-phone based program for vaccine recipients is also now available. Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safealso provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID- 19 vaccination. For more information, visit: www.cdc.gov/vsafe.

And now, few final but important notes. Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *(see the Full EUA Prescribing Information for further details)*. Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine. Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine. The vaccine may not protect all vaccine recipients.

For The Drug Report, I'm pharmacist, Dr. Linda Bernstein.

Announcer:
To access this episode and others from The Drug Report, visit ReachMD.com/drugreport, where you can be part of the knowledge. Thanks for listening.

© 2023 ReachMD