Transcript Details

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FDA Issues EUA for Pfizer-BioNTech COVID-19 Vaccine

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. The U.S. Food and Drug Administration announced on December 11 that it had issued the first Emergency Use Authorization (EUA) for a vaccine for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. The Emergency Use Authorization allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the U.S.

On December 17, 2020, the Center for Biologics Evaluation and Research's (CBER), Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet in open session to discuss Emergency Use Authorization (EUA) of the Moderna, Inc., COVID-19 Vaccine for the prevention of COVID-19 in individuals 18 years and older.

FDA Commissioner Stephen M. Hahn, M.D. stated, "Today's action follows an open and transparent review process that included input from independent scientific and public health experts and a thorough evaluation by the agency's career scientists to ensure this vaccine met FDA's rigorous, scientific standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization."

Peter Marks, M.D., Ph.D., Director of the FDA's Center for Biologics Evaluation and Research echoed Dr. Hahn's statement, "The tireless work to develop a new vaccine to prevent this novel, serious, and life-threatening disease in an expedited timeframe after its emergence is a true testament to scientific innovation and public-private collaboration worldwide."

The Pfizer-BioNTech COVID-19 Vaccine contains a small piece of the SARS-CoV-2 virus's messenger RNA that instructs cells in the body to make the virus's distinctive "spike" protein. When a person receives this vaccine, their body produces copies of the spike protein, which does not cause disease, but triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2.

The FDA evaluated both safety and effectiveness data.

Pfizer BioNTech COVID-19 Vaccine is administered as a series of two doses, three weeks apart. The available safety data to support the EUA was based upon 37,586 of the participants enrolled in an ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants. These participants, 18,801 of whom received the vaccine and 18,785 of whom received saline placebo, were followed for a median of 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, and fever. Of note, more people experienced these side effects 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.

It is mandatory for Pfizer Inc. and vaccination providers to report the following to the Vaccine Adverse Event Reporting System (VAERS) for Pfizer-BioNTech 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.

The effectiveness data to support the EUA involved an analysis of 36,523 participants in the ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants, who did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Among these participants, 18,198 received the vaccine and 18,325 received placebo. The vaccine was 95%

effective in preventing COVID-19 disease among these clinical trial participants with eight COVID-19 cases in the vaccine group and 162 in the placebo group. Of these 170 COVID-19 cases, one in the vaccine group and three in the placebo group were classified as severe. At this time, data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person.

The CDC has provided a useful website for further information about the vaccine and its administration athttps://www.cvdvaccine-us.com.

Important safety information provided by the CDC for healthcare professionals is as follows.

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)
- Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials. Additional adverse events, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine
- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA” in the description section of the report
- Vaccination providers should review the Fact Sheet for mandatory requirements and Information to Provide Vaccine Recipients/Caregivers and the Full EUA Prescribing Information for Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors
- Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), including Full EUA Prescribing Information available at www.cvdvaccine.com

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

Announcer:
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