FDA Authorizes Monoclonal Antibody for Treatment of COVID-19

Bamlanivimab is now authorized for nonhospitalized people at high risk for progressing to severe COVID-19.

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[On November 9], the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapy bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.

Bamlanivimab is authorized for patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization. This includes those who are 65 years of age or older, or who have certain chronic medical conditions.

While the safety and effectiveness of this investigational therapy continues to be evaluated, bamlanivimab was shown in clinical trials to reduce COVID-19-related hospitalization or emergency room visits in patients at high risk for disease progression within 28 days after treatment when compared to placebo.

Bamlanivimab is not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. A benefit of bamlanivimab treatment has not been shown in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

“As illustrated by today’s action, the FDA remains committed to expediting the development and availability of potential COVID-19 treatments and providing sick patients timely access to new therapies where appropriate, while at the same time supporting research to further evaluate whether they are safe and effective,” said FDA Commissioner Stephen M. Hahn, M.D. “Through our Coronavirus Treatment Acceleration Program, the FDA continues to work around the clock and use every tool at our disposal toward these efforts.”

Monoclonal antibodies are laboratory-made proteins that mimic the immune system’s ability to fight off harmful antigens such as viruses. Bamlanivimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2, designed to block the virus’

attachment and entry into human cells.

“The FDA’s emergency authorization of bamlanivimab provides health care professionals on the frontline of this pandemic with another potential tool in treating COVID-19 patients,” said Patrizia Cavazzoni, M.D., acting director of the FDA’s Center for Drug Evaluation and Research. “We will continue to evaluate new data on the safety and efficacy of bamlanivimab as they become available.”

The issuance of an EUA is different than FDA approval. In determining whether to issue an EUA, the FDA evaluates the available evidence and carefully balances any known or potential risks with any known or potential benefits of the product for use during an emergency. Based on the FDA’s review of the totality of the scientific evidence available, the agency determined that it is reasonable to believe that bamlanivimab may be effective in treating non-hospitalized patients with mild or moderate COVID-19. And, when used to treat COVID-19 for the authorized population, the known and potential benefits outweigh the known and potential risks for the drug. There are no adequate, approved and available alternative treatments to bamlanivimab for the authorized population. As part of the evaluation of the EUA, the agency imposed several quality measures to protect patients. The company is required to implement these quality measures to manufacture this drug under the EUA.

The data supporting this EUA for bamlanivimab are based on an interim analysis from a phase two randomized, double-blind, placebo-controlled clinical trial in 465 non-hospitalized adults with mild to moderate COVID-19 symptoms. Of these patients, 101 received a 700-milligram dose of bamlanivimab, 107 received a 2,800-milligram dose, 101 received a 7,000-milligram dose and 156 received a placebo within three days of obtaining the clinical sample for the first positive SARS-CoV-2 viral test.

The pre-specified primary endpoint in the phase two trial was change in viral load from baseline to day 11 for bamlanivimab versus placebo. Most patients, including those receiving placebo, cleared the virus by day 11. However, the most important evidence that bamlanivimab may be effective came from the predefined secondary endpoint of COVID-19-related hospitalizations or emergency room visits within 28 days after treatment. For patients at high risk for disease progression, hospitalizations and emergency room visits occurred in 3% of bamlanivimab-treated patients on average compared to 10% in placebo-treated patients. The effects on viral load and on reduction in hospitalizations and ER visits, and on safety, were similar in patients receiving any of the three bamlanivimab doses.

The EUA allows for bamlanivimab to be distributed and administered as a single dose intravenously by health care providers. The EUA requires that fact sheets that provide important information about using bamlanivimab in treating COVID-19 be made available to health care providers and to patients and caregivers, including dosing instructions, potential side effects and drug interactions. Possible side effects of bamlanivimab include: anaphylaxis and infusion-related reactions, nausea, diarrhea, dizziness, headache, itching and vomiting.

The EUA was issued to Eli Lilly and Company.

This news release was originally published on the Food and Drug Administration website on November 9, 2020.
