FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Authorizes New Monoclonal Antibody for Treatment of COVID-19 that Retains Activity Against Omicron Variant

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Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) (http://www.fda.gov/media/156151/download) for a new monoclonal antibody for the treatment of COVID-19 that retains activity against the omicron variant. The EUA for bebtelovimab is for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms, which is about 88 pounds) with a positive COVID-19 test, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.

Bebtelovimab is not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. Treatment with bebtelovimab has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bebtelovimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

"Today's action makes available another monoclonal antibody that shows activity against omicron, at a time when we are seeking to further increase supply," said Patrizia Cavazzoni, M.D., director of the FDA's Center for Drug Evaluation and Research. "This authorization is an important step in meeting the need for more tools to treat patients as new variants of the virus continue to emerge."

The issuance of an EUA is different than an FDA approval. In determining whether to issue an EUA, the FDA evaluates the totality of available scientific 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 has determined that it is reasonable to believe that bebtelovimab may be effective in treating certain patients with mild or moderate COVID-19. When used to treat COVID-19 for the authorized population, the known and potential benefits of these antibodies outweigh the known and potential risks. There are no adequate, approved and available alternative treatments to bebtelovimab.

The EUA for bebtelovimab is supported by clinical and nonclinical data. The clinical data are from a phase 2, randomized, single-dose clinical trial (https://clinicaltrials.gov/ct2/show/NCT04634409) evaluating the efficacy of bebtelovimab alone and bebtelovimab combined with other monoclonal antibodies for treating mild to moderate COVID-19.

What you need to know:

- Bebtelovimab works by binding to the spike protein of the virus that causes COVID-19, similar to other monoclonal antibodies that have been authorized for the treatment of high-risk patients with mild to moderate COVID-19 and shown a benefit in reducing the risk of hospitalization or death.
- The FDA is carefully monitoring circulating viral variants and their sensitivity to authorized monoclonal antibodies, including bebtelovimab. Laboratory testing showed that bebtelovimab retains activity against both the omicron variant and the BA.2 omicron subvariant.
- The placebo-controlled portion of the trial enrolled 380 low-risk patients (i.e., patients without risk factors for progression to severe COVID-19 illness). Patients in this part of the trial were randomized to receive a single infusion of bebtelovimab alone, bebtelovimab with other monoclonal antibodies or a placebo. Treatment with bebtelovimab resulted in a reduction in time to sustained symptom resolution compared to placebo. Reduction in viral load relative to placebo was also seen on Day 5 after treatment.
- In another part of the trial involving mostly high-risk individuals (i.e. patients with risk factors for progression to severe COVID-19 illness), 150 patients were randomized to receive a single infusion of bebtelovimab alone or a single infusion of bebtelovimab with other monoclonal antibodies. An additional 176 high-risk patients received bebtelovimab with other monoclonal antibodies in an open-label treatment arm.
- The rates of COVID-19 related hospitalization and death through Day 29 seen in those who received bebtelovimab alone or with other monoclonal antibodies were generally lower than the placebo rate reported in prior trials of other monoclonal antibodies in high risk patients. Conclusions are limited as these data are from different trials that were conducted when different viral variants were circulating and baseline risk factors varied.
- Clinical data were similar for bebtelovimab alone as compared to the combination of bebtelovimab with other monoclonal antibodies.
- Possible side effects of bebtelovimab include itching, rash, infusion-related reactions, nausea and vomiting.
- Serious and unexpected adverse events including hypersensitivity, anaphylaxis and infusion-related reactions have been observed with other SARS-CoV2 monoclonal antibodies and could occur with bebtelovimab. In addition, clinical worsening following administration of other SARS-CoV-2 monoclonal antibody treatment has been reported and therefore is possible with bebtelovimab. It is not known if these events were related to SARS-CoV-2 monoclonal antibody use or were due to progression of COVID-19.

Under the EUA, fact sheets that provide important information about using bebtelovimab treating COVID-19 as authorized must be made available to health care providers (http://www.fda.gov/media/156152/download) and to patients and caregivers (http://www.fda.gov/media/156153/download). These fact sheets include dosing instructions, drug interactions and potential side effects.

Bebtelovimab is not a substitute for vaccination in individuals for whom COVID-19 vaccination and a booster dose are recommended. The FDA has approved two vaccines and authorized others to prevent COVID-19 and the serious clinical outcomes associated with COVID-19, including hospitalization and death. The FDA urges the public to get vaccinated and receive a booster if eligible. Learn more about FDA-approved or -authorized COVID-19 vaccines (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines).

The EUA was issued to Eli Lilly and Co.

Related Information

- Bebtelovimab EUA Letter of Authorization (http://www.fda.gov/media/156151/download)
- Frequently Asked Questions for Bebtelovimab (http://www.fda.gov/media/156154/download)
- Emergency Use Authorization: Drugs and Non-Vaccine Biological Products (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs)
- Coronavirus Treatment Acceleration Program (CTAP) (https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap)
- Coronavirus Disease (COVID-19) (https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19)

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