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FDA approves monoclonal Abs for COVID-19 treatment

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The EUA was issued to Eli Lilly and Co.

The US Food and Drug Administration has issued an emergency use authorisation (EUA) for bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID-19 in adults and paediatric patients (12 years of age or older weighing at least 40 kilograms [about 88 pounds]) who test positive for SARS-CoV-2 and who are at high risk for progressing to severe COVID-19. The authorised use includes treatment for those who are 65 years of age or older or who have certain chronic medical conditions.

In a clinical trial of patients with COVID-19 at high risk for disease progression, a single intravenous infusion of bamlanivimab and etesevimab administered together significantly reduced COVID-19-related hospitalisation and death during 29 days of follow-up compared to placebo. The safety and effectiveness of this investigational therapy for use in the treatment of COVID-19 continue to be evaluated.

Bamlanivimab and etesevimab are not authorised for patients who are hospitalised due to COVID-19 or require oxygen therapy due to COVID-19.

Patrizia Cavazzoni, Acting Director, Center for Drug Evaluation and Research, FDA said, "The data supporting this emergency authorisation add to emerging evidence that points to the clinical utility of neutralising antibodies for the treatment of COVID-19 in certain patients."

The data supporting this EUA for bamlanivimab and etesevimab are based on a randomised, double-blind, placebo-controlled clinical trial in 1,035 non-hospitalised adults with mild to moderate COVID-19 symptoms who were at high risk for progressing to severe COVID-19.

The authorised dosage of 700 milligrams bamlanivimab and 1400 milligrams etesevimab administered together is based on analyses of available preclinical, clinical, and virologic data, as well as pharmacokinetic and pharmacodynamic modelling, which, in totality, support that the authorised dosage is expected to have a similar clinical and virologic effect to 2,800 milligrams bamlanivimab and 2,800 milligrams etesevimab administered together.

On November 9, 2020, the FDA issued an EUA for a single infusion of 700 mg bamlanivimab for the treatment of mild-to-

moderate COVID-19 in adult and certain paediatric patients.

Possible side effects of bamlanivimab and etesevimab administered together include nausea, dizziness, pruritus, and rash.

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