bebtelovimab – Emergency use authorization approval

- On February 11, 2022, the FDA announced the emergency use authorization (EUA) approval of Eli Lilly's bebtelovimab, for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory symptom coronavirus 2 (SARS-CoV-2) viral testing, 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 FDA are not accessible or clinically appropriate.

    - Bebtelovimab is not authorized for treatment of mild-to-moderate COVID-19 in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to this drug and regional variant frequency.
    - Bebtelovimab is not authorized for use in patients who are hospitalized due to COVID-19, or require oxygen therapy and/or respiratory support due to COVID-19, or require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity.
    - Eli Lilly has a government contract for bebtelovimab. The drug is supplied by the federal government and payers cover the administration costs.

- 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.

    - Laboratory testing showed that bebtelovimab retains activity against both the omicron variant and the BA.2 omicron subvariant.

- The EUA was approved based on data from a randomized, single-dose clinical study (BLAZE-4) evaluating the efficacy of bebtelovimab alone and bebtelovimab combined with other monoclonal antibodies for treating mild-to-moderate COVID-19.

    - In the placebo-controlled portion of the trial enrolling 380 low-risk patients, a single infusion of bebtelovimab alone, bebtelovimab with other monoclonal antibodies, or placebo was given. Treatment with bebtelovimab resulted in a reduction in time to sustained symptom resolution vs. placebo. Reduction in viral load vs. placebo was also seen on day 5 after treatment.
    - In other arms of the trial, 326 high-risk patients received a single infusion of bebtelovimab alone or bebtelovimab with other monoclonal antibodies. 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.

- Warnings and precautions for bebtelovimab include hypersensitivity including anaphylaxis and infusion-related reactions; clinical worsening after SARS-CoV-2 monoclonal antibody administration; and limitations of benefit and potential for risk in patients with severe COVID-19.

- The most common treatment-emergent adverse events with bebtelovimab use were infusion-related reactions, pruritus, and rash.

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- The recommended dose of bebtelovimab in adults and pediatric patients (12 years of age and older weighing at least 40 kg) is 175 mg administered as a single intravenous injection over at least 30 seconds. Bebtelovimab should be given as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 7 days of symptom onset.

- Eli Lilly plans to supply 600,000 doses of bebtelovimab to the U.S. government by March 31, 2022. Bebtelovimab will be available as a 175 mg/2 mL (87.5 mg/mL) injectable solution in a single-dose vial.

- The issuance of an EUA is different than FDA approval. In determining whether to issue an EUA, the FDA evaluates the totality of available evidence and carefully balances any known or potential risks with any known or potential benefits of the product for use during an emergency

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