NARFA
NATIONAL AUTOMOTIVE ROADS FUEL ASSOCIATION

Emergency Use Authorization for Bamlanivimab – A Monoclonal Antibody for Treatment of COVID-19

Advances in the fight against SARs-CoV-2 continue with the recent announcement of the FDA's Emergency Use Authorization (EUA)* for Eli Lilly's monoclonal antibody, bamlanivimab. This antibody is designed to block the virus' attachment and entry into human cells. Bamlanivimab is the first therapeutic antibody to receive this designation.

Highlights of the EUA:

- Bamlanivimab is authorized for use in mild to moderate COVID-19 infected patients 12 years of age and older who are at high risk for disease progression and hospitalization
  - o Data supporting the EUA for bamlanivimab are based on an interim analysis from a phase two randomized, placebo-controlled, clinical trial in 465 non-hospitalized adults with mild to moderate COVID-19 symptoms. Although there was no difference between the treatment and placebo groups in viral load over 11 days, the study's primary endpoint, there was a difference in hospitalization and emergency room visits within 28 days after treatment between the groups, the study's secondary endpoint (3% for bamlanivimab-treatment versus 10% placebo-treatment)
- Bamlanivimab is a one-time, 700mg intravenous infusion that must be administered by a healthcare provider as soon as possible after a positive test and within 10 days of symptom onset
- Eli Lilly will begin shipping the drug to AmerisourceBergen (300,000 doses) which will distribute the supply as directed by the US government allocation program. Lilly expects to manufacture up to one million doses of bamlanivimab by the end of 2020 and expects to increase supply during first quarter 2021
- Use of bamlanivimab under the EUA is temporary and will continue as long as data supports its clinical utility. Ongoing studies will determine whether bamlanivimab data supports a formal FDA review and approval

Considerations:

- The recommended use of bamlanivimab is somewhat unclear because high-risk patients have not been specifically defined. This may create confusion as to exactly who should be treated with bamlanivimab
- To be effective the drug needs to be administered soon after the infection is confirmed which is a narrow time window
- Bamlanivimab is not recommended for patients with more advanced or severe COVID-19 infections limiting its usefulness
- The demand for bamlanivimab may eventually decline with the more effective herd immunity that results from large scale vaccination initiatives.
- The federal government will allocate the supply of bamlanivimab based on the number of confirmed COVID-19 cases per state over the previous week
- If the drug should receive FDA approval coverage under the medical benefit would be most appropriate due to the administration requirements
- An EUA for other antibodies such as Regeneron's REGN-COV2 antibody cocktail are under review by the FD

*EUA allows unapproved products or unapproved uses of approved products to be used in emergency situations when no alternatives are available. The EUA is temporary and does not replace the formal FDA review and approval process.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19

*Content comes courtesy of Cambridge Advisory Group