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Monoclonal Antibody Treatment for COVID-19 Receives FDA Authorization

Announcer:
You're listening to The Drug Report on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to The Drug Report.

On November 10, 2020 the U.S. Food and Drug Administration granted an Emergency Use Authorization (EUA) for Eli Lilly and Company's investigational COVID-19 treatment, LY-CoV555, or bamlanivimab 700 mg. Bamlanivimab is a neutralizing IgG1 monoclonal antibody that binds to the receptor binding domain of the spike protein of SARS-CoV-2. The EUA is based on review of data from the preplanned interim analysis of the BLAZE-1 Trial, an ongoing randomized, double-blind, placebo-controlled, Phase 2 dose finding trial of bamlanivimab monotherapy in outpatients with recently diagnosed mild to moderate COVID-19. According to David A. Ricks, Lilly's chairman and CEO, "This emergency authorization allows us to make bamlanivimab available as a COVID-19 treatment for recently diagnosed, high-risk patients – adding a valuable tool for doctors fighting the now-increasing burden of this global pandemic."

The results of the interim analysis, published in the New England Journal of Medicine, October 28, 2020 indicated that patients who received the 2800-mg dose of LY-CoV555 had a significant reduction in viral load by a factor of 3.4 vs. placebo at day 11, the primary outcome. Smaller, non-statistically significant differences in viral load were observed in patients receiving the 700 mg and 7000 mg doses. The authors noted that a decreased viral load at day 11 did not appear to be a clinically meaningful end point since viral load went down in all groups, including placebo, a finding that was consistent with the natural course of the disease. On days 2 to 6, the patients who received the investigational agent had a slightly lower severity of symptoms than those who received placebo, showing a possible treatment effect. There were no substantial differences observed among the three doses. The percentage of patients who had a COVID-19-related hospitalization or visit to an emergency department was 1.6% in the LY-CoV555 group and 6.3% in the placebo group on day 29. In a post-hoc analysis in high-risk subgroups (an age of greater than or equal to 65 years or a BMI of greater than or equal to 35), the percentage of hospitalization was 4.2 percent in the treatment group and 14.6% in the placebo group. Disease symptoms reflected the hospitalization results, with findings that supported a possible reduction in symptoms severity as early as day 2 in the LY-CoV555 group. The safety profile of patients who received LY-CoV555 was similar to that of placebo-treated patients, with adverse effects of mild to moderate severity; thus, the authors felt the treatment is safe. Infusion reactions and other allergic hypersensitivity events have been reported. The authors concluded that in this interim analysis, the patients who received LY-CoV555 had fewer hospitalizations and a lower symptom burden than those who received placebo, with the most notable effects found in high-risk patients.

According to the EUA, bamlanivimab is authorized for the treatment of mild to moderate COVID-19 in adults and pediatric patients who are 12 years of age and older weighing at least 40 kg, with positive results of direct SARS-CoV-2 viral testing, who are at high risk for progressing to severe COVID-19 and/or hospitalization. FDA notes this includes older adults and those with certain chronic medical conditions.

The agent should be administered as soon as possible after a positive COVID-19 test and within 10 days of symptom onset. Bamlanivimab is administered via a single intravenous infusion.

Eli Lilly and Company will supply bamlanivimab to authorized distributors, who will distribute to healthcare facilities or healthcare providers as directed by the U.S. Government, in collaboration with state and local government authorities as needed. It is only to be

prescribed by authorized healthcare providers and may only be administered by health care providers who have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system as needed. The medication must only be administered in accordance with the proper dosing regimen.

Bamlanivimab is not authorized for use in:

- Adults or pediatric patients who are hospitalized due to COVID-19, or
- Adults or pediatric patients who require oxygen therapy due to COVID- 19, or
- Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19 in those patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity.

Product specific information is available in the form of Fact Sheets for Health Care Providers and for Patients, Parents and Parent/Caregivers. Healthcare facilities and healthcare providers receiving bamlanivimab will track serious adverse events that are considered to be potentially attributable to the medication and must report these to FDA in accordance with instruction set forth in the Fact Sheet for Healthcare Providers. Healthcare facilities and healthcare providers must ensure that appropriate storage and cold chain is maintained until the product is administered. Possible adverse effects of bamlanivimab include anaphylaxis and infusion-related reactions, nausea, diarrhea, dizziness, headache, itching, and vomiting.

The U.S. government has purchased 300,000 doses of bamlanivimab and committed that there will be no out-of-pocket cost for Americans taking the medicine although healthcare facilities may charge a fee for the product's administration. The federal government is responsible for the appropriate allocation of bamlanivimab and will allocate quantities based upon confirmed COVID-19 cases in each state and territory over the previous seven days. Product will be distributed by AmerisourceBergen. Lilly anticipates manufacturing up to one million doses of bamlanivimab 700 mg by year's end for use worldwide, with a substantial increase by the first quarter in 2021.

Bamlanivimab has not been approved by the FDA for any use. It is not known if bamlanivimab is safe and effective for the treatment of COVID-19.

It is authorized under an Emergency Use Authorization only for the duration of the declaration that circumstances exist justifying the authorization of emergency use of bamlanivimab under that statute. The authorization is temporary and does not replace the formal review and approval process. Bamlanivimab remains an investigational drug that has not been approved under a Biologics License Application. Research into the safety and efficacy of bamlanivimab is ongoing across a range of patient populations.

FDA Commissioner Stephen M. Hahn, M.D stated, "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. Through our Coronavirus Treatment Acceleration Program, the FDA continues to work around the clock and use every tool at our disposal toward these efforts."

For The Drug Report, I'm pharmacist, Dr. Linda Bernstein.

Announcer:
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