Eli Lilly 公司刚刚通过 EUA 的单克隆抗体 Bamlanivimab。这个单抗在最近的 BLAZE-1 trial 中显示高剂量有效降低体内病毒数量，减少最终的住院率。如果你或家人刚刚被诊断新冠阳性，还没有发展成严重缺氧，但是属于高风险人群。那么你和家人可以申请使用。这是一个 1 小时的静脉输液。只有在急诊可以进行。需由医生为你申请。

Lilly "s 24-hour support line at 1-855-LillyC19 (1-855-545-5921)

Eli Lilly has just passed EUA's monoclonal antibody Bamlanivimab. This monoclonal antibody was shown in the recent BLAZE-1 trial that high doses effectively reduce the number of viruses in the body and reduce the final hospitalization rate. If you or your family members have just been diagnosed as positive for the new crown, you have not developed severe hypoxia, but you are a high-risk group. Then you and your family can apply for it. This is a 1-hour intravenous infusion. It can only be done in the emergency department. The doctor must apply for you.

Please see the attached article for more information!

From The Medical Letter on Drugs and Therapeutics

An EUA for Bamlanivimab—A Monoclonal Antibody for COVID-19

The investigational neutralizing IgG1 monoclonal antibody bamlanivimab (LY-CoV555; Lilly) has been granted an FDA Emergency Use Authorization (EUA) for treatment of recently diagnosed mild to moderate COVID-19 in patients who are ≥12 years old, weigh at least 40 kg, and are at high risk for progressing to severe disease and/or hospitalization (see **Box**).[1]

Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation. Bamlanivimab is not authorized for use in patients who are hospitalized or require oxygen therapy because of COVID-19.

Pronunciation Key

Bamlanivimab: bam' lan i" vi mab

Mechanism of Action

Bamlanivimab binds to the receptor binding domain of the spike protein of SARS-CoV-2, blocking the spike protein's attachment to the human ACE2 receptor.

Clinical Studies

In an interim analysis of an ongoing phase 2 trial (BLAZE-1), 452 outpatients with recently diagnosed mild or moderate COVID-19 (within 3 days of first positive test) were randomized to receive a single IV infusion of one of three doses of LY-CoV555 or placebo. The primary endpoint was the decrease from baseline in SARS-CoV-2 viral load on day 11. The decrease was significantly greater with a 2800-mg dose of the antibody than with placebo, but not with 700- and 7000-mg doses, possibly because most patients, including those treated with placebo, had effectively cleared the virus by day 11.

The predefined secondary endpoint of hospitalization or emergency department visit for COVID-19 by day 29 occurred in 1.6% of antibody recipients and 6.3% of placebo recipients. In a post-hoc analysis of patients at high risk (BMI ≥35 or ≥65 years old) for disease progression, 4 of 95 patients (4%) who were treated with LY-CoV555 were hospitalized or visited the emergency department, compared to 7 of 48 (15%) of those treated with placebo.[2]

Hospitalized Patients

The NIH ACTIV-3 trial, which is evaluating multiple investigational agents in hospitalized patients with COVID-19, stopped randomizing patients to treatment with LY-CoV555 based on an analysis suggesting that the antibody was not beneficial in this population.[3]

Adverse Effects

In the BLAZE-1 trial, nausea occurred in 3.9%, dizziness in 3.2%, and mild infusion reactions in 2.3% of antibody recipients, compared to 3.5%, 2.1%, and 1.4%, respectively, of placebo recipients. According to the FDA's fact sheet for the EUA, one anaphylactic reaction and one serious infusion-related reaction were reported with infusion of bamlanivimab in ongoing, blinded trials.

Dosage and Administration

Bamlanivimab is authorized for administration as a single 700-mg IV infusion over at least 60 minutes. The drug should be given as soon as possible after a SARS-CoV-2 positive test result and within 10 days of COVID-19 symptom onset. Patients should be treated in a facility staffed and equipped to manage anaphylaxis and they should be monitored for hypersensitivity reactions during administration of the drug and for at least 1 hour after completion of the infusion.

The diluted solution for infusion should be used immediately after it is prepared. If immediate use is not possible, it can be stored in the refrigerator for up to 24 hours or at room temperature for up to 7 hours, including infusion time.

Availability

Bamlanivimab will be allocated to state health departments by the US Department of Health and Human Services (HHS) based on case counts and severity of outbreaks. These state health departments will be responsible for allocating the antibody to local health facilities. Finding facilities equipped to administer an IV infusion and capable of managing anaphylaxis while not exposing uninfected patients to SARS-CoV-2 may be difficult.

Box. Eligible Patients Considered High Risk[a]

Patients With ≥1 of the Following:
- BMI ≥35
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease
- Currently receiving immunosuppressive treatment
- ≥65 years old

Patients ≥55 Years Old and ≥1 of the Following:
- Cardiovascular disease
- Hypertension
- COPD or other chronic respiratory disease

Patients 12-17 Years Old and ≥1 of the Following:
- BMI ≥85th percentile for their age and gender[b]
- Sickle cell disease
- Congenital or acquired heart disease
- Neurodevelopmental disorders (eg, cerebral palsy)
- A medical-related technological dependence (eg, tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19])
- Asthma, reactive airway or other chronic respiratory disease that requires daily treatment

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease.

[a] Patients ≥12 years old who weigh ≥40 kg with ≥1 of the criteria listed are considered at high risk for progressing to severe COVID-19 and/or hospitalization. FDA fact sheet for health care providers emergency use authorization (EUA) of bamlanivimab. Available at: https://www.fda.gov/media/143603/download. Accessed November 19, 2020.

[b] Based on CDC growth charts (https://www.cdc.gov/growthcharts/clinical_charts.htm).

Conclusion

The investigational IV monoclonal antibody bamlanivimab (LY-CoV555) has been granted an Emergency Use Authorization (EUA) from the FDA based on its association with a reduction in emergency department visits and hospitalizations in recently diagnosed patients with mild or moderate COVID-19 considered to be at high risk of progressing to severe disease and/or hospitalization. The drug needs to be infused over 1 hour in a facility equipped to manage anaphylaxis. Bamlanivimab has not been beneficial in hospitalized patients.

ARTICLE INFORMATION

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STAT

Eli Lilly says its monoclonal antibody cocktail is effective in treating Covid-19

By Matthew Herper @matthewherper

October 7, 2020

Reprints

Eli Lilly said Wednesday a monoclonal antibody treatment is effective in reducing levels of the virus that causes Covid-19 in patients, and also appears to prevent patients from visiting the emergency room or hospital.

Lilly had previously released results for a similar treatment using one antibody, which experts viewed as promising. But the new results, of a combination of two antibodies, appear, based on limited data provided in a

press release, to be more robust. The results also appear roughly similar to those Regeneron presented last week of its own cocktail of two monoclonal antibodies. Last Friday, President Trump was treated with the Regeneron monoclonal antibodies.

Monoclonal antibodies are synthetic versions of the antibodies that are one of the main weapons of the immune system. Researchers believed that injecting them into patients could help treat them.

The patients in the study were sick with Covid-19, but had not been admitted to the hospital. Eli Lilly said that in a preliminary analysis the antibody combination reduced the amount of virus in nasal swabs of patients after 11 days.

Key data, including the actual viral loads of patients and the makeup of the study population, were not included in the press release.

In the study, 112 patients received 2.8 grams of each of the antibodies, and 156 received placebo. The difference in viral load was statistically significant at day 11, unlike some doses of Lilly's single-antibody cocktail. There was also a statistically significant reduction in viral levels three days and seven days after infection.

The treatment also improved symptoms, according to a scored questionnaire, and resulted in fewer hospital and emergency room visits. Visits to the hospital or ER were made by 5.8% of patients in the placebo group, but just 0.9% of those who received the antibody combination. That difference, however, was just barely statistically significant.

Lilly said that it has already begun talking to regulators around the world about its single antibody treatment, and has filed with the Food and Drug Administration for an emergency use authorization. It expects to submit a request for emergency use authorization for the combination therapy next month, after patients are enrolled in clinical trials and supply has been

manufactured. It could submit for full FDA approval of the combination treatment by the middle of next year.

Related:

Regeneron's Covid-19 antibody may help non-hospitalized patients recover faster, early data show

Lilly said it anticipates it could have as many as 1 million doses of its one-antibody treatment, LY-CoV555, available in the fourth quarter of 2020, with 100,000 available this month. But for the combination therapy, just 50,000 doses will be available in the fourth quarter of 2020.

Both antibody regimens have been well-tolerated, with no serious side effects, the company said. In the single-antibody studies, there have been reactions to the infusion of the treatment, which is given intravenously, including two "serious infusion reactions," from which patients recovered.

About the Author Reprints

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