BLAZE-4 Study Fact Sheet

Considering the BLAZE-4 Study?

COVID-19 was identified in late 2019 and has since affected the lives of millions of people around the world. There are currently no approved treatments for this new disease, which is why we need clinical research to test potential treatment options. Participating in a clinical research study like the BLAZE-4 Study is one way you could help contribute to ending this crisis.

Purpose of the BLAZE-4 Study

The purpose of the BLAZE-4 Study is to test whether the antibody medicines LY-CoV555 and LY-CoV016 may help the body fight the disease. Many antibody medications have been FDA approved to treat numerous diseases including cancers, autoimmune disorders, and infectious diseases.

About the Study Drug

Antibodies are protective proteins made by the body's immune system to fight viruses, bacteria, and other foreign substances. It takes time for the body to make antibodies against a new disease. LY-CoV555 and LY-CoV016 are antibodies derived from early survivors of COVID-19, and we are testing to see if they may help the body clear the virus faster and reduce symptoms when given soon after diagnosis.

LY-CoV555 and LY-CoV016 are investigational, which means they have not been approved by the FDA for any use. If you participate in this study, you may receive LY-CoV555 alone or in combination with LY-CoV016 or a placebo, which looks like the study drug but contains no active medicine. You will not know which one you've received.

Study Participation

Participation lasts approximately 12 weeks and may include up to 12 visits to see how you are feeling, how your body is responding to the antibody treatment, and how much virus is left in your body. Most of these check-ins will be performed in your home or by phone.

The study is made up of three sections.

- **Screening and treatment:** You will go through an informed consent process to make sure you understand the study and to determine if you are eligible. If you are eligible and decide to participate, you may receive LY-CoV555 alone or in combination with LY-CoV016 or the placebo via a single infusion into a vein.
- **Assessments and procedures:** The research team will perform certain tests and procedures to monitor your health and how your body reacts to the antibody treatment. These tests and procedures include physical exams, vital sign measurements, blood samples, and samples taken from the back of the nose to determine how much virus is in your body. Your health will be carefully monitored by a team of doctors, nurses, and other research staff. Your well-being is their primary concern.
- **Follow-ups:** Follow-up assessments, which are less frequent visits, allow the research team to monitor how you are doing.

Key Requirements

The following checklist will help determine if the BLAZE-4 Study may be a good fit for you. Place a check mark next to each statement that describes you.

- ○ 18 to less than 65 years of age
- ○ Tested positive for COVID-19 within three days prior to receiving this fact sheet
- ○ Experiencing one or more of the following mild to moderate COVID-19 symptoms: fever, cough, sore throat, headache, muscle pain, nausea, abdominal pain, diarrhea, shortness of breath when active
- ○ Not pregnant or breastfeeding
- ○ Not hospitalized

There are additional eligibility requirements, which the study doctor can explain to you.

Opting In and Opting Out of the BLAZE-4 Study

Taking part in a clinical research study is a voluntary decision. You have the right to leave a clinical research study at any time. If you decide to not join or to stop participating, your decision will not impact your ability to seek medical care. The study doctor also has the right to remove you from the study at any time in the interest of your well-being.

Thank you for your interest in the BLAZE-4 Study.
LillyCovidStudies.com

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BLAZE-4 Study Healthcare Professionals Fact Sheet

About the BLAZE-4 Study

The aims of the BLAZE-4 Study are to evaluate the impact of the study drug LY-CoV555 (LY3819253), alone and in combination with LY-CoV016 (LY3832479), on viral load, viral clearance, and clinical outcomes. The study design has a range of doses that will inform further clinical development. The participant population is those infected with SARS-CoV-2 that have developed symptoms consistent with COVID-19.

There is historical evidence that patients infected with upper respiratory viruses who are treated early in their disease course have better responses to anti-viral therapies (Aoki et.al., 2003). The population of participants with mild to moderate COVID-19 illness was chosen to evaluate if effective antiviral antibody therapy may prevent progression to the severe form of COVID-19 illness.

About LY-CoV555 (LY3819253) and LY-CoV016 (LY3832479)

LY-CoV555 and LY-CoV016 are potent, neutralizing IgG1 monoclonal antibodies (mAb) directed against the spike protein of SARS-CoV-2. They are designed to block viral attachment and entry into human cells, thus neutralizing the virus, potentially preventing and treating COVID-19.

LY-CoV555 and LY-CoV016 have unique binding properties utilizing a validated monotherapy antiviral antibody approach. As with Ebola and respiratory syncytial virus (RSV), the only two historically successful therapies in this class, the hope is that individual potent neutralizing antibodies are an effective way to treat viral pathogens.

Study Design Highlights

The BLAZE-4 Study is a randomized, double blind, placebo-controlled study. These patients will be randomized to receive either placebo or LY-CoV555 alone or in combination with LY-CoV016.

The study lasts approximately 85 days. On Day 1, participants who meet the screening criteria will be randomized to receive a one-time treatment with LY-CoV555 alone or in combination with LY-CoV016 or a placebo by intravenous infusion. Subsequently, the infusion will be followed by an assessment period of 29 days and a follow-up period, which concludes about three months from the start of the study. Study procedures include physical exams, vital signs, blood samples, and nasal/nasopharyngeal swabs.

To minimize participant burden, following the randomization and dosing visit at the research site, the remainder of the study visits will be conducted without the participant having to leave home.

Key Eligibility Information

- Be 18 to less than 65 years of age at the time of randomization
- Have first positive SARS-CoV-2 infection confirmation within three days prior to the study drug infusion
- Not hospitalized
- Not be pregnant or breast-feeding
- Be willing and able to comply with study requirements
- Have one or more mild or moderate COVID-19 symptoms
  - Fever (≥ 100.4°F)
  - Cough
  - Sore throat
  - Malaise
  - Headache
  - Muscle pain
  - Gastrointestinal symptoms
  - Shortness of breath with exertion

Thank you for your consideration of the BLAZE-4 Study as a potential treatment option for your patient. For more information about the BLAZE-4 Study and Lilly COVID-19 trials, visit LillyCovidStudies.com or contact the below research site near you.

[PI Name]
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