

Steve Poretz, RN, MSHA Executive Director

The Clinical Alliance for Research and Education (CARE-ID) Continues the Blaze-1 COVID-19 Clinical Trial

BLAZE-1 Study is evaluating a potential COVID-19 antibody treatment following successful laboratory studies

Annandale, VA; October 5, 2020 – CARE-ID announced it is continuing the clinical research study to evaluate the safety and effectiveness of LY-CoV555 in patients with early mild to moderate COVID-19. Sponsored by Eli Lilly and Company (Lilly), the BLAZE-1 Study is looking for adults ages 18 or older who have recently tested positive for COVID-19 and are not hospitalized. Several weeks ago, CARE-ID reached is target enrollment and re-directed it resources to the Pfizer vaccine study. Due to the nature of the 2 studies (one treatment and the other vaccine) it was critically important to maintain strict separation of the two study populations. Pfizer, however, within the past week has moved to re-allocate volunteer slots to geographies with higher infection rates in the general population. This pause in the vaccine study for CARE-ID makes it possible to reenergize its focus on the antibodies study.

LY-CoV555 is an antibody therapy engineered from one of the first individuals to recover from COVID-19, which may help newly diagnosed patients clear the SARS-CoV-2 virus faster. Laboratory studies have shown that LY-CoV555 binds with high affinity to the SARS-CoV-2 virus and neutralizes its ability to infect cells and replicate.

"The recent developments in study population allocations and the national exposure of polyclonal antibody treatments affords us the opportunity to renew our focus on this research which takes full advantage of our experience with IV infusions. Clinical trials like BLAZE-1 are vital in testing potential treatments for COVID-19 which, if successful, represent medicines which can be used to protect those most at risk of severe illness, such as the elderly and immunocompromised," said David A. Wheeler, MD, FACP, FIDSA, CARE-ID principle investigator and president and managing partner of Infectious Diseases Physicians, Inc. (IDP), a private clinical practice focusing on the care of people with a range of infectious diseases. "IV infusion studies tend to be a bit more involved. CARE-ID is very pleased to bring its expertise in this clinical area to the fight against COVID-19."

To be eligible for the BLAZE-1 Study, participants must have tested positive for SARS-CoV-2 infection within three days prior to the study drug infusion, and have one or more mild or moderate COVID-19 symptoms, including, fever, cough, sore throat, headache, muscle pain, nausea, abdominal pain, diarrhea, or shortness of breath when active.

If a person is eligible and decides to participate, the research staff at CARE-ID will perform specific tests and procedures to monitor the patient's health and how their body reacts to the LY-CoV555 antibody treatment. These tests and procedures include physical exams, vital sign measurements, blood samples, and nasopharyngeal swabs to measure levels of virus.

The study drug is being compared to a placebo, and both the study drug and the placebo will be administered as a single-dose intravenous (IV) infusion. Participants will be randomly selected to receive the placebo or the study drug.

"We have been fully committed to this antibody research study from the very beginning and we are continuing the on-going follow-up our current study population. We thought we could do more when we reached our allotted slots. And now we can rejoin the effort as Lilly continues the BLAZE-1 Study," said Stephen Poretz, RN, MSHA, Executive Director at CARE-ID. "How long it will run is still not entirely clear. But we are happy to be able to use our resources as long as we can to make a contribution to the outcome."

CARE-ID is located and can be contacted at:

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If someone has tested positive and exhibited symptoms for COVID-19, and are interested in participating in clinical research in their area, call 833.277.0197 or visit <u>JoinCOVIDStudy.com</u> to learn more.

About CARE-ID

CARE-ID conducts clinical research trials in the field of infectious diseases with particular focus on the safety and confidentiality of our participants, quality of our data, and integrity of our results. We partner with pharmaceutical and biotechnology companies to develop experimental therapies for both the prevention and treatment of infectious diseases.