Clinical trial testing efficacy of antibody against SARS-CoV-2 begins

September 3 2020

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The University of Chicago Medicine is launching a clinical trial to examine the potential of an antibody against the SARS-CoV-2 spike protein for treating COVID-19, the disease caused by the novel coronavirus.

For the BLAZE-1 trial, UChicago is recruiting 22 participants to be treated with the LY-CoV555 antibody developed by Eli Lilly and Company in collaboration with AbCellera. The antibody was first identified by scientists at the National Institute of Allergy and Infectious Diseases and AbCellera in a blood sample from a U.S. patient who had recovered from COVID-19.

The neutralizing monoclonal antibody targets and binds to the spike protein on the surface of the SARS-CoV-2 virus, preventing it from attaching and entering into human cells. Without access to cells, the virus can't replicate.

"There is data showing that the LY-CoV555 antibody can block the virus from replicating in cells in the lab," said David Pitrak, MD, Chief of the Section of Infectious Diseases and Global Health at UChicago Medicine. "Now we're going ahead with the human studies to see if treating patients with this antibody reduces their viral load, which is associated with better clinical outcomes, and would also likely make patients less contagious for the virus."

LY-CoV555's safety was initially evaluated in a Phase 1 clinical trial that started in June 2020. This Phase 2 trial will expand the safety testing of LY-CoV555, and will examine the effects of the antibody on reducing viral load, clinical symptoms and signs of infection in patients with mild to moderate cases of COVID-19. At UChicago Medicine, this study is a collaboration between the sections of Infectious Diseases and Global Health and Emergency Medicine.

"Right now, we're testing the effects of a single dose of the antibody," Pitrak said. "When a patient comes into the ER with compatible symptoms and is diagnosed with COVID-19, but isn't sick enough to require hospital admission, we can ask if they'd like to enroll in this study. They will be given an infusion of the antibody or a placebo right

there in the ER before they get sent home."

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.

Patients will be tracked for up to 90 days, with researchers testing three different doses of the antibody and monitoring any side effects, as well as measuring the viral load in the respiratory tract and the levels of the antibody in a person's bloodstream. These measures will help determine how effective the antibody is at treating the virus and how long it might provide protection for a patient after infection.

This study represents an alternative approach to passive immunity by giving convalescent plasma to treat COVID-19. Patients who have recovered from the virus have circulating antibodies that protect against the SARS-CoV-2 virus to varying degrees in their bloodstream; plasma transfusions from these recovered patients can bolster the immune systems of sick patients, giving them extra support for fighting off the infection. After recovery, these patients will retain these antibodies, providing some protection against reinfection. At this stage, however, the neutralizing ability of convalescent plasma on the virus is unknown.

The identification and production of LY-CoV555 allows for mass production of a specific antibody that targets and blocks the SARS-CoV-2 spike protein from infecting cells. This circumvents challenges such as plasma availability and biocompatibility issues, and provides a treatment that more thoroughly neutralizes the virus.

"While this specific neutralizing antibody is new, it's not without precedent," said Pitrak. "Disease-specific monoclonal antibody therapies

are already used in the clinic for treating HIV, as well as in children with respiratory syncytial virus and patients with recurrent C. difficile infections."

Overall, this study seeks to enroll 400 total patients by the end of August 2020 across several medical centers. If the antibody is effective, it will provide new opportunities for treating patients with COVID-19, particularly those with compromised immune systems who may not be good candidates for a future vaccine.

"Kicking off the BLAZE-1 Study with research sites around the country, including UChicago Medicine, is a huge milestone for the global fight against COVID-19, and we're excited to bring the industry one step closer to a potential treatment," said Daniel Skovronsky, MD, Ph.D., Chief Scientific Officer at Eli Lilly and Company. "We look forward to working with eligible patients who are not only interested in receiving investigational treatments for COVID-19, but who also understand how their participation can impact the health and well-being of millions of people around the world."

Provided by University of Chicago Medical Center