Two clinical studies to treat COVID-19 launched

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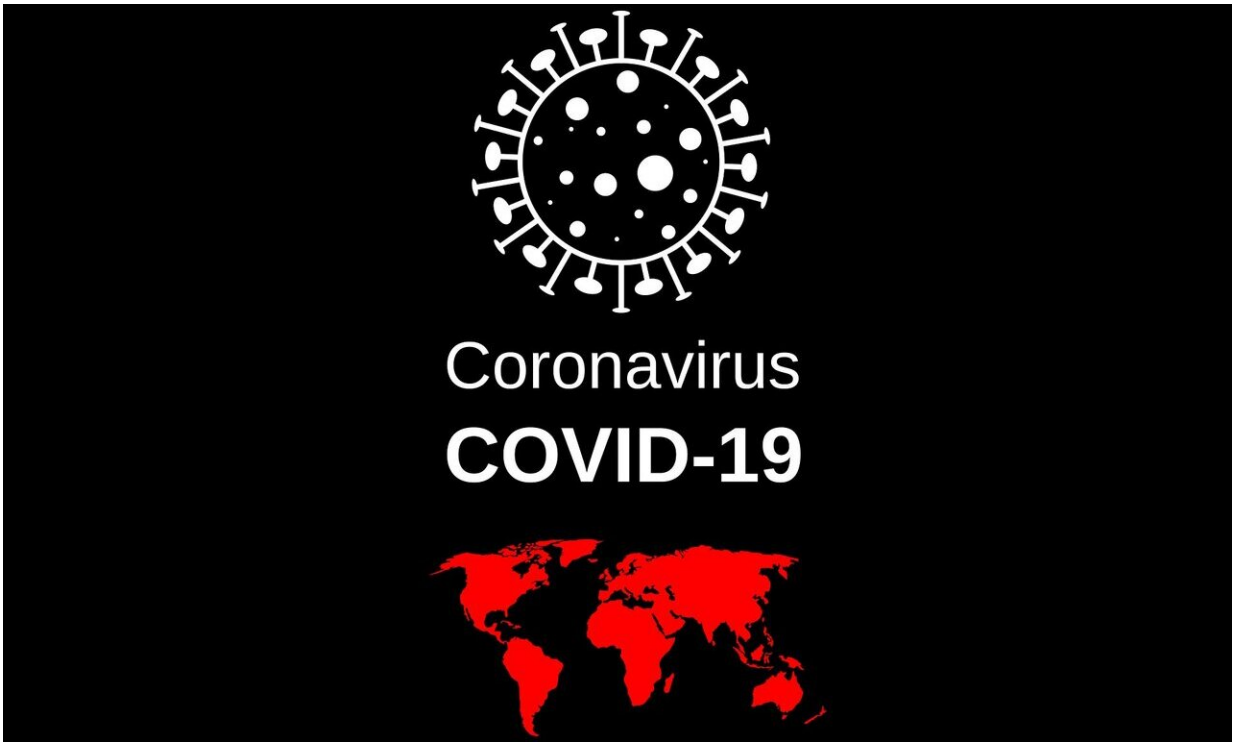

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UC Davis Health has two clinical trials underway for hospitalized patients with severe COVID-19, the disease caused by the novel coronavirus, SARS-CoV-2.

The studies are evaluating the safety and effectiveness of two drugs—the

investigational antiviral remdesivir, and sarilumab, a drug that blocks the body's acute inflammatory response.

"We have a critical need to confirm safe and effective treatments for COVID-19," said Allison Brashear, dean of the UC Davis School of Medicine. "Although some patients with severe infection have received remdesivir, we do not have solid data to indicate it can improve clinical outcomes for everyone. The nation's schools of medicine have the expertise and resources to advance knowledge about the infection to help guide the clinical care of patients worldwide."

There are no specific therapeutic agents approved by the Food and Drug Administration (FDA) to treat people with COVID-19. The infection can cause mild to severe respiratory illness. Symptoms can include fever, cough and shortness of breath. Current clinical care of hospitalized patients include supplemental oxygen therapy, antibiotics, influenza antiviral drugs and intensive care as needed.

As of March 26, there were 526,006 confirmed cases of COVID-19 worldwide, including 68,440 in the U.S. and 3,006 in California. There were more than 23,721 deaths, including 994 deaths in the U.S. and 65 in California.

Remdesivir study

UC Davis is one of approximately 75 sites worldwide evaluating the benefits of remdesivir for severe COVID-19 infection. Remdesivir is an investigational broad-spectrum antiviral treatment developed by Gilead Sciences Inc. It was previously tested in humans with Ebola virus disease and has shown promise in animal models for treating Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS), which are caused by other coronaviruses.

UC Davis physicians used remdesivir in February, with emergency approval from the Food and Drug Administration, to treat a critically ill patient who was the first known case of community-acquired infection in the U.S. The patient has since returned home to recover.

The study will enroll up to 440 patients over the next several months, including about 10 or more at UC Davis. Among other criteria, participants must be 18 years of age or older, have a confirmed SARS-CoV-2 test and poor lung function.

The clinical trial is funded by the National Institute of Allergy and Infectious Diseases. It is part of the study recently launched at the University of Nebraska. Stuart Cohen is leading the investigation at UC Davis. He is chief of the Division of Infectious Diseases in the Department of Internal Medicine at UC Davis Health and director of Hospital Epidemiology and Infection Control.

Sarilumab study

UC Davis is one of up to 50 sites in the U.S. assessing sarilumab, a drug jointly developed by Regeneron and Sanofi pharmaceutical companies for the treatment of rheumatoid arthritis. The drug is a human monoclonal antibody that blocks the receptor for interleukin-6 (IL-6), a cytokine that plays an important role in the body's immune response and in generating fever and acute inflammation. The study will evaluate whether the drug can control the progression of the inflammatory response in the lungs of patients with severe COVID-19 infection.

Approximately 400 hospitalized patients age 18 and older with acute COVID-19 infection can be enrolled in the study nationwide. Individuals will be grouped according to the severity of their illness and progression of symptoms, from severe to critical to having multi-system organ failure as well as whether cortisone drugs were used to reduce

inflammation. The researchers will be determining whether the health of individuals with high IL-6 levels and severe/critical levels of infection improve with the drug.

The study is sponsored by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response. Timothy Albertson, professor and chair of the Department of Internal Medicine, is leading the study at UC Davis.

Clinical studies essential

Both studies are double-blind, meaning trial investigators and participants will not know who is receiving the treatments. They are designed to identify the early signs of clinical benefit while avoiding the use of ineffective therapies in critically ill patients with COVID-19.

"Conducting well-controlled, randomized clinical trials enable us to confirm the safety and effectiveness of promising drugs to treat emerging infections like COVID-19," Albertson said.

An independent data and safety monitoring board (DSMB) also will closely monitor ongoing results to ensure patient well-being and safety as well as study integrity. The board also will recommend that a study be halted if there is clear and substantial evidence of a treatment difference between drug and placebo.

Provided by UC Davis