Possible safety issue spurs pause of COVID-19 antibody study

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Independent monitors have paused enrollment in a study testing the COVID-19 antiviral drug remdesivir plus an experimental antibody therapy being developed by Eli Lilly that's similar to a treatment President Donald Trump recently received.

Lilly confirmed Tuesday that the study had been paused "out of an abundance of caution" and said safety is its top concern. The company would not say more about what led to this step.

The U.S. National Institute of Allergy and Infectious Diseases, which sponsors the study, would not immediately comment.

Antibodies are proteins the body makes when an infection occurs; they attach to a virus and help it be eliminated. The experimental drugs are concentrated versions of one or two specific antibodies that worked best against the coronavirus in lab and animal tests.

This study was testing a single antibody that Lilly is developing with the Canadian company AbCellera. Trump received an experimental two-antibody combo drug from Regeneron Pharmaceuticals Inc.

Lilly and Regeneron have asked the U.S. Food and Drug Administration to grant emergency use authorization for their drugs for COVID-19 while late-stage studies continue.

The paused study, called ACTIV-3, started in August and aims to enroll

10,000 hospitalized COVID-19 patients in the United States, Denmark and Singapore. All are given remdesivir, which has been authorized in the U.S. as an emergency treatment for COVID-19, plus either the Lilly antibody or a placebo.

The main goals are reducing the need for extra oxygen and time to recovery. Deaths, relief of symptoms and other measures also are being tracked. All of the drugs are given through an IV.

Such pauses are not uncommon in long clinical studies. Unlike a study hold imposed by government regulators, a pause is initiated by the sponsor of the drug trial and often can be quickly resolved.

The pause in the Lilly study comes a day after a temporary halt to enrollment in a coronavirus vaccine study. Johnson & Johnson executives said Tuesday that it will be a few days before they know more about an unexplained illness in one participant that caused a pause in its late-stage vaccine study. Johnson & Johnson isn't disclosing the nature of the illness.

"It may have nothing to do with the vaccine," said Mathai Mammen, head of research and development for Janssen, Johnson & Johnson's medicine development business.

Mammen said the company doesn't know yet whether the ill participant received the experimental vaccine or a dummy shot. He says Johnson & Johnson gave information on the case to the independent monitoring board overseeing the safety of patients in the study, as the research protocol requires. It will recommend next steps.

The study of the one-dose vaccine will include up to 60,000 people from multiple countries. The company expects to complete enrollment in the study in two or three months.