Investigational COVID-19 Therapeutics To Be Evaluated in Large Clinical Trials

Two Phase III clinical trials are evaluating monoclonal antibodies for people hospitalized with moderate COVID-19.

December 21, 2020 By National Institutes of Health

Two randomized, controlled Phase III clinical trials have begun evaluating investigational monoclonal antibodies for their safety and efficacy in treating people hospitalized with moderate COVID-19.

The trials are part of the ACTIV-3 master protocol, which has an adaptive design allowing investigators to add new sub-studies of additional investigational agents. ACTIV-3 is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

One sub-study is evaluating VIR-7831, a monoclonal antibody developed through a partnership between GlaxoSmithKline plc (Brentford, United Kingdom) and Vir Biotechnology, Inc. (San Francisco). The other sub-study is evaluating the combination of BRII-196 and BRII-198, two neutralizing monoclonal antibodies manufactured by Brii Biosciences (Durham, North Carolina and Beijing).

Antibodies are infection-fighting proteins naturally made by the immune system. Antibodies can prevent viruses from infecting cells, sometimes by binding to the surface of the viruses. Synthetic versions of these antibodies, prepared in a laboratory, are known as monoclonal antibodies.

Participants in the new ACTIV 3 sub-studies will be randomized 1:1:1 to receive either a saline placebo, VIR-7831 or the Brii combination. The ACTIV-3 design allows researchers to evaluate each antibody in a small group of volunteers, and then to enroll a larger group of volunteers if the antibody appears safe and effective. Initially, researchers will enroll approximately 450 volunteers who have been hospitalized with mild to moderate COVID-19 with fewer than 13 days of symptoms. After five days, the participants' symptoms will be assessed on a seven-point ordinal scale ranging from being able to undertake usual personal activities with minimal or no symptoms, to death.

If an antibody appears to be safe and effective, each sub-study will enroll an additional 700 people. Three-hundred-fifty of those people will be assigned to receive the intervention, and 350

will receive the placebo. The new group of volunteers may include those with more severe illness. The primary endpoint of the trial is the participants' sustained recovery for 14 days after release from the hospital.

Prior to the addition of these therapeutics to the trial, ACTIV-3 previously tested a different monoclonal antibody known as LY-CoV555, developed by Eli Lilly and Company (Indianapolis). Following a recommendation from the Data and Safety Monitoring Board (DSMB) for this trial, ACTIV-3 investigators recently closed the sub-study, based on the low likelihood that the intervention would be of clinical value to the hospitalized patients in the study.

ACTIV-3 is part of the NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines.

The VIR/GSK sub-study also is receiving funding support through Operation Warp Speed, the U.S. government's multi-agency effort to develop, manufacture and distribute medical countermeasures for COVID-19. The Brii sub-study is supported by funding from NIAID.

People interested in learning more about the trial can visit clinicaltrials.gov and search identifier NCT04501978.

This news release was first published on the National Institute of Health website on December 17, 2020.

© 2026 Smart + Strong All Rights Reserved.

http://beta.docker.covidhealth.com/article/investigational-covid19-therapeutics-evaluated-large-clinical-trials