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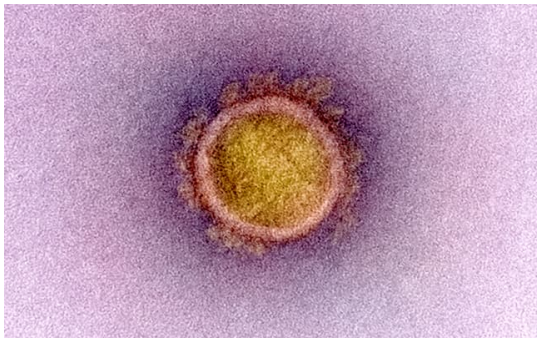
August 05, 2020 | By Scott LaFee

Imitation May Be a Sincere Form of Treatment

NIH to launch study of experimental monoclonal antibody therapy for COVID-19; a Q&A with the trial's protocol chair: Davey Smith, MD, at UC San Diego School of Medicine

Neutralizing antibodies are the Holy Grail in current efforts to create a safe and effective vaccine for COVID-19, the disease caused by the novel coronavirus SARS-CoV-2. These proteins, created by the immune system, not only bind to invasive viruses to block infections, they persist after the pathogen is gone, providing protection against future infections.



A colorized transmission electron micrograph of the SARS-CoV-2 virus. Photo credit: NIAID

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), will soon launch a Phase II clinical trial to evaluate the safety and efficacy of potential new therapeutics for COVID-19, including the use of investigational synthetic monoclonal antibodies (mAbs).

mAbs are laboratory-produced molecules designed to behave like antibody substitutes, restoring, enhancing or mimicking the natural immune response. mAbs are currently used to treat some forms of cancer, rheumatoid arthritis, multiple sclerosis, lupus, ulcerative colitis, cardiovascular disease and other conditions.

The new trial, known as ACTIV-2, is part of the NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) program, a public-private program to speed development of the most promising treatments and vaccines. ACTIV is supported by Operation Warp Speed, a multi-billion-dollar federal effort to develop, manufacture and distribute vaccines to prevent COVID-19.

The experimental drug to be tested is LY-CoV555, a mAb developed by the pharmaceutical company Eli Lilly in partnership with AbCellera, a Canadian biotechnology company.

The ACTIV-2 study team is led by protocol chair Davey Smith, MD, a translational research virologist, head of Infectious Diseases and Global Public Health at University of California San Diego School of Medicine and co-director of the San Diego Center for AIDS Research.

Question: Why are monoclonal antibodies considered particularly promising as potential therapeutics for COVID-19? What sets them apart from other approaches?

Smith: This therapy is made from antibodies that developed when someone had the infection. The antibody was then purified and then expanded so it could be used as a therapy in other people who got the infection. This approach has worked for other viral infections, like Ebola and HIV, so we think it will work for SARS-CoV-2 too.

Question: How will the ACTIV-2 trial work?

Smith: The first stage will enroll 220 volunteers who have tested positive for the novel coronavirus and who have experienced symptoms of COVID-19, but are not hospitalized. These volunteers will come from around the world, from member sites of the AIDS Clinical Trials Group. (The Antiviral Research Center at UC San Diego is a member of ACTG.)

Volunteer-participants will be randomly assigned to receive either an intravenous infusion of LY-CoV555 or a placebo infusion of saline solution: 110 persons in each group. Over the next 28 days, all participants will be monitored by clinicians tracking their COVID-19 symptoms. There will be swabs to measure the presence of SARS-CoV-2 viral RNA and blood tests to help researchers understand how the drug is functioning in their bodies.

The primary goal is to evaluate safety and to see if LY-CoV555 reduces the duration of symptoms and speeds clearance of the coronavirus from the body. If there are no serious side effects and the investigational drug appears promising, the study will move to a larger Phase III trial and enroll an additional 1,780 outpatient volunteers to determine if the drug can prevent either hospitalization or death from COVID-19. A Phase III would last 28 days as well.

Question: Will LY-CoV555 be the only drug tested?

Smith: No. The study is set up so that it can be adapted to investigate other experimental therapeutics using the same trial protocol.

Serving as protocol vice-chairs on the ACTIV-2 study are David Wohl, MD, professor of medicine at University of North Carolina at Chapel Hill (UNC) and Kara W. Chew, MD, an infectious disease specialist, and Eric S. Daar, MD, professor of medicine, both at UCLA. The

ACTG network is led by Judith Currier, MD, professor of medicine at UCLA, and Joseph Eron, MD, professor of medicine at UNC.

For more information on the ACTIV-2 trial, visit www.niaid.nih.gov.

For information on COVID-19 clinical trials at UC San Diego, visit clinicaltrials.ucsd.edu/covid-19.

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