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ACTG launches clinical trial testing treatment for COVID-19

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The AIDS Clinical Trials Group (ACTG), the world's largest and longest established HIV research network, today announced the initiation of ACTG 5395, a clinical trial to evaluate whether the drug combination hydroxychloroquine and azithromycin can prevent hospitalization and death from COVID-19 (which is caused by infection with the virus SARS-CoV-2). There is currently no approved vaccine or therapeutic to prevent or treat COVID-19, which has been spreading worldwide since cases were first reported in December 2019 in Wuhan, Hubei Province, China.

"There is an urgent public health need to rapidly evaluate interventions to treat COVID-19, which has emerged as a global pandemic in recent months," said ACTG Chair Judith Currier, M.D., M.Sc., University of California, Los Angeles. "Well-designed trials are needed to evaluate whether drugs that have been studied and used over many years to treat other conditions are effective against COVID-19. ACTG's history of implementing a wide variety of clinical trials over the last 33 years positions us well to quickly execute this clinical trial and help determine whether hydroxychloroquine and azithromycin may be an effective treatment for COVID-19."

ACTG is conducting this double-blind, placebo-controlled, randomized phase 2b clinical trial at 31 of its U.S.-based sites (the list can be accessed here) and will enroll approximately 2,000 adults with COVID-19. The study is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of

Health, which also funds the ACTG. Participants will be randomized to orally receive one of two regimens. The first arm will receive a loading dose of hydroxychloroquine (400 mg twice a day on the first day), followed by 200 mg twice a day for six days, plus 500 mg of azithromycin on the first day, followed by 250 mg every day for four days. The second arm will receive matching placebos.

In order to qualify for the study, participants must have tested positive for SARS-CoV-2 infection in the outpatient setting and be experiencing at least one of the following symptoms: fever, cough, or shortness of breath. Eligible participants include people living with HIV, women who are pregnant, and those currently breastfeeding.

ACTG 5395 is being led by protocol chair Davey Smith, M.D. of the University of California, San Diego, along with David Wohl, M.D. of the University of North Carolina and Kara W. Chew M.D., M.S. and Eric S. Daar, M.D. of the University of California, Los Angeles.

"Because the COVID-19 pandemic has been particularly devastating for people who are older and have underlying health issues, it is our goal that at least half of study participants will be members of these high-risk groups," said Dr. Smith. "By ensuring meaningful representation of individuals who are 60 years and older or immunocompromised and those with chronic lung, kidney, and liver disease, severe obesity, hypertension, or diabetes, we are hopeful that we will gain important insights that will directly impact care for people with COVID-19."

As of May 14, 2020, the World Health Organization (WHO) has reported 4,218,212 cases and 290,242 related deaths worldwide. The United States became the epicenter of the epidemic on March 26, 2020, reporting more cases than any other country worldwide. As of May 13, 2020, the Centers for Disease Control and Prevention (CDC) has reported 1,364,061 cases and 82,246 related deaths in the United States.

Hydroxychloroquine is currently approved for malaria treatment and prevention, as well as for the treatment of autoimmune conditions, including rheumatoid arthritis and lupus. Azithromycin is currently approved to treat bacterial infections, including sinusitis, community-acquired pneumonia, urethritis/cervicitis, pharyngitis, and acute exacerbations of COPD. While there has been some evidence that this drug combination may decrease viral loads among people with COVID-19, large, well-controlled clinical trials are needed to determine its true efficacy. The ACTG, with its ability to use existing sites and staff to rapidly conduct trials, is ideally positioned to conduct a major clinical trial among patients with COVID-19 (who currently have no proven treatment options) during this pandemic.

Provided by University of California, Los Angeles