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# ACTIV-2d, a global phase 3 trial of novel investigational COVID-19 oral antiviral agent, launches

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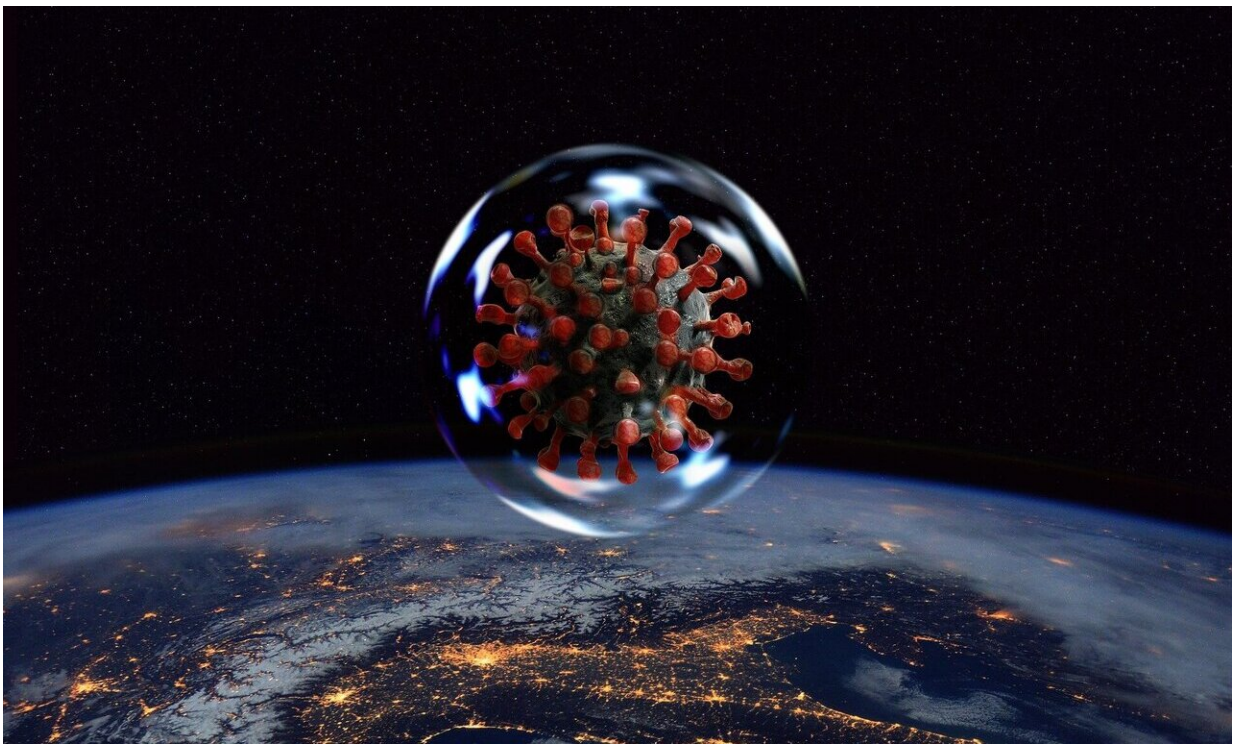

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The AIDS Clinical Trials Group (ACTG), the largest global HIV research network, which expanded its focus to conduct research into COVID-19, today announced the initiation of ACTIV-2d, a global,

phase 3, multicenter trial to evaluate the impact of S-217622, an investigational oral COVID-19 antiviral agent. ACTIV-2d will evaluate the safety and efficacy of S-217622 as a once-daily treatment to reduce the duration of COVID-19 symptoms in non-hospitalized adults with early COVID-19.

S-217622, a selective inhibitor of the 3CL protease (an enzyme essential for the replication of SARS-CoV-2) was created through joint research between Hokkaido University and Shionogi & Co. Ltd. Recent results from a trial conducted in Japan and Korea demonstrated that patients treated with S-217622 showed a significant and rapid decrease in viral level and culturability after the third dose of S-217622 compared to placebo. Previous clinical trials also showed that S-217622 was well-tolerated, with few treatment-related discontinuations, and no serious adverse events or death. The most common adverse events were mild headache and transient reduction in HDL cholesterol. Additionally, S-217622 has recently demonstrated high in vitro antiviral activity against the Omicron subvariants (BA.4 and BA.5), with antiviral potency against other existing variants.

ACTIV-2d is a global phase 3, multicenter, randomized, double-blind, 24-week study evaluating whether S-217622 can reduce the time it takes for COVID-19 symptoms to resolve among participants who have tested positive for SARS-CoV-2 in the outpatient setting and started experiencing symptoms within five days of enrolling. The study will include people at lower and higher risk of progression to severe COVID-19.

"S-217622 has the potential to simplify COVID-19 treatment, as it is administered once a day without a boosting agent," said Annie Luetkemeyer, M.D., University of California, San Francisco and a lead investigator of S-217622. "As COVID-19 remains a major global concern, we need to increase our treatment options. We are hopeful that

S-217622 will be an important addition to the COVID-19 treatment tool kit."

ACTIV-2d is being conducted with trial sites in countries in Europe, South America, North America, Africa, and Asia. Approximately 1,490 participants will be randomized in a 1:1 ratio receiving either S-217622 or placebo. Participants may take locally provided COVID-19 treatment after enrollment, as long as it is compatible with S-217622.

ACTIV-2d is led by Kara W. Chew, M.D., M.S., University of California, Los Angeles (UCLA), Dr. Luetkemeyer, and Davey Smith, M.D., University of California, San Diego (protocol co-chairs) and David Alain Wohl, M.D., University of North Carolina (UNC) and Eric S. Daar, M.D., Lundquist Institute at Harbor-UCLA Medical Center (vice-chairs), and is supported by Judith Currier, M.D., M.Sc., UCLA (ACTG Chair) and Joseph J. Eron, M.D., UNC, (ACTG Co-Chair).

Provided by AIDS Clinical Trials Group

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