



Steve Poretz, RN, MSHA, MBA
Chief Operating Officer

The COVID-19 Battle Continues with the Development of a New Preventive

Annandale, VA; May 31, 2022 – The leaders and researchers at the Clinical Alliance for Research and Education-Infectious Diseases (CARE-ID) are very pleased to announce their collaboration with Astra Zeneca for a new clinical trial (ENDURE) of its combination product of 2 monoclonal antibodies for pre-exposure prophylaxis (prevention) of COVID-19. The study will be a Phase II, randomized, open-label, multicenter, dose-ranging study.

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca, has reported: "Recent data from its Phase III pre-exposure prophylaxis (prevention) trial showed that AstraZeneca's Evusheld (tixagevimab and cilgavimab), formerly AZD7442, reduced the risk of developing symptomatic COVID-19 by 77% in the primary analysis and by 83% in the six-month follow-up analysis, compared to placebo. There were no cases of severe disease or COVID-19 related deaths in the Evusheld group through the six-month follow-up. This adds to the growing body of evidence supporting the use of Evusheld to help prevent symptomatic and severe COVID-19, especially for those individuals who can't respond adequately to vaccination and need additional protection. Evusheld is now available in many countries around the world, and we are progressing [with] filings in pre-exposure prophylaxis as well as mild-to-moderate treatment."

CARE-ID received its approval to begin recruiting potential participants on May 25th and has plans to begin enrolling the first week of June. The purpose of this study is to learn more about the effectiveness of varying doses and administration methods of Evusheld. Participants will be assigned to a dosing regimen every three months or every six months.

"At CARE-ID we are continuing to direct our resources in the fight against COVID-19. We're very pleased to now take on this very important research project because of our core mission to investigate better treatments for serious, life-threatening infectious diseases", said David Wheeler, MD, FACP, FIDSA, principal study investigator, managing partner of Infectious Diseases Physicians, Inc. (IDP), the private clinical practice partner of CARE-ID. "COVID-19 variants are making it challenging to get ahead of the virus. And we're learning the effectiveness of vaccines has a lot to do with the recipient. In the case of immunocompromised people, for whom vaccines can be an evasive approach for protection, this study will help us solidify another important option."

‘The timing around this study is a high priority and we are ramping up starting today’, said Stephen Poretz, RN, MSHA, MBA CARE-ID Chief Operating Officer. “Astra Zeneca’s results in earlier trials clearly point to the need to move quickly on this one. We’re hoping to get the message out far and wide across our service area for those with weakened or compromised immune systems who might be interested. We encourage individuals who may qualify to contact us as soon as possible. This type of preventative (a “pre-exposure prophylaxis”) can’t come fast enough for some people.”

As stated in Astra Zeneca Fact Sheets, “Evusheld is the only antibody therapy authorized in the US (currently an Emergency Use Authorization - EUA) for pre-exposure prophylaxis of COVID-19”. Additionally, the National Institutes of Health COVID-19 Treatment Guidelines Panel (the Panel) recommends “Evusheld as a pre-exposure prophylaxis (PrEP) for adults and adolescents (aged ≥ 12 years and weighing ≥ 40 kg) who do not have SARS-CoV-2 infection, who have not been recently exposed to an individual with SARS-CoV-2 **and** who: are moderately to severely immunocompromised and may have an inadequate immune response to COVID-19 vaccination; or, are not able to be fully vaccinated with any available COVID-19 vaccines due to a history of severe adverse reactions to a COVID-19 vaccine or any of its components.”

“Given this background, we at CARE-ID are very excited to be one of the research organizations collaborating in this open-label, multicenter, project covering our Northern Virginia community, said Stephen Poretz. “We’re moving forward with our recruiting activities as fast as we can”.

Anyone interested in participating in this study or needing more information about the study should contact CARE-ID directly.

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About CARE-ID

The Clinical Alliance for Research and Education-Infectious Diseases, CARE-ID, conducts clinical research trials in the field of infectious diseases with particular focus on the safety and confidentiality of study participants, quality of data, and integrity of results. It partners with pharmaceutical and biotechnology companies to develop experimental therapies for both the prevention and treatment of infectious diseases.

About Astra Zeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Anyone can visit astrazeneca.com and follow the Company on Twitter @AstraZeneca.