

## **COVID-19 Pre Exposure, Preventive Treatment for Those With Compromised Immune Systems Enters a New Phase**

**Annandale, VA; June 9, 2023** - The leaders and researchers at the Clinical Alliance for Research and Education-Infectious Diseases (CARE-ID) are pleased to announce a refocusing of their collaboration with Astra Zeneca for an advanced monoclonal antibody for pre-exposure prophylaxis (prevention) of COVID-19.

The COVID-19 Pandemic taught infectious diseases doctors around the world a lot about fighting a global, respiratory virus that had never been seen before. When the new virus infected millions, we discovered that currently available antiviral defenses were inadequate at stopping it. As the spread continued, people took extraordinary measures, including masking and social distancing, to prevent its spread and slow the virus from making more people severely sick and causing deaths. However, such measures alone were not enough to overcome the virus's threats.

To fight the new virus, pharmaceutical companies and governmental agencies responded like never before. Through this effort, several effective vaccines were developed and administered in record time. CARE-ID is very proud to have been a part of this historical effort through partnering with Pfizer to carry out clinical trials that showed how safe and effective its vaccine could be at preventing severe sickness and hospitalization due to COVID-19.

For all that was learned throughout the Pandemic, there are still challenges to overcome. The mutating corona virus is still circulating and attempting to outsmart current vaccines. Safe and effective booster shots continue to prevent serious sickness and save lives while a new generation of vaccines is under development.

But not everyone can take advantage of COVID-19 vaccines. In particular, people whose immune systems are compromised by genetic conditions and other illnesses have difficulty generating a strong enough immune response after receiving the available vaccines. Without such a response, the vaccines aren't as effective at preventing a COVID-19 infection and severe sickness.

For this reason, there is an effort underway to develop a COVID-19 preventive agent that can provide protection. AstraZeneca, a major pharmaceutical company, has been working on this new type of agent and CARE-ID is an active partner in this effort. CARE-ID began its participation in the study in 2022. At that time, CARE-ID announced their collaboration with AstraZeneca for the ENDURE clinical trial of its combination product of 2 monoclonal antibodies for pre-exposure prophylaxis (prevention) of COVID-19, Evusheld. The study was a Phase II, randomized, open-label, multicenter, dose-ranging study.

David Wheeler, MD, FACP, FIDSA, principal study investigator, managing partner of Infectious Diseases Physicians, Inc. (IDP), the private clinical practice partner of CARE-ID said last May, “At CARE-ID we are continuing to direct our resources in the fight against COVID-19. We’re very pleased to take on this important research project because of our core mission to investigate better treatments for serious, life-threatening infectious diseases. 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.”

“To be clear, antibody treatment is different from a vaccine”, says Stephen Poretz, RN, MSHA, MBA, CARE-ID Chief Operating Officer. “Pre-exposure prophylaxis (PrEP) agents like monoclonal antibodies behave like naturally occurring antibodies while vaccines behave like a pathogen trying to stimulate one’s own antibody production. This type of preventative (a “pre-exposure prophylaxis”) can’t come fast enough for some people.”

Early in 2023, the study of Evusheld was suspended when the [U.S. Food and Drug Administration \(FDA\)](#) determined that this combination antibody treatment was no longer effective against dominant COVID-19 variants. In its place AstraZeneca has a new, single compound therapeutic antibody. “Laboratory studies show the antibody, called AZD3152, neutralizes all known variants of COVID-19 and AstraZeneca has support from regulators to make the treatment available by the end of this year”, said Iskra Reic, executive vice president of Vaccines and Immune Therapies, in an interview at a [Pharma event in Spain.](#)

With the decisions on Evusheld and the positive laboratory results for AstraZeneca’s AZD3152, CARE-ID is shifting its clinical study efforts to this new preventive therapeutic antibody. “Starting earlier this month, we began enrolling participants in the Main Cohort of the AstraZeneca trial,” stated Dr Wheeler. “Participants will be randomized 1:1 to receive AZD3152 (+placebo to preserve the blind) or AZD7442 on day one. Participants will receive a second dose of their original randomized study intervention six months after visit one.”

“Our targeted enrollment is currently set at 20 participants,” said Mr. Poretz. “We expect the study to run about 15 months with enrollment expected to close in August.”

The primary enrollment qualifications include:

- Persons 12 years and older,
- Having an immunosuppressive disorder diagnosis, or taking immunosuppressive medications
- Not been diagnosed with COVID, or
- Not having received a COVID vaccine within the last 3 months

There are other enrollment conditions, such as time availability and visits to the CARE-ID office during the study period. Individuals interested should visit the [CARE-ID website](#) or call the office at (703) 560-7900 between the hours of 9:00 AM and 5:00 PM Monday through Friday for more information or to begin the enrollment process.

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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 AstraZeneca**

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