Steve Poretz, RN, MSHA
Executive Director

The Clinical Alliance for Research and Education (CARE-ID) Begins Recruiting Adults for COVID-19 Investigation Vaccine Clinical Trial

A Lead MRNA Vaccine Candidate Against COVID-19

Annandale, VA; August 24, 2020 – CARE-ID announced today it has begun recruiting volunteers in a clinical research study to evaluate the safety and effectiveness of a vaccine candidate against COVID-19. Sponsored by Pfizer, the C4591001 (NCT04368728) is a phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-COV-2-RNA vaccine candidates against COVID-19 in health adults.

Pfizer has established a team of clinical researchers in 120 clinical investigational sites around the world, including 39 states across the United States to accelerate enrolling and managing approximately 30,000 volunteers who are expected to participate in this study. "Clinical trials like Pfizer's vaccine investigation are vital in testing potential defenses against COVID-19. If successful, trials like these represent medicines which can be used to protect those most at risk of severe illness," said Donald M. Poretz, MD, FACP, FIDSA, CARE-ID principle investigator and one of the founding members of Infectious Diseases Physicians, Inc. (IDP), a private clinical practice focusing on the care of people with a range of infectious diseases. "CARE-ID is very pleased to again join the front lines of the fight against COVID-19, and we are honored to participate in this important investigational vaccine study with Pfizer."

To be eligible for this COVID-19 Vaccine Study, participants, male or female, must be between the age of 18 and 85 at the time of enrollment, be healthy and not been previously diagnosed with COVID-19, be willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures, and be determined by medical history, physical examination and clinical judgment of the investigator to be eligible for inclusion in the study.

If a person is eligible and decides to participate, the research staff at CARE-ID will perform specific tests and procedures to monitor the patient's health and how their body reacts to the investigative drug. These tests and procedures include physical exams, vital sign measurements, and blood samples.

The study drug is being compared to a placebo, and both the study drug and the placebo will be administered by needle injection. Participants will be randomly selected to receive the placebo or the study drug.

"Our selection of the BNT162b2 vaccine candidate and its advancement into a Phase 2/3 study are the culmination of an extensive, collaborative and unprecedented R&D program involving Pfizer, BioNTech, clinical investigators, and study participants with a singular focus of developing a safe and effective COVID-19 RNA vaccine. The Phase 2/3 study protocol follows all the U.S. Food and Drug Administration (FDA) guidance on clinical trial design for COVID-19 vaccine studies," said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. "The initiation of the Phase 2/3 trial is a major step forward in our progress toward providing a potential vaccine to help fight the ongoing COVID-19 pandemic, and we look forward to generating additional data as the program progresses."

CARE-ID is located and can be contacted at:

3289 Woodburn Rd. Suite 250
Annandale, Virginia 22003
info@careidresearch.com
703-560-4821 (phone)
703-641-8654 (fax)
http://www.careidresearch.com/

If anyone who meets the eligibility requirements is interested in participating in this study or learning more about this study and their eligibility please contact CARE-ID.

About CARE-ID

Located in the Washington, DC suburb of Annandale, VA, CARE-ID conducts clinical research trials in the field of infectious diseases with particular focus on the safety and confidentiality of our participants, quality of our data, and integrity of our results. We partner with pharmaceutical and biotechnology companies to develop experimental therapies for both the prevention and treatment of infectious diseases. We've been advancing medicine for over 15 years through our clinical trial efforts and during 2020 we're now expanding the science for effective COVID-19 treatments.