



ICON selected by BARDA to conduct anthrax vaccine clinical trial

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DUBLIN--(BUSINESS WIRE)--Oct. 6, 2022-- [ICON plc](#), (NASDAQ: ICLR) a world-leading healthcare intelligence and clinical research organisation, today announces that it has been selected by the US Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS), to execute an anthrax vaccine clinical trial.

BARDA is providing funding to the Government and Public Health Solutions team at ICON to develop and execute a clinical trial that will evaluate the immune response to the next-generation anthrax vaccine AV7909. The team will support the evaluation of AV7909 immunogenicity kinetics by conducting clinical trial activities including but not limited to project management, clinical operations and quality assurance.

ICON has extensive experience in supporting vaccine clinical trials. It has participated in over 160 vaccine studies in the past five years. ICON's vaccine clinical research professionals are therapeutically aligned with a leadership team that brings more than 200 years of combined experience in vaccine clinical development for commercial businesses, government, NGOs and multinational health organisations.

Edward Wright, President, ICON Government and Public Health Solutions, commented: "We are pleased to have been selected to execute this important clinical trial. The potential for an anthrax attack is still a very real and serious threat, and we are proud to be playing our part to increase the understanding of treatment options for anthrax exposure, ultimately supporting human health."

This clinical study will inform operational logistics and use of AV7909 should an anthrax emergency occur. The clinical studies will not expose participants to anthrax. The trial will enrol healthy adults aged 18 and older and will be conducted in the United States starting in early 2023.

BARDA, part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, is responsible for developing medical countermeasures to secure the U.S. against chemical, biological, radiological, and nuclear threats, as well as pandemic influenza and emerging infectious diseases. Since 2014, ICON has been a member of BARDA's Medical Countermeasures Clinical Studies Network (CSN). The network is responsible for planning and executing clinical studies to support medical countermeasure development.

Bacillus anthracis, the agent that causes anthrax, is a serious bioterrorism threat due to the delivery of aerosolised spores that can cause high-mortality disease through gastrointestinal, cutaneous, inhalational (pulmonary), or injection routes. Although clinical manifestations of the disease differ by route, inhalational anthrax is the most lethal. Inhalational anthrax infection usually develops within a week after exposure but can take up to two months. Without treatment, only about 10% to 15% of patients survive after exposure to inhaled *B. anthracis* spores.

Since 2015, BARDA has supported the late-stage development of AV7909, a next-generation anthrax vaccine which uses the U.S. Food and Drug Administration (FDA)-licensed anthrax vaccine Biothrax in combination with an immune system stimulant or adjuvant. The vaccine is being developed in partnership with its manufacturer Emergent Biosolutions Inc. to protect against anthrax post-exposure when used in combination with the recommended antibiotics.

About ICON plc

ICON is the world's leading clinical research organisation, powered by healthcare intelligence. From molecule to medicine, we advance clinical research providing outsourced development and commercialisation services to pharmaceutical, biotechnology, medical device and government and public health organisations. We develop new innovations, drive emerging therapies forward and improve patient lives. With headquarters in Dublin, Ireland, ICON employed approximately 40,500 employees in 119 locations in 53 countries as at June 30, 2022. For further information about ICON, visit: www.iconplc.com.

About ICON Government & Public Health Solutions

ICON Government & Public Health Solutions (GPHS) is ICON's business unit focused on direct US Government engagement, Non-Government Organisations (NGOs) and academia, providing full service and functional research solutions. In addition, ICON GPHS coordinates a Government Centre of Excellence (CoE) to lend internal federal government subject matter expertise that can be leveraged by other ICON business units when commercial clients receive federal funding on ICON awarded contracts.

About BARDA's Medical Countermeasures Clinical Studies Network (CSN)

The CSN provides BARDA partners and medical countermeasure developers with essential tools and services to develop vaccines, therapeutics, diagnostics, and medical devices. The CSN provides comprehensive (Phases 1-4) clinical study services to help evaluate the safety, dosage, pharmacokinetics/pharmacodynamics, immunogenicity, and efficacy of medical countermeasure candidates, provide long-term storage services for clinical and nonclinical biological specimens and investigational products for future assays, and provide a statistical and data coordinating centre for harmonisation across BARDA projects. ICON plc's work with BARDA is supported with federal funds under contract number 75A50120D00017.

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