



BARDA Partners With ICON to Execute Next Generation COVID-19 Vaccines Clinical Trial

September 13, 2023

DUBLIN--(BUSINESS WIRE)--Sep. 13, 2023-- [ICON plc](#), (NASDAQ: ICLR) a world-leading healthcare intelligence and clinical research organisation, today announces that it is partnering with the U.S. Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, to execute a clinical trial to evaluate the effectiveness of next generation COVID-19 vaccine candidates.

Next generation COVID-19 vaccines could have the potential to expand the breadth of coverage against existing and future variants of the virus, extend the duration of protection, and offer better protection in the prevention of illness and transmission over the current state of vaccine technologies. Against this backdrop, the Government & Public Health Solutions team at ICON will execute a Phase 2b clinical trial to assess the relative efficacy of a next generation COVID-19 vaccine compared to currently approved/authorised COVID-19 vaccines in the prevention of symptomatic, PCR confirmed SARS-CoV-2 infection.

The trial will involve 10,000 subjects, expected to be enrolled over a six-month period. BARDA will select the vaccine candidate to be investigated in this trial, thereby accelerating the start of the Phase 2b clinical trial to support in benchmarking its efficacy against existing vaccines.

ICON has extensive experience in vaccine clinical development for commercial businesses, governments and NGOs, having participated in over 184 vaccine studies in the past five years. This experience has already helped ICON play a significant role in the search for vaccines and treatments for COVID-19. The company has partnered with its customers on the development of a number of approved vaccines. ICON has conducted or is currently involved in over 86 COVID-19 related trials.

Edward Wright, President, ICON Government & Public Health Solutions, commented: *"We are pleased to be partnering with BARDA on this research at an important juncture in the fight against COVID-19. As new variants emerge, timely clinical research has a pivotal role to play in helping ensure the development of medicines is accelerating as quickly as possible in line with the virus. Our experience in executing COVID-19 trials effectively, efficiently and thoroughly means we are well placed to support those sponsors who are at the scientific forefront in this area."*

In addition to its Government & Public Health Solutions team, ICON draws on the expertise of its biotech division, which comprises over 8,000 staff dedicated to biotech customers. As the world's largest dedicated biotech division, the team works with over 500 biotech sponsors annually.

Chris Smyth, President, ICON Biotech Solutions commented: *"In addition to our vaccine clinical development experience, we understand the important role biotech companies have in innovative drug development, and the specific requirements they have as they look to develop their portfolios. We are pleased to have the opportunity to work with them on this trial."*

This trial is part of Project NextGen, which coordinates across the U.S. Government and the private sector to advance innovative vaccines and therapeutics into clinical trials, regulatory review, and potential commercial availability.

BARDA 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 supports planning and implementation of clinical studies for medical countermeasure development. ICON has worked on numerous clinical trials as part of this network, including, most recently, [the execution of an anthrax vaccine clinical trial](#).

This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50120D00017.

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About ICON plc

ICON plc is a world-leading healthcare intelligence and clinical research organisation. From molecule to medicine, we advance clinical research providing outsourced 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 41,160 employees in 108 locations in 53 countries as at June 30, 2023. For further information about ICON, visit: www.iconplc.com.

This press release contains forward-looking statements. These statements are based on management's current expectations and information currently available, including current economic and industry conditions. These statements are not guarantees of future performance or actual results, and actual results, developments and business decisions may differ from those stated in this press release. The forward-looking statements are subject to future events, risks, uncertainties and other factors that could cause actual results to differ materially from those projected in the statements, including, but not limited to, the ability to enter into new contracts, maintain client relationships, manage the opening of new offices and offering of new services, the integration of new business mergers and acquisitions, the impact of COVID-19 on our business, as well as other economic and global market conditions and other risks and uncertainties detailed from time to time in SEC reports filed by ICON, all of which are difficult to predict and some of which are beyond our control. For these reasons, you should not place undue reliance on these forward-looking statements when making investment decisions. The word "expected" and variations of such words and similar expressions are intended to identify forward-looking statements. Forward-looking statements are only as of the date they are made and we do not undertake any obligation to update publicly any forward-looking statement, either as a result of new information, future events or otherwise. More information about the risks and uncertainties relating to these

forward-looking statements may be found in SEC reports filed by ICON, including its Form 20-F, F-1, F-4, S-8, F-3 and certain other reports, which are available on the SEC's website at <http://www.sec.gov>.

About ICON Government & Public Health Solutions

ICON Government & Public Health Solutions (GPHS) is ICON's business unit focused on direct U.S. 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.

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Source: ICON plc