



A Symbol of Excellence

November 6, 2014

ICON Selected by the FDA to Develop New Patient-Reported Outcome Measure for Hospital-Acquired Bacterial Pneumonia Trials

New PRO measure being developed in conjunction with the FNIH Biomarkers Consortium

DUBLIN--(BUSINESS WIRE)-- [ICON plc, \(NASDAQ: ICLR\)](#) a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries, today announced that it has been awarded a project by the [US Food & Drug Administration](#) (FDA) to develop an industry-standard Patient Reported Outcome (PRO) measure that can be used in anti-bacterial drug development trials for hospital-acquired bacterial pneumonia (HABP).

HABP is the second most common hospital-acquired infection and is the primary cause of death in intensive care units. [ICON's Commercialisation and Outcomes group](#), in collaboration with the [Biomarkers Consortium](#) of the [Foundation for the National Institutes of Health](#) (FNIH), aims to address an unmet need for a well-defined, reliable endpoint that can measure the effects of antibacterial drugs on HABP patients. The project involves creating a HABP PRO instrument with established content validity in accordance with the FDA Drug Development Tool qualification process. The new PRO would assess the symptoms of HABP at various time points over the course of the infection.

The collaboration brings together scientists from ICON, the FDA, the [National Institute of Allergy and Infectious Diseases](#), the [Infectious Diseases Society of America](#), pharmaceutical and biotechnology companies, and the academic research community to develop new approaches to evaluating the efficacy of antibiotics in future clinical trials of therapies for HABP.

"We are proud to be working with FDA and the FNIH to develop a PRO measure that will enable a better understanding of the effects of anti-bacterial drugs on HABP patients," commented Elizabeth Thiele, President, ICON Commercialisation & Outcomes. *"This project is particularly important given the need for new medicines to treat emerging drug-resistant strains of HABP pathogens which are on the increase. ICON's PRO group offers the right blend of knowledge and industry expertise in all areas of outcomes research to develop a reliable endpoint for HABP trials which will help deliver new antibacterial drugs to patients faster."*

About ICON plc

ICON plc is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. The company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. ICON currently has approximately 10,700 employees, operating from 83 locations in 38 countries.

Further information is available at www.iconplc.com

About the FNIH

The Foundation for the National Institutes of Health creates and manages alliances with public and private institutions in support of the mission of the NIH, the world's premier medical research agency. The Foundation, also known as the FNIH, works with its partners to accelerate key issues of scientific study and strategies against diseases and health concerns in the United States and across the globe. The FNIH organizes and administers research projects; supports education and training of new researchers; organizes educational events and symposia; and administers a series of funds supporting a wide range of health issues. Established by Congress in 1996, the FNIH is a not-for-profit 501(c)(3) charitable organization.

Further information is available at www.fnih.org

About the Biomarkers Consortium

The Biomarkers Consortium is a public-private biomedical research partnership managed by the Foundation for the National Institutes of Health (FNIH) that endeavors to develop, validate, and/or qualify biological markers (biomarkers) to speed the development of medicines and therapies for detection, prevention, diagnosis and treatment of disease and improve patient care.

Further information is available at www.biomarkersconsortium.org

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, as well as 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, S-8 and F-3, which are available on the SEC's website at <http://www.sec.gov>.

ICON/ICLR-G

ICON

Rebecca Power

Weber Shandwick

Tel: +44 (0) 207 067 0866

Email: RPower@webershandwick.com

Source: ICON plc

News Provided by Acquire Media