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ICON: Pfizer and Roche Join ADDPLAN DF Consortium

New members join Novartis, Janssen, and Eli Lilly to develop adaptive design and execution methodologies for improved decision-making in exploratory studies

DUBLIN--(BUSINESS WIRE)-- **ICON plc (NASDAQ: ICLR)**, today announced that Pfizer and Roche have joined the ADDPLAN® DF Consortium. The consortium was founded in 2013 by Novartis Pharma AG, Janssen Pharmaceuticals Inc., Eli Lilly, and Aptiv Solutions, which is an ICON plc company leading the design and implementation of adaptive trials. The goal of the ADDPLAN DF Consortium is to develop methodologies and execution technologies that improve dose-selection, which remains a major barrier to resolving high failure rates in Phase III trials. Both Pfizer's and Roche's decision to join the Consortium comes as more companies recognise the value of adaptive design in improving decision making in exploratory development.

The ADDPLAN DF Consortium statisticians are currently collaborating to expand the utility of the Multiple Comparison Procedure and Modeling (MCP-Mod) approach, specifically by developing robust methodology for incorporating adaptive functionality. The current MCP-Mod procedure enables Proof of Concept (PoC) and dose selection to be established in a single trial. The ability to go beyond the current approach and include interim decision making into the MCP-Mod procedure will build in additional efficiency and flexibility.

"The membership of Pfizer and Roche, long time proponents of adaptive design, significantly strengthens the Consortium's ability to develop validated, regulatory-compliant software for the design and execution of adaptive trials," says Reinhard Eisebitt, Executive Vice President and Head of ICON's Adaptive Trial Innovation Center. "Since its formation last year, the ADDPLAN DF Consortium has provided invaluable insight to further enhance the software, including the addition of adaptive dose-escalation functionality and more simulation metrics, improved plotting functionalities for simulation results, and an extension to documentation."

ICON will hold an ADDPLAN User Group meeting on August 4, 2014 from 4:30 to 6:30 PM, at the Seaport Hotel, Boston, MA. Jose Pinheiro, Ph.D., Senior Director, Quantitative Decision Strategies at Janssen, and co-developer of MCP-Mod, will give a talk on the basics of MCP-Mod; David Ohlssen, Ph.D., Senior Expert Methodologist at Novartis, will present a case study on the use of adaptive MCP-Mod for a multiple sclerosis trial; and Tobias Mielke, Ph.D., Statistical Consultant at Aptiv Solutions, will speak about the use and development of ADDPLAN DF. An open Q&A will take place following the presentations. Registration is limited to 20 attendees and can be completed by emailing inquiry@aptivsolutions.com.

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 plc currently has approximately 11,000 employees in 38 countries.

Further information is available at www.iconplc.com

About ADDPLAN®

ADDPLAN is the leading fully validated statistical design, simulation and analysis software for adaptive clinical trials and is widely used by regulatory agencies and the pharmaceutical and medical device industries. It is available in the following modules:

- ADDPLAN Base: Adaptive group sequential designs and sample size re‑estimation
- ADDPLAN MC: Adaptive multiple comparison procedures
- ADDPLAN PE: Adaptive population enrichment designs
- ADDPLAN DF: Adaptive dose finding designs (including MCP-Mod)

For additional details about ADDPLAN software, including eLearning modules, pricing and ordering information, visit http://www.aptivsolutions.com/addplan-software/.

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.

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