



## **ICON Delivers New Electronic Solution to Expedite Clinical Trial Adjudication**

### **Enables Sponsors to Comply With Recent FDA Guidance on Diabetes Trials**

DUBLIN, Ireland, January 26, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- ICON plc, (NASDAQ: ICLR; ISIN:IE0005711209), a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries, today announced the launch of a new electronic solution that will accelerate the adjudication of cardiovascular events in diabetes studies.

The evaluation of cardiovascular risk in diabetic trials has been the subject of recent FDA guidance. Recommendations published in December 2008 require sponsors to establish an independent cardiovascular endpoints committee to adjudicate cardiovascular events, including cardiac death, acute myocardial infarction and stroke. FDA guidance applies to diabetes drugs evaluated in all Phase II and Phase III trials and some Phase IV trials. Historically, most of the adjudication performed by independent adjudication committees has been done in a paper-based environment, causing inefficiencies in project tracking and data evaluation, auditing challenges and increased costs associated with adjudicator travel, shipping and unnecessary patient enrolment. ICON's new electronic solution, which is currently being used in a number of trials, allows cardiovascular event data to be uploaded, reviewed and assessed online, delivering significant operational efficiencies.

Dr. Jonathan Goldman, MD, FACC, Chief Medical Officer at ICON Medical Imaging commented: "ICON's electronic adjudication solution provides the most secure and accurate method of defining true cardiovascular events in real-time. Because of its inherent regulatory compliance it is ideally suited to comply with the recent FDA guidelines for diabetes trials. It also provides significant savings in costs and timelines by preventing unnecessary enrolment of patients once the target number of endpoints has been achieved."

ICON's new endpoint solution is a fully validated module of the existing MIRA(TM) (Medical Imaging Review and Analysis) technology platform, developed and managed by ICON Medical Imaging. MIRA is a proprietary 21 C.F.R. Part 11 compliant system that provides functionality for imaging and clinical data management, image analysis, project management and document management. The new endpoint module stores all data relevant to the adjudication of cardiovascular events - including Case Report Form (CRF) output, patient charts, laboratory results, ECG, echocardiogram, Multi-Gated Acquisition Scan (MUGA), coronary angiogram, peripheral angiogram and x-rays - in a digital DICOM (Digital Imaging and Communications in Medicine) format. Adjudicators in different locations can simultaneously access and review this data in a secure online environment and complete the assessment in an electronic CRF. The CRF is logic driven and can also allow for queries for extra data as well as programmatic identification of cases that require consensus resolution.

Dr. Didier Saur, MD, Vice President, Endocrinology & Metabolism at ICON Clinical Research added: "This latest regulatory requirement will make the clinical development of diabetes drugs more demanding in terms of patient exposure and inclusion of patients at a higher cardiovascular risk. Companies developing oral anti-diabetic drugs can not only benefit from ICON's new technology solution but also from the vast experience of ICON's diabetes and cardiology specialists as well as the expertise of our Cardiac Scientific Advisory Board."

#### About ICON Medical Imaging

Located in Warrington, PA, ICON Medical Imaging, a division of ICON plc, is the leading provider of Medical Imaging core laboratory services to pharmaceutical, biotech and life science clients globally. The team's extensive experience and expert guidance enables clients to maximise the success of their medical imaging endpoints, supporting their current research and development capabilities. ICON Medical Imaging has managed over 260 imaging trials in oncology, cardiovascular, CNS, medical devices and imaging agents.

Further information is available at <http://www.iconmedicalimaging.com>

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