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Celerion Announces Membership into the Cardiac Safety Research Consortium (CSRC).

(Lincoln, NE; Oct 15, 2014) – Celerion is pleased to announce our membership into the Cardiac Safety Research Consortium (CSRC). As a member of the CSRC, Celerion will engage with other thought leaders on key issues that impact cardiovascular safety. This will include discussions regarding alternative approaches to ICH E14 to assess arrhythmia liability in early drug development.

Celerion is a leading provider of cardiovascular safety services in early clinical research. In our 40 years of experience, Celerion has conducted over 150 studies for cardiovascular compounds, and completed more than 50 Thorough QT (TQT) studies. By leveraging this expertise, Celerion developed the innovative Highly Automated ECG Core Lab that enables clients to expedite ECG review, thereby significantly reducing the time and cost for cardiac safety studies over traditional approaches. Membership into CSRC highlights Celerion's leadership role and contributions in cardiovascular safety evaluation, and allows us to collaborate in critical discussions to ensure we deliver on our clients' and public health needs.

The CSRC was launched in 2006 through an FDA Critical Path Initiative Memorandum of Understanding with Duke University to support research into the evaluation of cardiac safety of medical products.

CSRC supports research by enlisting stakeholders from industry, academia, and government to share data and expertise. Outputs of the CSRC include research projects taking advantage of waveforms released from the FDA ECG warehouse, Think Tank Incubator programs, and consensus white papers. Additional work is under way to expand the portfolio of research projects beyond the ECG data into other areas of cardiac safety evaluation from the preclinical through the postmarket periods.

"We are delighted to be a member of the CRSC, and help define novel paradigms for cardiovascular safety assessment of new chemical entities in clinical research," said Robert Lester MD FACC, Chief Cardiologist, and Global Medical Director, Cardiovascular Safety at Celerion. "Being part of this prestigious organization and collaborating with our peers in academia, the pharmaceutical industry, as well as other Contract Research Organizations (CROs) in the area of cardiovascular safety evaluation, will enable Celerion to help shape the future of cardiac safety in drug development."

About Celerion

Celerion, a leader in early clinical research, delivers Applied Translational Medicine. Celerion applies our expertise and experience to translating information gained in research discoveries, to knowledge of drug action and effect in humans to support early drug development decisions and the clinical pharmacology labeling of new medicines.

With over 40 years of experience and 750 global clinic beds (including 24 in-hospital), Celerion conducts and analyzes First-in-Human, clinical Proof-of-Concept, Cardiovascular Safety Services (TQT, robust QT), ADME and NDA-enabling clinical pharmacology studies. Celerion provides expertise on modeling and simulation, study design, medical writing (protocols and reports), clinical data sciences, biostatistics, and PK/PD analysis as well as small and large molecule bioanalytical assays through clinical drug development. Regulatory, drug development and program management complement Celerion's service offerings. For more information please visit www.celerion.com.