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Celerion Launches New Hybrid ECG Core Lab for Phase I Clinics

Hybrid ECG Core lab provides clients faster access to data, cost savings and higher quality of data

(Lincoln, NE; June 2, 2010) – [Celerion](#), the premier provider of innovative early stage clinical research solutions, announces the launch of a new Hybrid Phase I/ECG Core lab. The Hybrid Phase I/ECG Core lab provides highly automated ECG analysis for Celerion's global Phase I clinical network. Celerion's highly automated approach employs cutting-edge technology to perform automated measurement of ECG recordings, thereby minimizing cardiologist review and providing clients with faster access to data. The system also effectively identifies the small number of ECG recordings that will still require cardiologist review. This reduction in cardiologist involvement, combined with much smaller overhead compared to traditional ECG Core labs supporting global clinical trials, allows Celerion to offer significant cost and time savings to clients.

The Hybrid Phase I/ECG Core lab was developed in collaboration with AMPS-LLC (Analyzing Medical Parameters for Solutions), and Global Instrumentation, LLC (GI). AMPS-LLC is a world leader in high quality ECG analysis software utilized by many ECG Core labs. Global Instrumentation is a pioneer in the development of Bluetooth-enabled Holter monitors. Celerion is proud to host the first installation of AMPS' FAT-QT and TrialPerfect software platforms, in addition to being the first contract research organization (CRO) to deploy the Global Instrumentation technology for Phase I/ECG trials.

"The introduction of the Hybrid Phase I/ECG Core lab clearly establishes Celerion as the world leader in innovative early cardiac services," said Susan Thornton, CEO of Celerion. "By integrating the ECG functions within our clinic network, minimizing traditional ECG overhead and providing more automation, Celerion enables fast access to data and cost-effective solutions that deliver high-quality data for the execution of thorough QT studies and ECG assessment in SAD and MAD programs."

Fabio Badilini, founder and chief scientist at AMPS-LLC stated, "We are delighted to be collaborating with Celerion. The suite of AMPS-LLC software provides considerable advantage by ensuring optimal extraction of ECG recordings from Holters, providing accurate interval measurements in the vast majority of ECGs and identifying those recordings that may require a cardiologist's review."

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According to Jim DeMaso, President of Global Instrumentation, "The GI M12R recorder and M12A Enterprise software provide state-of-the-art Holter functions with full standard 12-lead ECG functionality in a centralized data management system designed for the requirements of clinical trials. We are pleased to be part of the Celerion/AMPS collaboration, which has led to the advancement in performing clinical trials using this new semi-automated process."

About Celerion

Celerion is the premier provider of innovative early stage clinical research solutions. It was formed through the acquisition of the early stage development operations and development and regulatory services consultancy of MDS Pharma Services. They offer a full spectrum of resources to meet the needs of the pharmaceutical, biotechnology and generic industries for Phase 0 through IIa proof-of-concept studies. From facilities strategically located around the world, they apply advanced scientific and technological expertise to clinical research (Phases 0, I and IIa), bioanalytical services (discovery through late stage), clinical pharmacology sciences and drug development services. For more information, please visit our website at www.celerion.com.

About AMPS

AMPS-LLC, based in New York, New York, is a leading-edge software company providing software solutions used specifically by clinical research organizations (CROs) and pharmaceutical corporations in the field of quantitative ECG analysis and blood pressure monitoring. They are well known for the support given to the FDA for the establishment of the HL7 XML ECG standard and for providing FDA Officials with the famous AMPS XMLFDA Viewer tool. The company's website is www.amps-llc.com.

About Global Instrumentation, LLC

Global Instrumentation is a privately owned company with headquarters located in Manlius, New York, and with operations in India and Florida. Global Instrumentation develops, manufactures and distributes its ECG devices worldwide and through OEM relationships. The company also provides design, manufacturing, and product support services to companies within the medical industries. The three principals of Global Instrumentation have over 90 years combined experience developing medical products. Global Instrumentation is an FDA-registered manufacturer with certification for ISO13485 and CMDCAS. Global Instrumentation's current products include a complete line of Holter products consisting of ECG recorders and Holter Analysis systems designed for stand-alone usage as well as enterprise web based usage. The company also has specific solutions for web-based data warehousing to support any clinical trial, scanning service or distributed processing centers. More information can be found at www.gimedical.com.

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