



QPS' Bio-Kinetic Clinical Applications Phase I Unit Announces Collaboration with Quintiles

(September 9, 2008; Springfield, MO) – QPS' clinical research unit, Bio-Kinetic Clinical Applications, announces a joint collaboration with Quintiles that creates an integrated Cardiac Safety Service for sponsors by incorporating clinical conduct, core ECG laboratory support, independent cardiologist and medical monitor oversight, pharmacokinetic and statistical analysis, and reporting of cardiac safety trials. These clinical trials, commonly called Thorough QTc (TQT) studies, typically are done early in development and evaluate a drug's effect on cardiac repolarization by indentifying any QT/QTc interval prolongation and/or proarrhythmic potential using methods described in ICH E14. This formal collaboration between QPS' Bio-Kinetic Phase I unit and Quintiles is the culmination of more than a 10-year relationship of conducting many Phase I clinical trials together, including TQT studies.

Contemporary with TQT research trends, QPS' and Quintiles' Phase I units are able to enroll large cohorts of subjects as commonly required for parallel group designs; to conduct trials in the US and/or Europe; and to provide first-in-man clinic environments when safety of the test article is not adequately defined. Five hundred and fifty (550) Phase I beds are available from the combined research facilities in Springfield, MO, Overland Park, KS, London, England, and Uppsala, Sweden. Our global core ECG service is a state-of-the-art analysis laboratory with high-throughput capability, highly efficient paperless operation, and in-process quality control of ECG reading and verification. It is manned 24/7 by full-time cardiologists and operational staff that manage your ECG data from project inception through submission to the FDA ECG Warehouse. The underpinning of the cardiac safety service is a well experienced clinical pharmacology team providing all other ancillary services from data management through report writing; however, its unique contribution is concentration-QT (C-QT) modeling and simulation now used as a powerful tool to more accurately interpret the results of a TQT study. The integrated Cardiac Safety Service created by QPS and Quintiles provides a full service, single-point solution for TQT studies from the first regulatory strategy through generation of the final clinical study report.

"Bio-Kinetic has a strong history and reputation in early-phase clinical research, having conducted over 800 clinical trials in the last several years. In collaboration with Quintiles we now offer the full suite of cardiac safety services," said Dale Bourg, CEO, Bio-Kinetic Clinical Applications. "Additionally, since Bio-Kinetic is a wholly-owned subsidiary of QPS, all sponsors have access to our industry experts in bioanalysis, DMPK, pharmacogenomics, and pharmacodynamics; complex procedures that can provide immense value in the decision-making process from drug discovery to preclinical and clinical development."

"Quintiles' Global Phase I and its Clinical Pharmacology team support early development needs globally with sites in the United States and Europe. We truly specialize in the design and quality performance of complex Phase I/IIa protocols. Our collaboration with QPS' Bio-Kinetic provides our clients with the capability to house large cohort studies for cardiac safety monitoring," said Eddie Caffrey, Head of Global Phase I, Quintiles. "Our pharmacokinetic scientists and statisticians have in-depth knowledge of the protocol requirements for acquiring, analyzing, and interpreting QTc data including C-QT modeling and simulation techniques."

About Quintiles

Quintiles Transnational Corp. is powering the next generation of healthcare by providing a broad range of professional services in drug development, financial partnering and commercialization for the biotechnology and healthcare industries. With more than 21,000 employees and offices in more than 50 countries, it is focused on providing customer-centric solutions that are the gold standard of the industry. For more information, please visit the company's Web site at www.quintiles.com.

About Bio-Kinetic

Bio-Kinetic, www.bkcaus.com, is a drug development services company that designs and conducts Phase I clinical studies for branded pharmaceutical, bio-technology, and generic drug companies. The company owns and operates a 240-bed Phase I facility in Springfield, Missouri which positions Bio-Kinetic as one of the larger independent Phase I facilities in the country. The Company is known for its clinical quality, having developed an outstanding reputation for study designs, recruiting and screening study participants, and collecting and reporting clinical data.

About QPS

Founded in 1995, QPS, www.questpharm.com has bioanalysis, DMPK, and Translational Medicine facilities at its Newark, DE, headquarters and a laboratory in Taipei, Taiwan. Regional sales offices are maintained in California, Connecticut, Massachusetts, Ohio, Pennsylvania, and Texas. QPS is a GLP-compliant CRO that supports discovery, preclinical and clinical drug development. It has been providing quality services in bioanalysis (LC-MS/MS, LBA, Hybridization-LBA), preclinical and clinical DMPK (pharmacokinetics, metabolism, autoradiography), translational medicine research (protein and biochemical markers, pharmacogenomics/pharmacogenetics biomarkers, pharmacodynamics) to its clients worldwide.