

Spaulding Clinical, US and Clinigene International, India Announce Strategic Partnership for Providing Comprehensive Early Clinical Solutions to Pharmaceutical and Biotech Clients

West Bend, WI – August 22, 2011 – Clinigene International Limited, India-based Clinical Research Organization with Phase I-IV clinical research and extensive Bioanalytical capabilities and Spaulding Clinical Research, LLC., US-based leading-edge Clinical Pharmacology, Cardiac Core Lab, and Medical Device Manufacturer, announce a strategic partnership agreement. This partnership establishes a reliable, trustworthy, and cost-efficient global footprint for clinical pharmacology services providing an opportunity for both organizations to engage pharmaceutical clients strategically and accelerate First-In-Human to Proof-of-Concept clinical development.

“Pharmaceutical clients globally are increasingly seeking strategies to expedite their early clinical development, streamlining processes while maintaining high quality. Our strategic partnership is designed to deliver this in a very cost-effective manner,” states Dr. Abhijit Barve, Chief Operating Officer of Clinigene. “The strengths of both companies are very complementary with Clinigene providing the preclinical development (through sister concern Syngene), Spaulding providing FIH/SAD/MAD, and Clinigene providing DDI and efficient Proof-of-Concept, supported by Clinigene’s Central and Bioanalytical Laboratories. With Clinigene’s expertise and cost-effective approach to BA/BE and Spaulding’s market-leading TQT study expertise, our clients are able to easily structure a program for their compound that delivers high-value while keeping the molecule knowledge experts involved throughout the entire early clinical development of the compound,” states Randol Spaulding, CEO of Spaulding Clinical.

Clinigene operates a CAP-accredited Central Laboratory and GLP-compliant Bioanalytical Laboratory for small and large molecules, both equipped with state-of-art technology, as well as a 94-bed clinical pharmacology unit in Bangalore, India which excels at Bioavailability/Bioequivalence studies, Drug-Drug Interaction and Early Patient Studies. Spaulding Clinical operates a 105-bed clinical pharmacology unit with 96-beds of Mortara telemetry in West Bend, Wisconsin. The facility is paperless with a phase I Electronic Data Capture system and bi-directional interfaces to safety lab, bedside devices and telemetry. As a Phase I-IV Core Laboratory provider, Spaulding offers the complete suite of equipment provisioning and electrocardiogram over-reading services, including the proprietary Spaulding iQ Electrocardiograph. Both partners have a data solutions team to support clients study data requirements.

About Clinigene International Limited

Established in 2000, Clinigene (www.clinigeneintl.com) became India's first CAP (College of American Pathologists) accredited Central Laboratory in 2002. Studies conducted at Clinigene's early phase clinic and bioanalytical lab have been inspected by EMEA and US-FDA without Form 483 or critical findings. Clinigene's services now span a broad spectrum of activities including human pharmacology, bioanalytical research, central laboratory, clinical operations, medical writing, medical monitoring, safety management, pharmacovigilance, clinical data management & biostatistics and regulatory services supporting early-phase through late-phase clinical development programs.

About Spaulding Clinical Research

Spaulding Clinical Research, LLC (www.spauldingclinical.com) is a leading-edge Clinical Pharmacology, Cardiac Core Lab and Medical Device Manufacturer that offers a full range of global services from study design through study execution/conduct, data management, statistical analysis, and clinical summary/expert reporting. Spaulding has extensive experience conducting TQT, first-in-human, multiple rising dose, bioavailability/bioequivalence, drug interaction, and food effect studies. As a Phase I - IV Core ECG Laboratory provider, Spaulding offers the complete suite of equipment provisioning and electrocardiogram over-reading services with state-of-the-art technologies and expertly trained cardiologists as well as a revolutionary new ECG device.

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