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ASIA EDITION

Clinical trial firm BioClinica expands in China

June 20, 2013 | News | By BioSpectrum Bureau



Singapore: BioClinica, a global provider of clinical trial management services, has merged with CoreLab Partners as an initiative to better serve its growing sponsor client base in China and other Asia Pacific countries. CoreLab Partners is a provider of cardiac safety monitoring and imaging core lab services.

BioClinica has also completed its first regulatory-mandated Thorough QT (TQT) cardiac safety study in China, a strategic partnership with TEDA International Cardiovascular Hospital (TICH) in Tianjin, China, and the expansion of local operational support for cardiac safety monitoring and imaging core lab services in Asia.

The cardiac safety study, proposed by China's State Food and Drug Administration (SFDA), was conducted in collaboration with the TEDA International Cardiovascular Hospital (TICH) in support of a new drug approval for a domestic sponsor.

BioClinica provides both in-country operational and scientific support for the study, including study design, project management, ECG data collection and extraction, ECG analysis and assistance with regulatory submission. This TQT study builds on BioClinica's cardiac safety leadership in the region, having successfully completed the first regulatory-mandated TQT study in Japan in 2010.

"Cardiac safety is gaining momentum in China and I am pleased to have been part of this collaborative TQT study in support of the changing regulatory landscape surrounding cardiac safety," said Dr Boaz Mendzelevski, BioClinica's VP of cardiology.

"The evolving regulatory environment in China will necessitate new safety standards and assessments of a similar nature for drugs in the pipeline, resulting in increased collaborative efforts and consultative input in support of Chinese pharmaceutical companies seeking domestic and global marketing approval for their new drugs."

Details of this unique TQT study were presented at the recent annual DIA China meeting in Beijing by Dr Jennifer (Jie) Hou, head, TICH phase I clinical trial unit, and Dr Mendzelevski.

"This study not only represents a remarkable success for BioClinica, but signals our continued investment of resources and expanding operational support in the emerging Asia Pacific markets," added Dr Mark Weinstein, president and CEO,

BioClinica. On the heels of this study, BioClinica will be supporting additional TQT studies in China later this year.