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Landmark Regulatory Revision Ushers in an Alternative to the Thorough QT Study

iCardiac, a key contributor, will conduct public webinars explaining the benefits to sponsors

December 21, 2015, Rochester, NY - iCardiac Technologies, Inc., a scientific leader in the conduct of cardiac safety assessments, today applauded the official release of a regulatory revision enacted by the International Council for Harmonisation (ICH) that defines and enables an alternative path to the conduct of a Thorough QT (TQT) study in clinical drug development. Likely the most significant regulatory shift in cardiac safety since the original E14 Guidance was adopted by the ICH in 2005, the new revision emerged following the successful conduct of a prospective validation study in 2014 that was sponsored by iCardiac and which utilized iCardiac's personnel and technology to perform the critical data analysis.

Currently, the FDA and other regulators expect nearly all new drugs to be tested using a costly, stand-alone TQT study to assess a drug's effect on the QT interval before market approval, since a prolonged QT interval is associated with a heightened risk for arrhythmias and possible sudden cardiac death. The revision adopted by the ICH, an international forum for regulators to harmonize drug approval practices, describes how data from ECGs collected during routine Phase I or other early clinical trials may be used to conclusively demonstrate a drug's QT effect. This approach relies on intensive, high quality ECG analysis and the use of exposure response modeling. A sponsor that submits QT data to a regulator meeting certain defined standards, as described in the ICH revision document, may seek a waiver from having to conduct a TQT study. The FDA granted the first TQT waiver based on this alternative approach earlier in 2015. In addition to representatives from the FDA, the ICH includes regulatory representatives from the European Union, Japan, Canada and Switzerland.

iCardiac has been at the forefront of championing this alternative approach for several years. Its proprietary High Precision QT methodology, which was optimized over many years to provide conclusive results from smaller studies, provided iCardiac with early confidence in the feasibility of gaining actionable QT data from Phase I studies. In addition to its role as the only ECG core laboratory involved in the conduct of the definitive 2014 validation study, iCardiac has developed a Certified Site network of Phase I sites that are trained and tested in the conduct of capturing high quality ECG data that is optimally suited for this alternative approach.

Given its unique experience with this type of study, iCardiac is conducting two free public webinars to explain the new ICH guidance and the standards it establishes for receiving a waiver from the TQT study. The public webinars will be held on January 12th and January 20th, and sponsors can register to attend using the information found below.

"The significance of the change in regulations is that it gives sponsors a choice. You can either perform a careful assessment of the drug's effect on ECG parameters as part of your standard early clinical trials, or you can later on conduct a formal TQT study. Both options are now viable

alternatives, provided you do things right," said Dr. Borje Darpo, a cardiologist and chief scientific officer at iCardiac.

"We are thrilled that the ICH has officially sanctioned this alternative approach and by the benefits this will provide to drug developers," said Alex Zapesochny, president and CEO of iCardiac. "In addition to saving considerable time and money, sponsors following this new approach will gain valuable insight about their drug's QT liability years earlier in the development process."

To view the ICH revision document, visit: http://bit.ly/1QuKHvB

To register for one of iCardiac's free public webinars, visit:

- For January 12 at 10 a.m. EST: http://bit.ly/1YmOjnD
- For January 20 at 1 p.m. EST: http://bit.ly/1IZ9l4B

About iCardiac Technologies:

iCardiac Technologies, Inc. is the world's most innovative centralized core laboratory for cardiac safety and respiratory services. Its high precision cardiac safety assessment methodology has set a new standard for precision and accuracy in all phases of clinical trials. The company serves 8 of the top 10 global pharmaceutical companies, as well as numerous small and mid-sized pharma and biotechnology firms. For more information, please visit: www.icardiac.com.

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