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Avoiding False Positives Key Priority in Cardiac Safety Studies

Pharmaceutical Companies Recognizing Risks with Traditional Cardiac Safety Approaches

Rochester, New York – May 4, 2009 – iCardiac Technologies, Inc., a leading innovator in advanced cardiac safety biomarkers and automated QT analysis, today announced the results of its online survey of pharmaceutical companies, biotechnology companies and industry consultants. When asked about the key priorities for cardiac safety studies, avoiding false positives was selected as the single highest priority with 46% of survey respondents ranking it as the most important attribute.

“The results of the survey are consistent with the growing recognition that conventional cardiac safety studies have significant limitations,” said Sasha Latypova, Executive Vice President of iCardiac Technologies. “Interest in avoiding both false positives as well as false negatives is especially acute in today’s environment as many drug developers are re-prioritizing their portfolios and focusing on fewer compounds.”

As drug developers and regulators have gained extensive experience with cardiac safety studies since the introduction of the E14 guidance in 2005, it is now evident that while progress has been made, there are still many issues to be addressed in cardiac safety. Specifically, techniques that can more accurately and cost-effectively assess the effect of a novel drug on cardiac repolarization are needed. It is commonly estimated that false positives and false negatives may impact as many as 10% to 25% of drugs in portfolios at Phase I and beyond because of current limitations of conventional techniques used in cardiac safety studies.

In addition to the desire to avoid false positives, 27% of the respondents selected the quality of the expert report as the most important criteria while 12% selected cost effective study design and 6% rapid study execution. A total of 419 pharmaceutical and biotechnology professionals responded to the survey which was conducted between February 25th and April 21st of 2009.

About iCardiac Technologies

iCardiac Technologies, Inc. is a technologically differentiated cardiac core lab providing expert scientific consultation, end-to-end project management, statistical analysis and the industry’s most sophisticated FDA-accepted cardiac safety assessment methodologies. iCardiac’s analysis service provides drug developers with more precise

and cost-effective methods for QT interval measurement, including Highly Automated QT, which has been validated by pharmaceutical companies and accepted by the FDA as equivalent to the manual evaluation of ECGs in Thorough QT studies. In addition, iCardiac provides Beyond QT, a suite of advanced ECG-based cardiac safety markers that have been accepted as secondary end-points by the regulators, and deliver a more accurate assessment of the cardiac safety profile of drugs in development. iCardiac's COMPAS technology has been used for over a decade in cardiac clinical trials conducted for and by leading large and medium sized pharmaceutical, biotechnology, and medical device companies. For more information, visit: www.icardiac.com.