

FOR IMMEDIATE RELEASE

Contact:

Sasha Latypova

(585) 295 7610 X103

sasha.latypova@icardiac.com

## **iCardiac's COMPAS Analytics Used in Recent New Drug Approval**

### **iCardiac's Advanced Analytics Help Demonstrate that QTc Prolonging Drug is Not Pro-Arrhythmic**

Rochester, New York – September 9, 2009 – iCardiac Technologies, Inc., a leader in advanced cardiac safety biomarker development and automated QT analysis, announced that its full suite of advanced cardiac safety methods including Highly Automated QT<sup>sm</sup>, Dynamic QT beat-to-beat<sup>sm</sup> as well as Beyond QT<sup>sm</sup> have been used in an FDA submission to support a new drug approval.

"We are enthusiastic about our continued progress in supporting drug approvals for our pharmaceutical and biotechnology clients," said Sasha Latypova, Executive Vice President. "What is especially exciting about this program is that iCardiac's methods were able to provide key scientific evidence indicating that the drug does not appear to have arrhythmia liability despite QT prolongation. The drug has now been approved by the FDA with a clean cardiac safety label."

In October 2005, the FDA introduced a new guidance for industry (ICH E14) requiring the evaluation of pro-arrhythmic potential of new drugs by measuring the QT segment of ECGs collected in clinical trials. The dissatisfaction among pharmaceutical developers with the poor precision, high rate of false positives/negatives, and high cost of the "gold standard" manual or semi-automated QT measurements has led to efforts toward providing more advanced cardiac safety analytics.

#### **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](http://www.icardiac.com).