



For Immediate Release
04.November.2009

For more information, contact
Veronica Palacios at +1.301.214.7624

Cardiocore's Thorough QT Performance Factors in FDA's Approval of Livalo

Cardiac Safety Profile Established in First Statin Thorough QT Study

Washington, DC—Cardiocore, a premier centralized cardiac testing lab, announced today that a Thorough QT study it performed for Kowa Pharmaceuticals contributed to the Japan-based drug developer's successful regulatory approval of pitavastatin which will be marketed under the name LIVALO®.

In a joint presentation by Cardiocore and Kowa scientists, the Thorough QT (TQT) results for LIVALO were initially introduced at the quadrennial World Conference on Clinical Pharmacology and Therapeutics, held in 2008. The Food and Drug Administration (FDA) announced the drug's approval for treatment of hypercholesterolemia on August 3, 2009.

LIVALO is the first statin to seek marketing approval after publication of the FDA/ICH Guidance for Industry, *E14: Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs*. As a result, it is also first statin to undergo Thorough QT testing. The TQT results were negative, and no signals of cardiotoxicity appeared in other trials of LIVALO.

Using the TQT data analyzed by Cardiocore, Kowa's clinical development team provided regulators a clean and thorough cardiac safety profile that factored into the approval of LIVALO. According to the FDA's announcement, "LIVALO was approved on the basis of five clinical trials comparing its efficacy and safety to that of three currently marketed statins."

Kowa Chief Medical Officer, Roger Morgan, MD, FACS said, "This Thorough QT study is part of a successful, collaborative partnership we enjoy with Cardiocore. As we achieve this important milestone, I'd like to thank Cardiocore for their valuable contributions along the way."

Cardiocore Chief Medical Officer, Lawrence Satin, MD, FACC added, "We are delighted by the approval of LIVALO, and proud to have supported Kowa in this endeavor. Most importantly, we are glad that clinicians will now have another means to mitigate the risks of heart disease and stroke associated with elevated cholesterol."

About Cardiocore: *Cardiocore has provided superior centralized cardiac testing services to the pharmaceutical industry for 17 years. Services include centralized electrocardiography (ECG), Holter monitoring, echocardiography (ECHO), multigated acquisition scans (MUGA), protocol development and statistical analysis. The company is experienced in cardiac safety and efficacy testing in Phase I-IV and Thorough QT clinical trials. These services are supported by the company's advanced data management system featuring the proprietary HolterGateway™ and CardioPortal™. Cardiocore's U.S. headquarters is located in Bethesda, Maryland, its West Coast office is located in San Francisco, California, and its European subsidiary, Cardiocore Limited, is located in London, England. www.cardiocore.com*