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## CoaguSense Receives FDA Clearance for the CoaguSense Blood Coagulation Testing System for Patient Home Use

*Company unveils first portable coagulation analyzer to directly detect blood clot formation; Abbott Point of Care to sell and market new offering*

**FREMONT, Calif., – June 1, 2010** – CoaguSense™, Inc., a diagnostic device company that has been in stealth mode for the past two years, today unveiled the first portable point-of-care Prothrombin Time/International Normalized Ratio (PT/INR) analyzer to directly detect blood clotting time for patients stabilized on oral anti-coagulation medications such as Coumadin® or warfarin. The CoaguSense PT/INR monitoring system has now been cleared by the Food and Drug Administration (FDA) for use by patients in the home by prescription. The analyzer is also now Clinical Laboratory Improvement Amendments (CLIA) waived for use in physician offices. The product consists of a low-cost meter and disposable test strip. Medical professionals can order the system through Abbott Point of Care, which formed an exclusive agreement with CoaguSense to sell and market the CoaguSense PT/INR Monitoring System™.

"CoaguSense was formed to address an important need for patients requiring the oral anticoagulant warfarin on a long-term basis," said Doug Patterson, president and CEO of CoaguSense. "For many patients, their blood coagulation levels are checked too infrequently to reduce the risk of bleeding and thrombotic complications. That is why The Joint Commission has reduction in the likelihood of patient harm associated with the use of anticoagulation therapy as a top national patient safety goal. By offering suitable patients the ability to test weekly at home with the CoaguSense PT/INR Monitoring System, patients and their doctors can have greater confidence that therapy is being proper monitored."

Patterson continued, "The CoaguSense system's direct micromechanical blood clot detection technology brings performance and reliability to a market that has traditionally been challenged by products employing indirect means of detecting clot formation. The elegance and simplicity of CoaguSense's proprietary design will give clinicians and patients comfort in knowing their test system is based on the same mechanical principle as the World Health Organization's gold standard tilt-tube method and the research grade fibrometer."

More than 7 million people worldwide are treated with oral anticoagulants for a variety of clinical conditions including, but not limited to: congestive heart failure, atrial fibrillation, prosthetic heart valve, myocardial infarction, joint replacement, deep vein thrombosis pulmonary embolism, thrombotic stroke, coronary artery disease, venous thromboembolism and cancer. The routine measurement of prothrombin time is a test performed to control the safe and effective management of oral anticoagulation therapy. Recently, Medicare expanded reimbursement to cover patient self-testing (PST) of prothrombin time at home for the majority

of those indications. This is a significant milestone as the CoaguSense PT/INR monitoring system is part of the emerging in-home PST market. The market is currently estimated at $100 million and is growing at over 500 percent per year, and projected to become a $1 billion market within five years.

**Important Product Usage and Safety information**

The CoaguSense™ PT/INR Monitoring System is intended for use by properly selected and trained patients or their caregivers on the order of the treating physician. Users should be stabilized on oral anticoagulation medications such as Coumadin® or warfarin prior to initiating self-testing with the system. Patients who have recently taken or are currently taking any type of Heparin or Low Molecular Weight Heparin anticoagulant should not use the system and should consult their doctor. The device is not to be used for screening purposes.

**About CoaguSense, Inc.**

Based in Fremont, California, CoaguSense was founded in 2008 to bring more accurate and robust anticoagulation monitoring technology to both clinicians and patients. The Company's lead product is the CoaguSense PT/INR Monitoring System which incorporates a novel direct micromechanical clot detection technology. This propriety technology emulates the World Health Organization (WHO) gold standard tilt-tube method while requiring only a very small blood sample. Direct clot detection technology provides clinicians with the system reliability they demand and patients with comfort of knowing that proper home testing can provide dependable results like a laboratory. Further information about CoaguSense can be found at www.coagusense.com.



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