ICU
MANAGEMENT & PRACTICE

BG Medicine Obtains CE Mark for CardioSCORE(TM) Test in Europe

Innovative Blood Test for the Prediction of Major Cardiovascular Events Expected to Launch in the First Half of 2013

BG Medicine, Inc., a diagnostics company focused on the development and commercialization of novel cardiovascular tests, announced yesterday that it obtained a CE Mark enabling the commercial sale of the CardioSCORE™ test in the EU and other countries that recognize the CE Mark. The CardioSCORE test is the company's patented diagnostic blood test designed to dramatically improve risk prediction of major cardiovascular events beyond traditional risk factor assessments, such as the Framingham Risk Score and European SCORE.

The CardioSCORE test is performed on a standard blood sample and utilizes algorithmic analysis to combine the results of seven reimbursed protein assays. The test involves an independent scoring system that yields a quantitative result ranging from 0.0 to 10.0, with higher values indicating elevated risk for a major cardiovascular event in the subsequent 3 years and with each 1.0 point increment representing a 30% increase in relative risk. In the 6,600 patient BioImage Study cohort, the primary clinical validation study for the CardioSCORE test, among those who experienced a near-term major cardiovascular event during follow-up, only 26% were identified as being at high risk at baseline by traditional risk factors, whereas 54% percent were identified as being at high risk upon addition of their CardioSCORE result ($p < 0.0001$).

"We are thrilled to bring the benefits of the CardioSCORE test to patients and physicians in Europe. We believe this test will be a pivotal and disruptive game-changer in the primary prevention of major cardiovascular events and treatment of disease, representing a major advancement over the diagnostic tools clinicians have used for the past 15 years," said Eric Bouvier, President and Chief Executive Officer of BG Medicine. "The majority of cardiovascular events occur among patients who are asymptomatic, and current risk factor assessment methods simply miss too many patients with hidden subclinical risk, delaying appropriate therapy and effective monitoring of response to such therapy. The CardioSCORE test will identify individuals at elevated risk for heart attack and stroke, enabling preventive intervention. We are working aggressively to launch the test in the first half of 2013 in Europe in collaboration with specialty laboratory partners."

"The CardioSCORE test may have the potential to help improve the care of many people by providing a simple, accurate and clinically meaningful score to assess an individual's risk for near-term major cardiovascular events," said Valentin Fuster, MD, PhD, Professor of Cardiology and Director of Mount Sinai Heart.

Last month, investigators at the American Heart Association (AHA) Scientific Sessions 2012 presented the results of several analyses of the CardioSCORE test performance in the BioImage Study. The presentations by investigators from the Mt. Sinai School of Medicine and the Baptist Hospital of Miami highlighted the predictive value of the test in assessing risk for near-term major cardiovascular events across a broad and diverse community-dwelling population. A summary of these findings is available here: http://investor.bg-medicine.com/releases.cfm.

"Obtaining the CE Mark for the CardioSCORE test is not only a significant milestone in the prevention and treatment of cardiovascular disease but also a critical advancement in our company's continued transformation into a full-scale commercial organization," continued Mr. Bouvier. "BG Medicine now has two products covering the continuum of heart disease diagnostics, positioning us strongly to drive the clinical usage of our important diagnostic tests for millions of patients who will benefit from them throughout the world."

The CardioSCORE test is not yet available commercially in the United States. BG Medicine is continuing its active discussions with the US Food and Drug Administration regarding 510(k) clearance for the test in the United States.

Source: BG Medicine Inc.

www.bg-medicine.com

Published on : Wed, 12 Dec 2012