FOR IMMEDIATE RELEASE

Boston Heart Reaches Milestone in Statin Intolerance Testing

Over 250,000 Genotypes Performed to Help Identify Individual Risk of Statin Induced Myopathy; Data Confirm Research Findings of Risk Prevalence for Statin Side Effects.

FRAMINGHAM, Massachusetts (September 8, 2015) – Boston Heart today announced that over 250,000 Statin Induced Myopathy (SLCO1B1) Genotype tests have been performed, a significant milestone for the company and the cardiovascular disease community at large. The SLCO1B1 Genotype test pinpoints a genetic variant in the SLCO1B1 gene. SLCO1B1 is the transporter that takes up statins in the liver. This test helps healthcare providers identify patients who do not process certain types of statins normally and are therefore at a more than a fourfold higher risk for statin induced myopathy – the onset of muscle aches, spasms and pain associated with statin therapy.

Statins have been shown to significantly lower heart disease and stroke rates. However, studies estimate that of the 25—50% of patients with cardiovascular disease who stop taking their statin medications as directed, 60% cite muscle pain as the primary reason for discontinuation. Research shows that patients who received SLCO1B1 genotype guided therapy were more likely to fill their statin prescription, take the medication as directed, and ultimately decrease their LDL cholesterol.

"Boston Heart's SLCO1B1 testing goes above and beyond the standard lipid panel testing – it helps me identify a patient's probability for tolerating certain statins so I can prescribe the best treatment," said Patrick Moore, MD, MBA, Founder, CEO and Medical Director of the Moore Healthcare Group. "When my patients understand the reasoning for their tailored treatments, compliance levels rise."

Based on the data collected from the 250,000 genotypes tested, Boston Heart has confirmed the prevalence of SLCO1B1 variants. Three genotypes have been identified and classified in terms of their effect on statin metabolism in the liver—normal (T/T), decreased (T/C), and markedly decreased (C/C):

- The T/T genotype (valine/valine) is classified as a normal statin metabolizer. These patients have a normal ability to metabolize statins (about 75% of the population).
- The T/C genotype (valine/alanine) is classified as a decreased statin metabolizer. These patients have a decreased ability to metabolize statins (about 23% of the population). They have up to a 4.5-fold increased risk for developing statin induced myopathy.
- The C/C genotype (alanine/alanine) is classified as a markedly decreased statin metabolizer. These patients have a significantly decreased ability to metabolize statins (about 2% of the population). They have up to a 17-fold increased risk of developing statin induced myopathy.

Additionally, individuals carrying the T/C or C/C genotype are less responsive to statins for LDL-C lowering than those carrying the T/T genotype. Boston Heart's data confirms previously published research on the prevalence of SLCO1B1 from Oxford University (N Engl J Med 2008;359:789-99) and

Duke University (J Am Coll Cardiol 2009;54:1609-16), indicating that 25% of the population is affected with a variant. Additional factors associated with risk of statin induced myopathy include: female gender, age (over 65 years), hypothyroidism, decreased kidney function, use of calcium channel blockers and amiodorone, deficiencies of vitamin D and co-enzyme Q10, and certain medications.

The SLCO1B1 Genotype test, together with the Boston Heart Cholesterol Balance® test which measures the complete cholesterol production pathway and all of the major absorption markers, provide insights into personalized therapeutic options for better patient management. In active development are next-generation sequencing to help determine the genetic causes of high LDL-C (>190 mg/dL off medications) in patients and also which patients will require and respond to PCSK9 inhibitors. “We’re proud to have reached this SLCO1B1 testing milestone – it’s a testament to our commitment to providing personalized medicine and optimizing treatment strategies for patients,” said Ernst Schaefer, MD, Founder and Chief Medical Officer, Boston Heart Diagnostics. “Early and advanced identification of those who are at higher risk for statin induced myopathy will reduce the time and expense required to achieve optimal therapeutic outcomes, and ultimately, better quality of life for those who are affected.”

About Boston Heart

Boston Heart Diagnostics is transforming the treatment of cardiovascular disease by providing healthcare providers and their patients with novel, personalized diagnostics and integrated customized lifestyle programs that have the power to change the way clinicians and patients communicate about disease and improve heart health. Boston Heart looks beyond the “good” and “bad” cholesterol assessment that conventional labs provide to give a more complete picture of heart health. Founded by renowned cardiovascular researchers and led by seasoned lab and diagnostic executives, Boston Heart is one of the fastest growing health companies in the country. For more information on Boston Heart Diagnostics, please visit www.BostonHeartDiagnostics.com

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