



For Immediate Release

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WARFARIN Study Launched to Assess Impact of Genetic Testing in Reducing Hospitalizations and Deaths Caused by Warfarin

First major personalized medicine study authorized by Centers for Medicare & Medicaid Services may drive reimbursement based on improved patient safety, reduced healthcare costs

Bothell, WA, March 1, 2011 -- Iverson Genetic Diagnostics, Inc. announced today that the WARFARIN Study (**W**arfarin **A**dverse Event **R**eduction for **A**dults **R**eceiving Genetic Testing at Therapy **I**nitiation) was initiated in major hospital systems nationwide to assess the utility of genetic testing to determine a personalized warfarin dose for individual patients to reduce their risk of serious bleeding or clotting events. Warfarin, the most commonly prescribed blood thinner worldwide, causes up to 100,000 serious and unnecessary adverse events every year, including thousands of deaths. Studies have shown that DNA testing can dramatically improve the safety and effectiveness of warfarin, with estimated savings to the U.S. healthcare system of approximately \$1.1 billion.

Warfarin is prescribed to 2 million patients in the U.S. annually and approximately 20 million Americans use the drug in total. Warfarin is difficult to dose as patients respond to it differently according to their genetic makeup -- too much warfarin can result in severe bleeding, and too little can cause clot formation and increased risk of stroke. In the past, warfarin dosing relied on trial-and-error, which exposed patients to serious medical risks. Warfarin is the second most frequent cause of drug-related emergency room visits.

Over the past few years, two genetic variants have been identified that predict an individual's response to warfarin. Using genetic testing to guide physicians in starting warfarin therapy has the potential to reduce deaths, increase overall patient safety and lower national healthcare system costs. Given the magnitude of these potential improvements in warfarin use, the Centers for Medicare & Medicaid Services (CMS) has authorized the WARFARIN Study to gather data on the potential impact of a pharmacogenetic test to reduce serious bleeding and clotting episodes in patients. Upon review of the Study, the first such personalized medicine trial authorized by CMS, the agency may establish reimbursement for the genetic warfarin test, which is marketed by Iverson Genetic Diagnostics.

Leroy Hood, M.D., Ph.D., co-founder of the Institute for Systems Biology and a member of Iverson Genetic Diagnostics' Board of Directors, commented, "The technological tools for molecular discovery that we continue to develop become truly valuable when they can actually improve human health. CMS is to be commended for its leadership in authorizing the WARFARIN Study. This study marks a step towards our goal of improving patient outcomes through personalized care."

Researchers have identified two specific genes, VKORC1 (for warfarin sensitivity) and CYP2C9 (for warfarin metabolism), which contribute up to 40% of individual patient variations in response to using warfarin. The WARFARIN Study will assess the extent to which serious adverse events – hemorrhage and clotting – can be avoided when warfarin dosing is guided by genetic testing for these two genes, as compared to warfarin dosing calculated without these pharmacogenetic data. The 18-month study will enroll more than 7,000 patients at up to 50 study sites nationwide; patients' rates of warfarin-related adverse events will be studied at 30, 60 and 90 days from initial warfarin dosing. Study results will be used by CMS for reimbursement decision-making. The multicenter, randomized, blinded, parallel-group study is being led by Principal Investigator Elizabeth Ofili, M.D., Chief of Cardiology, Director of Clinical Research, and Associate Dean for Clinical Research at Morehouse School of Medicine. Trial registration and study sites can be found at www.warfarinstudy.org.

"This landmark study is about more than warfarin," said Dean Sproles, CEO and Chairman, Iverson Genetic Diagnostics Inc., which initiated the WARFARIN Study. "It is about individualizing treatment to improve patient safety and outcomes, thereby reducing healthcare costs. CMS' support of the WARFARIN Study demonstrates their commitment to exploring the impact of genetic testing on individualized dosing, which may pave the way for other studies in the personalized medicine arena."

About Iverson Genetic Diagnostics, Inc.

Iverson Genetic Diagnostics, Inc. provides physicians with genetics-based testing to identify individual patients' predispositions to major diseases as well as the therapeutic considerations that can improve treatment outcomes and quality of life. With its growing portfolio of genetics-based tests and assays, the company is addressing one of today's major medical challenges by ushering in a new era of more timely, predictive, and affordable "personalized" healthcare. The Company markets the Warfarin GenoSTAT Test[®] to provide personalized genetic profiles of patients' potential responses to treatment with warfarin. Iverson Genetic Diagnostics is headquartered in Bothell, Washington, part of the greater Seattle technology corridor. The company's facilities are CLIA- and CAP-certified. For more information, visit www.IversonGenetics.com.

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