

## FOR IMMEDIATE RELEASE

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### **CMS Approves Clinical Study of Genetic Test to Predict Patient Response to Leading Anticoagulant Drug Warfarin**

*First-of-its-kind study to evaluate gene identification ability to predict patient response and improve safety when dosing world's leading anti-blood clotting drug*

**Atlanta, GA July 26, 2010** - Iverson Genetic Diagnostics today announced the company has received approval from CMS to conduct a WARFARIN Clinical Study. The two-year (2) study will assess the impact of genetic information in calculating doses and the changes in the rate of adverse events when initiating Warfarin drug therapy. These changes will be compared against doses initiated without genetic data. The randomized and blinded, multi-center study will involve more than 7000 participants at over 50 sites nationwide.

The specific CMS approval is for a *clinical study under Coverage with Evidence Development (CED) and will cover pharmacogenetic testing of CYP2C9 or VKORC1 alleles to predict warfarin responsiveness*. Iverson Genetic Diagnostic's CEO Dean Sproles commented, "The CMS approval of the WARFARIN Study is evidence of the growing role of genetics in helping doctors to develop optimal individual treatments for their patients. The data from this study will contribute to determining if the use of genetics in warfarin dosing reduces adverse health events."

Warfarin is a commonly used anticoagulant (blood thinner) and is most commonly known by the brand name of Coumadin<sup>®</sup>. The dosage and administration of warfarin must be individualized for each patient according to his or her response to the drug. Currently, these individual responses are evaluated on a trial-and-error basis.

Today, more than 2 million patients are prescribed warfarin in the United States each year. One (1) to five (5) percent experience a major bleeding event. The annual cost associated with warfarin complications is estimated to be \$1.1 billion.<sup>1</sup> Researchers have identified two specific genes, VKORC1 and CYP2C9 that contribute up to 60% of individual patient variations in response to using warfarin. The WARFARIN Study will evaluate changes in side-effects such as major hemorrhagic or thromboembolic events when using genetic information to determine individualized warfarin dosages.

The WARFARIN Study is being led by Principal Investigator Elizabeth Ofili, MD, Director of Clinical Research, Chief of Cardiology and Associate Dean for Clinical Research at the Morehouse School of Medicine in Atlanta, Georgia. Dr. Ofili indicated that, "Warfarin is an essential drug for preventing blood clots. However, the adverse event rates need to be lowered. This study should help us understand how to use each patient's genetic information to deliver a safer and more effective dose."

The WARFARIN Study Steering Committee is accepting clinical sites interested in participation. Please visit [www.warfarinstudy.org](http://www.warfarinstudy.org) to obtain updated information about participation and progress.

<sup>1</sup> McWilliam A, Letter R, and Nardinelli C. (2006) Health care savings from personalized medicine using genetic testing: the case of warfarin. *Working Paper 06-23, AEI-Brookings Joint Center for Regulatory Studies* ([http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/WP06-23\\_topost.pdf](http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/WP06-23_topost.pdf)).

**About Iverson Genetics Diagnostics**

Iverson Genetic Diagnostics is a leader in making actionable genetic information readily available to physicians in everyday practice. The mission of Iverson Genetic Diagnostics is to provide physicians with clinically relevant gene-based information to optimize therapy and enhance personal wellness for their patients. Through its gene-based health and treatment profiles, the company provides physicians with actionable genetic information to optimize clinical decision-making and patient care. Iverson Genetic Diagnostics is headquartered in the Seattle suburb of Bothell, Washington where it maintains CLIA and CAP certified genetic testing laboratories. In addition, the company operates two specialty-specific genetic testing labs through university relationships in Georgia and South Carolina. For more information, visit [www.IversonGenetics.com](http://www.IversonGenetics.com).

The Iverson laboratory in Atlanta is located at Morehouse School of Medicine.

**About Morehouse School of Medicine**

Morehouse School of Medicine (MSM), located in Atlanta, Georgia, was founded in 1975 as the Medical Education Program at Morehouse College. In 1981 Morehouse School of Medicine became an independently chartered institution and the first minority medical school established at a Historically Black College and University in the 20<sup>th</sup> century. MSM is among the nation's leading educators of primary care physicians, and was recently recognized as the top institution among US medical schools for its social mission. Our faculty and alumni are noted in their fields for excellence in teaching, research and public policy. MSM physicians are known in the community for exceptional, culturally appropriate patient care. MSM recognizes that the elimination of health disparities requires a paradigm shift to healthcare that is personalized, predictive, pre-emptive, and preventive. For more information about Morehouse School of Medicine, visit ([www.msm.edu](http://www.msm.edu)).

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