NEWS

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GENOMAS PRESENTS NEW FINDINGS ON STATIN SAFETY AND PATIENT ADHERENCE AT THE *AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY* ANNUAL MEETING

Prospects for Using DNA-Guided Medicine to Manage Statins Explored in Symposium with Leading Experts in Cardiovascular Pharmacogenetics

WASHINGTON, D.C. – Genomas®, a biomedical company advancing DNA-guided medicine and personalized healthcare, announced its participation in the symposium to be held today entitled *Pharmacogenomics of Statin Safety and Efficacy* at the Annual Meeting of the American Association for Clinical Chemistry (AACC). Gualberto Ruaño, MD, PhD, President and CEO of Genomas, is the symposium's chairman and will talk about *The Pathway to DNA-Guided Statin Therapy*.

The symposium participants and their topics are:

Ronald M. Krauss, MD
Senior Scientist and Director
Atherosclerosis Research
Children's Hospital and
Oakland Research Institute,
Oakland, CA
Statins: Role of Pharmaco-genomics in Clinical Practice

Stewart H. Lecker, MD, PhD
Assistant Professor of Medicine
Beth Israel Deaconess Medical Center
Harvard Medical School
Boston, MA
The Molecular Basis of Statin Myopathy

Georgirene Vladutiu, PhD
Professor of Pediatrics,
Neurology and Pathology
School of Medicine and
Biomedical Sciences
SUNY at Buffalo, NY
Genetic Susceptibility to Severe Statin-Induced Myopathy.

Statins are the most effective medications for managing elevated concentrations of low-density lipoprotein cholesterol (LDLc) and are the most prescribed drugs in the world. Drugs in this class include atorvastatin, rosuvastatin, and simvastatin. These drugs offer effective strategies to reduce cardiovascular disease and improve survival.

However, there are clinically relevant safety risks for some patients. Statin-induced neuro-myopathy (SINM) may present as muscle aches (myalgia), cramps, weakness, and muscle injury (myositis, monitored in serum by elevation of certain enzymes). SINM is more frequent at the higher doses required for treating advanced heart disease and varies in extent between individual statins and from patient to patient. In a previously published study, over 10% of statin patients were impacted by neuromuscular side effects, the consequences of which were disruptions of daily life activities, and reduction in regimen adherence.[1]

The symposium will describe the progress of DNA-guided medicine with respect to statin therapy. The participants will describe class-wide and drug-specific genetic associations with statin lipid lowering and neuromyopathy, explore clinical relevance, and survey directions for future research, particularly the utilization of total genome arrays.

"Statin myopathy is of major importance in any patient undergoing statin therapy, especially in high-risk cardiovascular patients," said Dr. Georgirene Vladutiu, one of the symposium participants. "As molecular knowledge emerges about possible mechanisms of statin myopathy, risk assessment tools are being developed to predict adverse responses to these drugs in individuals. As researchers in this area, it is our hope that effective risk assessment will not only reduce the morbidity and mortality associated with severe myopathic reactions but also increase compliance in those who most urgently need the medication," she added.

New research from an actuarial analysis supported by Genomas of over 4 million commercially insured persons from 2004 to 2006 will be presented by Dr. Ruaño. The incidence of SINM in new high-risk patients was 17% and the incidence of SINM in new and existing patients with coronary artery disease was 21%[2]. Dr. Ruaño will also discuss statin pharmacogenetic results from the consortium including Genomas, Hartford Hospital, University of California San Francisco and Rogosin Institute, which is funded by a recently awarded $1.2 million NIH grant. The goal is to integrate treatment response with physiogenomics technology to develop DNA-guided clinical management systems that predict and compare an individual's risk of SINM.

"We are seriously motivated about the role we can play in addressing what has been an under-appreciated health issue that affects millions of people," said Dr. Ruaño. "This presentation at AACC is part of a series of upcoming forums for Genomas to present its research and product development efforts, and to engage with international thought leaders." The AACC Annual Meeting is one of the premiere international forums for laboratory medicine and the clinical diagnostics industry. The 2008 meeting in Washington, D.C. will attract nearly 20,000 participants and 700 exhibitors from more than 100 countries.

ABOUT GENOMAS

Genomas® Inc. is a biomedical company advancing DNA-guided medicine and personalized healthcare. The company develops revolutionary PhyzioType™ Systems for DNA-guided diagnosis and prevention of metabolic disorders induced by drugs in cardiovascular and psychiatric medicine. PhyzioType Systems provide physicians with the unprecedented capability to select for each patient the safest drug treatment to enhance compliance. Genomas is located in Hartford, CT on the campus of Hartford Hospital. Please access www.genomas.net

ABOUT PHYZIOTYPE CLINICAL MANAGEMENT SYSTEMS

PhyzioType™ Systems are composed of an ensemble of inherited DNA polymorphisms genotyped by arrays and interpreted by a biomathematical algorithm in order to convey to physicians predicted comparisons of side effect risk among drugs for the individual patient. The research leading to the SINM PhyzioType System has been published in the renowned journals *Muscle & Nerve*[3] and *Pharmacogenomics*[4]. To date, Genomas has secured $3.1 million from NIH Small Business Innovation Research (SBIR) for PhyzioType System product development.

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References

[1] *Mild to Moderate Muscular Symptoms with High-Dosage Statin Therapy in Hyperlipidemic Patients – PRIMO Study* by Bruckert E, Hayem,G, Begaud B, et alia, *Cardiovascular Drugs Therapy,* 19: 403, 2005

[2] Data on file, Genomas Inc.

[3] *Physiogenomic Association of Statin-Related Myalgia to Serotonin Receptors* by Ruaño G, Thompson PD, Wu AHB, et alia, *Muscle & Nerve,* 36: 329, 2007

[4] *Physiogenomic analysis links serum creatine kinase activities during statin therapy to vascular smooth muscle homeostasis,* by Ruaño G, Thompson PD, Wu AHB, et alia, *Pharmacogenomics*, 6: 865, 2005