NEWS

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GENOMAS PRESENTS DRUG-SPECIFIC GENETIC DETERMINANTS OF STATIN SAFETY AND EFFICACY AT THE XV INTERNATIONAL SYMPOSIUM ON ATHEROSCLEROSIS

Data Being Used to Develop DNA-Guided Decision Support for Statin Prescription

BOSTON, MA – Genomas, a biomedical company advancing DNA-guided medicine and personalized healthcare, announced its participation at the XV International Symposium on Atherosclerosis, the world's largest and most prestigious symposium held triennially under the auspices of the International Atherosclerosis Society. Gualberto Ruaño, MD, PhD, President of Genomas, will present *"Physiogenomic Contours of Statin Safety and Efficacy"*, a clinical study examining the differences in response to statin drugs based on individual gene variations.

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). 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 previously published studies, over 10% of statin patients were affected by neuromuscular side effects, the consequences of which were disruptions of daily life activities, and reduction in regimen adherence.[1, 2]

In this study, 442 outpatients treated with atorvastatin, rosuvastatin and/or simvastatin were studied at lipid clinics in Hartford Hospital (Hartford CT) and the University of California San Francisco (San Francisco CA). They were evaluated for a wide range of potential side effects as well as their LDLc levels. In addition, each patient provided a small blood sample for pharmacogenetic analysis. Researchers genotyped 384 SNPs (single nucleotide polymorphisms) from 222 cardiometabolic and neuroendocrine genes with a potential role in determining the safety and efficacy of statins. The study was funded in part by a grant from the National Institute of General Medical Sciences of the National Institutes of Health.

"Contrasting quantitatively how the gene polymorphisms associate with clinical responses, we can visualize the *'physiogenomic contours'* of statin drugs," said Dr. Ruaño. "These contours represent the mechanistic differences among statins, which we plan to use as the foundation for DNA-guided rules for treatment on a patient-individualized basis." He added, "Statins provide important benefits to most patients but we must address what has been an under-appreciated problem affecting millions of people. Our goal is to use physiogenomics technology to develop DNA-guided clinical management systems that predict and compare a patient's risk of SINM."

Paul D. Thompson, M.D., Chief of Cardiology at the Henry Low Heart Center of Hartford Hospital and co-author of the study commented: "Growing evidence indicates that genetics determines who develops neuromuscular complaints on statin therapy. These new results suggest possible physiological differences between desired and undesired effects of these drugs. We are pursuing the necessary validation studies to support translation to clinical practice."

ABOUT GENOMAS

Genomas is a biomedical company advancing DNA-guided medicine and personalized healthcare. The company is developing and testing revolutionary PhyzioType™ Systems for DNA-guided diagnosis and prevention of metabolic disorders induced by drugs used to treat diabetes, and cardiovascular and psychiatric illnesses. PhyzioType Systems are designed to provide physicians with an 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 visit www.genomas.net for more information.*

ABOUT PHYZIOTYPE™ SYSTEMS FOR DNA-GUIDED MEDICINE

PhyzioType™ Systems are composed of an ensemble of inherited DNA polymorphisms genotyped by arrays and interpreted by a bioclinical algorithm in order to convey to physicians predicted comparisons of side effect risk among drugs for the individual patient. They are being developed for DNA-Guided Medicine in the prescription of cardiovascular, psychotropic and diabetes drugs and in preventive cardiology. The research leading to the *PhyzioType* Systems has been published in the renowned journals *Annals of Biomedical Engineering, Biomedical Engineering Handbook, Molecular Psychiatry, Muscle & Nerve, Pharmacogenomics* and *Clinica Chimica Acta*. To date, Genomas has secured $3.5 million from NIH Small Business Innovation Research (SBIR) and filed 8 patent applications for PhyzioType System product development. *Please visit www.genomas.net for more information.*

ABOUT THE HENRY LOW HEART CENTER AT HARTFORD HOSPITAL

The Henry Low Heart Center at Hartford Hospital provides the region's best cardiac heath options. It offers an array of comprehensive services and sophisticated techniques in a setting of highly personalized care. The Center is named for Dr. Henry Low, a pioneering cardiac surgeon who performed the first successful heart transplant operation in Connecticut in 1984. Within the Henry Low Heart Center are Laboratories for Cardiac Catheterization, Nuclear Cardiology, Electrophysiology; Clinics for Preventive Cardiology and Cardiac Rehabilitation; Cardiovascular Surgery, a Heart Transplant program, as well as separate Centers for Congestive Heart Disease, Chest Pain, and Heart Rhythm Disturbance. *For more information please access www.hartfordhospital.org.*

ABOUT THE XV INTERNATIONAL SYMPOSIUM ON ATHEROSCLEROSIS

Jointly sponsored by the National Lipid Association and the Giovanni Lorenzini Medical Science Foundation, the XV International Symposium on Atherosclerosis is the world's premier meeting focused on the presentation of new research and clinical findings on arterial disease. The National Lipid Association (NLA) is a nonprofit, multidisciplinary medical society focused on enhancing the practice of lipid management in clinical medicine. The primary objective of the Lorenzini Foundation is to pass on to the medical world and to the community the latest and most significant scientific discoveries, especially the most recent developments in the experimental sciences. *For more information please access www.isa2009.org.*

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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] *Physiogenomic Association of Statin-Related Myalgia to Serotonin Receptors* by Ruaño G, Thompson PD, Windemuth A, Seip RL, Wu AH, et alia, *Muscle & Nerve,* 36: 329, 2007