# **NEWS**

Contact:
Gualberto Ruaño, M.D., Ph.D.
President and CEO
Genomas, Inc.
860.545.4574

FOR IMMEDIATE RELEASE March 19, 2008



# GENOMAS AWARDED \$1.2 MILLION NIH SBIR GRANT TO DEVELOP DNA-GUIDED SYSTEM FOR MANAGEMENT OF STATIN THERAPY

Product Predicts, Compares Neuromuscular Side Effects of Statins for Each Patient

**HARTFORD, CT** – Genomas<sup>®</sup>, a biomedical company advancing DNA-guided medicine and personalized healthcare, today announced the award of a Fast-Track Phase I-II Small Business Innovation Research (SBIR) Grant totaling \$1.2 million. The grant, entitled "*DNA Diagnostic System for Statin Safety and Efficacy*", was awarded by the National Institute of General Medical Sciences (NIGMS)\*. NIGMS is the NIH lead institute for the nationwide Pharmacogenetics Research Network.

Statins are the most prescribed drugs in the world. Drugs in this class include atorvastatin (*Lipitor*<sup>®</sup>), rosuvastatin (*Crestor*<sup>®</sup>), and simvastatin (*Zocor*<sup>®</sup> and generic formulations). Statins are the most effective medications for managing elevated concentrations of low-density lipoprotein cholesterol (LDLc). These drugs offer effective strategies to reduce cardiovascular disease and improve survival.

Statin-induced neuro-myopathy (SINM) is the main clinically relevant safety risk of these drugs. In medical practice, SINM presents as a constellation of nerve and muscle side effects. Clinical symptoms of SINM include 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. Statin usage is ultimately limited by these side effects which are disabling to 10% of patients, require alteration of therapy, burden healthcare with management costs, and reduce compliance.

Under the SBIR program, Genomas will integrate the clinical expertise of its strategic partner, Hartford Hospital, with the company's proprietary physiogenomics technology to develop DNA-guided clinical management systems that predict and compare an individual's risk of SINM among atorvastatin, simvastatin and rosuvastatin. PhyzioType™ Clinical Management Systems are composed of an ensemble of inherited DNA markers 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.

In announcing the award, Gualberto Ruaño, M.D., Ph.D., President and CEO of Genomas commented: "By interfacing complex patient reactions to statin drugs with physiogenomics, we can translate the variability observed in medical practice into clinical decision support for DNA-guided medicine. Our revolutionary SINM PhyzioType™ System to enable the diagnosis and drug-specific prediction of statin neuromuscular side effects addresses a high impact medical need in cardiovascular medicine and will be significantly advanced with this major SBIR award."

The research leading to this award has been published in the renowned journal *Muscle & Nerve* in September 2007. Researchers at the Division of Cardiology of Hartford Hospital and at the Department of Laboratory Medicine, University of California San Francisco, were co-authors of the publication and are co-investigators in the grant, which also includes the Rogosin Institute.

Paul D. Thompson, M.D., Chief of Cardiology, and Director of Preventive Cardiology at the Henry Low Heart Center of Hartford Hospital and co-investigator in the grant commented: "Growing evidence indicates that genetics determine who does and does not have muscle complaints with statins. The grant will allow us to pursue additional studies to validate clinically this connection."

Laurine Bow, Ph.D., Vice President for Research at Hartford Hospital noted: "The Henry Low Heart Center at Hartford Hospital under the leadership of Paul D. Thompson, M.D., Chief of Cardiology, has received millions of dollars in major grant awards and industry contracts for cardiovascular research. We are pleased that this success is now mirrored in the awarded SBIR grant with Genomas, which paves the way for developing intellectual property and commercialization revenue from fundamental discoveries at Hartford Hospital."

To date, Genomas has secured \$3.1 million of NIH SBIR funding for PhyzioType™ product development. These programs have been anchored by the novel partnership the company established in 2004 with Hartford Hospital for translating DNA-guided medicine into clinical practice.

### **ABOUT GENOMAS**

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

#### 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. Within the Henry Low Heart Center are Laboratories for Cardiac Catheterization, Nuclear Cardiology, and Electrophysiology; Clinics for Preventive Cardiology and Cardiac Rehabilitation; and Centers for Cardiovascular Surgery, Heart Transplantation, Congestive Heart Disease, Chest Pain, and Heart Rhythm Disturbances. For more information please access <a href="https://www.hartfordhospital.org">www.hartfordhospital.org</a>

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# **Bibliographic Reference:**

"Physiogenomic Association of Statin-Related Myalgia to Serotonin Receptors", by Gualberto Ruaño, Paul D. Thompson, Alan H. B. Wu et alia, Muscle and Nerve, 36 (3): 329-35, 2007. The paper can be accessed at <a href="https://www.genomas.net">www.genomas.net</a> in the <a href="https://www.genomas.net">Publications</a> section.

\*The project described was supported by Grant Number R44GM085201. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of General Medical Sciences or the National Institutes of Health.