

NEWS

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GENOMAS AWARDED \$1.3 MILLION NIH SBIR GRANT TO BRING TO MARKET DNA-GUIDED STATIN THERAPY

Clinical Multi-Gene Informatic Product Predicts and Compares Both Efficacy and Safety of Leading Statins for Each Patient

HARTFORD, CT – Genomas®, a biomedical company enabling DNA-guided medicine for personalized healthcare, announced the award of a 2-year Phase II Renewal Small Business Innovation Research (SBIR) Grant totaling \$1.3 million. The grant, entitled “*System for DNA-Guided Optimization and Personalization of Statin Therapy*”, was awarded by the National Institute of General Medical Sciences (NIGMS)*.

Statins are the most prescribed drugs in the world. 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 have been documented to reduce morbidity in both coronary heart disease patients and in previously healthy subjects. There are more than 40 million Americans with high cholesterol of which 20 million are currently prescribed the statin class of cholesterol lowering drugs.

Statin Induction + Neuro-Myopathy (SINM), the balance of potency and safety, is the main clinical management challenge of these drugs, particularly when treatment targets are aggressive requiring LDL cholesterol levels below 100 mg/dl. In medical practice, Neuro-Myopathy presents as a constellation of neuromuscular side effects. Clinical symptoms include myalgia (muscle aches, cramps, weakness) and myopathy (muscular injury monitored by serum elevation of muscle enzymes). Neuro-myopathy is more frequent at the higher doses required for treating advanced cardiovascular disease and diabetes and varies in extent between individual statins and from patient to patient. Prescribing the most potent statin on an individual basis is critical as well to avoid maximal doses. Statin usage is ultimately limited by toxicity. Neuro-myopathy is disabling to 10-20% of patients on statins, requires alteration of therapy, burdens healthcare with management costs, and reduces compliance. Only 50% of patients remain on statins 6 months after initiation of therapy.

The SINM PhyzioType® System consists of 4 tests predicting LDL lowering and HDL raising efficacy, myalgia, and CK activity elevation (mopathy) in response to statins on a class-wide and drug-specific basis. The goal is to enable clinicians to deploy a genetic decision support system to manage statins, prescribe these drugs on a DNA-guided, personalized basis and effectively lower the risk of cardiovascular disease for each patient. The information can be employed prognostically before prescribing statin therapy or diagnostically to categorize SINM in those statin patients already evidencing lack of potency or neuromuscular symptoms and seeking remedial treatment.

In announcing the award, Gualberto Ruaño, M.D., Ph.D., President of Genomas and Director of Genetics Research at Hartford Hospital commented: "The expected outcome is final development of the SINM PhysioType® System, to manage the variable lipid-altering efficacy and the risk of neuromuscular side effects that are prevalent in high-risk patients with heart disease and diabetes. Through Phase II Renewal funding, Genomas will be able to serve confirmatory proof that the PhysioType® product is a reliable, reproducible and cost-effective product enabling physicians to optimize treatment strategies in lipid disorders."

The research leading to this award has been published in the renowned journals *Pharmacogenomics* and *Muscle & Nerve*. Researchers at the Division of Cardiology of Hartford Hospital and at the Cardiovascular Research Institute at the University of California San Francisco, were co-authors of the publications and are co-investigators in the grant, which also includes the Rogosin Institute, an affiliate of New York Presbyterian Hospital and Weill Cornell Medical College.

Paul D. Thompson, M.D., Chief of Cardiology at the Henry Low Heart Center of Hartford Hospital and co-investigator in the grant commented: "Growing evidence indicates that genetics determines who does not achieve LDL targets or develops muscle complaints with statins. The renewal grant will allow us to pursue the final validation studies of the multi-gene biomarker system to personalize cardiovascular therapy."

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 major cardiovascular grant awards. We are pleased that this success is now mirrored in the awarded SBIR grants with Genomas, the anchor of the Genetics Research Center which paves the way for developing intellectual property from fundamental discoveries at Hartford Hospital."

To date, Genomas has secured \$6.1 Million of NIH SBIR funding for PhysioType® 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 is a biomedical company advancing DNA-Guided Medicine and personalized healthcare. The company develops revolutionary *PhysioType*® Systems for DNA-guided management and prescription of drugs used to treat mental illness and diabetes. *PhysioType*® Systems are designed to provide physicians with an unprecedented capability to select for each patient the safest and most effective drug to achieve treatment goals and enhance patient compliance. *PhysioType*® 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 and efficacy among drugs for the individual patient. The company's clinical pharmacogenetic tests and consultation service are provided through its *Laboratory of Personalized Health* (LPH), an accredited and licensed high-complexity molecular diagnostic center and its *Personalized Health Portal* (PHP), a medical informatics interface for clinician decision support. Genomas is located on the campus of Hartford Hospital. Please visit www.genomas.com 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 health 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 www.hartfordhospital.org

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