

## NEWS

Contact:  
Robert Scherrer  
Genomas, Inc.  
860-545.4570



**FOR IMMEDIATE RELEASE**  
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### **FIRST DNA DIAGNOSTIC SYSTEM FOR PERSONALIZED DRUG SAFETY LAUNCHED BY GENOMAS AND CLINICAL LABORATORY PARTNERS**

**HARTFORD, CT** –Genomas®, Inc today launched its HILOmet PHYSIOTYPE™ System for personalized drug safety and announced an agreement with Clinical Laboratory Partners (CLP), Newington, CT for its distribution. These developments were announced at MEDi 2005 Conference and Exposition by Gualberto Ruaño, M.D., Ph.D., President and CEO of Genomas during a Personalized Medicine forum he chaired.

The safety of 90% of drugs depends on their metabolism by the cytochrome p450 (CYP) enzyme system. The HILOmet system uses DNA-based typing of 3 cytochrome p450 genes, CYP 2C9, 2C19 and 2D6 to determine individual rates of drug metabolism to optimize drug safety. Variability in the CYP system results in strikingly different drug blood levels among individuals now treated with doses for the “average” person. With the HILOmet tests, doctors can identify poor, deficient, normal, and ultra rapid metabolizers ahead of time to adjust drug dosages and increase patient monitoring. Examples of clinically relevant drugs now potentially monitored with this system include coumadin, ADHD drugs, and antidepressants.

Addressing the audience congregated at the Connecticut Convention Center in Hartford, Dr. Ruaño stated: “What is revolutionary for clinical practice is that by means of the HILOmet system and tests, the innate metabolic capacity of the patient relevant to drug treatment can be predicted and diagnosed simply from a blood sample. While it is acknowledged that the future practice of medicine will be personalized, Genomas and its CLP partners make possible the practice of personalized medicine now throughout Connecticut.”

The HILOmet tests are performed at the Company’s Laboratory of Personalized Health (LPH). Genomas had launched LPH last May 24<sup>th</sup>, after attaining its licensure by the Connecticut Department of Public Health and certification with the Centers for Medicare and Medicaid under CLIA (Clinical Laboratory Improvement Amendments). The license and registration allow the company to perform high-complexity clinical DNA typing to support medical treatments and to seek reimbursement from Medicare and health insurance. LPH is a state-of-the-art clinical laboratory utilizing microfluidic multi-analyte and array nanotechnologies for parallel processing of several DNA markers. LPH is one of the first clinical laboratories in the USA for delivery of DNA typing information for management of common clinical conditions.

George M. Kyriacou, President of Clinical Laboratory Partners stated, “We are excited that we will be able to offer our customers access to this cutting edge technology. Blood samples will be drawn by our phlebotomists at our many facilities throughout Connecticut and sent to the Laboratory of Personalized Health (LPH) for processing. LPH and CLP will provide DNA typing reports directly to the physicians ordering the tests and support their clinical application. We see immediate significant markets in psychiatric and cardiovascular medicine.”

The company also announced the deployment of a specialized new section of its website to support the HILOmet tests available by accessing [www.genomas.net](http://www.genomas.net) and the LPH icon. The site incorporates operational information on the ordering and interpretation of the tests with sample reports and requisition forms. The site also includes a presentation and primer on “The Science of

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Personalized Medicine”. Detailed information on the clinical use of HILOmet system for atomoxetine (Strattera®) in psychiatry and of warfarin (Coumadin®) in cardiovascular disease are included.

The presentation by Dr. Ruaño at MEDI 2005 included results from a population study at Hartford Hospital documenting that patients can be divided into three broad groups according to their DNA types. Poor and null metabolizers represent 10% of the population and are unable to metabolize specific drugs because they carry two copies of deficient gene forms, which could lead to deleterious drug accumulation and severe adverse reactions. Deficient metabolizers represent 40% of the population, and carry one copy of a deficient gene form. These individuals also face safety risks, because drug interactions can turn them into poor metabolizers by inhibiting the function of the normal copy. There is 1% of the population who are ultra-metabolizers, with gene duplications. These individuals break down drugs at higher rates resulting in lesser effective dose and efficacy. Dr. Ruaño commented, “This study demonstrates the common occurrence of these CYP variants in a Connecticut population. Significantly, carriers of these variants do not have a disease. These individuals simply have an inherited trait that can only be manifested during drug therapy. We can now predict that response and avoid adverse drug responses.”

Drug safety has become a major issue in healthcare. Over the last year, various best selling drugs have been withdrawn for safety concerns arising from clinical studies after their market launch and approval. Drug withdrawals, multi million dollar lawsuits and out of court settlements have ensued. With side effects ranging from heart attacks and diabetes to suicide, there has been a national clamor for improved drug safety and post-market surveillance. “Yet, despite these significant concerns, the majority of patients is deriving benefit from these drugs,” Dr. Ruaño concluded. “Rather than pull all cars from highways because of occasional if devastating accidents, the transportation industry has adopted seatbelts and other passenger safety systems to keep traffic moving and people driving. For healthcare, our HILOmet system provides the first ‘DNA seatbelt’ for drugs.”

## **ABOUT GENOMAS**

*Genomas Inc. is a biomedical company advancing personalized health with revolutionary diagnostic PHYSIOTYPE™ systems to treat metabolic conditions induced by drugs and by obesity in cardiovascular and psychiatric medicine. PHYSIOTYPE systems provide physicians with the unprecedented capability to prescribe personalized drug treatments avoiding side effects and to recommend highly effective preventive exercise and diet programs for each patient. Genomas is located in Hartford, CT on the campus of Hartford Hospital with which it has established a research and development partnership in personalized medicine. For more information please access [www.genomas.net](http://www.genomas.net).*

## **ABOUT CLINICAL LABORATORY PARTNERS**

*Clinical Laboratory Partners, LLC (CLP) is the largest regional laboratory in Connecticut. CLP is an independent, full-service clinical laboratory directed by board-certified pathologists. Itsr Medical Directors are nationally recognized as specialists in pathology and laboratory medicine (Clinical Chemistry, Hematology, Microbiology, Anatomic Pathology, Cytology, Transfusion Medicine, Immunology and Molecular Pathology). Testing facilities are located in Hartford, Meriden and in Newington, CT with patient service centers throughout Connecticut. For more information please access [www.clinicallabpartners.com](http://www.clinicallabpartners.com).*