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The Hamner and Entelos Announce New Research Partnership

The Hamner Institutes and Entelos Announce Co-Development of Liver Injury PhysioLab Platform

RESEARCH TRIANGLE PARK, N.C. – The Hamner Institutes for Health Sciences and Entelos, Inc. announced they have established a partnership to create a computer model of liver function in virtual patients ("virtual liver") that will improve understanding of how pharmaceutical drugs and chemical agents can sometimes damage the liver. Drug induced liver injury(DILI) is the most frequent cause of acute liver failure and is a major reason why drugs are abandoned in development or fail to gain regulatory approval. Recent withdrawals and restrictions on use of marketed drugs, due to incidence of DILI, highlight the limitation of existing approaches to determine a drugs safety risk profile. The Hamner - Entelos partnership supports the FDA's Critical Path Initiative which aims to reduce the time it takes to develop and approve safe and effective medical products to serve patients in need. Two FDA scientists will join the scientific advisory board for the project. The resulting computational model will ultimately allow scientists to design safer drugs by providing a better understanding of mechanisms of drug induced injury and early prediction of safety and efficacy.

This partnership will combine Entelos' clinically validated PhysioLab biosimulation platform technology with The Hamner's expertise in liver injury and systems biology. The project will incorporate a steady stream of new knowledge coming from many avenues, including the study of patients who have experienced DILI. Additional important information will be supplied through Hamner research programs employing novel liver-derived cell models and special metabolism studies made possible by a new Hamner metabolomics laboratory.

The PhysioLab platform will incorporate this information into a dynamic, mathematical model of liver function in virtual human patients that will account for the effects of genetic variations and other factors, such as patient sex, age, behavioral characteristics and environmental influences. In parallel, virtual rodents will be developed that will provide an improved means by which to evaluate preclinical drug effects and mechanisms of liver injury across species. This mathematical model is expected to advance understanding of drug toxicity mechanisms, identify why patients vary widely in severity and susceptibility to liver injury, and help translate results from preclinical animal models to human response. The goal of the partnership is to use the computer platform to guide the development of predictive clinical biomarkers and pre-clinical assays that will help identify patient types who are at increased risk for developing liver injury in response to specific drug and/or combination-drug exposure. The platform will have many potential uses, including guiding the development of new diagnostic tests and new ways to test drug safety in the laboratory.

Related Links:
www.thehamner.org
www.entelos.com

Quotes:
"We are very excited about the potential for this collaboration to revolutionize how drug safety is tested." said Dr. Paul Watkins, Director of The Hamner - University of North Carolina Center for Drug Safety Sciences and chairman of the scientific advisory board. "For example, the goal of this model would be to create "virtual patients" that can be used to instantly simulate experiments that could take months or years to perform in living people while greatly reducing the need for animal studies."

"The DILI PhysioLab platform will provide a Rosetta stone for translational research," said Dr. Mikhail Gishizky, Chief Scientific Officer of Entelos. "For the first time clinical and preclinical researchers will be able to evaluate the potential effects of a drug on liver function in individual patients and across species in a quantitative manner - prior to exposing patients at risk. Our partnership with the Hamner Institute enables an iterative approach between simulation and confirmatory laboratory and clinical research, the result of which will be development of robust analytic tools that will significantly advance drug safety and risk assessment."

About Entelos:
Entelos, Inc. (www.entelos.com) is a life sciences company improving human health through predictive biosimulation. Using its patented PhysioLab technology, Entelos develops dynamic large-scale computer models of human disease. Each PhysioLab platform provides a framework for integrating data (e.g., genomic, proteomic, physiologic, environmental) in the context of a disease or therapeutic area, focusing on understanding and determining clinical responses to potential treatment. "Virtual patients" are created within this framework to represent real patient subpopulations. Entelos builds and customizes its PhysioLab systems using thousands of peer-reviewed papers, the expertise of its in-house research teams and world-class scientific advisors, and the proprietary information of its collaboration partners. Using *in silico* disease models and a virtual patient approach, Entelos identifies and validates targets, develops biomarkers, improves the success rates of clinical trials, and helps bring therapeutics to market faster.

About the Hamner Institutes for Health Sciences:
The Hamner Institutes for Health Sciences is a nonprofit research organization strategically located on a 56-acre campus in the heart of Research Triangle Park, North Carolina. For more than 30 years, scientists at The Hamner have conducted preeminent research in environmental health sciences and chemical risk assessment. Built upon an integrated systems-biology platform, The Hamner has broadened its mission to include translational research in biopharmaceutical safety, metabolic disorders, respiratory diseases, oncology, and nanosafety. The site also includes an Accelerator, which houses emerging companies and provides opportunities to develop collaborative research and educational programs with academia, industry and government. The Hamner model for translational research and technology development capitalizes on innovation and partnering to discover safer drugs, spin out new companies, and support public health policy. For more information, visit www.thehamner.org or call (919) 558-1200.

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