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The Hamner Institutes and Cellular Dynamics Collaborate to Develop In Vitro Assays Using Human iPS Cell-Derived Hepatocytes

Collaboration Will Accelerate Innovative Toxicity Testing Research

RESEARCH TRIANGLE PARK, N.C. and MADISON, Wis., Dec. 9, 2013 (GLOBE NEWSWIRE) -- [The Hamner Institutes](#) for Health Sciences today announced a collaborative agreement with Cellular Dynamics International (CDI) to develop predictive in vitro screening assays for chemical, environmental and pharmaceutical toxicology assessments that utilize CDI's human induced pluripotent stem (iPS) cell-derived hepatocytes.

Current in vitro models of liver function employ immortalized cell lines, animal models and primary tissue isolates harvested from human cadavers. Each of these model systems presents limitations in functionality, reproducibility, translatability and availability.

Human iPS cell-derived hepatocytes could provide a consistent, reproducible and limitless source of liver tissue that reflects native liver function and may offer significant improvement over existing in vitro models.

CDI will provide iCell® Hepatocytes to The Hamner for use in an on-going program of research, referred to as "Toxicity Testing in the 21st Century: Toxicity Pathways and Network Biology." This program employs several prototypical toxicity pathway case studies to develop human cell-based assays that map and model key cell signaling pathways in order to evaluate dose response. These assays, once validated with prototype chemicals, should enable toxicity testing and risk assessments based solely on in vitro test results, without progressing to toxicity studies in intact animals.

These in vitro-based toxicity testing schemes will speed testing of both important compounds in commerce and new compounds coming into use. More rapid testing will also help assess the backlog of thousands of chemicals for which there is very limited toxicity test data. As these test technologies mature, they could also provide a means to speed drug discovery by providing assessments of safety far earlier in the drug development process.

The Hamner toxicity pathway research program is a pre-competitive, multi-organization partnership designed to advance an integrated systems biology approach to toxicity testing research. Partners sponsoring the research include Agilent Technologies Inc., Illumina, Dow Chemical, Dow Corning Corporation, ExxonMobil, Unilever and CropLife America member companies. The Long-Range Research Initiative (LRI) of the American Chemistry Council supported earlier stages of this research. CDI will join this consortium and will collaborate with Hamner scientists on technical aspects of assay development.

"The Hamner's multi-stakeholder toxicity testing program needs a variety of normal cell types for studying chemical toxicity in human cells. New iPS-cell technologies, spearheaded by CDI, promise to make many stem cell-derived products available to transform in vitro testing. We are particularly enthusiastic about the use of iCell Hepatocytes to create models of liver toxicity and for evaluating pathways of metabolism," said Dr. Melvin Andersen, project director at The Hamner. "More broadly, stem cell products enhance work on the whole suite of pathways of interest to our diverse partners. As other stem cell platforms develop, we can connect them sequentially and examine multi-day treatment for many tissues with realistic exposures. These iCell Hepatocytes and other emerging stem cell-based products provide great value for safety assessments for all our partners."

Chris Parker, chief commercial officer of CDI, said, "We are excited to be working with The Hamner and this consortium to work toward better predictivity of human response to chemical compounds. Current models miss toxicities that might only manifest themselves in a human cell model, or falsely misidentify toxicities for compounds that would be safe. Published studies have shown numerous examples of our human iPS cell-derived iCell products to be more predictive than comparison current cell models. Through this collaboration we hope to further improve the safety of chemical compounds as well as the efficiency of research studies."

A report of a recent review of The Hamner program "Toxicity Testing in the 21st Century: Toxicity Pathways and Network Biology" is available at www.thehamner.org/tt21c and provides a synopsis of the first prototype pathways serving as examples of this integrated systems biology approach to toxicity testing.

About The Hamner Institutes for Health Sciences

The Hamner Institutes for Health Sciences is a nonprofit translational biomedical research institute located on an open, multidisciplinary campus in North Carolina's Research Triangle Park. Building upon 35 years of research excellence in toxicology, The Hamner works on drug and chemical safety in collaboration with academic, corporate, and government partners. Novel technologies used at The Hamner include genomic and bioinformatic approaches for improving toxicity testing, in silico models for predictive toxicology, in vitro models that utilize human cells or cell lines to evaluate perturbations of cellular responses, and in vivo models to elucidate genes that play a role in susceptibility to drug-induced toxicities. For more information, visit <http://www.thehamner.org>.

About Cellular Dynamics International, Inc.

Cellular Dynamics International, Inc. (CDI) is a leading developer of induced pluripotent stem cell technologies for in vitro drug development, stem cell banking and in vivo cellular therapeutic research. CDI harnesses its unique manufacturing technology to produce differentiated tissue cells in industrial quality, quantity and purity from any individual's induced pluripotent stem cell line created from a standard blood draw. CDI was founded in 2004 by Dr. James Thomson, a pioneer in human pluripotent stem cell research at the University of Wisconsin-Madison. CDI's facilities are located in Madison, Wisconsin, with a second facility in Novato, California. See www.cellulardynamics.com. Follow us on Twitter @CellDynamics or www.twitter.com/celldynamics

Forward-looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Cellular Dynamics International, Inc., including statements regarding our products and iPS-cell technologies, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "believe," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our product development efforts, actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statements. Cellular Dynamics undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see Cellular Dynamics' quarterly report on Form 10-Q filed with the Securities and Exchange Commission on August 29, 2013, and as may be described from time to time in Cellular Dynamics' subsequent SEC filings.

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