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CRITICAL PATH INSTITUTE AND HAMNER INSTITUTES FOR HEALTH SCIENCES ANNOUNCE COLLABORATION TO IMPROVE SAFETY OF MEDICAL PRODUCT DEVELOPMENT

Internationally renowned organizations share common commitment to advancing science focused on liver safety

Tucson, Arizona, and Research Triangle Park, North Carolina, December 20, 2011 – Critical Path Institute (C-Path) and The Hamner Institutes for Health Sciences (The Hamner) announced today that they have signed a Memorandum of Understanding (MOU) to develop innovative, collaborative activities in the areas of regulatory science research for predicting, detecting and monitoring liver safety issues during the development of new medicines.

Specifically, cooperative efforts between C-Path's Predictive Safety Testing Consortium (PSTC) and The Hamner will focus on the discovery and advancement of promising biomarkers for pre-clinical and clinical monitoring of drug induced liver injury (DILI). An overarching goal of the collaboration will be to mutually generate data and reach scientific consensus for biomarkers and other methods of testing that can be formally submitted by C-Path to the U.S. Food and Drug Administration (FDA) to be qualified for specific uses in medical product development.

The MOU indicates the intent of C-Path and The Hamner to find opportunities to leverage one another's work in order to accelerate progress and prevent duplication of efforts while developing new data and knowledge and identifying gaps in specific areas of applied science as it relates to predicting DILI. Both organizations lead innovative, multi-stakeholder, public-private partnerships aimed at not only improving the safety of medicines but also speeding the development of new, breakthrough medicines.

The collaboration will work closely with the FDA and its newly developed process for biomarker qualification. This process is focused on regulatory science and the application of scientific advances as new tools to aid drug development. The collaboration will bring together basic scientific research, clinical science, and medical product development, to accelerate the availability of new products that might also be more effective or safer.

According to Raymond Woosley, MD, PhD, President and CEO of C-Path, "It is imperative that we continue to build important synergies to support cutting-edge research that ultimately translates to getting safer, more effective medicines into the hands of patients. We are excited to work with The Hamner in the area of liver safety."

The director of the Hamner-University of North Carolina Institute for Drug Safety Sciences, Paul Watkins, M.D., stated that liver toxicity is now the most problematic adverse drug reaction encountered during drug development. "For 50 years we have been using the same tests for liver effects, and they are simply failing to adequately detect or predict liver safety liabilities of new drugs. There is a natural synergy between C-Path and our research programs that should greatly accelerate the discovery and validation of better tests."

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ABOUT CRITICAL PATH INSTITUTE (C-PATH): An independent, non-profit organization established in 2005 with public and private philanthropic support from the Southern Arizona community, Science Foundation Arizona (SFAz), and the U.S. Food and Drug Administration (FDA), C-Path is committed to improving health and saving lives by accelerating the development of safe, effective medicines. An international leader in forming collaborations around this mission, C-Path has established global, public-private partnerships that currently include over 1,000 scientists from government regulatory agencies, academia, patient advocacy organizations, and thirty five major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona, with offices in Phoenix, Arizona, and Rockville, Maryland. For more information, visit www.c-path.org and follow us on Facebook. Click here to view a video showing why the work of C-Path is essential.

The C-Path Vision: Creating collaborations that advance scientific innovations to improve human health and save lives by accelerating the development of safe, effective medicines.

ABOUT THE HAMNER INSTITUTES FOR HEALTH SCIENCES (THE HAMNER): The Hamner is a nonprofit research organization located in the heart of Research Triangle Park (RTP), N.C. The two flagship institutes at The Hamner, the Institute for Chemical Safety Sciences and the Hamner University of North Carolina Institute for Drug Safety Sciences, build upon 37 years of preeminent research in toxicology and human health research to develop and validate new cutting-edge tools for safety assessment. Novel technologies currently being developed include *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. The Hamner continues to grow its open, multidisciplinary campus through global partnerships with academia, industry, and government, and remains dedicated to positively impacting human health. For more information, please visit http://www.thehamner.org.

ABOUT THE PREDICTIVE SAFETY TESTING CONSORTIUM (PSTC): The PSTC is a unique public-private partnership led by C-Path that brings together pharmaceutical companies to share and validate each other's safety testing methods under advisement of the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). The 17 pharmaceutical company members of the consortium share internal experience with pre-clinical and clinical safety biomarkers. All programs have a strong translational focus to select new safety tools that are applicable across the drug development spectrum.