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CRITICAL PATH INSTITUTE'S PREDICTIVE SAFETY TESTING CONSORTIUM ANNOUNCES SPECIAL ISSUE OF *NATURE BIOTECHNOLOGY* DEDICATED TO NEWLY QUALIFIED KIDNEY SAFETY BIOMARKERS

Tucson, Arizona, May 11, 2010 – A special May 10, 2010 issue of *Nature Biotechnology* (NBT) includes ten scientific publications from Critical Path Institute's (C-Path) Predictive Safety Testing Consortium's (PSTC) evaluation of seven kidney biomarkers for use in drug safety assessment. The seven urinary proteins (KIM-1, Albumin, Total Protein, β 2-microglobulin, Cystatin C, Clusterin, Trefoil Factor-3) were evaluated for their utility to outperform current tests to detect drug-induced kidney injury, i.e., BUN and serum creatinine. PSTC submitted the data to the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japanese Pharmaceutical and Medical Devices Agency (PMDA) for evaluation. The FDA and EMA reached the formal conclusion that the biomarkers are considered qualified for use in regulatory decision-making for drug safety to detect acute drug-induced kidney injury in preclinical studies and, on a case by case basis after discussion with agencies, in early clinical studies in combination with standard biomarkers. A final conclusion from the PMDA is expected imminently. The biomarkers are now being used successfully to more efficiently advance or terminate drug development programs. The scientific details of the studies and analyses, as well as a description of the evolution of the qualification process at the regulatory agencies, will be reported publicly for the first time in this issue of *Nature Biotechnology*.

The NBT publications reflect the collaborative work that constituted the biomarker qualification submissions, as well as the progressive dialogue between industry, regulatory, and academic scientists that helped refine the new qualification pathways for evaluating such biomarker data at the FDA, EMA and PMDA. Kidney biomarker data from PSTC member companies Novartis and Merck, as well as from leading scientists at Harvard Medical School and FDA's research laboratories, are presented. Raymond Woosley, MD, PhD, President of Critical Path Institute, noted that one manuscript in the issue describes the evolution of the concept of a progressive qualification process, whereby incremental data can be submitted to support the expanded context of use for a particular biomarker. "This article is both a chronology and a roadmap for the future qualification of new methods that will transform drug development to have far greater efficiency and predictive accuracy," he stated.

According to Barry J. Gertz, M.D., PhD, head of Global Clinical Development and Regulatory Affairs at Merck Research Laboratories, “As a member of C-Path’s PSTC, Merck is proud to have collaborated with other industry leaders on the creation of an effective strategy for accelerating the discovery and adoption of safety biomarkers. Advancing the science and use of biomarkers in drug development is a critical area of focus for Merck, and we will continue to lend our expertise in this area to help achieve the universal goal of more rapid delivery to patients of safe and innovative medicines.”

PSTC, a public-private partnership that includes fifteen global pharmaceutical companies, was launched by Critical Path Institute and announced publicly by Secretary of Health, and Human Services, Michael Leavitt in March of 2006. Regulatory scientists from FDA and EMA, along with PSTC member* scientists, work to evaluate the performance of novel safety biomarkers.

“PSTC has over 300 participating scientists from its member companies dedicated to finding the most accurate and efficient tests for assessing drug safety,” said C-Path’s Elizabeth Gribble Walker, PhD, Director of the Predictive Safety Testing Consortium.

*Current members of the Critical Path Institute’s PSTC are: Abbott, Amgen Inc., AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals, Inc., Bristol-Myers Squibb Company, ClinXus, Daiichi Sankyo, Eli Lilly and Company, GlaxoSmithKline, Johnson&Johnson Pharmaceutical Research and Development LLC, Merck & Co., Inc., Mitsubishi Tanabe Pharmaceutical Corporation, Novartis Pharmaceutical Corporation, Pfizer, Inc., Roche, sanofi-aventis, U.S., Inc, and FDA and EMA as observers.

About Critical Path Institute

Critical Path Institute (C-Path) is an independent, non-profit organization whose mission is to serve as the impartial facilitator of collaborative efforts among scientists from government, academia, patient advocacy organizations, and the private sector to support the U.S. Food and Drug Administration’s regulatory science initiatives. This involves creating faster, safer, and smarter pathways for innovative new drugs, diagnostics, and devices that will significantly improve public health. Established in 2005, C-Path is headquartered in Tucson, Arizona, with offices in Phoenix, Arizona, and Rockville, Maryland. Visit www.c-path.org for more information.

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