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CRITICAL PATH INSTITUTE SECURES REGULATORY SUPPORT FOR KIDNEY SAFETY BIOMARKERS

Letter of Support Opens Door for Clinical Qualification

TUCSON, Ariz., October 21, 2014 — The Critical Path Institute (C-Path) announced today that the U.S. Food and Drug Administration (FDA) has issued a first-of-its kind Biomarker Letter of Support for two essential kidney safety biomarkers identified and evaluated by C-Path's Predictive Safety Testing Consortium (PSTC)'s Nephrotoxicity Working Group.

"This Letter of Support intends to encourage scientists to collect data from exploratory studies, which may lead to qualification of these types of biomarkers," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "We are excited to see legislation from the fifth authorization of the Prescription Drug User Fee Act in action, supporting further development of biomarkers of safety and efficacy. We are optimistic about how this effort will further advance biomarker development."

The kidney safety biomarkers, osteopontin (OPN) and neutrophil gelatinase-associated lipocalin (NGAL), are proteins that can be measured in urine. Higher levels of OPN and NGAL could indicate the kidneys are being damaged and result in a loss of kidney function.

"We are pleased to continue our work with the FDA, academia, and industry on identifying tools, processes, and methods to improve the drug development process," said Martha Brumfield, Ph.D., president and chief executive officer of C-Path. "With this Letter of Support, the FDA has opened doors that encourage the generation of necessary, rigorous clinical data to determine if these biomarkers hold clinical utility."

The FDA's Letter of Support indicates that a biomarker has strong potential for use in humans and warrants additional exploration and gathering of data. The FDA granted the Letter of Support for OPN and NGAL to encourage their use in both nonclinical and exploratory clinical studies as markers of proximal renal tubule degeneration/necrosis. With this milestone, work will continue in earnest on the qualification of OPN and NGAL for use in clinical trials.

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"What's notable is that the collaborative efforts of the PSTC and FDA have led to the Letter of Support, a mechanism to benefit the clinical qualification of new Drug Development Tools," said Jonathan Phillips, Ph.D., head of translational safety biomarkers at Boehringer Ingelheim Pharmaceuticals, Inc.

The Letter of Support for OPN and NGAL is posted on the FDA DDT website and the C-Path website, along with a summary data package describing the studies that support the use of these kidney safety biomarkers.

About the Critical Path Institute

The Critical Path Institute (C-Path) is an independent, non-profit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the U.S. Food and Drug Administration (FDA). C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established seven global, public-private partnerships that currently include over 1,000 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org.

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