Critical Path Institute Secures Additional Regulatory Support For Kidney Safety Biomarkers

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EMA Letter of Support Opens Door for Clinical Qualification

TUCSON, Ariz., January 12, 2015 – The Critical Path Institute (C-Path) announced today that the European Medicines Agency (EMA) issued a first-of-its kind Biomarker Letter of Support for two essential kidney safety biomarkers identified and evaluated by the Predictive Safety Testing Consortium (PSTC)'s Nephrotoxicity Working Group.

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 that the kidneys are being damaged, which may result in a loss of kidney function. The Letter of Support intends to encourage scientists to collect data from nonclinical and exploratory clinical studies, which may lead to qualification of these biomarkers.

"We are pleased to continue working collaboratively with the EMA, academia, and industry to identify 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 EMA has opened doors that encourage the generation of necessary, rigorous clinical data to determine if these biomarkers hold clinical utility."

The EMA's Letter of Support indicates that these biomarkers have strong potential for use in humans and warrant additional exploration and data gathering. The EMA 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.

"We are all incredibly excited about our collaborative interactions with EMA and the creation of the Letter of Support, enabling us to further define the path to clinical biomarker qualification," said John Michael Sauer, Ph.D., Executive Director, Predictive Safety Testing Consortium, Critical Path Institute.

The Letter of Support is posted on the EMA website and can also be accessed via the C-Path PSTC website under the Regulatory Successes tab, 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 http://www.c-path.org.