FNIH Biomarkers Consortium and Critical Path Institute Achieve the First Ever Qualification of a Clinical Safety Biomarker by the U.S. Food and Drug Administration

Major Milestone will Improve Detection of Drug-Induced Acute Kidney Injury in Clinical Trials.

October 25, 2018 — The Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium (BC) and the Critical Path Institute (C-Path) Predictive Safety Testing Consortium (PSTC) have received the first ever qualification of a clinical safety biomarker awarded by the U.S. Food and Drug Administration (FDA) –a major milestone that will improve the detection of drug-induced kidney injury in early phase drug development. The newly qualified biomarker can now be used in Phase I clinical trials to aid in the detection of acute kidney tubular injury in healthy volunteers. This will help improve the development of safe and effective medicines where concern has been raised that an investigational drug may cause kidney injury.

This significant achievement was made possible by the efforts of the Clinical Evaluation and Qualification of Translational Kidney Safety Biomarkers Project (Kidney Safety Project) team. Its members include the FNIH, C-Path's PSTC Nephrotoxicity Working Group, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), academia and industry, with advice from the FDA.

In achieving this milestone, PSTC, C-Path's longest running consortium, celebrates the successful translation of its preclinical biomarkers previously qualified for use in animal studies, for use now in Phase 1 clinical trials. "The acceptance of these clinical safety biomarkers marks our first successful translation of biomarkers qualified for preclinical use to use in clinical drug development. This is a major step forward in our efforts to accelerate the development of safer medicines for patients in need," said Dr. John-Michael Sauer, Executive Director, PSTC.

This qualification applies to a single composite measure of six urine biomarkers, to be used in conjunction with traditional measures of kidney function. It measures the change over time of the urine biomarkers that the team selected for tracking acute damage to the kidney tubules. The qualification submission to the FDA included analyses of data collected from a Normal Healthy Volunteer Study funded by the PSTC and a collaborative Harvard-Merck Study of cancer patients with mesothelioma treated with cisplatin, a common chemotherapy drug known to cause kidney injury.

“This latest achievement reflects the collective commitment of the Kidney Safety Project team to expand the toolbox for evaluating safety of medicines in clinical trials,” said Dr. Frank Sistare, Scientific Associate Vice President, Safety Assessment, Merck Research Laboratories and Kidney Safety Project Chairperson. “While we are proud of the progress made to date, our collaborative work continues as we near another critical milestone in 2019.”

“This impressive milestone was made possible by the unwavering commitment and tireless efforts of our government, not-for-profit and industry partners that shared intellectual and financial resources to fast-track the development of these critical biomarkers,” said Joseph Menetski, Ph.D., Associate Vice President for Research Partnerships, FNIH.

Funding for this project was provided by Amgen, Inc., AstraZeneca, C-Path, Johnson & Johnson, Eli Lilly and Company, Merck (known as MSD outside the United States and Canada) and Pfizer.

For more information on the continuing progress goals of the Kidney Safety Project, please click here.

About Critical Path Institute

C-Path (Critical Path Institute) is an independent, nonprofit organization established in 2005 as a public and private partnership. 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 numerous global consortia that currently include over 1,500 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path is headquartered in Tucson, Arizona, with additional staff in multiple remote locations. For more information, visit www.c-path.org.

About the Foundation for the National Institutes of Health

The Foundation for the National Institutes of Health creates and manages alliances with public and private institutions in support of the mission of the NIH, the world’s premier medical research agency. The Foundation, also known as the FNIH, works with its partners to accelerate biomedical research and strategies against diseases and health concerns in the United States and across the globe. The FNIH organizes and

administers research projects; supports education and training of new researchers; organizes educational events and symposia; and administers a series of funds supporting a wide range of health issues. Established by Congress in 1990, the FNIH is a not-for-profit 501(c)(3) charitable organization. For additional information about the FNIH, please visit fnih.org.

C-Path Contact:
Kissy Black
President and CEO
LotosNile
(615) 310-1894
kissyblack@lotosnile.com

FNIH Contact:
Abbey Meltzer
Vice President of Communications
FNIH
(301) 435-4103
ameltzer@fnih.org