Critical Path Institute and Japan's Pharmaceuticals and Medical Devices Agency Collaborate on First-of-its-Kind Biomarker Project

Aim is to generate critical data to support safety decisions made in early-stage clinical trials

TUCSON, Ariz., March 26, 2019 — Critical Path Institute (C-Path) announced today that a formal consultation between its Predictive Safety Testing Consortium (PSTC) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has resulted in an agreement on a first-of-its-kind approach to compare the levels of eight novel urinary kidney safety biomarkers in healthy Japanese volunteers to data collected on these same biomarkers in healthy Western volunteers in a bridging study. Results from the project are expected to provide clinical evidence for PMDA evaluation to support utilization of these biomarkers to help guide decisions in early-stage clinical trials to ensure the safety of trial participants.

The new study, to be conducted in Japan by PSTC member companies beginning in late 2019, will compare healthy Japanese volunteers with subjects enrolled in a similar U.S.-based study conducted by PSTC from 2011-2012 completed to support U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) submissions on these novel kidney safety biomarkers. Results from the Japanese study will inform subsequent work in Japan to be defined during future consultations between PSTC and PMDA. Biomarkers to be measured in Japanese subjects in this study include clusterin (CLU), cystatin C (CysC), kidney injury molecule-1 (KIM-1), N-acetyl-beta-D-glucosaminidase (NAG), neutrophil gelatinase-associated lipocalin (NGAL), osteopontin (OPN), albumin (ALB) and total protein. More information on the bridging study is available here.

"Drug-induced kidney injury is a serious issue that can occur during drug development," said John-Michael Sauer, Ph.D., C-Path Biomarkers Program Officer and Executive Director of PSTC. "Results from this and other PSTC clinical safety biomarker projects are designed to generate critical data to support safety decisions about whether to pause or discontinue early phase clinical trials at the tested dose and duration."

PSTC has a successful track record of qualifying kidney safety biomarkers to support clinical drug development. In August 2010 PSTC qualified seven novel biomarkers, with PMDA for use in rat studies for the detection of drug-induced acute kidney injury. In August 2018, the FDA issued its first-ever qualification of a clinical safety biomarker, a single composite measure of six urine biomarkers to be used in conjunction with traditional measures of kidney function, to PSTC and the Foundation for the National Institutes of Health Biomarkers Consortium.

“The recent FDA qualification of a clinical kidney safety biomarker and our latest interactions with PMDA exemplify C-Path’s expanding global reach and our role as a catalyst in the development of new approaches to advance medical innovation and regulatory science,” said C-Path President and CEO Martha Brumfield, Ph.D. “All of this is critical for our mission to speed development of safe drugs and facilitate development and qualification of tools that shape clinical trials, advance research and help create a healthier world.”

PSTC’s global reach will be showcased at its 2019 Japan Safety Biomarker Workshop to be held April 17-18 at the RIKEN Institute’s Yokohama Campus. Presentations, panel discussions and a poster session will address emerging and important topics in this rapidly-evolving field, including the role of miRNA, and small-circulating RNA as safety biomarkers; safety testing, drug efficacy and disease diagnosis; genomics and epigenetics; and evidentiary considerations across regulatory agencies in Japan, the European Union, and the U.S.

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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 major 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.

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