C-Path and Cerveau Technologies, Inc. Announce Data Sharing Collaboration to Accelerate Drug Development for Alzheimer's Disease and Related Dementias

TUCSON, Ariz., November 15, 2022 — The Critical Path for Alzheimer's Disease (CPAD) at the Critical Path Institute (C-Path) and Cerveau Technologies, Inc. are proud to announce a data sharing collaboration to advance the scientific understanding of disease pathology and progression and enable development of novel quantitative Drug Development Tools in Alzheimer's disease (AD) and related dementias.

Cerveau has an exclusive worldwide license from Merck for [18F]MK-6240, a second-generation Positron Emission Tomography (PET) imaging biomarker for detection of tau protein, in the form of Neurofibrillary Tangles in the living brain. Detecting tau pathology in vivo is crucial to understanding the evolving relationship between tau pathology and clinical symptoms of AD, evidence of target engagement for anti-tau therapies, and monitoring treatment efficacy in AD clinical trials. [18F]MK-6240 is one of multiple tau-imaging PET tracers being used in clinical trials, each having different pharmacokinetic characteristics and differences in specific, nonspecific, and off-target binding. Such differences hamper interpretation of imaging results and limit the ability to make direct data comparisons across sites and studies that use different tracers.

To solve this problem, CPAD is leading a pre-competitive effort, in partnership with leaders from industry and academia, to develop a standardized scale for quantification of tau deposition that will allow comparison and generalizability across studies, cohorts and different tau radiotracers. C-Path will leverage its proven proficiencies in generating tangible and actionable drug development tools through multiple pathways, including regulatory qualification of biomarkers, development of surrogate endpoints, neuroimage data aggregation and analysis, and quantitative modeling. A standardized tau-PET scale will improve the utility of tau-PET in various research and drug development efforts, including for trial enrichment, monitoring tau deposition over time, spatio-temporal characterization, and its use in disease-specific anti-amyloid and/or anti-tau therapeutic research and clinical trials.

This effort will utilize global tau-PET datasets, including data from head-to-head studies, within the pre-competitive framework of CPAD. Cerveau Technologies Inc.'s datasets will be crucial to this effort. Harmonized tau-PET quantification and results will be closely integrated with CPAD's ongoing effort to generate comprehensive quantitative disease progression models to evaluate the longitudinal changes in tau deposition. Tau-PET will be evaluated in such models for predictive power of future brain atrophy or decline in clinical outcome measures of cognition and function, while assessing longitudinal dynamics for disease-modifying drug effects.

Cerveau and CPAD share a mission to create new tools and methods that can be applied to increase the efficiency of the development process for new treatments in AD and related neurodegenerative dementias. The Data Contribution Agreement (DCA) between Cerveau and C-Path will allow for continuous sharing of patient-level data of potentially 7,000 imaging sets from industry sponsors and academic researchers relating to Cerveau's tau-PET tracer. Generous contributions such as these ensure that CPAD can continue its mission to develop innovative quantitative tools and methods to de-risk and speed up the drug development process in AD. Cerveau's commitment to sharing data is a testament to its continued support to facilitate precompetitive collaborations between pharmaceutical companies and academia, and to facilitate drug development for the benefit of patients and their families.

“This partnership with Cerveau Technologies reflects the crucial transformation period in AD drug development around the world, and importantly, highlights Rick Hiatt’s, and his team’s, shared vision towards pre-competitive efforts to accelerate development of meaningful therapies in Alzheimer’s disease. With thousands of tau-PET exposures, combined with clinical data, Cerveau will significantly enhance CPAD’s efforts to advance regulatory-grade novel tools and solutions for the benefit of all researchers and drug developers,” said Sudhir Sivakumaran, Ph.D., Vice President, Neuroscience Program and Executive Director, CPAD.

“Cerveau’s vision is to provide information and technology to researchers and clinicians in order to improve brain health,” said Rick Hiatt, President and CEO of Cerveau Technologies, Inc. “With a mission focused on developing tools to accelerate development, and ultimately approval, of effective therapies to treat Alzheimer’s disease and other neurodegenerative disease, this collaboration with CPAD is a critical step forward in achieving these goals.”

“This is a major step in accelerating the process of developing effective therapies for Alzheimer’s disease,” said Daniel Jorgensen, M.D., MPH, MBA, CEO of C-Path. “We are proud to be part of this effort, and we look forward to working with the team at Cerveau.”

CERVEAU technologies

About Cerveau Technologies, Inc.
Cerveau’s vision is to globally develop diagnostics and technology that positively impact patients with neurodegenerative dementias including Alzheimer’s disease.

Contact:
Cerveau Technologies, Inc.
Rick Hiatt, 617-906-2715
RFhiatt@cerveautechnologies.com

CRITICAL PATH INSTITUTE

About Critical Path Institute
Critical Path Institute (C-Path) 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 more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and hundreds of pharmaceutical and biotech companies. C-Path U.S. is headquartered in Tucson, Arizona, C-Path in Europe is headquartered in Amsterdam, Netherlands and C-Path Ltd. operates from Dublin, Ireland with additional staff in multiple other locations. For more information, visit c-path.org.

Critical Path Institute is supported by the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) and is 55% funded by the FDA/HHS, totaling $17,612,250, and 45% funded by non-government source(s), totaling $14,203,111. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government.

Contact:
Kissy Black
C-Path
615.310.1894
kblack@c-path.org