C-Path Receives Letter of Support from EMA for Parkinson's Disease Clinical Trial Simulation Platform

TUCSON, Ariz., Dec. 20, 2022 — Critical Path Institute (C-Path) today announced that the European Medicines Agency (EMA) has issued a letter of support for the Critical Path for Parkinson's (CPP) Consortium's Model-based Clinical Trial Simulation Platform to Optimize Design of Efficacy Evaluation Studies in Parkinson's Disease (PD).

In their response, issued on November 10, 2022, the EMA stated, "The EMA supports the primary objectives of the Applicant and agrees to issue a Letter of Support to the CPP Consortium to encourage industry sponsors to share with CPP the patient-level data from completed phase II and III clinical trials in the intended target population as defined in the context of use statement. This will allow the CPP team to continue to enhance quantitative novel methodology in drug development, while also encouraging the CPP team to disseminate and provide access to the current version of the model for implementation by sponsors actively designing clinical trials in early motor PD."

"This Letter of Support represents a major milestone for the consortium, and we want to recognize the outstanding work of all C-Path programs that support CPP, as well as the generous contribution of all collaborators worldwide for their role in this achievement," said CPP Executive Director Diane Stephenson, Ph.D. "This is an example of C-Path's role as a neutral convener for collaboration between regulators, industry and researchers, in the public and private sectors, working together to accelerate delivery of Parkinson's disease therapies into the hands of patients."

It is estimated that over 10 million people are affected by Parkinson's worldwide. PD is a degenerative neurological disorder in which the brain loses its ability to control movement. People with PD may eventually experience tremors in the hands and feet, lose their ability to walk and talk and can sometimes suffer from memory loss, chronic pain, depression and fatigue.

Currently, the CPP Consortium has developed three clinical trial simulators with EMA endorsement. The first one helps sponsors deploy molecular dopamine neuroimaging to optimize patient selection for PD clinical trials targeting early stages of the disease (qualified by EMA in 2018). The second and third (covered in this EMA letter of support), help sponsors optimize the design of PD trials that intend to use the Movement Disorder Society -Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II or Part III as primary endpoints. This regulatory achievement for this CPP drug development tool is one of currently 10 letters of support from EMA across a range of disease conditions that are aimed to streamline the path to regulatory endorsement of novel tools to enhance drug development.

Created in partnership with Parkinson's UK, one of the world's largest charity funders of Parkinson's research, CPP was launched in 2015 as a global collaboration that promises to pave the path to new treatments for Parkinson's. "On behalf of all of those affected by Parkinson's, we acknowledge the need for global collaborations that aim to assure that all clinical trials, whether successful or not, can be used to develop innovative tools that accelerate the path to new treatments," said David Dexter, Ph.D., Associate Research Director, Parkinson's UK.

By facilitating collaboration among scientists from the bio-pharmaceutical industry, academic institutions, government agencies, and patient-advocacy associations, CPP fosters consensus and data-driven research to

increase efficiency, safety, and speed in developing new therapies.

The Letter of Support can be found on the EMA website here or on the C-Path website here.

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.

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Media Contact:

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