C-Path's Transplant Therapeutics Consortium Receives EMA Qualification Opinion for iBox Scoring System

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Eledon to Incorporate the iBox Scoring System in Future Kidney Transplant Trials

IRVINE, Calif., Dec. 21, 2022 (GLOBE NEWSWIRE) -- Critical Path Institute (C-Path) announced on December 20, 2022, that its Transplant Therapeutic Consortium (TTC) received a qualification opinion for the iBox Scoring System as a novel secondary efficacy endpoint for kidney transplant clinical trials through the European Medicines Agency's (EMA) qualification of novel methodologies for drug development. This novel secondary endpoint supports the evaluation of new immunosuppressive therapy (IST) applications for the prevention of kidney transplant rejection and is the first EMA qualified endpoint for any transplant indication.

The iBox Scoring System is a composite endpoint of kidney graft function that utilizes multiple clinical, histological and serum biomarkers for the early prediction of graft failure, including measures of renal function (eGFR and proteinuria) and immunologic response to the graft (donor-specific antibody), with or without direct assessment of allograft health through histopathology (Banff lesion scores). The TTC has been key in advancing the application of the iBox Scoring System from an online assessment of graft function utilized by physicians and researchers to a robust online system now accepted as an efficacy endpoint in clinical trials.

“We are proud to be collaborators with the Transplant Therapeutic Consortium and congratulate it on receiving this important qualification opinion from the EMA,” said David Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “New ISTs are needed to improve kidney transplant outcomes and extend both allograft function and survival. We look forward to incorporating the iBox Scoring System as an endpoint in our trials, as we continue our development of tegoprubart for the prevention of allograft rejection in patients receiving a kidney transplant.”

About Eledon Pharmaceuticals and tegoprubart (formerly AT-1501)

Eledon Pharmaceuticals is a clinical stage biotechnology company using its expertise in targeting the CD40 Ligand (CD40L, also called CD154) pathway to develop potential treatments for persons requiring an organ or cell-based transplant, living with autoimmune disease, or living with ALS. The company’s lead compound in development is tegoprubart, an anti-CD40L antibody with high affinity for CD40 Ligand, a well-validated biological target with broad therapeutic potential. Eledon is headquartered in Irvine, Calif. For more information, please visit the company’s website at www.eledon.com. Follow Eledon Pharmaceuticals on social media: LinkedIn; Twitter

About Transplant Therapeutic Consortium

The Transplant Therapeutics Consortium (TTC) was launched in April 2017 and co-founded by the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS). TTC brings together pharmaceutical companies, diagnostic companies, academic and nonprofit partners working toward a common goal of moving the field forward toward drug development solutions in transplantation. TTC is managed and supported by the Critical Path Institute (C-Path).

About Critical Path Institute

The 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.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Any statements about the company’s future expectations, plans and prospects, including statements about planned clinical trials, the development of product candidates, expected timing for initiation of future clinical trials, and expected timing for receipt of data from clinical trials, as well as other statements containing the words “believes,” “anticipates,” “plans,” “expects,” “estimates,” “intends,” “predicts,” “projects,” “targets,” “looks forward,” “could,” “may,” and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are inherently uncertain and are subject to numerous risks and uncertainties, including: risks relating to the safety and efficacy of our drug candidates; risks relating to clinical development timelines, including interactions with regulators and clinical sites, as well as patient enrollment; risks relating to costs of clinical trials and the sufficiency of the company’s capital resources to fund planned clinical trials; and risks associated with the impact of the ongoing coronavirus pandemic. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors. These risks and uncertainties, as well as other risks and uncertainties that could cause the company’s actual results to differ significantly from the forward-looking statements contained herein, are discussed in our quarterly 10-Q, annual 10-K, and other filings with the U.S. Securities and Exchange Commission, which can be found at www.sec.gov. Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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