Eledon Pharmaceuticals Announces the First Patient Dosed in Phase 1b Trial Evaluating Tegoprubart in Kidney Transplantation

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IRVINE, Calif., July 18, 2022 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (NASDAQ: ELDN), a patient-focused clinical stage biopharmaceutical company committed to the development of innovative and impactful treatments for organ and cell transplantation, autoimmune conditions, and neurodegenerative disease, today reported that the first patient has been dosed in a Phase 1b study to evaluate tegoprubart in patients undergoing kidney transplantation.

This open-label study, which has received clearance in Canada and the United Kingdom, is enrolling up to 12 patients who will undergo kidney transplantation. The patients will receive tegoprubart in combination with rabbit anti-thymocyte globulin (rATG) induction, and mycophenolate mofetil and an oral steroid taper as maintenance therapy. The study will evaluate the safety, pharmacokinetics, and efficacy of tegoprubart, including incidence of biopsy-proven acute rejection, immune cell infiltrate of graft biopsy, and biomarker measures of kidney injury and rejection risk.

More than 20,000 people a year undergo a kidney transplant in the United States, and another 90,000 people will wait an average of 3-5 years for a transplant. Re-transplants represent up to 15% of yearly transplant surgeries and thus decreasing the need for re-transplantation would lead to greater organ availability for new patients. In addition, tegoprubart seeks to address the challenges with current immunosuppressive calcineurin inhibitor (CNI)-based regimens, associated with up to an approximately 30% incidence of new onset diabetes post-transplant, as well as hypertension, kidney-toxicity and neuro-toxicity.

“We are pleased to announce that the first patient has been dosed with tegoprubart in our Phase 1b study for kidney transplantation. This trial marks a significant step towards our goal of providing a first line alternative to calcineurin inhibitors,” said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “We believe tegoprubart has the potential to transform the clinical management of kidney transplantation by preventing graft rejection, mitigating the multiple toxicities associated with CNIs, and ultimately improving long term outcomes.”

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.

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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 the 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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