Eledon Pharmaceuticals Receives FDA Clearance of IND Application to Evaluate Tegoprubart for the Prevention of Rejection in Kidney Transplant Recipients

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IRVINE, Calif., Aug. 01, 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 announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application to evaluate tegoprubart for the prevention of organ rejection in patients receiving a kidney transplant.

The IND-opening phase 2 study will be a multicenter, open-label, 2-arm, active comparator safety, pharmacokinetic, and efficacy study that will enroll approximately 120 participants (60/arm) undergoing kidney transplant. Participants will receive tegoprubart or the active comparator, tacrolimus, as part of an immunosuppressive regimen including corticosteroids and mycophenolate mofetil (MMF) or mycophenolate sodium (MPS). The study’s primary objective is to assess superiority of graft function at 12 months post-transplant in tegoprubart-treated participants compared with tacrolimus-treated participants. The primary endpoint will compare the mean estimated glomerular filtration rate (eGFR) at 12 months for tegoprubart vs. current standard of care. Better graft function as assessed by eGFR has been associated with improved long-term patient and graft survival. Secondary objectives include safety, incidence of new onset diabetes, and participant and graft survival.

More than 23,000 people undergo a kidney transplant in the United States every year. Nationwide, only about a quarter of persons on the transplant waitlist will receive a deceased donor kidney transplant within 5 years, in part because approximately 10% of yearly kidney transplants are re-transplants. Tegoprubart seeks to reduce drug-associated morbidity and improve graft survival associated with current standard of care regimens including calcineurin inhibitors (CNIs).

"We believe strongly in tegoprubart’s potential to supplant CNIs in the immunosuppressive regimen of kidney transplant patients, potentially leading to reduced side effects such as diabetes and hypertension, better kidney allograft function, and a resulting longer functional life of transplanted kidneys," said David-Alexandre C. Gros, MD, Chief Executive Officer of Eledon. "We look forward to launching this trial and to the initial data from our ongoing kidney transplantation study in Canada, the UK and Australia."

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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