Eledon Provides Enrollment Update for Phase 2 BESTOW Trial Assessing Tegoprubart for the Prevention of Organ Rejection

July 29, 2024

80 Participants (Two-thirds of Projected Recruitment) Enrolled

IRVINE, Calif., July 29, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today announced that it has enrolled the 80th participant in its ongoing Phase 2 BESTOW trial assessing tegoprubart for the prevention of rejection in kidney transplantation.

"As of this week, we have already enrolled two-thirds of the projected study participants across sites in the United States, Europe and Latin America," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "We are grateful to the participants and their clinical teams, whose high level of interest enabled us to achieve this level of enrollment in our Phase 2 BESTOW trial. This progress underscores the urgency and need for innovative solutions in preventing kidney transplant rejection. We remain on track to complete enrollment by the end of the year."

BESTOW, a multicenter, two-arm, active comparator clinical study, will enroll approximately 120 participants undergoing kidney transplantation in the United States, Europe and Latin America to evaluate the safety, pharmacokinetics, and efficacy of the anti-CD40 ligand antibody tegoprubart compared to the calcineurin inhibitor tacrolimus. The study's primary objective is to assess graft function at 12 months post-transplant, as measured by estimated glomerular filtration rate (eGFR), in participants treated with tegoprubart compared to tacrolimus. Better graft function as assessed by eGFR has been associated with improved long-term patient and graft survival.

Eledon is currently conducting a Phase 2 trial (BESTOW; NCT05983770), a Phase 1b trial (NCT05027906), and a long-term safety and efficacy extension study (NCT06126380) to evaluate tegoprubart for the prevention of organ rejection in patients receiving a kidney transplant.

About Eledon Pharmaceuticals and tegoprubart

Eledon Pharmaceuticals, Inc. is a clinical stage biotechnology company that is developing immune-modulating therapies for the management and treatment of life-threatening conditions. The Company's lead investigational product is tegoprubart, an anti-CD40L antibody with high affinity for the CD40 Ligand, a well-validated biological target that has broad therapeutic potential. The central role of CD40L signaling in both adaptive and innate immune cell activation and function positions it as an attractive target for non-lymphocyte depleting, immunomodulatory therapeutic intervention. The Company is building upon a deep historical knowledge of anti-CD40 Ligand biology to conduct preclinical and clinical studies in kidney allograft transplantation, xenotransplantation, and amyotrophic lateral sclerosis (ALS). Eledon is headquartered in Irvine, California. 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, expected timing for receipt of data from clinical trials, expected or future results of tegoprubart trials and its ability to prevent rejection in connection with kidney transplantation, 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; and risks relating to costs of clinical trials and the sufficiency of the company's capital resources to fund planned clinical trials. 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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