Eledon Pharmaceuticals Announces First Participant Dosed in Phase 2 BESTOW Trial Evaluating Tegoprubart for the Prevention of Rejection in Kidney Transplantation

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Trial to assess potential of tegoprubart-based immunosuppression to improve graft function compared to tacrolimus-based immunosuppression

IRVINE, Calif., Sept. 05, 2023 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (NASDAQ: ELDN) today announced the first participant has been dosed in the Company’s Phase 2 BESTOW trial evaluating tegoprubart for the prevention of organ rejection in patients receiving a kidney transplant.

BESTOW, a multicenter, two-arm, active comparator clinical study, will enroll approximately 120 participants undergoing kidney transplantation in the United States and other countries 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.

Secondary objectives will include graft survival, biopsy-proven acute rejection, and the incidence of new onset diabetes mellitus after transplant. Eledon will also be using the iBox Scoring System, a composite endpoint of kidney graft function using clinical, histological, and serum biomarkers for the early prediction of graft failure, as an exploratory endpoint.

“We are excited to initiate enrollment in the Phase 2 BESTOW clinical trial, a critical next step in our evaluation of tegoprubart as a potential new immunosuppressive regimen to prevent rejection and improve graft function in patients receiving kidney transplants,” said David-Alexandre C. Gros, M.D., Eledon’s Chief Executive Officer. “This study aims to build on the growing body of evidence, including recently reported results from our Phase 1b trial, reinforcing our belief in the potential of tegoprubart to replace calcineurin inhibitors and provide kidney transplant recipients a much-needed alternative associated with better kidney function, reduced side effects and longer lifespans for transplanted organs. We look forward to generating further insights into the therapeutic potential of tegoprubart in comparison to the standard of care, while continuing to run our Phase 1b in parallel, positioning us to report multiple data updates over the next 18 months.”

Eledon previously reported results from the first three participants dosed in the Company’s ongoing Phase 1b trial. Results showed no incidence of acute rejection and strong graft function observed in all three participants, with mean eGFRs above historical averages with standard of care at measured timepoints out to 31 weeks. The trial currently has enrolled 11 participants to date and will continue in parallel with the Phase 2 BESTOW trial. Eledon expects to report additional data from the ongoing Phase 1b study during the American Society of Nephrology’s Kidney Week 2023, taking place November 2-5, 2023 in Philadelphia.

Visit clinicaltrials.gov (NCT05983770) for more information about the BESTOW trial.

About Eledon Pharmaceuticals and tegoprubart

Eledon Pharmaceuticals is a clinical stage biotechnology company with immunology expertise that is developing therapies to protect and prevent rejection of transplanted organs, as well as to treat amyotrophic lateral sclerosis (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, 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, the company’s capital resources and ability to finance planned 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 sides, 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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