Eledon Announces Completion of Enrollment in Phase 2 BESTOW Clinical Trial Assessing Tegoprubart for Prevention of Organ Rejection in Kidney Transplant Patients

September 4, 2024

Enrollment Completed Four Months Ahead of Schedule

IRVINE, Calif., Sept. 04, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (NASDAQ: ELDN) today announced that it has successfully completed enrollment for its Phase 2 BESTOW clinical trial, which is designed to assess the safety and efficacy of its investigational immunosuppression therapy tegoprubart for the prevention of organ rejection in patients undergoing kidney transplantation. The trial reached its target enrollment of 120 participants approximately four months earlier than originally planned.

“We are very pleased to achieve this critical milestone ahead of schedule in our BESTOW trial,” said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “The accelerated pace of enrollment reflects the strong interest among both clinicians and patients in new innovative therapies that have the potential to improve outcomes in kidney transplantation compared to current standard of care immunosuppression regimens. We are proud to be leading the effort to transform the prevention of organ rejection and based on the early completion of enrollment, we now anticipate reporting top-line results for the BESTOW trial in the fourth quarter of 2025.”

BESTOW, a multicenter, two-arm, active comparator clinical study, enrolled 120 participants undergoing kidney transplantation at sites in North America, Europe and Latin America to evaluate the safety, pharmacokinetics, and efficacy of tegoprubart, an anti-CD40 ligand antibody, 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. Research has shown that better graft function as assessed by eGFR has been associated with improved long-term graft survival following kidney transplantation.

“Completing enrollment in the Phase 2 BESTOW trial is a significant achievement for our team and, more importantly, for the transplant community,” said Steve Perrin, Ph.D., Chief Scientific Officer and President of Eledon. “It is a testament to the strong collaboration with our clinical sites and the enthusiasm within the community for advances in immunosuppression therapy, an area of research that has not seen major therapeutic innovation in decades. We are deeply grateful to the patients, their families, and the clinical teams for their continued support in advancing this important study.”

The BESTOW trial builds upon results from Eledon’s ongoing Phase 1b trial presented at the American Transplant Congress (ATC) in June 2024, and further demonstrates that tegoprubart has the potential to provide kidney transplant recipients with a safe and effective alternative to calcineurin inhibitors, which are often associated with side effects such as hyperglycemia, new onset diabetes, hypertension, or tremors. Eledon plans to continue advancing its tegoprubart clinical program with the goal of offering a new standard of care immunosuppression therapy for organ transplant patients.

Eledon is currently conducting the Phase 2 BESTOW trial (NCT05983770), the 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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