Eledon Reports Updated Data from Ongoing Phase 1b Trial Evaluating Tegoprubart for Prevention of Rejection in Kidney Transplantation

November 2, 2023

Data from 11 participants demonstrates tegoprubart successfully prevented kidney transplant rejection and was generally safe and well-tolerated

Aggregate mean eGFR was above 70 mL/min/1.73m^2 at all reported time points after day 90 supporting tegoprubart's potential to protect organ function in patients undergoing kidney transplantation

Eledon will host a conference call today at 5:00 p.m. ET

IRVINE, Calif., Nov. 02, 2023 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today reported results from the Company's ongoing Phase 1b open-label trial evaluating tegoprubart for the prevention of rejection in patients undergoing de novo kidney transplantation. Results were presented at the American Society of Nephrology Kidney Week 2023 Annual Meeting taking place in Philadelphia, PA from November 2-5, 2023.

"We are excited to present updated safety and efficacy results from our ongoing Phase 1b trial which continue to support the potential of tegoprubart as a novel kidney transplant immunosuppressive therapy to prevent rejection and better preserve organ function without many of the side effects associated with tacrolimus, the current standard of care," said David-Alexandre C. Gros, M.D., Chief Executive Officer. "We remain committed to the transplant community who are in urgent need of better treatment options, and we look forward to continuing this study in parallel with our Phase 2 BESTOW study initiated earlier this year."

At the time of data submission, results from the 11 participants in the Phase 1b trial demonstrated that tegoprubart is generally safe and well-tolerated in patients undergoing kidney transplantation. There have been no cases of hyperglycemia, new onset diabetes, tremor, or cytomegalovirus infection commonly seen with tacrolimus. One participant experienced a mild T cell mediated rejection (Banff score 1a) on day 99. This patient was treated for the rejection and remains in the study. There were no cases of graft loss or death.

Aggregate mean estimated glomerular filtration rate (eGFR) – a measure of kidney function – was above 70 mL/min/1.73m^2 at all reported time points after day 90. Historical studies have reported average eGFRs generally in the low 50 mL/min/1.73m^2 range during the first year after kidney transplant using standard of care. One participant has completed the study with an eGFR of 91 at one year (day 374) and is now enrolled in a Phase 2 open-label extension (OLE) study, which will evaluate the long-term safety, pharmacokinetics, and efficacy of tegoprubart in participants who have completed one year of treatment in either the ongoing Phase 1b or Phase 2 BESTOW study.

"In this Phase 1b trial, patients treated with tegoprubart demonstrated robust improvements in eGFR with a strong safety profile," said Dr. John S. Gill, MD, Professor of Medicine at the University of British Columbia, St. Paul's Hospital, Vancouver, Canada, and Principal Investigator of the study. "These results further support the promise of CD40L costimulatory blockade in organ transplantation. I look forward to additional readouts from this study in 2024."

The Phase 1b open-label study has enrolled 11 participants who underwent kidney transplantation in Canada, Australia, and the United Kingdom. Each participant received rabbit antithymocyte globulin (ATG) induction and a maintenance regimen consisting of tegoprubart, mycophenolate mofetil, and corticosteroids. The primary endpoint of the study is safety. Other endpoints include characterizing the pharmacokinetic profile of tegoprubart, the incidence of biopsy proven rejection, and eGFR.

In September, Eledon announced that the first participant had been dosed in the Company's Phase 2 BESTOW trial evaluating tegoprubart for the prevention of organ rejection in patients receiving a kidney transplant. The multicenter, two-arm, active comparator clinical study is enrolling approximately 120 participants undergoing kidney transplantation in the United States and other countries to evaluate the safety, pharmacokinetics, and efficacy of tegoprubart compared to the calcineurin inhibitor tacrolimus. The BESTOW trial's primary endpoint is designed to test the potential superiority of tegoprubart vs. tacrolimus in post kidney transplant kidney function at 12 months as measured by eGFR. The Company expects to complete enrollment at the end of 2024.

Full details on the poster presentations are below:

Title: Tegoprubart for the prevention of rejection in kidney transplant: update of emerging data from an ongoing trial
Presenter: Steve Perrin, Ph.D., President and Chief Scientific Officer, Eledon Pharmaceuticals
Poster Number: TH-PO835
Session Title: Transplantation: Clinical - I [PO2102-1]
Session Date and Time: November 2, 2023 from 10:00 AM to 12:00 PM EDT

Following the presentation, a copy of the poster will be available on the Investor section of the Company's website at https://ir.eledon.com/news-and-events/publications-and-presentations.

Conference Call

Eledon will hold a conference call today, November 2, 2023 at 5:00 p.m. Eastern Time to discuss the updated trial results. The dial-in numbers are 1-888-886-7786 for domestic callers and 1-416-764-8658 for international callers. The conference ID is 66816567. A live webcast of the conference call will be available on the Investor Relations section of the Company's website at www.eledon.com. The webcast will be archived on the website following the completion of the call.

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 CD40 Ligand, a well-validated biological target within the costimulatory CD40/CD40L cellular pathway. 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, 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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