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

June 3, 2024

Data from 13 participants presented at the American Transplant Congress continue to support safety and tolerability profile of tegoprubart

Overall mean eGFR of all reported time points after day 30 post-transplant of 70.5 mL/min/1.73m²

Mean eGFR measured above 60 mL/min/1.73m² at all reported time points after day 30 post-transplant

IRVINE, Calif., June 03, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today presented updated data from the Company's ongoing open-label Phase 1b trial and open-label extension study evaluating tegoprubart for the prevention of organ rejection in kidney transplant patients. Results from the poster, titled "Biomarkers of Inflammation and eGFR in an Ongoing Phase 1B Study of an Anti-CD40L Antibody Tegoprubart, for the Prevention of Rejection in Kidney Transplant," were presented at the American Transplant Congress (ATC) taking place in Philadelphia, PA from June 1-5, 2024.

"Eledon continues to build a robust set of encouraging results demonstrating the safety and efficacy of tegoprubart in kidney transplant recipients in our Phase 1b trial," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "Calcineurin inhibitors, the current standard of care, do not adequately serve the transplant community due to frequent and difficult–to-manage side effects. By contrast, tegoprubart's observed clinical profile to date gives us confidence in its potential to supplant calcineurin inhibitors as a next-generation immunosuppression agent for patients who have received a new kidney. We look forward to accruing incremental data through the ongoing Phase 1b and open-label extension studies while continuing to enroll in our Phase 2 BESTOW trial, with enrollment completion anticipated by the end of the year."

As of the April 2024 cutoff date, updated data from the 13 participants in the ongoing Phase 1b trial support tegoprubart's potential to protect organ function in patients undergoing kidney transplantation. Data from historical studies using standard of care, calcineurin inhibitor-based immunosuppression therapy typically report aggregate mean estimated glomerular filtration rates (eGFRs) of approximately 50 mL/min/1.73m^2 during the first year after kidney transplant. In the ongoing Phase 1b trial, mean eGFR was above 60 mL/min/1.73m² at each reported time points after day 30, with an overall mean eGFR of 70.5 mL/min/1.73m² for all the reported time points after day 30 post-transplant. Two participants completed 12 months on therapy post-transplant, and both demonstrated mean eGFRs above 90 mL/min/1.73m² at one-year post-transplant.

Results demonstrated that tegoprubart is generally safe and well tolerated in patients undergoing de novo kidney transplantation. Three subjects have discontinued the study due to hair loss and fatigue, viral infection, and rejection, respectively. There have been no cases of hyperglycemia, new onset diabetes, or tremor, all of which are side effects often associated with standard of care immunosuppression therapy. There have been no cases of graft loss or death.

Eledon is currently conducting a Phase 1b trial (NCT05027906), a Phase 2 trial (BESTOW; NCT05983770), 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.

A copy of the ATC poster can be found on the Investor section of the Company's website at https://ir.eledon.com/news-and-events/publications-and-presentations.

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.

Investor Contact:

Stephen Jasper
Gilmartin Group
(858) 525 2047
stephen@gilmartinir.com

Media Contact:

Jenna Urban
Berry & Company Public Relations
(212) 253 8881
jurban@berrypr.com

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