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

August 6, 2025

Data from patients who remained on tegoprubart for a year showed overall mean 12-month eGFR of approximately 68 mL/min/1.73 m² post-transplant

Preliminary iBox data, a key biomarker of kidney function and immunologic response, supports that tegoprubart may improve 5-year graft survival vs. current standard of care

Tegoprubart continues to be well tolerated with no cases of death, graft loss, drug related tremor, or new-onset diabetes

Conference call to be held today at 4:30 p.m. ET

IRVINE, Calif., Aug. 06, 2025 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today announced updated data from the Company's ongoing open-label Phase 1b trial evaluating tegoprubart for the prevention of organ rejection in kidney transplant patients. Results from the oral presentation, titled "Tegoprubart, an Anti-CD40L Antibody, for the Prevention of Rejection in Kidney Transplantation: An Ongoing Phase 1b Study," were presented today at the World Transplant Congress (WTC) taking place in San Francisco, CA.

"The data presented today at WTC further reinforce our belief that tegoprubart has the potential to not only provide better protection and long-term preservation of kidney function following transplantation, but also to offer a safer alternative to traditional immunosuppressive therapies by minimizing harmful side effects," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "The continued strength of the Phase 1b data through 12 months of treatment is highly encouraging as we look ahead to topline results from our Phase 2 BESTOW trial, expected in November, which compares tegoprubart to tacrolimus, the current standard of care."

As of the July 2025 cutoff date, 32 patients undergoing kidney transplantation have been enrolled in the Phase 1b study. Updated data showed that kidney function, as assessed by estimated glomerular filtration rate (eGFR), stabilized after the first month post-transplant and remained in the range of approximately 68 mL/min/1.73 m^2 through 12 months for patients (n=12) who remained on tegoprubart. Kidney function in the intention-to-treat population (n=15) was approximately 63 mL/min/1.73 m^2 at 12 months. Data from historical studies using the standard of care, calcineurin inhibitor-based immunosuppression therapy, typically report aggregate mean estimated glomerular filtration rates (eGFRs) of approximately 53 mL/min/1.73 m^2 during the first year after kidney transplant.

In addition, preliminary abbreviated iBox data was presented suggesting that tegoprubart may improve 5-year graft survival. Abbreviated iBox, a composite biomarker panel developed by the Paris Transplant Group, incorporates kidney function (eGFR, proteinuria) and immunologic response (donor-specific antibodies) parameters into a single prognostic score. Based on data collected to date, abbreviated iBox scores were -3.75 in the intention-to-treat population and -4.11 in the on-treatment population, which compare favorably to a -2.98 historical mean for calcineurin inhibitors. A difference in abbreviated iBox score of -0.40 at 12 months is considered predictive of a 4-5% difference in 5-year graft survival suggesting that tegoprubart may have a predicted 5-year allograft survival rate of over 96%.

Mean tegoprubart treatment exposure to date was 233 days. Tegoprubart continues to be well-tolerated with no cases of death, graft loss, drug related tremor, or new-onset diabetes, a side effect associated with standard of care immunosuppression therapy.

There were six (18.8%) rejection episodes, and 75% of patients who experienced a rejection had received low-dose rabbit antithymocyte globulin (rATG) induction. All rejection episodes were successfully treated. Of the patients who experienced a rejection episode and completed a year in the study, three who remained on tegoprubart had a mean eGFR of approximately 73 mL/min/1.73 m^2 at 12 months, indicating full recovery of kidney function, while the two patients who switched to standard of care tacrolimus had a mean eGFR of approximately 34 mL/min/1.73 m² at 12 months.

All 32 patients received rATG induction therapy and a maintenance regimen consisting of tegoprubart, mycophenolate mofetil, and corticosteroids.

- Cohort 1 has completed enrollment and evaluated tegoprubart at a dose of 20 mg/kg with rATG induction up to 6 mg/kg.
- Cohort 2 is currently enrolling and is evaluating a lower tegoprubart dose of 10 mg/kg, with a required rATG dose of 4.5 mg/kg.
- The primary endpoint of the study is safety and pharmacokinetics. Secondary and exploratory endpoints include patient and graft survival, biopsy-proven acute rejection, kidney function as measured by estimated by eGFR, and abbreviated iBox score.

Eledon is also conducting 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. Topline results from the Phase 2 BESTOW trial are anticipated in November 2025.

Full details of the WTC oral presentation are below:

Title: Tegoprubart, an Anti-CD40L Antibody, for the Prevention of Rejection in Kidney Transplantation: An Ongoing Phase 1b Study
Session: Oral Presentation, Kidney Novel Immunosuppressant Strategies
Presenter: John Gill, MD, MS, University of British Columbia, Vancouver, Canada
Session Date and Time: Wednesday, August 6, 2025: 10:00 a.m. – 11:15 a.m. PT

Conference Call

Eledon will hold a conference call today, August 6, 2025 at 4:30 p.m. Eastern Time to discuss the updated Phase 1b trial results. To join the conference

call, please dial 1-800-717-1738 for domestic callers or 1-646-307-1865 for international callers. The conference ID is 34575. Registration for the live webcast can be found here and available on the “Events” section of Eledon’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 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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About iBox

iBox is a composite biomarker panel developed by the Paris Transplant Group to predict long-term kidney graft survival. It combines kidney function (eGFR, proteinuria), immunologic response (donor-specific antibodies), and histopathology (Banff scores) into a single prognostic score. Validated across four independent cohorts, including two Phase 3 trials (BMS BENEFIT and BENEFIT-EXT), iBox has demonstrated strong predictive accuracy (C-statistic >0.8) for 5-year graft loss and outperforms traditional markers like biopsy-proven acute rejection. Both full and abbreviated iBox models have been qualified by the European Medicines Agency (EMA) and accepted by the U.S. FDA into the Biomarker Qualification Program. The iBox Composite Biomarker Panel is under review by the FDA as a Reasonably Likely Surrogate Endpoint (RLSE) for use as a co-primary endpoint in Phase 2/3 trials, supporting potential accelerated approval of novel immunosuppressive therapies. This makes iBox the first transplant-specific endpoint formally recognized under FDA’s biomarker qualification framework.

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 ongoing 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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Investor Contact:

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

Media Contact:

Jenna Urban
CG Life
(212) 253 8881
jurban@cglife.com

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