Eledon Presents Updated Long-Term Phase 2 BESTOW Extension Study Results at the International Congress of The Transplantation Society

September 22, 2026

Tegoprubart-treated patients maintained statistically significantly higher kidney function as measured by mean eGFR through 24 months, with an approximately 13 mL/min/1.73 m² advantage versus tacrolimus (71 vs. 58 mL/min/1.73 m²) at month 24

No rejections occurred in the tegoprubart arm beyond six months post-transplant, compared with seven in the tacrolimus arm

Tegoprubart granted U.S. FDA Fast Track designation for the prevention of rejection in kidney transplantation

Phase 3 LEGACY study expected to initiate in the fourth quarter of 2026

IRVINE, Calif., Sept. 22, 2026 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (Nasdaq: ELDN) today announced updated long-term data from its Phase 2 BESTOW clinical program evaluating tegoprubart in patients undergoing kidney transplantation, presented at the International Congress of The Transplantation Society, taking place September 20-23, 2026, in Sydney, Australia. The Company also announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to tegoprubart for the prevention of rejection in kidney transplantation.

“The BESTOW extension study data and continued improvements in kidney function and safety profile with tegoprubart versus standard of care tacrolimus further strengthen our belief in tegoprubart’s potential to become the new cornerstone immunosuppression therapy for kidney transplant recipients,” said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “These long-term results, together with FDA Fast Track designation, support our plans to initiate the Phase 3 LEGACY study in kidney transplantation in the fourth quarter and advance tegoprubart as quickly as possible for transplant patients in need of better immunosuppressive options to improve long-term outcomes.”

The FDA’s Fast Track process is designed to facilitate the development and expedite the review of drugs that treat serious conditions and address significant unmet medical needs. Companies receiving Fast Track designation may be eligible for more frequent interactions with the FDA, rolling review of future marketing applications, and eligibility for Accelerated Approval and Priority Review.

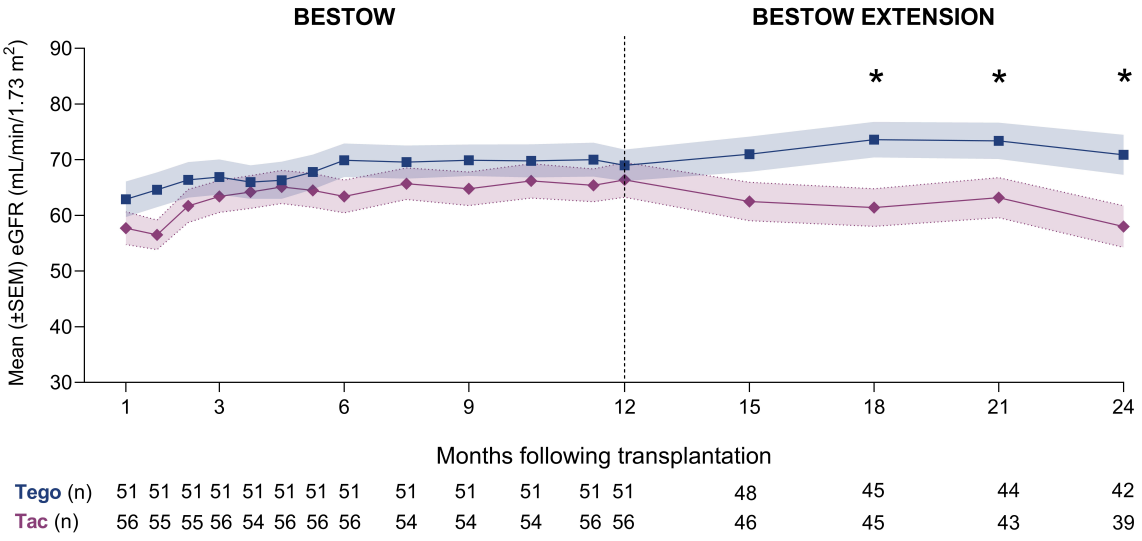

Figure 1: Patients who completed treatment were those who completed 52 weeks of the study and received all planned doses of the randomized study drug. Data for M15 onward were collected from patients who completed treatment and enrolled in BESTOW EXTENSION. *p < 0.05 (treatment difference at M18, M21 and M24). Data extraction date: 31 Aug 2026. CI, confidence interval; eGFR, estimated glomerular filtration rate; M, Month; SEM, standard error of the mean; tac, tacrolimus; tego, tegoprubart.

Updated Phase 2 BESTOW Results

- As of the data cutoff in the BESTOW long-term extension study, 90 patients had been followed through 18 months, and 81 patients had been followed through 24 months. Tegoprubart-treated patients maintained statistically significantly higher mean estimated glomerular filtration rate (eGFR), a measure of kidney graft function, at months 18, 21, and 24, with an approximately 13 mL/min/1.73 m² advantage over tacrolimus at month 24 (71 vs. 58 mL/min/1.73 m² [95% CI: 2.6, 23.3]). See Figure 1.
- There were no reported cases of biopsy-proven acute rejection (BPAR) in the tegoprubart arm beyond six months post-transplant compared with seven in the tacrolimus arm. One new case of graft loss was observed in the tacrolimus arm.

Next Steps

Following its successful End-of-Phase 2 meeting with the FDA, Eledon remains on track to initiate its global Phase 3 trial of tegoprubart in kidney transplantation (LEGACY) in the fourth quarter of 2026. The LEGACY trial is expected to enroll approximately 600 patients, with a primary endpoint of non-inferiority of tegoprubart versus tacrolimus on a composite efficacy failure endpoint at 12 months, defined as a combination of biopsy-proven acute rejection (BPAR), graft loss, and death.

Details of the oral presentation at the International Congress of The Transplantation Society are below:

Title: Phase 2 BESTOW trial and the BESTOW EXTENSION: Evaluating the long-term safety and efficacy of tegoprubart in preventing kidney transplant rejection
Presenter: Andrew Adams, M.D., Ph.D., Professor of Surgery and Chief, Division of Transplantation, John S. Najarian Surgical Chair in Clinical Transplantation, Department of Surgery, University of Minnesota; Executive Medical Director, Solid Organ Transplant Service Line, M Health Fairview
Session Title: Novel immunosuppression
Session Date and Time: Tuesday, September 22, 2026, from 8:00 a.m. to 9:00 a.m. AEST
Session Room: Room C4.9
Presentation Time: 8:00 a.m. AEST

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-CD40L biology to conduct preclinical and clinical studies in kidney allograft transplantation, xenotransplantation, islet cell transplantation, liver transplantation 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, 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. Specifically, our ability to achieve our anticipated future development and corporate milestones depends on our ability to obtain additional financing on acceptable terms. Forward-looking statements are inherently uncertain and are subject to numerous risks and uncertainties, including: our short operating history and shifts in our business strategy; our operating losses since inception; our need for additional funding to develop our lead drug candidate and our ability to secure additional funding on acceptable terms or at all; the impact of issuances of our common stock, including in the possibility of dilution or a decline in our stock price; our ability to successfully develop our product candidates; unfavorable global economic and financial market conditions; the regulatory environment of our business and our ability to obtain required regulatory approvals; results of non-clinical studies and clinical trials, and risks that non-clinical studies or early clinical trials may not be predictive of results of later-stage clinical trials; delays or difficulties in enrollment of patients in clinical trials; our ability to attract and retain our executives and key employees; legislation of the pharmaceutical and healthcare industries; cybersecurity and data privacy risks; the ability of our products to achieve marketing approval; competition in our industry; our ability to obtain insurance coverage; our dependence on contract research organizations; our ability to protect our intellectual property; public health crises; our ability to maintain proper and effective internal control over financial reporting and other risks disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission on March 19, 2026. 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 materially from the forward-looking statements contained herein, are discussed in our 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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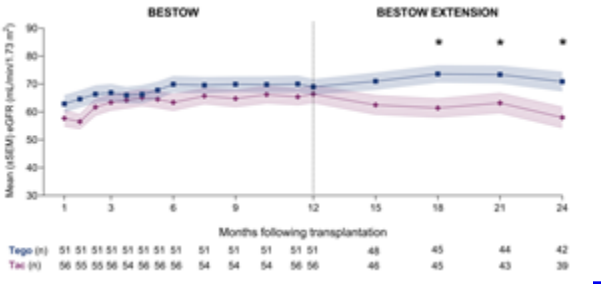
Source: Eledon Pharmaceuticals, Inc

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/48a2ff2b-c346-426c-a886-6377e5c48d1a

Figure 1



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