Eledon Pharmaceuticals Highlights Recent Business Milestones and Provides 2026 Outlook

January 8, 2026

Phase 2 BESTOW trial data evaluating tegoprubart in kidney transplantation showed favorable efficacy, safety and tolerability, supporting advancement into Phase 3 development

Reported positive preliminary results from first six patients with type 1 diabetes treated with tegoprubart following islet transplantation in UChicago Medicine-led study

Tegoprubart continues to be used as key component of immunosuppression regimen in xenotransplants, including three transplants of a genetically modified pig kidney into a human at Massachusetts General Hospital

Completed $57.5 million financing, with funds expected to support operations into 2Q 2027

IRVINE, Calif., Jan. 08, 2026 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (Nasdaq: ELDN) today announced a summary of 2025 accomplishments and provided guidance for anticipated upcoming 2026 business milestones.

“2025 was a significant year for Eledon as we achieved multiple key milestones across our tegoprubart clinical programs in kidney allotransplantation, islet transplantation and xenotransplantation. We were particularly encouraged by results from our Phase 2 BESTOW trial, presented at ASN Kidney Week in November, which further validated the favorable safety and tolerability profile of tegoprubart, reducing the metabolic, neurologic and cardiovascular toxicities commonly associated with tacrolimus,” said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “We look forward to engaging with regulatory authorities, including the FDA, as we advance tegoprubart into Phase 3 development this year, with the goal of delivering a safer alternative to tacrolimus-based immunosuppression. We also remain focused on expanding the potential of tegoprubart to address broader challenges such as organ shortages and type 1 diabetes and look forward to providing additional updates throughout the year.”

2025 Key Highlights

- Presented results from the Phase 2 BESTOW clinical trial evaluating tegoprubart for the prevention of organ rejection in patients receiving a kidney transplant at the American Society of Nephrology’s Kidney Week 2025 Annual Meeting in Houston, TX. Tegoprubart demonstrated a favorable safety and tolerability profile, reducing the metabolic, neurologic, and cardiovascular toxicities commonly associated with tacrolimus, the current standard of care in immunosuppression therapy. Kidney function, as measured by estimated glomerular filtration rate (eGFR), for study participants treated with tegoprubart was 69 mL/min/1.73 m² (n=51) at 12 months, delivering what the Company believes is the highest mean eGFR level reported to date in larger kidney transplant clinical trials evaluating rejection prevention. The efficacy failure composite endpoint including rejection rate was 22.2% in the tegoprubart group vs. 17.2% in the tacrolimus group demonstrating non-inferiority for tegoprubart vs. tacrolimus, using a 20% non-inferiority margin. The data support the advancement of tegoprubart into Phase 3 clinical development as a potential new standard immunosuppression approach for the prevention of organ rejection in patients undergoing kidney transplantation.
- Reported positive preliminary results from the first six patients with type 1 diabetes (T1D) treated with tegoprubart as the core immunosuppressant following islet transplantation in an investigator-initiated trial conducted at the University of Chicago Medicine’s Transplant Institute. All six treated patients achieved insulin independence with marked improvements in glycemic control after one or two transplants, with the first three remaining insulin-free for more than one year after transplant. Results demonstrated prevention of islet rejection without calcineurin inhibitors (CNIs), such as tacrolimus, and sustained insulin-free HbA1c control. To date, a total of eight patients have undergone islet transplantation with tegoprubart as the core immunosuppressant, and one additional patient with CNI-associated nephrotoxicity was transitioned to tegoprubart from tacrolimus.
- Announced the use of tegoprubart as a cornerstone component of the immunosuppression treatment regimen in a patient who received a xenotransplant of a genetically modified pig kidney, conducted at Massachusetts General Hospital (MGH) in collaboration with eGenesis. This procedure marked the fourth use of tegoprubart in a pig-to-human xenotransplant and the third use at MGH.
- Completed a $57.5 million underwritten public offering of common stock and pre-funded warrants, which is anticipated to support company operations into the second quarter of 2027.

Anticipated 2026 Milestones

- Present 24-month data from eight patients in Phase 1 extension study evaluating tegoprubart in kidney transplantation at the American Society of Transplant Surgeons (ASTS) Winter Symposium in Phoenix, AZ. Details are below:

  Title: Long-Term Outcomes of a Phase 1, Single Arm Cohort of De Novo Kidney Transplant Recipients Treated with Tegoprubart, an Anti-CD40L Antibody, as the Core Immunosuppression Regimen
  Abstract ID: #44

Session Title: Poster Session B
Date: Friday, January 23, 2026, from 5:45 - 7:15 p.m. PT

- Receive U.S. Food & Drug Administration ("FDA") guidance on the Phase 3 trial design assessing tegoprubart in kidney transplantation, followed by initiation of the Phase 3 trial pending regulatory alignment.
- Report long-term data from the Phase 1 and Phase 2 BESTOW studies evaluating tegoprubart in kidney transplantation.
- Report updated data from T1D patients in the investigator-led islet cell transplantation study evaluating tegoprubart at UChicago Medicine.
- Receive FDA regulatory guidance on path to market for tegoprubart in islet cell transplantation and xenotransplantation.
- Initiate an investigator-led study evaluating tegoprubart for the prevention of organ rejection in patients with renal dysfunction receiving an islet cell transplant.
- Initiate an investigator-led study evaluating tegoprubart for the prevention of organ rejection in patients receiving a de novo liver transplant.
- Initiate an investigator-led study evaluating tegoprubart for kidney transplant tolerance induction.

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, islet cell 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, 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: 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 establish and maintain proper and effective internal control over financial reporting and other risks disclosed in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, filed with the Securities and Exchange Commission on November 14, 2025. 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 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
CG Life
(212) 253 8881
jurban@cglife.com

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