# Eledon Pharmaceuticals Announces Islet Cell Transplantation IND Submission, First Patients Enrolled in Multiple Transplant Programs, and Reaffirms Plan to Initiate Phase 3 Kidney Transplantation Trial in Fourth Quarter 2026

September 3, 2026

*IND submitted to FDA for Eledon-sponsored, registrational study of tegoprubart in islet cell transplantation for patients with type 1 diabetes*

*First patients enrolled in new investigator-initiated study of tegoprubart in patients with renal dysfunction receiving an islet cell transplant*

*First patient dosed under compassionate use of tegoprubart for conversion from tacrolimus in islet cell transplant recipients with calcineurin inhibitor related kidney dysfunction*

*First patients dosed under compassionate use of tegoprubart in highly sensitized patients with pre-existing antibodies receiving a kidney transplant*

*Company on track to initiate global Phase 3 LEGACY trial of tegoprubart in kidney transplantation in Q4 2026*

IRVINE, Calif., Sept. 03, 2026 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (Nasdaq: ELDN) today announced significant progress across multiple tegoprubart development programs in kidney allotransplantation and islet cell transplantation. The Company also reaffirmed that it remains on track to initiate LEGACY, its global Phase 3 clinical trial evaluating its investigational novel immunosuppression therapy tegoprubart, an anti-CD40L antibody, in patients undergoing kidney transplantation, in the fourth quarter of 2026.

“The progress announced today reflects the growing breadth and momentum of tegoprubart’s clinical development across multiple transplant settings as we work to redefine transplant immunomodulation,” said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “We remain on track to initiate our global Phase 3 LEGACY trial in kidney transplantation in the fourth quarter of 2026, while the submission of an IND for our first Company-sponsored islet cell transplantation study represents an important regulatory milestone for the tegoprubart program. In parallel, investigator-initiated studies and compassionate-use experience are expanding the clinical evaluation of tegoprubart into transplant populations with significant unmet needs, including in patients experiencing calcineurin inhibitor-related toxicities and in highly sensitized kidney transplant recipients who face elevated immunologic risk. These new programs are expected to generate important clinical insights and data updates over the next 12 months.”

**Islet Cell Transplantation**

- **IND submitted for Eledon-sponsored islet cell transplantation study in type 1 diabetes.** Eledon has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for a planned Company-sponsored, registrational clinical trial evaluating tegoprubart for the prevention of allograft rejection in type 1 diabetes (T1D) patients undergoing pancreatic islet cell transplantation. The planned study would be Eledon’s first Company-sponsored clinical trial in islet cell transplantation and represents an important step in the Company’s registrational pathway for tegoprubart in this patient population.
- **First patients enrolled in a new investigator-initiated study involving islet cell transplant recipients with T1D and chronic kidney disease.** The first patients have been enrolled in an investigator-initiated clinical trial evaluating tegoprubart for the prevention of allograft rejection in patients with T1D and renal dysfunction from chronic kidney disease receiving an islet cell transplant. The study, underway at the University of Chicago Medicine Transplant Institute, evaluates a calcineurin inhibitor–free, tegoprubart-based immunosuppression regimen in patients who are especially susceptible to tacrolimus toxicity, including kidney damage, which has long constrained the use of islet cell transplantation.
- **First islet cell transplant recipient dosed with tegoprubart following conversion from tacrolimus.** The first islet cell transplant recipient has been dosed with tegoprubart under a compassionate-use protocol allowing them to switch from their previous tacrolimus-based immunosuppression therapy due to calcineurin inhibitor–related renal dysfunction. This compassionate use of tegoprubart may address an important unmet need among transplant recipients who require lifelong immunosuppression therapy to preserve graft function but experience renal complications often associated with calcineurin inhibitors such as tacrolimus, today’s standard of care.
- **Ongoing UChicago Medicine investigator-initiated study in participants with T1D undergoing islet cell transplantation expanded by three patients.** UChicago Medicine is adding three additional patients in its ongoing investigator-initiated islet cell transplantation study evaluating tegoprubart as the core immunosuppressant, expanding the study beyond the 12 patients treated to date. This enrollment expansion builds on previously reported results in which all 12 patients with T1D achieved insulin independence, producing their own insulin and no longer requiring exogenous insulin therapy to manage their disease, and a hemoglobin A1c (HbA1c) level below 7.0% following islet cell transplantation and treatment with tegoprubart. Stable islet graft function was observed across all 12 study participants through a maximum reported follow-up of 22 months. Tegoprubart demonstrated a favorable tolerability profile, with no evidence of nephrotoxicity, hypertension, or neurotoxicity, which are side effects often associated with calcineurin inhibitors such as tacrolimus.

**Kidney Transplantation**

- **Phase 3 LEGACY clinical trial on track to initiate in Q4 2026.** 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 versus tacrolimus at 52 weeks based on a composite of biopsy-proven acute rejection (BPAR), graft loss, and death.
- **First highly sensitized kidney transplant patient dosed under compassionate use.** The first highly sensitized kidney transplant patient has been dosed with tegoprubart under a compassionate-use protocol at Duke University Medical Center. Highly sensitized patients requiring a kidney transplant face a substantial unmet need because pre-existing antibodies can significantly limit access to compatible donor organs and increase the risk of antibody-mediated rejection and graft loss post-transplant. The compassionate use of tegoprubart in this setting will help expand our clinical insights and understanding of tegoprubart's potential in a particularly challenging patient population.
- **Third patient treated in investigator-initiated kidney transplant tolerance study.** A third patient has been treated in the investigator-initiated study evaluating tegoprubart for kidney transplant tolerance induction at Massachusetts General Hospital (MGH). Tolerance induction has the potential to eliminate the need for patients to require lifelong immunosuppression therapy.

**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, 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. 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 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 Report on Form 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 as 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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