



Eledon Pharmaceuticals Announces Use of Tegoprubart as Key Component of Immunosuppression Regimen in its Second Transplant of a Genetically Modified Pig Kidney into a Human

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Patient treated in procedure, conducted at Mass General Transplant Center and in collaboration with partner eGenesis, was recently released from hospital

Investigational therapy tegoprubart targets CD40 ligand (CD40L) with potential to improve both safety and efficacy compared to standard of care immunosuppression regimens

IRVINE, Calif., Feb. 07, 2025 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (Nasdaq: ELDN) today announced that tegoprubart, the company's investigational anti-CD40L antibody, was used as a key component of the immunosuppression therapy regimen in a patient who recently received a transplanted kidney from a genetically modified pig. The procedure was performed on January 25, 2025, by surgeons at Massachusetts General Hospital (MGH) in collaboration with our partner eGenesis. In December 2024, MGH received Food and Drug Administration (FDA) approval to proceed with this transplant and plans to perform two additional xenotransplants this year, further advancing the field of xenotransplantation. Following the successful transplant, the patient was discharged from the hospital and is now off dialysis for the first time in over two years.

"This second kidney xenotransplant conducted at MGH represents another important milestone in the effort to consider new strategies in transplantation and immunosuppression to address the global organ shortage crisis. We are grateful to the patient, the team at MGH, and our partner eGenesis for supporting tegoprubart's central role in these landmark procedures," said David-Alexandre C. Gros, M.D., Eledon Chief Executive Officer. "Blocking the CD40 Ligand is a critical component of the immunosuppression regimen for effective translation of organ transplant from nonhuman primates into humans. Our anti-CD40L antibody tegoprubart represents a novel approach to immunosuppression therapy with the potential to improve safety and efficacy and enable patients to live longer with their transplanted organs."

Similar to the first-ever kidney xenotransplant, also conducted at MGH in March 2024, tegoprubart is being administered to the current patient investigational as part of a regimen designed to prevent the body from rejecting the transplanted pig organ. Tegoprubart is designed to block CD40L and has been shown to inhibit multiple costimulatory receptors including CD40 and CD11, key components of how immune cells communicate with one another. Based on extensive prior research, tegoprubart has been observed to be generally safe and well-tolerated in multiple potential indications, including for the prevention of rejection following kidney allotransplantation.

"I would like to thank Eledon for their work supporting this historic xenotransplant. Immunosuppression presents one of the greatest challenges for transplantation in both human and non-human organs. The need for advancements in immunosuppressive medications is critical for advancing our field and improving the quality of life for transplant patients everywhere," said Dr. Leonardo Riella, MD, PhD, Medical Director for Kidney Transplantation at Massachusetts General Hospital.

Tegoprubart was also used as a cornerstone component of the chronic immunosuppression regimen administered following the second-ever transplant of a genetically modified heart from a pig to a human, performed at the University of Maryland Medical Center in September 2023. Currently, tegoprubart is being evaluated in three global clinical studies for the prevention of organ rejection in patients receiving kidney transplants and in a separate investigator sponsored trial for the prevention of islet transplant rejection in patients with type 1 diabetes (T1D). Eledon recently announced initial data from this investigator-initiated islet transplant trial, conducted by the research team at the University of Chicago Medicine Transplant Institute, that demonstrated potentially the first human cases of insulin independence achieved using an anti-CD40L monoclonal antibody therapy without the use of tacrolimus, the current standard of care for prevention of transplant rejection.

The Company plans to report updated interim clinical trial from its ongoing Phase 1b and long-term safety and efficacy extension studies in kidney transplant this summer, topline results from its Phase 2 BESTOW kidney transplant trial in the fourth quarter of 2025, and longer-term follow up results from the investigator-led islet transplant clinical trial at UChicago Medicine Transplant Institute later this year.

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, 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; risks relating to

costs of clinical trials and the sufficiency of the company's capital resources to fund planned clinical trials; and risks associated with the impact of the ongoing coronavirus pandemic. 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
CG Life
(212) 253 8881
jurban@cglife.com

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