# Eledon Pharmaceuticals Announces Use of Tegoprubart anti-CD40L Antibody in Second-ever Transplant of Genetically Modified Heart from a Pig to a Human

September 25, 2023

*Landmark cardiac xenotransplantation procedure conducted at University of Maryland Medical Center*

*Tegoprubart, administered investigationally to prevent organ rejection post-transplant, targets the CD40L pathway known to play an essential role in both innate and adaptive immune cell activation and function.*

IRVINE, Calif., Sept. 25, 2023 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today announced that tegoprubart , the company's investigational anti-CD40 antibody, was used as a cornerstone component of the chronic immunosuppressive regimen administered following the second-ever transplant of a genetically modified heart from a pig to a human. The procedure was completed on September 20th at University of Maryland Medical Center on a 58-year-old male suffering from heart failure.

"This is a momentous milestone for the transplant community and serves as a testament to the continued progress being made towards advancing novel treatment options for patients requiring an organ transplant," said David-Alexandre C. Gros, M.D., Eledon Chief Executive Officer. "As the field of organ transplantation continues to make important scientific advances, Eledon is dedicated to delivering a novel immunosuppressive regimen with the potential to protect and prevent rejection of transplanted organs, and we are honored to play a role in this historic development."

Following the successful transplantation, tegoprubart was administered to the patient as a novel, key component of a chronic immunosuppressive regimen designed to suppress the immune system and prevent the body from rejecting the implanted organ. In prior clinical research, tegoprubart has demonstrated a favorable safety and tolerability profile across multiple indications, including kidney transplantation, as well as clinical benefit in the prevention of rejection and the protection of organs after transplantation.

"The historic procedure we conducted on our courageous patient brings us to a pivotal moment in the history of organ transplantation. It is also a critical step in our ongoing mission to address the growing shortage of available organs," said Muhammad M. Mohiuddin, MD, professor of surgery at University of Maryland School of Medicine (UMSOM) and scientific/program director of its Cardiac Xenotransplantation Program. "The ability to expand options in all areas including access to available organs and strategies to reduce the risk of rejection means that we are getting closer to realizing the full potential of transplantation for patients. I look forward to continued advancements so that we can hopefully make xenotransplantation an available organ source for patients in the years ahead."

Eledon is advancing multiple research efforts related to the use of tegoprubart to reduce the risk of rejection in organ transplant. In collaboration with eGenesis, the company is currently advancing preclinical studies in which tegoprubart will be administered as part of an immunosuppression regimen to reduce the risk of rejection in nonhuman primate recipients in xenotransplant procedures. The company recently announced initiation of patient dosing in the phase 2 BESTOW clinical trial to further assess the use of tegoprubart in kidney transplantation and expects to present an updated readout from its ongoing phase 1b kidney transplantation study in November 2023. BESTOW is a head-to-head superiority study evaluating tegoprubart vs. standard of care in kidney transplantation, with a primary endpoint assessment of kidney graft function (eGFR) at 52 weeks.

**The Risk of Organ Failure in Transplantation**

In transplantation procedures, organ rejection is a major cause of graft failure which can be a life-threatening condition. To reduce the risk of organ damage and rejection, patients are typically treated with immunosuppressive therapies including calcineurin inhibitors (CNIs) such as tacrolimus. Strategies to better and more safely protect transplanted organs and thus increase how long they function represent a significant area of unmet need in organ transplantation.

**About Eledon Pharmaceuticals and Tegoprubart (formerly AT-1501)**

Eledon Pharmaceuticals is a clinical stage biotechnology company with immunology expertise that is developing therapies to protect and prevent rejection of transplanted organs, as well as to treat amyotrophic lateral sclerosis (ALS). The Company's lead compound in development is tegoprubart, an anti-CD40L antibody with high affinity for CD40 Ligand (also called "CD154"), a well-validated biological target with broad therapeutic potential. 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 planned clinical trials and the Company's other future expectations, plans and prospects, 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 sides, 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.

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