Eledon Pharmaceuticals Announces Use of Tegoprubart in First-ever Transplant of Genetically Modified Kidney from a Pig to a Human

March 21, 2024

Historic kidney xenotransplantation procedure conducted at Massachusetts General Hospital

Tegoprubart administration has now been used investigationally to prevent rejection in both kidney and heart pig-to-human xenotransplantations, as well as in human-to-human kidney transplantation

Eledon recently presented results from its ongoing Phase 1b kidney transplantation study which demonstrated that tegoprubart was generally safe and well tolerated and successfully prevented rejection with post-transplant kidney function above historical averages

IRVINE, Calif., March 21, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today announced that tegoprubart, the company's investigational anti-CD40L antibody, was used as a component of the immunosuppressive treatment regimen following the first-ever transplant of a kidney from a genetically modified pig to a human. The procedure was completed on March 16, 2024, at Massachusetts General Hospital on a 62-year-old man living with end-stage kidney disease.

"This first-ever kidney xenotransplant marks a pivotal moment for the transplant community and provides hope that this option may one day help solve the current shortage of available organs," said David-Alexandre C. Gros, M.D., Eledon Chief Executive Officer. "Eledon has now participated in both heart and kidney xenotransplant procedures, further demonstrating tegoprubart's broad potential in transplant. We are thankful to the patient, the entire medical team at Massachusetts General Hospital, and our partner eGenesis for the privilege to participate in this landmark procedure as we work to achieve our goal of developing tegoprubart as a new and better immunosuppressive option for transplant patients."

Tegoprubart is being administered to the patient investigationally as part of a regimen designed to suppress the immune system and prevent the body from rejecting the transplanted pig organ. Tegoprubart has been observed to be safe and well-tolerated in multiple studies and in multiple indications, including for the prevention of rejection following kidney transplantation.

"It is exciting to see the clinical application of xenotransplantation to a patient with end stage renal disease," said Andrew Adams, MD, PhD, Chief, Division of Transplant Surgery, University of Minnesota. "Based on all of the studies performed in preclinical models to date, it is clear that therapies targeting CD40L, like tegoprubart, are critical to controlling the immune response to the xenograft, potentially leading to superior long-term outcomes compared to other immunosuppressive therapies. CD40L sits at the interface of the adaptive and innate immune responses which may explain why therapies designed to block it have such potent effects in xenotransplantation."

"This procedure represents a significant milestone in the transplantation field and a promising step to address a medical crisis: the worldwide shortage of available organs," said Leonardo V. Riella, MD, PhD, Medical Director for Kidney Transplantation at Massachusetts General Hospital. "Xenotransplantation represents a unique approach with the potential to provide patients with additional options to access life-saving treatments in a timely manner. We commend the courage of our patient and the skill of the entire team involved in the operation, and I look forward to continued advancements in research with the hope that we can make this novel treatment option available to more patients in the future."

Multiple clinical and preclinical research efforts are currently underway to evaluate the ability of tegoprubart to reduce the risk of rejection in organ transplant. Eledon is advancing preclinical studies in which tegoprubart is being used as a part of the immunosuppression regimen designed to reduce the risk of rejection in nonhuman primate recipients in xenotransplant procedures. In parallel, Eledon is running two global clinical studies evaluating tegoprubart for the prevention of organ rejection in persons receiving a de novo kidney transplant. The company recently presented results from 11 participants enrolled in its ongoing Phase 1b kidney transplantation study, which demonstrated that tegoprubart, as part of a calcineurin inhibitor free immunosuppressive regimen, was generally safe and well tolerated and both successfully prevented rejection as well as permitted above historical average post-transplant kidney function. The company's Phase 2 BESTOW study, assessing tegoprubart head-to-head with tacrolimus for the prevention of rejection in kidney transplantation, is currently recruiting participants, and plans to complete enrollment at the end of 2024.

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 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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