Eledon Pharmaceuticals Announces Orphan Drug Designation Granted to Tegoprubart for the Prevention of Allograft Rejection in Liver Transplantation

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IRVINE, Calif., March 10, 2026 (GLOBE NEWSWIRE) -- **Eledon Pharmaceuticals, Inc.** ("Eledon") (NASDAQ: ELDN) today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug designation to tegoprubart for the prevention of allograft rejection in liver transplantation. Tegoprubart has previously received orphan drug designation from the FDA for the prevention of allograft rejection in pancreatic islet cell transplantation and for the treatment of amyotrophic lateral sclerosis (ALS).

"Clinical studies in kidney transplantation have demonstrated that tegoprubart has the potential to improve graft survival and function while reducing the side effects associated with calcineurin inhibitors, supporting its promise as a novel immunosuppressive therapy across multiple organ transplant settings," said David-Alexandre C. Gros, MD, Chief Executive Officer of Eledon. "Based on the encouraging preclinical evidence we have generated to date, we believe liver transplantation represents a significant incremental opportunity for tegoprubart, and we look forward to evaluating its potential in the clinical setting through an anticipated investigator sponsored trial initiating later this year."

Orphan Drug Designation is intended to support the development of therapies for rare diseases, defined as conditions affecting fewer than 200,000 people in the United States or fewer than 5 in 10,000 individuals in the European Union. These designations provide sponsors with a range of incentives intended to encourage the development of medicines for diseases with high unmet medical needs.

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, 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 planned clinical trials, the development of product candidates, expected or future results of tegoprubart trials and its ability to prevent rejection in connection with liver transplantation, 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; and risks relating to costs of clinical trials and the sufficiency of the company's capital resources to fund planned clinical trials. 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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