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

June 9, 2022

IRVINE, Calif., June 09, 2022 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (NASDAQ: ELDN), a patient-focused clinical stage biopharmaceutical company committed to the development of innovative and impactful treatments for organ and cell transplantation, autoimmune conditions, and neurodegenerative disease, 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 pancreatic islet cell transplantation. Tegoprubart previously received orphan drug designation from the FDA for the treatment of amyotrophic lateral sclerosis (ALS).

Pancreatic islet cell transplantation requires immunosuppressive therapy to protect transplanted cells from immune rejection. Adoption of islet cell transplantation as a treatment option for type 1 diabetes has been hampered, in part, by the toxicity associated with part of the current immunosuppressive standard of care, calcineurin inhibitors (CNIs). CNIs are required to prevent transplanted islet cell rejection yet result in acute islet cell dysfunction and loss. CNI-associated islet cell dysfunction and loss can result in the need for multiple islet cell transplant procedures to achieve optimal glucose control and potentially eliminate the need for exogenous insulin. Tegoprubart is in a Phase 2a clinical study for the prevention of allograft rejection in pancreatic islet cell transplantation as part of a CNI-free immunosuppressive regimen.

“Tegoprubart has the potential to ameliorate islet cell transplant therapy outcomes by improving graft survival and function while also reducing side effects associated with CNIs,” said David-Alexandre C. Gros, MD, Chief Executive Officer of Eledon. “Coming on the heels of positive topline data results from our Phase 2a clinical trial in ALS, this marks another important milestone for tegoprubart as a potentially transformative treatment option.”

The FDA's Office of Orphan Products Development grants orphan designation status to drugs and biologics that are intended to treat, diagnose or prevent rare diseases that affect fewer than 200,000 people in the United States. Orphan drug designation provides certain benefits, including financial incentives to support clinical development and the potential for up to seven years of market exclusivity in the U.S. upon regulatory approval.

About Type 1 Diabetes (T1D)

T1D results from the autoimmune destruction of insulin-producing islet cells in the pancreas, thus leading to a loss of insulin production and a resulting impairment of blood glucose control. Current standard of care is primarily exogenous insulin but it can be difficult for people living with T1D to achieve and maintain optimal glucose control because of the need to balance the different factors that impact glucose levels, including insulin, diet and exercise. High blood glucose, or “hyperglycemia,” can lead to diabetic ketoacidosis and to longer term complications including cardiovascular disease, kidney disease, eye disease, and nerve damage, and can be fatal. Low blood glucose, or “hypoglycemia,” may lead to cardiac rhythm abnormalities, lightheadedness, and confusion, while severely low blood glucose can cause loss of consciousness, coma, seizures, and even death. Some persons living with T1D may have impaired awareness of hypoglycemia which can result in life-threatening events since severe hypoglycemia needs to be treated immediately.

About Eledon Pharmaceuticals and tegoprubart (formerly AT-1501)

Eledon Pharmaceuticals is a clinical stage biotechnology company using its expertise in targeting the CD40 Ligand (CD40L, also called CD154) pathway to develop potential treatments for persons requiring an organ or cell-based transplant, living with autoimmune disease, or living with ALS. The company’s lead compound in development is tegoprubart, an anti-CD40L antibody with high affinity for CD40 Ligand, a well-validated biological target with broad therapeutic potential. Eledon is headquartered in Irvine, Calif. 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.

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Source: Eledon Pharmaceuticals, Inc.