Eledon Pharmaceuticals Receives Health Canada Approval to Commence Human Trials to Evaluate AT-1501 in Kidney Transplantation

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Interim data expected in late 2022 in a multicenter, open label study to replace tacrolimus with AT-1501

IRVINE, Calif., July 26, 2021 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN), a clinical stage biopharmaceutical company focused on developing targeted medicines for persons living with autoimmune disease, requiring an organ or cell-based transplant, or living with amyotrophic lateral sclerosis (ALS), received a No Objection Letter (NOL) from Health Canada for its Clinical Trial Application, thereby allowing Eledon to commence a study evaluating AT-1501 as a replacement for tacrolimus as an immunosuppressive regimen component in patients undergoing kidney transplantation.

The study will be a multicenter, open label clinical trial, in 6 to 12 subjects, to evaluate the safety, efficacy and pharmacokinetics of AT-1501 in de novo kidney transplant recipients. Exploratory biomarker endpoints will also be assessed. Interim data read-outs are expected beginning in late 2022.

"Replacing calcineurin inhibitors with AT-1501 in the immunosuppressive regimen of kidney transplant patients has the potential to improve outcomes by both decreasing current immunosuppressive side effects and extending the functional life of transplanted kidneys," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon Pharmaceuticals. "Increasing transplant durability and mitigating side effects from calcineurin inhibitors could mean that fewer patients require a repeat transplant or dialysis, and would thus help alleviate pressure on kidney transplant waiting lists. Today's announcement represents a meaningful step forward in our goal to benefit patients undergoing kidney transplantation."

Additional details of the trial will be announced in connection with Eledon's second quarter earnings release and teleconference to be held in August 2021.

About Eledon Pharmaceuticals and AT-1501

Eledon Pharmaceuticals is a clinical stage biotechnology company using its expertise in targeting the CD40L pathway to develop potential treatments for patients living with an autoimmune disease, patients requiring an organ or cell-based transplant, and for patients living with ALS. The company's lead compound in development is AT-1501, an anti-CD40L antibody with high affinity for CD40 ligand (CD40L, also called CD154), a well-validated biological target with broad therapeutic potential. AT-1501 is a humanized IgG1 antibody engineered to potentially both improve safety and provide pharmacokinetic, pharmacodynamic, and dosing advantages compared to other anti-CD40 approaches. The CD40L/CD40 pathway is widely recognized for its prominent role in immune regulation. CD40L is primarily expressed on activated CD4+ T cells, platelets and endothelial cells while the CD40 receptor is constitutively expressed on antigen presenting cells such as B cells, macrophages, and dendritic cells. By blocking CD40L and not the CD40 receptor, AT-1501 inhibits both the CD40 and CD11 costimulatory signaling pathways, providing the potential for improved efficacy compared to anti-CD40 receptor approaches. Blocking CD40L also increases polarization of CD4+ lymphocytes to Tregs, a specialized subpopulation of T cells that act to suppress an immune response, thus creating a more tolerogenic environment, which may also play a therapeutic role for autoimmune diseases and in the transplant setting. 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 a planned clinical trial in kidney transplant patients, the development of product candidates, expected timing for initiation of future clinical trials, expected timing for receipt of data from clinical trials, the company's capital resources and ability to finance planned 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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