Eledon Pharmaceuticals Announces Update on Development Strategy for AT-1501 in Renal Transplantation

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IRVINE, Calif., April 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), today announced an updated development strategy for AT-1501 in renal transplantation.

As part of ongoing discussions with the U.S. Food and Drug Administration (FDA) regarding the AT-1501 renal transplant program, the FDA requested that Eledon provide AT-1501 specific, renal transplant data in non-human primates prior to initiating a Phase 2 trial in renal transplantation in the United States. As a result, Eledon plans to initiate an evaluation of AT-1501 in a standard non-human primate model of renal transplantation which is expected to be completed by late 2022. In parallel, the company will continue to explore potentially conducting a renal transplantation clinical trial outside the United States.

The FDA request and this shift in development strategy is specific to the previously planned Phase 2 trial in renal transplantation; the company’s other ongoing development programs are continuing in both the United States and Canada as previously communicated. No significant drug-related safety signals with AT-1501 have been identified to date, and this change in development strategy is not due to any specific event in or data from the company’s ongoing trials of AT-1501.

“We will continue to work collaboratively with the FDA to generate additional renal transplantation preclinical data prior to conducting a Phase 2 trial in renal transplantation with AT-1501 in the United States,” stated Steve Perrin, Ph.D., President and Chief Scientific Officer. “We continue to believe that AT-1501 is a differentiated anti-CD40L antibody that can be an important treatment option for patients undergoing renal transplantation. We remain committed to designing and executing a robust clinical development program to show that AT-1501 has the potential to prevent rejection and prolong allograft survival. We look forward to providing further updates on our revised renal transplantation program in the coming months.”

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 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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