Eledon Reports Data from Ongoing Phase 1b Trial Evaluating Tegoprubart in Patients Undergoing Kidney Transplantation at World Congress of Nephrology

March 31, 2023

Results from three participants demonstrated no incidence of acute rejection at durations of 56, 154, and 232 days

Strong graft function observed in all three participants with mean eGFRs above 70 mL/min/1.73m^2 at measured timepoints

Data from 16 participants in the Phase 2 IgAN study demonstrated tegoprubart to be safe and well tolerated, with no serious or severe adverse events reported

IRVINE, Calif., March 31, 2023 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today reported results from the Company's ongoing Phase 1b open-label trial evaluating tegoprubart in patients undergoing kidney transplantation at the World Congress of Nephrology, which is taking place March 30 to April 2, 2023. In addition, Eledon reported safety data from the Company's Phase 2a trial of tegoprubart in IgA Nephropathy (IgAN).

The Phase 1b open-label study is enrolling up to 12 participants undergoing kidney transplantation in Canada, Australia, and the United Kingdom. Each participant receives rabbit antithymocyte globulin (ATG) induction and a maintenance regimen consisting of tegoprubart 20 mg/kg IV (administered every 3 weeks after an initial loading regimen), mycophenolate mofetil, and corticosteroids. The primary endpoint of the study is safety. Other endpoints include characterizing the pharmacokinetic profile of tegoprubart, the incidence of biopsy proven rejection, changes in estimated glomerular filtration rate (eGFR), and exploratory biomarkers including donor derived cell free DNA.

Results from the first three participants at the time of data submission to the conference demonstrated no incidence of acute rejection at 56, 167, and 232 days. The three participants had eGFRs of 54, 85, and 77 at the latest available timepoint of 49, 154, and 217 days, respectively. Regarding adverse events, one participant was discontinued from the study on day 55 after developing BK viremia, a common occurrence after kidney transplant that is related to immunosuppression and reported to occur in approximately 20% or more of kidney transplant patients. A second participant elected to discontinue the study after 33 weeks for reasons not attributed to tegoprubart or related to kidney function.

"We are highly encouraged by the results to date from our ongoing Phase 1b trial evaluating tegoprubart as a novel component of an immunosuppressive regimen in kidney transplant patients," said David-Alexandre C. Gros, M.D., Chief Executive Officer. "Previously in our Phase 2 ALS trial, we reported dose dependent target engagement and how that target engagement resulted in a broad, dose dependent decrease in proinflammatory biomarkers. Now, we are demonstrating how tegoprubart's broad anti-inflammatory effect results in a clinical benefit in the prevention of rejection and the protection of kidneys after transplantation. We look forward to completing enrollment in this kidney transplant trial and continuing to develop a much-needed treatment option that better protects an organ that many patients wait years to receive."

Eledon also presented safety data in a poster presentation from the Company's Phase 2a open-label study evaluating tegoprubart for the treatment of IgAN. The available data suggests that tegoprubart is safe and well tolerated in people with IgAN, with no serious or severe adverse events reported. To date, approximately 100 human subjects have been dosed with tegoprubart across multiple disease indications.

Copies of each poster will be available on the Investor section of the Company's website at https://ir.eledon.com/events-and-presentations/presentations.

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, 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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