Eledon Pharmaceuticals Receives FDA Clearance of IND Application to Evaluate Tegoprubart in IgA Nephropathy

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IRVINE, Calif., Sept. 06, 2022 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (NASDAQ: ELDN), today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application to evaluate tegoprubart for the treatment of IgA Nephropathy (IgAN).

Eledon plans to open U.S. sites under this IND as part of its ongoing global Phase 2a clinical trial evaluating tegoprubart for the treatment of IgAN. Including the U.S., the trial has now received regulatory clearances in 10 countries with plans to expand the study in up to 2 additional countries, including China. Multiple patients in the Phase 2a study have begun receiving treatment with tegoprubart.

IgAN, the most common primary glomerulonephritis disease, affects approximately 150,000 Americans and is characterized by gradual, progressive kidney function deterioration which can potentially lead to End-Stage Renal Disease (“ESRD”), dialysis, renal transplant, and death. Leakage of blood proteins into the urine, or proteinuria, is a clinical sign of IgAN, and the severity of proteinuria predicts the rate of progression to ESRD. In addition, reducing proteinuria has been shown to delay progression to ESRD. Current standard of care with ACEi/ARB therapies and budesonide are effective in a subset of patients with IgAN, but many patients on these therapies continue to have progressive disease and continue to be at risk of ESRD.

The global multicenter, open-label study is enrolling up to 21 patients in each of two dose cohorts with confirmed diagnosis of IgAN and at least 0.75 g/24 hours of protein in their urine at the time of screening. The study will evaluate the safety and efficacy of tegoprubart, with the primary endpoint being change from baseline in urine protein (assessed as urine protein to creatinine ratio) after 24 weeks of therapy. Dosing will continue through 96 weeks, and change from baseline in eGFR slope will be assessed at 96 weeks. Preclinical evidence has demonstrated that blocking CD40L signaling can improve proteinuria, reduce autoantibodies, decrease immune cell infiltration into the kidneys, and improve survival.

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, and the 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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