Eledon Pharmaceuticals Provides Business and Pipeline Updates

January 9, 2023

Company plans to prioritize and focus resources on the advancement of tegoprubart in kidney transplantation

Continued enrollment in open-label Phase 1b kidney transplant trial with initial data release expected at the World Congress of Nephrology in March 2023

Phase 2 BESTOW trial planned to evaluate tegoprubart for the prevention of rejection in patients receiving a kidney transplant with site initiation anticipated in mid-2023

Deprioritize clinical development of tegoprubart in IgA Nephropathy (IgAN) and discontinue islet cell transplantation to focus on kidney transplant opportunity; high dose cohort safety data from IgAN trial expected at the World Congress of Nephrology in March 2023

Sufficient financial resources to fund operating activities into 2024

IRVINE, Calif., Jan. 09, 2023 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN), today announced a business update aimed at maximizing shareholder value by prioritizing resources on its ongoing clinical development efforts in kidney transplantation.

Every year more than 24,000 people undergo a kidney transplant in the United States, and over 240,000 Americans are living with a functioning transplanted kidney. Eledon's investigational drug candidate, tegoprubart, seeks to address the challenges associated with current immunosuppressive transplantation regimens, such as those that administer calcineurin inhibitors (CNIs). The ability to prevent acute and chronic transplant rejection without the need for CNIs has the potential to transform the clinical management of transplantation by mitigating the nephrotoxicity and other side effects associated with CNIs, and potentially increasing the functional life of transplanted organs.

"We are excited with the progress we made last year advancing our kidney transplantation program and remain on track to achieve important milestones in 2023," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "We believe tegoprubart has the potential to reduce the nephrotoxicity and side effect burden associated with current calcineurin inhibitor-based standard of care immunosuppressive regimens that can lead to graft dysfunction, diabetes and other side effects. Given the significant market opportunity and unmet need, we made the strategic decision to prioritize and focus both our financial and organizational resources on our kidney transplantation programs."

"In order to allow us to focus on kidney transplantation, we are deprioritizing our IgAN program and have discontinued our islet cell transplant trial. As such, we do not expect to report out data in IgAN except for data relevant to our kidney transplant program, such as safety data. With respect to our amyotrophic lateral sclerosis program, we remain very enthusiastic about the positive Phase 2 biomarker data we announced last year – including data relevant to our kidney transplant program – and we plan to continue to seek funding for a subsequent ALS trial."

Pipeline Update

Kidney Transplantation

- The Company received regulatory clearance to initiate a Phase 1b open-label trial in Canada, the United Kingdom and Australia, for up to twelve patients, evaluating tegoprubart as a replacement for tacrolimus as a component of an immunosuppressive regimen in patients undergoing kidney transplantation. Enrollment is currently ongoing, with three patients dosed in the second half of 2022.
- The Company received Investigational New Drug (IND) application clearance from the U.S. Food and Drug Administration (FDA) for BESTOW, a Phase 2 trial of tegoprubart for the prevention of transplant rejection in persons receiving a kidney allograft. BESTOW will be a multicenter, open-label, active control, trial to assess the safety and efficacy of tegoprubart compared with tacrolimus in the preservation of allograft function after kidney transplantation. The trial's primary endpoint is mean eGFR at one year post-transplantation. Secondary objectives include safety, incidence of new onset diabetes, biopsy-proven rejection, and graft survival. The trial will enroll approximately 120 participants (60/arm) undergoing kidney transplant and will run in parallel to the ongoing Phase 1b clinical trial of tegoprubart in kidney transplantation.
- BESTOW includes an open-label extension trial allowing for the collection of long-term efficacy and safety from both this Phase 2 as well as the ongoing Phase 1b trial.
- The Company announced a collaboration agreement with eGenesis for the use of tegoprubart in preclinical xenotransplantation studies. Anti-CD40L costimulatory blockade has been demonstrated as a key component of effective immunosuppressive regimens to suppress xenograft rejection in non-human primate models of organ transplantation.

IgAN

- The Company received IND application clearance from the FDA to evaluate tegoprubart for the treatment of IgAN. This global clinical trial is a 96-week open-label clinical trial that may include up to 42 total participants, equally split between an initial high dose and a potential subsequent low dose cohort. Ten patients have been dosed to date in the high dose cohort.

Amyotrophic Lateral Sclerosis (ALS)

- In mid-2022, the Company announced positive topline results from a Phase 2a trial of tegoprubart in patients with ALS. Tegoprubart successfully met the primary endpoints of safety and tolerability, with no drug-related serious adverse events. Tegoprubart treatment was associated with dose dependent target engagement and a reduction in pro-inflammatory biomarkers in circulation.
- The Company continues to work closely with key stakeholders on potential next steps, as well as evaluating a range of approaches to fund a potential future trial.

Anticipated 2023 Milestones

- 1Q 2023: initial three and six-month open-label data from the Phase 1b trial of tegoprubart in kidney transplantation.
- 1Q 2023: initial open-label safety data from the Phase 2a trial of tegoprubart in IgAN.
- Mid-2023: initiate Phase 2 BESTOW trial of tegoprubart in kidney transplantation.
- 2H 2023: complete enrollment in Phase 1b trial of tegoprubart in kidney transplantation.

About Eledon Pharmaceuticals and tegoprubart

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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