Eledon Pharmaceuticals Highlights Recent Business Milestones and Provides 2024 Outlook

January 4, 2024

Reported updated data from ongoing Phase 1b trial in kidney transplantation demonstrating tegoprubart treatment successfully prevented kidney transplant rejection and was generally safe and well-tolerated

Dosed first participants in Phase 2 BESTOW trial in kidney transplantation

Tegoprubart dosed in second-ever pig to human xenotransplant procedure

IRVINE, Calif., Jan. 04, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today announced a summary of 2023 accomplishments and provided guidance for anticipated upcoming 2024 milestones.

2023 Key Highlights

- Reported updated data from ongoing Phase 1b trial evaluating tegoprubart for prevention of rejection in kidney transplantation. Data from 11 trial participants demonstrated that tegoprubart was generally safe and well-tolerated in patients undergoing kidney transplantation, with aggregate mean estimated glomerular filtration rate (eGFR) above 70 mL/min/1.73m^2 at all reported time points after 90 days post-transplant. Amended the Phase 1b trial protocol to add a second cohort, now allowing enrollment of up to 24 trial participants who are undergoing kidney transplantation.
- Dosed first participants in Phase 2 BESTOW trial assessing tegoprubart head-to-head with tacrolimus for the prevention of rejection in kidney transplantation.
- Dosed tegoprubart in second-ever transplant of genetically modified heart from a pig to a human.
- Completed financing of up to $185 million, with $35 million in upfront funding and additional aggregate financing of up to $105 million, subject to achieving clinical development milestones, volume weighted share price levels, and trading volume conditions, as well as up to an additional $45 million upon exercise of warrants. If all commitments are met, the financing is expected to be sufficient to fund the Company through the completion of the Phase 2 BESTOW trial, subject to the achievement of specified milestones, including clinical development enrollment targets.
- Partnered with the University of Chicago Transplantation Institute to secure financing from the Juvenile Diabetes Research Foundation (JDRF) and The Cure Alliance to fund an investigator sponsored study in pancreatic islet cell transplantation in participants with type 1 diabetes. Tegoprubart treatment will be evaluated for the prevention of transplant rejection.
- Strengthened leadership team with appointment of Eliezer Katz, M.D., FACS as Chief Medical Officer and strengthened board of directors with appointment of Allan Kirk, M.D., Ph.D. and James Robinson.

"Eledon made significant progress in 2023 on multiple fronts, highlighted by the presentation of the first clinical evidence of tegoprubart's potential to prevent organ rejection while producing robust improvements in eGFR and maintaining a favorable safety profile. We were also honored to play an important role in the second-ever transplant of a genetically modified heart from a pig to a human with the use of tegoprubart as part of the patient's cornerstone immunosuppressive regimen," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "In the coming year, we look forward to building upon the promising results from our tegoprubart kidney transplant Phase 1b trial, generating additional long-term data from the Phase 1b extension study, and completing enrollment in our Phase 2 BESTOW trial."

Anticipated 2024 Milestones

- First half of 2024: Report updated interim clinical data from the ongoing Phase 1b trial of tegoprubart in kidney transplantation.
- First half of 2024: Dose the 12th participant in the Phase 2 BESTOW trial. Upon the dosing of the 12th participant, the Company will have completed both clinical development milestones related to the second financing tranche from the private placement announced on May 1, 2023.
- End of 2024: Complete enrollment in the Phase 2 BESTOW trial of tegoprubart in kidney transplantation.
- 2024: Dose the first islet cell transplant participant for the treatment of type 1 diabetes at the University of Chicago Transplantation Institute.

About Eledon Pharmaceuticals and tegoprubart

Eledon Pharmaceuticals, Inc. is a clinical stage biotechnology company that is developing immune-modulating therapies for the management and treatment of life-threatening conditions. The Company's lead investigational product is tegoprubart, an anti-CD40L antibody with high affinity for CD40 Ligand, a well-validated biological target within the costimulatory CD40/CD40L cellular pathway. The central role of CD40L signaling in both adaptive and innate immune cell activation and function positions it as an attractive target for non-lymphocyte depleting, immunomodulatory therapeutic

intervention. The Company is building upon a deep historical knowledge of anti-CD40 Ligand biology to conduct preclinical and clinical studies in kidney allograft transplantation, xenotransplantation, and amyotrophic lateral sclerosis (ALS). Eledon is headquartered in Irvine, California. 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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