Eledon Pharmaceuticals Highlights Recent Business Milestones and Provides 2025 Outlook

January 13, 2025

Completed enrollment in Phase 2 BESTOW trial assessing tegoprubart in kidney transplantation four months ahead of schedule; on track to report topline results in fourth quarter of 2025

Presented updated data on 13 participants from ongoing Phase 1b trial that continue to support safety and tolerability of tegoprubart for prevention of organ rejection in kidney transplantation

Announced positive initial data from first three subjects with type 1 diabetes treated with tegoprubart as part of immunosuppression regimen following islet transplantation in investigator-initiated trial at UChicago Medicine

Completed two financings totaling $135 million in combined gross proceeds, with funds expected to support operations through end of 2026

IRVINE, Calif., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (Nasdaq: ELDN) today announced a summary of 2024 accomplishments and provided guidance for anticipated 2025 business milestones.

"2024 was a transformative year for Eledon as we achieved multiple key clinical milestones for tegoprubart across kidney, islet cell, and xenograft transplantation," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "Moreover, the data we reported reinforced the potential of tegoprubart to be a best-in-class immunosuppression therapy to prevent transplant rejection and disrupt the current standard of care. We now look forward to another pivotal year ahead."

2024 Key Highlights

- Completed enrollment of 120 patients in the Phase 2 BESTOW clinical trial approximately four months earlier than originally planned. The Phase 2 trial is designed to assess the safety and efficacy of tegoprubart for the prevention of organ rejection in patients undergoing kidney transplantation.
- Presented updated data at the American Transplant Congress (ATC) from the ongoing Phase 1b open-label trial evaluating tegoprubart for the prevention of organ rejection in kidney transplant patients. Updated data from 13 participants demonstrated that tegoprubart was generally safe and well tolerated, with an overall mean estimated glomerular filtration rate (eGFR) of 70.5 mL/min/1.73m^2 at all reported time points after day 30 post-transplant. Two participants completed more than 12 months on therapy post-transplant, and both demonstrated mean eGFRs above 90 mL/min/1.73m^2 at one-year post-transplant.
- Announced positive initial data for the first three islet transplant recipients treated with tegoprubart as part of an immunosuppression regimen for the prevention of islet transplant rejection in subjects with type 1 diabetes in an investigator-initiated trial at the University of Chicago Medicine's Transplant Institute. The data demonstrated potentially the first human cases of insulin independence achieved using an anti-CD40L monoclonal antibody immunosuppression therapy without the use of tacrolimus, the current standard of care for prevention of transplant rejection.
- Announced the use of tegoprubart as part of the immunosuppression treatment regimen used following the first-ever kidney xenotransplant procedure of a genetically modified pig kidney to a human.
- Completed two financings for combined total gross proceeds of $135.0 million, before deducting any offering related expenses, which is anticipated to support company operations to the end of 2026.

Anticipated 2025 Milestones

- Summer 2025: Report updated interim clinical data from the ongoing Phase 1b and long-term efficacy extension studies of tegoprubart in kidney transplantation.
- 4Q 2025: Report topline results from the Phase 2 BESTOW trial of tegoprubart in kidney transplantation.
- 2025: Report longer-term follow up results from the investigator-led clinical trial at UChicago Medicine Transplant Institute for pancreatic islet transplantation in subjects with type 1 diabetes involving use of tegoprubart as part of immunosuppression regimen.

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 the CD40 Ligand, a well-validated biological target that has broad therapeutic potential. 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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