Celldex Announces First Patient Dosed in Phase 2 Study of Barzolvolimab in Eosinophilic Esophagitis

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HAMPTON, N.J., July 06, 2023 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that the first patient has been dosed in the Company's Phase 2 subcutaneous study of barzolvolimab in eosinophilic esophagitis (EoE). EoE is the most common type of eosinophilic gastrointestinal disease, a chronic inflammatory disease of the esophagus. Several studies have suggested that mast cells may be an important driver in this disease. Barzolvolimab is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity, which is required for the function and survival of the mast cell.

"There is a growing body of literature that suggests that eosinophilic esophagitis may be a misnomer for this difficult to treat disease and that other cell types, including mast cells, may play an important role in the disease process," said Diane C. Young, M.D, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. "This is further supported by the finding that mast cells are present in the biopsy tissue of some patients who continue to suffer from EoE even after eosinophils have been fully depleted. We look forward to exploring the role of our mast cell depleting agent, barzolvolimab, in this setting and believe learnings from this study may inform expanded development into other GI disorders in the future."

The randomized, double-blind, placebo-controlled, parallel group Phase 2 study is evaluating the efficacy and safety profile of subcutaneous barzolvolimab in patients with active EoE. Approximately 60 patients will be randomly assigned on a 1:1 ratio to receive subcutaneous injections of barzolvolimab at 300 mg every 8 weeks or placebo during a 16-week placebo-controlled treatment phase. Patients then enter a 12-week active treatment phase, in which all patients will receive barzolvolimab 300 mg every 8 weeks. Patients then enter a follow-up phase for an additional 16 weeks. The primary endpoint of the study is reducing esophageal intraepithelial infiltration of mast cells as assessed by peak esophageal intraepithelial mast cell count. Secondary endpoints include the reduction of symptoms of dysphagia and esophageal intraepithelial infiltration of eosinophils and safety. When all clinical trial sites are open, the study will include approximately 60 clinical trial centers across 8 countries, including the United States.

EoE, the most common type of eosinophilic gastrointestinal disease, is a chronic inflammatory disease of the esophagus characterized by the infiltration of eosinophils. This chronic inflammation can result in trouble swallowing, chest pain, vomiting and impaction of food in the esophagus – a medical emergency. Currently, there are limited treatment options for EoE. Several studies have suggested that mast cells may be an important driver in the disease. Given the lack of effective therapies for EoE and barzolvolimab's potential as a mast cell depleting agent, Celldex believes EoE is an important indication for study. For additional information on this trial (NCT05774184), please visit www.clinicaltrials.gov.

About Barzolvolimab
Barzolvolimab is a humanized monoclonal antibody that binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity. KIT is expressed in a variety of cells, including mast cells, which mediate inflammatory responses such as hypersensitivity and allergic reactions. KIT signaling controls the differentiation, tissue recruitment, survival and activity of mast cells. In certain inflammatory diseases, such as chronic urticaria, mast cell activation plays a central role in the onset and progression of the disease.

About Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company dedicated to developing monoclonal and bispecific antibodies that address devastating diseases for which available treatments are inadequate. Our pipeline includes antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with inflammatory diseases and many forms of cancer. Visit www.celldex.com.

Forward Looking Statement
This release contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct or that those goals will be achieved, and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to successfully complete research and further development and commercialization of Company drug candidates, including barzolvolimab (also referred to as CDX-0159), in current or future indications; the uncertainties inherent in clinical testing and accruing patients for clinical trials; our limited experience in bringing programs through Phase 3 clinical trials;

our ability to manage and successfully complete multiple clinical trials and the research and development efforts for our multiple products at varying stages of development; the effects of the outbreak of COVID-19 on our business and results of operations; the availability, cost, delivery and quality of clinical materials produced by our own manufacturing facility or supplied by contract manufacturers, who may be our sole source of supply; the timing, cost and uncertainty of obtaining regulatory approvals; the failure of the market for the Company's programs to continue to develop; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; our ability to continue to obtain capital to meet our long-term liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that we have initiated or plan to initiate; and other factors listed under "Risk Factors" in our annual report on Form 10-K and quarterly reports on Form 10-Q.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

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