



Celldex Announces First Patient Dosed in Phase 1 Healthy Volunteer Study of CDX-622, a Bispecific Antibody, for the Treatment of Inflammatory Diseases

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HAMPTON, N.J., Nov. 20, 2024 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that the first patient has been dosed in the Company's Phase 1a study of CDX-622 in healthy volunteers. CDX-622 is a bispecific antibody that targets two complementary pathways that drive chronic inflammation, potentially neutralizing the alarmin thymic stromal lymphopoietin (TSLP) and depleting mast cells via stem cell factor (SCF) starvation.

"The introduction of our first bispecific candidate for inflammatory diseases, CDX-622, builds on our leadership in mast cell biology," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "CDX-622 combines mast cell depletion with inhibition of Type 2 inflammatory responses and could be broadly applicable across a wide range of respiratory and dermatological disorders. Upon successful completion of this study in healthy volunteers, we look forward to building a robust pipeline beginning initially with a study in asthma. Importantly, we believe CDX-622 complements our barzolvolimab program, further strengthening our existing pipeline which is now advancing across five diseases."

TSLP has been directly implicated in several respiratory and dermatological disorders, such as asthma, chronic obstructive pulmonary disease, eosinophilic esophagitis, atopic dermatitis and chronic spontaneous urticaria, and in fibrotic diseases such as systemic sclerosis and idiopathic pulmonary fibrosis. In these disorders, TSLP is often upregulated and associated with disease severity. Similarly, mast cells drive or contribute to the pathophysiology of allergic, inflammatory, autoimmune and fibrotic disorders and CDX-622 contains a unique SCF neutralizing function that is expected to inhibit and deplete mast cells. Combined neutralization of SCF and TSLP with CDX-622 is expected to simultaneously reduce tissue mast cells and inhibit Type 2 inflammatory responses to potentially offer enhanced therapeutic benefit in inflammatory and fibrotic disorders.

The Phase 1a clinical trial is a two-part, randomized, double-blind, placebo-controlled, dose escalation study designed to assess the safety, pharmacokinetics, and pharmacodynamics of single ascending doses (Part 1) and multiple ascending doses (Part 2) of CDX-622 in up to 56 healthy participants. A single dose of CDX-622 or placebo will be administered intravenously once during Part 1. In Part 2, CDX-622 or placebo will be administered every 3 weeks (Q3W) for up to 6 weeks following the first dose, for a total of 3 doses. Participants will be followed for 12 weeks in both Parts 1 and 2 following the last dose of study drug. Celldex will also assess blood and skin biomarkers associated with and related to SCF and TSLP signaling and other immune inflammatory pathways in healthy participants as exploratory endpoints. A subcutaneous formulation is currently being manufactured and will be added to this study in 2025.

For additional information on this trial (NCT06650761), please visit www.clinicaltrials.gov.

About Celldex Therapeutics, Inc.

Celldex is a clinical stage biotechnology company leading the science at the intersection of mast cell biology and the development of transformative therapeutics for patients. 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 severe inflammatory, allergic, autoimmune and other devastating diseases. 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 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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