Celldex Therapeutics Presents Positive Preclinical Data from Inflammatory Bispecific Antibody Program CDX-622 at AAAAI 2025

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- CDX-622 inhibits SCF and TSLP-dependent inflammatory signatures in human skin -
- Phase 1 study in healthy volunteers ongoing -

HAMPTON, N.J., March 03, 2025 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) announced today positive preclinical data from CDX-622, a novel bispecific antibody that targets two non-redundant, complementary pathways implicated in inflammation and fibrosis—thymic stromal lymphopoietin (TSLP) and mast cell depletion via stem cell factor (SCF) starvation.

The data demonstrate that CDX-622 neutralizes both SCF and TSLP, reducing tissue mast cells and inhibiting Type 2 inflammatory responses, supporting its potential to improve clinical activity over single target inhibition in inflammatory diseases and fibrotic disorders. The data were presented by Diego Alvarado, PhD, Vice President of Research at Celldex Therapeutics, in a poster presentation (#708) as part of the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting 2025.

“We are pleased to present these data which demonstrate the exciting potential of CDX-622,” said Tibor Keler, Ph.D., Executive Vice President and Chief Scientific Officer of Celldex Therapeutics. “We believe dual neutralization of SCF and TSLP can potentially deliver profound clinical benefit for patients with inflammatory and fibrotic disorders where both mast cells and TSLP play a pathogenic role. Based on these preclinical findings, last November, we initiated a Phase 1 study in healthy volunteers that is actively enrolling and look forward to presenting initial data from this important clinical program later this year.”

In the poster presented, preclinical studies demonstrate that CDX-622:

- Inhibits TSLP and SCF-dependent activities *in vitro* with similar potency as its parental mAbs as well as tezepelumab and barzolvolimab
- Preferentially inhibits the soluble over the membrane form of SCF, which may lead to differential impact on KIT-dependent processes
- Inhibits both SCF and TSLP-dependent inflammatory signatures in a human skin explant model
- Exhibits mAb-like PK properties and leads to significant reduction in skin mast cell signatures
- Was well tolerated in a GLP toxicology study at all dose levels, with no observed adverse effect level, including at the highest dose level tested (75 mg/kg) and led to a profound mast cell depletion in several tissues

About CDX-622
CDX-622 is a bispecific antibody that targets two complementary, clinically validated pathways that drive chronic inflammation, potently neutralizing the alarmin thymic stromal lymphopoietin (TSLP) and depleting mast cells via stem cell factor (SCF) starvation. SCF activation of the KIT receptor is required for mast cell survival and plays a key role in their activation, maturation and tissue recruitment. 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. A Phase 1 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 is actively enrolling.

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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