Celldex Announces Initial Positive Results from Phase 1 Trial of CDX-622 Demonstrating Favorable Safety and PK Profile and Sustained Mast Cell Inhibition

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--Data from Phase 1 Study in healthy volunteers presented at CIA Biennial Symposium--

HAMPTON, N.J., Oct. 30, 2025 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) announced today positive data from the ongoing Phase 1 study of CDX-622, a novel bispecific antibody that targets two non-redundant, complementary pathways implicated in inflammation and fibrosis—mast cell depletion via stem cell factor (SCF) starvation and neutralization of the alarmin thymic stromal lymphopoietin (TSLP). CDX-622 was well tolerated, exhibited a good pharmacokinetic profile and induced rapid and sustained reductions in serum tryptase, indicative of mast cell inhibition and depletion. The data were presented by Diego Alvarado, PhD, Vice President of Research at Celldex, in an oral presentation at the CIA (Collegium Internationale Allergologicum) Biennial Symposium in Dubrovnik, Croatia.

“Celldex continues to lead the field in therapeutic targeting of mast cells, presenting promising data today from the first stem cell factor neutralizing antibody to be studied in humans,” said Tibor Keler, PhD, Executive Vice President and Chief Scientific Officer of Celldex Therapeutics. “Combining this unique approach of mast cell depletion with the blockade of a validated and critical inflammation pathway driven by TSLP could potentially deliver profound clinical benefit for patients with inflammatory and fibrotic disorders where both mast cells and TSLP play a pathogenic role.”

“The data presented today demonstrate that CDX-622 has a long half-life with no measurable immunogenicity observed to date—two critical hurdles for bispecific antibodies,” continuedDr. Keler. “We are very pleased with the safety profile and the sustained dose dependent reductions in serum tryptase we observed over a 12 week period following a single dose. Based on these data, we have progressed this study to the next phase of development and are now testing multiple ascending doses of CDX-622. We expect to complete this study next year and plan to initiate a Phase 1b proof of mechanism study in patients with mild to moderate asthma, where we will be able to assess the impact of dual neutralization of SCF and TSLP, which could support broad development in a number of clinical indications with significant unmet need.”

Key presentation highlights:

- CDX-622 potently neutralizes TSLP and soluble SCF and leads to mast cell reduction in preclinical models.
- CDX-622 preferentially inhibits the soluble form of SCF over the membrane form, which may lead to differential impact on KIT-dependent processes.
- In a GLP toxicology study, the No-Observed-Adverse-Effect-Level (NOAEL) was the highest dose level tested (75 mg/kg) and led to profound mast cell depletion in the tissues.
- In healthy participants, CDX-622 was well tolerated with no dose limiting toxicities, serious adverse events, or infusion reactions and no emergent events related to systemic KIT inhibition.
- CDX-622 exhibited mAb-like pharmacokinetics (serum half-life of approximately 18 days at 9 mg/kg) without any evidence of antidrug antibodies (ADA).
- A single dose of CDX-622 resulted in a rapid and sustained decrease (~50%) in circulating tryptase consistent with systemic mast cell inhibition and depletion

The Phase 1 trial is a randomized, double-blind, placebo-controlled, dose escalation study designed to assess the safety, pharmacokinetics, pharmacodynamics and immunogenicity of single ascending doses (Part 1) and multiple ascending doses (Part 2) of CDX-622 in healthy participants. The study has recently been amended to include a single ascending dose of CDX-622 administered subcutaneously (Part 3). 32 participants were enrolled in Part 1 across 4 cohorts (8 patients per cohort; n=6 CDX-622, n=2 placebo) and received single ascending intravenous doses of CDX-622 (0.3, 1.0, 3.0 and 9.0 mg/kg) and were observed over a 12 week period. Data from Part 1 were presented at the meeting and participants are now being enrolled to Part 2. Celldex expects to report data from Part 2 and Part 3 of the study in Q3 2026.

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), multiple ascending doses (Part 2) and a single ascending dose administered subcutaneously (Part 3) of CDX-622 in up to 80 healthy participants is actively enrolling.

About Celldex
Celldex is pioneering new horizons in immunology to deliver life-changing therapies. We are relentless in our pursuit of novel antibody-based treatments that engage the human immune system and directly affect critical pathways to improve the lives of patients with allergic, inflammatory and autoimmune disorders.
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) and CDX-622, 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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