Celldex Presents Positive First-in-Human Results from Phase 1 Study of Novel Bispecific CDX-622 at the European Academy of Allergy and Clinical Immunology Annual Meeting

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- *CDX-622 is a novel, bispecific antibody combining mast cell depletion and TSLP inhibition, two independent pathways contributing to multiple I&I diseases*
- *CDX-622 targets the soluble form of stem cell factor (SCF), depleting mast cells without measurably impacting other KIT functions*
- *Rapid, profound, dose-dependent, and durable reductions in serum tryptase observed*
- *Well-tolerated at all dose levels*
- *First company to demonstrate that neutralizing soluble SCF can selectively inhibit KIT signaling in mast cells*

HAMPTON, N.J., June 14, 2026 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) today presented positive results from the Phase 1 healthy participant study of CDX-622, a novel, bispecific antibody that targets soluble SCF and TSLP, at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Meeting in Istanbul, Türkiye. Data demonstrated that CDX-622 induced rapid, durable, dose-dependent reductions in serum tryptase, indicative of mast cell depletion, and was well-tolerated at all dose levels. Building on Celldex's leadership in mast cell science, the data also demonstrated that neutralizing soluble stem cell factor (SCF) enables the potential for meaningful mast cell inhibition and depletion without impacting other KIT-dependent functions. CDX-622 is currently being studied in a Phase 1b proof of mechanism study in mild to moderate asthma to assess the impact of dual neutralization of SCF and TSLP.

"Celldex continues to drive groundbreaking science and is the first company to directly demonstrate that neutralizing soluble stem cell factor can selectively inhibit KIT signaling in mast cells, a historically challenging target," said Tibor Keler, Ph.D., Co-founder, Executive Vice President and Chief Scientific Officer at Celldex. "Importantly, the approach of targeting soluble SCF provides a promising anchor mechanism enabling the development of a robust portfolio of bispecific candidates designed to overcome the heterogeneity inherent in the pathophysiology of many inflammatory diseases. Today's results from CDX-622 highlight the potential of this approach and we look forward to initiating additional proof of concept studies in multiple indications where both mast cells and TSLP play a pathogenic role, focusing next on allergic rhinitis and food allergy."

"Mast cell targeting strategies are rapidly emerging as powerful therapeutic approaches in inflammatory diseases. Leveraging our expertise in antibody drug development, and building on our success with barzolvolimab, Celldex is committed to driving innovation across the field of mast cell science to bring our leading science to additional patient populations that could benefit from our medicines," said Anthony Marucci, Co-Founder, President and Chief Executive Officer at Celldex. "Barzolvolimab and CDX-622 target mast cells through two distinct, highly synergistic platform approaches. Together, these novel candidates build a powerful foundation for a broad portfolio of therapeutics targeting a wide range of inflammatory diseases where mast cells are implicated. We look forward to sharing more about our growing pipeline in the future."

Data Summary:
CDX-622 is a uniquely engineered novel bispecific antibody that targets soluble SCF and alarmin thymic stromal lymphopoietin (TSLP), two critical pathways that may contribute to the pathology of several allergic and inflammatory disorders with significant unmet medical need. Combined neutralization of SCF and TSLP with CDX-622 is expected to simultaneously reduce tissue mast cells and inhibit Type 2 inflammatory responses, allowing for a complementary dual mechanism approach that may overcome the heterogeneity inherent in the pathophysiology of many inflammatory disorders. CDX-622 has been engineered to disable effector function (AQQ) and enhance half-life (YTE).

- Rapid, profound, dose-dependent, and durable reductions in serum tryptase were observed, indicative of tissue mast cell inhibition and depletion.
    - Tryptase decreases were comparable to KIT-targeting following multiple doses.
    - Biopsy data were consistent with greater impact on mucosal mast cells than skin mast cells.

- CDX-622 exhibited monoclonal antibody-like pharmacokinetics, with extended half-life and good exposure with subcutaneous administration, consistent with good bioavailability.
    - There was no evidence of immunogenicity at any dose.

- CDX-622 was well-tolerated in all study parts and at all dose levels. There were no dose-limiting toxicities or related serious adverse events.
    - The most commonly reported adverse event across the study was Grade 1 headache.
    - There were no changes in hair or skin pigmentation.

- There was no meaningful impact on hematologic parameters.

- Additionally, in June, Celldex presented new non-human primate data at the European Mast Cell and Basophil Research Network (EMBRN) that validates the approach of targeting soluble SCF to deplete mast cells. The preclinical study evaluated antibodies either targeting soluble SCF or both soluble and the membrane form of SCF. The data showed that targeting soluble SCF effectively depleted mast cells in a manner similar to targeting membrane SCF, but without measurable effect on spermatogenesis or melanogenesis in non-human primates.

- Results support that combined TSLP neutralization and mast cell depletion with CDX-622 may result in broad efficacy in inflammatory diseases where both pathways play a pathogenic role.

About the Phase 1 Study
The Phase 1 trial was 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 also included a single ascending dose of CDX-622 administered subcutaneously (Part 3). 32 participants were enrolled in Part 1 across 4 cohorts (8 participants 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. 24 participants were enrolled in Part 2 across 3 cohorts (8 participants per cohort; n=6 CDX-622, n=2 placebo) and received multiple ascending intravenous doses of CDX-622 (1.0, 3.0, and 9.0 mg/kg at weeks 2, 4, and 6) and were observed for 18 weeks. 24 participants were enrolled in Part 3 across 3 cohorts (8 participants per cohort; n=6 CDX-622, n=2 placebo) and received single ascending subcutaneous doses of CDX-622 (290, 580, and 870 mg) and were observed for 12 weeks. Data from Part 1 were previously presented in October 2025.

About 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.

About Barzolvolimab: Barzolvolimab is a humanized monoclonal antibody with a novel mechanism of action that targets mast cells by binding with high specificity to a unique part of the KIT receptor and potently inhibiting its activity. The KIT receptor is abundantly expressed by mast cells and critical for their function and survival. Mast cells are drivers of inflammatory responses such as hypersensitivity and allergic reactions and, in certain inflammatory diseases, such as chronic urticarias, mast cell activation plays a central role in the onset and progression of the disease. Based on data from robust, randomized, placebo controlled Phase 2 studies, barzolvolimab has significant potential as a first-in-class and best-in-disease treatment option for patients with chronic spontaneous urticaria (CSU), cold urticaria (ColdU) and symptomatic dermographism (SD). Barzolvolimab is currently being studied in Phase 3 studies in CSU and ColdU/SD and Phase 2 studies in prurigo nodularis (PN) and atopic dermatitis (AD), with additional indications planned for the future.

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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