Celldex Reports Results from Phase 2 Study of Barzolvolimab in Atopic Dermatitis

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- *Study did not meet key efficacy measures or internal hurdle rate for continued development*
- *Systemic mast cell depletion observed, consistent with prior studies, as evidenced by significant reduction in serum tryptase*
- *Favorable safety and tolerability demonstrated, consistent with prior studies*
- *BLA submission for barzolvolimab in CSU anticipated in 2027*
- *Phase 3 barzolvolimab cold urticaria and symptomatic dermographism study (EMBARQ-ColdU and -SD) actively enrolling*
- *Additional indications for barzolvolimab to be announced by year end*

HAMPTON, N.J., Nov. 19, 2026 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) today reported topline results from the Company's Phase 2 study of barzolvolimab in moderate to severe atopic dermatitis (AD). Barzolvolimab, a first-in-class humanized monoclonal antibody with a novel mechanism of action that uniquely targets the KIT receptor and depletes mast cells, is being studied across multiple indications where mast cells are implicated in the disease pathology. The primary endpoint of the Phase 2 AD study, the percent change from baseline in the weekly average of the daily Peak Pruritus Numerical Rating Scale (PP-NRS) score at Week 16 compared to placebo, and key secondary endpoints were not met. While some benefit from barzolvolimab treatment was observed, these improvements did not meet the Company's internal hurdle rate for continued development. Data suggest that while mast cells contribute to AD, they are not a primary driver of the disease. Based on these results, Celldex is discontinuing development in AD. Consistent with previously reported studies, barzolvolimab demonstrated a favorable safety and tolerability profile.

"Celldex is leading the exploration of mast cell science to understand the contribution of mast cells to various diseases and how targeted mast cell depletion can best be implemented to improve the lives of patients," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex. "We have delivered best in disease data in chronic spontaneous urticaria, cold urticaria and symptomatic dermographism while also increasing our understanding of which diseases, like atopic dermatitis, might not be primarily driven by mast cells. We are thankful to the patients and investigators who have played an important role in furthering this science. We remain focused on delivering on barzolvolimab's promise for patients and look forward to announcing additional indications for barzolvolimab based on learnings to date, while also advancing our planned 2027 BLA submission in CSU and executing across our Phase 3 studies in CSU, symptomatic dermographism and cold urticaria."

In the Phase 2 AD study, 131 patients from 28 US-based centers were randomized in a 1:1:1 ratio to receive subcutaneous injections of barzolvolimab at either 150 or 300 mg every 4 weeks after an initial loading dose of 450 mg or placebo during a 16-week placebo-controlled treatment phase. Patients then entered a 16-week active treatment period, in which patients in the 150 mg and 300 mg dose groups continued to receive barzolvolimab at the same dose, while patients randomized into the placebo arm were re-randomized into one of the two active treatment arms. The primary endpoint of the study evaluates the percent improvement of the two barzolvolimab dose levels compared to placebo using the Peak Pruritus Numerical Rating Scale (PP-NRS) at Week 16. The study is 80% powered with a type I error of p=0.1. Key secondary endpoints include the percentage improvement in Eczema Area and Severity Index (EASI) score and proportion of patients achieving an Investigator's Global Assessment (IGA) score of 0 or 1.

Summary of Key Findings

- The primary endpoint, percent change from baseline (CFB) in the weekly average of the daily PP-NRS score at Week 16, did not meet statistical significance (p=0.1) at either dose evaluated. At Week 16, percent CFB was -19.5% for placebo compared to -29.2% for 300mg Q4W [Diff (90% CI): -9.7 (-21.7, 2.4); p=0.187] and -16.2% for 150mgQ4W [Diff (90% CI): 3.3 (-8.7, 15.3); p=0.651].
- The change from baseline EASI score and the percentage of patients with IGA 0/1, key secondary endpoints, did not meaningfully differentiate from placebo.
- There was no improvement observed with longer treatment across the primary and key secondary endpoints (Week 32).
- While there were numerical differences from placebo observed, these improvements did not meet the Company's internal requirements for continued development.
- Rapid and profound suppression of circulating tryptase, indicative of systemic mast cell depletion, was observed with both doses. The addition of the 450 mg loading dose led to early, profound tryptase reduction that was sustained over the duration of the treatment period.
- Barzolvolimab was well tolerated. Loading dose (450 mg) followed by Q4W dosing (150 or 300 mg) demonstrated a favorable safety profile consistent with prior studies.

For additional information on this trial (NCT06727552), please visit www.clinicaltrials.gov.

About Barzolvolimab
Barzolvolimab is a first-in-class 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 and 3 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, ColdU and SD with additional indications planned for the future. In September 2026, Celldex reported topline data from the Phase 3 studies in CSU—the primary and all key secondary endpoints were met across both studies at 12 weeks and a favorable safety profile was demonstrated. Treatment continues in both trials to 52 weeks and a BLA submission is planned for 2027.

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 current expectations regarding the submission of a Biologics License Application (“BLA”) to the FDA in 2027; 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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