Celldex Presents Results from Barzolvolimab Phase 2 Study in Cold Urticaria (ColdU) and Symptomatic Dermographism (SD) Demonstrating Sustained Efficacy and Favorable Safety Profile over 20 Week Placebo Controlled Treatment Period; Up to 66% of Patients with ColdU and 49% with SD Obtain Complete Response at Week 20

Nov 6, 2025

- *First large, randomized, placebo-controlled study to demonstrate clinical benefit in patients with Cold Urticaria (ColdU) and Symptomatic Dermographism (SD)*
- *All primary and secondary endpoints met with high statistical significance at 12 weeks and sustained through end of treatment period (20 weeks)*
- *Up to 78% of patients with ColdU and 58% of patients with SD obtained a partial or complete response at Week 20*
- *Well tolerated through 20 weeks of dosing*
- *Phase 3 study in ColdU and SD to initiate in December 2025*

HAMPTON, N.J., Nov. 06, 2025 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) announced today new data demonstrating sustained efficacy and a well tolerated safety profile over a 20 week treatment period for barzolvolimab in two of the most common forms of chronic inducible urticaria (CIndU)—cold urticaria (ColdU) and symptomatic dermographism (SD). Barzolvolimab is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity, which is required for mast cell function and survival. CIndU is characterized by the occurrence of hives or wheals that have an attributable trigger associated with them—exposure to cold temperatures in ColdU and scratching/rubbing of the skin in SD. Mast cell activation is known to be a critical driver in ColdU and SD.

The data is being presented (presentation #R097) at the American College of Allergy, Asthma & Immunology's Annual Scientific Meeting (ACAAI) in Orlando, Florida (November 6-10, 2025) by Dr. Jonathan Bernstein, Professor of Clinical Medicine, Department of Internal Medicine, Division of Rheumatology, Allergy and Immunology, University of Cincinnati Medical Center and Partner, Bernstein Allergy Group and Clinical Research Center.

“Barzolvolimab is the first drug to achieve success in a large, randomized, placebo-controlled study in chronic inducible urticaria —providing hope for patients who are impacted by severe itching and hives that dramatically impact all aspects of their lives despite constant vigilance to avoid disease triggers,” said Diane C. Young, MD, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. “We previously reported that the study met all primary and secondary endpoints with high statistical significance and the data reported today continue to demonstrate that patients experience these clinically meaningful improvements through the longer treatment period with a favorable safety profile. We are excited to initiate our Phase 3 study in these indications next month—an important step forward for patients who currently have no approved treatment options other than antihistamines.”

Summary of Phase 2 data as assessed at end of 20 week placebo controlled treatment period:

- Patients on study (n=196) had poorly controlled disease on initial provocation testing (ColdU—mean baseline critical temperature threshold of approximately 19°C or 66°F on TempTest®; SD—average baseline critical friction thresholds of 3.6 out of 4 pins on FricTest®).
- Up to 66% of patients with ColdU and 49% of patients with SD obtained a complete response compared to 16% and 10% of patients on placebo, respectively.
- Up to 78% of patients with ColdU and 58% of patients with SD obtained a partial or complete response compared to 25% and 16% of patients on placebo, respectively.

- Marked improvement in critical temperature threshold (from baselines values of 18.7°C and 20.7°C to Week 20 values of 10.7°C and 9.2°C for barzolvolimab 150 mg Q4W and 300 mg Q8W respectively compared to baseline values of 18.6°C to Week 20 values of 18.2°C for placebo) and friction thresholds (from baseline values of 3.6 and 3.6 pins to 1.5 and 1.4 pins for barzolvolimab 150 mg Q4W and 300 mg Q8W, respectively compared to baseline values of 3.6 pins to 2.9 pins for placebo) were observed over the course of the 20 week treatment period. Sustained improvement in itch reduction at the time of provocation testing (WI-NRSprovo) was also observed at Week 20.

- After completing the treatment period, patients were eligible to enter a 24 week open label extension (OLE) upon resumption/continuation of symptoms. Consistent with the clinical endpoint results at Week 20, placebo-treated patients entered the OLE at a faster rate compared to barzolvolimab-treated patients.

Barzolvolimab was well tolerated with a favorable safety profile over the 20 week treatment period consistent with previous studies. There was no difference between active treatment (2%) and placebo groups (3%) in rate of discontinuations due to adverse events. Most adverse events for patients on study drug were grade 1 (mild), mechanism related (KIT) and, as demonstrated in previous studies, expected to be reversible. The most common adverse events occurring in greater than 10% of patients in any treatment group through Week 20 were hair color changes (18%; Grade 1, n=22 / Grade 2, n=2) and neutropenia (12%; Grade 1, n=9 / Grade 2, n=6). Neutropenia was transient and there was no association with infections.

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About Barzolvolimab
Barzolvolimab is a humanized monoclonal antibody that binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity. KIT is expressed in a variety of cells, including mast cells, which mediate inflammatory responses such as hypersensitivity and allergic reactions. KIT signaling controls the differentiation, tissue recruitment, survival and activity of mast cells. In certain inflammatory diseases, such as chronic urticaria, mast cell activation plays a central role in the onset and progression of the disease. Barzolvolimab is currently being studied in chronic spontaneous urticaria (CSU), two forms of chronic inducible urticaria (CIndU) – cold urticaria (ColdU) and symptomatic dermographism (SD), prurigo nodularis (PN) and atopic dermatitis (AD), with additional indications planned for the future.

About the Phase 2 CIndU Study: This study is a randomized, double-blind, placebo-controlled, parallel group study evaluating the efficacy and safety profile of two dose regimens of barzolvolimab in patients with CIndU who remain symptomatic despite antihistamine therapy. 196 patients in 2 cohorts (differentiated by CIndU subtype) including 97 patients with ColdU and 99 patients with SD were randomly assigned on a 1:1:1 ratio to receive subcutaneous injections of barzolvolimab at 150 mg every 4 weeks, 300 mg every 8 weeks or placebo during a 20-week treatment phase. Patients then entered a follow-up phase for an additional 24 weeks. The study also included an Open Label Extension that allowed patients with symptoms during the follow-up phase (including patients who were on placebo during the 20-week treatment phase) to receive active study drug for an additional 20 weeks. The primary endpoint of the study was the percentage of patients with a negative provocation test at Week 12 (using TempTest® for ColdU and FricTest® for SD). Secondary endpoints included safety and other assessments of clinical activity including CTT (critical temperature threshold), CFT (critical friction threshold) and WI-NRSprovo (worst itch numeric rating scale associated with provocation testing). Celldex previously reported that barzolvolimab achieved all primary and secondary endpoints in the study.

About Chronic Inducible Urticaria (CIndU), Cold Urticaria (ColdU) and Symptomatic Dermographism (SD):
Cold Urticaria (ColdU) and Symptomatic Dermographism (SD) are forms of Chronic Inducible Urticaria (CIndU), characterized by the occurrence of hives or wheals that have an attributable trigger associated with them. ColdU symptoms include itching, burning wheals/hives and angioedema when skin is exposed to cold temperatures. SD symptoms include the development of wheals in response to stroking, scratching or rubbing of the skin. Approximately 0.5% of the total population suffers from chronic inducible urticarias. For these diseases, mast cell activation leading to release of soluble mediators is thought to be the driving mechanism leading to the wheals and other symptoms. There are currently no approved therapies for ColdU and SD other than antihistamines and patients attempt to manage symptoms associated with their disease through avoidance of triggers.

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.
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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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