Celldex Presents Additional Positive Data Demonstrating Barzolvolimab's Ability to Drive Rapid, Profound and Durable Complete Urticaria Control in Phase 2 Chronic Spontaneous Urticaria (CSU) Study

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HAMPTON, N.J., Nov. 06, 2025 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) announced today new data on exploratory endpoints (UCT7) further demonstrating barzolvolimab's ability to improve urticaria control from the Company's recently completed Phase 2 study in chronic spontaneous urticaria (CSU). The data (presentation #R080) are being presented at the American College of Allergy, Asthma & Immunology's Annual Scientific Meeting (ACAAI) in Orlando, Florida by Dr. Steven Greenberg, Vice President of Clinical Science at Celldex.

"The data presented at ACAAI continue to demonstrate a level of complete disease control, including after the completion of active therapy, that is unprecedented in CSU," said Diane C. Young, MD, Senior Vice President and Chief Medical Officer of Celldex. "Further, we believe the cumulative data we have presented across this study reinforce barzolvolimab's significant potential to transform the treatment landscape and meet the goals of CSU therapy—rapid, profound, durable complete response and improved quality of life, offering new hope for the patients suffering from this often very severe and debilitating disease."

Key data highlights from the ACAAI presentation:

- Barzolvolimab treatment demonstrated rapid and profound improvement in urticaria control with sustained efficacy, including after the completion of active therapy, in patients with CSU refractory to antihistamines.
- Significant improvements in urticaria control test over seven days (UCT7[1]) scores were observed. UCT7 evaluates symptoms, quality of life, treatment adequacy and overall disease control within the past week. Patients on barzolvolimab experienced up to an 8.6 point improvement (mean) from baseline UCT7 scores compared to only 2.5 points for placebo at Week 12. This improvement deepened for patients on barzolvolimab to up 10.0 points at Week 52. Notably, meaningful clinical benefit continued beyond the active treatment period and at Week 76, seven months after the last dose of barzolvolimab, a 7.4 point improvement was observed.
- At Week 52, 71% of patients achieved complete disease control (UCT7=16) and 86% of patients achieved well-controlled disease (UCT7>12) at the 150 mg Q4W dose.
- Similar activity across both omalizumab naïve and omalizumab refractory CSU was observed.
- Most patients had well controlled disease at Week 76 suggestive of disease modification.
- Barzolvolimab was well tolerated with no new safety findings during the follow up period.

The barzolvolimab presentation at ACAAI adds to a growing body of potentially field-changing data in CSU. The Phase 2 study met its primary endpoint —a significant improvement in UAS7 compared to placebo at 12 weeks—across all dose groups tested Barzolvolimab also demonstrated rapid, profound complete response rates (UAS7=0; no itch/no hives) in up to 51% of patients at 12 weeks, which continued to deepen over 52 weeks of active therapy to up to 71% of patients. Seven months after completion of dosing, patients continued to experience profound clinical benefit, with up to 41% of patients reporting a complete response at 76 weeks and 48% of patients reporting that their disease no longer impacted their quality of life. Barzolvolimab demonstrated a well tolerated safety profile throughout the study and KIT related tolerability events, mild hair color changes and skin hypopigmentation, were demonstrated to be reversible following discontinuation of treatment. Barzolvolimab has also demonstrated profound improvements in angioedema, a painful, debilitating symptom of CSU that has significant impact on quality of life, characterized by swelling of the deeper dermal layers of the skin and mucous membranes and has been show to have strong efficacy regardless of baseline immunoglobulin E (IgE) levels.

The Company is currently enrolling patients in a global Phase 3 Program for barzolvolimab in CSU, consisting of two Phase 3 trials (EMBARQ-CSU1; NCT06445023 and EMBARQ-CSU2; NCT06455202) designed to establish the efficacy and safety of barzolvolimab in adult patients with CSU who remain symptomatic despite H1 antihistamine treatment. The studies also include patients who remain symptomatic after treatment with biologics.

[1]Patient-reported questionnaire to retrospectively assess how well chronic urticaria is controlled in the past seven days that evaluates symptoms, quality of life, treatment adequacy and overall control. Scoring system ranges from 0 (no disease control) to 16 (complete disease control).

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 CSU Study
The randomized, double-blind, placebo-controlled, parallel group Phase 2 study evaluated the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients with CSU who remained symptomatic despite antihistamine therapy, to determine the optimal dosing strategy. 208 patients were randomly assigned on a 1:1:1:1 ratio to receive subcutaneous injections of barzolvolimab at 75 mg every 4 weeks, 150 mg every 4 weeks, 300 mg every 8 weeks or placebo during a 16-week placebo-controlled treatment period. After 16 weeks, patients then entered a 36-week active treatment period, in which patients receiving placebo or the 75 mg dose were randomized to receive barzolvolimab 150 mg every 4 weeks or 300 mg every 8 weeks; patients already randomized to the 150 mg and 300 mg treatment arms remained on the same regimen as during the placebo-controlled treatment period. After 52 weeks, patients entered a follow-up period for an additional 24 weeks. Barzolvolimab achieved the primary efficacy endpoint of the study—a statistically significant mean change from baseline to week 12 in UAS7 (weekly urticaria activity score) compared to placebo at all dose levels. For additional information on this trial (NCT05368285), please visit www.clinicaltrials.gov.

About the Phase 3 Program
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About Chronic Spontaneous Urticaria (CSU)
CSU is characterized by the occurrence of hives or wheals for 6 weeks or longer without identifiable specific triggers or causes. The activation of the mast cells in the skin (release of histamines, leukotrienes, chemokines) results in episodes of itchy hives, swelling and inflammation of the skin that can go on for years or even decades. Current therapies provide symptomatic relief only in some patients.

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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