Celldex Presents Data Demonstrating Barzolvolimab Improves Chronic Spontaneous Urticaria Independent of Baseline Immunoglobulin E levels in Phase 2 Study at EADV Congress 2025

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Rapid and sustained efficacy regardless of baseline IgE levels in patients with CSU

HAMPTON, N.J., Sept. 17, 2025 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) announced today new data demonstrating rapid and strong efficacy regardless of baseline immunoglobulin E (IgE) levels in patients with chronic spontaneous urticaria (CSU), an immune-related condition driven by mast cell activation. Barzolvolimab specifically targets mast cells by binding the receptor tyrosine kinase KIT with high specificity and potently inhibiting its activity, which is required for mast cell function and survival.

The data were presented in an oral e-poster presentation (EPS02.09) at the EADV Congress 2025 by Martin Metz, M.D., Professor, Department of Dermatology and Allergy, Head of Translation Research and Deputy Head of Clinical Trials at Charité – Universitätsmedizin in Berlin and the lead investigator of the study.

“These data reinforce that mast cells are important drivers of CSU and that barzolvolimab, with its novel mechanism of action, has significant potential to be a meaningful treatment for all patients with CSU, regardless of underlying disease endotype,” said Diane C. Young, MD, Senior Vice President and Chief Medical Officer of Celldex. “This is especially important for patients with low IgE levels, who typically have more severe disease and are less likely to respond to IgE targeted therapies, including omalizumab.”

Key data highlights:

- Barzolvolimab demonstrated rapid and sustained efficacy in patients with CSU with both low (<40) and normal/high (>40) IgE levels.
- Similar improvement in weekly urticaria activity scores (UAS7; mean change from baseline) were observed across both IgE low and IgE normal/high subgroups at Weeks 12 and 52.
- Similar rates of well-controlled disease (UAS7<6) and complete disease control (both UAS7=0) were also observed across both IgE normal/high and IgE low subgroups at Weeks 12 and 52.
- Similar rates of well-controlled disease (UCT7>12) and complete disease control (UCT7=16) were also observed across both IgE normal/high and IgE low subgroups at Weeks 12 and 52.
- Data reinforce that mast cells are important drivers of CSU regardless of the underlying endotype and are consistent with the novel mechanism of action of barzolvolimab.
- Barzolvolimab is a promising therapy for all patients with moderate to severe CSU, regardless of underlying endotype.

The Company previously announced that this Phase 2 study of barzolvolimab in patients with moderate to severe CSU refractory to antihistamines, including patients with biologic-refractory disease, 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.

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.

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), 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.

Company Contact
Sarah Cavanaugh
Senior Vice President, Corporate Affairs & Administration
(508) 864-8337
scavanaugh@celldex.com

Patrick Till
Meru Advisors
(484) 788-8560
ptill@meruadvisors.com

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