Celldex Presents Data Demonstrating Profound Long Term Improvement in Angioedema in Barzolvolimab Phase 2 Study in Chronic Spontaneous Urticaria at EAACI 2025

Jun 14, 2025

- *77% of patients* (150 mg Q4W) *treated with barzolvolimab who had angioedema at baseline were angioedema free at Week 52*
- *Data further support barzolvolimab clinical benefit to patients with CSU*

HAMPTON, N.J., June 14, 2025 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced data demonstrating that barzolvolimab profoundly improves angioedema at 52 weeks in the Company's Phase 2 clinical trial in chronic spontaneous urticaria (CSU). Angioedema, characterized by swelling of the deeper dermal layers of the skin and mucous membranes, is a painful, debilitating symptom of CSU that has significant impact on quality of life. It commonly affects the face (lips and eyelids), hands, feet, and genitalia but can also involve the tongue, uvula, soft palate, and pharynx[1].

The data were presented today by Dr. Martin Metz, Professor, Department of Dermatology and Allergy, Head of Translational Research and Deputy Head of Clinical Trials at Charité – Universitätsmedizin in Berlin, in an oral presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Congress 2025. Celldex previously announced that the Phase 2 study in CSU met its primary and secondary endpoints at 12 weeks with clinically meaningful and statistically significant decreases in UAS7 (weekly urticaria activity score) compared to placebo across multiple dose groups, including improvements in quality of life and angioedema measurements, and demonstrated a favorable safety profile. The data presented today further support these results by demonstrating improvements in AAS7 (weekly angioedema activity score) and additional measures of angioedema control over the 52 week treatment period. AAS7 measures the frequency and intensity of angioedema episodes, where higher scores indicate increased angioedema activity.

"The majority of patients with severe CSU suffer with angioedema, which is often extremely painful and causes disfigurement, dramatically impacting quality of life," said Diane C. Young, MD, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. "Consistent with previously reported clinical outcomes, we observed rapid, profound angioedema relief with barzolvolimab treatment and this benefit continued to improve over 52 weeks of therapy for patients. These data add to the unprecedented 76 week efficacy and safety data we presented yesterday at EAACI and continue to support barzolvolimab's potential to redefine the treatment landscape and meet the goals of CSU therapy—rapid, profound, durable complete response and improved quality of life across a broad patient population."

Summary of Key Findings:

- Patients on study had severe CSU. Over 70% of patients had a weekly urticaria activity score (UAS7) greater than 28 at baseline and reported very high rates of angioedema at baseline.
- Barzolvolimab demonstrated rapid, robust and durable improvements in angioedema symptoms over the treatment period. At Week 52, an 86% mean reduction from baseline was reported for 150 mg Q4W arm and an 82% reduction was reported for the 300 mg Q8W.
- Up to 77% of patients treated with barzolvolimab who had angioedema at baseline were angioedema free (AAS7=0) at Week 52.
- Patients treated with barzolvolimab were angioedema free up to 72% of the time over the 52 week treatment period.
- Up to 87% of patients reported clinically meaningful improvement (>8 point) in AAS7 at Week 52.

[1] DermNet.

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), chronic inducible urticaria (CIndU), prurigo nodularis (PN), eosinophilic esophagitis (EOE) 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 remain 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
Celldex is currently conducting 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. Enrollment is underway.

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.

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Source: Celldex Therapeutics, Inc.