Celldex Presents Long-Term Barzolvolimab Results Demonstrating Sustained Off-Treatment Improvement in Angioedema in Patients with CSU at the European Academy of Allergy and Clinical Immunology Annual Meeting

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- *Treatment with barzolvolimab resulted in rapid, significant, and durable improvements in angioedema in patients with moderate to severe CSU*
- *Seven months after the completion of dosing (Week 76), up to 64% of patients treated with barzolvolimab who had angioedema at baseline remained angioedema-free*
- *Barzolvolimab has potential to shift treatment goals from symptom control to disease modification*
- *Results continue to support ongoing Phase 3 trials of barzolvolimab in CSU; topline data expected in Q4 2026*

HAMPTON, N.J., June 14, 2026 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) announced today the presentation of long-term results from the Phase 2 study of barzolvolimab in a flash talk session at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Meeting in Istanbul, Türkiye. The data presented demonstrated that barzolvolimab treatment results in rapid, significant, and durable improvements in angioedema in patients with chronic spontaneous urticaria (CSU) refractory to antihistamines. These results were sustained off-treatment, seven months after completion of barzolvolimab dosing (Week 76). The data continue to demonstrate barzolvolimab's potential to shift the goal of CSU treatment from symptom control to disease modification and further support the ongoing Phase 3 trials of barzolvolimab in CSU.

"Angioedema plays a major role in the physical and mental health of the majority of people living with CSU, causing extremely painful swelling and disfigurement that dramatically impacts quality of life," said Diane C. Young, MD, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. "Barzolvolimab has consistently shown profound, lasting results including high rates of complete response, defined as complete absence of itch and hives, and dramatic improvements in quality of life and angioedema control through 52 weeks of therapy and now seven months after the last dose, demonstrating its potential for disease modification and the ability to change how CSU patients live their lives."

Angioedema occurs in 55% of people with CSU[1] and patients report a mean of 7.7 angioedema episodes annually.[2] Patients with CSU-related angioedema report significantly worse physical and mental health outcomes, lower health related quality of life, a higher percentage of anxiety and depression, along with significantly increased emergency room visits and hospitalizations compared to patients without angioedema in the United States.[3,4] Similarly, these patients report significantly higher work and activity impairment than those without angioedema.[5] Both patients and physicians report being free of angioedema as an important treatment goal in CSU.[6]

As previously reported, data from the Phase 2b trial showed that treatment with barzolvolimab resulted in rapid, significant, and durable improvements in angioedema. Relief from angioedema symptoms began as early as Week 1 and deepened over 52 weeks of treatment. Furthermore, newly presented data show that barzolvolimab treatment led to robust and sustained reductions in angioedema symptoms at Week 76, demonstrating prolonged off-treatment benefits. Up to 64% of patients who had angioedema at baseline were angioedema-free 7 months after the last dose.

Two Phase 3 trials of barzolvolimab in CSU are ongoing and enrollment is complete. 1,939 patients were enrolled, the largest program conducted in antihistamine-refractory CSU, including patients with advanced therapy experienced/refractory CSU. The studies included 43 countries across 500 sites. Topline data are anticipated in Q4 2026, supporting a planned BLA submission in 2027.

[1]Kolkhir P, et al. *Nat Rev Dis Primers*. 2022 Sep 15;8(1):61 [2]Weller, et al. Dermatol Ther, 2025. [3]Balp M, et al. *Burden of angioedema in patients with chronic spontaneous urticaria in EU5 and US*, EADV Congress 2023. [4]Balp M, et al. *Characterization of chronic spontaneous urticaria among patients in EU5, US and Japan*. EADV Congress 2023. [5]Soong W, et al. World Allergy Organ J. 2025. [6]Bernstein J, et al. *Frequency of angioedema in chronic spontaneous urticaria patients: Report from the Urticaria Voices study*, GA[2]LEN Global Urticaria Forum 2024.

About Barzolvolimab
Barzolvolimab is a 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 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 and ColdU/SD and Phase 2 studies in 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 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 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.

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

Elizabeth Higgins
Executive Director, Investor Relations & Corporate Communications
(857) 404-2088
ehiggins@celldex.com

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