Celldex Presents Unprecedented 76 Week Results from Barzolvolimab Phase 2 Study in Chronic Spontaneous Urticaria at EAACI Congress 2025

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- Seven months after the completion of dosing:
  - 41% of patients (150 mg Q4W) continue to experience complete response (UAS7=0)
  - 48% of patients (150 mg Q4W) report that CSU no longer impacts their quality of life (DLQI=0/1)
  - KIT related tolerability events demonstrated to be reversible
- Enrollment to Phase 3 CSU trials ongoing
- Company to host webcast today at 6:00 pm ET

HAMPTON, N.J., June 12, 2025 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) announced today new data demonstrating profound, sustained complete response and improved quality of life at 76 weeks, 7 months after the completion of dosing with barzolvolimab in 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 are being presented in a late breaking oral presentation (#100227) at the EAACI Congress 2025. 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 continue 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 impacts their quality of life. Barzolvolimab demonstrated a well tolerated safety profile throughout the study.

“In this large Phase 2 study, patients on barzolvolimab experienced rapid, profound, durable complete response which correlated with meaningful improvements in quality of life—the goal of treatment for patients and physicians,” saidMartin Metz, M.D., Professor, Department of Dermatology and Allergy, Head of Translational Research and Deputy Head of Clinical Trials at Charité – Universitätsmedizin in Berlin and the lead investigator of the study. “By addressing the root driver of chronic spontaneous urticaria, the mast cell, barzolvolimab provided meaningful clinical benefit to more than 90% of the patients on study, including patients with severe disease refractory to omalizumab, and demonstrated a level of sustained complete response after the completion of active therapy that is unprecedented in CSU. Importantly, across this large, 76 week Phase 2 trial, barzolvolimab also presented a favorable safety profile, further supporting barzolvolimab’s significant potential to become a transformative treatment option for patients suffering from this often very severe and debilitating disease.”

Data highlights at 76 weeks (7 months/28 weeks after completion of barzolvolimab treatment)

- Rapid, profound improvements in UAS7 (weekly urticaria activity score) were reported as early as one week after dosing. Barzolvolimab achieved the primary efficacy endpoint, a statistically significant mean change from baseline to Week 12 in UAS7 (weekly urticaria activity score) compared to placebo, at all dose levels. These improvements were sustained or deepened at Week 52 and continued to Week 76. UAS7 mean change from baseline at Week 76 was -20.42 for patients treated with 150 mg Q4W and -21.10 for patients treated with 300 mg Q8W.

- 41% of patients treated with barzolvolimab 150 mg Q4W and 35% of patients treated with 300 mg Q8W had a complete response (no itch/hives; UAS7=0) at Week 76.

- 56% of patients treated with barzolvolimab 150 mg Q4W and 47% of patients treated with 300 mg Q8W had well controlled disease (UAS7≤6) at Week 76.

- 48% of patients treated with barzolvolimab 150 mg Q4W and 40% of patients treated with 300 mg Q8W reported that CSU had no impact on their quality of life at 76 weeks as measured by the Dermatology Life Quality Index (DLQI). Current clinical guidelines recommend complete response (UAS7=0) as the goal of treatment[1] and achieving complete response is directly correlated to the greatest improvements in quality of life for patients[2].

- These robust responses and improvements in quality of life were observed regardless of prior omalizumab experience.

Barzolvolimab was well tolerated with a favorable safety profile through 76 weeks. The most common adverse events were grade 1 (mild), mechanism related (KIT) and reversible. No new safety signals were identified during the follow-up period. As previously

disclosed, neutropenia events resolved rapidly and while still receiving barzolvolimab treatment and there was no association between neutropenia and infections. As expected, neutrophil counts returned to baseline following the completion of barzolvolimab treatment and the mild hair color changes and skin hypopigmentation observed on study were demonstrated to be reversible following discontinuation of treatment.

“At every analysis across multiple endpoints in this Phase 2 study, barzolvolimab has demonstrated best in disease data, suggesting barzolvolimab holds great promise as a transformational treatment for patients suffering from CSU— a disease of misery that often impacts all aspects of patients’ lives,” said Diane C. Young, M.D., Senior Vice President and Chief Medical Officer of Celldex. “On behalf of Celldex, I want to thank the patients and physicians who participated in this study. We remain diligently focused on executing across our clinical trials to bring this potential important new medicine to patients.”

Results presented at the EAACI Congress 2025 are available on the "Publications” page of the "Science" section of the Celldex website.

[1]Zuberbier T, et al. Allergy, 2022; [2]Kolkhir P, et al. JACI, 2023

Webcast
The Company will host a conference call/webcast today to discuss the results at 6:00 pm ET. To access the live and archived webcast, please visit the Events section on the Investor Relations page of Celldex’s website . Parties interested in participating via telephone may register here to receive the dial-in numbers and unique PIN to seamlessly access the call. Otherwise please access the listen-only webcast link. The archived webcast will be available for a limited time on the Company’s website.

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 enter 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.

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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