Celldex Announces Positive Results from Phase 3 EMBARQ-CSU1 and EMBARQ-CSU2 Studies of Barzolvolimab Which Met Primary and All Key Secondary Endpoints

Sep 22, 2026

- *Best-in-disease results showed rapid, profound, sustained efficacy, supporting barzolvolimab's potential to be a transformational therapy in CSU*
- *EMBARQ-CSU1 and -CSU2 met primary and all key secondary endpoints at 12 weeks across both studies and both dose groups*
- *Clinically meaningful and statistically significant benefit demonstrated in omalizumab refractory CSU and patients with severe disease or severe angioedema*
- *Efficacy sustained or deepened from weeks 12 to 24*
- *Well tolerated with a favorable safety profile through 24 weeks; consistent with prior studies*
- *Treatment will continue in both trials to 52 weeks; BLA submission anticipated in 2027*
- *Company to host webcast today at 8:00 am ET*

HAMPTON, N.J., Sept. 22, 2026 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) today reported positive topline results from the Company's Phase 3 EMBARQ-CSU1 and EMBARQ-CSU2 trials evaluating two doses of barzolvolimab in patients with chronic spontaneous urticaria (CSU) whose symptoms are inadequately controlled by H1-antihistamines. The EMBARQ-CSU1 and EMBARQ-CSU2 studies are the largest program conducted in antihistamine refractory CSU, including patients with advanced therapy experienced/refractory CSU. Both Phase 3 trials met the primary endpoint of mean change from baseline in weekly urticaria activity score (UAS7) at Week 12, and all key secondary endpoints, demonstrating clinically meaningful and statistically significant improvements in disease activity. Barzolvolimab was well-tolerated through the 24 week placebo controlled treatment period with a favorable safety profile consistent with prior Phase 2 experience. The EMBARQ-CSU trials are ongoing, with treatment continuing through 52 weeks. The Company intends to present the EMBARQ-CSU data at an upcoming medical meeting and plans to submit a Biologics License Application (BLA) to the FDA in 2027.

"We are proud of the results shared today and believe that barzolvolimab has the potential to address the enormous unmet need in CSU," said Diane Young, MD, Senior Vice President and Chief Medical Officer of Celldex. "Barzolvolimab continued to show unprecedented complete response rates across the overall studies and demonstrated strong differentiation in patient populations underserved by existing therapies, including those with severe disease or angioedema, and those whose disease is refractory to omalizumab. We believe that barzolvolimab can be a transformational therapy for people living with CSU and thank the CSU community, trial participants, and investigators around the world for their support of the EMBARQ-CSU trials and the entire barzolvolimab clinical program."

"The results from our two Phase 3 EMBARQ-CSU trials showed efficacy that is best-in-disease in CSU," said Anthony Marucci, Co-Founder, President, and Chief Executive Officer at Celldex. "We believe barzolvolimab is well-positioned to address large CSU populations of high unmet need—as a first-line therapy for patients with severe CSU or angioedema, and as the second-line advanced therapy of choice. We look forward to continuing to grow our leadership in mast cell biology as we advance to our next stage of development—establishing a commercial-stage organization committed to delivering barzolvolimab to patients and physicians in need as quickly as possible."

Summary of Key Findings
Data cutoff: September 9, 2026

The Phase 3 EMBARQ-CSU1 and EMBARQ-CSU2 studies demonstrated rapid, profound, sustained efficacy consistent with Phase 2 and unparalleled in CSU. Efficacy was sustained or deepened from weeks 12 to 24 across primary and all key secondary endpoints

Primary Endpoint: Mean Change from Baseline in UAS7 at Week 12:				
	EMBARQ-CSU1		EMBARQ-CSU2	
	Baseline UAS7	LS Mean Change (SE) at Week 12	Baseline UAS7	LS Mean Change (SE) at Week 12
Placebo	30.9	-10.7 (0.65)	29.3	-11.4 (0.64)
150 mg Q4W	30.6	-20.2 (0.64) (p<.00001)	29.7	-20.2 (0.63) (p<.00001)
300 mg Q8W	30.3	-20.5 (0.65) (p<.00001)	29.6	-19.7 (0.64) (p<.00001)

P-values are for LS Mean treatment difference versus placebo.

- The primary endpoint showed clinically meaningful and highly statistically significant improvement.

Key Secondary Endpoints: All key secondary endpoints in both EMBARQ-CSU trials were met at Week 12 with high statistical significance and were clinically meaningful.

Given the importance of Complete Response (complete absence of itch and hives) to patients and physicians, and barzolvolimab's unique ability to drive sustained Complete Response, the Company is presenting UAS7=0 data observed at both 12 and 24 weeks.

Proportion of Patients with Complete Response (UAS7=0) at Weeks 12 and 24		
	EMBARQ-CSU1	EMBARQ-CSU2
	12 Weeks	
Placebo	9.3%	12.6%
150 mg Q4W	42.4% (p<.00001)	45.7% (p<.00001)
300 mg Q8W	42.1% (p<.00001)	44.0% (p<.00001)
	24 Weeks	
Placebo	15.4%	17.6%
150 mg Q4W	49.0% (p<.00001)	54.0% (p<.00001)
300 mg Q8W	45.1% (p<.00001)	48.4% (p<.00001)

P-values are based on adjusted odds ratio of logistic regression models.

- Significantly more patients achieved Complete Response (UAS7=0) with both barzolvolimab doses vs. placebo at Weeks 12 and 24.

Proportion of Patients with Complete Response (UAS7=0) at Week 12 in Omalizumab-Refractory CSU		
	EMBARQ-CSU1	EMBARQ-CSU2
Placebo	9.3%	15.1%
150 mg Q4W	55.3% (p<.00001)	41.7% (p=.0089)
300 mg Q8W	44.3% (p=.00017)	46.4% (p=.0036)

P-values are based on adjusted odds ratio of logistic regression models.

- A higher proportion of patients achieved Complete Response (UAS7=0) vs placebo at Week 12 in the sub-population of patients with CSU refractory to omalizumab.

Proportion of Patients with AAS7=0 at Week 12 in Patients with Baseline AAS7>0		
	EMBARQ-CSU1	EMBARQ-CSU2
Placebo	33.8%	33.7%
150 mg Q4W	62.7% (p<.00001)	74.3% (p<.00001)
300 mg Q8W	66.3% (p<.00001)	66.2% (p<.00001)

P-values are based on adjusted odds ratio of logistic regression models.

- A statistically higher proportion of patients achieved complete resolution of angioedema (AAS7=0) at Week 12 vs. placebo in patients with baseline AAS7>0.

Barzolvolimab was well-tolerated and demonstrated a favorable safety profile consistent with prior experience through the end of the placebo controlled period at Week 24.

The Phase 3 EMBARQ-CSU1 and CSU2 studies are ongoing. A BLA submission is planned for 2027.

The Phase 3 Program is designed to establish the efficacy and safety of barzolvolimab in adult patients with CSU who remain symptomatic despite H1 antihistamine treatment. Both Phase 3 trials are randomized, double-blind, placebo-controlled, parallel group, global studies. 1,939 patients were randomized (n=963 EMBARQ-CSU1; n=976 EMBARQ-CSU2) evenly to barzolvolimab 150 mg every 4 weeks (following 300 mg loading dose), barzolvolimab 300 mg every 8 weeks (following 450 mg loading dose) for

52 weeks or placebo for 24 weeks. At 24 weeks, patients on placebo were re-randomized to active treatment across both dosing groups. The primary endpoint of the study evaluated the clinical effect of barzolvolimab in reducing urticaria activity (weekly urticaria activity score; UAS7) at Week 12. The studies were designed to detect a clinically meaningful difference between each of the active arms vs placebo in the overall population as well as in the subpopulation of omalizumab refractory participants. The primary endpoint analysis was performed when all patients completed the placebo controlled portion of the study at 24 weeks. A global Phase 3b long term extension study (LTE) has been established and is ongoing, which patients can enter following completion of the EMBARQ-CSU Phase 3 trials.

Please visit clinicaltrials.gov for additional information on EMBARQ-CSU1; NCT06445023 and EMBARQ-CSU2; NCT06455202.

Webcast and Conference Call
The Company will host a conference call/webcast today to discuss the results at 8:00am 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 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 a Phase 2 study in atopic dermatitis (AD), with additional indications planned for the future.

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, including the Company's plan to submit a BLA in 2027; 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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