Celldex Reports Results from Phase 2 Study of Barzolvolimab in Prurigo Nodularis

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- *Study did not meet key efficacy objectives*
- *Favorable safety profile consistent with prior studies, including with new 450mg loading dose and up to 300mgQ4W regimen*
- *Profound systemic mast cell depletion, as evidenced by significant reduction in serum tryptase, observed*
- *Phase 3 CSU topline data expected in Sept/Oct 2026; Phase 3 SD and ColdU Enrollment On Track; Phase 2 topline data in AD in late 2026*
- *Company to host webcast today at 4:30 pm ET*

HAMPTON, N.J., July 21, 2026 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) today reported topline results from the Company's Phase 2 study of barzolvolimab delivered subcutaneously in prurigo nodularis (PN), a chronic skin disease that causes hard, intensely itchy lumps/nodules to form on the skin. The primary endpoint of the study, the proportion of patients who achieve a four point or greater improvement in WI-NRS (Worst Itch Numeric Rating Scale) from baseline to Week 12, and key secondary endpoints were not met.

Barzolvolimab, a humanized monoclonal antibody with a completely novel mechanism of action that uniquely targets the mast cell, is being studied across multiple indications. Profound mast cell depletion as evidenced by significant reduction in serum tryptase was observed and did not result in improvement in itch or skin lesions in patients with PN compared to placebo, indicating mast cells may not be a key pathogenic driver of symptoms in PN. Based on these results, Celldex is discontinuing the Phase 2 study in PN. Consistent with previously reported studies, barzolvolimab demonstrated a favorable safety and tolerability profile.

"At Celldex, we are leading important science in the exploration of mast cell biology, with the goal of ultimately delivering life-changing therapies for patients," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex. "Barzolvolimab profoundly depletes mast cells with best-in-disease data observed in three indications to date; chronic spontaneous urticaria, symptomatic dermographism, and cold urticaria, all of which demonstrated unequivocal Phase 2 proof-of-concept data and progressed quickly to Phase 3. It is disappointing that this study did not confirm the promising signal we observed in the intravenous Phase 1b trial, and that the robust tryptase reductions seen in this study did not result in improvement of PN symptoms for patients who greatly need effective treatments. We remain focused on driving mast cell category creation and delivering on barzolvolimab's promise for patients with allergic, inflammatory, and autoimmune diseases, and look forward to sharing topline data from our Phase 3 CSU trials early this fall."

Summary of Key Findings

- The study did not meet primary or key secondary endpoints at Week 12 at either dose level evaluated.
  - Percentage of patients with at least 4 point improvement in WI-NRS did not differentiate from placebo.
  - Percentage of patients with IGA-CPNG-S 0/1 (Investigator's Global Assessment for Chronic Nodular Prurigo - Stage) did not differentiate from placebo.
  - No improvement observed with longer treatment (Week 24).
- Barzolvolimab was well tolerated. Loading dose (450mg) followed by Q4W dosing (150 or 300mg) demonstrated favorable safety profile consistent with prior studies.
- Rapid and profound suppression of circulating tryptase, indicative of systemic mast cell depletion, was observed. The addition of the 450mg loading dose led to early, profound tryptase reduction that was sustained over the duration of the treatment period.

This Phase 2 randomized, double-blind, placebo-controlled, parallel group study evaluated barzolvolimab compared to placebo in patients with moderate to severe PN who had inadequate response to prescription topical medications, or for whom topical medications were medically inadvisable. 140 patients were randomly assigned to receive barzolvolimab 150mgQ4W after an initial loading dose of 450mg, 300mgQ4W after an initial loading dose of 450mg, or placebo during a 24-week Treatment Phase. Patients were then followed for an additional 16 weeks with no study treatment. The primary endpoint was to evaluate the clinical effect of barzolvolimab compared to placebo on itch response as measured by the proportion of patients with ≥ 4-point improvement in the worst intensity itch per a numeric rating scale (WI-NRS) at Week 12. Key secondary objectives included itch response at different timepoints, the assessment of skin lesions as measured by the Investigator Global Assessment (IGA) and

safety. In addition, the study included the option for patients who had symptoms following the treatment phase, including patients who were on placebo, to enroll in an open label extension. The study enrolled patients at 48 centers across six countries, including the United States. For additional information on this trial (NCT06366750), please visit www.clinicaltrials.gov.

Webcast and Conference Call
The Company will host a conference call/webcast today to discuss the results at 4:30 p.m. 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; 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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