Celldex Presents Additional Positive Data from Phase 2 Chronic Spontaneous Urticaria (CSU) and Phase 2 Cold Urticaria (ColdU) and Symptomatic Dermographism (SD) Studies Further Demonstrating First-in-Class and Best-in-Disease Barzolvolimab Profile at AAAAI 2026

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- Sustained off-treatment efficacy despite barzolvolimab clearance and normalization of tryptase, suggesting disease modification in patients with CSU treated for full 52 weeks -
- Greatly improved quality of life and reduced disease impact for patients with ColdU/SD at Week 20 -

HAMPTON, N.J., Feb. 27, 2026 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) presented additional positive data from the completed Phase 2 clinical trials of barzolvolimab in chronic spontaneous urticaria (CSU) and cold urticaria (ColdU) and symptomatic dermographism (SD). Barzolvolimab is a humanized monoclonal antibody with a completely novel mechanism of action that uniquely targets the root cause of CSU, ColdU and SD—the mast cell. The data were presented today at the 2026 Allergy, Asthma & Immunology's (AAAAI) Annual Meeting being held in Philadelphia, PA.

“Barzolvolimab’s novel mechanism of action uniquely targets the root cause of chronic urticarias—the mast cell—and is driving the unparalleled efficacy we are seeing across our studies in chronic spontaneous urticaria, cold urticaria and symptomatic dermographism,” said Diane Young, MD, Senior Vice President and Chief Medical Officer of Celldex. “The data presented at AAAAI continue to demonstrate that barzolvolimab has the potential to transform the treatment landscape by providing rapid, profound and durable efficacy, including symptom free complete control and dramatic improvements in quality of life and angioedema—offering new hope for the patients suffering from these often severe and debilitating diseases.”

Summary of Friday, February 27rd Presentations:

Prolonged Off-Treatment Efficacy of Barzolvolimab in Chronic Spontaneous Urticaria; presented by Martin Metz, M.D., Professor, Department of Dermatology and Allergy, Head of Translational Research and Deputy Head of Clinical Trials at Charité – Universitätsmedizin in Berlin

Data from the abstract associated with this presentation were also highlighted by AAAAI in a press release issued in early February.

- As previously reported in the Phase 2 CSU study, up to 51% of patients on study experienced symptom free complete response (UAS7=0; no itch/no hives) at 12 weeks, which continued to deepen over 52 weeks of active therapy to up to 71% of patients. This profound clinical benefit continued even after patients were off therapy—up to 41% of patients reported complete response seven months after receiving their last dose of barzolvolimab.
- In the analysis presented at AAAAI, the experience for the subset of patients who received 52 weeks of barzolvolimab therapy with 150 mg Q4W or 300 mg Q8W and completed treatment with at least well controlled disease (UAS7≤6) at Week 76 was explored. The vast majority of patients included in this analysis had substantial disease burden at baseline, including severe disease (67%), angioedema (69%), very large impact on quality of life, and long disease duration (mean of 6 years).
    - At the end of the treatment period (52 weeks) 71% of patients had at least well controlled disease and, of these patients, 88% reported complete response (UAS7=0).
    - 69% of patients who achieved well controlled disease after 52 weeks of treatment also had well controlled disease at week 76, 7 months after their final dose of barzolvolimab.
    - 50% of patients who achieved well controlled disease after 52 weeks of treatment also had complete response at week 76, 7 months after their final dose of barzolvolimab.
    - Findings correlated with profound improvements in quality of life and angioedema in this subset of patients. 83% reported no impact of disease on QoL (DLQI 0/1) at Week 76 and 74% of patients with angioedema at baseline were angioedema free (AAS7=0)[3] at Week 76.
    - For patients who did experience recurrence of disease symptoms after treatment completion, their disease was much milder than what it was at baseline.
- This sustained off-treatment efficacy was observed despite barzolvolimab clearance and normalization of tryptase (a measure of mast cell burden), suggesting disease modification and supports barzolvolimab’s significant potential to become a transformative treatment option for patients suffering from CSU.
- Celldex recently announced the completion of enrollment in the Company’s global Phase 3 program in CSU. The Program, which fully accrued six months ahead of guidance, consists of two trials—EMBARQ-CSU1 and EMBARQ-CSU2. 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 and over 500 sites.

Treatment with Barzolvolimab Improves Urticaria Control and Quality of Life in Patients with Chronic Inducible Urticaria* (20 week analysis) *presented by Martin Metz, M.D., Professor, Department of Dermatology and Allergy, Head of Translational Research and Deputy Head of Clinical Trials at Charité – Universitätsmedizin in Berlin

- As previously reported in the Phase 2 ColdU and SD study, up to 53% of patients with ColdU and 58% with SD achieved complete response (negative provocation test) at Week 12 (primary endpoint analysis).
- As previously reported, at Week 20, up to 66% of patients with ColdU and 49% with SD achieved complete response.
- Marked and rapid improvement in urticaria control (UCT[1]) and quality of life (DLQI[2]) in patients with ColdU and SD were observed and sustained through the 20-week period.
    - Up to 60% of patients reported that disease symptoms no longer impacted QOL at Week 20.
    - Up to 69% of patients reported at least well-controlled urticaria based on UCT at Week 20.
- This Phase 2 study is the first large randomized, placebo-controlled study to demonstrate clinical benefit in patients with CIndU.
- In December 2025, Celldex initiated a global Phase 3 study in cold urticaria (ColdU) and symptomatic dermographism (SD), *EMBARQ-ColdU and -SD,* and enrollment is ongoing.

References:

[1]Urticaria Control Test (UCT) consists of four questions (on a scale of 0-4; total 0-16) used to assesses symptoms, quality of life, treatment effectiveness and overall disease control in patients with chronic urticaria (spontaneous and inducible). UCT≥12 is well controlled and UCT=16 is complete control.

[2]Dermatology Life Quality Index (DLQI) consists of ten questions (on a scale of 0–3, total 0–30) used to measure the impact of skin disease on patient quality of life related to symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. DLQI 0–1 indicates no effect on a patient's life.

[3]Angioedema Activity Score for 7 days (AAS7) assesses the severity of disease activity in patients with recurrent angioedema or urticaria. It sums daily scores (0-15) over one week (total: 0 -105), evaluating frequency, duration, severity, disfigurement, and impact on daily life.

About Chronic Spontaneous Urticaria (CSU)

CSU is an underdiagnosed disease of misery marked by spontaneous hives, unbearable itch, and unpredictable episodes of disfiguring swelling (angioedema) that causes substantial mental health burden, profound impact on quality of life and is associated with a 1.7-fold increase in all cause mortality at 5 years. Mast cell activation plays a central role in the onset and progression of CSU. While the goal of CSU treatment is the complete absence of symptoms, the vast majority of patients today, even those receiving the most advanced approved and available therapies, continue to suffer from itch, hives, swelling, sleep disruption, and unrelenting anxiety about when the next flare up will occur.

About Chronic Inducible Urticaria (CIndU), Cold Urticaria (ColdU), Symptomatic Dermographism (SD)

CIndU is characterized by the occurrence of hives or wheals that have an attributable trigger associated with them. ColdU symptoms include itching, burning wheals/hives and angioedema when skin is exposed to cold temperatures. SD symptoms include the development of wheals in response to stroking, scratching or rubbing of the skin. For these diseases, mast cell activation leading to release of soluble mediators is thought to be the driving mechanism leading to the wheals and other symptoms. There are currently no approved therapies for chronic inducible urticarias other than antihistamines and patients attempt to manage symptoms associated with their disease through avoidance of triggers.

About Barzolvolimab

Barzolvolimab is a humanized monoclonal antibody with a completely 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 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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