Celldex Therapeutics Presents Positive Results from Barzolvolimab Phase 2 Studies in Patients with Chronic Urticaria Demonstrating Improved Disease Control and Quality of Life at AAAAI 2025

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- Greatly improved patient quality of life and reduced disease impact in patients with CSU and CIndU -
- 82% of CSU patients reported that symptoms no longer had an impact on their quality of life at Week 52 -
- 60% of CIndU patients reported that symptoms no longer had an impact on their quality of life at Week 12 -

HAMPTON, N.J., March 01, 2025 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) announced today positive data on measurements of disease control and quality of life from the Company's Phase 2 barzolvolimab studies in patients with chronic urticaria. Barzolvolimab is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity, which is required for mast cell function and survival.

In a Phase 2 chronic spontaneous urticaria (CSU) study (52 week analysis) and a Phase 2 chronic inducible urticaria (CIndU) study (12 week analysis), barzolvolimab demonstrated rapid and sustained improvement in urticaria control and greatly reduced disease impact on quality of life, as measured by the Urticaria Control Test[1] (UCT) and Dermatology Life Quality Index[2] (DLQI). The data were presented by Martin Metz, M.D., Deputy Director, Head of Translational Research at Charité - Universitätsmedizin Berlin in poster presentations (CSU #L11, CIndU #183) as part of the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting 2025.

"Patients suffering with chronic urticaria have symptoms which severely impact their daily lives for years or even decades—often with devastating impacts on their quality of life—and treatment options are very limited," saidMartin Metz, MD, Deputy Director, Head of Translational Research at Charité - Universitätsmedizin Berlin. "Barzolvolimab has demonstrated its potential to completely change the treatment paradigm and enable patients to live normally again. We are especially excited to see these meaningful improvements consistently across patients with both CSU and CIndU in large clinical studies."

The quality of life impairment that patients with CSU experience have been well studied and shown to impact many aspects of life including daily activities, work performance, sleep quality, social functioning and relationships, and mental health, which can manifest as depression, anxiety and suicidal ideation[3,4]. A recent multi-national patient survey found that the majority of patients report a moderate to high impact from CSU on their daily life[5]. Current clinical guidelines recommend complete disease control as the goal of treatment[6], and several published analyses have shown that patients have minimal or no impact on their quality of life when they are able to achieve complete disease control[7,8].

Phase 2 CSU trial disease control and quality of life measurements (52 week analysis)

- Up to 71% of patients with CSU achieved complete response (UAS7 = 0) at Week 52—thehighest rate of complete response observed in a well-controlled study
- Rapid and sustained improvement in urticaria control (UCT) and quality of life (DLQI) observed in patients with CSU refractory to antihistamines
- Up to 82% of patients reported that CSU symptoms no longer had an impact on their quality of life at Week 52
- Up to 95% of patients reported meaningful improvement in quality of life based on DLQI at Week 52
- Up to 82% of patients reported well-controlled urticaria based on UCT, and approximately half of patients reported complete control at Week 52

Phase 2 CIndU trial disease control and quality of life measurements (12 week analysis)

- Up to 53% of patients with ColdU and 58% of patients with SD achieved complete response (negative provocation test)—first large randomized, placebo-controlled study to demonstrate clinical benefit in patients with CIndU
- Marked and rapid improvement in urticaria control (UCT) and quality of life (DLQI) in patients with ColdU and SD; sustained through the 12-week period
- Up to 60% of patients reported that CIndU symptoms no longer had an impact on their quality of life at Week 12
- Up to 69% of patients reported well-controlled urticaria based on UCT at Week 12

Global Phase 3 studies are actively enrolling for barzolvolimab in patients with CSU (EMBARQ-CSU1 and EMBARQ-CSU2). Celldex plans to advance barzolvolimab into Phase 3 development for CIndU in 2025.

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]Maurer, et al. *The burden of chronic spontaneous urticaria is substantial: Real-world evidence from ASSURE-CSU*. Allergy, 2017.

[4]Kolkhir P, et al. *Mortality in adult patients with chronic spontaneous urticaria: A real world cohort study.* Journal of Allergy and Clinical Immunology, 2025.

[5]Winders, TA, et al. *Impact of Chronic Spontaneous Urticaria on Health-related quality of life domains: Country specific data from patients participating in the Urticaria Voices study*. EADV 2024.

[6]Zuberbier T, et al. *The international EAACI/GA2LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria.* Allergy, 2022.

[7]Kolkhir P, et al. *The Benefit of Complete Response to Treatment in Patients With Chronic Spontaneous Urticaria-CURE Results.* Journal of Allergy and Clinical Immunology Practice, 2023.

[8]Bernstein J, et al. *Why a Complete Response is the Treatment Aim in Chronic Spontaneous Urticaria.* Journal of Clinical Medicine, 2023.

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 Chronic Inducible Urticaria (CIndU)
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 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 Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company leading the science at the intersection of mast cell biology and the development of transformative therapeutics for patients. Our pipeline includes antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with severe inflammatory, allergic, autoimmune and other devastating diseases. 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.

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