Celldex Therapeutics Initiates Global Phase 3 Program for Barzolvolimab in Patients with Chronic Spontaneous Urticaria

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- EMBARQ-CSU1 and EMBARQ-CSU 2 will enroll more than 1800 patients suffering from CSU -
- Studies include both biologic naïve and experienced patients -

HAMPTON, N.J., July 16, 2024 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) announced today the initiation of its global Phase 3 program, consisting of two Phase 3 trials (EMBARQ-CSU1 and EMBARQ-CSU2) designed to establish the efficacy and safety of barzolvolimab in adult patients with CSU who remain symptomatic despite H1 antihistamine treatment. The studies will also include patients who remain symptomatic after treatment with biologics.

For patients with CSU, the activation of mast cells in the skin results in episodes of itchy hives, swelling and inflammation of the skin that can severely impact their daily lives for years or even decades. Treatment options are limited, particularly for patients not adequately controlled by omalizumab. Barzolvolimab, a novel monoclonal antibody, works upstream of other treatment approaches for CSU, targeting the root driver of the disease—mast cells—by blocking the receptor tyrosine kinase KIT, which is required for mast cell function and survival.

“Across multiple studies in CSU, barzolvolimab has demonstrated a unique and profound ability to offer rapid, durable and complete disease control, regardless of prior treatment history, to patients suffering from this often severe and debilitating disease,” said Marcus Maurer, MD, Professor of Dermatology and Allergy at Charité – Universitätsmedizin in Berlin and a Principal Investigator in the Phase 3 studies of barzolvolimab. “Advancing a promising agent that addresses the root driver of the disease—the mast cell—into late stage studies is a significant and hopeful step forward for patients and physicians who desperately need better treatment options.”

EMBARQ-CSU1 and EMBARQ-CSU2 are 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 where approximately 915 patients will be randomized evenly to barzolvolimab 150 mg every 4 weeks (following 300 mg loading dose), barzolvolimab 300 mg every 8 weeks (following 450 mg loading dose) or placebo for 52 weeks. At 24 weeks, patients on placebo will be re-randomized to active treatment across both dosing groups. The primary endpoint of the study will evaluate the clinical effect of barzolvolimab in reducing urticaria activity (weekly urticaria activity score; UAS7) at Week 12. The study is 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.

“Treatment options that deliver complete disease control for more patients are sorely needed in CSU and advancing barzolvolimab into registrational studies is an important step forward for patients,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We are focused on executing these trials seamlessly and achieving our goal of making barzolvolimab available to meet the needs of patients with CSU, while also advancing barzolvolimab across additional indications.”

Results from a placebo controlled Phase 2 study in CSU demonstrated that barzolvolimab met the primary endpoint of the study, a statistically significant mean change from baseline to week 12 in UAS7, across all dose levels. Secondary and exploratory endpoints in the study were also achieved at week 12 and strongly support the primary endpoint results, including changes in ISS7 (weekly itch severity score) and HSS7 (weekly hives severity score) and responder analyses (UAS7<=6 or UAS7=0). Importantly, barzolvolimab demonstrated rapid, durable and clinically meaningful responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment and was well tolerated with a favorable safety profile.

For additional information on EMBARQ-CSU1 and EMBARQ-CSU2 (NCT06455202 and NCT06445023), please visit www.clinicaltrials.gov

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 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) and eosinophilic esophagitis (EOE) with additional indications planned for the future, including atopic dermatitis (AD).

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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