Celldex Announces Upcoming Presentation of Barzolvolimab Phase 2 Results in Chronic Spontaneous Urticaria at AAAAI 2024

February 5, 2024

HAMPTON, N.J., Feb. 05, 2024 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that an abstract describing 12 week results from the Company's Phase 2 clinical trial of barzolvolimab in patients with moderate to severe chronic spontaneous urticaria (CSU) refractory to antihistamines, including patients with biologic-refractory disease, has been accepted as a late breaking oral presentation at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting 2024 being held in Washington, DC on February 23-26, 2024. Abstracts will be available on the meeting website today, February 5, 2024.

Presentation details are below:

Abstract Title: Barzolvolimab Significantly Decreases Chronic Spontaneous Urticaria Disease Activity and is Well Tolerated: Top Line Results from a Phase 2 Trial
Presenting Author: Marcus Maurer, M.D., Professor of Dermatology and Allergy at Charité - Universitätsmedizin in Berlin
Session: Late Breaking Oral Abstract Session
Date/Time: Saturday, February 24 at 2:05 pm - 2:15 pm ET

The abstract is comprised of the topline 12-week primary endpoint results the Company disclosed on November 6, 2023.

The Phase 2 randomized, double-blind, placebo-controlled, parallel group study is evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients with CSU who remain symptomatic despite antihistamine therapy, to determine the optimal dosing strategy. 208 patients were randomly assigned on a 1:1:1:1 ratio to receive subcutaneous injections of barzolvolimab at 75 mg every 4 weeks, 150 mg every 4 weeks, 300 mg every 8 weeks or placebo during a 16-week placebo-controlled treatment period. After 16 weeks, patients then enter a 36-week active treatment period, in which patients not already randomized to barzolvolimab at 150 mg every 4 weeks or 300 mg every 8 weeks are randomized 1:1 to receive one of these two dose regimens; patients already randomized to these treatment arms remain on the same regimen as during the placebo-controlled treatment period. After 52 weeks, patients then enter a follow-up period for an additional 24 weeks. The primary endpoint of the study is mean change in baseline to Week 12 in UAS7. Secondary endpoints include other assessments of safety and clinical activity including ISS7, HSS7 and AAS7.

Webcast and Conference Call
The Company will host a webcast presentation of the data on Sunday, February 25th at 9:45 AM ET. The event will be webcast live and can be accessed by going to the "Events & Presentations" page under the "Investors & Media" section of the Celldex Therapeutics website at www.celldex.com.

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 and 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 effects of the outbreak of COVID-19 on our business and results of operations; 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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