Celldex Announces Completion of Enrollment in Phase 2 Study of Barzolvolimab in Patients with Chronic Inducible Urticaria

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HAMPTON, N.J., April 17, 2024 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that patient enrollment has been completed in the Company's Phase 2 clinical study of barzolvolimab for the treatment of the two most common forms of chronic inducible urticaria (CIndU)—cold urticaria (ColdU) and symptomatic dermographism (SD). CIndU is characterized by the occurrence of hives or wheals that have an attributable trigger associated with them—temperatures below skin temperature in ColdU and scratching/rubbing of the skin in SD. Mast cell activation is known to be a critical driver in ColdU and SD. 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 February 2024, the Company presented positive 12 week primary endpoint results from its ongoing Phase 2 study of barzolvolimab in the most common form of chronic urticaria—chronic spontaneous urticaria (CSU).

"We are very grateful to all the investigators and patients who supported this trial," said Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics. "While individuals with inducible urticaria go to great lengths to avoid disease triggers in their daily lives, many find it impossible to do so and are severely burdened by this disease. This is compounded by the fact that there are currently no approved therapies for CIndU other than antihistamines. We believe barzolvolimab holds significant promise as a much needed potential treatment for patients with CIndU and look forward to presenting topline data from this study in the second half of the year."

The randomized, double-blind, placebo-controlled, parallel group Phase 2 study is evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients with CIndU who remain symptomatic despite antihistamine therapy, to determine the optimal dosing strategy. 196 patients in 2 cohorts (differentiated by CIndU subtype) including 97 patients with ColdU and 99 patients with SD were randomly assigned on a 1:1:1 ratio to receive subcutaneous injections of barzolvolimab at 150 mg every 4 weeks, 300 mg every 8 weeks or placebo during a 20-week treatment phase. Patients then enter a follow-up phase for an additional 24 weeks. The primary endpoint of the study is the percentage of patients with a negative provocation test at Week 12 (using TempTest® for ColdU and FricTest® for SD). Secondary endpoints include safety and other assessments of clinical activity including CTT (critical temperature threshold), CFT (critical friction threshold) and WI-NRS (worst itch numeric rating scale).

For additional information on this trial (NCT05405660), please visit www.clinicaltrials.gov.

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 and angioedema when skin is exposed to temperatures below skin temperature. SD symptoms include the development of wheals and a flare reaction in response to stroking, scratching or rubbing of the skin. Approximately 0.5% of the total population suffers from chronic inducible urticarias. 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) and eosinophilic esophagitis (EOE) 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 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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