Celldex Announces First Patient Dosed in Phase 2 Study of Barzolvolimab in Patients with Chronic Inducible Urticaria

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HAMPTON, N.J., July 21, 2022 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that the first patient has been dosed in a 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). Barzolvolimab is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity. 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.

"We are pleased that dosing has begun in this Phase 2 trial, which brings us a step closer to delivering a new treatment option to patients worldwide suffering with chronic inducible urticaria," said Diane C. Young, M.D., Senior Vice President and Chief Medical Officer of Celldex Therapeutics. "Our previously reported Phase 1b data in cold urticaria and symptomatic dermographism patients demonstrated unprecedented results and we believe barzolvolimab could potentially provide meaningful change to the treatment paradigm for patients living with these severe diseases."

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. Approximately 180 patients in 2 cohorts (differentiated by CIndU subtype) including 90 patients with ColdU and 90 patients with SD will be 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 will 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. Celldex is exploring two subtypes, ColdU and SD. 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 (also referred to as CDX-0159) is a humanized monoclonal antibody that specifically 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.

About Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company dedicated to developing monoclonal and bispecific antibodies that address devastating diseases for which available treatments are inadequate. 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 inflammatory diseases and many forms of cancer. 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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