Celldex Announces First Patient Dosed in Phase 2 Study of Barzolvolimab in Prurigo Nodularis

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HAMPTON, N.J., May 15, 2024 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that the first patient has been dosed in the Company's Phase 2 subcutaneous study of barzolvolimab in prurigo nodularis (PN). 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 the function and survival of the mast cell. Mast cells are believed to play an important role in amplifying chronic itch and neuroinflammation, including in PN where mast cells are associated with pruritic sensory neurons in PN lesions.

In November 2023, Celldex presented first in class data from the Company's Phase 1b study in PN demonstrating that barzolvolimab and its novel mast cell depleting mechanism could play a meaningful role in breaking the stubborn scratch/itch cycle of this disease, resulting in lesion healing.

"Prurigo nodularis is a miserable disease and treatment options are desperately needed that offer early and durable relief by both reducing the relentless itching associated with the disease and allowing for healing of the painful lesions that are the hallmark of PN," said Diane C. Young, M.D, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. "In our Phase 1b PN study, with just a single dose of barzolvolimab, we demonstrated remarkable clinical results. We are very excited to see what multiple doses of barzolvolimab may offer patients in this important Phase 2 study."

The randomized, double-blind, placebo-controlled, parallel group study is evaluating the efficacy and safety profile of 2 dose levels of barzolvolimab compared to placebo in approximately 120 patients with moderate to severe PN who had inadequate response to prescription topical medications, or for whom topical medications are medically inadvisable (such as concerns for safety), including patients who received prior biologics. Patients will be randomly assigned on a 1:1:1 ratio to receive barzolvolimab injections of 150 mg Q4W after an initial loading dose of 450 mg, 300 mg Q4W after an initial loading dose of 450 mg, or placebo during a 24-week treatment phase. Participants will then enter a follow-up phase with no study treatment for an additional 16 weeks through week 40. The primary objective of this study is to evaluate the clinical effect of barzolvolimab, compared to placebo, on itch response as measured by the proportion of participants with ≥ 4-point improvement in the worst intensity itch per a numeric rating scale (WI-NRS). Secondary objectives include but are not limited to additional measures of itch response from baseline compared to different timepoints, the assessment of skin lesions as measured by the Investigator Global Assessment (IGA), QoL outcomes and safety. The study will include approximately 50 clinical trial centers worldwide, including the United States.

For additional information on this trial (NCT06366750), please visit www.clinicaltrials.gov.

About Prurigo Nodularis (PN)
PN is a chronic skin disease that causes hard, intensely itchy lumps/nodules to form on the skin. The itching (pruritus) can be intense, causing people to scratch themselves to the point of bleeding or pain, which can form lesions and perpetuate the disease cycle. With limited treatment options available, PN is also associated with significant impact on quality of life including sleep disturbance, psychological distress, social isolation, anxiety and depression. Mast cells are believed to play an important role in amplifying chronic itch and neuroinflammation, including in PN where mast cells are associated with pruritic sensory neurons in PN lesions.

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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