Celldex Initiates Phase 2 Study of Barzolvolimab in Atopic Dermatitis

December 19, 2024

HAMPTON, N.J., Dec. 19, 2024 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that the Company has initiated a Phase 2 study of barzolvolimab in atopic dermatitis (AD) and that the study is actively enrolling patients. AD is one of the most common chronic inflammatory skin diseases, with a lifetime prevalence of up to 20% of the US population and a substantial impact on quality of life[1]. Mast cells are strongly implicated in all facets of AD pathophysiology and the fundamental processes that characterize AD, including epithelial barrier dysfunction, immune cell recruitment, neuroinflammation[2] and multiple other mast cell-associated factors that correlate with disease severity. Activated mast cells are also found in increased numbers in lesional biopsies. Barzolvolimab is a humanized monoclonal antibody that specifically binds and blocks 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.

“Two-thirds of patients treated with first line systemic therapy do not achieve complete control of their atopic dermatitis [3] and desperately need new therapies that offer rapid, meaningful relief from the severe itching and breakdown of the skin associated with AD,” said Diane C. Young, M.D, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. “We believe mast cells play a critical role in the pathophysiology of AD and utilizing our mast cell depleting agent, barzolvolimab, could yield meaningful benefit for patients by helping them resolve their disease and reclaim their quality of life. We’re pleased to end this year with the advancement of barzolvolimab into its fifth indication and look forward to an exciting year ahead in 2025 with multiple upcoming data readouts.”

The randomized, double-blind, placebo-controlled Phase 2 study is evaluating the efficacy and safety profile of subcutaneous barzolvolimab in patients with moderate to severe atopic dermatitis. Approximately 120 patients will be randomly assigned on a 1:1:1 ratio to receive subcutaneous injections of barzolvolimab at either 150 or 300 mg or placebo every 4 weeks after an initial loading dose of 450 mg or placebo during a 16-week placebo-controlled treatment phase. Participants randomized into the placebo arm will be re-randomized at Week 16 into 1 of the 2 active treatment arms. Patients then enter a 16-week active treatment phase, in which all patients will receive barzolvolimab every 4 weeks. The primary endpoint of the study is to evaluate the clinical efficacy of the two dose levels compared to placebo using the Peak Pruritus Numerical Rating Scale (PP-NRS) at Week 16, a well-defined, reliable, sensitive and valid scale for evaluating worst itch intensity in adults with moderate-to-severe AD. Secondary endpoints include the evaluation of the clinical efficacy of barzolvolimab, compared to placebo across multiple patient-reported outcomes, including assessing impressions of disease change and severity and improvements in quality of life. When all clinical trial sites are open, the study will include up to 50 clinical trial centers in the United States.

AD is one the most common chronic, relapsing, inflammatory skin diseases, impacting up to 20% of the US population (lifetime prevalence). AD clinically manifests as red papules or vesicles that are very pruritic in the acute phase and can evolve to a more lichenified appearance in the chronic phase as a consequence of tissue remodeling and dermal fibrosis due to inflammation and scratching of the skin[4]. Up to 50% of adult AD patients have moderate to severe disease[5] and approximately 86% experience pruritus every day, with 61% of these patients having severe or unbearable pruritus[6]. The disease is generally associated with other atopic diseases such as asthma, rhinitis, conjunctivitis, and food allergy, where mast cells have also been shown to play a role[7]. Given the unmet need in AD and barzolvolimab’s potential as a mast cell depleting agent, Celldex believes AD is an important indication for study.

For additional information on this trial (NCT06727552), please visit www.clinicaltrials.gov.

1. Kawakami, et al. 2009; 2. Keith, et al. 2023; 3. Simpson, Bieber, Guttman-Yassky, et al. 2016; 4. Bieber 2022; 5. Zhang, et al. 2021; 6. Simpson, Bieber, Eckert, et al. 2016; 7. Fania, et al. 2022

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), eosinophilic esophagitis (EOE) and atopic dermatitis (AD), 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 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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Source: Celldex Therapeutics, Inc.