Celldex Doses First Patient in Phase 1b Study of CDX-0159 in Chronic Inducible Urticaria

Dec 9, 2020

HAMPTON, N.J., Dec. 09, 2020 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) announced today that the first patient has been dosed in its open label clinical trial in cold contact urticaria and symptomatic dermographism, the two most common forms of chronic inducible urticaria (CIndU). CDX-0159 is a humanized monoclonal antibody developed by Celldex that binds the KIT receptor with high specificity and potently inhibits its activity. The KIT receptor tyrosine kinase 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. As previously presented, CDX-0159 demonstrated a favorable safety profile as well as profound and durable reductions of plasma tryptase, indicative of systemic mast cell ablation in a Phase 1a single dose, healthy volunteer study. In October, Celldex also announced the initiation of a Phase 1b study in chronic spontaneous urticaria.

“Inducible urticarias can significantly impact a patient’s quality of life, including insomnia, lack of energy, poor self-image, social withdrawal and depression,” said Dr. Marcus Maurer, Professor of Dermatology and Allergy and Director of Research at the Department of Dermatology and Allergy at the Allergie-Centrum-Charité of the Charité - Universitätsmedizin in Berlin and the lead investigator for the study. “This is especially true for cold contact urticaria and symptomatic dermographism as avoiding the triggers for these diseases is extremely difficult and therapies that address the root cause of disease—mast cell activation—are sorely needed. We look forward to completing this study and believe CDX-0159 could be a much needed disease-modifying drug for these patients.”

“With the initiation of our second study in urticaria, Celldex has laid an exciting foundation for the CDX-0159 program,” said Diane C. Young, MD, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. “The CIndU study should provide rapid clinical proof of concept in a disease setting that is clearly driven by mast cells. In addition to continuing to assess the safety and potential clinical benefit of CDX-0159, we also hope to confirm its impact on mast cells through the collection and analysis of serial skin biopsies, answering an important question about CDX-0159’s mechanism of action.”

The Phase 1b study is an open label clinical trial designed to evaluate the safety of a single dose of CDX-0159 in up to 20 patients with cold contact urticaria (n=10) or symptomatic dermographism (n=10) who are refractory to antihistamines. Patients' symptoms will be induced via provocation testing that resembles real life triggering situations. Secondary and exploratory objectives include pharmacokinetic and pharmacodynamic assessments, including changes from baseline provocation thresholds, measurement of tryptase and stem cell factor levels, clinical activity outcomes (impact on urticaria symptoms, disease control, clinical response), quality of life assessments and measurement of tissue mast cells through skin biopsies. CDX-0159 will be administered intravenously (3.0 mg/kg) as add on treatment to H1-antihistamines. More information about this study is available on www.clinicaltrials.gov (Identifier: NCT04548869). Initial data from the study are expected at the end of the first quarter of 2021.

CIndUs are forms of urticaria that have an attributable cause or trigger associated with them, typically resulting in hives or wheals. Approximately 0.5% of the total population suffers from inducible urticarias. Celldex is exploring the two most common forms, cold-induced and dermographism (scratch-induced) urticarias. People afflicted with cold induced urticaria experience symptoms like itching, burning wheals and angioedema where their skin comes in contact with temperatures below skin temperature. Symptomatic dermographism is characterized by the development of a wheal and flare reaction in response to a stroking, scratching or rubbing of the skin, usually occurring within minutes of the inciting stimulus. For both of these diseases, mast cell activation leading to release of soluble mediators is thought to be the driving mechanism leading to the wheals and other symptoms. There are currently no approved therapies for CIndUs and patients attempt to manage symptoms associated with their disease through avoidance of triggers and the use of antihistamines. Celldex believes that CDX-0159 has significant potential to directly inhibit and/or ablate mast cells which, in turn, could be disease modifying for patients.

About CDX-0159
CDX-0159 is a monoclonal antibody that binds the KIT receptor with high specificity and potently inhibits its activity. The KIT receptor tyrosine kinase 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. Celldex is currently studying CDX-0159 in chronic urticarias. Currently approved therapies for chronic urticarias target symptomatic relief. Celldex believes that CDX-0159 has significant potential to interfere with mast cells at multiple steps upstream of current treatments, which, in turn, could be disease modifying for patients. In addition, Celldex is also evaluating additional opportunities in other mast cell driven diseases where CDX-0159’s potency and high specificity for KIT could be important.

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 effect critical pathways to improve the lives of patients with inflammatory diseases and many forms of cancer.

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; the effects of the outbreak of COVID-19 on our business and results of operations; 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 cost of paying development, regulatory approval and sales-based milestones under our merger agreement with Kolltan, including the cost, timing, and outcome of our declaratory judgment action against the Kolltan stockholder representative with respect to certain of those milestones; the availability, cost, delivery and quality of clinical and commercial grade 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.