Celldex Therapeutics, Inc. Logo

Celldex Therapeutics Initiates Phase 1b Study of CDX-0159 in Chronic Spontaneous Urticaria

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HAMPTON, N.J., Oct. 13, 2020 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) announced today that enrollment has opened and the first patient has been dosed in its randomized, double-blind Phase 1b study of CDX-0159 in patients with chronic spontaneous urticaria (CSU). 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.

“We believe the profound decreases in plasma tryptase demonstrated in our Phase 1a study suggest CDX-0159 has significant potential as a disease-modifying therapeutic for mast cell driven disorders,” said Diane C. Young, MD, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. “This latest study will build on prior results as we seek to establish the safety and potential clinical benefit of multi-dosing in a disease setting fundamentally driven by mast cells—CSU. In the coming weeks, we will further expand these efforts, initiating a second Phase 1b study in chronic inducible urticaria.”

The Phase 1b study is a randomized, double-blind, placebo-controlled clinical trial designed to assess the safety of multiple ascending doses of CDX-0159 in patients with CSU who remain symptomatic despite treatment with antihistamines. Secondary and exploratory objectives include pharmacokinetic and pharmacodynamic assessments, including measurement of tryptase and stem cell factor levels and clinical activity outcomes (impact on urticaria symptoms, disease control, clinical response) as well as quality of life assessments. The study is expected to enroll approximately 40 patients with CSU across four cohorts (8 CDX-0159; 2 placebo). CDX-0159 dosing for each cohort is as follows:

- Cohort 1 - 0.5 mg/kg Q 4 weeks;
- Cohort 2 - 1.5 mg/kg Q 4 weeks;
- Cohort 3 – 3 mg/kg Q 8 weeks; and,
- Cohort 4 – 4.5 mg/kg Q 8 weeks.

CDX-0159 will be administered intravenously as add on treatment to H1-antihistamines, either alone or in combination with H2-antihistamines and/or leukotriene receptor agonists.

More information about this study is available on www.clinicaltrials.gov (Identifier: NCT04538794). Results from the study are expected in the second half of 2021.

CSU is one of the most frequent dermatologic diseases with a prevalence of 0.5-1% of the total population (up to 3.2M in the US). Mast cell activation drives disease through the release of histamines, leukotrienes and chemokines, resulting in episodes of itchy hives, swelling and inflammation of the skin that can go on for years or even decades. Currently approved therapies target symptomatic relief. About 50% of patients with CSU achieve symptomatic control with antihistamines or leukotriene receptor antagonists. Omalizumab, an IgE inhibitor, provides relief for roughly half of the remaining antihistamine/leukotriene refractory patients. 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.

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 affect 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 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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