Celldex Announces First Patient Dosed in Phase 1 Study of CDX-0159 in Prurigo Nodularis

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HAMPTON, N.J., Dec. 08, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that the first patient has been dosed in a Phase 1 study of CDX-0159 for the treatment of prurigo nodularis (PN). CDX-0159 is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity. 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.

“The initiation of this study represents a significant milestone in the clinical development of CDX-0159 and its exciting potential to impact diseases with mast cell involvement,” said Diane C. Young, MD, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. “Research suggests mast cells play an important role in amplifying chronic itch and neuroinflammation in PN and we believe CDX-0159 has the potential to disrupt these pathways. PN is an often severe and debilitating disease with a significant impact on quality of life for patients and currently no approved treatment options. We look forward to advancing this program along with the rest of our clinical pipeline.”

The randomized, double-blind, placebo-controlled, Phase 1 study is evaluating CDX-0159 in patients with prurigo nodularis. Approximately 40 patients will be enrolled across 4 parallel groups and treated for 8 weeks (1.5 mg/kg dose every 4 weeks, 3.0 mg/kg single dose followed by placebo 4 weeks later, 4.5 mg/kg single dose followed by placebo four weeks later and placebo dose every 4 weeks) with 10 patients in each group. Patients will be followed for 16-weeks after dosing. The primary endpoints of the study are safety and tolerability; secondary endpoints include clinical effect, pharmacokinetics and pharmacodynamics. For additional information on this trial (NCT04944862), please visit www.clinicaltrials.gov.

About Prurigo Nodularis
Prurigo nodularis (PN) is a skin disease that causes hard, 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. Scratching can cause more skin lesions to appear. The itching is worsened by heat, sweating, or irritation from clothing. Diagnosis of the disease is based on observing signs such as extremely itchy skin with the formation of nodules. In some cases, a skin biopsy is used to confirm the diagnosis. There are currently no approved therapies for prurigo nodularis.

About CDX-0159
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 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.

Company Contact
Sarah Cavanaugh
Senior Vice President, Corporate Affairs & Administration
(508) 864-8337
scavanaugh@celldex.com

Patrick Till
Senior Director, Investor Relations & Corporate Communications
(484) 788-8560
ptill@celldex.com

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