# Celldex Presents Positive Data on Symptom Control and Quality of Life Measurements that Further Support CDX-0159 Clinical Benefit in Phase 1b Study in Chronic Inducible Urticaria at EADV 2021

September 29, 2021

*- Rapid and sustained improvement in urticaria control after single dose of CDX-0159 -*
*- Greatly improved patient quality of life and reduced disease impact -*
*- Data further support 95% complete response rate to provocation testing -*

HAMPTON, N.J., Sept. 29, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced positive data on measurements of symptom control and quality of life from the Company's ongoing, open label Phase 1b clinical trial of CDX-0159 in patients with antihistamine refractory cold urticaria and symptomatic dermographism, the two most common forms of chronic inducible urticaria. These diseases, which are often severe and debilitating, can significantly impact patients' lives. CDX-0159 is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity.

A single dose of CDX-0159 (3 mg/kg) resulted in a rapid and sustained improvement in urticaria control and greatly reduced disease impact on quality of life, as measured by the Urticaria Control Test (UCT) and Dermatology Life Quality Index (DLQI). These data build on the previously reported results which demonstrated rapid, profound, and durable responses in 100% of patients with 95% achieving complete response, as assessed by provocation testing (TempTest® and FricTest®).

These data were presented by Dr. Marcus Maurer, Professor of Dermatology and Allergy at Charité – Universitätsmedizin, during an e-poster session (#P0368) as part of the European Academy of Dermatology and Venereology (EADV) 2021 Virtual 30th Congress.

"In July, we reported that 95% of patients on study with cold urticaria or symptomatic dermographism experienced a complete response to provocation testing and described feeling better in their day to day lives," said Diane C. Young, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. "The data reported today provide further support of CDX-0159's significant potential to meaningfully impact multiple facets of disease burden including the elimination of hives, disease control and improvements in quality of life. We believe CDX-0159's ability to elicit these results rapidly and sustain them over the 12-week follow up period with just a single dose, offers patients suffering from these diseases real promise for improved outcomes."

**Summary of symptom control and quality of life measurements data from ongoing Phase 1b Trial of CDX-0159:**
As of the data cut-off on August 13, 2021, 21 patients had received a single intravenous infusion of CDX-0159 at 3 mg/kg, including 11 patients with cold urticaria and 10 patients with symptomatic dermographism; 20 of 21 patients completed the 12-week study observation period and 1 was ongoing. Safety results are reported for all 21 patients; Urticaria Control Test (UCT), Dermatology Life Quality Index (DLQI) and provocation test data are reported for the 20 patients who received a full dose of CDX-0159.

- In patients with chronic inducible urticaria refractory to antihistamines, a single dose of CDX-0159 (3 mg/kg) resulted in rapid, profound, and durable responses in 100% of patients with 95% achieving complete response, as assessed by provocation testing and as previously reported.
- Response to provocation testing was also accompanied by markedly improved and sustained urticaria control and quality of life:
    - A single dose of CDX-0159 resulted in rapid improvement in urticaria control as measured by the UCT score, within 4 weeks which was sustained to week 12.
    - 80% and 100% of patients achieved "well controlled" status (UCT≥12) by week 4 and 8, respectively.
        - 63% of patients achieved "complete control" status (UCT=16) by week 8.
    - 93% and 92% of patients achieved at least a 4-point reduction in the DLQI scale by week 4 and 8, respectively, the defined "minimal clinically important difference." This assessment continued to improve or was maintained over the course of 12 weeks.
        - 58% and 68% of patients achieved a DLQI score of 0-1 (no impact of disease on quality of life) by week 4 and 8, respectively and generally maintained improvement through 12 weeks.
- Rapid and durable improvement in provocation response mirrored reduction in tryptase.
- CDX-0159 was generally well tolerated.

The UCT consists of four questions (on a scale of 0-4; total 0-16) used to assess disease control in patients with chronic urticaria (spontaneous and inducible). UCT≥12 is well controlled and UCT=16 is complete control. The DLQI consists of ten questions (on a scale of 0–3, total 0–30) used to measure the impact of skin disease on patient quality of life. DLQI 0–1 indicates no effect on a patient's life.

The Phase 1b study is an open label clinical trial designed to evaluate the safety of a single dose of CDX-0159 in patients with cold urticaria, symptomatic dermographism and cholinergic urticaria who are refractory to antihistamines. Patients' symptoms are 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 is administered intravenously as add on treatment to H1-antihistamines and patients are followed for 12 weeks after dosing, with an optional longer term follow up period. For additional information on this trial (NCT04548869), please visit www.clinicaltrials.gov.

The poster presented at EADV can be viewed on the "Publications" page of the Celldex website.

**About Chronic Inducible Urticaria**
Chronic inducible urticarias are forms of urticaria that have an attributable trigger associated with them, typically resulting in wheals (hives) or angioedema. Approximately 0.5% of the total population suffers from chronic inducible urticarias. Celldex is exploring the three most common forms, cold-induced, dermographism (scratch-induced) and cholinergic (exercise/sweat-induced). People afflicted with cold urticaria experience symptoms like itching, burning wheals and angioedema when their skin is exposed to temperatures below skin temperature. Symptomatic dermographism is characterized by the development of a wheal and flare reaction in response to stroking, scratching or rubbing of the skin and usually occurs within minutes of the inciting stimulus. Cholinergic urticaria is triggered by the body's sweating response to active or passive body warming, and is characterized by small (1–4 mm) wheals surrounded by bright red flares. Common triggers include exercise, hot baths/showers, fever, occlusive dressings, eating spicy foods and emotional stress. For 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 chronic inducible urticarias other than antihistamines and patients attempt to manage symptoms associated with their disease through avoidance of triggers.

**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

Source: Celldex Therapeutics, Inc.