



Celldex Announces Acceptance of Abstract for CDX-0159 Phase 1b Results in Inducible Urticaria for Late-Breaking Presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2021

June 1, 2021

HAMPTON, N.J., June 01, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that an abstract describing results from the Phase 1b study of CDX-0159 in patients with antihistamine refractory cold contact urticaria (ColdU) and symptomatic dermographism (SD), the two most common forms of chronic inducible urticaria (CIndU), has been accepted as a late-breaking electronic Poster Discussion Session (ePDS) at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2021, being held July 10-12, 2021. The ePDS is chaired and will consist of a pre-recorded presentation followed by questions from session chairs during a dedicated timeslot.

Presentation details:

Presentation #1046:	The anti-KIT antibody, CDX-0159, reduces disease activity and tryptase levels in patients with chronic inducible urticaria
Dates:	(1) Pre-recorded poster discussion available on demand from Saturday, July 10, 2021 at 00:01 a.m. CET (Friday, July 9 at 6:01 p.m. EDT) (2) Q&A with session chair, Monday, July 12, 2021 12:30-13:30 p.m. CET (6:30-7:30 a.m. EDT)
Session type:	Late Breaking electronic Poster Discussion Session (ePDS)
Session number:	ePDS 06
Session category:	Cutting edge issues in allergy and clinical immunology

Interim data included in the abstract were current as of the time of submission in March and were presented by the Company on March 29, 2021. Updated results from additional patients with cold induced urticaria and symptomatic dermographism will be presented at EAACI including long term follow up that continues to characterize magnitude and duration of treatment effect and their association to changes in tryptase levels.

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. In a Phase 1a single dose, healthy volunteer study, CDX-0159 demonstrated a favorable safety profile as well as profound and durable reductions of plasma tryptase, indicative of systemic mast cell ablation or suppression. Based on these data, Celldex has initiated two Phase 1b studies in the mast cell-driven disease chronic spontaneous urticaria (CSU) and the three most common forms of chronic inducible urticaria (CIndU)—cold contact urticaria, symptomatic dermographism and cholinergic urticaria. The Company is also planning a third study in prurigo nodularis (PN), where mast cells through their interactions with sensory neurons and other immune cells are believed to play an important role in amplifying chronic itch and neurogenic inflammation.

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; 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 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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