Celldex Therapeutics to Expand Development of CDX-0159 into Prurigo Nodularis (PN)

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--Dermatological indication characterized by chronic, intensely itchy nodules; mast cell activation believed to play an important role in amplifying chronic itch and neuroinflammation--
--Potential to expand future CDX-0159 development beyond chronic urticarias to chronic pruritic diseases and other significant indications driven by itch and neuroinflammation--

HAMPTON, N.J., Feb. 22, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today announced that the Company will expand clinical development of CDX-0159 into prurigo nodularis (PN), a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. Mast cells through their interactions with sensory neurons and other immune cells are believed to play an important role in amplifying chronic itch and neuroinflammation, both of which are a hallmark of PN. 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.

In a Phase 1a single dose, healthy volunteer study, CDX-0159 demonstrated profound and durable reductions of plasma tryptase, indicative of systemic mast cell suppression/ablation. Celldex is evaluating CDX-0159 in two ongoing Phase 1b clinical trials in patients with chronic spontaneous urticaria and chronic inducible urticaria, both mast cell driven diseases. By exploring the potential of CDX-0159 to suppress chronic itch and neuroinflammation in PN, Celldex believes it may have the opportunity to expand future development to also include other chronic pruritic skin conditions and other medically significant conditions driven by itch and neuroinflammation.

Diane C. Young, MD, Senior Vice President and Chief Medical Officer of Celldex Therapeutics stated, “As we look to expand our clinical development plan for CDX-0159, we are considering a number of key factors, including the scientific rationale, patient need, the market opportunity and the clinical and regulatory path forward. We look forward to data this year from ongoing trials in chronic urticarias, and results from these studies will position us to evaluate expansion into other mast cell driven diseases where we believe suppressing mast cells will minimize patient symptoms. We have selected prurigo nodularis for further study because emerging science suggests mast cell activation plays an important role in amplifying a cascade of mediators that drive itch signaling with associated neuroinflammation. Here we aim to learn whether mast cell suppression with CDX-0159 can impact this cascade to diminish itch and allow for lesion healing. PN also offers an opportunity for an early clinical signal and could bring a much-needed treatment to patients while opening a door to development opportunities in other significant conditions driven by itch and neuroinflammation.”

Individuals with PN develop multiple, sometimes hundreds, of elevated, hard, nodular lesions on the skin. Patients experience intense itch and other sensations such as stinging, burning and pain which often leads to scratching to the point of bleeding and increased pain. This scratching, in turn, causes more lesions to develop, perpetuating the disease cycle. PN significantly impacts quality of life, often leading to sleep disturbance, psychological distress, social isolation, anxiety and depression. There are currently no FDA approved therapies for PN, representing an area of significant unmet need. Physicians typically attempt to address the immunological or neural component of PN through the use of topical therapies, which are not effective for many patients. While PN is classified as a rare disease by some organizations, a report by John Hopkins University[1] suggests that prevalence of PN may be substantially under-reported, in part because of other underlying dermatologic or systemic conditions. Celldex anticipates initiating the study in PN in the fourth quarter of 2021. Celldex continues to assess potential opportunities for CDX-0159 in other diseases where mast cells play an important role, such as dermatologic, respiratory, allergic, gastrointestinal and ophthalmic conditions.

[1]J Invest Dermatol, Feb 2020

About CDX-0159
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 suppression or ablation. Based on this data, Celldex has initiated two Phase 1b studies in the mast cell driven disease chronic spontaneous urticaria (CSU) and the two most common forms of chronic inducible urticaria (CIndU)—cold contact urticaria and symptomatic dermographism. 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

neuroinflammation in PN.

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 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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