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Celldex Therapeutics Initiates Phase 1 Study of New Product Candidate CDX-1140 in Solid Tumors

HAMPTON, N.J., Nov. 30, 2017 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) announced today that enrollment has opened in its open-label, Phase 1 study of CDX-1140 in patients with advanced solid tumors. CDX-1140 is a fully human antibody targeted to CD40, a key activator of immune response that is found on dendritic cells, macrophages and B cells and is also expressed on many cancer cells.

"CD40 has long been an important target for immunotherapy, as it plays a critical role in the activation of innate and adaptive immune responses; however, balancing systemic dosing and safety has proven elusive to date for CD40 targeted activating therapeutics. CDX-1140 is a unique, potent CD40 agonist that we believe has the potential to successfully balance systemic doses for good tissue and tumor penetration with an acceptable safety profile," said Tibor Keler, Ph.D., Executive Vice President and Chief Scientific Officer of Celldex Therapeutics. "We look forward to characterizing CDX-1140 in this Phase 1 study and rapidly moving into combination studies with other anti-tumor agents."

Study Overview
This study, which is expected to enroll up to approximately 105 patients with recurrent, locally advanced or metastatic cancers, is designed to determine the maximum tolerated dose during a dose-escalation phase and to recommend dose(s) for further study in a subsequent expansion phase. During the dose-escalation phase, patients will receive CDX-1140 at dose levels ranging from 0.01 mg/kg to 3.0 mg/kg once every four weeks until disease progression or intolerance. The expansion phase is designed to further evaluate the tolerability and biologic effects of selected dose(s) of CDX-1140 in specific tumor types. Secondary objectives of the study include analyses of safety and tolerability, pharmacodynamics, pharmacokinetics, immunogenicity and assessment of anti-tumor activity across a broad range of endpoints, such as objective response rate, clinical benefit rate, duration of response, progression-free survival and overall survival. More information about this study is available on www.clinicaltrials.gov (Identifier: NCT03329950).

About CDX-1140
CDX-1140 is a fully human antibody targeted to CD40, a key activator of immune response that is found on dendritic cells, macrophages and B cells and is also expressed on many cancer cells. Potent CD40 agonist antibodies have shown encouraging results in early clinical studies; however, systemic toxicity associated with broad CD40 activation has limited their dosing. CDX-1140 has unique properties relative to other CD40 agonist antibodies: potent agonist activity is independent of Fc receptor interaction, contributing to more consistent, controlled immune activation; CD40L binding is not blocked, leading to potential synergistic effects of agonist activity near activated T cells in lymph nodes and tumors; and the antibody does not promote cytokine production in whole blood assays. CDX-1140 has shown direct anti-tumor activity in preclinical models of lymphoma. The Company believes that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments.

About Celldex Therapeutics, Inc.
Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline includes antibodies, antibody-drug conjugates and other protein-based therapeutics derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors to treat specific types of cancer or other diseases. 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 glembatumumab vedotin and other Company drug candidates; our ability to obtain additional 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; our ability to realize the

anticipated benefits from the acquisition of Kolltan and to operate the combined business efficiently; 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; our ability to maintain and derive benefit from the Fast Track designation for glembatumumab vedotin which does not change the standards for regulatory approval or guarantee regulatory approval on an expedited basis, or at all; 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; 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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