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Celldex Therapeutics Initiates Phase 1/2 Clinical Trial of New Product Candidate CDX-014 in Advanced Renal Cell Carcinoma

Antibody-drug conjugate directed to TIM-1, a novel target upregulated in several cancers

HAMPTON, N.J., July 11, 2016 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) announced today that enrollment has opened in its Phase 1/2 study of CDX-014 in advanced renal cell carcinoma (RCC). CDX-014 is a novel antibody-drug conjugate that targets the transmembrane protein T-cell immunoglobulin mucin-1 (TIM-1). TIM-1 expression is upregulated in several cancers, most notably renal cell and ovarian carcinomas, and is associated with a more malignant phenotype of RCC and tumor progression[1,2]. TIM-1 has very restricted expression in healthy tissue. The study is open to patients with both clear cell and papillary RCC.

"Although significant advances have been made in the treatment of metastatic renal cell carcinoma, patients who progress through currently approved therapies have extremely limited options," said Thomas Davis, M.D., Executive Vice President and Chief Medical Officer of Celldex Therapeutics. "Selectively targeting TIM-1, which is expressed in the majority of metastatic renal cell carcinomas, presents a novel approach that could provide new options for patients. CDX-014 has also demonstrated an ability to effectively kill tumor cells without negatively impacting immune response in preclinical studies, which may make it an ideal candidate for future combination therapy. We are pleased to initiate this first study of CDX-014, further broadening our pipeline to meet the needs of patients with difficult to treat cancers."

The Phase 1 dose-escalation portion of the study will evaluate cohorts of patients receiving increasing doses of CDX-014 to determine the maximum tolerated dose and a recommended dose for Phase 2 study. The Phase 2 portion of the study will enroll approximately 25 patients to assess the anti-tumor activity of CDX-014 at the recommended dose in advanced renal cell carcinoma as measured by objective response rate (RECIST 1.1). Secondary objectives include safety and tolerability, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity, including clinical benefit rate. The study is being conducted in the United States and is expected to include approximately 10 sites. Patients must have advanced/metastatic clear cell or papillary renal cell carcinoma and have experienced progressive disease after at least two prior lines of therapy, including at least one VEGF-targeted tyrosine kinase inhibitor, or be otherwise inappropriate candidates for all approved therapies. Data analysis will be conducted separately in clear cell RCC and papillary RCC, as well as by the total population.

[1]Vila, Kaplan, et al. *Kidney Int*. 2004; 65(5): 1761-1773.

[2]Cuadros, Trilla, et al. *Eur J Cancer.* 2013; 49 (8): 2014-2047.

About CDX-014
CDX-014 is a fully human monoclonal antibody-drug conjugate (ADC) that targets T-cell immunoglobulin mucin-1 (TIM-1). TIM-1 expression is upregulated in several cancers, most notably renal cell and ovarian carcinomas, and has very restricted expression in healthy tissue. The TIM-1-targeting antibody, CR014, is linked to a potent cytotoxic, monomethyl auristatin E (MMAE), using Seattle Genetics' proprietary technology. CDX-014 is designed to be stable in the bloodstream, but to release MMAE upon internalization into TIM-1-expressing tumor cells, resulting in a targeted cell-killing effect. CDX-014 is in development for the treatment of advanced/metastatic clear cell or papillary renal cell carcinoma.

About Celldex Therapeutics, Inc.
Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline is built from a proprietary portfolio of antibodies and immunomodulators used alone and in strategic combinations to create novel, disease-specific therapies that induce, enhance or suppress the body's immune response. 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, including those related to the Company's strategic focus and the future development and commercialization (by Celldex and others) of glembatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127), CDX-014 and other products and our goals for 2016. 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 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; 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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