



April 7, 2014

## **Celldex Therapeutics Establishes Preclinical Proof of Concept for New Antibody Drug Conjugate CDX-014; Data presented at AACR 2014**

HAMPTON, N.J., April 7, 2014 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported results of preclinical studies evaluating the anti-tumor activity of CDX-014 against a variety of cell lines. Based on the results, CDX-014 will enter clinical development. CDX-014 is an antibody drug conjugate (ADC) that targets the protein TIM-1 (T cell immunoglobulin and mucin domain). TIM-1 expression is upregulated in several cancers, including renal cell and ovarian carcinomas. It is associated with kidney injury and the shedding of its ectodomain is a predictive biomarker for tumor progression. TIM-1 has very restricted expression in healthy tissues, making it a promising target for antibody mediated therapy. The data were presented in a [poster presentation](#) at the American Association of Cancer Research (AACR) Annual Meeting 2014.

"We believe CDX-014 will be another exciting addition to our clinical pipeline," said Tibor Keler, PhD, Senior Vice President and Chief Scientific Officer of Celldex. "The data presented today confirm that CDX-014 effectively targets the tumor marker TIM-1 *in vitro* and elicits significant anti-tumor activity in key models. We are currently completing manufacturing and IND-enabling studies and anticipate that CDX-014 will enter Phase 1 clinical studies in renal cell carcinoma and potentially other TIM-1 expressing tumors in 2015."

CDX-014 was developed internally by Celldex. A fully human monoclonal antibody specific for extracellular domain of TIM-1 was selected to bind to TIM-1 expressed on a variety of transformed cell lines, including human renal cell and ovarian carcinoma. Internalization studies demonstrated that the antibody was rapidly internalized by cells *in vitro* and the internalization was confirmed by quantitative imaging flow symmetry. The ADC CDX-014 was produced by the covalent linkage of the anti-TIM-1 antibodies to monomethyl auristatin E (MMAE), a potent cytotoxin. CDX-014 demonstrated *in vitro* cytostatic or cytotoxic activity against a variety of TIM-1 expressing cell lines, but did not impact TIM-1 negative cell lines. Significant anti-tumor activity was observed in predictive preclinical xenograft models of human renal clear cell carcinoma, human ovarian adenocarcinoma and human lung carcinoma. The results were presented in a poster entitled "*Development of an Antibody-drug Conjugate Targeting TIM-1 for the Treatment of Ovarian and Renal Cell Carcinoma*" by Lawrence J. Thomas, PhD, DABT, ATS, Senior Director Preclinical Research and Development at Celldex Therapeutics.

### **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](http://www.celldex.com).

### **Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995:**

*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 rindopepimut (CDX-110), glembatumumab vedotin ("glemba"; CDX-011), CDX-1135, CDX-1401, CDX-1127, CDX-301, CDX-014, Belinostat and other products. 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 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 rindopepimut, 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; our ability to adapt our APC Targeting Technology<sup>TM</sup> to develop new, safe and effective vaccines against oncology and infectious disease indications; our ability to successfully complete product research and further development of our programs; the uncertainties inherent in clinical testing; our limited experience in bringing programs through Phase 3 clinical trials; our ability to manage research and development efforts for multiple products at varying stages of development; 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; and other factors listed under "Risk Factors" in our annual report on Form 10-K.*

*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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