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Celldex Therapeutics Presents Data Supporting the Clinical Development of Glembatumumab Vedotin and the Preclinical CD40 Program at the AACR Annual Meeting 2016

HAMPTON, N.J., April 20, 2016 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) announced three poster presentations at the American Association for Cancer Research (AACR) Annual Meeting 2016 in New Orleans. The Company previously reported on four poster presentations at AACR, which included Phase 1 safety and immune response data from the ongoing study evaluating varlilumab and nivolumab in patients with advanced cancers. New presentations included data enhancing the understanding of glembatumumab vedotin's mechanism of action and further validation of the overexpression of its target, gpNMB, in a wide range of tumor types. Additionally, the Company also presented research with lead agonist antibodies targeting the CD40 receptor, a promising target for immunotherapy, in a poster titled "Development and characterization of novel CD40 antibody agonists for cancer immunotherapy."

Found on antigen presenting cells, such as dendritic cells, macrophages and B cells, CD40 is a key activator of immune responses. The Company has characterized two fully human antibodies that demonstrated potent agonist activity, such as activating human dendritic cells and B cells and indirectly inducing T cell proliferation. Importantly, Fc receptor interaction, which could cause signal amplification and is required for some CD40 agonist antibodies in development, was not required for agonist ability, enabling controlled, sensitive activation of CD40. Additionally, the drug candidates were shown to upregulate CD95/Fas, a receptor involved in apoptosis, on B cell lymphoma cell lines and to mediate potent anti-tumor activity against the lymphomas *in vivo*.

"The CD40 pathway has a unique and powerful role in bridging the innate and adaptive immune response, and if properly modulated, it could become a very important part of cancer immunotherapy. We have identified some promising and differentiated antibodies, from which we will select a lead clinical candidate to complement our growing immunotherapy pipeline," said Tibor Keler, Ph.D., Executive Vice President and Chief Scientific Officer of Celldex Therapeutics. "In addition, we are enthusiastic about new research demonstrating gpNMB overexpression in a broad set of tumor types, further reinforcing the wide potential clinical applicability of glembatumumab vedotin."

The CD40 poster is available on the "Publications" page of the "Science" section of the Celldex website.

Celldex and its collaborating investigators also presented two additional posters supporting the clinical development of glembatumumab vedotin:

Title: Glycoprotein NMB (gpNMB) overexpression is prevalent in human cancers: pancreatic cancer, non-small cell lung cancer, head and neck cancer, and osteosarcoma

gpNMB is the target of Celldex's antibody-drug conjugate glembatumumab vedotin. Using a validated immunohistochemistry (IHC) assay to detect the expression of gpNMB, the Company examined tissues from multiple types of solid tumors and normal tissue. Overexpression of gpNMB in samples of tumor tissue versus normal tissue was found in squamous cell carcinoma of the lung (85%), osteosarcoma (62%), pancreatic cancer (55%), lung adenocarcinoma (45%) and squamous cell carcinoma of the head and neck (40%). These results support the potential broad applicability of gpNMB as a therapeutic target across a wide range of tumor types. Celldex is currently investigating glembatumumab vedotin in the pivotal METRIC study in triple-negative breast cancer and in a Phase 2 study in metastatic melanoma. Independent investigators are also studying glembatumumab vedotin in uveal melanoma and osteosarcoma. A Phase 1/2 study in squamous cell carcinoma of the lung is expected to commence in the second quarter of 2016.

The poster is available on the "Publications" page of the "Science" section of the Celldex website.

Title: Targeting gpNMB with 89Zr-CR011 for PET imaging of triple negative breast cancer
Abstract: 4209

Collaborating investigators used a radio-labeled form of the glembatumumab antibody to study uptake by tumor cells *in vitro* and *in vivo*. Using positron emission tomography (PET) imaging with xenograft models of triple-negative breast cancer (TNBC), the investigators detected specific localization of glembatumumab in the tumor and plan to perform similar studies

with patient derived tumor samples. These studies contribute to understanding the mechanisms of action for glembatumumab vedotin, Celldex's antibody-drug conjugate targeting gpNMB, and may provide a diagnostic approach for selecting patients with the greatest likelihood of clinical benefit.

About Glembatumumab Vedotin
Glembatumumab vedotin is a fully-human monoclonal antibody-drug conjugate (ADC) that targets glycoprotein NMB (gpNMB). gpNMB is a protein overexpressed by multiple tumor types, including breast cancer, melanoma, lung cancer, uveal melanoma and osteosarcoma. gpNMB has been shown to be associated with the ability of the cancer cell to invade and metastasize and to correlate with reduced time to progression and survival in breast cancer. The gpNMB-targeting antibody, CR011, is linked to a potent cytotoxic, monomethyl auristatin E (MMAE), using Seattle Genetics' proprietary technology. Glembatumumab vedotin is designed to be stable in the bloodstream but to release MMAE upon internalization into gpNMB-expressing tumor cells, resulting in a targeted cell-killing effect. Glembatumumab vedotin is in development for the treatment of locally advanced or metastatic breast cancer with an initial focus in triple negative disease, stage III and IV melanoma, uveal melanoma and osteosarcoma.

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) 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 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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