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Celldex Therapeutics Initiates Phase 1/2 Study of Glembatumumab Vedotin in Squamous Cell Lung Cancer

HAMPTON, N.J., April 27, 2016 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today announced that it has initiated an open-label Phase 1/2 safety and tolerability study of glembatumumab vedotin in patients with unresectable stage IIIB or IV, gpNMB-expressing, advanced or metastatic squamous cell carcinoma (SCC) of the lung, who have progressed on prior platinum-based chemotherapy. Glembatumumab vedotin is a fully human monoclonal antibody-drug conjugate (ADC) that targets gpNMB, a protein overexpressed by multiple tumor types, including SCC of the lung, where approximately 85 percent of patients overexpress the marker. Overexpression of gpNMB has been shown to promote the invasion and metastasis of cancer and has been associated with poor clinical outcome. Celldex has entered into a collaborative relationship with PrECOG, LLC, which represents a research network established by the Eastern Cooperative Oncology Group (ECOG), and PrECOG, LLC will conduct the study.

"While checkpoint inhibitor therapy has been an important development for patients with squamous cell lung cancer, the majority of patients still require new, effective treatment options—especially targeted therapies," said Thomas Davis, M.D., Executive Vice President and Chief Medical Officer of Celldex Therapeutics. "gpNMB, the target of glembatumumab vedotin, is strongly expressed in the vast majority of squamous cell lung cancers. Glembatumumab vedotin has consistently induced notable response rates in other difficult to treat cancers that overexpress gpNMB. We hope to elicit similar activity in squamous cell carcinoma and look forward to completing this study."

Glembatumumab vedotin is currently being evaluated in patients with metastatic triple negative breast cancers that overexpress gpNMB in the registrational METRIC study, as well as in a Phase 2 study in patients with advanced melanoma who have progressed after at least one checkpoint inhibitor therapy and, if applicable, BRAF- or MEK-targeted therapy. It has been previously evaluated in a Phase 2 study in advanced breast cancer (the EMERGE study), a Phase 1/2 study in advanced breast cancer and a Phase 1/2 study in patients with unresectable stage III or IV melanoma. Also, Celldex and the National Cancer Institute (NCI) have entered into a Cooperative Research and Development Agreement (CRADA) under which the NCI is sponsoring two studies of glembatumumab vedotin—one in uveal melanoma and one in pediatric osteosarcoma. Both studies are currently open to enrollment.

Study Design
This Phase 1/2 study will enroll patients with gpNMB-positive stage IIIB or IV non-small cell lung cancer (NSCLC) of squamous histology who have previously been treated with platinum-based chemotherapy. gpNMB positivity will be determined by a greater than, or equal to, five percent gpNMB expression in tumor epithelial cells. Glembatumumab vedotin will be administered once every three weeks until disease progression or intolerance. The study is expected to include 10 sites in the United States.

The study will include a dose-escalation phase followed by a two-stage Phase 2 portion (Simon two-stage design). The Phase 1, dose-escalation portion of the study will assess the safety and tolerability of glembatumumab vedotin at the current dose of 1.9 mg/kg and then 2.2 mg/kg in order to determine whether higher dosing is feasible in this population. The first stage of the Phase 2 portion will enroll approximately 20 patients, and if at least two patients achieve a partial response or complete response, a second stage may enroll an additional 15 patients. The primary objective of the Phase 2 portion of the study is to assess the anti-tumor efficacy of glembatumumab vedotin in squamous cell lung cancer as measured by objective response rate (ORR). Secondary objectives of the study include analyses of safety and tolerability and further assessment of anti-tumor activity across a broad range of endpoints.

About Squamous Cell Lung Cancer
Lung cancer is the leading cause of cancer related deaths in the world, with an estimated one million new cases worldwide and around 216,000 in the U.S. annually. Non-small cell lung cancer (NSCLC) represents more than 80 percent of all lung cancers, and squamous cell carcinoma (SCC) of the lung accounts for approximately 30 to 40 percent of NSCLC. While new treatment options, especially targeted therapies, have become available for patients with adenocarcinoma, another type of NSCLC, clinical studies have not identified targeted therapies with major benefits for patients with SCC of the lung. Recent improvements for patients with SCC of the lung include checkpoint immunotherapy; however, not all patients respond to this treatment, and new therapeutic options are needed. Approximately 85 percent of patients with SCC of the lung have tumors that overexpress gpNMB, the target of glembatumumab vedotin.

About Glembatumumab Vedotin
Glembatumumab vedotin (CDX-011) 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, head and neck cancer, uveal melanoma, osteosarcoma, pancreatic cancer and glioblastoma. 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, squamous cell lung cancer, 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), varlilumab ("varli"; CDX-1127), 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.

Contact:
Sarah Cavanaugh
Vice President of Investor Relations & Corp Communications
(781) 433-3161
scavanaugh@celldex.com

Charles Liles
Manager of Investor Relations & Corp Communications
(781) 433-3107
cliles@celldex.com

Media Contact:
Dan Budwick
Pure Communications, Inc.
(973) 271-6085
dan@purecommunicationsinc.com