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Celldex Therapeutics Initiates METRIC, an Accelerated Approval Study of Glembatumumab Vedotin in Patients with Triple Negative Breast Cancer

Antibody drug conjugate targets gpNMB, a protein which promotes the migration, invasion and metastasis of breast cancer

HAMPTON, N.J., Dec. 2, 2013 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today announced that it has launched a randomized study (METRIC) of Glembatumumab vedotin (CDX-011) in patients with metastatic triple negative breast cancers that over-express glycoprotein NMB (gpNMB). Glembatumumab vedotin is an antibody-drug conjugate that targets and binds to gpNMB, a specific protein that is expressed in breast cancer which promotes the migration, invasion and metastasis of the disease. It is also highly expressed in triple negative breast cancers where it is associated with increased risk of recurrence. Initial sites are now open to screen patients in the United States. Additional sites in the United States and in Canada and Australia will open in early 2014. The study is expected to include up to 100 sites and will enroll approximately 300 patients.

"In the Phase 2 EMERGE study, Glembatumumab vedotin elicited impressive response rates that correlated with a survival benefit for patients with metastatic breast cancer that also had high levels of gpNMB on the surface of their tumor cells," said Thomas Davis, M.D., Senior Vice President and Chief Medical Officer of Celldex. "Currently, patients with triple negative breast cancer have very limited treatment options and no targeted interventions. We believe gpNMB could be an important marker in breast cancer and that Glembatumumab vedotin holds significant potential as a possible targeted therapy for women facing this disease."

"Given the lack of treatment options available for women with triple negative breast cancer, we are gratified that we are able to conduct the METRIC study on an accelerated approval path and are committed to enrolling the study expeditiously," said Anthony Marucci, President and Chief Executive Officer of Celldex. "We also plan to further expand the clinical development program for Glembatumumab vedotin in 2014 by initiating additional studies in other cancers known to express gpNMB including melanoma and squamous cell lung cancer."

About the METRIC Study

The METRIC study is a pivotal, open-label, prospectively controlled, randomized study of Glembatumumab vedotin in patients with metastatic gpNMB-expressing triple-negative breast cancer. Eligible patients must have received no more than 1 prior line of chemotherapy for advanced disease and therapy must have included a taxane and anthracycline. Patients will be randomized (2:1) to receive Glembatumumab vedotin or capecitabine. Study treatment will continue until disease progression or intolerance with tumor assessments performed at six week intervals for six months and nine week intervals thereafter. The primary objective is to evaluate the anti-cancer activity of Glembatumumab vedotin as measured by the objective response rate (ORR) and duration of progression-free survival (PFS). The study is designed to enable Celldex to apply for registration with positive results for either endpoint. Secondary endpoints include duration of response, overall survival, safety and tolerability. The Company will also assess improvements in quality of life and/or cancer-related pain as exploratory endpoints.

Patients will be stratified as follows:

- No prior chemotherapy for advanced disease vs. 1 prior line of chemotherapy for advanced disease
- "Resistant" to anthracycline therapy (i.e., progression-free interval of ≤ 6 months after completing treatment) vs. "Exposed" to anthracycline therapy (i.e., progression-free interval of > 6 months after completing treatment)

Clinical Data Supporting Glembatumumab vedotin in Triple Negative Breast Cancer

In the Phase 2 EMERGE study, final data supported an overall survival benefit in specific sub-groups of breast cancer patients with tumors that over-express gpNMB. Treatment of patients with both triple negative breast cancer and over-expression of gpNMB showed a high overall response rate (ORR) of 33% (n=12) when treated with Glembatumumab vedotin. In comparison, no responses (n=4) were seen in patients with both triple negative breast cancer and over-

expression of gpNMB with standard chemotherapies. In this same patient population, the median overall survival (OS) for patients treated with Glembatumumab vedotin was 10 months vs. 5.5 months (p= 0.003) and progression free survival (PFS) was 3 months for the Glembatumumab vedotin arm vs. 1.5 months for the control arm (p=0.008), respectively. The most common adverse event was rash.

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 and melanoma. 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. In May 2010, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to Celldex's Glembatumumab vedotin for the treatment of advanced, refractory/resistant gpNMB-expressing breast cancer. Glembatumumab vedotin is also in development for the treatment of Stage III and IV melanoma.

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.

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, 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™ 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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