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Celldex Therapeutics' Phase 2 EMERGE Study of Glembatumumab Vedotin in Metastatic Breast Cancer Published in Journal of Clinical Oncology

HAMPTON, N.J., April 6, 2015 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today announced that data from the Phase 2 EMERGE study of glembatumumab vedotin in metastatic breast cancer have been published in the *Journal of Clinical Oncology*. The data from this study supported the initiation of the ongoing, pivotal Phase 2 METRIC study in patients with triple negative breast cancers that over-express glycoprotein NMB (gpNMB). Glembatumumab vedotin is an antibody-drug conjugate that targets and binds to gpNMB, a protein expressed by multiple tumor types, including breast cancer. Overexpression of gpNMB has been shown to promote the invasion and metastasis of cancer and has been associated with poor clinical outcome.

"Previous studies of glembatumumab vedotin suggested that gpNMB over-expression might correlate with the potential anti-cancer activity of glembatumumab vedotin in breast cancer," said Thomas Davis, MD, Executive Vice President and Chief Medical Officer of Celldex Therapeutics. "We designed the EMERGE study to thoroughly explore this hypothesis and observed impressive response rates and prolonged survival in patients that over-expressed gpNMB on the surface of their tumor cells. These data supported the initiation of the METRIC study in patients with triple negative breast cancer—where gpNMB over-expression is seen in approximately 40% of patients. 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."

EMERGE was a randomized, multi-center, controlled study. 124 patients with advanced, heavily pre-treated (2-7 lines of prior chemotherapy including a taxane, an anthracycline, capecitabine, and, if HER2-positive, trastuzumab and lapatinib) breast cancer were enrolled and randomized (2:1) to receive glembatumumab vedotin or "Investigator's Choice" (IC) single agent, approved chemotherapy. The primary endpoint of the study was overall response rate. Secondary endpoints included duration of response, progression-free survival, overall survival, safety, and pharmacokinetic and pharmacodynamic analyses. gpNMB expression levels were evaluated via central immunohistochemistry on archived tumor tissue.

Key findings:

- Glembatumumab was well tolerated in patients with treatment-refractory breast cancer. The most common treatment-related adverse events were nausea, rash, fatigue, neuropathy, alopecia and neutropenia.
- Virtually all patients (99%) with breast cancer screened for potential enrollment into the study expressed gpNMB at or greater than 5%, the predefined expression level required for entry into the study.
- A stratification and analysis explored whether intensity of gpNMB expression in malignant epithelial (tumor) cell or stromal tissues was associated with greater treatment effect and determined that:
  - Low or high expression in the stroma did not generally correlate with outcome after glembatumumab vedotin, although there was a trend towards increased PFS and OS for patients with high stromal intensity.
  - Patients whose tumors expressed higher levels of gpNMB in malignant epithelial cells (> 10 and > 25%), had a significantly greater likelihood of tumor response when compared with all other pooled patients. No such correlation was seen in patients treated with IC. Specifically, an ORR of 30% (7/23) was observed for patients with > 25% expression in malignant epithelial cells as compared to 9% (1/11) on the IC arm. This was also associated with improved progression-free survival and overall survival. (PFS: 2.8 ms glembatumumab vs 1.5 ms IC; hazard ratio: 0.63; p=0.18. OS: 10.0 ms glembatumumab vs 5.7 ms IC; hazard ratio 0.67; p=0.31).
- In patients with triple negative breast cancer (TNBC), where gpNMB is correlated with the metastatic phenotype and is more frequently expressed, noteworthy activity was observed for glembatumumab vedotin in patients with higher gpNMB expression levels (> 25% gpNMB expression in malignant epithelial cells), with an ORR of 40% (4/10) for the glembatumumab vedotin arm and 0% (0/6) for the IC arm. An improvement in PFS and OS was also noted (PFS: 3.5 ms glembatumumab vs 1.5 ms IC; hazard ratio 0.11; p=0.0017. OS: 10.0 ms glembatumumab vs 5.5 ms IC; hazard ratio 0.14; p=0.003).

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, and for the treatment of Stage III and IV melanoma. Additional studies are planned in squamous cell lung cancer, osteosarcoma, uveal melanoma and pediatric sarcoma.

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.

Celldex 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 Rintega® ("rindopepimut"; "rindo"; CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127), CDX-1401, CDX-301 and other products and our goals for 2015. 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 Rintega, 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; 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 our 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: Celldex Company Contacts:

Investors:

Sarah Cavanaugh

Vice President of Investor Relations &

Corp Communications

Celldex Therapeutics, Inc.

(781) 433-3161

scavanaugh@celldex.com

or

Media:

Dan Budwick

Pure Communications, Inc.

(973) 271-6085

dan@purecommunicationsinc.com

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