December 8, 2012

Final Data from Celldex Therapeutic's CDX-011 Phase 2 Study in Metastatic Breast Cancer Supports Overall Survival Benefit in Patients with High GPNMB Expression

--Broad activity with greatest benefit in patients with high GPNMB-expressing triple negative breast cancer--

--Data presented today in a poster session at San Antonio Breast Cancer Symposium--

NEEDHAM, Mass.--(BUSINESS WIRE)-- Celldex Therapeutics, Inc. (NASDAQ: CLDX) today announced final results from the Company's randomized Phase 2b EMERGE study of CDX-011 in patients with glycoprotein NMB (GPNMB)-expressing, advanced, heavily pretreated breast cancer. CDX-011 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. The results presented today at the 2012 CTRC-AACR San Antonio Breast Cancer Symposium confirm preliminary findings reported in May and establish proof of principle with evidence of higher activity in patient subgroups with high GPNMB expression (expression in ≥25% of tumor cells), including those with triple negative disease. Progression free and overall survival benefits were demonstrated in the subgroup of patients with triple negative disease that also highly expressed GPNMB, and strong trends towards benefits were seen in all patients with high GPNMB expression. This benefit in overall survival is seen despite the fact that more than a third of control patients received CDX-011 as a cross over at the time of disease progression.

While the study was not powered to demonstrate statistical significance between the arms, beneficial activity in targeted patient populations that highly expressed GPNMB was consistently observed and, in some cases, was statistically significant. Treatment of patients with both triple negative breast cancer and high GPNMB expression showed high overall response rates (ORR) for the CDX-011 arm (CDX-011 ORR of 33% vs 0% in the Investigator's Choice (IC) arm) and an overall survival and progression free survival (PFS) benefit for CDX-011 that reached statistical significance (CDX-011 median survival of 10.0 months vs IC of 5.5 months; p=0.003); (CDX-011 median PFS of 3.0 months vs IC of 1.5 months; p=0.008). In patients with high GPNMB expression, a high response rate was observed in the CDX-011 arm (CDX-011 ORR of 32% vs IC of 13%) and a trend of improvement in overall survival and PFS was demonstrated for the CDX-011 arm (CDX-011 median survival of 10.0 months vs IC of 5.7 months; p=0.18); (CDX-011 median PFS of 2.7 months vs IC of 1.5 months; p=0.14). For the overall study population, response rates, overall survival and progression free survival after treatment with CDX-011 suggested anti-tumor activity consistent with the standard of care. Patients receiving IC alone who crossed over to receive CDX-011 upon disease progression appeared to represent the better outcomes in the control arm, with a median survival of 12.5 months, as compared to those who did not cross over, with a median of 5.4 months.

"CDX-011 is eliciting impressive response rates in these patients with heavily-pretreated metastatic disease, where physicians typically have little expectation of clinical response. Most importantly, these responses appear to translate into a survival benefit in the patients where we would expect CDX-011 to work best, the targeted patient populations with high levels of GPNMB on the tumor cell surface," said Denise A. Yardley, MD, Senior Investigator in the Breast Cancer Research Program at the Sarah Cannon Research Institute and a lead investigator in the EMERGE study. "Based on these results, it appears that GPNMB is emerging as a potentially important marker in breast cancer and that CDX-011 holds significant potential as a possible targeted therapy for triple negative patients, a patient population that currently has no targeted interventions."

Thomas Davis, MD, Senior Vice President and Chief Medical Officer of Celldex Therapeutics, commented, "The mature results presented today confirm the preliminary results shown previously and support advanced clinical development of CDX-011, which may play a critical role in treating patients with advanced breast cancer. We look forward to discussions with the Food and Drug Administration later this month to design a pivotal study intended to support approval of CDX-011 for specific patients with breast cancer."

Final Study Results:

A total of 122 patients were treated on the study, with 81 patients randomized to the CDX-011 arm and 41 patients to the IC single-agent chemotherapy arm, of which 15 later crossed over to receive CDX-011. In total, 81 CDX-011 patients (including cross overs) and 36 IC patients had on-study radiographic assessments and were evaluable for response. Nearly all patients had Stage IV, or metastatic, disease. Patients on the CDX-011 arm received a median of six prior courses of

therapy and patients on the IC arm received a median of five prior courses of therapy. Adverse events prominent with the CDX-011 arm included rash and peripheral neuropathy, while hematologic toxicity was more frequent and severe in the IC arm. The Phase 2b EMERGE study required patients' tissue to have at least 5% of cells expressing GPNMB at entry and, based on this low threshold, 99% of screened patients were eligible for entry allowing for a specific focus on expression pattern subgroups. High GPNMB expression is defined as ≥25% of tumor epithelial cells expressing GPNMB by IHC.

Phase 2b EMERGE Final Survival Results: Survival Benefit of CDX-011 is Greatest in Patients with Triple Negative Disease that Highly Expresses (≥25%) GPNMB and All Patients with High GPNMB Expression*

	All Patients		Triple Negative		High GPNMB Expression		Triple Negative and High GPNMB Expression	
	CDX-011	**IC**	**CDX-011**	**IC**	**CDX-011**	**IC**	**CDX-011**	**IC**
Median PFS (months)	2.1	2.0	2.3	1.6	2.7	1.5	3.0	1.5
	p=0.38		p=0.43		p=0.14		p=0.008	
Median OS (months)	7.5	7.4	6.9	6.5	10.0	5.7	10.0	5.5
	p=0.24		p=0.30		p=0.18		p=0.003	

**Analyses include all treated patients. Patients who initially received Investigator's Choice (IC) and subsequently crossed over to receive CDX-011 (n=15) are included in the PFS analysis for each treatment. These patients, with a median OS of 12.5 months (range 4.4 to 21.0 months), are assigned to the IC arm only for OS analysis.*

Phase 2b EMERGE Final Overall Response Results: Activity of CDX-011 is Greatest in Patients with Triple Negative Disease that Highly Expresses (≥25%) GPNMB and All Patients with High GPNMB Expression*

	All Patients		Triple Negative		High GPNMB Expression		Triple Negative and High GPNMB Expression	
	CDX-011 (n=81)	**IC (n=36)**	**CDX-011 (n=27)**	**IC (n=9)**	**CDX-011 (n=25)**	**IC (n=8)**	**CDX-011 (n=12)**	**IC (n=4)**
% Response (% Confirmed)	16 (10)	14 (8)	19 (7)	0	32 (16)	13 (13)	33 (8)	0
% Disease Control Rate	57	53	67	33	64	38	75	25

**Responses per RECIST 1.1; IC = Investigator's Choice; CDX-011 arm includes 15 patients who crossed over to receive CDX-011 treatment after progression on IC. Analysis of best response excludes patients who discontinued from study without evaluable post-baseline radiographic imaging (n=16 for CDX-011 arm; n=5 for IC arm).*

About CDX-011:

CDX-011 (glembatumumab vedotin) is an antibody-drug conjugate (ADC) that consists of a fully-human monoclonal antibody, CR011, linked to a potent cell-killing drug, monomethyl-auristatin E (MMAE). The ADC technology, comprised of MMAE and a stable linker system for attaching it to CR011, was licensed from Seattle Genetics, Inc. The ADC is designed to be stable in the bloodstream. Following intravenous administration, CDX-011 targets and binds to GPNMB, a specific protein that is expressed in breast cancer and other tumor types which promotes the migration, invasion and metastasis of breast cancer. Upon internalization into the targeted cell, CDX-011 is designed to release MMAE from CR011 to produce a cell-killing effect. CDX-011 has been shown to be well tolerated and active, with observed objective responses in two positive Phase 1/2 trials in metastatic breast cancer and advanced melanoma. In May 2010, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to Celldex's CDX-011 for the treatment of advanced, refractory/resistant GPNMB-expressing breast cancer.

About Celldex Therapeutics, Inc.:

Celldex Therapeutics is the first antibody-based combination immunotherapy company. Celldex has a pipeline of drug candidates in development for the treatment of cancer and other difficult-to-treat diseases based on its antibody focused Precision Targeted Immunotherapy (PTI) Platform. The PTI Platform is a complementary portfolio of monoclonal antibodies, antibody-targeted vaccines and immunomodulators used in optimal combinations to create novel disease-specific drug candidates. For more information, please visit http://www.celldextherapeutics.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 of CDX-011 or any of our other drug candidates, including rindopepimut (CDX-110), CDX-1135 (formerly TP10), CDX-1401, CDX-1127, CDX-301, Belinostat and any future action we or the FDA (or any other regulator) might take with respect to regulatory approvals. 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, future actions that the FDA and other regulators might take or not take with respect to CDX-011 or any drug candidate, the market for CDX-011 or any other drug candidate or assay, future clinical testing which will be necessary before FDA approval could be sought, our ability to obtain additional capital on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that we initiated in 2012 and plan to initiate in 2013; our ability to adapt 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 limited cash reserves and our ability to obtain additional capital on acceptable terms, or at all; 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 risks detailed from time to time in the Company's filings with the Securities and Exchange Commission, including the Company's Form 10-K for the fiscal year ended December 31, 2011, and its Forms 10-Q and 8-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.

Celldex Therapeutics, Inc.
Sarah Cavanaugh, 781-433-3161
Vice President of IR & Corp Comm
scavanaugh@celldextherapeutics.com
or
For Media:
BMC Communications
Brad Miles, 646-513-3125
bmiles@bmccommunications.com

Source: Celldex Therapeutics, Inc.

News Provided by Acquire Media