May 23, 2012

Celldex's CDX-011 Demonstrates High Response Rates In Patients With Metastatic Breast Cancer Expressing Elevated Levels Of GPNMB and In Triple Negative Disease

WEBCAST SCHEDULED FOR 4:30 PM ET TODAY

NEEDHAM, Mass.--(BUSINESS WIRE)--May. 23, 2012-- Celldex Therapeutics, Inc. (NASDAQ: CLDX) today announced preliminary results from the Company's randomized Phase 2b EMERGE study of CDX-011 (glembatumumab vedotin) antibody drug conjugate in patients with glycoprotein NMB (GPNMB) expressing, advanced, heavily pretreated breast cancer. Preliminary results suggest that CDX-011 induces impressive response rates compared to current, available therapies in patients with advanced, refractory breast cancers with high GPNMB expression (expression in ≥25% of tumor cells). In this high expressing patient population, treatment with CDX-011 resulted in a 32% overall response rate (ORR; includes confirmed and unconfirmed responses), whereas treatment with Investigator's Choice (IC) single-agent chemotherapy resulted in a 13% ORR. CDX-011 also demonstrated strong response rates in patients with triple negative breast cancer across all levels of GPNMB expression (CDX-011 ORR of 21%; IC ORR of 0%), where treatment options are extremely limited. In addition, in patients with triple negative breast cancer who also highly express GPNMB, greater activity was observed (CDX-011 ORR of 36%; IC ORR of 0%). The ORR across all levels of GPNMB expression was 19% for the CDX-011 arm and 14% for the IC arm, and a direct, positive correlation was observed between increasing levels of GPNMB expression and increased CDX-011 response rates. Based on these data, the Company believes CDX-011 has significant promise as a targeted therapy for patients with breast cancer and high expression of GPNMB, and especially for those with triple negative disease.

While data in the study are not yet mature, in patients with high GPNMB in the CDX-011 arm, a trend of improvement in progression-free survival (PFS) has been observed. In patients with both triple negative breast cancer and high GPNMB expression, a statistically significant PFS benefit is currently observed (p=0.0032). Study data continue to mature and patients continue to be followed. The Company anticipates updating results in the fourth quarter of 2012.

"The correlation with GPNMB expression rates and clinical responses in this study confirms the role of GPNMB as a potentially new and important cancer target," said Linda Vahdat, MD, Professor of Medicine, Chief of Solid Tumor Service and Director of the Breast Cancer Research Program at Weill Cornell Medical College and the lead investigator of the EMERGE study. "These results are promising in this heavily pretreated patient population for which there are few treatment options left. With continued positive results, CDX-011 has the potential to offer a possible new and important targeted therapy."

GPNMB has been associated with the migration, invasion, and metastasis of breast cancer. It is also highly expressed in triple negative breast cancers where it is associated with increased risk of recurrence. The Phase 2b EMERGE study required patients' tissue to have at least 5% of cells expressing GPNMB at entry and, based on the low threshold for marker positivity, 99% of patients screened for GPNMB expression met the entry requirement, allowing for a specific focus on expression pattern subgroups. A total of 122 patients were treated on the study, with 81 patients (81 evaluable) randomized to the CDX-011 arm and 41 patients (36 evaluable) to the IC single-agent chemotherapy arm. Greater than 98% of the patient population across both arms had Stage IV 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. The study overall replicated previous data in all comers, but subgroup analyses show enrichment for improved outcome in triple negative and high expressing subsets. Adverse events prominent with the CDX-011 arm include rash and peripheral neuropathy.

Preliminary Topline Results:

Phase 2b EMERGE Preliminary Results: Activity of CDX-011 is Greatest in Patients with Triple Negative and ≥ 25% GPNMB-Expressing Disease (High)*

	All Patients		Triple Negative		High GPNMB Expression		Triple Negative and High GPNMB Expression	
	CDX-011 (n=81)	IC (n=36)	CDX-011 (n=24)	IC (n=9)	CDX-011 (n=25)	IC (n=8)	CDX-011 (n=11)	IC (n=3)
% Response (% Confirmed)	19 (12)	14 (8)	21 (8)	0	32 (16)	13 (13)	36 (9)	0

Disease Control Rate	59	50	71	33	64	38	82	33
Any Tumor Shrinkage	50	46	54	33	57	38	64	33

**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 =15 for CDX-011 arm; n=5 for IC arm); Analysis of tumor shrinkage excludes additional patients without evaluable post-baseline imaging of all target lesions (n=5 for CDX-011 arm; n=1 for IC arm).*

Thomas Davis, MD, Chief Medical Officer of Celldex Therapeutics, commented, "The data in all patients, which includes both low and high GPNMB expression levels, replicates our previous study and shows CDX-011 to have activity similar to drugs currently approved for advanced breast cancer. The results in triple negative and high expressing patient populations suggest these groups are a highly responsive patient subset for targeted treatment with CDX-011. This result is in contrast with other agents, which tend to have limited effects in these populations. With a defined patient population for targeted therapy established for CDX-011, we can now confidently discuss possible approval paths with the regulators to determine next steps."

Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics, concluded, "It is increasingly clear that targeted therapies will be needed to make meaningful progress in difficult to treat cancers like advanced and triple negative breast cancer. We have developed a reliable diagnostic assay that identifies GPNMB expression patterns and levels in breast cancer, and the results to date from the Phase 2b EMERGE study suggest we have clearly identified patient populations that have significant potential to benefit from CDX-011. Together, patients with ≥25% GPNMB expression levels and patients with triple negative disease account for more than 35% of the total breast cancer patient population and we believe CDX-011 could play a vital role as a much needed treatment option for these patients."

Webcast Details:

The data will be presented in a webcast today, May 23, 2012, at 4:30 p.m. ET by Celldex management. Linda Vahdat, MD, Professor of Medicine, Chief of Solid Tumor Service and Director of the Breast Cancer Research Program at Weill Cornell Medical College and the lead investigator of the EMERGE study, will join Celldex on the webcast to discuss results to date from the study. Accompanying slides for the webcast will be made available on the Celldex website at the start of the call.

The conference call will be webcast live over the Internet and can be accessed by logging on to the "News & Events" section of the Celldex Therapeutics website at http://www.celldextherapeutics.com. The call can also be accessed by dialing 800-299-0148 (within the United States) or 617-801-9711 (outside the United States). The passcode for participants is 98560829.

A replay of the call will be available approximately two hours after the live call concludes through June 6, 2012. To access the replay, dial 888-286-8010 (within the United States) or 617-801-6888 (outside the United States). The passcode is 41731858. The webcast will also be archived on the Company's website.

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, and 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 2011 and plan to initiate in 2012; 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.

Source: Celldex Therapeutics, Inc.

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