



October 29, 2012

Celldex Therapeutics Makes Significant Advancements in the Field of Protein-Based Vaccine Development

--Dendritic Cell Targeted Vaccine CDX-1401 is Well-tolerated and Elicits Robust Antibody and T cell Responses in Patients with Cancer--

NEEDHAM, Mass.--(BUSINESS WIRE)-- [Celldex Therapeutics, Inc.](#) (NASDAQ: CLDX) today announced positive results demonstrating promising clinical effects in a Phase 1 study of CDX-1401 in solid tumors in combination with the toll-like receptor (TLR) agonists resiquimod and/or Poly ICLC (HiltonolTM). CDX-1401 is a fusion protein consisting of a fully human monoclonal antibody with specificity for the dendritic cell receptor DEC-205 linked to the NY-ESO-1 tumor antigen. The NY-ESO-1 antigen is expressed in a variety of cancer cells. Targeting protein antigens to the DEC-205 receptor on dendritic cells was pioneered by the late Ralph Steinman, MD, a member of Celldex's Scientific Advisory Board. Dr. Steinman received the 2011 Nobel Prize in Physiology or Medicine for his discovery of the dendritic cell and its role in adaptive immunity. In preclinical studies, CDX-1401 has been shown to induce potent and broad immunity. The Phase 1 study of CDX-1401 is the first clinical study to demonstrate that an off-the-shelf vaccine that targets dendritic cells *in vivo* through DEC-205 can safely lead to robust humoral and cellular immunity when combined with TLR agonists in cancer patients - overcoming a significant challenge in the development of protein based vaccines.

"In the CDX-1401 study, we were able to translate the important preclinical work led by Dr. Steinman's lab into clinical benefit, generating protein specific immunity including both antibody and T cell responses in patients with advanced cancers known to express NY-ESO-1. This is an important milestone for the field of targeted vaccine development and for the development of CDX-1401 specifically. Importantly, some patients had evidence of clinical benefit with significant stable disease and measurable tumor shrinkage, despite their advanced stage of metastatic disease. The ability to target proteins to dendritic cells represents a promising approach for the next generation of vaccines against pathogens and cancer," said Madhav V. Dhodapkar, MBBS, Arthur H. and Isabel Bunker Professor of Medicine and Immunobiology, Chief of the Section of Hematology at the Department of Internal Medicine and Clinical Research Program Leader of the Hematology Program at Yale Cancer Center and the lead investigator of the study.

"CDX-1401 is at the forefront of a new generation of off-the-shelf dendritic cell targeted vaccines that Celldex believes hold significant promise as a platform for protein-based vaccines," said Tibor Keler, PhD, Chief Scientific Officer of Celldex Therapeutics. "The immunological and clinical data demonstrated in this study clearly support continued investigation and we plan to study additional combination regimens of CDX-1401 in melanoma and other indications where we believe a dendritic cell vaccine regimen could play an important role. We expect that a study sponsored by the Cancer Immunotherapy Trials Network will be initiated in 2013."

The results from the Phase 1 study of CDX-1401 were presented in a poster session entitled, "*A Phase 1 Trial of a Novel Vaccine Targeting NY-ESO-1 to the Dendritic Cell Receptor DEC-205 in Combination with Toll-like Receptor Agonists*" at the Society for Immunotherapy Annual Meeting on Friday, October 26, 2012 by Dr. Dhodapkar. The study was conducted at multiple centers including Yale Cancer Center, Henry Ford Hospital and Medical Group, Memorial Sloan Kettering Cancer Center, Weill Cornell Medical College, Providence Portland Medical Center, Mount Sinai Medical Center and the Carolina BioOncology Institute.

Study results:

The Phase 1 study of CDX-1401 assessed the safety, immunogenicity and clinical activity of escalating doses of CDX-1401 plus resiquimod and/or Poly ICLC in 45 patients with advanced malignancies (21 melanoma, six ovarian, five sarcoma, four non-small cell lung cancer, four colorectal, five other) that had progressed after any available curative and/or salvage therapies. 87% of patients had distant metastases at entry. 60% of patients had confirmed NY-ESO expression in archived tumor sample. Ten patients received multiple cycles of the treatment regimen (six weeks of treatment followed by a six week rest), including five patients who received three or more cycles. Eight patients completed two years on study and eight patients remain in follow-up. Thirteen patients maintained stable disease for up to 13.4 months with a median of 6.7 months. In addition, two patients had significant tumor shrinkage (-20% and -21% decrease in area of target lesions). Treatment was well-tolerated and there were no dose limiting toxicities.

Significant anti-NY-ESO-1 titers (up to 1:800,000) occurred in 79% (33/42) of evaluable patients. Approximately 54% of

patients with NY-ESO-1 positive tumors had anti-NY-ESO-1 titers at baseline and most increased after vaccination. Humoral responses were elicited in both NY-ESO-1 positive and negative patients. NY-ESO-1-specific T cell responses were absent or low at baseline, but increased post-vaccination in 53% (18/34) of evaluable patients, including both CD4 and/or CD8 T cell responses. Robust immune responses were observed with CDX-1401 with resiquimod and Poly ICLC alone and in combination. Importantly, a well-tolerated and immunogenic regimen has been identified to take forward into the future study.

About the CDX-1401 Vaccine

CDX-1401 is a next-generation, off-the-shelf, cancer vaccine designed to activate the patient's immune system against cancers that express the tumor marker, NY-ESO-1. The product consists of a fully human monoclonal antibody with specificity for the dendritic cell receptor DEC-205 genetically linked to the NY-ESO-1 tumor antigen. Celldex has accessed NY-ESO-1 through a licensing agreement with the Ludwig Institute for Cancer Research. By selectively delivering the NY-ESO-1 antigen to dendritic cells in the body, this product candidate is intended to induce robust immune responses against the antigen-expressing cancer cells.

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 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 (by Celldex and others) of rindopepimut (CDX-110), 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 limited cash reserves and 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 have initiated or plan to initiate; 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 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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