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Celldex Therapeutics' CDX-1401, CDX-301 Combination Generates Potent NY-ESO-1 Immune Responses in Patients with Melanoma

CDX-301's utility as a dendritic cell growth factor in combination therapy established

HAMPTON, N.J., June 04, 2016 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) announced today results from a Phase 2 clinical study evaluating CDX-1401 and CDX-301 in patients with malignant melanoma, which was conducted by the Cancer Immunotherapy Trials Network (CITN) under a Cooperative Research and Development Agreement (CRADA) between Celldex and the Cancer Therapy Evaluation Program of the National Cancer Institute. CDX-1401 is an NY-ESO-1-antibody fusion protein for immunotherapy, and CDX-301 (recombinant human Flt3 ligand) is a potent hematopoietic cytokine that uniquely expands dendritic cells and hematopoietic stem cells. Results from the study were presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago in a poster titled "A Phase 2, Open-label, Multicenter, Randomized Study of CDX-1401, a Dendritic Cell Targeting NY-ESO-1 Vaccine, in Patients with Malignant Melanoma Pre-Treated with CDX-301, a Recombinant Human Flt3 Ligand."

The study randomized 60 patients with resected stage IIb through IV melanoma into two cohorts (n=30 each) to assess whether the immune response to NY-ESO-1 elicited by CDX-1401 could be substantially increased by pre-treatment with CDX-301 to expand the number of dendritic cells, which are key cells in initiating immune responses. As this study was intended primarily for safety and immune endpoints, patients were not selected for NY-ESO-1 expression. Both treatment cohorts received four monthly cycles of CDX-1401 and poly-ICLC (Hiltonol®). Cohort 1 received pre-treatment with CDX-301 for the first two cycles, whereas Cohort 2 did not receive CDX-301. Both combination regimens were well tolerated, and no drug-related adverse events required discontinuation from treatment.

NY-ESO-1 specific T cell responses were significantly greater and developed earlier in Cohort 1 compared to Cohort 2. In addition, all patients in Cohort 1 (n=30) achieved a specific NY-ESO-1-specific T cell response compared to 22 out of 30 patients in Cohort 2. Substantial increases in innate immune cells (dendritic cells, natural killer cells and monocytes) and greater increases in antibody titer were observed in the CDX-301 pre-treated Cohort 1.

"The Cancer Immunotherapy Trials Network has prioritized CDX-301 as a dendritic cell growth factor. The current study validates that Flt3 ligand can greatly expand peripheral blood dendritic cells and is highly effective at immunizing cancer antigen specific T cells when combined with CDX-1401, the immunotherapy that delivers NY-ESO-1 to dendritic cells," said Martin "Mac" Cheever, M.D., a member of the Vaccine and Infectious Disease Division at Fred Hutchinson Cancer Research Center, Professor of Medicine at the University of Washington and Director of the Fred Hutch-based Cancer Immunotherapy Trials Network. "These results, which show rapid cellular immune responses in a majority of patients, should stimulate significant interest in what appears to be a highly applicable, effective immunologic approach."

"This study confirms that CDX-1401 is effective at driving NY-ESO-1 immunity and further shows the value of CDX-301 as a combination agent for enhancing tumor-specific immune responses," said Thomas Davis, M.D., Executive Vice President and Chief Medical Officer of Celldex Therapeutics. "With these results, we are initiating a targeted study in patients with NY-ESO-1 positive disease to determine if these enhanced immune responses can translate to improved clinical outcomes. This also provides exciting new opportunities for use of CDX-301 in other combination immunotherapy regimens."

The poster is available on the "Publications" page of the "Science" section of the Celldex website.

About CDX-301
CDX-301 (Flt3L) is a potent hematopoietic cytokine that has demonstrated a unique capacity to increase the number of circulating dendritic cells in both laboratory and clinical studies. In addition, CDX-301 has shown impressive results in models of cancer, infectious diseases and inflammatory/autoimmune diseases. Celldex believes this ligand may hold significant opportunity for synergistic development in combination with other proprietary molecules in the Company's portfolio.

About CDX-1401
CDX-1401 is an NY-ESO-1-antibody fusion protein for immunotherapy, which is designed to activate the patient's immune

system against cancers that express the tumor marker, NY-ESO-1. CDX-1401 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, CDX-1401 is intended to induce robust immune responses against the antigen-expressing cancer cells.

Hiltonol is a registered trademark of Oncovir, Inc.

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.

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 glembatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127) and other products and our goals for 2016. 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 or that those goals will be achieved, 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 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; our ability to maintain and derive benefit from the Fast Track designation for glembatumumab vedotin which does not change the standards for regulatory approval or guarantee regulatory approval on an expedited basis, or at all; 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 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.

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