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Celldex Presents Preliminary Cohort Data from Pilot Study of CDX-301 in Allogeneic Hematopoietic Stem Cell Harvest at the 2016 BMT Tandem Meeting

HAMPTON, N.J., Feb. 20, 2016 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today presented new clinical data on CDX-301 (recombinant human Flt3 ligand), a potent hematopoietic cytokine that uniquely expands dendritic cells and hematopoietic stem cells. An open label, pilot study of CDX-301, alone and in combination with Mozobil (plerixafor), in sibling-matched donors for allogeneic hematopoietic stem cell transplantation (HSCT) recipients who have certain hematologic malignancies is currently enrolling donor/patient pairs. Early data were presented in a poster entitled "Preliminary Safety and Efficacy Data using CDX-301 (Flt3 ligand) as a Sole Agent to Mobilize Hematopoietic Cells Prior to HLA-matched Sibling Donor Transplantation" at the 2016 BMT Tandem Meeting, the annual meeting of the American Society for Blood and Marrow Transplantation (ASBMT). The poster is available on the "Publications" page of the "Science" section of the Celldex website.

Three donor/patient pairs showed that CDX-301 given as a single agent for 5 days was well tolerated and effective at mobilizing hematopoietic stem cells in healthy donors. The stem cell graft contained notable increases in naïve lymphocytes and plasmacytoid dendritic cells compared to administration of G-CSF (granulocyte colony-stimulating factor) and is consistent with preclinical data suggesting a possible better outcome for recipients. Notably, no donors required rescue with either G-CSF or Mozobil in this arm of the study, and none experienced any grade 3 or 4 adverse events. Recipients experienced successful engraftment in an expected time frame. Additional donor/patient pairs are being accrued to a second, planned cohort in order to assess the potential synergies and feasibility of combining CDX-301 with Mozobil in this setting.

"From these data and preclinical studies, CDX-301 appears to be an effective, targeted approach to mobilization comparable to G-CSF. With a relatively short course of treatment, we are observing specificity for mobilized stem cells and a lack of toxicity, instead of broad cellular mobilization and side effects," said Steven Devine, M.D., Professor of Internal Medicine, Division of Hematology, Department of Internal Medicine, and Program Director, Blood and Marrow Transplant Program at The Ohio State Comprehensive Cancer Center.

"CDX-301 shows a favorable safety profile and effectively mobilizes early stem cells when used alone, and we expect even greater yields in the next cohort where we combine with Mozobil," said Thomas Davis, M.D., Executive Vice President and Chief Medical Officer of Celldex Therapeutics . "CDX-301 could potentially provide good engraftment, less graft-versus-host disease and mitigated side effects, which would be a breakthrough for these patients undergoing HSCT. We are also looking forward to receiving data from investigators who are using CDX-301 in other drug combination studies designed to assess its potential in immunotherapy for cancer and other indications."

In addition, CDX-301 has shown impressive results in models of cancer, infectious diseases, inflammatory/autoimmune diseases and immune suppression. Celldex believes CDX-301 may hold significant opportunity for synergistic development in combination with other proprietary molecules in the Company's portfolio and in external development. CDX-301 is in clinical development for cancers in combination with vaccines, adjuvants, and other treatments that result in release of tumor antigens to enhance tumor immunogenicity.

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 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 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 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; our ability to maintain and derive benefit from the Breakthrough Therapy Designation for RINTEGA, 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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