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Celldex Therapeutics Initiates Pilot Study of CDX-301 in Allogeneic Hematopoietic Stem Cell Transplantation

HAMPTON, N.J., Sept. 25, 2014 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today announced the initiation of a pilot study of CDX-301 for the mobilization and transplantation of allogeneic hematopoietic stem cells in patients with hematological malignancies undergoing hematopoietic stem cell transplantation (HSCT). The study will explore the utility of CDX-301, also known as FMS-like tyrosine kinase-3 ligand or Flt3L, alone and in combination with Mozobil® and is supported by preclinical data demonstrating that the combination of CDX-301 and Mozobil increased hematopoietic stem cell mobilization and improved transplantation of mobilized cells.

The open-label, pilot study will enroll up to 36 participants, or 18 recipient/donor pairs, ages 18 to 65 across two sequentially enrolled cohorts in approximately 10 clinical trial sites in the United States. Study participants include patients (recipients) with specified hematologic malignancies (AML, ALL, MDS, CML, NHL and CLL) and Human Leukocyte Antigen (HLA) sibling-matched healthy volunteers (donors). The primary objective is to assess the safety and tolerability of CDX-301 when given with or without Mozobil. Secondary endpoints will evaluate the adequacy of the resultant grafts as determined by CD34+ yield, the cellular composition of the resultant grafts, and the safety and effectiveness of the resulting grafts across multiple measures.

"Improvements in stem cell mobilization are needed to enhance the potency of hematopoietic stem cell grafts and lower the risk of graft-versus-host disease," said Steven Devine, MD, Professor of Internal Medicine and Director, Blood and Marrow Transplant Program, The Ohio State University Comprehensive Cancer Center. "This study will determine whether CDX-301 alone or in combination with Mozobil can improve the stem cell transplant process, leading to better, safer outcomes for current transplant candidates and potentially expanding the procedure to an even broader range of donors and candidates across a number of malignant and non-malignant indications in the future." Dr. Devine and his team led the preclinical work evaluating CDX-301 and Mozobil for hematopoietic stem cell mobilization and transplantation and played an integral role in generating data and developing the design of this pilot study.

"CDX-301 appears to function as a key immune regulator, both activating and disarming the immune system as needed," said Tom Davis, MD, Executive Vice President and Chief Medical Officer of Celldex Therapeutics. "CDX-301 has broad potential to support and control immune function across multiple indications including cancer immunotherapy, marrow disorders like sickle cell disease, immunosuppression from trauma, burns and radiation, and even autoimmunity. We look forward to assessing the activity of CDX-301 in this initial setting and expanding the program, including in combination with a number of internal programs, over time."

Mozobil is a registered trademark of sanofi-aventis U.S. LLC.

About CDX-301

CDX-301 (Flt3L) is a potent hematopoietic cytokine currently in Phase 2 development that stimulates the expansion and differentiation of hematopoietic progenitor and stem cells. CDX-301 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 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 rindopepimut ("rindo"; CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127), CDX-1401, CDX-301 and other products and our goals for 2014. 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 rindopepimut, 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; 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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