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Celldex Therapeutics Initiates Pilot Study in Dense Deposit Disease

PHILLIPSBURG, N.J., July 1, 2013 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported that the first patient has been dosed in the Company's pilot study of CDX-1135 (a soluble form of human complement receptor type 1) in dense deposit disease (DDD). DDD is an ultra-rare, progressive kidney disease that ultimately results in kidney failure in the majority of affected individuals. DDD is caused by dysregulation of the C3 Convertase, a major early component of the alternative pathway of complement. CDX-1135 has been shown to inhibit complement activation and has yielded promising results in an animal model of DDD and in a single patient with DDD that was treated under a compassionate use protocol.

The open-label study will enroll up to five patients (ages four and older) from clinical centers across the United States to determine the CDX-1135 dose level required to normalize alternative complement activity on an individual patient basis. Potential effects on renal function will also be assessed. Patients will initially be treated at the University of Iowa under the leadership of Richard J.H. Smith, MD and Carla M. Nester, MD. If selected complement levels normalize on therapy, patients may be able to return to their local treatment center to continue in the study. Dr. Smith, a widely recognized expert in DDD, is Professor of Otolaryngology and Internal Medicine and the Director of the Molecular Otolaryngology and Renal Research Laboratories (MORL) at the University of Iowa. MORL maintains the largest DDD patient database in the world. Dr. Nester, also a member of MORL, is an Assistant Professor at the University of Iowa, trained in adult and pediatric nephrology.

"CDX-1135 is a much needed and exciting entrant to the dense deposit disease field," said Dr. Smith. "There are currently no treatments and nearly half of all patients progress to end-stage renal disease within 10 years of presentation, often spending the rest of their lives on dialysis. In a mouse model of dense deposit disease, CDX-1135 has been shown to control the abnormal complement activity and to reduce deposits in the kidneys. Short term use of CDX-1135 in a patient with dense deposit disease and end-stage renal disease was well-tolerated and normalized the activity of the alternative complement pathway. We are optimistic that if we can control complement activation earlier in the disease course and at a critical step in the complement pathway, CDX-1135 may be able to restore kidney function and provide long term disease control—a long-awaited outcome for patients, their families and physicians."

Dr. Thomas Davis, Chief Medical Officer of Celldex, added, "Based on research to date in dense deposit disease and other indications, we believe CDX-1135 has the potential to play an important role in complement mediated diseases, uniquely in indications where the C3 Convertase is very active leading to a consumption of C3 and deposition of harmful breakdown products onto the kidney. We look forward to completing this study in dense deposit disease and, with positive results, given the unmet need for these patients, we will seek to expand the CDX-1135 program into a larger study in dense deposit disease as quickly as possible."

About Dense Deposit Disease:

Dense Deposit Disease (DDD) is a rare kidney disease affecting two persons per million. DDD is caused by uncontrolled activation of the alternative pathway of complement, which leads to the consumption of the circulating complement component C3, deposition of C3 and other proteins in the kidneys, and subsequent damage to kidney function. Approximately 50% of patients with dense deposit disease progress to end stage renal disease (ESRD) within 10 years of diagnosis. Patients diagnosed at a younger age (≤ 12 years old) are more likely to progress to ESRD and progress more rapidly (typically within 4 years). Kidney transplantation is not a viable option because DDD recurs in virtually all patients who receive a transplant. There are no treatments at this time for DDD.

About CDX-1135:

CDX-1135 is soluble complement receptor type 1 (sCR1), a recombinant human protein made in mammalian cell cultures that is a potent inhibitor of complement activation, including the classical, lectin and alternative complement pathways, both at the early (C3) and late (C5) activation steps in these pathways. Previous clinical studies of CDX-1135 in more than 500 patients in other indications have suggested that CDX-1135 has a favorable safety profile and is a potent inhibitor of the complement pathway. In dense deposit disease, CDX-1135 has been shown to control the activation of alternative pathway complement in patient serum samples *in vitro*. In a mouse model of DDD, the administration of CDX-1135 was shown to control complement activation *in vivo*, preventing the damaging deposition of C3 in the kidneys. Short term compassionate use of CDX-1135 in a patient with DDD also showed control of complement abnormalities. This patient was already in renal

failure requiring dialysis and so reversal of disease was not expected. The newly initiated pilot study is exploring the potential for clinical benefit in patients with earlier stage DDD, where C3 consumption and deposition play an important role in disease progression, and where the greatest potential to restore kidney function and provide long term disease control exists.

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 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 (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 ability to successfully complete research and further development and commercialization of rindopepimut, CDX-011 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; our ability to adapt our 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.

CONTACT: Sarah Cavanaugh

Vice President of IR & Corp Comm

Celldex Therapeutics, Inc.

(781) 433-3161

scavanaugh@celldextherapeutics.com

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