December 15, 2014

Celldex Announces Completion of Enrollment in Phase 3 Study of Rindopepimut in Frontline Glioblastoma

HAMPTON, N.J., Dec. 15, 2014 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) announced today that patient enrollment has been completed in the Company's Phase 3 ACT IV study of rindopepimut in EGFR*vIII* positive glioblastoma, an aggressive form of brain cancer.

"We are extremely grateful to the ACT IV investigators and the patients and families who supported this trial," said Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics. "ACT IV is the most comprehensive study conducted by a biotech company to date in this orphan disease and by far the largest study ever conducted in the EGFR*vIII* patient population. With a strong scientific rationale and consistent, supportive data from three Phase 2 studies in the frontline setting and the ReACT study in the recurrent setting, we believe rindopepimut holds significant promise as a potential new treatment for patients with this devastating disease."

The ACT IV study is a randomized, double-blind, placebo controlled study of rindopepimut plus GM-CSF added to standard of care temozolomide in patients with newly diagnosed, surgically resected, EGFR*vIII*-positive glioblastoma. In total, over 4,800 patients were screened for EGFR*vIII* status from more than 200 clinical trial sites across 22 countries and, consistent with prior studies, 30% were positive for the EGFR*vIII* mutation. 745 patients were enrolled into ACT IV to reach the required 374 patients with minimal residual disease (assessed by central review) needed for analysis of the primary overall survival endpoint. All patients, including patients with disease that exceed this threshold, will be included in a secondary analysis of overall survival as well as analyses of progression-free survival, safety and tolerability, and quality of life. The timing of the overall survival primary endpoint data is event-driven. Interim analyses will be conducted by an independent Data Safety and Monitoring Board at 50 and 75% of events. The first interim analysis is expected in mid-2015 and will provide insight into the frequency of events to inform estimates regarding timing for the second interim and final data read out.

The ACT IV study was designed with formal input from both the United States Food and Drug Administration and the European Medicines Agency. Rindopepimut has received Fast Track Designation in the United States and Orphan Drug Designation in both the United States and the European Union.

About Rindopepimut

Rindopepimut is an investigational immunotherapy that targets the tumor specific oncogene EGFR*vIII* (v3), a functional and permanently activated variant of the epidermal growth factor receptor (EGFR), a protein that has been well validated as a target for cancer therapy. Expression of EGFR*vIII* correlates with increased tumorigenicity in mouse models and poor long term survival in clinical studies of patients with glioblastoma (GBM). In addition, EGFR*vIII*-positive cells are believed to stimulate proliferation of non-EGFR*vIII* cells through IL-6 cell-to-cell signaling and to release microvesicles containing EGFR*vIII*, which can merge with neighboring cells, transferring tumor-promoting activity. EGFR*vIII* expression may also be associated with tumor stem cells that have been identified in GBM. These stem cells contribute to resistance to cytotoxic therapy and tumor recurrence. EGFR*vIII* is expressed in tumors in about 30% of patients with GBM. It has not been detected at a significant level in normal tissues; therefore, targeting of this tumor-specific molecule is not likely to impact healthy tissues.

Three Phase 2 trials of rindopepimut—ACTIVATE, ACT II, and ACT III—have been completed in newly diagnosed EGFR*vIII*-positive GBM and have shown consistent improvements in both overall survival and median progression-free survival. The most common adverse events for rindopepimut include injection site reactions, fatigue, rash, nausea and pruritus. Rindopepimut is currently being studied in two clinical trials in EGFR*vIII*-positive GBM—an international Phase 3 study called ACT IV in newly diagnosed GBM and a Phase 2 study called ReACT in recurrent GBM.

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 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.

CONTACT: Company Contact:

Sarah Cavanaugh

Vice President of Investor Relations &

Corp Communications

Celldex Therapeutics, Inc.

(781) 433-3161

scavanaugh@celldex.com

Media Inquiries:

Dan Budwick

Pure Communications, Inc.

(973) 271-6085

dan@purecommunicationsinc.com

Celldex Therapeutics logo

Source: Celldex Therapeutics, Inc.