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Celldex's Rindopepimut (Rintega(R)) Receives FDA Breakthrough Therapy Designation for the Treatment of Adult Patients with EGFRvIII-positive Glioblastoma

HAMPTON, N.J., Feb. 23, 2015 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today announced that the U.S. Food and Drug Administration (FDA) has granted rindopepimut (Rintega®) Breakthrough Therapy Designation for the treatment of adult patients with EGFRvIII-positive glioblastoma (GBM).

This application was based on data from the Phase 2 ReACT study in recurrent GBM, the Phase 2 ACT III study in newly diagnosed GBM and additional supportive Phase 2 studies. An international Phase 3 study of rindopepimut, called ACT IV, in newly diagnosed GBM completed enrollment (n=745) in December of 2014.

"The FDA's decision to grant Breakthrough Designation underscores rindopepimut's therapeutic potential for patients with glioblastoma," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "These patients have extremely limited treatment options, with only three new drugs approved in more than twenty years. Emerging clinical data suggests that rindopepimut may offer an improvement over existing standard of care for EGFRvIII-positive patients. With continued positive data, we look forward to working closely with the FDA to support potential approval of rindopepimut as expeditiously as possible."

According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

Rindopepimut (Rintega) is an investigational immunotherapy that targets the tumor specific oncogene EGFRvIII. Patients with EGFRvIII-positive glioblastoma typically have a worse prognosis than the overall glioblastoma population, including poor long term survival.

About Rindopepimut

Rindopepimut (Rintega®) is an investigational immunotherapy that targets the tumor specific oncogene EGFRvIII (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 EGFRvIII correlates with increased tumorigenicity in mouse models and poor long term survival in clinical studies of patients with glioblastoma (GBM). In addition, EGFRvIII-positive cells are believed to stimulate proliferation of non-EGFRvIII cells through IL-6 cell-to-cell signaling and to release microvesicles containing EGFRvIII, which can merge with neighboring cells, transferring tumor-promoting activity. EGFRvIII 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. EGFRvIII 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 EGFRvIII-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 EGFRvIII-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 future development and commercialization (by Celldex and others) of Rintega® ("rindopepimut"; "rindo"; CDX-110). 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; 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 rindopepimut, 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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