



March 7, 2016

Data Safety and Monitoring Board Recommends Celldex's Phase 3 Study of RINTEGA® (rindopepimut) in Newly Diagnosed Glioblastoma be Discontinued as it is Unlikely to Meet Primary Overall Survival Endpoint in Patients with Minimal Residual Disease

--Conference Call Scheduled for 8:00 AM ET Today--

HAMPTON, N.J., March 07, 2016 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that the independent Data Safety and Monitoring Board (DSMB) has determined, based on a preplanned interim analysis, that continuation of the Phase 3 ACT IV study of RINTEGA® (rindopepimut) in patients with newly diagnosed EGFRvIII-positive glioblastoma will not reach statistical significance for overall survival in patients with minimal residual disease, the primary endpoint of the study, as both the RINTEGA arm and the control arm are performing on par with each other. In the ACT IV study, RINTEGA has performed consistently with prior Phase 2 studies but the control arm has significantly outperformed expectations (Hazard ratio = 0.99; median OS: RINTEGA 20.4 months vs. control 21.1 months). Based on this recommendation, Celldex is discontinuing the study and does not anticipate incurring substantial additional costs related to RINTEGA at this time. All patients on the RINTEGA arm of the ACT IV study, prior Phase 2 studies and existing compassionate use recipients will be offered ongoing access to RINTEGA on a compassionate use basis. Celldex first received the data after market close on Friday, March 4th and is in the process of reviewing the results.

"We are extremely disappointed for patients that the ACT IV study was not successful," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "On behalf of Celldex, I want to express our gratitude to the ACT IV investigators, patients and families who participated in this trial. While this is certainly not the desired outcome, we remain steadfast believers in the power of immunotherapy to transform the future of cancer treatment."

Celldex currently has seven company-led clinical trials across five product candidates ongoing. The Company expects to report data from a number of these studies over the next three to 18 months, including a registration study in triple negative breast cancer and a number of Phase 1 and 2 cancer immunotherapy combination trials.

Conference Call Details:

Celldex executives will host a conference call at 8:00 a.m. ET today. It will be webcast live over the Internet and can be accessed by going to the "Events & Presentations" page under the "Investors & Media" section of the Celldex Therapeutics website at www.celldex.com. The call can also be accessed by dialing (866) 743-9666 (within the United States) or (760) 298-5103 (outside the United States). The passcode is 66780816.

A replay of the call will be available approximately two hours after the live call concludes through March 14, 2016. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 66780816. The webcast will also be archived on the Company's website.

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 discontinuation of the ACT IV study of RINTEGA® (rindopepimut), future costs associated with RINTEGA, the Company's ability to offer RINTEGA on a compassionate use basis; and research and development related to the Company's other product candidates, and our expectations that data will be reported over the next 18 months with respect to other product candidates. 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 continue or complete research and further development of product

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 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 terminate, reduce or cancel any contractual agreement or arrangement relating to RINTEGA; 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.

Company Contact:

Sarah Cavanaugh
Vice President of Investor Relations & Corp Communications
(781) 433-3161
scavanaugh@celldex.com

Charles Liles
Manager of Investor Relations & Corp Communications
(781) 433-3107
cliles@celldex.com

Media Inquiries:

Dan Budwick
Pure Communications, Inc.
(973) 271-6085
dan@purecommunicationsinc.com

 [Primary Logo](#)

Source: Celldex Therapeutics, Inc.

News Provided by Acquire Media