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Celldex Announces Completion of Enrollment in Phase 2b Study of Glembatumumab Vedotin in Triple Negative Breast Cancer

HAMPTON, N.J., Aug. 23, 2017 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) announced today that patient enrollment has been completed in the Company's Phase 2b METRIC study of glembatumumab vedotin in patients with metastatic triple negative breast cancers that overexpress gpNMB. Glembatumumab vedotin is an antibody-drug conjugate that targets and binds to gpNMB, a protein expressed by multiple tumor types, including breast cancer. Overexpression of gpNMB has been shown to promote the migration, invasion and metastasis of the disease. It is highly expressed in triple negative breast cancers, where it is associated with increased risk of recurrence and poor clinical outcome.

"We are extremely grateful to the METRIC investigators and the patients and families who supported this trial," said Anthony Marucci, Co-Founder, President and Chief Executive Officer of Celldex Therapeutics. "Patients with triple negative breast cancer have very limited treatment options. We believe glemba holds significant promise as a potential new targeted treatment for patients with this devastating disease and look forward to topline data, likely in the second quarter of 2018."

The METRIC study is a randomized Phase 2b study of glembatumumab vedotin in patients with metastatic triple negative breast cancers that overexpress gpNMB. In this indication, overexpression is defined as greater than or equal to 25% of tumor cells testing positive for gpNMB. Patients are randomized 2 to 1 to either glembatumumab vedotin or to capecitabine, also known by the tradename Xeloda®, as a comparator. In total, 327 patients were enrolled into METRIC. The primary endpoint of the study is progression-free survival (PFS), which is defined as the time from randomization to the earlier of disease progression or death due to any cause. The study calls for 203 progression events for evaluation of the primary endpoint, which will be assessed based on an independent, central reading of patient scans. The sum of the data, including the secondary endpoints of response rate, overall survival, duration of response and safety, will be important in assessing clinical benefit. The Company projects that topline primary endpoint data should be available in the second quarter of 2018, but it could occur earlier or later based on the rate of events in the study.

Xeloda® is a registered trademark of Genentech, Inc.

About Glembatumumab Vedotin

Glembatumumab vedotin is a fully human monoclonal antibody-drug conjugate (ADC) that targets glycoprotein NMB (gpNMB). gpNMB is a protein overexpressed by multiple tumor types, including breast cancer, melanoma, lung cancer, uveal melanoma and osteosarcoma. gpNMB has been shown to be associated with the ability of the cancer cell to invade and metastasize and to correlate with reduced time to progression and survival in breast cancer. The gpNMB-targeting antibody, CR011, is linked to a potent cytotoxic, monomethyl auristatin E (MMAE), using Seattle Genetics' proprietary technology. Glembatumumab vedotin is designed to be stable in the bloodstream but to release MMAE upon internalization into gpNMB-expressing tumor cells, resulting in a targeted cell-killing effect. Glembatumumab vedotin is in development for the treatment of locally advanced or metastatic breast cancer with an initial focus in triple negative disease, stage III and IV melanoma, squamous cell lung cancer and uveal melanoma.

About Celldex Therapeutics, Inc.

Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline includes antibodies, antibody-drug conjugates and other protein-based therapeutics derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors to treat specific types of cancer or other diseases. 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. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These 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 or that those goals will be achieved, 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 glembatumumab vedotin and other Company 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 realize the anticipated benefits from the acquisition of Kolltan and to operate the combined business efficiently; 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 Fast Track designation for glembatumumab vedotin 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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