



April 16, 2018

## **Celldex's METRIC Study in Metastatic Triple-negative Breast Cancer Does Not Meet Primary Endpoint**

### **Conference Call Scheduled for 8:00 a.m. ET Today**

HAMPTON, N.J., April 16, 2018 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported that the Company's randomized, Phase 2b METRIC Study of glebatumumab vedotin compared to Xeloda<sup>®</sup> (capecitabine) in patients with metastatic triple-negative breast cancers that overexpress gpNMB failed to meet its primary endpoint, progression-free survival (PFS) as assessed by an independent, central reading of patient scans (Hazard ratio = 0.95; median PFS: glebatumumab vedotin 2.9 months vs. Xeloda 2.8 months; p=0.76). There was no significant advantage for glebatumumab vedotin in key secondary endpoints, including overall response rate, duration of response and overall survival. The glebatumumab vedotin safety profile was consistent with prior experience.

"Triple-negative breast cancer is a very difficult disease to treat, and we are extremely disappointed for patients that the METRIC 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 METRIC investigators, patients and families who participated in this study. Based on these results, we have also made the decision to discontinue the glebatumumab vedotin program across all indications and are currently prioritizing our pipeline, which includes five candidates in ongoing clinical studies. In line with this, we are evaluating our operational and workforce needs to extend our financial resources and direct them to continued pipeline advancement. Once we solidify these plans, we intend to update investors."

Celldex's clinical-stage pipeline includes the following compounds:

- ┆ Varlilumab, a CD27 agonist, currently completing a Phase 2 study in combination with Opdivo<sup>®</sup> in multiple indications with data expected to be presented at multiple medical meetings in 2018;
- ┆ CDX-3379, an ErbB3 inhibitor, which is expected to complete enrollment in the first stage of a Phase 2 study in combination with Erbitux<sup>®</sup> in head and neck cancer during the third quarter of 2018;
- ┆ CDX-014, a TIM-1 targeted agent, which is actively enrolling patients in a Phase 1 study in renal cell and ovarian clear cell carcinomas;
- ┆ CDX-1140, a CD40 agonist, which is actively enrolling patients in a Phase 1 study in various solid tumors; and,
- ┆ CDX-301, a dendritic cell mobilizer, currently being studied in an investigator-sponsored study in combination with radiation therapy in advanced non-small cell lung cancer. Data from this study were presented in a plenary session at the AACR Annual Meeting on Sunday, April 15, 2018.

Celldex believes its pipeline prioritization and organizational restructuring efforts will extend financial resources beyond the guidance issued in the Company's year-end 2017 earnings press release and associated filings. The Company plans to provide revised guidance in its first quarter 2018 financial results in early May.

### **Webcast and Conference Call**

Celldex executives will host a conference call at 8:00 a.m. ET today to discuss topline METRIC results. The conference call 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](http://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 7786951.

A replay of the call will be available approximately two hours after the live call concludes through April 23, 2018. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 7786951. The webcast will also be archived on the Company's website.

### **About METRIC**

The METRIC study is a randomized Phase 2b study of glebatumumab 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 were randomized 2 to 1 to either glebatumumab vedotin or to capecitabine, also known by the tradename Xeloda<sup>®</sup>, 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, assessed based on an independent, central reading of patient scans, or death due to any cause. The study called for 203 progression events for evaluation of the primary endpoint. The sum of the data, including the secondary endpoints of response rate, overall survival, duration of response and safety, are also important in assessing clinical benefit.

#### **About Glebatumumab Vedotin**

Glebatumumab 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. The gpNMB-targeting antibody, CR011, is linked to a potent cytotoxic, monomethyl auristatin E (MMAE), using Seattle Genetics' proprietary technology. Glebatumumab 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.

*Xeloda<sup>®</sup> is a registered trademark of Genentech, Inc. Opdivo<sup>®</sup> is a registered trademark of Bristol-Myers Squibb. Erbitux<sup>®</sup> is a registered trademark of Eli Lilly & Co.*

#### **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](http://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 our discontinuation of our glebatumumab vedotin program across all indications, prioritizing our pipeline, evaluating our operational and workforce needs to extend our financial resources, research and development related to our remaining clinical-stage pipeline and other product candidates, and our expectations that data will be reported in 2018 with respect to certain of those programs. 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 continue or complete research and further development and commercialization of our 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; the failure of the market for our programs to continue to develop; our ability to terminate, reduce or cancel any contractual agreement or arrangement relating to glebatumumab vedotin; our ability to protect our 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 our drug candidates or programs; 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.

#### **Company Contact:**

Sarah Cavanaugh  
Senior Vice President, Corporate Affairs & Administration  
(781) 433-3161  
[scavanaugh@celldex.com](mailto:scavanaugh@celldex.com)

Charles Liles  
Associate Director, Investor Relations & Corp Communications

(617) 383-3433  
[cliles@celldex.com](mailto:cliles@celldex.com)

**Media Inquiries:**

Dan Budwick  
Founder, 1AB Media  
(973) 271-6085  
[dan@1abmedia.com](mailto:dan@1abmedia.com)