March 7, 2018

Celldex Provides Corporate Update and Reports Full Year 2017 Results

Conference Call Scheduled for 4:30 p.m. ET Today

HAMPTON, N.J., March 07, 2018 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the fourth quarter and year ended December 31, 2017. The Company will host a conference call at 4:30 p.m. ET today to provide an in-depth update on its pipeline and upcoming milestones for 2018.

"2017 was a significant year for Celldex. Notably we completed enrollment in the METRIC study of glembatumumab vedotin for patients with triple negative breast cancer whose tumors overexpress gpNMB. We are hopeful that glemba will offer patients, families and caregivers a potential new option, where there are few approved therapies and none that target gpNMB, which is associated with a more aggressive form of the disease," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "We anticipate topline primary endpoint data from the study will be available in the second quarter of 2018."

"We also made considerable progress across our pipeline in the fourth quarter, including initiating the Phase 2 study of CDX-3379 in combination with Erbitux for patients with advanced head and neck squamous cell carcinoma and the Phase 1 study of CDX-1140, a CD40 agonist antibody that we believe holds great potential as an immune activating agent. Both of these antibodies are engineered to be best-in-class molecules. Recently, we completed enrollment in the glemba plus checkpoint inhibitor cohort in our Phase 2 metastatic melanoma study and also in all cohorts in the varlilumab plus Opdivo collaborative Phase 2 study with BMS. In 2018, we expect to present data across multiple programs and execute across our clinical pipeline of novel biologics to improve outcomes and change the standard of care for patients who suffer from life-threatening diseases."

Recent Highlights

- **Topline primary endpoint data from the METRIC study of glembatumumab vedotin in triple negative breast cancer anticipated in the second quarter of 2018:** Enrollment was closed in August 2017 with 327 patients whose tumors overexpressed gpNMB. Patients were randomized 2 to 1 to either glembatumumab vedotin or to Xeloda® (capecitabine). 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 (OS), duration of response and safety, will be important in assessing clinical benefit. Efforts to ensure delivery of manufactured drug that is ready for commercialization and a companion diagnostic are underway. As previously disclosed, Celldex made the decision to stage some of the more costly work in these areas to begin after the Company has received results from the study. Assuming positive data, Celldex plans to work with the FDA on a regulatory strategy that would support submitting a Biologics License Application (BLA) in the second half of 2019.

- **Fourth arm added to glembatumumab vedotin Phase 2 study in metastatic melanoma:** Enrollment has opened in a glembatumumab vedotin plus CDX-301 cohort for patients who failed checkpoint therapy. Enrollment recently completed in the glembatumumab vedotin plus checkpoint inhibitor cohort.

- **Enrollment complete in Phase 2 varlilumab/Opdivo® collaborative study:** Enrollment was completed in January 2018. Cohorts include colorectal cancer (n=21), ovarian cancer (n=58), head and neck squamous cell carcinoma (n=24), renal cell carcinoma (n=14) and glioblastoma (n=22). The primary objective of the Phase 2 cohorts is objective response rate (ORR), except glioblastoma, where the primary objective is the rate of 12-month OS. Secondary objectives include pharmacokinetic assessments, determining the immunogenicity of varlilumab when given in combination with Opdivo, evaluating alternate dosing schedules of varlilumab and further assessing the anti-tumor activity of combination treatment. Working with Bristol-Myers Squibb, data from the study will be presented at appropriate medical meetings in 2018.

- **Initiated Phase 2 study of CDX-3379/Erbitux® in head and neck squamous cell carcinoma:** In November 2017, Celldex opened enrollment to an open-label Phase 2 study in combination with Erbitux in approximately 30

patients with HPV negative, Erbitux-resistant, advanced head and neck squamous cell carcinoma. Patients must have been treated previously with an anti-PD1 checkpoint inhibitor, a population with limited options and a particularly poor prognosis. The primary objective of the study is ORR. Secondary objectives include assessments of clinical benefit rate, duration of response, PFS and OS, and safety and pharmacokinetics associated with the combination.

- **Ongoing Phase 1 study of CDX-014 expanded to include patients with ovarian cancer:** Enrollment is ongoing in a Phase 1 study of CDX-014, an antibody-drug conjugate that targets TIM-1. The study initially enrolled patients with both clear cell and papillary renal cell carcinoma. In January 2018, we amended the protocol, expanding enrollment to include patients with ovarian clear cell carcinoma, an indication where TIM-1 expression is also upregulated, and enabling the evaluation of alternate dosing regimens. The study includes a dose-escalation portion across three separate cohorts to determine the maximum tolerated dose (MTD) followed by expansion cohorts of up to 15 patients each to assess the preliminary anti-tumor activity of CDX-014, as measured by ORR. Secondary objectives include safety and tolerability, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity.

- **Initiated Phase 1 study of CDX-1140:** A Phase 1 study of CDX-1140 was initiated in November 2017. The study is expected to enroll up to approximately 105 patients with recurrent, locally advanced or metastatic solid tumors and is designed to determine the MTD during a dose-escalation phase and to recommend a dose level for further study in a subsequent expansion phase. The expansion is designed to further evaluate the tolerability and biologic effects of selected dose(s) of CDX-1140 in specific tumor types. Secondary objectives include assessments of safety and tolerability, pharmacodynamics, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity, including clinical benefit rate. The Company believes that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments.

Fourth Quarter and Twelve Months 2017 Financial Highlights and 2018 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2017 were $139.4 million compared to $140.5 million as of September 30, 2017. The decrease was primarily driven by fourth quarter cash used in operating activities of $19.5 million and partially offset by $18.4 million in net proceeds from sales of common stock under the Cantor agreement. At December 31, 2017, Celldex had 138.5 million shares outstanding.

Revenues: Total revenue was $3.5 million in the fourth quarter of 2017 and $12.7 million for the year ended December 31, 2017, compared to $1.9 million and $6.8 million for the comparable periods in 2016. The increase in revenue was primarily due to the manufacturing service agreements with the International AIDS Vaccine Initiative and Frontier Biotechnologies, Inc.

R&D Expenses: Research and development (R&D) expenses were $23.5 million in the fourth quarter of 2017 and $96.2 million for the year ended December 31, 2017, compared to $24.6 million and $102.7 million for the comparable periods in 2016. The decrease in R&D expenses for the year ended December 31, 2017, as compared to 2016, was primarily due to lower contract manufacturing and clinical trial costs of $9.9 million and $7.6 million, respectively, related to varlilumab and Rintega. These decreases were partially offset by increases in (i) glembatumumab vedotin contract manufacturing expenses of $2.7 million, (ii) glembatumumab vedotin, anti-KIT and CDX-3379 clinical trial costs of $3.6 million and (iii) personnel and facility costs related to the Kolltan acquisition.

G&A Expenses: General and administrative (G&A) expenses were $5.9 million in the fourth quarter of 2017 and $25.0 million for the year ended December 31, 2017, compared to $11.9 million and $36.0 million for the comparable periods in 2016. The decrease in G&A expenses for the year ended December 31, 2017, as compared to 2016, was primarily due to lower commercial planning costs of $4.5 million, lower stock-based compensation of $1.9 million and lower severance expense related to the Kolltan acquisition of $2.6 million.

In-Process Research and Development Impairment: The Company recorded a non-cash partial impairment charge of $13.0 million on the anti-KIT program IPR&D asset acquired from Kolltan during the year ended December 31, 2017 due to changes in the anti-KIT program projected development and regulatory timelines.

Income Tax Benefit: The Company recorded a non-cash income tax benefit of $24.3 million during the year ended December 31, 2017 relating to the partial impairment of the anti-KIT program IPR&D asset and the impact of the Tax Cuts and Jobs Act of 2017.

Gain on Fair Value Remeasurement of Contingent Consideration: The Company recorded a gain on the fair value remeasurement of contingent consideration related to the Kolltan acquisition of $0.8 million for the year ended December 31, 2017.

Net Loss: Net loss was $3.8 million, or ($0.03) per share, for the fourth quarter of 2017 and $93.0 million, or ($0.72) per share, for the year ended December 31, 2017, compared to a net loss of $32.3 million, or ($0.30) per share, and $128.5

million, or ($1.27) per share, for the comparable periods in 2016.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at December 31, 2017 combined with the (i) $6.1 million in net proceeds from sales of common stock under the Cantor agreement from January 1, 2018 through February 28, 2018 and (ii) anticipated proceeds from future sales of common stock under the Cantor agreement, are sufficient to meet estimated working capital requirements and fund planned operations through 2019. This could be impacted by clinical data results from the METRIC study and their impact on the pace of commercial manufacturing and the rate of expansion of commercial operations. This could also be impacted if Celldex elects to pay Kolltan contingent milestones, if any, in cash.

Webcast and Conference Call

Celldex executives will host a conference call at 4:30 p.m. ET today to discuss financial and business results and to provide an update on key 2018 objectives. The conference call and presentation 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 8296067.

A replay of the call will be available approximately two hours after the live call concludes through March 15, 2018. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 8296067. The webcast will also be archived on the Company's website.

Xeloda® is a registered trademark of Genentech, Inc. Opdivo® is a registered trademark of Bristol-Myers Squibb. Erbitux® 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.

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.

CELLDEX THERAPEUTICS, INC.
(In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
	(Unaudited)			
REVENUES:				
Product Development and Licensing Agreements	$ 665	$ 623	$ 3,153	$ 2,174
Contracts and Grants	2,791	1,251	9,590	4,612
Total Revenue	3,456	1,874	12,743	6,786
OPERATING EXPENSES:				
Research and Development	23,464	24,558	96,171	102,726
General and Administrative	5,894	11,933	25,003	35,979
In-Process Research and Development Impairment	-	-	13,000	-
Gain on Fair Value Remeasurement of Contingent Consideration	(600)	-	(800)	-
Amortization of Acquired Intangible Assets	224	235	896	997
Total Operating Expense	28,982	36,726	134,270	139,702
Operating Loss	(25,526)	(34,852)	(121,527)	(132,916)
Investment and Other Income, Net	2,603	2,545	4,214	4,386
Net Loss Before Income Tax Benefit	(22,923)	(32,307)	(117,313)	(128,530)
Income Tax Benefit	19,082	-	24,282	-
Net Loss	$ (3,841)	$ (32,307)	$ (93,031)	$ (128,530)
Basic and Diluted Net Loss per Common Share	$ (0.03)	$ (0.30)	$ (0.72)	$ (1.27)
Shares Used in Calculating Basic and Diluted Net Loss per Share	136,515	107,876	128,543	101,529

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	December 31, 2017	December 31, 2016
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 139,427	$ 189,776
Other Current Assets	5,329	5,793
Property and Equipment, net	10,372	13,192
Intangible and Other Assets, net	160,496	174,597
Total Assets	$ 315,624	$ 383,358
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 27,736	$ 35,223
Long-Term Liabilities	51,519	82,704

Stockholders' Equity	236,369	265,431
Total Liabilities and Stockholders' Equity	$ 315,624	$ 383,358

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