



August 8, 2016

Celldex Reports Second Quarter 2016 Results

Conference Call Scheduled for Monday, August 8 at 4:30 p.m. Eastern Time

HAMPTON, N.J., Aug. 08, 2016 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the second quarter ended June 30, 2016.

"Celldex continues to build one of the most robust pipelines in immuno-oncology, most recently advancing CDX-014 into the clinic in renal cell carcinoma," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "In collaboration with our investigators, we also presented a significant body of data in the second quarter with eight presentations across both AACR and ASCO that spoke to the broad utility of our product candidates in combination immunotherapy and highlighted a number of the novel targets we are pursuing."

"We continue to enroll patients to the pivotal METRIC study of glembatumumab vedotin in triple negative breast cancer, with a focus on a number of new sites in Europe that were added over the last quarter and look forward to presenting data from the Phase 2 study of glembatumumab vedotin in metastatic melanoma later this year," concluded Marucci.

Program Updates:

Glembatumumab vedotin ("glemba"; CDX-011), an antibody-drug conjugate (ADC) targeting gpNMB in multiple cancers

- | Enrollment continues in the Company's Phase 2b randomized study (METRIC) of glembatumumab vedotin in patients with metastatic triple negative breast cancers that overexpress gpNMB, a molecule associated with poor outcomes for triple negative breast cancer patients and the target of glembatumumab vedotin. Enrollment is open across the United States, Canada, and Australia and opened in the European Union in April, with close to 25 sites added in the EU in the second quarter. Additional sites continue to be added to support enrollment completion.
- | Patient enrollment is complete, and the primary endpoint has been met in the Phase 2 single-agent study of glembatumumab vedotin in metastatic melanoma (post-progression on checkpoint therapy). The primary endpoint of the study, objective response rate, required a minimum of six responses in the first 52 patients to be deemed successful. Celldex plans to present data from this study at the European Society for Medical Oncology (ESMO) Congress in October 2016. As previously announced, the Company has amended the protocol to add a second cohort of patients to a glembatumumab vedotin and varlilumab combination arm to assess the potential clinical benefit of the combination and to explore varlilumab's potential biologic and immunologic effect when combined with an ADC. This additional cohort is open to enrollment.
- | Celldex is also evaluating glembatumumab vedotin in other cancers in which gpNMB is expressed.
 - | Celldex has entered into a collaborative relationship with PrECOG, LLC, which represents a research network established by the Eastern Cooperative Oncology Group (ECOG), and PrECOG, LLC is conducting a Phase 1/2 study in squamous cell lung cancer. This study opened to enrollment in April 2016.
 - | Celldex and the National Cancer Institute (NCI) have entered into a Cooperative Research and Development Agreement (CRADA) under which the NCI is sponsoring two studies of glembatumumab vedotin—one in uveal melanoma and one in pediatric osteosarcoma. Both studies are currently open to enrollment.

Varlilumab ("varli"; CDX-1127), a fully human monoclonal agonist antibody that binds and activates CD27, a critical co-stimulatory molecule in the immune activation cascade

- | The Phase 2 portion of the varlilumab and nivolumab (Opdivo[®]) study opened to enrollment in April 2016. A protocol amendment was recently finalized to include additional arms evaluating alternate dosing schedules in both renal cell carcinoma and squamous cell head and neck cancer. The non-small cell lung cohort was removed prior to enrolling any patients to accommodate the addition of these new arms. As amended, the overall study size has increased and

includes cohorts in colorectal cancer (n=18), ovarian cancer (n=18), head and neck squamous cell carcinoma (n=48), renal cell carcinoma (n=75) and glioblastoma (n=20). The study is being conducted by Celldex under a clinical trial collaboration with Bristol-Myers Squibb Company. The companies are sharing development costs.

[Data](#) from the Phase 1 portion (n=36) of the varlilumab and nivolumab study were presented at the American Association for Cancer Research (AACR) Annual Meeting in April. The combination showed acceptable tolerability and safety across all dose levels without any evidence of increased autoimmunity or inappropriate immune activation. Combination therapy led to marked changes in the tumor microenvironment including increased infiltrating CD8+ T cells and increased PD-L1 expression, which have been shown to correlate with a greater magnitude of treatment effect from checkpoint inhibitors in other clinical studies. Additional favorable immune biomarkers, such as increase in inflammatory chemokines and decrease in T regulatory cells, were also noted. In a subset of patients (n=17) on study who had both pre- and post-tumor biopsies available, preliminary evidence also suggested a correlation between biomarker data and stable disease or better in seven of these patients (4 ovarian cancer, 2 colorectal cancer, 1 squamous cell carcinoma of the head and neck).

- | Enrollment has been completed in the Phase 1 dose-escalation portion of the Phase 1/2 study of varlilumab and atezolizumab (Tecentriq[®]; anti-PDL1) in patients with multiple solid tumors. The Company anticipates the Phase 2 portion of the study in renal cell carcinoma will be initiated in the third quarter of this year. This study is being conducted by Celldex under a clinical trial collaboration with Roche. Roche is providing study drug, and Celldex is responsible for conducting and funding the study.
- | Additional combination studies of varlilumab continue to enroll patients including:
 - | A Phase 1/2 safety and tolerability study examining the combination of varlilumab and sunitinib (Sutent[®]) in patients with metastatic clear cell renal cell carcinoma. The Company anticipates the Phase 1 portion of the study will complete enrollment in the next few months and that the Phase 2 portion of the study will initiate by year-end.
 - | A Phase 1/2 safety and tolerability study examining the combination of varlilumab and ipilimumab (Yervoy[®]) in patients with stage III or IV metastatic melanoma. In the Phase 2 portion of the study, patients with tumors that express NY-ESO-1 will also receive Celldex's CDX-1401, an NY-ESO-1-antibody fusion protein for immunotherapy.
 - | As discussed above, a Phase 2 study of varlilumab and glembatumumab vedotin in metastatic melanoma (post-progression on checkpoint therapy).

CDX-1401, an NY-ESO-1-antibody fusion protein for immunotherapy

- | As discussed above, a Phase 1/2 study examining the combination of varlilumab and ipilimumab continues to enroll patients with stage III or IV metastatic melanoma. In the Phase 2 portion of the study, patients with tumors that express NY-ESO-1 will also receive CDX-1401.
- | Celldex continues to support several external collaborations, including an NCI sponsored Phase 2 study of CDX-1401 and CDX-301 for patients with metastatic melanoma, which has completed enrollment (n=60 patients; not selected for NY-ESO-1 expression). [Initial data](#) from this study were presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting. The data confirmed that CDX-1401 is effective at driving NY-ESO-1 immunity and further demonstrated the value of CDX-301 as a combination agent for enhancing tumor-specific immune response. Based on results to date, plans for additional studies are being considered, including a targeted study in NY-ESO-1 positive disease to determine if these enhanced immune responses can translate to improved clinical outcomes.
- | Additionally, Roswell Park Cancer Center is conducting an investigator sponsored study evaluating CDX-1401, poly-ICLC (Hiltonol[®]) and the IDO1 inhibitor epacadostat (INCB24360) in patients in remission with ovarian, fallopian tube or primary peritoneal cancer. Patients' tumors must have expressed NY-ESO-1 or the LAGE-1 antigen to be eligible for the study. Celldex is providing CDX-1401 and poly-ICLC in support of this study.

CDX-301 (recombinant human Flt3L), a potent hematopoietic cytokine that uniquely expands the number of dendritic cells to prime the immune system for more robust immune responses to cancer antigens

- | As outlined above, data were presented from the Phase 2 study of CDX-1401 and CDX-301 in metastatic melanoma that further demonstrated the value of CDX-301 as a combination agent for enhancing tumor-specific immune response. CDX-301 greatly expanded peripheral blood dendritic cells and was highly effective at increasing cancer antigen specific T cells and antibodies when combined with CDX-1401. These results, which also showed rapid cellular immune responses in a majority of patients, suggests that pre-treatment with CDX-301 could provide a highly applicable, effective immunologic approach.

- CDX-301's potential activity is also being explored in a Phase 1/2 study of CDX-301 and poly-ICLC in combination with low-dose radiotherapy in patients with low-grade B-cell lymphomas conducted by the Icahn School of Medicine at Mount Sinai.

CDX-014, an antibody-drug conjugate (ADC) targeting the transmembrane protein T-cell immunoglobulin mucin-1 (TIM-1) in renal cell carcinoma

- In July 2016, Celldex announced that enrollment had opened in the Phase 1 dose-escalation portion of the Company's Phase 1/2 study of CDX-014 in advanced clear cell and papillary renal cell carcinoma (RCC). The Phase 1 study will evaluate cohorts of patients receiving increasing doses of CDX-014 to determine the maximum tolerated dose and a recommended dose for Phase 2 study.

RINTEGA® ("rindopepimut"; "rindo"; CDX-110), an EGFRvIII(v3)-specific therapeutic vaccine for glioblastoma (GBM)

- As previously disclosed, in March, during a pre-planned interim analysis, the independent Data Safety and Monitoring Board (DSMB) recommended discontinuation of the Phase 3 ACT IV study of RINTEGA (rindopepimut) in patients (n=745) with newly diagnosed EGFRvIII-positive glioblastoma. Study closure activities are substantially complete, and Celldex continues to anticipate that the Company will not incur substantial additional costs related to RINTEGA at this time. Celldex is in the process of conducting a thorough review of the data and plans to present the ACT IV results at the Society for Neuro-Oncology Annual Meeting in November of 2016. All patients on the RINTEGA arm of the ACT IV study, prior Phase 2 studies and existing compassionate use recipients have been offered ongoing access to RINTEGA on a compassionate use basis.

Second Quarter and First Six Months 2016 Financial Highlights and Updated 2016 Guidance

Cash position: Cash, cash equivalents and marketable securities as of June 30, 2016 were \$220.1 million compared to \$254.0 million as of March 31, 2016. The decrease was primarily driven by our second quarter cash used in operating activities of \$33.8 million, \$5.9 million of which were RINTEGA-related payments. At June 30, 2016, Celldex had 99.4 million shares outstanding.

Revenues: Total revenue was \$1.4 million in the second quarter of 2016 and \$2.7 million for the six months ended June 30, 2016, compared to \$2.2 million and \$2.7 million for the comparable periods in 2015. Total revenue was primarily derived from our clinical trial collaboration with Bristol-Myers Squibb and our research and development agreement with Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were \$25.7 million in the second quarter of 2016 and \$53.2 million for the six months ended June 30, 2016, compared to \$26.5 million and \$51.6 million for the comparable periods in 2015.

The decrease in R&D expenses of \$0.8 million between the three-month periods was primarily due to lower clinical costs of \$3.2 million, offset in part by increased contract manufacturing costs of \$0.8 million and personnel costs of \$1.6 million, including higher stock-based compensation of \$0.8 million.

The increase in R&D expenses of \$1.6 million between the six-month periods was primarily due to higher contract manufacturing and other contract service costs and personnel costs, including higher stock-based compensation of \$1.3 million, offset by lower clinical costs.

G&A Expenses: General and administrative (G&A) expenses were \$7.8 million in the second quarter of 2016 and \$17.1 million for the six months ended June 30, 2016, compared to \$8.2 million and \$14.3 million for the comparable periods in 2015.

The decrease in G&A expenses of \$0.4 million between the three-month periods was primarily due to lower commercial planning costs of \$1.1 million, partially offset by higher stock-based compensation of \$0.7 million.

The \$2.8 million increase in G&A expenses between the six-month periods was primarily due to higher stock-based compensation of \$1.8 million, facility costs and legal costs.

Net loss: Net loss was \$32.0 million, or (\$0.32) per share, for the second quarter of 2016 and \$66.6 million, or (\$0.67) per share, for the six months ended June 30, 2016, compared to a net loss of \$32.4 million, or (\$0.33) per share and \$62.5 million, or (\$0.65) per share for the comparable periods in 2015.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at June 30, 2016 combined with the anticipated proceeds from future sales of our common stock under our \$60 million sales agreement with Cantor Fitzgerald & Co. are sufficient to meet estimated working capital requirements and fund planned operations through 2018.

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 2016 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 53265640.

A replay of the call will be available approximately two hours after the live call concludes through August 15, 2016. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 53265640. The webcast will also be archived on the Company's website.

RINTEGA[®] is a registered trademark of Celldex Therapeutics. Opdivo[®] and Yervoy[®] are registered trademarks of Bristol-Myers Squibb. Sutent[®] is a registered trademark of Pfizer. Tecentriq[®] is a registered trademark of Genentech. Hiltono[®] is a registered trademark of Oncovir.

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 strategic focus and the future development and commercialization (by Celldex and others) of glebatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127) and other products and our goals for 2016. 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 glebatumumab vedotin and other 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; 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 glebatumumab 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.

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

STATEMENTS OF OPERATIONS DATA	Quarter Ended June 30, Consolidated		Six Months Ended June 30, Consolidated	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
REVENUE				
Product Development and Licensing Agreements	\$ 604	\$ 334	\$ 1,057	\$ 676
Contracts and Grants	785	1,844	1,635	1,988
Total Revenue	1,389	2,178	2,692	2,664
OPERATING EXPENSE				
Research and Development	25,711	26,490	53,158	51,615
General and Administrative	7,790	8,184	17,097	14,273
Amortization of Acquired Intangible Assets	254	254	507	507
Total Operating Expense	33,755	34,928	70,762	66,395
Operating Loss	(32,366)	(32,750)	(68,070)	(63,731)
Investment and Other Income, Net	414	391	1,445	1,198
Net Loss	\$ (31,952)	\$ (32,359)	\$ (66,625)	\$ (62,533)
Basic and Diluted Net Loss per Common Share	\$ (0.32)	\$ (0.33)	\$ (0.67)	\$ (0.65)
Weighted Average Common Shares Outstanding	98,817	98,482	98,753	95,477

CONDENSED BALANCE SHEETS DATA	Consolidated	
	June 30, 2016	December 31, 2015
	(Unaudited)	
ASSETS		
Cash, Cash Equivalents and Marketable Securities	\$ 220,128	\$ 289,889
Other Current Assets	8,654	5,047
Property and Equipment, net	11,293	11,461
Intangible and Other Assets, net	31,131	31,187
Total Assets	<u>\$ 271,206</u>	<u>\$ 337,584</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	\$ 20,003	\$ 30,240
Long-Term Liabilities	16,494	17,239
Stockholders' Equity	234,709	290,105
Total Liabilities and Stockholders' Equity	<u>\$ 271,206</u>	<u>\$ 337,584</u>

Company Contact

Sarah Cavanaugh
Vice President of Investor Relations & Corp Communications
Celldex Therapeutics, Inc.
(781) 433-3161

scavanaugh@celldex.com

Charles Liles
Associate Director of Investor Relations & Corp Communications
Celldex Therapeutics, Inc.
(781) 433-3107
cliles@celldex.com

Media Inquiries

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