



November 7, 2016

## Celldex Reports Third Quarter 2016 Results

HAMPTON, N.J., Nov. 07, 2016 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the third quarter ended September 30, 2016.

"Celldex continues to demonstrate our commitment to combining therapeutic approaches to drive innovation in immuno-oncology for patients and their families," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "In the third quarter, we presented important data from our Phase 2 study of glembatumumab vedotin in checkpoint-refractory metastatic melanoma at ESMO, meeting the primary overall response endpoint and demonstrating clinically meaningful duration of response in this difficult-to-treat setting. Building on these promising signals, we are now enrolling a combination arm with our CD27 agonist, varlilumab, and are in the process of finalizing an additional arm to explore a glembatumumab vedotin and checkpoint inhibitor combination."

"Last week, we also announced the proposed acquisition of Kolltan Pharmaceuticals. This transaction would add a highly compatible platform of unique antibodies targeting receptor tyrosine kinases to our pipeline that we believe can be developed both independently and in combination with Celldex's existing product candidates. We are in the process of finalizing our integrated clinical development strategy and look forward to outlining these plans after closing the transaction. As multi-drug combination regimens become the standard in oncology, we fully recognize that the development programs to explore these opportunities become increasingly complex. We believe Celldex is well positioned to meet this challenge and will draw upon the leadership and expertise of Elizabeth Crowley, whom we promoted to the newly created role of Chief Product Development Officer in the third quarter," concluded Marucci.

### Business Update:

#### *Proposed Acquisition of Kolltan Pharmaceuticals*

- | On November 1, 2016, Celldex announced that the Company entered into a [definitive agreement to acquire](#) Kolltan Pharmaceuticals, Inc., a privately held clinical-stage company focused on the discovery and development of novel, antibody-based drugs targeting receptor tyrosine kinases (RTKs). Kolltan has reported clinical and preclinical data that its drug candidates can help overcome tumor resistance mechanisms associated with current tyrosine kinase inhibitors and seen in patients who have failed other cancer therapies. Celldex believes Kolltan's clinical candidates and preclinical platform are highly compatible with the Company's scientific approach and can be developed independently and in combination with Celldex's existing product candidates. The transaction, which is subject to the receipt of Kolltan stockholder approval and other customary closing conditions, is expected to be completed by year-end. Upon closing, the following programs would be included in Celldex's pipeline:
  - | KTN0158 — a humanized monoclonal antibody that is a potent inhibitor of KIT activation and receptor dimerization in tumor cells and mast cells, which is currently in a Phase 1 dose escalation study in refractory gastrointestinal stromal tumors (GIST).
  - | KTN3379 — a human monoclonal antibody designed to block the activity of ErbB3 (HER3), which recently completed a Phase 1b study with combination cohorts where meaningful responses and stable disease were observed in cetuximab (Erbix<sup>®</sup>) refractory patients in head and neck squamous cell carcinoma and in BRAF-mutant non-small cell lung cancer (NSCLC).
  - | A multi-faceted TAM program — a broad antibody discovery effort underway to generate antibodies that modulate the TAM family of RTKs, comprised of Tyro3, AXL and MerTK, which are expressed on tumor-infiltrating macrophages, dendritic cells and some tumors. Research supports TAMs having broad application and potential across immuno-oncology and inflammatory diseases.

### 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, Australia and the European Union. Enrollment rates have increased, and the Company anticipates providing guidance in early 2017 on projected enrollment completion.

- | [Data from the Phase 2 single-agent study of glembatumumab vedotin in metastatic melanoma](#), post-progression on checkpoint therapy, were presented in October at the European Society for Medical Oncology (ESMO) Congress. The primary endpoint of the study (6 or more objective responses in the first 52 patients enrolled) was exceeded. 7 of 62 (11%) patients experienced a confirmed response, and an additional 3 patients also experienced single time-point responses. The median duration of response in this heavily pre-treated patient population was 6.0 months, and the median progression-free survival (PFS) for all patients was 4.4 months.

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. The Company is exploring opening a new arm in the study to assess a glembatumumab vedotin and checkpoint inhibitor combination. This rationale is strongly supported by preclinical data that suggest that the anti-tumor activity may be enhanced with the combination.

- | 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***

- | Preclinical data on combination regimens with varlilumab are expected to be presented at the American Society of Hematology Annual Meeting in December 2016.
- | The Phase 2 portion of the varlilumab and nivolumab (Opdivo<sup>®</sup>) study opened to enrollment in April 2016 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.
- | Enrollment has been completed in the Phase 1 dose-escalation portion of the Phase 1/2 study of varlilumab and Tecentriq<sup>®</sup> (atezolizumab) in patients with multiple solid tumors. 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.
- | Enrollment is expected to complete by year-end in the Phase 1 portion of a Phase 1/2 safety and tolerability study examining the combination of varlilumab and sunitinib (Sutent<sup>®</sup>) in patients with metastatic clear cell renal cell carcinoma.
- | As discussed above, a Phase 2 study of varlilumab and glembatumumab vedotin in metastatic melanoma (post-progression on checkpoint therapy) continues to enroll patients.
- | A Phase 1/2 safety and tolerability study examining the combination of varlilumab and ipilimumab (Yervoy<sup>®</sup>) in patients with stage III or IV metastatic melanoma was opened to enrollment in April 2015. Since initiating the study, the standard of care has evolved, and there has been increasing physician reluctance to use Yervoy in this setting. As such, given the broad development strategy in place for varlilumab, the Company has decided to close this study.

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

- | 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 (n=60 patients; not selected for NY-ESO-1 expression). [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.

- 1 Additionally, Roswell Park Cancer Center is conducting an investigator sponsored study evaluating CDX-1401, poly-ICLC (Hiltonol<sup>®</sup>) 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***

- 1 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.
- 1 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. Data from this study will be shared in an oral presentation at the American Society of Hematology Annual Meeting in December 2016.

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

- 1 Enrollment continues in the Phase 1 dose-escalation portion of the Phase 1/2 study of CDX-014 in advanced clear cell and papillary renal cell carcinoma (RCC). The Phase 1 study is evaluating cohorts of patients receiving increasing doses of CDX-014 to determine the maximum tolerated dose and a recommended dose for Phase 2 study.

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

- 1 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. Data from this study will be presented in a plenary session at the Society for Neuro-Oncology Annual Meeting in November. The Company continues to guide that it will not incur substantial additional costs related to RINTEGA at this time.

***CDX-1140, a fully human antibody targeted to CD40 that has demonstrated potent agonist activity.***

- 1 Preclinical data supporting this program will be presented at the Society for Immunotherapy of Cancer Annual Meeting in November 2016 and at the American Society of Hematology Annual Meeting in December 2016.

***Third Quarter and First Nine Months 2016 Financial Highlights and Updated 2016 Guidance***

**Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2016 were \$203.2 million compared to \$220.1 million as of June 30, 2016. The decrease was primarily driven by our third quarter cash used in operating activities of \$24.0 million. At September 30, 2016, Celldex had 101.2 million shares outstanding.

**Revenues:** Total revenue was \$2.2 million in the third quarter of 2016 and \$4.9 million for the nine months ended September 30, 2016, compared to \$1.0 million and \$3.7 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 \$25.0 million in the third quarter of 2016 and \$78.2 million for the nine months ended September 30, 2016, compared to \$24.7 million and \$76.3 million for the comparable periods in 2015.

The increase in R&D expenses of \$0.4 million between the three-month periods was primarily due to higher contract manufacturing of \$1.7 million and personnel costs of \$1.1 million, including higher stock-based compensation of \$0.3 million, offset in part by lower clinical costs of \$2.4 million.

The \$1.9 million increase in R&D expenses between the nine-month periods was primarily due to higher contract manufacturing costs of \$4.0 million and personnel costs of \$4.9 million, including higher stock-based compensation of \$1.6 million, offset by lower clinical costs of \$8.1 million.

**G&A Expenses:** General and administrative (G&A) expenses were \$7.0 million in the third quarter of 2016 and \$24.0 million for the nine months ended September 30, 2016, compared to \$8.5 million and \$22.8 million for the comparable periods in 2015.

The decrease in G&A expenses of \$1.5 million between the three-month periods was primarily due to lower commercial planning costs of \$0.4 million and lower personnel costs of \$0.6 million, including lower stock-based compensation of \$0.4 million.

The \$1.2 million increase in G&A expenses between the nine-month periods was primarily due to higher stock-based compensation of \$1.4 million, offset by lower commercial planning costs of \$0.3 million.

**Net Loss:** Net loss was \$29.6 million, or (\$0.29) per share, for the third quarter of 2016 and \$96.2 million, or (\$0.97) per share, for the nine months ended September 30, 2016, compared to a net loss of \$32.0 million, or (\$0.32) per share and \$94.5 million, or (\$0.98) per share for the comparable periods in 2015.

**Financial Guidance:** Celldex believes that the cash, cash equivalents and marketable securities at September 30, 2016 combined with the anticipated proceeds from future sales of our common stock under the Cantor agreement, are sufficient to meet estimated working capital requirements and fund planned operations, including the proposed acquisition and integration of Kolltan Pharmaceuticals, through 2018; however, this could be impacted if we elected to pay Kolltan's shareholders contingent milestones in cash.

*RINTEGA<sup>®</sup> is a registered trademark of Celldex Therapeutics. Opdivo<sup>®</sup> and Yervoy<sup>®</sup> are registered trademarks of Bristol-Myers Squibb. Sutent<sup>®</sup> is a registered trademark of Pfizer. Tecentriq<sup>®</sup> is a registered trademark of Genentech. Hiltonol<sup>®</sup> is a registered trademark of Oncovir. 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 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](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. 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, the ability of Kolltan and the Company to satisfy the closing conditions of the acquisition, including the risk that Kolltan's stockholders may not approve the merger; our ability to successfully integrate the business and programs of Kolltan with our business and programs; our ability to successfully complete research and further development and commercialization of glembatumumab vedotin and other Company and Kolltan 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 (or which Kolltan has initiated or plans 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 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 and Kolltan'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)

<b>STATEMENTS OF OPERATIONS DATA</b>	<b>Quarter Ended September 30, Consolidated</b>		<b>Nine Months Ended September 30, Consolidated</b>	
	<b>2016 (Unaudited)</b>	<b>2015</b>	<b>2016 (Unaudited)</b>	<b>2015</b>
<b>REVENUE</b>				
Product Development and Licensing Agreements	\$ 493	\$ 377	\$ 1,551	\$ 1,053
Contracts and Grants	1,727	649	3,362	2,636
<b>Total Revenue</b>	<b>2,220</b>	<b>1,026</b>	<b>4,913</b>	<b>3,689</b>
<b>OPERATING EXPENSE</b>				
Research and Development	25,009	24,656	78,168	76,271
General and Administrative	6,950	8,487	24,049	22,761
Amortization of Acquired Intangible Assets	254	254	760	760
<b>Total Operating Expense</b>	<b>32,213</b>	<b>33,397</b>	<b>102,977</b>	<b>99,792</b>
Operating Loss	(29,993)	(32,371)	(98,064)	(96,103)
Investment and Other Income, Net	395	391	1,841	1,590
<b>Net Loss</b>	<b>\$ (29,598)</b>	<b>\$ (31,980)</b>	<b>\$ (96,223)</b>	<b>\$ (94,513)</b>
Basic and Diluted Net Loss per Common Share	\$ (0.29)	\$ (0.32)	\$ (0.97)	\$ (0.98)
Weighted Average Common Shares Outstanding	100,672	98,568	99,398	96,518

**CONDENSED  
BALANCE SHEETS**

	<b>Consolidated</b>	
	<b>September 30, 2016 (Unaudited)</b>	<b>December 31, 2015</b>
<b>ASSETS</b>		
Cash, Cash Equivalents and Marketable Securities	\$ 203,248	\$ 289,889
Other Current Assets	6,466	5,047
Property and Equipment, net	11,355	11,461
Intangible and Other Assets, net	30,878	31,187
<b>Total Assets</b>	<b>\$ 251,947</b>	<b>\$ 337,584</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities	\$ 18,630	\$ 30,240
Long-Term Liabilities	16,225	17,239
Stockholders' Equity	217,092	290,105

Total Liabilities and Stockholders' Equity

\$ 251,947 \$ 337,584

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