November 4, 2014

Celldex Reports Third Quarter 2014 Results

HAMPTON, N.J., Nov. 4, 2014 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported business and financial highlights for the third quarter ended September 30, 2014.

"In the third quarter, we significantly advanced a number of key programs," said Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics. "Most notably, following completion of screening, we met our target enrollment of 700 patients in our Phase 3 study of rindopepimut in newly diagnosed glioblastoma and enrollment will be completed in the coming weeks."

"With new opportunities to expand the METRIC study of glembatumumab vedotin in triple negative breast cancer emerging in the EU and in an effort to increase enrollment, we have implemented a protocol amendment to expand entry criteria. We believe this change provides advantages to the glemba program, including the opportunity to potentially file for full approval across a broader subset of patients in both the US and the EU. We look forward to presenting data from the rindo program in recurrent GBM at the SNO meeting this month and completing planning for a number of new studies across our pipeline, including the initiation of the combination varlilumab and nivolumab study," concluded Marucci.

Program Updates:

Rindopepimut ("rindo"; CDX-110) in EGFRvIII(v3)-Positive Glioblastoma (GBM):

- Target enrollment (n=700) in ACT IV, the Phase 3 registration study of newly diagnosed patients with GBM has been reached. Given the lack of treatment options for patients with GBM, previously screened patients who are positive for the EGFR*vIII* mutation will be allowed to enter the study before enrollment is formally completed later this year. The primary objective of the study is to determine whether rindopepimut added to the standard of care (radiation and temozolomide) improves the overall survival (OS) of patients with minimal residual disease compared to standard of care alone. All patients, including patients with disease that exceeds the minimum residual disease threshold, will be included in a secondary analysis of OS as well as analyses of progression-free survival, safety and tolerability, and quality of life.

- The Phase 2 ReACT study in patients with recurrent GBM has completed enrollment of both Group 1 (n=70; randomized cohort of rindopepimut + bevacizumab versus control + bevacizumab in bevacizumab-naïve patients) and the first 23 patients of Group 2C (n=up to 73; single arm cohort of rindopepimut + bevacizumab in bevacizumab-refractory patients).
  - Data from the ReACT study will be presented in a platform presentation entitled "ReACT: A Phase 2 study of rindopepimut vaccine (CDX-110) plus bevacizumab in relapsed glioblastoma" at 19th Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology (SNO) on Friday, November 14, 2014 from 3:35 to 3:45 pm ET.
  - Data from the rindopepimut compassionate use experience will also be presented in a platform presentation entitled "Vaccination against Epidermal Growth Factor Receptor variant III in glioblastoma: the rindopepimut compassionate use experience" at SNO on Friday, November 14 from 4:05 to 4:15 pm ET.

Glembatumumab vedotin ("glemba"; CDX-011) targeting gpNMB in multiple cancers:

- In December 2013, Celldex initiated a randomized, accelerated approval study (METRIC) of glembatumumab vedotin in patients with metastatic triple negative breast cancers that overexpress gpNMB, a molecule associated with poor outcome for triple negative breast cancer patients and the target of glemba.
  - To date, 86 sites are open to enrollment across the United States, Canada and Australia and investigators have expressed enthusiasm for the study. However, they have reported that previously established eligibility criteria are limiting their ability to enroll patients they feel are clinically appropriate on study. In addition, Celldex has spoken to country-specific members of the EMA and believes a significant opportunity exists to expand the study into the EU.
  - To this end, Celldex is amending the METRIC study to position it for full marketing approval with global regulators, including the EMA, and to improve enrollment in the study. Specifically, the protocol amendment will:
    - Allow for inclusion of a broader triple negative breast cancer patient population, including patients who

may not yet be fully refractory to taxanes;
- Permit physicians to determine the appropriateness of anthracyclines for their patients; and
- Include the broader definition of triple negative status (less than 10% ER/PR expression) that is used in clinical practice.
- The primary endpoint will be progression-free survival (PFS) as PFS is an established endpoint for full approval registration studies in this patient population in both the US and the EU (previously the primary endpoint was both PFS and overall response rate). The sample size (n=300) and the secondary endpoint of overall survival remain unchanged.

- The Company is implementing these changes in parallel to regulatory discussions to maintain momentum at open clinical trial sites.
- Based on current projections, we believe enrollment will likely extend into 2016.

- Celldex continues to advance plans to expand the study of glembatumumab vedotin into other cancers in which gpNMB is expressed.
  - The protocol for the Phase 2 study in metastatic melanoma has been finalized and the study will be initiated by year end 2014.
  - Assay optimization and validation for the Phase 2 study in squamous cell lung cancer is expected to be completed by year-end and the study will commence soon thereafter.
  - Celldex and the National Cancer Institute have entered into a Cooperative Research and Development Agreement (CRADA) under which NCI will sponsor two studies of glembatumumab vedotin—one in uveal melanoma and one in pediatric osteosarcoma. Celldex will provide support for these studies.

Varlilumab ("varli"; CDX-1127), an immune modulating mAb targeting CD27 in solid tumors and hematologic malignancies:

- In May, Celldex announced that it had entered into a clinical trial collaboration with Bristol-Myers Squibb Company (BMS) to evaluate the safety, tolerability and preliminary efficacy of nivolumab, BMS's investigational PD-1 immune checkpoint inhibitor, and varlilumab. The study, which will be conducted by Celldex, is expected to begin in the fourth quarter.
- In May, Celldex announced that it had agreed to collaborate with Oncothyreon Inc. on a combined clinical trial of ONT-10, a therapeutic vaccine targeting the tumor-associated antigen MUC1, and varlilumab. This study, which will be conducted by Oncothyreon, is expected to begin in the fourth quarter.
- Multiple efforts are underway for additional Phase 2 studies of varlilumab and the Company will provide updates on these studies as they are initiated, including but not limited to:
  - A Phase 1/2 study of varlilumab and ipilumumab in patients with metastatic melanoma; plus CDX-1401 in NY-ESO+ patients
  - A Phase 1/2 of varlilumab plus sunitinib in renal cell carcinoma
  - A Phase 1/2 study of varlilumab plus a mek pathway agent (followed sequentially by a checkpoint inhibitor) for patients with B-raf mutated metastatic melanoma

CDX-1401, an antibody-based dendritic cell targeted vaccine aimed at tumors expressing the NY-ESO-1 oncoprotein:

- Celldex continues to provide support for the National Cancer Institute sponsored Phase 2 study of CDX-1401 and CDX-301 for patients with metastatic melanoma, which is currently actively enrolling patients.
- Additional studies of CDX-1401 combined with immune modulators are planned to initiate in 2015.

CDX-301 (Flt3L), a potent hematopoietic cytokine that stimulates the expansion and differentiation of hematopoietic stem cells and dendritic cells:

- A pilot study of CDX-301 alone and in combination with Mozobil® in hematopoietic stem cell transplantation was initiated in September of 2014.
- An investigator sponsored Phase 1/2 study of intratumoral injection of CDX-301 and Hiltonol® in combination with low-dose radiotherapy for patients with low-grade B-cell lymphomas is ongoing.

Third Quarter and Nine Months 2014 Financial Highlights and 2014 Guidance

Cash position: Cash, cash equivalents and marketable securities as of September 30, 2014 were $224.1 million compared to $252.4 million as of June 30, 2014. The decrease was primarily driven by our third quarter net cash burn of $28.3 million. As of September 30, 2014 Celldex had 89.4 million shares outstanding.

Revenues: Total revenue was $1.1 million in the third quarter of 2014 and $2.1 million for the nine months ended September 30, 2014, compared to $1.0 million and $3.5 million for the comparable periods in 2013. The increase in the

third quarter of 2014 was primarily due to our clinical trial collaboration with BMS. The decrease in the nine months ended September 30, 2014 was primarily due to the decrease in Rotarix® royalty revenue. Our agreement with GlaxoSmithKline terminated upon the anticipated expiration of the last relevant patent right covered by the GlaxoSmithKline agreement. We do not expect additional royalty revenue or royalty expense related to Rotarix.

R&D Expenses: Research and development (R&D) expenses were $26.2 million in the third quarter of 2014 and $77.4 million for the nine months ended September 30, 2014, compared to $20.4 million and $49.6 million for the comparable periods in 2013. The increase in Celldex's R&D investment was primarily due to the continued progression of our late-stage clinical development programs, rindopepimut and glembatumumab vedotin, and the continued expansion of the varlilumab program.

G&A Expenses: General and administrative (G&A) expenses were $5.0 million in the third quarter of 2014 and $14.4 million for the nine months ended September 30, 2014, compared to $3.6 million and $10.1 million for the comparable periods in 2013. The increase in G&A expenses was primarily attributable to higher personnel-related expenses and rindopepimut and glembatumumab vedotin commercial planning costs in 2014.

Net loss: Net loss was $28.1 million, or ($0.31) per share, for the third quarter of 2014 and $86.3 million, or ($0.97) per share, for the nine months ended September 30, 2014, compared to a net loss of $23.1 million, or ($0.29) per share and $59.5 million, or ($0.76) per share for the comparable periods in 2013.

Financial guidance: Celldex expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements through 2016.

Avastin® is a registered trademark of Genentech; Yervoy® and Opdivo® are registered trademarks of Bristol-Myers Squibb; Mozobil® is a registered trademark of Genzyme Corporation; Hiltonol® 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 rindopepimut ("rindo"; CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127), CDX-1401, CDX-301 and other products and our goals for 2014. 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 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 rindopepimut, glembatumumab 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; 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.

--table follows—

CELLDEX THERAPEUTICS, INC.

(In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	Quarter Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(Unaudited)		(Unaudited)	
REVENUE				
Product Development and Licensing Agreements	$ 284	$ 40	$ 518	$ 117
Contracts and Grants	817	940	1,591	1,040
Product Royalties	--	--	--	2,334
Total Revenue	1,101	980	2,109	3,491
OPERATING EXPENSE				
Research and Development	26,185	20,417	77,355	49,597
Royalty	--	--	--	2,334
General and Administrative	5,004	3,578	14,373	10,128
Amortization of Acquired Intangible Assets	254	254	760	760
Total Operating Expense	31,443	24,249	92,488	62,819
Operating Loss	(30,342)	(23,269)	(90,379)	(59,328)
Investment and Other Income, Net	2,260	142	4,121	682
Interest Expense	--	(13)	--	(842)
Net Loss	$ (28,082)	$ (23,140)	$ (86,258)	$ (59,488)
Basic and Diluted Net Loss per Common Share	$ (0.31)	$ (0.29)	$ (0.97)	$ (0.76)
Weighted Average Common Shares Outstanding	89,404	81,015	89,346	78,676

CONDENSED CONSOLIDATED BALANCE SHEETS	September 30, 2014 (Unaudited)	December 31, 2013
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 224,078	$ 302,983
Other Current Assets	5,747	2,206
Property and Equipment, net	10,716	9,973
Intangible and Other Assets, net	31,124	31,933

Total Assets	$ 271,665	$ 347,095
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 21,614	$ 20,350
Long-Term Liabilities	10,679	6,950
Stockholders' Equity	239,372	319,795
Total Liabilities and Stockholders' Equity	$ 271,665	$ 347,095

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Celldex Therapeutics logo

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