May 1, 2014

Celldex Reports First Quarter 2014 Results

HAMPTON, N.J., May 1, 2014 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported business and financial highlights for the first quarter ended March 31, 2014.

"Celldex continues to advance one of the most robust, well-staged pipelines in immuno-oncology," said Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics. "We anticipate completing enrollment in our Phase 3 study of rindopepimut in brain cancer later this year and are making excellent progress with our accelerated approval study of glembatumumab vedotin in triple negative breast cancer with more than 50 sites now open to screen patients. We are also completing the necessary preparations to significantly expand clinical development of glembatumumab vedotin into metastatic melanoma and squamous cell lung cancer and varlilumab into several Phase 1/2 trials and look forward to updating on our progress as new studies begin over the coming months."

Program Updates:

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

- Celldex continues to enroll newly diagnosed patients with GBM in ACT IV, the Phase 3 registration study and, consistent with previous guidance, anticipates completion of enrollment in mid-2014.
- Celldex continues to enroll patients with recurrent GBM in ReACT, a Phase 2 study that includes patients both naïve and refractory to Avastin®. Enrollment to Group 1 (n=70 Avastin-naïve patients) and enrollment of at least the first 23 patients in Group 2C (n=up to 73 Avastin-refractory patients) is expected to be completed by year-end 2014. (Group 2C is designed as a two-stage cohort; evidence of anti-tumor activity in the first 23 patients will trigger full completion of enrollment to this arm of the study). Updated data from the study will be presented by year-end 2014.

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

- In December, Celldex initiated a randomized, accelerated approval study (METRIC) of glembatumumab vedotin in patients with metastatic triple negative breast cancers that overexpress the tumor associated marker gpNMB. To date more than 50 sites are open to enrollment. In total, the study is expected to include approximately 100 sites in the United States, Canada and Australia.
- Celldex continues to advance plans to initiate Phase 2 studies of glembatumumab vedotin in metastatic melanoma and squamous cell lung cancer in the second half of 2014.

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

- Celldex continues to advance plans to initiate multiple Phase 1/2 studies of varlilumab in combination with various agents in the second half of 2014, including a Phase 1/2 study of varlilumab and Yervoy® (and potentially other checkpoint inhibitors) plus CDX-1401 in NY-ESO+ patients with metastatic melanoma and a Phase 1/2 study of varlilumab plus B-raf targeted pathway agents (followed sequentially by a checkpoint inhibitor) for patients with B-raf mutated metastatic melanoma.
- Celldex will present data from the Phase 1 varlilumab program in two separate Poster Highlight Sessions at the 2014 American Society of Clinical Oncology (ASCO) Annual Meeting. The first presentation will include dose-escalation data from the solid tumor arm of the study and data from the expansion cohorts in metastatic melanoma and renal cell carcinoma; the second will include dose-escalation data from the hematologic malignancies arm of the study.

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

- On April 16, 2014, final data from the Phase 1 study of CDX-1401 in solid tumors, including long-term patient follow-up, was published in *Science Translational Medicine* (Vol 6 Issue 232). The data demonstrated robust antibody and T

cell responses and evidence of clinical benefit in patients with very advanced cancers and suggested that CDX-1401 may predispose patients to better outcomes on subsequent therapy with checkpoint inhibitors.

- A Phase 1/2 study of varlilumab and Yervoy (and potentially other checkpoint inhibitors) plus CDX-1401 in NY-ESO+ patients with metastatic melanoma is planned to initiate in the second half of 2014. In addition, Celldex will provide support for a National Cancer Institute sponsored Phase 2 study of CDX-1401 and CDX-301 for patients with metastatic melanoma to start later this year.

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

- Celldex continues to advance plans to initiate combination studies of CDX-301 in 2014 to explore its potential for improving hematopoietic stem cell transplantation and potentiating immune activation. A pilot study of CDX-301 alone and in combination with Mozobil® in hematopoietic stem cell transplantation will be initiated in the third quarter. In addition, Celldex will support 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 in 2014.

First Quarter 2014 Financial Highlights and 2014 Guidance

Cash position: Cash, cash equivalents and marketable securities as of March 31, 2014 were $274.2 million compared to $303.0 million as of December 31, 2013. The decrease was primarily driven by our first quarter net cash burn of $28.8 million which includes a one-time $2.5 million milestone payment to Seattle Genetics for the METRIC study initiation. As of March 31, 2014 Celldex had 89.4 million shares outstanding.

Revenues: Total revenue was $0.4 million in the first quarter of 2014 compared to $2.4 million for the comparable period in 2013. The decrease in revenue was 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 $27.1 million in the first quarter of 2014 compared to $14.1 million for the comparable period 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 $4.6 million in the first quarter of 2014 compared to $3.1 million for the comparable period in 2013. The increase in G&A expenses was primarily attributable to higher personnel-related expenses, professional services and rindopepimut and glembatumumab vedotin commercial planning costs in 2014.

Net loss: Net loss was $29.9 million, or ($0.33) per share, for the first quarter of 2014 compared to a net loss of $17.3 million, or ($0.23) per share for the comparable period 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® is a registered trademark of Bristol-Myers Squibb; Rotarix® is a registered trademark of GlaxoSmithKline; 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 (CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab (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.

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 STATEMENT OF OPERATIONS DATA	**Quarter Ended March 31,**	
	2014	**2013**
	(Unaudited)	
OPERATING REVENUE		
Product Development and Licensing Agreements	$ 35	$ 30
Contracts and Grants	381	50
Product Royalties	--	2,334
Total Revenue	416	2,414
OPERATING EXPENSE		
Research and Development	27,070	14,090
Royalty	--	2,334
General and Administrative	4,582	3,138
Amortization of Acquired Intangible Assets	253	253
Total Operating Expense	31,905	19,815
Operating Loss	(31,489)	(17,401)
Investment and Other Income, Net	1,586	379
Interest Expense	--	(310)
Net Loss	$ (29,903)	$ (17,332)
Basic and Diluted Net Loss per Common Share	$ (0.33)	$ (0.23)

Weighted Average Common Shares Outstanding	89,270	74,027

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	March 31, 2014 (Unaudited)	December 31, 2013
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 274,226	$ 302,983
Other Current Assets	2,593	2,206
Property and Equipment, net	10,216	9,973
Intangible and Other Assets, net	31,664	31,933
Total Assets	$ 318,699	$ 347,095
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 19,507	$ 20,350
Long-Term Liabilities	7,346	6,950
Stockholders' Equity	291,846	319,795
Total Liabilities and Stockholders' Equity	$ 318,699	$ 347,095

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