April 29, 2015

Celldex Reports First Quarter 2015 Results

HAMPTON, N.J., April 29, 2015 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported business and financial highlights for the first quarter ended March 31, 2015.

"2015 began with a significant accomplishment for RINTEGA®—the granting of Breakthrough Therapy Designation for the treatment of adult patients with EGFRvIII-positive glioblastoma. We believe this designation underscores RINTEGA's therapeutic potential for these patients," said Anthony Marucci, Co-founder, President and Chief Executive Officer. "To this end, we look forward to presenting updated data from the ReACT study in the recurrent setting at ASCO and eagerly await data from the fully enrolled ACT IV study in the frontline setting.

"This momentum is further supported by our growing pipeline. In the first quarter, we continued to advance several combination studies specifically designed to intervene at key points of immune regulation. The varlilumab/Opdivo® study and the varlilumab/Yervoy®/CDX-1401 study are now both open to enrollment. We also announced a clinical trial collaboration with Roche to combine their anti-PDL1 agent with varlilumab in a Phase 1/2 study that will initiate later this year. Additionally, glembatumumab vedotin is enrolling patients in two trials with plans for a third trial to start by year-end. Importantly, these initiatives, including our ongoing efforts to prepare for the potential commercial launch of RINTEGA, were further bolstered with the successful completion of an over-subscribed public offering in early March."

Program Updates:

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

- In February 2015, the U.S. Food and Drug Administration (FDA) granted RINTEGA Breakthrough Therapy Designation for the treatment of adult patients with EGFRvIII-positive glioblastoma.
- Enrollment was completed in late 2014 in ACT IV (n=745), the Phase 3 registration study in newly diagnosed patients with GBM. Interim analyses will be conducted by an independent Data Safety and Monitoring Board at 50 and 75% of events. The first interim analysis is expected in mid-2015.
- Data from the Phase 2 ReACT study in patients with recurrent GBM will be presented in an oral session in the Clinical Science Symposium "Immunotherapy for Central Nervous System Tumors: Biomarkers and Novel Data" at the 2015 ASCO Annual Meeting on Sunday, May 31, 2015 at 8:00 a.m. by David A. Reardon, M.D., Clinical Director, Center for Neuro-Oncology, Dana-Farber Cancer Center and Associate Professor of Medicine, Harvard Medical School, and the lead investigator of the ReACT study.

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

- Patient enrollment is accelerating in the Company's Phase 2b randomized study (METRIC) of glemba 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. To date, 95 sites are open to enrollment across the United States, Canada and Australia. Trial expansion into the European Union is planned. Based on current projections, enrollment will extend into 2016.
- The METRIC study will be presented in a clinical trial in progress poster session at the 2015 ASCO Annual Meeting on Saturday, May 30, 2015.
- Data from the Phase 2 EMERGE study of glembatumumab vedotin in metastatic breast cancer were published in the Journal of Clinical Oncology. The data from this study supported the initiation of the METRIC study.
- Patient enrollment continues in the Phase 2 study of glembatumumab vedotin in metastatic melanoma. To date, eight of 10 planned sites are open to enrollment in the United States.
- Celldex continues to advance plans to expand the study of glembatumumab vedotin into other cancers in which gpNMB is expressed.
    - Study design is being finalized for a Phase 2 study in squamous cell lung cancer and the study will commence 2H 2015.
    - 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. Protocols for the study are currently being developed.

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

- In April 2015, the Company presented preclinical data that support varlilumab's expansion into combination studies with PD-1 inhibitors in a poster session at the AACR Annual Meeting 2015. Data demonstrated that the combination of varlilumab and anti-PD-L1 induces a potent immune-mediated effect that results in important changes in the tumor microenvironment. Most notably, it was observed that the combination strategy improved the ratio of effector T cells to regulatory T cells, which was accompanied by a reduction in the expression of PD-1 on both effector and regulatory T cells.
- In April 2015, Celldex announced the initiation of a Phase 1/2 study examining the combination of varlilumab and ipilimumab (Yervoy®; Bristol-Myers Squibb) in patients with Stage III or IV metastatic melanoma. This study is currently open to enrollment. In the Phase 2 portion of the study, patients with tumors that express NY-ESO-1 will also receive CDX-1401, Celldex's off-the-shelf antibody-based dendritic cell vaccine that targets tumors expressing the NY-ESO-1 oncoprotein.
- In April 2015, Celldex announced that it had entered into a clinical trial collaboration with Roche to evaluate the combination of varlilumab, Celldex's CD27 targeting investigational antibody, and MPDL3280A (anti-PDL1), Roche's investigational cancer immunotherapy in a Phase 1/2 study in renal cell carcinoma. Under the terms of this agreement, Roche will provide study drug and Celldex will be responsible for conducting and funding the study, which is expected to open to enrollment in 2H 2015.
- In January 2015, Celldex announced that enrollment had opened in the Phase 1/2 study of varlilumab and Opdivo® in adult patients with advanced non-small cell lung cancer, metastatic melanoma, colorectal cancer, ovarian cancer, and head and neck squamous cell carcinoma. This study is being conducted by Celldex under a clinical trial collaboration with Bristol-Myers Squibb Company. The companies are sharing development costs.
- The Phase 1b study of varlilumab and ONT-10, Oncothyreon's therapeutic vaccine targeting the tumor-associated antigen MUC1, continues to actively enroll patients with advanced breast or ovarian cancer. Celldex is providing study drug and Oncothyreon is conducting the study.
- Efforts are underway for additional Phase 2 studies of varlilumab and the Company will provide updates on these studies as they are initiated.

CDX-1401, an antibody-based NY-ESO-1-specific therapeutic vaccine for multiple solid tumors

- In April 2015, Celldex announced the initiation of a Phase 1/2 study examining the combination of varlilumab and ipilimumab (Yervoy®; Bristol-Myers Squibb) in patients with Stage III or IV metastatic melanoma. This study is currently open to enrollment. In the Phase 2 portion of the study, patients with tumors that express NY-ESO-1 will also receive CDX-1401, an off-the-shelf antibody-based dendritic cell targeted vaccine.
- Celldex continues to support several external collaborations, including a National Cancer Institute sponsored Phase 2 study of CDX-1401 and CDX-301 for patients with metastatic melanoma, which is open to enrollment.

CDX-301 (recombinant human Flt3L), a potent hematopoietic cytokine that uniquely expands dendritic cells and hematopoietic stem cells

- CDX-301 is being developed as a combination product with other immuno-oncology agents in a number of investigator-sponsored studies.
- A pilot study of CDX-301 alone and in combination with Mozobil® in hematopoietic stem cell transplantation was initiated in September of 2014 and is open to enrollment.

First Quarter 2015 Financial Highlights and 2015 Guidance

Cash position: Cash, cash equivalents and marketable securities as of March 31, 2015 were $359.8 million compared to $201.0 million as of December 31, 2014. The increase was primarily driven by net proceeds to Celldex of $188.8 million from an underwritten financing; partially offset by our first quarter net cash burn of $30.0 million. As of March 31, 2015 Celldex had 98.5 million shares outstanding.

Revenues: Total revenue was $0.5 million in the first quarter of 2015 compared to $0.4 million for the comparable period in 2014. The increase in the first quarter of 2015 was primarily due to our clinical trial collaboration with BMS, partially offset by a decrease in revenue related to our Rockefeller University services agreement.

R&D Expenses: Research and development (R&D) expenses were $25.1 million in the first quarter of 2015 compared to $27.1 million for the comparable period in 2014. The decrease in Celldex's R&D investment was primarily due to the one-time $2.5 milestone payment incurred in the first quarter of 2014 as a result of the METRIC initiation and a decrease in ACT IV clinical trial costs, partially offset by increases in glembatumumab vedotin and varlilumab clinical trial costs.

G&A Expenses: General and administrative (G&A) expenses were $6.1 million in the first quarter of 2015 compared to $4.6

million for the comparable period in 2014. The increase in G&A expenses was primarily attributable to higher personnel-related expenses and RINTEGA and glembatumumab vedotin commercial planning costs in 2015.

Net loss: Net loss was $30.2 million, or ($0.33) per share, for the first quarter of 2015 compared to a net loss of $29.9 million, or ($0.33) per share for the comparable period in 2014.

Financial guidance: Celldex expects that its cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements through 2017, however, this could be impacted by our clinical data results from the RINTEGA program and their potential impact on our pace of commercial manufacturing and the rate of expansion of our commercial operations.

RINTEGA® is a registered trademark of Celldex Therapeutics. Opdivo® and Yervoy® are registered trademarks of Bristol-Myers Squibb. Mozobil® is a registered trademark of sanofi-aventis U.S. LLC.

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 RINTEGA® ("rindopepimut"; "rindo"; CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127), CDX-1401, CDX-301 and other products and our goals for 2015. 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 RINTEGA, 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; our ability to maintain and derive benefit from the Breakthrough Therapy Designation for RINTEGA, 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.

—table follows—

CELLDEX THERAPEUTICS, INC.

(In thousands, except per share amounts)

CONSOLIDATED STATEMENT OF OPERATIONS DATA	**Quarter Ended March 31,**	
	2015	**2014**
	(Unaudited)	

OPERATING REVENUE		
Product Development and Licensing Agreements	$ 342	$ 35
Contracts and Grants	144	381
Total Revenue	486	416
OPERATING EXPENSE		
Research and Development	25,125	27,070
General and Administrative	6,089	4,582
Amortization of Acquired Intangible Assets	253	253
Total Operating Expense	31,467	31,905
Operating Loss	(30,981)	(31,489)
Investment and Other Income, Net	807	1,586
Net Loss	$ (30,174)	$ (29,903)
Basic and Diluted Net Loss per Common Share	$ (0.33)	$ (0.33)
Weighted Average Common Shares Outstanding	92,437	89,270

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	**March 31, 2015 (Unaudited)**	**December 31, 2014**
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 359,773	$ 201,043
Other Current Assets	4,356	3,942
Property and Equipment, net	11,236	10,535
Intangible and Other Assets, net	32,335	32,494
Total Assets	$ 407,700	$ 248,014
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 21,148	$ 24,491
Long-Term Liabilities	11,000	11,863
Stockholders' Equity	375,552	211,660
Total Liabilities and Stockholders' Equity	$ 407,700	$ 248,014

CONTACT: Company Contact:

Sarah Cavanaugh

Vice President of Investor Relations &

Corp Communications

Celldex Therapeutics, Inc.

(781) 433-3161

scavanaugh@celldex.com

Media Inquiries:

Dan Budwick

Pure Communications, Inc.

(973) 271-6085

dan@purecommunicationsinc.com

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