May 5, 2016

Celldex Reports First Quarter 2016 Results

HAMPTON, N.J., May 05, 2016 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the first quarter ended March 31, 2016.

"While the recent setback of the RINTEGA program was certainly a disappointment, the Company is focused on executing across the breadth and depth of our pipeline, including six ongoing company-led clinical trials—the pivotal METRIC study in triple negative breast cancer, two Phase 2 studies across a broad range of indications and multiple Phase 1/2 studies that are actively enrolling patients," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics.

"To this end, Celldex and our collaborators presented seven posters at the recent AACR meeting across multiple compounds in our pipeline and introduced a new preclinical program that has identified promising agonist antibodies targeting the CD40 receptor. Most importantly, we reported favorable safety and immune monitoring data from the Phase 1 study of varlilumab and Opdivo®. The Phase 2 study enrolled its first patients last month and will continue to add to a wealth of data slated for presentation later in 2016 and throughout 2017, including the presentation of Phase 2 data from the glembatumumab vedotin study in metastatic melanoma later this year. With the recent realignment of our pipeline, we believe our current cash position will carry us through the first half of 2018, allowing us to read out all current ongoing studies and to initiate several new studies, as well," concluded Marucci.

Program Updates:

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

- In March, Celldex announced that the independent Data Safety and Monitoring Board (DSMB) determined, based on a preplanned interim analysis, that continuation of the Phase 3 ACT IV study of RINTEGA in patients with newly diagnosed EGFRvIII-positive glioblastoma would not reach statistical significance for overall survival in patients with minimal residual disease, the primary endpoint of the study, as both the RINTEGA arm and the control arm were performing on par with each other. In the ACT IV study, RINTEGA performed consistently with prior Phase 2 studies, but the control arm significantly outperformed expectations. Based on this recommendation, Celldex discontinued the study and does not anticipate incurring substantial additional costs related to RINTEGA at this time. The Company is conducting an analysis of the data and plans to present the study at a future scientific/medical meeting or in a peer-reviewed publication. 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.

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 recently opened in the European Union, with the goal of completing enrollment by year-end 2016.
- Patient enrollment is complete in the Phase 2 single-agent study of glembatumumab vedotin in metastatic melanoma. The Company is currently amending 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. The Company expects to present data from the single-agent cohort at an appropriate medical meeting in the second half of 2016.
- 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.

- Data enhancing the understanding of glembatumumab vedotin's mechanism of action and further validation of the overexpression of its target, gpNMB, in a wide range of tumor types were presented at the American Association for Cancer Research (AACR) Annual Meeting 2016 in April. Using a validated immunohistochemistry (IHC) assay to detect the expression of gpNMB, the Company examined tissues from multiple types of solid tumors and normal tissue. Overexpression of gpNMB in samples of tumor tissue versus normal tissue was found in squamous cell carcinoma of the lung (85%), osteosarcoma (62%), pancreatic cancer (55%), lung adenocarcinoma (45%) and squamous cell carcinoma of the head and neck (40%). These results support the potential broad applicability of gpNMB as a therapeutic target across a wide range of tumor types. In addition, in a preclinical study investigating resistance mechanisms in melanoma, glembatumumab vedotin demonstrated synergies with therapies for BRAF mutated melanoma and overcame phenotypes associated with resistance, suggesting use of glembatumumab vedotin may be particularly effective as a single-agent or in combination in this refractory patient population.

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. The study includes cohorts in advanced non-small cell lung cancer (n=35), colorectal cancer (n=18), ovarian cancer (n=18), head and neck squamous cell carcinoma (n=18), renal cell carcinoma (n=25) 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 were presented from the Phase 1 portion of the varlilumab and nivolumab study in a poster at the AACR Annual Meeting in April 2016. The Phase 1 portion of the study, conducted in patients with solid tumors, has completed enrollment (n=36) and primarily enrolled patients with colorectal and ovarian cancer. The primary objective of the Phase 1 portion of the study was to evaluate the safety and tolerability of the combination.
  - The combination showed acceptable tolerability and safety across all dose levels without any evidence of increased autoimmunity or inappropriate immune activation.
  - 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, were observed.
  - 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 suggest 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).
- The Phase 1/2 study of varlilumab and atezolizumab (anti-PDL1) is currently enrolling patients with multiple solid tumors in the dose escalation Phase 1 portion of the study. The Phase 2 portion of the study will be conducted in renal cell carcinoma. 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 (CC-RCC).
  - 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.

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. Based on results to date, plans for additional studies are being considered by NCI. 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 dendritic cells and hematopoietic stem cells

- The Company presented early data from the pilot study of CDX-301 alone and in combination with plerixafor (Mozobil®) in hematopoietic stem cell transplantation (HSCT) in February at the annual meeting of the American Society for Blood and Marrow Transplantation (ASBMT). Data on three donor/patient pairs from the non-plerixafor treated arm showed that CDX-301 given as a single agent was well tolerated and effective at mobilizing hematopoietic stem cells in healthy donors. The stem cell graft contained notable increases in naïve lymphocytes and plasmacytoid dendritic cells consistent with preclinical data suggesting a possible better outcome. Recipients experienced successful engraftment in an expected time frame. Given that hematopoietic stem cell transplantation is outside of Celldex's core focus, in an effort to prioritize human and capital resources, the Company has decided not to advance CDX-301 in this particular indication at this time and instead to focus near-term efforts on its potential role in combination immunotherapy.
- CDX-301's potential activity is 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.

First Quarter 2016 Financial Highlights and Updated 2016 Guidance

Cash position: Cash, cash equivalents and marketable securities as of March 31, 2016 were $254.0 million compared to $289.9 million as of December 31, 2015. The decrease was primarily driven by our first quarter cash used in operating activities of approximately $34.9 million. As of March 31, 2016 Celldex had 98.7 million shares outstanding.

Revenues: Total revenue was $1.3 million in the first quarter of 2016, compared to $0.5 million for the comparable period in 2015. The increase in revenue was primarily due to our clinical trial collaboration with Bristol-Myers Squibb, our research and development agreement with Rockefeller University and an increase in grant revenue.

R&D Expenses: Research and development (R&D) expenses were $27.4 million in the first quarter of 2016, compared to $25.1 million for the comparable period in 2015. The increase in R&D expenses was primarily attributable to increased headcount.

G&A Expenses: General and administrative (G&A) expenses were $9.3 million in the first quarter of 2016, compared to $6.1 million for the comparable period in 2015. The increase in G&A expenses was primarily due to higher stock-based compensation of $1.1 million, increased headcount, and RINTEGA and glembatumumab vedotin commercial planning costs.

Net loss: Net loss was $34.7 million, or ($0.35) per share, for the first quarter of 2016, compared to a net loss of $30.2 million, or ($0.33) per share, for the comparable periods in 2015.

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 the first half of 2018.

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. Mozobil® is a registered trademark of sanofi-aventis U.S. LLC. 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 glembatumumab 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 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 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 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)

STATEMENTS OF OPERATIONS DATA	**Consolidated Quarter Ended March 31, 2016**	**Quarter Ended March 31, 2015**
	(Unaudited)	
OPERATING REVENUE		
Product Development and Licensing Agreements	$ 453	$ 342
Contracts and Grants	850	144
Total Revenue	1,303	486
OPERATING EXPENSE		
Research and Development	27,447	25,125
General and Administrative	9,307	6,089
Amortization of Acquired Intangible Assets	253	253
Total Operating Expense	37,007	31,467
Operating Loss	(35,704)	(30,981)
Investment and Other Income, Net	1,031	807
Net Loss	$ (34,673)	$ (30,174)
Basic and Diluted Net Loss per Common Share	$ (0.35)	$ (0.33)
Weighted Average Common Shares Outstanding	98,689	92,437

CONDENSED BALANCE SHEETS DATA	**Consolidated March 31, 2016**	**December 31, 2015**
	(Unaudited)	
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 254,017	$ 289,889

Other Current Assets	6,938	5,047
Property and Equipment, net	11,392	11,461
Intangible and Other Assets, net	29,584	31,187
Total Assets	$ 301,931	$ 337,584
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 25,307	$ 30,240
Long-Term Liabilities	16,592	17,239
Stockholders' Equity	260,032	290,105
Total Liabilities and Stockholders' Equity	$ 301,931	$ 337,584

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