November 5, 2015

Celldex Reports Third Quarter 2015 Results

HAMPTON, N.J., Nov. 5, 2015 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the third quarter ended September 30, 2015.

"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. "As we move closer to final data from the ACT IV study in newly diagnosed glioblastoma, we continue to build on the potential promise of RINTEGA in the recurrent setting and look forward to presenting long-term survival data from the ReACT study at the SNO meeting later this month. In the third quarter we continued to execute on all fronts, including enrolling patients to seven ongoing Celldex-sponsored clinical trials. In addition, there are now numerous investigator initiated studies ongoing with additional concepts under discussion. We look forward to data in 2016 from several of these studies that we believe will further support the critical role of immunotherapy in oncology."

Program Updates:

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

- The ACT IV study is a randomized, double-blind, placebo controlled study of RINTEGA plus GM-CSF added to standard of care temozolomide in patients with newly diagnosed, surgically resected, EGFRvIII-positive glioblastoma. 745 patients were enrolled into ACT IV to reach the required 374 patients with minimal residual disease (assessed by central review) needed for analysis of the primary overall survival endpoint. All patients, including those with disease that exceed this threshold, will be included in a secondary analysis of overall survival as well as analyses of progression-free survival, safety and tolerability, and quality of life. The study design includes interim analyses conducted by an independent Data Safety and Monitoring Board (DSMB) at 50 and 75% of events (deaths). The first interim analysis occurred in June 2015, and the DSMB recommended continuation of the study as planned. The Company anticipates that the study will reach the required number of events to perform the second interim analysis in late 2015 and that the analysis will occur in early 2016.

- As previously reported, data from the Phase 2 ReACT study in patients with recurrent glioblastoma were presented in an oral session at the 2015 ASCO Annual Meeting by David A. Reardon, M.D., Clinical Director, Center for Neuro-Oncology, Dana-Farber Cancer Institute and Associate Professor of Medicine, Harvard Medical School, and the lead investigator of the ReACT study. Patients on the RINTEGA arm experienced a statistically significant overall survival (OS) benefit, and an impressive, emerging long-term survival benefit was observed. The primary endpoint of the study, progression-free survival at six months (PFS6), was met, and a clear advantage was demonstrated across multiple, clinically important endpoints including long-term progression-free survival, objective response rate (ORR) and need for steroids. The Company will present an update on overall survival and long-term survival in a podium presentation at the 20th Annual Scientific Meeting of the Society for Neuro-Oncology (SNO) on Friday, November 20th at 1:30 PM CT/2:30 PM ET.

Glembatumumab vedotin ("glemba"; CDX-011), an antibody-drug conjugate 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. Trial expansion into the European Union (EU) is underway, and the Company plans to open enrollment in up to 50 sites in the EU in early 2016. Based on current projections, enrollment will be completed in the second half of 2016.

- Patient enrollment continues in the Phase 2 study of glembatumumab vedotin in metastatic melanoma.

- Celldex continues to advance plans to expand the study of glembatumumab vedotin in other cancers in which gpNMB is expressed.
  - A Phase 2 study in squamous cell lung cancer is expected to commence in Q1 2016.
  - Celldex and the National Cancer Institute have entered into a Cooperative Research and Development

Agreement (CRADA) under which the NCI will sponsor two studies of glembatumumab vedotin—one in uveal melanoma and one in pediatric osteosarcoma.

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 1/2 study of varlilumab and nivolumab (Opdivo®) in adult patients with advanced non-small cell lung cancer, metastatic melanoma, colorectal cancer, ovarian cancer, and head and neck squamous cell carcinoma is actively enrolling patients. This study is being conducted by Celldex under a clinical trial collaboration with Bristol-Myers Squibb. The companies are sharing development costs.

- In April 2015, Celldex announced that it had entered into a clinical trial collaboration with Roche to evaluate the combination of varlilumab and atezolizumab (anti-PDL1) 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 Q4 2015.

- 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); and,
  - 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.

- Celldex will present a preclinical poster on the contribution of varlilumab's immune stimulating properties versus regulatory T cell (Treg) depletion in multiple tumor models on Friday, November 6, 2015 at 6:15 PM ET at the 2015 Society for Immunotherapy of Cancer (SITC) Annual Meeting.

- Oncothyreon recently completed evaluation of two dosing cohorts in the Oncothyreon-led Phase 1b trial of ONT-10, a therapeutic vaccine targeting the tumor-associated antigen MUC1, in combination with varlilumab in patients with advanced breast and ovarian cancers. Preliminary data from these two cohorts did not demonstrate sufficient activity to move forward with the program, and Oncothyreon does not plan to enroll additional patients in the Phase 1b trial. Varlilumab biomarker analyses from peripheral blood samples from this study are consistent with prior experience including an increase in activated T cells and natural killer cells and a decrease in regulatory T cells.

- Patient treatment in the Phase 1 dose-escalation study of varlilumab is complete. Any incremental data updates will be included in a future scientific presentation/publication.

- 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

- A Phase 1/2 study examining the combination of varlilumab and ipilimumab (Yervoy®) 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, 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 recently completed 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 investigator-sponsored studies.

- A pilot study of CDX-301 alone and in combination with Mozobil® in hematopoietic stem cell transplantation was initiated in September 2014 and is currently enrolling patients and sibling-matched donors. The Company anticipates presenting early data from this study in Q1 2016.

Third Quarter and First Nine Months 2015 Financial Highlights and 2015 Guidance

Cash position: Cash, cash equivalents and marketable securities as of September 30, 2015 were $304.6 million compared to $334.0 million as of June 30, 2015. The decrease of $29.4 million was primarily driven by our third quarter net cash used in operating activities of $27.8 million. As of September 30, 2015 Celldex had 98.6 million shares outstanding.

Revenues: Total revenue was $1.0 million in the third quarter of 2015 and $3.7 million for the nine months ended September 30, 2015, compared to $1.1 million and $2.1 million for the comparable periods in 2014. The increase in the nine months ended September 30, 2015 was primarily due to 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 $24.7 million in the third quarter of 2015 and $76.3 million for the nine months ended September 30, 2015, compared to $26.2 million and $77.4 million for the comparable periods in 2014.

G&A Expenses: General and administrative (G&A) expenses were $8.5 million in the third quarter of 2015 and $22.8 million for the nine months ended September 30, 2015, compared to $5.0 million and $14.4 million for the comparable periods in 2014. The increase in G&A expenses was primarily attributable to higher personnel-related expenses as we prepare for potential product launches and a $3.3 million increase year to date in RINTEGA and glembatumumab vedotin commercial planning costs over the $2.6 million spent in the comparable period in 2014.

Net loss: Net loss was $32.0 million, or ($0.32) per share, for the third quarter of 2015 and $94.5 million, or ($0.98) per share, for the nine months ended September 30, 2015, compared to a net loss of $28.1 million, or ($0.31) per share and $86.3 million, or ($0.97) per share for the comparable periods 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. Sutent® is a registered trademark of Pfizer. 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.

CELLDEX THERAPEUTICS, INC.

(In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	Quarter Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(Unaudited)		(Unaudited)	
REVENUE				
Product Development and Licensing Agreements	$ 377	$ 284	$ 1,053	$ 518
Contracts and Grants	649	817	2,636	1,591
Total Revenue	1,026	1,101	3,689	2,109
OPERATING EXPENSE				
Research and Development	24,656	26,185	76,271	77,355
General and Administrative	8,487	5,004	22,761	14,373
Amortization of Acquired Intangible Assets	254	254	760	760
Total Operating Expense	33,397	31,443	99,792	92,488
Operating Loss	(32,371)	(30,342)	(96,103)	(90,379)
Investment and Other Income, Net	391	2,260	1,590	4,121
Net Loss	$ (31,980)	$ (28,082)	$ (94,513)	$ (86,258)
Basic and Diluted Net Loss per Common Share	$ (0.32)	$ (0.31)	$ (0.98)	$ (0.97)
Weighted Average Common Shares Outstanding	98,568	89,404	96,518	89,346

CONDENSED CONSOLIDATED BALANCE SHEETS	September 30, 2015 (Unaudited)	December 31, 2014
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 304,610	$ 201,043
Other Current Assets	4,646	3,942
Property and Equipment, net	11,864	10,535
Intangible and Other Assets, net	31,512	32,494
Total Assets	$ 352,632	$ 248,014

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 23,635	$ 24,491
Long-Term Liabilities	10,370	11,863
Stockholders' Equity	318,627	211,660
Total Liabilities and Stockholders' Equity	$ 352,632	$ 248,014

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