May 10, 2018

Celldex Provides Corporate Update and Reports First Quarter 2018 Results

HAMPTON, N.J., May 10, 2018 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the first quarter ended March 31, 2018.

"Celldex has made considerable progress on an important strategic prioritization of our pipeline, following announcement in April of the METRIC study results in triple-negative breast cancer and discontinuation of the glembatumumab program across all indications," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "In 2018, we will focus primarily on continued clinical development of two company-sponsored programs—CDX-1140, a promising CD40 agonist, and CDX-3379, which blocks ErbB3, a receptor thought to play an important role in regulating cancer cell growth and survival. Development of varlilumab and CDX-301 will also continue externally through investigator-sponsored initiatives and internally through inclusion in combination studies."

"In line with this, to extend our financial resources and direct them to the advancement of the programs we believe can bring the most value to both patients and shareholders, we made significant cuts to our business operations, including executing a corporate restructuring in late April. Based on our progress to date, we believe our cash on hand combined with proceeds from our established ATM will support the continued development of our pipeline through 2020. This extended runway will provide for multiple inflection points, and we are solely focused on executing along these lines."

Pipeline Prioritization:

Celldex is focusing its efforts and resources on the continued research and development of:

- CDX-1140, an agonist human monoclonal antibody targeted to CD40, a receptor expressed on dendritic cells and a key activator of immune response, currently in a Phase 1 dose-escalation study in multiple types of solid tumors. CD40 agonist antibodies have shown encouraging results in early clinical studies, but systemic toxicity associated with broad CD40 activation has limited their dosing. CDX-1140 is differentiated by potent agonist activity that is independent of Fc receptor interaction, allowing for more consistent, controlled immune activation without promoting cytokine production. Additionally, CD40 ligand binding is not blocked, allowing for potential synergistic effects near activated T cells in lymph nodes and tumors. Celldex is currently focusing its efforts on executing the Phase 1 dose-escalation activities and advancing to combination cohorts. The combination cohorts will include CDX-301, which as a dendritic cell growth factor can increase the number of cells responding to CDX-1140. In addition, combination with varlilumab, especially in lymphomas which co-express these receptors, could have significant potential.

- CDX-3379, a human monoclonal antibody designed to block the activity of ErbB3 (HER3), currently in an early Phase 2 study in advanced head and neck squamous cell cancer in combination with Erbitux®. The proposed mechanism of action for CDX-3379 sets it apart from other drugs in development in this class due to its ability to block both ligand-independent and ligand-dependent ErbB3 signaling by binding to a unique epitope. It has a favorable pharmacologic profile, including a longer half-life and slower clearance relative to other drug candidates in this class. CDX-3379 also has potential to enhance anti-tumor activity and/or overcome resistance in combination with other targeted and cytotoxic therapies to directly kill tumor cells. Tumor cell death and the ensuing release of new tumor antigens have the potential to serve as a focus for combination therapy with immuno-oncology approaches, even in refractory patients. Celldex intends to complete enrollment to the first stage of the Phase 2 study and will use this data to inform next decisions. In line with this, the Company continues to explore potential other opportunities in additional indications where ErbB3 is believed to play a role.

- Varlilumab, an immune modulating antibody targeting CD27 designed to enhance a patient's immune response against cancer, being studied in multiple investigator initiated research studies and currently completing a Phase 1/2 study across multiple solid tumors in combination with Opdivo®. Celldex is conducting the study in collaboration with Bristol-Myers Squibb Company (BMS) and plans to present data at various medical meetings in 2018, including in an oral presentation at the ASCO 2018 Annual Meeting in June. The Company intends to explore varlilumab externally through several investigator-initiated studies and internally through inclusion in combination studies.

- CDX-301, a dendritic cell growth factor, currently being evaluated in an investigator-initiated pilot study with radiation therapy in patients with advanced non-small cell lung cancer (NSCLC) and planned for combination study with CDX-

1140. Celldex believes CDX-301's potential as a dendritic cell mobilizer could play an important role in immuno-oncology regimens. The Company will continue to support investigator initiated research and will seek to combine CDX-301 with CDX-1140 in its ongoing Phase 1 study of CDX-1140 in the future.

- Celldex's preclinical pipeline includes CDX-0159, which is planned to enter the clinic in 2019; the TAM program, comprised of the targets Tyro3, AXL and MerTK; and a bispecific antibody (BsAb) program. Celldex's initial BsAb candidate couples CD27 co-stimulation with blockade of the PD-L1/PD-1 pathway using novel, highly active anti-PD-L1 antibodies. Data from this program were presented in a poster at the AACR 2018 Annual Meeting. The BsAb was more potent in human T cell activation and anti-tumor activity compared to the combined CD27 and PD-L1 antibodies. Enhanced efficacy has been attributed to more efficient cross-linking of the CD27 receptor, resulting in stronger T cell activation.

To conserve resources, Celldex is discontinuing development of:

- Glembatumumab vedotin, a targeted antibody-drug conjugate (ADC), across all indications, as previously disclosed;
- CDX-014, an ADC (which are typically more costly to develop than other therapeutics), in early Phase 1 development in renal cell and clear cell ovarian carcinomas; and
- CDX-1401, an NY-ESO-1-antibody fusion protein, that was being explored in investigator-sponsored and collaborative studies.

Recent Program Highlights Presented at the American Association for Cancer Research (AACR) 2018 Annual Meeting in April

- **Data from the CDX-1140 program were presented in a poster session.** Building off previously presented preclinical work, CDX-1140 was further characterized showing tumor shrinkage and prolonged survival in several xenograft models. These preclinical studies support the potential of CDX-1140 having direct anti-tumor effects on CD40-positive tumors that may supplement its activity as an immune activating agent.

- **Data from the CDX-3379 program were presented in two poster sessions.**
  - Data were presented from a preoperative "window of opportunity" study in 12 patients with head and neck squamous cell carcinoma (HNSCC). The study was designed to evaluate the effect of CDX-3379 on phosphorylated ErbB3 (pErbB3) and other potential biomarkers in patients with HNSCC. Patients with newly diagnosed HNSCC received two doses of CDX-3379, at a two-week interval prior to tumor resection. CDX-3379 reduced pErbB3 levels in 83% (10/12) of patient samples, with greater than or equal to 50% decreases in 58% of patients (7/12), which met the primary study objective. Stable disease was observed in 92% (11/12) of patients prior to surgery, and a patient with HPV-negative disease experienced significant tumor shrinkage (92% in primary tumor; 26% in metastatic lesion). CDX-3379 was well-tolerated, and no treatment-related adverse events were observed.
  - Data were presented from a study that explored the reduction of PD-L1 expression by simultaneous blockade of EGFR and ErbB3 in HNSCC. Investigators examined the effects of combining CDX-3379 and cetuximab, a monoclonal antibody targeting EGFR, in xenograft models of HNSCC. Combining CDX-3379 and cetuximab inhibited tumor growth more potently than cetuximab alone. Mechanistic studies demonstrated a reduction of PD-L1 expression from the combination.

- **Early promising data (n=9) from an ongoing, investigator-initiated pilot study of CDX-301 were presented in a plenary session.** This Phase 2 study is evaluating the combination of CDX-301 and stereotactic body radiotherapy (SBRT) in up to 29 patients with advanced non-small cell lung cancer (NSCLC). The presentation included data from nine patients, seven of whom were previously treated with anti-PD(L)1 checkpoint inhibitors. The one-week course of treatment included subcutaneous injections of CDX-301 and SBRT directed to a single lung tumor lesion. Non-irradiated tumors were evaluated for response. Enrollment is ongoing.

  - Progression-free survival at four months (PFS4), the primary endpoint of the study, was achieved in 56% (5/9) of patients overall and in 100% (5/5) of patients who experienced partial responses (PRs) by PERCIST.
  - Notably, PRs were observed in non-irradiated tumors in 56% (5/9) of patients at two months; 3 PRs (3/9) were confirmed by immune-related response criteria (irRC).
  - In the patients previously treated with immune checkpoint inhibitors, 71% (5/7) experienced PRs and PFS4 versus 0% (0/2) in patients not treated with an anti-PD(L)1 therapy.
  - SBRT in combination with CDX-301 induced and reactivated anti-tumor immune responses in patients who had progressive disease on checkpoint inhibitors.
  - No dose-limiting toxicities were observed.

First Quarter 2018 Financial Highlights and Updated 2018 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2018 were $123.2 million compared to

$139.4 million as of December 31, 2017. The decrease was primarily driven by first quarter cash used in operating activities of approximately $28.0 million and partially offset by the receipt of $11.7 million from sales of common stock under our Cantor agreement. At March 31, 2018, Celldex had 143.4 million shares outstanding.

Revenues: Total revenue was $4.1 million in the first quarter of 2018, compared to $1.5 million for the comparable period in 2017. The increase in revenue was primarily due to the contract manufacturing and research and development agreements with International AIDS Vaccine Initiative and Frontier Biotechnologies, Inc. signed in the second quarter of 2017.

R&D Expenses: Research and development (R&D) expenses were $21.9 million in the first quarter of 2018, compared to $25.8 million for the comparable period in 2017. The decrease in R&D expenses was primarily due to lower varlilumab, CDX-3379 and anti-KIT program product development expenses of $0.9 million, $0.7 million and $0.3 million, respectively, and lower personnel and facility costs of $1.4 million.

G&A Expenses: General and administrative (G&A) expenses were $5.6 million in the first quarter of 2018, compared to $7.2 million for the comparable period in 2017. The decrease in G&A expenses was primarily due to lower personnel expenses of $0.7 million, lower commercial planning costs of $0.4 million and lower legal, consulting and professional services expense of $0.3 million.

Changes in Fair Value Remeasurement of Contingent Consideration: The $13.6 million gain on the fair value remeasurement of contingent consideration in the first quarter of 2018 was primarily due to updated assumptions for glemba-related milestones and discount rates. The $3.4 million loss on fair value remeasurement of contingent consideration in the first quarter of 2017 was primarily due to changes in discount rates and the passage of time.

Intangible Asset and Goodwill Impairments: The Company recorded $18.7 million in non-cash impairment charges related to fully impaired glemba-related intangible assets and $91.0 million in goodwill impairment charges as the carrying value of the Company's net assets exceeded the Company's fair value by an amount in excess of the goodwill asset in the first quarter of 2018.

Income Tax Benefit: The Company recorded a $0.8 million non-cash income tax benefit related to the impaired glemba in-process research and development (IPR&D) assets in the first quarter of 2018.

Net Loss: Net loss was $118.1 million, or ($0.84) per share, for the first quarter of 2018, compared to a net loss of $34.3 million, or ($0.28) per share, for the comparable period in 2017.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at March 31, 2018, combined with the anticipated proceeds from future sales of our common stock under the Cantor agreement, are sufficient to meet estimated working capital requirements and fund planned operations through 2020. This could be impacted if Celldex elects to pay Kolltan contingent milestones, if any, in cash.

Opdivo® is a registered trademark of Bristol-Myers Squibb. Erbitux® is a registered trademark of Eli Lilly & Co.

About Celldex Therapeutics, Inc.
Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline includes immunotherapies and other targeted biologics derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors to treat specific types of cancer or other diseases. 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. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These 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 Company 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; our ability to realize the anticipated benefits from the acquisition of Kolltan and to operate the combined business efficiently; 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.

CELLDEX THERAPEUTICS, INC.
(In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	**Three Months Ended March 31,**	
	2018	**2017**
REVENUES:		
Product Development and Licensing Agreements	$ 992	$ 556
Contracts and Grants	3,076	978
Total Revenue	4,068	1,534
OPERATING EXPENSES:		
Research and Development	21,875	25,793
General and Administrative	5,593	7,229
Goodwill Impairment	90,976	-
Intangible Asset Impairment	18,677	-
(Gain)/Loss on Fair Value Remeasurement of Contingent Consideration	(13,600)	3,400
Amortization of Acquired Intangible Assets	224	224
Total Operating Expense	123,745	36,646
Operating Loss	(119,677)	(35,112)
Investment and Other Income, Net	780	851
Net Loss Before Income Tax Benefit	(118,897)	(34,261)
Income Tax Benefit	765	-
Net Loss	$ (118,132)	$ (34,261)
Basic and Diluted Net Loss per Common Share	$ (0.84)	$ (0.28)
Shares Used in Calculating Basic and Diluted Net Loss per Share	140,548	122,648

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	March 31, 2018	December 31, 2017
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 123,248	$ 139,427
Other Current Assets	7,724	5,329
Property and Equipment, net	9,785	10,372
Intangible and Other Assets, net	50,619	160,496
Total Assets	$ 191,376	$ 315,624
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 24,012	$ 27,736
Long-Term Liabilities	33,282	51,519
Stockholders' Equity	134,082	236,369
Total Liabilities and Stockholders' Equity	$ 191,376	$ 315,624

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