Celldex Therapeutics, Inc. Logo

Celldex Provides Corporate Update and Reports Third Quarter 2019 Results

November 12, 2019

HAMPTON, N.J., Nov. 12, 2019 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the third quarter ended September 30, 2019.

“Celldex achieved a significant milestone last week, reporting data at SITC that CDX-1140 has exceeded the hurdles we defined for Phase 1 monotherapy development and has the potential to be a best in class CD40 agonist,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We are very encouraged by the results we have seen to date across the study and have expanded the trial to more broadly explore the clinical activity we observed in head and neck squamous cell carcinoma and to include a combination cohort with KEYTRUDA under a clinical trial collaboration with Merck.

We also continue to make excellent progress in our Phase 2 program of our ErbB3 inhibitor, CDX-3379, and reported the potential for a promising biomarker strategy in head and neck squamous cell carcinoma at ASCO this summer. Earlier this month, our IND for our KIT inhibitor, CDX-0159, was accepted by the FDA and we look forward to initiating a Phase 1 trial by year-end. The positive advancements across our pipeline will continue to drive us towards multiple milestones over the next six to 18 months and we look forward to keeping our shareholders updated on our progress,” concluded Marucci.

Recent Pipeline Highlights:

CDX-1140—a potent CD40 agonist that Celldex believes has the potential to successfully balance systemic doses for good tissue and tumor penetration with an acceptable safety profile.

- The monotherapy arm of the Phase 1 dose-escalation study of CDX-1140 in patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas has been completed with an identified maximum tolerated dose (MTD) and recommended Phase 2 dose of 1.5 mg/kg. The combination cohort with CDX-301 has been generally well tolerated to date and the cohort is progressing on track. Patient enrollment is ongoing in the final cohort of CDX-1140 at 1.5 mg/kg plus CDX-301.

- Interim data from the study were presented at the Society for Immunotherapy of Cancer's (SITC) 34th Annual Meeting on November 8, 2019. As of the cut-off date for data reporting, 38 patients with advanced refractory solid tumors had pre- and post-treatment scans available. Patients were heavily pretreated (median of 4 prior therapies) and per protocol were required to have received all standard of care treatments prior to study entry. CDX-1140 demonstrated clinical and biological activity in the study.
  - Two of five patients with head and neck squamous cell carcinoma (HNSCC) treated with CDX-1140 monotherapy at doses of 0.72 mg/kg or higher experienced clinical benefit. The first patient experienced dramatic shrinkage of a large, protruding neck mass on physical exam after two doses of CDX-1140 at 1.5 mg/kg with documented evidence of tumor necrosis/cavitation on CT scan. This patient also reported decreased tumor pain. A second patient experienced cavitation of greater than 50% of lung metastases on CT scan after one dose of CDX-1140 3 mg/kg.
  - A patient with gastroesophageal carcinoma experienced a RECIST response after two cycles of CDX-1140 0.36 mg/kg plus CDX-301 that included 41% shrinkage of liver and lymph node target lesions, with near complete resolution of the liver lesion. This response was durable for four months.
  - Six patients experienced stable disease (n=4 CDX-1140 monotherapy; n=2 CDX-1140/CDX-301 combination) with a duration of 1.8 months to 5.4 months.
  - One patient experienced immune unconfirmed progressive disease on their first scan and continues on treatment for 10+ months without confirmation of progressive disease at CDX-1140 0.09 mg/kg plus CDX-301.
  - In the CDX-1140 monotherapy cohort, two patients out of six experienced pneumonitis as DLTs in the CDX-1140 3.0 mg/kg monotherapy cohort. No dose limiting toxicities have been reported to date in the CDX-301 combination cohort up to 0.72 mg/kg CDX-1140.
  - Potent pharmacological effects associated with immune activation were also observed, including transient induction of inflammatory cytokines and chemokines associated with dendritic cell and T cell activation at higher dose levels. Similar activation was observed with each cycle of therapy. Peripheral blood immune cells had upregulated immune activation markers. CDX-301 markedly increased the number of dendritic cells and was associated with higher IL-12p40 induction; IL-12 is a key molecule for inducing anti-tumor T cell responses.

- Based on the clinical activity observed in HNSCC, up to an additional 15 patients with HNSCC will be enrolled to the study at 1.5 mg/kg CDX-1140 monotherapy. In addition, Celldex has amended the ongoing Phase 1 study to evaluate CDX-1140 in combination with KEYTRUDA® (pembrolizumab), Merck’s anti-PD-1 therapy under a clinical trial collaboration agreement with Merck (known as MSD outside of the U.S. and Canada). The cohort is designed to characterize the safety, pharmacodynamics and activity of CDX-1140 in combination with pembrolizumab in patients refractory to PD-1/PDL-1 treatment. This cohort is expected to open to enrollment in Q1 2020.

CDX-3379—a differentiated human monoclonal antibody designed to block the activity of ErbB3 (HER3). ErbB3 is expressed in many cancers, including head and neck squamous cell cancer (HNSCC) and is believed to be an important receptor regulating cancer cell growth and survival as well as resistance to targeted therapies.

- Enrollment continues in the Phase 2 study of CDX-3379 in advanced HNSCC in combination with Erbitux® in Erbitux-resistant patients who have been previously treated with or are ineligible for checkpoint therapy.
  - Interim data from the study (n=15) were presented at the 2019 American Society for Clinical Oncology (ASCO) Annual Meeting in June that suggested notable clinical activity in this refractory patient population and a promising biomarker strategy.
  - Emerging data from the Phase 2 study and earlier studies of CDX-3379 suggest that antitumor activity may be associated with somatic mutations in the FAT1 and NOTCH1, NOTCH2 or NOTCH3 (NOTCH1-3) genes—genes associated with tumor suppression.
  - In the exploratory analyses presented at ASCO, seven patients were identified as having FAT1 mutated tumors and four of these patients demonstrated clinical response (3 confirmed).
  - Based on these biomarker observations and the clinical activity observed in the ongoing Phase 2 study, the study has been expanded (n= ~45 patients, including at least 15 patients with FAT1 mutations) to allow for an evaluation of the utility of biomarkers for patient selection. Enrollment is ongoing.

CDX-0159—a monoclonal antibody that specifically binds the KIT receptor and potently inhibits its activity. The KIT receptor tyrosine kinase is expressed in a variety of cells, including mast cells. In certain inflammatory diseases, such as chronic idiopathic urticaria (CIU), mast cell degranulation plays a central role in the onset and progression of the disease.

- Celldex's Investigational New Drug (IND) Application for CDX-0159 has been accepted by the Food and Drug Administration and the Company plans to initiate a Phase 1a study of CDX-0159 by year-end 2019. The study is designed to evaluate the safety profile, pharmacokinetics and pharmacodynamics of single ascending doses of CDX-0159 in healthy subjects. Following completion of this study, the Company plans to further study CDX-0159 in chronic idiopathic urticaria (CIU), a mast cell-related disease. CIU presents as itchy hives, angioedema or both for at least six weeks without a specific trigger; multiple episodes can play out over years or even decades. The prevalence of CIU is estimated to be 0.5% to 1% of the total population or up to 3.2 million cases in the United States. About 50% of patients with CIU achieve symptomatic control with antihistamines or leukotriene receptor antagonists. Omalizumab, an IgE inhibitor, provides relief for roughly half of the remaining antihistamine/leukotriene refractory patients. Consequently, there is a need for more effective later line therapies. A review of the CDX-0159 early development program was presented at the American College of Allergy, Asthma & Immunology Annual Scientific Meeting on November 9, 2019 in the Distinguished Industry Oral Abstract Session.

Celldex continues to advance a robust preclinical portfolio and data from the Company's CDX-527 bispecific candidate were presented on November 9th at the Society for Immunotherapy of Cancer (SITC) 34th Annual Meeting (SITC 2019). Bispecific antibodies that engage two independent pathways involved in controlling immune responses to tumors are a rapidly growing area for the development of next generation PD-1 inhibitors. CDX-527 uses Celldex's proprietary highly active anti-PD-L1 and CD27 human antibodies to couple CD27 co-stimulation with blockade of the PD-L1/PD-1 pathway. Celldex's prior clinical experience with combining CD27 activation and PD-1 blockade provide the rationale for linking these two pathways into one molecule. The data presented at SITC demonstrate that CDX-527 is more potent at T cell activation and anti-tumor immunity than the combination of parental monoclonal antibodies. Celldex is currently completing CDX-527 GMP manufacturing activities and IND-enabling studies and plans to file an IND in the first quarter of 2020.

Third Quarter 2019 Financial Highlights and First Nine Months 2019 Financial Highlights and 2019 Guidance

Cash Position: Cash, cash equivalents and marketable securities were $72.9 million as of September 30, 2019 compared to $81.3 million as of June 30, 2019. The decrease was primarily driven by third quarter cash used in operating activities of $11.1 million, partially offset by $2.5 million in net proceeds from sales of common stock under the Cantor agreement. At September 30, 2019, Celldex had 15.9 million shares outstanding.

Revenues: Total revenue was $0.5 million in the third quarter of 2019 and $2.7 million for the nine months ended September 30, 2019, compared to $0.9 million and $7.8 million for the comparable periods in 2018. The decrease in revenue was primarily due to lower revenue from the collaboration agreement with Bristol-Myers Squibb Company and the contract manufacturing and research and development agreements with the International AIDS Vaccine Initiative and Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were $11.1 million in the third quarter of 2019 and $32.3 million for the nine months ended September 30, 2019, compared to $11.9 million and $55.2 million for the comparable periods in 2018. The decrease in R&D expenses was primarily due to lower clinical trial, personnel and contract manufacturing costs.

G&A Expenses: General and administrative (G&A) expenses were $3.4 million in the third quarter of 2019 and $12.2 million for the nine months ended September 30, 2019, compared to $3.7 million and $14.9 million for the comparable periods in 2018. The decrease in G&A expenses was primarily due to lower personnel and commercial planning costs and lower lease restructuring expense.

Changes in Fair Value Remeasurement of Contingent Consideration: The gain on fair value remeasurement of contingent consideration was $2.1 million in the third quarter of 2019 and $1.6 million for the nine months ended September 30, 2019, primarily due to changes in discount rates, the passage of time and updated assumptions for the varlilumab program.

Net Loss: Net loss was $11.4 million, or ($0.75) per share, for the third quarter of 2019, and $40.4 million, or ($2.92) per share, for the nine months ended September 30, 2019, compared to a net loss of $7.2 million, or ($0.66) per share, for the third quarter of 2018 and $141.8 million, or ($14.12)

per share, for the nine months ended September 30, 2018.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at September 30, 2019, combined with the anticipated proceeds from future sales of 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.

Erbitux® is a registered trademark of Eli Lilly & Co. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ USA.

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 maintain compliance with Nasdaq listing requirements; our ability to realize the cost benefits of consolidating our office and laboratory space and to retain key personnel after that consolidation; our ability to realize the anticipated benefits from the acquisition of Kolltan; 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.

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

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	**Quarter Ended September 30,**		**Nine Months Ended September 30,**	
	2019	**2018**	**2019**	**2018**
	(Unaudited)		**(Unaudited)**	
REVENUES:				
Product Development and Licensing Agreements	$ 55	$ 131	$ 379	$ 2,792
Contracts and Grants	491	810	2,307	4,982
Total Revenue	546	941	2,686	7,774
OPERATING EXPENSES:				
Research and Development	11,101	11,918	32,333	55,242
General and Administrative	3,403	3,722	12,207	14,936
Goodwill Impairment	-	-	-	90,976
Intangible Asset Impairment	-	-	-	18,677
Other Asset Impairment	-	-	1,800	-
Gain on Fair Value Remeasurement of Contingent Consideration	(2,114)	(6,935)	(1,612)	(27,968)

Amortization of Acquired Intangible Assets	-	-	-	224
Total Operating Expense	12,390	8,705	44,728	152,087
Operating Loss	(11,844)	(7,764)	(42,042)	(144,313)
Investment and Other Income, Net	431	521	1,611	1,767
Net Loss Before Income Tax Benefit	(11,413)	(7,243)	(40,431)	(142,546)
Income Tax Benefit	-	-	-	765
Net Loss	$ (11,413)	$ (7,243)	$ (40,431)	$ (141,781)
Basic and Diluted Net Loss per Common Share	$ (0.75)	$ (0.66)	$ (2.92)	$ (14.12)
Shares Used in Calculating Basic and Diluted Net Loss per Share	15,282	10,912	13,854	10,042

CONDENSED CONSOLIDATED BALANCE SHEETS DATA

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 72,918	$ 94,022
Other Current Assets	2,185	5,057
Property and Equipment, net	4,488	6,111
Intangible and Other Assets, net	52,250	50,619
Total Assets	$ 131,841	$ 155,809
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 11,888	$ 12,602
Long-Term Liabilities	18,573	19,147
Stockholders' Equity	101,380	124,060
Total Liabilities and Stockholders' Equity	$ 131,841	$ 155,809

Source: Celldex Therapeutics, Inc.