Celldex Therapeutics, Inc. Logo

Celldex Provides Corporate Update and Reports First Quarter 2020 Results

May 6, 2020

HAMPTON, N.J., May 06, 2020 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the first quarter ended March 31, 2020.

“Despite the ongoing challenges associated with the COVID-19 pandemic, Celldex continued to make considerable progress advancing our pipeline in the first quarter of 2020,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “Notably, the Company completed enrollment and treatment of all subjects in the Phase 1 healthy volunteer study of our KIT inhibitor, CDX-0159, which we intend to study in mast cell driven disorders. Results from this study have been accepted as a late-breaking poster presentation with voice over at the EAACI Annual Congress 2020 and will be presented in early June by Dr. Marcus Maurer, a leading medical expert in urticaria. We are excited about the promising data observed to date and, based on these results, have expanded development of CDX-0159. We are planning to initiate studies in chronic urticaria later this year.

“We are also completing preparations to advance CDX-527, the first candidate from our bispecific platform, into a Phase 1 study in refractory, advanced cancers and look forward to initiating this study in the second half of 2020. Finally, we continue to enroll patients in the ongoing studies of CDX-1140 and CDX-3379 and plan to report data updates from these programs later this year,” concluded Marucci.

Recent Pipeline Highlights:

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 urticarias, mast cell degranulation plays a central role in the onset and progression of the disease.

- Enrollment and treatment was recently completed in the ongoing Phase 1 randomized, double-blind, placebo-controlled, single ascending dose escalation study of CDX-0159 in healthy subjects. Subjects received a single intravenous infusion of CDX-0159 at 0.3, 1, 3, or 9 mg/kg or placebo. This study is designed to evaluate the safety profile, pharmacokinetics and pharmacodynamics of CDX-0159 and to select a dose for further study in mast cell driven diseases. The Phase 1 study also evaluates plasma tryptase levels in healthy subjects. Tryptase is an enzyme synthesized and secreted by mast cells and decreases in plasma tryptase levels reflect a systemic reduction in mast cell burden, even in healthy volunteers. If CDX-0159 is able to decrease systemic mast cell load in healthy volunteers, Celldex believes the drug candidate could have significant potential in mast cell driven diseases. Based on promising results observed to date, Celldex is expanding development of CDX-0159 into both chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CINDU).

  -- Results from the Phase 1 study of CDX-0159 have been accepted as a late-breaking poster presentation with voice over at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2020, which this year will be held digitally June 6-8, 2020. Following the press release issued this morning announcing the presentation, Celldex became aware that the full abstracts had been temporarily published on the EAACI website ahead of the lifting of the embargo. Information included in the published abstract was current as of the time of submission in March and did not include the full results that will be presented in June. Results published in the abstract outlined that mild infusion reactions were the most common adverse event occurring in 50% of subjects and did not appear dose related. The infusion reactions spontaneously resolved shortly after the infusions were completed. Transient, mild decreases in hemoglobin and white blood cell count were observed, which spontaneously resolved without intervention. Remarkably, patients who received a single 0.3 mg/kg dose of CDX-0159 decreased serum tryptase—a specific marker of mast cell load—by approximately 50% from baseline for a week, while a single dose at 1 or 3 mg/kg rapidly reduced serum tryptase below the levels of assay detection for at least 3 weeks and 6 weeks, respectively. The poster presentation with voice over in June will include complete, unblinded results from the study, including the 9 mg/kg cohort and pharmacokinetic, immunogenicity and stem cell factor data. The study will be presented by Dr. Marcus Maurer, Professor of Dermatology and Allergy and Director of Research at the Department of Dermatology and Allergy at the Allergie-Centrum-Charité of the Charité - Universitätsmedizin in Berlin. Dr. Maurer is also head of the Specialty Clinics for Urticaria, Mastocytosis, Pruritus and Angioedema and the Dermatological Allergology Lab. Dr. Maurer´s research focuses on the physiological and pathological functions of mast cells.

  -- The Company plans to initiate Phase 1b studies of CDX-0159 in CSU and CINDU, both mast cell-related diseases, by year end. CSU 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. About 50% of patients with CSU 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. CINDUs are forms of urticaria that have an attributable cause or trigger associated with them, typically resulting in hives or wheals. Celldex is exploring cold-induced and dermographism (scratch-induced) urticarias.

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.

- In the Phase 1 dose-escalation study of CDX-1140 in patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas both the monotherapy and combination with CDX-301 dose escalation portions of the trial are complete with an identified maximum tolerated dose (MTD) and recommended Phase 2 dose of CDX-1140 at 1.5 mg/kg—one of the highest systemic dose levels in the CD40 agonist class. Expansion cohorts are actively recruiting including:

  -- CDX-1140 with KEYTRUDA® (pembrolizumab) in patients who have progressed on checkpoint therapy; and,
  -- CDX-1140 with CDX-301 in patients with head and neck squamous cell carcinoma (HNSCC).

  In addition, a combination of CDX-1140 with chemotherapy in first line metastatic pancreatic cancer is planned.

CDX-3379—a differentiated human monoclonal antibody designed to block the activity of ErbB3 (HER3). ErbB3 is expressed in many cancers, including 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® (cetuximab) in Erbitux-resistant patients who have been previously treated with or are ineligible for checkpoint therapy. Data reported at the 2019 American Society for Clinical Oncology (ASCO) Annual Meeting in June suggested that observed antitumor activity with CDX-3379 might be associated with somatic mutations in the FAT1 and NOTCH1-3 genes—genes associated with tumor suppression. Based on these biomarker observations and the clinical activity observed in the ongoing Phase 2 study, the study was 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.

Celldex continues to advance a robust preclinical portfolio and is preparing to advance the first candidate from the Company's bispecific platform, CDX-527, into the clinic in the second half of 2020. 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. The Phase 1 dose escalation study will enroll up to 90 patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy, followed by tumor specific expansion cohorts to further evaluate the tolerability, biologic and anti-tumor effects of selected dose level(s) of CDX 527 in specific tumor types.

Recent Business Highlights:

- In March 2020, Celldex announced a milestone payment related to an existing 2013 agreement with Rockefeller University under which Celldex performed manufacturing and development services for Rockefeller University's portfolio of broadly neutralizing antibodies (bNAbs) against HIV, including two clinical-stage candidates 3BNC117 and 10-1074. These investigational agents have potential for use in HIV long-acting therapies for treatment and prevention, as well as cure strategies. This portfolio was licensed by Gilead Sciences in January of 2020 from Rockefeller University and pursuant to Celldex's agreement with Rockefeller, Celldex received an upfront payment of $1.8 million as a result of this transaction and is eligible to receive additional payments from Rockefeller if this portfolio progresses through clinical and commercial development. Under the terms of the agreement, Celldex utilized internal capabilities in production cell line development, process development and GMP manufacturing to support the rapid and successful execution of Rockefeller University's clinical development of 3BNC117 and 10-1074 and contributed to the IND and clinical studies by managing key IND-enabling studies and clinical sample testing for pharmacokinetics and anti-drug antibodies. The close collaboration between Celldex and Rockefeller University allowed for efficient program development and the ability to rapidly overcome challenges.

First Quarter 2020 Financial Highlights and 2020 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2020 were $53.7 million compared to $64.4 million as of December 31, 2019. The decrease was primarily driven by first quarter cash used in operating activities of $12.1 million, partially offset by $1.6 million in net proceeds from sales of common stock under the Cantor agreement. At March 31, 2020, Celldex had 17.7 million shares outstanding.

Revenues: Total revenue was $2.7 million in the first quarter of 2020 compared to $1.4 million for the comparable period in 2019. The increase in revenue was primarily due to the $1.8 million milestone payment from Rockefeller University related to our manufacturing and development services agreement.

R&D Expenses: Research and development (R&D) expenses were $11.7 million in the first quarter of 2020 compared to $11.2 million for the comparable period in 2019. The increase in R&D expenses was primarily due to higher laboratory supply and clinical trial costs, offset by lower contract research costs.

G&A Expenses: General and administrative (G&A) expenses were $3.7 million in the first quarter of 2020 compared to $4.9 million for the comparable period in 2019. The decrease in G&A expenses was primarily due to lower stock-based compensation expense and professional service costs.

Changes in Fair Value Remeasurement of Contingent Consideration: During the quarter ended March 31, 2020, the Company recorded a $0.2 million loss on fair value remeasurement of contingent consideration primarily due to the passage of time. During the quarter ended March 31, 2019, the Company recorded a $1.5 million loss on the fair value remeasurement of contingent consideration primarily due to changes in discount rates and the passage of time.

Net Loss: Net loss was $12.6 million, or ($0.73) per share, for the first quarter of 2020 compared to a net loss of $17.2 million, or ($1.40) per share, for the comparable period in 2019.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at March 31, 2020 are sufficient to meet estimated working capital requirements and fund planned operations into the second quarter of 2021. This guidance excludes anticipated proceeds from future sales of common stock under the Cantor agreement or other potential fundraising.

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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; the effects of the outbreak of COVID-19 on our business and results of operations; 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	**Three Months Ended March 31,**	
	2020	**2019**
	(Unaudited)	
REVENUES:		
Product Development and Licensing Agreements	$ 2,286	$ 129
Contracts and Grants	442	1,296
Total Revenue	2,728	1,425
OPERATING EXPENSES:		
Research and Development	11,695	11,151
General and Administrative	3,666	4,896
Other Asset Impairment	-	1,800
Loss on Fair Value Remeasurement of Contingent Consideration	234	1,519

Total Operating Expense	15,595	19,366
Operating Loss	(12,867)	(17,941)
Investment and Other Income, Net	242	702
Net Loss	$ (12,625)	$ (17,239)
Basic and Diluted Net Loss per Common Share	$ (0.73)	$ (1.40)
Shares Used in Calculating Basic and Diluted Net Loss per Share	17,406	12,297

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	**March 31, 2020 (Unaudited)**	**December 31, 2019**
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 53,722	$ 64,383
Other Current Assets	2,196	2,315
Property and Equipment, net	4,116	4,031
Intangible and Other Assets, net	52,470	52,204
Total Assets	$ 112,504	$ 122,933
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 10,932	$ 11,643
Long-Term Liabilities	17,869	17,264
Stockholders' Equity	83,703	94,026
Total Liabilities and Stockholders' Equity	$ 112,504	$ 122,933

Source: Celldex Therapeutics, Inc.