Celldex Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 5, 2022

HAMPTON, N.J., May 05, 2022 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the first quarter ended March 31, 2022 and provided a corporate update.

“This quarter, we continued to focus on advancing our clinical programs and are on track to report data from our chronic spontaneous urticaria Phase 1b study early this summer,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “After successfully completing important readiness activities, including the development of a CDX-0159 subcutaneous formulation, we remain excited to initiate our Phase 2 chronic urticaria programs during the second quarter. We are well-positioned to further build on this positive momentum as we anticipate executing on several other significant key milestones across our pipeline in the year ahead.”

Recent Program Highlights

CDX-0159 (also referred to as barzolvolimab) - KIT Inhibitor Program

Barzolvolimab is a humanized monoclonal antibody developed by Celldex that binds the KIT receptor with high specificity and potently inhibits its activity. The KIT receptor tyrosine kinase is expressed in a variety of cells, including mast cells, which mediate inflammatory responses such as hypersensitivity and allergic reactions. KIT signaling controls the differentiation, tissue recruitment, survival and activity of mast cells.

- Celldex is currently completing enrollment in the Phase 1b multi-center, randomized, double-blind, placebo-controlled study of barzolvolimab in chronic spontaneous urticaria. This study is designed to assess the safety and treatment effects of multiple ascending doses of barzolvolimab in up to 40 patients with chronic spontaneous urticaria who remain symptomatic despite treatment with antihistamines. Data from this study (0.5, 1.5 and 3 mg/kg cohorts) have been submitted for a late breaking presentation at EAACI 2022.

- Celldex remains on track to initiate Phase 2 studies in chronic spontaneous urticaria and chronic inducible urticaria (cold urticaria and symptomatic dermographism) in the second quarter of 2022. As previously reported, in the fourth quarter of 2021 and first quarter of this year, Celldex successfully advanced important activities to support the initiation of these studies, including the development of a barzolvolimab subcutaneous formulation and the completion of the in-life dosing portion of a six month chronic toxicology study.

- In February 2022, Celldex announced that the development of barzolvolimab will be expanded into eosinophilic esophagitis, the most common type of eosinophilic gastrointestinal disease. Several studies have suggested that mast cells may be an important driver in the disease, demonstrating that the number and activation state of mast cells are greatly increased in eosinophilic esophagitis biopsies and that mast cell signatures correlate with markers of inflammation, fibrosis, pain and disease severity. Given the lack of effective therapies for eosinophilic esophagitis and barzolvolimab’s potential as a mast cell depleting agent, Celldex believes this is an important indication for future study and plans to initiate a Phase 2 trial in the fourth quarter of 2022.

- Celldex continues to enroll patients in the Phase 1b multi-center, randomized, double-blind, placebo-controlled study of barzolvolimab in patients with prurigo nodularis, a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. Enrollment also remains ongoing in the barzolvolimab Phase 1b open label study in inducible urticaria in a third cohort (single dose, 3 mg/kg) in cholinergic urticaria and a fourth cohort at a lower dose (single dose, 1.5 mg/kg) in cold urticaria.

CDX-1140 - CD40 Agonist Program

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

- In the Phase 1 study of CDX-1140 in patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas, the monotherapy cohort, the combination cohort with CDX-301 and the safety run-in combination cohort with gemcitabine/nab-paclitaxel have been completed. In late March 2022, Celldex closed enrollment to expansion cohorts in combination with KEYTRUDA® (pembrolizumab) in patients with squamous cell head and neck cancer and non-small cell lung cancer who have progressed on checkpoint therapy. Patients in these cohorts continue to be dosed and followed for safety and potential treatment effect.

CDX-527 - Bispecific Antibody Program

CDX-527 is the first candidate developed by Celldex from its bispecific platform which utilizes the Company'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.

- In the Phase 1 dose-escalation study of CDX-527 in patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy, enrollment to the dose escalation portion of the study has been completed and an expansion cohort in ovarian cancer is currently enrolling patients.

First Quarter 2022 Financial Highlights and 2022 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2022 were $380.5 million compared to $408.3 million as of December 31, 2021. The decrease was primarily driven by first quarter cash used in operating activities of $24.5 million. At March 31, 2022, Celldex had 46.8 million shares outstanding.

Revenues: Total revenue was $0.2 million in the first quarter of 2022 compared to $0.7 million for the comparable period in 2021. The decrease in revenue was primarily due to a decrease in services performed under our manufacturing and research and development agreements with Rockefeller University and Gilead Sciences.

R&D Expenses: Research and development (R&D) expenses were $17.1 million in the first quarter of 2022 compared to $12.7 million for the comparable period in 2021. The increase in R&D expense was primarily due to an increase in clinical trial and personnel expenses.

G&A Expenses: General and administrative (G&A) expenses were $6.9 million in the first quarter of 2022 compared to $4.1 million for the comparable period in 2021. The increase in G&A expense was primarily due to higher personnel, legal and commercial planning expenses.

Changes in Fair Value Remeasurement of Contingent Consideration: The gain on fair value remeasurement of contingent consideration was $0.5 million for the first quarter of 2022, primarily due to changes in discount rates.

Net Loss: Net loss was $23.1 million, or ($0.49) per share, for the first quarter of 2022, compared to a net loss of $16.5 million, or ($0.42) per share, for the comparable period in 2021.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at March 31, 2022 are sufficient to meet estimated working capital requirements and fund planned operations through 2025.

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 a clinical stage biotechnology company dedicated to developing monoclonal and bispecific antibodies that address devastating diseases for which available treatments are inadequate. Our pipeline includes antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with inflammatory diseases and many forms of cancer. 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, including barzolvolimab (also referred to as CDX-0159), in current or future indications; 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 effects of the outbreak of COVID-19 on our business and results of operations; the availability, cost, delivery and quality of clinical 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; our ability to continue to obtain 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; 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,**	
	2022	**2021**
	(Unaudited)	
Revenues:		
Product development and licensing agreements	$ 30	$ 3
Contracts and grants	144	682
Total revenues	174	685
Operating expenses:		
Research and development	17,056	12,720
General and administrative	6,911	4,121
(Gain) loss on fair value remeasurement of contingent consideration	(536)	483
Total operating expenses	23,431	17,324
Operating loss	(23,257)	(16,639)
Investment and other income, net	207	101
Net loss	$ (23,050)	$ (16,538)
Basic and diluted net loss per common share	$ (0.49)	$ (0.42)
Shares used in calculating basic and diluted net loss per share	46,739	39,614

Condensed Consolidated Balance Sheet Data	**March 31,**	**December 31,**
	2022	**2021**
	(Unaudited)	
Assets		
Cash, cash equivalents and marketable securities	$ 380,468	$ 408,250
Other current assets	10,231	2,589
Property and equipment, net	3,484	3,551
Intangible and other assets, net	29,858	30,264
Total assets	$ 424,041	$ 444,654
Liabilities and stockholders' equity		
Current liabilities	$ 14,560	$ 16,528
Long-term liabilities	11,380	8,650
Stockholders' equity	398,101	419,476
Total liabilities and stockholders' equity	$ 424,041	$ 444,654

Source: Celldex Therapeutics, Inc.