Celldex Reports Third Quarter 2023 Financial Results and Provides Corporate Update

November 2, 2023

- Phase 2 CSU enrollment complete; topline data by YE 2023 -
- Phase 1b PN data accepted at World Congress on Itch -

HAMPTON, N.J., Nov. 02, 2023 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the third quarter ended September 30, 2023 and provided a corporate update.

"During the third quarter, we were pleased to complete enrollment of our Phase 2 chronic spontaneous urticaria study well ahead of schedule. We look forward to presenting topline data from this study by end of year as we also plan for the potential advancement of barzolvolimab into registrational studies in 2024," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "Our Phase 1b study results in prurigo nodularis met our internal hurdle for advancement and we are actively planning for the initiation of a Phase 2 study early next year. We are excited to discuss these data next week in an oral presentation at the World Congress on itch and continue to deepen our leadership role in furthering the science of mast cell biology."

"Enrollment continues as planned to our Phase 2 studies in chronic inducible urticaria and eosinophilic esophagitis where we anticipate important data read outs in 2024 and beyond. In closing, we look forward to a data rich end of the year and remain focused on successfully executing across our ongoing studies as we also make plans to broaden barzolvolimab into other mast cell mediated diseases," concluded Marucci.

Recent Program Highlights

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 conducting Phase 2 clinical studies of barzolvolimab for the treatment of chronic spontaneous urticaria (CSU) and the two most common forms of chronic inducible urticaria (CIndU) - cold urticaria (ColdU) and symptomatic dermographism (SD). These randomized, double-blind, placebo-controlled Phase 2 studies are evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients who remain symptomatic despite antihistamine therapy, to determine the optimal dosing strategies.
    - In July 2023, Celldex announced that enrollment to the CSU study (n=208) had been completed and that topline data is anticipated by the end of 2023.
    - In October 2023, data on quality of life outcomes from the Phase 1b CSU study were presented at the European Academy of Dermatology & Venereology (EADV) Congress. The Dermatology Life Quality Index (DLQI) assesses patients' perceptions of the impact of their disease across different aspects of their health-related quality of life and includes questions on symptoms and feelings, daily activities, leisure, work and school performance, personal relationships and treatment. A rapid improvement in the DLQI was noted within 4 weeks in all barzolvolimab treated patients. DLQI improvement was sustained at doses ≥1.5mg/kg. Physician Global Assessment (PhysGA) for the treated cohorts also improved by week 1 and was sustained through week 24. DLQI and PhysGA trended closely with the dose-dependent improvement in UAS7 (Urticaria Activity Score over 7 days) and UCT (Urticaria Control Test), tryptase suppression, and increases in SCF.
    - Enrollment to the Phase 2 CIndU study is ongoing.
- Celldex is currently planning for the initiation of a Phase 2 subcutaneous study in prurigo nodularis (PN) in early 2024. Data from the Phase 1b randomized, double-blind, placebo-controlled study in patients with prurigo nodularis have been accepted for oral presentation at the 12th World Congress on Itch (WCI), being held in Miami, November 5-7, 2023 and will be presented by Martin Metz, M.D., Professor of Dermatology and Allergy at Charité - Universitätsmedizin in Berlin.
- In July, the first patient was dosed in the Phase 2 randomized, double-blind, placebo-controlled study in eosinophilic esophagitis (EoE); enrollment is ongoing.

Bispecific Antibody Platform

CDX-585 – **Bispecific ILT4 & PD-1**

CDX-585 combines highly active PD-1 blockade with anti-ILT4 blockade to overcome immunosuppressive signals in T cells and myeloid cells. ILT4 is emerging as an important immune checkpoint on myeloid cells.

- In May 2023 the first patient was dosed in the Phase 1 study of CDX-585. This open-label, multi-center study of CDX-585 is evaluating patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy. Enrollment is ongoing in the dose-escalation portion of the study.

Third Quarter 2023 Financial Highlights and 2023 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2023 were $235.3 million compared to $252.7 million as of June 30, 2023. The decrease was primarily driven by third quarter cash used in operating activities of $19.0 million for the three months ended September 30, 2023. At September 30, 2023, Celldex had 47.3 million shares outstanding.

Revenues: Total revenue was $1.5 million in the third quarter of 2023 and $2.8 million for the nine months ended September 30, 2023, compared to $0.4 million and $0.7 million for the comparable periods in 2022. The increase in revenue was primarily due to an increase in services performed under our manufacturing and research and development agreements with Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were $34.5 million in the third quarter of 2023 and $87.6 million for the nine months ended September 30, 2023, compared to $21.6 million and $59.4 million for the comparable periods in 2022. The increase in R&D expenses was primarily due to an increase in barzolvolimab clinical trial, barzolvolimab contract manufacturing, and personnel expenses.

G&A Expenses: General and administrative (G&A) expenses were $8.2 million in the third quarter of 2023 and $22.1 million for the nine months ended September 30, 2023, compared to $6.5 million and $20.6 million for the comparable periods in 2022. The increase in G&A expenses was primarily due to an increase in stock-based compensation and recruiting expenses, partially offset by a decrease in legal expenses.

Changes in Fair Value Remeasurement of Contingent Consideration: The gain on fair value remeasurement of contingent consideration was $6.9 million for the nine months ended September 30, 2022, primarily due to the Company's decision to deprioritize the CDX-1140 program in the second quarter of 2022.

Net Loss: Net loss was $38.3 million, or ($0.81) per share, for the third quarter of 2023, and $98.1 million, or ($2.08) per share, for the nine months ended September 30, 2023, compared to a net loss of $26.8 million, or ($0.57) per share, for the third quarter of 2022, and $85.8 million, or ($1.83) per share, for the nine months ended September 30, 2022.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at September 30, 2023 are sufficient to meet estimated working capital requirements and fund planned operations through 2025, which include our ongoing and planned Phase 2 studies in CSU, CIndU, EoE, and PN.

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	
Revenues:				
Product development and licensing agreements	$ 2	$ -	$ 19	$ 30
Contracts and grants	1,515	407	2,733	714
Total revenues	1,517	407	2,752	744
Operating expenses:				
Research and development	34,535	21,572	87,585	59,359
General and administrative	8,221	6,531	22,082	20,596
Gain on fair value remeasurement of contingent consideration	-	-	-	(6,862)
Litigation settlement related loss	-	-	-	15,000
Total operating expenses	42,756	28,103	109,667	88,093
Operating loss	(41,239)	(27,696)	(106,915)	(87,349)
Investment and other income, net	2,979	912	8,792	1,511
Net loss	$ (38,260)	$ (26,784)	$ (98,123)	$ (85,838)
Basic and diluted net loss per common share	$ (0.81)	$ (0.57)	$ (2.08)	$ (1.83)
Shares used in calculating basic and diluted net loss per share	47,261	46,916	47,243	46,806

Condensed Consolidated Balance Sheet Data	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 235,348	$ 304,952
Other current assets	10,585	12,741
Property and equipment, net	4,162	3,747
Intangible and other assets, net	30,161	31,295
Total assets	$ 280,256	$ 352,735
Liabilities and stockholders' equity		
Current liabilities	$ 27,836	$ 18,610
Long-term liabilities	5,702	7,921
Stockholders' equity	246,718	326,204
Total liabilities and stockholders' equity	$ 280,256	$ 352,735

Source: Celldex Therapeutics, Inc.