Celldex Reports First Quarter 2025 Financial Results and Provides Corporate Update

May 8, 2025

- *Strong execution and progress across pipeline with multiple key data read outs expected in 2025*
- *Late breaking oral presentation on Phase 2 CSU program at EAACI 2025 in June*
- *Phase 3 barzolvolimab CSU studies enrollment ongoing; Phase 3 program in CIndU under development*
- *Phase 2 EOE study enrollment complete; ongoing enrollment in Phase 2 PN and AD studies*
- *Celldex's first bispecific for inflammatory diseases, CDX-622, Phase 1 study ongoing*

HAMPTON, N.J., May 08, 2025 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the first quarter ended March 31, 2025 and provided a corporate update.

"In the first quarter of 2025, we presented data from our Phase 2 studies in chronic spontaneous and chronic inducible urticaria that demonstrated that barzolvolimab greatly improved quality of life for patients," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "Barzolvolimab has consistently demonstrated best-in-class efficacy in chronic urticaria, with very high rates of complete response, and it's especially meaningful to see these results translate into improved quality of life for patients living with a severe disease that impacts nearly every aspect of their daily lives."

"We expect 2025 will be a year of continued execution across our robust pipeline supported by important data from our barzolvolimab Phase 2 studies in CSU, CIndU and EOE and our CDX-622 Phase 1 study in healthy volunteers. Next month, 76 week data from the Phase 2 CSU study will be presented in a late breaking oral session at EAACI where we will discuss barzolvolimab's potential to achieve sustained disease control after treatment withdrawal. We think this data will be important to the field and to patients who need treatment options that offer rapid, profound and durable control of their disease. To this end, we continue to work to bring this important medicine to patients."

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.

Chronic Urticarias

Phase 3 Development

- A global Phase 3 program in chronic spontaneous urticaria (CSU) consisting of two Phase 3 trials (EMBARQ-CSU1 and EMBARQ-CSU2) was initiated in July and enrollment is ongoing. The studies are designed to establish the efficacy and safety of barzolvolimab in adult patients with CSU who remain symptomatic despite H1 antihistamine treatment and also include patients who remain symptomatic after treatment with biologics. EMBARQ-CSU1 and EMBARQ-CSU2 will enroll approximately 915 patients each across approximately 40 countries and 500 sites.
- The Company is currently planning a global Phase 3 program in chronic inducible urticaria (CIndU), which is expected to initiate in 2025.

Phase 2 Development

- Barzolvolimab met all primary and secondary endpoints at 12 weeks across the Company's Phase 2 studies in CSU and CIndU. Results were highly statistically significant and clinically meaningful.
    - 76 week data, which includes 24-weeks of off-treatment follow-up, from the Phase 2 study in CSU have been accepted for a late breaking oral presentation on Friday, June 13th at 9:12 am BST/10:12 am CEST/4:12 am ET at the European Academy of Allergy and Clinical Immunology (EAACI) Congress 2025 being held in Glasgow, Scotland. The Company will host a webcast on Thursday, June 12th at 6:00 pm ET to present the data.
    - 20 week treatment data from the Phase 2 CIndU study will be presented later this year. After completing treatment, patients on study are followed for 24 weeks and patients with returning symptoms can enter an open label extension during the follow up period.
    - 52 week quality of life data from the Phase 2 CSU study were presented in March at the American Academy of

Allergy, Asthma & Immunology (AAAAI) Annual Meeting 2025. Rapid and sustained improvement in urticaria control (UCT) and quality of life (DLQI) were observed in patients with CSU refractory to antihistamines. Up to 82% of patients reported that CSU symptoms no longer had an impact on their quality of life at Week 52 and up to 95% of patients reported meaningful improvement in quality of life based on DLQI at Week 52. Up to 82% of patients reported well-controlled urticaria based on UCT and approximately half of patients reported complete control at Week 52.

- 12 week quality of life data from the Phase 2 CIndU study were presented in March at the AAAAI Annual Meeting 2025. A marked and rapid improvement in UCT and DLQI was observed and sustained through the 12-week period in patients with ColdU and SD. Up to 60% of patients reported that CIndU symptoms no longer had an impact on their quality of life at Week 12 and up to 69% of patients reported well-controlled urticaria based on UCT at Week 12.

Additional Indications

- Enrollment is complete in the Phase 2 study in eosinophilic esophagitis (EoE) and data from this study is expected in 2025. This randomized, double-blind, placebo-controlled, parallel group study is evaluating the efficacy and safety profile of barzolvolimab in patients with active EoE.
- Enrollment continues in the Phase 2 study in prurigo nodularis (PN). This randomized, double-blind, placebo-controlled, parallel group study is evaluating the efficacy and safety profile of barzolvolimab in approximately 120 patients with moderate to severe PN.
- Enrollment is ongoing in the Phase 2 study in atopic dermatitis (AD). This randomized, double-blind, placebo-controlled, parallel group study is evaluating the efficacy and safety profile of barzolvolimab in approximately 120 patients with moderate to severe AD.

Bispecific Antibody Platform

CDX-622 – Bispecific SCF & TSLP

CDX-622 targets two complementary pathways that drive chronic inflammation, potently neutralizing the alarmin thymic stromal lymphopoietin (TSLP) and depleting mast cells via stem cell factor (SCF) starvation. Combined neutralization of SCF and TSLP with CDX-622 is expected to simultaneously reduce tissue mast cells and inhibit Type 2 inflammatory responses to potentially offer enhanced therapeutic benefit in inflammatory and fibrotic disorders.

- Enrollment is ongoing in the Phase 1 study in healthy volunteers. This two-part randomized, double-blind, placebo-controlled, dose escalation study is designed to assess the safety, pharmacokinetics, and pharmacodynamics of single ascending doses (Part 1) and multiple ascending doses (Part 2) of CDX-622 in up to 56 healthy participants. The pharmacodynamic biomarkers from blood and skin will be highly informative on the ability of CDX-622 to engage and neutralize SCF and TSLP. Data from Part 1 of the study is expected in 2025.

First Quarter 2025 Financial Highlights and 2025 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2025 were $673.3 million compared to $725.3 million as of December 31, 2024. The decrease was primarily driven by first quarter cash used in operating activities of $54.4 million. At March 31, 2025, Celldex had 66.4 million shares outstanding.

Revenues: Total revenue was $0.7 million in the first quarter of 2025, compared to $0.2 million for the comparable period in 2024. 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 $52.6 million in the first quarter of 2025, compared to $31.7 million for the comparable period in 2024. 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 $10.8 million in the first quarter of 2025, compared to $9.1 million for the comparable period in 2024. The increase in G&A expenses was primarily due to an increase in stock-based compensation expense.

Net Loss: Net loss was $53.8 million, or ($0.81) per share, for the first quarter of 2025, compared to a net loss of $32.8 million, or ($0.56) per share, for the comparable period in 2024.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at March 31, 2025 are sufficient to meet estimated working capital requirements and fund current planned operations through 2027.

About Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company leading the science at the intersection of mast cell biology and the development of transformative therapeutics for patients. 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 severe inflammatory, allergic, autoimmune and other devastating 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, 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 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,	
	2025	2024
	(Unaudited)	
Revenues:		
Product development and licensing agreements	$ 50	$ 2
Contracts and grants	645	154
Total revenues	695	156
Operating expenses:		
Research and development	52,614	31,661
General and administrative	10,820	9,103
Total operating expenses	63,434	40,764
Operating loss	(62,739)	(40,608)
Investment and other income, net	8,943	7,800

Net loss	$	(53,796)	$	(32,808)
Basic and diluted net loss per common share	$	(0.81)	$	(0.56)
Shares used in calculating basic and diluted net loss per share		66,383		58,871

Condensed Consolidated Balance Sheet Data		**March 31 2025 (Unaudited)**		**December 31 2024**
Assets				
Cash, cash equivalents and marketable securities	$	673,291	$	725,281
Other current assets		20,466		21,878
Property and equipment, net		4,601		4,346
Intangible and other assets, net		41,113		40,835
Total assets	$	739,471	$	792,340
Liabilities and stockholders' equity				
Current liabilities	$	32,018	$	39,501
Long-term liabilities		4,472		5,834
Stockholders' equity		702,981		747,005
Total liabilities and stockholders' equity	$	739,471	$	792,340

Source: Celldex Therapeutics, Inc.