Celldex Reports Third Quarter 2024 Financial Results and Provides Corporate Update

Nov 6, 2024

- *Enrollment continues in Phase 3 barzolvolimab CSU studies; Phase 3 program in CIndU under development*
- *All primary and secondary endpoints met with high statistical significance in global Phase 2 CIndU study*
- *Long term 52 week treatment data in landmark, global Phase 2 CSU study demonstrated deepening of response and a favorable safety profile*
- *Enrollment continues in Phase 2 PN and EOE studies; Phase 2 AD study to start in Q4*
- *Celldex's first bispecific for inflammatory diseases, CDX-622, to enter the clinic in Q4*

HAMPTON, N.J., Nov. 06, 2024 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the third quarter ended September 30, 2024 and provided a corporate update.

"Celldex recently presented best-in-disease data across both our Phase 2 studies of barzolvolimab in CSU and CIndU," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "The data demonstrated barzolvolimab's unique potential to provide a rapid, durable treatment option and complete disease control for patients suffering from these severe, debilitating diseases. These are transformative results for patients with CSU, many whom do not see meaningful benefit from the current standard of care, and CIndU, where there are currently no approved therapies other than antihistamines. We continue to make strong progress across our entire pipeline, with enrollment ongoing in global Phase 3 CSU trials and our Phase 2 PN and EOE studies. As we look to the end of this year, we remain excited for our Phase 2 study in AD to initiate and our first bispecific for inflammatory diseases, CDX-622, to enter the clinic."

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) was initiated in July, consisting of two Phase 3 trials (EMBARQ-CSU1 and EMBARQ-CSU2) designed to establish the efficacy and safety of barzolvolimab in adult patients with CSU who remain symptomatic despite H1 antihistamine treatment. The studies also include patients who remain symptomatic after treatment with biologics. The studies will enroll approximately 915 patients each across 40 countries and 500 sites and are actively enrolling patients.

- 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. Patients continue to be followed on both studies.

    - 52 week long term follow up data from the Phase 2 study in CSU (n=208) were presented in a late breaking oral presentation at the EADV Congress 2024 in September. A deepening of response was observed over the 52 week treatment period and barzolvolimab demonstrated the highest rate of complete response observed in a well controlled study in CSU with 71% of patients (150 mg Q4W) achieving a complete response at Week 52. Importantly, barzolvolimab was also well tolerated through 52 weeks.

    - 12 week primary endpoint data from the Phase 2 study in CIndU (n=196) were presented in a late breaking oral presentation at ACAAI 2024 in October. Barzolvolimab is the first drug to demonstrate clinical benefit in patients with cold urticaria (ColdU) in a large, randomized, placebo-controlled study. Per provocation test, up to 53.1% of

patients with ColdU and 57.6% of patients with symptomatic dermographism (SD) treated with barzolvolimab experienced a complete response compared to placebo rates of only 12.5% (p=0.0011) in ColdU and 3.2% (p<0.0001) in SD—the primary endpoint of the study. Secondary and exploratory endpoints were highly supportive of the primary endpoint. Patients on study continued to receive barzolvolimab or placebo for up 20 weeks and are being followed for an additional 24 weeks. The study also includes an Open Label Extension that allows patients with symptoms during the follow-up phase (including patients who were on placebo) to receive active study drug.

Additional Indications

- A Phase 2 study in eosinophilic esophagitis (EoE) was initiated in July 2023 and enrollment is ongoing. This randomized, double-blind, placebo-controlled study is evaluating the efficacy and safety profile of barzolvolimab in approximately 75 patients with active EoE. Data from this study is expected in the second half of 2025.

- A Phase 2 study in prurigo nodularis (PN) was initiated in early 2024 and enrollment is ongoing. 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 who had inadequate response to prescription topical medications, or for whom topical medications are medically inadvisable, including patients who received prior biologics.

- In May 2024, Celldex announced that atopic dermatitis (AD) has been selected as the fifth indication for the development of barzolvolimab. Barzolvolimab's novel mast cell depleting mechanism could play an important role in addressing patients with moderate to severe AD who do not achieve complete disease control on currently available systemic therapies. Celldex plans to initiate a Phase 2 study in AD by year end.

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.

- Celldex has completed preclinical, manufacturing and IND-enabling activities for CDX-622 and plans to initiate a Phase 1 study in healthy volunteers by the end of 2024. In preclinical studies, CDX-622 inhibits TSLP and SCF with similar potency to both its respective parental mAbs and comparator mAbs *in vitro*. CDX-622 was well tolerated in a multi-dose 8 week toxicology study in non-human primates and the No Adverse Event Level (NOAEL) was established to be 75 mg/kg, the highest dose level tested. In inflammatory and fibrotic disorders, TSLP is often upregulated and associated with disease severity. Similarly, mast cells drive or contribute to the pathophysiology of many of these disorders and CDX-622 contains a unique SCF neutralizing function that is expected to inhibit and deplete mast cells.

CDX-585 – Bispecific ILT4 & PD-1

- The dose-escalation portion of this open-label, multi-center Phase 1 study of CDX-585 in patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy has been completed. We are prioritizing our expanding clinical development program in the inflammatory space and will not advance CDX-585.

Third Quarter 2024 Financial Highlights and 2024 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2024 were $756.0 million compared to $802.3 million as of June 30, 2024. The decrease was primarily driven by third quarter cash used in operating activities of $55.3 million. From June 30, 2024 to September 30, 2024, prepaid and other current assets increased $13.9 million and other assets increased $9.6 million as a result of non-recurring advance payments related to our Phase 3 studies in CSU and late-stage barzolvolimab commercial manufacturing batches. At September 30, 2024, Celldex had 66.3 million shares outstanding.

Revenues: Total revenue was $3.2 million in the third quarter of 2024 and $5.8 million for the nine months ended September 30, 2024, compared to $1.5 million and $2.8 million for the comparable periods in 2023. 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 $45.3 million in the third quarter of 2024 and $116.6 million for the nine months ended September 30, 2024, compared to $34.5 million and $87.6 million for the comparable periods in 2023. The increase in R&D expenses was primarily due to an increase in barzolvolimab clinical trial and personnel expenses, partially offset by a decrease in barzolvolimab contract manufacturing expenses.

G&A Expenses: General and administrative (G&A) expenses were $10.1 million in the third quarter of 2024 and $28.3 million for the nine months ended September 30, 2024, compared to $8.2 million and $22.1 million for the comparable periods in 2023. The increase in G&A expenses was primarily due to an increase in stock-based compensation and barzolvolimab commercial planning expenses.

Net Loss: Net loss was $42.1 million, or ($0.64) per share, for the third quarter of 2024, and $110.8 million, or ($1.74) per share, for the nine months ended September 30, 2024, compared to a net loss of $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.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at September 30, 2024 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Revenues:				
Product development and licensing agreements	$ 3	$ 2	$ 5	$ 19
Contracts and grants	3,188	1,515	5,840	2,733
Total revenues	3,191	1,517	5,845	2,752

Operating expenses:				
Research and development	45,263	34,535	116,611	87,585
General and administrative	10,054	8,221	28,285	22,082
Total operating expenses	55,317	42,756	144,896	109,667
Operating loss	(52,126)	(41,239)	(139,051)	(106,915)
Investment and other income, net	10,005	2,979	28,280	8,792
Net loss	$ (42,121)	$ (38,260)	$ (110,771)	$ (98,123)
Basic and diluted net loss per common share	$ (0.64)	$ (0.81)	$ (1.74)	$ (2.08)
Shares used in calculating basic and diluted net loss per share	66,294	47,261	63,737	47,243

Condensed Consolidated Balance Sheet Data	**September 30, 2024 (Unaudited)**	**December 31, 2023**
Assets		
Cash, cash equivalents and marketable securities	$ 755,999	$ 423,598
Other current assets	22,843	8,095
Property and equipment, net	4,230	4,060
Intangible and other assets, net	40,107	29,874
Total assets	$ 823,179	$ 465,627
Liabilities and stockholders' equity		
Current liabilities	$ 32,093	$ 31,125
Long-term liabilities	5,181	5,331
Stockholders' equity	785,905	429,171
Total liabilities and stockholders' equity	$ 823,179	$ 465,627

Source: Celldex Therapeutics, Inc.