Carisma Therapeutics Announces Strategic Restructuring to Re-prioritize Pipeline

December 9, 2024

Resources realigned to focus primarily on in vivo macrophage engineering platform for fibrosis, oncology and autoimmune disease therapies

Development of CT-0525 to be discontinued; workforce reduced by 34%

PHILADELPHIA, Dec. 9, 2024 /PRNewswire/ -- Carisma Therapeutics Inc. (Nasdaq: CARM) ("Carisma" or the "Company"), a leader in macrophage-focused therapeutics, today announced a strategic reprioritization of its pipeline, cessation of development of CT-0525, and a reduction in the workforce by 34%. These measures will enable Carisma to focus its resources on advancing its *in vivo* macrophage engineering platform for the development of fibrosis, oncology and autoimmune disease therapies. This decision aligns Carisma's efforts with next-generation, high-potential programs addressing significant unmet patient needs while enhancing operational efficiency.

"Following a comprehensive review of our portfolio, we have made the strategic decision to prioritize advancing our *in vivo* macrophage engineering platform," said Steven Kelly, President and Chief Executive Officer of Carisma. "The compelling data generated by both the Moderna-partnered *in vivo* CAR-M oncology programs as well as our internal liver fibrosis program underscore the potential to revolutionize treatment paradigms with an innovative and patient-centric approach."

"These strategic initiatives, re-directing our investments to the *in vivo* macrophage engineering platform, discontinuing development of our anti-HER2 program and reducing our workforce, aim to streamline our operations and reduce operating expenses over time," Kelly continued. "While these decisions are very challenging, they are made in the best interest of our shareholders. We remain deeply grateful for the significant contributions of the employees departing Carisma."

Reprioritization Plan, Pipeline Updates, and Upcoming Milestones:

As part of this reprioritization of our pipeline, Carisma will discontinue development of the anti-human epidermal growth factor receptor 2 ("anti-HER2") program, and redirect the Company's focus to developing off-the-shelf products using its *in vivo* macrophage engineering platform:

Fibrosis

- Carisma's initial fibrosis program is focused on addressing liver fibrosis, a significant global health challenge. Preclinical data presented at the American Association for the Study of Liver Diseases (AASLD) Liver Meeting® 2024 demonstrated the potential of Carisma's engineered macrophages to reduce inflammation, resolve fibrosis, and promote liver regeneration.
- The Company plans to nominate a development candidate for its liver fibrosis program in the first quarter of 2025, reflecting its expertise in macrophage biology and fibrotic diseases.

Oncology

- In collaboration with Moderna, Inc. (Nasdaq: MRNA), Carisma is advancing multiple programs utilizing an *in vivo* chimeric antigen receptor macrophage and monocyte ("CAR-M") plus mRNA/LNP approach. The lead program is an anti-glypican 3 (GPC3) *in vivo* CAR-M therapy that has demonstrated the potential for this scalable, patient-friendly approach to transform solid tumor therapy. In addition to this program, Moderna has nominated four undisclosed oncology research targets under the collaboration and has the right to designate up to ten oncology targets as development targets.

Autoimmune

- In collaboration with Moderna, Carisma has two *in vivo* CAR-M research programs for the treatment of autoimmune diseases associated with two distinct targets where there is significant unmet medical need.
- Carisma retains all rights in autoimmune disease beyond these two nominated targets.

Discontinuation of anti-HER2 Development

- The Company's decision was based on an assessment of the competitive landscape in anti-HER2 treatments, including the impact of recently approved anti-HER2 therapies on HER2 antigen loss/downregulation, and the effects on the future development strategy of any anti-HER2 treatment.
- The Company has completed patient enrollment of the Phase 1 clinical trial of CT-0525 and will not enroll patients in the previously planned Cohort 3 of the study.
- Based on the data available to date from the anti-HER2 program, CAR-M cell therapy has been shown to be safe, well-tolerated, and feasible to manufacture, and it holds the potential to become a meaningful treatment option for patients.

Corporate Updates

- As part of the strategic restructuring, Carisma will reduce its workforce by 34%. The Company expects the reduction in workforce to be substantially complete and to pay the majority of related reduction in workforce amounts by the end of the first quarter of 2025. The Company is committed to supporting affected employees through this transition.
- As part of the workforce reductions, our Chief Financial Officer, Richard Morris, our General Counsel, Eric Siegel, and our Senior Vice President, Human Resources, Terry Shields, will leave the Company effective December 31, 2024. Carisma expresses gratitude for their contributions.
- The Company expects to incur approximately $2.7 million in connection with the reduction in the workforce, which primarily represents one-time employee termination benefits directly associated with the workforce reduction.

About Carisma

Carisma Therapeutics is a biopharmaceutical Company pioneering macrophage engineering to develop groundbreaking therapies for fibrosis, cancer, and other diseases. With a strong commitment to patient-centric innovation, Carisma aims to deliver scalable, next-generation solutions that transform treatment paradigms. Carisma is headquartered in Philadelphia, PA. For more information, please visit www.Carismatx.com.

Cautionary Note on Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to the Company's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the expected timing for the completion of the reduction in workforce; the expected charges to be incurred and the related cash payments and the timing thereof; future employment relationships; the future development focus of the Company and related timelines; and other statements that are not historical fact. The words "continue," "estimate," "expect," "may," "plan," "will," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, changes to the assumptions on which the estimated charges associated with the reduction in workforce are based; the "at-will" nature of employment relationships; changes in the macroeconomic environment or competitive landscape that impact the Company's business; and risks related to the Company's business and the Company's ongoing evaluation of strategic alternatives. For a discussion of these risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, as well as discussions of potential risks, uncertainties, and other important factors in the Company's other recent filings with the Securities and Exchange Commission. Any forward-looking statements that are made in this press release speak as of the date of this press release. The Company undertakes no obligation to revise the forward-looking statements or to update them to reflect events or circumstances occurring after the date of this press release, whether as a result of new information, future developments or otherwise, except as required by the federal securities laws.

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