Milestone Pharmaceuticals Provides 2025 Corporate Outlook and Will Host Investor Event on February 25 in NYC

January 28, 2025

- PDUFA date of March 27, 2025 for CARDAMYST™ (etripamil) nasal spray for Paroxysmal Supraventricular Tachycardia (PSVT)

- Commercial capabilities build out in process, with proposed launch in PSVT targeted for mid-2025

- Plans to initiate Phase 3 Study in AFib-RVR in H1 2025

MONTREAL and CHARLOTTE, N.C., Jan. 28, 2025 (GLOBE NEWSWIRE) -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today provided a corporate update and outlined its strategic priorities for 2025.

“2025 is set to be a transformative year for Milestone as we prepare for potential FDA approval of CARDAMYST and the opportunity to empower patients suffering with PSVT to self-manage episodes outside of the healthcare setting,” said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. “Our leadership team is building a solid foundation for the planned launch of CARDAMYST mid-year, and we look forward to sharing a comprehensive update at our investor event on February 25.”

CARDAMYST for Paroxysmal Supraventricular Tachycardia

- **FDA Prescription Drug User Fee Act (PDUFA) target date is March 27, 2025.** Milestone’s New Drug Application (NDA) for CARDAMYST™ (etripamil) nasal spray, its lead investigational product, for the management of PSVT, is under review at the U.S. Food and Drug Administration (FDA). The FDA has communicated that an advisory committee is not planned.
- **Launch in PSVT targeted for mid-2025.** Milestone is currently preparing for a commercial launch of CARDAMYST in mid-2025 pending FDA approval. The launch leadership team has been strengthened by the recent hiring of Jeff Moore as VP of Sales, adding to already established expertise in Marketing, Medical Affairs, and Market Access. Regional sales management is expected to be on board in February to lead a launch sales team of approximately 60 professionals initially focused on clinical cardiologists, electrophysiologists, and cardiac-focused primary care physicians. Sales representatives will be hired around the time of FDA approval and will be added to our current field based Medical Affairs and Market Access Teams engaged with regional and national Key Opinion Leaders, Patient Advocacy Organizations and Payer Organizations.

Investor Event in New York, February 25

- The company will host a live investor event to provide an overview of its commercial strategy for CARDAMYST. The event will feature presentations by Joseph Oliveto, President and CEO, and Lorenz Muller, Chief Commercial Officer. To register, click here or contact Sam Matel at smatel@lifesciadvisors.com.
- **Upcoming Medical Conferences.** Assuming approval on the PDUFA date, Milestone will have its first branded product presence at ACC.2025 (American College of Cardiology annual meeting, March 29 to 31, 2025 in Chicago) and the Heart Rhythm Society Annual Meeting (April 24 to 27, 2025 in San Diego).

Etripamil for patients with atrial fibrillation with rapid ventricular rate (AFib-RVR)

- **Phase 3 pivotal trial in AFib-RVR expected to begin enrollment in H1 2025.** Milestone plans to initiate a trial of etripamil nasal spray in patients with AFib-RVR in the at-home setting. The protocol has been finalized, incorporating FDA feedback, and the study is sized based on achieving approximately 150 events in patients with symptomatic episodes. A self-administered, repeat-dose regimen of 70 mg/dose will be evaluated (the same approach that was studied in the successful RAPID trial in PSVT).

About Etripamil

Etripamil is Milestone's lead investigational product. It is a novel calcium channel blocker nasal spray under clinical development for frequent and often highly symptomatic episodes of PSVT and AFib-RVR. It is designed as a self-administered rapid response therapy for patients thereby bypassing the need for immediate medical oversight. If approved, etripamil is intended to provide health care providers with a new treatment option to enable on-demand care and patient self-management. This portable, self-administered treatment may provide patients with active management and a greater sense of control over their condition. CARDAMYST™, the conditionally approved brand name for etripamil nasal spray, is well studied with a robust clinical trial program that includes a completed Phase 3 clinical-stage program for the treatment of PSVT and Phase 2 trial for the treatment of patients with AFib-RVR.

About Milestone Pharmaceuticals

Milestone Pharmaceuticals Inc. (Nasdaq: MIST) is a biopharmaceutical company developing and commercializing innovative cardiovascular solutions to improve the lives of people living with complex and life-altering heart conditions. The Company's focus on understanding unmet patient needs and improving the patient experience has led us to develop new treatment approaches that provide patients with an active role in self-managing their care. Milestone's lead investigational product is etripamil, a novel calcium channel blocker nasal spray that is being studied for patients to self-administer without medical supervision to treat symptomatic episodic attacks associated with PSVT and AFib-RVR.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "continue," "could," "demonstrate," "designed," "develop," "estimate," "expect," "may," "pending," "plan," "potential," "progress," "will", "intend" and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Milestone's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding the timing and outcomes of future interactions with the FDA, including the PDUFA target date; the timing and enrollment of our Phase 3 trial in AFib-RVR; the timing of our potential commercial launch of CARDAMYST; the timing of our first branded product presence; the potential of etripamil to provide health care providers with a new treatment option to enable on-demand care and patient self-management and provide patients with active management and a greater sense of control over their condition. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, whether our future interactions with the FDA will have satisfactory outcomes; whether and when, if at all, our NDA for etripamil will be approved by the FDA; uncertainties related to the timing of initiation, enrollment, completion, evaluation and results of our clinical trials; risks and uncertainty related to the complexity inherent in cleaning, verifying and analyzing trial data; and whether the clinical trials will validate the safety and efficacy of etripamil for PSVT or other indications, among others, general economic, political, and market conditions, including deteriorating market conditions due to investor concerns regarding inflation, Russian hostilities in Ukraine and ongoing disputes in Israel and Gaza and overall fluctuations in the financial markets in the United States and abroad, risks related to pandemics and public health emergencies, and risks related the sufficiency of Milestone's capital resources and its ability to raise additional capital in the current economic climate. These and other risks are set forth in Milestone's filings with the U.S. Securities and Exchange Commission, including in its annual report on Form 10-K for the year ended December 31, 2023, under the caption "Risk Factors," as such discussion may be updated from time to time by subsequent filings Milestone may make with the U.S. Securities & Exchange Commission. Except as required by law, Milestone assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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