Milestone Pharmaceuticals Submits Response to the FDA's CRL for CARDAMYST (etripamil) Nasal Spray for PSVT Following Type A Meeting

June 16, 2025

MONTREAL and CHARLOTTE, N.C., June 16, 2025 (GLOBE NEWSWIRE) -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST) today announced submission of its response to the U.S. Food and Drug Administration (FDA)'s Complete Response Letter (CRL) regarding its New Drug Application (NDA) for CARDAMYST™ (etripamil) nasal spray, a prescription medication in development for the conversion of acute episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults. The response follows a Type A meeting recently held with the FDA. The acceptance of the response and corresponding Prescription Drug User Fee Act (PDUFA) date will be determined within the next thirty days per FDA policy. The review time is expected to be within 2 or 6 months from the resubmission, depending on the classification.

"Our recent Type A meeting with the FDA was productive and we believe it provided the guidance necessary to submit our response to the CRL directly after the meeting," said Joe Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "We appreciate the engagement with the FDA and are excited to prepare for a potential new PDUFA date this year. We continue to believe in the value of CARDAMYST which, if approved, will be the first and only self-administered therapy for the rapid termination of episodes of 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 outcomes of future interactions with the FDA; the outcome of the NDA resubmission; CARDAMYST's potential as a novel treatment option to help patients with PSVT; the timing and expectations related to a new PDUFA date; and other statements not related to historical facts. 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 (SEC), including in its annual report on Form 10-K for the year ended December 31, 2024, under the caption "Risk Factors," as such discussion may be updated from time to time by subsequent filings Milestone may make with the SEC. 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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Source: Milestone Pharmaceuticals Inc.