Milestone® Pharmaceuticals Notice of Allowance on New U.S. Patent for Etripamil

February 19, 2025

Extends US patent protection until 2042

MONTREAL and CHARLOTTE, N.C., Feb. 19, 2025 (GLOBE NEWSWIRE) -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST) a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced that it has received Notice of Allowance from the United States Patent and Trademark Office (USPTO) on a new Method of Use patent for etripamil nasal spray (proposed trade name CARDAMYST™), its lead investigational product for the management of paroxysmal supraventricular tachycardia (PSVT).

The patent, once issued on U.S. Patent Application No.: 17/865,697, covers the repeat dose regimen used in the RAPID Phase 3 study that evaluated CARDAMYST in PSVT and proposed for the package insert as part of the CARDAMYST New Drug Application (NDA) currently under review by the U.S. Food and Drug Administration (FDA). The issuance of the Notice of Allowance potentially extends our intellectual property protection for CARDAMYST in the United States until July 2042, which is an additional 6 years of potential protection for our intellectual property portfolio.

“This added protection will position us to optimize the commercial value of CARDAMYST,” said Joseph Oliveto, President, and Chief Executive Officer of Milestone Pharmaceuticals. “The new patent underscores Milestone’s continued development of our patent portfolio and our commitment to innovation in cardiology.”

The repeat dose regimen, proposed in the NDA for CARDAMYST, directs the patient to administer a second 70 mg dose of CARDAMYST should the patient continue to experience symptoms from their PSVT episode ten minutes after their initial dose.

Milestone’s NDA for CARDAMYST is currently under review at the FDA with a Prescription Drug User Fee Act (PDUFA) target date of March 27, 2025. The Company continues to advance commercial preparations to support the anticipated launch in mid-2025. The CARDAMYST brand name is conditionally approved by the FDA.

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 potential extension of protection under our intellectual property portfolio; 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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