Milestone Pharmaceuticals Announces Acceptance of Marketing Authorization Application for Etripamil Nasal Spray in PSVT by the European Medicines Agency

January 06, 2026

- European decision on approval is expected by Q1 2027
- If approved, etripamil nasal spray is expected to offer patients a safe and effective self-administered treatment option for PSVT outside of the healthcare setting

MONTREAL and CHARLOTTE, N.C., Jan. 06, 2026 (GLOBE NEWSWIRE) -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced the acceptance of a Marketing Authorization Application (MAA) by the European Medicines Agency (EMA) seeking the approval of etripamil nasal spray, developed to be the first rapid, reliable option in the treatment of paroxysmal supraventricular tachycardia (PSVT) outside of the healthcare setting. Etripamil, which has the conditionally approved brand name TACHYMIST™ in Europe, is an investigational, novel calcium channel blocker delivered via a nasal spray by the patient for the potential treatment of PSVT and other cardiac arrhythmias. A decision on approval is expected by the first quarter of 2027.

“Following guidance from the EMA, this MAA incorporates the global clinical data package that supported the U.S. Food and Drug Administration approval of etripamil for the treatment of PSVT,” said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. “TACHYMIST could become the first approved patient self-administered therapy representing a meaningful step forward in patient care for the approximately two million people suffering from PSVT in Europe.”

About the Pivotal RAPID Phase 3 Trial
The MAA submission is supported by efficacy, safety, and tolerability results from a robust clinical trial program based on data from more than 1,800 participants and more than 2,000 episodes of PSVT. This includes the successful Phase 3 RAPID trial, a global, randomized, double-blind comparison of etripamil vs. placebo, published in *The Lancet* in 2023. In clinical studies, participants using etripamil were two times more likely to convert symptomatic PSVT to sinus rhythm and did so more than three times faster compared with placebo. The RAPID trial achieved its primary endpoint with 64% of those who self-administered etripamil (N=99) converting from PSVT to sinus rhythm within 30 minutes compared to 31% on placebo (N=85) (HR=2.62; p<0.001). At one hour, the benefit was demonstrated in 73% of participants. In addition, significant reductions in time to conversion in those who took etripamil were evident early and were durable, with a median time to conversion of 17 minutes (95% CI: 13.4, 26.5) for those treated with etripamil vs. 54 minutes (95% CI: 38.7, 87.3) for those treated with placebo.

A consistent safety profile and treatment effects were observed across all subgroups, including participants concurrently on beta blockers or calcium channel blockers. The most frequent adverse events occurring in ≥5% of participants in randomized clinical trials were mild-to-moderate and transient in nature, including local-site nasal discomfort, nasal congestion, rhinorrhea, throat irritation, and epistaxis. Less than 2% of trial participants discontinued therapy due to adverse events.

About Paroxysmal Supraventricular Tachycardia
An estimated two million people in the United States, and an additional two million people in Europe, are currently diagnosed with PSVT, which is a type of arrhythmia or abnormal heart rhythm. PSVT is characterized by episodes of sudden onset rapid heartbeats often exceeding 150 to 200 beats per minute. The heart rate spike is unpredictable and may last several hours. The rapid heart rate often causes disabling severe palpitations, shortness of breath, chest discomfort, dizziness or lightheadedness, and distress, forcing patients to limit their daily activities. The uncertainty of when an episode of PSVT will strike or how long it will persist can provoke anxiety in patients and negatively impact their day-to-day life between episodes. The impact and morbidity from an attack can be especially detrimental in patients with underlying cardiovascular or medical conditions, such as heart failure, obstructive coronary disease, or dehydration. Many health care providers are dissatisfied with the lack of effective treatment options with patients often requiring prolonged, burdensome, and costly trips to the emergency department or even invasive cardiac ablation procedures.

About Etripamil
Etripamil is approved by the U.S. Food and Drug Administration (FDA) for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults under the brand name CARDAMYST™. Etripamil is a novel calcium channel blocker nasal spray designed as a self-administered rapid response therapy for patients, thereby bypassing the need for direct medical oversight. 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. TACHYMIST™, the conditionally approved brand name for etripamil nasal spray in Europe, is well studied with a robust clinical trial program that includes a completed Phase 3 clinical-stage program for the treatment of PSVT. Currently, etripamil is in Phase 2 development for treatment of PSVT in pediatric patients and Phase 3 development for acute treatment of atrial fibrillation with rapid ventricular rate (AFib-RVR) in adults.

About Milestone Pharmaceuticals
Milestone Pharmaceuticals Inc. (Nasdaq: MIST) is a biopharmaceutical company developing and commercializing innovative cardiovascular medicines to benefit people living with certain heart conditions. Milestone’s lead product is CARDAMYST™ (etripamil) nasal spray, a novel calcium channel blocker, which is FDA approved for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults. Etripamil is also in development for the treatment of symptomatic episodic attacks associated with AFib-RVR.

Cautionary Note on 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: timing and expectations regarding the EMA’s review of the MAA, including the timing around a decision on approval; Milestone’s expectations on the market for PSVT in Europe; expectations in regards to etripamil’s efficacy; etripamil’s potential as a novel treatment option to help patients with PSVT; 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 Milestone’s future interactions with the EMA will have satisfactory outcomes; whether and when, if at all, Milestone’s MMA for etripamil will be approved by the EMA; uncertainties related to the timing of initiation, enrollment, completion, evaluation and results of Milestone’s 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, international tariffs, Russian hostilities in Ukraine and ongoing disputes in the Middle East 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, 2025 and its quarterly report on Form 10-Q for the quarter ended September 30, 2025, in each case under the caption “Risk Factors,” as such discussions 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.

Investor Relations
Kevin Gardner, kgardner@lifesciadvisors.com
Media Relations
Rebecca Novak, rnovak@milestonepharma.com

Source: Milestone Pharmaceuticals Inc.