Milestone Pharmaceuticals to Present New Analysis from Investigational Etripamil Nasal Spray Clinical Trials for PSVT at the American Heart Association Scientific Sessions 2025

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Data show consistent efficacy, safety, and tolerability findings across multiple clinical trials that evaluated self-administered etripamil

MONTREAL and CHARLOTTE, N.C., Nov. 03, 2025 (GLOBE NEWSWIRE) -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced that new data analyses surrounding its lead investigational product for the management of paroxysmal supraventricular tachycardia (PSVT), etripamil nasal spray, consistently showed efficacy and a favorable safety profile across multiple studies comprising the global development program. The poster, **"Combined Efficacy, Safety, and Test Dose Tolerability of Etripamil for Acute Paroxysmal Supraventricular Tachycardia (PSVT) Across Multiple Clinical Trials,"** will be presented on Monday, November 10 (10:30–11:30 AM CST) at the American Heart Association Scientific Sessions 2025, in New Orleans, La. The data will be presented by James Ip, M.D., Professor of Medicine and Director of Cardiac Pacing and Implantable Devices, Division of Cardiology, Department of Medicine, New York Weill Cornell-Presbyterian Hospital.

Key Findings:

- Analysis of data from 622 unique enrolled patients across multiple trials showed consistent efficacy of etripamil across multiple study phases, types of trial design, and geographic regions, with etripamil treatment showing similarly greater conversion rates for symptomatic PSVT episodes compared with placebo arms.
- Across studies, the median time to conversion in patients self-administering etripamil was 18.5 minutes (95% CI: 15.7 to 21.0 minutes).
- The Kaplan-Meier estimate, from the pooled data for conversion of PSVT to sinus rhythm (SR) by 30 minutes of drug administration, was 59.6% (range: 53.6% to 64.3%). By 60 minutes post-administration, etripamil conversion rates rose to 63.2% to 75.1% across studies.
- Safety data from over 1,050 etripamil-treated patients were favorable, consistently shown, and characterized by predominantly mild, transient, and nasal-site localized adverse events.
- The low rate of test-dose failures (1.4%) among over 1,100 patients administered etripamil in SR further indicates the consistent tolerability of etripamil.

"These results show the consistent efficacy, with onset soon after self-administration, and safety of etripamil nasal spray across a wide range of studies and patient populations," said David Bharucha, M.D., PhD, FACC, Chief Medical Officer of Milestone. "The potential for patients to self-administer etripamil and achieve rapid termination of symptomatic PSVT episodes would represent a meaningful advance in the management of PSVT, a condition that frequently leads to emergency room visits and causes significant burden for patients."

Study Methods

This analysis involved a systematic review of randomized-controlled and open-label trials evaluating etripamil in adult patients with documented PSVT. Studies were selected based on their focus on self-administered etripamil for acute termination of symptomatic PSVT episodes, with inclusion criteria encompassing patients aged 18 years or older with a history of PSVT confirmed by electrocardiogram (ECG). These studies included: Phase 2: NODE-1; Phase 3: NODE-301 (Parts 1 and 2 [RAPID] and its extensions); and NODE-302 and NODE-303 (open-label extensions).

A New Drug Application (NDA) for CARDAMYST is currently being evaluated by the U.S. Food & Drug Administration (FDA) which has set a new Prescription Drug User Fee Act (PDFUA) target date of December 13, 2025.

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 medicines to benefit people living with certain heart conditions. Milestone recently submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for etripamil for the treatment of an abnormal heart rhythm, paroxysmal supraventricular tachycardia or PSVT.

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: expectations in regards to etripamil’s efficacy; CARDAMYST’s potential as a novel treatment option to help patients with PSVT; the timing of the 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, international tariffs, 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, 2025 and its quarterly report on Form 10-Q for the quarter ended June 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

Source: Milestone Pharmaceuticals Inc.