Milestone® Pharmaceuticals Announces Etripamil Data Demonstrating Patients' Ability to Self-Manage Recurring PSVT, Presented at The American College of Cardiology Annual Meeting

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Data from this large safety-trial also published in The Journal of the American College of Cardiology

MONTREAL and CHARLOTTE, N.C., April 08, 2024 (GLOBE NEWSWIRE) -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST) a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced new clinical data demonstrating real-world application of etripamil, an investigational new drug, for conversion of recurrent paroxysmal supraventricular tachycardia (PSVT).

"The promising results of this real-world design study demonstrated patients' ability to self-manage multiple episodes of PSVT with etripamil," said David Bharucha, MD, PhD, FACC, Chief Medical Officer of Milestone Pharmaceuticals. "These data, coupled with our prior published etripamil Phase 3 studies, completes an exceptionally large data package assessing acute treatment of PSVT in the at-home setting."

Conducted in North and South America, this open label, Phase 3 study of etripamil in PSVT today was both presented at The American College of Cardiology Scientific Sessions in Atlanta, GA and published in *The Journal of the American College of Cardiology*. CARDAMYST™, the conditionally approved brand name for etripamil nasal spray, if approved, will be the first rapid, reliable, and at-the-ready option in the acute treatment of PSVT.

NODE-303 (ClinicalTrials.gov ID NCT04072835) evaluated self-administered etripamil (70 mg, nasal spray) in an outpatient setting for up to multiple episodes of PSVT, without prior test dosing. It did not exclude patients with a history of co-morbid atrial fibrillation (AFib) or atrial flutter. The results demonstrated that symptom-prompted treatment with etripamil was effective at restoring sinus rhythm as compared to placebo with a median time-to-conversion of 17.0 minutes and was generally well tolerated. The conversion of PSVT to sinus rhythm was similar among multiple PSVT episodes and the frequency of treatment-emergent adverse events at 24 hours decreased with successive episodes. Adverse events were predominantly localized to the drug's nasal administration site, consistent with prior trial findings. The protocol was amended during the trial to allow for a repeat dose of drug if symptoms persisted 10 minutes following the first dose. Efficacy of etripamil for PSVT conversion (restoration of sinus rhythm) in NODE-303 was 60% by 30 minutes after drug self-administration, and 69.9% by 60 minutes after drug self-administration; these rates of conversion are similar to those demonstrated in double-blinded and other open-label studies. These data support a potentially significant shift in the management approach for recurrent PSVT.

Both the presentation and publication will be available on the Milestone Pharmaceuticals corporate website at the conclusion of the ACC presentation.

About Paroxysmal Supraventricular Tachycardia

An estimated two million people in the United States 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 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 patients' ability to self-manage multiple episodes of PSVT with etripamil; and the potential for etripamil to present a significant shift in the management approach for recurrent PSVT. 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; whether the FDA will require additional trials or data which may significantly delay and put at risk our efforts to obtain approval and may not be successful, the risks inherent in biopharmaceutical product development and clinical trials, including the lengthy and uncertain regulatory approval process; 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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