Milestone Pharmaceuticals Announces Presentation of Data from Phase 3 NODE-302 Study of Etripamil for the Treatment of PSVT

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- Patients successfully self-managed PSVT episodes with etripamil which reduced need for ED intervention -

- As in other studies, etripamil was well tolerated by patients -

- Data to be featured during late breaking session at Heart Rhythm 2022 -

MONTREAL and CHARLOTTE, N.C., April 30, 2022 /PRNewswire/ -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced data from NODE-302, its Phase 3 open-label extension study of etripamil nasal spray, the Company's novel, investigational, calcium channel blocker in patients with paroxysmal supraventricular tachycardia (PSVT). The presentation, titled "*Etripamil Nasal Spray Is Effective and Safe for Conversion of Repeated Spontaneous Episodes of Paroxysmal Supraventricular Tachycardia During Long-term Follow-up: Results From the NODE-302 Study,*" will be featured during a late-breaking clinical trial session at the Heart Rhythm Society's Heart Rhythm 2022 meeting being held April 29-May 1, 2022 in San Francisco.

"PSVT is a highly disruptive condition that places a heavy burden on patients because of the unpredictable and sudden onset of symptoms that can require visits to the emergency department (ED) for treatment," said James Ip, M.D., Associate Professor and Director of Cardiac Pacing and Implantable Devices, Division of Cardiology, Weill Cornell Medicine, New York Presbyterian Hospital, and the study's lead author. "Results from the NODE-302 trial support the potential role of etripamil intranasal spray for patients to safely and effectively self-treat recurrent PSVT episodes without direct medical supervision and reduce their need for ED visits."

"These data, which show that 85% of the eligible patients chose to enter the NODE-302 extension study after experiencing etripamil administration in the prior study, are very encouraging as we progress in our mission of helping patients suffering from tachycardias," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "I would like to thank Dr. Ip and all the NODE-302 study investigators, study personnel, and our Milestone team members for generating these data, and the patients for putting their trust in our program."

NODE-302 was a single-arm, open-label extension study of the Phase 3, randomized, double-blind, placebo-controlled NODE-301 study. The primary objective of the NODE-302 study was to assess the safety of patients dosing 70 mg of etripamil over multiple episodes. Patients were eligible to participate in NODE-302 if they dosed themselves for a perceived episode of PSVT in NODE-301. In NODE-302, patients self-administered 70 mg of etripamil nasal spray in response to a perceived PSVT episode after a failed attempt at a vagal maneuver and were monitored for five hours using an ambulatory cardiac monitoring system. The study allowed patients to treat up to 11 unique episodes.

Of 198 eligible NODE-301 patients, 169 (85%) enrolled in NODE-302 and 105 (62%) experienced a perceived episode of PSVT, self-administered etripamil, and were included in the safety population. The calculated median (mean) number of treated episodes extrapolated over the course of one year was 3.7 (6.0). Of the 105 patients who treated themselves for a perceived episode, 92 (88%) had a positively adjudicated PSVT episode. There was a total of 188 positively adjudicated PSVT episodes (range 1-10 episodes per patient) over a median of 7.4 months follow-up. Overall, the PSVT conversion rate at 30 minutes following etripamil administration was 60.2%, with a median time to conversion of 15.5 minutes (95% CI, 11.3-22.1 minutes). Among 40 patients who self-treated two consecutive episodes, 21 of 26 (81%) who converted on their first episode were also successfully converted on their second. Moreover, the need for ED intervention to terminate a PSVT episode was low (13% of patients and 8.5% of positively adjudicated PSVT episodes). Etripamil was generally well-tolerated, with adverse events consistent with those observed in previous trials; the majority of adverse events related to treatment were localized to the nasopharynx administration site, and were mild and brief.

A copy of the presentation will be available on the Publications section of the Milestone Pharmaceuticals website.

About Paroxysmal Supraventricular Tachycardia

Paroxysmal supraventricular tachycardia (PSVT) is a condition characterized by intermittent episodes of rapid heartbeat that start and stop suddenly and without warning that Milestone Pharmaceuticals estimates affects approximately two million Americans. Episodes of PSVT are often associated with symptoms including palpitations, sweating, chest pressure or pain, shortness of breath, sudden onset of fatigue, lightheadedness or dizziness, fainting, and anxiety. Certain intravenous medications, including adenosine, beta-blockers, and calcium channel blockers, have long been used for the acute treatment of PSVT. However, these medications must be administered under medical supervision, usually in an emergency department or other acute care setting.

About Etripamil

Etripamil, Milestone's lead investigational product, is a calcium channel blocker designed to be a rapid-response therapy for episodic cardiovascular conditions. As a nasal spray that is self-administered by the patient, etripamil has the potential to shift the current treatment experience for many patients from the emergency department to a medically-unsupervised setting. Milestone is conducting a comprehensive development program for etripamil, with Phase 3 trials ongoing in PSVT and a Phase 2 proof-of-concept trial underway in patients with atrial fibrillation with rapid ventricular rate (AFib-RVR).

About Milestone Pharmaceuticals

Milestone Pharmaceuticals Inc. (Nasdaq: MIST), is a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines. Milestone's lead product candidate etripamil is currently in a Phase 3 clinical-stage program for the treatment of PSVT and in a Phase 2 proof-of-concept trial for the treatment of patients with atrial fibrillation with AFib-RVR. Milestone Pharmaceuticals operates in Canada and the United States. For more information, visit www.milestonepharma.com and follow the Company on Twitter at @MilestonePharma.

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," "will," "expect," "continue," "estimate," "potential," "progress" 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 potential of etripamil to serve as a promising therapy for PSVT patients to safely and effectively self-treat PSVT episodes, the design, procedure, timing, scope and results of the NODE-302 extension study; Milestone's ability to execute on the remainder of the PSVT program and Milestone's ongoing plans to study etripamil in atrial fibrillation patients. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, 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 and evaluation of clinical trials, and whether the clinical trials will validate the safety and efficacy of etripamil for PSVT or other indications, among others, as well as risks related to pandemics and public health emergencies, including those related to the ongoing COVID-19 pandemic, and risks related the sufficiency of Milestone's capital resources and its ability to raise additional capital. 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, 2021, under the caption "Risk Factors," as such discussion may be updated from time to time by subsequent filings we 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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