Milestone Pharmaceuticals Announces First Patient Enrolled in the ReVeRA Study, its Phase 2 Trial of Etripamil in Atrial Fibrillation and Rapid Ventricular Rate

March 29, 2021

MONTREAL and CHARLOTTE, N.C., March 29, 2021 /PRNewswire/ -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced the first patient has been enrolled in its Phase 2 proof-of-concept study of etripamil nasal spray for the **Re**duction of **Ve**ntricular **R**ate in patients experiencing **A**trial fibrillation and rapid ventricular rate (AFib-RVR), or the ReVeRA study.

"Initiation of the AFib ReVeRA trial represents a key advancement in our strategic effort to expand the development program for etripamil beyond paroxysmal supraventricular tachycardia," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "We believe etripamil, if approved by FDA, has the potential to offer patients with AFib-RVR a treatment for symptomatic episodes of elevated heart rate in the at–home setting."

The Phase 2 double blind, placebo controlled, proof-of-concept study is designed to assess the safety and efficacy of etripamil nasal spray to reduce ventricular rate in patients with AFib-RVR experiencing an episode of elevated heart rate requiring treatment. The trial, which will be conducted in Canada in collaboration with the Montreal Heart Institute and other research centers, is expected to enroll approximately 50 patients randomized 1:1 to receive either 70 mg of etripamil nasal spray or placebo. The primary endpoint will assess reduction in ventricular rate, with key secondary endpoints including the time to achieve the maximum reduction in rate and duration of the effect.

About Atrial Fibrillation and Rapid Ventricular Rate

Atrial fibrillation (AFib) is a common arrhythmia marked by an irregular and often rapid heartbeat. AFib is estimated to affect five million patients in the United States, a prevalence projected by the Centers for Disease Control to increase to twelve million patients within the next 10 years. Atrial fibrillation and rapid ventricular rate (AFib-RVR) is a condition in which patients with AFib experience episodes of abnormally high heart rate, often with symptoms such as palpitations, shortness of breath, dizziness, and weakness. Oral calcium channel blockers and/or beta blockers are commonly used to manage heart rate in this condition. When episodes do occur, the corresponding symptoms often cause patients to seek care in the acute care setting such as the emergency department, where standard of care procedures include intravenous administration of calcium channel blockers or beta blockers under medical supervision. Milestone's initial qualitative market research indicates approximately 40% of patients with AFib experience one or more symptomatic episodes of AFib-RVR per year that require treatment, suggesting a target addressable market for etripamil in patients with AFib of approximately two million patients.

About Etripamil

Etripamil, Milestone's lead investigational product, is a novel 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 the at-home setting. Milestone is conducting a comprehensive development program for etripamil, with Phase 3 trials ongoing in paroxysmal supraventricular tachycardia (PSVT) and now a Phase 2 proof-of-concept trial underway in patients with atrial fibrillation and 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 paroxysmal supraventricular tachycardia (PSVT) and in a Phase 2 proof-of-concept trial for the treatment of patients with atrial fibrillation and rapid ventricular rate (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 "may," "will," "expect," "plan," "anticipate,", "continue" "estimate," "potential,", "prepare", "believe," "remain," "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 (i) the design, progress, timing, scope and endpoints of the ReVeRA trial, (ii) potential clinical trials in other cardiac conditions, (iii) the possibility that etripamil will provide patient benefit and, (iv) estimates about the addressable market and commercial potential for treatments of atrial fibrillation with rapid ventricular rate. 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, including the ReVeRA trial, and whether the clinical trials will validate the safety and efficacy of etripamil for atrial fibrillation with rapid ventricular rate, PSVT or other indications, among others, as well as risks related to pandemics and public health emergencies, including those related to COVID-19, risks related the sufficiency of Milestone's capital resources and its ability to raise additional capital, and risk inherent in estimating the market for and commercial potential of etripamil. These and other risks are set forth in Milestone's filings with the U.S. Securities and Exchange Commission, including in its quarterly report on Form 10-K for the year ended December 31, 2020, under the caption "Risk

Factors." 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.

Contact:

David Pitts
Argot Partners
212-600-1902
david@argotpartners.com

Milestone™
PHARMACEUTICALS

View original content to download multimedia:http://www.prnewswire.com/news-releases/milestone-pharmaceuticals-announces-first-patient-enrolled-in-the-revera-study-its-phase-2-trial-of-etripamil-in-atrial-fibrillation-and-rapid-ventricular-rate-301257905.html

SOURCE Milestone Pharmaceuticals, Inc.