Milestone Pharmaceuticals Announces Etripamil AFib-RVR Study is Selected for Featured Science Presentation at the American Heart Association Scientific Sessions 2023

September 27, 2023

MONTREAL and CHARLOTTE, N.C., Sept. 27, 2023 /PRNewswire/ -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST) today announced that results from a double-blind, randomized, placebo-controlled Phase 2 etripamil study will be presented at the American Heart Association (AHA) Scientific Sessions 2023. Selected for a Featured Science Presentation, the ReVeRA study evaluated etripamil in emergency department patients with atrial fibrillation with rapid ventricular rate (AFib-RVR). The presentation will take place at the AHA Scientific Sessions in Philadelphia, PA and virtually from November 11-13, 2023.

"Current AFib-RVR treatment goals include quickly resolving the discomfort and disruption of episodes of rapid heart rate. We're optimistic that the data will demonstrate etripamil's potential to meet this goal for patients who have limited options to self-manage their disease," said David Bharucha, M.D., Ph.D., F.A.C.C., Chief Medical Officer of Milestone Pharmaceuticals. "This is an important step in understanding the potential clinical utility of etripamil in indications beyond our lead program in paroxysmal supraventricular tachycardia."

The Feature Science presentation details are:

Session Title: Featured Science: Innovations in EP Care
Session number: FS.01
Presenter: A. John Camm, M.D., British Heart Foundation Emeritus Professor of Clinical Cardiology, The Cardiology Clinical Academic Group, Molecular and Clinical Sciences Research Institute, St. George's University of London, London, UK
Title: Randomized, Controlled Study of the Efficacy and Safety of Etripamil Nasal Spray for the Acute Reduction of Rapid Ventricular Rate in Patients with Symptomatic Atrial Fibrillation (Phase 2, ReVeRA-201)
Time, Date: 9:57-10:05 AM ET, Saturday, November 11, 2023

About ReVeRA

ReVeRA is a Phase 2 double-blind, randomized, placebo-controlled, proof-of-concept trial of etripamil in patients presenting to an emergency department with AFib-RVR. The trial, in which patients were randomized 1:1 to receive either etripamil nasal spray 70 mg or placebo, is designed to assess the safety and efficacy of etripamil to reduce elevated ventricular rates in patients with symptomatic AFib-RVR. 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 with Rapid Ventricular Rate

An estimated five million Americans suffer from AFib, a common arrhythmia marked by an irregular, disruptive and often rapid heartbeat. The Centers for Disease Control projects the prevalence of AFib will grow to an estimated 12 million patients by 2030. A subset of AFib patients experience episodes of abnormally high heart rate most often accompanied by palpitations, shortness of breath, dizziness, and weakness. While these episodes, known as AFib-RVR, may be treated by oral calcium channel blockers and/or beta blockers, patients frequently seek acute care in the emergency department (ED) to resolve symptoms. In 2016, nearly 800,000 patients were admitted to the ED due to AFib symptoms where treatment includes medically supervised intravenous administration of calcium channel blockers or beta blockers, or electrical cardioversion. With little available data for AFib-RVR, Milestone's initial market research indicates that 30-40% of patients with AFib experience one or more symptomatic episodes of RVR per year that require treatment, suggesting a target addressable market of approximately three to four million patients in 2030 for etripamil in patients with AFib.

About Etripamil

Etripamil, Milestone's lead investigational product, is a novel calcium channel blocker nasal spray. It is designed to be a rapid-response therapy that is self-administered by the patient, without the need for direct medical oversight, and is being developed for elevated and often highly symptomatic heart rate attacks associated with PSVT and AFib-RVR. If approved, etripamil is intended to provide health care providers with a new tool to enable virtual care and patient self-management, and to impart upon the patient a greater sense of control over their condition. Etripamil is well studied with a robust clinical trial program that includes a completed Phase 3 clinical-stage program for the treatment of PSVT and soon to be reported Phase 2 proof-of-concept trial for the treatment of patients with 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 recently completed its Phase 3 clinical-stage program for the treatment of paroxysmal supraventricular tachycardia (PSVT) and is in a Phase 2 proof-of-concept trial for the treatment of patients with AFib-RVR. Milestone Pharmaceuticals operates in Canada and the United States. Find out more at www.milestonepharma.com.

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" 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 ability of the data from the ReVeRa study to demonstrate etripamil's potential to meet certain goals for patients with AFib-RVR; the ability of the data from the ReVeRa study to provide an important step in understanding the potential clinical utility of etripamil in indications beyond our lead program in paroxysmal supraventricular tachycardia; the ability of the ReVeRa study to assess reduction in ventricular rate; growth in the number of AFib patients by 2030; the potential of etripamil to serve as a promising therapy for PSVT patients; and the timing of clinical trial data from the Phase 2 etripamil study. 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, 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 and Russian hostilities in Ukraine 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, 2022, 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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