Milestone Pharmaceuticals Announces First Patient Enrolled in NODE-303 Open-label Safety Study of Etripamil in PSVT

October 3, 2019

MONTREAL and CHARLOTTE, N.C., Oct. 3, 2019 /PRNewswire/ -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST), a Phase 3 clinical-stage biopharmaceutical company dedicated to developing and commercializing etripamil for the treatment of cardiovascular indications, today announced that the first patient has been enrolled in the Phase 3 NODE-303 study. NODE-303 is the Company's open-label, global safety study of etripamil, the Company's novel, potent and short-acting calcium channel blocker, in patients with paroxysmal supraventricular tachycardia (PSVT).

"Commencement of enrollment in NODE-303 marks an important step forward for our Phase 3 program of etripamil in PSVT, where current standards of care are restricted to the burdensome and costly acute care setting," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "We believe etripamil has the potential to alter the PSVT treatment paradigm, providing patients with a self-administered intervention to effectively terminate PSVT episodes wherever and whenever they occur. We remain focused on the execution of the entirety of the program, and continue to expect topline results from NODE-301 in the first half of 2020."

Milestone's pivotal Phase 3 program of etripamil in PSVT, which was designed in consultation with U.S. and European Union regulatory authorities, is designed to support potential filings in the U.S. and European Union. It consists of three distinct trials, including one randomized, double-blind, placebo-controlled efficacy trial, NODE-301, its open-label safety extension study, NODE-302, and NODE-303.

NODE-303 is a global study which will primarily evaluate the safety of etripamil when self-administered without medical supervision during single or multiple PSVT episodes. Important secondary measures include efficacy, patient quality of life and pharmacoeconomic assessments. The study represents the largest study ever conducted in PSVT, assessing up to 1,500 patient episodes from patients who did not participate in NODE-301 or NODE-302. As previously announced, the U.S. Food and Drug Administration agreed to allow initiation of patient enrollment in the NODE-303 study in a population consistent with NODE-301 and NODE-302, including older patients and those patients taking concomitant beta-blockers and calcium channel blockers, and without the in-office safety test dose that is currently required in NODE-301.

About Etripamil in Paroxysmal Supraventricular Tachycardia (PSVT)

Paroxysmal Supraventricular Tachycardia (PSVT) is a rapid heart rate condition that starts and stops without warning, often experienced by patients with symptoms including palpitations, sweating, chest pressure or pain, shortness of breath, sudden onset of fatigue, lightheadedness or dizziness, fainting and anxiety. Calcium channel blockers have long been approved for the treatment of PSVT as well as other cardiac conditions, however, calcium channel blockers are currently administered intravenously under medical supervision, usually in the emergency department. By contrast, etripamil is designed to serve as a self-administered therapy for the rapid termination of episodes of PSVT. With its combination of convenient delivery, rapid onset and short duration of action, etripamil has the potential to shift the current treatment paradigm for PSVT away from the burdensome and costly emergency department settings by treating episodes of PSVT wherever and whenever they occur.

About Milestone Pharmaceuticals

Milestone is a Phase 3 clinical-stage biopharmaceutical company dedicated to developing and commercializing the investigational new drug etripamil for the treatment of cardiovascular indications. Etripamil is a novel, potent and short-acting calcium channel blocker designed by Milestone and being developed as a rapid-onset nasal spray to be administered by the patient to terminate episodes of PSVT as they occur. Milestone is actively recruiting patients for a Phase 3 clinical trial of etripamil for the treatment of PSVT. Milestone plans to initiate a Phase 2 clinical trial in atrial fibrillation, another rapid heart rate condition, and expects to subsequently initiate an additional Phase 2 clinical trial in angina to establish proof-of-concept for the broader use of etripamil.

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," "estimate," "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 results of clinical trials, (ii) the anticipated timing of disclosure of results of clinical trials, (iii) the potential benefits and success of the commercialization of product candidates, and (iv) the likelihood data will support future development. 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 and completion of clinical trials, and whether the clinical trials will validate the safety and efficacy of etripamil for PSVT or other indications, among others. 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-Q for the period ended June 30, 2019, 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

View original content to download multimedia:http://www.prnewswire.com/news-releases/milestone-pharmaceuticals-announces-first-patient-enrolled-in-node-303-open-label-safety-study-of-etripamil-in-psvt-300930260.html

SOURCE Milestone Pharmaceuticals, Inc.