30 October 2023

Re: Milestone Pharmaceuticals NODE-303 – Reason for Study Not Starting in the EU

Study Title:	Multi-Centre, Multi-National, Open Label, Safety Study of Etripamil Nasal Spray for Patients with Paroxysmal Supraventricular Tachycardia
EudraCT Number:	2019-001857-13
VHP Number:	VHP1572 (VHP2019125)
Protocol Number:	NODE-303
Sponsor:	Milestone Pharmaceuticals Inc. 1111 Dr. Frederik-Philips Blvd., Suite 420 Montreal, Quebec CA H4M 2X6
Investigational Medicinal Product:	Etripamil Nasal Spray (MSP-2017)

The NODE-303 study sponsored by Milestone Pharmaceuticals, Inc. ("Milestone") received initial approvals from multiple European Union country regulatory authorities but was never initiated in any of these countries. The reason for the study not starting in any EU country is provided below.

The NODE-303 study was designed to deliver the necessary safety data to complete the overall safety database for Milestone's Paroxysmal Supraventricular Tachycardia (PSVT) program for investigational product MSP-2017 (Etripamil Nasal Spray). Following initial authorisations of the clinical trial by the concerned EU country regulatory authorities, but prior to activation of any sites in the EU, Milestone re-prioritized company resources toward another study in their etripamil development program (the RAPID Study, NODE-301 Part 2). This led to an increase in expected number of PSVT events to be generated from the RAPID study and a reduction in expected number of patients and sites that would be needed from the NODE-303 study to complete the safety database. Consequently, Milestone Pharmaceuticals reduced the number of countries participating in the NODE-303 study overall and as a result did not initiate this study in any EU country. Therefore, no EU sites were activated nor were any patients enrolled in the EU for the NODE-303 study.