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Milestone Medical, Inc. Provides Regulatory Update Regarding Epidural Instrument; Expects Marketing Clearance in the United States in First Half of 2017

LIVINGSTON, NJ, February 1, 2017 -- Milestone Medical Inc. (WAR:MMD) today announced that management expects to receive U.S. Food & Drug Administration (FDA) marketing clearance for its epidural instrument in the first half of 2017.

As previously announced, the Company completed its COMPASS Study (CompuFlo® Assessment Study), a randomized, controlled, parallel group, multicenter, pivotal study to assess the safety and effectiveness of the epidural space verification with the CompuFlo® Epidural Computer Controlled System. The clinical trial for the epidural instrument reached an enrollment of 400 patients and consisted of two separate arms: (i) pain management; and (ii) labor and delivery. Both arms were compared against the current medical standards of care. The goal of the pivotal Investigational Device Exemption (IDE) clinical trial was to demonstrate the accuracy of the CompuFlo technology in identifying and confirming the epidural space location. The Company submitted what it believes to be the favorable results of this study to the FDA in its 510(k) application for marketing clearance of its epidural instrument and disposables for birthing and pain management.

The epidural instrument has already obtained CE mark approval and may now be marketed and sold in most European countries and many other countries accepting CE approved instruments. The Company has entered into a limited number of European and Middle East distributor arrangements for its epidural instrument and plans to develop an international marketing network of independent distributors upon receipt of FDA approval.

Leonard Osser, Chief Executive Officer of Milestone Medical stated, “We have completed our regulatory submissions and are prepared, along with our regulatory advisors, to respond to any further questions from the FDA. In advance of marketing clearance, we have been cultivating relationships with key opinion leaders, who have been supportive and recognize the advantages of our technology.”

“Milestone Scientific Inc., our majority shareholder, recently completed a public offering of its shares and warrants for gross proceeds of $3.0 million, which will allow us to accelerate sales and marketing activities related to the planned launch of our epidural instrument.”

Milestone’s epidural injection instrument using CompuFlo® pressure sensing technology provides an objective tool that consistently and accurately identifies the epidural space by detecting the difference in pressure between the ligamentum flavum and the extraligamentary tissue. In studies, the CompuFlo® technology has been shown to be effective in correctly identifying the epidural space. Knowing the precise location of a needle during an epidural injection procedure provides a measure of safety not presently available to doctors using only conventional syringes, where the epidural space is identified by relying on the subjective perception of loss of resistance to saline.

About Milestone Medical Inc.

Milestone Medical, Inc. has developed epidural and intra-articular drug delivery systems based on a patented, painless, computer-controlled injection and drug delivery technology originally developed by Milestone Scientific, Inc. Development of both the epidural and intra-articular instruments is now complete and the Company is currently pursuing regulatory approval for both instruments in the U.S. Milestone Medical received CE Mark approval to sell and market its intra-articular and epidural instruments across European Union. For more information please visit www.medicalmilestone.com.

Safe Harbor Statement

This press release contains forward-looking statements regarding the timing and financial impact of Milestone's ability to implement its business plan, receipt of regulatory approvals, expected revenues and future success. These statements involve a number of risks and uncertainties and are based on assumptions involving judgments with respect to future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond Milestone's control. Some of the important factors that could cause actual results to differ materially from those indicated by the forward-looking statements are general economic conditions, failure to achieve expected revenue growth, changes in our operating expenses, adverse patent rulings, FDA or legal developments, competitive pressures, changes in customer and market requirements and standards, and the risk factors detailed from time to time in Milestone's periodic filings with the Securities and Exchange Commission, including without limitation, Milestone's Annual Report for the year ended December 31, 2015. The forward looking statements in this press release are based upon management's reasonable belief as of the date hereof. Milestone undertakes no obligation to revise or update publicly any forward-looking statements for any reason.