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Milestone Scientific Inc. Provides Regulatory Update

LIVINGSTON, NJ, December 14, 2016 -- Milestone Scientific Inc. (NYSE MKT: MLSS), a medical R&D and dental products company that designs, patents, incubates and commercializes a growing portfolio of innovative therapeutic injection technologies, today provided an update regarding its U.S. submission for marketing clearance of the intra-articular instrument.

The Company received notification from the FDA that based upon the 510(k) application submitted for the Company's Compu-Flo Intra Articular Computer Controlled Injection System, the Company did not adequately document that the device met the equivalency standard required for 510(k) clearance. Following consultation with the FDA Office of Device Evaluation, the Company intends to provide additional data, including a new Human Factor Validation study (HFV Study) in support of a new 510(k) application for the device. An HFV Study demonstrates the ease of use of a product. The cost to generate this incremental data is estimated to be approximately \$100,000.

The Company believes that the new 510(k) application as supported by the new HFV Study will demonstrate substantial equivalency. Although, there can be no assurance that the FDA will clear the 510(k) application, the Company's confidence is reinforced by the approval and successful commercialization of its dental instrument, which has been used successfully in over 60 million injections to date. The Company's intra-articular instrument has previously received CE clearance to market the device in the European market.

Leonard Osser, CEO of Milestone Scientific, commented, "We were surprised by the FDA's response to our application for the intra-articular instrument; however, based on the feedback, we will make the necessary adjustments and resubmit a new application and we are confident that with the results of the incremental HFV Study and other data, 510(k) equivalency will be demonstrated."

Leonard Osser further commented, "This development does not detract from our current commercialization initiatives, substantially all of which have focused on our CompuFlo epidural instrument including our recent staffing enhancements, strategic partnerships and key opinion leader relationships. The epidural instrument remains our primary focus among our medical instruments for near term commercialization and revenue."

About Milestone Scientific Inc.

Milestone Scientific Inc. (MLSS) is a medical R&D company that designs, patents, incubates and commercializes a growing portfolio of innovative injection technologies. Milestone's computer-controlled systems make injections precise, efficient, and virtually painless. For more information please visit our website: www.milestonescientific.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, 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.