

## **Contact:**

David Waldman or Justyna Gudaszewska Crescendo Communications Europe Sp. z o.o.

Email: mmd@crescendo-ir.com

Tel: +48 71 79 11 551

## Milestone Medical Announces Clinical Trial Registration Approval by the FDA for its Epidural Instrument

**LIVINGSTON, NJ, March 3, 2015** -- **Milestone Medical Inc. (WAR: MMD)** today announced that it met FDAAA 801 requirements for submission of the clinical trial information to the Director of the National Institutes of Health (NIH) for inclusion in the registry and results database established via ClinicalTrials.gov regarding its CompuFlo Epidural Computer Controlled System for accurately and safely identifying the epidural space. Study details have been registered with The United States National Library of Medicine (NLM) clinical trials database. Recruitment for the trial is now underway.

Leonard Osser, Chief Executive Officer of Milestone Medical, stated, "Approval for this final round of clinical trials in the U.S. will allow us to further demonstrate the benefits, safety and effectiveness of our pressure sensing injection technology and moves us closer towards commercialization on a global basis. The epidural market in the US alone is estimated to be over \$1 billion, with 2.4 million epidurals administered for childbirth annually and more than 8.9 million other epidurals."

Mr. Osser continued, "In the United States, we have teamed up with a major distributor who will commence purchases upon marketing clearance of our instrument by the FDA. Our agreement with this U.S. distributor includes minimum purchase orders, reinforcing their confidence in the market potential of our instrument. Successful completion of these clinical trials with the FDA will also open the way to CFDA marketing clearance in China where we already have a distribution agreement in place with our joint venture partner that also includes minimum purchase orders."

## **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 in the U.S. and China and has recently received CE approval for both instruments in the European Union. For more information please visit <a href="https://www.medicalmilestone.com">www.medicalmilestone.com</a>.

## 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. 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.