

Contact: David Waldman or Justyna Gudaszewska Crescendo Communications, LLC Email: <u>mmd@crescendo-ir.com</u> Tel: +48 693 354 580

## Third Study Verifies Milestone Medical's CompuFlo<sup>®</sup> Instrument Differentiates False Loss of Resistance During Epidural Blocks

Easier, more reliable identification essential to reducing failed epidurals and complications

LIVINGSTON, NJ, February 7, 2019 – Milestone Medical Inc. (WAR: MMD) today announced a new 120patient clinical study published in *Anesthesiology Research & Practice* that verifies the CompuFlo<sup>®</sup> Epidural System ("CompuFlo") consistently different\iates false loss of resistance from true loss of resistance during epidural placement. In all cases where CompuFlo pressure measurements were used to objectively identify the epidural space, the block was performed successfully with no complications.

Easier identification of false losses of resistance is essential to reducing the number of epidural attempts and risk of accidental dural puncture. The occurrence of false losses of resistance is one reason why accurate placement of an epidural needle is a difficult skill for anesthesiologists to master, needing approximately 60-90<sup>1</sup> placements before reaching an adequate basic skill. While analgesic failure can usually be detected in less than 30 minutes after the initial placement, it often requires treatments that can result in new difficulties, complications and cost. Other academic researchers report 17 percent failure rates<sup>2</sup> due to false positive loss of resistance.

Giorgio Capogna, M.D., Director of the European School of Obstetric Anesthesia and Maternal Neonatal Simulation Center, comments, "Loss of resistance technique has been the standard of care since its introduction in 1933, but its subjective nature is not without limitations. The pressure sensing innovation in CompuFlo offers a more objective, reliable and simpler way to identify the epidural space. This confidence in recognizing a true loss of resistance can help improve the efficacy of anesthesia, reduce complications, and speed the procedure learning curve for trainees." Dr. Capogna is a member of Scientific Advisory Board at Milestone Scientific Inc., the licensor and the majority shareholder of Milestone Medical Inc.

The CompuFlo instrument is the first commercial technology to assist anesthesia providers with objective, realtime identification of the epidural space. CompuFlo features an innovative Dynamic Pressure Sensing technology<sup>®</sup> that differentiates tissue types by pressure signatures that are imperceptible by touch. This allows the instrument to accurately identify location and discriminate between true and false loss of resistance. A true loss of resistance and entrance to the epidural space is confirmed with three indicators: tactile feel, a visual sudden drop in pressure forming a low and stable plateau that lasts for more than 5 seconds, and an audible decrease in pitch. CompuFlo is clinically proven to objectively identify the epidural space with 99% success on the first attempt.

Study investigators include Pasquale Vaira, Michela Camorcia, Tiziana Palladino, Matteo Velardo, and Giorgio Capogna from Casa Sollievo della Sofferenza Hospital CdC Città di Roma, and the European School of Obstetric Anesthesia, in Rome, Italy. The publication is available at: <u>https://doi.org/10.1155/2019/5185901</u>

<sup>&</sup>lt;sup>1</sup> D. J. Kopacz, J. M. Neal, and J. E. Pollock, "The regional anesthesia "learning curve." What is the minimum number of epidural and spinal blocks to reach consistency?," Regional Anesthesia, vol. 21, no. 3, pp. 182–190, 1996.

<sup>&</sup>lt;sup>2</sup>Q. H. Tran, A. P. Gonz`ales, F. Bernucci, and J. Finlayson, "Confirmation of loss-of-resistance for epidural analgesia," Regional Anesthesia and Pain Medicine, vol. 40, no. 2, pp. 166–173, 2015.

## 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. The Company was granted the FDA marketing clearance of the epidural instrument in U.S. and is currently pursuing regulatory approval for intra-articular instrument 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.

## About Milestone Scientific Inc.

Milestone Scientific Inc. (MLSS) is a medical device company that patents, designs, develops and commercializes innovative diagnostic and therapeutic injection technologies and instruments for medical, dental, cosmetic and veterinary applications. Milestone's computer-controlled systems are designed to make injections precise, efficient, and virtually painless. Milestone's proprietary *DPS* Dynamic Pressure Sensing technology<sup>®</sup> is our technology platform that advances the development of next-generation devices, regulating flow rate and monitoring pressure from the tip of the needle, through platform extensions for local anesthesia for subcutaneous drug delivery, with specific applications for cosmetic botulinum toxin injections, epidural space identification in regional anesthesia procedures and intra-articular joint injections. 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, timing of regulatory approvals 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, future business decisions and regulatory developments, 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, 2017. 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.

###