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Milestone Medical Announces Publication of Study Validating Efficacy of CompuFlo® CathCheck™ System to Confirm and Monitor the Placement of an Epidural Catheter

Pressure waveform recording through the epidural catheter resulted in 100% sensitivity and specificity, as well as a positive predictive value of 100%

LIVINGSTON, NJ, May 13, 2020 – Milestone Medical Inc. (WAR: MMD) today announced the publication of a study in the Open Journal of Anesthesiology, in an article entitled, "[Confirmation of Epidural Catheter Location by Epidural Pressure Waveform Recordings by the CompuFlo® Cath-Checker System](#)," reinforcing the efficacy of the CompuFlo® CathCheck™ System to confirm the correct placement and positioning of an epidural catheter for use during and after an epidural procedure.

For the purposes of this study, the CompuFlo Epidural System utilized the new CathCheck™ technology to combine both objective in-line pressure measurements and detection of a pulsatile pressure waveform in a single system. This prospective, open trial is the first study to investigate the capability of the CompuFlo® CathCheck™ System to detect the pulsatile waveform confirming the correct placement of an epidural catheter, which provides an important metric in seconds to a healthcare worker in order to determine if a catheter is functioning properly or not. The current standard-of-care lacks such an objective means when making this determination and relies primarily on the administration of a medication through the catheter and then waiting 20 to 40 minutes for a patient's response to determine if that catheter is dysfunctional or not. In contrast, the CathCheck™ system provides the important information in real-time to make the appropriate determination, allowing greater efficiency and improved patient care.

The study received formal approval from the Institutional Ethics Committee of Lazio 1 in Roma, Italy. The study was performed on 30 epidural catheters previously used for post cesarean analgesia and about to be removed. All the patients were given 5 mL 2% lidocaine to test the catheter before its removal. After priming with 5 mL saline, the catheter was connected to CompuFlo® CathCheck™ System to record the occurrence of pulsatile waveforms or their disappearance during its removal. Pulsatile waveforms (originating from the spinal cord and transmitted through the dura in synchrony with heart rate) were observed in all the catheters properly located in the epidural space and disappeared when the catheter was extracted from the epidural space. The pulsatile pressure waveform analysis through the epidural catheter resulted in a sensitivity of 100%, a positive predictive value of 100%, a specificity of 100% and a negative predictive value of 100%.

Leonard Osser, Interim Chief Executive Officer of Milestone Medical, stated, "We are honored to have the results of this study featured in this journal with its global audience of anesthesiologists. The findings of this open trial further validate the ability of the CompuFlo® CathCheck™ System to safely and accurately identify location of the needle or catheter in the epidural space. Publications such as these serve to highlight the benefits of our technology, which should help drive broad adoption among leading anesthesia providers around the world. Our unique computer-controlled real-time pressure sensing technology combined with pulsatile pressure waveform measurement has the potential to transform the administration of epidural procedures and subsequent monitoring of catheter placement following an epidural procedure by confirming the placement of a catheter within seconds, versus 20–40 minutes using conventional methods. We believe the CathCheck™ feature will help to significantly reduce time and cost for the institution by providing a more reliable way to re-check the catheter throughout the day to ensure that the catheter has not been displaced."

Study investigators include, Giorgio Capogna, Michela Camorcia, Cristiana Berritta, Mark Hochman and Matteo Velardo from EESOA Maternal Neonatal Simulation Center, Roma, Italy and Città di Roma Hospital, Roma, Italy. Dr. Capogna is MD, Head of the Department of Anesthesiology at Città di Roma Hospital in Rome and a Member of Milestone Scientific's Scientific Advisory Board. Mark Hochman is D.D.S, Director of Clinical Affairs for Milestone Scientific, the licensor of computer-controlled injection and drug delivery technology. The publication is available online at: <https://www.scirp.org/journal/ojanes>

About Milestone Medical Inc.

Milestone Medical, Inc. (WAR:MMD) 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 biomedical technology research and development 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[®] 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, 2019. 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.

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