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

# Milestone Medical Announces 510(k) FDA Clearance for the Use of CompuFlo Epidural System in Thoracic Indications

**Roseland, NJ., February 27, 2023 – Milestone Medical Inc. (WAR: MMD, "the Company")** today announced that its CompuFlo® Epidural System has received 510(k) FDA clearance for use in the thoracic region of the spine, including the cervical thoracic junction. This approval expands upon the Company's prior approval of CompuFlo for use within the lumbar region of the spine, where the focus has been on labor and delivery.

The use of the CompuFlo Epidural System, with its patented DPS Dynamic Pressure Sensing Technology® in these newly expanded indications, provides anesthesiologists and pain management providers the ability to navigate challenging anatomical regions in the thoracic region and cervical thoracic junction in real-time, confirming needle placement both audibly and visually, thereby making the epidural procedure easier and safer to perform. The clinical and safety benefits of the CompuFlo Epidural System are backed by extensive published clinical data demonstrating significant reductions in dural punctures, as well as complication rates, and contribute to savings of time on the part of providers. An independent study has shown that the CompuFlo Epidural System has the potential to reduce costs associated with morbidity, providing a direct economic benefit to healthcare institutions.

Dr. Ronny Hertz, MD, an anesthesiologist and pain management physician, as well as an advisor to Milestone Scientific and Milestone Medical, stated, "Each year spinal cord injury cases are reported as a result of epidural procedures, especially in the thoracic and cervical regions. We believe this approval will be of benefit to physicians who have been trained in the placement of epidurals in the thoracic and cervical regions of the spine, including anesthesiologists and pain management providers due to the difficulties accessing the epidural space, especially in the higher thoracic cervical regions of the spine. The use of the CompuFlo Epidural System in these regions will add another level of safety, efficiency and confidence as it audibly and visually measures tissue pressures in real time, allowing a provider to confirm the needle placement. I believe it will also be of tremendous assistance for spinal cord stimulator cases."

Dr. Hertz added, "The CompuFlo device should also be beneficial in teaching residents and nurse anesthetists the proper placement of epidural needles since it provides the instructor and student audible and visual confirmation when the tip of the needle is in the correct location. Every medical technique has risks, but it is the job of the healthcare provider to try to reduce those risks, and I believe CompuFlo has the potential to become the new standard of care."

Arjan Haverhals, Chief Executive Officer of Milestone Medical, noted, "We are delighted to receive marketing clearance from the FDA for this new thoracic indication. Given the extensive published clinical data supporting successful epidural placement, we are pleased to expand the scope of indications beyond labor and delivery into challenging thoracic and cervical epidural procedures, where the incidence rates of morbidity are believed to be much higher, at 17% and 30%, respectively. The FDA clearance represents a major milestone as it broadens the market

opportunity for CompuFlo Epidural System, with approximately 11 million epidural procedures performed in the U.S. on an annual basis. We look forward to expanding the use of our technology within the area of pain management and remain encouraged by the interest in our epidural instruments by anesthesiologists and pain management providers, especially for patients with complex anatomy and difficult cases that involve the thoracic and cervical thoracic junction."

**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), a technology-focused medical research and development company that patents, designs and develops innovative injection technologies and instruments for medical, dental and cosmetic applications. Milestone Scientific's computer-controlled systems are designed to make injections precise, efficient and increase the overall patient comfort and safety. Their proprietary DPS Dynamic Pressure Sensing Technology® instruments is the platform to advance the development of next-generation devices, regulating flow rate and monitoring pressure from the tip of the needle, through platform extensions of subcutaneous drug delivery, including local anesthetic. To learn more, view the MLSS brand video or visit 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,* 2021*. 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.*