Flowonix Medical Inc. Announces FDA PMA(S) Approval of Prometra II

Next-generation Intrathecal Infusion Device offers MRI Patient Safety Valve Technology

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Mount Olive, NJ, January 19, 2015/PRNewswire/--Flowonix Medical, Inc., announced that the FDA has granted PMA-Supplement approval for its next-generation intrathecal infusion device, the Prometra® II system. The approval was granted on December 18, 2014 and product introduction will occur in the coming months. The most significant advancement associated with the Prometra II drug infusion device is the flow-activated safety valve (FAV™), which allows patients to have an MRI without the necessity of drug removal prior to the procedure.

"The proprietary flow-activated safety valve was designed to shut off drug flow to the patient in the event a high flow rate occurs during an MRI procedure," stated Timothy R. Deer, MD, Clinical Professor of Anesthesiology at West Virginia University School of Medicine. "While the Flowonix Prometra infusion technology is already the most accurate and longest-lasting option for our patients, Prometra II increases safety and clinical convenience, should the patient require an MRI. This is an important advancement for the Prometra family of products and one that will be welcomed by physicians who treat chronic pain and cancer pain patients."

Magnetic resonance imaging (MRI) is an imaging procedure that may be contraindicated for patients with implanted devices. The strong electromagnetic energy produced by MRI systems can interfere with proper device function. The Prometra II system is labeled as MR-Conditional and can safely undergo such scans providing specific conditions are followed. These specific steps are described in the Instructions for Use supplied with the product.

"The new Prometra II drug infusion device is a major breakthrough for Flowonix, physicians, and patients, since it will improve the MR compatibility of the already state-of-the-art Prometra drug infusion device," remarked Steve Adler, President of Flowonix. "The development and approval of the flow-activated valve demonstrates Flowonix's commitment to innovation and safety."

Intrathecal drug infusion systems like Prometra II are small, self-contained, battery-powered devices aimed at providing safe, dependable, automatic dosing of drugs directly into the intrathecal space around the spine. Over 100 million Americans suffer from chronic pain, which sometimes cannot be effectively treated with oral pain medications. Intrathecal pain therapy offers an important alternative to patients with refractory chronic pain and can often control pain with a very small amount of pain medication.

"The Prometra brand has always been associated with unrivaled accuracy, which is an important clinical consideration for chronic pain and cancer pain patients. Prometra II demonstrates our commitment to continuous innovation," concluded Steve Adler. "Prometra II is an important milestone for Flowonix."

About Flowonix

Flowonix Medical Inc. (www.flowonix.com), headquartered in Mt. Olive, NJ, is dedicated to working with healthcare professionals to help ease suffering associated with chronic pain and allow patients to reclaim their lives through innovation and therapy advancements. The strategic business goal of Flowonix Medical Inc. is to become the leading implantable drug delivery company in the world. Founded in 2005, Flowonix Medical Inc. received approval to conduct its first clinical trial in 2007 on the Prometra programmable implantable pump. The company received approval by the FDA to market the Prometra in 2012. Flowonix Medical Inc. has been granted multiple patents, and is focused on working closely with physicians to rapidly improve the capabilities of implantable drug delivery and management systems.
For more information, please visit http://www.flowonix.com.