FDA Clears SPR Therapeutics Pain Management Device

Minimally Invasive, Non-Opioid Alternative, Stimulates Peripheral Nerves to Provide Sustained Relief of Chronic and Acute Pain

CLEVELAND, OH—(Marketwired - Jul 27, 2016) - SPR® Therapeutics received clearance from the United States Food and Drug Administration to commercialize the SPRINT™ Peripheral Nerve Stimulation (PNS) System, the company announced today. SPRINT is the first and only completely reversible and minimally-invasive peripheral nerve stimulation system cleared to provide relief of chronic and acute pain, including post-operative and post-traumatic pain.

"The FDA's clearance comes at a critical time when physicians, patients and the U.S. healthcare system are seeking therapies to manage pain while reducing opioid use," said Maria Bennett, SPR Therapeutics Founder, President and CEO. "SPR has developed a drug-free treatment for relieving chronic and acute pain. With more than 100 million Americans suffering from chronic pain, and more than two million people suffering severe acute and post-operative pain every year, we believe SPRINT will be a game changer in the world of pain management."

The SPRINT PNS System includes a threadlike, coiled wire, or lead, and a matchbox-sized wearable stimulator, about the weight of four quarters. The lead is placed percutaneously, or through the skin, via a fine needle and connects externally to the wearable stimulator. The stimulator delivers electrical stimulation through the lead, which activates peripheral nerves to achieve pain relief.

SPRINT is unique in that it allows lead placement as far as two to three centimeters from the targeted nerve. This simplifies the lead placement procedure for physicians and gives them the distinct ability to preferentially stimulate specific fibers of the nerve to maximize pain relief. This innovative approach to PNS is fully reversible, as the device is designed to be withdrawn without surgery at the end of the 30-day treatment period.

"SPRINT brings the benefits of PNS to physicians seeking safe and effective alternatives to opioids in the treatment of chronic and acute pain," said Peter Staats, MD, MBA and immediate past-president of the American Society of Interventional Pain Physicians. "Unlike all other PNS systems, SPRINT does not require permanent implantation which should reduce invasiveness, risk and cost."

A physician can place the system during a short outpatient procedure without surgery or anesthesia. Because SPRINT is minimally invasive and completely reversible, physicians may use it earlier in a patient's treatment process in an effort to reduce or eliminate the need for opiates and to avoid costly alternatives in managing acute and chronic pain. SPRINT is an important step in providing a drug-free therapy especially since a Mayo Clinic report last year stated nearly 25 percent of patients who start opioids for pain relief progress to episodic or long-term use.

Multiple clinical trials evaluating SPRINT have demonstrated its ability to reduce pain and improve quality of life. In one study funded by the National Institutes of Health, use of SPR's system was associated with a 72 percent reduction in average pain. SPR will continue to sponsor clinical trials to further expand into specific indications.

"Patient access to this therapy has been made possible by support and research grants from the United States Department of Defense, the National Institutes of Health and the State of Ohio," said Bennett. "We are grateful for the enduring dedication of our team of physician investigators, clinical professionals, engineers and business colleagues."

SPRINT will soon be available at select health care facilities in the United States. To view a picture of the SPRINT PNS System, visit SPR's website here.

About SPR® Therapeutics
SPR Therapeutics (www.sprtherapeutics.com) has developed a proprietary percutaneous peripheral nerve stimulation platform intended to address the critical unmet need for non-opioid, minimally invasive, reversible, and cost-effective treatments for acute, post-operative and chronic pain.
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