

Relievent MedSystems Begins SMART Trial for the Alleviation of Chronic Low Back Pain

REDWOOD CITY, Calif., Oct. 31, 2011 – Relievent MedSystems Inc. today announced the company has enrolled the first patient in its SMART trial to evaluate the Intracept® Basivertebral Nerve Ablation Procedure. The **Surgical Multi-center Assessment of RF Ablation for the Treatment of Vertebrogenic Back Pain (SMART)** trial is a Level 1, prospective, randomized, double-blind, sham-controlled clinical trial evaluating the reduction of pain in patients with chronic axial low back pain.

The landmark SMART trial is enrolling 200 patients in up to 20 leading medical centers across the U.S. to determine the safety and effectiveness of the Intracept procedure. The primary endpoint is the evaluation of patient improvement in Oswestry Disability Index (ODI) at three months compared to baseline between treatment and sham populations. In addition, change in multiple patient-reported outcomes from baseline will be assessed at three, six, and twelve months as well as safety evaluations at all time points. Importantly, patients and clinicians who perform the follow-up evaluations are blinded to the randomization of the sham vs. experimental procedure.

“The Relievent Intracept procedure is a potential breakthrough for the treatment of chronic low back pain, which addresses the unmet clinical need for patients who have failed traditional conservative treatment modalities.” stated Jeffrey S. Fischgrund, M.D., Professor of Orthopaedic Surgery at Oakland University William Beaumont School of Medicine in Royal Oak, Michigan and the Principal Investigator of the SMART trial. “I look forward to evaluating the Intracept procedure in the SMART Trial which also has the opportunity of treating patients without the morbidity and expense of more invasive procedures.”

“The Intracept system brings important new capabilities to spine specialists to treat chronic low back pain. This revolutionary procedure and Level 1 clinical study demonstrate our commitment to advancing patient care for millions of pain sufferers,” said CEO Alex DiNello. Relievent is also initiating a separate and similar Level 1 study in Europe. Enrollment for both studies is expected to be completed in early 2013.

Chronic low back pain impacts nearly one-third of the population and represents the largest and most expensive non-lethal condition in our health care system. Every year, approximately 12 million new patients seek treatment for back pain. Unfortunately, nearly 2 million of these patients fail to respond to conservative therapies, and these patients have few options – escalating use of pain medications, invasive surgical procedures (including fusions) or continued suffering. The Intracept procedure may be a viable treatment alternative for patients who suffer from chronic low back pain but no longer respond to conservative therapies.

About Relievent Medsystems

Relievent Medsystems is a privately held company based in Redwood City, California. Its Intracept® System is a minimally invasive procedure that uses radiofrequency energy delivered through a small access tube into the vertebral body to ablate the Basivertebral nerve. The nerve, thought to significantly contribute to chronic low back pain, can no longer generate pain signals following ablation. Relievent’s primary investors include Canaan Partners, Emergent Ventures, Morgenthaler Ventures, and ONSET Ventures.

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