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Relievant Medsystems Receives FDA Approval to Begin Pivotal Study to Evaluate the Intracept System for Minimally Invasive Treatment of Chronic Low Back Pain

REDWOOD CITY, Calif., Aug. 8, 2011 -- (Healthcare Sales & Marketing Network) -- Relievant Medsystems, Inc. today announced the company has received Food and Drug Administration approval of an Investigational Device Exemption (IDE) to begin their SMART pivotal trial to evaluate the safety and effectiveness of the Intracept® System for treatment of chronic low back pain.

The SMART trial (Surgical Multi-center Assessment of RF Ablation for the Treatment of Vertebrogenic Back Pain) is a prospective, randomized, double-blind, sham-controlled investigation evaluating the reduction of pain in patients with chronic axial low back pain. The pivotal study will treat 200 patients at major medical centers around the United States with the Intracept System to determine the safety and effectiveness of this product. Enrollment in the SMART trial will begin this summer, with data analysis after the last subject has completed six months of follow-up.

Based on the research of Michael Heggeness, MD, PhD of the Baylor College of Medicine, Relievant's Intracept System treats chronic low back pain with a simple, minimally invasive procedure using radiofrequency energy delivered through a small access tube into the vertebral body to ablate the basiverterbal nerve. The nerve, which is believed to significantly contribute to chronic low back pain, no longer functions once it is ablated. There is no implant with the Intracept procedure, and based on a pilot study the treatment can usually be performed in about one hour

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, a major, invasive surgery(such as spinal fusion) or continued suffering. The Intracept procedure may be a viable treatment alternative for patients suffering from axial low back pain who no longer respond to conservative therapies.

"Relievant's Intracept procedure is simple, easy to perform, and the results seen in the pilot study are encouraging," said Jeffrey S. Fischgrund, M.D. of the Oakland University William Beaumont School of Medicine in Royal Oak, Michigan and the Principal Investigator of the trial. "Given the ineffectiveness or limitations of existing options that are available to this very large, underserved group of suffering patients, Intracept could represent one of the most significant advances in the treatment of chronic low back pain. The SMART trial is designed to provide level 1 clinical evidence in determining the safety and effectiveness of the Intracept procedure."

"In the initial pilot study of the Intracept system, treated patients reported immediate relief and were able to resume normal activities the next day," stated Adam Savakus, President and Chief Executive Officer of Relievant Medsystems. "We look forward to working with some of the leading spine specialists in the United States to investigate this promising technology and providing definitive results in our pivotal trial."

Relievant Medsystems is a privately held company based in Redwood City, California.

Source: **Relievant Medsystems**