



BIONESS ANNOUNCES THE PUBLICATION OF STIMROUTER™ NEUROMODULATION SYSTEM CLINICAL TRIAL

Valencia, California – February 01, 2016 – Bioness, Inc. announced today the successful results from the company’s 1-year clinical trial of the StimRouter™ Neuromodulation System. The results have been published in the January issue of *Neuromodulation*. The prospective, multi-center, randomized, double blinded, partial crossover study assessed safety and efficacy of the StimRouter Neuromodulation System for the treatment of patients with chronic pain of peripheral nerve origin. The StimRouter Treatment Group achieved primary endpoints of efficacy and safety and demonstrated a statistically significant ($p < 0.0001$) improvement in pain reduction as compared to the control group.

StimRouter received clearance from the Food and Drug Administration (FDA) last year and is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy. StimRouter is the only implantable neuromodulation device indicated and marketed to treat chronic pain of peripheral nerve origin.

“I am very pleased to have a minimally invasive peripheral nerve stimulation approach for my patients,” said Timothy R Deer, M.D., president and chief executive officer of The Center for Pain Relief in Charlestown, West Virginia. “This is the only device in this category to undergo a prospective Food and Drug Administration monitored study and meet the goals of success. This will be a critical tool for patients going forward, and potentially relieve pain and enhance the quality of life.”

Unlike traditional pain management neuromodulation devices (e.g. spinal cord stimulators), StimRouter requires no trial lead, is minimally invasive and performed under local anesthesia. As a potential cost-effective alternative to injections, ongoing medication regimens and complex surgeries, StimRouter is enabling underserved patient populations to access neuromodulation technology to treat chronic pain. “For decades peripheral nerve stimulation would require implantation of a pulse generator and significant tunneling from the distal peripheral nerve to the IPG location,” explained William Porter McRoberts, M.D., interventional spine and pain management expert. “With the Bioness StimRouter, everything has changed. Tens of thousands of patients are suffering from the painful and disabling condition of post-stroke shoulder pain and now I can implant a single lead along the axillary nerve to treat their pain.”

In addition to meeting the primary efficacy and safety endpoints, the Treatment group also showed improvements in activity level, emotional state and quality of life. “These long-term results reveal that the StimRouter Neuromodulation System provides a clinically significant and sustaining pain management solution,” stated Todd Cushman, President & CEO Bioness. “These clinical trial results enhance and further our goal of expanding StimRouter accessibility in pain management and rehabilitation.”

Bioness Contact:

Joel H Behnke
joel.behnke@bioness.com
707.888.2617



About StimRouter™ Neuromodulation System

StimRouter is the only implantable peripheral nerve stimulation device indicated and marketed to treat chronic pain of peripheral nerve origin. StimRouter is a minimally invasive neuromodulation medical device consisting of an implanted lead, external pulse transmitter (EPT) and conductive electrode, controlled by a small, handheld wireless patient programmer. Electrical signals are transmitted transdermally from the EPT through the electrode, down the lead to the target nerve. StimRouter is programmed at the direction of the physician to meet patient requirements.

About Bioness Inc.

Bioness is the leading provider of innovative technologies helping people regain mobility and independence. Bioness solutions include external and implantable functional electrical stimulation (FES) systems, robotic systems and software-based therapy programs providing functional and therapeutic benefits for individuals affected by pain, central nervous system disorders and orthopedic injuries. Individual results vary. Consult with a qualified physician to determine if this product is right for you. Contraindications, adverse reactions and precautions are available online at www.bioness.com

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Additional information about StimRouter can be found at www.stimrouter.com.

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