Study To Examine Safety Of Minimally Invasive Interspinous Spacer

(BUSINESS WIRE)--VertiFlex(R), Inc., a leading innovator of minimally invasive and motion preserving spinal surgery technologies, today announced the completion of enrollment in its pivotal IDE clinical trial of the Superion(R)Interspinous Spacer (ISS). The results of the Superion trial will form the basis for a PMA approval application to the U.S. Food and Drug Administration (FDA).

"Our Superion IDE study is the largest ever FDA clinical trial for lumbar spinal stenosis with 470 patients enrolled," said Earl R. Fender, President and Chief Executive Officer of VertiFlex, Inc.

"Completion of enrollment in this pivotal trial marks a significant milestone for minimally invasive spine surgery. We greatly appreciate the invaluable support from each of our clinical investigator teams across the country, who helped VertiFlex achieve our enrollment goal ahead of schedule, and brings us closer to the day when hundreds of thousands of patients suffering from lumbar spinal stenosis will have access to Superion's differentiated, advanced, and least invasive technology."

The Superion IDE trial is a prospective, multi-center, controlled clinical trial studying the safety and efficacy of the Superion ISS compared to control arm X-STOP(R) IPD(R) in healthy adults suffering from at least six months of moderate lumbar spinal stenosis who have been unresponsive to conservative care. The national trial is being conducted at 31 leading spine surgery sites in the United States. The study endpoint is the rate of overall success at 24 months.

"Spinal stenosis can have a tremendous impact on a person's mobility and physical activity. While there are treatment options available, many patients want less invasive options for lower back and leg pain relief," said Peter Whang, M.D., Associate Professor, Department of Orthopedics and Rehabilitation at Yale University School of Medicine and a principal investigator in the Superion trial. "The Superion ISS from VertiFlex may offer a less invasive, motion preserving solution to traditional spine surgery. We are excited to complete enrollment of the trial, and over the next 24 months we will be further evaluating the data for submission to the FDA."

Spinal stenosis is the degenerative narrowing of the spaces in the spine that can lead to spinal cord and/or nerve compression and is the cause of leg and back pain for over 1.5 million Americans each year. A significant portion of these patients are currently living with the limited pain relief received from existing non-surgical treatments, and are strong candidates for a minimally invasive, outpatient surgical option.

The SuperionISS was designed as an alternative to more invasive traditional spinal surgery. The Superion's minimally invasive surgical technique is performed through a single, half-inch skin incision. Once in place, the device is intended to act as a support column to open the passageways that contain the spinal cord and nerve roots. This may reduce the compression on the nerves, resulting in potential pain relief in the leg, groin and buttocks, and the return to a more active lifestyle.

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