SI-BONE, Inc. Announces Publication of 3-Year Long-term Prospective Outcomes Including Randomized Controlled Trial Data on 103 Patients Post SI Joint Fusion with Triangular iFuse Implant System®

March 27, 2018

Results include 57 Patients at 4 years showing continued durability

SAN JOSE, Calif., March 26, 2018 -- SI-BONE, Inc., a medical device company that pioneered the minimally invasive surgical (MIS) treatment of the sacroiliac (SI) joint with the iFuse Implant System®("iFuse") announced the publication of results from a long-term outcomes study called LOIS (Long Term Outcomes from INSITE and SIFI). The publication, titled *Long-term prospective outcomes after minimally invasive trans-iliac sacroiliac joint fusion using triangular titanium implants*[1]reports 3-year results of a subset of patients who participated in INSITE (Investigation of Sacroiliac Fusion Treatment)[2], a U.S. randomized controlled trial and SIFI (Sacroiliac Joint Fusion with iFuse Implant System)[3], a U.S. prospective multicenter trial. The 3-year results from LOIS demonstrated that improvements in pain, function and quality of life achieved at 2-years were sustained at 3-years and patient satisfaction remained high for patients treated with the iFuse Implant, available in the US since 2009. There were no reported adverse events related to the study device or procedure in the extended follow-up period.

The 3-year LOIS study results include 103 subjects at 12 medical centers with SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption who were evaluated in study clinics at study start and at 3, 4 and 5 years follow-up. 3-year follow-up was 93%. Mean preoperative SI joint pain was 81.5 (0 to 100 VAS) and decreased to 26.2 at 3-years, a 55-point improvement (Figure 1). Mean preoperative Oswestry Disability Index (ODI) was 56.3 and decreased to 28.2 at 3-years, a 28.1-point improvement (Figure 2).

"The 3-year LOIS results show that clinically significant improvements from both INSITE and SIFI patients were sustained at 3-years demonstrating that the benefits of SI joint fusion with iFuse are durable," said Emily Darr, MD, Assistant Professor, Orthopaedic Surgery, Medical University of South Carolina College of Medicine and lead author on the publication. "Furthermore, the diagnosis of SI joint mediated pain has been described as challenging, but our results suggest that SI joint dysfunction can be reliably diagnosed through appropriate history, physical exam and response to diagnostic block and can be effectively treated."

"Based on the 56 peer-reviewed publications on iFuse, fourteen (14) commercial payers have established positive coverage policies for MIS SI joint fusion exclusively for the triangular iFuse Implant System from SI-BONE and no other SI joint fusion implants are covered by those payers," stated Daniel Cher, MD, Vice President of Clinical Affairs at SI-BONE.

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About SI joint dysfunction

The SI joint has been attributed as a source of pain in 15-30 percent of patients with chronic low back pain[4-7], and in up to 43 percent of patients with new onset or persistent low back pain after lumbar fusion.[8] SI joint dysfunction is often misdiagnosed and the resulting pain can be incorrectly attributed to other causes. SI joint dysfunction can be identified when a patient points to the source of their pain directly over the posterior superior iliac spine (PSIS), known as the Fortin Finger Test[9], combined with a number of positive provocative maneuvers that stress the SI joint and elicit pain, followed by image-guided diagnostic injections to confirm the diagnosis. The SI joint is the largest of the eight major joints in the human body and the last to have a proven surgical treatment. The iFuse Implant, first FDA-cleared in 2009, is the only device for treatment of certain causes of SI joint dysfunction supported by significant published clinical evidence, including level 1 trials, showing safety and durable effectiveness, including providing lasting pain relief. The iFuse Implant was designed specifically to withstand the extreme forces resulting from load-bearing and the unique rotational and translational motion of the SI joint referred to as nutation, and is supported by more than 50 peer-reviewed publications, including two Level 1 randomized controlled trials (www.si-bone.com/results).

About SI-BONE, Inc.

SI-BONE, Inc.(San Jose, California) is a leading medical device company that developed the iFuse Implant System, a proprietary minimally invasive surgical implant system to fuse the sacroiliac joint to treat common disorders of the joint that can cause lower back pain. Patients with certain types of sacroiliac joint dysfunction experience pain that can be debilitating.

The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit: www.si-bone.com/risks

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