SI-BONE, Inc. Announces SelectHealth of Utah to Cover Minimally Invasive Sacroiliac Joint Fusion Exclusively Using the iFuse Implant System® as the Only Proven Technology

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Largest Commercial Payor in Utah to Provide Coverage for ≈ 900,000 lives with iFuse Implant System Only

SAN JOSE, Calif., Oct. 27, 2016 /PRNewswire/ -- SI-BONE, Inc., a medical device company that pioneered the use of the iFuse Implant System ("iFuse"), a minimally invasive surgical (MIS) device indicated for fusion for certain disorders of the sacroiliac (SI) joint, announced that SelectHealth, a health plan division of Intermountain Healthcare, a Utah-based not-for-profit healthcare system, will provide coverage specific for iFuse and exclusive of all other MIS SI joint fusion systems, beginning November 1, 2016. SelectHealth joins Geisinger Health System as the second commercial health plan in the United States to provide exclusive coverage for iFuse and a growing list of commercial payors to provide positive coverage policies for MIS SI joint fusion, including Blue Cross Blue Shield (BCBS) of Michigan, Priority Health of Michigan and BCBS of Nebraska.

Based on an extensive review of the published medical literature, the SelectHealth Medical Technology Assessment Committee determined that coverage of minimally invasive (MIS) SI joint fusion specific to iFuse was appropriate as the literature related to other MIS SI joint fusion systems was inadequate to determine safety and effectiveness. Use of all other technologies is considered experimental/investigational or unproven and therefore not covered.

The coverage decision was based on two systematic reviews of the literature and 27 primary studies that met inclusion criteria. The primary literature included outcomes from 7,589 patients who underwent SIJ fusion. The two systematic reviews included 34 studies, 18 of which reported on outcomes from MIS SIJ fusion and 16 that compared open to MIS fusion procedures. All of the 27 primary studies used only iFuse, with no studies identified for any other MIS SI joint fusion systems. iFuse is the only SI joint fusion device with an FDA cleared indication citing clinical studies that demonstrate improvements in pain, patient function and quality of life. Peer-reviewed published data supporting the use of iFuse includes two randomized controlled trials (RCTs) of iFuse vs non-operative care (INSITE and iMIA), long term results from a prospective single-arm multi center trial (SIFI) as well as data from over 40 additional publications.

"This latest exclusive positive coverage policy for iFuse by SelectHealth brings the exclusive coverage total to almost 4 million lives throughout Utah and parts of Pennsylvania and New Jersey and further demonstrates the importance of high quality published clinical evidence, establishing iFuse as the only proven option for MIS SI joint fusion," said Jeffrey Dunn, President and CEO of SI-BONE. "We are committed to continuing to work with other payors and health plans across the US to ensure all patients who may benefit from this procedure have access to iFuse."

About SI-BONE, Inc.
SI-BONE, Inc. (San Jose, California) is a leading sacroiliac joint medical device company dedicated to the development of tools and products for patients with low back complaints related to certain SI joint disorders. The company develops, manufactures and markets minimally invasive products for the SI joint. SI-BONE, Inc. received original 510(k) clearance in November 2008 from the Food and Drug Administration (FDA) to market its iFuse Implant System. The CE mark for European commercialization was obtained in November 2010. The iFuse Implant System is a minimally invasive surgical system that uses titanium implants with a porous surface to create an interference fit designed to help decrease joint motion and allow for bone ongrowth and ingrowth, supporting long-term fusion.

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. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life. 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