SI-BONE, Inc.® Announces iFuse Implant System® Receives Indication Cleared by the FDA that Includes Improved Pain, Patient Function and Quality of Life at 12-Months

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FDA clearance and triangular-shape with published safety and effectiveness data differentiates it from competitors

SAN JOSE, Calif., Nov. 9, 2015 /PRNewswire/ -- SI-BONE, Inc., a medical device company that pioneered the use of the iFuse Implant System, a minimally invasive surgical (MIS) device indicated for fusion for certain disorders of the sacroiliac (SI) joint, announced that the US Food and Drug Administration (FDA) has cleared the iFuse Implant System to include in its indication statement that "Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function and quality of life at 12 months post-implantation." This addition was based on prospective and retrospective clinical studies demonstrating consistent improvement in pain, patient function and quality of life at 12-months in patients treated with iFuse.

The new full indication for use statement is: "*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 six months. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life at 12-months post-implantation.*"

"We are pleased with the FDA's review of our clinical data supporting this 510(k) clearance and look forward to additional filings as SI-BONE continues to conduct studies and follow-up on patients treated with the iFuse Implant System. Data supporting these claims came from retrospective and prospective studies, including INSITE (Investigation of Sacroiliac Fusion Treatment; 148 patients), SIFI (Sacroiliac Joint Fusion with iFuse Implant System; 172 patients) and additional studies reviewed by the Agency," said Roxanne Dubois, Vice President of Quality and Regulatory Affairs at SI-BONE, Inc.

"Over twenty clinical studies demonstrating safety and effectiveness with the iFuse Implant System have been published in peer reviewed journals including studies with follow up out to as much as five years. Over 18,000 iFuse procedures have been performed worldwide making it the leading minimally invasive solution for these patients," commented Jeff Dunn, President and CEO of SI-BONE, Inc.

About SI-BONE, Inc.
SI-BONE, Inc. (San Jose, California) is the leading sacroiliac joint medical device company dedicated to the development of tools and products for patients with low back issues related to certain SI joint disorders. The company develops, manufactures and markets minimally invasive products for patients with these disorders. 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 option that uses titanium implants coated with a porous, titanium plasma spray (TPS) that acts as an interference surface, designed to help decrease implant motion, provide immediate fixation and allow for biological fixation to support 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 at 12-months post-implantation. 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.