Clinical Trials Positive For Joint Fusing Device

(PRNewswire) SI-BONE, Inc., a medical device company that is pioneering the use of a minimally invasive surgical (MIS) device to fuse the sacroiliac (SI) joint announced today the publication of the first peer-reviewed journal article on the iFuse Implant System for the treatment of sacroiliac joint disruptions or degenerative sacroiliitis. The article, entitled *Sacroiliac Joint Arthrodesis – MIS Technique with Titanium Implants: Report of the First 50 Patients and Outcomes* is a retrospective study of the first 50 consecutive patients treated by a single surgeon in a single center. Patients were evaluated for pain and functional outcomes and showed early and sustained statistically significant improvement at all post-operative time points. Complication rates were low and after an average of 40 months, more than 80 percent of patients report that they would have the same surgery again.

In addition, the company also announced it has surpassed another significant milestone with over 5,000 patients treated with the iFuse Implant System since the product became commercially available in early 2009. In a recent analysis performed by Covance Market Access Services, Inc., overall SI joint fusion procedure growth has increased over ten-fold from 2008 to 2012 and minimally invasive SI joint fusion appears to account for almost all of that growth and now comprises 85 percent of all SI joint fusions.

The porous coated iFuse is intended to provide immediate post-operative stabilization, and allow for fusion to occur over the next several months. In addition, the iFuse is placed through a small incision intended to minimize disruption of the surrounding soft tissues.

SI-BONE received original clearance in November 2008 from the Food and Drug Administration (FDA) to market its iFuse Implant System for fracture fixation of long bones and large bone fragments of the pelvis, and an additional clearance in April 2011 for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. The CE mark for European commercialization was obtained in November 2010.

Clinical publications have identified the SI joint as a pain generator for up to 22 percent of low back pain patients. The iFuse Implant System is a commercially available device in the U.S. and Europe.

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