



IlluminOss Medical Announces Conditional FDA Approval for Clinical Trials of Groundbreaking Photodynamic Bone Stabilization System in the U.S.

Currently Recruiting Clinical Sites for Trial that May Offer Significant Advantages to Surgeons Treating Impending and Pathologic Fractures

East Providence, RI (November 18, 2014) – [IlluminOss Medical](#), a privately-held, commercial stage medical device company focused on minimally invasive orthopedic fracture repair, today announced that it has received conditional approval from the FDA to conduct a clinical trial for the treatments of impending and pathologic fractures in the humerus due to metastatic carcinoma. IlluminOss expects to begin enrolling clinical sites and initiate the trial shortly.

IlluminOss' [Photodynamic Bone Stabilization System \(PBSS\)](#) is the world's first and only system of its kind and offers significant advantages for the treatment of complex fractures. It is commercially available in international markets and has been in clinical use since 2010. IlluminOss' novel approach has proven successful in its widespread use in Europe, where PBSS has been used in the treatment of over 700 patients. Benefits observed from the use of the product in patients include smaller incisions, shorter procedure times, and more rapid post-procedure patient mobility with reduced hospital stays and lower complication rates.

The minimally invasive procedure incorporates the use of a thin walled PET balloon that is infused with a liquid monomer and inserted into the intramedullary canal of the bone conforming to the shape of the patient's specific bone. The device forms as an implant once the surgeon activates the visible light delivered within the PET balloon. Once cured, the implant provides longitudinal strength and rotational stability over the length of the implant.

Dr. Martin Malawer, director, Orthopedic Surgical Oncology and Professor of Orthopedic Surgery at George Washington University Hospital and Professor (Clinical Scholar) of Orthopedic Surgery at Georgetown University, is positioned to lead the first U.S. trial of PBSS. Dr. Malawer is widely respected for pioneering many surgical techniques used today in cancer centers throughout the world. In the trial, he will be applying IlluminOss' technology to the treatment of metastatic lesions.

“From what I have seen to date, IlluminOss' Photodynamic Bone Stabilization System could prove to be a true disruptive technology in the treatment of pathological and non-pathological fractures by orthopedic surgeons,” said Dr. Malawer. “This technology will potentially reduce surgery time and morbidity rates, as well as lessen complications and improve patient outcomes.”

“We have been exceedingly pleased with the results that surgeons internationally have achieved using our Photodynamic Bone Stabilization System and we are confident that we will see similar

benefits for patient outcomes in the U.S. clinical trials,” said Robert Rabiner, president & founder of IlluminOss Medical. “Obtaining this FDA approval has been the vital first step towards ultimately applying our technology to the treatment of fractures in the U.S. and we look forward to serving this critical market.”

About IlluminOss

IlluminOss Medical is a privately-held, commercial stage medical device company focused on designing, developing and marketing orthopedic fracture repair products that leverage its proprietary bone stabilization technology, Photodynamic Bone Stabilization System (PBSS). This minimally invasive technology allows for fracture fixation through patient specific intramedullary implants. The PBSS System utilizes a light-curable polymer, contained within an expandable balloon catheter, to achieve bone stabilization. The revolutionary procedure is made through a small percutaneous surgical approach providing patients and clinicians with a fast, patient-specific, method of orthopedic bone stabilization. The company currently markets its products in international countries under a CE Mark for approved clinical applications through both a direct sales force and distribution networks.

Founded in 2007, IlluminOss is headquartered in East Providence, RI, and funded by Foundation Medical Partners, New Leaf Venture Partners, Tekla Capital, Life Sciences Partners, SR One, Longwood Fund, Excel Venture Management, Pappas Ventures, Mieza Capital and Slater Technology. Learn more at www.illuminoss.com.

The IlluminOss products are Investigational Devices; limited by Federal law to Investigational Use and are not approved for sale in the USA.

Media Contact:

Jordan Bouclin

SVM Public Relations

Jordan.bouclin@svmpr.com

(401)490-9700