IlluminOss Medical Completes Enrollment for U.S. Clinical Trial Using Groundbreaking Photodynamic Bone Stabilization System

Minimally Invasive System May Offer Significant Advantages to Surgeons Treating Impending and Pathologic Fractures using Patient-Specific Implants

East Providence, RI (July 18, 2016) – IlluminOss Medical, a privately-held, commercial stage medical device company focused on minimally invasive orthopedic fracture repair, today announced it has completed enrollment in its first U.S. clinical trial towards FDA approval of its IlluminOss System, the world's first and only system of its kind which supports the treatment of fractures using patient-specific intramedullary implants. Thirteen surgical sites around the country participated in the trial, which included 80 patients - all with impending or pathologic fractures in the humerus due to metastatic carcinoma.

IlluminOss' 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 a hardened 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.

The IlluminOss implant was developed as an alternative to currently used nails and plates, with the potential to provide better patient experiences and outcomes. This novel approach to fracture repair has proven successful in international markets, where the IlluminOss System has been approved for clinical use since 2010. To date, it has been used in the treatment of over 1,500 patients worldwide and has been observed to result in smaller incisions, shorter procedure times, and more rapid post-procedure patient mobility with reduced hospital stays and lower complication rates for patients.

"The IlluminOss System is a transformative technology, providing versatility in the way advanced fracture repair can be approached and enabling orthopedic surgeons to extend the functional benefits of surgical stabilization to more patients while also allowing them to preserve the rotator cuff," said Dr. John Healey, Chief, Orthopaedic Service; Stephen McDermott Chair in Surgery at Memorial Sloan Kettering Cancer Center.

"We've seen that the IlluminOss implant can be a game changer for patients with humeral metastatic disease. This technology allows us to stabilize the bone with less pain, less surgical time, and less difficulty for the patients. We can therefore treat this problem on an outpatient basis in some patients, and can condense treatments fairly dramatically," said Dr. Richard McGough, Chief of Musculoskeletal Oncology at the University of Pittsburgh Medical Center. "I'm very excited by where this can go in the future, pending FDA approval, as I think this technology could allow us to treat conditions we formerly could not, and can offer ways to treat cancer in the skeleton that were previously impossible."

The full list of surgical sites participating in the trial includes: University of Pittsburgh Medical Center, Memorial Sloan Kettering Cancer Center, Marshall University Medical Center, Duke

University Medical Center, Hackensack University Medical Center, Wake Forest Baptist Medical Center, Medstar Franklin Square Medical Center, Stanford University Medical Center, Ohio State University Wexner Medical Center, Rhode Island Hospital, Medstar Washington Hospital Center, Emory University Hospital, and Rush University Medical Center.

"We are pleased to have completed enrollment in our U.S. trial and exceedingly satisfied with the feedback we have received so far from participating surgical sites," said Manny Avila, president and CEO of IlluminOss. "Consistent with what we have observed in international use cases, the IlluminOss System has demonstrated benefits to both orthopedic surgeons and their patients. The IlluminOss implant has the potential to redefine how complex fracture repair may be approached pending FDA clearance."

The clinical outcomes data collected will allow IlluminOss to submit a DeNovo marketing application to the FDA and seek marketing clearance for its advanced fracture repair solution in the U.S. in 2017.

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, the IlluminOss System. This minimally invasive technology allows for fracture fixation through patient specific intramedullary implants. The 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.

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.

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