Orthopedic Medical Device Phase III Clinical Trial Awarded to Intrinsic Imaging

Imaging acquisition, quality control and orthopedic assessment for an international Phase III trial of a novel medical device.

Bolton, MA / San Antonio, TX

Bolton, MA / San Antonio, TX — September 18, 2012 — Intrinsic Imaging, an FDA audited, ISO 9001:2008 certified and GAMP 5® medical imaging core lab specializing in providing imaging core lab services for clinical trials, announces today that it was recently awarded an international Phase III clinical trial for the assessment of a novel orthopedic medical device.

This multicenter clinical trial consists of over 400 patients and approximately 7,000 computed tomography (CT) scans, magnetic resonance (MRI) scans and conventional radiographs. During this trial, Intrinsic Imaging will provide imaging core lab services including, but not limited to, the acquisition of the images from the investigator sites, quality control, and the complex quantitative and qualitative orthopedic assessment of the images to determine the medical device's safety and effectiveness.

Intrinsic Imaging's team of more than sixty board-certified diagnostic radiologists possesses sub-specialization in all therapeutic areas. The Intrinsic Imaging orthopedic radiologists dedicated to this trial have extensive experience in supporting Sponsors conducting orthopedic clinical research in joint reconstruction hardware, spinal fusion and spinal motion preserving devices, novel biologics ranging from articular and fibrocartilage repair as well as tendon and ligament regrowth and reconstruction.

"Imaging provides an abundance of qualitative and quantitative data useful in the evidence based assessment of new orthopedic interventions and devices. As investigational devices are often novel, an intimate understanding of all aspects of the device including engineering, material composition, surgical placement technique, and device positioning are important in the design of imaging protocols tailored to assess the success or failure of such device." said Dr. Jack Clement, Medical Director of Musculoskeletal Radiology at Intrinsic Imaging. "Intrinsic Imaging's radiologists are experts in the complex quantitative and qualitative orthopedic assessments to determine efficacy, safety, and longevity of these orthopedic advancements."

As novel orthopedic devices enter clinical evaluation, the selection of imaging modalities, acquisition parameters and analysis tools must be tailored to the needs of the trial. Each modality provides different, but complementary qualitative and quantitative data. Advancements in CT and MRI techniques afford these modalities a greater role in precise evaluation of orthopedic devices. Additionally, the use of traditional radiography is enhanced by the application of software evaluation techniques, especially in the case of spinal motion analysis.

"Intrinsic Imaging's orthopedic medical device expertise includes dynamic and static evaluations of the full complement of joint and spine disorders and diseases." said Todd A. Joron, BSc. MBA, President and Chief Operating Officer, Intrinsic Imaging. "We are very pleased to contribute our operational and therapeutic expertise towards this international Phase III clinical trial for the assessment of this novel orthopedic medical device."

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 750 board-certified and fellowship-trained physicians, Intrinsic Imaging's team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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