EKOS Corporation Announces Two More Pulmonary Embolism Clinical Studies

SEATTLE I and II Clinical Studies Will Further Establish the Safety and Efficacy of Ultrasound-Accelerated Thrombolysis for Treatment of Pulmonary Embolism

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BOTHELL, Wash.--(BUSINESS WIRE)--

EKOS Corporation today announced the launch of two more landmark clinical studies named SEATTLE I & II, intended to further establish the safety and efficacy of its unique, ultrasound-accelerated thrombolysis in treating patients with life-threateningpulmonary embolism (PE).

The SEATTLE I & II studies are, respectively, a multi-center, retrospective analysis of PE patients treated with EKOS, and a multi-center, prospective study of both massive and submassive PE patients treated with EKOS. The principal investigator for the SEATTLE series is Samuel Z. Goldhaber, MD, Professor of Medicine at Harvard Medical School, and Director of the Brigham And Women's Hospital Venous Thromboembolism Research Group. The first patients to be enrolled in SEATTLE II are expected in June 2012 with complete enrollment from up to 25 study sites expected by mid-2013.

Collection of retrospective data for the SEATTLE I study has already begun at nine international sites and should be completed in Q4 2012.

EKOS launched its first PE study, ULTIMA, in 2010 with lead principal investigator Dr. Nils Kucher of Bern University Hospital (Switzerland). ULTIMA is an international, multi-center, randomized, controlled study comparing submassive PE patients treated with EKOS to standard-of-care anticoagulation. This study is more than half enrolled and is expected to be completed in 2013.

"When completed, the ULTIMA and SEATTLE studies will represent the largest and most rigorous medical device studies in medical history for the treatment of pulmonary embolism," said Dr. Goldhaber.

Robert W. Hubert, President/CEO, states, “With the staggering statistics of deaths and morbidity associated with PE, these trials are essential in fully defining the role that EKOS will play in addressing this major unmet medical need.”

The U.S. Surgeon General reports over 600,000 patients are stricken with this disease in the U.S. alone, resulting in up to 180,000 deaths annually, more than AIDS, breast cancer and auto accidents combined. A PE is caused when a large blood clot, usually from a vein in the upper leg, or pelvic veins, breaks away and lodges in the lungs. The resulting strain on the heart, which must push blood past the obstruction, causes symptoms similar to a heart attack and can result in death or permanent disability. The use of blood thinners can reduce the risk of more clots developing; however, blood thinners do not remove the existing obstruction. The patented EKOS EkoSonic®Endovascular delivery catheters are designed to condition the clot for more rapid absorption of clot-busting drugs – a critical factor when every minute counts. The EKOS system was cleared by the U.S. Food and Drug Administration in 2005 and since then has been used by physicians worldwide to treat blood clots in arteries and veins throughout the body, especially in the arms and legs.

The FDA further cleared the device to be used in the pulmonary artery in 2008. Shortly thereafter, users in the U.S. and Europe began reporting success in treating patients with PE using the EKOS device. EKOS received the CE Mark to treat massive and submassive PE in January 2010. “Since 2009, over 600 PE cases have been treated with EKOS,” concluded Robert W. Hubert, President/CEO.

The most critical patients with major lung obstructions are those with massive PE who have deteriorated into cardiogenic shock and are close to death; less dramatic but still potentially life-threatening are those who are stable but still show clinical signs of cardiac dysfunction. These are sometimes referred to as **submassive PEs**. These two groups account for 5% and 40% of all PE patients, respectively. Multiple international medical journals report that patients who leave the hospital with residual cardiac strain from a remaining thrombus occlusion are at increased risk for long-term, permanent heart damage or even death.

The timeliness of these studies was highlighted in a featured syndicated television broadcast, *The Doctors*, May 2, 2012, on the CBS network. Dr. Tod Engelhardt, a cardiothoracic surgeon from East Jefferson General Hospital (Metairie, LA) featured in

the broadcast, described his pioneering use of EKOS to treat 42 PE patients. The published summary on his first 24 patients can be found in the May 2011 *Thrombosis Research* journal (128 (2011) 149–154).

About EKOS Corporation: EKOS Corporation pioneered the development and clinical application of ultrasound infusion technologies in medicine, introducing its first system for the treatment of vascular thrombosis in 2005. Today, interventional radiologists, cardiologists, cardiothoracic and vascular surgeons at leading institutions around the world use the EKOS EkoSonic® Endovascular System to provide faster, safer and more complete dissolution of thrombus. www.ekoscorp.com

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