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EKOS Corporation Announces U.S. Enrollment Completion of the SEATTLE II Trial that Studies the Safety and Efficacy of Ultrasound Accelerated Thrombolysis for Treatment of Massive and Submassive Pulmonary Embolism

BOTHELL, Wash.--(BUSINESS WIRE)--EKOS Corporation, a privately held medical device company located in Bothell, Washington, announced today the completion of their second major trial for the treatment of pulmonary embolism (PE). The SEATTLE II study is a 150 patient single arm prospective study measuring the rapid reduction in right heart strain in a patient population with both massive and submassive PE.

Robert W. Hubert, President and CEO of EKOS Corporation, cited U.S. patient statistics: "There are over 600,000 cases of PE each year alone of which upwards of 45% are considered major having significant clot in one or both pulmonary arteries. This clot burden interferes with the heart's ability to pump blood into the lungs for oxygenation, causing enlargement of the right side of the heart. Not removing the clot burden quickly may result in permanent pulmonary hypertension or even death."

"EKOS is committed to supporting cutting-edge clinical research and generating outstanding quality clinical data to help physicians make well-informed decisions. Plans are underway to extend our PE studies and to focus on longer-term outcomes"

Up to this point, the current standard of care has been anticoagulation or in the most serious cases intravenous (IV) clot dissolving drugs called thrombolytics. Anticoagulation therapy does not dissolve clots, but rather helps prevent further clots from forming. IV thrombolytics do help dissolve clot but the high dosage required causes serious bleeding in as many as 20% of patients and causes the most feared and devastating bleeding complication, hemorrhagic stroke, in 1% to 3% of patients.

Samuel Z. Goldhaber, MD, Professor of Medicine, Harvard Medical School and Director, Venous Thromboembolism Research Group, Brigham and Woman's Hospital (Boston, MA), serves as principal investigator for SEATTLE II. Goldhaber is one of the foremost authorities in the area of PE treatment and has published hundreds of peer-reviewed articles on the subject.

Dr. Goldhaber notes, "It is almost unheard of to exceed ambitious enrollment goals in any clinical trial. With enrollment of 150 patients from June 2012 through February 2013, SEATTLE II Trial recruited patients at a galloping pace that was more than double our expected enrollment rate. This study utilized EKOS in a uniform protocol of thrombolytic (tPA) drug dose and drug infusion time. We instituted uniform inclusion and exclusion criteria, and we amassed an impressive safety record, especially considering that our patient population was gravely ill with either massive or submassive PE. We fully expect to see confirmation of the hemodynamic benefit of rapid aggressive EKOS therapy suggested by previously reported single center studies."

Thrombolysis can prevent death and hemodynamic collapse in patients with PE. Goldhaber points out, "The challenge has been to minimize the major bleeding complication of intracranial hemorrhage which occurs 10 times more often with IV administered thrombolysis than with heparin alone. It is no surprise that EKOS, utilizing less than one-fourth of the standard thrombolytic dose, shows a much improved safety record compared with traditional therapy."

Hubert advises, "We expect this study to continue demonstrating the safety and effectiveness of the EKOS device for the treatment of PE, as did our first trial (ULTIMA), a randomized controlled trial of 59 patients recently presented at the American College of Cardiology annual meeting in San Francisco."

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concluded Hubert. The next phase is expected to commence in the 2nd half of this year.

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