EKOS® Corporation Announces Presentation of Clinical Reviews at International Symposium on Endovascular Therapy (ISET)

Presentations Highlight Advantages of EKOS® EndoWave™ Ultrasound Accelerated Thrombolysis in Treating Both Peripheral Arterial and Venous Disease

International Symposium on Endovascular Therapy (ISET)

BOTHELL, Wash.--(BUSINESS WIRE)--EKOS® Corporation today announced that four presentations at the International Symposium on Endovascular Therapy (ISET) being held in Hollywood, Florida, featured results of clinical studies using the EKOS® EndoWave™ Ultrasound Accelerated Thrombolysis (USAT) System. The clinical studies involved both peripheral arterial and deep venous thrombosis cases.

Each year over 500,000 patients in the US develop blood clots (thrombus) in the arteries and veins of their arms or legs. In most cases, the clot resolves itself or can be treated with medication, e.g., blood thinners. However, in over half of these cases, the obstruction is so severe that the patient's leg or foot is at risk. Two common treatment alternatives are 1) to surgically or mechanically remove the clot or bypass the obstructed blood vessel, or 2) to deliver clot-dissolving (thrombolytic) drug directly to the affected area via a catheter. The catheter-directed approach is less traumatic, but historically has required several days in the hospital to be effective. Also, the long time that it takes for infusion of the thrombolytic drug has been associated with the risk of major bleeding.

The EKOS® EndoWave™ Peripheral Infusion System combines a proprietary multiple-side-hole drug infusion catheter with a guidewire-exchangeable ultrasound core for simultaneously infusing therapeutic agents and delivering high frequency, low power ultrasound energy. In the case of thrombolysis, the ultrasound energy has been shown to reversibly loosen and disaggregate fibrin strands in clot, and to drive drug deep into it to access more binding sites faster than conventional lytic infusion. The unique EKOS technology accelerates the action of the clot-dissolving drug so that treatment time can be shortened and less drug may be used.

"We are pleased by the growing utilization of the EKOS® EndoWave™ system fueled by reports such as these at the ISET meeting," comments Douglas Hansmann, Ph.D., Chief Operating Officer of EKOS. "These results demonstrate that EKOS Ultrasound Accelerated Thrombolysis offers a better, faster and safer option for treatment than

conventional catheter-directed thrombolysis or mechanical thrombectomy in the peripheral vasculature."

The presentations at ISET include:

Dr. Thomas McNamara from the University of California Los Angeles presented "Combining Ultrasound with Lytic Infusion Accelerates Lysis with Less Bleeding." Data from 91 peripheral arterial disease cases treated with the EKOS device at nine centers in the U.S. showed that 86% were completely clear of clot at angiographic evaluation times that averaged 18.5 hours, as compared to historical studies where only 68% of patients were completely clear after 24 hours of treatment. Further, in 11 of 21 cases (52%) that were checked after only 4-6 hours of treatment, the clot was completely cleared. In only two of the 91 cases was there a complication due to bleeding, and in only two of the 91 cases was there any reported distal embolization. Dr. McNamara reported that the end result is patients typically leave the hospital a day earlier after ultrasound-enhanced delivery of clot-busting drugs versus standard delivery.

Dr. Thomas Zeller, speaking on behalf of Prof. Hermann Steinkamp of the German Red Cross Hospital Mark Brandenburg in Berlin, presented a paper titled "Treatment of Critical Limb Ischemia Using Ultrasound Enhanced Thrombolysis (PARES Trial): Final Results." This study similarly reported complete lysis achieved in 92% of the 24 patients studied at a mean final angiogram time of 16.9 hours. Importantly, in 23 patients (96%) a minimum of 50% of the clot was resolved within 6 hours and in 8 cases complete lysis was achieved in this timeframe. In these Critical Limb Ischemia patients, the median time to discharge was 4 days; there was no intracranial hemorrhage, there was only one bleeding complication due to dislocation of the introducer sheath; and there were no amputations or deaths during follow-up, leading the authors to conclude that the EKOS system is a "very safe treatment option" in this patient population.

Dr. Rodney Raabe of Sacred Heart Medical Center, Spokane, WA, presented a "New Treatment of DVT with Ultrasound Assisted Thrombolysis." Data from 53 DVT occlusions in the upper and lower extremities of 47 patients were reported from an open enrollment registry across eight centers in the U.S. Average infusion time was 24.7 hours with 70% of cases achieving complete lysis, a significant improvement over the average lysis time observed in the National Venous Thrombolysis Registry (53.4 hours). Further, the incidence of only two major bleeding complications (3.8%) and zero incidence of intracranial hemorrhage compare very favorably to the 11% incidence of major bleeding complications reported in the National Registry. Dr. Raabe commented that the ability to achieve complete clot lysis, including clearing clot behind the valves, offers potential benefit in prevention of post thrombotic syndrome (PTS) by rapidly eliminating venous obstruction and preserving valvular function. He further states, "We have been waiting for a device which combines the advantages of traditional catheter-directed lysis with the speed of mechanical thrombectomy. The EKOS® system is the first real invention in years in this field."

Dr. James Swischuk of the University of Illinois, Peoria, presented a review of "Arterial Lysis Techniques" in which he highlighted the EKOS® EndoWave™ system. In his presentation he characterized the evolution of treatment for acute peripheral arterial thrombosis from the early nineties to today when newer therapeutic agents, devices and infusion systems contribute to more patients with acute ischemia being candidates for endovascular forms of treatment. Many of the new devices have made very positive strides in rapidly restoring blood flow to the affected limb. Of these, Dr. Swischuk reports that "the EKOS® system has become a first line treatment in our practice for those patients requiring catheter-directed thrombolysis. Our initial results suggest that infusion times are significantly shortened with the use of this device."

About EKOS® Corporation

EKOS® Corporation, a privately held company based in Bothell, Washington, is the world leader in providing ultrasound-accelerated, fluid infusion catheters for diagnosis and therapy. The company's EKOS® EndoWave™ Peripheral Infusion System and EKOS® Micro-Infusion™ Catheter are cleared for the delivery of therapeutic agents, including clot-dissolving thrombolytics, into the peripheral vasculature of patients with peripheral arterial occlusions (PAO) and deep vein thrombosis (DVT). The EKOS Micro-Infusion™ Catheter is also cleared for the administration of contrast media into the brain. A Phase II study, using the Micro-Infusion™ Catheter and sponsored by the National Institutes of Health (NIH), has shown promising results in the treatment of ischemic thrombo-embolic stroke. For more information about EKOS®, visit: http://www.ekoscorp.com