



Contact: Pauline T. Mayer  
PTM Healthcare Marketing, Inc.  
631.979.3780 or PTM@ptmhcm.com

**EKOS Corporation Announces a Groundbreaking Study for the Treatment of  
Intracerebral and Intraventricular Hemorrhage Using Ultrasound  
Presented at the American Heart Association International Stroke Conference 2010**

**BOTHELL, WASHINGTON – (Business Wire) – February 25, 2010:** EKOS Corporation announced today that Dr. David W. Newell, Co-Executive Director, Swedish Neuroscience Institute (SNI, Seattle, WA) presented a SNI clinical study known as ‘SLEUTH’ (Safety of Lysis with Ultrasound in the Treatment of Intracerebral (ICH) and Intraventricular Hemorrhage (IVH) at the American Heart Association International Stroke Conference (San Antonio, TX).

Dr. Newell said, “The objective of this study was to evaluate the safety and efficacy of a novel therapy which combines ultrasound with recombinant tissue plasminogen activator (rt-PA) delivered through a microcatheter directly into spontaneous IVH or ICH in humans, to facilitate evacuation of the hemorrhage.”

Dr. Newell said that the 35 patients presented at SNI with ICH and IVH were screened between November 2008 and July 2009 for entry into the study. Entry criteria included the spontaneous onset of ICH  $\geq$  25cc and or IVH producing ventricular obstruction. Nine patients

(ages 38-83, average = 63, 6 male, 3 female) who met entry criteria were consented and entered into the trial. A ventricular drainage catheter and an ultrasound microcatheter were stereotactically delivered together, directly into the IVH or ICH. Recombinant tissue plasminogen activator (rt-PA) and 24 hours of continuous ultrasound were delivered and gravity drainage was performed. In patients with IVH a total of 3 mg of rt-PA was injected, and in patients with intraparenchymal hemorrhages a total of 0.9 mg rt-PA was injected, in three doses over 24 hours.

Dr. Newell reported that all patients had significant volume reductions of the treated hemorrhage. The mean percentage volume reduction after 24 hours of treatment, compared to the pre-treatment stability scans, as determined by CT were  $59\% \pm 5$  (sem) for ICH, and  $45.1\% \pm 13$  (sem) for IVH (1 ICH patient was excluded from analysis due to catheter breakage). There were no intracranial infections and there were no significant episodes of re-bleeding by clinical or CT assessment. There was 1 death by 30 days after admission. Clinical improvements as determined by a decrease in the National Institutes of Health Stroke Score (NIHSS) were demonstrated at 30 days in 7/9 patients. The rate of thrombolysis was compared between 8 patients who completed treatment, to cohorts of patients treated using identical doses of tPA and catheter drainage without ultrasound for IVH and ICH (courtesy of MISTIE and CLEAR studies which are large IVH/ICH studies sponsored by the NIH which are already underway and do not use ultrasound acceleration). Compared to MISTIE / CLEAR data we observed a faster rate of lysis during the first 24 hours of treatment for IVH ( $p=0.046$ ) and for ICH ( $p=0.074$ ) in the patients treated with sonolysis + tPA.

Dr. Newell noted, "Lysis and drainage of spontaneous ICH and IVH with reduction of mass effect can be accomplished rapidly and safely by sonothrombolysis using stereotactically

delivered drainage and ultrasound catheters through a burr hole. A larger clinical trial with catheters specifically designed for brain blood clot removal is warranted.”

Dr. Douglas Hansmann, one of the study co-authors and EKOS co-founder said, “This research was possible because of the collaborative atmosphere in the Seattle biotech community. Funds from the Washington State Life Sciences Discovery Fund through money that Governor Christine Gregoire successfully helped appropriate for Washington State through the tobacco settlement provided a \$170,000 grant that allowed EKOS to approach Dr. Newell and SNI with the proposal to study this exciting new application of EKOS technology.”

Robert W. Hubert, President/CEO of EKOS Corporation said, “This is another example of how EKOS’ unique ultrasound accelerating drug delivery technology is applying to another critically unmet medical need. These patients desperately need alternatives to therapy where today there are none. We think we can make a major contribution with this new initiative.” Mr. Hubert concluded, “Our technology is already being used successfully in the peripheral vasculature with over 16,000 devices sold. The company is also focused on pulmonary embolism, another major unmet need and we are about to commence a prospective randomized trial in this area.”

ICH is a devastating form of stroke. Half of all patients die within one month of the event, and those who survive typically suffer dramatic loss of brain function and motor skills. Often, they are unable to resume normal activities such as caring for themselves, straining family members or requiring more extensive, expensive ongoing professional care further plaguing our health system.

“The fastest, safest and complete way to remove a clot can make a difference between life and death. EKOS Corporation has developed the technology, minimally invasive, combining

catheter-delivered ultrasound in conjunction with a clot-busting drug. This new therapy has clearly shown promising results and we are excited to learn more,” concluded Dr. Newell.

**About EKOS Corporation:** EKOS Corporation pioneered the development and clinical application of ultrasonic accelerated drug delivery in medicine, introducing its first system for the treatment of vascular thrombosis in 2005. Today, interventional radiologists, cardiologists and vascular surgeons at leading institutions around the world use the EKOS EkoSonic<sup>®</sup> Endovascular System to provide faster, safer and more complete dissolution of thrombus. In 2008, the company introduced its 2nd generation EkoSonic<sup>®</sup> Endovascular System with Rapid Pulse<sup>™</sup> Modulation, and in 2009 introduced the MACH4e upgrade. The EkoSonic System is FDA-cleared for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. It is currently used to treat patients with peripheral arterial occlusions (PAO) and deep vein thrombosis (DVT) and additional applications are being investigated. EKOS is currently participating in the ATTRACT trial as a supplier of one of the devices permitted for use. Visit [www.ekoscorp.com](http://www.ekoscorp.com).