NIH Sponsored Trial Shows Ultrasound Microcatheter Improves Blood Flow in Ischemic Stroke Patient

VENICE, Italy – October 20, 2005 - At the VIII Congress of the World Federation of Interventional and Therapeutic Neuroradiology (WFITN) meeting today, Dr. Thomas Tomsick of the University of Cincinnati presented data that further supports the concept that ultrasound energy can accelerate the action of a thrombolytic (clot dissolving) drug. Using a novel microcatheter that is threaded via a leg artery into a stroke patient's brain, a small ultrasonic transmitter at the catheter tip bathes the offending blood clot with low energy ultrasound while simultaneously infusing clot dissolving drug. "The ultrasound," says Dr.

Tomsick, "is thought to cause the clot to become more permeable to the drug, allowing faster dissolution from both the outside and inside; speeding reliquification of the obstruction, and more quickly restoring blood flow to the ischemic brain tissue." It is believed that faster artery recanalization will result in better clinical outcomes and lower mortality rate.

Stroke is the third leading cause of death, behind heart disease and cancer. Each year, about 700,000 people in the United States suffer a stroke. In 2003 275,000 people died. This accounts for 1 out of 15 deaths in the United States.

In the USA, the only therapy currently approved by the FDA is the intravenous infusion of a clot-dissolving drug called tPA. However, the drug is diluted throughout the body and only a small portion actually reaches a blood clot in the brain. Two leading research clinicians at the Univ. of Cincinnati, Dr. Tom Tomsick, an interventional neuroradiologist, and Dr. Joe Broderick, a neurologist, hypothesized that there might be a better approach. They administered a portion of the intravenous dose of tPA, then rushed the patient to a neuro catheterization laboratory where the blood clot was located using standard x-ray imaging equipment. This allowed placement of a microcatheter at the location of the blood clot so additional tPA could then be delivered directly. This so-called 'bridging protocol" used in a pilot study at the University of Cincinnati produced encouraging early results. Subsequently, the National Institutes of Health funded the Interventional Management of Stroke (IMS I) study, an 80 patient study at 17 sites in the US and Canada that showed the combined approach increased the percent of patients with good clinical outcomes by about 6%, compared to the data that was the basis for the original FDA approval of tPA. However, the IMS investigators were frustrated that, after 2 hours of therapy with the microcatheter placed in the occlusion, only 51% of patients were completely cleared.

In 2001, EKOS Corporation (Bothell, Washington) was approached by Dr. Tomsick because early reports showed that the unique EKOS ultrasound catheter technology could accelerate the clot dissolving process. With the continued support of the NIH, an extension of the IMS study, called IMS II, was started in 2002 using the identical protocol and study sites as IMS I, but replacing the standard microcatheter with the EKOS device. As of the spring of 2005, 73 patients had been studied. Some received intravenous tPA only. Others were treated with a combination of intravenous and microcatheter delivered therapy; of these 30 were treated with an EKOS ultrasound microcatheter.

To assess the impact of the EKOS ultrasound, Dr. Tomsick reviewed the x-ray images, called angiograms, taken every 15 minutes during the therapy of patients in the IMS I study and compared them to similar films taken during the IMS II study using the ultrasound catheters. Of the 145 sequential films of the ultrasound catheters, 69/145 (48%) showed some clot lysis had occurred since the previous 15 min film. This compared to only 39/111 films (35%) that showed sequential clot dissolution with the non-ultrasound catheters in the IMS I study. This was statistically significant (p less than 0.05). Even more promising, was the examination of the IMS II patients at the end of two hours where 69% (18/26) of the patients treated with the ultrasound catheters in IMS II had cleared their primary obstruction compared to only 51% (30/59) in the IMS I study. "This may be the highest rate of complete recanalization documented in a stroke study using drugs and/or devices," said Tomsick.

"We are pleased to support the IMS series of clinical trials," said Douglas Hansmann, PhD, General Manager of EKOS. "Stroke is a huge unmet medical need and we feel we can make a significant contribution."

EKOS Corporation, located in Bothell, Washington, is a privately held manufacturer of catheter-based ultrasound technology which applies low energy ultrasound to accelerate the absorption of therapeutic agents into targeted areas of the body. In addition to their unique ultrasound micro-infusion systems for use in the brain, EKOS also manufacturers a family of peripheral vascular drug infusion catheters indicated for delivery of physician prescribed fluids, including thrombolytics, trademarked the LYSUS® Ultrasound Infusion System.

Media Contact:

Douglas R. Hansmann
Ph: 425-482-1108

E-mail: dhansmann@ekoscorp.com