Medical Device Daily™
The Daily Medical Technology News Source
Thursday, June 10, 2010 Vol. 14, No. 109 Page 1 of 11

Ekos wins $2.7M NIH grant for ICH treatment device

By OMAR FORD
***Medical Device Daily* Staff Writer**

A $2.7 million grant from the **National Institutes of Health** is paving the way for the development of a therapy that could treat intracerebral hemorrhagic stroke (ICH). The disease cripples more than 100,000 Americans each year and has a high mortality rate and healthcare costs associated with it. The financial burden alone is estimated to be at $125,000 per ICH patient each year, resulting in an overall annual cost of $6 billion for ICH patients in the U.S.

Ekos (Bothell, Washington) is developing a device designed to treat ICH.

"What we've done is take one of our existing products . . . a three-french device for ischemic stroke and combined it with a drain catheter to see if we could make a positive difference for ICH," Bob Hubert president/CEO of the

See Ekos, Page 7

Ekos

Continued from Page 1

company, told *Medical Device Daily*.

ICH is fatal in nearly 50% of all occurrences and the majority of survivors have significant motor and cognitive disability. In 40% of ICH cases, bleeding extends into the brain cavities (ventricles) causing intraventricular hemorrhage (IVH), increasing mortality to 80%. There are currently no good medical therapies for either ICH or IVH.

Data showing the safety of Ekos' combo device from a recent study known as Safety of lysis with EKOS ultrasound in the treatment of ICH and IVH (SLEUTH) headed by principal investigator, David Newell, MD, co-executive director of the **Swedish Neuroscience Institute** (Seattle) was presented at the 2010 **American Heart Association**'s (Dallas) International Stroke Conference in San Antonio.

"Ekos innovative and minimally invasive technology combines local delivery of tissue Plasminogen Activator (rt-PA) with ultrasound enhancement that results in effective blood clot removal," Newell said. "There is no doubt the results of this study shows the potential for the Ekos ultrasound as a minimally invasive treatment option . . ." A ventricular drainage catheter and an ultrasound microcatheter were stereotactically delivered together, directly into the IVH or ICH. 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.

All of the 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% for ICH and 45% for IVH. One 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. One patient died within 30 days after admission.

"We will use this money to develop the product," he added. "Obviously the next step for is to put the device in a larger clinical trial. The NIH award allows Ekos to optimize our technology in a product specifically designed for this critically unmet area of medicine. The findings from the SLEUTH study clearly show the promise of increased survival and improved outcomes with Ekos technology."

But that funding from an additional trial would come from either a corporate partner or an additional grant. Hubert said that having a trial in Europe hasn't been ruled out either.

The current funding will now be used to develop a simpler device which isn't as difficult to use as the combination device. The company will look at additional funding to further develop the product and evaluate it. "Now we're putting together a product that puts the two devices together," Hubert said. "We don't need to do any more research, we just need to build a prototype."

The company hasn't decided on a name for the product yet, but said that could come shortly.

Since its inception, Ekos has raised more than $8 million in grant funding.

"I think this is a testament to the effectiveness of our research and our products," Hubert said. ■

Omar Ford, 404-262-5546
omar.ford@ahcmedia.com

Med-Tech Notes

Freescale introduces portable medical kiosk

Freescale Semiconductor (Austin, Texas), partnering with **Pounce Consulting** (Orange County, California), developed a portable telemonitoring reference design, which allows patients and physicians to run routine health screenings at home or remotely. Grant funding for the reference design came from the Jalisco State Secretariat of Economic Development and the National Council of Science and Technology in Guadalajara, Mexico.

Dubbed the Intelligent Hospital kiosk, Freescale says this furthers its efforts to help improve patient care and lower healthcare costs by driving innovation and enabling medical device manufacturers to leverage the latest technology available. Patients can use the kiosk as a monitor at home to send their personal vital signs and medical tests remotely to a healthcare provider in order to proactively monitor and prevent acute complications of chronic degenerative diseases. In addition, the kiosk can be made available in a public location for individuals to perform various medical tests and transmit data to a hospital.

Texas Instruments offers imaging upgrade

Texas Instruments (Dallas) reported the availability of its version 2.0 medical imaging software toolkit (STK), an updated and expanded collection of imaging algorithms optimized for TI's TMS320C64x+ digital signal processors (DSPs). Complementing TI's full portfolio of analog and embedded processing solutions for medical imaging, the updated toolkit offers new image processing kernels that shorten product development time and enable real-time medical imaging applications such as diagnostic ultrasound and Optical Coherence Tomography (OCT).

Leveraging the sophisticated processing capabilities of TI's C64x+ architecture for efficient performance and power consumption, upgraded features in the STK 2.0 enable B-mode ultrasound processing, 3-D rendering and real-time processing for OCT. For example, TI's new 3-D affine warp algorithm can be used for image transformations such as rotation, scaling or shifting, to enable portable real-time OBGYN visualizations as well as cost effective solutions to accurately guide needles and catheters.