Avinger Reports Results of Clinical Study Evaluating New Imaging Catheter Designed To Help Cross CTOs in Patients with Peripheral Artery Disease (PAD)

The Associated Press

LAS VEGAS--(BUSINESS WIRE)--Oct 11, 2012--Avinger, Inc., a medical device manufacturer of innovative, multi-functional catheters for crossing CTOs in patients with Peripheral Artery Disease (PAD), announces its CONNECT II global clinical trial results today at the Vascular Interventional Advances (VIVA) Conference 2012 in Las Vegas, Nevada.

“These results are impressive and exciting,” said Matt Selmon, M.D. at Heart Hospital of Austin and CONNECT II Trial Co-Principal Investigator. “Having the ability to visually navigate, in real time, inside of the artery during these procedures is going to change the way physicians cross CTOs in order to treat severe PAD.” Dr. Selmon will present the results at VIVA this afternoon: the Ocelot System successfully crossed the target CTO lesion in 97% (97/100) of primary cohort subjects with an overall MAE rate of 2% (2/98), indicating both the primary safety and efficacy endpoints were statistically met. Both endpoints were assessed through independent angiographic review.

Gray Bennett, M.D., one of the physicians at the highest enrolling site in the trial, Mississippi Heart and Vascular Institute at St. Dominic Hospital in Jackson, Mississippi, stated, “Using the Ocelot catheter has changed my practice. I now have additional information to help me confidently cross CTOs. Feeling like I can help more patients than ever is a great feeling.” Avinger successfully completed enrollment in its CONNECT II global clinical trial in June 2012.

“The enrollment rate was well ahead of our projected schedule,” said Dr. John B. Simpson, Avinger founder and CEO. “This is a high achievement and we hope Ocelot helps as many PAD patients as possible avoid ever having to undergo needless amputation.” More about CONNECT II CONNECT II was a 2012 global clinical study that evaluated the safety and efficacy of Ocelot, the first-ever interventional Chronic Total Occlusion (CTO) crossing catheter to incorporate Optical Coherence Tomography, or OCT. This technology allows physicians to navigate and cross totally blocked arteries in the legs of patients suffering from PAD using a real-time cross-sectional image of the artery.

The trial was a prospective, multi-center, non-randomized, U.S. IDE study conducted at 17 centers that evaluated the safety and effectiveness of the Ocelot System in crossing femoropopliteal CTO lesions. It included 122 subjects, including 22 roll-ins enrolled across 15 investigational sites in the U.S. and EU from February 23, 2012 to June 7, 2012. Two investigational sites did not enroll patients. Enrollment continues

through the Continued Access phase of the study until FDA clearance.

Arne Schwindt, M.D. of St. Franziskus Hospital in Muenster, Germany was also a Co-Principal Investigator alongside Dr. Selmon in Austin.

Avinger expects to receive 510K FDA clearance for Ocelot at the end of the year.

To learn more about PAD, visit http://avinger.com/pad.

Avinger representatives remain on-site at VIVA Booth #320 in Las Vegas through Friday.

About Avinger Founded in 2007 by renowned cardiologist and medical device entrepreneur Dr. John B. Simpson, Avinger develops next-generation catheter-based technologies for the treatment of peripheral artery disease (PAD). Leveraging core competencies in medical device catheter engineering and intravascular Optical Coherence Tomography (OCT), Avinger markets Wildcat and Kittycat catheters, and received CE Mark in 2011 to market Ocelot, the first ever real-time OCT crossing catheter. www.avinger.com.

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