Physicians discuss trial use of Ocelot, the first-ever intravascular imaging technology

The Associated Press

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Jun 12, 2012-- Avinger, Inc., a medical device manufacturer of innovative, multi-functional catheters for treating patients with peripheral artery disease (PAD), announced that it has successfully completed enrollment in its CONNECT II global clinical trial. PAD is a silent epidemic that affects 8 to 12 million adults in the U.S., 30 million globally and is the leading cause of amputation in patients over 50. A study published in the January 2012 American Heart Association journal Circulation claims that PAD is an unsung "pandemic" that afflicts even more women than men.

CONNECT II is a global clinical study that evaluated the safety and efficacy of Ocelot, the first-ever interventional Chronic Total Occlusion (CTO) crossing catheter to use real-time intravascular imaging technology called Optical Coherence Tomography, or OCT. It allows physicians to cross, see and navigate inside totally blocked arteries in the legs of patients suffering from PAD.

"We are pleased to reach this significant milestone ahead of schedule and already see promising preliminary data collected," said Avinger CEO and founder, Dr. John B. Simpson. "We appreciate the patient participation and dedicated efforts of our employees, physician investigators and their research staffs. Together, we are now one step closer to bringing the Ocelot technology to patients who need it most." The company will present CONNECT II aggregate results at the VIVA conference in October 2012, file a 510K with the FDA later this summer, and expects to receive 510K clearance in late 2012. In order to ensure Ocelot is available for use at U.S. CONNECT II sites during the 510K review period, Avinger has also requested FDA approval of an additional 125 patients to be enrolled and treated in a Continued Access Cohort.

Global and U.S. physicians discuss use of Ocelot Dr. Matthew Selmon of the Heart Hospital in Austin, Texas, Co-Principal Investigator for the trial, commented, "I believe the results from this trial will have a major impact on how physicians treat patients with severe PAD. We are pleased that a request for Continued Access has been submitted. It means the Heart Hospital may be able to continue treating patients with Ocelot in order to quickly improve their mobility and return to a healthier quality of life." "This is the first-ever interventional device that allows us to drill through the totally blocked arteries in the legs while using an integrated camera to see it from the inside," said Dr. Arne Schwindt, St. Franziskus Hospital in Muenster, Germany. "This is a major advance for patients suffering from PAD, and holds the potential to postpone or entirely avoid surgical bypasses and amputations." Dr. Schwindt was also a Co-Principal Investigator in the trial.

"Dr. Simpson has invented a technology that enables us to treat CTOs with more

precision than ever before possible," said Dr. Louis Lopez at St. Joseph Hospital in Fort Wayne, Indiana. "We're looking forward to Ocelot being commercially available here in the U.S. so we can help more patients avoid unnecessary amputations." To date, Dr. Lopez has individually treated the most patients in the U.S. using Ocelot.

More about CONNECT II CONNECT II is a prospective, multi-center, non-randomized global clinical study that evaluated 100 PAD patients with femoropopliteal CTO lesions at 15 hospital and clinic sites, including two in the EU, where Ocelot received CE Mark in 2011. As part of the trial, an independent group of physicians are reviewing the angiographic results to determine Ocelot's safety and efficacy.

Avinger's global product portfolio has already helped physicians treat more than 8,000 patients suffering from PAD. Major causes of PAD include smoking, obesity, high cholesterol, high blood pressure, diabetes, inactivity, and poor diet.

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

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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