Avinger’s Ocelot System is FDA Cleared

The Associated Press

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Nov 8, 2012--Avinger, Inc., a medical device manufacturer of innovative, multi-functional catheters for crossing chronic total occlusions (CTOs) in patients with Peripheral Artery Disease (PAD), announces its Ocelot System has been cleared for sale in the U.S. by the Food and Drug Administration (FDA).

“It has taken my entire career to get to this moment,” said John B. Simpson PhD, MD, Avinger Founder and CEO. “Incorporating intravascular OCT into therapeutic devices has been the biggest priority here at Avinger. We have amazing investors who have allowed us to demonstrate how revolutionary Avinger can be. I’m so proud of our employees, all the physicians and hospitals around the world that helped us bring this amazing technology to the patients in the US.” PAD is an unrecognized epidemic that affects between eight and 12 million adults in the U.S. and 30 million people globally. It is caused by a build-up of plaque in the arteries that blocks blood flow to the legs and feet. “Often times, bypass surgeries or amputations are the recommended solutions. Ocelot can help save patients from such dire circumstances and patients can be back on their feet in days,” continued Dr. Simpson.

Patients walk out of the unknown A total of 122 patients from both Europe and the U.S. took part in the Ocelot global clinical trial, the results of which led to today’s FDA clearance. Available here are several stories, told by the Ocelot patients, their family members, friends, work colleagues, and the doctors and nurses who helped them. Here’s a snapshot: Meet John Brindley, Jackson, Mississippi. John is a 66-year old musical choir director in a small town near Jackson. His mysterious leg pain was becoming unbearable, to the point where it was almost impossible for him to walk. Dr. Gray Bennett of St. Dominic Hospital informed him about Ocelot and got him involved in the trial. Now, he’s back to work, exercising and feeling motivated to improve his diet.

Meet Jerome Doczekalski, Niles, Illinois. Jerome is a 63-year old passionate golfer. Four years ago, he had a toe infection that simply wouldn’t heal. The pain grew worse to the point of being excruciating. He could hardly walk. He couldn’t figure out what was going on until he visited Dr. Jack Chamberlin at Alexian Brothers Health System in Chicago. Thanks to Ocelot, Jerome was back on the golf course within just a few days.

Meet Manfred Selenschick, Muenster, Germany. 56 years old, Manfred has been dealing with PAD for years. He had several surgeries that just weren’t working. He still could hardly walk and the pain was unbearable in his legs. For the first time in ten years, since Dr. Arne Schwindt of St. Franziskus Hospital used Ocelot to unblock his artery, he’s out of pain and walking again. His family is very happy.

More about Ocelot The Ocelot catheter, supported by the Lightbox console, allows physicians to see from inside an artery during the actual procedure, using OCT. In the past, operators have had to rely solely on x-ray as well as touch and/or feel to guide catheters through complicated blockages. With Ocelot, physicians can more accurately navigate through CTOs thanks to the images from inside the artery.

Avinger successfully completed enrollment in its CONNECT II global clinical trial in June 2012. The Ocelot System demonstrated a CTO crossing success of 97 percent with a 98 percent freedom from Major Adverse Events (MAEs).

More about PAD Often dismissed as normal signs of aging, symptoms of PAD include painful cramping, numbness, or discoloration in the legs or feet. Hospitalization costs of PAD alone are estimated to exceed $21 billion annually, largely due to late detection and patients experiencing a decreased quality of life from invasive bypass surgery or amputation.

Because some blockages can become so severe and difficult to penetrate with traditional catheters, patients (unaware of advanced treatment options like Ocelot) often are subjected to extremely invasive bypass surgeries that result in even higher health risks and lengthy, painful recoveries.

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

To learn more about the Ocelot System, visit http://avinger.com/ocelot or email sales@avinger.com.

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 globally markets Ocelot, the first ever real-time OCT crossing catheter, in addition to its Wildcat and Kittycat catheters. www.avinger.com.

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