Advanced Catheter Therapies Receives FDA 510(k) Clearance on Occlusion Perfusion Catheter

The Associated Press

Advanced Catheter Therapies, Inc. has announced that its Occlusion Perfusion Catheter (OPC) has received U.S. Food and Drug Administration (FDA) 510(k) clearance. ACT is a research and development medical device company with a portfolio of innovative catheter technologies initially targeting vascular disease and restenosis.

"ACT is very excited about the FDA 510(k) approval for the OPC," said Paul J. Fitzpatrick, CEO of ACT. "It marks a significant advance for ACT and our lead product, and we look forward finding a partner to move the OPC forward to full commercialization. We strongly feel the OPC, which has strong intellectual property and patent protection, is positioned to be the next generation of therapeutic agent delivery devices."

The OPC is a multi-lumen balloon catheter designed to temporarily occlude a specific region from blood flow to allow the local delivery of therapeutic agents to the peripheral and eventually the coronary vasculature. The device has the ability to create a localized treatment chamber for the delivery of various types of therapeutic agents to treat a variety of disease states and place the agent circumferentially into the vasculature of the treatment chamber.

The OPC is unique in its ability to measure pressure applied inside the treatment chamber and its inflow and outflow ports for chamber evacuation, filling and flushing. It affords clinicians substantial procedural control and the ability to select the treatment agent and volume along with significantly limiting systemic release of the treatment agent.

Earlier this year ACT announced it is in the process of raising $3 million in Series B preferred equity financing and has already obtained a portion of that amount. In 2011, the company raised a total of $2.98 million in Series A equity financing through an investment consortium in Chattanooga, TN.

ACT operates as a highly efficient research and development organization, developing its product line through a phased approach. The company's role in product development includes design, IP patent filing, engineering, working prototyping, testing and regulatory approvals. Once the device is ready for human trials and/or manufacturing, sales and distribution, ACT will out-license or sell each device technology to a strategic partner.

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