Medtronic Reaches Major Milestone in Clinical Program for 'IN.PACT Admiral' Drug-Eluting Balloon

The Associated Press

Company Plans to Submit First Module of U.S. Approval Application for Novel Peripheral Angioplasty Device to FDA Over Summer

Continuing to demonstrate its ongoing commitment to advancing interventional treatments of peripheral artery disease and the evidence to support their adoption, Medtronic, Inc. announced today that enough patients have been enrolled in its clinical studies of the IN.PACT Admiral drug-eluting balloon to support the company's U.S. regulatory approval submission of the novel angioplasty device, which is designed to treat atherosclerotic lesions in the superficial femoral artery.

In a related development, Medtronic also announced today that it plans to submit the first module of the pre-market approval (PMA) application for the IN.PACT Admiral drug-eluting balloon to the U.S. Food and Drug Administration (FDA) over the summer.

"The IN.PACT Admiral drug-eluting balloon represents a novel angioplasty device from Medtronic that we foresee launching in the United States in late 2015, pending FDA approval," said Tony Semedo, president of Medtronic's Endovascular Therapies business. "It targets atherosclerotic lesions in the superficial femoral artery with a treatment modality that aims to deliver an anti-restenotic drug while leaving nothing behind."

More than 1,000 patients have been enrolled in the IN.PACT SFA I, II, II pharmacokinetics (PK) and Global studies to date. Clinical data from these studies will comprise a significant portion of Medtronic's PMA application to the FDA for the IN.PACT Admiral drug-eluting balloon. IN.PACT SFA I is a European study; IN.PACT SFA II and II PK, both U.S. studies; and IN.PACT Global, an international study being conducted outside the United States.

The ongoing global IN.PACT clinical program includes 29 studies involving more than 4,600 patients at approximately 230 sites worldwide. Through these company-sponsored and physician-initiated studies, Medtronic's portfolio of IN.PACT drug-eluting balloons will be investigated thoroughly for the treatment of arterial disease in a variety of vessel beds. As part of this program, Medtronic is currently enrolling the IN.PACT Global study, a first-of-its-kind, "real-world" evaluation of the company's IN.PACT drug-eluting balloons involving 1,500 patients with femoropopliteal lesions of any length at up to 80 sites worldwide.

IN.PACT drug-eluting balloons feature a proprietary coating called FreePac that is a formulation of paclitaxel and urea, an excipient that facilitates absorption of the

drug into the vessel wall. They received the CE (Conformité Européenne) mark in 2008 and 2009 and are available in many countries around the world.

In the United States, the IN.PACT Admiral drug-eluting balloon is limited to investigational use under an investigational device exemption (IDE) granted by the FDA and, like every drug-eluting balloon, is not yet commercially available.

The superficial femoral artery (SFA) runs close to the surface of the upper leg, from the groin to the knee. As a result of its location, the SFA experiences a variety of torsion and compression forces that pose inherent challenges with the use of permanent metallic stents in the treatment of atherosclerosis, which causes the body's arteries to narrow with the accumulation of fatty deposits (called plaque) inside them.

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

ABOUT MEDTRONIC
Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology-alleviating pain, restoring health and extending life for millions of people around the world.

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