Covidien Releases Two-Year Study Results Demonstrating Sustained Effectiveness of Drug-Coated Angioplasty Balloon Technology

Covidien

ILLUMENATE First-in-Human Clinical Trial Supports the Stellarex Balloon with EnduraCoat Technology in Treating Peripheral Arterial Disease

Covidien [1]'s Stellarex drug-coated angioplasty balloon (Stellarex DCB) continues to be shown as safe and effective for treatment of peripheral arterial disease (PAD), according to new 24-month data released today from the company's ILLUMENATE First-in-Human (FIH) Study. The Stellarex DCB uses EnduraCoat technology, a durable, uniform balloon coating designed to prevent drug loss during transit and facilitate controlled, efficient drug delivery to the treatment site. The FIH study results were reported at the EuroPCR Scientific Congress [2] in Paris, held May 20-23, 2014.

According to The Lancet [3], 40.5 million cases of PAD were reported in Europe in 20101. PAD is one of the most common vascular diseases and is associated with heart attack, stroke, amputation and death. It occurs when arteries in the legs become narrowed or blocked by plaque. These blockages can result in severe pain, limited physical mobility and non-healing leg ulcers.

The ILLUMENATE FIH study is a prospective, multi-center, single arm study designed to assess the safety and effectiveness of the Stellarex DCB. In the study, 58 superficial femoral and/or popliteal lesions in 50 patients were pre-dilated with an uncoated angioplasty balloon, followed by treatment with the Stellarex DCB. When used to treat lesions in leg arteries, the Stellarex DCB is intended to open narrowed or occluded vessels to restore blood flow and simultaneously deliver paclitaxel, the drug used in the balloon coating, to the vessel wall. This helps prevent restenosis, or the formation of new blockages within an artery, after the artery has been treated.

The study found the Stellarex DCB to be safe, with durable results to 24 months, including:

- Primary patency (defined as the treated artery remaining open without further treatment required or renewed blockage detected by ultrasound scanning) was 82.3 percent at 24 months.
- Freedom from clinically-driven target lesion revascularization at 24 months was 87.9 percent. This is the same rate observed at 12 months; no new events were reported demonstrating a sustained low rate of repeat treatment out to 24 months.
- No amputations or cardiovascular deaths were reported.

“We are very pleased with the study’s promising results, as they support the use of an important emerging treatment for a painful and physically limiting condition that affects millions of people around the world,” said Dr. Henrik Schröder, MD, Radiologist, Vascular Center-Jewish Hospital, Berlin, Germany, and principal investigator, ILLUMENATE FIH Study. “Good patency after two years, which translated into the absence of new clinically-driven target lesion revascularizations after one year and through the second year patient follow up, demonstrates the durability of the Stellarex drug-coated angioplasty balloon.”

Covidien is conducting additional large clinical trials to further validate the FIH findings.

“ILLUMENATE’s long-term results represent some of the best 24-month patency and freedom from target lesion revascularization rates seen in first-in-human studies to date. “These encouraging, long-term findings suggest Stellarex may be uniquely effective compared with other paclitaxel-based DCBs,” said Dr. Mark A. Turco, MD, chief medical officer, Vascular, Covidien. “The ILLUMENATE trial series demonstrates Covidien’s ongoing commitment to develop innovative solutions for treating vascular diseases.”

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