Six-month data of the LEVANT 2 trial presented

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The first clinical trial in the United States to study the use of drug coated balloons (DCB) for femoropopliteal artery disease found the procedure is promising for safety and efficacy at six months. Six month data of the LEVANT 2 trial was presented today at the 25th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

An estimated 8-10 million Americans suffer from peripheral arterial disease (PAD), a chronic, debilitating condition that often results in a reduced quality of life, disability due to limb loss/amputation, and/or death. The femoropoliteal arteries that run between the hip and knee are the most commonly diseased arteries in peripheral circulation.

There are a number of minimally invasive therapies used to treat femoropopliteal disease, including standard percutaneous transluminal angioplasty (PTA) stents (both drug-eluting and bare metal), and atherectomy devices. Unfortunately, restenosis rates in the femoropopliteal arteries remain high due to the length and complexity of disease. LEVANT 2 is the first trial in the United States to examine the use of a drug coated balloon in the treatment of femoropopliteal artery disease. While this treatment is available in other countries, it is not currently approved in the United States.

The primary safety endpoint was composite freedom from all-cause peri-

operative death and freedom at one year in the index limb from amputation, re-intervention, and index-limb-related death. The primary efficacy endpoints were primary patency of the target lesion at one year and absence of restenosis.

LEVANT 2 randomized 476 patients presenting with claudication or ischemic rest pain and an angiographically significant lesion in the superficial femoral or popliteal artery and a patent outlflow artery to the foot. After a successful protocol-defined pre-dilation, subjects unlikely to require a stent based on strict angiographic criteria were randomized 2:1 to the treatment with either a drug coated balloon (DCB) or PTA alone with a standard balloon.

At six months by Kaplan-Meier time-to-event analysis, primary patency of the treated vessel was higher among patients treated with a DCB (92.3 percent vs. 82.7 percent). Patients treated with DCB experienced similar freedom from major adverse events compared to the PTA group (94.0 percent in the DCB group and 94.1 percent in the PTA group). Repeat revascularization rates at this interim time point were low and consistent among both groups.

"During angioplasty, DCBs are designed to deliver an anti-proliferative drug directly to the tissues of the treated vessel wall, thus inhibiting neointimal hyperplasia and restenosis without the need for a permanent foreign body implant," said co-primary investigator, Kenneth Rosenfield, MD. Dr. Rosenfield is Section Head, Vascular Medicine and Intervention and Chairman, STEMI & Acute MI Quality Improvement Committee at Massachusetts General Hospital.

"These findings are an important step toward making this novel treatment available to patients in the United States."