BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Terumo completes patient enrollment in the US for trial

12 July 2012 | News | By BioSpectrum Bureau

Terumo completes patient enrollment in the US for trial

Singapore: Terumo Interventional Systems, a strategic business unit of Terumo Medical Corporation, a US subsidiary of Tokyo-based Terumo, has completed patient enrollment in the Occlusive/Stenotic Peripheral Artery REvascularization StudY (OSPREY) in the US designed to evaluate the safety and effectiveness of the MISAGOSelf-expanding Stent System. OSPREY is a single-arm, multi-center, non-randomized prospective clinical trial for the treatment of atherosclerotic stenoses and occlusions of the superficial femoral artery that included 200 patients in 31 centers in the US and 100 patients in seven centers in Japan.

A unique feature of this landmark study is that it simultaneously enrolled patients in the US and Japan as part of the larger Harmonization by Doing (HBD) pilot program, a cooperative effort led by the US Food & Drug Administration, the Japan's regulatory body, Terumo Corporation, based in Tokyo, Japan, and Terumo Medical Corporation, based in Somerset, New Jersey.

The HBD initiative is intended to shorten the gap between product approvals in these two significant world healthcare markets. "OSPREY is Terumo Medical Corporation's first US clinical trial for a premarket approval (PMA) device and we are exceptionally pleased with its progress. Terumo is greatly appreciative of the tremendous support given by our US clinical investigators, which helped us meet the critical enrollment goal in this landmark HBD initiative," said James Rushworth, President of Terumo Interventional Systems and Onset Medical Corporation. "The OSPREY trial and the MISAGO Stent truly speak to our three strategic pillars of introducing innovative technologies that create Clinical, Economic, and Quality of Life Benefits."

The MISAGO self-expanding stent consists of a nitinol stent pre-mounted on the distal portion of a rapid-exchange delivery catheter system. The stent has three radiopaque markers located on each end of the stent to help ensure accurate placement in the lesion. The stent is currently available for sale in Europe.