Results of the EVOLVE trial reported at TCT 2011

November 11 2011

A clinical trial has established the non-inferiority of a drug-eluting stent with a bioabsorbable polymer compared to a drug-eluting stent with a durable polymer. Results of the EVOLVE clinical trial were presented today at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

Durable polymer coatings on drug-eluting stents have been associated with chronic inflammation and impaired healing. Bioabsorbable polymer-coated drug-delivery systems may reduce the risk of late events, including stent thrombosis, and the need for prolonged dual antiplatelet therapy.

The EVOLVE trial is a prospective, multi-center, randomized, single blind, first in-human non-inferiority trial. Subjects were randomized 1:1:1 to either of two formulations of a stent (full or one-half dose) with the bioabsorbable polymer and a standard drug-eluting stent.

The primary clinical endpoint was the 30-day rate of target lesion failure, defined as cardiac death related to the target vessel (TV), myocardial infarction related to the TV, or target lesion revascularization. The primary angiographic endpoint was 6-month in-stent late loss.

A total of 291 subjects were enrolled in the EVOLVE trial between July 29, 2010 and January 20, 2011 at 29 sites in Europe, Australia, and New

Zealand. The mean subject age was 63 years, 73.1% were male, and 19.3% had medically treated diabetes.

In the bioabsorbable stent group with the full dose (n= 94), late loss at six months was .10 mm and 30-day target lesion failure was 1.1%. In the bioabsorbable stent group with ½ dose (n=99), late loss at six months was 0.13 mm and 30-day target lesion failure was 3.1%.

These results compare to the use of a traditional drug-eluting stent (n=98), in which late loss at 6 months was .15 mm and 30-day target lesion failure was 0%.

"Clinical events were low and comparable with no stent thromboses in any group," said lead investigator, Ian T. Meredith, MBBS, PhD. Dr. Meredith is Professor and Director of Monash HEART and Executive Director of Monash Cardiovascular Research Centre at Monash Medical Centre and Monash University in Melbourne, Australia.

"These results support the safety and efficacy of the novel abluminal bioabsorbable polymer everolimus-eluting stent for the treatment of patients with de novo coronary artery disease. Additional research is needed to evaluate clinical event rates and the potential for dual antiplatelet therapy reduction with this novel stent. " said Prof. Meredith.

Provided by Cardiovascular Research Foundation