Results from the AMULET OBSERVATIONAL STUDY reported

November 2 2016

Initial results from the largest, prospective evaluation of a percutaneous transcatheter left atrial appendage (LAA) closure device (Amplatzer Amulet) for stroke prevention in patients with non-valvular atrial fibrillation show that the device has a high implant success rate and low major adverse events.

Findings from the AMULET OBSERVATIONAL STUDY were reported today at the 28th 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.

The study enrolled 1,073 patients between June 2015 and September 2016 at 64 clinical sites in Europe, the Middle East, Asia, Australia and South America. 1,060 patients had device implantation, giving a technical success rate of 98.8%. Major adverse events (MAEs) within 7 days of implant included ischemic stroke (0.3%, n=3), pericardial effusion requiring intervention (0.5%, n=5), embolization (0.1%, n=1), and bleeding (0.9%, n=10). There were three deaths (0.2%) that occurred within seven days of attempted implant, two of which were adjudicated as procedure or device related, and one as unrelated to the device. At 1-3 month follow-up, the majority of patients were on antiplatelet therapy only and the CoreLab analyzed results of transesophageal echocardiography (TEE) showed a closure rate of 99%.

"These results indicate that the Amplatzer Amulet is safe and associated with low rates of peri-procedural and early adverse events, as well as demonstrating high closure rates," said David Hildick-Smith, MD, from the Sussex Cardiac Centre, Brighton and Sussex University Hospitals in Brighton, United Kingdom. "In addition, antiplatelet therapy appears to be an effective treatment strategy post-implantation in the short-term. Additional long-term data is necessary to confirm these promising early findings."

The AMULET trial was funded by St. Jude Medical. Dr. Hildick-Smith reported grant/research support and consulting fees/honoraria from St Jude Medical, Boston Scientific, Medtronic, Gore, Abbott, Occlutech and Edwards.

The results of the AMULET OBSERVATIONAL STUDY will be presented on Wednesday, November 2 at 9:40 AM ET in the Main Arena (Ballroom, Level 3) in the Walter E. Washington Convention Center.

Provided by Cardiovascular Research Foundation