PRIMARY RESULTS OF THE AMPLATZER AMULET LEFT ATRIAL APPENDAGE OCCLUDER IDE RANDOMIZED CONTROLLED TRIAL

Dhanunjaya Lakkireddy,[1], David Thaler,[2], Christopher Ellis,[3], Vijendra Swarup,[4], Lars Søndergaard,[5], John Carroll,[6], Michael R. Gold,[7], James Hermiller,[8], Hans-Christoph Diener,[9], Boris Schmidt,[10], Lee Macdonald,[11], Mousa Mansour,[12], Brijeshwar Maini,[13], Joseph Levine,[14], Stephan Windecker,[15], Laura O'brien,[16], Stephen Worthley,[17]

[1] Kansas City Heart Rhythm Institute and Research Foundation, [2] Tufts Medical Center, [3] Vanderbilt Heart Institute, [4] Arizona Cardiovascular Research Center, [5] The Heart Center - Rigshospitalet; Adult Cardiology; Department of Cardiology, [6] Univ. of Co Hospital, Anschultz Med. Campus, [7] Medical University of South Carolina, [8] St. Vincent Medical Group, Inc., [9] University Duisburg-Essen, [10] Cardiovascular Center Bethanien, [11] South Denver Cardiology Associates P.C, [12] Massachusetts General Hospital, Boston, [13] Delray Medical Center, [14] St Francis Hospital, Roslyn, [15] Bern University Hospital; Cardiology, [16] Abbott, [17] Royal Adelaide Hospital

Background:

The Amulet IDE Trial is an ongoing, prospective, global, multi-center trial with 1:1 randomization comparing the safety and effectiveness of the Amplatzer™ Amulet™ Left Atrial Appendage (LAA) Occluder (Abbott, Plymouth, MN) to the Watchman™ LAA closure device (Boston Scientific, St. Paul, MN) in patients with non-valvular atrial fibrillation.

Objective:

The objective of this trial is to demonstrate the Amulet occluder is non-inferior to the commercially available Watchman device in terms of safety and effectiveness.

Methods:

Eligible patients had non-valvular atrial fibrillation and were at a high risk of stroke or systemic embolism defined as $CHADS_2$ score ≥ 2 or a CHA_2DS_2-VASc score of ≥ 3. Patients also had an appropriate rationale to seek an alternative to long-term anticoagulant medication but were suitable for short-term warfarin.

The primary mechanism of action endpoint is device closure (residual jet around the device ≤ 5 mm) as assessed by an independent core laboratory on transesophageal echocardiography (TEE/TOE) at the 45-day visit (non-inferiority margin of -3%). The primary safety endpoint is a composite of procedure-related complications, all-cause death, or major bleeding (Type 3 or greater per Bleeding Academic Research Consortium (BARC) definition) at 12 months (non-inferiority margin of 5.8%). The primary effectiveness endpoint is a composite of ischemic stroke or systemic embolism at 18 months (non-inferiority margin of 3.2%). Pre-specified

secondary endpoints include 1) a composite of all stroke, systemic embolism, or cardiovascular/unexplained death at 18 months 2) major bleeding at 18 months 3) superiority test of the primary mechanism of action endpoint 4) superiority test of the primary safety endpoint 5) superiority test of the effectiveness endpoint. Descriptive endpoints related to procedural outcomes, device performance, and mortality are also assessed. An independent echocardiographic core laboratory was used to analyze TEE/TOE images and adverse events are adjudicated by an independent clinical events committee.

Results:

Between September 8, 2016 and March 8, 2019, a total of 1878 subjects at 108 sites were randomized to receive either an Amulet occluder (N=934) or a Watchman device (N=944). Baseline characteristics and medical history were well-matched between the Amulet and Watchman groups. Endpoint results will be available at the time of the presentation.

Conclusions:

The three primary endpoints of the trial will evaluate the safety and effectiveness of the Amplatzer™ Amulet™ Left Atrial Appendage Occluder compared to the Watchman™ LAA closure device.holographic imaging of cardiac structures and devices, which may ultimately improve outcomes in structural heart interventions.