Extremely Low 90-Day Cardiac Device Infection Rates with TYRX Antibacterial Envelope Use

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New prospective data presented on 1,000 patients at 2013 Heart Rhythm Society shows over 90 percent fewer major device infections

Use of TYRX, Inc.'s AIGISRx Antibacterial Envelope reduced major infection rates by more than 90% in patients undergoing Cardiovascular Implantable Electronic Device (CIED) replacement procedures compared to similar high-risk cohorts, according to the CITADEL & CENTURION clinical study results presented on Saturday at the Late Breaking Clinical Trials session at Heart Rhythm 2013, the Heart Rhythm Society's 34th Annual Scientific Sessions.

CITADEL / CENTURION is a prospective, multicenter clinical study to evaluate the major device infection and mechanical complication rates in the 12 months after implantation, in patients at high risk for CIED infection who have their CIED implanted with an AIGISRx Antibacterial Envelope. Study patients were enrolled at 55 US centers, and were at high-risk for infection because they were undergoing a CIED replacement procedure with an implantable cardioverter-defibrillator (ICD), (CITADEL), or a cardiac resynchronization therapy (CRT) device (CENTURION). The results from a planned interim analysis of the primary endpoints for the first 1000 eligible patients after 90 days of follow up were presented by Dr. Charles A. Henrikson, the Chief of Electrophysiology at the Oregon Health Sciences University.

Key study findings include:

- The CITADEL / CENTURION cohort at 90 days of follow-up had 95% fewer major CIED infections than the pre-defined published control cohort of 533 ICD and CRT replacement procedures (Gould et al. JAMA 2006, 295(16); 1907-1911) which had a major CIED infection rate of 1.88% at a mean follow-up of 81 days (0.1% vs. 1.88%; P<0.001).
- The CITADEL / CENTURION cohort at 90 days of follow-up had 94% fewer major infections than the 45-day major infection rate of 1.7% reported for the cohort of 1081 ICD/CRT replacement procedures in the Ontario ICD Database (Krahn et al. Circulation Arrhythmia and Electrophysiology 2011 4(2) 136-42 (0.1% vs. 1.7%; P<0.001).
- There was 1 major infection (0.1%), the primary efficacy endpoint of the study, after 90 days of follow-up. There were 11 minor infections (limited to the incision and skin) (1.1%).
- The incidence of the most common mechanical complication, major hematomas (1.5%), was not significantly different than the pre-defined control cohort (2.3%; P = NS).
- There were no unanticipated serious AIGISRx-related adverse events. There

were 20 (2%) deaths, none related to the AIGISRx.

"CIED infections are increasing in frequency, are associated with substantial morbidity, mortality, and cost, and present significant challenges to patients and for the physicians who provide care for them," stated Charles A. Henrikson, MD, FHRS, Oregon Health Sciences University, Portland, Oregon. "The CITADEL & CENTURION are large prospective studies enrolling patients at community, academic, and VA medical centers which will provide us with useful clinical information on the use of the AIGISRx Envelope in a variety of patients who are at high risk for CIED infection." The CITADEL (NCT01043861) & CENTURION (NCT01043705) studies are registered in the ClinicalTrials.gov registry of federally and privately supported clinical trials conducted in the US and around the world [1].

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[1] http://www.ClinicalTrials.gov