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# **TYRX enrolls first patient in CENTURION study for AIGIS<sub>Rx</sub> Anti-Bacterial Envelope with CRT Replacements**

**Monmouth Junction, NJ, (January 14, 2010)** -- TYRX, Inc., a leader in the commercialization of implantable drug-device combination products, announced today that it has enrolled its first patient in CENTURION, the first of two large scale, prospective, multicenter studies.

CENTURION will enroll 2000 patients at 50 clinical study sites across the U.S. Each patient is currently implanted with either a pacemaker, implantable cardioverter defibrillator (ICD) or a cardiac resynchronization therapy (CRT) device which will be replaced with a CRT device accompanied by AIGIS<sub>Rx</sub>. This patient population will be compared to 2000 case-matched controls that have also undergone a pacemaker, ICD or CRT device replacement without AIGIS<sub>Rx</sub>. The primary endpoints will be 1) major CRT device-related infection and 2) CRT device mechanical complication. Patients will be followed for 12 months, with pre-defined interim analyses at 3 and 6 months.

The second study, CITADEL, will enroll 2300 patients, at 50 clinical study sites across the U.S. Each patient is currently implanted with either a pacemaker, ICD or CRT device which will be replaced with an ICD accompanied by AIGIS<sub>Rx</sub>. This patient population will be compared to a group of published control patients who have also undergone a pacemaker, ICD or CRT device replacement with an ICD without AIGIS<sub>Rx</sub>. The primary endpoints will be 1) major ICD device-related infection and 2) ICD device mechanical complication. Patients will be followed for 12 months, with pre-defined interim analyses at 3 and 6 months.

AIGIS<sub>Rx</sub> is an anti-bacterial mesh envelope developed to deliver anti-microbial agents that help provide protection against infections associated with implanted pacemakers and cardioverter defibrillators. AIGIS<sub>Rx</sub> also securely holds a pacemaker (PM) or implantable cardioverter defibrillator (ICD) in order to create a stable environment when implanted in the body.

Dr. Dan Lerner, TYRX Chief Medical Officer notes, “CRM device infections are associated with substantial morbidity, mortality, and cost. Published data reveal the frequency of these infections is increasing faster than the rate of CRM device implants, indicating there is a need for more effective antimicrobial prophylaxis. CITADEL and CENTURION are large, multicenter, prospective studies that will provide important information on the clinical performance of AIGIS<sub>Rx</sub> in two groups at particularly high risk for infection – CRM device replacements with an ICD or a CRT.”

Dr. Lerner also commented, “Published data indicate the risk of CRM device infection is higher for CRM device implants with more than two leads, and for replacement procedures compared to initial implants. The CENTURION study will enroll 2000 patients who have undergone CRM device replacements with a CRT, and follow them prospectively for CRM device infection and mechanical complications in the 12 months following the procedure, to better understand the clinical performance of AIGIS<sub>Rx</sub> in this group at particularly high risk for CRMD infection.”

Dr. David Lee Scher, Director, Cardiac Electrophysiology, Pinnacle Health System in Harrisburg, PA enrolled the first patient in CENTURION. Dr. Scher stated “These studies represent an important step in determining the impact of the AIGIS on infection rates of implantable defibrillator procedures. I am pleased to offer this important technology to my patients.”

CENTURION and CITADEL are registered in the ClinicalTrials.gov registry of federally and privately supported clinical trials conducted in the United States and around the world ([www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)).

#### **About TYRX, Inc.**

TYRX, Inc., an ISO 9001:2000 and ISO 13485:2003 certified medical device manufacturer, commercializes implantable combination drug/device products, including the AIGIS<sub>Rx</sub> Anti-Bacterial Envelope. AIGIS<sub>Rx</sub> contains the antimicrobial agents, rifampin and minocycline, which have been shown to reduce infection by organisms representing a majority of the infections reported in cardiac rhythm device related endocarditis, including “superbugs” or MRSA. In addition, AIGIS<sub>Rx</sub> is intended to securely hold a pacemaker or implantable cardioverter defibrillator (ICD) in order to create a stable environment when implanted in the body. Following commercial release in June, 2008, AIGIS<sub>Rx</sub> has been implanted in over 6,000 patients nationwide. In February, 2008 TYRX raised \$25 million in a venture capital financing led by Clarus Ventures and co-led by Pappas Ventures. TYRX products utilize novel biomaterials, including technology licensed exclusively from Rutgers, The State University of New Jersey. Additionally, TYRX has exclusively licensed from Baylor College of Medicine and The University of Texas M. D. Anderson Cancer Center product patents and associated technologies to address the problem of postsurgical nosocomial infection. TYRX is deploying its capabilities across a broad range of combination implantable medical-pharmaceutical devices. The combination products sector (products incorporating both a drug & a device component) is expected to be the highest growth

segment of the medical products industry and TYRX is positioned to be an innovative applications leader in the space.

For more information, please visit [www.TYRX.com](http://www.TYRX.com).

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