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TYRX Presents Early Clinical Results from AIGISRX™ Antibacterial Envelope Retrospective Registry

Monmouth, NJ, (May 14, 2009) -- TYRX, Inc., a leader in the commercialization of implantable medical-pharmaceutical devices announced today at the 30th Annual Scientific Sessions of the Heart Rhythm Society the initial, interim clinical results from its AIGISRX™ Antibacterial Envelope Retrospective Registry.

AIGIS 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 also securely holds a pacemaker (PM) or implantable cardioverter defibrillator (ICD) in order to create a stable environment when implanted in the body.

During the Heart Rhythm Society 2009 Annual Scientific Sessions*, TYRX held an AIGIS Retrospective Registry (ARR) Investigator's Meeting at which the study's early results were presented and discussed. The intent of the IRB-sanctioned, multi-centered, retrospective study is to define the implant success rate and incidence of infection, in patients implanted with cardiac rhythm management device (CRMD) and the AIGIS.

To date, 393 patients from seven (7) clinical sites have been enrolled in the study with a 98% success rate of CRMD implantation, with the 2% of failures not being AIGIS related. Of the 393 patients enrolled, at least one follow-up visit has been completed for 254 patients with a mean follow-up period of 59 days and a median follow-up of 32 days. Noting that De Oliveira et al.¹ report the median time to CRMD infection as 14 days, and Klug et al.² reported a median time to infection of 52 days, the preliminary infections rates in the ARR are as follows:

All Patients w/ ≥ 1 Follow-up

Implant Type	PM			ICD/CRT			Other			Total		
	implants	infections	infection rate	implants	infections	infection rate	implants	infections	infection rate	implants	infections	infection rate
De novo	15	0	0.0%	51	0	0.0%	1	0	0.0%	67	0	0.0%
Revision	38	0	0.0%	141	5	2.0%	8	0	0.0%	187	5	2.0%
Total	53	0	0.0%	192	5	2.0%	9	0	0.0%	254	5	2.0%

All Patients w/ ≥ 1 Follow-up & CRMD Infection designation restricted to Generator Pocket Infections Only

Implant Type	PM			ICD/CRT			Other			Total		
	implants	infections	infection rate	implants	infections	infection rate	implants	infections	infection rate	implants	infections	infection rate
De novo	15	0	0.0%	51	0	0.0%	1	0	0.0%	67	0	0.0%
Revision	38	0	0.0%	141	3	1.2%	8	0	0.0%	187	3	1.2%
Total	53	0	0.0%	192	3	1.2%	9	0	0.0%	254	3	1.2%

All Patients w/ ≥ 1 Follow-up & CRMD Infection designation restricted to Generator Pocket Infections w/o CRMD infection in prior 6 mos.

Implant Type	PM			ICD/CRT			Other			Total		
	implants	infections	infection rate	implants	infections	infection rate	implants	infections	infection rate	implants	infections	infection rate
De novo	15	0	0.0%	51	0	0.0%	1	0	0.0%	67	0	0.0%
Revision	38	0	0.0%	141	1	0.4%	8	0	0.0%	187	1	0.4%
Total	53	0	0.0%	192	1	0.4%	9	0	0.0%	254	1	0.4%

Dr. Dan Lerner, TYRX’s Chief Medical Officer, noted that “when one looks at the characteristics of the patients enrolled in the AIGIS Retrospective Registry to-date it is noteworthy that there is a high percentage of patients who are, according to published studies, at high risk of CRMD-related infections.”

Risk Factors for developing a CRMD infection	All n = 393		≥ 1 Follow-up Visit n = 254	
	n	%	n	%
CHF	218	55.5	152	59.8
Chronic Renal Insufficiency	93	23.7	56	22.1
Chronic Renal Failure	41	10.4	24	9.5
Oral anti-coagulant	140	35.6	90	35.4
Corticosteroid use	30	7.6	22	8.7
Temporary pacing wire	8	2	3	1.18
> 2 leads in place	163	41.5	105	41.3
Device Revision	278	70.7	187	73.6
Early reintervention	9	2.3	9	3.5

Dr. Dan Lerner continued, “Of the 3 generator pocket infections reported to date, 2 occurred in patients who had prior explants for infection within the past 6 months. Importantly, these early data indicate AIGIS does not interfere with CRMD implant success. The AIGIS Retrospective Registry continues with the expectation that, with the enrollment of 3 additional clinical sites, TYRX will collect data on over 500 AIGIS patients, representing more than 15% of the 3,000 AIGIS implanted to-date. The company plans to continue the AIGIS Retrospective Registry follow-up period will provide clinicians greater insight into the clinical utility of AIGIS.”

“We are delighted these data indicate clinicians are using AIGIS in the full spectrum of CRMD implant procedures. In particular, it is gratifying to see that AIGIS is being used in patients who are at very high risk for CRMD infection,” added Bill Edelman, CEO of

TYRX, Inc. “In addition to the AIGIS Retrospective Registry, we have begun the process of recruiting approximately 20 clinical sites for the AIGIS Prospective Registry, which will follow AIGIS patients for 12 months and compare the incidence of infection to published historical and case-matched controls of cardiac rhythm management device (CRMD) recipients. TYRX is committed to better understanding how the AIGIS envelope can help the greatest number of patients.”

Additional information regarding TYRX, Inc.’s Retrospective and Prospective Registries, and associated clinical results, can be found at www.TYRX.com.

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^{rx}**TM Anti-Bacterial Envelope. **AIGIS** 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** 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** has been implanted in over 3,000 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.

* This program was not part of the Heart Rhythm 2009 Official Scientific Sessions as planned by the HRS Scientific Sessions Committee.

1. de Oliveira et al, Circulation 2009 2, 29.
2. Klug et al, Circulation 2007 116, 1349.

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