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## **TyRx Pharma, Inc. Announces the First Human Implant of the AIGIS<sub>RX</sub><sup>TM</sup> Anti-Bacterial Envelope in Cardiac Patient**

**Monmouth Junction, NJ, (May 14, 2008)** -- TyRx Pharma, Inc., the leader in the marketing of convergent drug—device products, announced today that the first commercial implant of the **AIGIS<sub>RX</sub><sup>TM</sup>** Anti-Bacterial Envelope in a CRMD procedure was conducted at St. Luke’s Episcopal Hospital of the Texas Heart Institute in Houston. The new antibacterial envelope device is designed to stabilize pacemakers (IPG) and implantable cardioverter defibrillators (ICD) with the additional benefit of reducing potential risks of infections associated with implantation.

The first in-man commercial implant was performed during a pacemaker replacement procedure on a 72-year-old male patient by Dr. Ali Massumi, Director of the Center for Cardiac Arrhythmias and Electrophysiology at St. Luke’s and Clinical Professor of Medicine at Houston’s Baylor College of Medicine. Dr. Massumi inserted a replacement dual chamber pacemaker into the **AIGIS<sub>RX</sub><sup>TM</sup>** antibacterial envelope in less than a minute. The **AIGIS<sub>RX</sub><sup>TM</sup>** IPG device combination was subsequently implanted in the patient and the IPG replacement procedure was conducted normally thereafter.

**AIGIS<sub>RX</sub><sup>TM</sup>** CRMD is intended to securely hold a pacemaker or implantable cardioverter defibrillator (ICD) in order to create a stable environment when implanted in the body. In addition, **AIGIS<sub>RX</sub><sup>TM</sup>** CRMD contains the antimicrobial agents, rifampin and minocycline, which have been shown to reduce infection by organisms representing a majority of the infections reported in CRMD related endocarditis, including “superbugs” or MRSA.

**AIGIS<sub>RX</sub><sup>TM</sup>** CRMD is constructed of knitted filaments of polypropylene coated with a proprietary resorbable polymer that elutes the antimicrobial agents rifampin and minocycline for a minimum of seven days to reduce the risk of infection of the implanted CRMD following surgery. In *in vitro* studies, **AIGIS<sub>RX</sub><sup>TM</sup>** CRMD demonstrated antimicrobial activity against Methicillin Resistant *Staphylococcus aureus* (MRSA),

*Staphylococcus aureus*, *Staphylococcus epidermidis*, *Acinetobacter baumannii*, *Enterobacter aerogenes* and *Proteus mirabilis*.

**AIGISRX™** CRMD also demonstrated *in vivo* effectiveness in reducing infection compared to control in a series of animal studies in which CRMDs were placed into **AIGISRX™** CRMD envelopes and implanted into subcutaneous pockets inoculated with various bacterial strains, representing a majority of the infections associated with CRMD related endocarditis. Both **AIGISRX™** CRMD and the controls (CRMD without envelope) were inoculated and observed for a minimum of seven days to validate the presence of infection in the animals. The bacteria tested included *Staphylococcus epidermidis*, *Acinetobacter baumannii*, *Staphylococcus capitis* and *Escherichia coli*, and separately, *Staphylococcus aureus* which represent a majority of the infections reported in CRMD-related endocarditis. The *in vitro* and *in vivo* activity of the **AIGISRX™** CRMD antimicrobials is variable against non-epidermidis strains of coagulase-negative staphylococci. **AIGISRX™** was cleared for market by the US FDA in January of this year.

According to a recent study presented during the Heart Rhythm Society *Heart Rhythm 2006* Scientific Sessions (Boston), the University of Pittsburgh Medical Center noted that the 2003 national incident of infection for pacemakers was estimated to be 5.82% and for ICDs 3.71%. Recent market research indicates that more than 400,000 CRMDs are implanted each year in the U.S.

“The first in-man implant of **AIGISRX™** CRMD is of course a significant milestone for this innovative product,” said Bill Edelman, CEO of TyRx Pharma, who today introduced the product to attendees of the Heart Rhythm Society *Heart Rhythm 2008*, the premier conference on cardiac arrhythmias, in San Francisco. “There are more than 400,000 annual U.S. implants of CRMDs, and we’re confident that **AIGISRX™** CRMD will enable doctors everywhere to substantially suppress bacterial infection of CRMD pockets.”

“Pacemakers are placed in an area where there aren’t a lot of blood vessels, so systemic antibiotics may not reach the specific area. Replacing leads which run from the pacemaker to the heart can be quite difficult because of scarring in the area. These high risk patients are more prone to infection and obviously we want to avoid any infection to the heart,” said Dr. Massumi.

The patient who received the new pacemaker received his first pacemaker about seven years ago. The patient received the new pacemaker Monday morning and was discharged from St. Luke’s Episcopal Hospital several hours later.

“The envelope provides antibiotic protection for about 10 days after the procedure. It also helps to stabilize the device in the body. This device will also make it easier for future device replacement. Our patient had a large amount of scar tissue around his previous pacemaker, and we removed the scar tissue before implanting the new pacemaker,” said Dr. Massumi.

According to *Infection Control Today* (8/2003), the average cost of each infection related to invasive medical devices varies from \$34,000 to \$56,000; these infections incur an annual financial burden up to \$2.3 billion to the American healthcare system. *The New*

*England Journal of Medicine* (2004;350:1422-9) states about half of the two million cases of nosocomial infection that occur each year in the United States are associated with indwelling devices. Infections associated with surgical implants are generally more difficult to manage because they require a longer period of antibiotic therapy and repeated surgical procedures.

**About TyRx Pharma, Inc.**

TyRx Pharma, Inc., an ISO 9001:2000 and ISO 13485:2003 certified medical device manufacturer, commercializes implantable combination drug—device products utilizing 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.tyrxpharma.com](http://www.tyrxpharma.com).

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