



FOR IMMEDIATE RELEASE

Contact:

Bill Edelman, CEO

TyRx Pharma, Inc.

Office: 732-246-8676

Direct: 732-964-1101

Cell: 617-759-5451

william@tyrxpharma.com

TyRx Pharma, Inc. Announces Food and Drug Administration (FDA) 510(k) Clearance of the AIGIS_{RX}[™] Cardiac Rhythm Medical Device (CRMD) Anti-Bacterial Envelope, an Innovative Mesh Envelope Designed to Immobilize and Reduce Bacterial Infection of a Pacemaker or Implantable Cardioverter Defibrillator (ICD) When Implanted in the Body

AIGIS_{RX} 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. AIGIS_{RX} CRMD contains the antimicrobial agents rifampin and minocycline, which have been shown to reduce infection in an in-vivo model of bacterial contamination. This device is only intended to be used in conjunction with pacemakers and implantable cardioverter defibrillators (ICD).

Monmouth Junction, NJ, (January 17, 2008) -- TyRx Pharma, Inc., a leader in the commercialization of implantable combination drug—device products, announced today the Food and Drug Administration (FDA) clearance of a Premarket 510(k) Application to market its AIGIS_{RX}[™] CRMD Anti-Bacterial Envelope. CRMD post-implant infection including cases of “super bug” or MRSA is a growing and potentially fatal complication.

AIGIS_{RX}[™] CRMD has two functions. It 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_{RX}[™] 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 MRSA. This device is only intended to be used in conjunction with pacemakers and implantable cardioverter defibrillators (ICD).

AIGIS_{RX}[™] 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 7 days to reduce the risk of infection of the implanted CRMD following surgery. In *in vitro* studies, AIGIS_{RX}[™] CRMD demonstrated antimicrobial activity against Methicillin Resistant *Staphylococcus aureus* (MRSA), *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Acinetobacter baumannii*, *Enterobacter aerogenes* and *Proteus mirabilis*.

AIGIS_{RX}TM CRMD also demonstrated *in vivo* effectiveness in reducing infection compared to control in a series of animal studies in which CRMDs were placed into **AIGIS_{RX}**TM CRMD envelopes and implanted into subcutaneous pockets inoculated with various bacterial strains, representing a majority of the infections associated with CRMD related endocarditis. Both **AIGIS_{RX}**TM CRMD and the controls (CRMD without envelope) were inoculated and observed for a minimum of 7 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. It should be noted that the *in vitro* and *in vivo* activity of the **AIGIS_{RX}**TM CRMD antimicrobials is variable against non-epidermidis strains of coagulase-negative staphylococci.

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.

“We are thrilled to have reached this value-creating milestone with the FDA clearance of **AIGIS_{RX}**TM CRMD,” said Bill Edelman, CEO of TyRx Pharma. “With over 400,000 annual U.S. implants of CRMDs, we believe **AIGIS_{RX}**TM CRMD will become a valuable tool in the effort to suppress bacterial infection of CRMD pockets.” Mr. Edelman continued, “We anticipate **AIGIS_{RX}**TM CRMD U.S. national commercial distribution to begin within the quarter following this FDA clearance, with full market release coinciding with the Heart Rhythm Society *Heart Rhythm 2008*, the premier conference on cardiac arrhythmias in San Francisco May 14-17, 2008.”

Rabih O. Darouiche, M.D., Director of the Center for Prostheses Infection at Baylor College of Medicine, Houston, Texas commented, "This first-in-class anti-infective approach is likely to yield tremendous benefit to both patients and clinicians taking into consideration the growing risk of infection and the severe consequences for those patients who may develop an infection."

This is the third in a series of implantable combination drug—device products for which TyRx has gained FDA Premarket Application clearance. In December 2005, FDA granted 510(k) clearance for PIVITTM, TyRx’s 1st bioresorbable polymer coated surgical mesh product. In July, 2006, FDA granted TyRx 510(k) clearance for PIVITTM AB, TyRx’s Antimicrobial Surgical Mesh coated with rifampin and minocycline. The unique properties associated with the PIVITTM surgical mesh products provide excellent handling characteristics that facilitate precise placement during surgical repair of soft tissue defects, leaving less implant material following the resorption of the bioresorbable polymer coating.

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* (*New England Journal of Medicine*, 2004;350:1422-9) states about half of the 2 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.

This notice follows TyRx's January 8th announcement of Robert M. Mattioli joining TyRx as Vice President, Commercial Development.

On October 24, 2007, TyRx announced presentation of pre-clinical results on TyRx's new **AIGIS_{RX}TM** Drug Eluting Breast Implant (DEB) technology. The paper entitled "Prevention of Experimental Capsular Contracture in Breast Implants by an Antimicrobial-Impregnated Biodegradable Wrap" was presented at by William P. Adams, Jr., MD, Principal Investigator, Plastic Surgeon, Dallas, during the Plastic Surgery 2007 Meeting on October 28, 2007 in Baltimore MD. According to the American Society of Plastic Surgeons, Capsular Contracture, a deformation of the breast implant due to formation of fibrotic tissue following breast augmentation, affects up to 40% of the approximately 290,000 elective breast implant procedures performed annually in the U.S. and has been the single biggest complication in aesthetic and reconstructive breast surgery since breast implants were invented 45 years ago (Aesthetic and Plastic Surgery, 31:358-364, 2007).

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 post surgical 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.

#####