

New Clinical Trial Will Evaluate Antibacterial Envelope in Cardiac Implantable Electronic Device Patients at Risk for Major Infections

January 7, 2015 9:30 AM CT



Medtronic Announces First Patient Enrollment in the WRAP Infection Clinical Trial

MINNEAPOLIS - Jan. 7, 2015 - Medtronic, Inc. (NYSE: MDT) today announced the first patient enrollment in the WRAP Infection Clinical Trial, which will evaluate the effectiveness of the TYRX(TM) Absorbable Antibacterial Envelope in reducing major infections in patients with cardiac implantable electronic devices (CIEDs) at risk for infection. The global clinical trial also will assess healthcare costs related to treatment of major infections in CIED patients. The first patient implant was performed by Edward J. Schloss, M.D., director of electrophysiology at The Christ Hospital in Cincinnati.

The TYRX Absorbable Antibacterial Envelope is a mesh envelope that holds an implantable cardiac device and is designed to stabilize the device after implantation while releasing antimicrobial agents, minocycline and rifampin, over a minimum of seven days. The envelope is fully absorbed by the body approximately nine weeks after implantation. The TYRX Absorbable Antibacterial Envelope was cleared by the FDA in May 2013 and received CE Mark in September 2014.

"This large-scale trial is the first of its kind to evaluate an antibacterial envelope in cardiac device patients who are at risk for infections," said Bruce Wilkoff, M.D., director of Cardiac Pacing and Tachyarrhythmia Devices at the Cleveland Clinic, principal investigator in the trial and a paid consultant for Medtronic who serves on several Medtronic advisory boards and also receives royalty payments from Medtronic for technology he developed. "It's important that we continue to find new ways to help reduce infections in patients with implantable cardiac devices, especially for those patients who are having repeat procedures."

The rate of major infection in CIED patients at 12 months following a procedure, and the consequent healthcare costs, will be compared between patients receiving a TYRX Absorbable Antibacterial Envelope at implantation and those not receiving the envelope. While infection rates remain relatively low (less than 3 percent of all CIED patients), the potential for driving even lower rates of infection and lower healthcare costs with TYRX are supported by U.S. Centers for Medicare & Medicaid Services, which estimates the average cost of a CIED infection in the U.S. at \$72,485.¹

The Trial will enroll approximately 7,000 patients at 225 sites worldwide. The trial will include patients who are recommended for a new cardiac resynchronization therapy with defibrillation (CRT-D) device, and patients who are recommended for a replacement, system revision or generator upgrade of an existing implantable pulse generator (IPG), cardiac resynchronization therapy pacemaker (CRT-P) device, implantable cardioverter-defibrillator (ICD) or CRT-D device.

"Even though the risk of major infection is low for patients receiving implantable cardiac electronic devices, the TYRX Envelope offers an added layer of protection for patients at increased risk of infection," said Marshall Stanton, M.D., vice president and general manager of the tachycardia business at Medtronic. "The TYRX Envelope is designed to be a simple, but cost-effective solution to help keep patients safer from major post-procedure infections and mechanical complications."

The Trial also will prospectively evaluate the performance of Medtronic lead monitoring algorithms - such as Lead Integrity Alert (LIA) and Lead Noise Alert (LNA) software - to identify lead system issues in defibrillator patients.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac

arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

-end-

¹ Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services Inpatient Prospective Payment System (IPPS) Final Rule FY13.

Contacts:

Joey Lomicky
Public Relations
+1-763-526-2494

Jeff Warren
Investor Relations
+1-763-505-2696

HUG#1884843