Medtronic TYRX(TM) Antibacterial Envelope Reduces Cardiac Device Infection Rates at 12 Months

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Long-term Citadel/Centurion Clinical Trial Findings and Independent Data Presented at Heart Rhythm Society 36th Annual Scientific Sessions

DUBLIN and BOSTON - MAY 15, 2015 - Medtronic plc (NYSE: MDT) today announced that its TYRX(TM) Antibacterial Envelope reduces major cardiac device site infections by 80 percent, up to 12 months after implantation. These data were presented at Heart Rhythm 2015, the Heart Rhythm Society's 36th Annual Scientific Sessions in Boston.

The Citadel/Centurion Clinical Trials are the first prospective, multicenter studies to evaluate the impact of the TYRX Antibacterial Envelope on cardiac implantable electronic device (CIED) major infections and mechanical complication rates following implantation in high-risk patients. The results show a low rate of surgical site infection at 12 months (0.44 percent) in the 1,129 patients who received the TYRX Antibacterial Envelope compared with a control group of similar patients reported in previously published literature[1] who did not receive an envelope (2.2 percent; p=0.0023).

CIED infections are associated with substantial morbidity, mortality and cost[2,3,4] and are increasing in frequency. The average cost of a CIED infection in the United States is estimated at $54,926.[5]

"Clinical studies show that the use of the TYRX Envelope is associated with a significant reduction in implant-related cardiac device site infections," said Charles A. Henrikson, M.D., M.P.H., FHRS, chief of electrophysiology at Oregon Health & Science University in Portland. "These new findings reveal that the TYRX Envelope decreases the rate of infections that can occur within the first year after implantation. This is very good news for patients, especially given the associated mortality and costs tied to CIED infection."

12-Month Results of Citadel/Centurion Clinical Trials

The Citadel/Centurion Clinical Trials enrolled 1,129 patients at 55 centers in the United States. Study participants were at high risk for infection because they were undergoing a CIED replacement procedure with either an implantable cardioverter-defibrillator (ICD) (Citadel) or a cardiac resynchronization therapy (CRT) device (Centurion). Primary endpoints were major CIED infection (involving any site other than skin or subcutaneous tissue of the incision, or endocarditis) and CIED mechanical complication over 12 months of follow-up. The frequency of CIED mechanical complications in patients implanted with the TYRX Envelope was low.

"These data support the long-term safety and efficacy of the TYRX Envelope and showcase the clinical benefit of this novel technology for cardiac device patients at increased risk for infection," said Marshall Stanton, M.D., vice president and general manager of the Tachycardia business, which is part of the Cardiac and Vascular Group at Medtronic.

Results of Independent Study of TYRX(TM) Absorbable Antibacterial Envelope

Additionally at Heart Rhythm 2015, researchers at Vanderbilt University Medical Center independently reported that the TYRX(TM) Absorbable Antibacterial Envelope was associated with a very low incidence of CIED-related infection in a high-risk population, comparable to that seen with the original non-absorbable TYRX Antibacterial Envelope.

"Our study is the first-of-its-kind, comparing the incidence of major cardiac device-related infection in high-risk patients who, during implantation, received either the TYRX Absorbable Envelope or the non-absorbable Envelope, with a control group of patients who did not receive a TYRX envelope," said Christopher R. Ellis, M.D., FHRS, FACC, principal investigator of the study and assistant professor of medicine at Vanderbilt University Medical Center. "After a minimum of three months, results showed only one reported infection in the 488 patients who received either the original or newer, absorbable TYRX Envelope, compared with 20 infections in the control group of 638 patients. Additionally, it was

encouraging to find no difference in infection rates between the original TYRX Envelope and the newer, fully absorbable version."

About CIED Infections

CIED infections occur in 1-7 percent[6] of all CIED patients and about 3 percent of high-risk patients. High-risk patients include those patients with diabetes, with a previous history of infection, having a revision or upgrade procedure, or with renal failure or congestive heart failure. Most CIED site infections occur within the first three months. However, bacteria introduced during the implant can lay dormant in the subcutaneous pocket that houses the device under the skin and cause a delayed infection six months or more after implantation.

About the TYRX Antibacterial Envelope

The TYRX Antibacterial Envelope is a mesh envelope that holds an implantable cardiac device and is designed to stabilize the device after implantation while releasing two antimicrobial agents, minocycline and rifampin, over a minimum of seven days to help reduce surgical-site infections.

The TYRX Absorbable Antibacterial Envelope is fully absorbed by the body approximately nine weeks after implantation. Both TYRX Envelopes are FDA-cleared and have received CE Mark and are available in the United States and Europe.

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 plc (www.medtronic.com), headquartered in Dublin, Ireland, 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.

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[4] Habib A, Le KY, Baddour LM, et al. Predictors of mortality in patients with cardiovascular implantable electronic device infections. *Am J Cardiol* 2013; 111:874-879.

[5] Shariff N, Eby E, Adelstein E, et al. J Cardiovasc Electrophysiol. Health and Economic Outcomes Associated with Use of an Antimicrobial Envelope as a Standard of Care for Cardiac Implantable Electronic Device Implantation. 2015 Apr 6. doi: 10.1111/jce.12684. [Epub ahead of print]

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