Medtronic News

FDA Approves Expanded Indication for Medtronic Freezor® Xtra Cryoablation Catheter

Demonstrated Safe and Effective for Treating Patients with Abnormal Heart Rhythm of AVNRT

DUBLIN - Feb. 16, 2017 - Medtronic plc (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) has approved its Freezor® *Xtra* Cryoablation Catheter for treating patients with atrioventricular nodal re-entrant tachycardia (AVNRT), a life-threatening abnormal heart rhythm. The Freezor *Xtra* Catheter is a flexible, single-use device used to freeze cardiac tissue and block unnecessary electrical signals within the heart.

AVNRT is an abnormal heart rhythm, or arrhythmia; approximately 319,000 people live with AVNRT and more than 49,000 people are diagnosed each year.1,2

"The expanded indication for this catheter will allow more patients to benefit from a safe and effective therapy that can prevent heart racing, and allow them to get back to their normal activities," said Peter Wells, M.D., heart rhythm doctor at Baylor Heart and Vascular Hospital, Dallas, and principal investigator of the ICY-AVNRT clinical trial.

The expanded indication is supported by data from the Intracardiac CrYoablation for AtrioVentricular Nodal Reentrant Tachycardia (ICY-AVNRT) clinical study, which demonstrated safety and effectiveness of the Freezor Xtra Catheter for the treatment of patients with AVNRT. With 397 enrolled patients in 34 clinical trial sites across the U.S. and Canada, the study showed freedom from AVNRT was 92.6 percent at six months post-procedure. All of the safety endpoints were met, with no primary safety events related to the Freezor *Xtra* Catheter.

"Medtronic is pleased with the FDA's decision to approve the expanded use of the Freezor*Xtra* Catheter for the AVNRT patient population," said Colleen Fowler, vice president and general manager of the AF Solutions business, part of the Cardiac and Vascular Group at Medtronic. "This treatment option expands our efforts to improve care for these 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 of the highest quality 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 among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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 Wetzel GT. Atrioventricular Node Reentry Supraventricular Tachycardia. Medscape, 2016.

2 Porter M, et al. Influence of age and gender on the mechanism of supraventricular tachycardia. Heart Rhythm (2004), 4: 393-396

Contacts:
Tracy McNulty
Public Relations
+1-763-526-2492

Ryan Weispfenning
Investor Relations
+1-763-505-4626

---

https://news.medtronic.com/2017-02-16-FDA-Approves-Expanded-Indication-for-Medtronic-Freezor-R-Xtra-Cryoablation-Catheter