Medtronic News

Medtronic Resolute(TM) Drug-Eluting Stent (DES) Platform Receives Expanded Indication for Treatment of Chronic Total Occlusion (CTO)

FDA Approval Allows Interventional Cardiologists Access to Resolute DES Technology to Treat De Novo CTO

DUBLIN - February 26, 2019 - Medtronic plc (NYSE:MDT) today announced the U.S. Food and Drug Administration (FDA) approval of its Resolute Drug-Eluting Stent (DES) platform (including the Resolute Onyx(TM) and Resolute Integrity(TM) DES) for the treatment of patients with coronary artery disease who have *de novo* chronic total occlusion (CTO), a complex vessel condition involving complete blockage of a coronary artery. CTO is considered more difficult to treat with percutaneous coronary intervention (PCI) due to a greater risk of complications.

"Revascularization of CTO presents physicians with many challenges - both regarding procedural technique and tools - given the patient and disease complexity. In part because of these challenges, CTO remains undertreated in interventional cardiology," said David Kandzari, M.D., director of interventional cardiology and chief scientific officer, Piedmont Heart Institute in Atlanta, Ga., and principal investigator in the PERSPECTIVE Study, from which data were used to obtain FDA approval. "The newest-generation, thin-strut Resolute Onyx DES, in particular, is well-suited to address the procedural challenges of deliverability and conformability, with now demonstrated excellent early and late safety and efficacy."

Affecting approximately 20 to 30 percent of patients undergoing routine diagnostic coronary angiography, CTO occurs when there is heavy build-up of atherosclerotic plaque within the artery, one of the complications of coronary artery disease. Currently, approximately 5-7 percent of the patients who are diagnosed with a CTO are able to undergo PCI.

The expanded CTO indication was supported by data from the PERSPECTIVE Study, a single-center, observational study of 183 CTO patients who underwent a stent procedure with the older-generation Resolute Integrity(TM) DES. Results showed that patients treated with the Resolute DES exhibited low rates of repeat revascularization (1.1 percent), cardiac death (2.2 percent) and minimal stent thrombosis (0.6 percent) at one year.

"This expanded indication will allow physicians the option to treat these more complex CTO cases with the Resolute Onyx DES, which has shown strong clinical performance across a variety of vessel sizes and anatomies," said Dave Moeller, vice president and general manager of the Coronary and Renal Denervation business, which is part of the Cardiac and Vascular Group at Medtronic. "Medtronic is committed to helping interventional cardiologists better treat the tough, complex coronary cases that have historically required more invasive treatment options, such coronary artery bypass grafting (CABG), or open-heart surgery."

Physicians will have an opportunity to learn more about Resolute Onyx for the treatment of CTO at the Chronic Total Occlusion Summit, an interventional cardiology meeting in New York City, sponsored by the Cardiovascular Research Foundation, with sessions focused on advanced techniques and evidence-based medicine.

Approved in the U.S. in 2017 following Resolute Integrity DES, the newest-generation Resolute Onyx is the first and only DES to feature Core Wire Technology, a unique Medtronic method of stent manufacturing that involves forming a single strand of cobalt alloy wire into a sinusoidal wave to construct a stent. Core Wire Technology enables greater deliverability and conformability to the vessel wall, along with thinner struts while maintaining structural strength. With a size matrix covering 2.0-5.0 mm, physicians can use Resolute Onyx in complex CTO lesions in a broad range of vessel sizes.

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 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 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-

Contacts:

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

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

---

https://news.medtronic.com/2019-02-26-Medtronic-Resolute-TM-Drug-Eluting-Stent-DES-Platform-Receives-Expanded-Indication-for-Treatment-of-Chronic-Total-Occlusion-CTO