Medtronic News

Medtronic RESOLUTE ONYX(TM) 2.0 mm Clinical Study Meets Primary Endpoint in Extra-Small Vessels at One-Year

First-Ever Study on 2.0 mm DES, EuroPCR Late-Breaking Data Show Exceptional Deliverability and No Stent Thrombosis for the Resolute Onyx DES

DUBLIN and PARIS- May 18, 2017 - Medtronic plc (NYSE: MDT) today announced that the Resolute Onyx(TM) Drug-Eluting Stent (DES) met its primary endpoint of Target Lesion Failure (TLF) at one year for the treatment of coronary artery disease in extra-small vessels. Results from the RESOLUTE ONYX 2.0 mm Clinical Study were presented today as a Hot Line/Late-Breaking Trial Session at the 2017 EuroPCR Annual Meeting and simultaneously published in the *Journal of the American College of Cardiology (JACC): Cardiovascular Intervention*.

It is estimated that approximately 65 percent of extra-small vessels are located in critical locations of the heart, making them significant lesions to treat.1 Designed specifically for extra-small vessels, Resolute Onyx 2.0 mm DES yielded excellent clinical outcomes in the study compared to a pre-specified performance goal with patients experiencing significantly low rates of TLF at one year (5.0 percent, $p<=0.001$). The study enrolled 101 patients with extra-small vessel sizes (2.0 mm - 2.25 mm) who received the Resolute Onyx 2.0 mm diameter DES across 20 sites in the United States and Japan.

"Treating coronary disease in extremely small arteries presents a real clinical challenge, as these lesions tend to be located in difficult-to-reach areas of the heart, have greater restenosis rates, and until now, we lacked the right stents to treat them safely and successfully," said Matthew J. Price, M.D., interventional cardiologist at Scripps Clinic in La Jolla, Calif. and principal investigator of the RESOLUTE ONYX 2.0 mm Clinical Study who presented the one-year data at EuroPCR. "The excellent clinical performance we observed demonstrates the importance of designing stents like the Resolute Onyx DES that address a relevant unmet need. Thinner struts with enhanced radiopacity and a lower crossing profile provide excellent deliverability, and the stent can be over-expanded to treat tapered, challenging lesions."

In the study, the events included in the TLF primary endpoint were low at one-year, as defined by low target-vessel MI (3 percent), low target lesion revascularization (2 percent) and no cardiac death. Additionally, Resolute Onyx DES showed no stent thrombosis.

The Resolute Onyx DES is the first and only DES to feature Core Wire Technology, an evolution of Continuous Sinusoid Technology (CST). CST is a unique Medtronic method of stent manufacturing, which involves forming a single strand of cobalt alloy wire into a sinusoidal wave to construct a stent. This enables greater deliverability and conformability to the vessel wall. With Core Wire Technology, a radiopaque inner core is incorporated within the cobalt alloy wire to enhance visibility for accurate stent placement. Core Wire Technology also enables thinner struts while maintaining structural strength.

"The RESOLUTE ONYX 2.0 mm Clinical Study builds on the positive body of evidence supporting the clinical performance of the Resolute Onyx stent," said Jason Weidman, vice president and general manager of the Coronary and Renal Denervation business, which is part of the Cardiac and Vascular Group at Medtronic. "These initial results reinforce the unique design of the Resolute Onyx, providing physicians and patients around the globe with the gold standard in drug-eluting stents."

The Resolute Onyx 2.0 mm diameter DES are for investigational use only in the United States. The Resolute Onyx DES received approval by the Food and Drug Administration (FDA) in April 2017 and is now available for use in the United States for a broad range of sizes from 2.25 mm - 5.0 mm. It is also approved for use in Europe and other countries that recognize the CE (*Conformité Européene*) Mark.

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 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 more than 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 Schunkert et al. *JACC* July 1999

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

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

---

https://news.medtronic.com/2017-05-18-Medtronic-RESOLUTE-ONYX-TM-2-0-mm-Clinical-Study-Meets-Primary-Endpoint-in-Extra-Small-Vessels-at-One-Year