Medtronic Drug-Filled Stent Shows Promising Initial Results Following First Implants

October 12, 2015 8:00 AM CT

Medtronic

Presented for the First Time at TCT, Early Results from the RevElution Trial Demonstrate Early Vessel Healing and Controlled, Polymer-Free Drug Elution in Patients Treated with the Novel Next-Generation Stent

DUBLIN and SAN FRANCISCO - Oct. 12, 2015 - Medtronic plc (NYSE: MDT) unveiled today new data from the first implants of its novel Drug-Filled Stent (DFS) at the Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. The early results from an initial subset of patients in the RevElution Trial show that the DFS achieved rapid and well-controlled stent coverage. The unique DFS is designed to eliminate potential drawbacks experienced with bioabsorbable polymers and polymer-free technologies, such as inflammation due to polymer degradation, and uncontrolled drug release in the absence of a polymer.

"The novel DFS truly represents an innovative stent platform with advanced stent manufacturing to optimize clinical performance without the need of a polymer," said Stephen Worthley, professor at the Royal Adelaide Hospital in Adelaide, Australia and co-principal investigator of the DFS trial who performed the first implants in the study and presented the data at TCT. "These patients implanted with the DFS have shown very promising early outcomes of strut coverage and healing that indicate the new platform may provide many clinical benefits, including shorter DAPT duration, and we look forward to evaluating how well the stent continues to perform throughout the trial."

The Optical Coherence Tomography (OCT) data from the Trial demonstrate an early healing profile with an average of 90 percent strut coverage (new cell growth over stent struts) at one month, with a low rate of malapposed struts (2 percent) across the six patients analyzed. The rate of malapposed struts dropped by 50 percent within one month post-procedure, further demonstrating the stent's ability to allow for rapid healing within the vessel. Importantly, the data also showed minimal neointimal hyperplasia (NIH) formation.

The DFS is built on the proven platform of the Resolute Integrity(TM) DES with Continuous Sinusoid Technology (a unique Medtronic method of stent manufacturing that forms one single strand of wire into a sinusoidal wave enabling a continuous range of motion), as well as the next-generation Resolute Onyx(TM) DES with CoreWire Technology that allows it to have a denser core metal surrounded by a cobalt alloy outer layer for thinner struts with enhanced radiopacity (visibility during imaging).

The new DFS features a novel tri-layer wire design, which allows the inner sacrificial layer to become a lumen continuously coated with drug. The drug (sirolimus) is contained on the inside of the stent and is released from a single continuous inner lumen through multiple laser-drilled holes on the abluminal side (outer surface) of the stent. This allows for a controlled and sustained polymer-free drug elution over a desired period of time directly into the arterial wall thereby potentially avoiding chronic inflammation and adverse vascular responses. In patients with complex lesions, containing the drug on the inside of the stent protects the coating to reduce concerns related to coating durability during tracking.

"Through our collaboration with interventional cardiologists from around the world to advance our coronary portfolio together, we believe the drug-filled stent represents a significant breakthrough in stent design and engineering that helps address current and next-generation technology challenges," 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.

The global DFS study is underway at multiple sites in geographies including Australia and Brazil. The study will enroll 100 patients and will evaluate late lumen loss as measured by quantitative coronary angiography. The Drug-Filled Stent is available for investigational use only outside of the United States.

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 85,000 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-

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

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