Medtronic News

Medtronic Announces Early Data and Completes Enrollment in CE Mark Cohort in Drug-Filled Stent Trial

RevElution Trial with Next-Gen Polymer-Free Stent Continues to Show Excellent Rapid Healing and Controlled Drug Delivery at ACC.16

DUBLIN and CHICAGO - April 3, 2016 - Medtronic plc (NYSE: MDT) announced new clinical data today from one of the endpoints in the RevElution Trial for its novel, next-generation Drug-Filled Stent (DFS). These new data showed rapid vessel healing without inflammation in Optical Coherence Tomography (OCT) data of the complete one-month follow-up patient cohort. The results were unveiled at the 65th Annual Scientific Session of the American College of Cardiology (ACC) on the heels of completing enrollment in the 50-patient cohort of the RevElution Trial, which will be used to support CE (Conformité Européenne) Mark.

The DFS is an innovative, polymer-free stent design, which elutes the drug (sirolimus) from the inside of the stent through laser-drilled abluminal holes. This allows for a controlled and sustained drug elution directly into the arterial wall, which may 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 unique attribute of DFS technology is that it allows for controlled elution of drug directly from within a next-generation stent, obviating the need for a polymer," said Ajay Kirtane, M.D., director, New York-Presbyterian Hospital/Columbia University Cardiac Catheterization Laboratories, associate professor of medicine at Columbia University and member of the RevElution Trial Steering Committee. "If the encouraging early data from the RevElution Trial continue to show promise with longer-term follow-up, they will set the stage for further pivotal investigations of the DFS. Furthermore, the ability to potentially reduce the mandatory duration of dual antiplatelet therapy following DFS implantation is vitally important for patients and treating physicians."

In the fully completed one-month cohort of patients (N=15) from the RevElution Trial, which evaluated healing with OCT imaging, the DFS showed an early healing profile with an average of nearly 90 percent full strut coverage (new cell growth over stent struts) and a low rate of malapposed struts (1.5 percent). Importantly, the data also showed minimal neointimal hyperplasia (NIH) formation.

"These data indicate that the DFS has the potential to positively address issues associated with polymer-based stents to optimize care for a wide range of patient populations," 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. "This breakthrough technology is a great example of our commitment to innovation through collaboration with physicians to address real unmet needs."

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.

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