Medtronic News

Medtronic to Unveil Pivotal U.S. Data on Resolute(R) Drug-Eluting Stent at ACC.11

Late-Breaking Clinical Trials Feature One-Year Results of RESOLUTE US Study; Latest Evidence from Comprehensive Research Program Completes FDA Approval Submission

MINNEAPOLIS, Mar 28, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT), today announced the imminent release of the pivotal U.S. data on its Resolute(R) drug-eluting stent (DES) at ACC.11, the 60th Annual Scientific Session & Expo of the American College of Cardiology, which takes place April 2-5 in New Orleans.

The one-year results of the study, called RESOLUTE US, will be presented in the late-breaking clinical trials session for interventional cardiology on Monday, April 4. These new data complete Medtronic's submission to the U.S. Food and Drug Administration (FDA) for pre-market approval of the Resolute DES, which remains investigational in the United States.

The principal investigators of RESOLUTE US are:

- Martin B. Leon, M.D., director of the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center
- Laura Mauri, M.D., chief scientific officer of the Harvard Clinical Research Institute and an interventional cardiologist at Brigham and Women's Hospital in Boston
- Alan Yeung, M.D., director of interventional cardiology at Stanford University School of Medicine in Palo Alto, Calif.

"We look forward to sharing these important data from RESOLUTE US with our colleagues at the meeting," said Dr. Yeung. "Since the release last year of impressive results from two all-comers studies conducted outside the United States, the clinical community has been eagerly awaiting additional data on the use of this device in a U.S. patient population."

The two-year results from RESOLUTE All Comers, a randomized controlled trial comparing the Resolute DES to the Xience V DES from Abbott Laboratories in a complex patient population representative of routine clinical practice, will be highlighted in a featured clinical studies session on Sunday, April 3. The one-year results of the study, published in *The New England Journal of Medicine* (July 8, 2010), showed parity between the Resolute DES and the market-leading alternative - the Xience V DES and, by extension, the Promus DES from Boston Scientific Corp.

Presentations of the latest data from the RESOLUTE clinical program will occur during the following sessions (listed in U.S. Central Standard Time):

Sunday, April 3

- 4:45 - 6:15 pm / Interventional Featured Clinical Studies II (Session No. 2132)
  "Two-Year Outcomes from the Randomized RESOLUTE All-Comers Trial"

Monday, April 4

- 10:45 am - 12:15 pm / Late-Breaking Clinical Trials III: Interventional Cardiology (Session No. 3014)
  "One-year Clinical Outcomes from the Pivotal Multicenter RESOLUTE US Study"

"Pending FDA approval, the Resolute DES will strengthen our U.S. portfolio of coronary stents, which are designed to address

the spectrum of clinical need," said Michael J. Coyle, executive vice president of Medtronic, Inc., and president of its Cardiac and Vascular Group. "The Resolute DES serves as an excellent example of the innovative devices that Medtronic offers."

In addition to stents and other angioplasty technologies for the treatment of coronary and peripheral artery disease, Medtronic's ACC.11 exhibition booth will feature:

- *Revo MRI(TM) SureScan(R) Pacing System*. The Revo MRI System was designed from the ground up to address safety concerns around MRI procedures for patients who have implanted pacemakers. The pacemaker system includes hardware modifications to the device and leads that are designed to reduce or eliminate several hazards produced by the MRI environment. In addition, since MRI scanners may cause other current pacemakers to misinterpret MRI-generated electrical noise and withhold pacing therapy or deliver unnecessary pacing therapy, this new pacemaker includes a proprietary SureScan feature that sets the device into an appropriate mode for the MRI environment. The Revo MRI pacing system must consist solely of a Medtronic Revo MRI SureScan device and two CapSureFix MRI(TM) SureScan Model 5086MRI leads. Prior to scanning a patient, clinicians should refer to the Revo MRI Pacing System MR Conditions for Use located in the device manuals.
- *Arctic Front(R) Cardiac CryoAblation Catheter System*. The Arctic Front System is the first and only Cryoballoon in the United States indicated for the treatment of drug refractory paroxysmal atrial fibrillation (PAF). The Cryoballoon treatment involves a minimally-invasive procedure that efficiently creates circumferential lesions around the pulmonary vein, which is the primary source of erratic electrical signals that cause the irregular heartbeat. This balloon-based technology is novel because it ablates or blocks the conduction of atrial fibrillation (AF) in cardiac tissue through the use of a coolant rather than heat, which is delivered through a catheter. This freezing technology enables the catheter to adhere to the tissue during ablation, allowing for greater catheter stability.
- *CoreValve(R) System.* The CoreValve System, which is available in more than 40 countries outside the United States, and the subclavian approach for transcatheter aortic valve implants, will be available in the International section of the Medtronic booth. In addition, the Medtronic Technology Suite will provide education and training opportunities with simulators and other hands-on tools for international physicians. In the United States, the CoreValve System is investigational, and the Medtronic CoreValve U.S. Clinical Trial began in December and is enrolling patients with severe aortic stenosis in clinical trial sites across the country.

The Resolute DES and the CoreValve System are both investigational devices in the United States, where their use is limited by U.S. law to clinical studies approved by the FDA. The Arctic Front System and the Revo MRI System are both approved by the FDA and commercially available for clinical use in the United States.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional treatment of cardiovascular disease and cardiac arrhythmias.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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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