Medtronic News

Medtronic Presents IN.PACT Global Study Three-Year Data and Total IN.PACT(TM) Imaging and Propensity Analyses

Clinical Evidence Shared at TCT and CIRSE Reaffirm IN.PACT(TM) Admiral(TM) Drug-Coated Balloon as a Primary Therapy to Treat Complex, Real-World Patient Populations

SAN DIEGO and LISBON, Portugal - September 22, 2018 - Medtronic plc (NYSE:MDT) data announced today continue to reinforce the safety, durability, and consistency of the IN.PACT(TM) Admiral(TM) drug-coated balloon (DCB) in real-world patients with peripheral arterial disease (PAD). Three-year real-world results from the full clinical cohort of the IN.PACT Global Study and one-year data from the Total IN.PACT(TM) pooled imaging and propensity analyses were presented at the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) annual meeting and the 30th Transcatheter Cardiovascular Therapeutics (TCT) conference, the annual scientific symposium of the Cardiovascular Research Foundation, respectively.

"The two datasets presented today at TCT and CIRSE are testaments to the breadth and depth of our IN.PACT Admiral clinical program. We are committed to providing the clinical community with timely and transparent access to data to better inform their treatment decisions," said Mark Pacyna, vice president and general manager of the Peripheral business, which is part of the Aortic, Peripheral, and Venous division at Medtronic. "Consistently across trials, IN.PACT Admiral has demonstrated its ability to treat varying PAD patient populations, while effectively preserving future treatment options."

IN.PACT Global Study: Three-Year Results Show Durability of Treatment Effect in Real-World Population

Professor Gunnar Tepe, M.D., director of Diagnostic and Interventional Radiology at the Academic Hospital RoMed Clinic in Rosenheim, Germany, presented the new, three-year results from the full clinical cohort of the IN.PACT Global Study. The results are the first three-year, real-world, fully adjudicated DCB data to be presented in a scientific congress and showed durability of treatment effect in a real-world population.

The freedom from clinically-driven target lesion revascularization (CD-TLR) rate calculated using Kaplan Meier survival estimates was 76.9 percent in a real-world patient cohort with a mean lesion length of 12.09 ± 9.54 cm, 18.0 percent in-stent restenosis, 35.5 percent occluded lesions, and 39.9 percent diabetic subjects. Additionally, the proportion of patients undergoing repeat procedures were low through three years: major target limb amputations, 0.8 percent, and CD-TLR, 23.5 percent (n=1,406).

"Superficial femoral artery (SFA) disease is becoming more prevalent globally and is often difficult to treat due to its complex nature. Now more than ever, it is important to carefully assess how therapies to treat this condition perform over the long-term among real-world patients," said Prof. Tepe. "IN.PACT Global was designed with this goal in mind and has now demonstrated the durability, efficacy, and safety of IN.PACT Admiral in complex lesions out to three years - something few SFA studies have been able to achieve thus far."

The IN.PACT Global Study is the largest and most rigorous real-world evaluation of any peripheral artery intervention ever undertaken and intends to characterize the performance of the IN.PACT Admiral DCB in treating real-world patients with challenging and complex lesions. The study included adjudication of events by an independent clinical events committee.

Total IN.PACT(TM) Pooled Imaging and Propensity Analyses: Delta in Patency Rates Demonstrates DCB's Persistent Superiority to Standard Percutaneous Transluminal Angioplasty (PTA)

Dr. Mehdi Shishehbor, D.O., M.P.H., Ph.D., director of the Heart and Vascular Institute, University Hospitals

Cleveland Medical Center, presented one-year overall imaging and propensity-matched imaging data from the Total IN.PACT Pooled Analysis at TCT. The Total IN.PACT Pooled Analysis is an undertaking by Medtronic to enhance the understanding of PAD patient treatment algorithms by characterizing the clinical performance of IN.PACT Admiral in the largest and most diverse study population treated with DCBs to date.

Total IN.PACT combined independently adjudicated data from a total of 1,837 patients treated with IN.PACT Admiral DCB from all IN.PACT Admiral randomized clinical trials and real-world studies from 147 sites across 28 countries. The analyses presented today at TCT specifically looked at two different groups - a core laboratory-adjudicated imaging cohort and a propensity matched imaging cohort. The data showed that IN.PACT Admiral DCB demonstrated consistently superior patency and freedom from clinically-driven target lesion revascularization (CD-TLR) compared to standard PTA alone.

The imaging cohort, which evaluated 926 DCB and 143 PTA subjects, demonstrated a patency rate of 88.8 percent for IN.PACT Admiral compared to 53.9 percent for PTA ($p<0.001$) and a freedom from clinically-driven target lesion revascularization (CD-TLR) rate of 94.3 percent compared to 80.2 percent for PTA ($p<0.001$). Additional safety and effectiveness outcomes from the DCB arm also included low rates of thrombosis (2.4 percent), and CD-TLR (5.8 percent), and no occurrences of major target limb amputation at one year.

The propensity analysis (a subset of the imaging cohort) matched one PTA subject with up to four IN.PACT Admiral DCB subjects based on baseline variables (136 PTA subjects and 466 DCB subjects). The propensity-matched analysis showed a patency rate of 90.5 percent for the IN.PACT Admiral DCB as compared to 53.8 percent for PTA ($p<0.001$) and a freedom from CD-TLR rate of 96.9 percent compared to 80.7 percent for PTA ($p<0.001$). Additional safety and effectiveness outcomes from the DCB arm also included low rates of thrombosis (1.6 percent) and CD-TLR (3.3 percent), and no occurrences of major target limb amputation at one year.

"By pooling data from multiple IN.PACT study cohorts, we are able to glean valuable insights into clinical outcomes across a broad spectrum of patient and lesion types beyond the reach of typical cohort DCB analyses," said Dr. Shishehbor. "Despite having more advanced lesions, the Total IN.PACT data presented today at TCT further confirm the consistent performance we've seen across IN.PACT studies by showing approximately 35 percent superior patency with DCB compared to PTA in the imaging cohort and approximately 37 percent superior patency with DCB compared to PTA in the propensity-matched cohort at one year. This calls into question the use of primary PTA therapy in an era of drug eluting technologies like IN.PACT Admiral."

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 of the highest quality 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 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.

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