Medtronic News

Medtronic Statement Regarding FDA Circulatory System Devices Panel

DUBLIN - June 20, 2019 - Medtronic plc (NYSE:MDT) today issued the following statement regarding the U.S. Food and Drug Administration (FDA) Circulatory System Devices Panel of the Medical Devices Advisory Committee on paclitaxel-coated therapies in patients with peripheral artery disease (PAD) in the superficial femoropopliteal artery (SFA):

For Medtronic, patient safety is our top priority - and has been since our company's founding more than 60 years ago. These panel deliberations are critically important as the Food and Drug Administration (FDA), societies, physicians, and industry consider and address the recent questions around the safety of paclitaxel devices in peripheral arterial disease (PAD) above-the-knee. As an industry leader, we take our responsibility to patients and physicians very seriously and look forward to further collaboration on a response to the panel's recommended next steps.

The Medtronic presentation included the independent, patient-level analysis from our two randomized controlled trials (RCTs)-IN.PACT SFA and IN.PACT Japan. This analysis also accounts for vital status data on 97 percent of patients from our RCTs, representing the highest rate obtained across all industry clinical data presented at the panel. Results demonstrate:

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- No drug-related mechanism for observed transient mortality signal
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- No observed dose relationship with mortality
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- No pattern of adverse events or cause of death to suggest unifying mechanism
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- No relatedness between deaths and paclitaxel, as adjudicated by a newly convened independent Clinical Events Committee (CEC) with paclitaxel toxicity expertise

Additionally, Peter A. Schneider, M.D., professor of Surgery, Division of Vascular & Endovascular Surgery, University of California San Francisco and principal investigator of the IN.PACT SFA trial, presented the clinical benefit of IN.PACT Admiral. In the IN.PACT SFA trial, three out of four DCB patients remained intervention-free through five years, and for DCB patients who required a repeat procedure, the time to reintervention was prolonged for more than two years. Medtronic remains confident that the IN.PACT Admiral benefit-risk profile is positive and supports IN.PACT Admiral DCB as a first-line strategy for the treatment of PAD.

The panel presentations and deliberations addressed a wide range of considerations related to paclitaxel drug-coated balloons (DCB) and drug-eluting stents (DES). Laura Mauri, M.D., vice president, Global Clinical Research & Analytics, Medtronic also presented alongside Dan Clair, M.D., chair of the Department of Surgery for the University of South Carolina (USC) and the Palmetto Health-USC Medical Group and Eric A. Secemsky, M.D., MSc, RPVI, FACC, FVSM, Beth Israel Deaconess Medical Center, Harvard Medical as part of an unprecedented pan-industry presentation.

Medtronic remains steadfast in our leadership and commitment to data transparency and continues to encourage collaboration across industry and regulatory stakeholders around the world to further address this issue.

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 90,000 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 health care 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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