Medtronic News

# Medtronic Statement Regarding Revised IN.PACT Post Market Study Data

DUBLIN - February 15, 2019 - Medtronic plc (NYSE:MDT) today issued the following statement regarding revised clinical study data:

Recently, Medtronic became aware of a programming error in the clinical data reporting isolated to the two- and three-year follow-up periods in our IN.PACT Global post-market study, part of the IN.PACT Admiral clinical program for the treatment of femoropopliteal artery disease. Preliminary results of this study were first released at the Leipzig Interventional Course (LINC) and Medtronic issued a press release summarizing the results on January 22, 2019.

Due to a programming error, mortality data were inadvertently omitted from the summary tables included in the statistical analysis. These deaths were, however, previously included and reported in Medtronic's database, captured in the appropriate study exit forms and adjudicated by an independent clinical events committee. In addition, the deaths were previously recorded in Medtronic's complaint system, and MDR/Vigilance reporting has been completed in compliance with the company's Quality Systems, which are governed by external regulatory requirements.

Immediately upon learning of this error, Medtronic notified the FDA and the study authors. While a component of the recent patient-level meta-analysis will need to be updated, Medtronic has found the revised analysis still supports earlier conclusions that: there was no statistically significant difference in all-cause mortality between the IN.PACT(TM) Admiral(TM) drug-coated balloon (DCB) and plain balloon angioplasty at five years; there is no correlation between paclitaxel dosing and long-term survival in the studied population; and, there was no difference in mean nominal dose of paclitaxel between overall survival in patients treated with DCB and those who died.

The data update impacts the publication of the IN.PACT Global two-year data in the*Journal of the American College of Cardiology: Cardiovascular Interventions (JACC CI)*, and the IN.PACT paclitaxel safety analysis, which is in print with the *Journal of the American College of Cardiology (JACC)* Medtronic has confirmed no other IN.PACT studies are affected by this error, and it's important to note this discrepancy is limited to deaths after the one-year timepoint.

Respecting the scientific process, the revised analysis is currently moving through the appropriate peer-review with the study authors and *JACC* so the manuscripts can be appropriately corrected.

Medtronic also notes a related study published on February 12, 2019 in*JAMA Cardiology*, "Association of Survival With Femoropopliteal Artery Revascularization With Drug-Coated Devices." The study authors concluded: "In this large nationwide analysis of Centers for Medicare and Medicaid Services beneficiaries, there was no evidence of increased all-cause mortality following femoropopliteal artery revascularization with drug-coated devices compared with non-drug-coated devices." https://jamanetwork.com/journals/jamacardiology/fullarticle/2725047

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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