Medtronic News

Medtronic Statement Regarding IN.PACT Paclitaxel Safety Analysis Correction Letter in The Journal of the American College of Cardiology

DUBLIN - March 1, 2019 - On February 15, 2019, Medtronic issued a statement regarding 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.

As we noted in our previous statement, this programming error impacted the IN.PACT Paclitaxel Safety analysis, which recently presented at the Leipzig Interventional Course (LINC) in Leipzig, Germany and published online in the *Journal of the American College of Cardiology (JACC)*.

The revised analysis has been accepted by *JACC*. Prior to publication of the revised manuscript, the authors of the study have issued a correction letter addressing key revisions to the data. The updated analysis will also be presented by Dr. Peter Schneider at the VIVA Physicians Vascular Leaders Forum (VLF) from March 1-2, 2019 in Washington, D.C.

It is important to reiterate that the initial conclusions from the patient level meta-analysis remain intact:

- Data found no correlation between paclitaxel dose and long-term survival.
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- Data demonstrated no difference in mean nominal dose of paclitaxel between overall survival in patients treated with DCB and those who died.
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- At five years there was no statistically significant difference in all-cause mortality between the drug-coated balloon (DCB) and plain balloon angioplasty (PTA) arms.

In addition to the full cohort, a standard cohort has been included by the authors in the *JACC* analysis. This was done to correct a baseline imbalance between DCB and PTA by identifying a subgroup of DCB patients who met the inclusion criteria for the pivotal studies from the IN.PACT clinical program, including IN.PACT SFA, IN.PACT Japan, and IN.PACT China. When only the subjects that mirror the baseline variables in the control PTA group are included, we observe a smaller difference in mortality. When adjusted for these baseline imbalances, all-cause mortality between DCB and PTA was 13.2 percent vs 11 percent (p=0.188).

In line with our commitment to transparency, we have shared all our patient-level data with FDA in support of their paclitaxel safety analysis and will plan to do the same to support the upcoming independent VIVA Physicians analysis. Following publication of the revised *JACC* manuscript, we will also work to correct all impacted materials that live in the public domain.

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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