Medtronic News

# Medtronic Statement Regarding Updated FDA Letter To Healthcare Providers On Paclitaxel Devices to Treat Peripheral Artery Disease

DUBLIN – August 7, 2019 – Medtronic plc (NYSE:MDT) today issued the following statement regarding the U.S. Food and Drug Administration's (FDA) updated Letter to Healthcare Providers for paclitaxel-devices in patients with peripheral artery disease (PAD) in the superficial femoropopliteal artery (SFA):

Medtronic would like to thank FDA and the panel members for their thoughtful deliberations and dedication to providing physicians, patients, and administrators with updated recommendations following the Advisory Committee meeting of the Circulatory System Devices Panel in June. The next steps as outlined by FDA are critical to ensuring that physicians and their patients with PAD retain the option to utilize paclitaxel-coated therapies. The IN.PACT™ Admiral™ drug coated balloons (DCB) has demonstrated a clear positive benefit on clinical outcomes and quality of life across multiple randomized controlled clinical trials.

Importantly, this guidance will allow:

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- Physicians and patients to discuss the benefits and risks of all available PAD treatment options in order to support an informed treatment decision.
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- Patients to have continued access to paclitaxel devices as a first-line treatment option, particularly those at high risk of restenosis.
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- Trial sponsors to continue enrollment in clinical studies to further evaluate the long-term safety and effectiveness of paclitaxel devices.
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- FDA and industry to analyze of additional randomized controlled trials (RCTs) and registry datasets to help provide more insights into the mortality signal in question.

Medtronic is encouraged by this path forward, but our work to evaluate the root cause of this safety signal is not complete. It is important to remember that causality was not able to be established in the FDA or VIVA/NAMSA analyses. Therefore, it is critical that Medtronic and our industry partners continue to work together to share safety and effectiveness data to further facilitate the benefit-risk conversation. This work is consistent with the Medtronic Mission, and we look forward to continued collaboration with physician societies, FDA, and our industry partners throughout the next phase of this effort.

Medtronic remains confident in the safety and effectiveness 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. In line with FDA's recommendations, we encourage physicians to talk to their patients about the benefits and risks of all available treatment options.

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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