Medtronic News

Medtronic to Stop Distribution and Sale of HVAD™ System

- Company Developing Support Program for Current HVAD Patients

- Medtronic Coordinating with Global Regulators to Assure Patient Access to Left Ventricular Assist Devices

DUBLIN, June 3, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, is stopping the distribution and sale of the Medtronic HVAD™ System. This morning, the company notified physicians to cease new implants of the HVAD System and transition to an alternative means of durable mechanical circulatory support.

Medtronic also announced that it is developing a support program for patients who have had an HVAD implanted and for caregivers and health care professionals who participate in their care. This program is being developed with an independent panel of clinician advisors to ensure the ongoing care and safety of patients who are currently supported by the HVAD system. Though the company will stop distribution and sale of the HVAD System, Medtronic is committed to serving the needs of the approximately 4,000 HVAD patients currently implanted with the device.

Medtronic initiated this action in light of a growing body of observational clinical comparisons indicating a higher frequency of neurological adverse events, including stroke, and mortality with the HVAD System as compared to other circulatory support devices available to patients.

In addition, Medtronic previously issued an Urgent Medical Device Communication informing physicians that the HVAD pump may experience a delay to restart or a failure to restart after it is stopped. Pump restart failure can potentially worsen a patient's heart condition, lead to a heart attack, require hospitalization, and result in death.

Considering these findings and the availability of alternative devices, Medtronic made the decision to stop the distribution and sale of the HVAD System, consistent with its commitment to prioritize patient safety.

"The Medtronic Mission guides us to always do what is in the best interests of patients and that is exactly what we are doing and will do for those impacted by this decision. There is nothing more important than the safety and well-being of patients," said Nnamdi Njoku, president of the Mechanical Circulatory Support business, which is part of the Cardiovascular Portfolio at Medtronic. "We recognize this information may be concerning for patients and their caregivers, and Medtronic is committed to supporting them in coordination with their physicians."

Medtronic has been working closely with the U.S. Food and Drug Administration (FDA), along with other regulatory bodies around the world, to share information related to this decision and its commitment to ongoing support for patients implanted with the HVAD device.

Patient Management Recommendations

Medtronic is committed to patient safety and to serving the needs of the approximately 4,000 HVAD patients currently implanted with the device. Medtronic has consulted with an independent panel of clinician advisors to develop patient management recommendations to reduce stroke risk and mitigate against other potential risks associated with the HVAD System. Elective explant of the HVAD device is not recommended, as risks associated with explantation may outweigh the potential benefits.

Medtronic is also developing an ongoing support program for patients who have had an HVAD implanted, caregivers, and health care professionals who participate in their care. The program will include financial assistance for eligible patients and other resources for physicians and their caregivers. Further details of the program will be announced when they become available.

Medtronic is working closely with other stakeholders including Abbott, which manufactures the HeartMate 3™ LVAD device, and with regulatory bodies globally, to help ensure that alternative treatment options are available for patients who may be candidates for a LVAD device.

Patients with a HVAD implanted should contact their physician with questions or concerns. For more information, please visit www.Medtronic.com/HVADsafety.

Financial Information

In terms of financial impact, the company estimates that on a non-GAAP basis, the actions announced today are expected to be neutral to slightly accretive to fiscal year 2022 non-GAAP diluted earnings per share (EPS). The HVAD System and associated accessory revenue was $141 million in fiscal year 2021. In addition, the potential loss of revenue was contemplated in the guidance issued by the company on May 27, 2021. As such, there is no change to:

- the 9% organic revenue growth outlook for fiscal year 2022;
- the Cardiovascular organic revenue growth outlook of 10-11% for fiscal year 2022, including 14-15% in the first quarter; and
- the diluted non-GAAP EPS guidance of$5.60 to $5.75 for fiscal year 2022, including the first quarter outlook of$1.31 to $1.34.

About the HVAD™ System

The Medtronic HVAD System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned.

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 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.

HeartMate 3 is a trademark of Abbott group of companies.

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