Medtronic News

Medtronic Receives FDA “Breakthrough Device Designation” for Developing Fully Implantable Heart Pump

DUBLIN, Oct. 29, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for the Medtronic Fully Implantable Left Ventricular Assist Device (LVAD) for patients with advanced heart failure, currently in development.

Currently, LVAD systems include an implanted heart pump to increase the amount of blood that circulates through the body. The pump is connected to a driveline cable that extends outside the body to a controller, which is connected to power sources (AC or DC adapter, batteries). The future system is designed to be fully implanted inside the body.

The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide Medtronic with priority review and interactive communication regarding device development and clinical trial protocols, through to commercialization decisions. *The Medtronic Fully Implantable LVAD is in early-stage research and development, and is not available for sale anywhere in the world.*

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

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.

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