Medtronic News

Medtronic VenaSeal(TM) Closure System Demonstrates Durable and Consistent Outcomes at Five Years in Patients with Chronic Venous Disease

(GLOBE NEWSWIRE via COMTEX) --DUBLIN and LONDON - April 17, 2019 - Medtronic plc (NYSE:MDT) today announced five-year outcomes from the VeClose Extension Study. Nick Morrison, M.D., Center for Vein Restoration, Mesa, Ariz., presented at the 2019 Charing Cross Symposium in London. The new data demonstrate durable and consistent long-term outcomes of the Medtronic VenaSeal(TM) Closure System in treating patients with chronic venous disease.

The VeClose Extension Study is a follow-on study with the purpose of evaluating long-term outcomes at five years post-treatment with the VenaSeal Closure System. The aggregate complete closure rate of the great saphenous vein (GSV) was 94.6 percent (53/56) in the VenaSeal subjects who completed five-year follow-up, including 47 randomized subjects and nine roll-in subjects.

In the original VeClose Study, patients were randomized to receive treatment with VenaSeal or the Medtronic ClosureFast(TM) radiofrequency ablation (RFA) device. By Kaplan-Meier analysis of the randomized cohorts to evaluate success over the life of the study through five years, vein closure estimates were 91.4 percent for VenaSeal and 85.2 percent for RFA, demonstrating continued non-inferiority of VenaSeal to RFA through five years.

Patient improvement was rated on three assessments: Venous Clinical Severity Score (VCSS), a clinical venous disease assessment; and the Aberdeen Varicose Vein Questionnaire (AVVQ) and EQ-5D - both of which provide patient-reported quality of life (QoL) outcomes. By all measurements, subjects sustained or maintained improvements in QoL after treatment with either VenaSeal or RFA. These first prospective five-year data for VenaSeal demonstrate a strong clinical portfolio with sustained long-term outcomes.

"The five-year data support the safety, effectiveness, and quality of life-enhancing capability of both VenaSeal and ClosureFast in treating patients with chronic venous disease," said Dr. Morrison. "Furthermore, the data demonstrate long-term, strong, and consistent outcomes. The industry will benefit from long-term data like this so that physicians and patients can be confident in their treatment choice."

The original VeClose Study was a U.S. pivotal clinical trial that was conducted under an investigational device exemption (IDE) as a prospective, randomized, controlled trial comparing the safety and effectiveness of the VenaSeal Closure System to RFA. VeClose Study outcomes have been previously reported, and the study has since concluded.

"The Medtronic commitment to long-term clinical evidence and improving patient outcomes is underscored by the release of this five-year VeClose Extension Study data," said Sandra Lesenfants, vice president and general manager of the endoVenous business, which is part of the Aortic, Peripheral, and Venous division at Medtronic. "VenaSeal has already been used in more than 100,000 procedures and that number is growing daily. We want to continue to expand minimally invasive innovation to improve the quality of life for all patients with venous disease."

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 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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