Medtronic News

New Medtronic Data Demonstrate Clinical and Quality of Life Benefits for VenaSeal Closure System in Venous Reflux Disease Patients

Three-Year VeClose Trial and One-Year WAVES Study Data Presented at Charing Cross

DUBLIN and LONDON - April 25, 2017 - Medtronic plc (NYSE: MDT) today announced three-year outcomes from the VeClose U.S. pivotal clinical trial and one-year data from the WAVES study. Both results were presented by Kathleen Gibson, M.D., of Lake Washington Vascular in Bellevue, Wash., at the 2017 Charing Cross Symposium in London. The new data demonstrate the clinical and quality of life benefits of the Medtronic VenaSeal(TM) closure system in treating patients with venous reflux disease.

Three-Year Data from VeClose Trial

The VeClose U.S. pivotal clinical trial is a prospective, randomized, controlled trial comparing the safety and effectiveness of the VenaSeal closure system to the Medtronic ClosureFast(TM) endovenous radiofrequency ablation (RFA) procedure in a non-inferiority design. The trial enrolled 242 patients with symptomatic refluxing great saphenous veins (GSV), of which 222 were randomized 1:1 to receive treatment with VenaSeal or ClosureFast.

At three-years, the complete closure of the GSV was achieved in 94.4 percent of patients treated with VenaSeal compared to 91.9 percent of patients treated with ClosureFast - showing both the continued long-term, non-inferior outcomes (p=0.005) and the durability of the treatment.

Additionally, 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 scores. In all three assessments, patients treated with either VenaSeal or ClosureFast reflected statistically significant improvement from baseline.

"The three-year outcomes for this randomized trial reinforce the consistent clinical performance of VenaSeal and ClosureFast," said Dr. Gibson. "These long-term VenaSeal data along with post-market WAVES study results continue to build on the prior findings for this innovative treatment option for venous reflux disease, demonstrating safety, effectiveness, and quality of life."

One-Year WAVES Study Data Presented for the First Time

In a separate session at Charing Cross, Dr. Gibson presented the one-year data from the independent, physician-initiated WAVES study, demonstrating quality of life impacts along with safety and effectiveness of the VenaSeal closure system. The single-center study enrolled 50 patients in a real-world assessment of the treatment of one or more incompetent truncal veins in a single setting without mandatory post-operative compression stockings.

Key findings from the WAVES study are summarized as follows:

- The one-year GSV closure rate for VenaSeal was 100 percent. In comparison, the GSV closure rate for VenaSeal in VeClose, which required post-operative compression stockings, was 96.8 percent. Further, the mean vessel diameter in WAVES was larger than in VeClose.
- The mean time for patients' return to work was 0.2 days ± 1.1 days. Furthermore, the mean time for returning to normal activities, including a patient's exercise routine, was 2.4 days ± 4.1 days.

"The data presented at Charing Cross further demonstrate the VenaSeal closure system as a safe and effective therapy for treating venous reflux disease," said Sandra Lesenfants, vice president and general manager of the endoVenous business, which is part of the Cardiac and Vascular Group at Medtronic. "Together with the clinical community, we look forward to continuing our investment in clinical research to support the use of this innovative, minimally invasive treatment for venous reflux disease."

About VenaSeal Closure System

VenaSeal closure system is a non-tumescent, non-thermal, non-sclerosant procedure that uses a proprietary medical adhesive to close superficial veins of the lower extremities, such as the great saphenous vein (GSV), in patients with symptomatic venous reflux.

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 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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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Contacts:
Krystin Hayward Leong
Public Relations
+1-508-261-6512

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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