Medtronic News

Medtronic Launches IDE Study to Evaluate the Abre(TM) Venous Self-Expanding Stent System in Patients with Deep Venous Disease

Study to Enroll Subjects at up to 35 Sites Across the U.S. and Europe

DUBLIN - January 26, 2018 - Medtronic plc (NYSE: MDT) today announced the initiation of its investigational device exemption (IDE) study for the Abre(TM) venous self-expanding stent system. The ABRE IDE Study will evaluate the safety and effectiveness of the Abre stent in subjects with iliofemoral venous outflow obstruction. The first procedure was performed in December of 2017, by Dr. Erin Murphy, director of the venous and lymphatic program at Carolinas HealthCare System's Sanger Heart & Vascular Institute in Charlotte, North Carolina, and national principal investigator for the ABRE IDE Study in the U.S.

The multi-center, single arm study intends to enroll 200 subjects with deep venous disease from up to 35 sites throughout the U.S. and Europe. The primary efficacy endpoint will evaluate patency at 12 months, which is defined by freedom from occlusion and freedom from clinically-driven target lesion revascularization (CD-TLR). The primary safety endpoint will evaluate the incidence of composite Major Adverse Events (MAE) at 30 days following stenting of an obstruction in the iliofemoral venous segment. Data from the study will be used to support the Abre stent U.S. pre-market approval (PMA) application for the treatment of symptomatic iliofemoral venous outflow obstruction in patients with venous occlusive disease.

"The launch of the ABRE IDE Study marks the beginning of an important journey to establish new options for the treatment of deep venous disease," said Dr. Murphy. The first procedure was performed at Sanger Heart & Vascular Institute on a patient with Nonthrombotic Iliac Vein Lesion (NIVL) who is doing well post-treatment. We are excited to continue enrollment at our sites throughout the U.S. and Europe."

Medtronic estimates deep venous obstruction affects more than 24 million individuals worldwide. Deep venous obstruction occurs when veins in the deep venous system become compressed and restrict blood flow. It can result in discomfort and pain, limit a patient's mobility, and impair quality of life.

The Abre stent is an investigational device in the U.S. intended for permanent implant in the iliofemoral vein. It is pre-mounted on a 9 French delivery system and features a nitinol stent with a tri-axial shaft design. The stent utilizes an open-cell design with three connection points between the cells that are intended to enable flexibility and conformability. Upon deployment, the Abre stent uses an optimized balance of strength and flexibility to exert an outward force and open the vein.

"Deep venous disease can cause pain, swelling, and blood clots, which can potentially be devastating to patients," said Stephen Black, M.D., consultant vascular surgeon, Guy's and St. Thomas' Hospital, London and European principal investigator for the ABRE IDE Study. "As a result, there is a critical need for treatment options that are safe, effective, and durable. We look forward to using the Abre stent in the restoration of patency in patients with deep venous disease."

"With the growth of our superficial venous product portfolio, we have established ourselves as leaders in this space. Now, with our entry into the deep venous space, we are well positioned to offer a comprehensive portfolio for the treatment of venous disease," said Sandra Lesenfants, vice president and general manager of the endoVenous business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "While our entrance into the deep venous space is recent, we believe the ABRE IDE Study and our regulatory approval in

Europe positions us well for future growth in this area. We look forward to continuing to enroll patients in the IDE study and working with the clinical community to address critical needs of patients with deep venous disease."

In the U.S., Abre is an investigational device and not yet approved for commercial use. Abre received CE (Conformité Européene) Mark approval in April of 2017 and is intended for use in the iliofemoral veins for treatment of symptomatic venous outflow obstruction.

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 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 84,000 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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