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ABRE clinical study 36-month data shows sustained effectiveness of Abre™ venous self-expanding stent system

Study data show clinically meaningful impact on quality of life and disease severity, even in the most complex patients

Medtronic, a global leader in medical technology, today announced the 36-month final results from the ABRE clinical study. The purpose of the ABRE clinical study was to evaluate the safety and effectiveness of the Abre venous self-expanding stent system, intended for the treatment of symptomatic iliofemoral venous outflow obstruction.

The study results were presented in a late-breaking clinical trial session at the American Vein and Lymphatic Society (AVLS) 2022 annual meeting. Professor Stephen Black, M.D., consultant vascular surgeon, Guy's and St. Thomas' Hospital, London and co-principal investigator for the ABRE Study, presented the data.

“The 36-month ABRE data has continued to demonstrate the long-term durability of interventions in patients suffering from deep venous disease,” Professor Black said. “The results show a sustained result in both technical aspects, but more importantly, in patient outcomes.”

The ABRE Study included a complex set of patients. Within this patient group:

- 47.5% of subjects were categorized as having post-thrombotic syndrome (PTS),
- 35.8% of PTS subjects presented with a complete venous occlusion confirmed by the core lab
- Mean lesion length of subjects was 112.4 mm
- 44.0% of subjects had stents that extended below the inguinal ligament.

Of note, the study results showed:

- Overall, effectiveness following treatment with the Abre venous stent was sustained through 36 months as evidenced by a Kaplan-Meier estimated primary patency rate of 81.6% and a Kaplan-Meier estimated freedom from clinically driven target lesion revascularization (CD-TLR) rate of 89.3%.
- No stent fractures or delayed stent migrations were reported through 36 months.
- Sustained and clinically meaningful improvements were observed through 36 months compared to baseline

as measured by EQ-5D and VEINES-QoL quality of life.

- Sustained and clinically meaningful improvements through 36 months as measured by Villalta and VCSS venous functional assessments indicates less severity of PTS disease and venous disease overall.

“Medtronic is strongly committed to the deep venous market. As the 36-month results show, the Abre venous stent system safely and effectively treats venous disease,” said Dave Moeller, president of the Peripheral Vascular Health Operating Unit at Medtronic. “This study included many patients with highly challenging cases, showing that Abre is meaningfully able to improve patients’ quality of life – including those with severe disease – for a long period.”

About the ABRE Study

The ABRE Study is a prospective, interventional, single-arm, multi-center, worldwide study. The study enrolled subjects across the spectrum of deep venous disease, including those with post-thrombotic syndrome (PTS), non-thrombotic iliac vein lesions (NIVL), and those who presented with an acute deep vein thrombosis (aDVT). Professor Stephen Black, M.D., consultant vascular surgeon, Guy's and St. Thomas' Hospital, London, and Dr. Erin Murphy, M.D., FACS, Director Venous and Lymphatic Program, Sanger Heart and Vascular, Atrium Health, Charlotte, NC, are co-principal investigators for the ABRE Study.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solu tions. Our Mission – to alleviate pain, restore health, and extend life – unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.medtronic.com.

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.

For more information contact:
Laura Hennen
Public Relations
+1-763-213-3034

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