Medtronic News

Medtronic Valiant(TM) Captivia(TM) Demonstrates Durability, Safety, and Efficacy at Five Years in Transection Patients

New RESCUE Trial Data Presented in Blunt Thoracic Aortic Injury

DUBLIN and SAN DIEGO - January 30, 2019 - Medtronic plc (NYSE:MDT) today announced new data supporting the long-term durability, safety, and efficacy of the Valiant(TM) Captivia(TM) thoracic stent graft system for the treatment of blunt thoracic aortic injury (BTAI). The presentation by Himanshu J. Patel, M.D., University of Michigan Department of Cardiac Surgery at The Society of Thoracic Surgeons Annual Meeting, was the first and only five-year industry-issued dataset ever reported for patients with aortic transections undergoing thoracic endovascular aortic repair (TEVAR).

BTAI is an emergency medical condition in which the aorta is damaged due to traumatic force to the chest, usually the result of elevated falls or other high-impact injuries such as motor vehicle accidents. It is the second leading cause of traumatic death after head injuries. The data presented today by Dr. Patel came from the Evaluation of the Clinical PeRformancE of the Valiant Thoracic Stent Graft with the Captivia Delivery System for the EndovaSCUlar TrEatment of Blunt Thoracic Aortic Injuries (RESCUE) trial, a long-term study of this high-risk cohort of patients.

"These data from the RESCUE trial demonstrate that TEVAR with Valiant Captivia continues to be a valuable, safe, and less invasive alternative to open surgery for patients facing life-threatening aortic injury of BTAI, especially in the setting of critical multi-system injuries," said Dr. Patel. "This is the first five-year industry-issued dataset ever disseminated. The outcomes demonstrate Valiant Captivia to be a safe and durable therapy for high-risk BTAI patients."

The RESCUE study is a prospective, multi-center, non-randomized, descriptive study that evaluated a total of 50 patients with BTAI of the descending thoracic aorta. Subjects enrolled had a mean injury severity score (ISS) of 38.4 ± 14.4 and 70 percent (35/50) of BTAI extent was grade III or higher, including one grade IV free rupture, indicative of this extremely high-risk patient cohort. The extent of arch repair required full (40.0 percent, 20/50) or partial (18.0 percent. 9/50) left subclavian artery coverage. Of the 31 patients available at five years, 90.3 percent (28/31) received clinical follow-up, while 67.7 percent (21/31) received imaging follow-up.

Data highlights at five-year follow up:

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- Kaplan Meier Freedom from All-Cause Mortality of 85.2 percen
- No stroke or spinal cord ischemia observed
- 100 percent freedom from Type I or III endoleaks
- Kaplan-Meier Freedom from Secondary Procedures of 90.6 percent
- 100 percent freedom from retrograde type A dissections, conversions to open repair, or aortic perforations
- 100 percent complete exclusion of the traumatic injury maintained
- No instances of stent graft kinking, fracture, loss of patency, or migration

"The Valiant Captivia five-year transection results demonstrate our commitment to life-saving treatments, and transparency in reporting long-term data to improve patient safety," said John Farquhar, vice president and general manager of the Aortic business, which is part of the Aortic, Peripheral, and Venous division at Medtronic. "These data also support our continuing focus on providing safe and durable endovascular repair to patients who have traditionally been challenging to treat."

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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