Medtronic News

Valiant Captivia Thoracic Stent Graft System From Medtronic Receives FDA Approval for Treating Aortic Dissections

Supported by Recently Presented Study Results, New Indication Expands Treatment Options for Patients with Dangerous Tear in Upper Segment of Body's Main Artery

MINNEAPOLIS -- Jan. 28, 2014 -- Continuing to expand the role of endovascular aortic repair, Medtronic, Inc. (NYSE: MDT) has received approval from the U.S. Food and Drug Administration (FDA) for the Valiant Captivia Thoracic Stent Graft System to be used in the treatment of type B aortic dissections, a serious cardiovascular condition associated with high morbidity and mortality in which the upper segment of the body's main artery has become torn along the innermost layer of the vessel wall.

Supported by the results of the U.S. Medtronic DISSECTION trial, the new indication expands treatment options for this challenging patient population by providing physicians with a minimally invasive alternative to open surgical repair and medical therapy.

"Acute type B aortic dissection is a potentially life-threatening condition that historically has been treated with either medical therapy or, when necessary, through invasive surgical techniques," explained Joseph Bavaria, MD, professor of surgery and director of the thoracic aortic surgery program at the University of Pennsylvania in Philadelphia, and a national principal investigator for DISSECTION.

"The trial we conducted shows that endovascular repair with the Valiant Captivia System provides a safe, effective and potentially life-saving treatment option for acute dissection patients."

Trial Results

Presented by Dr. Bavaria yesterday at the 2014 annual meeting of the Society for Thoracic Surgery, 12-month data from the 50 patients evaluated in Dissection demonstrate safety and efficacy of the Valiant Captivia System in the treatment of dissections, with excellent technical success.

Conducted at 16 U.S. sites, the trial met its primary safety endpoint by achieving an 8 percent all-cause mortality rate at 30 days, which represents a three- to four-fold mortality improvement over open surgical repair.[1],[2] Additionally, 100 percent technical success and 100 percent coverage of the primary entry tear at implant were achieved in the trial.

Rodney White, MD, chief of vascular surgery at Harbor-UCLA Medical Center in Torrance, Calif., and the trial's leading enroller, added: "Data out to one year continue to show positive aortic remodeling of the stented segment, with a 100 percent increase in true lumen volume and no ruptures."

Indicated for a variety of thoracic aortic lesions, the Valiant Captivia System features a unique proximal tip-capture mechanism, which enables controlled deployment and accurate placement of the stent graft. Based on independent conformability bench testing of multiple thoracic stent grafts, the Valiant stent graft is the only device that maintains complete apposition to the vessel wall regardless of angulation or oversizing.[3] Since its initial 2005 launch in Europe, the Valiant stent graft has been implanted in about 50,000 patients worldwide -- more than any device of its kind.

Other Studies

The growing body of evidence in support of thoracic endovascular aortic repair (TEVAR) as a treatment for type

B aortic dissection also includes other studies, many of which Medtronic has sponsored.

Some of the most notable and robust long-term data come from a landmark randomized controlled trial called INSTEAD XL, which evaluated 140 patients with stable type B aortic dissections who were equally randomized to optimal medical therapy and TEVAR or to optimal medical therapy alone.

Published in *Circulation: Cardiovascular Interventions* in August 2013 by Christoph Nienaber *et al.,* the five-year results from INSTEAD XL demonstrate significant improvement in long-term survival, delayed disease progression and fewer late complications with TEVAR plus medical therapy compared with medical therapy alone.[4]

In addition to INSTEAD XL and DISSECTION, other clinical research on TEVAR that Medtronic has sponsored includes:

- VIRTUE, the first TEVAR registry to evaluate patient outcomes by timing of diagnosis; and
- MOTHER, a TEVAR registry of more than 1,000 patients with a variety of pathologies that includes more than 300 patients treated for dissection.

"We have an abiding interest in supporting high-quality studies that yield the clinical evidence required to characterize the long-term safety, efficacy and cost-effectiveness of our devices," said Tony Semedo, a senior vice president at Medtronic and president of the company's Endovascular Therapies business. "That interest is evident in our ongoing support of various TEVAR studies."

Line Extension

In a related development, Medtronic recently expanded the size matrix of the Valiant Captivia Thoracic Stent Graft System with 11 new proximal FreeFlo tapered pieces, increasing configuration possibilities by 30 percent to address a wider range of patient anatomies.

The line extension enables physicians to use the market-leading thoracic stent graft system in tapered aortas, which account for approximately 20 percent of all thoracic aortic aneurysm cases.[5] The new pieces all taper by 4mm along their approximately 150mm length, and have proximal diameters that range from 26mm to 46mm. These additional system components received FDA approval, the CE *(Conformité Européene)* Mark and Health Canada approval in January, but their approved indications vary by geography: in Europe, they are approved for use in treating thoracic aortic aneurysms, transections and dissections; in the United States, for thoracic aortic aneurysms and transections; and in Canada, for thoracic aortic aneurysms.

"The anatomy of the thoracic aorta is complex and unique to every individual," said Matt Thompson, MD, professor of vascular surgery at St. George's Hospital in London and the MOTHER registry's primary investigator. "For patients with tapered aortas, thoracic endovascular aortic repair is not always straightforward and requires careful device sizing to ensure treatment success. The addition of tapered pieces to the Valiant Captivia System provides physicians with more options to confidently and effectively accommodate both straightforward and challenging anatomies."

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular diseases and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

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:
Joseph McGrath
Public Relations
+1-707-591-7367

Jeff Warren
Investor Relations
+1-763-505-2696

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