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Two-Year Data from INNOVATION Trial on INCRAFT® AAA Stent Graft System Continues to Demonstrate Safety and Performance in Treatment of Abdominal Aortic Aneurysms

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Fremont, Calif., January 28, 2014 - Cordis Corporation today announced the presentation of two-year data from its INNOVATION Trial at the 2014 Leipzig Interventional Course (LINC) in Germany. Data from the study continues to demonstrate that the INCRAFT® System performs well in patients suffering from abdominal aortic aneurysms (AAA) two years after treatment.

"These positive results are encouraging and build on the favorable short and mid-term outcomes of the INCRAFT® System observed in the recently published one-year results of the INNOVATION Trial," said Prof. Gioachino Coppi, MD, Department of Vascular Surgery at the University of Modena in Italy. "In light of these results and the unique low-profile configuration of the device, Cordis' INCRAFT® System has the potential to be a valuable alternative to current devices on the market. The system is designed to offer increased applicability in the broad spectrum of anatomical sizes encountered in patients undergoing endovascular aneurysm repair."[1]

The INNOVATION Trial is a multicenter, open-label, prospective study designed to assess the safety and performance of the device in the treatment of patients with AAA with investigational sites in Germany and Italy. Study Investigator Prof. Giovanni Torsello, MD, of the University Hospital Münster in Germany presented the two-year results of the INNOVATION study at LINC. At two years, there were no incidences of aneurysm enlargement, endoleaks (type I, III or IV), device or procedure related major adverse events, stent-graft migrations or stent fractures. One patient in the study developed a late graft occlusion unrelated to the device that was caused by shrinkage of the aneurysm.[2]

"We are very pleased with these excellent longer term results and look forward to making our INCRAFT® System available to clinicians in need of alternative therapeutic options for patients suffering from abdominal aortic aneurysms," said Celine Martin, Worldwide President, Cordis Corporation. "The INCRAFT® System was designed to address some of the limitations of current AAA stent-grafts and to increase access to this life-saving therapy to a broader range of patients including those with small or diseased vasculature."

The INCRAFT® System is an endovascular stent graft used in the treatment of AAA featuring an integrated delivery system with an ultra-low profile equivalent to that of a regular 13 French catheter sheath introducer. Most traditional endovascular aortic repair (EVAR) stent grafts have a system profile ranging from 16 to 22 French in size. This ultra-low profile device is designed for proximal and distal placement accuracy and can be customized during the procedure. The INCRAFT® System provides broad anatomical coverage with a minimal number of product codes to support ease of procedural planning.

The INCRAFT® System is approved for investigational device use only and it not for sale anywhere in the world. The device is currently being investigated in a global pivotal clinical study in the U.S. and Japan called the INSPIRATION Trial, which completed enrollment in August 2013. One-year follow-up data from the trial will support a Premarket Approval application to the U.S. Food and Drug Administration and a Shonin application in Japan.

About AAA and Endovascular Aortic Repair

An estimated 24 million people worldwide suffer from abdominal aortic aneurysms (AAA), an abnormal enlargement of the large blood vessel (aorta) that supplies blood to the abdomen, pelvis and legs. Left untreated, most aneurysms will eventually rupture, with life-threatening consequences. In the U.S. alone, approximately 15,000 people die every year due to an AAA rupture. Endovascular aneurysm repair (EVAR) is a minimally invasive alternative to open surgery for the repair of AAAs. The procedure involves the placement of a stent graft into the aneurysm through a small incision in the groin to prevent it from rupturing.

About Cordis Corporation

Cordis Corporation, part of the Johnson & Johnson family of companies, is a worldwide leader in the development and manufacture of interventional vascular technology. Through the company's innovation, research and development, Cordis partners with interventional cardiologists worldwide to treat millions of patients who suffer from vascular disease. More information about Cordis Corporation can be found at www.cordis.com.

[1] Coppi et al. INCRAFT® Stent-Graft System: one-year outcome of the INNOVATION Trial; J Cardiovasc Surg 2014; 55:51-9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24356046

[2] Cordis data on file

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