Fenestrated Endovascular Aneurysm Repair (FEVAR) Demonstrates Excellent Outcomes: Midterm Data From Starnes' Physician-Sponsored IDE

Starnes' Methodology has been Replicated and Automated by Aortica™ Corp.

February 23, 2017—BELLEVUE, WA—Benjamin W. Starnes, MD, Chief of Vascular Surgery at the University of Washington and one of the world's foremost authorities on the treatment of abdominal aortic aneurysms (AAA) announced midterm results from his physician-sponsored IDE study, administered in conjunction with Harborview Medical Center. The ongoing study evaluates physician-modified endovascular grafts (PMEG) for the treatment of juxtarenal aortic aneurysms and assesses a new technology developed by Aortica™ Corporation that could significantly reduce the need for invasive open surgery in patients with aneurysms originating too close to branch arteries that supply blood to vital organs. Results from the first 60 patients using manual planning were recently published in the February issue of the *Journal of Vascular Surgery* (JVS).

The midterm results (out to 4 years) in non-operative candidates are highly favorable and confirm an early report of clinical success with low morbidity and mortality. Ninety four percent (94%) of patients met the primary effectiveness endpoint and the overall major adverse event rate was low at 12%. In addition, no patient required conversion to open surgical repair. "With a remarkably low rate (6%) of aneurysm related mortality, 100% branch artery patency, and no type 1a endoleaks out to 4 years along with a sac regression or stabilization rate of 95%, this report supports the use of fenestrated endografts as an effective and durable repair in patients who suffer from juxtarenal AAA," stated Dr. Starnes.

"In our study, we utilize a system which dramatically simplifies the FEVAR procedure," Dr. Starnes added. "The system digitizes a patient's CT scan, utilizes software algorithms to account for the effect of the implant on the geometry of the anatomy, and creates an exact replica of each patient's aortic anatomy as it would look with the introduction of the implant. We then modify an 'off-the-shelf' endograft with fenestrations to precisely match each patient's anatomy." This system has been advanced by an early stage privately held company founded by Starnes called Aortica™ Corporation, which has replicated and automated the manual technique that Dr. Starnes has used successfully in over 300 cases. The AortaFit™ automated FEVAR case planning software was incorporated into his study in early 2016 and has been used successfully in over 20 patients.

Dr. Starnes continued, "These midterm results exceed those of alternative therapies in high risk patients and surpass even standard EVAR in several studies. We have found that a well-planned fenestrated EVAR will optimize two critical success factors. First is the "Effective Seal Zone Length," meaning by using fenestrations we place the graft higher up in the aortic anatomy and obtain seal from the proximal edge of the graft fabric all the way to the beginning of the aneurysm. This allows for secure anchoring of the endograft in healthy parallel walled aortic tissue. Second is "Circumferential Seal Zone," meaning by using fenestrations rather than scallops we create a circumferential seal along the entire effective seal zone length. I believe these are key factors contributing to the absence of type 1a endoleaks out to 4 years. We are securely anchoring and sealing

the fenestrated endograft in healthy aortic tissue while allowing continued blood flow to vital arteries," stated Starnes. "As we gain more experience with the automated approach using Aortica's AortaFit™ System, the next step will be collaboration with an endograft manufacturer, moving beyond 'physician modification' of endografts to a more elegant, simplified and rapid 'direct manufacture' of a FEVAR graft. I believe FEVAR will then become the preferred method of treatment for the vast majority of juxtarenal AAA patients and perhaps any AAA patients with disease in the infrarenal neck."

About Abdominal Aortic Aneurysm (AAA) Disease

Each year approximately 525,000 people worldwide are diagnosed with abdominal aortic aneurysms (AAA). An aneurysm is a large bulge in the aorta (the largest artery in the human body). It can gradually expand over time—without any symptoms—until it bursts, causing massive internal bleeding that results in death if not treated at a specialized center immediately. For years, major open surgery was the only treatment option, which is risky due to its complicated nature and because it carries a 3.0% mortality rate within 30 days of surgery.

About Endovascular Aneurysm Repair (EVAR) & Fenestrated EVAR (FEVAR)

In the 1990's, a new technique for controlling aneurysms was developed using a graft inserted through the femoral arteries. This technique is called **e**ndo**v**ascular **a**neurysm **r**epair (EVAR). EVAR is significantly less invasive than open surgery and is associated with a mortality rate six times lower. Patients recover faster, leave the hospital sooner, and return to activities of normal daily life more quickly. Consequently, EVAR has become the gold standard for treatment of AAA disease. Unfortunately, approximately 40% of patients are not candidates for EVAR because their aortic anatomy is structured in a manner that does not allow an endograft to be anchored properly without blocking blood flow to vital organs. These juxtarenal patients face either open surgery or may be treated sub-optimally with standard EVAR. FEVAR involves placing reinforced, radiopaque holes (or fenestrations) in the endograft that align with branch arteries. This allows the physician to place the graft higher up in the aortic anatomy allowing for reliable anchoring and secure seal, while preserving blood flow to vital organs.

About Aortica Corporation

Aortica Corporation was founded to design, manufacture, and market tools for treatment of patients with juxtarenal AAA disease. Aortica is dedicated to simplifying Fenestrated EVAR (FEVAR), and advancing the science of Personalized Vascular Therapy.

For further information on Aortica, visit the company's website at www.aorticacorp.com

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