TriVascular, Inc. Receives U.S. Humanitarian Device Exemption Approval for the Ovation™ Abdominal Stent Graft System

First of its kind approval expands access to minimally invasive aortic repair

Santa Rosa, CA, November 2, 2011 – TriVascular, Inc. today announced the approval of the Ovation™ Abdominal Stent Graft System by the US Food and Drug Administration (FDA) under a Humanitarian Device Exemption (HDE). This is the first HDE granted by the FDA in the field of Abdominal Aortic Aneurysm (AAA) treatment. With this approval, patients previously ineligible for Endovascular Aneurysm Repair (EVAR) will gain access to a minimally invasive therapy.

"The design and available sizing of the Ovation Abdominal Stent Graft are well suited to treat patients with small aortic anatomy who are currently left without less invasive treatment options," said Michael Dake, MD, Professor of Cardiothoracic Surgery and Medical Director, Catheterization and Angiography Laboratories, Stanford University Hospital. "Coupled with Ovation's extremely low profile, 14F OD delivery system, this Humanitarian Use Device will expand treatment options for patient groups currently underserved by EVAR, such as women."

At 14F OD, Ovation is the lowest profile commercially available AAA device. The innovative, low profile system separates and optimizes the two most important elements of EVAR, fixation and seal, and is designed to expand the pool of treatable patients by addressing a wider range of diseased anatomy.

"We are thrilled to receive the first-ever HDE approval in EVAR and are excited to partner with physicians across the United States," said Michael Chobotov, Ph.D., President and CEO of TriVascular, Inc. "This represents an important step in expanding access to minimally invasive treatment for patients with aortic disease."

TriVascular's Ovation Abdominal Stent Graft System was launched commercially in Europe in January 2011. In the United States, the pivotal study of the Ovation Abdominal Stent Graft completed enrollment in March 2011. Enrollment in the Continued Access study is ongoing.

Under the HDE, Ovation is approved for use in patients with access vessels of less than 7mm in diameter and aortic necks with lengths of at least 7mm and diameters between 15.5mm and 17.4 mm.

About TriVascular, Inc. - TriVascular's initial product offerings are novel endovascular grafts focused on significantly advancing EVAR. Building upon partnerships with thought leading clinicians worldwide, TriVascular's products are designed to address unmet clinical needs and expand the pool of patients who are candidates for EVAR. Based in Santa Rosa, California, TriVascular offers highly talented, motivated individuals the opportunity to positively impact global healthcare.

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