TriVascular Annouces Post-Approval Study of the Ovation Prime

TriVascular

TriVascular has announced the initiation of a U.S. Post-Approval Study (PAS) of the Ovation Prime Abdominal Stent Graft System for the treatment of abdominal aortic aneurysms (AAA). The study's national principal investigator will be Dr. Syed Hussain, Director of Vascular and Endovascular Surgery at OSF/HeartCare MidWest and Assistant Clinical Professor of Surgery at University of Illinois College of Medicine in Peoria, Illinois.

The Ovation™ System received Premarket Approval (PMA) from the U.S. Food and Drug Administration in October 2012 and the Ovation Prime System received PMA approval in December 2012. Both systems are approved and are marketed throughout Europe. To date, over 2,000 patients worldwide have undergone a successful EVAR procedure with either the Ovation or Ovation Prime System, with nearly 500 of these patients treated in the United States.

"The Ovation device allows us to treat AAA patients that otherwise would not have been candidates for EVAR therapy. In our clinical experience, we have found the Ovation stent graft's low profile and unique O-ring sealing technology to be highly effective in treating both straightforward and challenging anatomies," said Dr. Hussain. "We are impressed with the Ovation System's capability to expand EVAR to a broader AAA patient population including patients with narrow access arteries, short aortic necks and other challenging anatomies. We are very excited to partner with TriVascular on this study."

The Ovation Prime System has the broadest set of indications for use (IFU) of any approved abdominal stent graft system. Nearly 40% of the patients treated in the

Ovation IDE pivotal study had complex anatomies, with proximal neck lengths shorter than 10 mm, distal access vessels smaller than 6 mm, or, in some patients, both. The Ovation and Ovation Prime devices are approved for placement using the minimally invasive percutaneous access technique known as PEVAR; 43% of patients treated in the Ovation IDE pivotal study were treated percutaneously. The results from the Ovation IDE pivotal study reported no device related major adverse events, no aneurysm ruptures, and no type I or type III endoleaks. In addition, TriVascular has enrolled and successfully treated over 400 patients in a 30-center, European post-market registry (PMR), further bolstering the body of clinical evidence in support of the Ovation System. The U.S. PAS is a prospective, multi-center study that will further evaluate the safety and effectiveness of the Ovation Prime System in a routine clinical setting. As in the IDE trial and the PMR study, the PAS will include patients with challenging anatomies given the Ovation device's expanded IFU.

"We believe aneurysm access advantages enabled by our low profile system, combined with our unique O-Ring sealing technology will enable physicians to offer this clinically proven minimally invasive therapy to a significant number of patients previously not considered candidates for EVAR," said Christopher G. Chavez, Chairman, CEO and President of TriVascular, Inc. "We are excited about the Ovation Prime System's clinical potential and thank our clinical investigators, whose partnership allows us to improve EVAR and make EVAR available to more patients."

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