Two-Year Clinical Study Supports Safety and Efficacy of Covidien Solitaire™ FR Revascularization Device

The Associated Press

MANSFIELD, Mass.--(BUSINESS WIRE)--Feb 7, 2013--Covidien (NYSE:COV), a leading global provider of healthcare products, today released the results of the Solitaire™ FR Thrombectomy for Acute Revascularization (STAR) study. The two-year study evaluated the safety and efficacy of the Solitaire FR revascularization device in the treatment of acute ischemic stroke.

Covidien's Solitaire FR device is designed to restore blood flow in patients experiencing ischemic stroke. (Photo: Business Wire) Acute ischemic stroke (AIS) is the most prevalent form of stroke, representing up to 87% of all stroke-related cases worldwide. 1 In AIS, the patient suffers from an acute blockage of blood flow (ischemia) to the brain, which, if not treated in a timely manner, leads to permanent neurological damage and possibly death. In 2008, the direct and indirect cost of stroke in U.S. was $39 billion. 2 Covidien’s Solitaire FR device is designed to restore blood flow in patients experiencing ischemic stroke. The device, based on advanced overlapping stent technology, is used to mechanically remove blood clots from blocked vessels.

“The findings of the STAR study reflect the recent advances in stroke treatment,” said Jan Gralla, MD, MSc, STAR Principal Investigator, Department of Diagnostic and Interventional Neuroradiology, Inselspital, University of Berne, Switzerland. “In highly specialized stroke centers, endovascular treatment using novel stent retriever technology results in high rates of good functional outcome and low morbidity.” STAR Study Design and Findings The prospective, multi-center, single arm clinical study started with an enrollment of 202 patients at 14 centers across Europe, Australia and Canada in May 2010, with the last patient completing participation in October 2012. In the study, patients diagnosed with AIS (as confirmed by radiographic assessment) were treated with the Solitaire FR device in order to reopen, or recanalize, the blocked blood vessels. The results of the STAR study indicated that 84.2% (160/190) of patients with complete angiographic data sets and 79.2% (160/202) of patients with missing angiographic data, as determined by an independent Core Lab, achieved the highest degree of recanalization (TICI 2b/3). Long-term follow-up was obtained at 90 days to evaluate neurological health. Using the Modified Rankin Score (mRS), 57.9% achieved a score of 2 or less, indicating functional independence, with little to no disability. In addition, an independent Clinical Events Committee reported a 6.9% (14/202) mortality rate and a 1.5% (3/202) symptomatic intracranial hemorrhage rate.

“In the wake of the failed IMS III Study, a NINDS-funded randomized controlled trial, there will be some physicians who will question the benefit of mechanical thrombectomy,” said Vitor Mendes Pereira, M.D., MSc, STAR Principal Investigator,

Head of Interventional Neuroradiology, University Hospital of Geneva, Switzerland. “The results of the STAR prospective, multi-center clinical study demonstrate that mechanical thrombectomy is both safe and effective for the treatment of acute ischemic stroke when treating the right patients, in comprehensive stroke centers, with the Solitaire FR device.” The results of the STAR clinical study indicate that treatment with the Solitaire FR device in intracranial anterior circulation occlusions is associated with: Low risk of clinically relevant procedural and device-related complications; High rates of revascularization (TICI ≥2b) and Good Clinical Outcomes (mRS 0-2); and Low mortality at 90 days. The data also support the further investigation of the Solitaire FR device in a Randomized Controlled Trial against best medical treatment.

“We are pleased to report that the STAR study adds to the growing body of evidence supporting the use of the Solitaire FR device as a superior tool for revascularization in acute ischemic stroke care,” said Mark A. Turco, MD, Chief Medical Officer, Vascular Therapies, Covidien. “Given the medical and economic burden of AIS to patients and healthcare systems, there is an urgent need to develop innovative solutions for the timely, safe and effective treatment of acute ischemic stroke. The Solitaire FR device represents new hope in addressing this widespread public health issue.” About AIS and the Solitaire FR Revascularization Device In the U.S., AIS afflicts approximately 800,000 patients annually and this number is expected to increase by 22% in the next 20 years. 2 It is estimated that, on average, 1.9 million neurons are lost every minute an AIS goes untreated. 3 AIS leads to regions of brain tissue that have no blood supply and are at risk for permanent tissue damage.

Strokes in general are the leading cause of adult disability in the Western world and are the second leading cause of death worldwide. 4 The Solitaire FR revascularization device is intended to restore blood flow by removing blood clots from a large intracranial vessel in patients experiencing ischemic stroke within eight hours of symptom onset. It is designed for mechanical blood clot removal in the neurovasculature, including the internal carotid artery, M1 and M2 segments of the middle cerebral artery, Basilar and vertebral arteries. The Solitaire FR received CE Mark approval in 2009 and U.S. Food and Drug Administration 510(k) clearance in 2012.

About Covidien Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2012 revenue of $11.9 billion, Covidien has 43,000 employees worldwide in 70 countries, and its products are sold in over 140 countries. Please visit www.covidien.com to learn more about our business.

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