NEWS RELEASE
TSX Venture Exchange: NVC

NEOVASC REDUCER™ ACHIEVES PRIMARY ENDPOINT IN COSIRA TRIAL, SIGNIFICANTLY IMPROVING FUNCTIONAL CAPABILITIES IN PATIENTS WITH REFRACTORY ANGINA

—Primary Efficacy Endpoint Achieved in Multicenter, Prospective, Randomized, Sham-Controlled Trial Assessing Novel Percutaneous Device in Untreatable Patients Severely Disabled by Angina—

Vancouver, BC, Canada – November 6, 2013 – Neovasc Inc. (TSXV: NVC) today reported topline results for its COSIRA trial assessing the efficacy and safety of the Neovasc Reducer™, a novel percutaneous device for the treatment of refractory angina. The data shows that the Reducer achieved its primary endpoint, significantly improving the symptoms and functioning of patients disabled by previously untreatable refractory angina. The COSIRA trial also confirmed that the Reducer is safe and well-tolerated, with no reports of device-related serious adverse events. The safety and efficacy data from the randomized, controlled COSIRA trial is consistent with results seen in previous non-randomized pilot studies of the Reducer.

The Reducer is CE-marked in the European Union for the treatment of refractory angina, a painful and debilitating condition that occurs when the coronary arteries deliver an inadequate supply of blood to the heart muscle, despite treatment with standard revascularization or cardiac drug therapies. It affects millions of patients worldwide, who typically lead severely restricted lives as a result of their disabling symptoms, and its incidence is growing. The Reducer provides relief of angina symptoms by altering blood flow in the heart’s venous system, thereby increasing the perfusion of oxygenated blood to ischemic areas of the heart muscle. Placement of the Reducer is performed using a minimally invasive transvenous procedure that is similar to implanting a coronary stent and takes approximately 20 minutes.

“These results represent a breakthrough for the millions of patients severely disabled by refractory angina who until now had few effective treatment options,” said Dr. Stefan Verhey, Senior Interventional Cardiologist at the Antwerp Cardiovascular Center / ZNA Middelheim and Principal Investigator of the COSIRA trial. “The topline data confirms that the Reducer can improve the ability of many of these patients to engage in the daily activities that can have a profound impact on their quality of life. We also find that implantation of the Reducer is safe, quick and straightforward.”

The COSIRA (Coronary Sinus Reducer for treatment of Refractory Angina) trial is a prospective, multicenter, sham-controlled, randomized, double-blinded study assessing the safety and efficacy of the Reducer in 104 patients in the European Union and Canada. Patients were randomized 1:1 between treatment and sham control arms. Its primary endpoint is a two-class improvement six months after implantation in patients’ ratings on the Canadian Cardiovascular Society (CCS) angina grading scale, a four-class functional classification that is widely used to characterize the severity of angina symptoms and disability. Only patients with severe angina, CCS Class 3 or 4, were enrolled in the COSIRA trial.

The COSIRA analysis showed that the study met the primary endpoint, with patients receiving the Reducer achieving a statistically significant improvement in CCS scores (two classes or better) compared to patients receiving a sham control (p-value = 0.024). The analysis also showed that patients treated with the Reducer showed a statistically significant improvement of one or more CCS classes compared to the sham control patients (p-value = 0.003).

Christopher White, MD, Medical Director of the John Ochsner Heart & Vascular Institute in New Orleans, commented, “Physicians are frustrated by the current lack of options for treating the growing population of refractory angina patients, who can have great difficulty simply walking to the mailbox or going to the bathroom. Reducing a patient’s angina disability by even a single class can have a major positive effect on their quality of life, so it’s very encouraging that the COSIRA data shows the Reducer improved CCS angina ratings in a
significant proportion of patients. We are also optimistic that its simplicity of implantation and strong safety data will help make the Reducer widely accessible to patients with severe angina."

Tim Henry, MD, Director of Cardiology, Cedars-Sinai Heart Institute in Los Angeles, noted, "Patients with refractory angina are a growing subset of patients and have limited treatment options. Although we await the final results, these preliminary results from the COSIRA study suggest that the Neovasc Reducer may provide an exciting new option for these challenging patients."

Alexei Marko, CEO of Neovasc, commented, "We were excited about the Reducer from day one because of its life-changing potential for refractory angina patients whose lives are severely limited by their crippling chest pain. The topline COSIRA results confirm our high expectations, showing that the Reducer has the potential to transform the treatment of refractory angina by significantly and safely reducing the debilitating symptoms that limit the lives of millions of patients worldwide. We are now actively exploring strategic options for a full commercial launch in Europe, as we also prepare to advance our Reducer clinical and regulatory program in the US."

The complete results of the COSIRA trial are being submitted as a Late Breaking Clinical Trial presentation at ACC.14, the 63rd Annual Scientific Session & Expo of the American College of Cardiology that will take place in Washington, DC, March 29-31, 2014.

About Neovasc Inc.
Neovasc Inc. is a specialty medical device company that develops, manufactures and markets products for the rapidly growing global cardiovascular marketplace. Its products include the Neovasc Reducer™ for the treatment of refractory angina and the Tiara™ transcatheter mitral valve replacement device in development for the treatment of mitral regurgitation. In addition, Neovasc's advanced biological tissue products are widely used as key components in a variety of third-party medical products, such as transcatheter heart valves. For more information, visit: www.neovasc.com.

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