

## Neovasc, an OPKO Supported Company, Reports That Reducer<sup>™</sup> Achieves Primary Endpoint in COSIRA Trial, Significantly Improving Function in Patients with Refractory Angina

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK), a multi-national biopharmaceutical and diagnostics company, today reported that Neovasc Inc. (NVC.V), a Vancouver-based company in which OPKO has made a strategic investment, reported topline results for its COSIRA trial assessing the efficacy and safety of the Neovasc ReducerTM, 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.

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) <u>angina grading scale</u>, 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 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 value 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.

## About OPKO Health, Inc.

We are a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies.

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding expected benefits of the Neovasc Reducer<sup>™</sup> and whether the Neovasc Reducer™ will be commercialized at all, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause actual activities or results to differ materially from the activities and results anticipated in forwardlooking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, that compounds or diagnostic products under development may fail, may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of products for the indications being studied or for other indications, that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

## **OPKO Health, Inc.**

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