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Neovasc, an OPKO Investee, Receives FDA Conditional Approval to Initiate TIARA-I Trial in U.S.: A Multinational, Multicenter Early Feasibility Trial of the TiaraTM Transcatheter Mitral Valve

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) announced that its investee, Neovasc, has received conditional Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) to initiate the U.S. arm of its TIARA-I Early Feasibility Trial for the Company's Tiara™ transcatheter mitral valve. The TIARA-I Early Feasibility Trial is a multinational, multicenter trial being conducted to assess the safety and performance of Neovasc's Tiara mitral valve system and implantation procedure in high-risk surgical patients suffering from severe mitral regurgitation (MR).

Severe MR is a critical condition that affects millions of patients and, if left untreated, can lead to heart failure or death. This FDA conditional approval allows clinical investigators to begin enrolling patients at participating U.S. medical centers once local hospital and related approvals are in place.

"This is a significant affirmation of Neovasc's Tiara device as we believe that Neovasc is the first company to start a feasibility trial with a transcatheter mitral valve in the US," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "FDA's conditional approval and the commencement of the feasibility trial in the US is an important step towards Tiara becoming one of the first transcatheter mitral valve replacement devices available for treating U.S. patients."

The TIARA-I Early Feasibility Trial will enroll up to 30 patients globally and is being overseen by a multidisciplinary committee of internationally recognized physicians co-chaired by Dr. Martin Leon (Director, Center for Interventional Vascular Therapy Columbia University Medical Center / New York-Presbyterian Hospital) and Dr. Anson Cheung (Professor of Surgery and Director of Cardiac Transplant at St. Paul's Hospital, Vancouver Canada). With this FDA approval, TIARA-I is expected to enroll patients at three highly respected U.S. medical centers: Columbia University Medical Center / New York-Presbyterian Hospital (New York), Lenox Hill Hospital (New York) and Cedars-Sinai Medical Center (Los Angeles). The Company is now focusing on training participating clinical teams and obtaining institutional approvals with the goal of enrolling the first U.S. patients by early 2015.

TIARA-I also has received ethics committee approval at Antwerp Cardiovascular Center / ZNA Middelheim in Belgium and competent authority notification is pending. First European enrollment is expected before the end of the year. Applications are underway for additional centers in Europe and Canada.

About Tiara:

Tiara is a self-expanding mitral bioprosthesis specifically designed to treat mitral valve regurgitation (MR) by replacing the diseased valve. Significant MR can lead to heart failure and death. Conventional surgical treatments are only appropriate for about half of MR patients, who number an estimated four million in the U.S. alone. Tiara is implanted in the heart using a minimally invasive, transapical transcatheter approach and is designed to replace the diseased native mitral valve without the need for open-heart surgery or use of a cardiac bypass machine.

The first human implantations of Tiara were completed successfully earlier this year under Canadian Special Access, by the medical team at St. Paul's Hospital in Vancouver, Canada. Early clinical results of Tiara implantations have been promising, resulting in fully functional valves, with complete resolution of mitral regurgitation, and no valve leakage. There have been no device related complications observed to date in patients treated with Tiara.

About OPKO Health, Inc.

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry leading positions in large, rapidly growing markets by leveraging its discovery, development and commercialization expertise and 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 Tiara transcatheter mitral value, whether the device will be successful in treating mitral valve regurgitation, whether trials will be successful and whether the device will be commercialized at all, the timing for enrollment in U.S. and European trials, and whether the device will be one of the first transcatheter mitral valve replacement devices available in the U.S., as well as other non-historical statements about our expectations, beliefs or intentions regarding 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 forward-looking 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.

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