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OPKO Health Announces Completion of Enrollment for Its Phase III Clinical Trial of Bevasiranib for Treatment of AMD

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (AMEX:OPK) announced today that it has completed enrollment in the Company's Phase III clinical trial of bevasiranib for the treatment of wet age-related macular degeneration (wet AMD). The multi-national study has enrolled more than 330 patients and is designed to assess the efficacy and safety of bevasiranib administered every 8 or 12 weeks in preventing vision loss due to wet AMD.

Bevasiranib is a first-in-class small interfering RNA (siRNA) drug designed to silence the genes that produce vascular endothelial growth factor (VEGF). VEGF is believed to be largely responsible for the vision loss from wet AMD and bevasiranib is the first drug based on the Nobel Prize-winning RNA interference (RNAi) concept to be in Phase III clinical trials.

"This first-ever Phase III trial of an agent based on RNAi technology is a milestone in the field of RNAi," said Phillip Frost, M.D., Chairman and CEO of OPKO Health. "With the completion of enrollment, we are one step closer to our goal of submitting a New Drug Application to regulatory agencies worldwide."

About Wet AMD

Wet age-related macular degeneration is a leading cause of irreversible vision loss in the developed world and its incidence is growing rapidly. Advanced age is the main risk factor for wet AMD, and it is expected to become an increasingly common condition as the population grows older. Until recently, treatments for wet AMD were of limited efficacy. In the search for more effective treatments, researchers targeted VEGF, shown to be a key cause of the excess growth and leakiness of ocular blood vessels that result in loss of vision in these patients. Current VEGF antagonists, such as Lucentis$^{(R)}$, slow this vision loss, but require injections into the eye every four weeks, a particular issue for elderly patients who often have limited mobility.

For more information about the COBALT bevasiranib clinical study, please visit www.opko.com/clinicaltrials.

About OPKO Health, Inc.

Miami-based OPKO is a specialty healthcare company. Its lead investigational drug, the gene silencing agent bevasiranib, is in Phase III trials after successfully completing Phase II trials for wet age-related macular degeneration and diabetic macular edema. OPKO is developing a pipeline of novel agents for ophthalmic diseases, and it markets innovative diagnostic imaging systems that complement the company's therapeutic products. For more information visit the company's website at www.opko.com.

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 our product development efforts, our ability to develop a preclinical pipeline of novel agents for ophthalmic diseases, our ability to commercialize bevasiranib and the effectiveness of bevasiranib in preventing vision loss and silencing genes that produce vascular endothelial growth factor, 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 our 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 risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. 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.

Source: OPKO Health, Inc.