Opko Health Initiates Phase 3 Trial of Bevasiranib for the Treatment of AMD

-Trial Designed to Compare Efficacy of Bevasiranib Administered Every 8 Weeks or 12 Weeks with Lucentis(R) Administered Every 4 Weeks-

-Represents First-Ever Phase 3 Pivotal Trial of an RNAi Therapeutic-

MIAMI, July 11 /PRNewswire-FirstCall/ -- Opko Health Inc. (Amex: OPK) today announced the initiation of the Phase 3 COBALT (Combining Bevasiranib And Lucentis Therapy) clinical trial of bevasiranib for the treatment of wet age-related macular degeneration (wet AMD.) The multi-national COBALT study is currently open and enrolling patients. The trial will include more than 330 wet AMD patients and will assess whether bevasiranib administered every 8 or 12 weeks is safe and has equivalent efficacy in preventing vision loss as Genentech's Lucentis(R) administered every four weeks.

Bevasiranib is a first-in-class small interfering RNA (siRNA) drug designed to silence the genes that produce vascular endothelial growth factor (VEGF), believed to be largely responsible for the vision loss of wet AMD. Bevasiranib is the first therapy based on the Nobel Prize-winning RNA interference (RNAi) technology to advance to Phase 3 clinical trials.

"This first-ever Phase 3 trial of an agent based on RNAi technology is an important milestone in this new field. We are proud of the ability demonstrated by our clinical group to have successfully moved this innovative compound through development rapidly and cost effectively," said Philip Frost, M.D., Chairman and CEO of Opko Health. "Currently patients with wet AMD undergo intravitreal injections every four weeks to achieve the vision-preserving benefits of Lucentis, so the potential ability of bevasiranib to achieve similar results while requiring less frequent injections would be an important benefit for these patients who often have limited mobility."

"Bevasiranib's demonstrated safety profile, its ability to inhibit the growth of the retinal lesions associated with wet AMD and its potential for prolonged duration are a promising foundation for this pivotal trial," said Lawrence Singerman M.D., founder and Executive Secretary of the Macula Society, Clinical Professor of Ophthalmology at Case University and a Principal Investigator for the Phase 3 study. "Bevasiranib's potential to serve as a long-term maintenance therapy for wet AMD could provide important benefits to patients, and I look forward to helping to assess its utility in this groundbreaking study."

"We are very pleased at the enthusiastic reception the COBALT trial has received from retinal centers around the globe," said Denis O'Shaughnessy, Ph.D., Senior Vice President of Clinical Development at Opko. "Retinal physicians are keenly aware of the burden that frequent drug injections places on elderly patients and their families, and they are eager to help test an innovative new approach that has the potential to significantly reduce that burden while preserving patients' vision."

About Wet AMD

Wet age-related macular degeneration is the 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. An estimated 1.65 million Americans have wet AMD today and an estimated 11 million people worldwide will have AMD by 2013. 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, 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 COBALT bevasiranib clinical sites currently open and enrolling patients, please visit www.opko.com/clinicaltrials

About Opko Health, Inc.

Miami-based Opko is a specialty healthcare company. Its lead investigational drug, the pioneering gene silencing
agent bevasiranib, has entered a pivotal Phase 3 trial after successfully completing Phase 2 trials for wet age-related macular degeneration and macular degeneration. Opko is developing a preclinical pipeline of novel agents for ophthalmic diseases, and it also intends to market diagnostic systems that complement its therapeutic products. The company recently announced it has entered into an agreement to acquire Ophthalmic Technologies, Inc. (OTI), a provider of innovative patient imaging systems to eye care professionals worldwide.

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), regarding product development efforts and other non-historical facts 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, including the risks that enrollment of patients for the Phase 3 clinical trial for bevasiranib, may not be successful, that the Phase 3 clinical trial itself may not be completed on a timely basis or at all, that any of our compounds under development, including bevasiranib, 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. 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. 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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