

NeoVista Presents 24-month Visual Acuity Data Outcomes of Novel Therapy for the Treatment of Neovascular Age-Related Macular Degeneration

Long-Term Data Continues to Highlight Potential of NeoVista's Epimacular Brachytherapy Procedure

New York, NY ([PRWEB](#)) October 1, 2009 -- NeoVista, Inc. made public today at the Combined Retina Meeting, 24-month data from the company's Phase II study (NVI-111). The study was designed to examine the company's novel epimacular brachytherapy procedure when used in conjunction with Bevacizumab anti-VEGF therapy for the treatment of neovascular age-related macular degeneration (AMD). The long-term data from the study showed that a majority of patients maintained their visual acuity and at least 20% also experienced a marked improvement in vision at month 24. The data also showed that 76 percent of the patients only needed 2 protocol required injections of Avastin® throughout the 24-month period.

"We're excited with the latest data from this Phase II study, said John N. Hendrick, President and CEO of NeoVista. "Safety remains the primary purpose of this study and to date there is no evidence of long-term radiation toxicity at 2 years follow-up, with many patients being followed for as long as 3 years. A large majority of patients in the study maintained their visual acuity over the course of follow-up, while some patients in the trial experienced significant vision gain. We are encouraged by the reduction in the number of injections delivered to patients in this study (mean of 2.4 injections over the 24 month period). This therapy has the potential to decrease treatment burden both for patients and physicians, not to mention the overall financial burden for healthcare systems around the world."

In contrast to other forms of radiation therapy for wet AMD, NeoVista's approach delivers a focused dose of energy directly to the choroidal neovascular lesion without damaging the adjacent healthy retinal vasculature. Utilizing strontium 90, the focused energy is delivered to a target area up to 3 mm in depth and up to 5.4 mm in diameter. Importantly for patients, the systemic exposure to radiation is minimal, as the effective dose to the entire body from NeoVista's epimacular device is less than that from a typical chest x-ray.

The ongoing multicenter feasibility study enrolled 34 trial participants (with a mean age of 72 years) from June 2006 to April 2007 at two centers in Brazil and one in Mexico. These patients, with predominantly classic, minimally classic, or occult (with no classic) choroidal neovascularization (CNV), received a single exposure of epimacular brachytherapy in combination with two intravitreal injections of Avastin, one dose prior to or at the time of radiation delivery and another one month later, depending on which arm of the trial the patient was enrolled in. Additional therapy was delivered based upon the investigator's evaluation of disease activity.

There was an expected increase in the incidence (50%) of cataract formation related to the vitrectomy, the surgical procedure performed when administering epimacular brachytherapy. Comparative data was examined to look at outcomes of patients who entered the study with their natural lens versus those who had already undergone cataract surgery. This analysis showed that 80% of patients who had cataract surgery prior to study entry maintained their visual acuity and 30% gained significant vision at 24 months. When comparing to the cohort of patients that entered the study with their natural lens, 65% percent of patients maintained their visual acuity and 20% percent had significant vision gain, highlighting the fact that cataract formation played a role in long term visual acuity data..

There were a limited number of adverse events in the trial which were related to the vitrectomy procedure (retinal tear, retinal detachment, subretinal hemorrhage, and vitreous hemorrhage), rather than the epimacular brachytherapy. To date, no instances of radiation toxicity have been reported with many patients followed for as long as 3 years.

The data were presented by Pravin U. Dugel, MD, managing partner, Retina Consultants of Arizona, Phoenix, AZ. "The potential of this treatment is enormous", said Dr. Dugel. "I believe that epimacular brachytherapy will be used in combination with the current standard of care to make this treatment more effective by offering a broad spectrum of action. In addition, epimacular brachytherapy may also improve the quality of life for our patients by relieving them from having to receive monthly intraocular injections. The potential impact of epimacular brachytherapy for patients, physicians and the entire healthcare system is prodigious".

NeoVista has recently completed enrollment in the company's first pivotal trial, CABERNET (CNV Secondary to AMD Treated with BEta Radiation Epiretinal Therapy). CABERNET is a multicenter, randomized, controlled study that has enrolled 450 subjects at 45 sites worldwide, and is evaluating the safety and efficacy of NeoVista's therapy delivered concomitantly with the FDA-approved anti-VEGF therapy Lucentis® (ranibizumab) versus Lucentis alone.

About NeoVista, Inc.

NeoVista, Inc. is a privately held medical device company based in Fremont, California. The company's first commercial product, the VIDION® ANV® Therapy System, is cleared for commercial sale in all markets that accept a CE Mark. NeoVista, Inc is planning to begin commercial activity in the US in early 2011 pending Food and Drug Administration (FDA) approval. For more information about the company, or this novel neovascular AMD therapy, please visit the company's Web site at www.neovistainc.com.