

NeoVista Presents One-Year Study Results of Novel Therapy for the Treatment of Neovascular Age-Related Macular Degeneration

Data suggests that Epimacular Brachytherapy may reduce the burden of treatment and further improve Visual Acuity

Chicago, IL ([PRWEB](#)) October 15, 2010 -- NeoVista, Inc. made public today at the American Academy of Ophthalmology meeting the company's one-year results from their MERITAGE Study. This study was designed to examine NeoVista's novel Epimacular Brachytherapy procedure when used in patients who require chronic therapy with anti-VEGF agents on an ongoing basis to control Neovascular Age-Related Macular Degeneration (Wet AMD). The study enrolled patients who had as many as 38 prior injections of anti-VEGF therapy before receiving Epimacular Brachytherapy. The study population had a trend toward losing vision, even with regular anti-VEGF therapy in the year prior to enrollment. Prior to entry into the study, all patients were required to have received a loading dose of 3 monthly anti-VEGF injections and then a minimum of 5 additional injections in the 12 months preceding enrollment or 3 injections in the 6 months preceding enrollment. This ensured that the full benefit of anti-VEGF therapy was realized prior to entry into the study.

Study results (n=53) to date suggest that a single procedure of Epimacular Brachytherapy can stabilize visual acuity in a majority of this patient population (79%) while decreasing the number of anti-VEGF injections required. Most importantly, 47% of patients enrolled in the study experienced some improvement in their visual acuity while 10% of patients gained 15 or more letters of visual acuity at 12 months. This improvement is significant in patients that have been receiving chronic anti-VEGF treatment with no vision improvement in the year prior to enrollment, as compared to all other trials that are treating patients with newly onset disease.

The study results also pointed to a favorable trend with respect to a reduced number of anti-VEGF injections following delivery of Epimacular Brachytherapy (Mean=3.9) versus the period of time leading up to Epimacular Brachytherapy intervention (Mean=12.3). In addition, 25% of patients remained injection-free at 12 months following the Epimacular Brachytherapy procedure.

"MERITAGE is the first of its kind study designed to evaluate the potential role of the NeoVista device in treating chronic disease and decreasing the burden of treatment while maintaining or improving visual acuity," said John N. Hendrick, President and CEO of NeoVista. "Data from recent randomized trials suggest that most patients suffering from Neovascular AMD will require anti-VEGF treatment on an ongoing basis for an indefinite period of time. We are very excited that our procedure, Epimacular Brachytherapy, not only has the potential to significantly decrease the number of injections administered but may also improve visual acuity in a significant percentage of this patient population."

In contrast to other forms of radiation therapy for Neovascular AMD, NeoVista's approach delivers a focused dose of energy directly to the wet AMD lesion without damaging the adjacent healthy retinal vasculature. Utilizing strontium 90, the targeted energy is delivered to an 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 and highly controlled to a local area. The effective dose to the entire body from NeoVista's device is less than that from a typical chest x-ray. There were a limited number of adverse events in the trial, which were related to the surgical vitrectomy procedure, rather than Epimacular Brachytherapy.

The MERITAGE Study was conducted in two centers in the United States, one center in the United Kingdom, and two centers in Israel. Principal investigators were Pravin U. Dugel (USA), Michael D. Bennett (USA), Timothy L. Jackson (UK), Adiel Barack (Israel), and Dov Weinberger (Israel). The data was presented by Pravin Dugel, MD, managing partner, Retinal Consultants of Arizona, Phoenix, AZ. "The potential of this treatment is enormous," said Dr. Dugel, "as this patient population represents the majority of patients that I see in my clinic each and every day. I believe that Epimacular Brachytherapy, unlike anti-VEGF therapy alone, offers a broad spectrum of activity and may therefore inhibit multiple disease processes involved in the pathology of wet AMD. To observe not only a reduction in treatment burden, but also an improvement in visual acuity in almost half of these difficult to treat patients at the one year mark is quite encouraging."

NeoVista 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 over 490 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.

A second pivotal trial MERLOT (Macular Epiretinal Brachytherapy versus Lucentis® Only Treatment), sponsored by King's College Hospital, London, England, (Principal Investigator-Mr. Tim Jackson), is being conducted in 20 centers throughout the United Kingdom. MERLOT is also a multicenter, randomized, controlled study, with targeted patient enrollment of 363 subjects. This study is analyzing the effects of Epimacular Brachytherapy used concomitantly with as needed Lucentis injections versus continued Lucentis therapy alone, in patients who require chronic therapy with anti-VEGF agents on an ongoing basis to control Wet AMD.

About NeoVista, Inc.

NeoVista, Inc. is a privately held medical device company based in Newark, California. The company's first commercial product, VIDION® ANV® Therapy System, is cleared for commercial use in all markets that accept a CE Mark. For more information about the company, or this novel therapy, please visit the company's Web site at www.neovistainc.com.