



NEOVISTA™

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FDA Grants NeoVista's Request to Utilize Novel Wet AMD Treatment in Compassionate Case

NeoVista's Epiretinal Brachytherapy Granted Compassionate Use to Attempt to Prevent Complete Vision Loss in Patient

FREMONT, Calif. – December 10, 2008 – NeoVista, Inc., announced today that the U.S. Food and Drug Administration (FDA) had approved the company's "compassionate case" waiver to utilize its novel wet age-related macular degeneration (AMD) treatment on a patient with an advanced form of the disease who did not meet criteria for inclusion into current NeoVista investigational treatment protocols. The patient received NeoVista's therapy today in Nashville, Tenn.; the procedure was performed by Dr. Carl Awh, President of Tennessee Retina, and an investigator in NeoVista's ongoing Phase III study, CABERNET (CNV Secondary to AMD Treated with **BE**tta **R**adiatio**N** Epiretinal Therapy).

The patient suffered from advanced wet AMD in both eyes and had not benefited from any available treatment, including anti-vascular endothelial growth factor (anti-VEGF) agents, the current standard of care for wet AMD. The patient's left eye had progressively worsened despite treatment with photodynamic therapy and intravitreal steroids prior to the advent of anti-VEFG therapy, as well as later injections of anti-VEGF agents. Her right eye was following a parallel course, with advanced vision loss due to an enlarging exudative retinal detachment caused by wet AMD. Because of the similarity in the appearance of the two eyes and the failure of prior therapies to successfully treat the left eye, a decision was made to treat the patient's right eye with NeoVista's therapy.

"With the FDA granting a waiver for this case, today both my patient and I had access to a promising, new therapy for the treatment of her case of severe wet AMD," said Dr. Awh. "If this approach proves effective in her case, other patients with similar types of advanced, progressive wet AMD may also benefit under compassionate use waivers from the FDA."

NeoVista's novel therapy applies a targeted dose of beta radiation to the abnormal leaking blood vessels that affect central vision in patients with wet AMD. Preliminary data show that NeoVista's targeted radiation therapy can be safe for both the patient and the physician, and may be able to improve patient's vision. The current standard of care for wet AMD requires monthly injections of anti-VEGF drugs into the eye for an indefinite period of time.

In contrast to other forms of radiation therapy for wet AMD, NeoVista's approach delivers the peak dose of energy directly to the lesion without damaging the normal 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 epiretinal device is less than that from a typical chest x-ray.

"We're extremely pleased that the FDA has granted us a compassionate use waiver in this circumstance," said John N. Hendrick, President and CEO of NeoVista. "Even though this patient has not benefited from currently approved therapies, our hope is that she will benefit from our treatment as a final effort to avoid complete loss of vision."

The purpose of the compassionate use waiver is to offer a limited number of patients with serious conditions and no other alternatives the opportunity to potentially benefit from an investigational treatment that has not yet been approved for use by the FDA. While receiving the compassionate use approval for this patient, NeoVista continues to enroll patients in the company's pivotal trial, CABERNET.

CABERNET is a multicenter, randomized, controlled study that will enroll 450 subjects at 45 sites worldwide, evaluating the safety and efficacy of NeoVista's epiretinal brachytherapy delivered concomitantly with the FDA-approved anti-VEGF therapy Lucentis® (ranibizumab) versus Lucentis alone.

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About NeoVista, Inc.

NeoVista, Inc. is a privately held development-stage medical device company based in Fremont, California. NeoVista's epiretinal beta radiation therapy is currently being studied in a definitive Phase III clinical study to support eventual filing for regulatory approval to market the product in the United States. For more information about the company, the clinical trial or this novel wet AMD therapy, please visit the company's Web site at www.neovistainc.com. For detailed information about the CABERNET clinical trial, please visit the study Web site at www.cabernetstudy.com.