



FOR IMMEDIATE RELEASE

## **LEVEL Study Published in *British Journal of Ophthalmology* Evaluates Macugen as Maintenance Treatment for Patients with Neovascular Age-Related Macular Degeneration**

**Palm Beach Gardens, FL – May 18, 2010** – Eyetech Inc. announced today that the *British Journal of Ophthalmology* (BJO) published online results from the LEVEL study evaluating Macugen™ (pegaptanib sodium) as a maintenance therapy in neovascular age-related macular degeneration (AMD). This large, open-label, uncontrolled, exploratory study enrolled 568 patients who had been treated one to three times for neovascular AMD, primarily with a non-selective VEGF-inhibitor such as ranibizumab or bevacizumab. During this induction phase, the mean visual acuity improved by 15.9 letters (49.6 letters to 65.5 letters). After entering the study, patients were switched to Macugen, a selective VEGF-inhibitor, with the possibility of using additional treatments if needed. At the end of this 54-week maintenance phase, mean final visual acuity was 61.8 letters. From the beginning of the induction phase to the end of maintenance phase, an approximately 16-month follow-up, 41 percent of patients gained at least 3 lines of visual acuity.

The study authors concluded that this induction-maintenance treatment strategy, using non-selective VEGF inhibitors then switching to Macugen, a selective VEGF inhibitor, may be an option for the long-term treatment of neovascular AMD. “A treatment protocol that combines the efficacy of a non-selective VEGF inhibitor with the safety profile of a selective VEGF inhibitor may be an attractive option, since elderly patients with AMD are already at increased risk of hypertension, stroke and other cardiovascular disease,” said Thomas R. Friberg, M.D., lead investigator of the LEVEL study and Professor of Ophthalmology and Bio-Engineering at the University of Pittsburgh.

“This treatment approach may be of particular interest to retina specialists and their AMD patients with cardiovascular co-morbidities who require long-term treatment with anti-VEGF drugs to manage their neovascular AMD,” continued Dr. Friberg. “Unlike non-selective VEGF inhibitors that should be administered monthly, Macugen is administered every six weeks. This substantially reduces the treatment burden on patients and their families.”

Despite the limitations of an uncontrolled study, Macugen when used as a maintenance therapy showed adverse events rates similar to those observed in the pivotal Phase III V.I.S.I.O.N trial at one year. During one year of follow-up, there was no evidence of increased risk of endophthalmitis, retinal detachment or traumatic cataract. Most common ocular adverse events

were punctate keratitis, eye pain and vitreous floaters. Reports of serious non-ocular, vascular events (including cardiovascular events) were rare.

### **About the LEVEL Study**

LEVEL (EvaLUation of Efficacy and safety in maintaining Visual acuity with sEquential treatment of neovascuLar AMD) is a Phase IV, prospective, open-label, uncontrolled exploratory study designed to assess the efficacy of Macugen as a maintenance therapy in neovascular AMD patients who had at least one but not more than three prior treatments (induction phase) 30 to 120 days prior to study entry. Patients who showed significant clinical and/or anatomical improvement in their neovascular AMD, as determined by the study investigator, were enrolled in the LEVEL study and administered intravitreal injections of Macugen 0.3 mg every six weeks for 48 weeks with follow-up through week 54.

Additional treatments with other agents were allowed in the study eye at investigators' discretion for deteriorating AMD. Half of patients (283/568) required an additional treatment during the study, which was given approximately 5 months post-baseline on average. Of those who received an additional treatment, 46% required only one such treatment.

The results from the exploratory trial suggest that this induction/maintenance regimen may be a promising approach in the long-term treatment of neovascular AMD. From the beginning of induction treatment to week 54 of the maintenance phase, 41% of patients gained  $\geq 3$  lines of vision, 79% gained  $\geq 0$  lines and 92% lost  $< 3$  lines of vision. Randomized, controlled trials are needed to corroborate the findings of the LEVEL study.

### **About Age-Related Macular Degeneration (AMD)**

AMD is a chronic, progressive disease of the central portion of the retina called the macula, resulting in the loss of central vision. The most common symptoms are a central blurred or blank spot, distortion of objects or simply blurred vision. Peripheral vision usually remains intact. AMD is classified into two forms: atrophic, referred to as dry AMD, and neovascular or wet AMD.

In neovascular AMD, abnormal blood vessels grow and leak into the macula, resulting in loss of vision. Neovascular AMD is the more severe form of the disease and progresses more rapidly than the dry type. Although it accounts for only about 10-15 percent of all macular degeneration cases, neovascular AMD is responsible for 90 percent of blindness caused by the disease.

### **About Macugen**

Macugen, a selective inhibitor of VEGF-165, is indicated in the United States for the treatment of neovascular age-related macular degeneration (neovascular AMD) and is administered in a 0.3-mg dose once every six weeks by intravitreal injection. Macugen is a pegylated anti-VEGF aptamer, which binds to vascular endothelial growth factor (VEGF). VEGF is a protein that plays a critical role in angiogenesis (the formation of new blood vessels) and increased permeability (leakage from blood vessels), two pathological processes that contribute to the vision loss associated with neovascular AMD.

Eyetechnic Inc. markets and sells Macugen in the United States and Pfizer Inc. markets and sells Macugen outside of the United States. For full prescribing information about Macugen, please visit <http://www.macugen.com/>.

### **Important Safety Information**

Macugen is contraindicated in patients with ocular or periocular infections or with known hypersensitivity to pegaptanib sodium or any other excipient of this product.

Safety or efficacy of Macugen beyond two years has not been demonstrated.

Intravitreal injections including those with Macugen have been associated with endophthalmitis. Proper aseptic injection technique – which includes use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent) – should always be utilized when administering Macugen. In addition, patients should be monitored during the week following the injection to permit early treatment, should an infection occur.

Increases in intraocular pressure (IOP) have been seen within 30 minutes of injection with Macugen. Therefore, IOP as well as the perfusion of the optic nerve head should be monitored and managed appropriately.

Rare cases of anaphylaxis/anaphylactoid reactions, including angioedema, have been reported in postmarketing experience following the intravitreal administration procedure.

Serious adverse events related to the injection procedure occurring in less than 1% of intravitreal injections included endophthalmitis, retinal detachment, and iatrogenic traumatic cataract.

Most frequently reported adverse events in patients treated for up to two years were anterior chamber inflammation, blurred vision, cataract, conjunctival hemorrhage, corneal edema, eye discharge, eye irritation, eye pain, hypertension, increased IOP, ocular discomfort, punctate keratitis, reduced visual acuity, visual disturbance, vitreous floaters, and vitreous opacities. These events occurred in approximately 10% to 40% of patients.

### **About Eyetechnic Inc.**

Eyetechnic Inc. is a unique, independent 100% employee-owned and operated biotechnology company dedicated exclusively to the treatment of sight-threatening diseases of the retina. For additional information about Eyetechnic, please visit [www.eyetechnic.com](http://www.eyetechnic.com).

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