



**FOR IMMEDIATE RELEASE:**

## **EYEGATE PHARMA ENROLLS FIRST DRY EYE PATIENT IN PHASE II CLINICAL TRIAL OF LEAD PRODUCT EGP-437**

### ***Enrollment Marks Second Clinical Trial Initiation for EGP-437 in 2008***

**Waltham, MA – November 10, 2008** – EyeGate Pharma, the leader in ocular drug delivery, a specialty pharmaceutical company using iontophoresis technology to safely and non-invasively deliver therapeutics to treat serious ocular diseases, today announced that it has enrolled the first dry eye patient in a Phase II safety and efficacy clinical study of EGP-437 (a combination drug/device). This patient enrollment marks the Company's second clinical trial initiated in the second half of 2008. In July, the Company initiated a landmark Phase II clinical study in severe uveitis, which represented the first U.S. study under an open IND to employ iontophoresis technology to deliver an active compound into the eye.

EyeGate is partnering with Ophthalmic Research Associates (ORA), a leading global clinical research and development organization, located in North Andover, MA. Over the past 30 years, ORA has played a central role in the development and FDA approval of more than 25 ophthalmic products.

“Dry eye is the most prevalent form of ocular discomfort and irritation, and currently has no cure and few treatment options to alleviate symptoms that only provide temporary relief. It is estimated that as many as 20 to 40 million Americans suffer from mild-to-moderate dry eye. Symptoms such as pain, light sensitivity, blurred vision, and irritation decrease the quality of life for patients and can ultimately lead to loss of function and blindness,” commented George Ousler, Director of Dry Eye Research at ORA.

The Phase II study is a single-center, randomized, double-masked, placebo-controlled safety and efficacy study of two doses of a corticosteroid solution (EGP-437) over a period of three weeks in dry eye patients. ORA's proprietary Controlled Adverse Environment (CAE) clinical model is being used in this study to support the clinical development of EGP-437.

This Phase II safety and efficacy study builds on a series of clinical trials, including a pilot and a Phase I study. The pilot study was instrumental in establishing EyeGate's clinical development

roadmap and was designed to assess the safety, tolerability, and efficacy of EyeGate's first-generation iontophoretic drug delivery device. This trial included 89 patients suffering from a variety of severe ocular inflammatory conditions and involved a total of 216 iontophoretic applications of a corticosteroid. The treatments significantly decreased inflammatory markers and improved visual acuity while demonstrating exceptional safety and tolerability. The second study is a fully enrolled Phase I safety and tolerability study in 105 healthy volunteers. This GCP Phase I study is designed to establish the maximum tolerated current that can be employed with the EyeGate® II Delivery System. Data from this study aided dose selections for on-going trials and will provide valuable information for future clinical trials and support future regulatory filings. This Phase I study should be completed by the end of 2008.

Gail Torkildsen, M.D., of Ophthalmic Research Associates, principal investigator of the study, commented, "EyeGate's non-invasive, patient-friendly approach of dosing EGP-437 with the Company's ocular delivery system will be beneficial in treating dry eye patients. I look forward to working with EyeGate and reporting on the results of this important study."

This U.S. Phase II safety and efficacy study utilizing the EyeGate® II Delivery System will administer the Company's lead clinical compound, EGP-437, with the objective of assessing safety and efficacy in up to 80 dry eye patients.

Stephen From, President and Chief Executive Officer of EyeGate Pharma, commented, "The number of patients suffering from ocular diseases such as dry eye are increasing at a rapid rate due to a variety of demographical circumstances such as the aging population, evolving environmental conditions, and internal factors relating to heating and excessive computer use. Treatments such as artificial tear solutions only provide limited temporary symptomatic relief for this disorder. EyeGate is looking to provide a safe, patient-friendly alternative with longer lasting effect on the signs and symptoms of this impairing disease. We look forward to working with Ophthalmic Research Associates and finalizing results of this trial in early 2009."

### **About Iontophoresis**

The EyeGate® II Delivery System works through iontophoresis, which occurs when an applied electric field enhances the mobility of molecules through cells and tissues primarily through electrochemical repulsion. Specifically, a low level of electrical current creates an electrical field that repels like-charged ionized drugs, thus, more effectively delivering drug substances through different tissues to targeted areas in efficacious quantities. These principles can be applied to anionic and cationic molecules.

To deliver a therapeutic to both the anterior (front) and posterior (back) tissues of the eye, the drug must be specially adapted and formulated for iontophoretic delivery. EyeGate has concentrated its efforts on optimizing the EyeGate® II Delivery System to administer a wide range of therapeutics while developing a highly specialized laboratory dedicated to formulating drugs for iontophoretic delivery.

#### **About EyeGate Pharma**

EyeGate was founded in 1998 with technology licensed from Bascom Palmer Eye Institute at the University of Miami. EyeGate's transscleral (white membrane of the eye) iontophoresis delivery platform, the EyeGate® II Delivery System, was developed to safely deliver a wide range of therapeutics to both the anterior and posterior chambers of the eye. For more information, please visit [www.eyegatepharma.com](http://www.eyegatepharma.com).

#### **About Ophthalmic Research Associates (ORA)**

ORA is a drug development company that creates and deploys rigorous scientific and management processes that accelerate the pace of drug development and improve patient care for vision-related illnesses. For more information, please visit [www.eyedrop.com](http://www.eyedrop.com).

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