



**FOR IMMEDIATE RELEASE:**

## **EYEGATE PHARMA RECEIVES ORPHAN DRUG DESIGNATION FOR CORNEAL GRAFT REJECTION FROM U.S. FDA**

### ***Plans to Initiate Pivotal Trial in 2009***

**Waltham, MA – January 9, 2009** – EyeGate Pharma, the leader in ocular drug delivery, and a specialty pharmaceutical company using iontophoresis technology to safely and non-invasively deliver therapeutics to treat serious ocular diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for EyeGate's lead clinical compound, EGP-437 (dexamethasone phosphate), delivered via the EyeGate® II Iontophoretic Delivery System for the treatment of corneal graft rejection. To date, the U.S. FDA has not approved any product for treating corneal graft rejection.

The Orphan Drug Act of 1983 is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders, defined as those affecting fewer than 200,000 Americans. Orphan Drug Designation qualifies the sponsor for exclusive U.S. marketing rights for seven years if the company is first to receive marketing approval, as well as tax credits for clinical trial costs, marketing application filing fee waivers, and assistance from the FDA in the drug development process.

Stephen From, President and Chief Executive Officer of EyeGate Pharma, commented, "Orphan Drug Designation for our lead compound for treating corneal graft rejection marks an important milestone for the Company. The iontophoretic delivery of dexamethasone phosphate is a more effective means of achieving therapeutic drug levels in the front of the eye than existing therapies, and we look forward to initiating a pivotal trial in this indication during 2009."

Currently, EyeGate is enrolling two Phase II clinical studies utilizing EGP-437 in uveitis and dry eye patients. The results from these studies are expected in the first half of 2009. The Phase II study in uveitis represents a landmark proof-of-concept study of EGP-437 and the EyeGate® II; the first-ever U.S. clinical trial under an open IND to employ iontophoresis technology to deliver an active compound into the eye.

EyeGate utilizes iontophoresis technology to safely and non-invasively deliver drugs to both the front and back of the eye. EGP-437, dexamethasone phosphate ophthalmic solution (ultimately releasing dexamethasone), is delivered via the EyeGate<sup>®</sup> II, which consists of an ocular applicator, a syringe and adapter for transferring the drug product from the vial to the applicator, a generator that provides a consistent current to the electrode of the applicator, and a return electrode to complete the continuous current circuit.

Michael Patane, Chief Scientific Officer of EyeGate Pharma, commented, "For corneal graft recipients, a rejection episode can be a debilitating condition, and prompt diagnosis and treatment can halt the rejection process and enable the retention of a clear graft. Given the imperative to intervene early and aggressively in this condition, and the requisite high frequency of dosing required to achieve therapeutic steroid levels in the anterior chamber, innovative methods that are capable of delivering more substantial steroid concentrations into the eye are of clinical interest and importance."

Corneal graft, also known as keratoplasty, is one of the most common transplant procedures in humans and is the only available treatment for a number of corneal disorders. Each year, more than 40,000 corneal transplants are performed in the U.S., and of all the patients undergoing a transplant, 20 percent will have a rejection in their lifetime -- 30 percent of that number will experience a rejection episode in the first year.

Rejection episodes most often occur at least two weeks post-transplant, and are more likely to occur in high-risk patients. As a result of a rejection, irreplaceable graft cells die and can lead to corneal graft failure, which can lead to permanent vision loss. Early detection and aggressive corticosteroid therapy are critical to successfully managing corneal graft rejection.

Currently, topical and/or systemic corticosteroid therapy is the standard-of-care in corneal graft rejection. As a rejection progresses, the steroid treatment becomes more aggressive, including hourly instillations combined with systemic administration.

Mr. From continued, "The EyeGate<sup>®</sup> II delivers the drug to the front and back of the eye more efficiently than any delivery method currently available, and there is a real need for less frequent iontophoretic delivery of superior steroid levels that can circumvent some of the issues encountered with chronic topical dosing. The EyeGate<sup>®</sup> II Delivery System is a natural next step for achieving this delivery."

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### **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).

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