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EyeGate Pharma Receives Positive Guidance From FDA on NDA Filing Requirements of EGP-437 for the Treatment of Anterior Uveitis

Agency Provides Guidance That Positive Data From Upcoming Phase 3 Trial Sufficient to Support NDA Filing

WALTHAM, Mass., May 4, 2015 (GLOBE NEWSWIRE) -- Eyegate Pharmaceuticals, Inc. (OTCQB:EYEG) ("EyeGate" or the "Company"), a specialty pharmaceutical company that focuses on developing and commercializing therapeutics and drug delivery systems for treating diseases of the eye, today announced receipt of comments from the U.S. Food & Drug Administration ("FDA") in response to questions submitted by the Company ahead of a Type B meeting scheduled for May 5, 2015. The FDA provided guidance that if the planned Phase 3 trial of EGP-437 in anterior uveitis meets non-inferiority criteria, data from this trial along with data from a previously completed Phase 3 trial in anterior uveitis will be sufficient to support a New Drug Application ("NDA") filing. The FDA also communicated that the design of the planned Phase 3 is acceptable and that the nonclinical work completed to date is sufficient to support a NDA filing. Based on this positive feedback, the Company has elected to cancel the face-to-face portion of the meeting.

The planned trial will be a prospective, multi-center, randomized, double-masked, parallel-arm, positive control non-inferiority study evaluating Iontophoretic Dexamethasone Phosphate Ophthalmic Solution compared to the standard of care, Prednisolone Acetate Ophthalmic Suspension (1%) in patients with non-infectious anterior segment uveitis. The trial is expected to enroll up to 250 subjects at approximately 60 U.S. clinical sites. Non-inferiority will be evaluated based on the proportion of subjects with total anterior chamber cell clearing at Day 14 of EGP-437 treatment versus standard of care.

"The FDA comments are an important milestone in our clinical development plan for EGP-437, and we are pleased that they have determined that the proposed Phase 3 trial design is acceptable. The guidance that data from this planned study, along with our previous Phase 3 study of EGP-437 should be sufficient to support a NDA filing gives us a clear clinical and regulatory path for our lead product candidate," said Stephen From, President and Chief Executive Officer of EyeGate. "We believe that EGP-437 represents a potential breakthrough in the treatment of ocular diseases and that this trial, if successful, would provide a significant validation of the use of iontophoresis for delivery of drug to the eye. We expect that iontophoretic delivery could be applied to a variety of ocular drugs that have traditionally been administered topically or via injection, and could provide a viable therapeutic alternative to patients in need. We look forward to initiating this trial, and to providing further details as we continue to advance."

About EyeGate:

EyeGate is a clinical-stage specialty pharmaceutical company that is focused on developing and commercializing therapeutics and drug delivery systems for treating diseases of the eye. EGP-437, the Company's first and only product in clinical trials, incorporates a reformulated topically active corticosteroid, dexamethasone phosphate that is delivered into the ocular tissues through EyeGate's proprietary innovative drug delivery system, the EyeGate(R) II Delivery System. For more information, please visit www.EyeGatePharma.com.

Safe Harbor Statement:

Some of the statements in this press release are "forward-looking" and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These "forward-looking" statements include statements relating to, among other things, the commercialization efforts and other regulatory or marketing approval efforts pertaining to EyeGate's products, including EGP-437, as well as the success thereof, with such approvals or success may not be obtained or achieved on a timely basis or at all. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this press release, including, among other things, certain risk factors described under the heading "Risk Factors" in our Annual Report on Form 10-K filed with the SEC on March 31, 2015, or described in our other public filings. Our results may also be affected by factors of which we are not currently aware. The forward-looking statements in this press release speak only as of the date of this press release. EyeGate expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions or circumstances on which any such statement is based.

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