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EyeGate Announces Encouraging Interim Data from Phase 1b/2a Clinical Trial of EGP-437 for Treatment of Ocular Inflammation and Pain Post Cataract Surgery

WALTHAM, Mass., June 01, 2016 (GLOBE NEWSWIRE) -- EyeGate Pharmaceuticals, Inc. (NASDAQ: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 interim data from its Phase 1b/2a trial evaluating its lead product candidate, iontophoretic EGP-437, in the treatment of ocular inflammation and pain in cataract surgery patients.

“Overall, this interim data is encouraging as it further validates the safety profile of the EGP-437 combination product while also demonstrating potential clinical benefit in post-operative cataract surgery patients. The majority of subjects treated to-date in the two higher dose cohorts have displayed clinically relevant reductions in anterior chamber cell count (ACC) with little to no pain, and no steroid related increase in intraocular pressure (IOP) by 2 weeks,” said Victor L. Perez M.D. of University of Miami Miller School of Medicine, Bascom Palmer Eye Institute. “We look forward to further data as we treat patients in the remaining cohorts of the study and continue the clinical development of EGP-437 in the treatment of post-surgery inflammation and pain.”

The ongoing Phase 1b/2a clinical trial is a multi-center, open-label trial enrolling up to 50 subjects who have undergone unilateral cataract extraction and implantation of a monofocal intra-ocular lens. The primary objective of this trial is to assess the safety and efficacy of iontophoretic EGP-437 in these patients following surgery. The trial design includes 5 cohorts whereby iontophoretic doses of 4.0 mA-min, 9.0 mA-min and 14.0 mA-min were employed and the 9.0 and 14.0 mA-min cohorts included 2 different dosing regimens. Subjects in the 9.0 and 14.0 mA-min cohorts had three treatments administered on day 0, day 1 and day 2 or day 0, day 1 and day 4 with potential for an additional treatment at Day 7 in all cohorts. The primary endpoint for all cohorts is ACC at day 14, with secondary endpoints measuring pain score and intra-ocular pressure.

A positive response was observed in the majority of the patients, with some patients in 9.0 and 14.0 mA-min cohorts presenting with ACC of zero at day 14 and others presenting with trace ACC levels. Additionally, all subjects experienced low pain throughout the duration of the trial.

Enrollment will continue for the remaining cohorts with additional planning for next steps; including additional clinical development work to determine the optimal dose and dosing

regimen. A double-masked, prospective randomized, controlled trial is expected to initiate by the end of 2016.

“For many of the approximately 3 million cataract surgeries performed in the U.S. every year, post-surgical rehabilitation can be delayed due to inflammatory processes. This problem can be exacerbated by low adherence to the current post-surgical standard-of-care, a topical corticosteroid regimen involving as many as four daily administrations for up to four weeks post-surgery. Iontophoretic EGP-437 administered postoperatively by the surgeon has the potential to eliminate the need for daily corticosteroid eye drops to manage post-surgery pain and inflammation, which could lead to improved outcomes for this large patient population. We expect to complete this trial in the third quarter of 2016 and look forward to the continued development of EGP-437 in this highly prevalent indication,” added Dr. Barbara Wirostko M.D., Chief Medical Officer of EyeGate.

EGP-437 incorporates a reformulated topically active corticosteroid, Dexamethasone Phosphate, which is delivered into the ocular tissues through EyeGate’s proprietary drug delivery system, the EyeGate® II Delivery System. Iontophoresis employs the use of a low electrical current that promotes the migration of a charged drug substance across biological membranes. The current produces ions, which through electrorepulsion, drive a like-charged drug substance into the tissues.

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® II Delivery System. In addition, EyeGate is developing, through its wholly-owned Jade subsidiary, products using cross-linked thiolated carboxymethyl hyaluronic acid (“CMHA-S”), a modified form of the natural polymer hyaluronic acid (HA), which possesses unique physical and chemical properties such as viscoelasticity and water retention. The ability of CMHA-S to adhere longer to the ocular surface, resist degradation and protect the ocular surface makes it well-suited for treating various ocular surface injuries. EyeGate intends to initiate a clinical study for Jade’s lead product candidate for corneal epithelial defects. 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 EyeGate’s EGP-437 combination product, and those of Jade Therapeutics, Inc., a wholly owned subsidiary of EyeGate, 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” contained in EyeGate’s Annual Report on Form 10-K filed with the SEC on March 30, 2016, EyeGate’s Quarterly Report on Form 10-Q filed with the SEC on May 13, 2016 or described in EyeGate’s other public filings. EyeGate’s results may also be affected by factors of which EyeGate is 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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