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EyeGate Announces Positive Top-line Data from Phase 1b/2a Clinical Trial of EGP-437 for Treatment of Post-Operative Inflammation and Pain in Cataract Surgery Patients

WALTHAM, Mass., Aug. 01, 2016 (GLOBE NEWSWIRE) -- EyeGate Pharmaceuticals, Inc. (NASDAQ:EYEG) ("EyeGate" or the "Company"), a specialty pharmaceutical company that focuses on developing and commercializing products for treating diseases and disorders of the eye, today announced positive data from its Phase 1b/2a trial assessing its lead product candidate, iontophoretic EGP-437, in the treatment of post-operative ocular inflammation and pain in cataract surgery patients.

This portion of the trial enrolled 40 subjects that had previously undergone cataract surgery with the implantation of a posterior chamber intraocular lenses. The dose ascending trial was designed to assess the safety and efficacy of iontophoretic EGP-437 in these patients post cataract surgery. Patients were divided into four cohorts and administered iontophoretic EGP-437 at either 9mA-min or 14mA-min 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.

A positive response, determined by reduction in Anterior Chamber Cell count (ACC) at day 28, was observed in the majority of patients in cohort 4. Subjects receiving the 14 mA-min dose at days 0, 1 and 4 demonstrated the most significant ACC improvement, with 40% of subjects in this cohort achieving an ACC count of 0 at day 14 which increased to 88% on day 28. Additionally, all subjects administered the iontophoretic treatment experienced reduction in pain at all time points with 90% having no pain as early as day 1 and increasing to 100% on day 14 again in this 14 mA-min cohort. Patients tolerated the procedure well and liked the idea of not using daily eyedrops. No steroid related increase in intraocular pressure was reported.

"The effective management of pain and inflammation is key to optimizing post-surgical outcomes for cataract surgery patients. The results of the 14mA-min dose administered on days 0, 1 and 4 compares favorably to historical control data from current standard of care on Days 7, 14 and 28 for subjects with an ACC count of zero and with little to no pain at all time points for our product," said Randall Olson M.D., Scientific Advisory Board Member of EyeGate. "We believe these data warrant further assessment of iontophoretic EGP-437 through the addition of three new cohorts to the current trial to evaluate additional doses and dosing regimens and further improve upon these encouraging results. We expect top-line data from the additional cohorts in the fourth quarter of 2016, and remain on track to initiate a randomized, placebo-controlled trial of iontophoretic EGP-437 in cataract surgery patients by the end of the year."

“With approximately 3 million cataract surgeries performed in the U.S. each year, postoperative pain and inflammation represent a significant market opportunity for EyeGate and our novel therapy,” added Barbara Wirostko M.D., Chief Medical Officer of EyeGate. “Cataract surgery patients, many of whom are older, may have difficulty instilling eyedrops and thus adhering to the current post-surgical standard of care, a topical corticosteroid eyedrop. We believe that iontophoretic EGP-437 administered by the surgeon has the potential to significantly reduce adherence burden and dramatically improve patient outcomes. We are excited by the data this trial has generated to-date and look forward to the continued evaluation of our lead iontophoretic product in this highly prevalent indication.”

About EyeGate

EyeGate Pharma (NASDAQ:EYEG) is a clinical-stage specialty pharmaceutical company that is focused on developing and commercializing products therapeutics and drug delivery systems for treating diseases and disorders 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 hydration and healing properties. 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 by the end of the year 2016. 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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