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EyeGate Pharma Receives Approval from FDA to Initiate PE Pilot Study

WALTHAM, MA / ACCESSWIRE / August 5, 2019 /EyeGate Pharmaceuticals, Inc. (NASDAQ:EYEG) ("EyeGate" or "the Company"), a clinical-stage company focused on developing products for treating disorders of the eye, announced today that it has received approval from the U.S. Food and Drug Administration ("FDA") to initiate its follow-on pilot study for punctate epitheliopathies ("PE"). The study will use the Ocular Bandage Gel ("OBG") eye drop to treat patients with PE, which can be associated with dry eye.

The FDA has determined that EyeGate provided sufficient data to support initiation of the clinical study and has requested that EyeGate make some modifications to the case report forms (CRFs) and patient instructions. EyeGate will address these modifications and plans to initiate the study immediately, with enrollment expected to begin in the latter part of the third quarter of 2019. As a reminder, the objective of this study is to evaluate several different exploratory performance endpoints in PE patients.

"We are excited to get underway with another clinical study and very pleased with our continued cooperation and collaboration with the FDA," said Stephen From, Chief Executive Officer of EyeGate. "Pending the success of our PE agenda, we believe our unique OBG eye drop will be the first approved eye drop in the U.S. for the treatment of PE. Following the data readout of this pilot study, which we expect by year-end, we will re-convene with the FDA to establish the most suitable endpoint to use in a pivotal study."

About EyeGate
EyeGate is a clinical-stage specialty pharmaceutical company focused on developing and commercializing products for treating diseases and disorders of the eye.

EyeGate's lead product, Ocular Bandage Gel ("OBG"), is based on a modified form of the natural polymer hyaluronic acid, which is a gel that possesses unique properties providing hydration and healing when applied to the ocular surface. EyeGate is in the clinic for two different patient populations: photorefractive keratectomy ("PRK") surgery to demonstrate corneal wound repair and punctate epitheliopathies ("PE"), which includes dry eye.

The objective of OBG is to re-epithelialize the cornea, reduce the risk of infection, improve symptoms, and improve ocular surface integrity. Often current treatments fall short as they are ineffective in protecting and enabling corneal re-epithelialization.

If EyeGate achieves successful completion of the PRK pivotal study and subsequent FDA approval, EyeGate believes OBG will be the only prescription hyaluronic acid eye drop in the U.S. and the only eye drop in the U.S. approved for the healing of corneal epithelial defects. Additionally, if the clinical trial for patients with PE is successful, EyeGate believes OBG will be the only eye drop in the U.S. approved for the treatment of PE.

EGP-437, EyeGate's other product, 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.

For more information, please visit www.EyeGatePharma.com.

EyeGate Social Media
EyeGate uses its website (www.EyeGatePharma.com), Facebook page (https://www.facebook.com/ EyeGatePharma/), corporate Twitter account (https://twitter.com/EyeGatePharma), and LinkedIn page (https://www.linkedin.com/company/135892/) as channels of distribution of information about EyeGate and its product candidates. Such information may be deemed material information, and EyeGate may use these channels to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor EyeGate's website and its social media accounts in addition to following its press releases, SEC filings, public conference calls, and webcasts. The social media channels that EyeGate intends to use as a means of disclosing the information described above may be updated from time to time as listed on EyeGate's investor relations website.

Forward-Looking Statements
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 OBG product, its EGP-437 Combination Product, 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 1, 2019 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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