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EyeGate Receives FDA Feedback on Investigational Device Exemption Amendment for Second Pilot Study of Ocular Bandage Gel

Feedback Provides Clear Path to Resubmission; Expected July 2018

WALTHAM, Mass., April 09, 2018 (GLOBE NEWSWIRE) -- EyeGate Pharmaceuticals, Inc. (NASDAQ:EYEG) (“EyeGate” or the “Company”), a clinical-stage, specialty pharmaceutical company with two proprietary platform technologies for treating diseases and disorders of the eye, today announced that it has received a letter from the U.S. Food and Drug Administration (FDA) responding to the Company's amended investigational device exemption (IDE) application for a second pilot study of the Company's lead product, EyeGate Ocular Bandage Gel (EyeGate OBG), a cross-linked thiolated carboxymethyl hyaluronic acid (CMHA-S) platform being developed for the acceleration of re-epithelialization of large corneal epithelial defects in patients having undergone photorefractive keratectomy (PRK).

In its letter, the FDA identified four deficiencies in the Company's submission, requesting additional information on the manufacturing processes associated with the EyeGate OBG product. The primary comment relates to the validation of the filter specifically used for sterilization of the CMHA material, while the remaining comments include a request for clarification to the previously submitted data and modifications to the manufacturing process documents.

"We are pleased that our first IDE amendment addressed the majority of the 13 issues raised in the FDA’s initial response, and believe that the clarity of feedback provided in this letter gives us a clear path to approvability of the application,” said Stephen From, President and Chief Executive Officer of EyeGate. “We are now in the process of addressing the various points raised in the letter, mainly the validation of the sterile filtration of the CMHA material. According to the agency, one of the three filters used for validating the filter required for sterilizing the CMHA material did not pass the validation step by definition. To address this deficiency, our plan is to work with the manufacturer of the filter to complete the validation work using a different filter. We anticipate completing this work in the coming months, and are targeting the submission of a second amendment to the IDE application in July 2018. Assuming this next amendment is approved by the FDA, we would look to initiate the second EyeGate OBG pilot study in PRK patients later in the third quarter, with top-line data reported in Q4."

The IDE seeks approval for a proposed second pilot study of EyeGate OBG, enrolling up to 45 subjects undergoing a bilateral PRK procedure in a reading center masked trial. The goal

of this study is to compare EyeGate OBG to the current standard of care, bandage contact lens (BCL) plus artificial tears. The primary endpoint will be the percentage of subjects achieving complete wound healing (based on staining) on day 3. Subjects enrolled in the study will be randomized into three arms: EyeGate OBG administered four times daily (QID) for 14 days, EyeGate OBG administered eight times daily for three days, followed by QID administration for 11 days, and BCL with QID administration of artificial tears for 14 days.

In March 2018, the Company submitted an amended IDE comprising of the validation data on the manufacturing processes and bioburden tests related to production of EyeGate OBG, as well as data related to the analytical methods to identify and quantify impurities and degradation products.

The amended IDE submission is subject to review by the Center for Devices and Radiological Health (CDRH) of the FDA, and must be approved prior to initiating this study. Once submitted, the FDA will have 30 days to review the amendment and either request additional data or approve the initiation of the study.

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

EyeGate's CMHA-S platform is based on a cross-linked thiolated carboxymethyl hyaluronic acid (CMHA-S), a modified form of the natural polymer hyaluronic acid (HA), which is a gel that possesses unique physical and chemical properties such as hydrating and healing when applied to the ocular surface. 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.

EGP-437, EyeGate's other 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. 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 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 02, 2018 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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