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EyeGate Pharma Submits Investigational Device Exemption Amendment for Second Pilot Study of Ocular Bandage Gel

WALTHAM, Mass., March 08, 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 submitted an amended Investigational Device Exemption (IDE) application to the U.S. Food and Drug Administration (FDA) for a pilot study of the Company's lead product, EyeGate Ocular Bandage Gel (EyeGate OBG), a cross-linked thiolated carboxymethyl hyaluronic acid (CMHA-S) platform. The amendment summarizes the Company's responses to the FDA's questions and comments in response to the original IDE submission. The Company is developing EyeGate OBG for the acceleration of re-epithelialization of large corneal epithelial defects in patients having undergone photorefractive keratectomy (PRK).

The amendment includes validation data on the manufacturing processes and bioburden tests related to production of Eyegate OBG. It comprises data related to the analytical methods to identify and quantify impurities and degradation products.

“The second pilot study is a critical step in the development of our Eyegate OBG for re-epithelialization of large corneal epithelial defects,” said Stephen From, President and Chief Executive Officer of EyeGate. “The clarity of feedback received from the FDA was very useful in the process of addressing the additional information that was needed for our original submission. Our team has worked hard to compile the large volume of manufacturing validation data, which will be crucial as we continue to move forward toward our planned 510(k) de novo filing in 2019. We are confident that we have addressed the Agency's concerns in our amended application and look forward to working cooperatively with the FDA during the review process. We are committed to bringing this platform product to patients with epithelial defects and anticipate initiating the study as soon as our application is approved.”

The proposed IDE submission for the pilot study will enroll up to 45 subjects undergoing a bilateral PRK procedure in a reading center masked trial. The trial intends 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.

The IDE is subject to review by the Center for Devices and Radiological Health (CDRH) of

the U.S. Food and Drug Administration (FDA), and must be approved prior to initiating this study. The FDA has 30 days to review the submission and provide a verdict on whether or not we can proceed into the clinical study or if additional data is required.

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 most advanced 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 February 23, 2017 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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