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EyeGate Announces FDA Approval of Two IDE Submissions for Ocular Bandage Gel

FDA Grants Approval for Studies for Patients that have undergone Photorefractive Keratectomy and for Patients with Punctate Epitheliopathies

WALTHAM, Mass., July 24, 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 the U.S. Food and Drug Administration (FDA) has approved two of EyeGate's Investigational Device Exemption (IDE) applications for pilot studies of the company's Ocular Bandage Gel (OBG) product for the acceleration of re-epithelialization of large corneal epithelial defects in patients having undergone photorefractive keratectomy (PRK), as well as the reduction in corneal staining for patients with punctate epitheliopathies (PE). EyeGate anticipates entering the clinic for both indications in the third quarter of 2018.

Stephen From, EyeGate's Chief Executive Officer, said, "Receiving FDA approval for both pilot studies is a significant milestone in the development of our EyeGate OBG platform." Mr. From continued, "EyeGate is very pleased to have received these approvals and we look forward to getting these studies underway, as we expect to initiate the clinical trials in the third quarter."

The PRK pilot study will enroll up to 45 subjects undergoing a bilateral 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.

The PE study will enroll 30 patients in a two arm, 6-week trial with 15 patients per arm. PE is being defined in this trial by fluorescein staining of the cornea using the NEI scale. The primary performance outcome will be the change in NEI corneal staining score from day 0 to day 28 between the OBG arm and the comparator arm.

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 the EyeGate OBG 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 2, 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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