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EyeGate Submits Investigational Device Exemption (IDE) Filing for Second Pilot Study of Ocular Bandage Gel

WALTHAM, Mass., May 04, 2017 (GLOBE NEWSWIRE) -- EyeGate Pharmaceuticals, Inc. (NASDAQ:EYEG) ("EyeGate" or the "Company"), a clinical-stage specialty pharmaceutical company that focuses on developing and commercializing products for treating diseases and disorders of the eye, today announced that it has submitted an Investigational Device Exemption (IDE) for the lead product in its cross-linked thiolated carboxymethyl hyaluronic acid (CMHA-S) platform, EyeGate Ocular Bandage Gel (EyeGate OBG). The IDE, if accepted, will enable EyeGate to initiate a second pilot study of EyeGate OBG for the acceleration of re-epithelialization of large corneal epithelial defects in patients having undergone photorefractive keratectomy (PRK).

"The filing of this IDE represents an important step in the ongoing development of EyeGate OBG in corneal re-epithelialization. It comes as a direct result of our November 2016 pre-submission meeting with the FDA, at which the Agency confirmed that regulatory clearance via a De Novo 510(k) was the appropriate path forward for this novel medical device," said Stephen From, President and Chief Executive Officer of EyeGate. "We are encouraged by our dialogue with the FDA to-date, which has clarified the clinical and regulatory path for our lead CMHA-S product candidate. We look forward to continued interaction during the IDE review process and are excited by the prospect of initiating this second pilot study, for which we expect top-line data in the second half of the year."

The IDE submission 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 review process is expected to take a minimum of 30 days, with the total duration of the review to depend on a variety of factors including the extent of potential comments, questions and additional information requested by CDRH / FDA and the timeliness of EyeGate's responses to any such comments, questions or requests for information.

The IDE for this study proposes a reading center masked trial enrolling up to 45 subjects undergoing a bilateral PRK procedure, and aims to compare EyeGate OBG to the current standard of care, bandage contact lens (BCL) plus artificial tears. Enrolled subjects 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
- BCL, with QID administration of artificial tears for 14 days

The study's primary endpoint will be the percentage of subjects achieving complete wound healing (based on staining) on day 3.

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

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.

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 OBG and EyeGate's 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 our Annual Report on Form 10-K filed with the SEC on February 23, 2017 or described in our other public filings. Our results may also be affected by factors of which we are 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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