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# EyeGate Confirms Path to De Novo Filing with FDA

**WALTHAM, MA / ACCESSWIRE / March 26, 2019** /EyeGate Pharmaceuticals, Inc. (NASDAQ: EYEG) ("EyeGate" or "the Company") has met with the U.S. Food and Drug Administration ("FDA") regarding its Ocular Bandage Gel ("OBG") product and has confirmed its path to a de novo filing. The FDA has agreed that based on the strength of data from the photorefractive keratectomy ("PRK") pilot study, EyeGate is ready to move forward with a pivotal study, which will allow for a de novo filing. The Company plans to file the Investigational Device Exemption ("IDE") for initiation of the study in Q2 2019 and to complete the study in Q3 2019 with the de novo being filed soon thereafter. Additionally, the Company will continue with rapid clinical development for the second indication, punctate epitheliopathies.

Stephen From, CEO of EyeGate, said, "We are pleased with the FDA's feedback and are excited to be in a position to file the de novo application subsequent to completing the PRK pivotal study. We look forward to launching the OBG product for the PRK indication in 2020."

## 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 OBG platform is based on a crosslinked thiolated carboxymethyl hyaluronic acid ("CMHA-S"), a modified form of the natural polymer hyaluronic acid, 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 including surgical trauma.

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](http://www.EyeGatePharma.com).

## EyeGate Social Media

EyeGate uses its website ([www.EyeGatePharma.com](http://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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**SOURCE:** EyeGate Pharmaceuticals, Inc.