June 3, 2019

EyeGate Receives Approval from FDA to Initiate PRK Pivotal Study

WALTHAM, MA / ACCESSWIRE / June 3, 2019 /EyeGate Pharmaceuticals, Inc. (NASDAQ: EYEG) ("EyeGate" or "the Company") announced today it has received approval from the U.S. Food and Drug Administration ("FDA") to initiate its photorefractive keratectomy ("PRK") pivotal study. The FDA has determined that EyeGate provided sufficient data to support initiation of the clinical study and has requested that EyeGate make some modifications to the patient informed consent document prior to enrollment. EyeGate will address these modifications immediately and expects enrollment to begin this month.

Stephen From, CEO of EyeGate, said, "We are extremely pleased with the feedback received from the FDA regarding the design of our PRK pivotal study and plan to begin enrollment as soon as possible. We expect to receive topline results by year-end 2019 and, assuming these are positive, plan to submit the de novo application for commercialization shortly thereafter. Our OGB platform, if approved, will be the first prescription Hyaluronic Acid ("HA") eyedrop formulation in the U.S. market providing a huge opportunity for us."

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 development, 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 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.

Contact

Joseph Green / Laine Yonker
Edison Advisors for EyeGate Pharmaceuticals
646-653-7030 / 7035
jgreen@edisongroup.com / lyonker@edisongroup.com

SOURCE: EyeGate Pharmaceuticals, Inc.

View source version on accesswire.com:
https://www.accesswire.com/547443/EyeGate-Receives-Approval-from-FDA-to-Initiate-PRK-Pivotal-Study