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EyeGate Pharma Announces Additional Positive Top-Line Data in PRK Pivotal Study

WALTHAM, MA / ACCESSWIRE / December 2, 2019 / EyeGate Pharmaceuticals, Inc. (NASDAQ:EYEG) ("EyeGate" or "the Company"), a clinical-stage company focused on developing products for treating disorders of the eye, announced today that it has received additional positive topline data in its corneal wound repair pivotal study. As previously announced, the results of this pivotal study demonstrated statistically significant improvement in corneal re-epithelialization in patients treated with EyeGate's Ocular Bandage Gel ("OBG") eye drop versus the standard-of-care, a bandage contact lens ("BCL") post photorefractive keratectomy ("PRK") surgery. Additionally, OBG demonstrated a more rapid corneal wound closure over the standard-of-care as early as day two.

The statistical significance measurement was based on the number of subjects in each arm that achieved complete corneal defect closure three days post refractive surgery. At day 3, 80.2% of eyes receiving the OBG treatment regimen were completely healed, compared with 67.0% for BCL. This resulted in a p-value of 0.0203 in favor of OBG. In accordance with FDA standards, a p-value of 0.05 or less demonstrates superiority.

PRK surgery is performed on both eyes at the same time. The patients were randomized and received identical treatment in both eyes, either OBG or BCL. Per the primary endpoint, one eye was assigned as the study eye. The additional data demonstrated a similar outcome on both eyes as the primary endpoint with a p-value of 0.0119 in favor of OBG.

Furthermore, the data clearly demonstrated that patients treated with OBG experienced a faster healing process. At day 2, the average wound size for all eyes treated with OBG was only 3.61 mm^2, compared to 6.66 mm^2 for eyes treated with BCL, which is 46% smaller than the standard-of-care.

The OBG eye drop was well tolerated with no safety concerns. There were two recurrent epithelial erosions captured in the standard-of-care group and zero in the OBG group. There were no serious adverse events related to OBG in the study (ocular or non-ocular).

The Company expects to receive the full data package in mid-December, but this will not include any additional efficacy or safety information.

"These additional results further demonstrate the impressive efficacy and safety of our OBG eye drop," said Stephen From, EyeGate's CEO. "We are moving forward with our plan to submit a de novo application for commercialization in the first half of 2020. This is a large market opportunity for us with the potential to become a leader in this space."

About EyeGate

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

EyeGate's lead product, Ocular Bandage Gel ("OBG"), is based on a modified form of the natural polymer hyaluronic acid, which is a gel that possesses unique properties providing hydration and healing when applied to the ocular surface. EyeGate is in the clinic for two different patient populations: photorefractive keratectomy ("PRK") surgery to demonstrate corneal wound repair and punctate epitheliopathies ("PE"), which includes the treatment of dry eye.

The objective of OBG is to re-epithelialize the cornea, reduce the risk of infection, improve symptoms, and improve ocular surface integrity. Often current treatments fall short as they are ineffective in protecting and enabling corneal re-epithelialization.

If EyeGate receives FDA approval following successful completion of the PRK pivotal study, EyeGate believes OBG will be the only prescription hyaluronic acid eye drop in the U.S. and the only eye drop in the U.S. approved for the healing of corneal epithelial defects. Additionally, if the clinical trials for patients with PE are successful, EyeGate believes OBG will be the only eye drop in the U.S. approved for the treatment of PE.

EGP-437, EyeGate's other product, 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.

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