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EyeGate Pharmaceuticals Reports Full-year 2016 Financial Results and Provides Business Update

WALTHAM, Mass., Feb. 23, 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 financial results for the twelve-month period ended December 31, 2016, and provided an update on recent corporate and operational achievements.

2016 and Recent Business Highlights:

- Entered into exclusive, worldwide licensing agreement with Valeant Pharmaceuticals International, Inc. ("Valeant") for EGP-437 combination product to treat post-operative pain and inflammation in ocular surgery patients. Under the agreement, the Company received an upfront cash payment and is eligible to receive development and commercial milestone payments as well as royalties on the sale of the product;
- Reported positive top-line data from Phase 1b/2a clinical trial of the EGP-437 combination product for treatment of post-operative inflammation and pain in cataract surgery patients;
- Received additional milestone payments from Valeant under licensing agreement for EGP-437 combination product in uveitis;
- Continued enrolling patients in confirmatory Phase 3 clinical trial of the EGP-437 combination product targeting non-infectious anterior uveitis;
- Reported positive top-line data from first-in-human pilot study of EyeGate Ocular Bandage Gel ("EyeGate OBG") in the treatment of corneal epithelial defects;
- FDA Pre-Submission meeting confirmed 510(k) De Novo regulatory path for EyeGate OBG

"We made remarkable progress throughout 2016, setting the stage for 2017 to be a potentially transformational year for EyeGate. Following the positive top-line data from our cataract surgery trial reported in the fourth quarter, we recently signed our second licensing agreement with Valeant through which they will commercialize our EGP-437 combination product in this highly prevalent indication. We remain on-track to initiate a placebo-controlled Phase 2b study in cataract surgery patients in the first half of 2017 and continue to target the filing of a supplemental NDA in the second half of 2018," said Stephen From, Chief Executive Officer of EyeGate. "Our pivotal study of EGP-437 in anterior uveitis, the first indication licensed to Valeant, continues to progress as well. We expect to complete enrollment in Q3 2017 and to report top-line data in Q4 2017, leading to an NDA submission by the end of the year.

“In addition to the success of the EGP-437 program, 2016 was notable for the expansion of our clinical portfolio through the acquisition of Jade Therapeutics and its novel Cross-linked, Thiolated Carboxymethyl Hyaluronic Acid (CMHA-S) platform. Since completing the acquisition nearly a year ago, we generated positive data from a first-in-human pilot study of our lead CMHA-S product, EyeGate OBG, for the acceleration of re-epithelialization of large corneal epithelial defects in patients having undergone photorefractive keratectomy (“PRK”) and are currently planning to initiate a double-masked, controlled trial evaluating EyeGate OBG monotherapy against the current standard of care, bandage contact lens, in Q2 2017. Importantly, our fourth quarter pre-submission meeting with the FDA confirmed that EyeGate OBG will pursue regulatory clearance in the U.S. via the 510(k) De Novo path. Based on the encouraging data from the pilot study as well as continued discussions with the FDA, we are targeting submission of the 510(k) De Novo application by the end of this year. This is truly an exciting time for EyeGate and we believe our outlook has never been more positive. We are grateful to our shareholders for their ongoing support and look forward to sharing details of our future success.”

Full-year 2016 Financial Review

Net loss for 2016 was $13.3 million, compared with $8.4 million in 2015.

Research and development expenses for the year totaled $8.4 million compared with $2.7 million in 2015. The increase of $5.7 million in costs was primarily due to an increase in clinical and other activity, which we were able to undertake after our August 2015 follow-on offering and is also related to the initiation of our Phase 3 clinical trial for the treatment of anterior uveitis, the Phase 1b/2a trial for post-cataract surgery inflammation and pain, the development of and clinical trial for the EyeGate OBG, as well as research expenses attributable to the Company’s EGP-437-based and CMHA-S-based product pipelines.

General and administrative expenses were $5.6 million, compared with $4.0 million in 2015. The increase of $1.6 million was primarily due to increases in payroll, office and other expenses as company operations have expanded with the increase in clinical activity related to the EGP-437 Phase 3 trials for the treatment of anterior uveitis, the Phase 1b/2a trial for post-cataract surgery inflammation and pain, and the clinical trial for the EyeGate OBG, as well as the expansion of operations following the Jade Acquisition.

Cash and cash equivalents as of December 31, 2016 totaled $3.6 million, compared with $8.4 million as of December 31, 2015. Cash and cash equivalents as of December 31, 2016 does not include the upfront payment received in conjunction with the recently announced Valeant licensing agreement.

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. EGP-437, EyeGate’s first 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. In addition, EyeGate is developing, through its wholly-owned Jade subsidiary, products using cross-linked thiolated carboxymethyl hyaluronic acid (“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. 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’s EGP-437 combination product and those of Jade, a wholly owned subsidiary of EyeGate, 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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