
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 20549

FORM 8-K

**CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported): **September 14, 2020**

EYEGATE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36672

(Commission File Number)

98-0443284

(IRS Employer Identification No.)

**271 Waverley Oaks Road
Suite 108**

Waltham, MA

(Address of principal executive offices)

02452

(Zip Code)

(781) 788-9043

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock, \$0.01 par value	EYEG	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure.

EyeGate Pharmaceuticals, Inc. (the “Company”) hereby furnishes the updated investor presentation attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company may use in presentations to investors from time to time, including at the H.C. Wainwright 22nd Annual Global Investment Conference, being held September 14th – 16th, 2020, at which Stephen From, President and Chief Executive Officer of the Company, will be presenting at approximately 4:00 p.m. Eastern Time on September 15, 2020 via audio webcast at <https://wsw.com/webcast/hcw7/eyeg/1600890>.

The information furnished pursuant to Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

The information furnished in this report, including Exhibit 99.1, shall not be deemed to constitute an admission that such information or exhibit is required to be furnished pursuant to Regulation FD or that such information or exhibit contains material information that is not otherwise publicly available. In addition, the Company does not assume any obligation to update such information or exhibit in the future.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby furnishes the following exhibit:

[99.1 Presentation of the Company, dated as of September 14, 2020](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

EYEGATE PHARMACEUTICALS, INC.

By: /s/ Stephen From
Stephen From
President and Chief Executive Officer

Date: September 14, 2020

**Corporate
Presentation**

September 2020



NASDAQ: EYEG

Some of the matters discussed in this presentation contain forward-looking statements that involve significant risks and uncertainties, including statements relating to the prospects for the Company's OBG and EGP-437 product candidates, for the timing and outcome of the Company's clinical trials, the potential approval to market OBG and EGP-437, and the Company's capital needs. Actual events could differ materially from those projected in this presentation and the Company cautions investors not to rely on the forward-looking statements contained in, or made in connection with, the presentation.

Among other things, the Company's clinical trials may be delayed or may eventually be unsuccessful. The Company may consume more cash than it currently anticipates and faster than projected. Competitive products may reduce or eliminate the commercial opportunities of the Company's product candidates. If the U.S. Food and Drug Administration or foreign regulatory agencies determine that the Company's product candidates do not meet safety or efficacy endpoints in clinical evaluations, they will not receive regulatory approval and the Company will not be able to market them. Operating expense and cash flow projections involve a high degree of uncertainty, including variances in future spending rate due to changes in corporate priorities, the timing and outcomes of clinical trials, regulatory and developments and the impact on expenditures and available capital from licensing and strategic collaboration opportunities. If the Company is unable to raise additional capital when required or on acceptable terms, it may have to significantly alter, delay, scale back or discontinue operations.

Additional risks and uncertainties relating to the Company and its business can be found in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the SEC on March 04, 2020. The Company undertakes no duty or obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or changes in the Company's expectations, except as required by applicable law.

The Company 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 the Company and its product candidates. Such information may be deemed material information, and the Company may use these channels to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor the Company'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 the Company intends to use as a means of disclosing the information described above may be updated from time to time as listed on the Company's investor relations website.



Clinical-stage ophthalmology company focused on developing products for the treatment of ocular disorders



Main platform and intellectual property is based on modifying hyaluronic acid ("HA")



Lead product from the platform is the Ocular Bandage Gel ("OBG") eye drop



First combination product from the platform is MoxiGel (OBG + antibiotic)



EyeGate recently completed clinical development for OBG's first indication (corneal wound healing) and is preparing to initiate a pivotal study for the second indication (punctate epitheliopathies—dry eye).



OBG is a preservative-free eye drop that promotes corneal health by providing a protective barrier on the ocular surface.

Key ingredient is a crosslinked or chemically modified version of hyaluronic acid ("HA")

- HA is a natural substance found in the body, predominately in skin and joints
- HA is a highly viscous lubricant

Crosslinking HA provides ideal characteristics for an eye drop

- Extends product contact on the ocular surface from ~15 minutes to ~2 hours
- Prevents product degradation, maintaining protective barrier that promotes wound healing
- Shear-thinning properties mitigate blurriness and allow higher-concentration of product

OBG Development Franchise

1. As a stand-alone device AND
2. In combination with pharmaceutical ingredients (e.g. antibiotic and anti-inflammatories)

Product	Category	Indication	Pre-Clinical	Pilot / Phase 2	Pivotal / Phase 3	FDA Filing	Commercial
OBG	Wound Healing	Post PRK Surgery	Clinical Development Completed				
	Punctate Epitheliopathies	Moderate / Severe Dry Eye	Moving into Pivotal Study				
MoxiGel	Infectious Disease	Bacterial Conjunctivitis	IND				

OBG – Wound Healing

- PRK, a surgical procedure, is ideal for clinical development
- Large uniform wound (9mm) on a homogenous population

OBG – Epitheliopathies








- Dry eye, a chronic condition, is ideal for clinical development
- Easy to enroll and market opportunity is large

MoxiGel – Infectious Disease

Prevention vs. Treatment

- Bacterial conjunctivitis is an ideal indication for demonstrating treatment or eradication of bacteria
- Although all wounds are prescribed an antibiotic, demonstrating prevention requires very large studies

Key Development Milestones

Product	Indication	2020	2021	
		2H	1H	2H
OBG	Wound Healing Post-PRK	 File <i>de novo</i> Application		 <i>de novo</i> Clearance & Launch Preparation
	Punctate Epitheliopathies (Moderate / Severe Dry Eye)	 File IDE Pivotal Study	 First Patient In & Study Execution	 Top-line Data & File <i>de novo</i> Application
MoxiGel	Bacterial Conjunctivitis		 File IND	 First Patient In & Study Execution

- De Novo clearance for wound healing is anticipated at the same time as top-line data for the punctate epitheliopathies pivotal study
- Confirmed with FDA that the MoxiGel phase 2 study can qualify for one of the two required registrational studies for bacterial conjunctivitis

OBG drops are being developed to address ophthalmic conditions where epithelial cells are either missing (wounds) or compromised (epitheliopathies) and patients would benefit from accelerated healing and added lubrication.

Wounds: Surgery

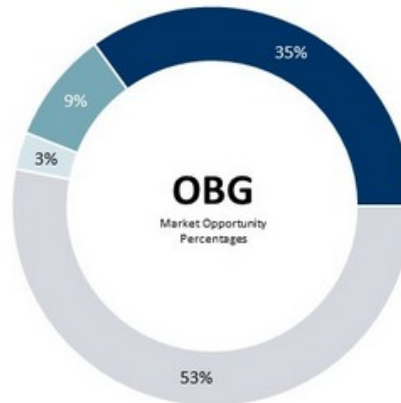
~5 million US patients

- Refractive surgeries (e.g. PRK)
- Cataracts
- Collagen cross-linking

Wounds: Trauma

~2 million US patients

- Injuries / abrasions
- Chemical burns
- Difficult to heal (PCED/ulcers)



Epitheliopathies: Dry Eye

~18 million US patients

- Episodic / mild
- Moderate
- Severe

Epitheliopathies: Non-Dry Eye

~28 million US patients

- Contact lens wear
- Ocular irritants
- Glaucoma medications

There are over 50 million potential patients with corneal wounds or epitheliopathies in the United States.

MoxiGel has the potential to become the first eye drop that both accelerates healing and includes an antibiotic.

Antibiotic eye drops are widely prescribed to help treat the following:

- Conjunctivitis
- Wounds
- Post-surgery recovery
 - Cataract surgery
 - Photorefractive Keratectomy (PRK)
 - Laser-assisted in-situ Keratomileusis (LASIK)

**16
million**

prescriptions are written for antibiotic eyedrops annually in the United States¹



Bacterial Conjunctivitis

Primary signs are discharge and redness



Anticipated Net Selling Price per unit

- Wound healing at ~\$100 per 5mL fill (one-time use)
- PE (dry eye) at ~\$140 per 10mL fill (monthly supply)



Cost of Goods Sold (COGS) – Objective is 90% gross margin

- Scale-up: completing increase from 40L to 200L batch size
- Packaging: FDA agreed on use of multi-dose preservative-free bottle



Anticipate launch for first indication—wound healing in patients that have undergone PRK surgery—first half 2022

- Go-to-market strategy underway for in-house commercialization
- Customer is a small group of specialists that perform the surgery
- Stepping-stone to launch second indication—dry eye—a much larger market with broader group of eye-care professionals



U.S. population being treated for developed indications

- Approximately 850,000 corneal refractive surgeries per year¹
- Approximately 9 million patients with moderate and severe dry eye²



OBG: Wound Healing

in patients who have undergone PRK surgery



What Is PRK?

- PRK is a **surgical correction of refractive errors** for patients who are **not suitable candidates for LASIK** due to:
 - Inadequate corneal thickness
 - Larger pupil size
 - Dry eye
 - Anterior basement membrane disease
- PRK involves controlled mechanical **removal of corneal epithelium** with subsequent **lasering of stroma**



What Is The Unmet Need?

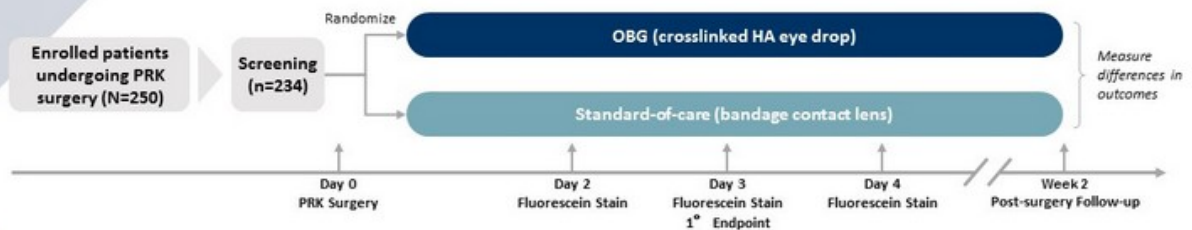
- While PRK yields superior visual results, **complications** include:
 - Post-operative pain
 - Risk of infection
 - Corneal haze
 - Decreased contrast sensitivity
 - Slower visual recovery
- **Standard-of-care is a Bandage Contact Lens (BCL)**, which can result in **subsequent erosion of epithelium**



What Is The Opportunity?

- Enabling the epithelium to heal faster may **mitigate peri-operative complications** and **improve long-term visual outcomes**
- The **PRK population is ideal** for clinical development:
 - Large population (~850,000 LASIK/PRK surgeries per year in the U.S.)¹
 - Large wound (9mm), same size for all patients and know time zero
 - Healthy eyes required and time to healing well-established

Primary Objective: assess the effect of Ocular Bandage Gel (OBG) vs. a Bandage Contact Lens (BCL) in subjects who have undergone bilateral photorefractive keratectomy (PRK)



Study Design	Two-arm, randomized, positive-controlled, masked via reading center
Outcome Measures	<p><u>Primary Endpoint:</u></p> <ul style="list-style-type: none"> Complete corneal re-epithelialization on Day 3 (% of eyes with fully closed wound and remain closed) Wound closure measured by staining of wound; photo of stained wound is sent to reading center <p><u>Secondary Endpoints:</u></p> <ul style="list-style-type: none"> Time to corneal re-epithelialization at Days 2, 3, and 4 post surgery (eyes are stained with fluorescein and photos are sent to reading center) Patient is followed for 2 weeks post-surgery
Enrollment	250 patients enrolled (9 US sites) with 234 qualified patients randomized to OBG or BCL group post-surgery (16 screen failures)

PRIMARY ENDPOINT

Percentage healed at day 3 in each group without a recurrent erosion

RECURRENT EROSION

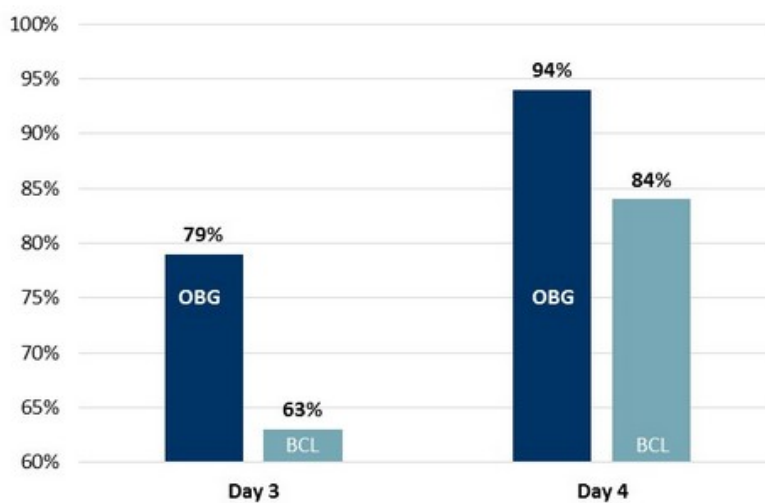
Only 1 (0.9%) study eye in the OBG group had a recurrent erosion; there were 4 (3.5%) in the BCL group

DAY 3 RESULTS

At day 3, 79% of study eyes receiving OBG were completely healed compared with 63% in the BCL group

Percent Of Patients With Complete Re-Epithelialization

(p-value 0.0068)

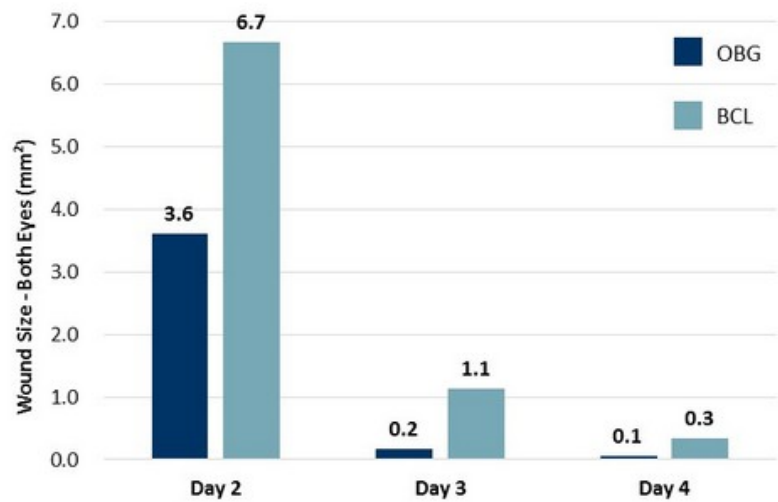


DAY 2 WOUND SIZE

Average wound size in the OBG arm was half that of the control arm (3.6mm² vs. 6.7mm², respectively)

The maximum wound size in the OBG arm was approximately one-third that of the control arm (19.9mm² vs. 58.1mm², respectively)

Wound Size On Average Was 46% Smaller For OBG Patients On Day 2





OBG: Punctate Epitheliopathies

in patients who have moderate and severe dry eye



What Is Punctate Epitheliopathy?

- Punctates are a sign of epithelial compromise (corneal barrier disruption) and is characterized by a breakdown of the epithelium of the cornea and an increased permeability to fluorescein dye
- Corneal barrier disruption is associated with an increased risk of corneal ulceration, corneal haze and decreased vision
- Corneal permeability to fluorescein dye is used to clinically evaluate severity of corneal barrier disruption



What Is The Opportunity?

- PE is associated with many pathologic ocular inflammatory conditions, which can include: dry eye, conjunctivitis, trauma/corneal abrasions, contact lens wear, and chemical irritation and burns
- No eye drop is currently approved for the treatment of PE in the U.S.

Major Opportunity In The Dry Eye Patient Population

Approximately 18 million patients are diagnosed with dry eye in the U.S.¹

Mild	Moderate	Severe	Total
9.0M	7.6M	1.4M	18.0M
50%	42%	8%	100%

Mild Patient Population

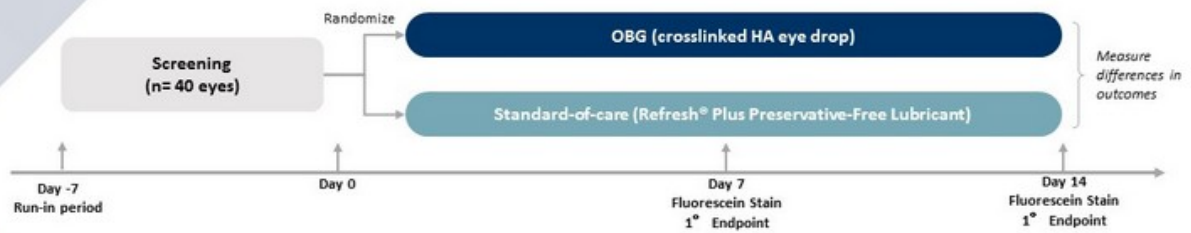
Mild population does not require healing of the ocular surface (lubrication only)

Moderate to Severe Patient Population

- OBG clinical studies target the moderate and severe population (50% of the market), both of which require healing of the ocular surface and lubrication
- The moderate population is underserved and provides a significant market opportunity; only 17% are actively taking Rx anti-inflammatory drops and 34% are using lubricants
- The severe population has more inflammation resulting in 63% actively taking Rx anti-inflammatory drops and 67% are taking lubricant eye drops

OBG benefits both moderate and severe dry eye populations by accelerating the healing of the ocular surface while providing lubrication.

Primary Objective: to evaluate the effect of Ocular Bandage Gel (OBG) vs. Refresh® Plus Preservative-Free Lubricant (RPF) in patients with punctate epitheliopathies (PE) due to dry eye.



Study Design

- Two-arm, randomized, positive-controlled, investigator-masked
- Seven-day run-in period followed by a fourteen-day treatment period
- Patient acted as own control; one eye randomized to OBG arm and one eye randomized to RPF

Outcome Measures

Primary Endpoint:

- Change in NEI corneal fluorescein staining score on Day 14 from baseline for central region and total region of the cornea

Secondary Endpoints:

- Blurriness: Change in tear film stability and visual acuity at 30 and 60 minutes post instilling drops

Enrollment

- 20 patients (40 eyes) where both eyes had to qualify for study randomization
- Subset analysis completed on 16 patients (32 eyes) – applying additional criteria (central staining)

There are 5 regions of the cornea, but the central region is the most important as it covers pupil area, which is responsible for vision quality and corneal sensitivity

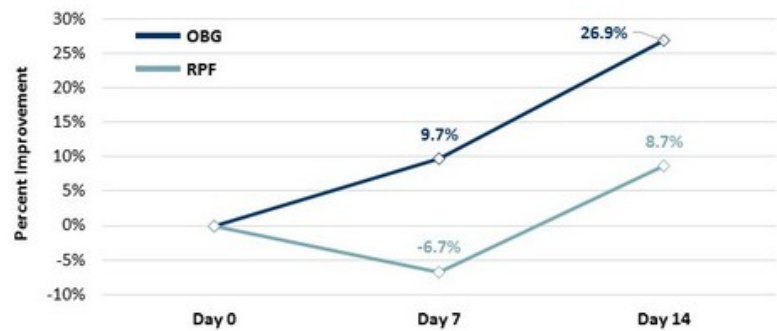
Central corneal staining demonstrated a positive treatment effect at Day 14

- OBG reduced staining by 27% from baseline versus only 9% for Refresh Plus
- OBG provided an overall positive treatment effect of 0.31

OBG also showed improvement more quickly than Refresh Plus with a positive treatment effect of 0.25 at Day 7

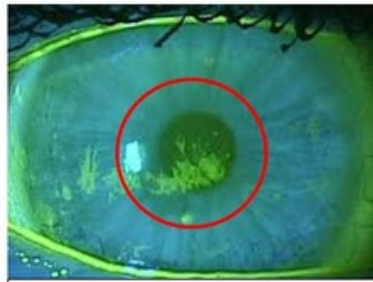
- Increased staining represents a more compromised ocular surface
- Objective is to reduce staining: (graph on upper right shows percent improvement or reduction of staining)

Improvement of Central Cornea Staining
(NEI Scale 0-3)



Central Cornea: NEI Score (Max=3)		
N=16 Subjects Per Group	RPF	OBG
Average Baseline Score	1.44	1.63
Day 7	1.53	1.47
Change from Baseline	0.10	(0.16)
Treatment Effect		0.25
Day 14	1.31	1.19
Change from Baseline	(0.13)	(0.44)
Treatment Effect		0.31

OBG Central Region



Staining of the Central Region
(over the pupil: affects vision)

Scoring for each region is from 0 to 3

OBG pilot study:

- Against REFRESH Lubricant (positive control)
- Improvement over REFRESH = 0.15

Product	Corneal Region	Control	Treatment Effect
OBG	Central	Refresh Lubricant	0.31
Xiidra	Inferior	Vehicle	0.17

Xiidra Inferior Region



Staining of the Inferior Region
(below the pupil: does not affect vision)

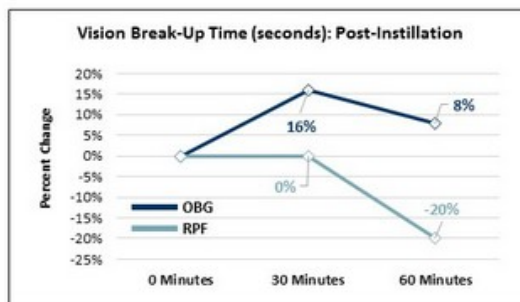
OPUS 3 Pivotal study:

- Against VEHICLE (negative control)
- Improvement over VEHICLE = 0.17

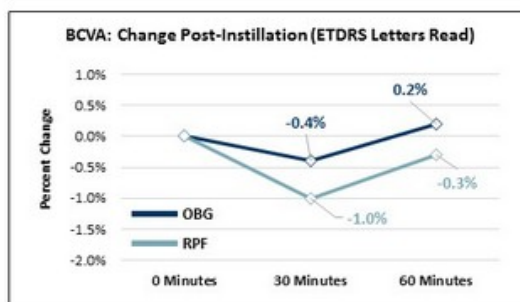
First clinical evidence demonstrating that OBG does not cause blurriness while residing on the ocular surface

A positive VBUT indicates OBG is still on the ocular surface

The BCVA data validates that despite OBG's high-viscosity, there is no blurriness while OBG is on the ocular surface



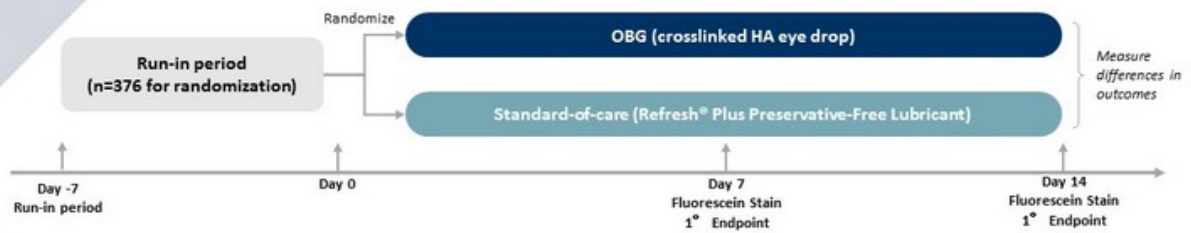
VBUT (seconds)	RPF	OBG
0 minutes	3.33	4.04
30 minutes	3.33	4.92
Change from 0 minutes	0.00	0.88
Treatment Effect		0.88
N = 4 per group		
60 minutes	2.54	4.50
Change from 0 minutes	(0.79)	0.46
Treatment Effect		1.25



BCVA (letters)	RPF	OBG
0 minutes	79.69	84.15
30 minutes	78.93	83.81
Change from 0 minutes	(0.76)	(0.34)
Treatment Effect		0.42
N = 20 per group		
60 minutes	79.43	84.31
Change from 0 minutes	(0.26)	0.16
Treatment Effect		0.42

VBUT: Vision Break-up Time; Using a HD Analyzer, it is a non-invasive method to determine Tear-Film Stability or Break-up Time
BCVA: Best Corrected Visual Acuity

Primary Objective: to evaluate the effect of Ocular Bandage Gel (OBG) vs Refresh® Plus Preservative-Free Lubricant (RPF) in patients with punctate epitheliopathies (PE) due to dry eye.



Study Design

- Two-arm, randomized, positive-controlled, double-masked
- Seven-day run-in period followed by a fourteen-day treatment period
- Main inclusion criteria: corneal staining, tear-film breakup-time and symptomology

Outcome Measures

Primary Endpoint:

- Change in NEI corneal fluorescein staining score on Day 14 from baseline for central region of the cornea
- Powered at 90% for demonstrating superiority over control

Secondary Endpoint:

- Change in NEI corneal fluorescein staining score on Day 14 from baseline for total cornea

Enrollment

- 376 patients to be randomized post 7-day run-in period



MoxiGel: Infectious Disease

in patients with bacterial conjunctivitis

FDA Confirmed

- Preclinical plan (i.e. only one 28-day ocular tox study required for IND filing)
- Two well-controlled registration studies required (one can be the Phase 2b study)
- One of the two registration studies must include an arm for each of the products separately

Phase 2b Anticipated Design

- Four arms: MoxiGel, Moxifloxacin, OBG, and placebo
- Eight-day study with primary endpoints at day 5:
 - Clinical: clearance of ocular injection (redness) and clearance of ocular discharge
 - Microbiology: eradication of bacteria

Phase 3 Anticipated Design

- FDA has agreed that the Phase 3 pivotal study only requires two arms, and the control can be placebo (i.e. MoxiGel vs placebo)



Next Steps

- OBG demonstrated superiority over standard-of-care in wound healing pivotal study
 - File *de novo* application by YE 2020
- Completed 3 FDA meetings with positive outcomes
 - Test new multi-dose preservative-free packaging for OBG
 - File OBG IDE for pivotal punctate epitheliopathies study in dry eye by YE 2020
 - File MoxiGel IND for bacterial conjunctivitis in H1 2021
- Prepare go-to-market strategy
 - Reduce COGS (scale-up and packaging)
 - Engage consulting firm to formalize plan and initiate (currently underway)



THANK YOU

NASDAQ: EYEG

Contact

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