



***OBG: The Ocular Liquid Bandage***

**A crosslinked hyaluronic acid (CMHA-S) eye drop for corneal wounds and epitheliopathies, including dry eye**

***NASDAQ: EYEG***

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EyeGate Pharmaceuticals, Inc.  
271 Waverley Oaks Road, Suite 108 Waltham, MA 02452  
[www.eyegatepharma.com](http://www.eyegatepharma.com)

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## Hyaluronic acid (HA) is a naturally occurring compound in the body

- ~15 grams of HA in an adult human body
- Possesses unique properties such as hydration (synovial fluid) and promotion of wound healing (skin): ideal for ocular surface
- Issue: rapidly degrades, one-third is naturally turned-over (degraded and synthesized) every day

### Properties

High-molecular weight HA is non-immunogenic

High-molecular weight HA binds up to 1,000 times its volume in water weight

HA provides: hydration, lubrication of joints, and a meshwork for cell migration

### Regulatory Approvals

#### U.S. – Dermatology & Osteoarthritis

- HA approved in the U.S. as a device for wound and burn management and injections to treat knee pain caused by osteoarthritis

#### Ex-U.S. – Dry Eye & Wound Healing

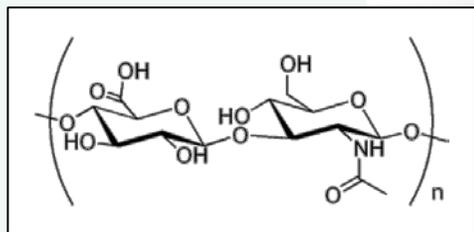
- Low concentration formulations of HA eye drops (0.1% to 0.4%) are the standard of care in Europe and Asia for ocular wound healing, dry eye and ocular surface damage

# EyeGate's CMHA-S Platform:

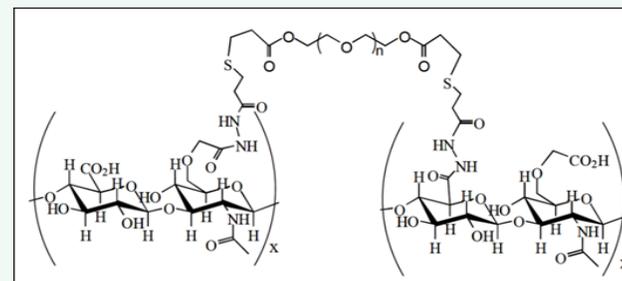
A unique crosslinked, high concentration version of Hyaluronic acid

First and Only Eye Drop in the U.S. Targeting Acceleration of Re-Epithelialization

## Hyaluronic Acid (HA)



## Crosslinked HA



## Crosslinking - Prevents Degradation and Increases Ocular Surface Retention

- Crosslinking creates a 3D structure that stabilizes the molecule → **Resists degradation**
- Prolonged residency time on the ocular surface → **90 to 120 minutes**
- Higher viscosity/shear rate → **Thins with blinking and is non-blurring**
- Scaffolding matrix → **Protects the ocular surface**
- Preservative-Free, 100% pure HA → **Natural product, safe, well tolerated, well known to physicians**

**A high concentration HA eye drop (0.75%) for potentially treating a wide variety of ocular surface pathologies from dry eye to wound healing**

## Demonstrated efficacy and safety in animals



### Commercially available as a veterinary device

- Manufactured by SentrX Animal Care
- Sold in the U.S. and certain European countries by Bayer Animal Health as Remend® Corneal Repair<sup>1</sup>
- 5 years in thousands of dogs, cats and horses, with an excellent efficacy/safety profile

## Efficacy of CMHA-S has been demonstrated in various animal pathologic conditions

- Post traumatic corneal stromal ulcers (real world dogs and cats)
- Corneal abrasion and alkali burn injuries (rabbit models)
- Dry eye (veterinary dogs who failed topical cyclosporine)

### Molly: 12 year old cat with a non-healing corneal defect



A. Non-healing at 42 days



B. Ulcer healing after 12 days of using 0.75% CMHA-S

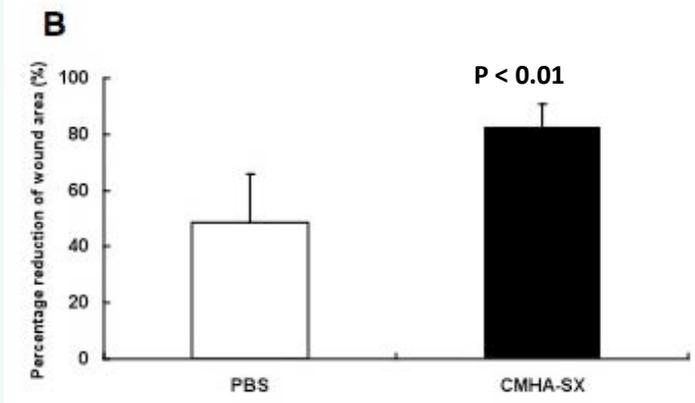
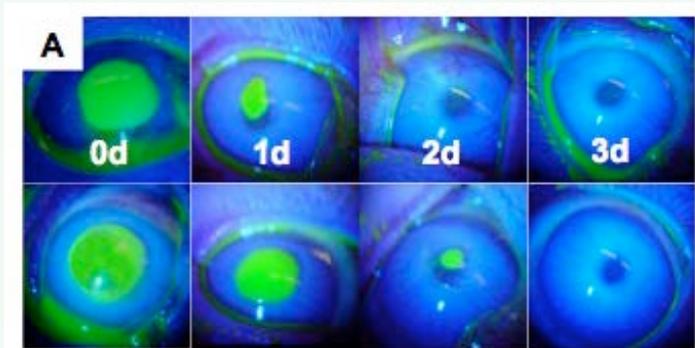
1. EyeGate has human ophthalmic rights only. Visit <http://www.bayerdvm.com/show.aspx/remend-cross-linking-video>

# Healing Corneal Abrasions and Alkali Burns

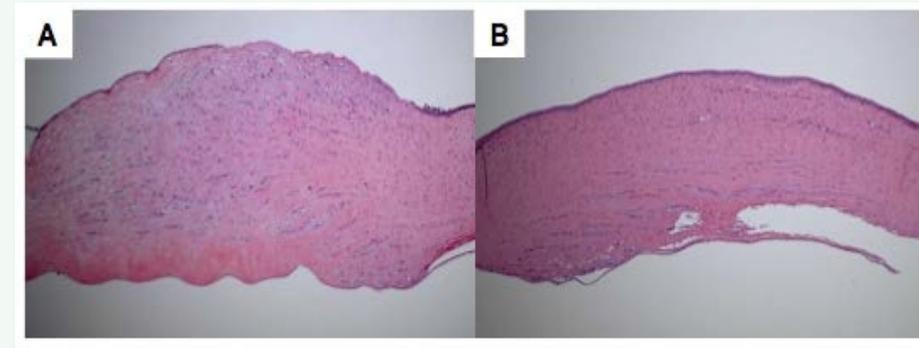
Efficacy Study: Rabbits<sup>1</sup>

**CMHA-S treated central corneal epithelium exhibited a faster wound closure**

**CMHA-S treated cornea exhibited “more normal” epithelial and stromal organization**



A. Fluorescein staining of corneal epithelial abrasions  
B. Quantitative analysis at 24 hours; 49% vs 83% complete



## Histology of alkali burn healing

- A. Control at Day 12 central wound with unhealed corneal epithelium
- B. CMHA-S treated central epithelium and corneal stroma showing a better organization than control

- **Abrasion:** Wound closure complete by 48 hours with CMHA-S
- **Burns:** Complete re-epithelization at Day 12 for CMHA-S but not for control

1. Guanghui Yang, Ladan Espandar, Nick Mamalis and Glenn D. Prestwich, Veterinary Ophthalmology 2010

# CMHA-S Eye Drop Accelerates Corneal Surface Re-Epithelialization

## Completed First Human Clinical Trial in PRK Patients

- ✓ **PRK surgery provides several advantages as indication to evaluate the Ocular Liquid Bandage Gel (OBG)**
  - A homogenous patient population with large epithelial defects of the same size
- ✓ **39 subjects randomized to one of three groups: both eyes received the same treatment**
  - (i) OBG alone (ii) OBG + Bandage Contact Lens (BCL) (iii) Standard of care (BCL + Artificial Tears)
  - OBG alone demonstrates accelerated wound healing vs. standard of care
    - 55% more patients healed by Day 3
    - Wound size up to ~36% smaller by Day 1 (24 hr. post-op), 83.3% smaller by Day 3 with OBG alone

	# Subjects per arm	Closed Wound: Day 3		Length in mm			
				Day 1		Day 3	
				#	%	Horizontal	Vertical
Arm 1: OBG	12	10	83.3%	4.1	4.5	0.10	0.20
Arm 2: OBG + BCL	14	9	64.3%	6.3	6.50	0.30	0.30
Arm 3: BCL + AT <sup>1</sup>	13	7	53.8%	6.4	6.20	0.60	0.60
<b>Total Subjects Enrolled</b>	<b>39</b>						
<b>OBG: % better than BCL</b>			<b>54.8%</b>	<b>35.9%</b>	<b>27.4%</b>	<b>83.3%</b>	<b>66.7%</b>

**Moving to formal pilot trials in PRK and Moderate Dry Eye Patients with Top-line Data expected Q3-2018**

### Meeting with FDA (Nov 2016) Confirms *de novo* 510(k) Filing Path

- No predicate device – label determined by clinical trials demonstrating superiority
- Initial superiority claim discussed: acceleration of re-epithelization of corneal wounds/defects
  - PRK is an excellent homogenous model for measuring time to corneal wound repair
- Current development plan includes additional clinical studies beyond PRK
  - Punctate Epitheliopathies: focus is on moderate dry eye
  - Superiority claim: reduction in corneal staining
- Broadening indication for use (IFU) post initial *de novo* clearance (PRK and PE)
  - Subsequent filings reviewed in approximately 4 months (i.e. 510(k) clearance)
  - Similar to PE, claims can be based on size of defect, not a specific indication

**Initial Two Indications: Photorefractive Keratectomy and Punctate Epitheliopathies**

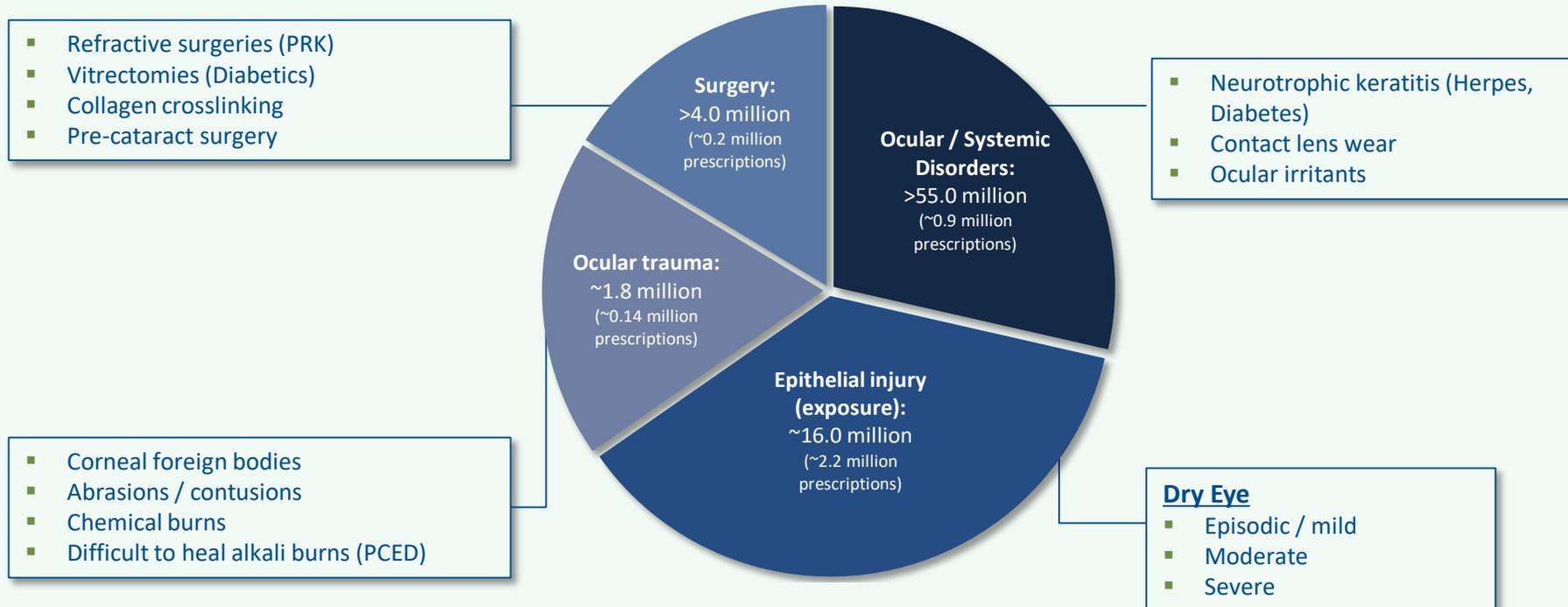
### Targeting Moderate Dry Eye Patients with Top-line Data expected Q2 2018

- **PE as defined by fluorescein staining of cornea: NEI scale**
  - Randomization: NEI score  $\geq 5$
- **30 subjects for 2 arm trial: 15 subjects per arm**
  - Safety will include both eyes (N = 60)
- **42 Day trial: 2 week wash-out/run-in followed by 4 weeks of two arms**
  - Day -14 screening: all subjects stop all topicals and take Refresh PF artificial tears QID OU for 14 days
  - Day 0 randomization: OBG QID for 28 days vs Refresh PF artificial tears QID OU for 28 days
- **Primary performance outcome:**
  - Change in NEI corneal staining score from baseline to Day 28 between OBG arm and artificial tears arm for the study eye

## EyeGate's proprietary crosslinking has potential to address multiple conditions

- Targeting data from next PRK trial and PE trial in first half of 2018, with anticipated filing of de novo 510(k) by first quarter 2019

### Corneal Wounds and Epitheliopathies: U.S. Numbers



1. Source: American Academy of Ophthalmology (<https://www.aaopt.org/newsroom/eye-health-statistics>)

# Continued Unmet Medical Need & Modest Development Investment Creates Opportunity Even in Face of Generic Restasis Entry



Over 76M patients with corneal wounds or epitheliopathies in US but only 3.5M Rx's of current treatment options

- **Primary focus on punctate epitheliopathy/moderate dry eye market**
  - Patients not adequately managed on artificial tears and/or adjunctive to Restasis / Xiidra
  - Physician research supports need for additional treatment options & strong support for OBG profile in dry eye and wound management
- **Payer research, which anticipates generic Restasis, supports WAC in the range of \$125-\$225 with Nets of \$105 - \$165 in Commercial plans where patient OOP is ~\$35**
  - As a medical device OBG will NOT be covered by Medicare Part D
  - A device outside of Medicare Part D, however, makes patients eligible for discount programs → Net patient OOP ~\$75
- **In early discussions regarding partnership or acquisition**
  - Building plans and capabilities for self launch if desired

# Development Timeline



Program	Disease Area	2017	2018	2019	2020
<b>OBG Eye Drop</b> <i>Crosslinked Hyaluronic Acid</i>	Large Corneal Wounds Photorefractive Keratectomy (PRK)	PoC Trial	IDE Work	Pilot Trial, Pivotal Trial	de novo 510(k), Launch
	Punctate Epitheliopathies Focus: Moderate Dry Eye		Pilot Trial, Pivotal Trial		
<b>OBG + Corticosteroid Eye Drop</b> <i>Crosslinked Hyaluronic Acid</i>	Punctate Epitheliopathies Focus: Severe Dry Eye		Preclinical Work	IND, Ph 1b/2a Trial	Ph 2b Trial

## Proprietary Formulation of HA Resists Degradation and Accelerates Re-Epithelialization

- Proprietary crosslinked HA produces a preservative-free, high concentration eyedrop that resists degradation and adheres to the ocular surface without blurring vision
- Hydrating, protectant and lubricant that facilitates acceleration of corneal re-epithelialization
- Positive results in human PRK trial has led to addition of clinical studies for moderate dry eye
- Physician and Payer research support demand and reimbursement
- Following a medical device pathway, approval by late 2019 possible



***Thank You!***

**NASDAQ: EYEG**

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