



Innovation In Ophthalmics

Virtual Investor & Analyst Event:

***Understanding the Potential of EYSUVIS™
for the Short-Term Treatment of the Signs
and Symptoms of Dry Eye Disease***

September 17, 2020



Disclaimers and Notices

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All information in this presentation is as of September 17, 2020 and should not be considered current after such date. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Agenda

1

Background on Dry Eye Disease (DED) and Dry Eye Flares

Kelly Nichols, OD, MPH, PhD, FAAO

Dean, School of Optometry, University of Alabama at Birmingham

2

EYSUVIS™ Clinical Trial Results and Implications for Clinical Practice

Edward J. Holland, MD

Director of Cornea Services at Cincinnati Eye Institute and Professor of Ophthalmology at the University of Cincinnati

First Q&A Session

3

EYSUVIS Commercial Opportunity

Todd Bazemore

Chief Operating Officer, Kala Pharmaceuticals Inc.

Second Q&A Session

Key Opinion Leader Presenters



Kelly Nichols, OD, MPH, PhD, FAAO

Dean, School of Optometry, University of Alabama at Birmingham

Topic: Background on Dry Eye Disease (DED) and Dry Eye Flares



Edward J. Holland, MD

Director of Cornea Services at Cincinnati Eye Institute and Professor of Ophthalmology at the University of Cincinnati

Topic: EYSUVIS Clinical Trial Results and Implications for Clinical Practice

Background on Dry Eye Disease (DED) and Dry Eye Flares

Kelly Nichols, OD, MPH, PhD, FAAO

Dean, School of Optometry, University of Alabama at Birmingham

What is DED?

Dry Eye Workshop (DEWS) II (2017): DED is a **multifactorial disease** of the ocular surface characterized by loss of homeostasis of tear film and accompanied by ocular symptoms in which tear film instability and hyperosmolarity, **ocular surface inflammation** and damage, and neurosensory abnormalities play etiological roles¹



DED is thought to be among the most common complaints to eye care professionals²

Symptomatic disease-causing dryness, irritation/discomfort, blurry/fluctuating vision, eye fatigue, tearing³

Symptoms of DED are a common motivation for patients to seek eye care⁴

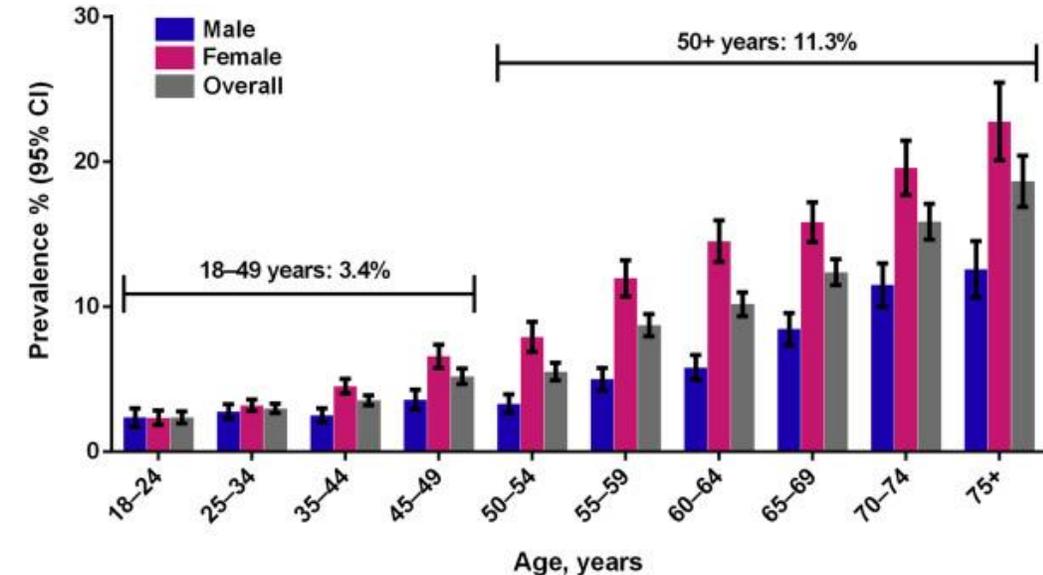
Uncontrolled and untreated DED negatively impact refractive and cataract surgery outcomes^{5,6}

1. Craig JP, Nichols KK, Akpek EK, et al. *Ocul Surf.* 2017;15(3):276-283. 2. American Academy of Ophthalmology Corneal/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology. 2018. Available at: www.aaopt.org/ppp. 3. National Eye Institute: Fact about Dry Eye <https://nei.nih.gov/health/dryeye/dryeye...> 4. Uchino et al, *Curr. Ophthalmol Rep.* 2013, 1: 51-57. 5. Epitropoulos AT, Matossian C, Berdy GJ, Malhotra RP, Potvin R. *J Cataract Refract Surg.* 2015;41(8):1672-1677. 6. Gomes JAP, Azar DT, Baudouin C, et al. *Ocul Surf.* 2017;15(3):511-538.

The Prevalence of DED Increases Every Year, Especially Among Women

- The prevalence of DED in US is consistent with global estimate: **5% to 50%**¹
- **~17 million diagnosed DED patients in the US**²
- The exact prevalence is difficult to accurately determine due to a lack of consensus on diagnosis methods, a mismatch between signs and symptoms, and the use of restricted cohorts that traditionally exclude **younger individuals with multiscreen lifestyles**^{1,3}
- **The burden of DED is predicted to escalate in the future**, likely because of an aging population and an increasing dependence on multiscreen technologies^{1,3,4}

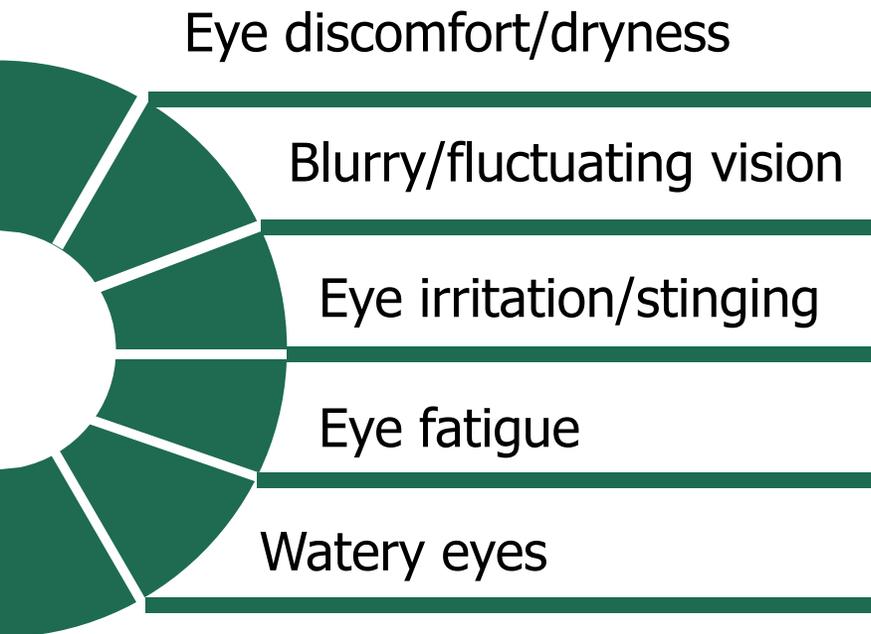
From 2005-2012 prevalence has increased⁴
0.5% among 18 to 39-year old population
1.44% among 40 to 49-year old population
4.23% among 50-year old or older population



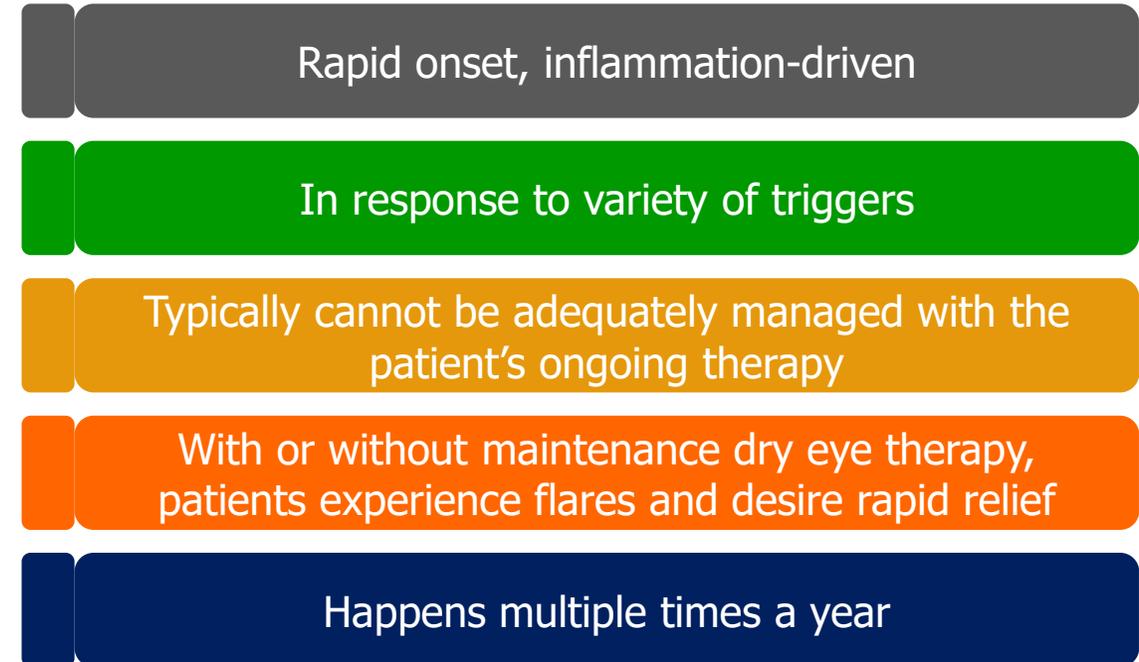
1. Stapleton F, Alves M, Bunya VY, et al. *Ocul Surf.* 2017;15:334-365. 2. Market Scope. 2019 Dry Eye Products Market Report. 3. Bron AJ, de Paiva CS, Chauhan SK, et al. *Ocul Surf.* 2017;15:438-510. 4. Dana R, Bradley JL, Guerin A, et al. *Am J Ophthalmol.* 2019;202:47-54.

DED is a Symptomatic Disease Characterized by Acute Exacerbations of Symptoms and/or Signs (Flares)

Most common symptoms¹



Characteristics of DED Flares²

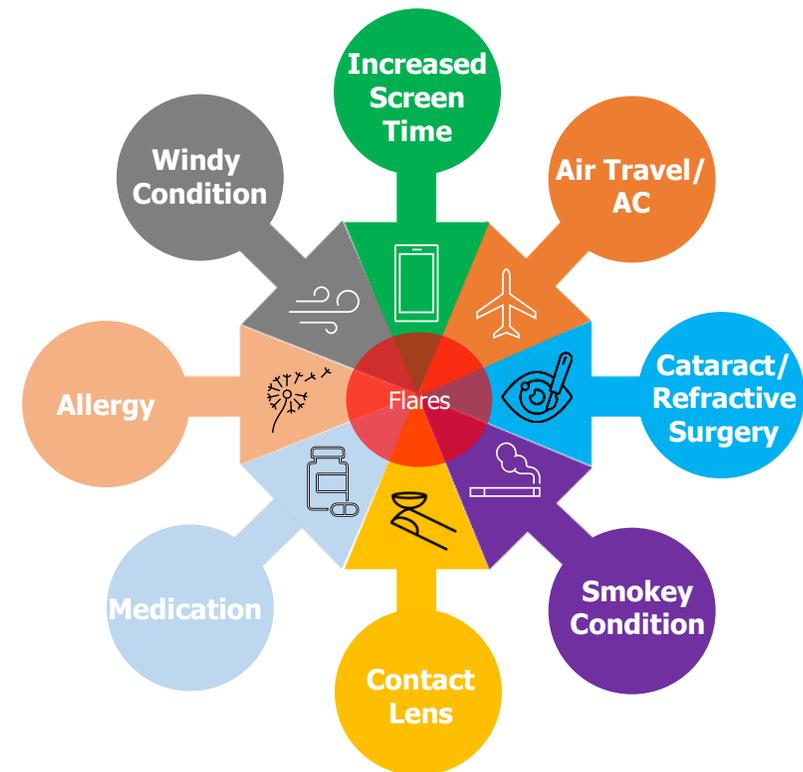


1. American Academy of Ophthalmology Corneal/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2018. Available at: www.aao.org/ppp.
2. ASCRS EyeWorld. <https://www.eyeworld.org/download/file/fid/453>. Published May 2019. Accessed Sept 1, 2020.

DED is a Chronic Disease but Most Patients Do Not Experience Constant Symptoms

Potential Triggers of DED Flares^{3,4}

- ~80% DED patients experience symptom flares and the majority have multi-day episodes^{1,2}



1. Brazzell RK, et al. Prevalence and Characteristics of symptomatic Dry Eye Flares: Results from Patient Questionnaire Surveys. American Academy of Optometry 2019 Orlando FL. 2. 2018 Study of Dry Eye Sufferers. Multi-Sponsor Surveys Inc. Princeton, NJ. 3. American Academy of Ophthalmology Corneal/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2018. Available at: www.aao.org/ppp. 4. Nettune GR, Pflugfelder SC. Post-LASIK tear dysfunction and dysesthesia. Ocul Surf 2010; 8:135–145



DED Decreases Quality-of-life, Workplace Productivity, and Compromises Cataract and Refractive Surgery Outcomes

- DED caused **~30% impairment** of workplace performance (presenteeism), work productivity, and non-job-related activities¹
- Patients with DED have **2-3 times more difficulty** with everyday activities ($P<0.001$), such as reading, working, computer use, watching television and daytime or night-time driving²
- DED induces **contact lens intolerance and discontinuation**
 - **79%** of contact lens wearers report discomfort and **77%** report feeling dryness³
- DED can adversely **affect cataract and refractive surgery outcomes**⁴
 - Regression after LASIK occurred in **27%** of patients with DED vs 7% patients without DED ($P<0.001$)⁵
 - DED caused blurry vision in **15%** of cataract surgery patients⁶

1. Nichols KK et al. *IOVS* 2016; 57(6):2975-2982; 2. Miljanović B, Dana R, Sullivan DA, Schaumberg DA. *Am J Ophthalmol.* 2007;143(3):409-415. 3. Begley CG, Chalmers RL, Mitchell GL, et al. *Cornea.* 2001;20(6):610-618. 4. Starr CE et al. *J. Cataract Refract Surg* 2019; 45(5):669-684; 5. Albietsz JM, Lenton LM, McLennan SG. *J Cataract Refract Surg.* 2004;30(3):675-684. 6. Woodward MA, Randleman JB, Stulting RD. *J Cataract Refract Surg.* 2009;35(6):992-997.

How is DED Diagnosed?



Symptoms and questionnaires
Ocular surface symptoms
Visual symptoms

Symptom
Assessment

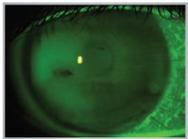
Tear breakup time (TBUT)
Lid & meibomian gland
evaluation

Tear film
Stability



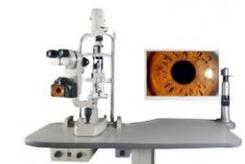
Ocular surface
Examination

Fluorescein staining
Lissamine green staining
Ocular/conjunctival redness



Tear film
Evaluation

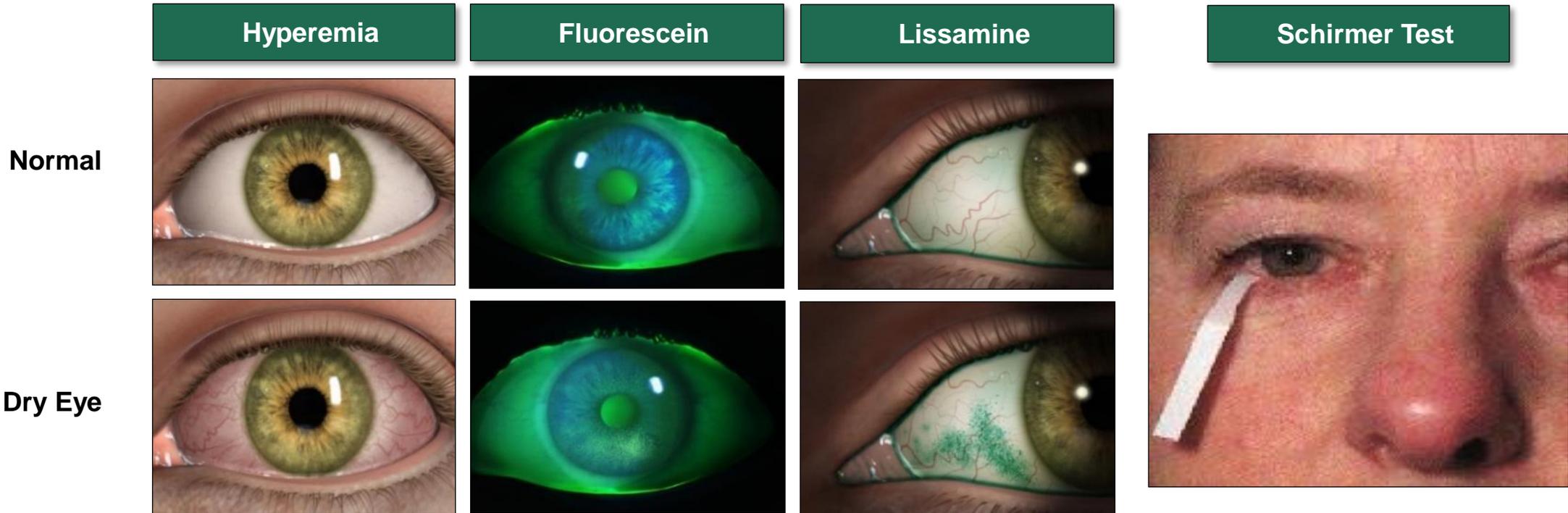
Slit lamp evaluation
Tear volume test
Tear osmolarity test



No single test is adequate to establish the diagnosis of DED^{1,2,3}

1. American Academy of Ophthalmology Corneal/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology. 2018. Available at: www.aao.org/ppp;
2. Care of patients with ocular surface disease. American Optometric Association Clinical Practice Guideline 2010; Available at www.aoa.org. Accessed on September 8, 2020;
3. Wolffsohn JS, Arita R, Chalmers R, et al. *Ocul Surf*. 2017;15(3):539-574.

DED Diagnosis: Evaluating Signs



- DED signs may include punctate erosions, low tear lakes, rapid tear break-up time, meibomian gland disease, and conjunctival hyperemia, an important indicator of inflammation.¹
- Multiple diagnostic tests are available to evaluate the signs DED.^{1,2,3} The most common include corneal fluorescein staining, lissamine green or rose bengal staining, tear break-up time, physical examination for conjunctival hyperemia, and the Schirmer tear test

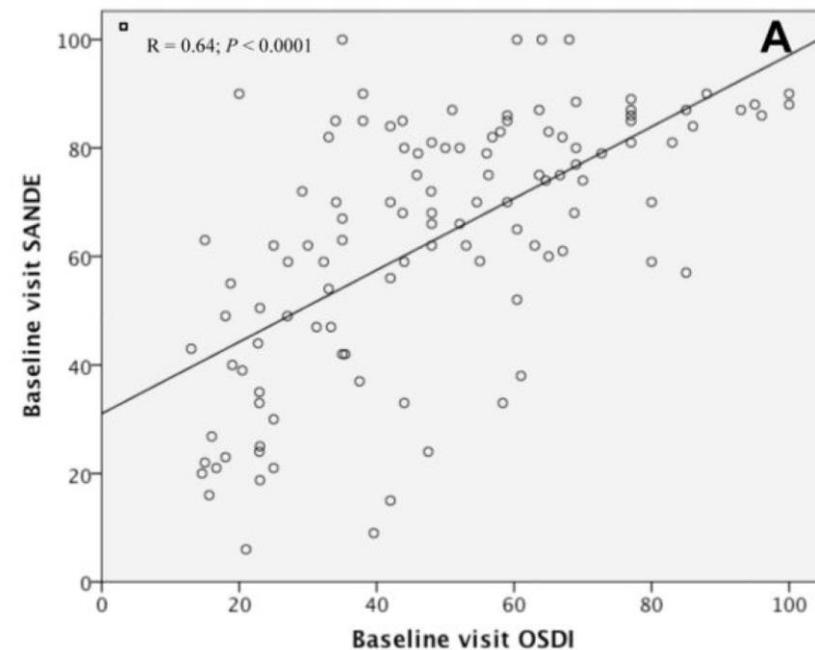
1. Zeev MS, et al. *Clin Ophthalmol.* 2014;8:581-590. 2. American Academy of Ophthalmology Corneal/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2018. Available at: www.aao.org/ppp; 3. Care of patients with ocular surface disease. American Optometric Association Clinical Practice Guideline 2010; Available at: www.aoa.org; Accessed on September 8, 2020

DED Diagnosis: Symptom Assessment

Validated Patient-reported Outcomes Questionnaires¹

- Ocular Surface Disease Index[®] (OSDI)
- The Dry Eye Questionnaire 5 (DEQ-5)
- Symptom Assessment in Dry Eye (SANDE)
- Standard Patient Evaluation of Eye Dryness[™] (SPEED)

Significant Correlation between OSDI and SANDE²



1. Wolffsohn JS, Arita R, Chalmers R, et al. *Ocul Surf.* 2017;15(3):539-574.
 2. Amparo F, Schaumberg DA, Dana R. *Ophthalmology.* 2015;122(7):1498-1503.

SANDE Questionnaire

PLEASE COMPLETE THE FOLLOWING QUESTIONS REGARDING THE FREQUENCY AND SEVERITY OF YOUR DRY EYE SYMPTOMS.

1. Frequency of symptoms:

Please place an 'X' on the line to indicate how often, on average, your eyes feel **dry and/or irritated**:

Rarely _____ All the time

2. Severity of symptoms:

Please place an 'X' on the line to indicate how severe, on average, you feel your symptoms of **dryness and/or irritation**:

Very Mild _____ Very Severe

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Ocular Surface Disease Index[®] (OSDI)²

Ask your patients the following 12 questions, and circle the number in the box that best represent answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

Have you experienced any of the following during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light? ...	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5 (A)

Have problems with your eyes limited you in performing any of the following during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A

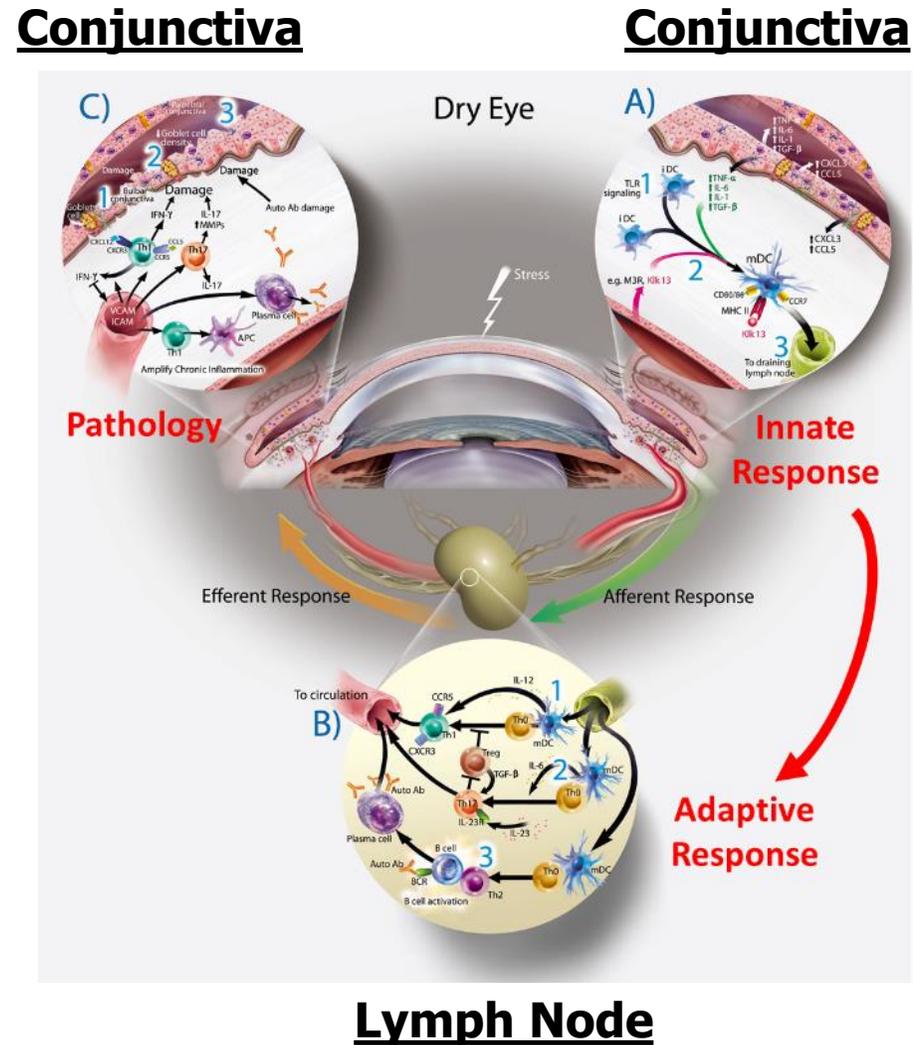
Subtotal score for answers 6 to 9 (B)

Have your eyes felt uncomfortable in any of the following situations during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned? ...	4	3	2	1	0	N/A

Subtotal score for answers 10 to 12 (C)

DED is a Complex Inflammatory Disease

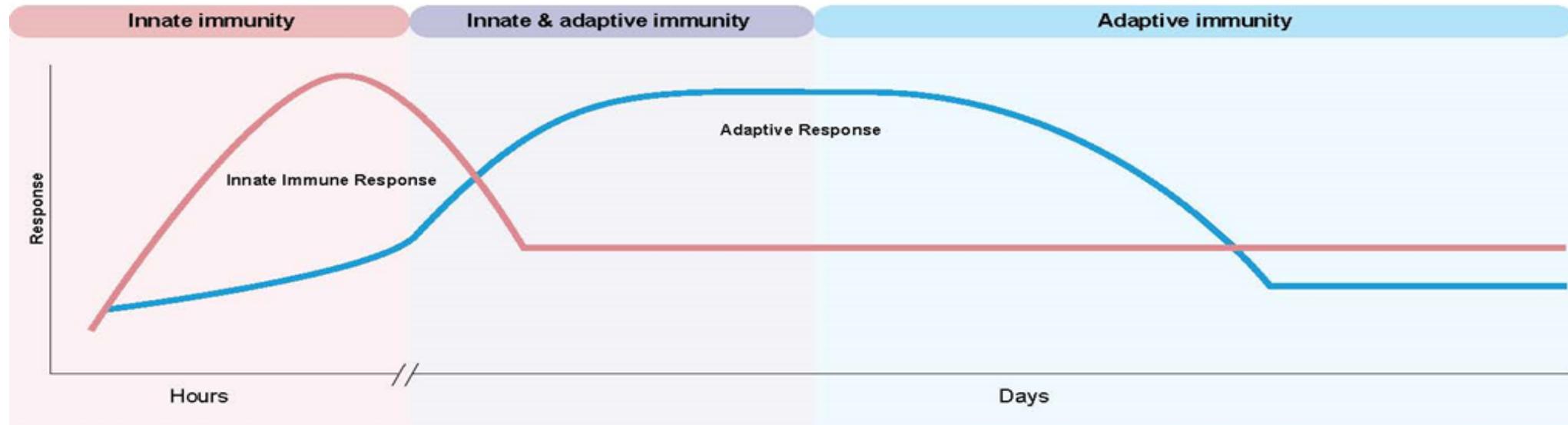
Ocular surface inflammation plays a key role in all types of DED



Conjunctival hyperemia in DED is a good indicator of inflammation

Dry Eye Flares: Fast Onset and Inflammation-Driven

Acute DED flares are driven by both innate and adaptative immune responses¹



Innate
On-set within
hours

**Innate to
adaptive
switch**

Adaptive
Prolonged (days or
longer) response

Resolution
Elevated
threshold

Corticosteroid targets both innate and adaptative immune response²

1. Perez VL, Stern ME, Pflugfelder SC, *Experimental Eye Research* 2020: Cornea Special Issue IV: Immunology, infection, neovascularization, and surgery submitted; 2.. Jones L, Downie LE, Korb D, et al. TFOS DEWS II Management and Therapy Report. *Ocul Surf.* 2017;15(3):575-628.

General Treatment Approach for DED

Step 1	Education, modification and elimination of offending factors: environmental, dietary, systemic and topical medications; Lid hygiene; Artificial tears.
+	
Step 2	Anti-inflammatories (topical corticosteroids); Immunomodulatory agents (cyclosporine; lifitegrast); Topical secretagogues; Punctal occlusion
+	
Step 3	Oral secretagogues; Autologous/allogeneic serum eye drops; Therapeutic contact lens
+	
Step 4	Topical corticosteroid for longer duration; Amniotic membrane graft; Permanent punctal occlusion; Other surgical approaches

Jones L, Downie LE, Korb D, et al. TFOS DEWS II Management and Therapy Report. *Ocul Surf*. 2017;15(3):575-628.

Current Pharmaceutical Treatments of DED

ARTIFICIAL TEARS AND LUBRICANTS

The most commonly-used, mainly palliative treatment.¹ Do not adequately address underlying inflammation.



ANTI-INFLAMMATORY AGENTS: CORTICOSTEROIDS

Broad spectrum, targeting both innate and adaptive immune response²
Previously lack of safety and efficacy data from large DED clinical trials
Limited off-label use. Not FDA-approved for DED.



IMMUNOMODULATORY AGENTS: CYCLOSPORINE, LIFITEGRAST

Mostly targeting adaptative immune response and T-cell activation.^{3,4} Intended for chronic, longer term treatment with slower onset.



1. Craig J and Downie LE; Tear and Contact Lens. (6th edition) 2019; 2.Perez P. et al. *Ocul Surf.* 2016; 14; 207-215; 3. Utine CA, Stern M, Akpek E. *Ocul Immunol Inflamm.* 2010; 18(5): 352-361; 4. Jones L, Downie LE, Korb D, et al. TFOS DEWS II Management and Therapy Report. *Ocul Surf.* 2017;15(3):575-628.

First-Line Short-Term Rx Therapy: An Unmet Need in DED Management

- **DED patients who can benefit from Rx short-term treatment**
 - Patients on artificial tears and/or other palliative treatments who experience episodic flares
 - Induction therapy for patients initiating chronic treatment for dry eye
 - Breakthrough flares for patients who are on chronic treatment such as cyclosporine and lifitegrast
 - Treatment of dry eye before cataract and refractive surgery to improve outcomes and satisfaction
 - Short-term treatment of signs and symptoms of dry eye after cataract or refractive surgery
- **Ideal 1st-line short-term Rx therapy**
 - Designed and developed for dry eye and ocular surface disease treatment
 - Fast onset and effective treatment for both symptoms and signs
 - Targeting inflammation driven by both innate and adaptive immune responses
 - Safe and well-tolerated and FDA-approved for dry eye treatment

Conclusions



DED is highly prevalent, chronic inflammatory disease characterized by episodic flares



Most DED patients experience dry eye flares that last days or longer



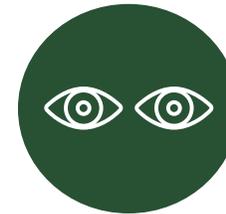
DED flare is inflammation-driven, initiated and maintained by both innate and adaptative immune responses and mediators



FDA-approved, safe and efficacious short-term treatment is an unmet need



Corticosteroids are broad spectrum anti-inflammatories that can suppress both innate and adaptative immune response



Optometrist and ophthalmologist both play a key role in the management of DED

EYSUVIS Clinical Trial Results and Implications for Clinical Practice

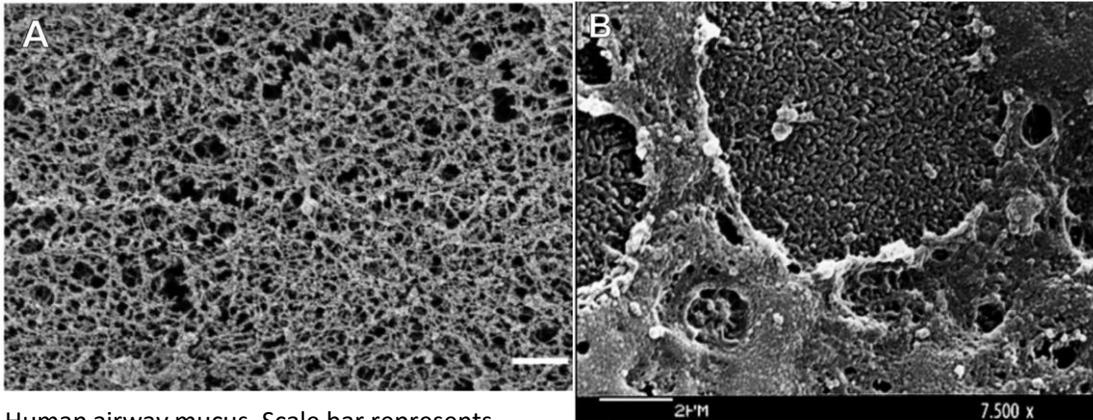
Edward J. Holland, MD

Director of Cornea Services at Cincinnati Eye Institute

Professor of Ophthalmology at the University of Cincinnati

AMPPLIFY® Technology

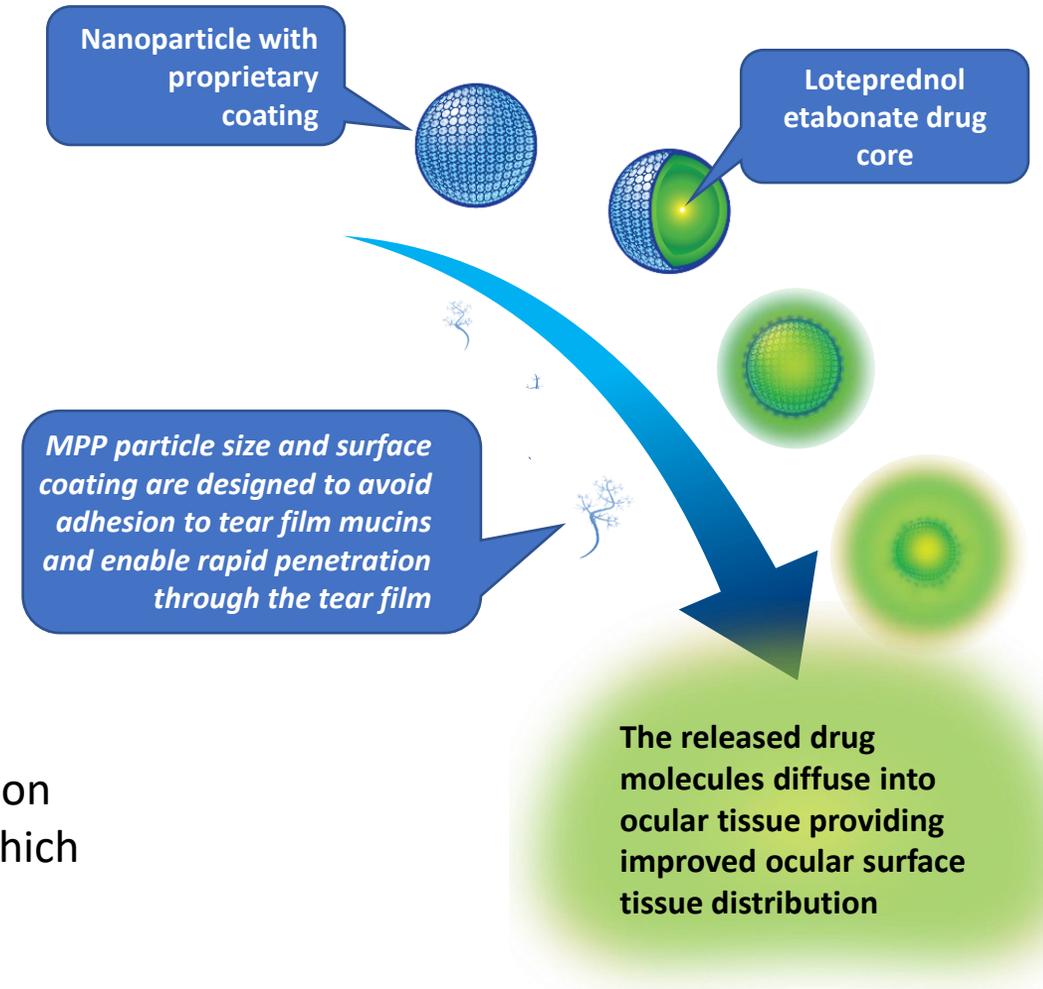
Mucus is a barrier for topical ophthalmic drug delivery



A Human airway mucus. Scale bar represents 500 nm.

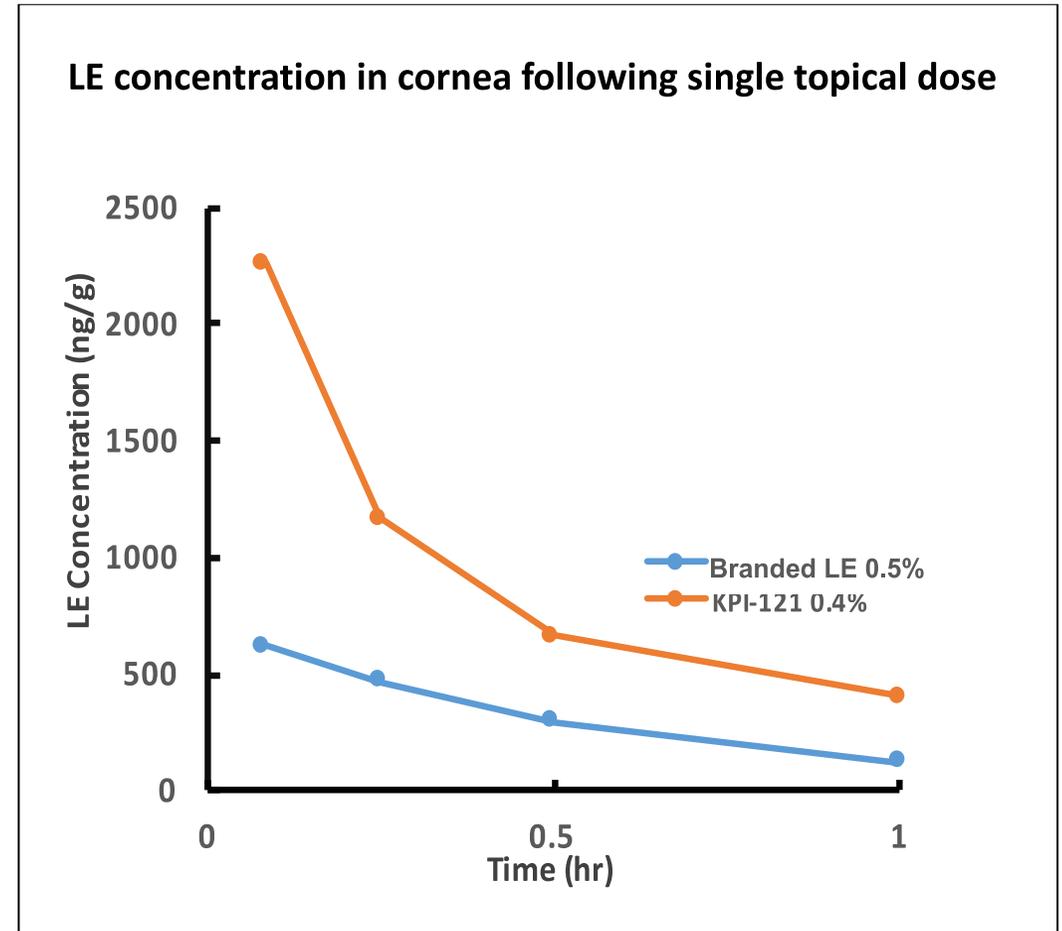
B Microvilli and mucus at the surface of human corneal epithelium

KPI-121 is a nanoparticle loteprednol etabonate ophthalmic suspension with proprietary mucus-penetrating (MPP) technology (AMPPLIFY) which improves ocular surface tissue penetration and distribution.^{1,2}



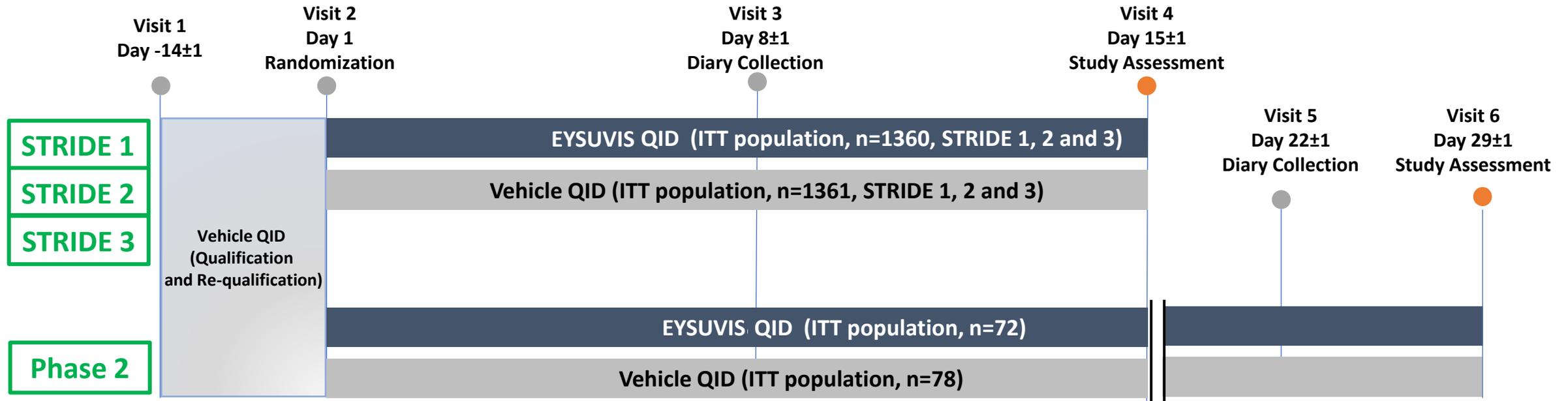
EYSUVIS: Leveraging AMPPLIFY® Technology to Enhance Delivery to Target Ocular Surface Tissues

- EYSUVIS™ (KPI-121 0.25%): Nanoparticle suspension of loteprednol etabonate (LE) formulated with proprietary AMPPLIFY® technology^{1,2}
- AMPPLIFY® enables 3-4 x increase in delivery of LE to ocular surface tissues^{1,2} relative to other LE products, leading to enhanced anti-inflammatory activity
- EYSUVIS under development for **short term treatment of signs and symptoms of dry eye disease**
 - Positive efficacy and safety data from 4 clinical trials in over 2800 patients (Ph 2, STRIDE 1, STRIDE 2, STRIDE 3)
 - Original NDA filed Oct 2017 based on Ph 2, STRIDE 1 and STRIDE 2; CRL received Aug 2019; only one deficiency noted – the need for an additional positive clinical trial
 - Positive STRIDE 3 addressed CRL deficiency; NDA resubmission April 30, 2020; PDUFA date Oct 30, 2020



Preclinical data from rabbit studies

Trial Design and Key Endpoints for EYSUVIS™ Clinical Trials

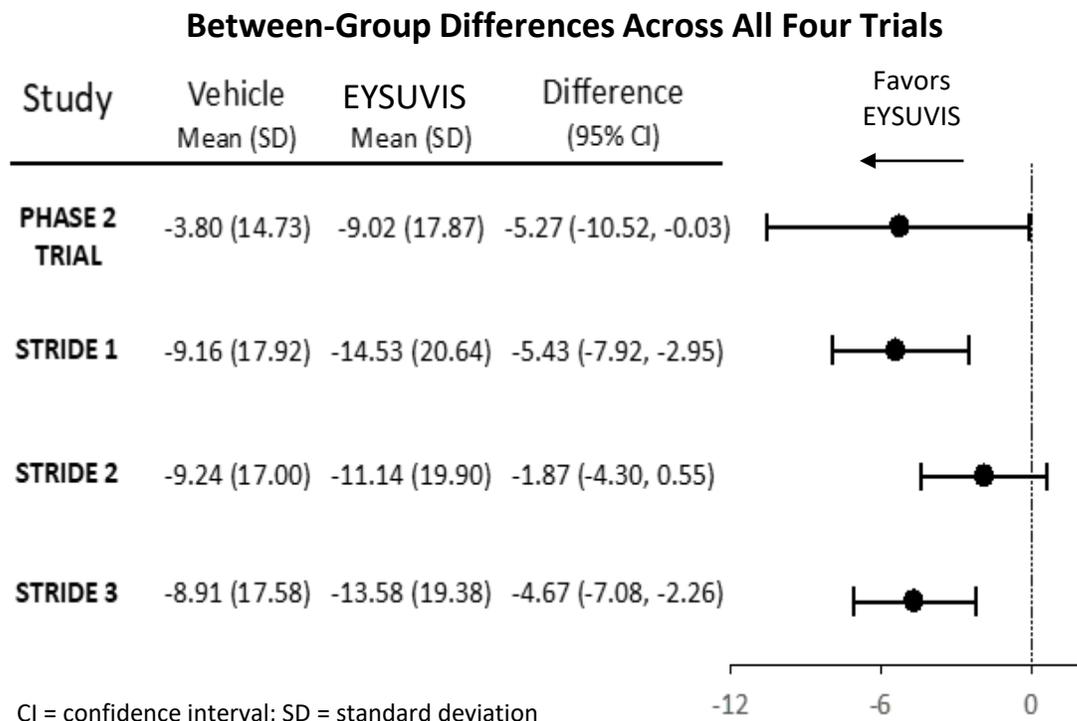


• Efficacy Endpoints:

- Signs: Conjunctival Hyperemia (CH) score CFBL¹ at Day 15; Total Corneal Fluorescein Staining (CFS) (summation of 5 zones: superior, inferior, nasal, temporal, central) CFBL¹ at Day 15
- Symptoms: Ocular Discomfort Severity Score (ODS) (assessed in both ITT and severe baseline symptom subgroup) CFBL¹ at Day 15
- Safety was monitored based on AEs, changes in IOP, evaluations of biomicroscopy, visual acuity, and dilated ophthalmoscopy
- Total intent to treat (ITT) population included 2871 subjects

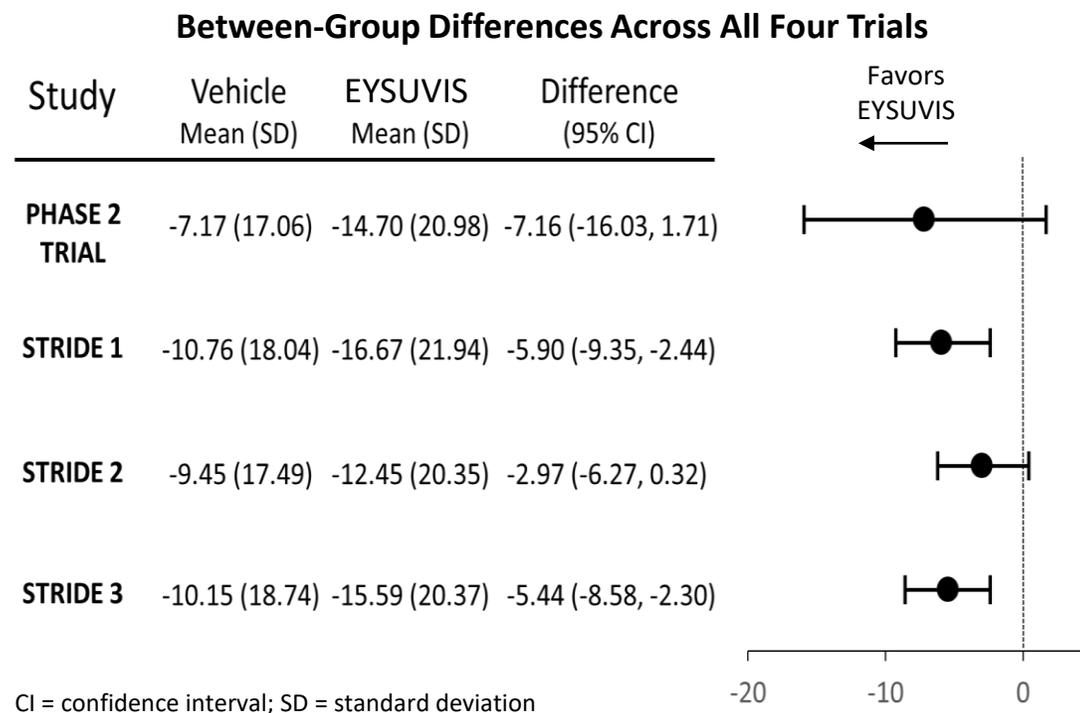
Efficacy Results: Symptom Improvements at Day 15

Ocular Discomfort Severity: CFBL at Day 15 in ODS



- Statistically significant treatment effect achieved for the primary ocular symptom endpoint of change from baseline to Day 15 in ODS scores in STRIDE 1 and STRIDE 3.
- A nominally significant treatment difference demonstrated for this endpoint in the Phase 2 Trial.
- **P values: Phase 2 (p=0.0489), STRIDE 1 (p<0.0001), STRIDE 2 (p=0.1298), and STRIDE 3 (p=0.0002).**

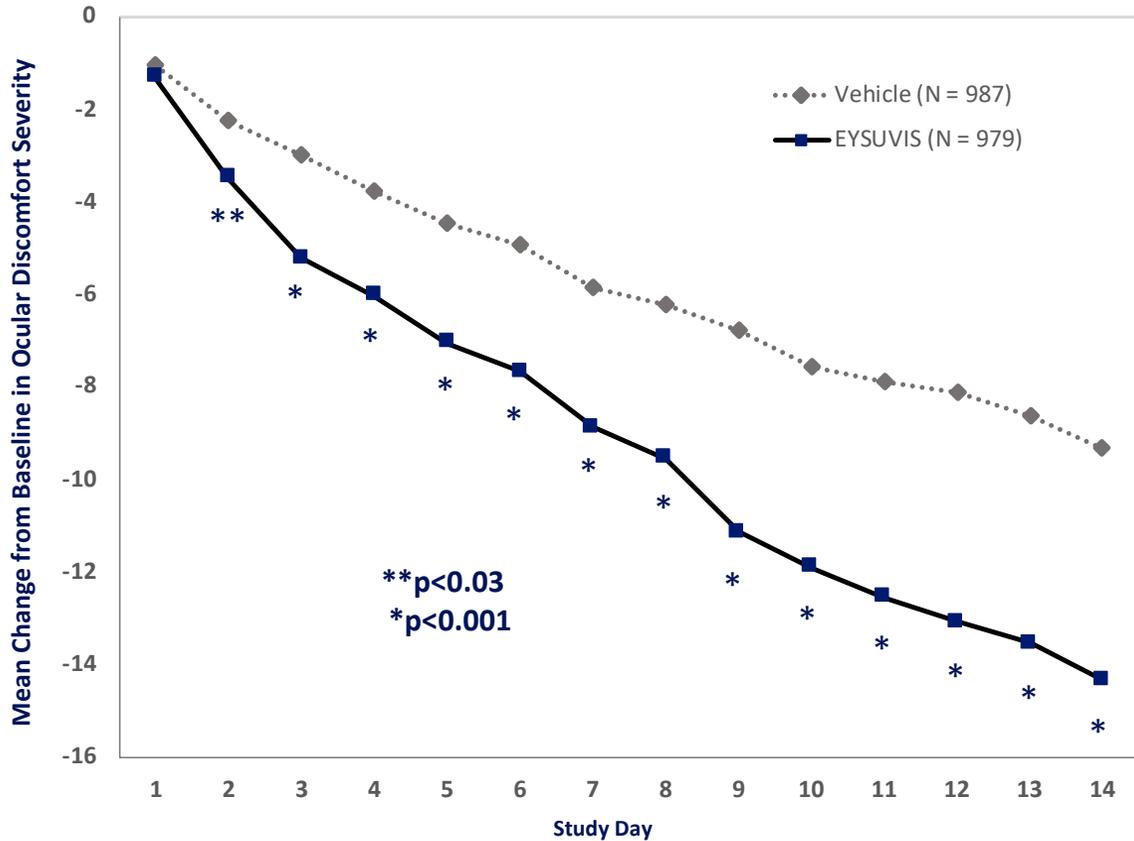
Ocular Discomfort Severity: CFBL at Day 15 in ODS in Subgroup With More Severe Baseline Symptoms



- Statistically significant treatment effect for second prespecified primary endpoint of change from baseline to Day 15 in ODS scores in patients with more severe baseline ocular discomfort (predefined as subjects with ODS scores ≥ 68 mm on the day prior to Day 1), observed in STRIDE 1 and STRIDE 3.
- Positive treatment effect in Ph 2 but did not achieve significance due to sample size
- **P Values: Phase 2 trial (p=0.1118), STRIDE 1 (p=0.0009), STRIDE 2 (p=0.771), and STRIDE 3 (p=0.0007).**

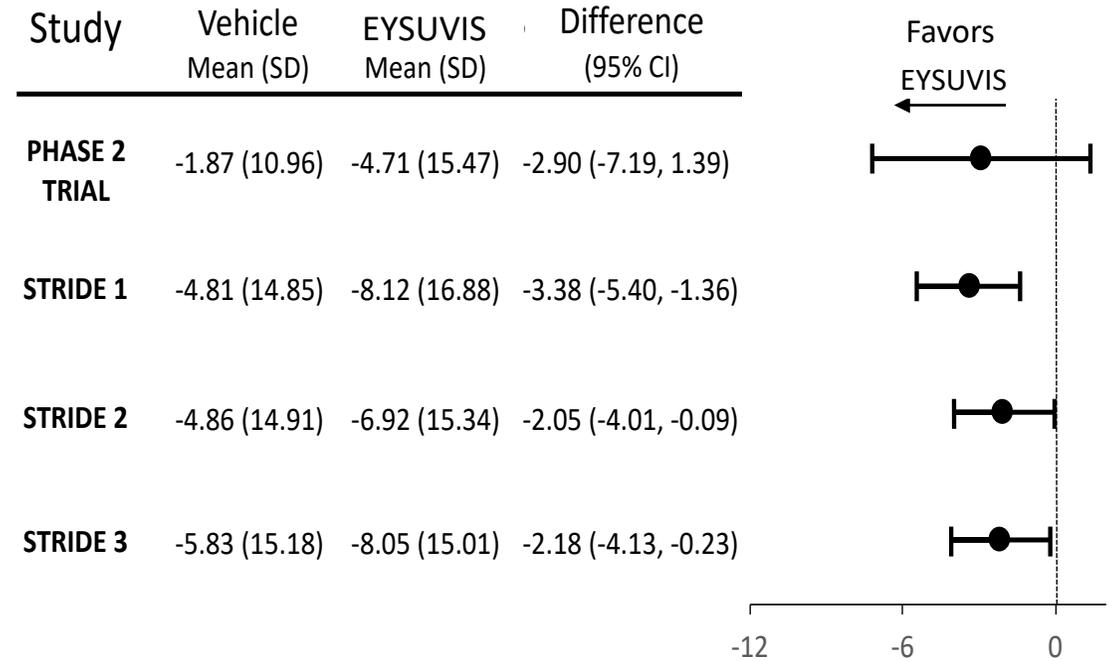
Rapid Onset of Symptom Improvement

Mean Change from Baseline on Daily ODS From Pooled Data



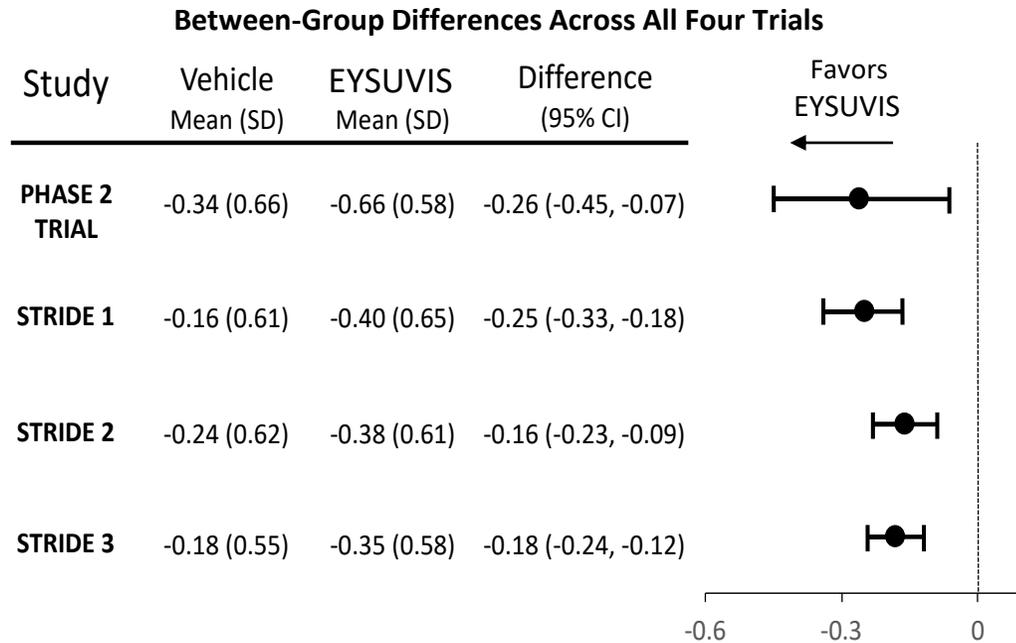
¹Pooled data from Phase 2, STRIDE 1 and STRIDE 3

Between-Group Differences Across All Four Trials



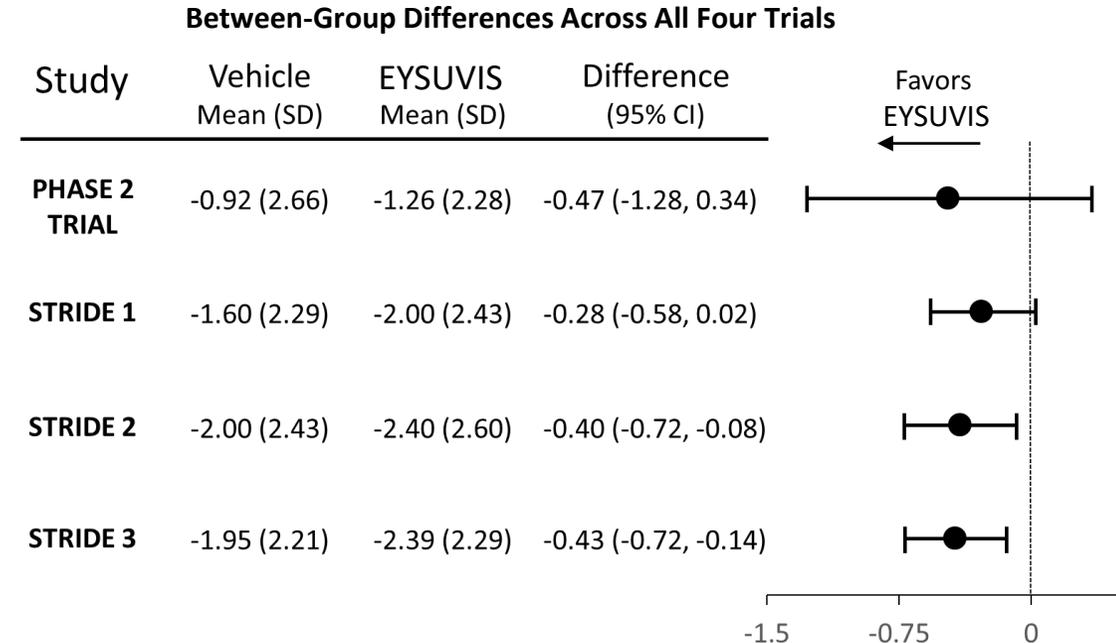
Efficacy Results: Improvement in Dry Eye Signs at Day 15

Conjunctival Hyperemia: CFBL at Day 15 Visit



- Significant treatment differences observed for change from baseline to Day 15 in conjunctival hyperemia in all 4 trials.
- **P values: Phase 2 (p=0.0090), STRIDE 1 (p<0.0001), STRIDE 2 (p<0.0001), and STRIDE 3 (p<0.0001).**

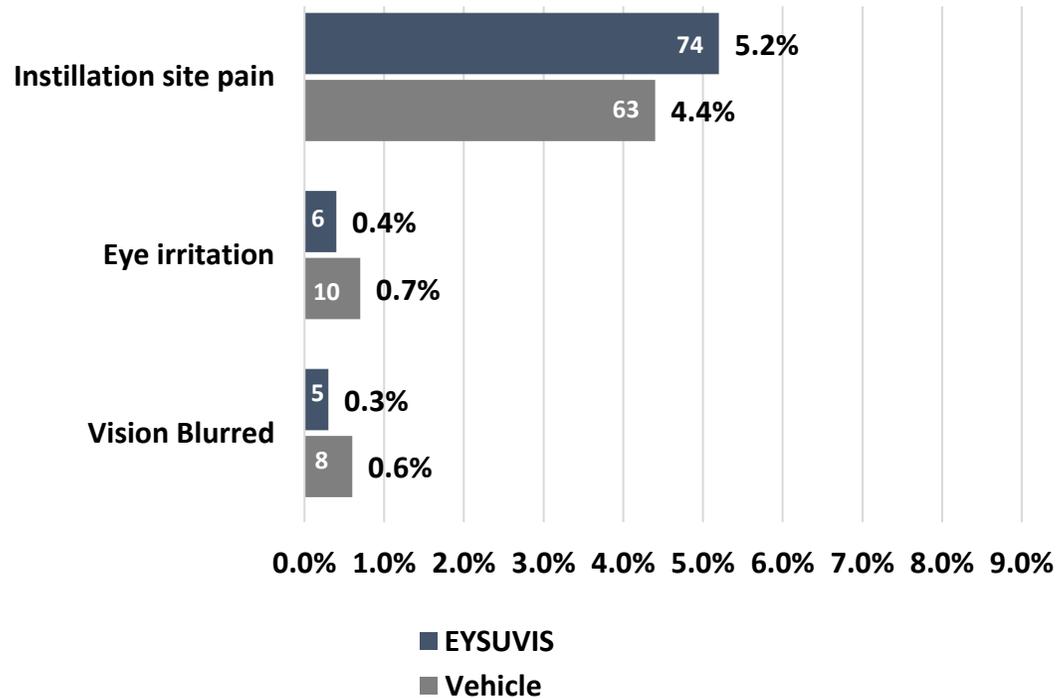
Total Corneal Fluorescein Staining: CFBL at Day 15 Visit



- Improvement in total corneal fluorescein staining favoring EYSUVIS was observed in STRIDE 2 (p=0.0134) and STRIDE 3 (p=0.0042)

Pooled Safety Findings From the Four Clinical Trials

Percentage of Subjects Reporting Treatment-related Adverse Event by >0.3% of subjects



The most frequently reported treatment-related AE was instillation site pain, reported by 5.2% of subjects in the EYSUVIS group and 4.4% of subjects in the vehicle group.

Number (%) of Subjects with Increased Intraocular Pressure Compared with Baseline at any Postbaseline Visit

	Study Eye		Fellow Eye	
	EYSUVIS (n = 1430)	Vehicle (n = 1438)	EYSUVIS (n = 1430)	Vehicle (n = 1438)
> 5 mmHg increase from BL	30 (2.1%)	22 (1.5%)	33 (2.3%)	20 (1.4%)
> 5 mmHg increase from BL and \geq 21 mmHg	9 (0.6%)	3 (0.2%)	8 (0.6%)	4 (0.3%)
\geq 10 mmHg increase from BL	4 (0.3%)	0	3 (0.2%)	1 (0.1%)
\geq 10 mmHg increase from BL and \geq 21 mmHg	3 (0.2%)	0	2 (0.1%)	1 (0.1%)

BL = baseline

In the EYSUVIS and vehicle groups, respectively, 0.6% and 0.3% of subjects experienced a > 5 mmHg increase from baseline resulting in an IOP of \geq 21 mmHg in 1 or both eyes at any postbaseline visit.

Summary

- **Significant improvements in both signs and symptoms in the same population in all four trials**
 - Statistical significance for predefined sign endpoint of change from baseline in conjunctival hyperemia at day 15 in all 4 trials
 - Significant improvement in patient-reported symptoms in Ph 2, STRIDE 1 and STRIDE 3, with positive trend in STRIDE 2
 - Significant improvement in total corneal fluorescein staining observed in 2 of the three Phase 3 trials
- **EYSUVIS QID for up to 29 days appeared safe and well-tolerated with no unexpected adverse events. The incidence of treatment-related adverse events was comparable between the EYSUVIS and vehicle arms**
 - IOP profile was similar between the vehicle and KPI-121 0.25% arms. Less than 1% of subject experienced IOP elevation >5mmHg from baseline resulting in a measurement ≥ 21 mmHg
 - Most ocular treatment emergent adverse events (TEAEs) were local to instillation site and mild or moderate in severity.
 - No serious ocular treatment emergent adverse events was reported or observed in either treatment arm
- **NDA resubmission currently under review by FDA with PDUFA target of Oct 30, 2020**
- **Potential to become preferred first-line therapy for the short-term treatment of dry eye disease - including the treatment of dry eye flares, which occur in the vast majority of dry eye patients**

EYSUVIS Could Address Key Unmet Needs in Dry Eye Disease

- **Broad anti-inflammatory activity** to address the key driver of DED
- In clinical trials **EYSUVIS** provided **rapid onset of relief** of signs and symptoms of DED
- In clinical trials **EYSUVIS** was **well tolerated** with low incidence of IOP elevations (similar to vehicle)
- If approved, **EYSUVIS** will be **first ocular steroid to have a dry eye disease indication**

Eye Care Professionals (ECPs) prefer an on-label steroid for DED:¹

- Off-label steroids have varied safety profiles
- Risk of IOP elevation when prescribing steroids off-label
- Patient comfort having DED indication in the Package Insert
- Efficacy and safety vetted by the FDA

Surveys suggest that 95% of ECPs are interested in the availability of a steroid with a DED indication¹

EYSUVIS Could Become Preferred First-line Therapy for the Short-Term Treatment of Dry Eye, Including Dry Eye Flares

Most Patients Suffer From Dry Eye Flares and Not Continual Symptoms

Dry Eye Disease (DED) Flare Definition¹:

Rapid-onset, inflammation-driven response to a variety of triggers that **typically cannot be adequately managed with patient's ongoing maintenance therapy** (e.g., artificial tears, chronic Rx therapies)

Frequency of Dry Eye Flares Highlighted in Several Patient surveys:

~75-90% of all DED patients report they **suffer from flares**^{2,3,4}

~81% of patients on artificial tears report they **suffer from flares**²

~91% of patients on cyclosporine or lifitegrast report they **suffer from flares**⁴

1. ASCRS EyeWorld. <https://www.eyeworld.org/download/file/fid/453>. Published May 2019. Accessed May 24, 2019.

2. Based on a survey of 297 patients commissioned by Kala and performed by a third party.

3. Based on a survey of 30 patients diagnosed with dry eye disease commissioned by Kala and performed by a third party.

4. Based on a survey of 30 patients diagnosed with dry eye disease commissioned by Kala and performed by a third party.

EYSUVIS™ Commercial Opportunity

Todd Bazemore

Chief Operating Officer



EYSUVIS™
(loteprednol etabonate
ophthalmic suspension) 0.25%

Highlights



Market Overview



Situation Analysis – Recent Key Learnings

- Prescriber
- Patient
- Payor



Brand Strategic Plan



Launch Update and Timing



Sales Force Plan



Summary

Significant Unmet Need

The majority of dry eye patients have **never tried Rx therapy** and those that have, want a more effective, rapid-acting and better tolerated option¹

EYSUVIS™ is Well Positioned to Disrupt the Dry Eye Market

Rapid onset with **meaningful improvements** in **signs/symptoms** and **favorable tolerability/safety**

Commercial Readiness

The Kala Commercial Organization is **Prepared to Launch EYSUVIS in Q4 2020**

Market Overview



38M

U.S. prevalence of dry eye, of which **17.2M** have been diagnosed and are under the care of an Eye Care Professional¹



75%

of dry eye patients have **never tried prescription therapy**²



Only ~10%

of dry eye patients are currently on an Rx Chronic therapy³



Only 2.9%

of dry eye patients receive Rx for off-label steroids³



6.1M

Chronic TRx per year⁴



~\$1.5B

Combined Net Revenue for Restasis, Cequa and Xiidra annually⁵



80%

of patients discontinue their chronic Rx medication by 4 months⁶



75–90%

of dry eye patients **routinely experience dry eye flares**^{7,8,9}

Majority of DED Patients Suffer From Episodic Flares, Not Continual Symptoms

Dry Eye Disease (DED) Flare Definition¹:

Rapid-onset, inflammation-driven response to a variety of triggers that **typically cannot be adequately managed with patient's current therapy** (e.g., artificial tears, chronic Rx therapies)

~75-90%

of all DED patients report they **suffer from flares**^{2,3,4}

~81%

of patients on artificial tears report they **suffer from flares**⁴

~91%

of patients on prescription medications report they **suffer from flares**⁴

Patients Suffer
a Median of
5.5 Flares a year⁴

1. ASCRS EyeWorld. <https://www.eyeworld.org/download/file/fid/453>. Published May 2019. Accessed May 24, 2019.

2. Based on a survey of 297 patients commissioned by Kala and performed by a third party.

3. Based on a survey of 500 patients diagnosed with dry eye disease commissioned by Kala and performed by a third party.

4. Based on a survey of 774 patients performed by a third party.

Annual Total Addressable US Market for Dry Eye Disease Flares

75-90%¹⁻³



of the **17.2M**⁴

diagnosed
DED patients
experience

Flares¹⁻³



Of these,

~13-15M

patients
have about

5.5 Flares

per year⁴



330M

treatable

Flare Days

per year



\$8B MARKET OPPORTUNITY⁵

1. Based on a survey of 297 patients commissioned by Kala and performed by a third party. 2. Based on a survey of 500 patients diagnosed with dry eye disease commissioned by Kala and performed by a third party. 3. Based on a survey of 774 patients performed by a third party. 4. Schaumberg et al, 2013, Prevalence of diagnosed dry eye in the US, MarketScope 2018 report – Diagnosed Dry Eye patients in the US; 4. Based on a survey of 297 patients commissioned by Kala and performed by a third party; 5. Assuming \$350 per Rx.

Situational Analysis and Customer Insights

Extensive and Ongoing Market Research Across Key Customers

Eye Care Professionals (ECPs), Patients and Payors



ECPs



Patients



Payors

~950

475 Ophthalmologists and
455 Optometrists
interviewed

1,600+

Patients in qualitative and
quantitative research

~40

Decision makers in
Health Plans and PBMS

Eye Care Professional (ECP) Key Insights



ECPs **are frustrated** with lack of broadly effective therapies for treating DED patients and are motivated to hear about new products



Most ECPs define DED as a chronic inflammatory condition – but recognize most patients have an episodic **pattern of symptoms** (flares) that do not require chronic Rx therapy



Believe there is an **opportunity to better manage many mild-to-moderate DED** patients that currently go untreated with Rx therapy because current therapies take too long to work, and often have significant tolerability issues



ECPs have a **large proportion of patients that suffer from flares**, and would discuss the topic of flares more proactively with patients if there was an FDA-approved, short-term treatment option



ECPs cited **rapid relief and safety/tolerability profile of EYSUVIS as top advantages** and viewed it favorably vs. other DED therapies, including off-label steroids



ECPs intend to use **EYSUVIS 1st line for the treatment of flares** and adjunctive to chronic Rx to treat breakthrough symptoms, induction to chronic Rx therapy and for short-term DED treatment prior to ocular surgery

Key Patient Insights



Patients often self-treat DED for several years with OTC artificial tears before bringing it up in their routine eye appointment



Once diagnosed, patients are often first recommended to try another artificial tear, and continue to suffer with symptoms until their next doctor's visit



Continuous source of frustration – artificial tears provide minimal palliative relief, but do not address inflammation – patients on current Rx therapy often report limited satisfaction due to unwanted side effects and the time it takes to work (slow onset of weeks to months)



Patients describe flares in terms of increased dryness, itching, burning and redness; majority say they suffer from flares whether on artificial tears or a chronic Rx therapy

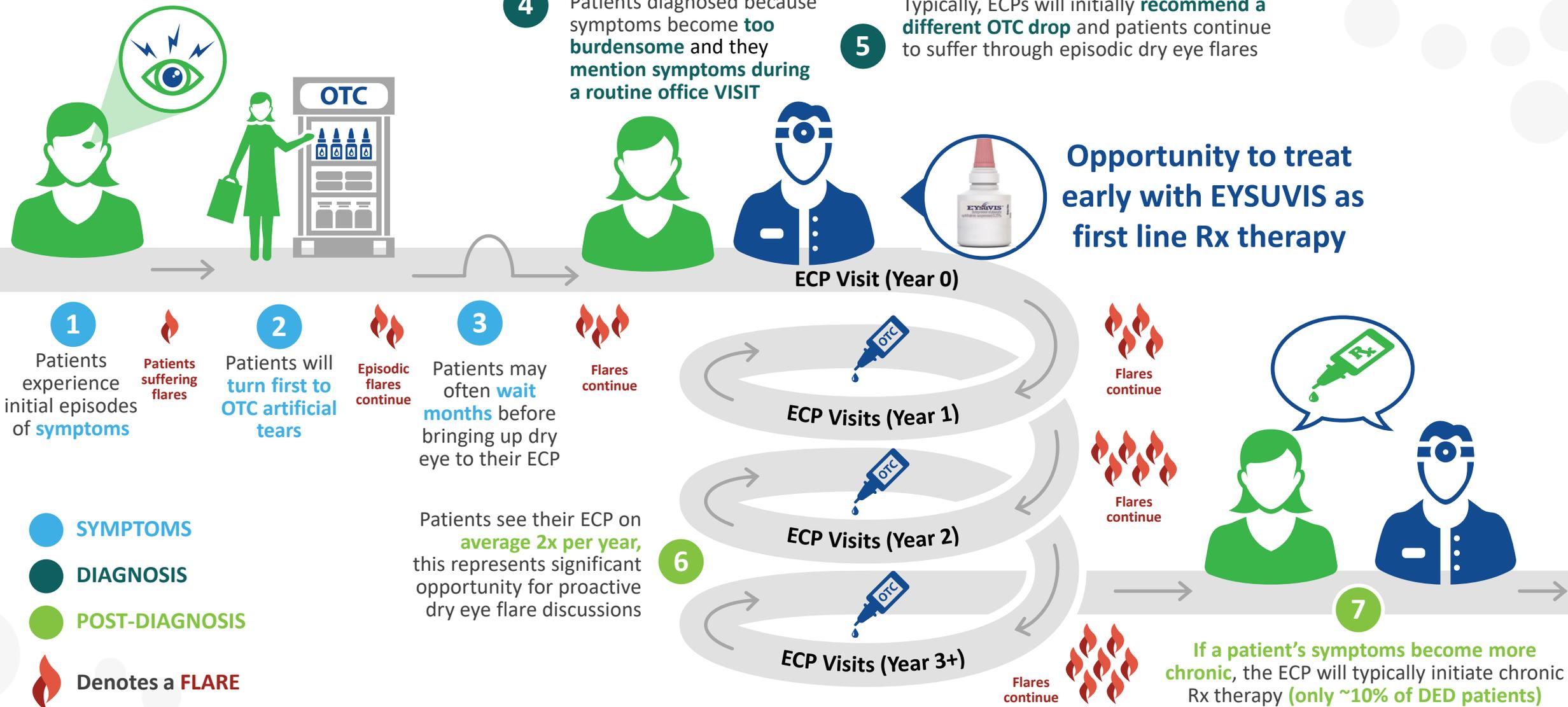


Regardless of DED severity, majority of patients say they suffer from flares and desire a fast-acting treatment they can use short term, during times when they are experiencing symptoms



Patients see EYSUVIS as a breakthrough therapy because it provides rapid relief and is used short term vs chronically – 90% of respondents report they intend to ask their ECP about EYSUVIS

DED Patient Journey



- SYMPTOMS
- DIAGNOSIS
- POST-DIAGNOSIS
- 🔥 Denotes a **FLARE**

Patients Are Suffering and “Coping” with the Impact of DED and Flares

What Patients Say About DED and Their Current Treatment Options

“ Once I start **feeling the burning, I know it’s coming**. I don’t know if it’s going to last a few days or weeks.

“ My **artificial tears** help my eyes feel better but not for long, **it’s like a band-aid**.

“ I know I should be using my **daily chronic drops** all the time, but I often stop or forget because **they don’t really help anyway**.

“ I want to tear my eyeballs out and **during the worst flares my drops don’t help at all**; there are times when I can’t function.

What Patients Say About EYSUVIS

After reviewing EYSUVIS profile:

“ I can take something for short term relief that will treat my flares, that works fast, won’t burn my eyes and is safe. **When will it become available?**

“ I only have a few episodes of dry eye a year and **don’t want to be on chronic therapy**, this sounds like a good option for me.

“ This would be **my security blanket**, it’s always **right there when I need it. That’s comforting**.

Opportunity to Drive Proactive Discussions About Flares and the Availability of a Short-Term Treatment Option



Patients

- Regardless of current treatment, **75–90% of patients suffer flares**¹⁻³
- Patients suffer on **average 5.5 flares per year** lasting days to weeks⁴
- Patients try to cope by self treating with OTC artificial tears with little success

“

I usually only tell my doctor about my flares in my routine yearly visits. Most times I suffer through it.



ECPs

- ECPs acknowledge **majority of their dry eye patients** suffer flares alone or break throughs while on a chronic medication
- ~42% of annual office visits, flares come up in discussion
- Because the patient doesn't always proactively bring it up, **ECPs agree** the patient is often left to deal with it on their own

“

I think **flares are underreported** because I only see my patients 1–2 times a year and I am not asking them about it. I need to be more proactive.

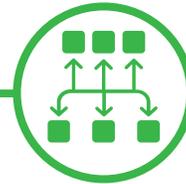
Availability of an FDA-Approved, Short-Term Treatment Option Anticipated to Drive Proactive Discussions About the Need to Identify and Treat Dry Eye Flares

Formulary Coverage Overview



MANAGEMENT

- DED is a moderate priority category for payors
- Coverage will depend on product net cost and clinical profile; short-term treatment option differentiated from currently marketed therapies



FORMULARY POSITIONING

- **Commercial:** ~50% of DED TRx Market
- **Faster product reviews and formulary coverage** provides opportunity to target commercial business and increase utilization
- **Medicare Part D:** ~ 40% of DED TRx Market
- Targeted formulary coverage in 2022 and **potential early adds in 2021**



RESTRICTIONS

- Majority of Commercial lives have **unrestricted access** with some soft Prior Authorizations (PA)
- Currently there are only **limited restrictions** in Part D

“This class has a moderate budget impact. It’s a large patient population, but there are a lot of OTCs, so not a major concern. DED is probably a top 30 spend category for us.”

– National PBM
Pharmacy Director

“I could see this product being used as a first line treatment for patients experiencing flares because of its rapid onset of action.”

– National Health Plan
Pharmacy Director

“This product has merit. The fact that we are seeing improvement in corneal staining is good, because this is used as a proxy for overall improvement.”

– National Health Plan
Pharmacy Director

Payor Insights and EYSUVIS Opportunity



KEY PAYOR INSIGHTS

- Only chronic medications are currently available for treatment of DE
- Payors perceive DED as a lower priority category and a moderate disease burden
- Payors had positive reactions to the EYSUVIS product profile
- EYSUVIS value messages are compelling to payors



APPROACH FOR EYSUVIS

- Educate payors on the data showing most patients suffer from flares and not continual symptoms
- Highlight the clinical results and rapid onset of action with favorable safety profile demonstrated in well-controlled clinical trials of EYSUVIS
- Highlight the clinical and economic benefits of short-term treatment vs. chronic therapies in mild-to-moderate DE patients

“Given what we discussed here today, I agree that there is a need for short-term treatment of DED symptoms.”

– National Health Plan
Pharmacy Director

“There seems to be a pretty significant improvement in ocular discomfort score, so that is definitely a positive from my perspective.”

– National PBM
Pharmacy Director

“This product would be used for the flare population bucket. So I guess there is potential that it could be used for 85% of DED patients.”

– National Health Plan
Pharmacy Director

WAC Pricing of DED Products

DED Products	Dosage / Package	Current WAC / Package
RESTASIS	0.4mL Vial (60 ct.)	\$585.61
XIIDRA	Blister pack (60 ct.)	\$553.54
CEQUA	Vial (60 ct.)	\$507.00

WAC Pricing of Ophthalmic Steroids

LE Steroid Products	Current WAC (10ml Package)
LOTEMAX® Suspension	\$503.91
Generic loteprednol etabonate (Akorn)	\$375.56
Generic loteprednol etabonate (Oceanside)	\$427.38
ALREX®	\$478.26

EYSUVIS is Poised to Answer Unmet Needs in DED

- **Broad anti-inflammatory activity** addresses key driver of DED
- In clinical trials, **EYSUVIS** provided **rapid onset of relief** of signs and symptoms of DED
- In clinical trials, **EYSUVIS** was **well tolerated** with low incidence of IOP elevations (similar to vehicle)
- If approved, **EYSUVIS** will be **first ocular steroid to have a dry eye disease indication**

Eye Care Professionals (ECPs) Prefer an On-label Steroid for DED:¹

- Off-label steroids have varied safety profiles
- Risk of IOP elevation when prescribing steroids off-label
- The DED indication provides patient comfort and confidence
- Efficacy and safety vetted by the FDA

99% of ECPs are interested in the availability of a steroid with a DED indication²



EYSUVIS Has
Potential to Be the
Preferred Rx Therapy
for DED Flares

Key Goals for EYSUVIS Launch



Educate

Short-term, Episodic Nature of DE Flares

- **Shape market by Educating** ECPs and Payors on the benefits of short-term treatment of episodic flares
- **Ensure ECPs routinely** discuss and ask patients about their DE flares



Establish

EYSUVIS 1st Line Rx in ECP office

- **Establish EYSUVIS as first-line** Rx therapy for the majority of DE patients
- **Promote first and only rapid-acting Rx** treatment for short-term relief that is safe and well tolerated
- **Target key prescribers** who account for majority of Dry Eye Business



Ensure

Access and Coverage to EYSUVIS

- **Optimize Coverage** in Commercial and Part D to provide unrestricted access for EYSUVIS
- **Ensure positive experience** with ECPs and patients to drive trial and adoption
- **Minimize fulfillment hassles** and barriers for ECPs and Patients

Kala is Built with Experienced Leaders Poised to Capture Market Opportunity

MARKET ACCESS / TRADE

A team of 8 professionals with deep customer relationships and an average of 15 years of MA/trade experience

MARKETING

Experienced team of marketers with collectively 46 years of OPH experience on brands such as: Restasis, Lotemax, Cequa, Prolensa, Bromsite, Refresh, Besivance, Azasite, Zymar, Acular, Bepreve



MEDICAL AFFAIRS

SVP of Medical Affairs with 12 years OPH experience
4 Medical Science Liaisons (MSL)*

SALES TEAM

Sales leadership team averages 11 years of OPH experience and sales representatives average >8 years of OPH experience
~50% of existing sales representatives have DED sales experience

Expanded Sales Team Expected to be on-board in Q4 2020

Sales Team Expansion Planned to Occur in Phases

Flexibility to Evolve with Expanded Payor Coverage and Changing Market Conditions

Q3-20 Sales Team Size

7 Regional Sales Leaders
56 Sales Reps

Q4-20 Sales Team Size

14 Regional Sales Leaders
90–100 Sales Reps

- Provides flexibility in event of 2nd COVID-19 wave
- Structure built to support future sales team growth
- Sales team hire date will be post EYSUVIS FDA approval

2021 Sales Team Size

14 Sales Leaders
125 Sales Reps

- Flexibility to evolve with expanded payor coverage and changing market conditions
- Designed to limit disruption when expanding

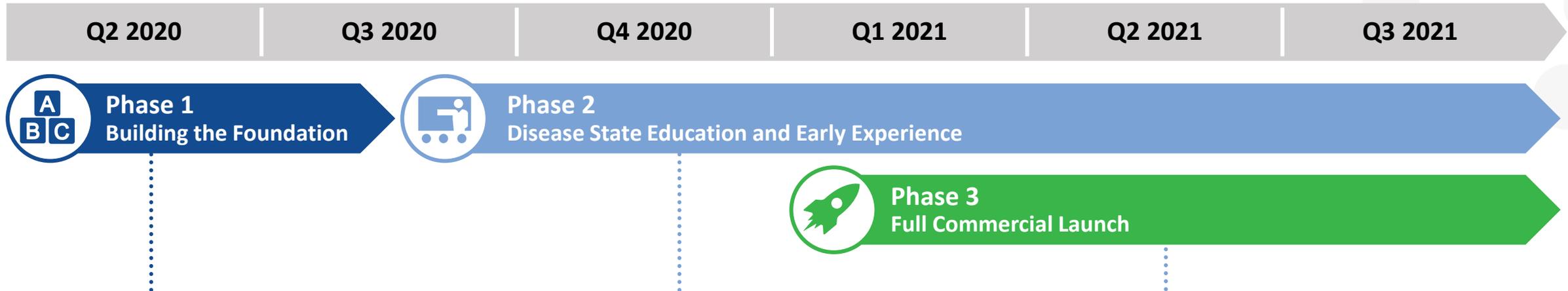
Targeting Output

~16,200 ECP targets
(~8,700 Ophthalmologists and
~7,500 Optometrists)

~85% coverage across all Chronic Dry
Eye and Steroid Dry Eye prescribers

97% of INVETYS® prescriptions covered

EYSUVIS Planned Launch Timeline



Objectives:

- Q3 - Prepare to expand sales force to cover DE opportunity including ODs
- Prepare for full EYSUVIS ECP launch including disease state and branded campaign
- Develop payor value proposition and messaging
- Target payors with disease state messaging
- Support medical publications to educate ECPs on the need for short-term treatment, including flares

Objectives:

- Train and prepare sales force for November launch
- Execute a disease awareness campaign and begin promotion of EYSUVIS
- Ensure positive EYSUVIS experience with top dry eye treaters through an early experience program
- Payor and market access pricing/contracting engagement

Objectives:

- Drive early uptake with high-value targets
- Provide patient access to EYSUVIS through sampling and access programs
- Expand payor coverage with commercial and Part D contracting
- Evaluate direct-to-patient opportunities to drive consumer call to action

Summary



- 1 Transformational opportunity for KALA
- 2 Potentially the FIRST and ONLY dry eye product with a rapid onset and approved for the short-term treatment of the signs/symptoms of DED
- 3 Opportunity to capture a large significant unmet need in dry eye with deep experience in ophthalmology/optometry across the organization
- 4 Strong IP position (2033) and proprietary manufacturing process
- 5 Cash and cash equivalents of \$184.6M as of June 30, 2020; existing cash resources expected to fund operations into at least Q2 2022

Total Addressable U.S. Market for DED Flares in Excess of \$8B Annually



Thank You

