
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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): October 10, 2017

ALDEYRA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36332
(Commission
File No.)

20-1968197
(IRS Employer
Identification No.)

**131 Hartwell Avenue, Suite 320
Lexington, MA 02421**
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 761-4904

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

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))

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.

On October 10, 2017, Aldeyra Therapeutics, Inc. (“Aldeyra”) intends to make a slide presentation at its Research and Development Day in person in New York City and by webcast on Aldeyra’s website. A copy of Aldeyra’s slide presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The furnishing of the attached slide presentation is not an admission as to the materiality of any information therein. The information contained in the slide presentation is summary information that is intended to be considered in the context of more complete information included in Aldeyra’s filings with the Securities and Exchange Commission and other public announcements that Aldeyra has made and may make from time to time by press release or otherwise. Aldeyra undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate.

The information in Item 7.01 of this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing, regardless of any general incorporation language in any such filing, unless Aldeyra expressly sets forth in such filing that such information is to be considered “filed” or incorporated by reference therein.

Item 8.01 Other Events.

On October 10, 2017, Aldeyra issued a press release that provided an update on Aldeyra’s clinical development plans. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Slide presentation of Aldeyra Therapeutics, Inc. dated October 10, 2017.
99.2	Press Release of Aldeyra Therapeutics, Inc. dated October 10, 2017.

SIGNATURES

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

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady, M.D., Ph.D.

Name: Todd C. Brady, M.D., Ph.D.

Title: President and Chief Executive Officer

Dated: October 10, 2017



2017 Research and Development Day

October 10, 2017

Disclaimers and Forward-Looking Statements

- This presentation and various remarks which may be made during this presentation contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's possible or assumed future results of operations, expenses and financing needs, business strategies and plans, research and development plans or expectations, trends, the structure, timing and success of Aldeyra's planned or pending clinical trials, expected milestones, market sizing, pricing and reimbursement, competitive position, regulatory matters, industry environment and potential growth opportunities, among other things. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or similar expressions and the negatives of those terms.
- Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Aldeyra's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect Aldeyra's current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including the development and clinical plans for Aldeyra's product candidates and Aldeyra's continuing review and quality control analysis of clinical data. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2016 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, to be filed with the SEC in the fourth quarter of 2017.
- In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this presentation is provided only as of October 10, 2017, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.

New Results from Phase 2 Clinical Trials in Allergic Conjunctivitis and Dry Eye Disease

- David Clark, MD, Chief Medical Officer, Aldeyra

Unmet Medical Need in Allergic Conjunctivitis and Dry Eye Disease

- Tim Surgenor, RedSky Partners, LLC

Clinical and Regulatory Opportunities in Dry Eye Disease

- Gary Novack, PhD, Visiting Professor of Pharmacology and Ophthalmology, University of California, Davis, School of Medicine

The Intersection of Dry Eye Disease and Allergic Conjunctivitis

- John Sheppard, MD, Professor of Ophthalmology at Eastern Virginia Medical School

Introduction of ADX-103 and the Retinal Disease Program

- Susan Macdonald, PhD, Vice President of Research and Development, Aldeyra



Clinically Important Response Results from Phase 2b
Clinical Trial in Allergic Conjunctivitis

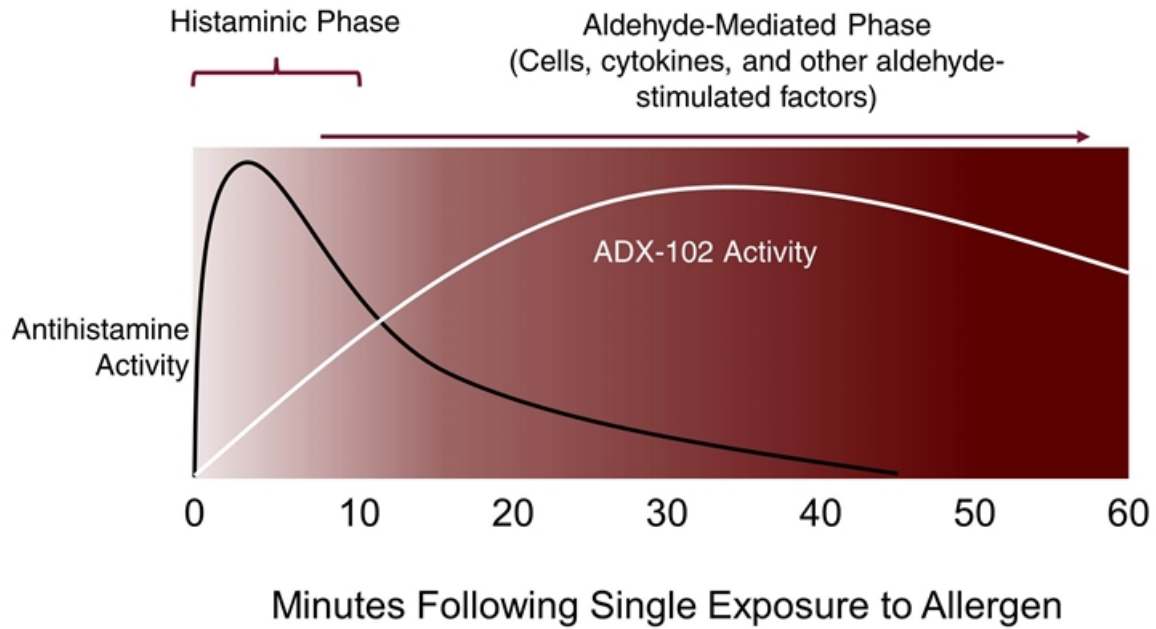
David Clark, MD
Chief Medical Officer
Aldeyra Therapeutics

Allergic Conjunctivitis Phase 2b Clinical Design

Groups	Topical Ocular ADX-102 0.1%, ADX-102 0.5%, or Vehicle
Randomization	Double-Masked, Vehicle-Controlled 1:1:1
Enrollment	154 Patients with History of Allergic Conjunctivitis
Model	Single Dose Seasonal and Perennial Allergen Challenge
Endpoint	Patient-Reported Itching Score (0 to 4)

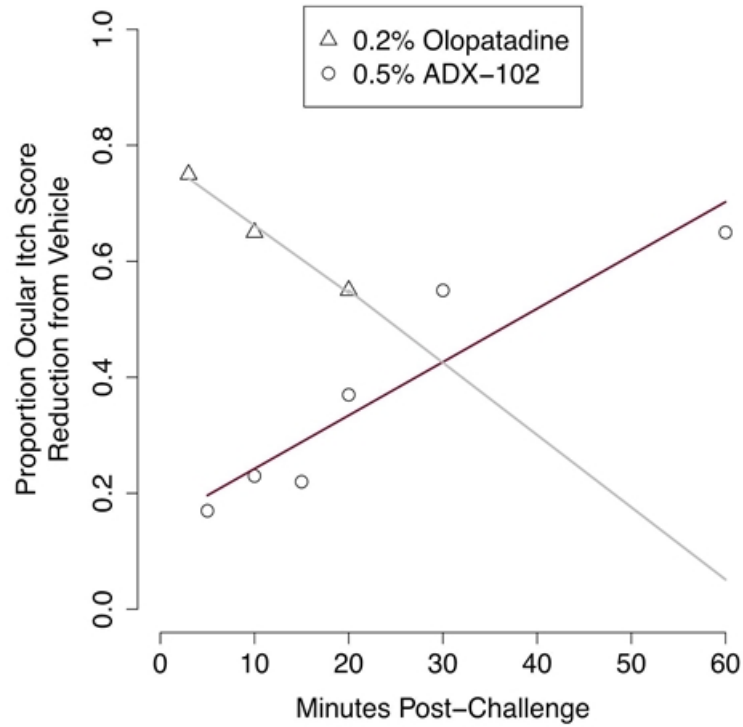
Further information can be found on www.clinicaltrials.gov: Trial #NCT03012165.

Histaminic and Aldehyde-Mediated Phases After Allergen Challenge



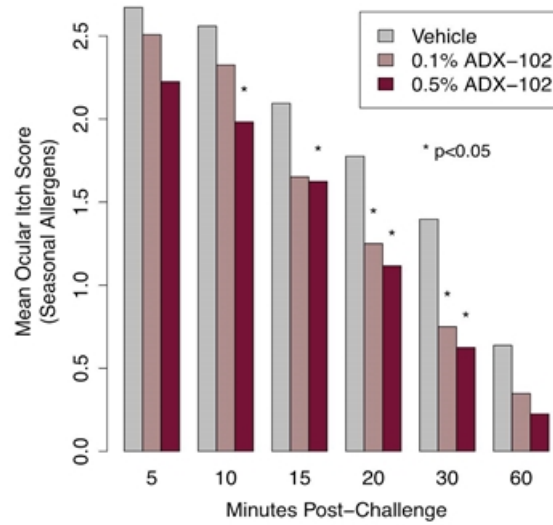
In Phase 2 clinical trials, ADX-102 shown to be effective for aldehyde-mediated allergy, for which no drug is approved, and which affects all allergic conjunctivitis patients.

The Activity of Antihistamines Diminishes Rapidly as ADX-102 Activity Increases



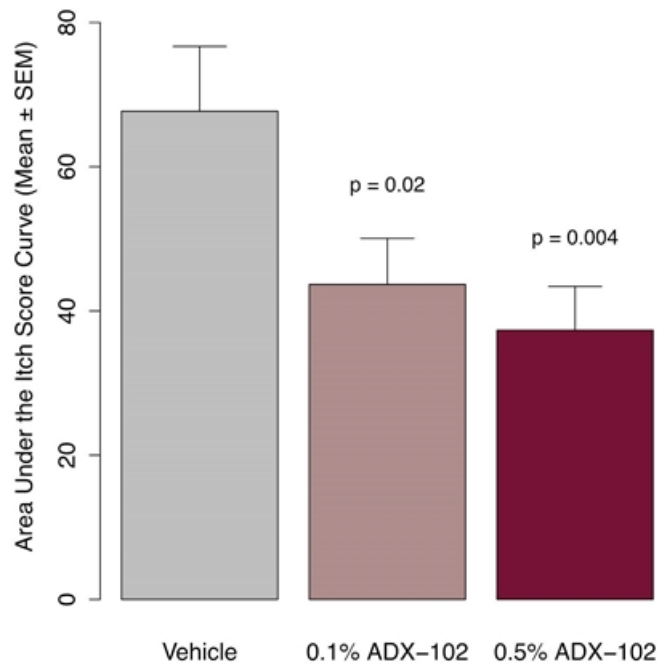
Data from olopatadine Summary Basis of Approval, ADX-102 Phase 2b clinical trial.

ADX-102 Decreased Ocular Itch in Phase 2b Clinical Trial



ADX-102 was statistically superior to control in reducing allergic ocular itch 10 to 60 minutes after allergen challenge, when the activity of antihistamines diminishes.

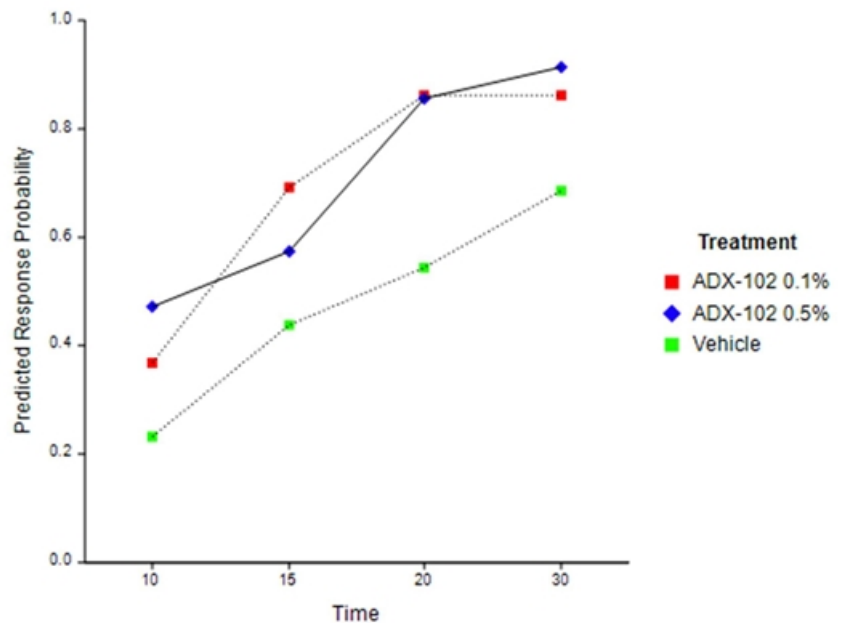
ADX-102 Decreased Area Under the Curve Ocular Itch Score in Phase 2b Clinical Trial



Area under the curve indicated a durable effect of ADX-102 in reducing ocular itch score in a manner that is statistically superior to that of control 10 to 60 minutes after allergen challenge, when the activity of antihistamines diminishes.

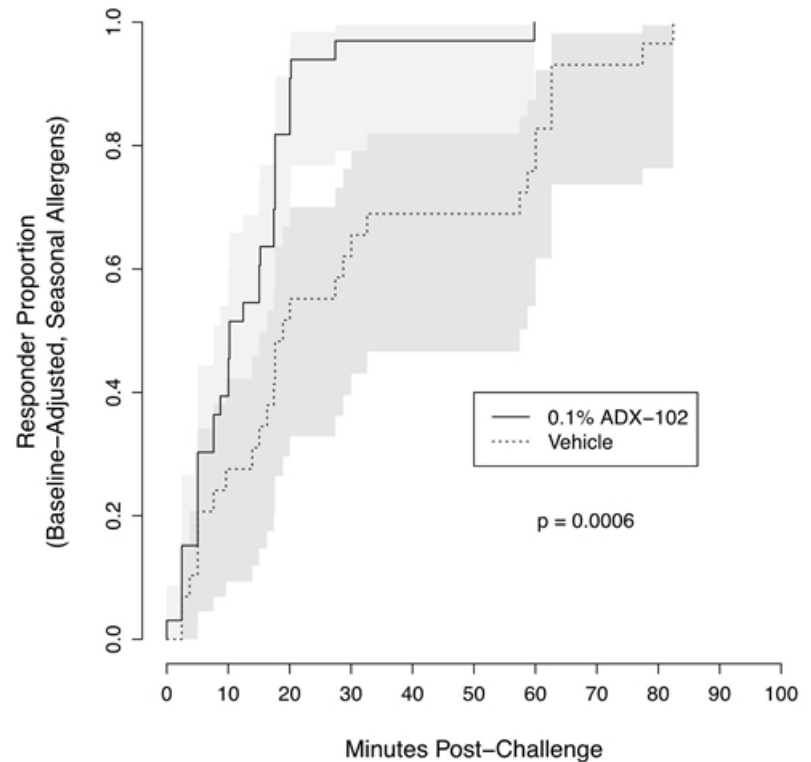
Probability of Clinically Important Response Was Statistically Higher in ADX-102-Treated Patients

- One-point improvement in ocular itch score is US FDA regulatory precedent
- When a responder is defined as a patient that improves one point from peak baseline itch score, odds ratio analysis indicated that ADX-102-treated patients were more than three times as likely to achieve clinical response ($p=0.02$ for each drug group) in the Phase 2b clinical trial



Clinical Response Achieved Faster in ADX-102 Group vs. the Vehicle Group

- 0.1% and 0.5% ADX-102 groups achieved statistically faster clinical response than vehicle ($p=0.0006$ and $p=0.008$, respectively).
- As an example, the graph to the right indicates that 94% of 0.1% ADX-102-treated patients responded by 20 minutes post-challenge in the Phase 2a clinical trial.



Allergic Conjunctivitis Phase 2b Key Conclusions

- ADX-102 was shown to be statistically superior to vehicle in durably reducing ocular itch score from 10 to 60 minutes after exposure to allergen, an efficacy profile that has not been demonstrated for antihistamines.
- Relative to control, the activity of ADX-102 increased during a period when the activity of antihistamines decreases.
- Using the US FDA regulatory precedent of one point improvement on the ocular itch score, the clinical response of drug-treated patients was statistically superior to that of vehicle treated patients, when response is measured vs. peak baseline itch score.
- Using odds ratio analysis, ADX-102-treated patients were more than three times more likely to respond than vehicle-treated patients.
- Time to response was statistically faster in ADX-102 treated patients vs. that of vehicle-treated patients.

Allergic Conjunctivitis Phase 3 Clinical Design

Groups	Topical Ocular ADX-102 0.1%, ADX-102 0.5%, or Vehicle
Randomization	Double-Masked, Vehicle-Controlled 1:1:1
Enrollment	150 Patients with History of Allergic Conjunctivitis
Model	Single Dose Seasonal Allergen Challenge
Endpoint	Patient-Reported Itching Score (0 to 4)

*Pending additional non-clinical data and other factors, which may not be in Aldeyra's control



A Market-Based Analysis of Unmet Medical Need in Allergic Conjunctivitis and Dry Eye Disease

Tim Surgenor

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tsurgenor@redskyco.com

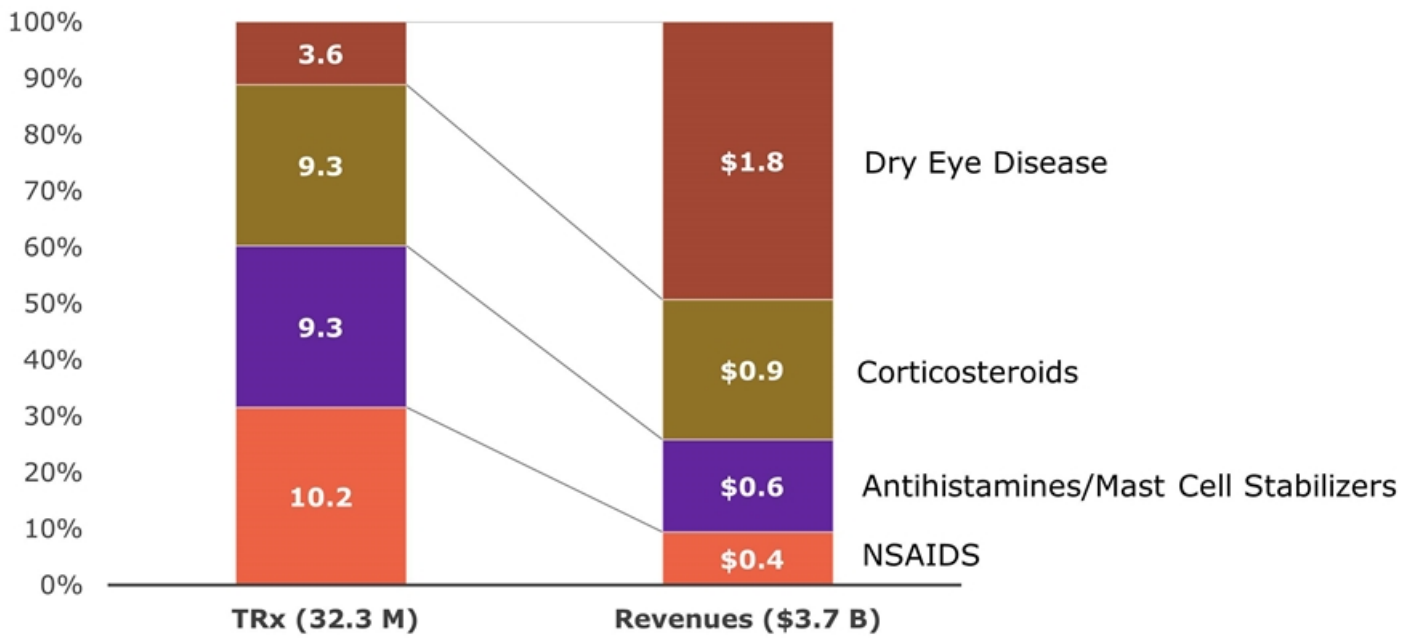
Cambridge Innovation Center
One Broadway, 4th Floor
Cambridge, MA 02142

The opinions expressed herein are those of RedSky Partners, LLC and do not necessarily reflect the views of Aldeyra.

Overview

- ADX-102, if approved, has potential to be differentiated, branded entry in market for eye drop treatments
- ADX-102 appears to provide clinically significant improvement in phase 2 studies in multiple indications
 - allergic conjunctivitis
 - dry eye disease
 - noninfectious anterior uveitis
- Positioning as first line anti-inflammatory with unique mechanism and without steroid adverse events may convey significant market potential in anterior uveitis and dry eye disease
- In allergic conjunctivitis, positioning between short-acting antihistamines and corticosteroids is differentiated and attractive to physicians

US Eye Drop Market in 2016



Source: IMS



Emerging Value Proposition – ADX-102

	Noninfectious Anterior Uveitis	Dry Eye	Allergic Conjunctivitis
Market Need	<ul style="list-style-type: none"> ~150,000 US patients Treated with corticosteroids, which may lead to cataracts and glaucoma 	<ul style="list-style-type: none"> ~20 million patients Only two approved drugs Therapy generally considered to be inadequate 	<ul style="list-style-type: none"> ~20% of US population ~60 million patients Antihistamines provide short term relief Off-label use of chronic corticosteroids represents safety risk
ADX-102 Efficacy Profile	<ul style="list-style-type: none"> Efficacy similar to corticosteroid monotherapy at 4 weeks in Phase 2b trial 	<ul style="list-style-type: none"> Statistically significant improvement in multiple signs and symptoms at 4 weeks, with apparent rapid onset in Phase 2a trial 	<ul style="list-style-type: none"> Statistically significant reduction in itching at 10-60 minutes after challenge in Phase 2b trial
Safety / Tolerability to Date	<ul style="list-style-type: none"> No observed increase in intraocular pressure No observed significant adverse events 	<ul style="list-style-type: none"> Favorable tolerability No observed significant adverse events 	<ul style="list-style-type: none"> Favorable tolerability No observed significant adverse events
Dose being studied	0.5%	0.1%, 0.25%	0.1%, 0.5%

- Opportunity for lifecycle management and dose form opportunities

Source: ALDX press releases



ADX-102 Opportunity in Allergic Conjunctivitis

- Allergic conjunctivitis – inflammatory disease of conjunctiva resulting from allergen exposure
- Affects ~20% of US population with range of severity
- Mast-cell stabilizers or antihistamines provide short term relief –acute phase allergic reaction (up to 20 minutes)
 - Histamine release is acute; antihistamines work immediately following allergen exposure
 - Activity of antihistamines diminishes rapidly
- Patients with chronic or severe forms of allergic conjunctivitis are treated with topical corticosteroids – creating long-term risks of cataracts and glaucoma
- ADX-102 Hypothesis
 - Aldehyde trap mechanism could be substantial market opportunity for patients with inadequate relief from antihistamines and who are not candidates for corticosteroids

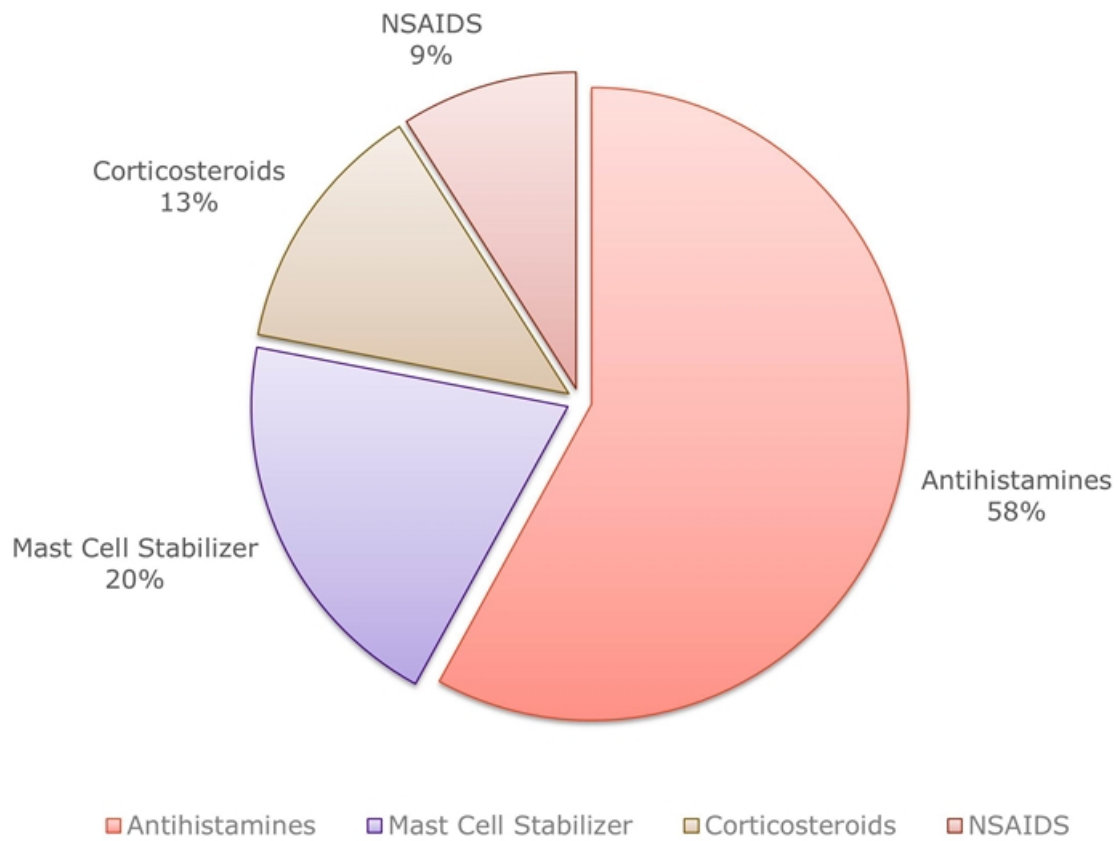
Survey Overview

- Survey of 75 US Physicians
 - Ophthalmology - 45
 - Optometry - 15
 - Allergy / Immunology - 15
- Conducted in July 2017 on behalf of Aldeyra
- Active in treatment of allergic conjunctivitis

Source: GLG market research

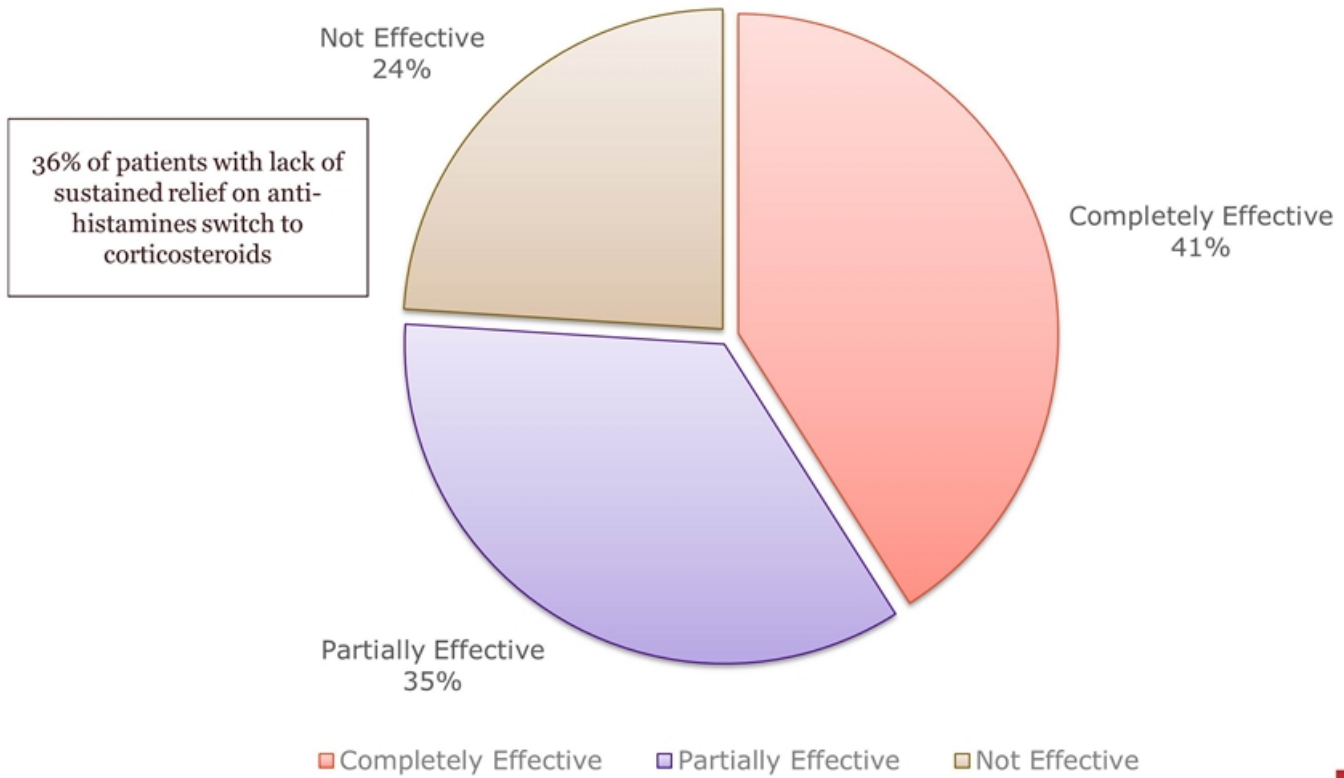


How do you currently treat your AC patients with topical products?



Source: GLG market research

For AC patients treated with topical ophthalmic antihistamines, what percent apply to each category below?



Source: GLG market research

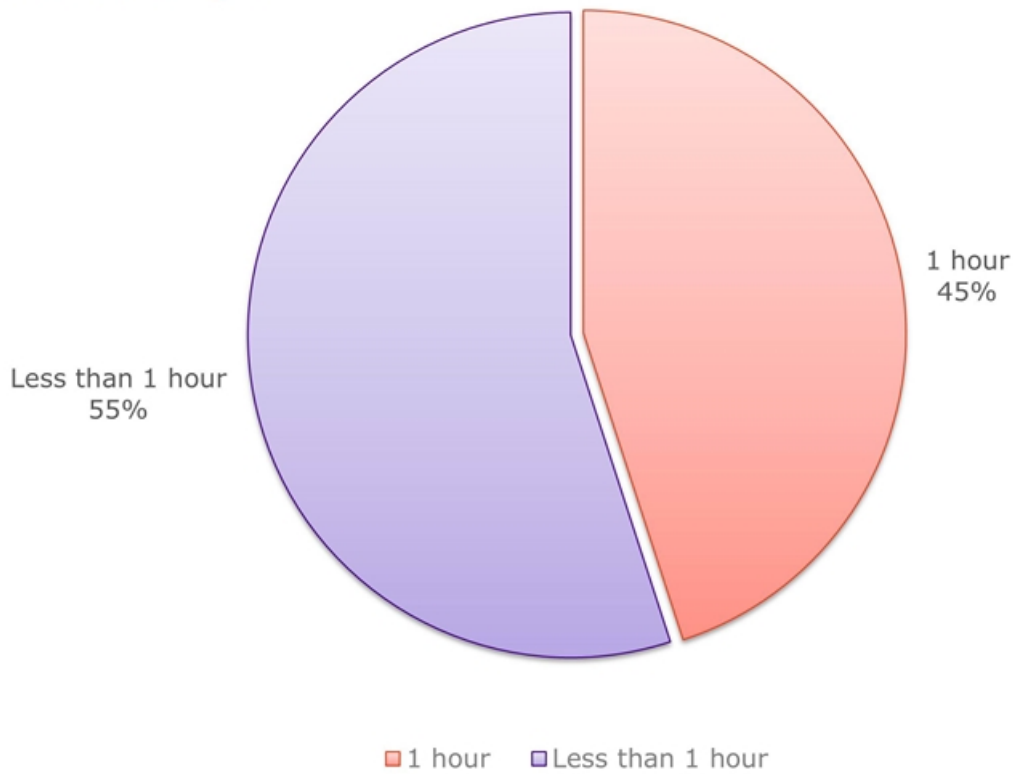


Cross-sectional study of allergic conjunctivitis consistent with survey results

- 2015 Study in Italy
- 2687 Allergic conjunctivitis patients
 - 43% used OTC
 - 29% used topical antihistamines
 - 41% used corticosteroids
 - 60% used multiple medications

Source: Allergic conjunctivitis: a cross-sectional study; A. Leonardi et al; Clinical & Experimental Allergy, 2015 (45) 1118-1125.

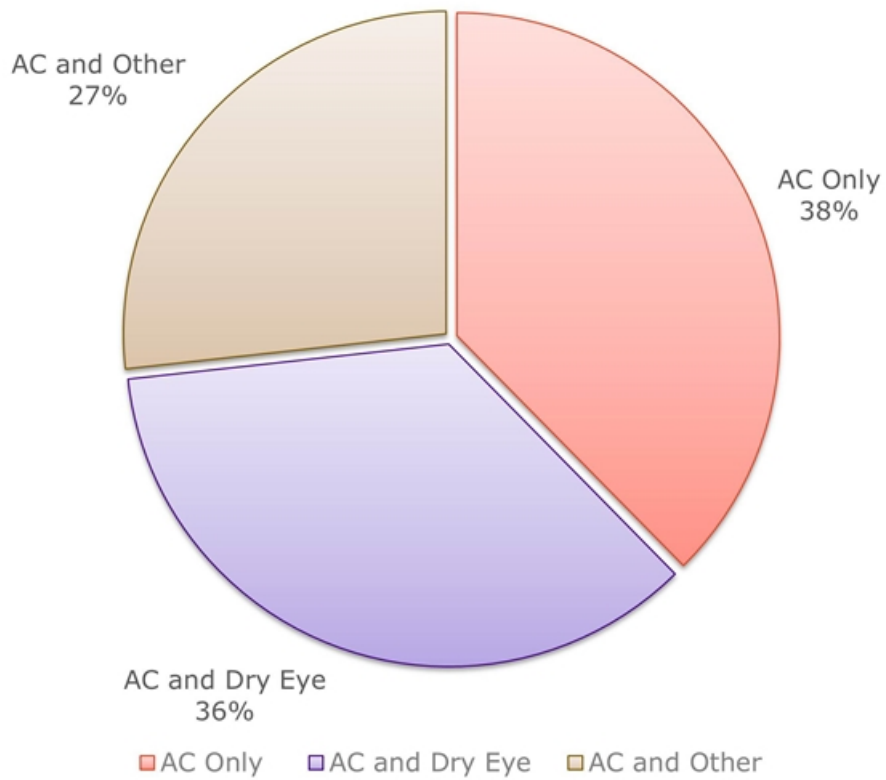
What percentage of your AC patients on anti-histamines, after a single dose, fall into the following categories of symptom relief?



Source: GLG market research

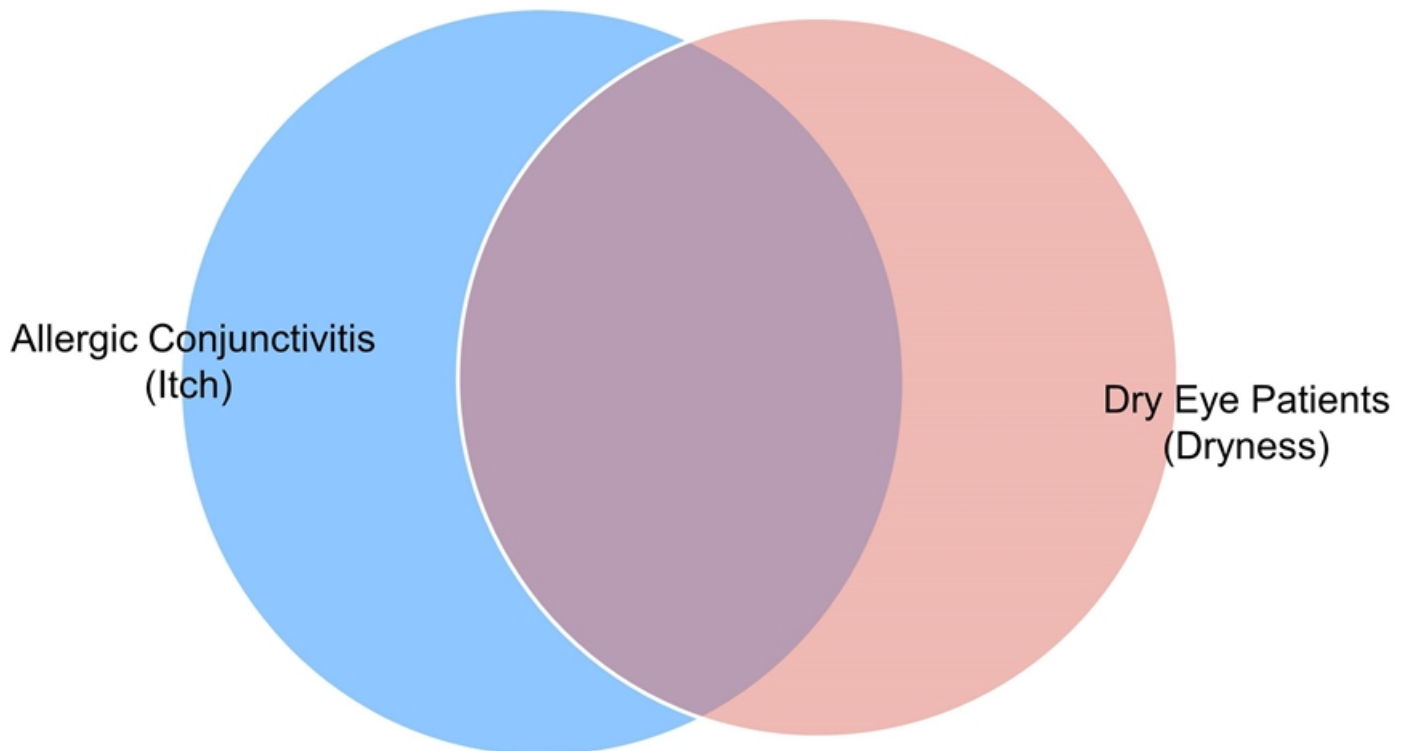


What percentage of your AC patients have some type of mixed condition?



Source: GLG market research

2011 Study of allergic conjunctivitis patients and dry eye syndrome consistent with survey results

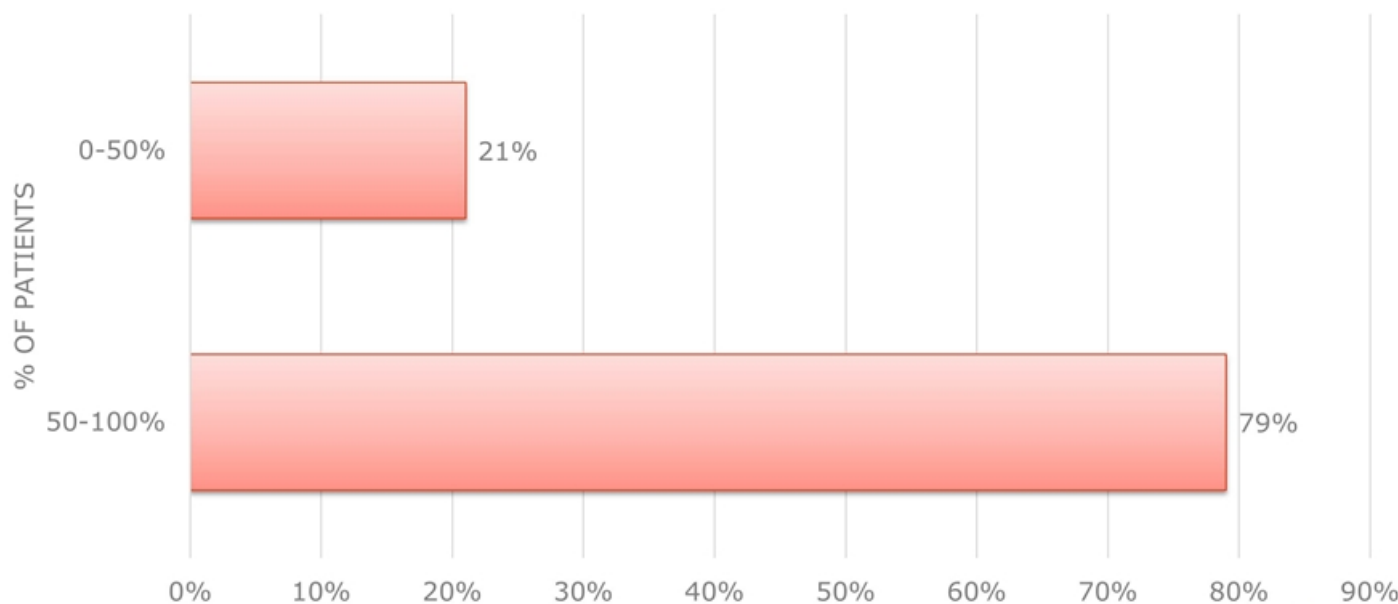


45% of Allergic Conjunctivitis Patients with Itch Symptoms Also Experience Dryness

M.M. Hom et al. / Ann Allergy Asthma Immunol 108 (2012) 163–166



If a safe, non-steroidal, anti-inflammatory product was available that provided a more sustained symptomatic response than antihistamines, what percent of your AC patients would be candidates for this therapy?



Source: GLG market research



Conclusions – ADX-102 has potential for differentiated profile in allergic conjunctivitis treatment

- ADX-102 has a novel therapeutic profile
 - In Phase 2 clinical trials, the largest reduction in itching occurred after typical antihistamine peak activity
 - This observation consistent with effect on aldehyde-mediated allergic response
 - Potential for positioning as treatment for allergic conjunctivitis and dry eye
- Despite common perceptions, antihistamine treatment of allergic conjunctivitis has significant limitations
 - Antihistamines work acutely following allergen exposure
 - Activity of antihistamines diminishes rapidly
- Physician survey showed large percentage of patients do not receive adequate therapy using antihistamines alone
 - Limited duration, effectiveness
 - Large population moves on to corticosteroids
- Physician survey identified strong physician preference for product with ADX-102 therapeutic profile
 - Potential to provide more sustained relief
 - Potential to avoid patient exposure to side effects of corticosteroids



Additional Data on Aldehyde Biomarker Correlation with
Clinical Efficacy from Phase 2a Dry Eye Disease Clinical Trial

David Clark, MD
Chief Medical Officer
Aldeyra Therapeutics

Dry Eye Disease Phase 2a Clinical Design

Groups	Topical Ocular ADX-102 Formulations: <ul style="list-style-type: none">• 0.1% ADX-102• 0.5% ADX-102• 0.5% (Lipid) ADX-102
Randomization	1:1:1 28-Day Four-Times-Daily Dosing
Enrollment	51 Patients with Dry Eye Disease
Primary Objective	Dose Selection for Phase 2b Based on Tolerability and Exploratory Efficacy
Endpoints	Standard Dry Eye Disease Signs and Symptoms

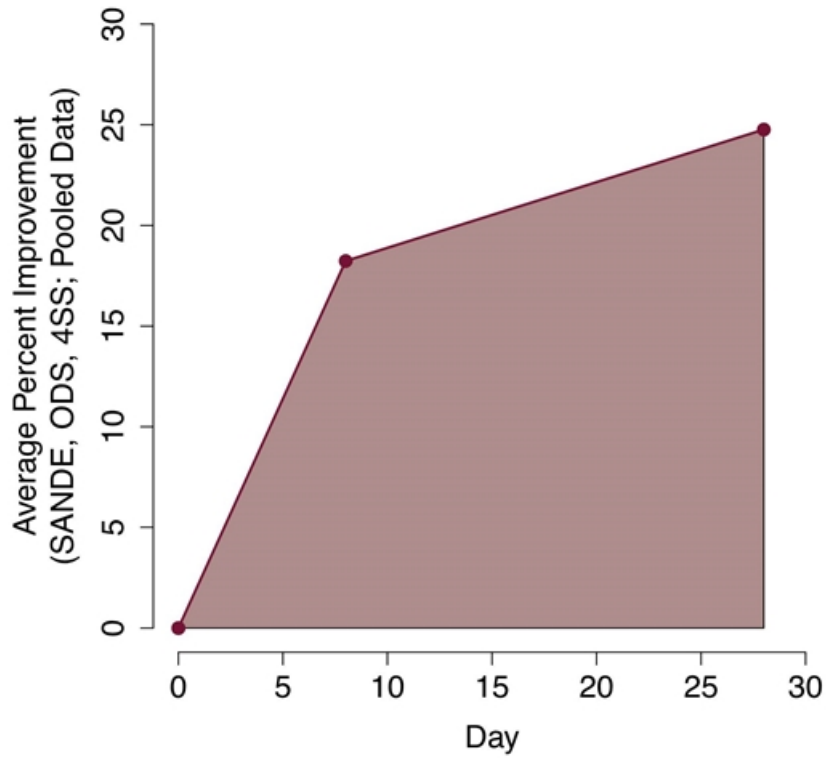
Further information can be found on www.clinicaltrials.gov: Trial #NCT03162783.

Statistically Significant Improvement in Multiple Dry Eye Disease Signs and Symptoms

Endpoint (Pooled Data)	Pre-Treatment	Post-Treatment	p value*
Symptom Assessment in Dry Eye (SANDE) Score	61	52	p = 0.003
Ocular Discomfort Score	2.3	1.5	p = 0.00002
Overall 4-Symptom Score	2.6	2.0	p = 0.0004
Tear Volume (Schirmer Test)	5.6	8.3	p = 0.008
Osmolarity	304	294	p = 0.003
Total Staining (Lissamine Green)	5.2	4.3	p = 0.002

p values are subject to change based on quality control analysis; Pre-Treatment = Day 0, Post-Treatment = Day 28.
Data from ADX-102 Phase 2a clinical trial.

Symptom Improvement Over Time Supportive of Drug Activity

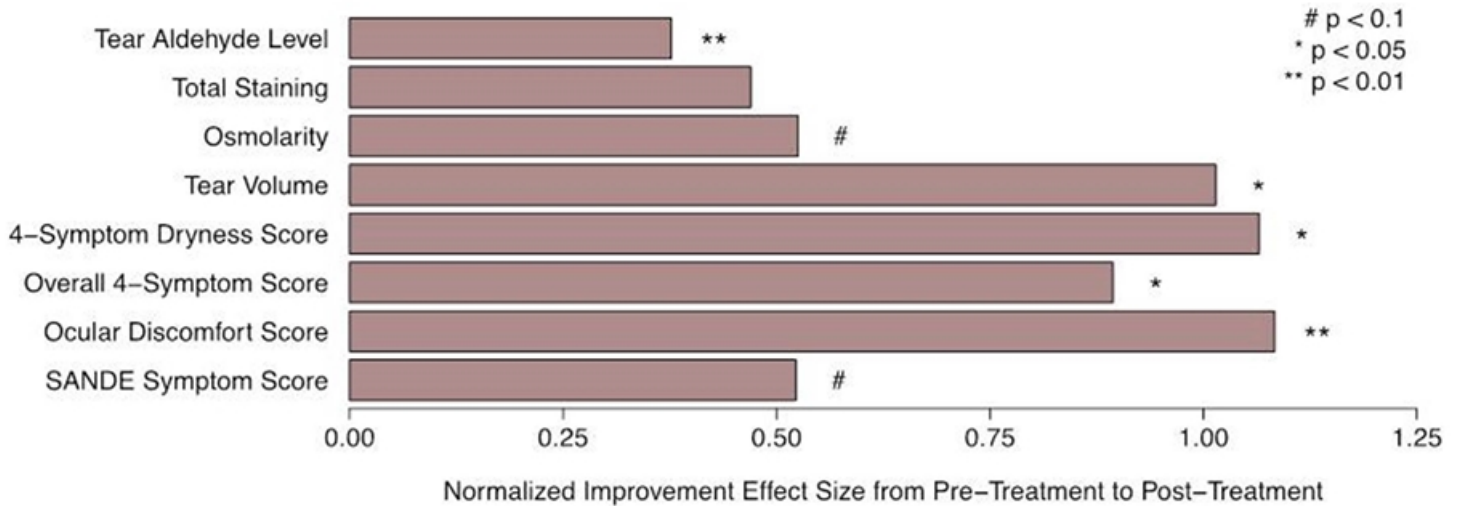


SANDE=Symptom Assessment in Dry Eye Score, ODS=Ocular Discomfort Score,
4SS=Overall 4-Symptom Score

Pooled data from ADX-102 Phase 2a clinical trial.

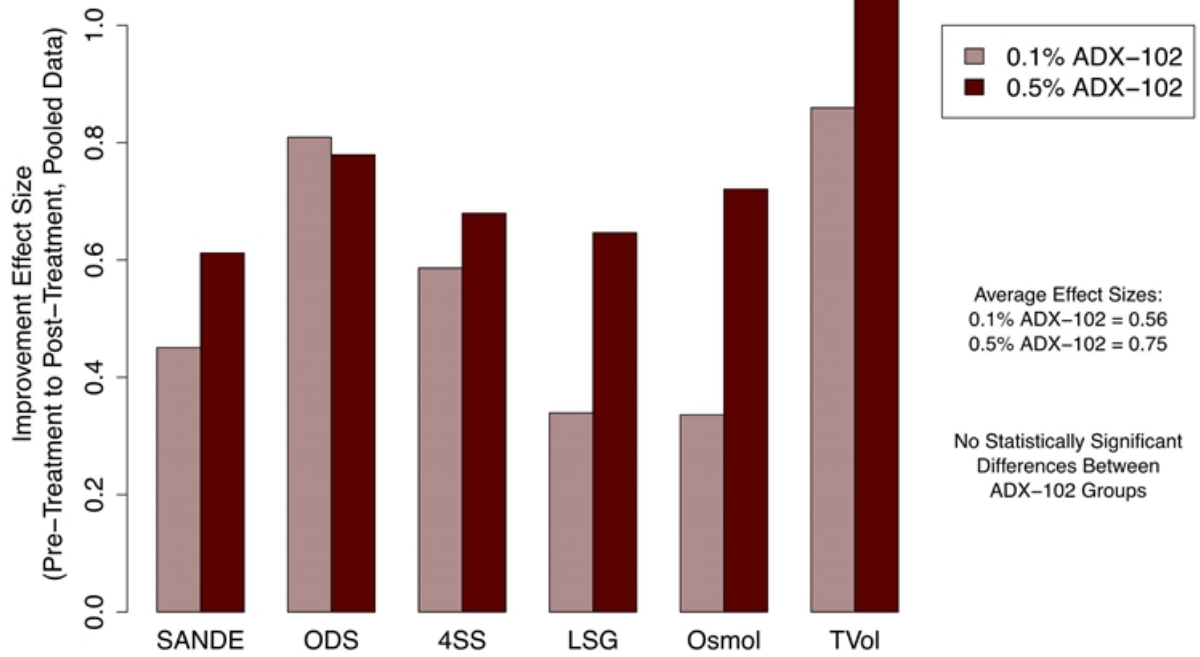
Improvement Effect Sizes Were Robust and Statistically Significant

0.1% ADX-102 Improvement Effect Size Across Dry Eye Disease Signs and Symptoms



p values are subject to change based on quality control analysis; Effect size = Mean difference from Day 0 to Day 28 / Standard Deviation of Day 0. Data from ADX-102 Phase 2a clinical trial.

Dose Response in Phase 2a Dry Eye Disease Clinical Trial

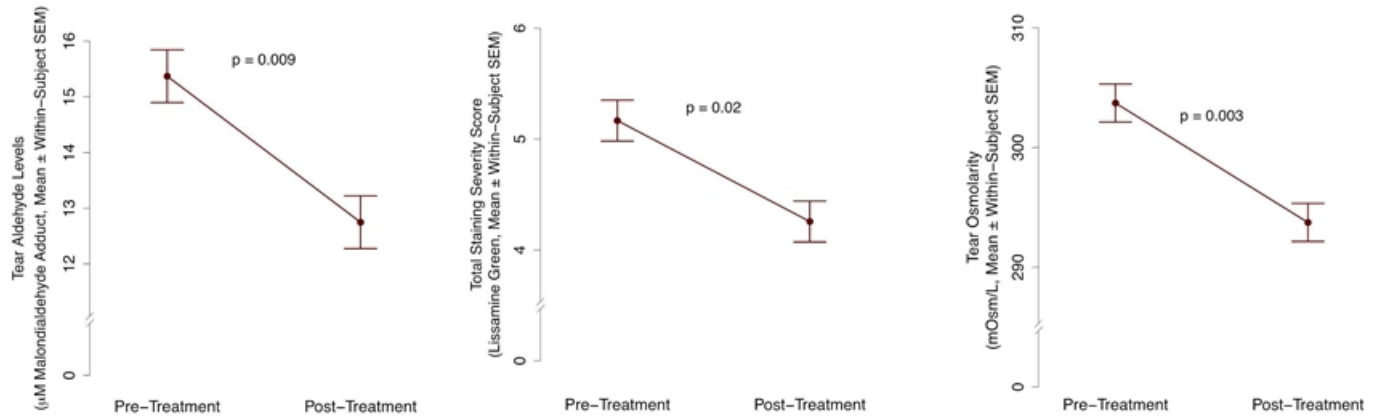


Average Effect Sizes:
0.1% ADX-102 = 0.56
0.5% ADX-102 = 0.75

No Statistically Significant Differences Between ADX-102 Groups

SANDE=SANDE Symptom Score, ODS=Ocular Discomfort Score,
4SS=Overall 4-Symptom Score, LSG=Lissamine Green Corneal Staining Score,
Osmol=Tear Osmolarity, TVol=Tear Volume (Schirmers Test)

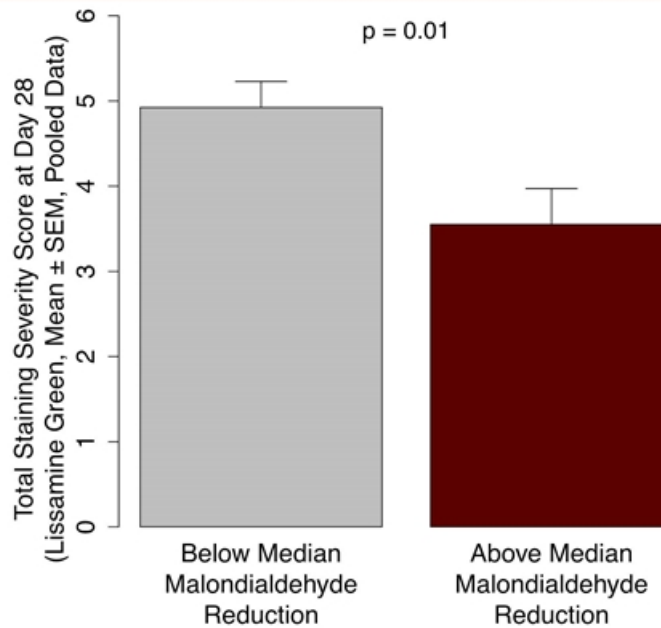
Tear Aldehyde Reduction Supportive of ADX-102 Aldehyde Sequestering Mechanism



- Statistically significant aldehyde reduction occurred in conjunction with statistically significant reductions in ocular staining score and tear osmolarity.
- The results are consistent with published data correlating dry eye disease severity with increased aldehyde levels (Curr Eye Res 41: 1143, 2016).
- To our knowledge, our data are the first report of drug biomarker changes correlated with clinical efficacy.

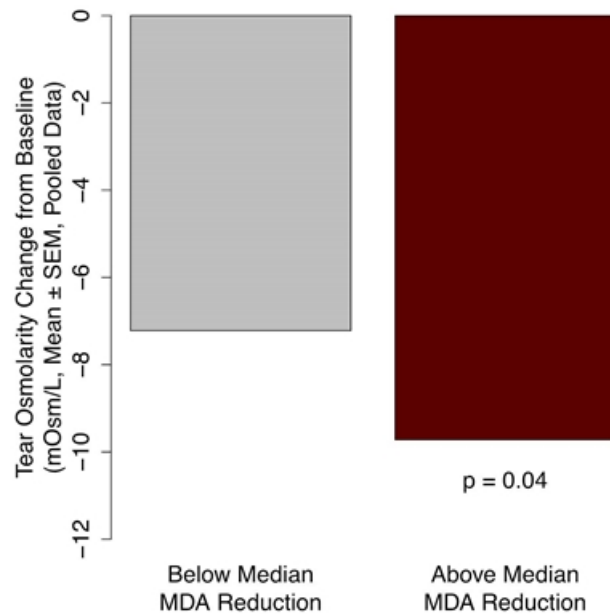
p values are subject to change based on quality control analysis; Pre-Treatment = Day 0, Post-Treatment = Day 28; pooled data from Phase 2a clinical trial.

Aldehyde Reduction Correlated with Sign Improvement Within Individual Patients



Patients with the most reduction in aldehyde levels also exhibited greater corneal staining improvement, suggesting that aldehyde reduction is correlated with treatment efficacy in dry eye disease.

Aldehyde Reduction Correlated with Sign Improvement Within Individual Patients



Patients with the most reduction in aldehyde levels also exhibited greater tear osmolarity improvement, suggesting that aldehyde reduction is correlated with treatment efficacy in dry eye disease.

Dry Eye Disease Expected Phase 2b Clinical Design*

Groups	0.1% ADX-102, 0.25% ADX-102, and Control
Randomization	1:1:1 Double-Masked
Treatment Time	12 Weeks
Enrollment	225 Patients with Dry Eye Disease
Endpoints	Standard Dry Eye Disease Signs and Symptoms

*Pending additional non-clinical data and other factors, which may not be in Aldeyra's control

Clinical and Regulatory Opportunities in Treatment of Dry Eye Disease

Gary D. Novack, Ph.D.

October 2017



The opinions expressed herein are those of Dr. Novack and do not necessarily reflect the views of Aldeyra.

(C) 2017 PharmaLogic Development, Inc.

38

Disclosures

- ℓ Dr. Novack consults for numerous pharmaceutical and medical device firms.



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Current Issue

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Volume 15, Issue 3

Issue Highlights

TFOS DEWS II Report

TFOS DEWS II Introduction

J. Daniel Nelson, Jennifer P. Craig, Esen K. Akpek, Dimitri T. Azar, Carlos Belmonte, Anthony J. Bron, Janine A. Clayton, Murat Dogru, Harminder S. Dua, Gary N. Foulks, José A.P. Gomes, Katherine M. Hammitt, Juha Holopainen, Lyndon Jones, Choun-Ki Joo, Zuguo Liu, Jason J. Nichols, Kelly K. Nichols, Gary D. Novack, Virender Sangwan, Fiona Stapleton, Alan Tomlinson, Kazuo Tsubota, Mark D.P. Willcox, James S. Wolffsohn, David A. Sullivan
Vol. 15, Issue 3

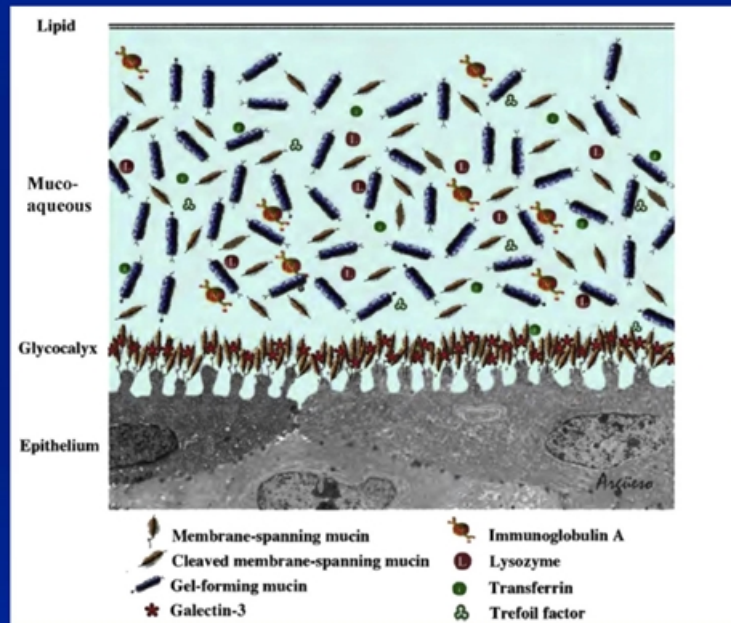
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Dry eye disease

- ℓ Dry eye disease
- ℓ KCS
 - King Charles Spaniel
- ℓ Keratoconjunctivitis sicca
- ℓ Misnomer
 - Implies aqueous deficiency – which is only part of dry eye

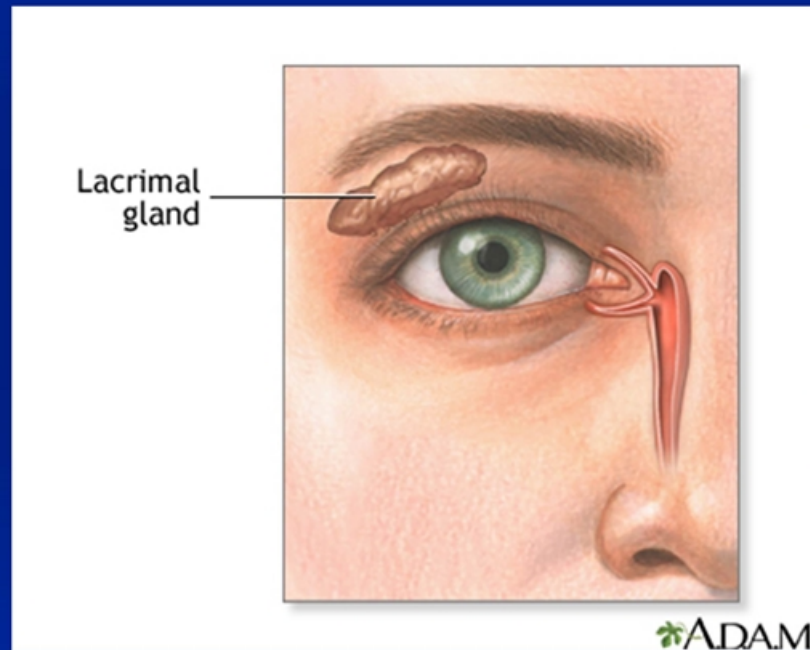


Tear film

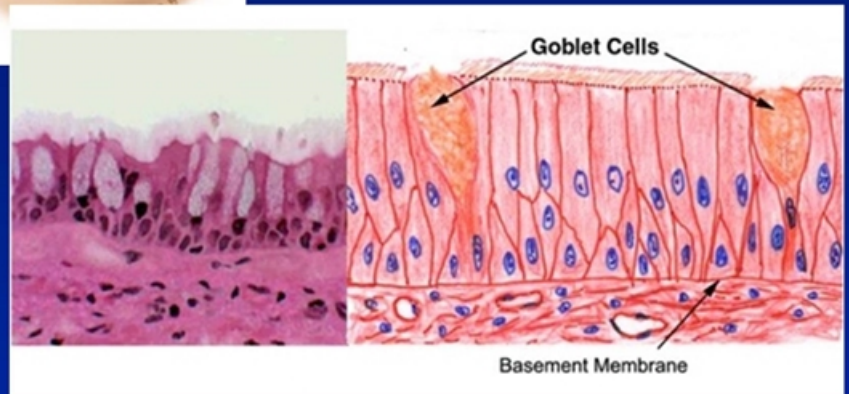
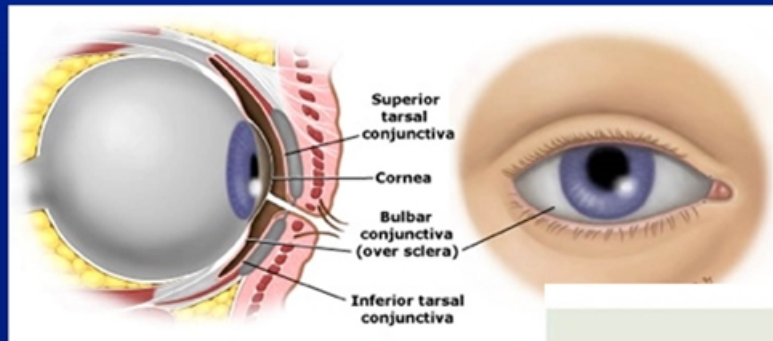


Willcox MDP et al TFOS DEWS II Tear Film Report.
Ocul Surf 2017;15(3): 366-403.

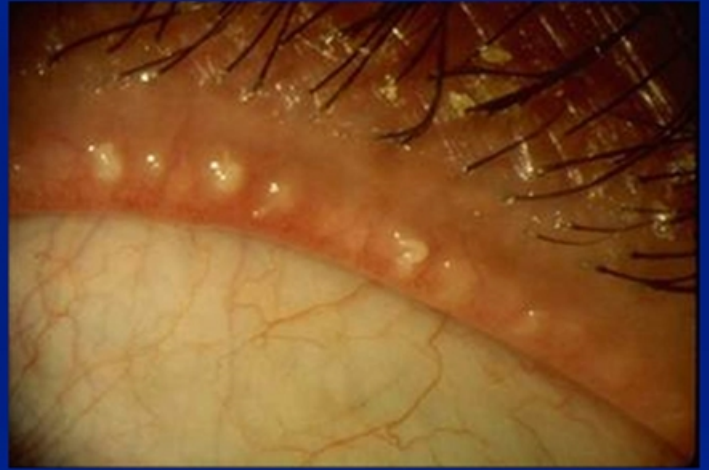
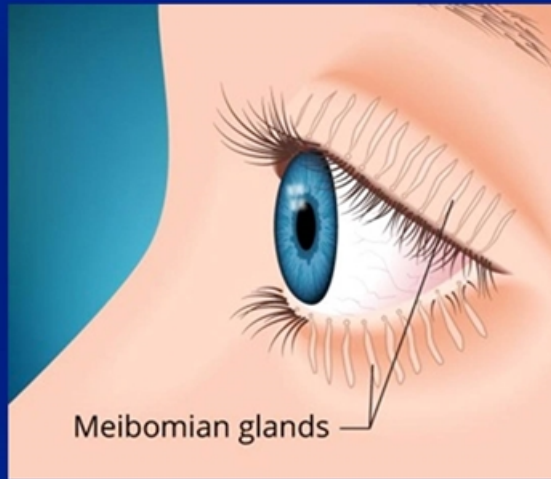
Source of Tears: Aqueous



Source of Tears: Mucin

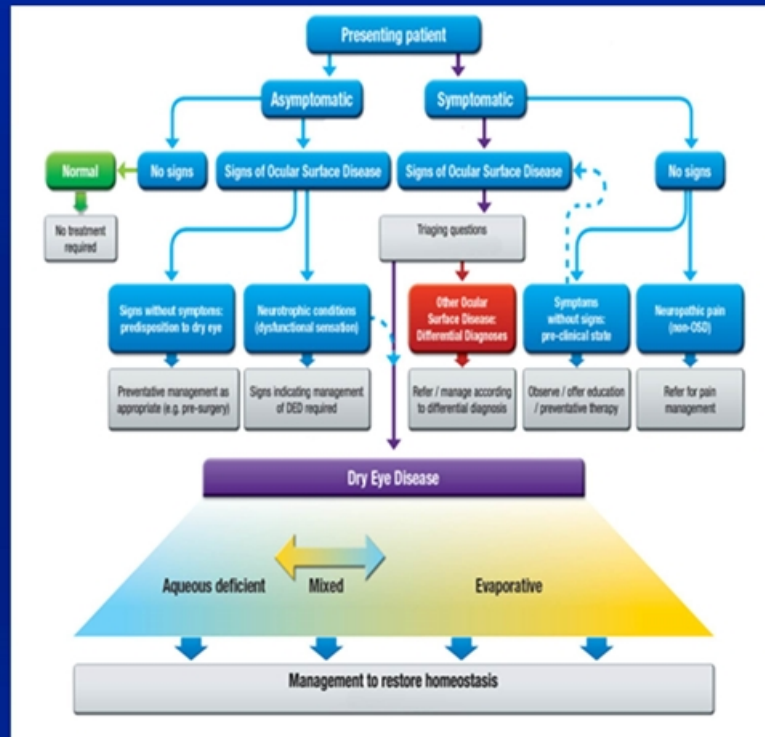


Source of Tears: Lipid



DEWS II definition of dry eye

- ℓ “Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and **hyperosmolarity**, ocular surface **inflammation** and damage, and neurosensory abnormalities play etiological roles.”



Craig, JP et al. TFOS DEWS II Definition and Classification Report. Ocul Surf 2017;15(3): 276-283.

Treatments

The Ocular Surface xxx (2017) 580–634



ELSEVIER

Contents lists available at [ScienceDirect](#)

The Ocular Surface

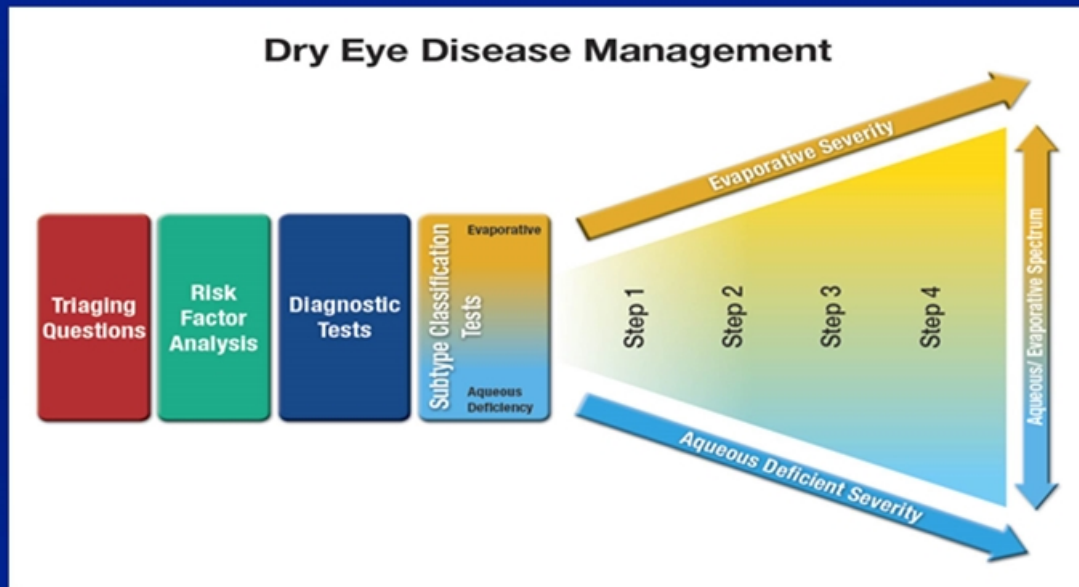
journal homepage: www.theocularsurface.com



TFOS DEWS II Management and Therapy Report

Lyndon Jones, FCOptom PhD ^{a,*}, Laura E. Downie, BOptom PhD ^b, Donald Korb, OD ^c,
Jose M. Benitez-del-Castillo, MD PhD ^d, Reza Dana, MD ^e, Sophie X. Deng, MD PhD ^f,
Pham N. Dong, MD ^g, Gerd Geerling, MD FEBO ^h, Richard Yudi Hida, MD ⁱ, Yang Liu, MD ^j,
Kyoung Yul Seo, MD PhD ^k, Joseph Tauber, MD ^l, Tais H. Wakamatsu, MD PhD ^m,
Jianjiang Xu, MD PhD ⁿ, James S. Wolffsohn, FCOptom PhD ^o,
Jennifer P. Craig, MCOptom PhD ^p

Treatment recommendations



Diagrammatic representation of the process associated with the management of DED

Step 1

- ℓ Education regarding the condition, its management, treatment and prognosis
- ℓ Modification of local environment
- ℓ Education regarding potential dietary modifications (including oral essential fatty acid supplementation)
- ℓ Identification and potential modification/elimination of offending systemic and topical medications
- ℓ Ocular lubricants of various types (if MGD is present, then consider lipid containing supplements)
- ℓ Lid hygiene and warm compresses of various types

Step 2

- ℓ Prescription drugs to manage DED
 - Topical antibiotic or antibiotic/steroid combination applied to the lid margins for anterior blepharitis (if present)
 - Topical corticosteroid (limited-duration)
 - Topical secretagogues
 - Topical non-glucocorticoid immunomodulatory drugs (such as cyclosporine)
 - Topical LFA-1 antagonist drugs (such as lifitegrast)
 - Oral macrolide or tetracycline antibiotics

Investigational Rx

ℓ Phase 3:

- Loteprednol etabonate nanoparticles (Kala)
- Tavilermide (Mimetogen / Allergan)
- Cyclosporine OTX-101 (Auven/SunPharma)
- Thymosin beta 4 – RegeneRx

Investigational Rx

ℓ Phase 2:

- P-321 (Parion/Shire)
- Lubricin™ (Lubris/Novartis)
- Lacritin™ (Tear Solutions)
- ADX-102 (Aldeyra)

Treatments for Tear Insufficiency



- ℓ Tear replacement
 - Artificial tears (lubricants)
 - Aqueous supplements; Lipid supplements
 - Biological supplements
 - Autologous serum



- ℓ Tear conservation
 - Punctal occlusion
 - Moisture chamber spectacles



- ℓ Tear stimulation
 - Topical secretagogues; Oral secretagogues; Nasal neurostimulation



Ocular Lubricants



- ℓ Mainstay of therapy
 - numerous topical formulations available
- ℓ Avoid preservatives in severe dry eye
- ℓ Very few RCT have compared the relative superiority of a particular OTC product to others for DED



Anti-Inflammatory Therapy

- ℓ Topical glucocorticoids
- ℓ Non-glucocorticoid immunomodulators
 - Cyclosporine
 - Tacrolimus
 - NSAIDs
 - Biologics
- ℓ LFA-1 antagonist (Lifitegrast)
- ℓ Inflammatory modulation with systemic & topical antibiotics
 - tetracyclines
- ℓ Macrolide treatments



Surgical Approaches

- ℓ Tarsorrhaphy
- ℓ Surgical treatment for conjunctivochalasis
- ℓ Essential blepharospasm treatment with botulinum neurotoxin
- ℓ Lid corrections
 - Dermatochalasis
 - Blepharoptosis (ptosis)
 - Lower lid blepharoplasty
- ℓ Conjunctival surgery and amniotic membrane grafts
- ℓ Mechanical dacryoreservoirs
- ℓ Major salivary gland transplantation
 - Parotid duct transposition
 - Microvascular submandibular gland transplantation
- ℓ Minor salivary gland autotransplantation

Local Environmental Considerations

- ℓ Chronic topical medications
- ℓ Systemic medications
- ℓ Decreased blink rate
- ℓ Desiccating conditions and environmental pollutants
- ℓ Contact lens wear



US FDA: OTC Ophthalmic monograph

PART 349—OPHTHALMIC DRUG PRODUCTS FOR OVER-THE- COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

349.1 Scope.

349.3 Definitions.

Subpart B—Active Ingredients

Pharmacotherapy: Approvals

Table 17. Regulatory status of therapies for DED

Product	Country/Region (Year approved)			
	USA	Canada	Japan	Europe
Cyclosporine	Restasis® (2002)	Restasis® (2010)		Ikervis® (2015)
Hyaluronic Acid	—	—	Hyalein® (1995)	—
Diquafasol	—	—	Diquas® (2010)	—
Rebamapide	—	—	Mucosta® (2011)	—

Modified from Sullivan DA, Hammitt KM, Schaumberg DA, et al. Report of the TFOS/ARVO Symposium on global treatments for DED: an unmet need. *Ocul Surf.* 2012;10:108-16.

Chao W. Report of the Inaugural Meeting of the TFOS i(2) = initiating innovation Series: Targeting the Unmet Need for Dry Eye Treatment." *Ocul Surf* 2016;14(2): 264-316.

Xiidra®

NDA 208073

NDA APPROVAL

Shire Development LLC
Attention: Alida D. Barry
Manager, Global Regulatory Affairs
300 Shire Way
Lexington, MA 02421

/s/

JOHN J FARLEY
07/11/2016

Indications

- ℓ Restasis® (cyclosporine):
 - to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.
- ℓ Xiidra® (lifitegrast):
 - For the treatment of the signs and symptoms of dry eye disease

FDA clinical efficacy requirements

- ℓ Two studies (per 1962 law)
- ℓ Efficacy:
 - One sign, one symptom
 - Statistically significantly different from vehicle
 - (or maybe) Non-inferior to approved product
- ℓ Safety: 300-500 subjects, 100 chronic

Intersection of Dry Eye Disease and Allergic Conjunctivitis

John D Sheppard, MD, MMSc

Professor of Ophthalmology, Microbiology & Molecular Biology
Clinical Director, Thomas Lee Ocular Pharmacology Laboratory
Ophthalmology Residency Research Director
Medical Director, Lions Eye Bank of Eastern Virginia
President, Virginia Eye Consultants
Norfolk, Virginia

The opinions expressed herein are those of Dr. Sheppard and do not necessarily reflect the views of Aldeyra.

- Dry eye prevalence estimates range from 14% to 33% of the general population
- 70% Female; 30% Males
- Common in Post-Menopausal Women
- Dry eye prevalence will continue its strong growth:
 - Aging population
 - Increasing visual tasking (computers, VDTs)
 - Worsening environmental factors (pollution, dry office environments)
 - Growing awareness by eye care providers, PCPs and patients through peers and DTC advertising

Level I Dry Eye: DEWS Report



Level II Dry Eye: DEWS Report



Dry Eye Rx Landscape: Restasis

- Restasis[®] (0.05% cyclosporine ophthalmic emulsion)
- Approved by FDA on 12/23/2002
- Product Profile / Label:



- Indication for treatment of a **sign only**: increased tear production
- Onset of treatment effect: increased tear production observed after 6 months of treatment
- Effective in 15% of patient population studied
- Adverse effects:
 - **17%** of patients experienced ocular burning



Xiidra® (5% lifitegrast ophthalmic solution)

Approved by FDA on July 11, 2016



Product Profile / Label:

- Indication for treatment of the signs and symptoms of dry eye disease
- Adverse effects in **5-25%** of patients:
 - Instillation site irritation, dysgeusia and decreased visual acuity



- Large growing USA market with limited treatment options:
 - Restasis® approved product in US (2016 sales ~\$1.4 billion)
 - Xiidra® approved product in the US (Aug-Dec 2016 ~ \$54 million)
- Large growing International market with limited treatment options:
 - Ikervis® Ciclosporin 0.1% emulsion (Mar 2015, Europe, Santen)
 - Mucosta® Rebamipide 2% suspension (Sep 2011, Japan, Otsuka)
 - Hyalein® Sodium Hyaluronate 1% (April 2010, Japan, Senju)
 - Diquas® Diquofosol tetrasodium 3% solution (Dec 2010, Japan, Santen)

Dry Eye is an Inflammatory Condition

Well-supported in the Literature



Dry Eye Disease

An Immune-Mediated Ocular Surface Disorder

William Stevenson, MD; Sunil K. Chauhan, PhD; Reza Dana, MD, MSc, MPH

Dry Eye Disease as an Inflammatory Disorder

Margarita Calonge, MD, Amalia Enriquez-de-Salamanca, PhD, Yolanda Diebold, PhD, María J. González-García, PhD, Roberto Reinoso, PhD, José M. Herreras, MD, and Alfredo Corell, PhD

ICAM-1 expression predisposes ocular tissues to immune-based inflammation in dry eye patients and Sjögren's syndrome-like MRL/lpr mice

Jianping Gao, Grant Morgan, David Tieu, Tammy A. Schwalb, Jessica Y. Luo, Larry A. Wheeler, Michael E. Stern*

Tear Cytokine Profiles in Dysfunctional Tear Syndrome

HELENE LAM, LAUREN BLEIDEN, CINTIA S. DE PAIVA, WILLIAM FARLEY, MICHAEL E. STERN, AND STEPHEN C. PFLUGFELDER

The Definition and Classification of Dry Eye Disease:
Report of the Definition and Classification Subcommittee of the International Dry Eye WorkShop (2007)

Analysis of Inflammatory Cytokines in the Tears of Dry Eye Patients

Morgan L. Massingale, MS, Xiaohong Li, MD, PhD, Maithreyi Vallabhajosyula, OD, Dongmei Chen, MD, PhD, Yi Wei, DVM, PhD, and Penny A. Asbell, MD, MBA

Epithelial-Immune Cell Interaction in Dry Eye

Stephen C. Pflugfelder, MD,* Cintia S. de Paiva, MD,* De-Quan Li, MD, PhD,* and Michael E. Stern, PhD*†

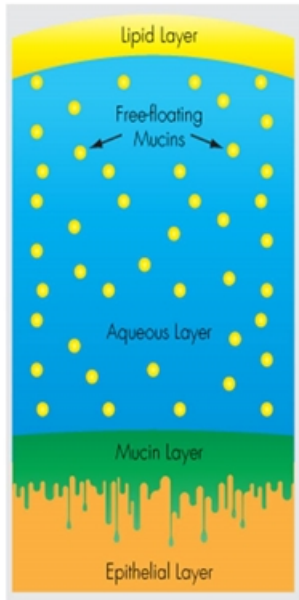
Conjunctival T-Cell Subpopulations in Sjögren's and Non-Sjögren's Patients with Dry Eye

Michael E. Stern,¹ Jianping Gao,¹ Tammy A. Schwalb,¹ Mylinh Ngo,¹ David D. Tieu,¹ Chi-Chao Chan,² Brenda L. Reis,¹ Scott M. Whitcup,³ Darby Thompson,⁴ and Janine A. Smith²

Conjunctival Epithelium Expression of HLA-DR in Dry Eye Patients

Kazuo Tsubota^{a,b,c} Tsutomu Fujihara^a Keiko Saito^b Tsutomu Takeuchi^d

Causes of Dry Eye

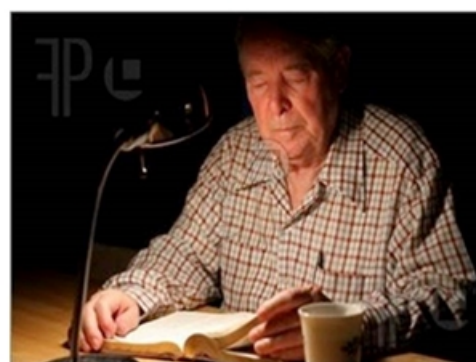


- Aqueous-Deficient
 - Autoimmune disease (Sjögren's Syndrome, RA, Lupus)
- Lipid-Deficient
 - Meibomian gland dysfunction, Hormonal changes
- Mucin-Deficient
 - Goblet cell loss
- Neural Loop-Associated
 - Abnormal corneal sensitivity, Blink disorders
- Environmentally Induced or Exacerbated

Environmental Factors



Corollary Factors



Secretagogues

Hormonal

Nutritional
Supplements

Mucomimetics

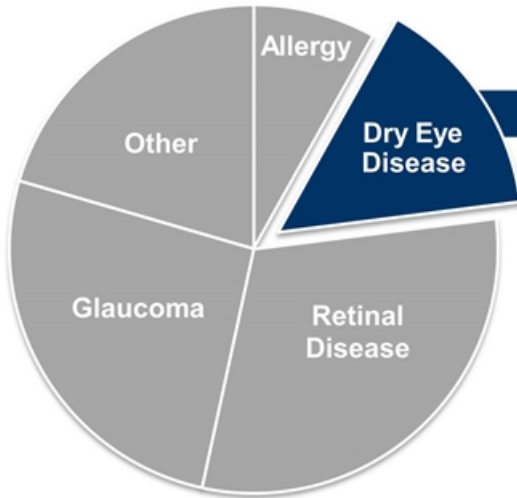
Anti-evaporatives

Improved Polymers

Anti-Inflammatories

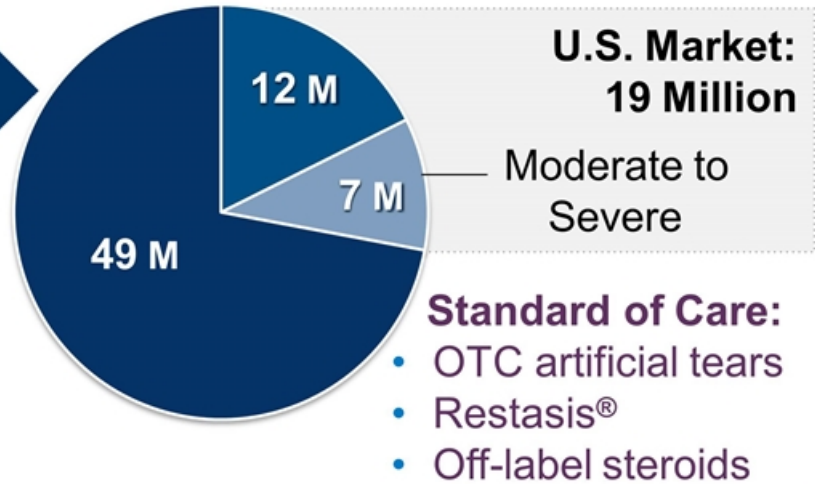
Significant Need for New Therapies for Dry Eye Disease

Total Global Ophthalmic Market- Large and Growing



Dry eye disease is one of the leading causes of patient visits to eye care professionals in the U.S.

Dry Eye Global Patient Population: 68 Million*

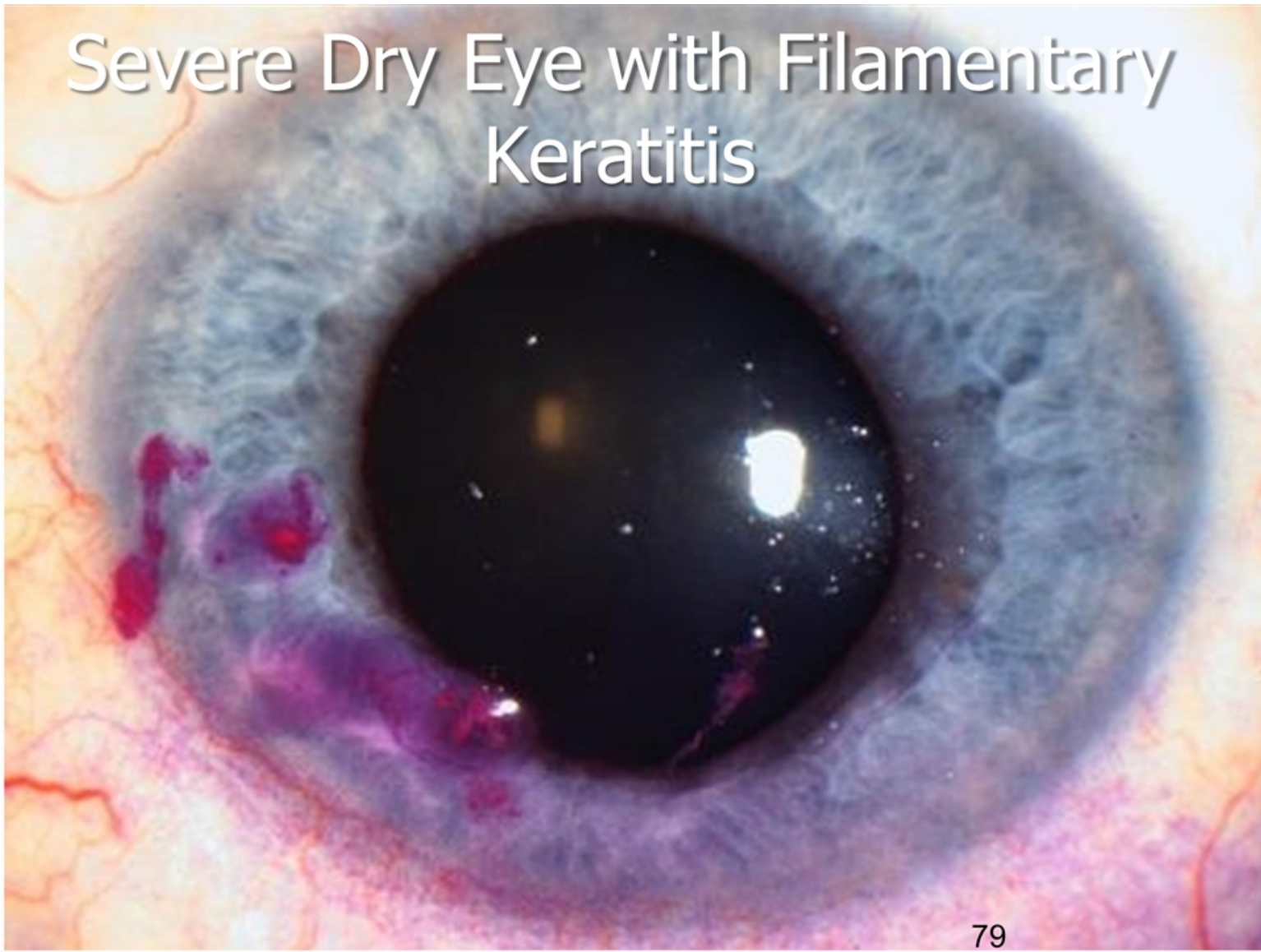


Commercial Opportunity:
Reachable with a specialty sales force detailing to ophthalmologists & optometrists

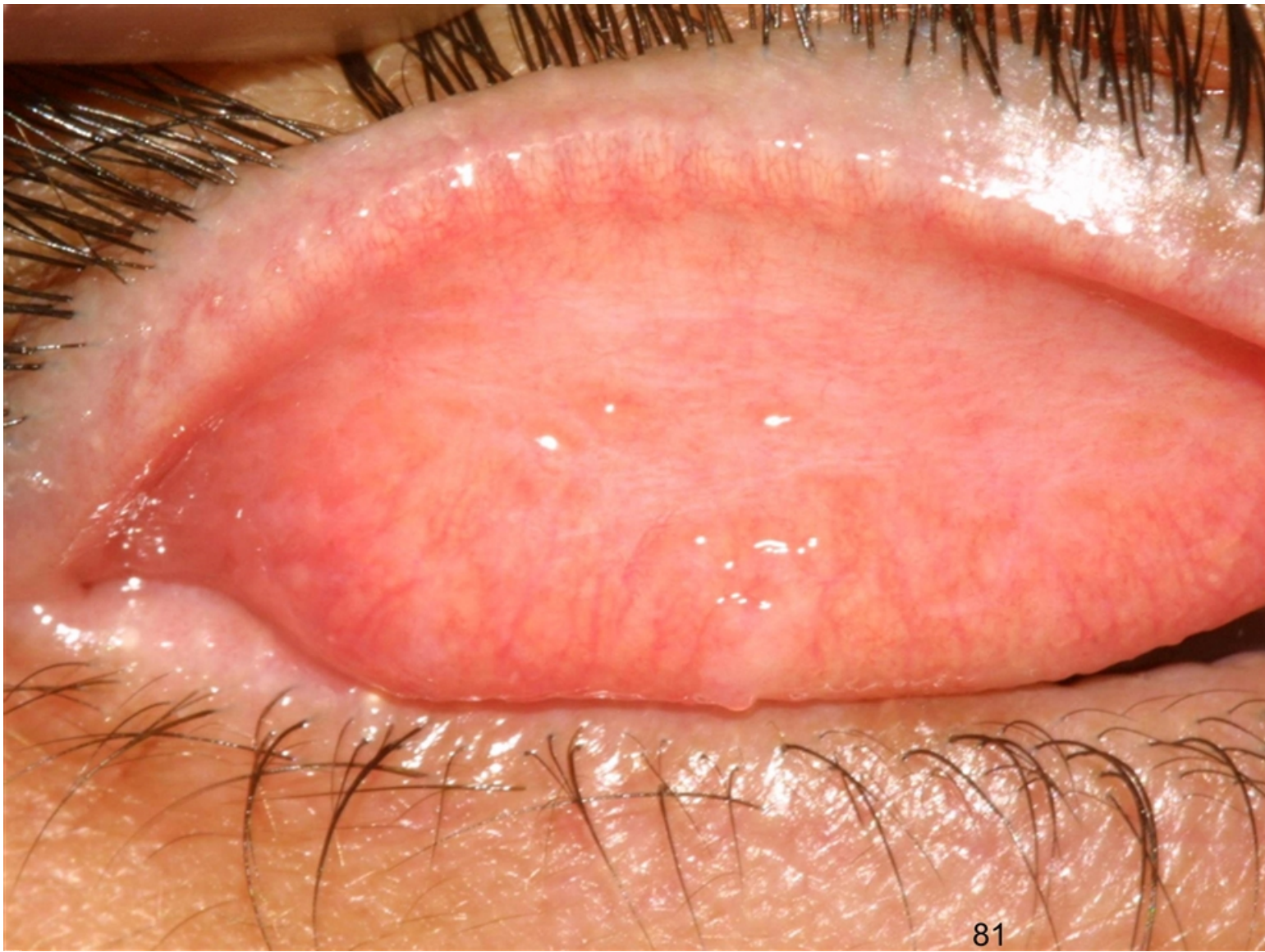
*Developed markets; Market Scope 2013

- Chronic Discomfort
- Foreign Body Sensation
- Visual Fluctuations
- Decreased Productivity
- Depression
- Contact Lens Intolerance
- Poor Surgical Predictability & Outcomes
- Infectious Keratitis

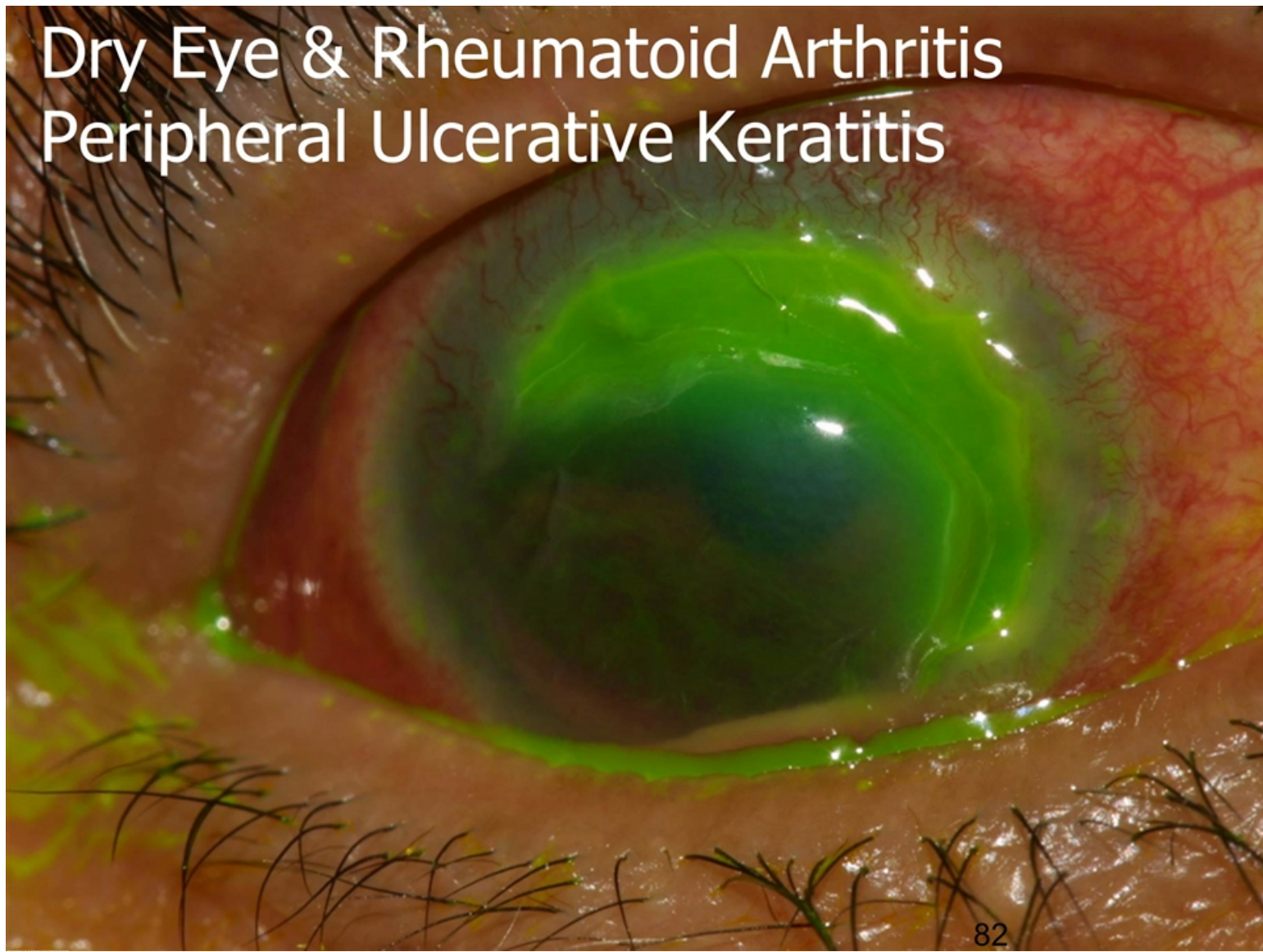
Severe Dry Eye with Filamentary Keratitis



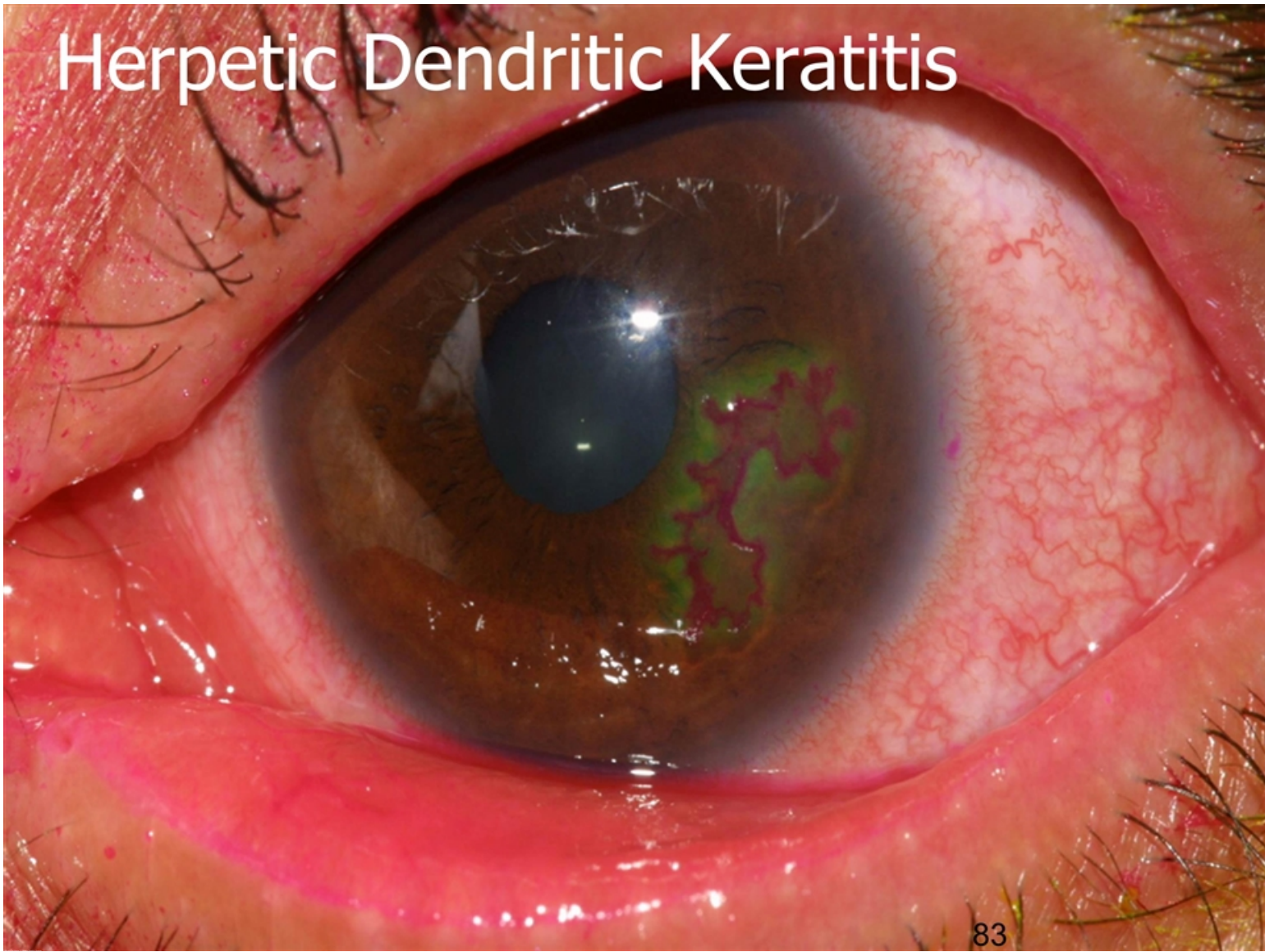


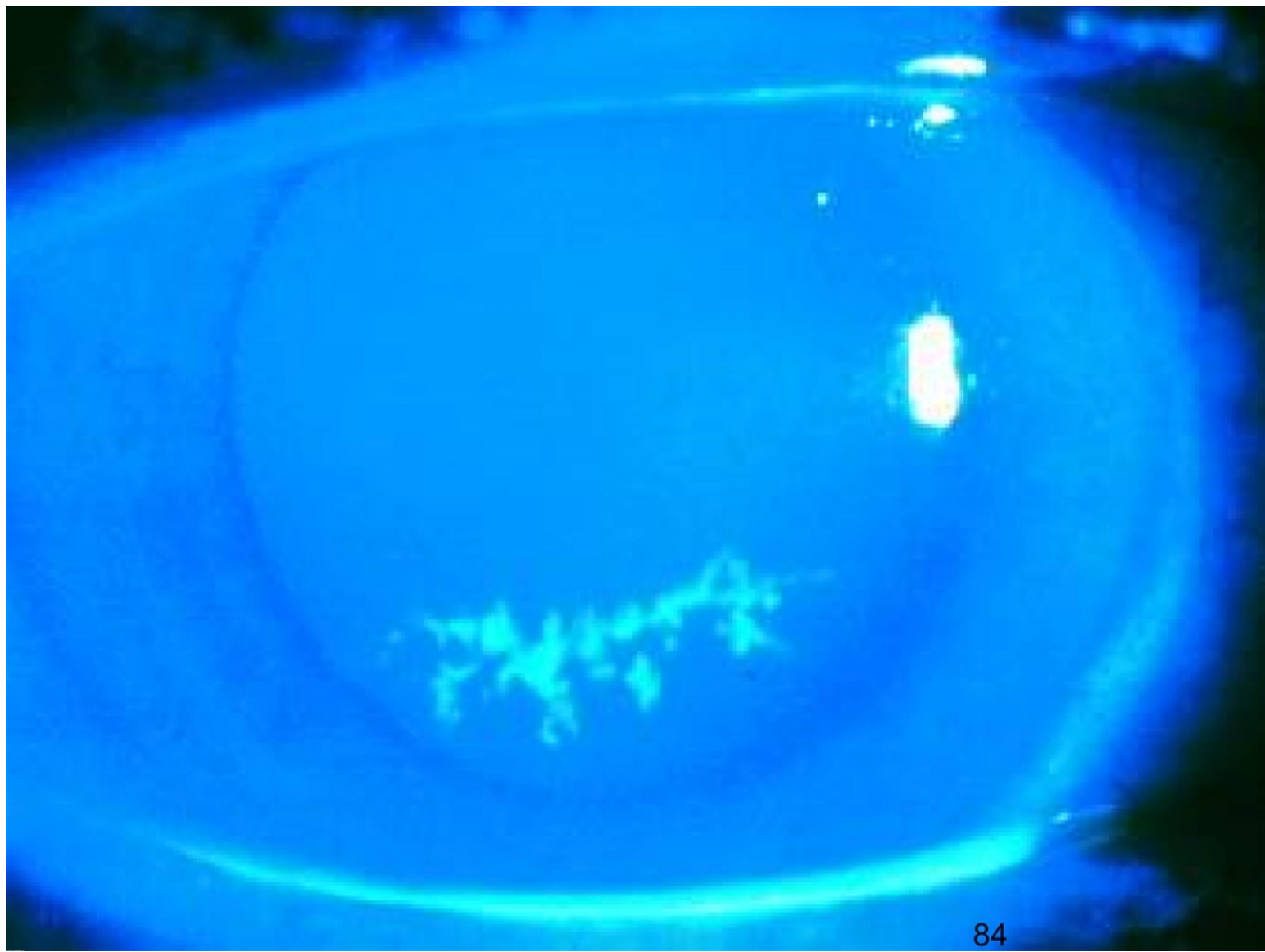


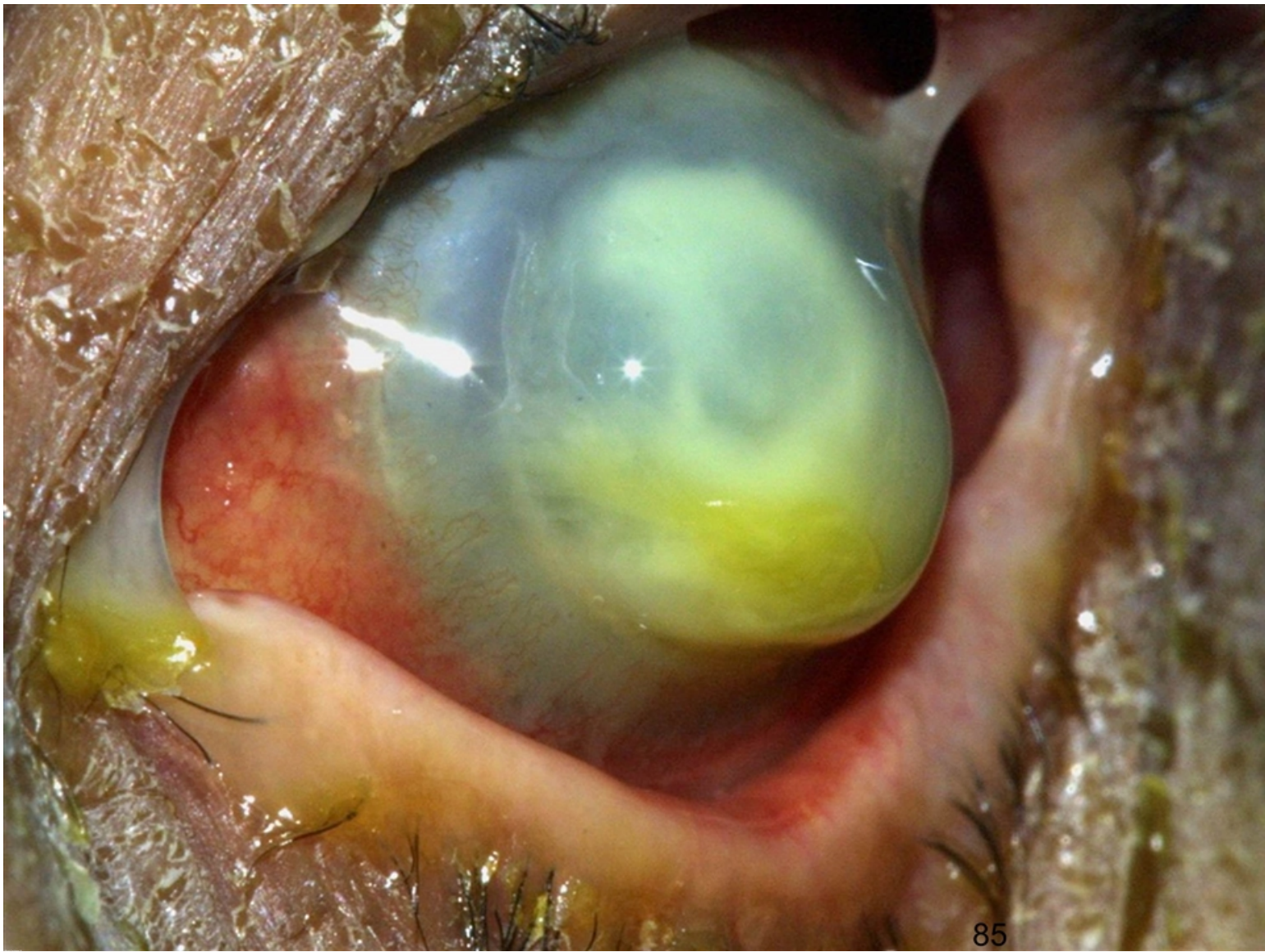
Dry Eye & Rheumatoid Arthritis Peripheral Ulcerative Keratitis

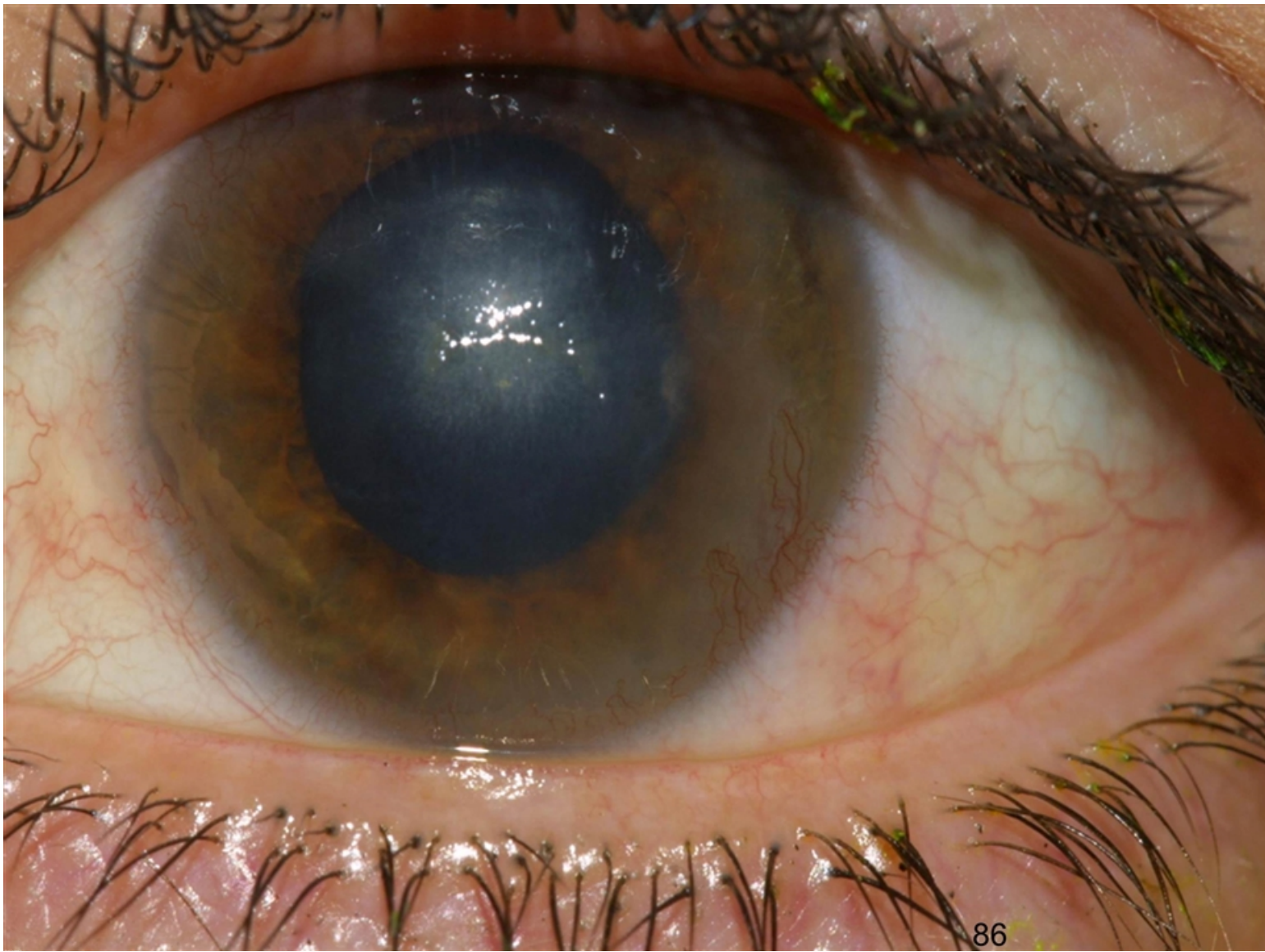


Herpetic Dendritic Keratitis

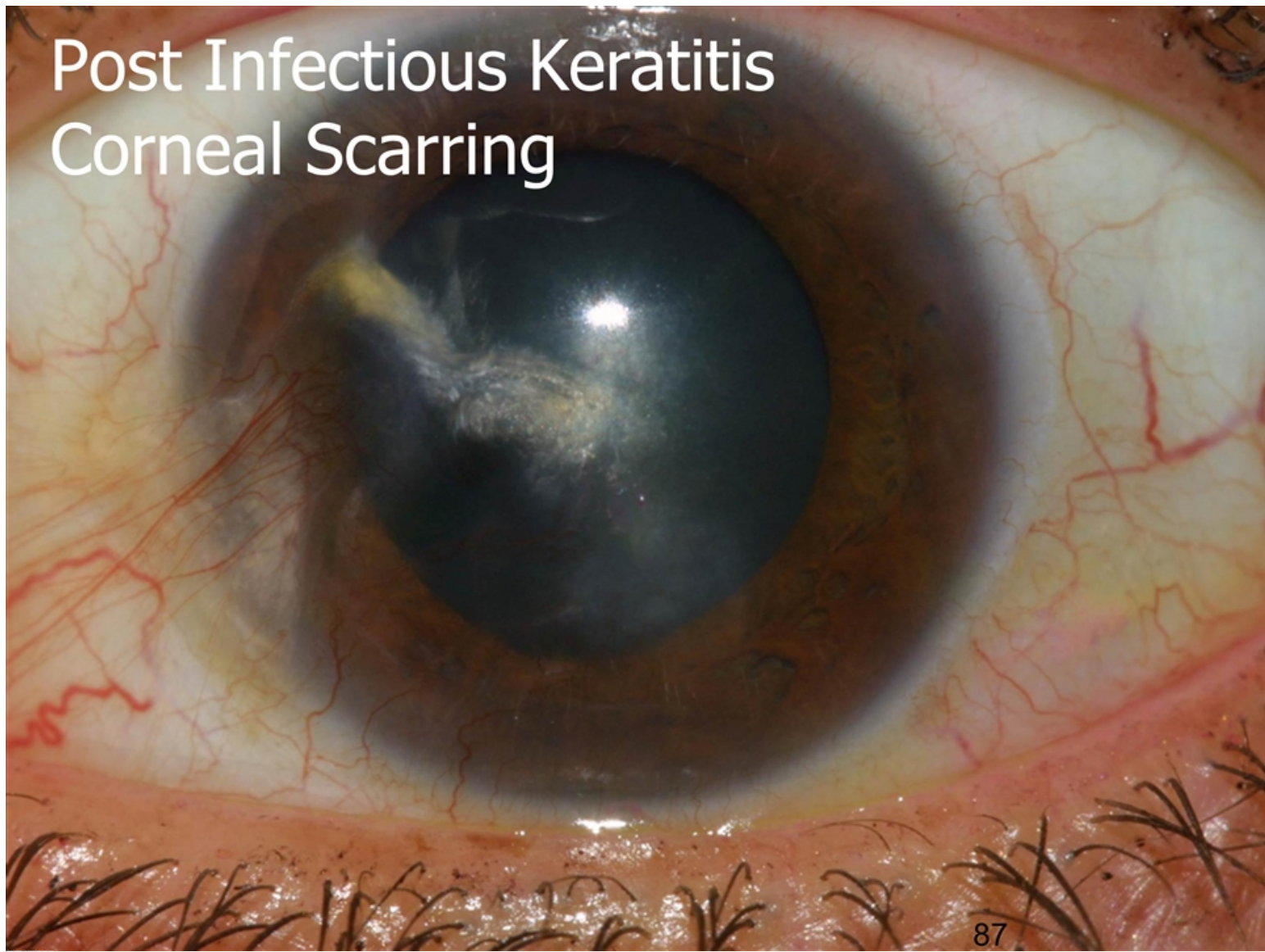


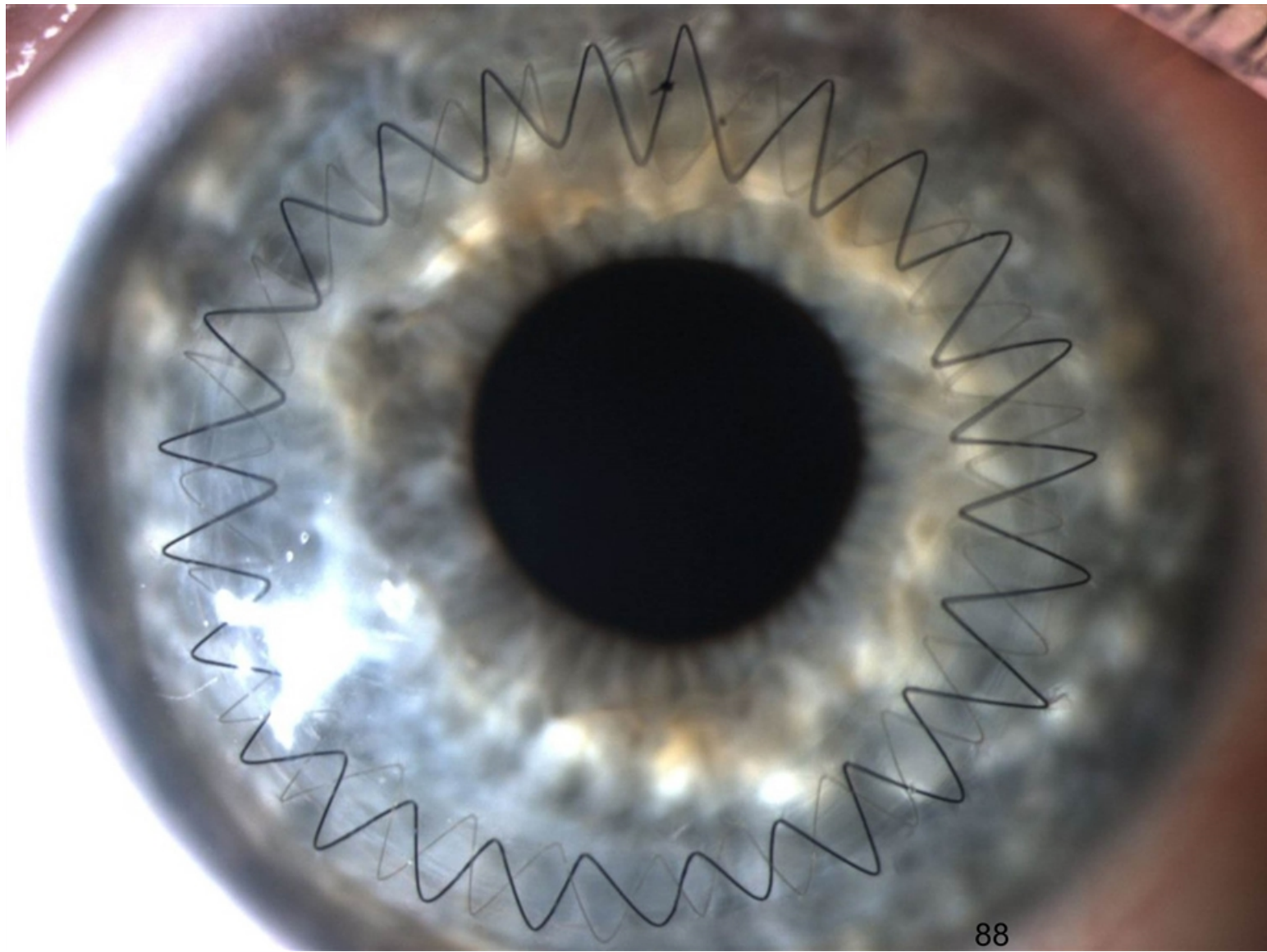







Post Infectious Keratitis Corneal Scarring





Tecnis Symphony IOL (AMO)





ReStor
Multifocal
Intraocular
Lens
(Alcon)



**Crystallens Accomodating
Intraocular Lens (Bausch & Lomb)**

DRY EYES?

VIRGINIAeye
consultants



CATARACTS?

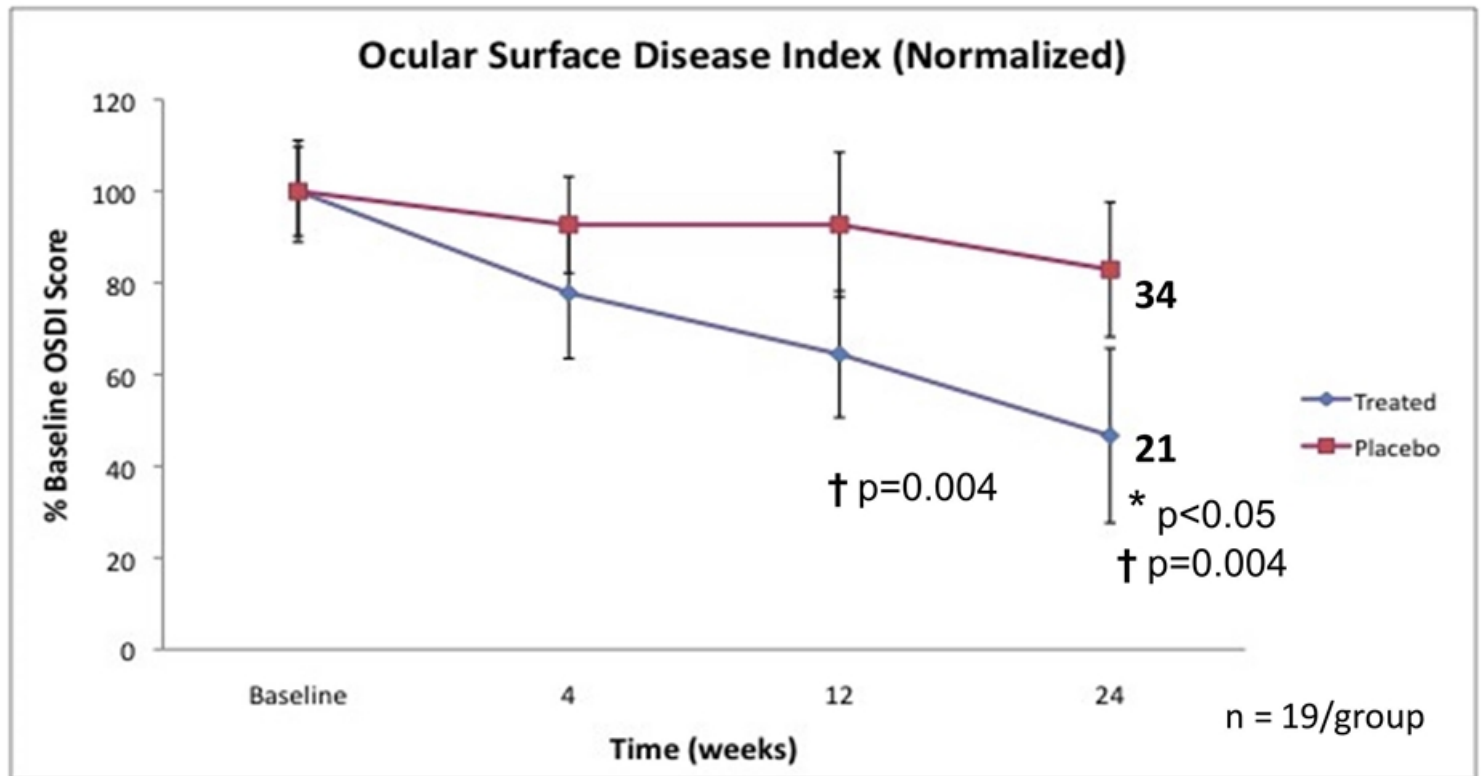
VIRGINIAeye
consultants



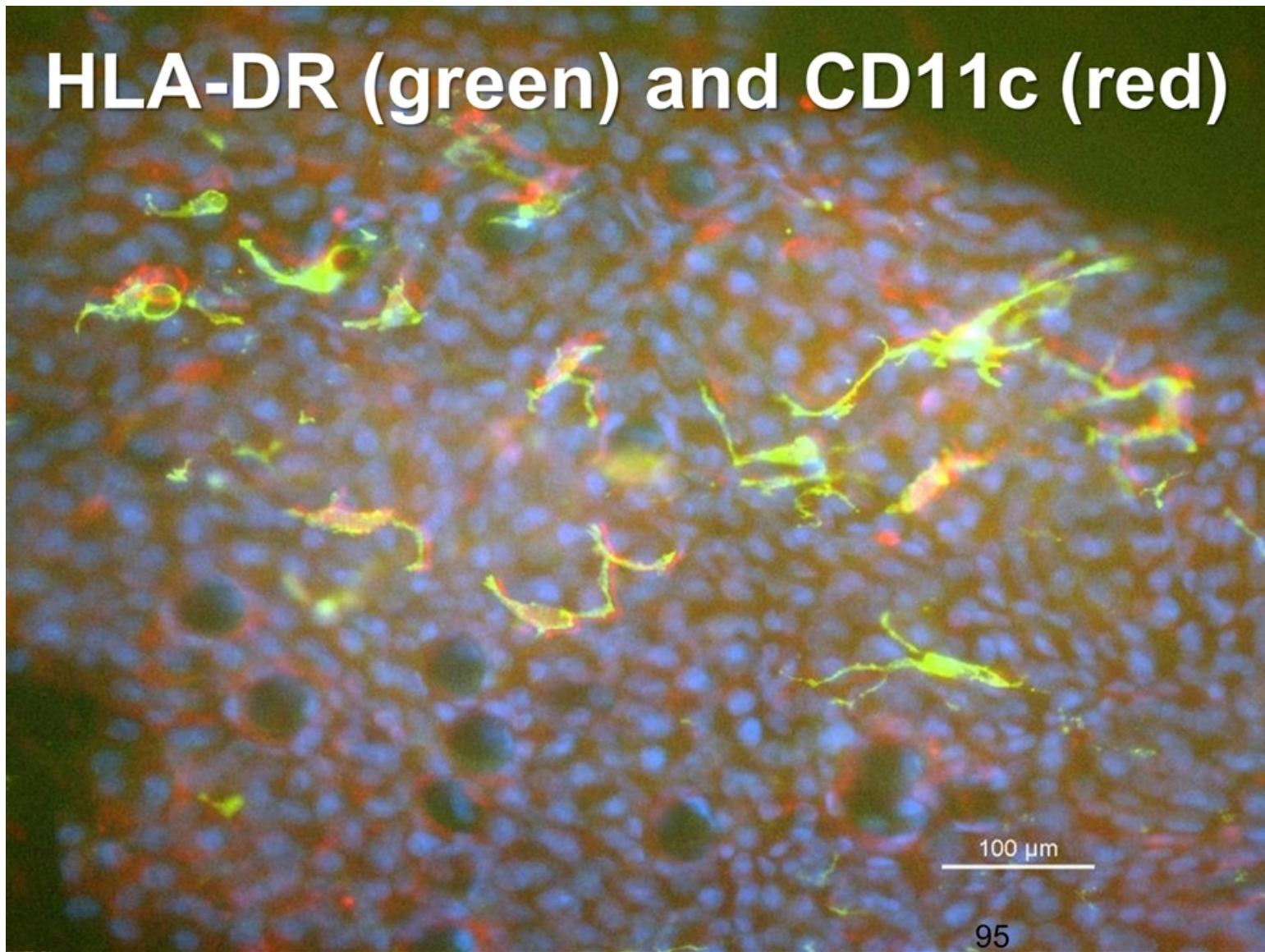
- Older Age
- Androgen Deficit: Female Sex, Prostate Cancer Rx
- Auto-Immune Disease: Sjogrens, RA, SLE
- Ocular Co-morbidity: Lids, MGD, Allergy, Surgery
- Cutaneous Disease: Rosacea, Eczema
- Poor Diet: Low Omega-3, High Fat
- Medications: Topical, Systemic
- Neurologic: Senescent Blink, Neurotrophic

1.Pflugfelder et al. *Cornea*. 1998 2.Nichols et al. *Cornea* 2000. 3.Pflugfelder et al. *Ophthalmology* 1990.
4.Lemp et al. *Am J Ophthalmol* 2011. 5.Schiffman et al. *Arch Ophthalmol* 2000.

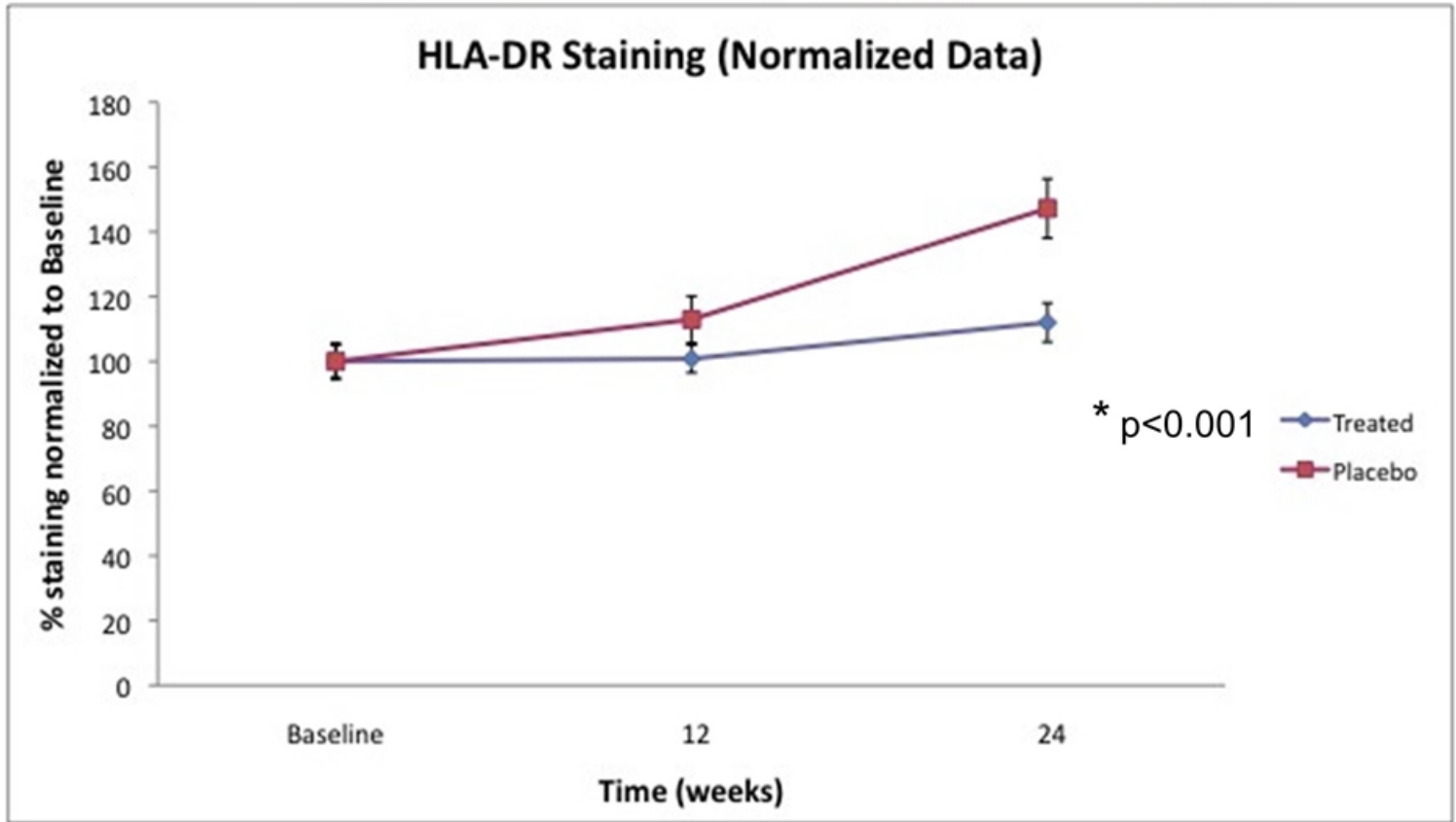
HydroEye® OSDI Results



HLA-DR (green) and CD11c (red)



HLA-DR Impression Cytology Results





- Cataract Surgery 77%
- Penetrating Keratoplasty 60%
- Lasik 27%
- Glaucoma Surgery 8%
- Blepharoplasty 26%

Trattler, ASCRS CME Supplement, 2013

Sheppard, WCC, 2015

Azuma, BMC Research Notes, 2014

Leung, Journal of Glaucoma, 2008

Prischmann, JAMA Facial Plastic Surgery, 2013

Surgery Impacts Dry Eye

Severity Level	1	2	3	4
Symptoms	Mild to moderate	Mild to moderate	Moderate to severe	Extremely severe
Conjunctival Signs	Mild to moderate	Mild to moderate	Moderate to severe	Extremely severe
Corneal Staining		Mild punctate epithelial staining; increased vision (blurring)	Severe staining; central staining; filamentary keratitis	Severe staining; corneal erosions
Other Signs				
Management Options	<ul style="list-style-type: none"> • Patient education • Environmental modification • Preserved tears • Control allergies 	<ul style="list-style-type: none"> • non-preserved tears • Gels, ointments 	<ul style="list-style-type: none"> • Oral tetracyclines • Punctal plugs • Contact lenses 	<ul style="list-style-type: none"> • Systemic anti-inflammatory therapy • Oral corticosteroids • Topical corticosteroids • Topical cyclosporine • Topical cysteine • Topical urea • Topical hyaluronic acid • Punctal cautery
	<i>If no improvement, add level 2 treatments</i>	<i>If no improvement, add level 3 treatments</i>	<i>If no improvement, add level 4 treatments</i>	99

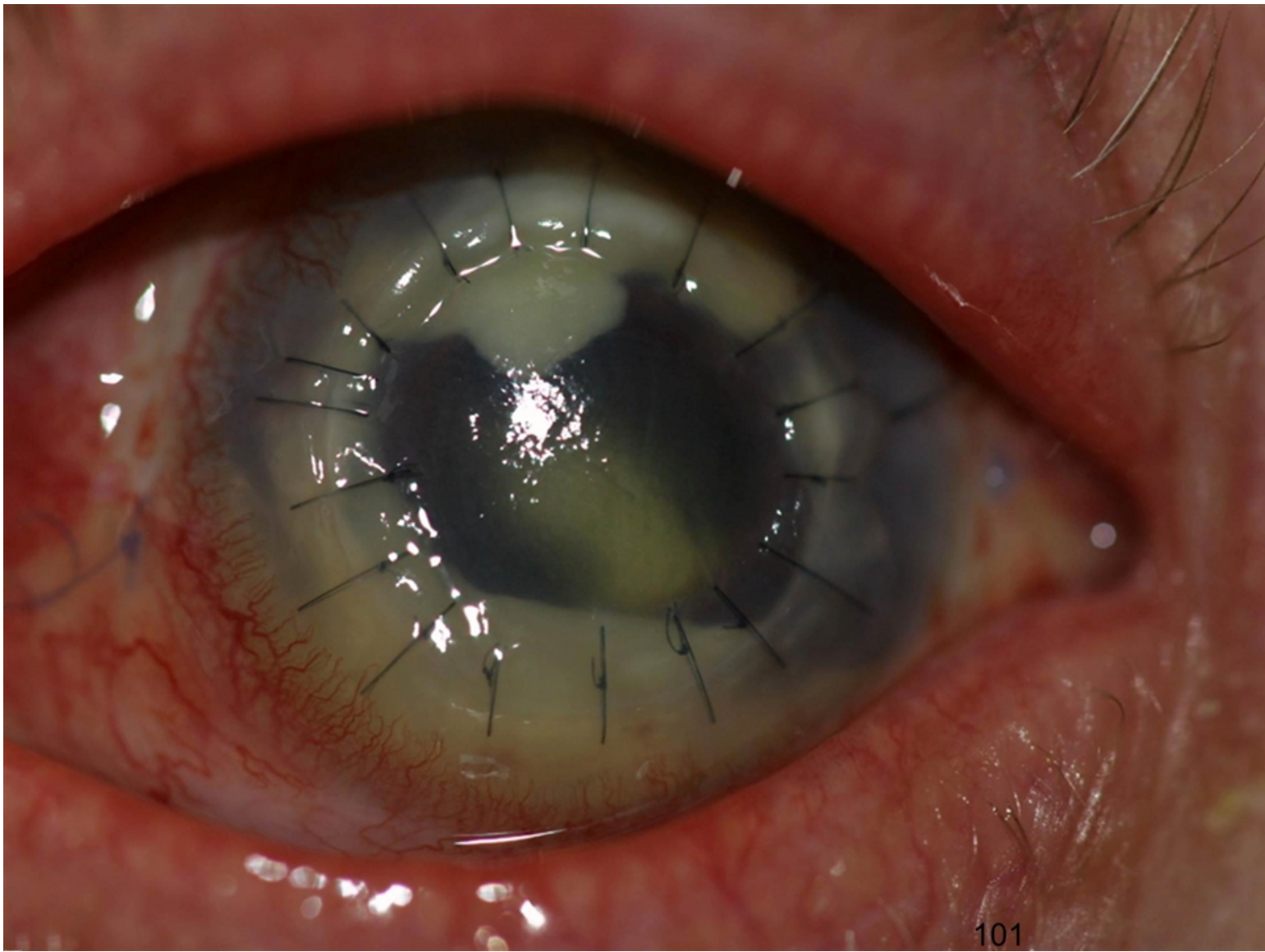
Cataract Surgery adds 1 severity step

LASIK adds 2 severity steps

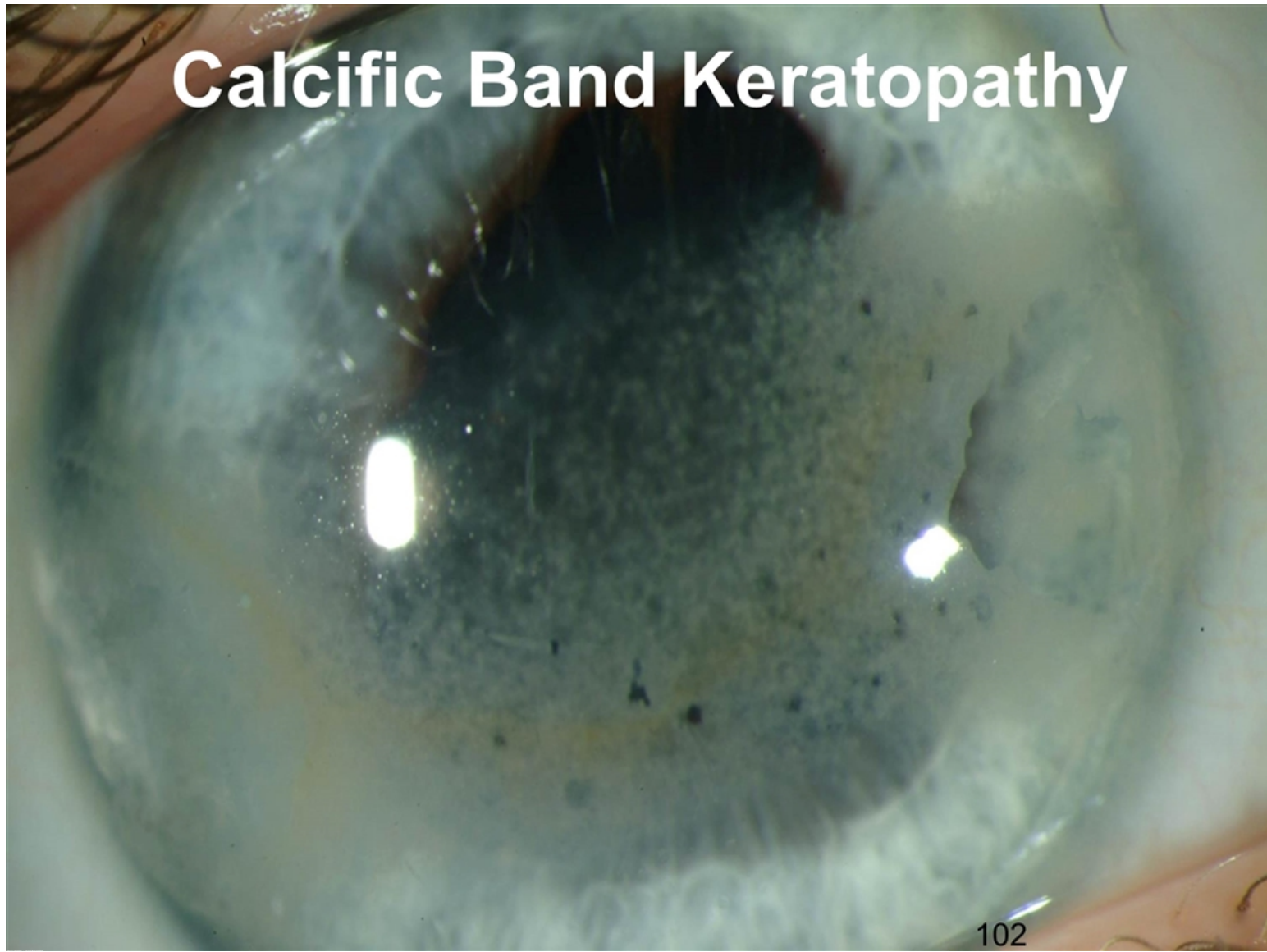
Plan pre-op and post-op care accordingly

Behrens A, et al. Cornea. 2006;25:900-7.





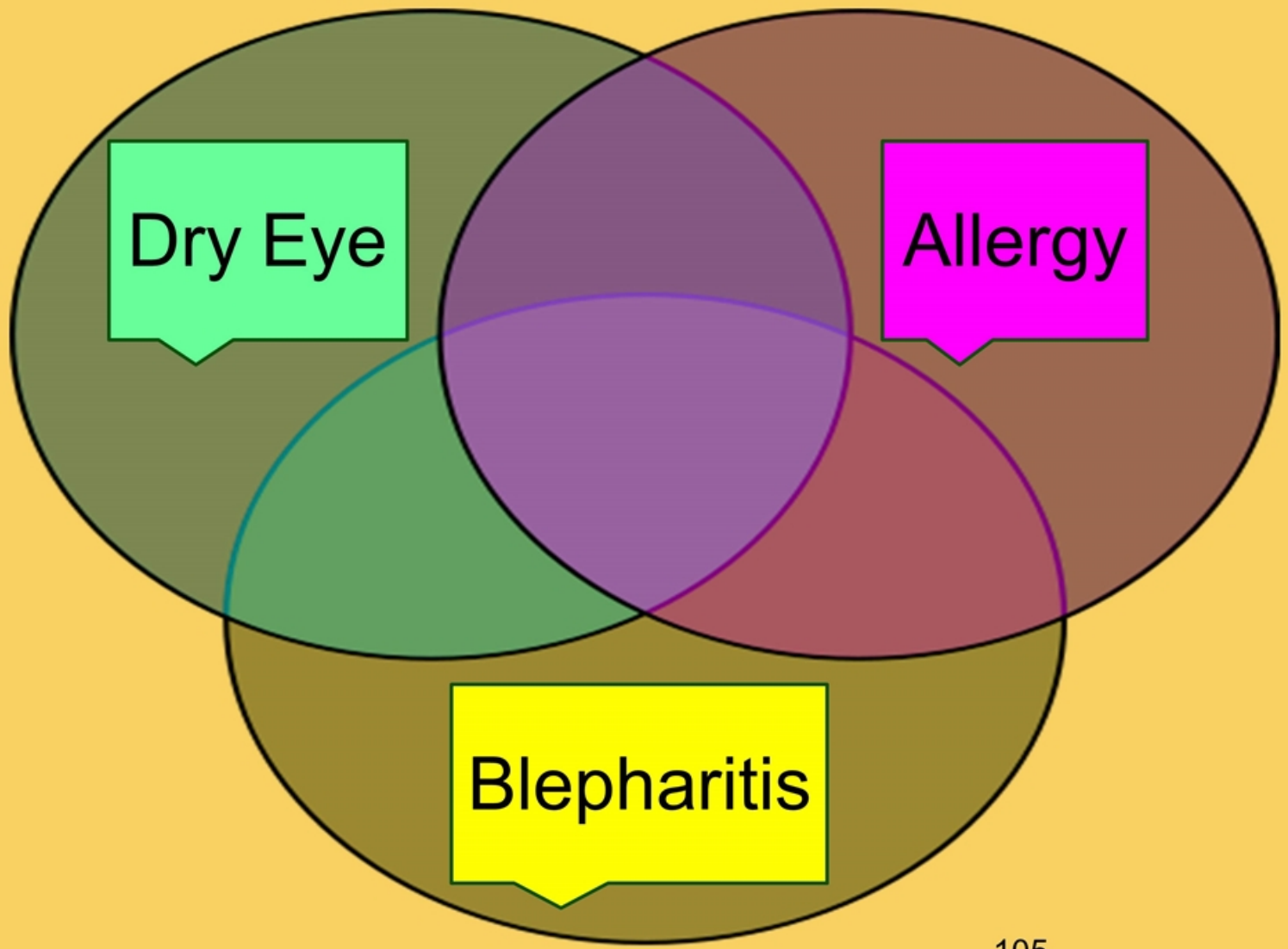
Calcific Band Keratopathy



No Magic Bullet: Dry Eye is a Highly Heterogeneous Disease









Allergic Conjunctivitis

CUSTOM ALLERGENS SPECIFIC TO YOUR AREA



CUSTOM ALLERGENS SPECIFIC TO YOUR AREA



Allergens vary by geographic location.

Customized & Regionalized

A proprietary, FDA-approved, diagnostic test specific for ocular allergies.

CUSTOM ALLERGENS SPECIFIC TO YOUR HOME





Rationale

Ocular Allergies affect about 20% of Americans.





Rationale

50% have concomitant Dry Eye Syndrome





Rationale

Over 30 million Americans have both eye disorders.



Annals of Allergy, Asthma & Immunology
March 2012; 108(3); 163-6.

Milton Hom OD, Andrew Nguyen PhD,
Leonard Bielory MD

Most patients with “itchy eyes” consistent with AC also have dry eyes and redness. These results suggest that some symptomatic patients concomitantly have features of AC and DES.

Ocular Allergy Treatments





Topical Antihistamines

The current treatment of choice for ocular allergies is topical antihistamines which typically are effective for the allergic component.

Neutraceuticals

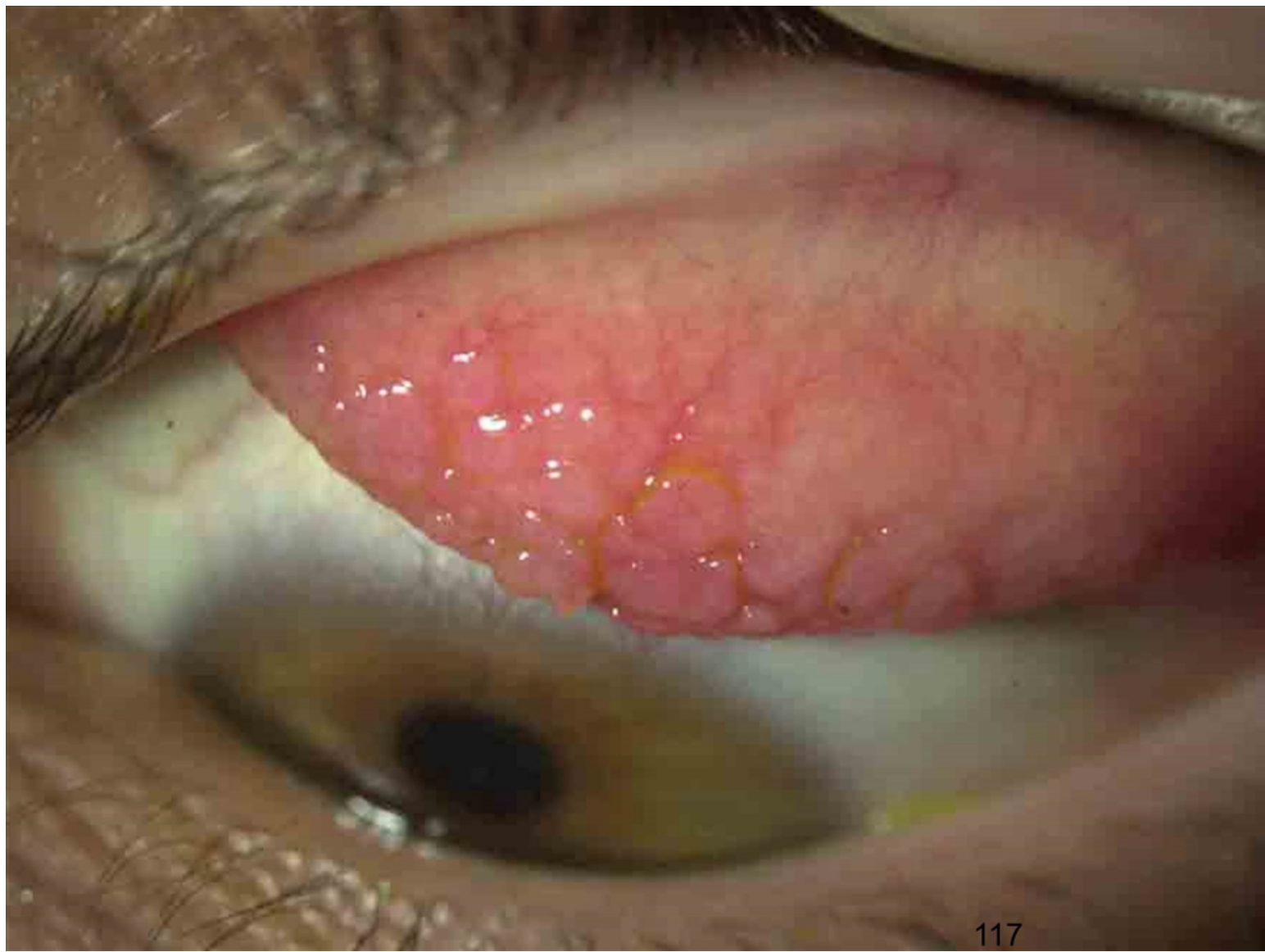
Allergy nutraceutical helps patients without the deleterious effects associated with Antihistamines. This success led to the development of the eye drop formula.



Exacerbating DES Symptoms

Unfortunately, these topical antihistamines exacerbate Dry Eye symptoms limiting their usefulness.

- Chronic Discomfort
- Foreign Body Sensation
- Pruritis & Epiphora (Itching & Tearing)
- Decreased Productivity
- Depression
- Contact Lens Intolerance
- Poor Surgical Predictability & Outcomes
- Inflammatory Keratitis



- Dry Eye Treatments (Restasis, Xiidra) are Ineffective for Ocular Allergy
- ADX-102 is Uniquely Positioned as a Unique MOA for safe long-term treatment of this growing patient cohort
- ADX-102 shows clinically relevant effects in the Phase IIb Allergy Trial *and*
- Clinical efficacy output is very encouraging in the Phase IIa Dry Eye Study



ADX-103 and a New Program in Retinal Disease

Susan Macdonald, PhD
Vice President, Research and Development
Aldeyra Therapeutics

A Novel Aldehyde Trap and a New Development Program in Retinal Disease

- ADX-103
 - Second-in-class aldehyde trap
 - Shown to have mechanism of action as ADX-102, but different structure
- ADX-103 for retinal disease
 - Like ADX-102, ADX-103 has shown activity in multiple pre-clinical models of ocular disease
 - Endotoxin-induced uveitis (intravitreal)
 - Macular degeneration (systemic)
 - Diabetic macular edema (intravitreal)

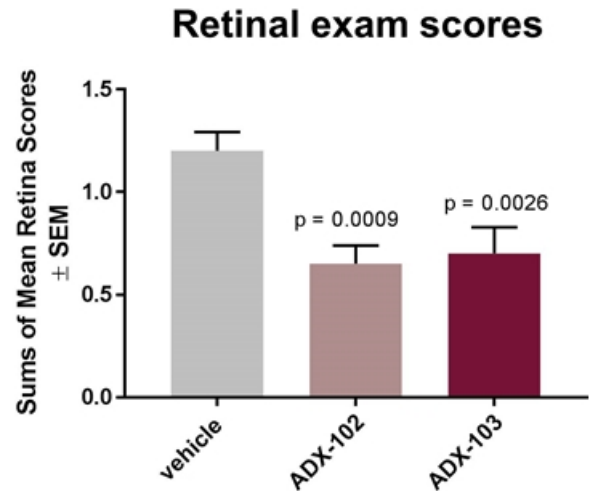
Uveitis: Aldehyde Traps Reduce Retinal Inflammation

Model: Ocular inflammation in rats induced by footpad injection of a bacterial endotoxin (LPS)

Disease-related aldehydes: Malondialdehyde (MDA) and 4-hydroxynonenal (4-HNE)

Dosing: Single intravitreal dose; 25 µg/eye, one hour following LPS challenge

Results: ADX-102 and ADX-103 reduced retinal inflammation, as measured by retinal exam scores¹



¹Vasculopathy; retinal hemorrhage, exudate or detachment; choroidal hemorrhage, exudate or detachment

Macular Degeneration: Aldehyde Traps Reduce Formation of Toxic Retinal Metabolite A2E

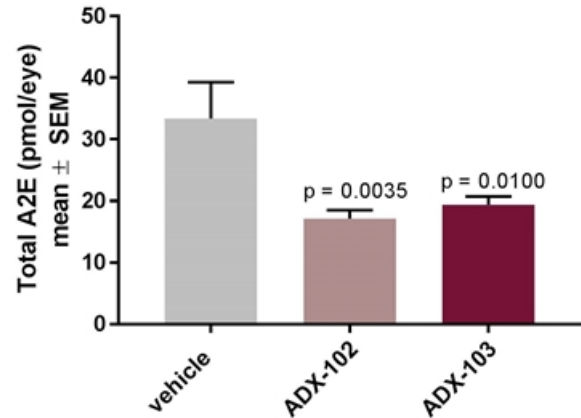
Model: Knockout mice that do not express ABCA4, which transports toxic all-*trans*-retinal metabolite (A2E) to a location in the retina where it is converted to a non-toxic substance

Disease-relevant aldehyde: Retinaldehyde

Dosing: 10 mg/kg, intraperitoneally, once daily for 56 days

Results: Both ADX-102 and ADX-103 significantly reduced the formation of A2E in the retina

A2E levels in *abcr*^{-/-} mice



Diabetic Macular Edema: ADX-103 Blocks Diabetic Retinal Degeneration

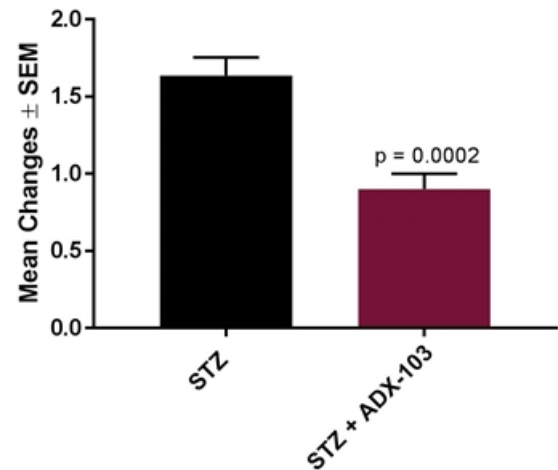
Model: Streptozotocin (STZ)-induced diabetes in rats. Retinal changes are monitored over time.

Disease-relevant aldehydes: Glyoxal and methylglyoxal

Dosing: Two single doses of ADX-103, intravitreally, over 29 days, after induction of diabetes

Results: Histopathology of the retina 29 days after the first dose of ADX-103 indicated that ADX-103 significantly reduced retinal thickness induced by diabetes.

Retinal thickness changes after two IVT doses of ADX-103



Scale:

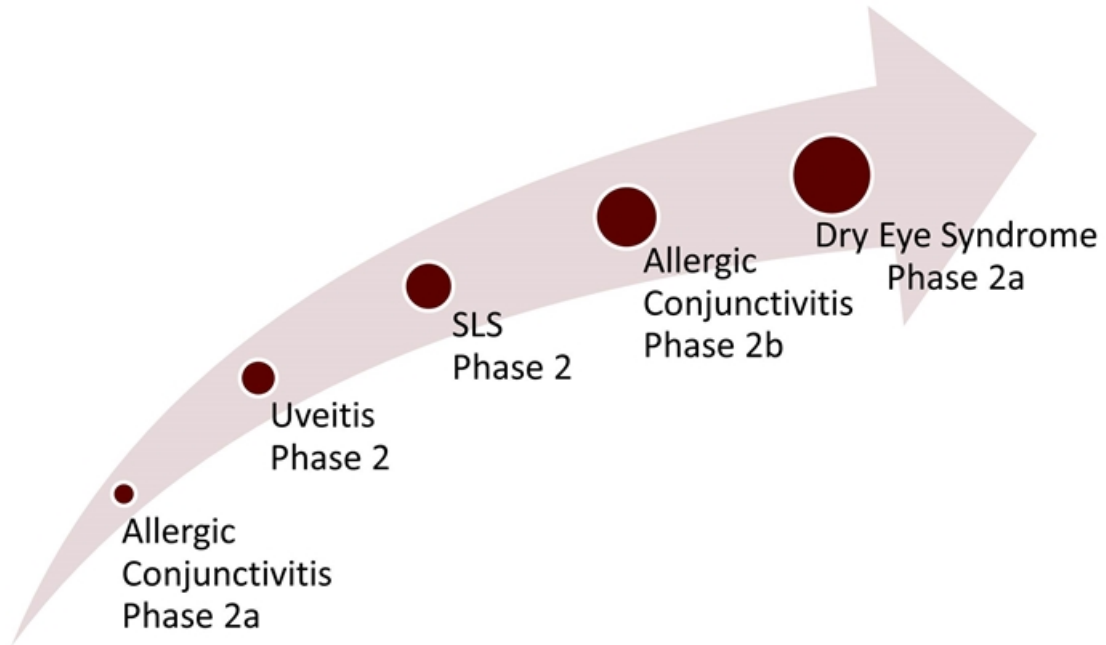
- 1 = minimal microscopically visible changes
- 2 = mild microscopically visible changes
- 3 = moderate microscopically visible changes



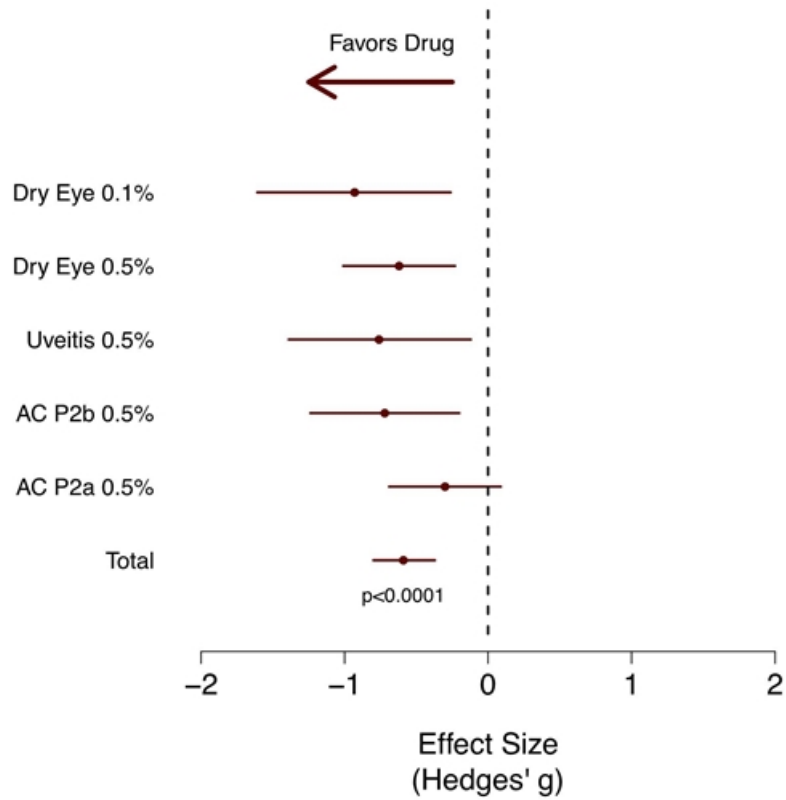
Clinical Trials Successes and
Expected 2018 Clinical Milestones

David Clark, MD
Chief Medical Officer
Aldeyra Therapeutics

Five Positive Phase 2 Trials Completed Over 18 Months



Meta-analysis of ADX-102 Strongly Supports Drug Activity



p value is subject to change based on quality control analysis; between-group comparisons used where placebo control, otherwise within-group comparisons used; dry eye results based on ocular discomfort symptom score.

Expected 2018 Clinical Trial Milestones*

	Product Candidate	Phase	Milestone
Ocular Inflammation	Noninfectious Anterior Uveitis	Phase 3	Results 2H18
	Allergic Conjunctivitis	Phase 3	Initiation 1H18 Results 2H18
	Dry Eye Disease	Phase 2b	Initiation 1H18 Results 2H18
Inborn Errors of Aldehyde Metabolism	Sjögren-Larsson Syndrome (SLS)	Phase 3 (Derm, Part I)	Initiation 1H18 Results 2H18
	Systemic ADX-10X [†]	Phase 1-2 (SLS, Inflammation)	Initiation 2H18

*Pending regulatory agency discussions, additional non-clinical data, and other factors, which may not be in Aldeyra's control

[†]Timing contingent on product candidate selection and additional non-clinical data

Aldeyra Therapeutics Announces New Data at 2017 Research & Development Day

Dry Eye Disease Clinical Activity Correlated with Aldehyde Reduction

Efficacy of ADX-102 in Allergic Conjunctivitis Demonstrated to be Clinically Relevant

ADX-103, a New Aldehyde Trap, Active in Three Preclinical Models of Retinal Disease

LExINGTON, Mass., October 10, 2017 /PRNewswire/ — Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (“Aldeyra” or “the Company”), a clinical-stage biotechnology company devoted to treating inflammation, inborn errors of metabolism, and other diseases related to endogenous aldehyde toxicity, announced new clinical data for ADX-102 from recently completed Phase 2 clinical trials of dry eye disease and allergic conjunctivitis, and the introduction of a retinal disease development program with ADX-103, a novel aldehyde trap.

“These newly released results from our Phase 2 clinical trials in dry eye disease and allergic conjunctivitis strongly support the broad and clinically relevant activity profile of ADX-102 in ocular inflammatory disease,” commented Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “In addition, we are pleased to announce the expansion of our ocular franchise with a new development program in retinal disease, featuring our second novel aldehyde trap, ADX-103.”

Dry Eye Disease Clinical Activity Correlated with Aldehyde Reduction. Newly announced results from the recent Phase 2a clinical trial in dry eye disease indicated that the statistically significant reduction in levels of a pro-inflammatory aldehyde mediator, malondialdehyde, was correlated with improvement of ocular staining scores and tear osmolality. To Aldeyra’s knowledge, these data represent the first correlation of drug biomarker improvement with dry eye disease clinical activity. Aldeyra plans to commence Phase 2b clinical testing of ADX-102 in dry eye disease in the first half of 2018.

ADX-102 Generated Clinically Important Responses Statistically Superior to Vehicle in Patients with Allergic Conjunctivitis. Newly announced results from the recent Phase 2b clinical trial in allergic conjunctivitis indicated that 0.1% and 0.5% ADX-102 groups were statistically superior to the vehicle group in achieving a clinical response ($p=0.02$ for each group), defined as within-patient one-point improvement in ocular itching score (range 0 to 4) from peak baseline values. Odds ratio analysis indicated that patients treated with each concentration of ADX-102 in the trial were greater than three times more likely to achieve a clinical response than patients treated with vehicle. For the 0.1% and 0.5% ADX-102 groups, time to within-patient one-point clinical response was significantly faster than the vehicle group ($p=0.0006$ and $p=0.008$). In the United States, ocular itching is an approvable endpoint for allergic conjunctivitis, and one-point improvement represents the regulatory precedent for clinical relevance. Allergic conjunctivitis is a persistently disturbing and common ocular disease affecting 20% or more of the worldwide population. Aldeyra plans to commence Phase 3 clinical testing of ADX-102 in allergic conjunctivitis in the first half of 2018.

Introduction of Retinal Disease Development Program with Novel Aldehyde Trap ADX-103. ADX-103, a novel aldehyde trap with a chemical structure distinct from ADX-102, demonstrated activity in pre-clinical retinal disease models of macular degeneration, uveitis, and diabetic macular edema. Retinal disease represents one of the largest markets in ophthalmology and is associated with the generation and accumulation of pro-inflammatory and toxic aldehyde mediators. Additional results are expected to be released at a major scientific meeting in 2018.

Webcast

A live webcast of the presentation and slide deck will be available on the investor relations page of Aldeyra's corporate website at ir.aldeyra.com. After the live webcast, the event will remain archived on Aldeyra's website for one year.

About Aldeyra Therapeutics

Aldeyra Therapeutics, Inc. is a biotechnology company devoted to improving lives by inventing, developing and commercializing products that treat diseases thought to be related to endogenous aldehydes, a naturally occurring class of pro-inflammatory and toxic molecules. Aldeyra's lead product candidate, ADX-102, is an aldehyde trap in development as topical eye drops for the treatment of ocular inflammation. ADX-102 has now been tested in over 250 patients in Phase 2 clinical trials in dry eye disease, allergic conjunctivitis, and noninfectious anterior uveitis. A dermatologic form of ADX-102 is in late-stage clinical development for the treatment of ichthyosis due to Sjögren-Larsson Syndrome, an inborn error of aldehyde metabolism. ADX-102 has not been approved for sale in the U.S. or elsewhere.

About Dry Eye Disease

Dry eye disease is a common inflammatory disease estimated to affect approximately 20 million people in the United States, and is characterized by insufficient moisture and lubrication in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, and in severe cases, decreased vision. Among physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate. In patients with dry eye disease, pro-inflammatory aldehyde mediators may contribute to ocular inflammation. By diminishing aldehyde levels, Aldeyra's topical ocular aldehyde trap platform represents a novel and differentiated approach for the treatment of dry eye disease.

About Allergic Conjunctivitis

Allergic conjunctivitis is a common allergic disease that affects 20% or more of the population worldwide. The disease is thought to be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in ocular itching, excessive tear production, lid swelling, and redness.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Aldeyra's plans and expectations for the development of ADX-102 and ADX-103; and the potential of ADX-102 as an agent for the treatment of dry eye disease and allergic conjunctivitis and ADX-103 as an agent for the treatment of retinal disease. Aldeyra intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "aim," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Aldeyra is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of enrollment, commencement and completion of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; updated or refined data based on Aldeyra's continuing review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols and endpoints acceptable to applicable regulatory authorities, the ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency of Aldeyra's cash resources and needs for additional financing; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's expectations regarding federal, state and foreign regulatory requirements; regulatory developments in the United States and foreign countries; Aldeyra's ability to obtain and maintain intellectual property protection for its product candidates; the anticipated trends and challenges in Aldeyra's business and the market in which it operates; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2016 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, which are on file with the Securities and Exchange

Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, to be filed with the SEC in the fourth quarter of 2017. All of Aldeyra's development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation or completion of clinical trials.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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