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Pooled Analysis Evaluating Efficacy and Safety of an Intracanalicular Dexamethasone Insert for the Treatment of Allergic Conjunctivitis

Walter Whitley, OD; Kenneth Kenyon, MD; Eugene McLaurin, MD; Michelle Sato, MD; Erin Reilly, MPH; Trung Tran, OD; Matthew Cheung, PharmD; Michael Goldstein, MD

Disclosures

- Walter Whitley (presenting author) has no relevant financial disclosures
- Kenneth Kenyon, Eugene McLaurin, and Michelle Sato were investigators in the clinical trials.
- Erin Reilly, Trung Tran, Matthew Cheung and Michael Goldstein are employees of Ocular Therapeutix, Inc.
- The clinical trials described in this presentation were sponsored by Ocular Therapeutix, Inc.

Background

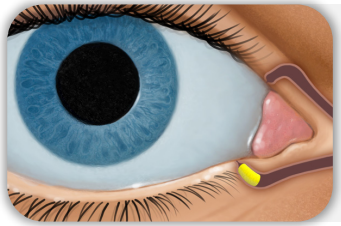
- Allergic conjunctivitis (AC) affects up to 40% of the U.S. population and symptoms can impair quality of life by negatively impacting[1-4]:

- Many topical AC treatments are limited by a short duration of action necessitating multiple daily instillations to maintain symptomatic relief and contain BAK which can cause discomfort and corneal cytotoxicity[5-7]
- Topical ophthalmic steroids, although effective in treating allergic conjunctivitis, require close supervision to avoid patient overuse and misuse[6,8]
- Other treatment approaches that address these key limitations are needed

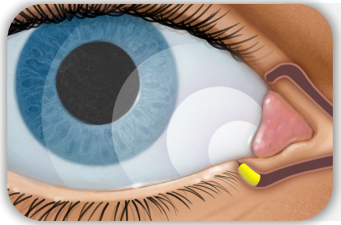
References: 1. Rosario N, et al. *Curr Opin Allergy Clin Immunol*. 2011;11(5):471–476. **2.** Singh K, et al. *J Allergy Clin Immunol*. 2010;126:778-783. 3. Meltzer EO, et al. *Allergy Asthma Proc*. 2009;30(3):244-254. **4.** Virchow JC, et al. *J Med Econ*. 2011;14(3):305-14. **5.** American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern Guidelines: Conjunctivitis. American Academy of Ophthalmology. Available at https://www.aaojournal.org/article/S0161-6420(18)32646-0/fulltext. Accessed October 18, 2021. **6.** Dupuis P, et al. *Allergy Asthma Clin Immunol*. 2020;16:5. **7.** Goldstein MH, et al. *Eye (Lond)*. 2021:1–8. **8.** Phulke S, et al. *J Curr Glaucoma Pract*. 2017;11(2):67-72.
BAK, benzalkonium chloride

DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg

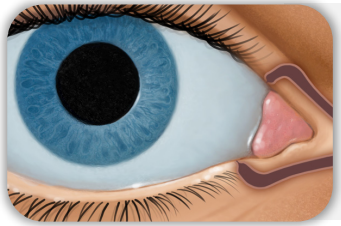
- Indicated for the treatment of ocular itching associated with allergic conjunctivitis, and ocular inflammation and pain following ophthalmic surgery
- A physician-administered intracanalicular insert designed to obviate the need for corticosteroid drops
- Contains 0.4 mg dexamethasone in a polyethylene glycol (PEG) hydrogel
- Preservative-free
- Fully resorbable with no need for removal
- Conjugated with fluorescein for visualization



Activates:
- With moisture
- Swells to fit in the canaliculus



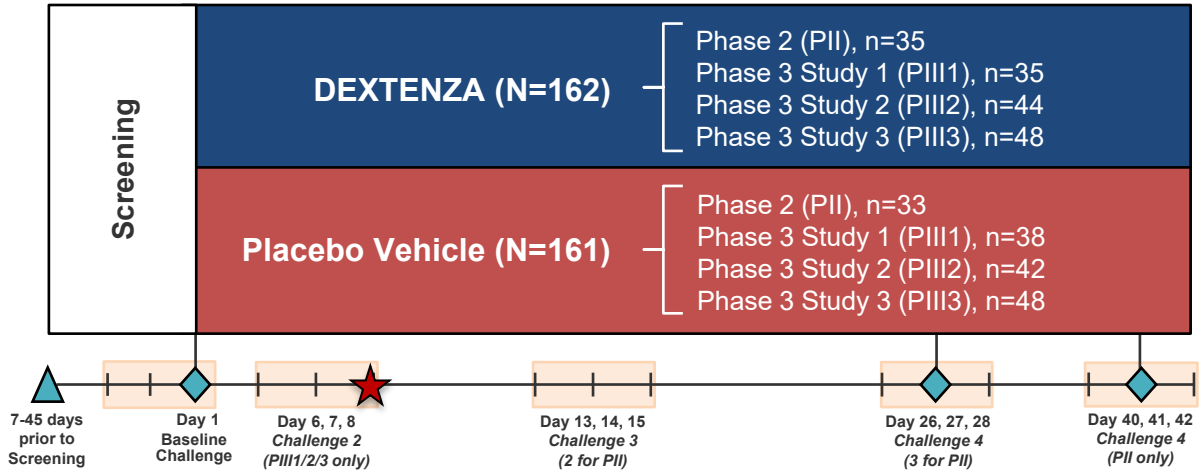
Releases:
- Dexamethasone in a tapered fashion for up to 30 days



Resorbs:
- Clears via the nasolacrimal duct

Pooled Analysis of Four DEXTENZA Clinical Trials

- One Phase 2 (PII) and three Phase 3 (PIII-1, PIII-2, PIII-3) clinical trials using a modified Ora-CAC® (Conjunctival Allergen Challenge) Model
  - Randomized, double-masked, vehicle-controlled studies in allergic conjunctivitis subjects
- Efficacy analysis included three Phase 3 studies and safety analysis included all four studies



Key Endpoints

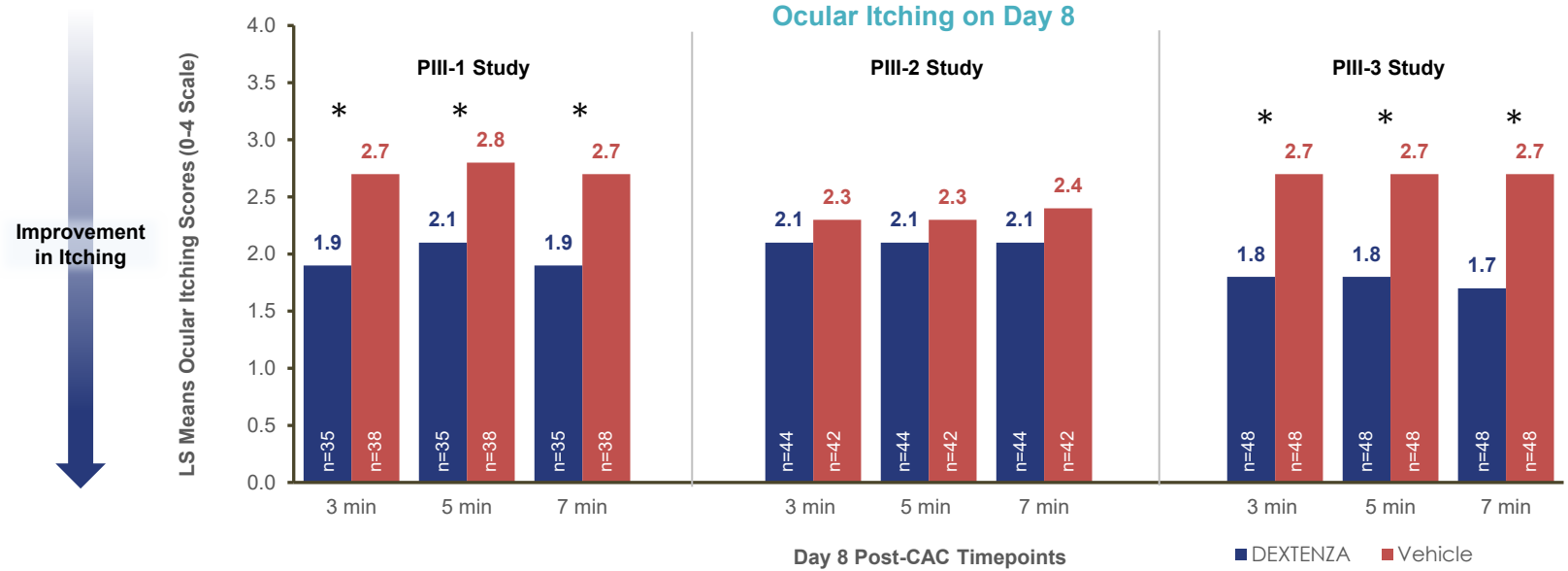
- Ocular itching at 3, 5 and 7 minutes post-CAC on Day 8
- Conjunctival redness at 7, 15, and 20 minutes post-CAC on Day 8

Primary Endpoint

Series of 4 CAC Challenges

Ocular Itching Primary Endpoint by Phase 3 Study

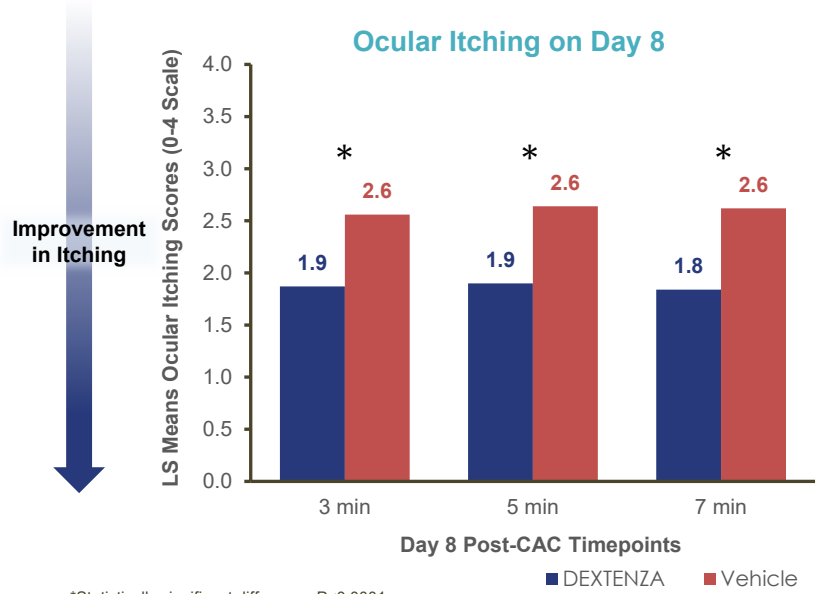
- DEXTENZA achieved statistically significant lower mean ocular itch scores compared to vehicle in two Phase 3 studies

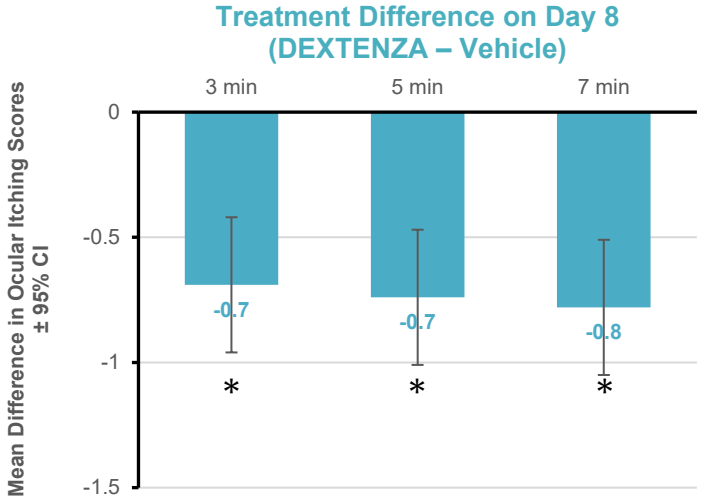


*Statistically significant difference p<0.05
Reference: DEXTENZA [package insert]. Bedford, MA: Ocular Therapeutix, Inc; 2021.
CAC, conjunctival allergen challenge; LS, least square

Pooled Ocular Itching Scores on Day 8

- DEXTENZA achieved statistically significant lower mean ocular itch scores at all 3 post-CAC timepoints on Day 8 (P<0.0001)

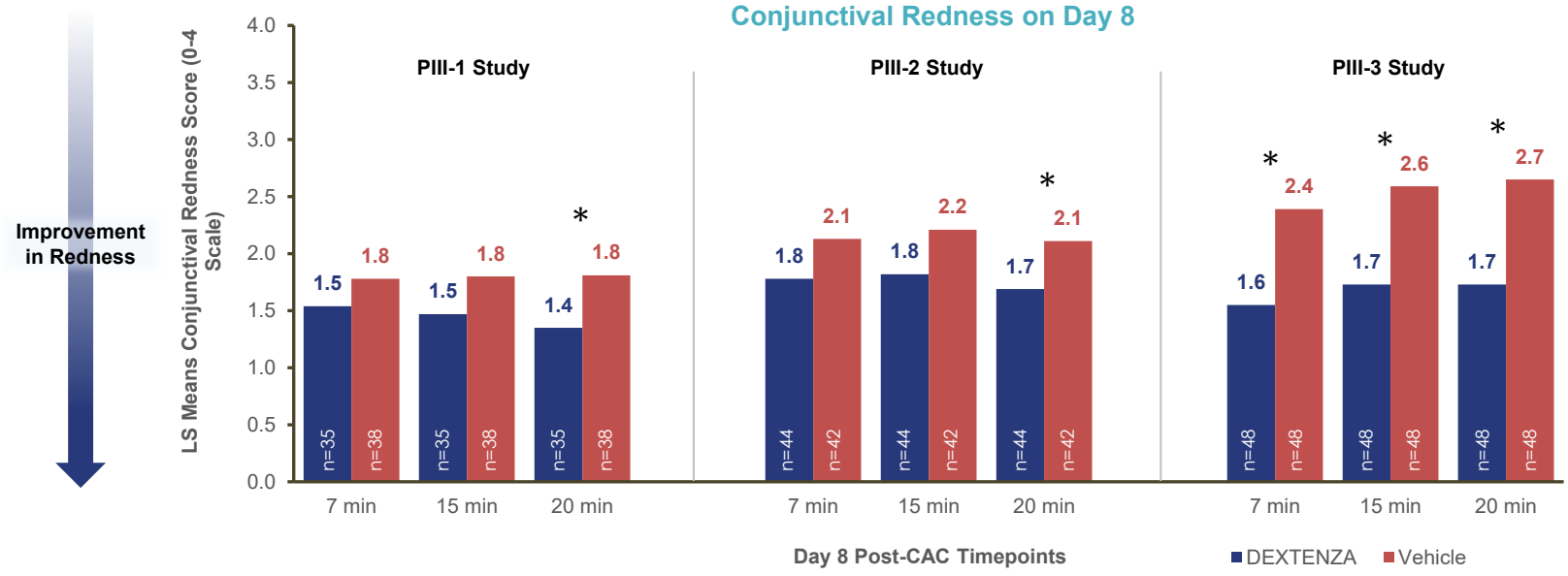




*Statistically significant difference; P<0.0001
Analysis populations: ITT with observed data
CAC, conjunctival allergen challenge; CI, confidence interval; ITT, intent to treat; LS, least square

Conjunctival Redness Endpoint by Phase 3 Study

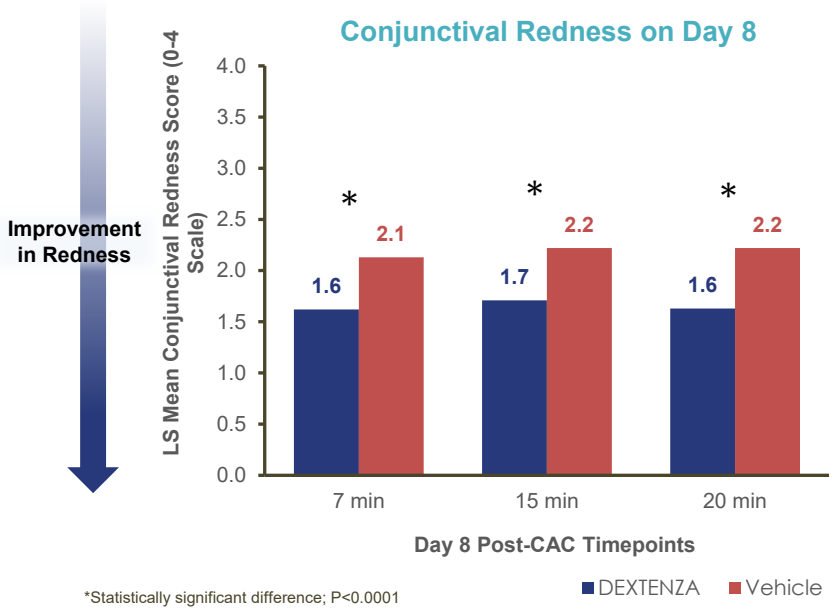
- DEXTENZA achieved statistically significant lower mean conjunctival redness scores compared to vehicle on Day 8 in Study 3 (P<0.05)

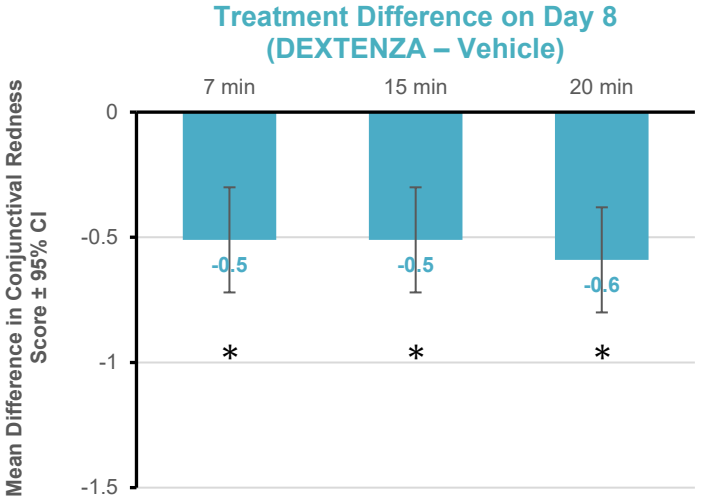


*Statistically significant difference; P<0.05
Analysis populations: ITT with observed data
CAC, conjunctival allergen challenge; ITT, intent to treat; LS, least squares

Pooled Conjunctival Redness Scores on Day 8

- DEXTENZA achieved statistically significant lower mean conjunctival redness scores at all 3 post-CAC timepoints on Day 8 (P<0.0001)





*Statistically significant difference; P<0.0001
Analysis populations: ITT with observed data
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DEXTENZA Safety Summary

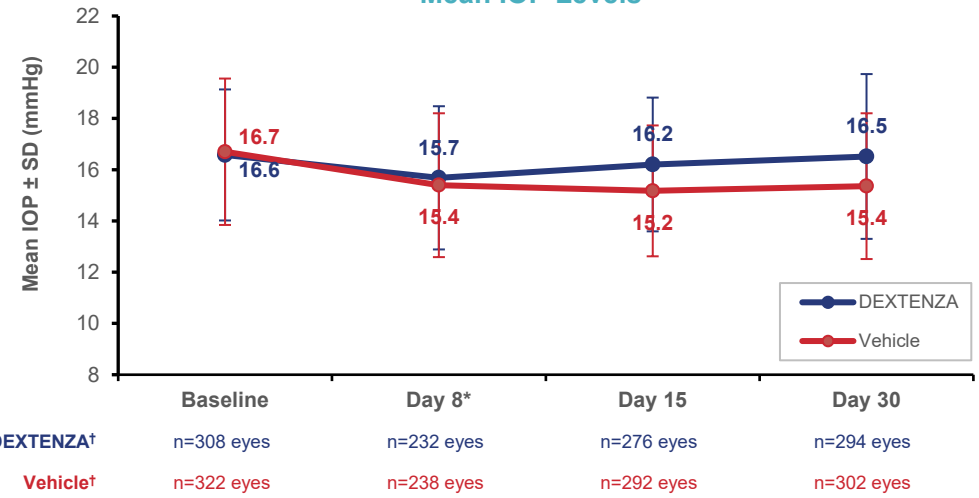
- No severe AEs were reported
  - All were mild or moderate in severity
- No ocular serious AEs were reported
- No dacryocanaliculitis AEs were reported in the DEXTENZA group
- One non-ocular serious AE deemed unrelated to treatment was observed in the DEXTENZA group
  - Hospitalization due to depression
- Lower proportion of the DEXTENZA group reported an AE compared to the vehicle group (18.8% vs. 24.2%, respectively)

Most Common Adverse Events (≥1%) Reported in the DEXTENZA Group

Adverse Event	DEXTENZA N=154 n (%)	Vehicle N=161 n (%)
Increased intraocular pressure	5 (3.2)	0
Reduced visual acuity	2 (1.3)	0
Increased lacrimation	2 (1.3)	6 (3.7)
Eye discharge	2 (1.3)	4 (2.5)

Intraocular Pressure Elevations with DEXTENZA

Mean IOP Levels



Management of Increased IOP in DEXTENZA Subjects

Increased IOP	DEXTENZA N=154
Total Number of Subjects	5
Management	
No action	1
Removal of DEXTENZA	0
Topical Medication Therapy	4

IOP, intraocular pressure; SD, standard deviation
* Study 2, 3 & 4 only. Study 1 did not have a Day 8 visit.
† Safety population. DEXTENZA N=154 subjects and Placebo N=161. Subjects received DEXTENZA or placebo vehicle insert bilaterally.

Conclusions

- DEXTENZA for the treatment of allergic conjunctivitis was evaluated in **four vehicle-controlled clinical trials with 315 subjects** using the modified CAC model with multiple repeated challenges
- DEXTENZA statistically significantly reduced ocular itching at 3, 5, and 7 min post-CAC on Day 8 in two Phase 3 studies and conjunctival redness at 7, 15, and 20 min post-CAC on Day 8 in one Phase 3 study
- Pooled analysis of three Phase 3 studies demonstrated **DEXTENZA statistically significantly reduced ocular itching and conjunctival redness** compared to placebo vehicle at all timepoints on Day 8
- DEXTENZA was generally **well tolerated with a favorable safety profile** and no serious ocular adverse events reported across four studies