Safety of an Intracanalicular Dexamethasone Insert for the Treatment of Allergic Conjunctivitis

Pooled Post Hoc Analysis of Four Studies

Meyer J, Kenyon K, Sato M, Silverstein SM, Meier EJ, Dewar K, Reilly E, Gomes PJ, Cheung M, Goldstein MH

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Disclosures

- This study was sponsored by Ocular Therapeutix
- **J Meyer (presenting author), K Kenyon, M Sato, S Silverstein,** and **E Meier** were investigators in the clinical trial sponsored by Ocular Therapeutix
- **K Dewar** is a consultant for Ocular Therapeutix
- **PJ Gomes** is an employee of Ora
- **E Reilly, M Cheung,** and **MH Goldstein** are employees of Ocular Therapeutix

Unmet Need in Allergic Conjunctivitis Therapy

Allergic conjunctivitis (AC) is a **prevalent**, **allergen-induced**, **inflammatory-mediated** eye disorder that places a burden on patients and healthcare practices.[1,2]

Current topical drop therapies have limitations including potential for **noncompliance**, and **preservatives toxicity**.[3,4]

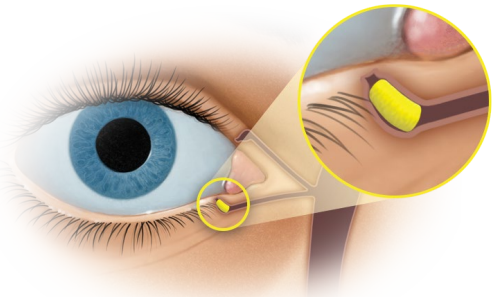
Although topical ophthalmic steroids are effective in treating allergic conjunctivitis, **physicians report infrequent use due to side effects and risk of abuse** associated with long-term use.[5,6]

DEXTENZA (dexamethasone ophthalmic insert) 0.4mg

DEXTENZA is a physician-administered, hydrogel-based, intracanalicular insert designed to obviate the need for corticosteroid drops.[7]

Product Attributes[7,8]

- Contains 0.4mg dexamethasone in a polyethylene glycol (PEG) hydrogel
- Designed to provide effective tapered therapy for up to 30 days with a single insert
- Alternative to conventional steroid eye drops
- Preservative-free
- Fully biodegradable
- Conjugated with fluorescein for visualization



Rendering of placement of insert in the canaliculus

References: 1. Leonardi A, et al. *Curr Opin Allergy Clin Immunol*. 2015;15(5):482-488. **2.** Rosario N, et al. *Curr Opin Allergy Clin Immunol*. 2011;11(5):471-476. **3.** Winfield AJ, et al. *Br J Ophthalmol*. 1990;74(8):477-480. **4.** Rosin LM, et al. *Clin Ophthalmol*. 2013;7:2131-2135. **5.** Bielory BP, et al. *Acta Ophthalmologica*. 2012;90(5):399-407. **6.** Bielory L, et al. *Allergy Asthma Proc*. 2013;34(5):408-420. **7.** DEXTENZA [prescribing information]. Bedford, MA: Ocular Therapeutix, Inc.; 2019. **8.** Sawhney AS, Jarrett P, Bassett M, Blizzard C, inventors; Incept, LLC, assignee. US patent 8,409,606 B2. April 2, 2020.

Study Objective and Design

Study Design

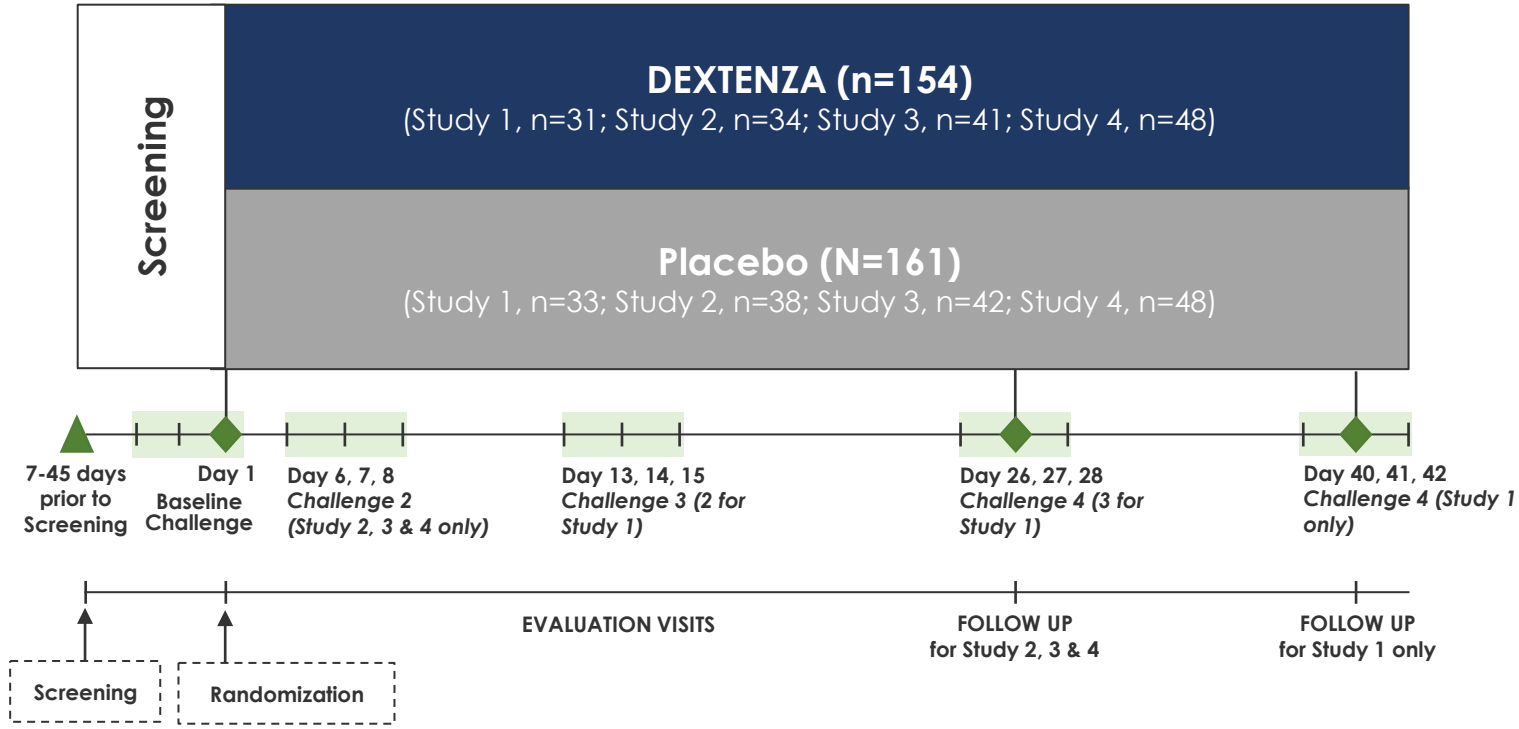
- Post hoc analysis of four prospective, randomized, double-masked, vehicle-controlled trials
  - One Phase II (Study 1)
  - Three Phase III (Study 2, 3 & 4)
- Used a modified Ora-CAC® (Conjunctival Allergen Challenge) model

Key Inclusion Criteria

- History of allergic conjunctivitis
- Positive skin test to seasonal and/or perennial allergens
- Bilateral CAC reaction

Primary Objective

- To evaluate the safety and efficacy of DEXTENZA for the treatment of signs and symptoms of allergic conjunctivitis



The safety of the four clinical trials is the focus of this presentation. Efficacy results will be included in an upcoming presentation.

Summary of Adverse Events

- Lower proportion of DEXTENZA-treated subjects reported AEs and ocular AEs compared to those in the placebo group
- **No severe AEs reported**; all AEs were mild or moderate in severity
- **No ocular serious AEs** were reported in either group
- Only one non-ocular serious AE (hospitalization due to depression) was reported in the DEXTENZA group and was deemed unrelated to treatment by the investigator

Subjects with at least one:	DEXTENZA N=154 n (%)	Placebo N=161 n (%)
AE	29 (18.8)	39 (24.2)
Mild	22 (14.3)	27 (16.8)
Moderate	7 (4.5)	12 (7.5)
Severe	0	0
Treatment-related AE	13 (8.4)	17 (10.6)
Ocular AE	19 (12.3)	23 (14.3)
Treatment-related Ocular AE	13 (8.4)	16 (9.9)
Serious AE (SAE)	1 (0.6)*	0
Treatment-related SAE	0	0
Ocular SAE	0	0
AE Leading to Study Withdrawal	2 (1.3)†	1 (0.6)

AE, adverse event
* non-ocular SAE (hospitalization due to depression) was not considered related to study treatment and was recovering/resolving upon study completion
† one subject in Study 1 withdrew due to an AE (IOP increased) which resolved. One subject in Study 4 withdrew due to an AE (eye irritation) which resolved.

Ocular Adverse Events

- Most common ocular AEs (≥1%) that occurred in DEXTENZA-treated subjects were: increased IOP, reduced visual acuity, increased lacrimation and eye discharge
- There were **no reported events of dacryocanaliculitis in the DEXTENZA group** across the four studies

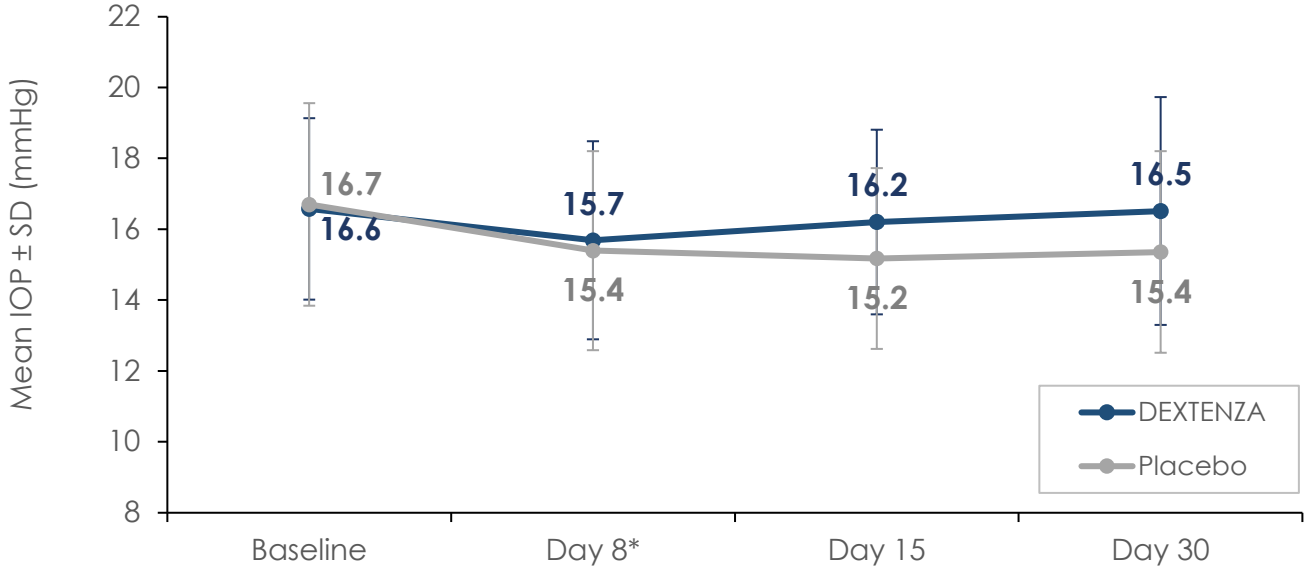
Most Common Ocular AEs (≥1%) in DEXTENZA-treated Subjects

Subjects with:	DEXTENZA N=154 n (%)	Placebo N=161 n (%)
Ocular AE	19 (12.3)	23 (14.3)
Increased IOP	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)

Changes in Intraocular Pressure

Mean IOP findings showed that subjects maintained normal ranges and this was consistent across study visits

Mean IOP Levels



DEXTENZA†	n=308 eyes	n=232 eyes	n=276 eyes	n=294 eyes
Placebo†	n=322 eyes	n=238 eyes	n=292 eyes	n=302 eyes

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.

Management of Increased IOP in DEXTENZA-treated Subjects

Increased IOP	DEXTENZA N=154
Total Number of Subjects	5
Management	
No action	1
Removal of DEXTENZA	0
Topical Medication Therapy	4
Median Duration of AE	23 days

Conclusions

- The clinical trials evaluating the safety and efficacy of DEXTENZA for the treatment of Allergic Conjunctivitis have enrolled over **300 clinical trial participants**
- Overall, findings from the pooled post hoc analysis of four studies demonstrated DEXTENZA was **generally safe and well tolerated for the treatment of allergic conjunctivitis**
- **Most common ocular AEs (≥1%)** that occurred in DEXTENZA-treated subjects were increased IOP, reduced visual acuity, lacrimation increased and eye discharge
- Rates of increased IOP following treatment with DEXTENZA **were low (3.2%)** and **comparable to topical ophthalmic steroids**[1,2]

DEXTENZA has the potential to be a non-abusable, physician-administered, preservative-free, alternative to steroid eye drops for allergic conjunctivitis, alleviating fear of side effects and risk of abuse with long term topical ophthalmic steroid use

References: 1. ALREX [package insert]. Bridgewater, NJ: Bausch + Lomb, Inc.; 2019. **2**. Wu LQ, et al. *Curr Med Res Opin*. 2015;31(8):1509-1518.