TOPLINE DATA

DEXTENZA FOR THE TREATMENT OF ALLERGIC CONJUNCTIVITIS

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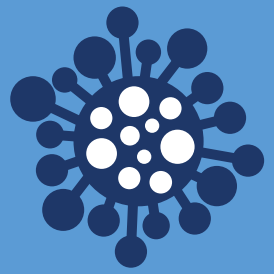
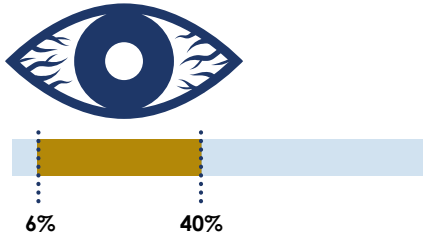
A TRANSFORMATIVE THERAPY FOR ALLERGIC CONJUNCTIVITIS



Seasonal and perennial allergic conjunctivitis are inflammatory-mediated ocular surface disorders induced by allergens

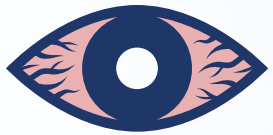
Topical antihistamines and mast cell stabilizers act to reduce the signs and symptoms of the early phase allergic reaction[1]. However, there is evidence that patients with ocular allergy exhibit a persistent late phase response[2,3]

Corticosteroids effectively treat the clinical signs and symptoms of acute and chronic allergy, and are particularly effective in treating late phase ocular allergic reactions, thus managing all the various facets of allergic symptoms[3,4]

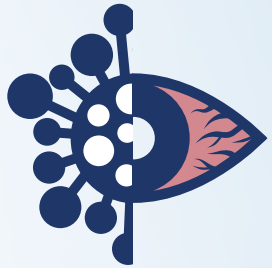


- Incidence varies widely depending on the source - **6%** to **40%** of the US population is affected by seasonal and/or perennial allergic conjunctivitis[5,6]
- It is often **underdiagnosed** and **undertreated** except when severe and then it is the primary reason for doctor visit[6]

- Corticosteroids, while effective, are atypically prescribed due to the **ability to abuse** and/or overuse the treatment, which can lead to further short-term and long-term complications



- Itchy, watery, and red eyes are the most common symptoms[6]
- Symptoms are managed by the frequent administration of eyedrops, which require **hands touching the face** several times per day



- Often **dry eye disease** and allergic conjunctivitis overlap further complicating diagnosis

1) Carr W, Schaeffer J, Donnenfeld E. Treating allergic conjunctivitis: A once-daily medication that provides 24-hour symptom relief. Allergy Rhinol (Providence). 2016;7(2):e107-e114.; 2.) Choi SH, Bielory L. Late-phase reaction in ocular allergy. Curr Opin Allergy Clin Immunol. 2008;8(5):438-444.; 3) Bielory BP, O'Brien TP, Bielory L. Management of seasonal allergic conjunctivitis: guide to therapy. Acta Ophthalmologica. 2012;90(5):399-407.; 4) Bielory L, Meltzer EO, Nichols KK, Melton R, Thomas RK, Bartlett JD. An algorithm for the management of allergic conjunctivitis. Allergy Asthma Proc. 2013;34(5):408-420.; 5) Leonardi A, Castegnaro A, Valerio ALG, Lazzarini D. Epidemiology of allergic conjunctivitis: clinical appearance and treatment patterns in a population-based study. *Curr Opin Allergy Clin Immunol*. 2015;15(5):482-488.; 6) Rosario N, Bielory L. Epidemiology of allergic conjunctivitis. *Curr Opin Allergy Clin Immunol*. 2011;11(5):471-476

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DEXTENZA FOR THE TREATMENT OF ALLERGIC CONJUNCTIVITIS
PHASE 3C STUDY DESIGN

- Double-masked, parallel-arm, vehicle-controlled study
- US study, 96 randomized subjects at 6 sites
- Key Inclusion criteria:
  - History of allergic conjunctivitis;
  - Positive skin test to both seasonal and perennial allergen
  - Bilateral Conjunctival Allergan Challenge (CAC) reaction

Primary Endpoint

- Ocular itching evaluated by the subject on Day 8 (Visit 6b) at 3, 5, and 7 minutes post-challenge

RESULTS: PATIENT DISPOSITION

Screening
n=316

Randomization
n=96

- 48 (50.0%) subjects were randomized to receive **DEXTENZA**
- 48 (50.0%) subjects were randomized to receive **Vehicle**

Study Populations

- 96 (100%) subjects were randomized and comprise the **Intent-To-Treat** population
- 96 (100%) were treated as randomized and comprise the **Safety** population
- 86 (89.6%) subjects comprise the **Per Protocol** population

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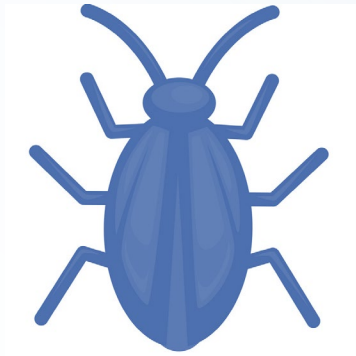
RESULTS: PATIENT DEMOGRAPHICS

	DEXTENZA N=48 n (%)	Vehicle N=48 n (%)	All Subjects N=96 n (%)
Age (Years)			
Mean (SD)	43.8 (12.45)	46.0 (12.92)	44.9 (12.67)
Min, Max	20, 67	24, 74	20, 74
Sex			
Male	21 (43.8%)	24 (50.0%)	45 (46.9%)
Female	27 (56.3%)	24 (50.0%)	51 (53.1%)
Ethnicity			
Hispanic or Latino	6 (12.5%)	4 (8.3%)	10 (10.4%)
Not Hispanic or Latino	42 (87.5%)	43 (89.6%)	85 (88.5%)
Unknown	0	1 (2.1%)	1 (1.0%)
Race			
Asian	0	1 (2.1%)	1 (1.0%)
African American	14 (29.2%)	17 (35.4%)	31 (32.3%)
White	32 (66.7%)	29 (60.4%)	61 (63.5%)
Other	2 (4.2%)	1 (2.1%)	3 (3.1%)

RESULTS: QUALIFYING ALLERGENS

Seasonal Allergens:

- Timothy Grass
- White Birch
- Meadow Fescue
- Ragweed
- Kentucky Bluegrass
- Rye Grass
- Maple
- Oak

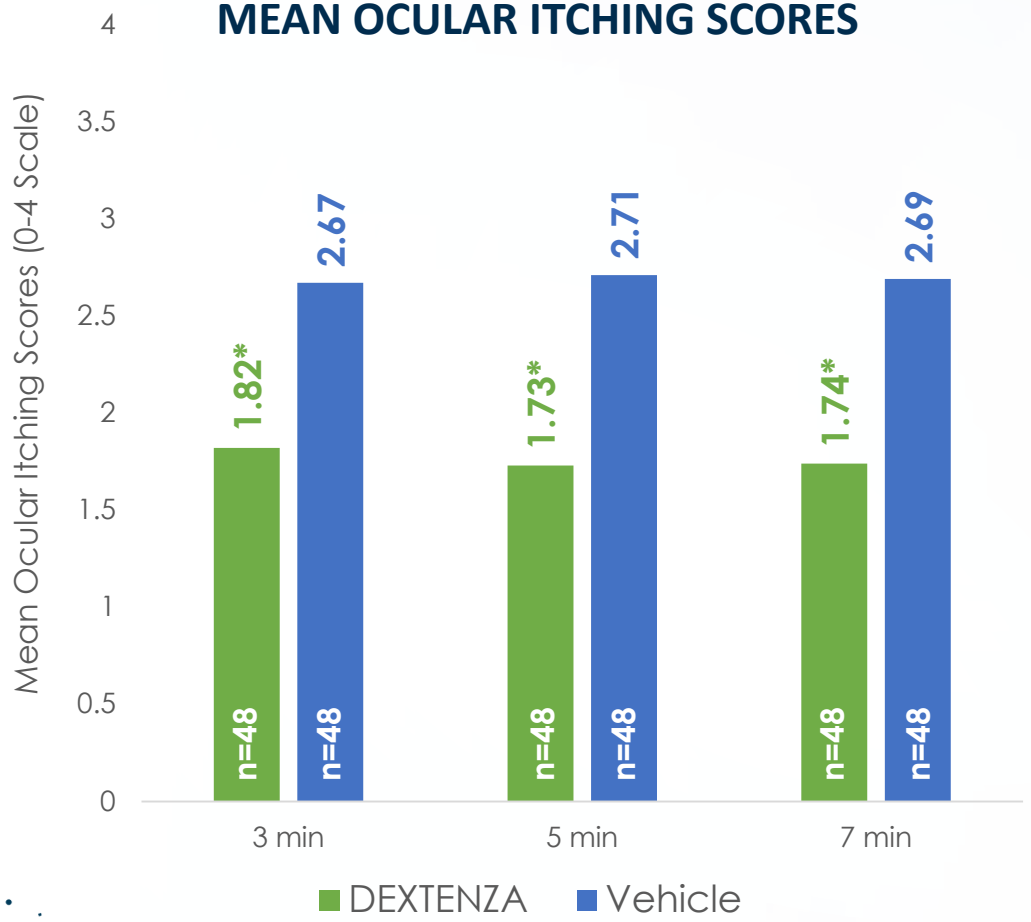


Perennial Allergens:

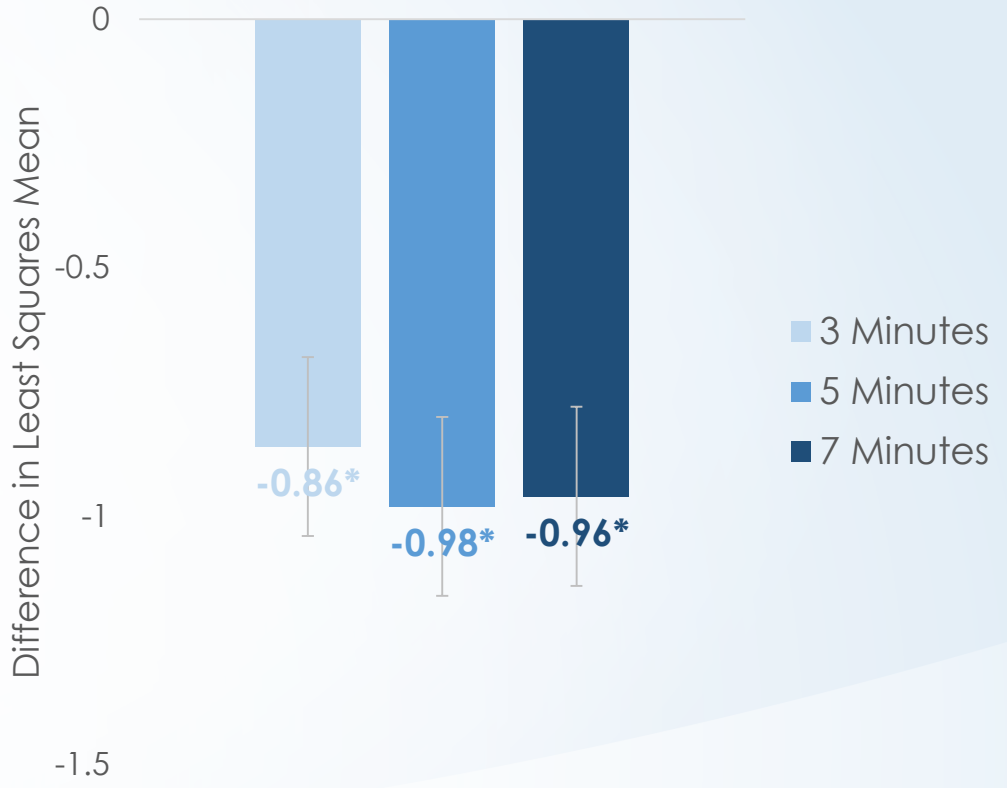
- Dust Mites
- Cat Dander
- Cockroach
- Dog Dander

RESULTS: PRIMARY EFFICACY ENDPOINT
OCULAR ITCHING SCORES ON DAY 8 (VISIT 6B)

MEAN OCULAR ITCHING SCORES



DIFFERENCE BETWEEN DEXTENZA AND VEHICLE



*Statistically Significant; *P*≤0.0001; Least Squares Means; Population: ITT + MCMC; Bars represent Standard Error

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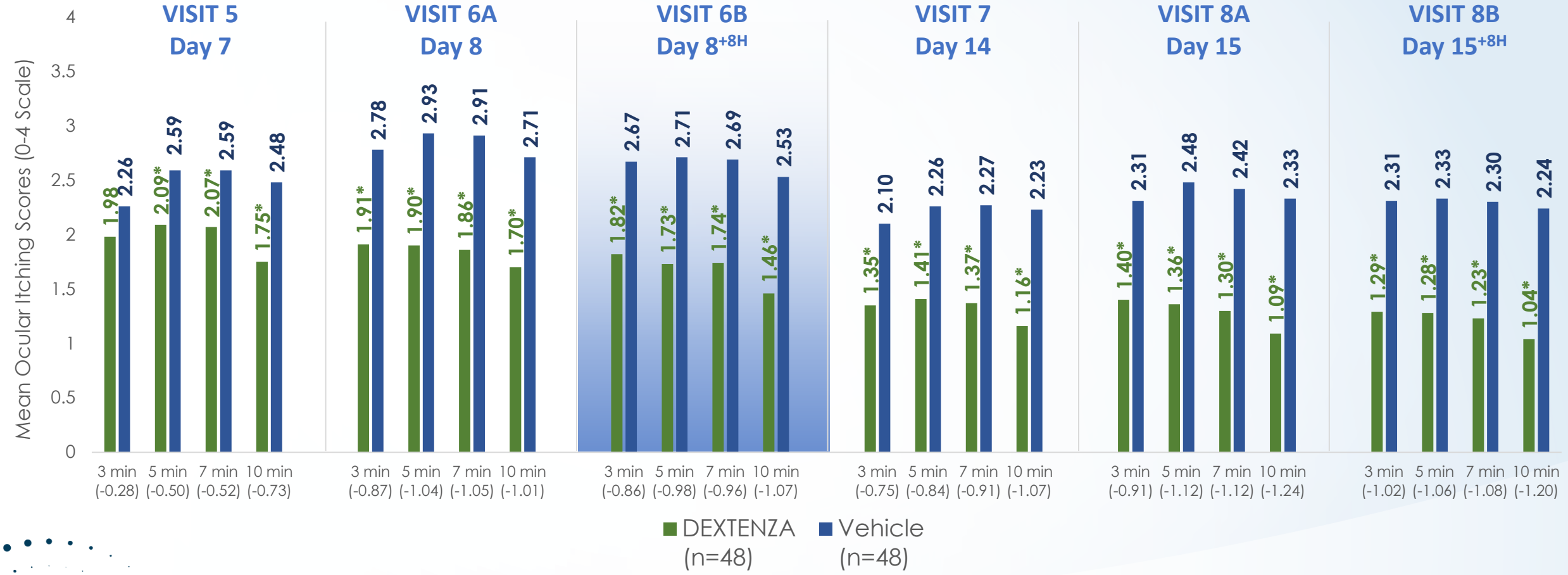
RESULTS: SECONDARY EFFICACY ENDPOINTS
MEAN OCULAR ITCHING SCORES ACROSS ALL VISITS



*$P \leq 0.05$; Least Squares Means; Population: ITT + MCMC

RESULTS: OVERALL SAFETY SUMMARY

Number of:	DEXTENZA N=48 n (%)	Vehicle N=48 n (%)	All Subjects N=96 n (%)
Treatment-Emergent Adverse Events (TEAEs)	16	14	30
Ocular TEAEs	2	6	8
Non-Ocular TEAEs	14	8	22
Treatment-Emergent Serious Adverse Events (SAEs)	0	0	0
Subjects with TEAEs Leading to Withdrawal	1 (2.1%)	0	1 (1.0%)
Subjects with TEAEs with Suspected Relation to IP			
Not Related	7 (14.6%)	11 (22.9%)	18 (18.8%)
Related	2 (4.2%)	3 (6.3%)	5 (5.2%)
Subjects with TEAEs by Severity			
Mild	8 (16.7%)	11 (22.9%)	19 (19.8%)
Moderate	1 (2.1%)	3 (6.3%)	4 (4.2%)
Severe	0	0	0

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RESULTS: OCULAR TREATMENT-EMERGENT ADVERSE EVENTS

Number of:	DEXTENZA N=48 n (%)	Vehicle N=48 n (%)	All Subjects N=96 n (%)
Ocular TEAEs	2	6	8
Eye Disorders			
Eye Discharge	**1 (2.1%)**	**1 (2.1%)**	2 (2.1%)
Lacrimation Increased	0	**2 (4.2%)**	2 (2.1%)
Conjunctival Hemorrhage	0	1 (2.1%)	1 (1.0%)
Eye Irritation*	**1 (2.1%)**	0	1 (1.0%)
Eyelid Edema	0	1 (2.1%)	1 (1.0%)
Swelling of the Eyelid	0	1 (2.1%)	1 (1.0%)

Zero cases of elevated IOP were reported in either group

*Study Drug withdrawn three days following insertion

Suspected related to drug (as designated by the Investigator) are in **bold text**

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TOPLINE CONCLUSIONS

Topline Efficacy

- The primary endpoint of the trial was successfully met.
- For the primary endpoint at Visit 6b (Day 8; 8 Hours post Visit 6a), this study demonstrated a statistically significant *(P*<0.0001) difference favoring subjects who received DEXTENZA for lowering ocular itch scores compared with subjects who received vehicle insert at all time points (3 min, 5 min, and 7 min post-CAC).
- For the primary endpoint at Visit 6b, the difference in ocular itching scores favored DEXTENZA over vehicle by 0.86 units at 3 minutes (*P*<0.0001), 0.98 units at 5 min (*P* <0.0001) and 0.96 units at 7 min (*P* <0.0001).
- These data are consistent with what has been observed in the prior Phase 2 and Phase 3A allergic conjunctivitis studies using a similar repeat CAC model.
- For secondary endpoints at all other visits (Visit 5, Visit 6a, Visit 6b (10 min), Visit 7, Visit 8a, Visit 8b), subjects treated with DEXTENZA did better than vehicle for ocular itching scores at 3 min, 5 min, 7 min and 10 min post-CAC (*P*<0.05 for all time points at all visits except Visit 5, 3 minutes).
- Allergens evaluated in this study include seasonal allergens and perennial allergens.
- Other secondary efficacy endpoints will be evaluated over the next several weeks including ocular redness and nasal symptoms.

Topline Safety

- DEXTENZA was generally safe and well tolerated in this study.
- There were no serious adverse events seen (ocular or non-ocular).
- No subjects required rescue medication.
- In this study, there were no subjects with adverse event of elevated IOP, IOP over 30 or IOP increases of 10 mm Hg.

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