A Randomized Double-Masked Phase 2 Clinical Trial of NS2 Ophthalmic Solution in Allergic Conjunctivitis

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Introduction

Aldehydes are pro-inflammatory mediators of allergic (TH2) and auto-immune (TH1) inflammation. NS2 (ADX-102) is a novel aldehyde sequestering agent that represents a new anti-inflammatory drug class.

Methods

A randomized, parallel group, single-center, double-masked, vehicle-controlled Phase 2 study was conducted in 100 subjects (written informed consent obtained) with grass, birch, or ragweed pollen allergic conjunctivitis in a Conjunctival Allergen Provocation Test (CAPT) model in which patient-reported ocular itching and tearing were assessed over 3 hours post-challenge. Topical ocular 0.5% NS2 and vehicle were dosed four times daily for 16 days, with CAPT conducted 30 minutes post-dosing on days 1, 14, 15, and 16.

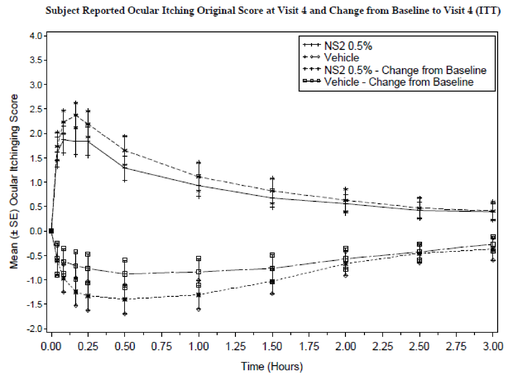
Conclusions

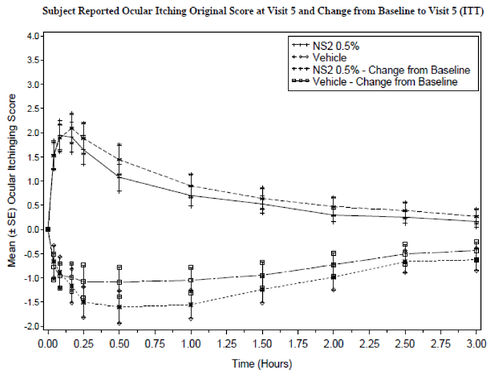
A clear pattern of clinically relevant effects was seen with NS2 0.5% in this allergic conjunctivitis population using the CAPT model and NS2 was well tolerated with no safety concerns raised.

These data are the first demonstration of the clinical efficacy of aldehyde trapping in human disease, and the results support continued development of NS2 in allergic conjunctivitis and potential in other inflammatory diseases.

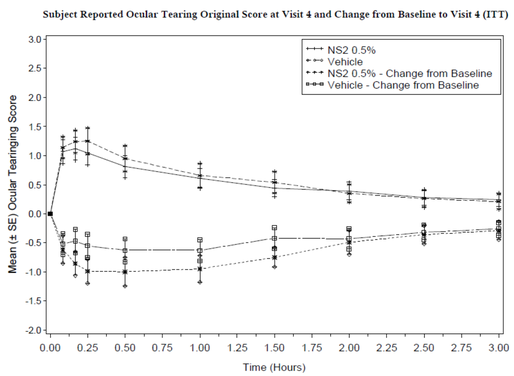
Results

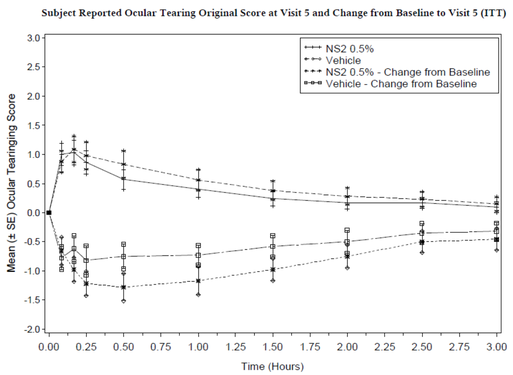
Efficacy Results: Relative to vehicle, itching and tearing scores were consistently lower in NS2-treated subjects throughout the assessment period at each visit. The ocular itching and tearing reductions with NS2 demonstrated maximum reductions from baseline greater than 1.5 and 1 point, respectively. Conjunctival redness also showed maximum reductions from baseline greater than 1, although NS2 did not significantly separate from vehicle. The change from baseline for original itching scores were significantly lower in the NS2 0.5% group compared to the vehicle group on Visit 4 (Day 1) at 10, 15 and 30 minutes (p=0.026 at 10min; p=0.028 at 15min; p=0.035 at 30min) and Visit 5 (Day 14) at 30 and 60 minutes (p=0.031 at 30min; p=0.024 at 60min).





The change from baseline for original ocular tearing scores were significantly lower in the NS2 0.5% group compared to the vehicle group on Visit 4 at 10, 15, 30 and 90 minutes (p=0.04 at 10min; p=0.016 at 15min; p=0.045 at 30 min; p=0.034 at 90 min), to Visit 5 at 10, 15, 30, 60 and 90 minutes (p=0.045 at 10min; p=0.041 at 15min; p=0.006 at 30min; p=0.013 at 60min; p=0.015 at 90min).





Safety Results: NS2 was generally well tolerated with no safety concerns as assessed by ocular exam, intraocular pressure, and visual acuity.