# LYNX-1: A Phase 3 Randomized Placebo-Controlled Clinical Trial of Phentolamine Ophthalmic Solution in Subjects with Dim Light Vision Disturbances

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## INTRODUCTION

- When the pupil dilates in low light conditions, patients with Dim Light Disturbances (DLD) experience photic phenomena and decreased vision, especially with night driving
- In the LYNX-1 Phase 3 clinical trial, the efficacy and safety of 0.75% phentolamine ophthalmic solution (POS) was evaluated in DLD subjects
- Moderate pupil reduction with POS may minimize peripheral aberration and benefit DLD patients

## METHODS

- Randomized, double-masked, placebo-controlled, multi-center Phase 3 clinical trial
- N=145; 1:1 POS or Placebo for one drop in each eye daily at bedtime for 2 weeks
- Study assessments were performed on Day 8 and Day 15
- Primary endpoint: % of POS-treated subjects with ≥15 ETDRS letters of improvement in mesopic Low Contrast Visual Acuity (mLCVA) (distance)
- Secondary efficacy endpoints and safety were evaluated at Day 8 and Day 15

| DEMOGRAPHICS AND BASELINE CHARACTERISTICS | |
|---|---|
| Age, years, Mean (range) | 46 (19-70) |
| Female, % (n) | 84% (120) |
| Race: White, % (n) | 92% (132) |
| Mesopic Low Contrast BCDVA Letters *55 letters = 20/20* | 16 (>20/100) |
| Mesopic High Contrast BCDVA Letters *55 letters = 20/20* | 46 (20/32) |
| Mesopic Baseline Pupil Diameter Mean (mm) | 6.1 |

**Disclosures**
Jay Stuart Pepose, Code C (Consultant/Contractor) Acufocus, Allergan, Azura. Bausch+Lomb, Brim Biotech, 2EyesVision, JNJ Vision, Mimetogen, Ocuphire Pharma, OKYO Pharma, Stuart Pharma, Thea Pharma, Telios Pharma, Louis Haddad, Code C (Consultant/Contractor) Ocuphire Pharma, Audrey Lazar, Code C (Consultant/Contractor) Ocuphire Pharma, Mina Sooch, Code E (Employment) Ocuphire Pharma, Mitchell G. Brigell, Code C (Consultant/Contractor) Ocuphire Pharma.

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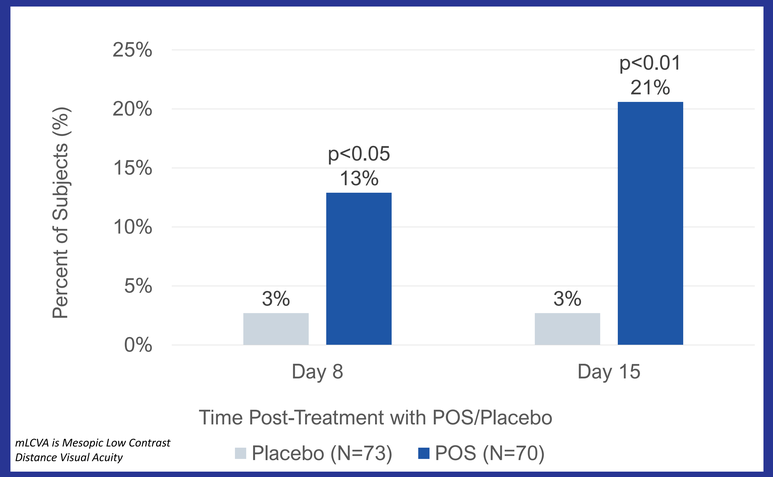
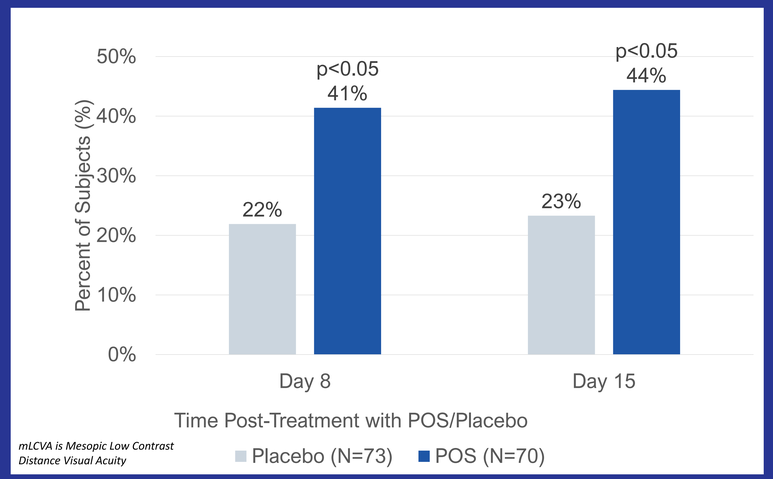
## Significantly Greater Percentage of DLD Patients Treated with POS Gained ≥15 Letters and ≥10 Letters From Baseline at Day 8 and Day 15

### Figure 1: Percent of Subjects with ≥15 Letter Improvement in mLCVA Study Eye (mITT)




### Figure 2: Percent of Subjects with ≥10 Letter Improvement in mLCVA Study Eye (mITT)

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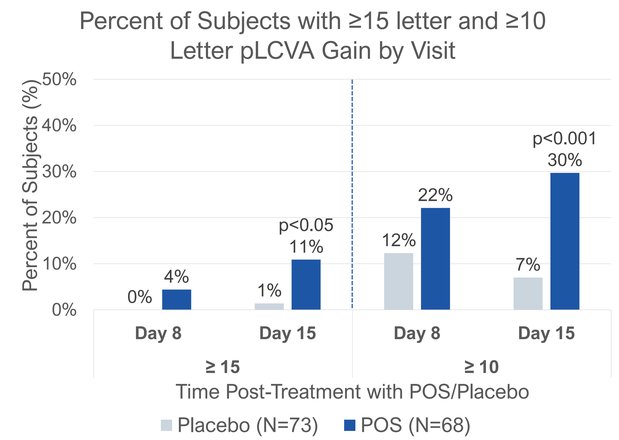
### Figure 3: Improvement in Photopic Low Contrast Distance Vision (pLCVA) in Study Eye (mITT)




## EFFICACY RESULTS

- POS met primary endpoint at Day 8 with 13% of subjects gaining ≥ 15 letters of mesopic LCVA vs. 3% on placebo (p<0.05)
- POS efficacy increased after 14 days of evening dosing, with 21% responders compared to 3% on placebo (p<0.01) gaining ≥ 15 letters in mLCVA
- POS statistically significantly reduced pupil diameter by an average of ~1 mm on Day 8 and Day 15 compared to placebo (p<0.0001)
- POS demonstrated significant improvements in photopic low contrast distance vision band a benefit in mesopic high contrast near vision

## SAFETY RESULTS

- No serious adverse events
- AEs were uncommon and primarily mild
  - Instillation site pain (13%)
  - Instillation site irritation (9%)
  - Conjunctival hyperemia (9%)
  - Dysgeusia (11%)
- No headaches or browaches
- No tachyphylaxis
- No change in vital signs or intraocular pressure

## NEXT STEPS

- With these positive LYNX-1 Phase 3 results, a second Phase 3 trial is planned to support an sNDA submission for POS in DLD indication