

March 23, 2023



# Ocuphire Announces APX3330 and Nyxol® Data Presentations at ARVO 2023 Annual Meeting

*Oral Presentation to Feature Results from ZETA-1 Phase 2 Trial of APX3330 in Diabetic Retinopathy Patients*

*Results from Phase 3 LYNX-1 Trial of Nyxol® in Dim Light Vision Disturbance to be Presented for the First Time to the Medical Community*

FARMINGTON HILLS, Mich., March 23, 2023 (GLOBE NEWSWIRE) -- Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of refractive and retinal eye disorders, today announced five presentations featuring results from the Company's recently completed trials of APX3330 and Nyxol at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, to take place in New Orleans, LA from April 23 to April 27, 2023.

## [ARVO Annual Meeting – April 23-27, 2023](#)

New Orleans Ernest N. Morial Convention Center

### ***APX3330 Oral Tablet in Diabetic Retinopathy***

**Title:** ZETA-1 Phase 2 Trial to Determine the Safety and Efficacy of APX3330: a Novel, Oral Ref-1 Inhibitor for the Treatment of Diabetic Retinopathy

**Presenter:** Daniel Su, M.D., [Retina-Vitreous Associates Medical Group](#)

**Paper Session:** #205 Diabetic Retinopathy Medical

Wednesday, April 26, 2023, 10:45 AM – 11:00 AM CT

**Location:** La Nouvelle Ballroom AB

**Abstract Number:** 3753

### ***Nyxol Eye Drops in Dim Light Vision Disturbances and Presbyopia***

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

Presenter: Jay Pepose, M.D., Ph.D.  
Poster #141 Presbyopia and Intraocular Lenses  
Session: Tuesday, April 25, 2023, 8:45 AM – 10:30 AM CT

Location: Exhibit Hall  
Abstract number: 2506 - B0008

**Title: Phentolamine Ophthalmic Solution, with and without Low Dose Pilocarpine, Provides Durable Improvement in Distance Corrected Near Vision in Presbyopic Patients: A Responder Analysis**

Presenter: Mitchell Brigell, Ph.D.  
Paper #297 Cataract and Intraocular Lenses  
Session: Thursday, April 27, 2023, 1:45 PM – 2:00 PM CT  
Location: Room 255-257  
Abstract number: 5423

Additional poster presentations at ARVO:

- **VEGA-1 Phase 2 Trial: Phentolamine Ophthalmic Solution Maintains Pupillary Light Reflex with Improved Distance-Corrected Near Vision in Presbyopes** (Ronil Patel, M.S.) Poster on Tuesday, April 25, 2023, 8:45 AM – 10:30 AM CT (Abstract number: 2507 - B0009)
- **Phentolamine Ophthalmic Solution Rapidly Reverses Pharmacologically Induced Mydriasis in Two Pivotal Phase 3 MIRA Trial** (Mina Sooch, M.B.A.) Poster on Tuesday, April 25, 2023, 11:45 AM – 1:30 PM CT (Abstract number: 3099 - C0231)

## About Ocuphire Pharma

Ocuphire is a publicly traded (Nasdaq: OCUP), clinical-stage, ophthalmic biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of refractive and retinal eye disorders.

Ocuphire has a previously disclosed partnership to develop and commercialize Nyxo<sup>®</sup> eye drops as a preservative-free eye drop formulation of phentolamine mesylate, a non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size by uniquely blocking the alpha-1 receptors found only on the iris dilator muscle without affecting the ciliary muscle. Nyxo has been studied in a total of 12 clinical trials (3 Phase 1, 5 Phase 2, 4 Phase 3) across three indications, including single-use for reversal of pharmacologically-induced mydriasis (RM), and once-daily for treatment of presbyopia and dim light (night) vision disturbances (DLD), pending regulatory approvals. Nyxo's NDA under the 505(b)(2) pathway for the first indication, RM has been accepted with a PDUFA date assigned of September 28, 2023. Nyxo is also currently in Phase 3 for presbyopia and DLD.

Ocuphire's other late-stage product candidate APX3330 is a first-in-class, small molecule,

oral drug that blocks downstream pathways regulated by transcription factor Ref-1 – including those involving angiogenesis (VEGF) and inflammation (NFkB). These pathways are implicated across several ocular diseases, including diabetic retinopathy (DR), diabetic macular edema (DME), and age-related macular degeneration (AMD). Ocuphire recently announced topline data from the ZETA-1 Phase 2 trial in which APX3330 achieved statistical significance on a key pre-specified secondary endpoint of preventing clinically meaningful progression of (DR) after 24 weeks of daily treatment. APX3330 has also shown a favorable safety and tolerability profile in diabetic subjects (ZETA-1 trial) and in 11 previous clinical trials conducted in healthy, liver disease, and cancer subjects.

For more information, visit [www.ocuphire.com](http://www.ocuphire.com).

## Contacts

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Source: Ocuphire Pharma