

September 7, 2023



Ocuphire Pharma to Present at ESCRS 2023 and MODLive! Conferences in September

ESCRS presentations will feature clinical data on APX3330 in diabetic retinopathy; Nyxol® data in presbyopia, dim light vision disturbance and reversal of pharmacologically induced mydriasis

FARMINGTON HILLS, Mich., Sept. 07, 2023 (GLOBE NEWSWIRE) -- Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of retinal and refractive eye disorders, today announced that it will present clinical data on APX3330 and Nyxol® at the 41st Congress of the [European Society of Cataract and Refractive Surgeons \(ESCRS\)](#) to take place September 8th - 11th, in Vienna, Austria. In addition, Bindu Manne, Head of Market Development and Commercialization at Ocuphire, will deliver a corporate presentation at the [MODLive!](#) Conference to take place September 8th - 10th, in Nashville, TN.

ESCRS Presentations

Title: **Oral APX3330 Reduces the DRSS Worsening After 24-Weeks of Daily Treatment: Efficacy And Safety Results Of the Zeta-1 Phase 2 Trial in Diabetic Retinopathy**

Author: James Katz, MD

Abstract ID PO106

Format E-poster

Title: **Vega-1: A Phase 3, Double-Masked, Randomized, Placebo-Controlled Study of POS And LDP in Presbyopic Patients**

Author: Cathleen McCabe, MD

Abstract ID PO0888

Format E-poster

Title: **Lynx-1: Phentolamine Ophthalmic Solution for Dim Light Vision Disturbance**

Presenter: Sheraz Daya, MD

Date: Monday, September 11, 2023

Time 5:00 - 5:06pm CEST
Room: Lehar 1-2-3 Free paper podium 3
Abstract ID FP23.05
Format Paper (oral)

Title: **Treatment With 0.75% Phentolamine Ophthalmic Solution Reverses Mydriasis in Healthy Subjects: Results From Mira-2 And Mira-3, Pivotal Phase 3 Clinical Trials**

Presenter: Cathleen McCabe, MD
Date: Monday, September 11, 2023
Time: 5:06 - 5:12pm CEST
Room: Lehar 1-2-3 Free paper podium 3
Abstract ID FP23.06
Format Paper (oral)

MODLive! Presentation

Session: Emerging Technology
Presenter: Bindu Manne, Head of Market Development and Commercialization, Ocuphire
Date: Friday, September 8, 2023
Time: 5:15pm CDT
Location: Grand Hall DE, Grand Hyatt Nashville

About Ocuphire Pharma

Ocuphire Pharma, Inc. is a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of retinal and refractive eye disorders.

Ocuphire's lead retinal product candidate, APX3330, is a first-in-class small-molecule inhibitor of Ref-1 (reduction oxidation effector factor-1 protein). Ref-1 is a regulator of transcription factors such as HIF-1a and NF-kB. Inhibiting REF-1 reduces levels of vascular endothelial growth factor ("VEGF") and inflammatory cytokines which are known to play key roles in ocular angiogenesis and inflammation. Through inhibition of Ref-1, APX3330 normalizes the levels of VEGF to physiologic levels, unlike biologics that abolish the VEGF levels required for normal function. APX3330 is an oral tablet administered twice per day for the treatment of diabetic retinopathy ("DR") and diabetic macular edema ("DME"). A Phase 2 study in subjects with DR or DME has recently completed, and an End-of-Phase 2 meeting is confirmed with the FDA in Q4 2023.

DR affects approximately 10 million people with diabetes and is projected to impact 14.6 million Americans by 2050. DR is classified as Non-Proliferative Diabetic Retinopathy ("NPDR"), the early stage of the disease in which symptoms may be mild or nonexistent or Proliferative Diabetic Retinopathy ("PDR") which is the more advanced stage of diabetic eye disease that can be highly symptomatic with loss of vision. Approximately 80% of DR patients have NPDR that will progress to PDR if left untreated. Despite the risk for visual loss

associated with this disease, over 90% of NPDR patients currently receive no course of treatment apart from observation by their eye care specialist until they develop sight-threatening complications. This is due to the burdensome and frequent eye injections currently required with currently approved therapies for this disease. APX3330 as an oral tablet has the potential to be an early, non-invasive treatment for the 8 million NPDR patients in the US. Treatment with APX3330 is expected to delay or prevent progression of NPDR, thereby reducing the need for expensive intravitreal injections with anti-VEGF therapies and reducing the likelihood of vision loss due to DR.

Ocuphire has also in-licensed APX2009 and APX2014, which are second-generation analogs of APX3330. The unique dual mechanism of action of these Ref-1 inhibitors of reducing angiogenesis and inflammation could potentially be beneficial in treating other retinal diseases such as age-related macular degeneration (“AMD”), and geographic atrophy (“GA”). Ocuphire is currently evaluating local delivery routes in addition to the systemic (oral) route as part of its pipeline expansion in retinal therapies.

Ocuphire has a partnership with Viatriis, Inc. to develop and commercialize Nyxo[®] 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. Nyxol has been studied in a total of 12 clinical trials 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. Nyxol’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. Nyxol is currently in Phase 3 for presbyopia and DLD.

For more information, visit www.ocuphire.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning the End-of-Phase 2 meeting with the FDA to confirm Phase 3 registration endpoints and study parameters, and the potential receipt of regulatory approval for Nyxol for the treatment of RM. These forward-looking statements are based upon Ocuphire’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts; (ii) regulatory requirements or developments; (iii) changes to clinical trial designs and regulatory pathways; (iv) changes in capital resource requirements; (v) risks related to the inability of Ocuphire to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (vi) legislative, regulatory, political and economic developments, (vii) changes in market opportunities, (viii) the effects of COVID-19 on clinical programs and business operations, (ix) risks that the Nyxol partnership may not facilitate the commercialization or market acceptance of Ocuphire’s product candidates; (x) the success and timing of

commercialization of any of Ocuphire's product candidates, and (xi) the maintenance of Ocuphire's intellectual property rights. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and may be filed by Ocuphire from time to time with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Ocuphire undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Contacts

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Source: Ocuphire Pharma