

April 26, 2022



Ocuphire Announces Upcoming Clinical Presentations at ARVO 2022 Medical Meeting and MODLive! 2022

Four ARVO presentations accepted will feature data from APX3330 Phase 2b trial in Diabetic Retinopathy and Nyxol® Phase 2 trial in Presbyopia and Phase 3 trial in Reversal of Mydriasis

FARMINGTON HILLS, Mich., April 26, 2022 (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 four poster presentations by key thought leaders Drs Boyer, Devries, Katz, and Pepose on APX3330 and Nyxol at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, which will take place in Denver, CO from May 1-4, 2022. In addition, Ocuphire represented by Bindu Manne, Head of Market Development and Commercialization, will be featured in a podium discussion at the MODLive! Optometry Meeting in Nashville, TN on May 5, 2022.

[ARVO Annual Meeting – May 1-4, 2022](#)

Session: [New drugs, mechanisms of action and ocular toxicology](#)
Title: **The safety of APX3330, an oral drug candidate for the treatment of diabetic eye disease, in the ongoing masked 24-week ZETA-1 Phase 2 clinical trial**
Presenter: David Boyer, M.D.
Date: Sunday, May 1, 2022
Time: 2:45 PM – 4:45 PM MDT
Location: Exhibit Hall, Colorado Convention Center
Presentation Number: 675 - F0129

Dr. Boyer will present masked safety data from the ongoing ZETA-1 Phase 2b trial of oral APX3330 for the treatment of diabetic retinopathy. The results show a favorable ophthalmic and systemic safety and tolerability profile, consistent with 11 prior safety trials of APX3330 in non-ophthalmic indications. The company expects to report top-line results from the ZETA-1 trial in second half of 2022.

Session: [Aqueous humor dynamics, IOP, corneal disease, cytokines and growth factors](#)

Title: **Phentolamine Ophthalmic Solution Reverses Pharmacologically Induced Mydriasis in Healthy Subjects: Subgroup Analyses in the Pivotal Phase 3 MIRA-2 Randomized Controlled Trial**

Author/Presenter: Douglas Devries, O.D. / Ronil Patel, M.S.

Date: Monday, May 2, 2022

Time: 10:00 AM – 12:00 PM MDT

Location: Exhibit Hall, Colorado Convention Center

Presentation 1300 - F0115

Number:

Ocuphire will present pre-specified subgroup analyses from the MIRA-2 Phase 3 trial of Nyxol (0.75% phentolamine ophthalmic solution) to reverse pharmacologically-induced mydriasis (RM). Analyses were stratified by drops, iris color, and mydriatic agent. Results showed that Nyxol rapidly reversed mydriasis by significantly returning pupil diameter to normal in 60 to 90 minutes using both one and two drops across mydriatic agents and iris colors. MIRA-2 and the recently completed MIRA-3 represent two well-controlled, confirmatory Phase 3 clinical trials evaluating Nyxol in RM to support an NDA submission with the FDA planned in late 2022.

Session: [IOLs and Presbyopia](#)

Title: **VEGA-1: Phentolamine Ophthalmic Solution as a Single Agent Improves Distance-Corrected Near Visual Acuity in Patients with Presbyopia**

Author/Presenter: James Katz, M.D. / Mina Sooch, M.B.A.

Date: Monday, May 2, 2022

Time: 12:30 PM – 2:30 PM MDT

Location: Exhibit Hall, Colorado Convention Center

Presentation 1813 - F0429

Number:

Ocuphire will present efficacy data from pre-specified endpoints in the VEGA-1 Phase 2 trial of Nyxol in presbyopia. Results demonstrated that Nyxol as a single agent provided 12 to 18 hour durability and statistically significant improvement in distance-corrected near visual acuity (DCNVA). In addition, results also showed a favorable safety and tolerability profile, particularly notable being the absence of headaches. VEGA-1 supports the advancement to pivotal Phase 3 trials planned for mid-2022 evaluating the efficacy of Nyxol alone and in combination with low dose pilocarpine for presbyopia.

Session: [IOLs and Presbyopia](#)

Title: **The Efficacy of Phentolamine Ophthalmic Solution and Low-Dose Pilocarpine to Improve Distance-Corrected Intermediate Visual Acuity in Patients with Presbyopia**

Presenter: Jay Pepose, M.D., Ph.D.

Date: Monday, May 2, 2022

Time: 12:30 PM – 2:30 PM MDT

Location: Exhibit Hall, Colorado Convention Center

Presentation 1809 - F0425
Number:

Dr. Pepose will present for the first time to the scientific community efficacy data from the VEGA-1 Phase 2 trial evaluating Nyxol in combination with low-dose pilocarpine (LDP) to improve distance-corrected intermediate visual acuity (DCIVA) in patients with presbyopia. The results demonstrated that Nyxol and LDP combination had statistically significant improvement in DCIVA at 1 hour with durable results through 6 hours.

MODLive! – May 5-7, 2022

Session: **Therapeutics Pipeline**
Date: Thursday, May 5, 2022, 4:30 PM – 5:45 PM EDT
Presenter: Bindu Manne, Head of Market Development and Commercialization
Location: Grand Hyatt, Nashville, TN
Conference Link: [Click here](#)

MODLive! is a unique meeting with an interactive educational program connecting optometrists with an emphasis on new innovations that may shape the future of medical eye care. The meeting attracts top clinicians in ophthalmology and optometry who work in integrated care settings or run medically focused independent practices. Ocuphire was selected by the MOD Live faculty as a company poised to make a major impact in eye care. Bindu Manne will present an overview of Nyxol at the MODLive! Session: Therapeutics Pipeline.

About Ocuphire Pharma

Ocuphire is a publicly-traded (NASDAQ: OCUP), clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of several eye disorders. Ocuphire's pipeline currently includes two small-molecule product candidates targeting refractive and retinal indications. The company's lead product candidate, Nyxol[®] eye drops (0.75% phentolamine ophthalmic solution) is a once-daily, preservative-free eye drop formulation of phentolamine mesylate, a non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size, and is being developed for several indications, including reversal of pharmacologically-induced mydriasis (RM), presbyopia and dim light or night vision disturbances (NVD), and has been studied in 10 completed clinical trials. Ocuphire has reported positive topline data from MIRA-2 and MIRA-3, two registration trials for the treatment of RM, and recently completed enrollment in a pediatric safety trial (MIRA-4) in RM. Ocuphire also reported positive top-line data from a Phase 2 trial of Nyxol for treatment of presbyopia, both Nyxol as a single agent and Nyxol with low-dose pilocarpine ("LDP") 0.4% as adjunctive therapy. The company recently completed enrollment in its Phase 3 trial of Nyxol for NVD (LYNX-1). Ocuphire's second product candidate, APX3330, is an oral tablet designed to inhibit angiogenesis and inflammation pathways relevant to retinal and choroidal vascular diseases, such as diabetic retinopathy (DR) and diabetic macular edema (DME) and has been studied in 11 Phase 1 and 2 trials. The company recently announced the completion of enrollment in a Phase 2b clinical trial of APX3330 to treat DR/DME (ZETA-1). Please visit www.clinicaltrials.gov to learn more about Ocuphire's recently completed Phase 3 registration trial in RM ([NCT05134974](https://clinicaltrials.gov/ct2/show/study/NCT05134974)), pediatric safety study in RM ([NCT05223478](https://clinicaltrials.gov/ct2/show/study/NCT05223478)), Phase 3 registration trial in

NVD ([NCT04638660](#)), and Phase 2b trial in DR/DME ([NCT04692688](#)). Ocuphire previously completed the first Phase 3 registration trial in RM ([NCT04620213](#)) and Phase 2 trial in presbyopia ([NCT04675151](#)). As part of its strategy, Ocuphire will continue to explore opportunities to acquire additional ophthalmic assets and to seek strategic partners for late-stage development, regulatory preparation, and commercialization of drugs in key global markets. 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, timing and results in RM, presbyopia, NVD and DR/DME future clinical trials, as well as statements concerning the success and timing of planned regulatory filings and commercialization. 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) the success and timing of commercialization of any of Ocuphire’s product candidates and (x) 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.

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Source: Ocuphire Pharma