

October 26, 2023



Ocuphire Pharma to Present at AAO 2023 and Eyecelerator Retina Showcase

FARMINGTON HILLS, Mich., Oct. 26, 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 presentations featuring APX3330 and phentolamine ophthalmic solution at the [American Academy of Ophthalmology Annual Meeting \(AAO 2023\)](#) to take place in San Francisco, California on November 3-6, 2023. In addition, Jay Pepose, M.D. Ph.D., Chief Medical Advisor at Ocuphire, will provide a corporate overview at the [Eyecelerator AAO 2023 Retina Showcase](#) in San Francisco, California on November 2, 2023.

AAO Presentations

Title: Phentolamine Ophthalmic Solution Rapidly and Safely Reverses Pharmacologically Induced Mydriasis in Two Phase 3 Trials
Presenting Author: Zaina N. Al-Mohtaseb, M.D.
Day/Time: Saturday, November 4, 2023 at 11:54am PDT
Session: PA015
Location: WEST 2006, Moscone Center

Title: LYNX-1: Positive Pivotal Phase 3 Trial of Phentolamine Ophthalmic Solution in Dim Light Vision Disturbance Patients
Presenting Author: P. Dee G. Stephenson, M.D. FACS
Session: PO020
Location: On demand

Title: VEGA-1: Efficacy, Durability and Safety of Phentolamine Ophthalmic Solution in Phase 2 Trial in Presbyopes
Presenting Author: Jay Pepose, M.D. Ph.D.
Session: PO456
Location: On demand

Eyecelerator AAO 2023 Retina Showcase

Title: Ocuphire Corporate Presentation
Presenter: Jay Pepose, M.D. Ph.D.
Day/Time: Thursday, November 2, 2023 at 1:19pm PDT
Location: San Francisco Marriott Marquis

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 been completed, and an End-of-Phase 2 meeting is confirmed with the U.S. Food and Drug Administration ("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 phentolamine ophthalmic solution. Phentolamine is a non-selective alpha-1 and alpha-2 adrenergic

antagonist designed to reduce pupil size by uniquely blocking the alpha-1 receptors found on the iris dilator muscle without affecting the ciliary muscle. In September 2023, the FDA approved RYZUMVI™ (phentolamine ophthalmic solution) 0.75% to treat pharmacologically induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents. Phentolamine is also in Phase 3 clinical development for the treatment of presbyopia and dim light (night) vision disturbances.

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. 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 phentolamine ophthalmic solution 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