

June 8, 2022



# Ocuphire to Present New Interim Masked Safety Data for Oral APX3330 in Diabetics at Annual Macula Society Meeting

*Of 103 Diabetic Subjects Enrolled in the 24-week ZETA-1 Phase 2b Trial, 70% Have Completed 12 or More Weeks*

*Topline Results with First-in-Class Non-Invasive Retinal Candidate APX3330 Expected in Second Half of 2022*

*Mina Sooch CEO to Participate in Ophthalmology Panel of Public/Private Biotechs Hosted Today by Cantor Fitzgerald*

FARMINGTON HILLS, Mich., June 08, 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 an oral presentation by key thought leader David Boyer, M.D. at the 45<sup>th</sup> Annual Macula Society Meeting, which will take place in Berlin, Germany from June 8–11, 2022. In addition, Mina Sooch, CEO and founder of Ocuphire Pharma, will participate in a virtual ophthalmology panel discussion hosted by Cantor Fitzgerald today, June 8<sup>th</sup>, at 10am EDT.

“APX3330 is a novel non-invasive oral therapy, which if approved, has the potential to address the large unmet needs in diabetic retinopathy patients and other diabetes-related complications,” said David Boyer, MD, Senior Partner at Retina-Vitreous Associates Medical Group, Medical Adviser to Ocuphire, and Investigator in the ZETA-1 trial. “The ongoing ZETA-1 Phase 2b trial is expected to provide valuable insights into the drug’s safety and efficacy in diabetics. In February 2022, I presented early masked safety data from the trial at the Bascom Palmer Eye Institute Angiogenesis 2022 conference, which demonstrated a favorable safety and tolerability profile similar to 11 prior trials in non-ophthalmic indications. Now, with 70% of subjects through 12 weeks or more of the 24-week trial, I am excited to present new favorable and consistent safety data to an international audience at the Macula Society Meeting. Ocuphire continues to make an impression on the retinal community through numerous abstract presentations at major medical conferences.”

## **45th Annual Macula Society Meeting**

Session: Diabetic Retinopathy III

Title: **Masked safety data from ZETA-1, an ongoing 24-week Phase 2 clinical trial of APX3330, an oral therapeutic being developed for the treatment of diabetic retinopathy**

Date: Saturday, June 11, 2022, 11:25 AM – 11:34 AM CEST  
Presenter: David Boyer, M.D.  
Location: Main Meeting Room, Ritz-Carlton, Berlin  
Link: [45<sup>th</sup> Annual Macular Society Meeting](#)

### **Ophthalmology Panel Hosted by Cantor Fitzgerald**

Title: **Eyeing Key Events in the Ophthalmology Space in 2022 2.0**

Date: Wednesday, June 8, 10:00 AM EDT

Participants: Kristen Kluska (Host, Cantor Fitzgerald), Mina Sooch (CEO of Ocuphire Pharma), Brian Culley (CEO of Lineage Cell Therapeutics) C. Russell Trenary III (CEO of Outlook Therapeutics), Dr. Daphne Haim-Langford (CEO of Tarsier Pharma)

Mina Sooch will participate in a virtual ophthalmology panel discussion hosted by Kristen Kluska, Managing Director, Biotechnology Equity Research at Cantor Fitzgerald. Topics to be covered for Ocuphire include updates on the oral APX3330 retinal program and Nyxol eye drops which reported positive late-stage clinical data in all 6 readouts from Phase 3 trials in RM, pediatric RM, and NVD as well as Phase 2 trial in presbyopia. This panel discussion is intended for institutional clients of Cantor Fitzgerald. To access the event, please contact your Cantor Sales Representative for registration information.

### **About ZETA-1**

The ZETA-1 Phase 2b trial is a randomized, placebo-controlled, double-masked study designed to evaluate the efficacy of APX3330 to improve diabetic retinopathy over 24 weeks. The study was conducted at 25 U.S. sites and enrolled 103 subjects (target 90-100) with moderately-severe to severe NPDR or mild PDR in the study eye. If patients who are enrolled also have DME in their non-study eye, this eye will also be followed during the trial for potential improvement. The primary endpoint of the study will evaluate the percentage of subjects with a  $\geq 2$  step improvement on the Diabetic Retinopathy Severity Scale (DRSS) score. Secondary endpoints include evaluation of central subfield thickness visual acuity, safety and tolerability. For more information, refer to clinicaltrials.gov identifier: [NCT04692688](#).

### **About Diabetic Retinopathy**

Diabetes is a worldwide epidemic and the leading cause of blindness among adults aged 20 to 74. DR is the most common diabetic complication that affects about 1 in 4 eyes and is manifested when chronically elevated blood sugar levels cause damage to blood vessels in the retina which can cause irreversible visual impairment due to retinal scarring and retinal detachment. Despite the approval of intravitreal injection therapies such as Eylea® for DR, patients are rarely treated at an early stage without macular edema or proliferative diseases because of the asymptomatic nature before progression and patients' resistance to adhere to invasive and frequent VEGF therapies. DR affects over 7 million patients in the U.S. and 93 million patients worldwide. This problem is projected to worsen as the number of individuals at risk of developing diabetes increases by 55% by 2035 to a worldwide total of

592 million people.

## 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. The Company's lead product candidate, Nyxol<sup>®</sup> 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 12 completed clinical trials. Ocuphire has reported positive data from MIRA-2 and MIRA-3 registration trials and MIRA-4 pediatric safety trial for the treatment of RM. Ocuphire also reported positive topline 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 also recently reported positive topline results from LYNX-1 Phase 3 trial of Nyxol for NVD. 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](http://www.clinicaltrials.gov) to learn more about Ocuphire's ongoing APX3330 Phase 2b trial in DR/DME ([NCT04692688](https://clinicaltrials.gov/ct2/show/study/NCT04692688)) and completed Nyxol trials: Phase 3 registration trial in NVD ([NCT04638660](https://clinicaltrials.gov/ct2/show/study/NCT04638660)), Phase 3 registration trials in RM MIRA-2 ([NCT04620213](https://clinicaltrials.gov/ct2/show/study/NCT04620213)) and MIRA-3 ([NCT05134974](https://clinicaltrials.gov/ct2/show/study/NCT05134974)), MIRA-4 pediatric safety study ([NCT05223478](https://clinicaltrials.gov/ct2/show/study/NCT05223478)), and VEGA-1 Phase 2 trial in presbyopia ([NCT04675151](https://clinicaltrials.gov/ct2/show/study/NCT04675151)). As part of its strategy, Ocuphire will continue to explore opportunities to acquire additional ophthalmic assets and seek strategic partners for late-stage development, regulatory preparation, and commercialization of drugs in key global markets. For more information, visit [www.ocuphire.com](http://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, the success and timing of planned regulatory filings, the results of the ZETA-1 Phase 2b trial, and the market for Ocuphire's indications. 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.

## **Contacts**

### **Corporate**

Mina Souch, President & CEO  
Ocuphire Pharma, Inc.  
[ir@ocuphire.com](mailto:ir@ocuphire.com)  
[www.ocuphire.com](http://www.ocuphire.com)

### **Investors**

Corey Davis, Ph.D.  
LifeSci Advisors  
[cdavis@lifesciadvisors.com](mailto:cdavis@lifesciadvisors.com)



Source: Ocuphire Pharma