

April 22, 2021



Ocuphire's APX3330 for Retinal Diseases to be Presented at the 2021 Association for Research in Vision and Ophthalmology (ARVO) Virtual Annual Meeting

Oral Administration of APX3330 Reduced Neovascularization in a Pre-Clinical Mouse Model of Laser-Induced Choroidal Neovascularization

New Data from Physiological-Based Pharmacokinetic (PBPK) Model Supports APX3330 Oral Dose for the Ongoing ZETA-1 Phase 2 Trial

FARMINGTON HILLS, Mich., April 22, 2021 (GLOBE NEWSWIRE) -- Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of several eye disorders, announced today that data from pre-clinical studies and pharmacokinetic modeling of the Company's proprietary APX3330 drug candidate will be presented on Sunday, May 2, 2021 during the upcoming Association for Research in Vision and Ophthalmology (ARVO) virtual Annual Meeting, May 1 – 7, 2021.

Details of the abstract and presentation are as follows:

Title: Oral APX3330 treatment reduces L-CNV lesions in preclinical mouse model and confirms Phase 2 DR/DME clinical dose with sufficient distribution to human retina using PBPK modeling

Session: Diabetic Retinopathy

Presentation Type: Paper Presentation

Date: 11:15 AM – 12:45 PM EDT on Sunday, May 2

On Saturday, May 1, 2021 at 7:00 AM ET, the virtual presentations will be available on demand to registered attendees of the ARVO Annual Meeting. Ocuphire plans to post the APX3330 abstract presentation to Ocuphire's website under [Posters and Publications](#).

Data from this pre-clinical study showed that oral administration of APX3330 was effective in reducing laser-induced choroidal neovascularization (L-CNV) in a mouse model, which is a widely validated model for studying antiangiogenic therapies. Additionally, new data will be presented from PBPK modeling that confirmed the dosing strategy for the ongoing ZETA-1 Phase 2 trial in patients with diabetic retinopathy (DR) and diabetic macular edema (DME).

Dr. Mark R. Kelley, Professor in the Department of Pediatrics and Glick Eye Institute at Indiana University School of Medicine, founder of the APX3330 program, and member of Ocuphire's Medical Advisory Board stated, "We are very pleased to share new data on the PBPK modeling results of APX3330 which quantitatively predict the amount of drug that

would be reaching the retina. At present, DR patients are less frequently treated with anti-VEGF intravitreal injections, so we are excited to initially develop APX3330 as a potential oral treatment option for DR patients.”

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 front and back of the eye indications. The company’s lead product candidate, Nyxol[®] (0.75% phentolamine ophthalmic solution) Eye Drops, 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 dim light or night vision disturbances (NVD), reversal of pharmacologically-induced mydriasis (RM), and presbyopia, and has been studied in 8 clinical trials including the recently completed Phase 3 trial in RM. Ocuphire reported positive topline data on March 15, 2021 for MIRA-2 Phase 3 FDA registration study for treatment of RM. Nyxol is also currently in Phase 3 clinical development for NVD and in Phase 2 for presbyopia. 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. APX3330 has entered Phase 2 clinical development for DR/DME. 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. Please visit www.clinicaltrials.gov to learn more about Ocuphire’s completed Phase 2 trials, recently completed Phase 3 registration trial ([NCT04620213](https://clinicaltrials.gov/ct2/show/study/NCT04620213)), ongoing Phase 3 registration trial ([NCT04638660](https://clinicaltrials.gov/ct2/show/study/NCT04638660)), Phase 2 trial in presbyopia ([NCT04675151](https://clinicaltrials.gov/ct2/show/study/NCT04675151)), and Phase 2 trial in DR/DME ([NCT04692688](https://clinicaltrials.gov/ct2/show/study/NCT04692688)). For more information, please 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 Ocuphire’s product candidates, results of ongoing and future clinical trials, and commercialization and market opportunities. 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, and (ix) the success and timing of commercialization of any of Ocuphire’s product candidates. 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.

Ocuphire Contacts

Mina Sooch, President & CEO
Ocuphire Pharma, Inc.

ir@ocuphire.com
www.ocuphire.com

Corey Davis, Ph.D.

LifeSci Advisors

cdavis@lifescieadvisors.com



Source: Ocuphire Pharma