

October 1, 2021



Ocuphire's Clinical Phase 2b Oral Drug Candidate APX3330 for Retina to be Featured at the OIS Retina@ASRS and ASRS 2021 Annual Meeting

FARMINGTON HILLS, Mich., Oct. 01, 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, today announced that its clinical-stage, novel oral Ref-1 inhibitor, APX3330, for the treatment of diabetic retinal disease will be featured at the Ophthalmology Innovation Summit (OIS) Retina@ASRS Innovation Company Showcase on October 7 in San Antonio, TX. The APX3330 abstract was accepted for podium presentation and discussion at the 39th Annual Meeting of the American Society of Retina Specialists (ASRS), to take place October 8 – 12 in San Antonio, TX.

OIS Retina@ASRS

Session: Innovation Showcase
Title: Ocuphire Presentation - APX3330 Program
Presenter: Mina Sooch, MBA, President & CEO of Ocuphire
Date: Thursday, October 7
Location: Grand Hyatt, San Antonio, TX
Time: 9:16 AM - 9:23 AM (Central Time)

Launched in 2009, the Ophthalmology Innovation Summit serves to showcase novel therapies in development for unmet needs in ophthalmic disease and vision disorders, bringing together entrepreneurs, ophthalmic start-up companies, clinical thought leaders, industry executives and investment professionals to facilitate an exchange of information and connections to drive innovation in the retina, anterior segment, and optometry. For more information, please visit [OIS Retina@ASRS](#).

39th Annual Meeting of ASRS

Session/Program: Diabetic Retinopathy 1 Symposium
Title: APX3330, an Oral Drug in Trial for DR and DME, Demonstrated a Favorable Safety and Tolerability Profile in Multiple Phase 1 and Phase 2 Studies
Presenter: Michael J Allingham, MD, PhD, Assistant Professor of Ophthalmology at Duke University School of Medicine
Date: Saturday, October 9

Location: JW Marriot, San Antonio, TX
Time: 8:51 AM - 8:55 AM (Central Time)

Dr. Allingham will present safety data on oral APX3330 from over 300 healthy volunteers and patients with chronic hepatitis across five Phase 1 and five Phase 2 clinical trials at doses up to 600 mg/day. A sixth Phase 1 study will also be presented, showing safety data from 19 patients with solid tumors who were treated with twice daily oral doses of APX3330 of up to 720 mg/day. The aggregate clinical data from these 11 completed trials support Ocuphire's ZETA-1 Phase 2b study, an ongoing, randomized, double-masked, placebo-controlled trial evaluating the safety and efficacy of oral APX3330 in the treatment of diabetic retinopathy (DR) and diabetic macular edema (DME). Additional information about the ZETA-1 Phase 2b trial can be found at www.clinicaltrials.gov ([NCT04692688](https://clinicaltrials.gov/ct2/show/study/NCT04692688)). For more information on the ASRS annual meeting, please visit [ASRS](https://www.asrs.org).

About Diabetic Retinopathy

Diabetes is the leading cause of blindness among adults aged 20 – 74. In the United States alone, over 7 million patients suffer from diabetic retinopathy (DR), a complication of diabetes in which chronically elevated blood sugar levels cause damage to blood vessels in the retina. An additional 750,000 patients suffer from diabetic macular edema (DME), one of the most common complications of diabetic retinopathy where the macula swells from fluid leaked from damaged blood vessels. The disease progression of both DR and DME involves abnormal vessel proliferation and inflammation. Thus, current approved treatments for DR and DME encompass an over \$10 billion global market and involve administering anti-VEGF injections (such as EYLEA[®] by Regeneron, Lucentis[®] by Genentech, and Avastin[®] by Genentech) to decrease vessel formation or steroids (such as OZURDEX[®] by Allergan) to decrease inflammation in eyes with advanced retinal disease. ZETA-1 is investigating the potential of APX3330 to offer an innovative and conveniently administered oral treatment for diabetic retinopathy that addresses both of these disease pathways.

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[®] 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 dim light or night vision disturbances (NVD), reversal of pharmacologically-induced mydriasis (RM), and presbyopia, and has been studied in 9 clinical trials including the recently completed Phase 3 trial in RM and Phase 2 trial in presbyopia. Ocuphire reported positive top-line data in March 2021 for MIRA-2, a Phase 3 FDA registration study for treatment of RM. Ocuphire also reported positive top-line data in June 2021 for VEGA-1, a Phase 2 trial for the treatment of presbyopia. Nyxol is also currently in Phase 3 clinical development 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. APX3330 is

currently enrolling subjects in a Phase 2b clinical trial in subjects with 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 in RM ([NCT04620213](https://clinicaltrials.gov/ct2/show/study/NCT04620213)), recently completed Phase 2 trial in presbyopia ([NCT04675151](https://clinicaltrials.gov/ct2/show/study/NCT04675151)), ongoing Phase 3 registration trial in NVD ([NCT04638660](https://clinicaltrials.gov/ct2/show/study/NCT04638660)), and Phase 2b 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. 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.

Ocuphire Contacts

Mina Sooch, President & CEO
Ocuphire Pharma, Inc.
ir@ocuphire.com
www.ocuphire.com

Corey Davis, Ph.D.
LifeSci Advisors
cdavis@lifesciadvisors.com



Source: Ocuphire Pharma