October 6, 2022

Ocuphire Pharma Hosting Key Opinion Leader Event on Oral APX3330 for Diabetic Eye Disease

Virtual Webinar to Take Place Friday, October 14th @ 11 AM ET

Topline Results from ZETA-1 Phase 2b Trial of APX3330 Expected Later in 4Q 2022

FARMINGTON HILLS, Mich., Oct. 06, 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 that it will host a key opinion leader (KOL) webinar highlighting oral APX3330, its lead drug candidate for diabetic retinopathy (DR) and diabetic macular edema (DME), on Friday, October 14, 2022 at 11AM to 12:30PM Eastern Time.

The event will feature KOLs Peter Kaiser, MD, from the Cleveland Clinic, Caroline Baumal, MD, from Tufts Medical Center, and David Lally, MD, from New England Retina Consultants. KOL presentations will set the stage for a discussion on Ocuphire's APX3330, a first-in-class, novel orally administered small molecule inhibitor of VEGF and inflammation currently in a completed multi-center, randomized, double-masked, placebo-controlled ZETA-1 Phase 2b trial for DR and DME. The discussion will highlight the unmet need and current treatment landscape for DR/DME. New data will be presented on study demographics and 24-week masked safety data from 103 enrolled diabetic retinopathy patients. The KOLs will share insights on the trial design, endpoints, and safety and efficacy expectations for a new novel oral treatment in DR. Topline results from ZETA-1 are expected later in the 4th quarter.

A live question & answer session will follow. To register for the event, please clickhere.

Dr. Peter Kaiser, MD is a clinical research expert, serving as Study Chairman of five major, multi-center, international clinical trials, and principal investigator in numerous studies for Age-related Macular Degeneration (AMD), DR, and other retinal disorders. He is the Editor-in-Chief of Retinal Physician, Associate Editor of International Ophthalmology Clinics, and serves on the editorial boards of Retina, Retina Today, and Ocular Surgery News. He is a major contributor to medical literature, having authored seven textbooks and more than 250 peer-reviewed papers, and has been recognized by the American Academy of Ophthalmology and American Society of Retina Specialists (ASRS) with Senior Achievement Awards and is listed as one of the "Best Doctors in America." Dr. Kaiser graduated magna cum laude with Highest Honors from Harvard College and Harvard Medical School. He completed an ophthalmology residency at the Massachusetts Eye and Ear Infirmary, and a vitreoretinal fellowship at Bascom Palmer Eye Institute before joining the vitreoretinal department of the Cole Eye Institute, Cleveland, Ohio.

Caroline R. Baumal, MD is a Professor of Ophthalmology, Co-Director of the Retina Service and Co-Director of the medical retina fellowship at New England Eye Center, Tufts Medical Center in Boston, MA. Her clinical interests include age-related macular degeneration, diabetic retinopathy, retinal circulatory disorders, complex vitreoretinal surgery, and retinopathy of prematurity (ROP). She has received multiple awards from various societies including the American Academy of Ophthalmology, and is on the editorial board for Retina Cases and Brief Reports and Ophthalmic Surgery, Lasers, and Imaging (OSLI) Retina. Dr. Baumal has authored over 170 publications, 33 book chapters on retinal diseases and recently edited the book Treatment of Diabetic Retinopathy. Dr. Baumal completed medical school and ophthalmology residency at the University of Toronto after undergraduate studies at McGill University. She completed two fellowships: one at New England Eye Center, Boston in Medical Retina and Lasers, and another in Vitreoretinal Diseases and Surgery at Wills Eye Hospital in Philadelphia. Dr. Baumal is Board Certified by the American Board of Ophthalmology.

Dr. David Lally is the Director of the Retina Research Institute at New England Retina Consultants. He is an attending surgeon at Baystate Medical Center in Springfield, Massachusetts and Assistant Professor in the Department of Surgery at the University of Massachusetts Medical School-Baystate. Dr. Lally is a clinical trial expert who has participated as an investigator in more than 40 clinical trials for retinal diseases. He lectures nationally and has authored over 30 peer-reviewed papers published in journals including the New England Journal of Medicine (NEJM), JAMA Ophthalmology, and Ophthalmology Retina. He also serves as a manuscript reviewer for several ophthalmology journals. Dr. Lally is an active member of the American Society of Retina Specialists with the Fellow of the American Society of Retina Specialist (FASRS) award designation. Dr. Lally graduated from Vanderbilt University and received a medical degree from Jefferson Medical College. He completed an ophthalmology residency at the Wills Eye Hospital in Philadelphia followed by a vitreoretinal fellowship at Tufts/New England Eye Center and Ophthalmic Consultants of Boston.

About Diabetic Retinopathy

Diabetes, a worldwide epidemic, is the leading cause of blindness among adults age 20 to 74. DR is the most common diabetic complication that affects the eyes and is manifested when chronically elevated blood sugar levels cause damage to blood vessels in the retina. DR affects over 8 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.

There are two major types of DR: (1) non-proliferative DR (NPDR) and (2) proliferative DR (PDR). NPDR is an earlier, more typical stage of DR that can progress to more severe forms of DR if untreated and if the underlying diabetes remains uncontrolled. PDR is a more advanced stage of DR that is characterized by retinal neovascularization that, if left untreated, can lead to permanent damage and blindness. When DR is in its early stages, blood vessels in the retina are damaged and can leak fluid into the retina, a complication called diabetic macular edema (DME). Fluid from DME and hemorrhage of the abnormal blood vessels formed in PDR can interfere with vision and can cause irreversible visual impairment due to retinal scarring and retinal detachment. Despite the approval of intravitreal injection therapies for DR, patients with DR are not widely treated.

About APX3330

APX3330 is a first-in-class, small molecule, oral inhibitor of the transcription factor regulator Ref-1 (reduction-oxidation effector factor-1). With a novel dual mechanism of action, APX3330 blocks the downstream pathways regulated by Ref-1 – including those involving angiogenesis (VEGF) and inflammation (NFkB) – to decrease abnormal activation of both angiogenesis, and of inflammatory pathways that are implicated across several ocular diseases, including DR, DME, and age-related macular degeneration (AMD).

APX3330 has shown a favorable safety and tolerability profile over 11 clinical trials conducted in healthy, hepatitis, and cancer subjects prior to the current Phase 2 ZETA-1 trial in diabetic retinopathy. The most recent interim analysis of masked safety data from ZETA-1 trial was presented by Dr. Michael Allingham, M.D., Ph.D., at the American Society of Retina Specialists' (ASRS) 40th Annual Scientific Meeting in July 2022. These data indicated that oral APX3330 continued to demonstrate a favorable safety profile consistent with the prior trials comprising hundreds of patients. Across all the trials, the safety findings represent over 9000 subject-days of exposure at the target dose of 600 mg/day.

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® 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). Nyxol has been studied in 12 completed clinical trials, with positive data reported from the MIRA-2 and MIRA-3 registration trials and the MIRA-4 pediatric safety trial for the treatment of RM. Ocuphire also reported positive top-line data from the VEGA-1 Phase 2 trial of Nyxol for treatment of presbyopia, which evaluated both Nyxol as a single agent and Nyxol with low dose pilocarpine ("LDP") 0.4% as adjunctive therapy. The Company recently announced positive top-line results from the LYNX-1 Phase 3 trial of Nyxol for night vision disturbances (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). APX3330 has been studied in 11 Phase 1 and 2 trials.

Please visit www.clinicaltrials.gov to learn more about Ocuphire's ongoing APX3330 Phase 2b trial in DR/DME ZETA-1 (NCT04692688) and completed Nyxol trials: Phase 3 registration trial in NVD LYNX-1 (NCT04638660), Phase 3 registration trials in RM MIRA-2 (NCT04620213) and MIRA-3 (NCT05134974), MIRA-4 Phase 3 pediatric safety study (NCT05223478), and Phase 2 trial in presbyopia VEGA-1 (NCT04675151). 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, the success and timing of planned regulatory filings, including the timing of the results of the ZETA-1 Phase 2b trial and the market for Ocuphire's indications including DR. 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