May 20, 2021

Ocuphire to Host Key Opinion Leader Event on Nyxol® as a Potential New Treatment Option for Reversing Pharmacologically Induced Mydriasis

Highlights of Recent Positive Data from Nyxol's Phase 3 Registration Trial

Roundtable Discussion by 3 KOLs with Unique Perspectives and Distinct Patient Populations

Webinar on Wednesday, May 26th @ 1:00 pm EDT

FARMINGTON HILLS, Mich., May 20, 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 it will host a key opinion leader (KOL) event on Nyxol, its late-stage product candidate under development as a potential new treatment option for reversing pharmacologically induced mydriasis (dilation of pupil for eye exams).

The Webinar will feature a roundtable discussion among three KOLs from across the spectrum of eye care providers - optometry, ophthalmology, and retina:

- Paul M. Karpecki, O.D., F.A.A.O. – Cornea and Refractive Optometrist, Kentucky Eye Institute
- Jay Pepose, M.D., Ph.D. – Cornea and Refractive Surgeon, Pepose Vision Institute
- Peter Kaiser, M.D. – Vitreoretinal Surgeon, Cole Eye Institute, Cleveland Clinic

Please register ahead of time for the Webinar on Wednesday, May 26, 2021 at 1:00 pm EDT using this link.

Drs. Karpecki, Pepose, and Kaiser will discuss the large unmet need for a treatment to reverse approximately 100 million pharmacological dilations that occur each year. Dr. Pepose will present the positive Phase 3 results from the recently completed pivotal MIRA-2 trial for Nyxol for the reversal of pharmacologically induced mydriasis, which met its primary endpoint and multiple secondary endpoints. The panel will also discuss the pharmacological approaches that have been considered in the past, how Nyxol has the potential to address an unmet medical need as there are no commercial treatments currently available for reversal of mydriasis, and how a reversal agent could benefit their clinical practice and patients. An update will be provided on the reversal of mydriasis program, including the remaining steps prior to NDA submission and plans for commercialization. The KOLs and Ocuphire management will be available to answer questions following the panel discussion.

“There is a significant unmet need for patients with regards to the reversal of mydriasis, an indication that currently lacks a treatment. We are excited to hear from these experts who will provide their clinical perspective on how Nyxol will benefit both patients and physicians alike,” says Susan Benton, MBA, a 30-year veteran of the ophthalmic pharmaceutical and device industry and a director on Ocuphire’s Board. “As we plan our commercial strategy for launch, it is critical to work closely with eye care professionals who will play an important role in the adoption of this potential new treatment option if approved by the FDA.”

About the KOLs

Paul M. Karpecki O.D., F.A.A.O. currently serves as Director of Cornea Services for Kentucky Eye Institute in Lexington KY, Gaddie Eye Centers in Louisville KY, and Center for Sight in Carmel IN. He is the Chief Medical Editor for Review of Optometry, chairman of the NTT Conferences and heads the journal’s clinical content. He is the Medical Director for KEPLR Vision. He was appointed co-chair for the previous two Tear Film and Ocular Surface Society (TFOS) Symposia and served on the DEWS II Diagnostic Methodology Committee. In 2017-2018 he completed a full year preceptorship in advanced retinal disease at Retina Associates of Kentucky, one of the top 20 retina programs in the country. He currently serves as an Associate Professor at the Kentucky College of Optometry and on the board of the charitable organization Optometry Giving Sight. Dr. Karpecki received his Doctor of Optometry degree from Indiana University and completed a Durrie Fellowship in Cornea & Refractive Surgery in Kansas City in affiliation with the Pennsylvania College of Optometry.

Jay Pepose, M.D., Ph.D. is a board-certified ophthalmologist specializing in cataract, corneal, and refractive surgery. He is the founder and an attending surgeon of Pepose Vision Institute and Professor of Clinical Ophthalmology and Visual Sciences at Washington University School of Medicine, where he held the Bernard Becker Chair. An advisor and consultant to numerous ophthalmic companies throughout the world, he has published hundreds of peer reviewed articles, holds ophthalmology related patents, and has been at the forefront of the industry's evolutionary changes throughout his career. He is recipient of the Lifetime Achievement Award from the American Academy of Ophthalmology, the Cogan Award from the Association of Research in Vision and Ophthalmology and has been elected to the American Ophthalmological Society. Dr. Pepose is actively involved in clinical research and has been the recipient of R-01 grant support from the National Eye Institute. He has served as executive editor of The American Journal of Ophthalmology, as well as on the editorial board of Investigational Ophthalmology and Visual Science, Cornea, and The Journal of Refractive Surgery. After obtaining a Bachelor of Arts degree Magna Cum Laude with High Honors in Biology along with a Master of Arts in Neurophysiology from Brandeis University, Dr. Pepose completed the MD-PhD program at UCLA School of Medicine as a Regent’s Scholar and was inducted into the Alpha Omega Alpha Honor Medical Society. Dr. Pepose received residency training in ophthalmology and the Distinguished Alumnus Award from The Wilmer Institute of The Johns Hopkins Hospital and fellowship training in cornea, external disease and refractive surgery at Georgetown University Medical Center.

Peter K. Kaiser, M.D., is a clinical research expert, serving as Study Chairman of 5 major, multi-center, international clinical trials, and principal investigator in numerous studies for Age-related Macular Degeneration, Diabetic Retinopathy, and other retinal disorders. He is the founder and director of the Digital Optical Coherence Tomography Reading Center

(DOCTR), 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 National Institute of Health (NIH) funded investigator, leading a team involved in the evaluation of vascular biology in age-related macular degeneration and diabetic retinopathy. Dr. Kaiser serves on numerous scientific advisory boards and addresses his research interests as an invited speaker at national and international conferences. He is a major contributor to the medical literature having authored 7 textbooks and more than 250 peer-reviewed papers, has been recognized by the American Academy of Ophthalmology and American Society of Retina Specialists 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.

About the Reversal of Mydriasis Market

Every year in the U.S., approximately 100 million eye exams are performed that require dilation of the pupil (mydriasis) to examine the back of the eye either for routine check-ups, disease monitoring or surgical procedures. Depending on the individual and the color of their eyes, the pharmacologically-induced dilation can last anywhere from 6 to 24 hours. Dilated eyes have heightened sensitivity to light and an inability to focus on near objects, causing difficulty with reading, working, and driving.

Market research conducted by GlobalData surveyed several hundred patients and eye care providers (optometrists and ophthalmologists) about reversal of mydriasis (as well as Night Vision Disturbances and Presbyopia). Over 65% of surveyed patients reported moderate to severe negative impact of a dilated exam. This underscores the potential value of the role of the investigational product candidate Nyxol in improving comfort and daily function after pupil dilation. Additionally, an estimated 45% of patients responded that they would be very likely to request a dilation reversal drop, and more than 40% of eye care providers would be likely to use a reversal drop if such a treatment were commercially available.

About Nyxol

Ocuphire'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. Nyxol has been studied in 8 clinical trials demonstrating a favorable safety and tolerability profile. Ocuphire recently reported positive top-line data for pivotal MIRA-2 Phase 3 trial for treatment of RM in March 2021. Nyxol met its primary endpoint in more rapidly reversing a dilated pupil back to its baseline diameter, as well as multiple secondary endpoints in this 185-patient clinical trial. Nyxol is also currently in Phase 2 for presbyopia with top-line results expected Q2 2021, and in Phase 3 clinical development for NVD with top-line results expected Q3 2021. Please visit www.clinicaltrials.gov to learn more about Ocuphire's completed Phase 2 trials in RM, Glaucoma, and NVD, recently completed Phase 3 registration trial in RM (NCT04620213), and ongoing Phase 2 trial in presbyopia (NCT04675151) and Phase 3 registration trial in NVD (NCT04638660).

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 – Nyxol and APX3330 – targeting front and back of the eye indications. 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 in key global markets. 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, (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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