May 2, 2023

Ocuphire Announces APX3330 and Nyxol® Data Presentations at ASCRS 2023 and Eyecelerator

FARMINGTON HILLS, Mich., May 02, 2023 (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 presentations featuring results from the Company's recently completed trials of APX3330 and Nyxol® at the American Society of Cataract and refractive Surgery (ASCRS) to be held in San Diego, CA May 5-8, 2023. In addition, Ocuphire, represented by Chief Medical Advisor Jay Pepose M.D., Ph.D, will also be featured in the Marketplace Company Showcase at Eyecelerator @ ASCRS 2023 on May 4.

Eyecelerator @ ASCRS 2023 – May 4, 2023
Marriott Marquis San Diego Marina

Format:	Company Presentation
Session:	Breakout and Break it Down: Marketplace Company Showcases
Presenter:	Jay Pepose, M.D., Ph.D., Ocuphire Chief Medical Advisor
Date/Time:	Thursday, May 4, 1:45 PM – 1:53 PM PDT

ASCRS Annual Meeting – May 5-8, 2023
San Diego Convention Center

Paper Presentations:

Title:	**Phentolamine Ophthalmic Solution Utilizes a Novel α-1 Antagonist Mechanism for Improving Near Visual Acuity in the Vega-1 Phase 2 Trial**
Presenter:	James Katz, M.D.,
Session/Location:	SPS-107 Presbyopia Correction: New Treatments and Studies; Upper Level, Room 5A
Date/Time:	Saturday, May 6 10:30 AM – 10:35 AM PDT

Title:	**Early Intervention for Diabetic Retinopathy (DR): Safety and Efficacy of Novel, Oral Therapeutic APX3330 from ZETA-1 Phase 2 Trial**
Presenter:	Christina Weng, M.D., M.B.A.

Session/Location: SPS-115 Retina; Upper Level, Room 5A
Date/Time: Saturday, May 6 2023, 1:40 PM – 1:45 PM PDT

Title: **Lynx-1 Pivotal Phase 3 Randomized Placebo-Controlled Trial of Phentolamine Ophthalmic Solution in Subjects with Dim Light Vision Disturbance**
Presenter: Jay Pepose, M.D., Ph.D.
Session/Location: SPS-208 Refractive Comparison & Complications; Upper Level, Room 5B
Date/Time: Sunday, May 7 2023, 10:05 AM – 10:10 AM PDT

Title: **Lynx-1 Phase 3 Trial: Phentolamine Ophthalmic Solution Improves Photic Symptoms and Quality of Life in Night Vision Disturbance Patients**
Presenter: Jay Pepose, M.D., Ph.D.
Session/Location: SPS-208 Refractive Comparison & Complications; Upper Level, Room 5B
Date/Time: Sunday, May 7 10:10 AM – 10:15 AM PDT

Title: **Effect of Phentolamine Ophthalmic Solution on Accommodation, Visual Acuity, and Restoration of Pupillary Light Reflex in the MIRA-3 Study**
Presenter: Zaina Al-Mohtaseb, M.D.
Session/Location: SPS-214 Cornea Diagnostics and Studies; Upper Level, Room 1A
Date/Time: Sunday, May 7, 1:30 PM – 1:35 PM PDT

Additional electronic poster presentations at ASCRS:

- **Lynx-1 Phase 3 Trial: Phentolamine Ophthalmic Solution Proves Effective in Post-Lasik Patients with Dim Light Vision Disturbances** (Marguerite McDonald, M.D., FACS)
- **The Safety and Efficacy of Phentolamine Ophthalmic Solution for Reversal of Pharmacologically Induced Mydriasis in Subjects Aged 3-11 Years** (Y. Ralph Chu, M.D.)
- **Vega-1 Phase 2 Trial: Phentolamine Ophthalmic Solution Maintains Pupillary Reflex with Improved Distance-Corrected Near Vision in Presbyopes** (Inder P. Singh, M.D.)

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.

Ocuphire has a partnership with Viatris, Inc. to develop and commercialize Nyxol® eye drops as a preservative-free eye drop formulation of phentolamine mesylate, a non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size by uniquely blocking the alpha-1 receptors found only on the iris dilator muscle without affecting the ciliary muscle. Nyxol has been studied in a total of 12 clinical trials (3 Phase 1, 5 Phase 2, 4 Phase 3) across three indications, including single-use for reversal of pharmacologically-induced mydriasis (RM), and once-daily for treatment of presbyopia and dim light (night) vision disturbances (DLD), pending regulatory approvals. Nyxol's NDA under the 505(b)(2) pathway for the first indication, RM, has been accepted with a PDUFA date assigned of September 28, 2023. Nyxol is currently in Phase 3 for presbyopia and DLD.

Ocuphire's other late-stage product candidate, APX3330, is a first-in-class, small molecule oral drug that blocks downstream pathways regulated by transcription factor Ref-1 – including those involving angiogenesis (VEGF) and inflammation (NFkB). These pathways are implicated in several ocular diseases, including diabetic retinopathy (DR), diabetic macular edema (DME), and age-related macular degeneration (AMD). Ocuphire recently announced topline data from the ZETA-1 Phase 2 trial in which APX3330 achieved statistical significance on a key pre-specified secondary endpoint of preventing clinically meaningful progression of DR after 24 weeks of daily treatment. APX3330 has also shown a favorable safety and tolerability profile in diabetic subjects (ZETA-1 trial) and in 11 previous clinical trials conducted in healthy, liver disease, and cancer subjects. An End-of-Phase 2 meeting with the FDA is planned for APX3330.

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, statements concerning the potential receipt of regulatory approval for Nyxol for the treatment of RM. 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) risks that the Nyxol partnership may not facilitate the commercialization or market acceptance of Ocuphire's product candidates; (x) the success and timing of commercialization of any of Ocuphire's product candidates and (xi) 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