July 26, 2023

Ocuphire to Present at American Society of Retina Specialists Annual Meeting and OIS Retina Innovation Summit

ASRS presentations will feature data from ZETA-1 Phase 2 trial evaluating APX3330 in diabetic retinopathy

End-of-Phase 2 meeting with FDA for APX3330 scheduled for Q4 2023

FARMINGTON HILLS, Mich., July 26, 2023 (GLOBE NEWSWIRE) -- Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of retinal and refractive eye disorders, today announced that results from the ZETA-1 Phase 2 trial evaluating APX3330 in diabetic retinopathy will be presented at the American Society of Retinal Specialists (ASRS) annual scientific meeting to take place in Seattle, Washington, July 28 to August 1. In addition, Ronil Patel, MTech, MS, SVP of Operations & Business Development at Ocuphire, will provide a corporate update at the OIS Retina Innovation Summit on July 27, also in Seattle, Washington.

Ocuphire also announced that it has scheduled an End-of-Phase 2 meeting with the FDA in Q4 2023 to discuss the specifics of the APX3330 development program. In the ZETA-1 trial, APX3330 achieved statistical significance in preventing clinically meaningful progression of diabetic retinopathy (DR), as measured by the percentage of subjects with binocular ≥3-step worsening in DRSS, the anticipated Phase 3 primary endpoint.

“APX3330 is the most advanced oral program currently in development for diabetic retinopathy, and the End-of-Phase 2 meeting confirmed for Q4 2023 is a critical milestone for our development program,” said Rick Rodgers, Interim Chief Executive Officer of Ocuphire. “Currently, patients with non-proliferative diabetic retinopathy (NPDR) are not treated due to the lack of non-invasive options on the market and the monthly time burden required for intravitreal injections. Eighty percent of physicians prefer to use a wait-and-see approach for these patients rather than delivering a monthly biologic treatment where patients often become incomplete responders. If approved, APX3330 has the potential to shift the treatment paradigm and be the first non-invasive, oral, early treatment for the 8 million NPDR patients who are at risk of progressing to vision-threatening complications. We look forward to working with the FDA to confirm the Phase 3 study design and advancing APX3330 towards a potential NDA submission.”

ASRS 41st Annual Scientific Meeting
Diabetic Retinopathy Symposium 4

Presentation:	*ZETA-1 Phase 2 Trial Efficacy Results for APX3330: a Novel, Oral Ref-1 Inhibitor for the Treatment of Diabetic Retinopathy*
Presenter:	David R. Lally, MD
Date / time:	Tuesday August 1, 9:35am PT

Presentation:	*ZETA-1 Phase 2 Trial Safety and Tolerability Results for APX3330: a New Oral Ref-1 Inhibitor for the Treatment of Diabetic Retinopathy*
Presenter:	Daniel Su, MD
Date / time:	Tuesday August 1, 9:41am PT

OIS Retina Innovation Summit

Session:	Innovation Showcase
Presenter:	Ronil Patel, MTech, MS, SVP, Operations & Business Development
Session date / time:	Thursday July 27, 8:35am to 10:00am PT
Location:	Hyatt Regency Seattle

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 retinal and refractive eye disorders.

Ocuphire's lead 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 confirmed for APX3330 in Q4 2023.

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 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.

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 End-of-Phase 2 meeting with the FDA to confirm Phase 3 registration endpoints and study parameters, and 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