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Ocuphire Presents APX3330 ZETA-1 Data at Clinical Trials at the Summit (CTS) 2023

FARMINGTON HILLS, Mich., June 12, 2023 (GLOBE NEWSWIRE) -- Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of retinal and refractive eye disorders, today announced that a presentation titled, *Safety and Efficacy of an Oral Therapeutic APX3330 from ZETA-1 Phase 2 Trial in Patients with Diabetic Retinopathy*, was delivered by David Lally, M.D. F.A.S.R.S. at the Clinical Trials at the Summit (CTS) 2023 meeting in Park City, Utah on Saturday, June 10. Dr. Lally is a member of Ocuphire's Medical Advisory Board. APX3330 was evaluated in patients with mild to moderate non-proliferative diabetic retinopathy (NPDR) and mild proliferative diabetic retinopathy (PDR).

"We were pleased to have had another opportunity to share the data from our ZETA-1 trial with the retina community at this year's CTS," said Rick Rodgers, Interim Chief Executive Officer. "The ZETA-1 trial achieved statistical significance for APX3330 preventing clinically meaningful progression of diabetic retinopathy, as measured by the percentage of subjects with binocular improvement/worsening in DRSS. This is a potential registration endpoint. We are now preparing for an End-of-Phase 2 meeting with the FDA to confirm Phase 3 registration endpoints and study parameters."

Dr. David Lally added, "Diabetic retinopathy affects approximately 8 million patients in the U.S. and is the leading cause of blindness among working-age adults. Most patients with DR are not treated as the disease is asymptomatic and patients are reluctant to undergo monthly injections. The current treatment paradigm for the majority of physicians is to wait and monitor NPDR patients, with anti-VEGF or steroid injectable therapy or laser treatment reserved for patients who progress to proliferative DR or DME. The data from ZETA-1 show that APX3330 can potentially slow disease progression and has a favorable safety and tolerability profile. If the ZETA-1 results are confirmed in Phase 3 and APX3330 is subsequently approved, it has the potential to be a non-invasive early intervention treatment for the millions of DR patients at risk of progressing to vision-threatening complications. In addition, an oral agent with a favorable safety profile can potentially allow for a wider prescriber base including general ophthalmology, optometry, and primary care to manage early DR."

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 planned for APX3330.

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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