September 12, 2022

Ocuphire Pharma Receives PDFUA Fee Waiver for Nyxol New Drug Application from FDA

NDA Submission for Nyxol Eye Drops in First Indication on Track for Late 2022

FARMINGTON HILLS, Mich., Sept. 12, 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 the U.S. Food and Drug Administration (FDA) has granted a small business waiver of the Prescription Drug User Fee Act (PDUFA) fee of $3.1 million for the 505(b)(2) New Drug Application (NDA) for Nyxol (phentolamine ophthalmic solution), the Company's late stage product candidate. Ocuphire remains on track to file the NDA for Nyxol in its first indication, reversal of mydriasis (RM), in late 2022.

"We are pleased to receive this meaningful NDA fee waiver for Nyxol and look forward to continuing to work with the FDA throughout the submission and review process," said Mina Sooch, MBA, Founder and CEO of Ocuphire Pharma. "NDA submission in late 2022 is a high priority. In parallel, we are ramping up our pre-commercial activities and continue discussions with commercial partners in preparation for the anticipated approval and launch of Nyxol in 2023 as potentially the only dilation reversal drops."

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 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). APX3330t has been studied in 11 Phase 1 and 2 trials. The Company announced the completion of last patient last visit in late August with top-line results expected in 4Q22.

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 planned NDA filing for Nyxol in RM, the market for Ocuphire's indications, business strategy, pre-commercialization activities, and commercialization of Ocuphire's product candidates. 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.

Contacts

Corporate

Mina Sooch, President & CEO
Ocuphire Pharma, Inc.
ir@ocuphire.com
www.ocuphire.com

Investors

Corey Davis, Ph.D.
LifeSci Advisors
cdavis@lifesciadvisors.com

Source: Ocuphire Pharma