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Ocuphire Extends U.S. Patent Protection for Late-Stage Drug Candidate Nyxol® for Reversal of Mydriasis by Five More Years into 2039 with New Patent Issuance

Issuance Extends Nyxol's U.S. Patent Protection from 2034 into 2039 for RM Indication

Growing Patent Estate Eligible for FDA Orange Book Listing

On Track to File NDA for Nyxol in First Indication RM in Late 2022

Potential Second Half 2023 Approval as Only Eye Dilation Reversal Drop

FARMINGTON HILLS, Mich., Aug. 03, 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 the issuance of U.S. Patent No. 11,400,077. The patent provides added intellectual property protection for the company's late-stage product candidate, Nyxol (phentolamine mesylate), with claims directed to methods for treating mydriasis using phentolamine mesylate. The patent is eligible for listing in the U.S. FDA Orange Book and has a term extending into year 2039.

"We are very pleased with the issuance of this new patent for Nyxol, which extends our intellectual property protection in the U.S. by an additional five years into 2039," said Mina Sooch, MBA, Founder and CEO of Ocuphire Pharma. "Last year we were granted a new U.S. Patent for presbyopia extending our existing patent estate into year 2039 and now we are very pleased with the issuance of this new patent for Nyxol in reversal of mydriasis," said Mina Sooch, MBA, President and CEO of Ocuphire Pharma. "As we own the worldwide rights to Nyxol for all indications, this added protection will position us to maximize the commercial value of Nyxol for at least 15 years in reversal of mydriasis as we plan to submit an NDA to the FDA later this year. If approved, Nyxol could be launched in the second half of 2023."

Nyxol® Eye Drops Patent Estate

Ocuphire owns all of the worldwide rights to Nyxol for all indications. Ocuphire's patent estate for Nyxol includes patents and patent applications for phentolamine mesylate formulations and methods of using phentolamine mesylate. Ocuphire's patent estate for Nyxol contains nine issued U.S. patents, eight pending U.S. non-provisional patent applications, as well as issued patents in Australia, Canada, Europe, Japan, and Mexico and pending patent applications in Australia, Canada, Europe, Japan, and other foreign countries. Ocuphire's first set of U.S. and foreign patents expire in year 2034, while

Ocuphire's second set of U.S. patents expire in year 2039. Patents, if granted based on Ocuphire's pending foreign patent applications, would expire in year 2039.

Reversal of Mydriasis Market Opportunity

An estimated 100 million eye dilations are conducted every year in the U.S. to examine the back of the eye either for routine check-ups, disease monitoring or surgical procedures across all eye care practice groups. Depending on the individual and the color of their eyes, the pharmacologically-induced dilation can last anywhere from 6 to 24 hours in adults. Dilated eyes have heightened sensitivity to light and an inability to focus on near objects, causing difficulty reading, working and driving. Currently, there are no approved or available treatment options to safely reverse mydriasis. If approved, Nyxol has the potential to be the only FDA-approved drug for the reversal of mydriasis, uniquely modulating the pupil by blocking or 'relaxing' the α1 receptors found only on the iris dilator muscle. This mechanism is differentiated from other miotics in that Nyxol moderately reduces the pupil size without engaging the ciliary muscle, resulting in favorable safety and tolerability seen across 12 completed trials in 3 indications by avoiding accommodative ciliary spasm, associated headaches and browaches, narrow angle closure, or risk of retinal detachment.

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), and has been studied in 12 completed clinical trials. Ocuphire has reported positive data from MIRA-2 and MIRA-3 registration trials and MIRA-4 pediatric safety trial for the treatment of RM. Ocuphire also reported positive topline data from the VEGA-1 Phase 2 trial of Nyxol for treatment of presbyopia, both Nyxol as a single agent and Nyxol with low dose pilocarpine ("LDP") 0.4% as adjunctive therapy. The Company recently reported positive topline results from LYNX-1 Phase 3 trial of Nyxol for 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) and has been studied in 11 Phase 1 and 2 trials. The Company announced in March the completion of enrollment in the ZETA-1 Phase 2b clinical trial of APX3330 to treat DR/DME. 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). As part of its strategy, Ocuphire will continue to explore opportunities to acquire additional ophthalmic assets and seek strategic partners for late-stage development, regulatory preparation, and commercialization of drugs in key global markets. 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, the timing of planned commercialization of Nyxol in RM, the market for RM, business strategy, pre-commercialization activities, our ability to protect our intellectual property rights, and the potential for and success of commercialization of Ocuphire's product candidates, including Nyxol. 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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