

# Ocuphire Granted Two New U.S. Patents Covering Late-Stage Drug Candidate Nyxol®, Including for the Treatment of Presbyopia

Newly Issued Claims Extend Patent Protection to Year 2039 for Nyxo<sup>®</sup> Combination Therapy for Presbyopia

Provides Broader Protection for Nyxol® Across Indications on Methods of Use as Daily Administration

FARMINGTON HILLS, Mich., May 18, 2021 (GLOBE NEWSWIRE) -- Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of several eye disorders, announced today that the United States Patent and Trademark Office (USPTO) has issued two patents covering the Company's late-stage product candidate, Nyxol (phentolamine mesylate). Both patents are directed to categories of subject matter eligible for listing in the U.S. FDA Orange Book:

- **Nyxol for Treatment of Presbyopia:** U.S. Patent No. 10,993,932 issued on May 4, 2021 with claims to methods of treating presbyopia using a combination of phentolamine mesylate and low-dose pilocarpine. The term of this patent is to year 2039.
- **Nyxol for Daily Administration:** U.S. Patent No. 11,000,509 issued on May 11, 2021 with claims to methods of improving visual performance by daily administration of phentolamine mesylate at or near bedtime of the patient alone or in combination with one or more additional therapeutic agents. The term of the patent is to year 2034.

"We are quite pleased to announce the issuance of these two new U.S. patents that further strengthen our already robust patent portfolio for Nyxol," said Mina Sooch, MBA, President and CEO of Ocuphire Pharma. "As we continue to meet milestones in our ongoing clinical trials investigating Nyxol for various refractive indications, patents like these provide the protection necessary to ensure commercial success. Importantly, Ocuphire owns all of the worldwide rights to Nyxol for all indications. These broader and new claims for daily use and presbyopia respectively reflect several years of strategic effort by our team and our patent counsel Dechert LLP. The timing is ideal with our recent announcement of enrollment completion in the VEGA-1 Phase 2 presbyopia trial and the upcoming expected top-line results by the end of June."

# Nyxol® Eye Drops Patent Estate

Ocuphire's patent estate for Nyxol includes patents and patent applications for phentolamine mesylate formulations and methods of using phentolamine mesylate. Patent expiry on issued patents in the U.S. and globally are at least through 2034. As of May 17, 2021, Ocuphire's patent estate relating to Nyxol contains seven issued U.S. patents, five pending U.S. non-provisional patent applications, one pending U.S. provisional patent application, as well as issued patents in Australia, Europe, Japan, and Mexico and pending patent applications in Australia, Canada, Japan, and other foreign countries. Ocuphire owns all of the worldwide rights to Nyxol for all indications.

## **About Ocuphire Pharma**

Ocuphire is a publicly traded (NASDAQ: OCUP), clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of several eye disorders. Ocuphire's pipeline currently includes two smallmolecule product candidates targeting front and back of the eye indications. The company's lead product candidate, Nyxol® (0.75% phentolamine ophthalmic solution) Eye Drops, 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 dim light or night vision disturbances (NVD), reversal of pharmacologically-induced mydriasis (RM), and presbyopia, and has been studied in 8 clinical trials including the recently completed Phase 3 trial in RM. Ocuphire reported positive topline data in March 2021 for MIRA-2, a Phase 3 FDA registration study for treatment of RM. Nyxol is also currently in Phase 3 clinical development for NVD and in Phase 2 for presbyopia. 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. APX3330 is currently enrolling subjects in a Phase 2 clinical trial in subjects with DR/DME. As part of its strategy, Ocuphire will continue to explore opportunities to acquire additional ophthalmic assets and to seek strategic partners for late-stage development, regulatory preparation, and commercialization of drugs in key global markets. Please visit www.clinicaltrials.gov to learn more about Ocuphire's completed Phase 2 trials, recently completed Phase 3 registration trial (NCT04620213), ongoing Phase 3 registration trial (NCT04638660), Phase 2 trial in presbyopia (NCT04675151), and Phase 2 trial in DR/DME (NCT04692688). For more information, please 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 Ocuphire's product candidates, results of ongoing and future clinical trials, and commercialization and market opportunities. 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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Source: Ocuphire Pharma