September 4, 2019

# Ocuphire Pharma Announces Completion of the First of Two Phase 2b Clinical Trials for Nyxol® Eye Drops

*Enrollment Completed for ORION-1 Phase 2b Glaucoma Trial with Data Expected in Q4 2019*

*Enrollment Near Completion for MIRA-1 Phase 2b Reversal of Mydriasis Trial with Data Expected in Q4 2019*

*Company to Present at H.C. Wainwright 21st Annual Global Investment Conference on Monday, September 9, 2019 in NYC*

FARMINGTON HILLS, Mich.--(BUSINESS WIRE)-- Ocuphire Pharma, Inc., a clinical-stage pharmaceutical company focused on the development and commercialization of therapies to treat patients with a variety of ophthalmic disorders, announced today that it has successfully enrolled 39 glaucoma patients in ORION-1 at 5 U.S. sites from late May to August 2019. The objectives of the randomized, placebo-controlled, double-masked study of once daily 1% Nyxol in subjects with open angle glaucoma or ocular hypertension are to evaluate Nyxol's efficacy in lowering intraocular pressure (IOP) and to evaluate safety (NCT03960866).

Ocuphire also initiated MIRA-1 in the summer and has already enrolled 26 subjects to date (representing 80% completion) at 4 U.S. sites. The objectives of this randomized, cross-over, double-masked, placebo-controlled study of a single 1% Nyxol dose in healthy subjects with medically-induced mydriasis are to evaluate Nyxol's efficacy in time-to-reverse pupil dilation and to evaluate safety (NCT04024891).

Clinical results from both ORION-1 and MIRA-1 Phase 2b trials are expected in the fourth quarter of 2019. Ocuphire has been collaborating closely with Oculos Development Services, a Tampa, Florida based clinical research organization, to achieve these clinical milestones. "We were pleased by the rapid enrollment of subjects in both Phase 2b trials over the summer which speaks to the unmet needs. We thank our investigators, clinical coordinators, staff, and subjects for their support and ease of trial execution," said Chuck Slonim, MD, Chief Medical Officer and Medical Monitor of Oculos.

Ocuphire recently announced that it raised over $5 million to advance Nyxol in the ORION-1 and MIRA-1 trials from angel and institutional investors, officers and directors. "We look forward to sharing the trial results in the fourth quarter and in future ophthalmic meetings. We are committed to advancing our lead drug candidate, Nyxol, in progressive, age-related ocular diseases and to adding novel ophthalmic drug candidates to our portfolio to create a leading ophthalmic biopharma company," said Mina Sooch, Chair, President, and Chief Executive Officer of Ocuphire. "We are excited to introduce investors to Ocuphire's late-

stage clinical program and the multiple large commercial opportunities for Nyxol, and specifically share our plans for a Phase 3 trial of Nyxol in night vision disturbances (NVD) (LYNX-1) to begin in 2020." The company will be presenting at the H.C. Wainwright 21st Annual Global Investment Conference in New York City on September 9, 2019 at 4:15 pm.

Additional milestones include expansion of the intellectual property portfolio with newly issued Nyxol formulation composition patents that extend through 2034 in Europe and Japan, as well as broader U.S. patent claims.

**About Nyxol**

Nyxol is a novel eye drop treatment for multiple front-of-the-eye disorders, including NVD, glaucoma, and medically-induced mydriasis. The company is also exploring a fixed-dose combination of Nyxol to create a "pinhole effect" through pupil modulation for the treatment of presbyopia. Nyxol is a proprietary ophthalmic formulation of phentolamine mesylate, an alpha-1 and alpha-2 inhibitor that has been approved previously as an injectable for other indications, allowing a more efficient 505(b)(2) development pathway for approval. With safety and efficacy data from five Phase 1 and Phase 2 trials, Nyxol has demonstrated a differentiated product profile that includes moderately reducing pupil size (which leads to improved night and day vision), significantly lowering IOP, and convenient once-daily dosing. Nyxol was originally invented by Dr. Gerald Horn, an ophthalmologist and laser vision specialist in Chicago, who also invented the recently-approved redness reliever eye drop Lumify®.

**About Night Vision Disturbances**

NVD causes people to experience glare, halos, starbursts, and poor vision in dim light. NVD is a significant unmet need, as it affects more than an estimated 4 million people in the U.S and there is no approved drug therapy.

**About Glaucoma**

Glaucoma affects 3 million people in the U.S. and is the second-leading cause of blindness. Its most common form is open-angle glaucoma, which is a progressive disease characterized by abnormally high IOP and can lead to irreversible damage to the optic nerve, causing vision loss. There are currently several different classes of approved glaucoma drugs, but due to inability to reach target IOP goals, there is still a large unmet need for complementary and convenient treatment options.

**About Medically-Induced Mydriasis**

Medically-induced mydriasis, or pupil dilation, occurs as part of more than 80 million eye exams conducted in the U.S. every year. Mydriasis increases light sensitivity and impairs vision for many hours, and there is currently no treatment available on the market.

**About Ocuphire**

Ocuphire is a clinical-stage biopharmaceutical company engaged in the development and commercialization of drugs to treat important ophthalmic disorders. The company's lead drug candidate, preservative-free Nyxol Eye Drops, is being developed for multiple indications

including night vision disturbances, glaucoma, reversal of mydriasis, and presbyopia. Please visit www.clinicaltrials.gov to learn more about the active Phase 2 clinical trials for glaucoma (NCT03960866) and reversal of mydriasis (NCT04024891). For more information, please visit www.ocuphire.com.

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