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Ocuphire Pharma Announces First Patient Enrolled in MIRA-2 Phase 3 Clinical Trial Investigating Nyxol® for Reversal of Mydriasis

Begins Enrollment in the First of Four Upcoming Late-Stage Trials in the U.S.

Announces MIRA-1 Phase 2b Study Accepted for Peer-Reviewed Publication in Optometry and Vision Science

FARMINGTON HILLS, Mich., Nov. 19, 2020 (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 the enrollment of the first patient in its MIRA-2 (NCT04620213) Phase 3 registration clinical trial evaluating the safety and efficacy of Nyxol® to reverse pharmacologically-induced mydriasis. A majority of the 12 clinical sites located around the US are open and recruiting as of this week.

Approximately 100 million eye exams are performed annually in the U.S., most of which require dilation (mydriasis) of the pupil to properly examine the back of the eye. In addition, 4 million eyes are dilated each year for surgical procedures. This pharmacologically-induced dilation can last anywhere from 6 to 24 hours depending on individual patient characteristics. These dilated eyes have heightened sensitivity to light and inability to focus on near objects, causing patients difficulty with activities such as reading, working, and driving. In a recently completed market research study surveying several hundred patients and eye care providers (optometrists and ophthalmologists) conducted by GlobalData, an estimated 45% of patients were very likely to request a reversal drop and over 40% of eye care providers were likely to use a reversal drop if such a treatment option was approved and commercially available.

Nyxol, a proprietary and stable eye drop formulation of phentolamine mesylate, has demonstrated reversing mydriasis in a recently completed Phase 2b clinical trial (MIRA-1). Nyxol eye drops work by reducing pupil size through acting on the iris dilator muscle, allowing patients to return to their normal pupil size more rapidly. The objectives of the MIRA-2 trial are to evaluate the efficacy and safety of Nyxol compared to placebo in healthy patients to reverse pharmacologically-induced mydriasis across several commonly used mydriatic (dilating) drops. This 24-hour, multi-center, randomized, double-masked, placebo-controlled Phase 3 registration trial is expected to enroll 168 patients with top-line results expected in Q1 2021. This is the first of two registration trials planned in this acute indication for eventual New Drug Application (NDA) submission.

“Any patient who has had a routine eye exam has experienced the frustrations that come with prolonged dilation, and many request some form of reversal agent. As of now, we have

no current commercially available options to offer, so we are excited to start this Phase 3 registration trial to evaluate Nyxol as a potential reversal agent," said Paul Karpecki, OD, Director of Cornea Services for Kentucky Eye Institute in Lexington KY.

Mina Sooch, President and CEO of Ocuphire Pharma added, "With so many eye exams performed every year that require dilation, there is a clear need for a safe and effective option to accelerate the return of patients to their daily activities and everyday vision. We designed the MIRA-2 Phase 3 trial to build on the positive results of our recently completed Phase 2b MIRA-1 trial which were presented at ARVO in May 2020. This is the first of our four planned clinical trials for Nyxol and APX3330. We are at various stages of start-up activities across these trials, and look forward to timely enrollment on this MIRA-2 Phase 3 trial in collaboration with our CRO partner, Oculos Development Services."

For more information about the MIRA-2 (NCT04620213) Phase 3 registration trial design and its US clinical sites, please visit www.clinicaltrials.gov.

Ocuphire is also pleased to announce the acceptance of a peer-reviewed written publication of the MIRA-1 study "Phentolamine Eye Drops Reverse Pharmacologically Induced Mydriasis in a Randomized Phase 2b Trial" in *Optometry and Vision Science (OVS), Journal of the American Academy of Optometry. Accepted articles will appear soon in print and on-line at* www.optvissci.com.

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 small-molecule product candidates targeting front and back of the eye indications. The company's lead product candidate, Nyxol® 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 pharmacologically-induced mydriasis (RM), and presbyopia. Ocuphire's second product candidate, APX3330, is a twice-a-day 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). Nyxol is entering Phase 3 clinical development for NVD and RM, and Phase 2 for presbyopia. APX3330 is entering Phase 2 clinical development for 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 recent Phase 2 clinical trials and upcoming trials. 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 and potential. 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; (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, and (vii) the effects of COVID-19 on clinical programs and business operations. 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 (including the proxy statement/prospectus included in that certain Registration Statement on Form S-4 (File No. 333-239702) initially filed with the SEC on July 6, 2020 and declared effective by the SEC on October 2, 2020. 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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