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Ocuphire Pharma Announces Expansion of Global Patents for Nyxol® and $1.7 Million NIH Grants for APX3330 Program

Allowed Japanese Patent Application for Daily Ophthalmic Use of Nyxol to Improve Visual Performance

R&D Funding for APX3330 and Pipeline Candidates with $1.7M NIH National Eye Institute Grant

FARMINGTON HILLS, Mich., Nov. 16, 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 milestones for patents and grants on both its lead drug candidates Nyxol and APX3330.

The Japanese Patent Office (JPO) has allowed Ocuphire's Japanese patent application (No. 2018-205168) having broad use claims encompassing repeat dosing for daily ophthalmic administration of phentolamine mesylate (Nyxol® eye drops) for improving visual performance through 2034. The allowed patent application claims cover chronic eye indications with evening dosing such as night vision disturbances and presbyopia, which are entering late stage trials in the coming quarters.

"We continue to see success building a comprehensive global patent portfolio for Nyxol® with issued composition and methods patents in the United States, Europe, Australia, Mexico, and Japan," said Mina Sooch, President and CEO of Ocuphire. "With these international patents as a foundation, we remain committed to engage with global pharma partners to expand our development and commercialization efforts in these markets, especially Asia and Europe. The focus is on Nyxol as well as APX3330 which also has a global patent footprint with issued patents covering methods of ophthalmic use in the U.S., Europe, Japan, and other foreign countries."

In addition Mark R. Kelley, PhD, co-founder of the APX3330 program and a member of Ocuphire's Medical Advisory Board, was recently awarded a $1.7 million grant from the National Institutes of Health's National Eye Institute (NEI) to continue studies on the Ref-1 protein as a unique target to treat ocular neovascularization and inflammation. APX3330, as well as second generation compounds, APX2009 and APX2014, are included in the NEI funded studies. APX3330 is a twice-a-day oral tablet entering Phase 2 stage development for diabetic retinopathy (DR) and diabetic macular edema (DME). Ocuphire's APX3330 Phase 2 trial in DR/DME, Zeta-1, is planned to begin in the first quarter of 2021.

Dr. Mark Kelley, Professor of Pediatrics and Ophthalmology and Adjunct Professor, Eugene and Marilyn Glick Eye Institute, IU School of Medicine commented, "The studies proposed in

our NEI grant will focus on how blocking the signaling mechanisms of Ref-1 that promote the growth of new blood vessels and inflammation could treat diseases like diabetic retinopathy, diabetic macular edema and even retinopathy of prematurity using both APX3330 and second generation molecules."

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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