June 6, 2024

Ocuphire Pharma Announces Presentations on the Development of APX3330 for Diabetic Retinopathy at Retina Meetings in June

FARMINGTON HILLS, Mich., June 06, 2024 (GLOBE NEWSWIRE) -- Ocuphire Pharma, Inc. (Nasdaq: OCUP) (“Ocuphire”), a clinical-stage biopharmaceutical company focused on developing small molecule therapies for the treatment of patients with retinal and refractive eye disorders, today announced that clinical updates on the Company’s lead candidate APX3330 for diabetic retinopathy (DR) will be featured in upcoming presentations at the Clinical Trials at the Summit meeting on June 8 in Park City, Utah, and the Retinal Imaging Biomarkers & Endpoints Summit meeting June 25-27 in Boston.

APX3330 is an oral small-molecule inhibitor of Ref-1 (reduction oxidation effector factor-1 protein) being developed for the treatment of non-proliferative diabetic retinopathy (NPDR). DR affects approximately 10 million of the 38 million Americans with diabetes and is the leading cause of blindness in working age adults, and 80 percent of DR patients have NPDR.

“Clinical Update on Oral APX3330 for Diabetic Retinopathy” will be presented by Veeral Sheth, M.D., M.B.A., a practicing retina specialist at University Retina and Clinical Assistant Professor at the University of Illinois, at the Clinical Trials at the Summit meeting. Clinical Trials at the Summit brings together a diverse group of experts to discuss ongoing clinical trials and the latest data to accelerate advances in vitreoretinal care.

“Multiplex Analysis of Clinical Imaging & Biomarker Data to Validate Novel Endpoints for Diabetic Retinopathy” will be presented by Ashwath Jayagopal, Ph.D., Ocuphire’s Chief Scientific and Development Officer, at the second annual Retinal Imaging Biomarkers & Endpoints Summit. The Retinal Imaging Biomarkers & Endpoints Summit is the only industry-dedicated event focusing on streamlining imaging data analysis with the implementation of AI-based predictive measures for earlier detection and diagnosis to optimize patient stratification, selection and recruitment for trials.

“APX3330 has the potential to be a novel treatment that addresses multiple established disease pathways for NPDR,” said George Magrath, M.D., M.B.A., M.S., Ocuphire’s Chief Executive Officer. “We are grateful for multiple opportunities to share an update on our APX3330 clinical program and our planned ZETA-2 pivotal trial, including the unmet need for an earlier intervention treatment to delay or prevent DR progression, the value of multimodal imaging in DR, and Phase 2/3 trial optimization and patient selection, with industry and scientific peers.”

Ocuphire anticipates initiating the ZETA-2 Phase 2/3 trial of APX3330 for NPDR in early 2025.

About Ocuphire Pharma

Ocuphire is a clinical-stage ophthalmic biopharmaceutical company focused on developing novel therapies for the treatment of retinal and refractive eye disorders.

Ocuphire's lead retinal product candidate, APX3330, is an oral small-molecule inhibitor of Ref-1 (reduction oxidation effector factor-1 protein) for the treatment of non-proliferative diabetic retinopathy (NPDR). Ref-1 is a regulator of the transcription factors HIF-1α and NF-κB. Inhibiting REF-1 reduces levels of vascular endothelial growth factor (VEGF) and inflammatory cytokines which are known to play key roles in ocular angiogenesis and inflammation. APX3330 is an oral tablet to be administered twice per day for the treatment of diabetic retinopathy (DR). A Phase 2 study in subjects with DR and an End-of-Phase 2 meeting have been completed, and a special protocol assessment (SPA) was submitted to the U.S. Food and Drug Administration (FDA) in February 2024.

In addition, Ocuphire has a partnership to develop and commercialize Phentolamine Ophthalmic Solution 0.75% ("PS"), a non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size. PS was approved by the FDA for the treatment for pharmacologically-induced mydriasis under the brand name RYZUMVI™ in September 2023. PS is also in Phase 3 clinical development for the treatment of presbyopia and for the treatment of decreased visual acuity under low light (mesopic) conditions after keratorefractive surgery.

Ocuphire is also developing APX2009 and APX2014, second-generation analogs of APX3330. These programs are being evaluated for treating other retinal diseases such as age-related macular degeneration and geographic atrophy. For more information, please visit www.ocuphire.com.

Forward Looking Statements

This press release contains 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 the efficacy of APX3330 in slowing the progression of diabetic retinopathy, the safety and tolerability of APX3330, ongoing discussions with the FDA regarding various of our drug products, and continued drug development under our partnership agreement.

These forward-looking statements relate to us, our business prospects and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading "Risk Factors" included in our Annual Report on Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "aim", "may," "ongoing," "plan," "potential," "predict," "project," "should," "will,"

“would” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise.

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:

- The success and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts;
- Regulatory requirements or developments;
- Changes to or unanticipated events in connection with clinical trial designs and regulatory pathways;
- Delays or difficulties in the enrollment of patients in clinical trials;
- Substantial competition and rapid technological change;
- Our development of sales and marketing infrastructure;
- Future revenue losses and profitability;
- Our relatively short operating history;
- Changes in capital resource requirements;
- Risks related to the inability of Ocuphire to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs;
- Domestic and worldwide legislative, regulatory, political and economic developments;
- Employee misconduct;
- Changes in market opportunities and acceptance;
- Reliance on third-parties;
- Future, potential product liability and securities litigation;
- System failures, unplanned events, or cyber incidents;
- The substantial number of shares subject to potential issuance associated with our equity line of credit arrangement;
- Risks that our partnership or other licensing arrangements, may not facilitate the commercialization or market acceptance of Ocuphire’s product candidates;

- Future fluctuations in the market price of our common stock;
- The success and timing of commercialization of any of Ocuphire's product candidates; and
- Obtaining and maintaining 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. Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the Securities and Exchange Commission that advise interested parties of the risks and factors that may affect our business. 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.

Contacts

Corporate	Investor Relations
Nirav Jhaveri, M.B.A. CFO ir@ocuphire.com	Corey Davis, Ph.D. LifeSci Advisors cdavis@lifesciadvisors.com

Source: Ocuphire Pharma