Ocular Therapeutix™ Announces First Subjects Screened in Phase 3 Pivotal Clinical Trial of AXPAXLI™ in Wet AMD

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Phase 3 SOL-1 study will evaluate the efficacy and safety of AXPAXLI in wet AMD

BEDFORD, Mass., Feb. 13, 2024 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye, today announced that the first three subjects have been screened and received their first aflibercept injection in the Phase 3 SOL-1 clinical trial of AXPAXLI™ (axitinib intravitreal implant, also known as OTX-TKI) for the treatment of wet age-related macular degeneration (wet AMD). The Company previously announced FDA agreement on its Special Protocol Assessment (SPA) Agreement Modification on January 25th.

“The screening of these subjects in the pivotal Phase 3 SOL-1 trial of AXPAXLI marks an exciting milestone for Ocular Therapeutix,” said Antony Mattessich, CEO of Ocular Therapeutix. “AXPAXLI has demonstrated promising durability, biological activity, and a favorable safety profile in earlier studies. We believe that AXPAXLI could set a new standard in wet AMD therapy by significantly extending time between treatments. If successful, this first-of-its-kind implant could reduce injection burden for patients and doctors alike while leading to better long-term outcomes.”

“Wet AMD patients need options that provide sustained therapy while minimizing their need for frequent injections and office visits,” said Allen Hu, M.D., a principal investigator in the SOL study and vitreoretinal surgeon at Cumberland Valley Retina Consultants. “I am thrilled to be participating in research that could shift the existing treatment paradigm for patients with wet AMD.” Dr. Hu is an active principal investigator of innovative technologies for the treatment of macular degeneration, diabetic retinopathy and retinal vascular disorders, having participated in over 40 clinical trials over the past 10 years.

“Clinical trials like the SOL-1 study for AXPAXLI represent a critical step forward in our pursuit of more patient-centric treatments for wet AMD. As a clinician dedicated to advancing retinal care, I am excited to contribute to the development of potentially transformative solutions for our patients,” said Dilsher Dhoot, M.D., a principal investigator in the SOL-1 study and vitreoretinal surgeon at California Retina Consultants. Dr. Dhoot has contributed to over 35 clinical trials in the past decade as an active principal investigator, pioneering new approaches in advancing the field of retinal therapies.

About AXPAXLI
AXPAXLI is an investigational bioresorbable, hydrogel implant incorporating axitinib, a small molecule, multi-target, tyrosine kinase inhibitor with anti-angiogenic properties, being evaluated for the treatment of wet AMD and other retinal diseases.

About Wet AMD
Wet age-related macular degeneration (wet AMD) is a leading cause of severe, irreversible vision loss affecting approximately 14 million individuals globally and 1.6 million in the United States alone (2022 Market Scope® Retinal Pharmaceuticals Market Report). Wet AMD causes vision loss due to abnormal new blood vessel growth and hyperpermeability and associated retinal vascularity in the macula, which is primarily stimulated by local upregulation of vascular endothelial growth factor (VEGF). Without prompt and continuous treatment to control this exudative activity, patients develop irreversible vision loss. With proper treatment, patients may maintain visual function for a period of time and may temporarily regain lost vision. Challenges with current therapies include repeated intraocular injections every 1 to 4 months, treatment-related adverse events, patient compliance, and lack of vision improvement.

About Ocular Therapeutix, Inc.
Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the formulation, development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary bioresorbable hydrogel-based formulation technology ELUTYX™. Ocular Therapeutix’s first commercial drug product, DEXTENZA®, is an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. Ocular Therapeutix’s earlier stage development assets include: AXPAXLI (axitinib intravitreal implant), currently in a pivotal Phase 3 trial for the treatment of wet AMD and a Phase 1 clinical trial for the treatment of diabetic retinopathy; PAXTRAVA™ (travoprost intracameral implant, also known as OTX-TIC), currently in a Phase 2 clinical trial for the treatment of primary open-angle glaucoma or ocular hypertension; and OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease and OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease, both of which have completed Phase 2 clinical trials.

Forward Looking Statements
Any statements in this press release about future expectations, plans, and prospects for the Company, including the development and regulatory status of the Company’s product candidates, including the timing, design, and enrollment of the Company’s pivotal trials of AXPAXLI (also called OTX-TKI) for the treatment of wet AMD; the Company’s plans to advance the development of AXPAXLI; and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company’s preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the timing and costs involved in commercializing DEXTENZA or any product or product candidate that receives regulatory approval; the ability to retain regulatory approval of DEXTENZA or any product or product candidate that receives regulatory approval; the ability to maintain and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA; the initiation, design, timing, conduct and outcomes of clinical trials, including the SOL-1 trial; the risk that the FDA will not agree with the Company’s interpretation of the written agreement under the SPA; the risk that even though the FDA has agreed with the overall design of the SOL-1 trial, the FDA may not agree that the data generated

by the SOL-1 trial supports potential marketing approval; uncertainty as to whether the data from earlier clinical trials will be predictive of the data of later clinical trials, particularly later clinical trials that have a different design or utilize a different formulation than the earlier trials; availability of data from clinical trials and expectations for regulatory submissions and approvals; the Company's scientific approach and general development progress; uncertainties inherent in estimating the Company's cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials; Company's existing indebtedness and the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default; the Company's ability to enter into strategic alliances or generate additional funding on a timely basis, on favorable terms, or at all; and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

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