



Ocular Therapeutix™ Receives FDA Agreement Under Special Protocol Assessment (SPA) for its First Pivotal Clinical Trial of OTX-TKI in Wet AMD

November 1, 2023

The first subject expected to be dosed by year-end

Company announces OTX-TKI trade name AXPAXLI

BEDFORD, Mass., Nov. 01, 2023 (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 it had received written agreement regarding the overall design from the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the Company's ongoing pivotal Phase 3 clinical trial for AXPAXLI (axitinib intravitreal implant), for the treatment of wet age-related macular degeneration (wet AMD), which the Company refers to as the SOL trial.

The Company initiated the SOL trial in September 2023 and expects to enroll approximately 300 evaluable wet AMD subjects who are treatment naïve in the study eye in the trial. The SOL trial is designed to be a multi-center, parallel-group trial run primarily at U.S. sites, with subjects randomized to one injection of aflibercept or one implant of AXPAXLI followed by supplemental anti-VEGF treatment based on pre-specified criteria. With the agreement under the SPA, the Company will begin enrolling patients in the SOL trial and expects to dose the first subject by year-end.

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. AXPAXLI is also referred to by its laboratory code, OTX-TKI.

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 wet AMD and a Phase 1 clinical trial for the treatment of diabetic retinopathy; OTX-TIC (travoprost intracameral implant), 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; the Company's cash runway and sufficiency of the Company's cash resources; 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 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 trial, the FDA may not agree that the data generated by the SOL 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 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.

Investors

Ocular Therapeutix
Donald Notman
Chief Financial Officer
dnotman@ocutx.com

or

ICR Westwicke
Chris Brinzey, 339-970-2843
Managing Director
chris.brinzey@westwicke.com

Media

ICR Westwicke
Ben Shannon, 443-213-0495
ben.shannon@westwicke.com



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