Ocular Therapeutix™ Enrolls First Patients in Phase 2b Clinical Trial for Sustained Release Travoprost for the Treatment of Glaucoma and Ocular Hypertension

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BEDFORD, Mass.--(BUSINESS WIRE)--Nov. 12, 2014-- Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, announced today enrollment of the first patients in a Phase 2b clinical trial evaluating Sustained Release Travoprost (OTX-TP) for the reduction of elevated intraocular pressure in patients with open-angle glaucoma and ocular hypertension. OTX-TP is administered by a physician as an insert into the punctum, a natural opening in the eyelid near the tear ducts, designed to deliver travoprost to the ocular surface for up to 90 days.

The prospective, multicenter, randomized, double-masked, parallel-arm, active controlled study is designed to evaluate 80 patients at 10 clinical sites for the safety and efficacy of the OTX-TP as compared to timolol. Study efficacy endpoints include difference in the mean intraocular pressure change between the treatment groups from baseline at multiple timepoints throughout the study.

Previous pilot and Phase 2a clinical trials evaluating OTX-TP showed robust reductions in intraocular pressure for up to three months, similar to results found with twice-daily timolol dosing. No serious adverse events occurred, including no increases in hyperemia, and patients were comfortable with use of the plug overall. “It is our hope that OTX-TP will have a significant impact in helping to fight one of the leading causes of blindness in the world,” stated Amar Sawhney, Ph.D., President and CEO of Ocular Therapeutix, Inc.

Glaucoma and ocular hypertension are chronic, sight-threatening diseases caused by elevated intraocular pressure, which affects approximately 2.7 million people in the United States alone, which resulted in 31 million prescriptions and sales over $2.1 billion in 2013.[1,2] Many of those afflicted with the disease have difficulty complying with the required dosing regimen or being able to self-administer eye drops, which is especially troublesome as patients get older. “Many patients do not adhere to dosing regimens, which can quickly lead to vision problems. Sustained release glaucoma therapy helps eliminate the burden placed on patients for daily administration of eye drops,” stated Steven D. Vold, M.D., Founder and CEO of Vold Vision in Fayetteville, Arkansas, a Principal Investigator on the trial.

About Sustained Release Travoprost

Sustained Release Travoprost (OTX-TP) is a preservative-free drug product candidate that resides within the canaliculus and delivers the prostaglandin analog (travoprost) to the ocular surface for approximately 90 days. The drug release is tailored such that a continuous, low-dose is sustained throughout the treatment period. A visualization aid is incorporated into the plug so that both the doctor and the patient may monitor drug presence through the entire course of therapy.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. Ocular Therapeutix’s lead product candidates are in Phase 3 clinical development for post-surgical ocular inflammation and pain, and Phase 2 clinical development for glaucoma and allergic conjunctivitis. The Company is also evaluating sustained-release injectable anti-VEGF drug depots for back-of-the-eye diseases. Ocular Therapeutix’s first product, ReSure® Sealant, is FDA-approved to seal corneal incisions following cataract surgery. For more information, please visit www.ocutx.com.

Forward-looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the development of the Company’s product candidates, such as the timing and conduct of the Company’s Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension , the potential utility and convenience of OTX-TP, the advancement of other product candidates in the Company's pipeline 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 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, those related to the timing and costs involved in commercializing ReSure® Sealant, the initiation and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory approvals, the Company’s scientific approach and general development progress, the availability or commercial potential of the Company’s product candidates, the sufficiency of cash resources and need for additional financing or other actions and other factors discussed in the “Risk Factors” section contained in the Company’s most recent Quarterly Report on Form 10-Q 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 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. 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 release.

[1] Vision problems in the U.S.: Prevalence of adult vision impairment and age-related eye disease in America. Prevent Blindness in America and National Eye Institute, 2010 Census data.

[2] IMS Health, 2014

Source: Ocular Therapeutix, Inc.

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