Ocular Therapeutix™ Begins Enrollment in First Phase 3 Clinical Trial with OTX-TP (Sustained Release Travoprost) for the Treatment of Glaucoma and Ocular Hypertension

October 4, 2016

Phase 3 study design to compare OTX-TP with placebo inserts; no timolol validation arm required

Refined product design shows significant improvement in patient retention over 3-month duration

BEDFORD, Mass.--(BUSINESS WIRE)--Oct. 4, 2016-- Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced the enrollment of the first patient in the first of two planned Phase 3 clinical trials with OTX-TP (sustained release travoprost) for the treatment of glaucoma and ocular hypertension. OTX-TP is a preservative-free drug product candidate that resides within the canaliculus and is designed to deliver the prostaglandin analog travoprost to the ocular surface for up to 90 days.

The U.S.-based, prospective, multicenter, randomized, parallel-arm, placebo-controlled study is expected to enroll approximately 550 patients with open angle glaucoma or ocular hypertension at 50 clinical sites. Importantly, the Phase 3 study design will not include a timolol comparator or validation arm, and will not have active or placebo eye drops administered in either arm. The comparator arm will utilize a non-drug eluting hydrogel-based intracanalicular insert. The primary efficacy endpoint will be statistically superior reduction of intraocular pressure (IOP) from baseline with OTX-TP compared to placebo at 2, 6 and 12 weeks following insertion.

“This is the first Phase 3 clinical trial to be conducted with a non-invasive, sustained release drug candidate for the treatment of glaucoma and represents an important advancement in the field of ophthalmology,” stated Robert Noecker, MD, MBA, Ophthalmic Consultants of Connecticut, and Assistant Clinical Professor, Yale University School of Medicine. “While currently approved topical therapies are effective when dosed ideally, studies show that more than 50% of patients are not compliant with their therapy within the first six months of treatment. This is a very significant issue in the treatment of glaucoma. Sustained release drug candidates such as OTX-TP address this issue directly, by allowing patients who are either unable to acquire, do not remember to, or who incorrectly administer eye drop regimens, to have a convenient way to manage their disease. The preservative-free and sustained nature of OTX-TP has the potential to improve the side effect profile as well.”

“This is the first of two planned Phase 3 clinical trials that will both include an OTX-TP treatment arm and a placebo-controlled comparator arm using a non-drug eluting hydrogel-based intracanalicular insert,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. “This reflects the most appropriate real-world study design, as learnings from previous studies have indicated that the presence of the inserts in the control arm may have inadvertently enhanced the effect of timolol. We expect topline results from the first Phase 3 clinical trial to be available in the first half of 2018, and plan to commence the second phase 3 clinical trial in the first half of 2017. With over $2.7 billion in sales of eye drop therapies for the treatment of glaucoma in the U.S. last year, glaucoma is a large and important market opportunity for Ocular Therapeutix.”

Dr. Sawhney continued, “We are also pleased with the results of the refined OTX-TP product configuration we will be using in these studies. Our most recent results from ongoing non-significant risk (NSR) investigational device exemption (IDE) human clinical studies using the non-drug eluting version of the insert show significant improvements in retention rates at three months compared to previous studies.”

About Glaucoma and Ocular Hypertension

Glaucoma is a chronic, sight-threatening disease in which abnormally high intraocular pressure may cause damage to the optic nerve, resulting in irreversible vision loss. Glaucoma is the second leading cause of blindness in the world. Ocular hypertension is characterized by higher levels of intraocular pressure without detectable optic nerve damage. Patients with ocular hypertension are at high risk of developing glaucoma. In the U.S. alone, 2.7 million people suffer from glaucoma. According to IMS Health data, there were 34 million prescriptions and sales of over $2.7 billion of drugs administered by eye drops for the treatment of glaucoma in the U.S. in 2015.

Compliance is seen as the biggest problem with existing therapies for glaucoma, and more than 50% of patients on topical prostaglandin analogs are not compliant with their therapy within the first six months of treatment.

About OTX-TP (Sustained Release Travoprost)

OTX-TP (sustained release travoprost) is a preservative-free drug product candidate that resides within the canaliculus and is designed to deliver the prostaglandin analog travoprost to the ocular surface for up to 90 days. OTX-TP is designed to deliver a continuous steady release throughout the treatment period. A fluorescent visualization aid is formulated within the product to enable both the physician and the patient to monitor drug presence throughout the course of therapy. If approved, OTX-TP may become the first non-invasive, sustained release therapy for the treatment of glaucoma.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. (NASDAQ: OCUL) 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 has submitted an NDA for post-surgical pain for its lead product candidate, DEXTENZA™ (dexamethasone insert), which is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and in Phase 2 clinical development for dry eye disease. OTX-TP (sustained release travoprost) is in Phase 3 clinical development for glaucoma and ocular hypertension. Ocular Therapeutix is also evaluating sustained-release injectable 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 additional information about the Company, 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 and regulatory status of the Company's product candidates, such as the Company's expectations and plans regarding regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA™ for post-surgical ocular inflammation and pain, including our expectations regarding the NDA filed with the FDA, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel depot technology and the advancement of the Company's other product candidates, the potential utility of any of the Company's product candidates, potential commercialization of the Company's product candidates, the 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 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 or any product candidate that receives regulatory approval, the initiation and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and 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 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 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20161004006504/en/

Source: Ocular Therapeutix, Inc.

Investors
Ocular Therapeutix, Inc.
Brad Smith
Chief Financial Officer
bsmith@ocutx.com
or
Burns McClellan on behalf of Ocular Therapeutix
Steve Klass, 212-213-0006
sklass@burnsmc.com
or
Media
Ocular Therapeutix, Inc.
Scott Corning
Vice President of Sales and Marketing
scorning@ocutx.com