Ocular TherapeutixTM Completes End-of-Phase 2 Review with FDA for OTX-TP (Sustained Release Travoprost) for Glaucoma and Ocular Hypertension

April 27, 2016

First Phase 3 trial expected to commence in the third quarter of 2016

Trial design to evaluate OTX-TP using placebo as comparator; no timolol validation arm required

BEDFORD, Mass.--(BUSINESS WIRE)--Apr. 27, 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 that it has completed its End-of-Phase 2 review with the U.S. Food and Drug Administration (FDA) for its OTX-TP (sustained release travoprost) product candidate for the treatment of glaucoma and ocular hypertension.

Based on this review, the company intends to initiate the first of two Phase 3 clinical trials during the third quarter of 2016. The FDA has stated that it agrees with the overall Phase 3 clinical development program proposed by Ocular Therapeutix in its briefing package submitted to the FDA, which includes the following:

- Two Phase 3 clinical trials that will include an OTX-TP treatment arm and a placebo-controlled comparator arm that would use a non-drug eluting hydrogel-based intracanalicular depot.
- The Phase 3 study design will not include a timolol comparator or validation arm.
- The study design will not have eye drops, placebo or active, administered in either arm.
- A primary efficacy endpoint of statistically superior and clinically meaningful reduction of intraocular pressure (IOP) from baseline with OTX-TP compared to placebo at 60 and 90 days. The FDA has also indicated that they will take into consideration the risk-reward profile of OTX-TP relative to currently available therapies in their evaluation of the Phase 3 clinical trial results.

“We are pleased with the End-of-Phase 2 feedback from FDA concerning our Phase 3 clinical development plan, which proposes a trial design that compares OTX-TP with a placebo arm. We believe this reflects a real-world appropriate clinical study design for this drug product candidate,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. “OTX-TP has shown a clinically meaningful IOP-lowering effect in clinical trials to date, and may offer an important advancement in the treatment of glaucoma. Importantly, we believe OTX-TP may be able to address the major issue of low patient compliance rates associated with currently approved topical therapies and their chronic, burdensome dosing schedules while potentially improving the safety profile due to the absence of preservatives.”

About Glaucoma and Ocular Hypertension
Glaucoma is a chronic, sight-threatening diseases in which elevated levels of intraocular pressure are associated with damage to the optic nerve, which may result in irreversible vision loss. Glaucoma is the second leading cause of blindness in the world. Ocular hypertension is characterized by elevated levels of intraocular pressure without any 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 delivers the prostaglandin analog travoprost to the ocular surface for up to 90 days. The drug depot 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.

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's lead product candidate, DEXTENZA™ (sustained release dexamethasone) Intracanalicular Depot, 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. A New Drug Application (NDA) for the post-operative ocular pain indication has been filed with FDA and has a Prescription Drug User Fee Act (PDUFA) date of July 24, 2016. A third Phase 3 clinical trial is being conducted for post-operative ocular inflammation and pain. For glaucoma and ocular hypertension, a Phase 2b clinical trial has been completed with OTX-TP (sustained release travoprost) and the first of two planned OTX-TP Phase 3 clinical trials is expected to be initiated in the third quarter of 2016. Ocular Therapeutix 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.

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 ongoing development of OTX-TP for glaucoma and ocular hypertension and the timing, design and conduct of the planned Phase 3 clinical trials of OTX-TP, the availability of data from clinical trials, the Company’s plans for regulatory submissions, the potential utility of any of the Company’s product candidates, the ongoing development of the Company’s sustained release

hydrogel depot technology and the advancement of the Company's other 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 other product candidates that may receive 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/20160427006688/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