Ocular Therapeutix™ Announces Phase 3 Clinical Development Plan for OTX-TP, an Innovative Therapy for Glaucoma and Ocular Hypertension

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Pivotal Phase 3 Trials to use Placebo as Comparator

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

BEDFORD, Mass.--(BUSINESS WIRE)--Feb. 16, 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 Phase 3 clinical development strategy for its OTX-TP (sustained release travoprost) drug product candidate for the treatment of glaucoma and ocular hypertension. Based on feedback from a recent meeting with the US Food and Drug Administration (FDA), Ocular Therapeutix intends to commence the first of two planned Phase 3 clinical trials in the third quarter of 2016.

The planned trial design for the two Phase 3 clinical trials includes an OTX-TP treatment arm and a placebo-controlled comparator arm that would use a non-drug eluting hydrogel-based intracanalicular depot. The Company does not expect that a timolol comparator or validation arm will be required in the study design and does not expect that eye drops, placebo or active, will be administered in either arm. The Company expects that the FDA will require that OTX-TP show a statistically superior and clinically meaningful reduction of intraocular pressure (IOP), compared to the placebo, as a primary efficacy endpoint.

“We are pleased with the outcome of our recent meeting with the FDA to discuss the Phase 3 clinical development plan for OTX-TP. We believe that a direct comparison of OTX-TP with a placebo comparator reflects the simplest and most real world appropriate clinical study design for this product,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. “This meeting was an important milestone for advancing this program into the next stage of its development. We expect to initiate the first of two planned Phase 3 clinical trials in the third quarter of 2016 after holding an End of Phase 2 meeting with the FDA and finalizing the protocol for the trials.”

Robert Noecker, MD, MBA, Ophthalmic Consultants of Connecticut, and Assistant Clinical Professor, Yale University School of Medicine, stated, “Compliance remains a major issue with all current glaucoma eye drop therapies. Sustained release drug candidates such as OTX-TP address this issue directly, and have the potential to put the control back into the hands of the physician by removing the burden on the patient to administer eye drops every single day. In clinical trials to date, OTX-TP has shown a clinically meaningful IOP lowering effect and has not caused hyperemia, or eye redness, a common side effect of topical glaucoma therapies. It offers a preservative-free formulation that appears to be benign to the ocular surface, which can be adversely affected by preservatives used in eye drops for chronic glaucoma therapy. OTX-TP is a product candidate that may offer an important advancement in the treatment of glaucoma.”

About Glaucoma and Ocular Hypertension

Glaucoma and ocular hypertension are 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 33 million prescriptions and sales of over $2.4 billion of drugs administered by eye drops for the treatment of glaucoma in 2014.

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 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™, is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and in Phase 2 clinical development for inflammatory dry eye disease. An NDA for the post-operative ocular pain indication has been accepted by the FDA with a 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, OTX-TP (sustained release travoprost) intracanalicular depot, has completed a Phase 2b clinical trial. 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 of the Company’s product candidates, such as the ongoing development and potential utility 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 and the advancement of the Company's other product candidates, the potential for the Company’s sustained release hydrogel depot technology 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 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.

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