# Ocular Therapeutix™ Reports Positive Topline Clinical Data for the First of Two Phase 3 Clinical Trials Evaluating OTX-DP for the Treatment of Post-Surgical Ocular Inflammation and Pain

March 10, 2015

***-- Topline results of the second Phase 3 clinical trial expected by the end of March --***

***-- NDA submission anticipated in 2Q 2015 --***

BEDFORD, Mass.--(BUSINESS WIRE)--Mar. 10, 2015-- 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 positive topline data from the first of two Phase 3 clinical trials evaluating the safety and efficacy of its lead product candidate, OTX-DP (Sustained Release Dexamethasone), for the treatment of ocular inflammation and pain following cataract surgery. The Phase 3a study, which enrolled 247 patients, met both primary efficacy measures, achieving a statistically significant improvement in the reduction of inflammatory cells and pain. 33.7% of OTX-DP-treated patients showed an absence of inflammatory cells in the anterior chamber of the study eye on day 14 following drug product insertion, compared to 14.6% of those receiving placebo vehicle control punctum plug (p=0.0015). In addition, 76.1% of patients receiving OTX-DP reported absence of pain in the study eye on day 8 following insertion of the drug product, compared to 36.1% of those receiving placebo vehicle control punctum plug (p< 0.0001). Ocular is continuing to analyze the safety findings from the clinical trial.

“This is an exciting day for Ocular Therapeutix as our sustained release drug delivery platform continues to provide strong data in our clinical trials in multiple indications,” said Amar Sawhney, Ph.D., President and CEO. “The ability to administer the entire course of therapy for post-operative inflammation and pain with a single dose would remove the onus from patients to follow complex pharmaceutical dosing regimens while providing the desired tapered therapeutic effect. If we also achieve positive results in our Phase 3b clinical trial, for which we expect to announce topline results by the end of March, we remain on track to submit an NDA to the FDA for OTX-DP for post-surgical ocular inflammation and pain in the second quarter of 2015.”

OTX-DP is a product candidate placed in the canaliculus and designed to deliver dexamethasone to the ocular surface for approximately four weeks. Following treatment, OTX-DP resorbs and exits the nasolacrimal system without need for removal. In November 2014, the Company announced encouraging data from its Phase 2 clinical trial evaluating the safety and efficacy of OTX-DP in allergic conjunctivitis and the Company plans to initiate Phase 3 clinical trials for this indication in the middle of 2015. The Company also initiated an exploratory Phase 2 clinical trial of OTX-DP for the treatment of inflammatory dry eye in January 2015. The Company is currently enrolling patients into a Phase 2b clinical trial of its second sustained release product candidate, OTX-TP (Sustained Release Travoprost), for the treatment of glaucoma and ocular hypertension. Data from this trial is expected in the fourth quarter of 2015.

**About the OTX-DP Post-Surgical Inflammation and Pain Clinical Trials**

Two prospective, multicenter, randomized, parallel-arm, double-masked, vehicle-controlled Phase 3 clinical trials, referred to as the Phase 3a and Phase 3b clinical trials, were completed with a total of 487 patients (247 patients in Phase 3a and 240 in Phase 3b) undergoing unilateral clear corneal cataract surgery. Patients were randomized 2:1 to receive either OTX-DP or a placebo vehicle control punctum plug without active drug. Both primary efficacy measures, differences in the proportion of patients in each treatment group with absence of cells in the anterior chamber of the study eye, as measured using slit lamp examination, at day 14 and absence of pain, as graded by a patient-reported score of zero on a scale from zero to ten, at day 8 were recorded at each study visit. Secondary efficacy measures were absence of flare in the anterior chamber of the study eye at each evaluation date and absence of inflammatory cells in the anterior chamber of the study eye and absence of pain in the study eye at each evaluation date other than the day used for the primary efficacy measure.

Topline data from the Phase 3b clinical trial are expected to be announced by the end of March. If the Company obtains favorable aggregate results for both the Phase 3a and Phase 3b clinical trials, the Company expects to submit a New Drug Application (NDA) for OTX-DP for post-surgical ocular inflammation and pain in the second quarter of 2015. The Company believes that OTX-DP is the first sustained release drug-eluting corticosteroid punctum plug to enter and complete Phase 3 clinical trials.

**About Post- Surgical Ocular Inflammation and Pain**

Ocular inflammation and pain are common side effects following ophthalmic surgery. Physicians prescribe anti-inflammatory drugs, such as corticosteroids, as the standard of care. If left untreated, inflammation of the eye may result in further ocular complications, including scarring and vision loss. Market Scope estimates approximately 5 million ocular surgeries will be performed in the United States in 2014.

**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, allergic conjunctivitis, and dry eye disease. 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.

**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 3 clinical trials of OTX-DP for the treatment of*

*post-surgical ocular inflammation and pain, the potential submission of an NDA for this indication, the potential utility of OTX-DP for post-surgical ocular inflammation and pain, the timing and conduct of the Company's Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension and the Company's Phase 3 clinical trials of OTX-DP for allergic conjunctivitis, the advancement of the Company's other product candidates 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.*

Source: Ocular Therapeutix, Inc.

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