Ocular Therapeutix™ Presents Additional Phase 3 Data and Patient Reported Outcomes Results for DEXTENZA™ at the American Society of Cataract and Refractive Surgery (ASCRS) Symposium

May 8, 2017

New Data Presented Evaluating the Use of DEXTENZA Following Cataract Surgery

BEDFORD, Mass.--(BUSINESS WIRE)--May 8, 2017-- Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development, manufacturing and commercialization of innovative therapies for diseases and conditions of the eye, presented yesterday new data from its most recent Phase 3 study evaluating the safety and efficacy of DEXTENZA (dexamethasone insert) 0.4 mg for the treatment of ocular pain and inflammation following cataract surgery. The data were released at the American Society of Cataract and Refractive Surgery Annual Symposium (ASCRS) in Los Angeles, CA.

The U.S. Food and Drug Administration (FDA) has set a target action date under the Prescription Drug User Fee Act (PDUFA) of July 19, 2017 for a decision regarding the potential approval of DEXTENZA for the treatment of ocular pain following ophthalmic surgery.

Primary endpoints included absence of anterior chamber (AC) cells (a sign of inflammation) at Day 14 and absence of pain at Day 8. Topical NSAIDs were not permitted. Both endpoints were statistically superior to placebo, with more than 52% of patients receiving DEXTENZA having no AC cells at Day 14 compared to 31.1% of placebo subjects. Additionally, 79% of patients in the DEXTENZA group reported no pain at Day 8 compared to 61.3% of the placebo group. Statistical superiority of DEXTENZA was also noticed at Day 2 for the absence of ocular pain and Day 4 for the absence of AC cells. There were no treatment-related serious adverse events (SAEs) and DEXTENZA was well tolerated in all clinical trials. No patients experienced any adverse events resulting in study withdrawal.

A cross-sectional, qualitative survey, commissioned by Ocular Therapeutix, evaluating patient experience of DEXTENZA among 25 patients from U.S. Phase 3 investigational clinical trials was also presented at the ASCRS meeting. In the survey, 92% of patients reported the highest level of overall satisfaction with the product, and would recommend DEXTENZA to family and friends. Further, 96% of patients reported the highest level of satisfaction with regard to convenience. Additionally, 84% of patients reported that they would be willing to pay more for DEXTENZA and would request DEXTENZA again.

“DEXTENZA’s safety and efficacy profile, combined with a positive patient experience, provide a strong foundation for offering an alternative to current post-operative steroid eye drops, which are associated with compliance issues,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman of Ocular Therapeutix. “If approved, DEXTENZA may reduce the patient burden of administering topical eye drops following ophthalmic surgery by enabling physicians to control the entire course of steroid therapy with a single administration.”

The Company also presented data on the importance of pain assessment following ophthalmic surgery; preservatives in topical ophthalmic medications used after ocular surgery; a literature review on medical adherence for glaucoma; and the evaluation of a Phase 3 clinical development program for OTX-TP, a sustained release travoprost intracanalicular insert for the treatment of glaucoma and ocular hypertension.

Phase 3 Study Design

This prospective, multicenter, 1:1 randomized, parallel-arm, double-masked, vehicle-controlled study was designed to evaluate the safety and efficacy of DEXTENZA for the treatment of ocular inflammation and pain following cataract surgery. The study enrolled 438 patients who were undergoing clear corneal cataract surgery at 21 sites throughout the United States. Immediately following surgery, patients were randomized to insertion of either DEXTENZA or a placebo vehicle. Primary efficacy endpoints evaluated the differences between the DEXTENZA treatment group and the placebo group for the absence of anterior chamber cells at day 14 and absence of pain at day 8. Secondary efficacy endpoints included absence of anterior chamber cells, absence of ocular flare, and absence of ocular pain across relevant time points during the 30-day treatment period.

About DEXTENZA™(dexamethasone insert) 0.4 mg for Intracanalicular Use

DEXTENZA is placed through the punctum, a natural opening in the eye lid, into the canaliculus and is designed to deliver dexamethasone to the ocular surface for up to 30 days. Following treatment, DEXTENZA resorbs and exits the nasolacrimal system without need for removal. The Company has completed three Phase 3 clinical trials with DEXTENZA for the treatment of post-surgical ocular inflammation and pain.

Ocular Therapeutix resubmitted an NDA to the FDA for DEXTENZA for the treatment of ocular pain following ophthalmic surgery, for which the FDA has set a PDUFA target action date of July 19, 2017. Subject to the approval of the NDA for post-surgical ocular pain by the FDA, Ocular Therapeutix intends to submit a supplement to its NDA for DEXTENZA to broaden its label to include a post-surgical ocular inflammation indication.

About Ocular Pain and Inflammation Following Ophthalmic Surgery

Ocular pain and inflammation are common side effects following ophthalmic surgery. Physicians prescribe topical corticosteroids as part of the standard of post-operative care. If left untreated, inflammation of the eye may result in further ocular complications, which in some cases may cause permanent loss of vision. According to US Census data, by the year 2020 it is estimated that the number of Americans diagnosed with cataracts is expected to rise to approximately 30 million, representing a 32% increase over current prevalence estimates.

According to Market Scope, approximately 3.9 million cataract cases and over 5.6 million ocular surgeries were performed in the United States in 2016.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the development, manufacturing 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™ (dexamethasone insert) 0.4 mg for intracanalicular use has completed Phase 3 clinical development for the treatment of ocular pain and inflammation following ophthalmic surgery. The FDA has accepted the Company's NDA resubmission for DEXTENZA for the treatment of ocular pain following ophthalmic surgery and has established a PDUFA target action date of July 19, 2017. If approved, the Company intends to submit a supplement to its NDA for ocular inflammation. OTX-TP (travoprost insert) is in Phase 3 clinical development for glaucoma and ocular hypertension. Ocular Therapeutix is also evaluating injectable drug delivery 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 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 the treatment of post-surgical ocular inflammation and pain, including our expectations regarding the NDA filed with the FDA and the FDA's response to the resubmitted NDA and the potential impact of the re-inspection of manufacturing operations, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for the treatment of dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel technology, the potential utility of any of the Company's product candidates, potential commercialization of the Company's 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 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.

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Source: Ocular Therapeutix, Inc.

Media
Medical Dynamics
Sandra Correa, 646-599-8637
Business & Media Group Director
scorrea@rxmedyn.com
or
Investors
Burns McClellan on behalf of Ocular Therapeutix
Steve Klass, 212-213-0006
sklass@burnsmc.com
or
Ocular Therapeutix
Scott Corning
Vice President of Marketing & Commercial Operations
scorning@ocutx.com