Ocular Therapeutix™ Presented Phase 3 Data for DEXTENZA™ at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting

May 11, 2017

Data Presented Evaluating Integrated Efficacy and Safety of DEXTENZA Following Cataract Surgery

BEDFORD, Mass.--(BUSINESS WIRE)--May 11, 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 ocular pain data from a pooled analysis from three Phase 3 clinical trials evaluating the efficacy and safety of DEXTENZA (dexamethasone insert) 0.4 mg for intracanalicular use, for the treatment of ocular pain and inflammation following cataract surgery, at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in Baltimore, MD.

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. The upcoming PDUFA date is for a New Drug Application (NDA) for the treatment of ocular pain following ophthalmic surgery based on a Phase 2 study and two Phase 3 trials. The third and most recent Phase 3 study results are not currently being evaluated by FDA as part of the current NDA.

The pooled analysis includes data from all three Phase 3 trials, in which 79% percent of DEXTENZA patients reported no pain at Day 8 compared to 56.9% of the placebo patients. Across all three Phase 3 trials, a greater proportion of placebo patients experienced at least one ocular adverse event (AE) as compared with DEXTENZA patients. The most frequent ocular AEs were anterior chamber inflammation, increased intraocular pressure, corneal edema, and eye inflammation. There were no treatment-related serious adverse events (SAEs) in either group.

“The pooled safety and efficacy profile suggests that DEXTENZA may offer an alternative to current post-operative steroid eye drops, which are associated with compliance issues,” said Jonathan H. Talamo, MD, Chief Medical Officer of Ocular Therapeutix. “If approved, DEXTENZA has the potential to reduce the burden of administering topical eye drops following ophthalmic surgery, and to enhance patient and provider experience by enabling physicians to control the entire course of steroid therapy with a single insertion.”

A poster describing the results of the pooled analysis from three Phase 3 clinical trials evaluating the efficacy and safety of DEXTENZA was presented at the ARVO Annual Meeting:

“DEXTENZA™ (dexamethasone insert) 0.4 mg vs. Placebo for the Treatment of Ocular Pain after Cataract Surgery: Results of Three Phase 3 Studies” - Posterboard #B0159, Abstract #1826-B0159

Three Phase 3 trials were pooled to evaluate the integrated efficacy of DEXTENZA when placed in the canaliculus of the eye for the treatment of post-surgical pain in subjects who have undergone cataract extraction with intraocular lens implantation. The pooled analysis confirmed the results of the individual Phase 3 trials. DEXTENZA, compared with placebo vehicle insert, resulted in a significantly greater proportion of patients who reported an absence of ocular pain following cataract surgery.

The Company also presented other data at the ARVO Annual Meeting including:

- Plasma pharmacokinetics of DEXTENZA in healthy volunteers
- The evaluation of a Phase 2b study for OTX-TP, the Company’s sustained release travoprost intracanalicular insert for the treatment of glaucoma and ocular hypertension compared to timolol drops
- Preclinical data on tolerability and pharmacokinetics of a 6 month sustained release hydrogel TKI depot for tyrosine kinase inhibitors (TKIs)
- Efficacy of a 6 month sustained release hydrogel TKI depot in a VEGF-induced retinal leakage model
- Outcomes in cataract surgery using ReSure® Sealant for the intraoperative management of clear corneal incisions

Phase 3 Study Design

DEXTENZA has been studied in three Phase 3 trials. All trials were prospective, multicenter, parallel-arm, double-masked, and vehicle-controlled to evaluate the safety and efficacy of DEXTENZA for the treatment of ocular pain and inflammation following cataract surgery. In two trials, patients were randomized 2:1 (DEXTENZA to placebo vehicle insert); while the in the most recent study patients were randomized 1:1. A total of 926 patients were enrolled (n=541, DEXTENZA; n=385, placebo vehicle insert) who were undergoing clear corneal cataract surgery. Immediately following surgery, patients were randomized to insertion of either DEXTENZA or a placebo insert. 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.

In January, Ocular Therapeutix resubmitted an NDA to the FDA for DEXTENZA for the treatment of ocular pain following ophthalmic surgery. 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, based on the results of the third Phase 3 study.

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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