New Publication Describes Positive Patient Experience in Study of Ocular Therapeutix' DEXTENZA™ Following Cataract Surgery

March 15, 2017

BEDFORD, Mass.--(BUSINESS WIRE)--Mar. 15, 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, today announced positive results of a patient experience study of DEXTENZA™ (dexamethasone insert) 0.4 mg for intracanalicular use. The study, published in *Patient Preference and Adherence,* evaluated the overall patient experience and perceived value of DEXTENZA following cataract surgery.

DEXTENZA is a hydrogel-based drug-eluting intracanalicular insert that incorporates the U.S. Food and Drug Administration (FDA)-approved corticosteroid, dexamethasone, as the active ingredient. Inserted non-invasively through the punctum, DEXTENZA resides within the canaliculus and delivers dexamethasone to the ocular surface for approximately 30 days. Following the completion of treatment, DEXTENZA resorbs and exits the nasolacrimal system without need for removal.

The goal associated with DEXTENZA is to reduce the patient burden of administration of topical eye drops following ophthalmic surgery by enabling the physician to control the entire course of steroid therapy with a single administration. The extended release benefit of DEXTENZA replaces the need for patients to administer steroid eye drops in a complex, tapering, several-times-a-day regimen over the course of a month. In parallel, DEXTENZA aims to remove the issues commonly associated with non-compliance of post-operative medications following ophthalmic surgery.

A New Drug Application (NDA) for DEXTENZA is currently under review by the FDA for the treatment of ocular pain occurring after ophthalmic surgery. The FDA has set a PDUFA target action date for July 19, 2017.

The patient experience retrospective study was conducted with 25 patients who had received active treatment in the Company's Phase 3 clinical trials of DEXTENZA for the treatment of post-surgical ocular pain and inflammation.

- All patients reported that the intracanalicular insert was comfortable.
- Ninety-six percent (96%) felt the insert was extremely or very convenient compared to topical eye drops on a tapered schedule.
- Ninety-two percent (92%) reported the highest level of overall product satisfaction, with eighty-eight percent (88%) saying they would request the insert if they were to undergo cataract surgery again.
- Ninety-two percent (92%) of patients surveyed said they would recommend DEXTENZA to friends or family members.

"We are encouraged by the experiences these patients shared, which add another dimension to the clinical results achieved in the Phase 3 clinical trials," said Jonathan H. Talamo, M.D., Chief Medical Officer of Ocular Therapeutix. "If approved, we believe that DEXTENZA, which incorporates the Company's proprietary hydrogel platform technology, will offer an attractive alternative to the current post-operative standard of care of steroid eye drops for those recovering from ophthalmic surgery."

In the Company's third and most recent Phase 3 clinical trial, DEXTENZA successfully met the two primary efficacy endpoints, absence of ocular pain on day 8 and absence of ocular inflammation on day 14, when compared to placebo. DEXTENZA has exhibited a favorable safety profile and has been well tolerated in all clinical trials, regardless of indication. Subject to the approval of the NDA for post-surgical ocular pain by the FDA, Ocular Therapeutix intends to submit an NDA supplement for DEXTENZA to broaden its label to include a post-surgical inflammation indication.

About DEXTENZA™
DEXTENZA™ (dexamethasone insert) 0.4mg for intracanalicular use 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.

In January, Ocular Therapeutix resubmitted an NDA to the FDA for DEXTENZA for the treatment of ocular pain occurring after ophthalmic surgery. The FDA has set a PDUFA target action date for July 19, 2017. Subject to the approval of the NDA for post-surgical ocular pain by the FDA, Ocular Therapeutix intends to submit an NDA supplement for DEXTENZA to broaden its label to include a post-surgical inflammation indication. DEXTENZA is also in Phase 3 development for the treatment of ocular itching associated with allergic conjunctivitis.

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) 0.4mg for intracanalicular use has completed Phase 3 clinical development for the treatment of ocular pain and inflammation occurring after ophthalmic surgery. The FDA has accepted the Company's NDA resubmission for DEXTENZA for the treatment of ocular pain occurring after ophthalmic surgery and has established a target PDUFA date of July 19, 2017. Ocular Therapeutix is also pursuing additional indications for DEXTENZA. 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, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for the treatment of inflammatory 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, the potential benefits and future operation of the Company's collaboration with Regeneron, including any potential future payments thereunder, 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 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20170315005218/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
Medical Dynamics
Sandra Correa, 646-599-8637
Media and Business Group Director
scorrea@rxmedyn.com
or
Ocular Therapeutix, Inc.
Scott Corning
Vice President of Marketing & Commercial Operations
scorning@ocutx.com