

# Ocular Therapeutix<sup>™</sup> to Present Additional Phase 3 Data and Patient Reported Outcomes Results for DEXTENZA<sup>™</sup> at the American Society of Cataract and Refractive Surgery (ASCRS) Symposium

April 24, 2017

## New Clinical Data to Be Presented Evaluating the Use of DEXTENZA Following Cataract Surgery

BEDFORD, Mass.--(BUSINESS WIRE)--Apr. 24, 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 new data to be presented from its most recent Phase 3 study evaluating the efficacy and safety of DEXTENZA<sup>TM</sup> (dexamethasone insert, 0.4mg) for intracanalicular use, for the treatment of ocular pain and inflammation following cataract surgery, at the upcoming American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting, being held May 5-9, in Los Angeles, Calif.

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

"We believe that DEXTENZA, which utilizes Ocular's proprietary hydrogel platform technology to provide sustained release of steroid therapy for up to 30 days, has the opportunity to offer an attractive alternative to the current post-operative standard of care for those recovering from ophthalmic surgery," said Jonathan H. Talamo, M.D., Chief Medical Officer of Ocular Therapeutix. "The new data to be presented highlight the efficacy and safety profile of DEXTENZA for the treatment of ocular pain and inflammation following cataract surgery, and underscore the Company's efforts to help address the needs of patients currently using steroid eye drops, which are associated with compliance issues."

Additional presentations will be made regarding recent positive results of a patient experience study of DEXTENZA as well as the importance of the assessment of pain. The Company will also present information surrounding its ongoing Phase 3 clinical development program with OTX-TP (travoprost insert) for the treatment of glaucoma and ocular hypertension.

#### **Poster Presentations:**

- Safety and Efficacy of an Extended Release Dexamethasone Insert for Treatment of Ocular Inflammation and Pain after Surgery: Phase 3 Study - May 7<sup>th</sup> from 2:16 PM - 2:21 PM at the L.A. Convention Center - Meeting Room Level, 409A
- Evaluating the Patient Experience After Implantation of a 0.4 mg Sustained Release Dexamethasone Intracanalicular Insert May 7th from 2:11 PM 2:16 PM at the L.A. Convention Center Meeting Room Level, 409AB
- Preservatives in Topical Ophthalmic Medications Used After Ocular Surgery May 7th from 1:56 PM 2:01 PM at the L.A. Convention Center Meeting Room Level, 409AB
- Adherence to Medical Therapy for Glaucoma: Review of the Literature May 7<sup>th</sup> from 8:43 AM 8:48 AM at the L.A. Convention Center Meeting Room Level, 410

### **E-poster Presentations:**

- The Importance of Pain Assessment Following Ophthalmic Surgery
- A Phase 3 Clinical Development Program for OTX-TP, a Novel Sustained Release Travoprost Intracanalicular Depot, for the Treatment of Patients with Open Angle Glaucoma or Ocular Hypertension

# About DEXTENZA™(dexamethasone insert, 0.4mg) 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.

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 a supplement to its NDA for DEXTENZA to broaden its label to include a post-surgical ocular 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 anti-inflammatory drugs, such as 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<sup>TM</sup> (dexamethasone insert, 0.4 mg) 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 following ophthalmic surgery and has established a target PDUFA date of July 19, 2017. If approved, the Company will 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<sup>®</sup> 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 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 forwardlooking 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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