Ocular Therapeutix™ Submits Amendment to Potentially Extend Review for DEXTENZA™ New Drug Application (NDA)

July 10, 2017

Conference Call Today at 5:00pm Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--Jul. 10, 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, announced today that it has submitted details of a manufacturing equipment change as an amendment to the NDA resubmission for DEXTENZA™ (dexamethasone insert) 0.4 mg, for intracanalicular use, for the treatment of ocular pain following ophthalmic surgery currently under review by the U.S. Food and Drug Administration (FDA).

The Company is requesting FDA to consider this submission a major amendment and extend the current NDA target action date of July 19, 2017 under the Prescription Drug Fee User Act (PDUFA) by three months and to review the submission during the current review cycle. As detailed in the amendment, Ocular Therapeutix has modified a piece of manufacturing equipment referenced in the NDA resubmission and will be submitting data on a new commercial batch to demonstrate that this modification, along with other improvements, has addressed outstanding issues regarding particulate matter.

As previously announced, following the completion of a re-inspection of manufacturing operations by the FDA, Ocular Therapeutix received an FDA Form 483 in May 2017. This report contained inspectional observations focused on procedures and training protocols for manufacturing processes and analytical testing related to commercial manufacturing of DEXTENZA. The Company submitted to the FDA its initial corrective action plans within 15 days of receipt of the Form 483 and has remained in ongoing communication with the FDA.

On July 10, 2017, Ocular Therapeutix submitted a close-out response to all inspectional observations included in the FDA Form 483 issued in May 2017. The close-out response focused on the characterization of particulates, defining and recognizing their source, implementing appropriate corrective and preventive actions, and revising training protocols and documents for manufacturing technicians. Adequate resolution of the outstanding Form 483 inspectional observations is a prerequisite to the approval of the NDA for DEXTENZA.

The Company follows appropriate industry guidance that permits specific tolerance levels in batch release qualifications. Inspection of all DEXTENZA batches has been an integral standard operating procedure within Ocular's manufacturing and quality control processes, with each dose (insert) inspected individually. Ocular Therapeutix maintains stringent manufacturing standards and conducts a 100% in-process inspection for DEXTENZA. Any inserts that do not pass inspection cannot be, and have not been, considered for either clinical or commercial use.

"We believe that the recent submission of our close-out response to the Form 483 and subsequent submission of the amendment to our NDA resubmission for FDA's consideration can support an acceptable regulatory pathway for the approval of DEXTENZA," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "We continue to be in close communication with the FDA to determine the best course of action in an effort to successfully bring DEXTENZA to market."

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 availability of DEXTENZA™ may enable physicians to control the entire course of steroid therapy following ophthalmic surgery with a single administration, and reduce patient burden of administration of topical eye drops. The extended release benefit of DEXTENZA™ eliminates the need for patients to administer steroid eye drops in a complex, tapering, multiple-times-a-day therapeutic regimen over the course of a month, and aims to overcome compliance issues frequently associated with post-operative medications following ophthalmic surgery.

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. Based on 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.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 5:00 pm Eastern Time. The live webcast can be accessed by visiting the Investors section of the Company's website at investors.ocutx.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 844-464-3934 (U.S.) or 765-507-2620 (International) to listen to the live conference call. The conference ID number for the live call will be 53212491. A replay of the webcast will be available until July 24, 2017 on the Company's website.

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. 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 with respect to the manufacturing deficiencies identified by the FDA and the prospects for approvability of DEXTENZA for these indications, 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 manufacturing operations, 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/20170710006380/en/

Source: Ocular Therapeutix, Inc.

Investors
Burns McClellan
Steve Klass, 212-213-0006
sklass@burnsmc.com
or
Ocular Therapeutix
George Migausky
Interim Chief Financial Officer
gmigausky@ocutx.com
Media
Medical Dynamics
Stephanie Eisenstat, 646-599-8627
seisenstat@rxmedyn.com
or
Ocular Therapeutix
Scott Corning
Vice President of Marketing & Commercial Operations
scorning@ocutx.com