Ocular Therapeutix™ Receives Complete Response Letter from FDA for DEXTENZA™ NDA

July 11, 2017

Outstanding items pertain to Form FDA-483 close-out of manufacturing deficiencies and analytical testing

No efficacy or safety issues raised by FDA

BEDFORD, Mass.--(BUSINESS WIRE)--Jul. 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, announced today that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA), regarding its resubmission of a New Drug Application (NDA) for DEXTENZA™ (dexamethasone insert) 0.4mg for the treatment of ocular pain following ophthalmic surgery. The CRL states that the FDA has determined that it cannot approve the NDA in its present form.

The CRL from the FDA refers to deficiencies in manufacturing processes and analytical testing related to manufacture of drug product for commercial production identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility that was completed in May 2017. As previously announced on July 10, 2017, the Company submitted a response intended to close out all inspectional observations included in the Form FDA-483 issued in May 2017. The Company also submitted details of a manufacturing equipment change on July 10, 2017 as an amendment to the NDA resubmission and requested that this be considered a major amendment that would extend the target action date under the Prescription Drug User Fee Act (PDUFA).

The CRL acknowledges receipt of the Company's NDA amendment dated July 10, 2017 and states that the amendment was not reviewed prior to the FDA's action of the CRL. As a result, the FDA did not have the opportunity to review the Company's close-out response prior to issuing the CRL. In addition, as noted in the CRL, the FDA indicated that applicable sections of the amendment submitted by Ocular Therapeutix could be incorporated when responding to deficiencies noted in the CRL.

Satisfactory resolution of the manufacturing deficiencies detailed in the Form FDA-483 is required before the NDA may be approved. The FDA's letter did not identify any efficacy or safety concerns with respect to the clinical data for DEXTENZA provided in the NDA nor any need for additional clinical trials for the NDA approval.

"We are evaluating the FDA's response and plan to work closely with the agency in an effort to satisfy the requirements related to the NDA," said Ocular Therapeutix President, Chief Executive Officer and Chairman, Amar Sawhney, Ph.D. "Importantly, there were no clinical issues identified in the CRL pertaining to efficacy or safety related to the post-surgical pain indication. We believe that DEXTENZA can be approved once these open manufacturing items are resolved."

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 without preservatives to the ocular surface for up to 30 days. Following treatment, DEXTENZA resorbs and exits the nasolacrimal system without need for removal.

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. If the Company's NDA for the treatment of ocular pain following ophthalmic surgery is 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 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.

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