



Ocular Therapeutix™ Receives Complete Response Letter from FDA for its NDA for DEXTENZA™ for the Treatment of Post-Surgical Ocular Pain

July 25, 2016

No efficacy or safety issues raised by FDA

Outstanding items pertain to manufacturing process and controls

BEDFORD, Mass.--(BUSINESS WIRE)--Jul. 25, 2016-- Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for DEXTENZA™ (dexamethasone insert) 0.4 mg, for intracanalicular use in the treatment of ocular pain occurring after ophthalmic surgery.

The concerns raised by the FDA pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility. The FDA's letter did not provide any details as to which manufacturing deficiencies identified during the facility inspection remain open since the last response submitted by the Company.

Satisfactory resolution of the manufacturing deficiencies identified during the FDA facility inspection 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 provided in the NDA nor any need for additional clinical trials for the approval of the NDA.

"We have previously responded to all requests in an effort to address the manufacturing items raised by the FDA during the application process, and we await completion of the review," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "Importantly, there were no clinical issues identified in the CRL pertaining to efficacy or safety related to the post-surgical pain indication. Labeling discussions with the FDA are ongoing. We remain optimistic that DEXTENZA will be approved once these open manufacturing items are closed. We will continue to work collaboratively with the FDA so they can finalize their review of our NDA, and are committed to bringing DEXTENZA to market as rapidly as possible."

About DEXTENZA™

DEXTENZA (dexamethasone insert) 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 is pursuing multiple indications for DEXTENZA, including the treatment of post-surgical ocular pain, post-surgical ocular inflammation, ocular itching associated with allergic conjunctivitis, as well as signs and symptoms associated with inflammatory dry eye disease.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. (NASDAQ: OCUL) is a biopharmaceutical company focused on the development 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), is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and in Phase 2 clinical development for dry eye disease. A third Phase 3 clinical trial is being conducted for post-surgical ocular inflammation and pain. For glaucoma and ocular hypertension, the Company plans to initiate the first of two OTX-TP (sustained release travoprost) Phase 3 clinical trials in the third quarter of 2016. Ocular Therapeutix is also evaluating sustained-release injectable anti-VEGF drug 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 statements about 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 post-surgical ocular inflammation and pain, including our expectations regarding the pending NDA filed with the FDA, DEXTENZA™ for the treatment of allergic conjunctivitis, DEXTENZA for dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel depot technology and the advancement of the Company's other product candidates, the potential utility of any of the Company's product candidates, 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.

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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

Ocular Therapeutix, Inc.

Scott Corning

Vice President of Sales and Marketing

scorning@ocutx.com