Ocular Therapeutix™ Provides Update on NDA for DEXTENZA™ for the Treatment of Post-Surgica Ocular Pain

August 3, 2016

One outstanding item remains pertaining to manufacturing process and controls

BEDFORD, Mass.--(BUSINESS WIRE)--Aug. 3, 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 provided an update on the status of 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.

On July 25, 2016, Ocular Therapeutix announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its NDA for DEXTENZA that identified issues pertaining to deficiencies in the manufacturing process and controls identified during a pre-NDA approval inspection of the Company's manufacturing facility. The CRL for DEXTENZA 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.

Recently, the FDA issued a letter to Ocular Therapeutix noting that corrective actions detailed in its responses as a whole appear to address the ten inspectional observations raised in the Form FDA 483 with one exception which relates to the proposed process for identity testing of an incoming inert gas component used in the manufacturing process. In this letter, the FDA also requested that the Company provide evidence (e.g., a final report) when migration to automatic integration of analytical testing is complete, which is anticipated during the third quarter of 2016.

"We are working closely with the FDA to address the one remaining item and are planning for a resubmission to our NDA as soon as possible," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "We remain 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.

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