Ocular Therapeutix™ Announces FDA Acceptance of NDA Resubmission for DEXTENZA™ for the Treatment of Ocular Pain Occurring After Ophthalmic Surgery

February 22, 2017

PDUFA target action date set for July 19, 2017

DEXTENZA initial target market comprises nearly 4 million cataract surgeries in the U.S.

BEDFORD, Mass.--(BUSINESS WIRE)--Feb. 22, 2017-- 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 the Company's New Drug Application (NDA) resubmission for DEXTENZA™ (dexamethasone insert) 0.4 mg for intracanalicular use, for the treatment of ocular pain occurring after ophthalmic surgery has been accepted as a filing for review by the U.S. Food and Drug Administration (FDA). DEXTENZA is a product candidate administered by a physician as a bioresorbable intracanalicular insert and designed for drug release to the ocular surface for up to 30 days.

The FDA determined that the NDA resubmission is a complete response and designated the resubmission as a Class 2 review, with a target action date under the Prescription Drug User Fee Act (PDUFA) of July 19, 2017 for the potential approval of DEXTENZA™.

"We are pleased the FDA has accepted our resubmission of the DEXTENZA NDA and that we now have clarity on the PDUFA target action date. We look forward to advancing this process toward our goal of the potential approval and commercial launch of DEXTENZA," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "With nearly four million cataract surgeries performed in the U.S. in 2016 as our initial target, the market opportunity for DEXTENZA is significant. If approved, we believe DEXTENZA will be the first non-invasive therapy available to patients and ophthalmologists that can provide a full post-operative course of therapy with a single placement."

About DEXTENZA™

DEXTENZA™ (dexamethasone insert) 0.4mg is placed through the punctum, a natural opening in the eye lid, into the canaliculus and is designed to deliver a tapered dose of 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. Subject to the approval of the NDA for post-surgical ocular pain by the FDA, Ocular Therapeutix intends to promptly submit an NDA supplement for DEXTENZA to broaden its label to include a post-surgical 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 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 total ocular surgeries were expected to be performed in the United States in 2016.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. 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 has resubmitted a new drug application (NDA) for post-surgical pain for its lead product candidate, DEXTENZA (dexamethasone insert), which has completed Phase 3 clinical development for ocular pain and inflammation following ophthalmic surgery, and the Company is pursuing additional indications for DEXTENZA. OTX-TP (sustained release travoprost) 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 our expectations regarding the resubmission of the NDA filed with the FDA and potential FDA approval, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for the treatment of inflammatory 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, the potential utility of any of the Company's product candidates, potential commercialization of the Company's product candidates, the potential benefits and future operation of the collaboration with Regeneron, including any potential future payments thereunder, 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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