Ocular Therapeutix™ Resubmits NDA for DEXTENZA™ for the Treatment of Ocular Pain Occurring After Ophthalmic Surgery

January 23, 2017

BEDFORD, Mass.--(BUSINESS WIRE)--Jan. 23, 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 it has resubmitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for DEXTENZA™ (dexamethasone insert) 0.4 mg, for the treatment of ocular pain occurring after ophthalmic surgery. 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.

“Following productive discussions with the FDA, we are pleased to announce the resubmission of our NDA for DEXTENZA for the treatment of ocular pain occurring after ophthalmic surgery,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. “If DEXTENZA is approved, we believe that its ability to provide a complete course of steroid therapy with one-time administration in the post-surgical setting will be extremely attractive for both ophthalmologists and patients. We continue to build our commercial organization and infrastructure in preparation for the earliest possible launch of DEXTENZA, subject to marketing approval.”

Ocular Therapeutix resubmitted the NDA in response to a complete response letter (CRL) the Company received from the FDA in July 2016, which identified items pertaining to deficiencies in manufacturing process and controls. The Company expects to receive an indication of the scope and timing of the FDA’s review of the Company’s NDA resubmission within approximately 30 days. The Company believes that the FDA review period of the NDA resubmission will be up to two months if a Class 1 (minor review) designation is received and up to six months if a Class 2 (major review) designation is received. Class 1 or 2 designation is dependent on whether an FDA re-inspection of the Ocular Therapeutix manufacturing facility will be a condition of NDA approval.

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 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 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 ocular surgeries were performed in the United States in 2016.

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 has resubmitted an NDA for post-surgical pain for its lead product candidate, DEXTENZA™ (dexamethasone insert) 0.4mg, which has completed Phase 3 clinical development for post-surgical ocular inflammation and pain. Subject to the approval of the NDA for post-surgical ocular pain, Ocular Therapeutix intends to submit a supplemental NDA for DEXTENZA to broaden its label to include an indication for post-surgical inflammation. DEXTENZA is also in Phase 3 clinical development for allergic conjunctivitis. 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. For additional information about the Company, please visit www.ocutx.com.

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 NDA filed with the FDA and the FDA’s response to the resubmitted NDA, 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 Company’s 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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