Ocular Therapeutix™ Submits New Drug Application to U.S. Food and Drug Administration for DEXTENZA® for the Treatment of Post-Surgical Ocular Pain

September 28, 2015

Third Phase 3 Clinical Trial for Post-Surgical Ocular Inflammation and Pain Expected to Be Initiated in October 2015

BEDFORD, Mass.--(BUSINESS WIRE)--Sep. 28, 2015-- 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 submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for DEXTENZA® (sustained release dexamethasone) 0.4mg Intracanalicular Depot, for the treatment of ocular pain following ophthalmic surgery. The data included in the NDA submission are from a Phase 2 clinical trial and two Phase 3 clinical trials conducted with this product candidate.

"This represents Ocular Therapeutix's first NDA filing with the FDA and is an important development milestone as we advance our broad-based programs for the treatment of ocular diseases and conditions through clinical development and potential commercialization pending FDA approval. We look forward to offering patients this exciting alternative to steroid eye drop therapy," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "DEXTENZA offers patients a full post-operative course of therapy with one-time administration as compared to the current standard of care requiring multiple eye drops daily. DEXTENZA also avoids the peaks and valleys of dosage associated with eye drops and provides the potential for an improved safety profile including minimal intraocular pressure spikes."

Based on the results of the Company's two completed Phase 3 clinical trials and following a Pre-NDA Clinical meeting with the FDA in April 2015, the Company formulated its plans for submitting an NDA for DEXTENZA for the treatment of post-surgical ocular pain and for conducting a third Phase 3 clinical trial of DEXTENZA for the treatment of post-surgical ocular inflammation and pain. The Company intends to submit a supplement to the NDA for the treatment of post-surgical inflammation as part of its label expansion strategy for DEXTENZA if it obtains favorable results from the third Phase 3 clinical trial, which is expected to commence later this year, and subject to the approval of the NDA for post-surgical ocular pain by the FDA.

About DEXTENZA

DEXTENZA (sustained release dexamethasone) 0.4 mg Intracanalicular Depot is a product candidate placed through the punctum, a natural opening in the eyelid, into the canaliculus and is designed to deliver dexamethasone to the ocular surface for four weeks. Following treatment, DEXTENZA resorbs and exits the nasolacrimal system without need for removal. Earlier this year, Ocular Therapeutix announced results from its two Phase 3 clinical trials of DEXTENZA for the treatment of post-operative ocular inflammation and pain. To capitalize on the broader opportunity for the sustained delivery of corticosteroids to the front of the eye, the Company is pursuing additional indications for DEXTENZA. The Company recently completed enrollment in a Phase 3 clinical trial of DEXTENZA for the treatment of allergic conjunctivitis and expects to report topline efficacy data from this trial in the fourth quarter of 2015. The Company has also completed patient enrollment in an exploratory Phase 2 clinical trial of DEXTENZA for the treatment of inflammatory dry eye and expects to report topline efficacy data from this trial in the fourth quarter of 2015.

Two prospective, multicenter, randomized, parallel-arm, double-masked, vehicle-controlled Phase 3 clinical trials were completed with a total of 487 patients undergoing unilateral clear corneal cataract surgery in the first half of 2015. Patients were randomized 2:1 to receive either DEXTENZA or a placebo vehicle control punctum plug without active drug. Both primary efficacy endpoints, differences in the proportion of patients in the DEXTENZA treatment group compared with the placebo group with absence of cells in the anterior chamber of the study eye, as measured using slit lamp examination, at day 14 and absence of pain, as graded by a patient-reported score of zero on a scale from zero to ten, at day 8, were recorded at each study visit. Secondary efficacy endpoints were absence of flare in the anterior chamber of the study eye at each evaluation date and absence of inflammatory cells in the anterior chamber of the study eye and absence of pain in the study eye at each evaluation date other than the day used for the primary efficacy measure.

About Post-Surgical Ocular Inflammation and Pain

Ocular pain and inflammation are common side effects following ophthalmic surgery. Physicians prescribe anti-inflammatory drugs, such as corticosteroids, as the standard of care. If left untreated, inflammation of the eye may result in further ocular complications, including scarring and vision loss. Approximately 5.3 million ocular surgeries were performed in the United States in 2014.

About Ocular Therapeutix

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 candidates are in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and Phase 2 clinical development for glaucoma and inflammatory dry eye disease. The Company 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 of the Company's product candidates, such as the Company's plans for regulatory submissions and the design, initiation and conduct of a third clinical trial of DEXTENZA® for post-surgical inflammation and pain, the ongoing development of the Company's sustained release hydrogel depot technology, the timing and conduct of the Company's Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension, the Company's Phase 3 clinical trials of DEXTENZA for allergic conjunctivitis and the Company's Phase 2 clinical trial of OTX-DP for the treatment of

inflammatory dry eye disease, the advancement of the Company's other 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, 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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