Ocular Therapeutix™ Begins Enrollment in Third Phase 3 Clinical Trial for DEXTENZA™ for the Treatment of Post-Surgical Ocular Inflammation and Pain

October 14, 2015

BEDFORD, Mass.--(BUSINESS WIRE)--Oct. 14, 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 the enrollment of the first patients in a third Phase 3 clinical trial for DEXTENZA™ (sustained release dexamethasone) 0.4mg Intracanalicular Depot, for the treatment of post-surgical ocular inflammation and pain.

Based on the results of the Company's two previously completed Phase 3 clinical trials and following a Pre-NDA Clinical meeting with the U.S. Food and Drug Administration (FDA) in April 2015, the Company recently submitted a New Drug Application (NDA) to the FDA for DEXTENZA™ (sustained release dexamethasone) 0.4mg Intracanalicular Depot, for the treatment of ocular pain following ophthalmic surgery. 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 this third Phase 3 clinical trial and subject to receiving approval of the pain indication pursuant to the initial NDA.

"This is an important step for Ocular as we continue to execute on our label expansion strategy for DEXTENZA and we look forward to offering patients this innovative alternative to steroid eye drop therapy," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman.

This prospective, multicenter, randomized, parallel-arm, double-masked, vehicle-controlled study is enrolling 436 patients undergoing clear corneal cataract surgery at 20 sites throughout the United States. Following surgery, patients will be randomized to either DEXTENZA or a placebo vehicle. Primary endpoints are absence of anterior chamber cells at day 14 and reduction of pain at day 8. Based on the learnings from the two previously conducted Phase 3 clinical trials and following a Pre-NDA Clinical meeting with the FDA, the Company has designed this trial to include key modifications, such as:

- 1:1 patient randomization of treatment and placebo groups instead of a 2:1 randomization;
- Exclusion of patients who are being treated with high dosage levels of oral nonsteroidal anti-inflammatory drugs, or NSAIDs; and
- Improvement of the training and guidance to the on-site clinical investigators regarding adherence to study protocols, including the appropriate use of rescue medications.

The Company anticipates that top-line efficacy results from this trial will be available in late 2016.

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 delivers dexamethasone to the ocular surface for four weeks. Following treatment, DEXTENZA resorbs and exits the nasolacrimal system without need for removal. To capitalize on the broader opportunity for the sustained delivery of corticosteroids to the front of the eye, the Company is pursuing multiple indications for DEXTENZA.

Earlier this year, Ocular Therapeutix announced results from its two completed Phase 3 clinical trials of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery. The Company recently submitted an NDA to the FDA for ocular pain following ophthalmic surgery and has initiated the third Phase 3 clinical trial for ocular inflammation and pain. 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.

About Ocular Inflammation and Pain Following Ophthalmic Surgery

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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