Ocular Therapeutix™ Announces FDA Acceptance of NDA Filing for DEXTENZA™ for the Treatmen of Post-Surgical Ocular Pain

December 9, 2015

PDUFA target action date of July 24, 2016

DEXTENZA initial target indication comprises over 5 million ocular surgeries

BEDFORD, Mass.--(BUSINESS WIRE)--Dec. 9, 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 the New Drug Application (NDA) for DEXTENZA™ (sustained release dexamethasone), Intracanalicular Depot, for the treatment of ocular pain following ophthalmic surgery, has been accepted for review by the U.S. Food and Drug Administration (FDA). The acceptance of the NDA by the FDA in its 74-day letter indicates that the application permits a substantive review and there are no issues that have been identified at present that would delay the FDA's review progress. The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of July 24, 2016 for potential FDA approval of DEXTENZA™.

"We are pleased that Ocular Therapeutix's first NDA filing with our lead product candidate, DEXTENZA, has been officially accepted for review by the FDA. This is an important milestone for the Company and we will continue to work diligently with the FDA as they complete their review," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "DEXTENZA would provide a full post-operative course of therapy with one-time administration as compared to the current standard of care, which requires a complex and tapering regimen of multiple eye drops on a daily basis. We are excited to potentially offer both surgeons and their patients a novel alternative to steroid eye drop therapy."

The data included in the NDA are from a Phase 2 clinical trial and two Phase 3 clinical trials conducted with DEXTENZA for the treatment of post-surgical ocular inflammation and pain. Based on the results of these trials and following a Pre-NDA Clinical meeting with the FDA, the Company submitted an NDA for the treatment of post-surgical ocular pain.

"DEXTENZA is designed to give a patient an entire 30-day course of medication with a single application of a depot, placed by the doctor in the tear punctum. Patients don't have to take the medication themselves, and doctors don't have to wonder whether patients are being compliant. This is a novel development in ophthalmology. It is also exciting to consider the additional possibilities the company is pursuing for DEXTENZA, as a one-time use steroid with a strong safety profile that could have broad applicability in ophthalmology," stated John Hovanesian, MD, Clinical Faculty, UCLA Jules Stein Eye Institute (Los Angeles, CA) and Harvard Eye Associates (San Clemente, CA).

About DEXTENZA™

DEXTENZA (sustained release dexamethasone) Intracanalicular Depot is 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. 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. These include treatment of:

- post-surgical ocular pain
- post-surgical ocular inflammation
- ocular itching associated with allergic conjunctivitis
- signs and symptoms associated with inflammatory dry eye disease

In addition to the NDA submission for the treatment of ocular pain following ophthalmic surgery, the Company has recently initiated a third Phase 3 clinical trial for post-surgical ocular inflammation and pain. The Company also recently completed its first Phase 3 clinical trial for allergic conjunctivitis and reported that DEXTENZA successfully met the primary endpoint for the treatment of ocular itching associated with allergic conjunctivitis, and recently initiated a second Phase 3 clinical trial for this indication. Subject to approval of the NDA for post-surgical pain and subject to obtaining favorable results for the Phase 3 trial of DEXTENZA for post-surgical ocular inflammation and pain, the Company intends to submit supplements to the NDA for the treatment of post-surgical inflammation, as well as for itching associated with allergic conjunctivitis, to seek to broaden DEXTENZA's label.

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 December of 2015.

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 following ophthalmic surgery. 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. There were 8.5 million prescriptions for topical single agent steroids in ophthalmology in 2014 representing $747 million in sales.

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™, is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and in Phase 2 clinical development for inflammatory dry eye disease. The Company's product candidate, OTX-TP (sustained release travoprost), completed a Phase 2b

clinical trial for glaucoma and ocular hypertension in October 2015. 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.

Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the development or potential commercialization of the Company's product candidates, such as the Company's plans and expectations regarding regulatory submissions and the design and conduct of a third Phase 3 clinical trial of DEXTENZA™ for post-surgical inflammation and pain, the timing and conduct of a second Phase 3 clinical trial of DEXTENZA for the treatment of allergic conjunctivitis, the Company's exploratory Phase 2 clinical trial of DEXTENZA for the treatment of inflammatory dry eye disease, the timing and conduct of the Company's additional development work and clinical trials of OTX-TP for the treatment of glaucoma and ocular hypertension and the ongoing development of the Company's sustained release hydrogel depot technology, the advancement of the Company's other product candidates, the potential utility of any of the Company's 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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