Ocular Therapeutix™ Begins Enrollment in its Second Phase 3 Clinical Trial for DEXTENZA™ for the Treatment of Allergic Conjunctivitis

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BEDFORD, Mass.--(BUSINESS WIRE)--Nov. 24, 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, announced today enrollment of the first patients in a second Phase 3 clinical trial to evaluate the safety and efficacy of DEXTENZA™ (sustained release dexamethasone), 0.4mg Intracanalicular Depot for the treatment of allergic conjunctivitis. DEXTENZA is a product candidate administered by a physician as a bioresorbable intracanalicular depot and designed for drug release to the ocular surface for up 30 days, which would far surpass the duration of the current standard of care for ocular allergy treatment which is one day.

This prospective, U.S.-based multicenter, 1:1 randomized, double-masked, vehicle-controlled trial is enrolling patients who exhibit chronic signs and symptoms of allergic conjunctivitis. This is the second Phase 3 trial that will evaluate DEXTENZA versus a placebo vehicle punctum plug using Ophthalmic Research Associate's modified Conjunctival Allergen Challenge (Ora-CAC®) Model (Ora, Inc., Andover, MA) which accommodates for the longer therapeutic effect of a seasonal one-time administered drug product. The trial is designed to assess the effect of DEXTENZA compared with placebo on allergic reactions using four series of successive allergen challenges over a 30-day period. DEXTENZA or placebo will be administered 48 to 72 hours after final confirmatory exposure to the allergen. The primary endpoint to be evaluated is ocular itching at day 7 following insertion.

"We are pleased to advance the DEXTENZA platform in allergic conjunctivitis, with the goal of providing patients with one-time, seasonal therapy that is preservative-free," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman of Ocular Therapeutix, Inc. "For the first time, DEXTENZA offers the potential for full-season relief to the patient, as a product candidate designed to both treat ocular itching for 4 weeks and offer prophylaxis against allergic conjunctivitis." Sawhney continued, "The start of another Phase 3 clinical trial for DEXTENZA demonstrates our commitment to applying our proprietary, hydrogel platform to additional indications where patients can benefit from sustained-release therapies. In addition to allergic conjunctivitis, the Company submitted a New Drug Application (NDA) to the FDA for a post-surgical ocular pain indication in October 2015, and an exploratory Phase 2 clinical trial in inflammatory dry eye is expected to read out with topline results before the end of the year."

Ocular Therapeutix reported topline results of its first Phase 3 allergic conjunctivitis clinical trial in October 2015. If the Company meets the primary efficacy endpoint for ocular itching in the second Phase 3 trial and subject to the approval of the NDA submitted for DEXTENZA for the treatment of post-surgical ocular pain, the Company expects to submit an NDA supplement to the FDA for ocular itching associated with allergic conjunctivitis. Many ocular drugs used to treat allergic conjunctivitis have been approved by the FDA solely for ocular itching. Under a revised protocol, the Company's only primary endpoint in the second Phase 3 trial is for ocular itching.

About Allergic Conjunctivitis
Allergic conjunctivitis is an inflammatory disease of the conjunctiva resulting primarily from a reaction to allergy-causing substances such as pollen or pet dander. The primary symptom of this inflammation is acute ocular itching and the primary sign is conjunctival redness. Allergic conjunctivitis ranges in clinical severity from relatively mild, common forms to more severe forms that can cause impaired vision. According to a study on the management of seasonal allergic conjunctivitis published in 2012 in the peer-reviewed journal *Acta Ophthalmologica*, allergic conjunctivitis affects 15% to 40% of the U.S. population. For patients with chronic or more severe forms of allergic conjunctivitis, antihistamines and mast cell stabilizers are often not sufficient to treat their signs and symptoms. Many ocular allergy sufferers are not responsive to the conventional dual-acting antihistamine/mast cell stabilizers. These refractory patients are frequently treated with topical corticosteroids administered by eye drops.

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. An NDA for the post-operative ocular pain indication has been submitted to the FDA and a third Phase 3 clinical trial is being conducted for post-operative ocular inflammation and pain. The Company's product candidate, OTX-TP (sustained release travoprost) intracanalicular depot, has completed a Phase 2b clinical trial for glaucoma and ocular hypertension. 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 timing and conduct of a second Phase 3 clinical trial of DEXTENZA for the treatment of allergic conjunctivitis, 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, and 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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