Ocular Therapeutix™ Announces First Patient Dosed in Phase 3 Clinical Trial of DEXTENZA® for the Treatment of Allergic Conjunctivitis

September 24, 2019

BEDFORD, Mass.--(BUSINESS WIRE)--Sep. 24, 2019-- Ocular Therapeutix ™, Inc. (NASDAQ: OCUL), a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye, today announced that it has dosed the first patients in its Phase 3 clinical trial of DEXTENZA® for the treatment of symptoms of allergic conjunctivitis (AC). AC refers to inflammation of the conjunctiva of the eye caused by an allergic reaction – generally from airborne allergens – that affects approximately 70 million people in the United States and results in itching and burning of the eyes.

"We are pleased to be advancing DEXTENZA for allergic conjunctivitis," said Antony Mattessich, President and Chief Executive Officer. "We believe DEXTENZA has the potential to replace the current standard of care eye drops with a one time, long-acting, seasonal therapy for the treatment of AC. With the start of this Phase 3 trial, following the recent approval of DEXTENZA in the U.S. by the Food and Drug Administration (FDA) for the treatment of ocular inflammation and pain following ocular surgery, we are clearly focused on demonstrating DEXTENZA's potential as a platform product for Ocular Therapeutix both in the surgical and outpatient settings."

The Phase 3 clinical trial is a U.S.-based, multi-center, 1:1 randomized, double-masked, placebo-controlled trial that intends to enroll approximately 80 subjects. The study's primary objective is to evaluate the safety and efficacy of DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg versus a placebo vehicle punctum plug using the Ophthalmic Research Associates' modified Conjunctival Allergen Challenge (Ora-Cac ®) Model for the treatment of ocular itching associated with AC. The trial is designed to assess the effect of DEXTENZA compared with a placebo on allergic reactions using a series of successive allergen challenges over a 30-day period. The primary efficacy endpoint being evaluated in the study is ocular itching following insertion of DEXTENZA at multiple time points during the 30 day period. DEXTENZA is administered by a physician as a bioresorbable intracanalicular insert and designed for drug release to the ocular surface for up to 30 days.

This trial represents the third Phase 3 clinical trial in AC conducted by Ocular Therapeutix and, if successful, the Company plans to submit a supplemental New Drug Application (sNDA) to the FDA for ocular itching associated with AC. Topline data from this trial are anticipated in the first half of 2020.

About DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg
DEXTENZA is an FDA-approved corticosteroid indicated for the treatment of ocular inflammation and pain following ophthalmic surgery. DEXTENZA is inserted into the canaliculus by the physician following ophthalmic surgery. A single DEXTENZA releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion. DEXTENZA is preservative free, resorbable and does not require removal.

DEXTENZA is contraindicated in patients with active corneal, conjunctival or canalicular infections. Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be monitored during the course of the treatment. Corticosteroids may suppress the host response to, and increase the hazard for and severity of, secondary bacterial, viral, or fungal infections. The use of steroids after cataract surgery may delay wound healing and increase the incidence of bleb formation.

The most commonly reported ocular adverse reactions that occurred in patients treated with DEXTENZA were anterior chamber inflammation including iritis and iridocyclitis (10%) and elevations in intraocular pressure (6%). The most common non-ocular adverse reaction was headache (1%).

Click here for the full Prescribing Information.

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. 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 corticosteroid eye drops.

About Ocular Therapeutix, Inc.
Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary bioresorbable hydrogel-based formulation technology. Ocular Therapeutix's first commercial drug product, DEXTENZA®, is FDA-approved for the treatment of ocular inflammation and pain following ophthalmic surgery. OTX-TP (intracanalicular travoprost insert) is an intracanalicular insert in Phase 3 clinical development for the reduction of intraocular pressure in patients with primary open-angle glaucoma and ocular hypertension. The Company's earlier stage assets include OTX-TIC, an extended-delivery intracameral travoprost implant for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension, as well as sustained release intravitreal implants for the treatment of retinal diseases. These intravitreal implants include OTX-TKI, containing a tyrosine kinase inhibitor (TKI), and, in collaboration with Regeneron, OTX-IVT, an extended-delivery protein-based anti-vascular endothelial growth factor (VEGF) trap. 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 the commercialization of

DEXTENZA®, ReSure Sealant, or any of the Company's product candidates, including the commercial launch of, and effectiveness of reimbursement codes for, DEXTENZA; the development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of DEXTENZA for additional indications including allergic conjunctivitis, OTX-TP for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TIC for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-IVT as an extended-delivery formulation of the VEGF trap aflibercept for the treatment of retinal diseases including wet AMD; the ongoing development of the Company's extended-delivery hydrogel depot technology; the potential utility of any of the Company's product candidates; the potential benefits and future operation of the collaboration with Regeneron Pharmaceuticals, 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 DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, the ability to maintain reimbursement codes for DEXTENZA, the initiation, timing 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, the Company's existing indebtedness, the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default, the outcome of the Company's ongoing legal proceedings 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 except as required by law. 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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