Ocular Therapeutix™ Announces Topline Results of Phase 3 Clinical Trial for DEXTENZA™ for the Treatment of Allergic Conjunctivitis

October 22, 2015

DEXTENZA successfully met primary endpoint for treatment of ocular itching associated with allergic conjunctivitis

Conference call today at 5:00 pm Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--Oct. 22, 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 topline efficacy results from a Phase 3 clinical trial to evaluate the safety and efficacy of DEXTENZA™ (sustained release dexamethasone) 0.4 mg, 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 extended drug release to the ocular surface for 30 days.

Treatment success was evaluated separately in this trial for ocular itching and conjunctival redness, and attainment of endpoints for both ocular itching and conjunctival redness has not been historically required by the U.S. Food and Drug Administration (FDA) for approval of drugs for allergic conjunctivitis.

The primary endpoint of treatment of ocular itching associated with allergic conjunctivitis was successfully achieved in this trial. There was a statistically significant difference ($p<0.0001$) in the mean scores between the DEXTENZA treatment group and the placebo group for ocular itching at all three time points measured on day 7 post-insertion of the drug product. The difference in the scores for ocular itching between the DEXTENZA group and the placebo group was greater than 0.5 units at all time points on day 7 post-insertion and was greater than 1 unit at a majority of the time points on day 7 post-insertion.

The primary endpoint of conjunctival redness is typically an endpoint included in Phase 3 trials for allergic conjunctivitis but has not been required for approval. The DEXTENZA treatment group did not achieve the primary endpoints for conjunctival redness in this trial. Many commercially available prescription medications for the treatment of allergic conjunctivitis have an ocular itching indication only. In this clinical trial, as well as other clinical trials completed to date, DEXTENZA has exhibited a strong safety profile and has been well tolerated.

“We are very pleased with the results of this Phase 3 clinical trial in terms of the treatment of ocular itching associated with allergic conjunctivitis,” stated Amar Sawhney, Ph.D., Chairman, Chief Executive Officer and President. “We believe that the design modifications made from our Phase 2 program contributed to the successful achievement of the primary endpoint for ocular itching. Based on the results from this trial, we expect to advance this program into a second Phase 3 clinical trial in allergic conjunctivitis before the end of 2015. We believe the results from this trial, as well as data from the previous Phase 2 study, provide evidence supporting the safety and efficacy of our sustained release drug delivery platform that we continue to leverage across multiple ocular diseases and conditions.”

Michael B. Raizman, MD, Ophthalmic Consultants of Boston, New England Eye Center, Tufts University School of Medicine, stated, “The clinical data for DEXTENZA indicate that this promising product candidate has potential to serve as an effective alternative to self-administered drops for patients experiencing itching associated with allergic conjunctivitis. DEXTENZA offers one-time seasonal administration in a preservative-free product, is designed to avoid the peaks and valleys associated with topical dosing, and has the potential to minimize or eliminate the side effects associated with eye drops. The results for ocular itching are encouraging given that I consider itching to be the most relevant endpoint for my patients.”

Phase 3 Study Design

The Phase 3 U.S.-based, multicenter, 1:1 randomized, parallel-arm, double-masked, vehicle-controlled trial in 73 patients was designed to evaluate the safety and efficacy of DEXTENZA™ (sustained release dexamethasone) 0.4mg, Intracanalicular Depot for the treatment of the signs and symptoms of allergic conjunctivitis. This is the first of two planned Phase 3 studies to be conducted by Ora, Inc., evaluating DEXTENZA versus a placebo drug delivery vehicle using the modified Ora-CAC® (Conjunctival Allergen Challenge) model. This model was developed by Ora to study the longer therapeutic effect of a one-time administered sustained release drug product.

The study was designed to assess the effect of DEXTENZA compared with a placebo drug delivery vehicle on allergic reactions using four series of successive allergen challenges over a 30-day period. According to the trial design, DEXTENZA or placebo was administered 48 to 72 hours after final confirmatory exposure to the allergen. The primary efficacy endpoints evaluated were the differences in mean scores in ocular itching and conjunctival redness between the treatment group and the placebo group at 7 days following insertion of the drug product.

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 sign of this inflammation is conjunctival redness, and the primary symptom is acute ocular itching. 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.

About the Modified Conjunctival Allergen Challenge Model

The modified Ora-CAC® model used in the recently completed study has been developed to study the interactions between the early and late phases of the allergic response in the eye, and to evaluate the effects of pharmaceutical intervention. The modified Ora-CAC model utilizes four challenges

conducted over a 2-day interval to evaluate the effectiveness of a test agent to prevent an acute ocular allergic reaction, as well as evaluate the test agent's ability to prevent an acute ocular allergic reaction in the presence of subclinical late phase inflammation.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 5:00 pm Eastern Time. The live webcast can be accessed by visiting the investor section of the Company's website at investors.ocutx.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 844-464-3934 (U.S.) or 765-507-2620 (International) to listen to the conference call. The conference ID number for the live call will be 66607929. An archive of the webcast will be available until November 5, 2015 on the company's website.

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 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 ongoing development and potential utility of OTX-DP for allergic conjunctivitis and the timing and conduct of the Company's second Phase 3 clinical trial of OTX-DP for allergic conjunctivitis, the Company's plans for regulatory submissions and the advancement of the Company's other product candidates, the potential for the Company's sustained release hydrogel depot technology 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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