Ocular Therapeutix™ Announces Top-Line Results from Phase 2 Sustained Release Dexamethasone Trial for Allergic Conjunctivitis

November 12, 2014

OTX-DP Demonstrated Statistically Significant Therapeutic Effect for Ocular Itching and Conjunctival Redness over Six Weeks with a Single Dose

BEDFORD, Mass.--(BUSINESS WIRE)--Nov. 12, 2014-- 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 top line results for a Phase 2 clinical trial evaluating Sustained Release Dexamethasone (OTX-DP) for treatment of allergic conjunctivitis.

The prospective, multicenter, randomized, double-masked statistically powered study evaluated OTX-DP versus a placebo vehicle control at two clinical sites in the United States. The Company used a modified Conjunctival Allergen Challenge (CAC™) Model to accommodate for the longer therapeutic effect of a one-time administered sustained release drug product. The well controlled trial enrolled 68 patients with the intent to treat for reactions to a variety of allergens over a 42-day period. The primary effectiveness measure was ocular itching and conjunctival redness at 14 days post-insertion.

OTX-DP treated subjects presented statistically significant lower ocular itching and conjunctival redness scores than the placebo group at all three time points measured on Days 14, 28, and 42 after insertion. OTX-DP met one of the two criteria for treatment success previously established by the FDA with other anti-allergic eye drops in the CAC model. As compared to placebo, patients in the OTX-DP treatment group achieved a mean difference of more than 0.5 units on a five point scale at day 14 for both ocular itching and conjunctival redness. The trial did not, however, achieve a mean difference of 1.0 unit at the majority of time points for either ocular itching or conjunctival redness.

OTX-DP is a product candidate placed in the canaliculus and designed to deliver dexamethasone to the ocular surface for approximately four weeks. Following treatment, OTX-DP resorbs and exits the nasolacrimal system without need for removal. We believe OTX-DP is the first sustained release corticosteroid punctum plug to be evaluated in clinical trials for the treatment of allergic conjunctivitis. OTX-DP is also in Phase 3 clinical trials for the treatment of post-operative inflammation and pain, having completed enrollment for two studies in October 2014.

Although effective for treatment of allergic conjunctivitis, topical corticosteroids are often limited in use due to potential side effects such as increased intraocular pressure. “A low-dose, sustained release corticosteroid may alleviate the symptoms of allergic conjunctivitis without unwanted side effects,” stated Amar Sawhney, Ph.D., President and CEO of Ocular Therapeutix. “This Phase 2 trial provided valuable insight into the advantages of utilizing a modified CAC model, which we may incorporate into future trial design. We look forward to further clinical evaluation of the product for the treatment of allergic conjunctivitis. ”

Approximately 6.7 million anti-allergy prescriptions, generating almost $800 million, were prescribed in the United States in 2013. “Eye allergy sufferers experience itchy, watery, and red eyes which often keep them from enjoying daily activities, and require daily administration of medication to control the symptoms,” stated Francis Mah, M.D., Ophthalmologist at Scripps Health System in San Diego, CA, and Medical Monitor for the study. “A sustained release corticosteroid punctum plug is a novel delivery device which may help relieve the symptoms of more chronic and/or severe allergic conjunctivitis while reducing the burden on appropriate patients for daily therapy.”

About Sustained Release Dexamethasone

Sustained Release Dexamethasone (OTX-DP) is a drug product candidate that is placed within the canaliculus and is designed to deliver the corticosteroid dexamethasone to the ocular surface for approximately four weeks. The drug release is tailored such that a low-dose is sustained throughout the treatment period.

About the Modified Conjunctival Allergen Challenge

The modified 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 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.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. 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 Phase 2 clinical development for glaucoma and allergic conjunctivitis. 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, the potential utility of OTX-DP for the treatment of allergic conjunctivitis, the design and conduct of future trials of OTX-DP, the advancement of other product candidates in the Company's pipeline 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 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 most recent Quarterly Report on Form 10-Q 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.

Source: Ocular Therapeutix, Inc.

Investors:
Ocular Therapeutix, Inc.
Brad Smith
Chief Financial Officer
bsmith@ocutx.com
or
Burns McClellan on behalf of Ocular Therapeutix
Kimberly Minarovich, 212-213-0006
kminarovich@burnsmc.com
or
Media:
Scott Corning
Vice President of Sales and Marketing
scorning@ocutx.com