Ocular Therapeutix™ Enrolls First Patient in Phase 2 Clinical Trial for Sustained Release Dexamethasone for the Treatment of Dry Eye Disease

January 21, 2015

Expands Clinical Program of Hydrogel Platform Technology into New Indication

BEDFORD, Mass.--(BUSINESS WIRE)--Jan. 21, 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 patient in a Phase 2 clinical trial to evaluate the safety and efficacy of Sustained Release Dexamethasone (OTX-DP), an ophthalmic corticosteroid for the treatment of inflammatory dry eye disease. Ocular Therapeutix's dexamethasone is being developed for administration as a one-time, bioresorbable intracanalicular plug for drug release to the ocular surface for up 30 days.

In this prospective, multicenter, randomized, parallel-arm, double-masked, vehicle-controlled study, 40 patients (up to 80 eyes) exhibiting signs and symptoms of dry eye disease are expected to be enrolled at two sites in the United States. Designed as a serial phase study, patients will initially be administered a placebo vehicle plug for 30 days to establish a baseline for the investigational drug treatment. Patients who respond to the placebo plug only in treatment of their dry eye disease will be excluded from the study. Patients who continue to exhibit symptoms of dry eye during the initial 30 days will be qualified for enrollment in the treatment phase of the study. Qualified patients will then be randomized to either OTX-DP or a placebo vehicle plug. Primary efficacy measures will include corneal and conjunctival staining, tear osmolarity, tear film break-up time, presence of the plug, ease of product use and visualization, and resorption of the plug following therapy.

"This Phase 2 exploratory study is designed to assist us in identifying the subgroup of patients that may benefit from a low-dose, Sustained Release Dexamethasone therapy for treatment of inflammatory dry eye disease, allowing us to refine clinical trials for this indication in the future," stated Amar Sawhney, Ph.D., President and CEO of Ocular Therapeutix, Inc. "Dry eye is one of the most common ophthalmic disorders affecting approximately 20 million people in the United States, and is expected to rise with an aging population. We look forward to potentially expanding the use of our Sustained Release Dexamethasone product candidate for this disorder."

"Ocular Therapeutix's Sustained Release Dexamethasone may offer more consistent therapeutic medication levels than traditional treatments for patients who suffer from dry eye disease, and, if successful, may reduce the burden and potential toxicity of continuous repeated drop applications," stated John Sheppard, M.D., of Virginia Eye Consultants in Norfolk, VA, and a Principal Investigator in the study.

About Dry Eye

Dry eye disease affects the ocular surface and is characterized by dryness, inflammation, pain, discomfort, and irritation. Dry eye is a complex, multifactorial disease which can present differently in patients, and becomes more common with age. Due to the prevalence of the disease, over one billion dollars is spent on treatment of the disease each year in the United States alone (IMS Health, 2013). One cause of the disease is inflammation of the ocular surface resulting from a patient's immune response. Although physicians may prescribe topical steroid eye drops for the treatment of dry eye disease, chronic use of topical steroids can lead to elevations in intraocular pressure, which is a risk factor for glaucoma. Conversely, patients often do not reliably self-administer these drops, which can lead to eye irritation and continual, if not more, inflammation.

About Ocular Therapeutix's Intracanalicular Plugs:
Ocular Therapeutix is developing the company's proprietary absorbable polyethylene glycol hydrogel intracanalicular plug technology to release drugs in a sustained fashion over a specified period of time depending on the drug and its corresponding therapeutic need. At the end of the treatment period, the plug is designed to absorb, and exit the nasolacrimal system without need for removal by the physician. The plugs contain a visualization agent for retention monitoring throughout the treatment period.

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, allergic conjunctivitis, and 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 Ocular Therapeutix, including statements about the development of the company's product candidates, such as the timing and conduct of the company's Phase 2 clinical program of Sustained Release Dexamethasone for the treatment of dry eye disease , the potential utility and convenience of Sustained Release Dexamethasone, 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 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 its 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.

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