Ocular Therapeutix™ Completes Enrollment in Phase 3 Sustained Release Dexamethasone Trials for Post-Operative Inflammation and Pain

October 8, 2014

BEDFORD, Mass.--(BUSINESS WIRE)--Oct. 8, 2014-- Ocular Therapeutix, Inc. (NASDAQ: OCUL) announced today completion of enrollment for its two Phase 3 clinical trials evaluating Sustained Release Dexamethasone (OTX-DP) for treatment of ocular inflammation and pain following cataract surgery. OTX-DP is a one-time administration 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 the need for removal.

The two prospective, multicenter, randomized, parallel-arm, double-masked, vehicle-controlled studies are evaluating 486 patients at 32 sites throughout the United States. Following surgery, patients were randomized to receive either OTX-DP or a placebo vehicle punctum plug without active drug. Primary efficacy endpoints for the studies are the absence of inflammatory cells in the anterior chamber of the eye at Day 14, and reduction of pain at Day 8.

“Completion of enrollment for OTX-DP is an extraordinary milestone for our company, not only as our first Phase 3 clinical trials for a sustained release pharmaceutical, but also the first Phase 3 trials ever to be completed for a sustained release, drug delivery punctum plug,” stated Amar Sawhney, Ph.D., President and CEO of Ocular Therapeutix, Inc. “We look forward to submitting results to the FDA in 2015.”

Topical corticosteroids are typically prescribed to treat ocular inflammation and pain following ophthalmic surgery. However, topical steroid regimens can be complex, which can lead to lower levels of compliance and thus may adversely affect outcomes. Conversely, chronic administration of topical corticosteroids can lead to spikes in intraocular pressure, which may induce glaucoma. A physician administered, single-dose corticosteroid puts compliance in the hands of physicians, and may improve issues of patient non-compliance with dosing regimens.

“OTX-DP is easily inserted, and can be monitored by the physician during the post-operative period,” stated Thomas R. Walters, M.D., Principal Investigator at Texan Eye in Austin, Texas. “In a previously completed Phase 2 clinical trial, treatment with OTX-DP significantly relieved pain at Day 8, as reported by the patient, and inflammation at Day 14, as measured by absence of inflammatory cells in the anterior chamber of the eye, compared to vehicle control, and patients were comfortable with the plug.”

About Sustained Release Dexamethasone

Sustained Release Dexamethasone (OTX-DP) is a drug product candidate that is placed within the canaliculus and delivers 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, and incorporates a natural taper to mimic a topical post-operative regimen.

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, such as the timing and conduct of the Company’s Phase 3 clinical trials of OTX-DP for the treatment of ocular inflammation and pain following cataract surgery , the expected timing to submit results from such trials to the FDA, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2014. 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.

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