Ocular Therapeutix™ Reports Topline Clinical Data for its Second Phase 3 Clinical Trial Evaluating OTX-DP for the Treatment of Post-Surgical Ocular Inflammation and Pain

April 6, 2015

Primary efficacy endpoint for pain met; primary efficacy endpoint for inflammatory cells not attained

Safety data for both Phase 3 clinical trials showed no ocular or treatment related serious adverse events

Conference call today at 5:00pm Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--Apr. 6, 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, today announced topline data from the Company's second of two Phase 3 clinical trials evaluating the safety and efficacy of its lead product candidate, OTX-DP (Sustained Release Dexamethasone, 0.4mg), for the treatment of ocular inflammation and pain following cataract surgery and reported additional details from the first Phase 3 clinical trial. The two primary efficacy endpoints for the OTX-DP Phase 3 clinical trials were statistically significant differences between the treatment group and the placebo group for the absence of pain on day 8 and absence of inflammatory cells on day 14. Both endpoints need to be met for the trials to be considered successful. In the second Phase 3 clinical trial, OTX-DP met one of the study's two primary efficacy endpoints. In this trial, 77.5% of patients receiving OTX-DP reported an absence of pain in the study eye on day 8 following insertion of the drug product, compared to 58.8% of those receiving placebo vehicle control punctum plug, a difference which was statistically significant (p=0.0025). 39.4% of OTX-DP-treated patients showed an absence of inflammatory cells in the anterior chamber of the study eye on day 14 following drug product insertion, compared to 31.3% of those receiving placebo vehicle control punctum plug , a difference which was not statistically significant (p=0.2182). Additionally, there were a total of 240 patients enrolled in the second clinical trial, with a 2:1 randomization of treated and control patients.

In March 2015, Ocular Therapeutix reported results from the Company's first Phase 3 clinical trial of OTX-DP, which enrolled 247 patients. In this trial, OTX-DP met both primary efficacy endpoints, achieving a statistically significant improvement in the reduction of inflammatory cells on day 14 and pain on day 8. 33.7% of OTX-DP-treated patients showed an absence of inflammatory cells in the anterior chamber of the study eye on day 14 following drug product insertion, compared to 14.6% of those receiving placebo vehicle control punctum plug (p=0.0015). In addition, 76.1% of patients receiving OTX-DP reported absence of pain in the study eye on day 8 following insertion of the drug product, compared to 36.1% of those receiving placebo vehicle control punctum plug (p< 0.0001).

Topline safety results have been evaluated for the two Phase 3 clinical trials of OTX-DP. There were no ocular or treatment related serious adverse events in the OTX-DP treatment group in either of the two Phase 3 clinical trials. There were two serious adverse events in the OTX-DP treatment group in the first Phase 3 trial (1.2% incidence), compared with three serious adverse events in the placebo group (3.6% incidence). There were two serious adverse events in the OTX-DP treatment group in the second Phase 3 trial (1.3% incidence), compared with three serious adverse events in the placebo group (3.8% incidence). Overall there were fewer adverse events in the treated group than in the placebo group. The Company expects to be able to use the safety data from these Phase 3 trials to support its other OTX-DP clinical development programs including allergic conjunctivitis.

The secondary efficacy endpoints for the first Phase 3 clinical trial have also been evaluated. Statistically significant differences were seen for the absence of pain at days 2, 4, 14 and 30 in the OTX-DP treatment group compared to the placebo group. Statistically significant differences were seen for the absence of inflammatory cells at day 30 in the OTX-DP treatment group compared to the placebo group, and there were no statistically significant differences seen in the secondary endpoint for absence of inflammatory cells at the other time points in the OTX-DP treatment group in the first Phase 3 trial. Statistically significant differences were seen for the absence of flare at day 8, day 14 and day 30 but not at day 2 or day 4. Data regarding secondary efficacy endpoints for the second Phase 3 trial are still being evaluated.

"Following the favorable results from our first Phase 3 trial, we are disappointed that the second Phase 3 clinical results for resolution of inflammation did not have the same magnitude of differential as what OTX-DP achieved in the first trial," said Amar Sawhney, Ph.D., President and CEO. "Although the efficacy results for the absence of inflammatory cells in the OTX-DP treatment group met our expectations, the placebo group response was significantly higher than expected. We have begun a thorough analysis of the data from the second Phase 3 trial to fully understand the difference in efficacy between these two trials that had essentially the same trial design and similar patient populations. We have examined the aggregate result on a post-hoc basis of the absence and very minimal presence of inflammatory cells (defined as 0 and 0.5 on a scale of 0 to 4.0) and the difference between the treatment and placebo groups was found to be highly significant (66.3% in the treatment group and 42.5% in the placebo group, p=0.0004)."

Dr. Sawhney continued, "We plan to meet with the FDA promptly to discuss the Phase 3 OTX-DP clinical trial results and chart the appropriate path forward. The safety data from these two trials further enhances the safety profile of this product and will serve as a foundation for the regulatory submissions for other indications with this product. We look forward to advancing our OTX-DP and OTX-TP clinical development programs to the next stage."

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. In March 2015, Ocular announced results from its first Phase 3 trial of OTX-DP in post-operative ocular inflammation and pain, which met both its primary efficacy endpoints, with OTX-DP-treated patients achieving a statistically significant improvement in the reduction of inflammatory cells and pain compared to those receiving placebo. In November 2014, the Company announced encouraging data from its Phase 2 clinical trial evaluating the safety and efficacy of OTX-DP in allergic conjunctivitis, and the Company plans to initiate Phase 3 clinical trials for this indication in the middle of 2015. The Company also initiated an exploratory Phase 2 clinical trial of OTX-DP for the treatment of inflammatory dry eye in January 2015. The Company is currently enrolling patients into a Phase 2b clinical trial of its second sustained release product candidate, OTX-TP (Sustained Release Travoprost), for the treatment of glaucoma

and ocular hypertension, and this trial is over 70% enrolled. Top-line efficacy data from this trial is expected in the fourth quarter of 2015.

About the OTX-DP Post-Surgical Inflammation and Pain Clinical Trials

Two prospective, multicenter, randomized, parallel-arm, double-masked, vehicle-controlled Phase 3 clinical trials were completed with a total of 487 patients (247 patients in the first Phase 3 trial and 240 patients in the second Phase 3 trial) undergoing unilateral clear corneal cataract surgery. Patients were randomized 2:1 to receive either OTX-DP or a placebo vehicle control punctum plug without active drug. Both primary efficacy endpoints, differences in the proportion of patients in each treatment group with absence of cells in the anterior chamber of the study eye, as measured using slit lamp examination, at day 14 and absence of pain, as graded by a patient-reported score of zero on a scale from zero to ten, at day 8 were recorded at each study visit. Secondary efficacy endpoints were absence of flare in the anterior chamber of the study eye at each evaluation date and absence of inflammatory cells in the anterior chamber of the study eye and absence of pain in the study eye at each evaluation date other than the day used for the primary efficacy measure.

About Post- Surgical Ocular Inflammation and Pain

Ocular inflammation and pain are common side effects following ophthalmic surgery. Physicians prescribe anti-inflammatory drugs, such as corticosteroids, as the standard of care. If left untreated, inflammation of the eye may result in further ocular complications, including scarring and vision loss. Market Scope estimated approximately 5 million ocular surgeries were to have been performed in the United States in 2014.

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.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast at 5:00 pm Eastern Time on April 6, 2015 to discuss the results of the Phase 3 clinical trials evaluating OTX-DP for the treatment of post-surgical inflammation and pain.

The live webcast and a replay may be accessed by visiting Ocular's website at investors.ocutx.com. Please connect to the Company's website 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 live conference call. The conference ID number for the live call is 22064396. Please dial in approximately 10 minutes prior to the call. Following the webcast, an archived version of the call will be available for three months.

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 plans to meet with the FDA to discuss the path forward for OTX-DP for the treatment of post-surgical ocular inflammation and pain, the ongoing development and potential utility of OTX-DP for post-surgical ocular inflammation and pain, the timing and conduct of the Company's Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension and the Company's Phase 3 clinical trials of OTX-DP for allergic conjunctivitis, the advancement of the Company's other product candidates 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 Annual Report on Form 10-K for the year ended December 31, 2014 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.

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