Ocular Therapeutix™ Announces Successful Topline Results for Both Inflammation and Pain Primary Efficacy Endpoints from Phase 3 Clinical Trial of DEXTENZA™

November 14, 2016

Conference Call Today at 8:30 am Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--Nov. 14, 2016-- 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 positive topline results from its phase 3 clinical trial of DEXTENZA™ (dexamethasone insert) 0.4 mg, for the treatment of post-surgical ocular inflammation and pain. DEXTENZA is a product candidate administered by a physician as a bioresorbable intracanalicular insert and designed for drug release to the ocular surface for up to 30 days.

The trial successfully met its two primary efficacy endpoints for inflammation and pain, achieving statistically significant differences between the treatment group and the placebo group for the absence of inflammatory cells on day 14 and the absence of pain on day 8, respectively. 52.3%% of patients treated with DEXTENZA showed an absence of inflammatory cells in the anterior chamber of the study eye on day 14, compared to 31.1% of those receiving the placebo vehicle control punctum plug ($p< 0.0001$). 79.6% of patients treated with DEXTENZA reported absence of pain in the study eye on day 8, compared to 61.3% of those receiving the placebo vehicle control punctum plug ($p< 0.0001$). For clarification of the endpoints, the day of surgery and insertion of DEXTENZA or the placebo is considered to be day 1.

“The successful results of this trial represent an important milestone for the Company, and we believe these results not only further validate the ability of DEXTENZA to provide a full post-operative course of therapy with a one-time administration, but also validate the broader utility of our multi-faceted hydrogel drug delivery technology platform,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. “We are preparing for the resubmission to our NDA for DEXTENZA for the post-surgical ocular pain indication by the end of the year, and subject to potential approval, we plan to submit an NDA supplement for DEXTENZA to include a post-surgical ocular inflammation indication. This is an exciting time for Ocular Therapeutix, as we advance our lead drug delivery product candidate toward potential commercialization.”

In this Phase 3 clinical trial with DEXTENZA for the treatment of post-surgical ocular inflammation and pain, as well as other DEXTENZA clinical trials completed to date regardless of indication, DEXTENZA has exhibited a strong safety profile and has been generally well-tolerated. There were no treatment-related serious adverse events observed in this Phase 3 clinical trial. DEXTENZA inserts were visible in almost all subjects through Day 30, with 99% present at the primary efficacy endpoint visits.

Secondary efficacy endpoints included differences between the DEXTENZA treatment group and the placebo group for the absence of anterior chamber (AC) cells at day 2, 4, 14 and 30 and for the absence of pain at day 2, 4, 14 and 30. All eight of these secondary endpoints were met at a level of statistical significance with the exception of the endpoint for the absence of AC cells at day 2. Additional secondary endpoints including flare, as well as an assessment of all safety data, are being evaluated.

“In parallel with steadily rising ophthalmic surgical volumes among the aging U.S. population is the requirement for safe and effective outcomes, driven not only by operative technique but also by appropriate post-operative drug delivery,” said Dr. Terry Kim, Chief of the Cornea and External Disease Service at the Duke University Eye Center and Professor of Ophthalmology, Duke University School of Medicine. “DEXTENZA’s demonstrated ability to provide a full post-operative course of therapy with a single placement is attractive for both patients and physicians. A large majority of my patients show poor compliance and improper technique when using current standard of care steroid eye drops, which can lead to prolonged recovery and suboptimal outcomes as well as unnecessary phone calls and office visits to the physician. DEXTENZA has the potential to improve both compliance and outcomes, enabling the transfer of control back to the physician for the entire course of therapy.”

Phase 3 Study Design

This prospective, multicenter, 1:1 randomized, parallel-arm, double-masked, vehicle-controlled study was designed to evaluate the safety and efficacy of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery. The study enrolled 438 patients who were undergoing clear corneal cataract surgery at 21 sites throughout the United States. Immediately following surgery, patients were randomized to either DEXTENZA or a placebo vehicle. Primary efficacy endpoints evaluated the differences between the DEXTENZA treatment group and the placebo group for the absence of anterior chamber cells at day 14 and absence of pain at day 8.

This was the third Phase 3 clinical trial that the Company has conducted with DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery. Based on the results from the first two Phase 3 clinical trials, Ocular Therapeutix submitted a New Drug Application (NDA) to the FDA for DEXTENZA for the treatment of ocular pain occurring after ophthalmic surgery. The purpose of conducting this third Phase 3 clinical trial is part of the Company’s label expansion strategy for DEXTENZA. Accordingly, subject to the approval of the NDA for post-surgical ocular pain by the FDA, Ocular Therapeutix intends to submit an NDA supplement for DEXTENZA to broaden its label to include a post-surgical inflammation indication.

About Ocular Inflammation and Pain Following Ophthalmic Surgery

Ocular pain and inflammation are common side effects following ophthalmic surgery. Physicians prescribe topical corticosteroids as part of the standard of post-operative care. If left untreated, inflammation of the eye may result in further ocular complications, including scarring and vision loss. According to US Census data, by the year 2020, it is estimated that the number of Americans diagnosed with cataracts is expected to rise to approximately 30 million, representing a 31.9% increase over current prevalence estimates. Approximately 3.8 million cataract cases were performed in the United States in 2015.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 8:30 am Eastern Time to discuss the topline results of the recently completed Phase 3 clinical trial of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery.

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 19890131. An archive of the webcast will be available until November 28, 2016 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 has submitted an NDA for post-surgical pain for its lead product candidate, DEXTENZA™ (dexamethasone insert), which is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis. OTX-TP (travoprost insert) is in Phase 3 clinical development for glaucoma and ocular hypertension. Ocular Therapeutix is also evaluating injectable drug delivery depots for back-of-the-eye diseases. Ocular Therapeutix's first product, ReSure® Sealant, is FDA-approved to seal corneal incisions following cataract surgery. For additional information about the Company, please visit www.ocutx.com.

Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company including the development and regulatory status of the Company's product candidates, such as the Company's expectations and plans regarding regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA™ for the treatment of post-surgical ocular inflammation and pain, including our expectations regarding the NDA filed with the FDA and the resubmission of the NDA, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for the treatment of inflammatory dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel depot technology, the potential utility of any of the Company's product candidates, potential commercialization of the Company's product candidates, the potential benefits and future operation of the collaboration with Regeneron, including any potential future payments thereunder, the sufficiency of the Company's cash resources 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 or any product candidate that receives regulatory approval, 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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Source: Ocular Therapeutix, Inc.

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