Ocular Therapeutix™ Announces Additional Successful Results for Phase 3 Clinical Trial of DEXTENZA™

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Statistically significant secondary endpoint of absence of ocular flare confirms further evidence of reduction of inflammation

BEDFORD, Mass.--(BUSINESS WIRE)--Jan. 4, 2017-- 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 additional positive secondary endpoint results from its most recent successful 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 to release drug to the ocular surface for up to 30 days.

The secondary endpoint, the absence of anterior chamber (AC) flare, an indicator of inflammation, was statistically superior to placebo at all measured time points. Approximately 46% of patients in the DEXTENZA treatment group were shown to have an absence of AC flare at day 4 after insertion, which Ocular believes provides further support of the early onset anti-inflammatory effect of DEXTENZA. Additional secondary efficacy endpoints included differences in the absence of AC cells and ocular pain on days 2, 4, 14, and 30 after insertion. As previously reported, all of these secondary endpoints were met with statistical significance with the exception of the endpoint for the absence of AC cells at day 2.

As also previously announced, DEXTENZA successfully met the trial's two primary efficacy endpoints, absence of ocular pain on day 8 and absence of ocular inflammation on day 14 when compared to placebo. In this Phase 3 clinical trial, for which the complete safety assessment will be available in the first quarter of 2017, no treatment-related serious adverse events were observed. DEXTENZA has exhibited a favorable safety profile and has been well tolerated in all clinical trials, regardless of indication.

"The positive results for the secondary endpoint of absence of ocular flare build upon the successful topline results from this trial which we announced last month," said Jonathan H. Talamo, M.D., Chief Medical Officer of Ocular Therapeutix. "Ocular flare occurs when the protein content of the aqueous humor increases due to intraocular inflammation, so the fact that we are seeing a statistically significant decrease in the absence of flare across all time points further supports the efficacy profile of DEXTENZA."

Summary of Efficacy Results from Third Phase 3 Trial of DEXTENZA for the Treatment of Post-Surgical Ocular Inflammation and Pain

Efficacy Endpoint		***Visit*** **Day 2***	**Day 4**	**Day 8**	**Day 14**	**Day 30**
Proportion of patients with an absence of AC cells	DEXTENZA Group *(P Value)*	1.9%***	14.1% (P<0.05)	29.1% (P<0.0001)	52.1%** (P<0.0001)	81.0% (P<0.0001)
	Placebo Group	2.3%	7.7%	11.7%	31.2%	63.3%
Proportion of patients with an absence of ocular pain	DEXTENZA Group *(P Value)*	73.0% (P<0.0001)	76.5% (P<0.0001)	79.3%** (P<0.0001)	84.2% (P<0.0001)	89.1% (P<0.05)
	Placebo Group	56.8%	61.1%	61.3%	70.1%	80.0%
Proportion of patients with an absence of AC flare	DEXTENZA Group *(P Value)*	28.8% (P<0.05)	46.0% (P<0.05)	58.2% (P<0.0001)	73.5% (P<0.0001)	90.0% (P<0.05)
	Placebo Group	19.8%	29.4%	36.9%	49.3%	79.5%

*Day following insertion
**Primary endpoints of trial; both primary efficacy endpoints were achieved
*** Did not achieve statistical significance; all other efficacy endpoints were achieved

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 insertion of 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. Secondary efficacy endpoints included absence of anterior chamber cells, absence of ocular flare, and absence of ocular pain across relevant time points during the 30-day treatment period.

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. Independent of the results of this third trial and based on the results from the first two Phase 3 clinical trials, Ocular Therapeutix plans to resubmit a New Drug Application (NDA) to the FDA for DEXTENZA for the treatment of ocular pain occurring after ophthalmic surgery early in the first quarter of 2017. The purpose of conducting this third Phase 3 clinical trial was to support 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 a supplemental NDA for DEXTENZA to broaden its label to include an indication for post-surgical inflammation.

About Ocular Pain and Inflammation 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, which in some cases, may cause permanent loss of vision. 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 32% increase over current prevalence estimates. Approximately 3.8 million cataract cases were performed in the United States in 2015.

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 plans to resubmit an NDA in the first quarter of 2017 for post-surgical pain for its lead product candidate, DEXTENZA™ (dexamethasone insert), which has completed Phase 3 clinical development for post-surgical ocular inflammation and pain. Subject to the approval of the NDA for post-surgical ocular pain, Ocular Therapeutix intends to submit a supplemental NDA for DEXTENZA to broaden its label to include an indication for post-surgical inflammation. DEXTENZA is also in Phase 3 clinical development for 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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