Ocular Therapeutix™ Announces Topline Results of Phase 3 Clinical Trial of OTX-TP for the Treatment of Glaucoma

May 20, 2019

OTX-TP failed to meet primary endpoint but achieved statistically significant reduction of intraocular pressure versus placebo at eight of the nine pre-specified time points

The Company plans to discuss the data from the clinical trial with the FDA and determine next steps

BEDFORD, Mass.--(BUSINESS WIRE)--May 20, 2019-- Ocular Therapeutix™, Inc(NASDAQ: OCUL), a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye, today announced topline results from the first pivotal Phase 3 clinical trial of OTX-TP, an intracanalicular insert that delivers a preservative-free formulation of the drug travoprost for the reduction of intraocular pressure (IOP) in patients with primary open-angle glaucoma or ocular hypertension. OTX-TP is designed to lower IOP for up to 90 days and to address the poor adherence associated with chronic, daily eye drop regimens, the current standard of care.

The Phase 3 randomized, double blind, placebo-controlled clinical trial was conducted across more than 50 sites and enrolled 554 subjects with open-angle glaucoma or ocular hypertension in the full analysis set (FAS) population. The trial's primary efficacy endpoint was to demonstrate a statistically superior mean reduction of IOP from baseline for OTX-TP treated subjects compared with placebo insert treated subjects at nine different time points, three diurnal time points (8 AM, 10 AM, and 4 PM) at each of 2, 6, and 12 weeks following insertion. Topline results show that the trial did not achieve its primary endpoint of statistically significant superiority in mean reduction of IOP compared with placebo at all nine time points. OTX-TP treated subjects did have a greater reduction in IOP from baseline relative to placebo insert at all nine time points, and these differences were statistically significant (p value < 0.05) for eight of the nine time points (Table 1). The reductions from baseline for OTX-TP treated subjects in this trial ranged from 3.27-5.72 millimeters of mercury (mm Hg) across the nine time points with higher levels of intraocular pressure reduction seen at the earlier time points in this trial.

Table 1: Reduction in Intraocular Pressure (Change from Baseline)

	2 Week			6 Week			12 Week		
	mm Hg			mm Hg			mm Hg		
Diurnal Time points	**OTX-TP**	**Vehicle**	**p-value**	**OTX-TP**	**Vehicle**	**p-value**	**OTX-TP**	**Vehicle**	**p-value**
8:00 AM	-5.72	-3.88	<.0001	-4.81	-4.01	0.0181	-3.91	-3.52	0.2521
10:00 AM	-4.92	-3.16	<.0001	-4.03	-3.23	0.0077	-3.34	-2.63	0.0234
4:00 PM	-5.22	-3.18	<.0001	-4.16	-3.14	0.0004	-3.27	-2.60	0.0310

FAS Population (OTX-TP=343 subjects, Vehicle=211 subjects) ***Least Squares (LS) Means***

OTX-TP was generally well tolerated and no ocular serious adverse events were observed. The most common ocular adverse events seen in the study eye were dacryocanaliculitis (approximately 7% in OTX-TP vs. 3% in placebo) and lacrimal structure disorder (approximately 6% in OTX-TP vs. 4% in placebo).

"We are encouraged by the results of this trial which shows OTX-TP's ability to lower IOP out to 12 weeks with a single insert using this novel dosage form," stated Michael Goldstein, MD, Chief Medical Officer. "In our opinion, this product candidate represents a new opportunity for treating glaucoma patients that has the potential to address one of the biggest issues we deal with in clinical practice, the challenges patients have in taking eye drops. We will continue to review the data from the trial, and we look forward to meeting with the FDA to discuss these results before determining the next steps in our clinical development plans."

About Ocular Therapeutix, Inc.
Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary bioresorbable hydrogel-based formulation technology. Ocular Therapeutix's first commercial drug product, DEXTENZA®, is FDA-approved for the treatment of ocular pain following ophthalmic surgery. OTX-TP (intracanalicular travoprost insert) is an intracanalicular insert in Phase 3 clinical development for the reduction of intraocular pressure in patients with primary open-angle glaucoma and ocular hypertension. The Company's earlier stage assets include OTX-TIC, an extended-delivery intracameral travoprost implant for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension, as well as sustained release intravitreal implants for the treatment of retinal diseases. These intravitreal implants include OTX-TKI, containing a tyrosine kinase inhibitor (TKI), and, in

collaboration with Regeneron, OTX-IVT, an extended-delivery protein-based anti-vascular endothelial growth factor (VEGF) trap. 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 the commercialization of DEXTENZA®, ReSure Sealant, or any of the Company's product candidates, including the anticipated commercial launch of, and receipt of reimbursement codes for, DEXTENZA; the development and regulatory status of the Company's product candidates, such as the Company's regulatory submissions for and the timing and conduct of, or implications of results from, clinical trials of DEXTENZA for the treatment of post-surgical ocular inflammation and the prospects for the approvability of, and discussions with regulatory authorities regarding, DEXTENZA for post-surgical ocular inflammation or any other indications, OTX-TP for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TIC for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-IVT as an extended-delivery formulation of the VEGF trap aflibercept for the treatment of retinal diseases including wet AMD; the ongoing development of the Company's extended-delivery hydrogel depot technology; the potential utility of any of the Company's product candidates; the potential benefits and future operation of the collaboration with Regeneron Pharmaceuticals, 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 DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, the ability to obtain reimbursement codes for DEXTENZA, the initiation, timing 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, the Company's existing indebtedness, the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default, the outcome of the Company's ongoing legal proceedings 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 except as required by law. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20190520005742/en/

Source: Ocular Therapeutix

Investors
Ocular Therapeutix
Donald Notman
Chief Financial Officer
dnotman@ocutx.com

or

Westwicke, an ICR Company
Chris Brinzey
Managing Director
chris.brinzey@westwicke.com

Media
Ocular Therapeutix
Scott Corning
Senior Vice President, Commercial
scorning@ocutx.com