Ocular Therapeutix™ Announces FDA Approval of DEXTENZA® for the Treatment of Ocular Pain Following Ophthalmic Surgery

December 3, 2018

DEXTENZA® (dexamethasone ophthalmic insert) is the First Intracanalicular Insert for Drug Delivery

Ocular Therapeutix to Host Conference Call Today at 8:30 am ET

BEDFORD, Mass.--(BUSINESS WIRE)--Dec. 3, 2018-- 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 that the U.S. Food and Drug Administration (FDA) has approved DEXTENZA® (dexamethasone ophthalmic insert) 0.4mg for intracanalicular use for the treatment of ocular pain following ophthalmic surgery.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20181203005281/en/

"We are extremely pleased to announce the approval of DEXTENZA, coming so soon after our pre-approval inspection and approximately one month ahead of the PDUFA date," said Antony Mattessich, the Company's President and Chief Executive Officer. "Just over a year ago, we set out to augment our scientific and formulation expertise with individuals who have the skills and experience to create a first-class team to get DEXTENZA approved and become a commercial stage biopharmaceutical company. We believe this approval is a major external validation of the drug delivery technology platform, and also of the transformation that has taken place at Ocular. While we are excited by the approval of our first drug product, our goal has always been to bring DEXTENZA to as many patients as possible in the near term and to revolutionize ophthalmic drug delivery by making drops obsolete. We now turn our efforts towards the successful commercial launch of DEXTENZA."

DEXTENZA is the first FDA-approved intracanalicular insert delivering dexamethasone to treat post-surgical ocular pain for up to 30 days with a single administration. The approval of DEXTENZA was based on (i) demonstrated efficacy in two randomized, vehicle-controlled Phase 3 studies in which a statistically significantly higher incidence of subjects were pain free at day 8 post-cataract surgery compared to the vehicle control group and (ii) safety in the two Phase 3 studies as well as a third randomized, vehicle-controlled Phase 2 study. The Company believes the delivery profile represents a differentiated and potentially transformational new product for patients and physicians. For patients, DEXTENZA offers the convenience of a full course of post-surgical steroid treatment with a physician's one-time placement of a single intracanalicular insert. DEXTENZA has the potential to replace a complex eye drop regimen that under the current standard of care requires up to 70 topical ocular steroid drops.

"Compliance with taking eye drops after eye surgery is very challenging for patients and a concern for surgeons," said Michael Goldstein, MD, Chief Medical Officer. "The approval of DEXTENZA offers surgeons the opportunity to treat patients with a preservative-free steroid after surgery with the placement of a single drug insert. With this product, patients may be liberated from having to deal with the burdensome regimen of using steroid eye drops after ophthalmic surgery."

In connection with the commercial launch of DEXTENZA, Ocular Therapeutix also submitted an application for transitional pass-through payment status after receiving FDA approval and intends to submit an application for a J-code ahead of the January 2019 deadline.

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 approval of DEXTENZA. The live webcast can be accessed by visiting the Investors 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 live conference call. The conference ID number for the live call will be 2384369. An archive of the webcast will be available until December 17, 2018 on the Company's website.

DEXTENZA® Label

DEXTENZA® (dexamethasone ophthalmic insert) is a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery.

DEXTENZA is a preservative-free ophthalmic insert that is inserted in the lower lacrimal punctum and into the canaliculus. A single DEXTENZA releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion.

DEXTENZA is resorbable and does not require removal. Saline irrigation or manual expression can be performed to remove the insert if necessary. DEXTENZA is intended for single-use only.

DEXTENZA was studied in two randomized, multicenter, double-masked, parallel group, vehicle-controlled Phase 3 clinical trials, with patients receiving DEXTENZA or its vehicle immediately upon completion of cataract surgery. In Study 1, 80% of DEXTENZA-treated patients (n=164) were pain-free at Day 8 compared to 43% of vehicle-treated patients (n=83) ($p<0.0001$). In Study 2, 77% of DEXTENZA-treated patients (n=161) were pain-free at Day 8 compared to 59% of vehicle-treated patients (n=80) ($p=0.025$).

Safety was assessed from the two Phase 3 clinical trials and a Phase 2 clinical trial. Overall, 351 subjects were exposed to DEXTENZA. The most common ocular adverse reactions in subjects treated with DEXTENZA were: anterior chamber inflammation including iritis and iridocyclitis (9%), increased intraocular pressure (5%), reduced visual acuity (2%), eye pain (1%), cystoid macular edema (1%), corneal edema (1%), and conjunctival hyperemia (1%). The most common non-ocular adverse event was headache (1%).

DEXTENZA® Important Safety Information

DEXTENZA is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella; mycobacterial infections; fungal diseases of the eye; and dacryocystitis.

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma and intraocular pressure should be monitored during treatment.

Corticosteroids may suppress the host response and thus increase the hazard for secondary ocular infections. In acute purulent conditions, steroids may mask infection and enhance existing infection.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

Please see Important Safety Information and Full Prescribing Information at www.DEXTENZA.com

About DEXTENZA®

DEXTENZA® (dexamethasone ophthalmic insert) 0.4mg is FDA approved for the treatment of ocular pain following ophthalmic surgery. DEXTENZA is a corticosteroid intracanalicular insert placed in the punctum, a natural opening in the inner portion of the lower eyelid, and into the canaliculus and is designed to deliver dexamethasone to the ocular surface for up to 30 days without preservatives. DEXTENZA resorbs and exits the nasolacrimal system without the need for removal.

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 ReSure Sealant, DEXTENZA® or any of the Company's product candidates, 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 approvability of 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 Company's post-approval studies of ReSure® Sealant and the Company's expectations regarding its appeal of the warning letter regarding ReSure Sealant; 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 ReSure Sealant, DEXTENZA or any product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of ReSure Sealant, DEXTENZA or any product candidate that receives regulatory approval, 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 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. 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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