Ocular Therapeutix™ Announces Commercial Launch of DEXTENZA® (dexamethasone intracanalicular insert) 0.4 mg for Ophthalmic Use in the United States

July 1, 2019

Pass-through payment status and C-code from the Centers for Medicare and Medicaid Services (CMS) now active

BEDFORD, Mass.--(BUSINESS WIRE)--Jul. 1, 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 the commercial launch in the United States of DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg for the treatment of ocular inflammation and pain following ophthalmic surgery. DEXTENZA is the first U.S. Food and Drug Administration (FDA)-approved intracanalicular insert, a drug product with a novel route of administration that enables the delivery of drug to the surface of the eye, obviating the need for a burdensome, monthly regimen of steroid eye drops. DEXTENZA originally received FDA approval in November 2018 for the treatment of ocular pain following ophthalmic surgery.

The launch comes less than two weeks after the June 21st announcement of FDA approval of a Supplemental New Drug Application (sNDA) for DEXTENZA for the treatment of ocular inflammation following ophthalmic surgery. DEXTENZA is now the only sustained release steroid product approved for the treatment of both ocular inflammation and pain following ophthalmic surgery.

The initial launch of DEXTENZA is supported by activation of its C-code, C9048. A C-code is a product code established by CMS for the Hospital Outpatient Prospective Payment System (HOPPS) used to report claims for hospital outpatient department and ambulatory surgical center services and procedures. The July 1, 2019 activation of the C-code facilitates the reimbursement of DEXTENZA until such time as CMS may potentially approve a J-code and such approval becomes effective. In May 2019, the Company announced that CMS has included DEXTENZA on its list of products that have been preliminarily recommended for a new dedicated Healthcare Common Procedure Coding System (HCPCS) J-code which, if granted, would become effective January 1, 2020. A J-code represents a permanent product code that could be used across settings of care.

“We are extremely proud to be bringing DEXTENZA to market in the U.S.,” said Antony Mattessich, President and Chief Executive Officer. “With reimbursement solidified through a unique C-code, the addition of inflammation to our label, and our direct, highly-experienced commercial team in place, we believe we are well-prepared for the launch of DEXTENZA. DEXTENZA represents a novel new treatment option that we believe offers significant value to both patients and physicians and we are excited for its potential in the market.”

There are approximately six million steroid prescriptions written each year for ocular surgeries in the U.S. Ocular’s commercial launch of DEXTENZA will initially focus on the roughly two million cataract procedures performed annually under Medicare Part B which is the market segment where DEXTENZA has full reimbursement established following the effectiveness of the C-code and pass-through payment status.

About DEXTENZA®

DEXTENZA® (dexamethasone ophthalmic insert) 0.4mg is FDA approved for the treatment of ocular inflammation and 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.

The safety of DEXTENZA was assessed from three Phase 3 clinical trials and a Phase 2 clinical trial. Overall, 567 subjects were exposed to DEXTENZA. The most common ocular adverse reactions in subjects treated with DEXTENZA were: anterior chamber inflammation including iritis and iridocyclitis (10%), increased intraocular pressure (6%), reduced visual acuity (2%), cystoid macular edema (1%), corneal edema (1%), eye pain (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. Intraocular pressure should be monitored during the course of the 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.

The use of steroids after cataract surgery may delay wound healing and increase the incidence of bleb formation.

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

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 inflammation and 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 commercial launch of, and receipt and effectiveness 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, and the prospects of approvability for, DEXTENZA for any additional 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 and maintain 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.

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