Ocular Therapeutix™ Announces Notification of FDA Acceptance of Supplemental New Drug Submission for DEXTENZA® (dexamethasone ophthalmic insert) for the Treatment of Ocular Inflammation Following Ophthalmic Surgery

April 2, 2019

PDUFA Target Action Date Set for November 10, 2019

BEDFORD, Mass.--(BUSINESS WIRE)--Apr. 2, 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 U.S. Food and Drug Administrations (FDA) has accepted for filing the supplemental New Drug Application (sNDA) for DEXTENZA® (dexamethasone ophthalmic insert) to include the treatment of ocular inflammation following ophthalmic surgery in its label. The notice of acceptance confirms the FDA has completed its initial review of the filing and has determined that the sNDA is sufficiently complete to permit formal review. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of November 10, 2019 for its review of the sNDA.

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. DEXTENZA received FDA approval in November 2018 for the treatment of ocular pain following ophthalmic surgery. DEXTENZA is a resorbable, preservative-free ophthalmic insert that is placed in the lower lacrimal punctum and into the canaliculus of the eye.

The sNDA application to include inflammation [following ophthalmic surgery] is supported by the two Phase 3 clinical trials used to obtain the pain approval and safety and efficacy data from a third prospective, multicenter, randomized, controlled Phase 3 clinical trial of DEXTENZA (n=438) in cataract surgery patients that demonstrated statistical significance compared to the vehicle control for the endpoints of absence of ocular pain ($p<0.0001$) and absence of inflammation ($p<0.0001$). The ocular safety profile was similar to that demonstrated in the two prior Phase 3 clinical trials. Data from the third Phase 3 clinical trial was recently published in the Journal of Cataract & Refractive Surgery (JCRS) in February 2019.

Current DEXTENZA Indication and Important Safety Information

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

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

WARNINGS AND PRECAUTIONS
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 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.

ADVERSE REACTIONS
The most common ocular adverse reactions that occurred 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%).

Please see 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 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; 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 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 ongoing communications with the U.S. Food and Drug Administration regarding the warning letter the Company received 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 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 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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