Ocular Therapeutix™ Announces FDA Approval of Supplemental New Drug Application (sNDA) for DEXTENZA® (0.4 Dexamethasone Intracanalicular Insert for Ophthalmic Use) for the Treatment of Ocular Inflammation Following Ophthalmic Surgery

June 21, 2019

DEXTENZA® Now Approved for the Treatment of Ocular Inflammation and Pain Following Ophthalmic Surgery

BEDFORD, Mass.--(BUSINESS WIRE)--Jun. 21, 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 Administration (FDA) approved a Supplemental New Drug Application (sNDA) for DEXTENZA to include the treatment of ocular inflammation following ophthalmic surgery as an additional indication. With the approval of the sNDA, DEXTENZA is now approved for the treatment of both ocular inflammation and pain following ophthalmic surgery.

DEXTENZA is the first FDA-approved intracanalicular insert, a novel route of administration that delivers drug to the surface of the eye without the need for eye drops. DEXTENZA is a preservative-free, resorbable hydrogel insert that delivers 0.4mg of dexamethasone to treat post-surgical ocular inflammation and pain for up to 30 days with a single administration. DEXTENZA originally received FDA approval in November 2018 for the treatment of ocular pain following ophthalmic surgery.

“We could not be more excited about both the approval and its earlier-than-expected timing,” said Antony Mattessich, the Company’s President and Chief Executive Officer. “With our C-Code and pass-through payment status effective on July 1, the expanded indication gives us tremendous momentum as we approach our commercial launch.”

The approval of the sNDA is supported by three Phase 3 randomized, vehicle-controlled trials; patients received DEXTENZA or a vehicle immediately upon completion of cataract surgery. In all three trials, DEXTENZA had, at a statistically significant level, a higher proportion of patients than the vehicle group who were pain free on post-operative Day 8. On post-operative Day 14, in two of the three studies, DEXTENZA had a higher proportion of patients than the vehicle group, at a statistically significant level, who had an absence of anterior chamber cells.

About DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg

DEXTENZA is a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery. DEXTENZA is inserted into the lower lacrimal punctum into the canaliculus by the physician following ophthalmic surgery. A single DEXTENZA releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion. DEXTENZA is preservative free, resorbable and does not require removal. Saline irrigation or manual expression can be performed to remove the insert, if necessary.

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 to, and increase the hazard for and severity of, secondary bacterial, viral, or fungal infections. The use of steroids after cataract surgery may delay wound healing and increase the incidence of bleb formation.

Safety was assessed from the 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%).

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 anticipated 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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