# Ocular Therapeutix™ Announces FDA Acceptance of Supplemental New Drug Application for DEXTENZA® (dexamethasone ophthalmic insert) for the Treatment of Ocular Itching Associated with Allergic Conjunctivitis

March 4, 2021

*PDUFA Action Date Set October 2021*

BEDFORD, Mass.--(BUSINESS WIRE)--Mar. 4, 2021-- 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 supplemental New Drug Application (sNDA) for DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg for intracanalicular use has been accepted for review by the U.S. Food and Drug Administration (FDA). The FDA has set an action date under the Prescription Drug User Fee Act (PDUFA) of no later than October 18, 2021. If approved, this sNDA would include the treatment of ocular itching associated with allergic conjunctivitis as an additional approved indication of DEXTENZA.

"We are excited to have received a PDUFA date from the FDA for our sNDA seeking to potentially broaden the label of DEXTENZA," said Patricia Kitchen, Chief Operating Officer of Ocular Therapeutix. "An estimated 10 million [1,2,3] people in the U.S. annually seek medical attention for the inflammatory response associated with allergic conjunctivitis caused by both seasonal and perennial allergens, representing a discrete market for DEXTENZA beyond its current use in the surgical setting. The use of topical steroids is an important part of the clinical armamentarium in the treatment of a patient with allergic conjunctivitis and if approved for this new proposed use, DEXTENZA could provide an office-based, physician administered, preservative-free method of steroid delivery that benefit patients with ocular itching associated with allergic conjunctivitis."

**About DEXTENZA**

DEXTENZA 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 in three Phase 3 clinical trials and a Phase 2 clinical trial evaluating DEXTENZA for the treatment of post-surgical inflammation and pain of the eye prior to its approval. Overall, 567 subjects were exposed to DEXTENZA in such clinical trials. 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%).

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 (dexamethasone ophthalmic insert) 0.4 mg for intracanalicular use, is FDA-approved for the treatment of ocular inflammation and pain following ophthalmic surgery. Ocular Therapeutix has also submitted a Supplemental NDA for DEXTENZA to include the treatment of ocular itching associated with allergic conjunctivitis as an additional approved indication. Ocular Therapeutix's earlier stage development assets currently in Phase 1 clinical trials include OTX-TKI (axitinib intravitreal implant) for the treatment of wet AMD and other retinal diseases and OTX-TIC (travoprost intracameral implant) for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension. Ocular Therapeutix is currently evaluating each of OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease and OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease in Phase 2 clinical trials. Also, in collaboration with Regeneron, OTX-AFS (aflibercept suprachoroidal injection) is in pre-clinical development as an extended-delivery formulation of aflibercept for the treatment of retinal diseases. Ocular Therapeutix's first product, ReSure® Sealant is an FDA-approved device to prevent wound leaks in corneal incisions following cataract surgery.

[1] Leonardi A, Castegnaro A, Valerio ALG, Lazzarini D. Epidemiology of allergic conjunctivitis: clinical appearance and treatment patterns in a population-based study. *Curr Opin Allergy Clin Immunol.* 2015;15(5):482-488.

[2] Rosario N, Bielory L. Epidemiology of allergic conjunctivitis. *Curr Opin Allergy Clin Immunol*. 2011;11(5):471-476

[3] Ora website, An Update on Ocular Allergy Trends, 2019 Ora, Inc., www.oraclinical.com

**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 commercial launch of, and effectiveness of reimbursement codes for, DEXTENZA; the conduct of post-approval studies of DEXTENZA; the development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of DEXTENZA for additional indications including allergic conjunctivitis, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-CSI for the chronic treatment of dry eye disease, OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-AFS as an extended-delivery formulation of the VEGF trap aflibercept for the treatment of retinal diseases including wet AMD; the potential receipt of a target action date under PDUFA; the ongoing development of the Company's extended-delivery hydrogel depot technology; the size of

potential markets for our product candidates; 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; projected net product revenue and other financial metrics of DEXTENZA; the expected impact of the COVID-19 pandemic on the Company and its operations; 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, 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 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 Company's ability to generate its projected net product revenue on the timeline expected, if at all, 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, the severity and duration of the COVID-19 pandemic including its effect on the Company's and relevant regulatory authorities' operations, the 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 press 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 press release.

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