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

December 22, 2020

PDUFA Target Action Date Anticipated for October 2021

BEDFORD, Mass.--(BUSINESS WIRE)--Dec. 22, 2020-- 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 submission of the supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg for intracanalicular use. 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 share the allergic conjunctivitis data with the FDA and feel this sNDA supports an expanded label. If approved, the sNDA would reflect the second expansion of the DEXTENZA label and would include the first indication for DEXTENZA treated primarily in the ophthalmology office setting,” said Antony Mattessich, President and Chief Executive Officer of Ocular Therapeutix. “It is estimated that up to 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 and significant potential market for DEXTENZA beyond its current use in the surgical setting. From a business perspective, ocular itching associated with allergic conjunctivitis is our first potential indication in the treatment of an ocular surface disease, paving the way for our two Phase 2 clinical programs in the treatment of dry-eye disease.”

The efficacy of DEXTENZA for the treatment of ocular itching was evaluated in four vehicle-controlled clinical trials for subjects with a positive history of ocular allergies and positive skin test reaction to perennial and seasonal allergens (n=323). The sNDA offers data that Ocular believes supports that DEXTENZA demonstrated superiority to placebo vehicle for the treatment of ocular itching due to allergic conjunctivitis as evidenced by statistically significant differences in a pooled analysis of three well controlled Phase 3 clinical trials as well as in the Phase 2 clinical trial. At the primary endpoint for the pooled analysis of the three Phase 3 clinical trials (Day 8), ocular itching scores favored DEXTENZA treated subjects compared with placebo vehicle treated subjects at all three timepoints: 3 min (1.85 vs 2.55, p value = <0.0001), 5 min (1.90 vs 2.63, p value = <0.0001) and 7 min (1.84 vs 2.61, p value = <0.0001). In addition, it is submitted that treatment with DEXTENZA consistently resulted in lower ocular mean itching scores relative to placebo vehicle at all other study visits throughout the duration of the respective studies.

DEXTENZA was observed to have a favorable safety profile and be generally well-tolerated in the allergic conjunctivitis, ocular inflammation and pain clinical program populations. The most common ocular adverse events seen in the pooled analysis of the allergic conjunctivitis studies were: increased intraocular pressure (n=6), increased lacrimation (n=2), eye discharge (n=2) and reduced visual acuity (n=2). The most common non-ocular adverse events seen were: headache (n=2), nasopharyngitis (n=1), gastroenteritis viral (n=1), dermatitis contact (n=1), and oropharyngeal pain (n=1).

“The use of topical steroids is an important part of the clinical armamentarium in the treatment of a patient with allergic conjunctivitis,” said Michael Goldstein, MD, MBA, Chief Medical Officer of Ocular Therapeutix. “As DEXTENZA is physician-administered and can’t be overused by patients, it provides a potentially safer method of steroid delivery. In addition, unlike current therapeutic options, DEXTENZA is a preservative-free steroid which may be a benefit for patients with allergic conjunctivitis who already have a compromised ocular surface.“

The Company has received acceptance of the sNDA submission to the FDA and anticipates a target action data under the Prescription Drug User Fee Act, commonly known as PDUFA, in October of 2021.

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, is FDA-approved for the treatment of ocular inflammation and pain following ophthalmic surgery. Ocular Therapeutix has completed Phase 3 clinical trials evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis. Ocular Therapeutix’s earlier stage development assets currently in Phase 1 clinical trials include OTX-TIC (travoprost intracameral implant) for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension and OTX-TKI (axitinib intravitreal implant) for the treatment of wet AMD

and other retinal diseases. Ocular Therapeutix is currently evaluating OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease in a Phase 2 clinical trial. Also, Ocular Therapeutix is currently developing OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease and, in collaboration with Regeneron, OTX-AFS (aflibercept suprachoroidal injection) 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 seal 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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