Ocular Therapeutix™ Announces FDA Approval of Supplemental New Drug Application (sNDA) for DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg for Intracanalicular Use for the Treatment of Ocular Itching Associated with Allergic Conjunctivitis

October 11, 2021

Approval represents the first primarily office-based indication for DEXTENZA

BEDFORD, Mass.--(BUSINESS WIRE)--Oct. 11, 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 U.S. Food and Drug Administration (FDA) has approved its Supplemental New Drug Application (sNDA) to broaden the DEXTENZA label to add an additional indication for the treatment of ocular itching associated with allergic conjunctivitis. With the approval, DEXTENZA is the first, FDA-approved, physician-administered intracanalicular insert capable of delivering a preservative-free drug for the treatment of ocular itching associated with allergic conjunctivitis with a single administration for up to 30 days. DEXTENZA originally received FDA approval in November 2018 for the treatment of ocular pain following ophthalmic surgery, followed by an expansion of the label to also include the treatment of ocular inflammation following ophthalmic surgery in June 2019.

“Allergic conjunctivitis is a common condition seen in the offices of eye care providers. We are really excited about this label expansion and the potential benefits for patients,” commented Michael Goldstein, MD, President, Ophthalmology and Chief Medical Officer. “The use of topical steroids is an important part of our current clinical armamentarium in the treatment of allergic conjunctivitis. DEXTENZA can now provide an office-based, physician-administered, preservative-free method of steroid delivery that benefits patients with ocular itching associated with allergic conjunctivitis.”

“We appreciate the FDA’s hard work and ability to complete its review of our sNDA ahead of the scheduled October 18th PDUFA date,” said Antony Mattessich, President and Chief Executive Officer of Ocular Therapeutix. “It is hard to overstate the strategic importance of this label expansion for Ocular Therapeutix. Allergic conjunctivitis, as our first in-office indication, lays the foundation for the rest of our pipeline.”

The efficacy of DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis was based on three randomized, multicenter, double-masked, parallel group, vehicle-controlled studies in subjects with a positive history of ocular allergies and positive skin test reaction to perennial and seasonal allergens (n=255). In all three trials, DEXTENZA demonstrated lower mean ocular itching scores compared with the vehicle group at all time points throughout the study duration of up to 30 days. In two of the three studies, a higher proportion of patients had statistically significant reductions in ocular itching on Day 8, at 3 minutes, 5 minutes and 7 minutes post-challenge in the DEXTENZA group compared to the vehicle group. Data for the primary endpoint, ocular itching at Day 8, is shown below for all three studies (scale 0-4):

Reduction in Ocular Itching

		Study 1			Study 2			Study 3		
Visit	Time Point	Dextenza (N=35) Least Square Means	Vehicle (N=38) Least Square Means	Difference (95% CI)	Dextenza (N=44) Least Square Means	Vehicle (N=42) Least Square Means	Difference (95% CI)	Dextenza (N=48) Least Square Means	Vehicle (N=48) Least Square Means	Difference (95% CI)
Day 8	3 min	1.9	2.7	-0.7 (-1.2, -0.3)	2.1	2.3	-0.2 (-0.7, 0.3)	1.8	2.7	-0.9 (-1.2, -0.4)
	5 min	2.1	2.8	-0.7 (-1.2, -0.3)	2.1	2.3	-0.2 (-0.8, 0.3)	1.8	2.7	-1.0 (-1.4, -0.6)
	7 min	1.9	2.7	-0.8 (-1.2, -0.4)	2.1	2.4	-0.3 (-0.8, 0.3)	1.7	2.7	-1.0 (-1.4, -0.6)

DEXTENZA was observed to have a favorable safety profile and be generally well-tolerated in the allergic conjunctivitis as well as the ocular inflammation and pain clinical populations. The most common ocular adverse events seen in the pooled analysis of the allergic conjunctivitis studies were: increased intraocular pressure (3%), increased lacrimation (1%), eye discharge (1%) and reduced visual acuity (1%). The most common non-ocular adverse reaction that occurred in patients treated with DEXTENZA for allergic conjunctivitis was headache (1%).

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 opportunity for DEXTENZA beyond its current use in the surgical setting.

[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

About DEXTENZA

DEXTENZA is FDA approved for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. 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.

IMPORTANT SAFETY INFORMATION

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

Intraocular Pressure Increase

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.

Bacterial Infection

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.

Viral Infection

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungal Infection

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.

Delayed Healing

Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

ADVERSE REACTIONS

Ophthalmic Surgery

The most common ocular adverse reactions that occurred in patients treated with DEXTENZA were: anterior chamber inflammation including iritis and iridocyclitis (10%); intraocular pressure increased (6%); visual acuity reduced (2%); cystoid macular edema (1%); corneal edema (1%); eye pain (1%) and conjunctival hyperemia (1%).

Allergic Conjunctivitis

The most common ocular adverse reactions that occurred in patients treated with DEXTENZA were: intraocular pressure increased (3%); lacrimation increased (1%); eye discharge (1%) and visual acuity reduced (1%).

The most common non-ocular adverse reaction that occurred in patients treated with DEXTENZA, for ophthalmic surgery and allergic conjunctivitis, was headache (1%).

Click here for full Prescribing Information.

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 an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. 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 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. Ocular Therapeutix's first product, ReSure® Sealant, is an FDA-approved device to prevent wound leaks in 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 commercial launch of, and effectiveness of reimbursement codes for, DEXTENZA; the conduct of post-approval studies of and compliance with related labeling requirements for DEXTENZA and ReSure Sealant; the development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of OTX-CSI for the chronic treatment of dry eye disease, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, and OTX-TKI for the treatment of retinal diseases including wet AMD; 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 operations of Company collaborations, including any potential future costs or payments thereunder; projected net product revenue, in-market sales and other financial and operational metrics of DEXTENZA and ReSure Sealant; potential market sizes for indications targeted by the Company's product candidates, if approved; 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 preclinical and 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 successfully develop and commercialize products for the ophthalmology office setting, the ability to retain regulatory approval of DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, the ability to maintain and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA, the initiation, timing, conduct and outcomes of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's ability to enter into and perform its obligations under collaborations and the performance of its collaborators under such collaborations, 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 and in-market sales 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 severity and duration of the COVID-19 pandemic including its effect on the Company's and relevant regulatory authorities' operations, any additional financing needs 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, whether as a result of new information, future events or otherwise, 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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