Ocular Therapeutix™ Announces Topline Results for Phase 2 Clinical Trial of OTX-DED for the Short-Term Treatment of Dry Eye Disease

December 6, 2021

Study shows statistically significant improvement for primary endpoint of bulbar conjunctival hyperemia for OTX-DED 0.2 mg (p=.004) and 0.3 mg (p=.028) formulations compared with vehicle hydrogel insert (punctal occlusion)

Both formulations were generally well tolerated with favorable safety profiles

Conference Call to Discuss Results to be Held at 8:00 a.m. ET

BEDFORD, Mass.--(BUSINESS WIRE)--Dec. 6, 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 positive topline results from its Phase 2 clinical trial of OTX-DED (dexamethasone intracanalicular ophthalmic insert) for the short-term treatment of dry eye disease.

The Phase 2 clinical trial is a U.S.-based, randomized, double-masked, vehicle-controlled, multi-center trial evaluating two different formulations of OTX-DED (dexamethasone intracanalicular ophthalmic insert) aimed to enroll approximately 150 subjects with dry eye disease. This trial was designed to assess the safety and efficacy of two formulations of OTX-DED for the short-term treatment of signs and symptoms of dry eye disease by evaluating the primary endpoint of bulbar conjunctival hyperemia and secondary endpoints of eye dryness symptoms using the visual analog scale (VAS), among other methodologies, in each case in comparison with a vehicle hydrogel insert. The clinical trial was not powered for statistical significance.

The clinical trial enrolled 166 subjects in the modified intent-to-treat (ITT) population which included subjects who were randomized and had the OTX-DED insert placed in the study eye. The clinical trial achieved its pre-specified primary endpoint, demonstrating a statistically significant change of bulbar conjunctival hyperemia from baseline to day 15 compared to vehicle hydrogel using a central reading photographic assessment in the modified ITT population. Change from baseline using the CCLRU Grading scale (0-4) was -0.51 for the OTX-DED 0.2 mg group (n=55), -0.43 for the OTX-DED 0.3 mg group (n=56), and -0.21 for the vehicle hydrogel insert group (n=55). These differences were statistically significant compared with the vehicle hydrogel for both the OTX-DED 0.2 mg group (p=.004) and the OTX-DED 0.3 mg group (p=.028). Sensitivity analysis using different methods of imputation including last observation carry forward (LOCF), Markov Chain Monte Carlo (MCMC), and fully conditional specification (FCS) were consistent with the primary analysis. Improvements from baseline were noted in the VAS dry eye symptoms for both OTX-DED 0.2 mg and OTX-DED 0.3 mg groups, but there was little separation between OTX-DED and the vehicle hydrogel insert. Other secondary endpoints are being evaluated.

OTX-DED inserts (both formulations) were observed to have a favorable safety profile and were generally well tolerated. There were two non-ocular serious adverse events, both in the vehicle hydrogel insert group, which were evaluated to be not related. There were no ocular serious adverse events. The most common ocular adverse events for subjects treated with OTX-DED were epiphora (lacrimation increase) (8.1%) and elevated intraocular pressure (IOP) (3.6%). All other ocular adverse events occurred in less than 1% of subjects. The most common non-ocular adverse event for subjects treated with OTX-DED was arthralgia (joint pain) which was seen in 1.8% of subjects. All other non-ocular adverse events occurred in less than 1% of subjects.

“We were extremely pleased with the results of the Phase 2 clinical trial. Results of the trial showed statistically significant improvement in bulbar conjunctival hyperemia in patients with dry eye disease for OTX-DED compared with the vehicle hydrogel control for both OTX-DED formulations,” said Michael Goldstein, MD, MBA, President, Ophthalmology and Chief Medical Officer. “In my clinical experience, many dry eye patients experience episodic flares of their signs and symptoms related primarily to inflammation. Topical steroids are commonly used for the short-term treatment of dry eye but all steroid eye drops contain preservatives that can lead to ocular surface toxicities such as irritation, burning, and stinging and, when used more chronically, other adverse events such as elevated IOP or cataracts. OTX-DED is a new, investigational, physician-administered, preservative-free intracanalicular insert designed to deliver dexamethasone and offering the potential to provide a differentiated treatment.”

“A key strategic initiative of Ocular is to expand our presence beyond the surgical setting and into ophthalmology and optometric offices, which we believe represent an enormous new opportunity to provide customers with our innovative buy-and-bill products,” said Antony Mattessich, President and Chief Executive Officer. “The recent approval of DEXTENZA® for the treatment of ocular itching associated with allergic conjunctivitis is our first beachhead to achieving this and the potential to offer a second product like OTX-DED, represents another large, office-based product opportunity. We look forward to advancing this exciting program in 2022.”

Conference Call & Webcast Information

Ocular management will host an investor webcast and conference call today at 8:00 a.m. ET to discuss the topline results for the Phase 2 clinical trial of OTX-DED for the short-term treatment of dry eye disease. The conference call may be accessed by dialing (844) 464-3934 (U.S.) or (765) 507-2620 (International) and entering conference ID 7364789. The accompanying slide presentation and live webcast may be accessed by visiting the investor relations section of the Ocular website at www.ocutx.com. An archive of the webcast and a copy of the Company’s presentation from the call (which has been posted) will be available until March 6, 2022 on the Company’s website.

About Dry Eye Disease

Dry eye disease is a common, multifactorial disease of the tears and ocular surface that results in symptoms of discomfort (such as burning sensation, itching, redness, stinging, pain and foreign body sensation), visual disturbance, and tear film instability that can cause potential damage to the ocular surface. Inflammation of the lacrimal gland and ocular surface have been shown to play a key role in dry eye disease, resulting in a reduction in tear

production.

The global market for ocular surface disease, which includes dry eye disease, was estimated by Market Scope at $5.1 billion in 2019 with the U.S. market representing $2.1 billion.

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 the effectiveness of and amounts applicable to 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, whether clinical trial data such as the data reported in this release will be indicative of the results of subsequent 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 meet supply demands, 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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