Ocular Therapeutix™ Announces First Patient Dosed in Phase 2 Clinical Trial of OTX-DED for the Short-Term Treatment of the Signs and Symptoms of Dry Eye Disease

March 1, 2021

BEDFORD, Mass.--(BUSINESS WIRE)--Mar. 1, 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 that it has dosed the first patient in its Phase 2 clinical trial of OTX-DED (dexamethasone intracanalicular ophthalmic insert) for the short-term treatment of the signs and symptoms of dry eye disease.

“We are excited to have recently begun dosing patients in the Phase 2 clinical trial of OTX-DED,” said Michael Goldstein, MD, MBA, President, Ophthalmology and Chief Medical Officer. “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 of them contain preservatives that can lead to ocular surface toxicities such as itching and stinging and, when used more chronically, other adverse events such as elevated intraocular pressure or cataracts. OTX-DED is a new, investigational, physician-administered, preservative-free intracanalicular insert designed to deliver either 0.2 or 0.3 mg doses of dexamethasone that has the potential to provide effective treatment with fewer of those toxicities and adverse events. Along with OTX-CSI, our cyclosporin-containing intracanalicular insert, we now have two potentially transformative dry eye product candidates in Phase 2 development, one to chronically treat dry eye disease (OTX-CSI) and the other to acutely treat dry eye disease (OTX-DED), thereby effectively covering the broad spectrum of the approximately $5 billion global dry eye disease market.”

The Phase 2 clinical trial is a U.S.-based, randomized, double-masked, vehicle-controlled, multi-center trial evaluating two different-strength formulations of OTX-DED (dexamethasone intracanalicular ophthalmic insert) in a total of approximately 150 subjects with dry eye disease. This trial is designed to assess the safety and efficacy of these two formulations of OTX-DED for the short-term treatment of signs and symptoms of dry eye disease by evaluating bulbar conjunctival hyperemia, corneal fluorescein staining eye dryness symptoms using visual analog scale (VAS), and other secondary endpoints in comparison with a matched vehicle control hydrogel insert.

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 dry ocular surface disease, which we refer to as 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 (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.

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; 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 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, any additional financing needs 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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