Ocular Therapeutix™ Announces First Patient Dosed in Phase 1 Clinical Trial of OTX-CSI for the Treatment of Dry Eye Disease

May 12, 2020

BEDFORD, Mass.--(BUSINESS WIRE)--May 12, 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 that it has dosed the first patients in its Phase 1 clinical trial of OTX-CSI (cyclosporine intracanalicular insert) for the treatment of dry eye disease (DED).

“We are pleased to be advancing OTX-CSI in the chronic treatment of dry eye disease,” said Michael Goldstein, MD, MBA, Chief Medical Officer. “We believe that the intracanalicular route of administration could provide key benefits in all ocular surface diseases but particularly in dry eye. The intracanalicular route allows for preservative-free delivery of a constant dose of cyclosporine, so it may be less irritating to the ocular surface than drop therapies. Also, blocking the punctum is a common treatment for DED itself and can provide immediate relief of symptoms. By being less-irritating and faster-acting than current therapies, we believe OTX-CSI has the potential to become a highly differentiated treatment that, if successfully developed, would significantly increase patient satisfaction.”

The Phase 1 clinical trial is a U.S.-based, open label, single center trial that intends to enroll 5 subjects and follow them for approximately 4 months. The study will evaluate safety and tolerability of OTX-CSI and assess biological activity by measuring signs and symptoms of DED over this time period. OTX-CSI is administered by a physician as a bioresorbable intracanalicular insert and is designed to release drug to the ocular surface for up to 3 months. After all subjects in the Phase 1 trial have been followed for at least two weeks, the safety committee will meet prior to proceeding to a U.S.-based, randomized, masked, multi-center Phase 2 clinical trial evaluating two different formulations of OTX-CSI with vehicle insert in approximately 105 subjects. The Company anticipates initiating the Phase 2 clinical trial in the fourth quarter of 2020.

About Dry Eye Disease

Dry eye 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. Dry eye disease is one of the most common ophthalmic disorders presenting to clinicians and it is estimated that more than 19 million adults in the United States have been diagnosed with the disorder and an estimated 7 million classified as having a moderate to severe form of the disease.

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 recently completed a Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis and intends to file an sNDA by the end of 2020. OTX-TP (intracanalicular travoprost insert) is an intracanalicular insert in clinical development for the reduction of intraocular pressure in patients with primary open-angle glaucoma and ocular hypertension. The Company’s earlier stage development assets include OTX-CSI, an intracanalicular cyclosporine insert for the treatment of dry eye disease, OTX-TIC, an extended-delivery intracameral travoprost implant for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension, as well as sustained release intravitreal implants for the treatment of retinal diseases. These intravitreal implants include OTX-TKI, containing the tyrosine kinase inhibitor (TKI) axitinib, and, in collaboration with Regeneron, OTX-IVT, an extended-delivery protein-based anti-vascular endothelial growth factor (VEGF) trap. Ocular Therapeutix's first product, ReSure® Sealant, is FDA-approved to seal 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 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-TP for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-CSI for the treatment of dry eye disease, OTX-TIC for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-IVT as an extended-delivery formulation of the VEGF trap aflibercept for the treatment of retinal diseases including wet AMD; the ongoing development of the Company’s extended-delivery hydrogel depot technology; 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; 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 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 release.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200512005315/en/

Investors
Ocular Therapeutix
Donald Notman
Chief Financial Officer
dnotman@ocutx.com

or

Westwicke, an ICR Company
Chris Brinzey, 339-970-2843
Managing Director
chris.brinzey@westwicke.com

Media
Ocular Therapeutix
Scott Corning
Senior Vice President, Commercial
scorning@ocutx.com

Source: Ocular Therapeutix