Ocular Therapeutix™ Announces First Patient Dosed in Phase 3 Clinical Trial of DEXTENZA® for the Treatment of Post-Surgical Ocular Inflammation and Pain in Children

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BEDFORD, Mass.--(BUSINESS WIRE)--Sep. 10, 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 a Phase 3 clinical trial of DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg for the treatment of post-surgical ocular inflammation and pain in children following cataract surgery.

“We are pleased to announce the start of a new clinical trial designed to evaluate the use of DEXTENZA for the treatment of post-surgical inflammation and pain in children undergoing cataract surgery,” said Michael Goldstein, MD, MBA, Chief Medical Officer. “Performing cataract surgery in children represents a different set of surgical and technical challenges. One area critical to surgical outcomes is postoperative medication non-compliance. It can be very challenging to successfully administer topical eye drops to children particularly when they have recently had surgery. If approved for pediatric use, DEXTENZA could provide pediatric ophthalmic surgeons with an interesting product to use to help their patients.”

The Phase 3 clinical trial is a U.S.-based, randomized, multicenter clinical trial that intends to enroll approximately 60 subjects between the ages of 0-3 years. The clinical trial is designed to evaluate the safety and biological activity of DEXTENZA compared to an active control, prednisolone acetate suspension eye drops, for the treatment of postoperative inflammation and pain following ocular surgery for pediatric cataract. This planned clinical trial is a post-approval requirement of the U.S. Food and Drug Administration (FDA), in accordance with the Pediatric Research Equity Act of 2003, in connection with the FDA's prior approval of DEXTENZA for the treatment of inflammation and pain following ophthalmic surgery in adults.

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. Overall, 567 subjects were exposed to DEXTENZA. 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 recently completed a Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis. The Company’s earlier stage development assets currently in Phase 1 trials include OTX-TIC (travoprost intracameral implant) for the reduction of intraocular pressure in patients with primary open-angle glaucoma and ocular hypertension, OTX-CSI (cyclosporine intracanalicular insert) for the treatment of the signs and symptoms of dry eye disease and OTX-TKI (axitinib intravitreal implant) for the treatment of retinal diseases. Also, Ocular Therapeutix is currently developing OTX-DED (dexamethasone intracanalicular insert) for the treatment of episodic dry eye and, in collaboration with Regeneron, OTX-AFS (aflibercept suprachoroidal injection) for an extended-delivery formulation of aflibercept for the treatment of retinal diseases, and 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 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 treatment of episodic dry eye disease, 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-AFS 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 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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