Ocular Therapeutix™ Announces FDA Acceptance of NDA Resubmission for DEXTENZA®

July 19, 2018

PDUFA date is set for December 28, 2018

BEDFORD, Mass.--(BUSINESS WIRE)--Jul. 19, 2018-- 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 received acknowledgement from the U.S. Food and Drug Administration (FDA) that the New Drug Application (NDA) for DEXTENZA® has been received. DEXTENZA (dexamethasone insert) 0.4mg is Ocular Therapeutix's lead product candidate for the treatment of ocular pain following ophthalmic surgery. The FDA considers the NDA resubmission as a class 2 response to its July 2017 Complete Response Letter with a PDUFA (Prescription Drug User Fee Act) target date of December 28, 2018 for the completion of the FDA's review of the DEXTENZA NDA.

"We are pleased with the recent news that the FDA has formally accepted our resubmission of the DEXTENZA NDA," said Antony Mattessich, President and Chief Executive Officer. "This marks one more important step towards our goal of bringing this important new treatment to the market."

About DEXTENZA®
DEXTENZA is a corticosteroid intracanalicular insert placed through the punctum, a natural opening in the eye lid, into the canaliculus and is designed to deliver dexamethasone to the ocular surface for up to 30 days without preservatives. Following treatment, DEXTENZA is intended to resorb and exit the nasolacrimal system without the need for removal. DEXTENZA has completed Phase 3 evaluation for the treatment of ocular pain and inflammation following ophthalmic surgery. Upon approval for pain, the Company intends to submit an NDA supplement for the treatment of inflammation following ocular surgery. DEXTENZA is also in Phase 3 clinical development for allergic conjunctivitis.

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 has resubmitted an NDA for post-surgical pain for its lead product candidate, DEXTENZA® (dexamethasone insert), which has completed Phase 3 clinical development for the treatment of ocular pain and inflammation following ophthalmic surgery. OTX-TP (travoprost insert) is in Phase 3 clinical development for the reduction of intraocular pressure in patients with primary open-angle glaucoma and ocular hypertension. The Company's earlier stage assets include OTX-TIC, an extended-delivery travoprost intracameral 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, a tyrosine kinase inhibitor (TKI), and, in collaboration with Regeneron, OTX-IVT, an extended-delivery protein-based anti-vascular endothelial growth factor (VEGF) trap, both for the treatment of retinal diseases. 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 development and regulatory status of the Company's product candidates, such as the Company's regulatory submissions for and the timing and conduct of, or implications of results from, clinical trials of DEXTENZA™ for the treatment of post-surgical ocular pain and inflammation, including with respect to manufacturing deficiencies identified by the FDA, the Company's expectations regarding the NDA filed with the FDA, the FDA's response to the resubmitted NDA and the prospects for approvability of DEXTENZA for these indications, OTX-TP for the treatment of primary open-angle glaucoma and ocular hypertension, 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; potential commercialization 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 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, those related to the timing and costs involved in commercializing ReSure® Sealant or any product candidate that receives regulatory approval, 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 sufficiency of cash resources, the outcome of the Company's ongoing legal proceedings and 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. 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.

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