Ocular Therapeutix™ Announces Successful Resolution of FDA Warning Letter Related to ReSure® Sealant

September 8, 2020

BEDFORD, Mass.--(BUSINESS WIRE)--Sep. 8, 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, announced it has received a letter from the U.S. Food and Drug Administration (FDA) dated September 2, 2020 closing out the Warning Letter it received from the FDA on October 18, 2018 concerning ReSure® Sealant. The violation cited in Warning Letter (CMS #564663) has been addressed and Ocular is committed to sustained compliance with all federal regulations.

“We are very excited to have cleared the way for ReSure’s future” said Antony Mattessich, President and Chief Executive Officer of Ocular Therapeutics. ”ReSure is well-regraded by anterior segment surgeons and fits perfectly into the bag with Dextenza. This resolution gives us the confidence to begin active promotion of ReSure and realize the synergies of a two-product field force.”

The Warning Letter was issued to Ocular based on the observed inability to conduct a study evaluating endophthalmitis rates following ReSure use in a post-approval Device Exposure Registry study required under 21 CFR 814.82(a)(2) as a condition within the premarket approval (PMA) application. It was determined the ability to enroll a study evaluating endophthalmitis rates was prohibitively challenging due to the size of the study that would have required tens of thousands of patients. Ocular has come to an agreement with the FDA to conduct a retrospective study looking at sites with access to ReSure compared to those without access to ReSure using the American Academy of Ophthamology’s Iris Registry data base.

About ReSure® Sealant

ReSure Sealant, a hydrogel ophthalmic wound medical device, is a product currently indicated for intraoperative management of clear corneal incisions (up to 3.5mm) with a demonstrated wound leak for which a temporary dry surface can be achieved, in order to prevent postoperative fluid egress from such incisions following cataract surgery with intraocular lens placement in adults.

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 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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