



## Ocular Therapeutix™ Fulfills Post-Marketing Approval Requirements for ReSure® Sealant

May 3, 2021

BEDFORD, Mass.--(BUSINESS WIRE)--May 3, 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, has received notification from the U.S. Food and Drug Administration (FDA) confirming it has fulfilled all post-approval study requirements for ReSure® Sealant, with a requirement to update the ReSure label reflecting the study results. As a condition for ReSure's pre-market approval application (PMA) in 2014, the FDA required two post-approval studies to be completed. The first, referred to as the Clinical Post-Approval Study, was completed in 2016. This notification marks the completion of the second, the Device Exposure Registry Study, a retrospective analysis comparing endophthalmitis rates from sites that purchased ReSure Sealant versus sites that did not.

"We are happy to have completed the FDA's post-approval requirements for our ReSure Sealant product" said Antony Mattessich, President and Chief Executive Officer of Ocular Therapeutix. "ReSure is well-regarded by anterior segment surgeons and this study only adds to the body of knowledge supporting its use."

This retrospective study evaluated endophthalmitis rates at sites with access to ReSure compared with the rate at sites without access to ReSure using the American Academy of Ophthalmology's IRIS® Registry (Intelligent Research in Sight) database. In total, 6.7 million eyes that underwent cataract surgery with insertion of an intraocular lens between January 2016 and December 2019 were evaluated in the study. The endophthalmitis rates for sites with access to ReSure was 0.609 per 1,000 surgeries, compared with 0.660 per 1,000 surgeries for sites without access to ReSure ( $p=0.01$ ). Overall, the results of the study demonstrated there was no clinically or statistically significant difference in the incidence of endophthalmitis within 30 days of any cataract surgery between cohorts with and without access to ReSure Sealant.

Ocular plans to submit a PMA supplement to modify the existing ReSure label to reflect the findings from the recently completed study.

### 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 has received a target action date under the Prescription Drug User Fee Act, commonly known as PDUFA, of October 18, 2021, for a supplemental new drug application to include the treatment of ocular itching associated with allergic conjunctivitis as an additional approved indication of DEXTENZA. 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 and compliance with related labeling requirements for DEXTENZA and ReSure Sealant; 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 the PDUFA target action date scheduled for October 18, 2021 for allergic conjunctivitis, OTX-CSI for the chronic treatment of dry eye disease, OTX-DED for the short-term treatment of the signs and symptoms 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 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, unit sales and other financial and operational 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, conduct and outcomes 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 and unit sales 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 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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Source: Ocular Therapeutix, Inc.