

# Ocular Therapeutix<sup>™</sup> to Present Data on Anterior and Posterior Segment Drug Product Candidates at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting

May 2, 2017

## First-time Presentation of Results on efficacy, tolerability and pharmacokinetics of TKI depot for the potential treatment of retinal diseases

BEDFORD, Mass.--(BUSINESS WIRE)--May 2, 2017-- Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development, manufacturing and commercialization of innovative therapies for diseases and conditions of the eye, today announced that 11 abstracts on drug product candidates incorporating its proprietary hydrogel platform technology will be presented at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, May 7-11, in Baltimore, MD. Clinical data on some of the Company's current pipeline products including DEXTENZA<sup>TM</sup> (dexamethasone insert) 0.4 mg, OTX-TP (travoprost insert) and OTX-TKI (tyrosine kinase inhibitor) will be presented during the conference.

"We remain steadfast in our commitment to continue to make clinical progress across our drug product development programs that target leading causes of blindness such as cataracts, glaucoma and wet age-related macular degeneration," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman of Ocular Therapeutix. "The data presented at ARVO demonstrate that we continue to successfully execute on our diversification strategy as we seek to improve the standard of care across multiple disease states within ophthalmology using our proprietary hydrogel platform technology to create innovative drug products."

## **Poster Presentations:**

- Tolerability of a Shape Changing Intravitreal Hydrogel Depot May 8 from 11:00AM 12:45PM in Exhibit/Poster Hall
- Tolerability of a 6-month Sustained Hydrogel Delivery System for Tyrosine Kinase Inhibitors in Dutch Belted Rabbits May 8 from 11:00AM 12:45PM in Exhibit/Poster Hall
- Pharmacokinetics of a 6-month Sustained Hydrogel Delivery System for Tyrosine Kinase Inhibitors in Dutch Belted Rabbits
   May 8 from 11:00AM 12:45PM in Exhibit/Poster Hall
- Efficacy of a 6-month Sustained Hydrogel Delivery System for Tyrosine Kinase Inhibitors in a VEGF Induced Retinal Leakage Model May 8 from 11:00AM 12:45PM in Exhibit/Poster Hall
- Outcomes in cataract surgery using ReSure® Sealant for the intraoperative management of clear corneal incisions: Results from a registry evaluation for pre-specified adverse ocular events May 8 from 11:00AM 12:45PM in Exhibit/Poster Hall
- A Single Center Study of the Plasma Pharmacokinetics of DEXTENZA<sup>TM</sup> (dexamethasone insert) 0.4 mg in Healthy Volunteers - May 10 from 8:30AM-10:15AM in Exhibit/Poster Hall
- Results of a Phase 3, Randomized, Double-Masked, Vehicle Controlled Study (Phase 3c) Evaluating the Safety and
   Efficacy of DEXTENZA<sup>TM</sup> (dexamethasone insert) 0.4 mg for the Treatment of Ocular Inflammation and Pain after Cataract
   Surgery May 8 from 11:00AM 12:45PM in Exhibit/Poster Hall
- DEXTENZA<sup>TM</sup> (extended release dexamethasone) 0.4 mg vs. Placebo for the Treatment of Ocular Inflammation after Cataract Surgery: Results of Three Phase 3 Studies May 8 from 11:45AM-12:00PM In Exhibit/Poster Hall
- DEXTENZA<sup>TM</sup> (extended release dexamethasone) 0.4 mg vs. Placebo for the Treatment of Ocular Pain after Cataract Surgery: Results of Three Phase 3 Studies - May 8 from 11:45AM-12:00PM in Exhibit/Poster Hall
- Safety of DEXTENZA<sup>TM</sup> (extended release dexamethasone) 0.4 mg: An Integrated Analysis Across Four Clinical Trials -May 8 from 11:45AM-12:00PM in Exhibit/Poster Hall
- Results of A Randomized, Double-Masked, Parallel-Arm Phase 2b Study Evaluating the Safety and Efficacy of OTX-TP (travoprost insert) Compared to Timolol Drops for the Treatment of Patients with Open-Angle Glaucoma or Ocular Hypertension - May 8 from 3:45PM - 5:30PM in Exhibit/Poster Hall

#### About OTX-TKI (tyrosine kinase inhibitor)

OTX-TKI is a preformed, bioresorbable hydrogel fiber depot with anti-angiogenic properties delivered by intravitreal tyrosine kinase inhibitor injection. Currently OTX-TKI is under initial investigation as a novel extended release drug product candidate.

# About DEXTENZA™(dexamethasone insert) 0.4 mg for Intracanalicular Use

DEXTENZA is 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. Following treatment, DEXTENZA resorbs and exits the nasolacrimal system without need for removal. The Company has completed three Phase 3 clinical trials with DEXTENZA for the treatment of post-surgical ocular pain and inflammation.

In January, Ocular Therapeutix resubmitted an NDA to the FDA for DEXTENZA for the treatment of ocular pain following ophthalmic surgery. The FDA has set a PDUFA target action date of July 19, 2017. Subject to the approval of the NDA for post-surgical ocular pain by the FDA, Ocular Therapeutix intends to submit a supplement to its NDA for DEXTENZA to broaden its label to include a post-surgical ocular inflammation indication.

OTX-TP is a drug product candidate that resides within the canaliculus and is designed to deliver the prostaglandin analog travoprost to the ocular surface for up to 90 days. OTX-TP is designed to deliver a continuous steady release of drug throughout the treatment period. A fluorescent visualization aid is formulated within the product to enable the physician to monitor the presence of the insert throughout the course of therapy. If approved, OTX-TP may become the first non-invasive, extended release therapy for the treatment of glaucoma.

#### About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the development, manufacturing and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. Ocular Therapeutix's lead product candidate, DEXTENZATM (dexamethasone insert) 0.4 mg for intracanalicular use has completed Phase 3 clinical development for the treatment of ocular pain and inflammation following ophthalmic surgery. The FDA has accepted the Company's NDA resubmission for DEXTENZA for the treatment of ocular pain following ophthalmic surgery and has established a PDUFA target action date of July 19, 2017. If approved, the Company intends to submit a supplement to its NDA for post-surgical ocular inflammation. OTX-TP (travoprost insert) is in Phase 3 clinical development for glaucoma and ocular hypertension. Ocular Therapeutix is also evaluating injectable drug delivery depots for back-of-the-eye 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 expectations and plans regarding regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA™ for the treatment of post-surgical ocular inflammation and pain, including our expectations regarding the NDA filed with the FDA and the FDA's response to the resubmitted NDA, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for the treatment of dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel technology, the potential utility of any of the Company's product candidates, potential commercialization of the Company's product candidates, 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 forwardlooking 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 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 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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