Ocular Therapeutix™ Presents Data Demonstrating a Clinically-Meaningful Reduction in Intraocular Pressure in Patients with Primary Open Angle Glaucoma or Ocular Hypertension Treated with OTX-TIC at Glaucoma 360 Conference

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BEDFORD, Mass.--(BUSINESS WIRE)--Feb. 7, 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, will today present data on OTX-TIC, a long acting travoprost intracameral implant for the treatment of patients with primary open angle glaucoma or ocular hypertension. Data from this Phase 1 clinical trial demonstrated a clinically-meaningful reduction in intraocular pressure (IOP) for up to 18 months in these patients treated with a single insertion of OTX-TIC. The presentation also included positive safety and tolerability data in both cohorts enrolled to date. These data will be presented at the Glaucoma 360 conference in San Francisco by the company's chief medical officer, Michael Goldstein, M.D., M.B.A.

"While glaucoma is a complex disease, lowering intraocular pressure remains a key target to prevent damage to the optic nerve," commented Dr. Goldstein. "There are many topical eye drop options on the market to treat IOP associated with glaucoma, but poor compliance rates are very high. By delivering the therapy through a single intracameral implant, we have the ability to ensure that patients are receiving the appropriate amount of therapy needed to lower IOP on an ongoing basis. While the number of patients treated so far is small, these data seem to show that not only has OTX-TIC lowered IOP levels quickly, but also decreased IOP levels for as long as up to 18 months. We are very excited by what we have seen with the early results from this trial and look forward to continuing enrollment and further evaluation of these patients over time."

The Phase 1, prospective, multi-center, open-label, dose escalation clinical trial is intended to evaluate the safety, efficacy, durability, and tolerability of OTX-TIC for the reduction of elevated intraocular pressure in patients with primary open angle glaucoma or ocular hypertension. Data from the first two fully enrolled cohorts (cohort 1=5 subjects, cohort 2=4 subjects) show decreased mean IOP values in patients receiving OTX-TIC. The data also show that the mean IOP values remained decreased from the baseline values through the study period and beyond and, in one patient, for eighteen months at the time of assessment. Overall, OTX-TIC was generally safe and well tolerated and no serious adverse events were reported. No changes in corneal health were noted as measured by corneal pachymetry and endothelial cell count evaluation. The implant biodegraded consistently in approximately 5-7 months. Enrollment has begun in the third and fourth cohorts of the trial while continued long-term evaluation remains ongoing in the first two cohorts. As is typical for Phase 1 trials, this Phase 1 clinical trial is not powered to measure any efficacy endpoints with statistical significance.

About OTX-TIC
OTX-TIC is designed to be a bioresorbable intracameral implant containing micronized travoprost that is injected into the anterior chamber of the eye and is intended for patients with glaucoma with a target duration of drug delivery of four to six months. Preclinical studies in beagles have demonstrated an acceptable safety profile, maintenance of drug levels in the aqueous humor and a sustained lowering of intraocular pressure. OTX-TIC is designed to directly address compliance issues by delivering travoprost over the course of several months with a single implant.

About Glaucoma
Glaucoma is a progressive and highly individualized disease in which elevated levels of IOP are associated with damage to the optic nerve, which results in irreversible vision loss. According to the World Health Organization, glaucoma is the second leading cause of blindness in the world. In the U.S., the Glaucoma Research Foundation estimates that over three million Americans have glaucoma.

To lower IOP, physicians typically initiate treatment by prescribing drugs administered as eye drops. These drugs either decrease fluid production or enhance fluid drainage. The classes of topical drugs used to treat glaucoma include prostaglandin analogs, or PGAs, beta-blockers, alpha-adrenergic agonists and carbonic anhydrase inhibitors. PGAs are the most widely prescribed class of drugs for glaucoma and are considered first-line glaucoma treatment. PGAs reduce IOP by enhancing the clearance and drainage of ocular fluid. The most frequently prescribed PGA is once-daily latanoprost, although travoprost, unoprostone and bimatoprost are also frequently used in the management of open-angle glaucoma. In cases where glaucoma is not easily managed by a drug regimen, surgical or laser treatments may be undertaken.

According to IMS Health data, approximately 35.2 million prescriptions were filled in the United States in 2018 for drugs administered by eye drops for the treatment of glaucoma, resulting in sales of approximately $3.1 billion. A typical prescription provides approximately one month of treatment. We expect prescription volume to grow, in large part as a result of the aging population. According to IMS Health, PGAs accounted for approximately half of the prescription volume in the glaucoma market in 2018.

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 also begun a Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis. OTX-TP (intracanalicular travoprost insert) is an intracanalicular insert 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 intracameral travoprost 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, containing a tyrosine kinase inhibitor (TKI), and, in collaboration with Regeneron, OTX-IVT, an extended-delivery protein-based anti-vascular endothelial growth factor (VEGF) trap. 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, including the impact of and restructuring costs and potential savings associated with the Company's operational restructuring, workforce reduction and development program deferrals; 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-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; 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 implementation of the operational restructuring, 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 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 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 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 release.

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