



Ocular Therapeutix™ Presents Interim Topline Data from the Phase 1 Clinical Trial of OTX-TIC in Patients with Primary Open Angle Glaucoma or Ocular Hypertension at the 10th Annual Glaucoma 360 New Horizons Forum

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BEDFORD, Mass.--(BUSINESS WIRE)--Jan. 20, 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, today announced plans to present data on OTX-TIC, a travoprost intracameral implant for the treatment of patients with primary open angle glaucoma or ocular hypertension at the Glaucoma 360 New Horizons Forum being held virtually on January 30th. As part of the event, Michael Goldstein, M.D., M.B.A., President, Ophthalmology and Chief Medical Officer of Ocular Therapeutix, has narrated a presentation on the OTX-TIC Phase 1 study that is available today and can be accessed [on](#) the "Events and Presentations" section of the Ocular Therapeutix website.

The Phase 1, prospective, multi-center, open-label, clinical trial is intended to evaluate safety, biological activity, durability, and tolerability of OTX-TIC for the reduction of elevated intraocular pressure (IOP) in patients with primary open angle glaucoma or ocular hypertension. Interim data presented at Glaucoma 360 are from the four fully enrolled cohorts (cohort 1=5 subjects, cohort 2=4 subjects, cohort 3=5 subjects, and cohort 4=5 subjects). Formulations of cohort 3 and 4 hydrogel implant include composition for faster dissolution when compared with cohorts 1 and 2.

In this Phase 1 clinical trial, all cohorts experienced a mean reduction in IOP from baseline of 7-11 mm Hg with onset of action as early as two days after insertion. Many subjects across the four cohorts demonstrated durability of activity of 6 months or longer with a single implant. Overall, no serious ocular adverse events were noted. The hydrogel drug delivery system consistently biodegraded in 5-7 months in cohorts 1 and 2 and in 3-5 months in cohorts 3 and 4. No meaningful changes in endothelial cell counts or pachymetry were observed across the cohorts. Evaluation remains ongoing for cohort 4. As is typical for early stage clinical trials, this trial is not powered to measure efficacy endpoints with statistical significance.

"Compliance with topical drop therapy remains a clinical problem in the treatment of glaucoma and represents a large unmet medical need. OTX-TIC was developed to deliver travoprost for an extended duration of time and, if shown to be safe and effective, represents a possible solution to this problem. Continued long-term evaluation is ongoing but we are very excited by what we have seen with the early results from this trial," commented Dr. Goldstein. "We continue to believe that OTX-TIC has the potential for a unique and differentiated drug product profile. Based on these data we continue to plan to initiate a Phase 2 clinical trial in mid-2021."

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 or ocular hypertension with a target duration of drug delivery of four months or longer. 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. 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 35.6 million prescriptions were filled in the United States in 2019 for drugs administered by eye drops for the treatment of glaucoma, resulting in sales of approximately \$3.3 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 2019.

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 submitted a Supplemental NDA for DEXTENZA to include the treatment of ocular itching associated with allergic conjunctivitis as an additional approved indication. Ocular Therapeutix's earlier stage development assets currently in Phase 1 clinical trials include OTX-TIC (travoprost intracameral implant) for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension and OTX-TKI (axitinib intravitreal implant) for the treatment of wet AMD and other retinal diseases. Ocular Therapeutix is currently evaluating OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease in a Phase 2 clinical trial. Also, Ocular Therapeutix has recently filed a Phase 2-enabling investigational new drug application for OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease. Also, in collaboration with Regeneron, OTX-AFS (afibercept suprachoroidal injection) is in pre-clinical development as an extended-delivery formulation of afibercept for the treatment of retinal diseases. Ocular Therapeutix's first product, ReSure® Sealant, is an FDA-approved device 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 its presentation at future scientific or medical conferences; 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 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 short-term treatment of the signs and symptoms of dry eye disease, OTX-CSI for the chronic treatment 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 afibercept for the treatment of retinal diseases including wet AMD; the potential receipt of a target action date under PDUFA; 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, 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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