



Ocular Therapeutix™ Announces Dosing of First Patient in OTX-TKI (tyrosine kinase inhibitor implant) Phase 1 Clinical Trial for the Treatment of Wet Age-related Macular Degeneration (AMD)

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BEDFORD, Mass.--(BUSINESS WIRE)--Feb. 20, 2019-- 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 the dosing of the first patient in a Phase 1 trial of OTX-TKI (tyrosine kinase inhibitor implant) in patients with wet Age-related Macular Degeneration (AMD). The first patient was dosed at the Sydney Retina Clinic in Sydney, Australia.

"We are excited to announce the first patient has been successfully dosed in our Phase 1 program with OTX-TKI, our tyrosine kinase inhibitor implant for the treatment of serious retinal disease," said Michael Goldstein, M.D., Chief Medical Officer at Ocular Therapeutix. "Our trial is primarily intended to demonstrate safety, but we will also evaluate biological activity in patients with increased retinal thickness and measure whether there are decreases over time. Given that TKI's act upstream of VEGF inhibitors, we believe this Phase 1 trial may bring us one step closer to understanding whether TKI's may represent a next-generation treatment for wet AMD and diabetic macular edema."

The Phase 1 trial is a multi-center, open-label study testing the safety, durability, and tolerability of OTX-TKI, a bioresorbable hydrogel fiber implant formulated with a tyrosine kinase inhibitor delivered by intravitreal injection to patients with wet AMD. The study will evaluate biological activity by measuring retinal thickness using standard optical coherence tomography and following visual acuity over time.

About OTX-TKI (tyrosine kinase inhibitor implant) Intravitreal Injection

OTX-TKI is a bioresorbable hydrogel formulated with TKI particles in an injectable fiber that can be delivered through a small-gauge, sterile injection needle to the back of the eye. OTX-TKI is designed to deliver drug to the target tissues for a period of up to nine months, thereby potentially extending the dosing interval from the one - to two - month frequency needed with the current standard of care. Preclinical data have demonstrated the ability to deliver TKI to the posterior segment of the eye with sustained pharmacokinetic/pharmacodynamic effect for the treatment of VEGF-induced retinal leakage for a duration of up to twelve months.

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 pain following ophthalmic surgery. 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 ReSure Sealant, DEXTENZA® or any of the Company's product candidates; the development and regulatory status of the Company's product candidates, such as the Company's regulatory submissions for and the timing and conduct of, or implications of results from, clinical trials of DEXTENZA for the treatment of post-surgical ocular inflammation and the prospects for approvability of DEXTENZA for post-surgical ocular inflammation or any other indications, 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 Company's post-approval studies of ReSure® Sealant and the Company's ongoing communications with the U.S. Food and Drug Administration regarding the Company's appeal of the warning letter it received regarding ReSure Sealant; 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 timing and costs involved in commercializing ReSure Sealant, DEXTENZA or any product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of ReSure Sealant, DEXTENZA or any product candidate that receives regulatory approval, 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. 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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