Ocular Therapeutix Announces DEXTENZA® (dexamethasone ophthalmic insert) Recommended for Unique J-Code by CMS

May 1, 2019

BEDFORD, Mass.--(BUSINESS WIRE)--May 1, 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, announced that the Centers for Medicare and Medicaid Services (CMS) has included DEXTENZA® (dexamethasone ophthalmic insert) 0.4mg for intracanalicular use on its list of products that have been preliminarily recommended for a new dedicated Healthcare Common Procedure Coding System (HCPCS) J-code, effective January 1, 2020.

A J-Code is a permanent product code established by CMS for the Prospective Payment System used to report drugs that ordinarily cannot be self-administered. J-codes are familiar to both medical practices and their billing staffs, as well as Medicare (Part B and Part C) and commercial insurers. As a result, J-codes allow for a simpler and more convenient reimbursement process. The Company believes that receipt of a J-code will facilitate reimbursement for a greater number of patients to be treated with DEXTENZA.

As previously disclosed, the Company also submitted an application for a HCPCS C-code for transitional pass-through payment status and expects notification from CMS by mid-year 2019 on the status of the C-code application. A C-code is a unique temporary product code established by CMS for the Prospective Payment System used to report claims for hospital outpatient department services and procedures. If the Company receives a C-code, it should enable the use and reimbursement of DEXTENZA until such time as CMS may potentially approve the J-code and such approval becomes effective.

DEXTENZA is the first FDA-approved intracanalicular insert delivering dexamethasone to treat post-surgical ocular pain for up to 30 days with a single administration. DEXTENZA is a resorbable, preservative-free ophthalmic insert that is placed in the lower lacrimal punctum and into the canaliculus of the eye.

“We are pleased that CMS has recommended a unique J-code for DEXTENZA,” said Antony Mattessich, President and Chief Executive Officer. “Finalization of this recommendation later this year would be an important achievement for the Company and for the potential commercial success of DEXTENZA.”

Per the HCPCS J-code review process, CMS is scheduled to hold a public hearing in May. The final list of J-codes is anticipated to be published in fourth quarter of 2019, with new codes expected to take effect on January 1, 2020.

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 DEXTENZA, ReSure Sealant or any of the Company’s product candidates, including the anticipated commercial launch of, and the receipt of reimbursement codes for, DEXTENZA; 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 warning letter the Company 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 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 obtain 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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