AffaMed Therapeutics, licensee of DEXTENZA® in Certain Asian Markets, Doses Their First Patient in Clinical Trial Evaluating the Safety and Efficacy of DEXTENZA® in China in Cataract Surgery Patients

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BEDFORD, Mass.--(BUSINESS WIRE)--Jan. 18, 2022-- 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 that AffaMed Therapeutics dosed its first patient in a real-world setting study being conducted in China evaluating the safety and efficacy of DEXTENZA® (0.4 mg dexamethasone ophthalmic insert) for the treatment of ocular inflammation and pain post-cataract surgery. In 2020, Ocular entered into a licensing agreement with AffaMed Therapeutics for the development and commercialization of DEXTENZA® in Greater China, South Korea, and the ASEAN markets. DEXTENZA® is currently approved in the U.S. for the treatment of ocular inflammation and pain following ophthalmic surgery and for the treatment of ocular itching associated with allergic conjunctivitis.

Dr. Dayao ZHAO, Chief Executive Officer of AffaMed Therapeutics, commented: “We are pleased to be dosing the first patient in Bo’ao, in the real-world study that evaluates the use of DEXTENZA® in China, and to support and accelerate registration applications for imported therapies, so that more patients can benefit from the world's leading innovative therapies.”

This prospective, single-arm, real-world trial is designed to assess the safety and efficacy of DEXTENZA® for the treatment of ocular inflammation and pain following cataract surgery in approximately 120 patients at the Bo’ao Super Hospital. The trial’s primary efficacy endpoint is the absence of anterior chamber cells in the study eye at Day 14, and the key secondary endpoint is the absence of pain in the study eye at Day 8.

“The market for prescription ophthalmology products in China is sizeable, with $5 billion in annual sales and growth exceeding 16% per year (IQVIA),” said Antony Mattessich, President and Chief Executive Officer of Ocular Therapeutix. “AffaMed shares our vision of developing and commercializing innovative ophthalmology products, and we look forward to working with them to bring our innovative therapies to these global markets.”

Under the terms of the agreement with AffaMed, Ocular Therapeutix has been paid an upfront payment of $12 million and is eligible to receive development, regulatory and commercial milestone payments and clinical development support payments of up to an additional $91 million in the aggregate, as well as royalties from future product sales. Royalties are tiered and will range from the low teens to low twenty percent range. In return, Ocular Therapeutix has agreed to grant AffaMed exclusive rights to develop and commercialize DEXTENZA® for the treatment of post-surgical inflammation and pain following ophthalmic surgery and ocular itching in patients with allergic conjunctivitis, and OTX-TIC for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension in Greater China, which includes mainland China, Hong Kong, Macau, and Taiwan; South Korea; and the ASEAN Countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam). Ocular Therapeutix retains the right to develop and commercialize DEXTENZA® and OTX-TIC in all other global markets.

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 an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. Ocular Therapeutix’s earlier stage development assets includes OTX-TKI (axitinib intravitreal implant), currently in Phase 1 clinical trials for the treatment of wet AMD and other retinal diseases. OTX-TIC (travoprost intracameral implant) recently began a Phase 2 clinical trial for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension. Ocular Therapeutix has completed Phase 2 clinical trials for OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease and OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease. Ocular Therapeutix's first product, ReSure® Sealant, is an FDA-approved device to prevent wound leaks in corneal incisions following cataract surgery.

About AffaMed Therapeutics

AffaMed Therapeutics is a clinical stage biopharmaceutical company focused on developing and commercializing transformative pharmaceutical, digital and surgical products that address critical unmet medical needs in ophthalmological, neurological and psychiatric disorders for patients in Greater China and around the world. The leadership team at AffaMed Therapeutics has gained deep industry expertise and an extensive track record in high-quality discovery, clinical development, regulatory affairs, business development, manufacturing, and commercial operations at leading multi-national biopharmaceutical companies in China and globally.

About DEXTENZA®

DEXTENZA® is FDA approved for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. DEXTENZA® is a corticosteroid intracanalicular insert placed in the punctum, a natural opening in the inner portion of the lower eyelid, and into the canaliculus and is designed to deliver dexamethasone to the ocular surface for up to 30 days without preservatives. DEXTENZA® resorbs and exits the nasolacrimal system without the need for removal.

Please see full Prescribing and Safety Information at www.DEXTENZA.com.

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; the commercial launch of, and the effectiveness of and amounts applicable to reimbursement codes for, DEXTENZA®; the conduct of post-approval studies of and compliance with related labeling requirements for DEXTENZA® and ReSure Sealant; the development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of OTX-CSI for the chronic treatment of dry eye disease, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, and OTX-TKI for the treatment of retinal diseases including wet AMD; 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 operations of Company collaborations, including any potential future costs or payments thereunder; projected net product revenue, in-market sales and other financial and operational metrics of DEXTENZA® and ReSure Sealant; potential market sizes for indications targeted by the Company's product candidates, if approved; 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 preclinical and 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 successfully develop and commercialize products for the ophthalmology office setting, the ability to retain regulatory approval of DEXTENZA®, ReSure Sealant or any product candidate that receives regulatory approval, the ability to maintain and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA®, the initiation, timing, conduct and outcomes of clinical trials, whether clinical trial data such as the data reported in this release will be indicative of the results of subsequent clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's ability to enter into and perform its obligations under collaborations and the performance of its collaborators under such collaborations, 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 meet supply demands, the Company's ability to generate its projected net product revenue and in-market sales 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 severity and duration of the COVID-19 pandemic including its effect on the Company's and relevant regulatory authorities' operations, any additional financing needs 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, whether as a result of new information, future events or otherwise, 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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