Ocular Therapeutix™ and Mosaic Biosciences Enter into Strategic Discovery Collaboration Targeting the Treatment of Dry Age-Related Macular Degeneration

June 29, 2021

BEDFORD, Mass.--(BUSINESS WIRE)--Jun. 29, 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, entered into a discovery collaboration with Mosaic Biosciences to identify new targets and therapeutic agents aimed at the treatment of Dry Age-related Macular Degeneration (dAMD).

Under terms of the agreement, the collaboration between Ocular Therapeutix and Mosaic focuses on the discovery and development of novel complement inhibitors with extended duration of activity. The complement pathway represents a key component of innate immunity and maintains immune homeostasis throughout the body, including ocular tissues. Within the retina, the complement pathway has been associated with the development of age-related macular degeneration. The goal of complement inhibition is to block the pathway that can initiate and drive these diseases.

“This agreement with Mosaic Biosciences marks an important step forward for our company and how we approach the discovery and development of ophthalmic products,” said Antony Mattessich, President and Chief Executive Officer of Ocular Therapeutix. “Historically, our products have been developed by combining a known active pharmaceutical ingredient (API) with our proprietary hydrogel technology to create innovate treatments for diseases of the eye. However, certain diseases are very challenging to treat with existing agents. Working with Mosaic, we hope to incorporate the discovery of new chemical entities into our current drug development approach and to identify novel, sustained release products to expand our innovative ophthalmic portfolio.”

“We are pleased to begin working with Ocular, one of the leading ophthalmology companies in the industry,” commented Eric Furfine, Co-Chief Executive Officer and Chief Scientific Officer of Mosaic Biosciences. “At Mosaic we are focused on leveraging our expertise in research and proprietary protein engineering to discover novel compounds. Based on our extensive working knowledge of the complement pathway, along with Ocular’s expertise in sustained release technology, we look forward to discovering and developing novel compounds to treat a debilitating disease like dAMD.”

Under the terms of the agreement, Ocular Therapeutix has agreed to fund the research performed under the collaboration and retains all program inventions and associated intellectual property.

About Age-Related Macular Degeneration

AMD, a progressive retinal disease that is the leading cause of blindness in adults over the age of 60, is estimated to affect approximately 11 to 15 million people in the U.S. AMD affects the center portion of the retina, called the macula, which is responsible for central vision and color perception. There are two forms of AMD; the dry form which affects between 85-90% of patients and the wet form which affects the remaining 10-15% of patients. The dry form of AMD features slowly progressive, degenerative changes in the retinal pigment epithelial cells, Bruch’s membrane, and the choroid (the area beneath the retina) that over time leads to a thinning of the macula, causing the macula to lose its function. As dry AMD progresses, it leads to an irreversible degeneration of retinal cells that results in permanent loss of vision. The disease and resulting vision loss is a major contributor to loss of independence and diminished quality of life in older persons. Although there are FDA-approved treatments for wet AMD, there are no treatments currently approved by the FDA for the dry form of AMD.

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 received a target action date under the Prescription Drug User Fee Act, commonly known as PDUFA, of October 18, 2021, for a supplemental new drug application to include the treatment of ocular itching associated with allergic conjunctivitis as an additional approved indication of DEXTENZA. Ocular Therapeutix’s earlier stage development assets currently in Phase 1 clinical trials include OTX-TKI (axitinib intravitreal implant) for the treatment of wet AMD and other retinal diseases and OTX-TIC (travoprost intracameral implant) for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension. Ocular Therapeutix is currently evaluating each of 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 in Phase 2 clinical trials. Also, in collaboration with Regeneron, OTX-AFS (aflibercept suprachoroidal injection) is in pre-clinical development as an extended-delivery formulation of aflibercept for the treatment of retinal diseases. Ocular Therapeutix's first product, ReSure® Sealant, is an FDA-approved device to prevent wound leaks in corneal incisions following cataract surgery.

About Mosaic Biosciences, Inc.

Mosaic Biosciences is a private biotechnology company focused on helping partners discover and develop novel protein therapeutics. Mosaic’s partners range from early-stage start-ups to development-stage companies. Mosaic’s approach leverages proprietary and public domain technologies to invent best-in-class antibody and other protein therapeutics, and to advance them into preclinical development. Mosaic’s team provides experienced pharmaceutical scientists, and the leadership and vision to drive and coordinate internal and external resources. Based on each partner’s needs, Mosaic offers the ability to execute any part or all of a program. Mosaic’s goals are its partners’ goals.

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 effectiveness of 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 DEXTENZA for additional indications including the PDUFA target action date scheduled for October 18, 2021 for allergic conjunctivitis, 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, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-AFS 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 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 and other 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; 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 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, conduct and outcomes 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 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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