Ocular Therapeutix™ Announces Positive Phase 2 PAXTRAVA™ Glaucoma Data at the American Society of Cataract and Refractive Surgery 2024 Annual Meeting

April 6, 2024

Phase 2 data highlight consistent and sustained reductions in Intraocular Pressure (IOP), statistically significant (p<0.0001) through six months, with clinically meaningful reductions of 24-30% achieved with a single PAXTRAVA implant

Generally well tolerated with no impact on corneal health observed

Consistent durability of IOP reduction and implant bioresorption shows potential for repeat dosing without stacking of implants

Expanded Focus on Retinal Disease Highlighted at the April 4th Eyecelerator

BEDFORD, Mass., April 06, 2024 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ:OCUL, "Ocular", the "Company"), a biopharmaceutical company committed to enhancing people's vision and quality of life through the development and commercialization of innovative therapies for wet age-related macular degeneration (wet AMD), diabetic retinopathy, and other diseases and conditions of the eye, today announced positive Phase 2 data for PAXTRAVA (travoprost intracameral implant or OTX-TIC) in patients with open-angle glaucoma or ocular hypertension (reported together as "glaucoma", below) The data are being presented by Mark Gallardo, MD during the 2024 American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting.

"Ocular is very pleased to report positive six-month topline results for PAXTRAVA in the Phase 2 glaucoma study. We designed the Phase 2 clinical trial to evaluate PAXTRAVA over several time points that we believe are clinically meaningful, through six months. Observation of IOP reduction as early as the first follow-up visit, at 2 weeks, and demonstration of a 24-30% reduction in mean IOP through six months, with consistent and sustained reductions at each and every timepoint, are at the core of our enthusiasm for these results. That the majority of eyes (81.3%) treated with PAXTRAVA did not require additional IOP lowering therapy through six months further supports the strength of the data," said **Rabia Gurses Ozden, MD, Chief Medical Officer at Ocular Therapeutix.** "As we incorporate these efficacy data, coupled with the expanded safety database, into our evaluation of next steps for the program, we thank all of the patients, caregivers and study sites who participated in this Phase 2 study."

Summary of Data and Findings:

Efficacy: **PAXTRAVA 26 µg single implant demonstrated consistent IOP control through 6 months**:

- Statistically significant IOP changes from baseline were observed for each and every individual and mean diurnal measurement at Week 2 (M0.5), Week 6 (M1.5), and Week 12 (M3), as well as Months 4.5 and 6 (p<0.0001), although no formal statistical testing was prespecified
- Clinically meaningful mean IOP reduction of ~24-30% from baseline observed over six months
- A majority (81.3%) of treated eyes did not require additional IOP-lowering therapy through 6 months indicating sustained and consistent treatment effects

Safety: **PAXTRAVA 26 µg was generally well-tolerated**

- No impact on corneal endothelium was observed at 6 months following a single administration
- Majority of adverse events (AEs) were mild in severity and generally resolved with topical medical treatment. Most ocular AEs within 3 days were deemed related to the injection procedure by the investigators. Post injection AEs observed (>3 days post injection procedure) were consistent with the travoprost label. One implant required removal (classified as a serious adverse event), most likely due to a peri-implantation bacterial infection, per investigator
- Consistent bioresorption of the implant coupled with the durable effect seen in the trial suggests redosing would be possible, without the risk of stacking implants

"I have dedicated my career to taking care of people with glaucoma and the evaluation of new therapies. I am enthusiastic about PAXTRAVA because of the positive, durable IOP reductions, accompanied by a good overall safety profile," **said Mark Gallardo, MD.** Dr. Gallardo is a Study Investigator and Glaucoma Specialist at El Paso Eye Surgeons. He is an active principal investigator of innovative new treatments, having participated in more than 20 clinical trials over the last 7 years.

"We were pleased to observe that PAXTRAVA generally stays in place at the site of implantation and maintains its form, that the majority of implants (64.5%) were significantly or fully bioresorbed at six months and that the implants were not observed to impact the surrounding corneal endothelium. Together, these features could address the compliance challenge of daily eyedrops and enable repeat dosing, without the risk of stacking, critical for the treatment of chronic disease. The totality of these features makes me optimistic about this product candidate."

The complete presentation (Travoprost Intracameral Implant for Open-Angle Glaucoma or Ocular Hypertension: Results from a Phase 2 Clinical Trial) will be available in the Scientific and Medical presentations section of the Company's investor website.

Phase 2 Study Overview: The PAXTRAVA Phase 2 study was designed as a randomized, parallel-group, controlled study to evaluate the safety and efficacy of PAXTRAVA in subjects with open-angle glaucoma ("OAG") or ocular hypertension ("OHT") and reported together as "glaucoma", per above. Following a standard medication wash-out, patients were randomized 1:1:1 into one of three dosing groups (5 µg or 26 µg of PAXTRAVA or DURYSTA® (bimatoprost implant)), dosed in 'the study eye' and followed for frequent assessments through the six month analysis point. Due to elevations in IOP observed in seven out of the 16 subjects enrolled in the PAXTRAVA 5 µg arm of the trial, the Company closed enrollment in this arm and continued with the PAXTRAVA 26 µg and DURYSTA arms of the trial. Safety and efficacy data presented at ASCRS and reported in this press release are based on the 26 µg dosing group, as a result.

The enrolled subjects had a mean age of 65 years and had been previously treated with a mean of about 1.2 IOP-lowering agents prior to study entry. The treatment groups were well balanced for key demographics and baseline characteristics. The primary efficacy endpoints included measurement of changes in intraocular pressure (IOP) at three diurnal measurements (8 AM, 10AM and 4 PM) at weeks 2, 6, 12 and secondary endpoints included measurements at all other visits including 4.5 and 6 months. No formal statistical testing was prespecified in the clinical trial protocol or the statistical analysis plan. Other assessments included an evaluation of the need for additional IOP-lowering therapy, changes in endothelial count and central corneal thickness, as well as an evaluation of safety for the period.

Summary of next steps: Seek an end-of-Phase 2 meeting with the FDA to finalize development plans for PAXTRAVA Phase 3 trials and move to a next generation, commercial injector that eases initiation of therapy.

Strategic Focus on Retinal Disease Highlighted at the April 4th Eyecelerator@ASCRS Conference

On Thursday, April 4th, **Pravin Dugel, MD, Executive Chairman of Ocular Therapeutix** presented at the Eyecelerator@ASCRS conference. "Ocular was very pleased to connect with the Eyecelerator community to share more about our strategic vision for Ocular as we transition to a retina-focused company", said Dr. Dugel. "There are **three important pillars related to our Phase 3 program for AXPAXLI™ for wet Age-related Macular Degeneration (wet AMD) that support our transformation to a leading retina company**: promising clinical data, de-risking regulatory pathway, and an expansive market opportunity. With our expanded strategic and clinical team of recognized experts in place to strengthen the Company's retinal expertise, I believe we are on a solid path to enrich and accelerate the AXPAXLI clinical program."

The complete presentation (Ocular Therapeutix, Evolving into a leading retina company) will be available in the Events and Presentations section of the Company's investor website.

About Ocular Therapeutix, Inc.
Ocular Therapeutix, Inc. is a biopharmaceutical company committed to enhancing people's vision and quality of life through the development and commercialization of innovative therapies for wet age-related macular degeneration (wet AMD), diabetic retinopathy, and other diseases and conditions of the eye. **AXPAXLI™** (axitinib intravitreal implant, also known as OTX-TKI), Ocular's product candidate for retinal disease, is based on its **ELUTYX™** proprietary bioresorbable hydrogel-based formulation technology. AXPAXLI is currently in the first of two planned pivotal Phase 3 trials for wet AMD, the SOL-1 trial, and a Phase 1 clinical trial for the treatment of non-proliferative diabetic retinopathy. The clinical portfolio also includes **PAXTRAVA ™** (travoprost intracameral implant, also known as OTX-TIC), currently in a Phase 2 clinical trial for the treatment of primary open-angle glaucoma or ocular hypertension.

Ocular's expertise in the formulation, development and commercialization of innovative therapies and the ELUTYX platform supported the development and launch of its first commercial drug product, **DEXTENZA®**, an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. ELUTYX is also the foundation for two other clinical-stage assets, **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, as well as several preclinical programs.

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DEXTENZA® is a registered trademark of Ocular Therapeutix, Inc. AXPAXLI™, PAXTRAVA™, and ELUTYX™ and Ocular Therapeutix™ a trademarks of Ocular Therapeutix, Inc.

DURYSTA® is a registered trademark of Allergan, an AbbVie company.

The travoprost label can be referenced using the accessdata.fda.gov site

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 the DEXTENZA website.

Forward-Looking Statements:
Any statements in this press release about future expectations, plans, and prospects for the Company, including the development and regulatory status of the Company's product candidates, including the timing, design, and enrollment of the Company's pivotal trials of AXPAXLI (also called OTX-TKI) for the treatment of wet AMD; the Company's plans to advance the development of AXPAXLI, PAXTRAVA and its other product candidates; the size of potential markets for its product candidates; the potential utility of any of the Company's product candidates; 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 or any product or product candidate that receives regulatory approval; the ability to retain regulatory approval of

DEXTENZA or any product or product candidate that receives regulatory approval; the initiation, design, timing, conduct and outcomes of clinical trials, including the SOL-1 trial, the planned SOL-2 trial and the Company's other ongoing clinical trials; the risk that the FDA will not agree with the Company's interpretation of the written agreement under Special Protocol Assessment for the SOL-1 trial; the risk that even though the FDA has agreed with the overall design of the SOL-1 trial, the FDA may not agree that the data generated by the SOL-1 trial supports potential marketing approval; uncertainty as to whether the data from earlier clinical trials will be predictive of the data of later clinical trials, particularly later clinical trials that have a different design or utilize a different formulation than the earlier trials; availability of data from clinical trials and expectations for regulatory submissions and approvals; the Company's scientific approach and general development progress; uncertainties inherent in estimating the Company's cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials; the Company's existing indebtedness and the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default; the Company's ability to enter into strategic alliances or generate additional funding on a timely basis, on favorable terms, or at all; 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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