Ocular Therapeutix™ To Close Enrollment This Week for SOL-R, its Second Registrational Trial Evaluating AXPAXLI™ in Wet Age-Related Macular Degeneration

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Enrollment for SOL-R, the largest retinal TKI trial to date, supports randomization of at least 555 subjects

SOL-1, Ocular's first registrational trial in wet AMD, completed randomization in December 2024 and retention remains exceptional as the trial continues on track for top-line readout in 1Q 2026

These two complementary trials are intended to form the basis of an NDA submission of AXPAXLI in wet AMD

BEDFORD, Mass., May 28, 2025 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular"), a fully-integrated biopharmaceutical company committed to redefining the retina experience, today announced that enrollment in the SOL-R registrational trial of its product candidate AXPAXLI™ in wet age-related macular degeneration (wet AMD) will close this week.

"Completing enrollment in SOL-R – the largest retinal TKI trial to date – one year after the study was conceptualized reflects an extraordinary pace of execution and underscores our commitment to advancing innovation for patients with wet AMD," said **Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer.** "Together with SOL-1, these two complementary, FDA-aligned registrational trials have the potential to form a robust clinical foundation to support an AXPAXLI label with a distinct superiority claim and unprecedented 6- to 12-month dosing. With recruitment ending, we are focused on disciplined trial execution, and we are encouraged by the remarkable retention and adherence to protocol we've observed to date in both SOL-1 and SOL-R. We're immensely grateful to the patients, investigators, and study sites whose partnership brings us one step closer to introducing a potential new standard of care in retinal disease."

Based on current and projected screening, loading, and randomization failure rates observed in SOL-R to date, Ocular believes it has enrolled enough subjects to ensure the Company's target randomization of at least 555 subjects in SOL-R. Subjects for SOL-R are enrolled across approximately 100 sites in the U.S., Argentina, India, and Australia. SOL-R is Ocular's second registrational study for AXPAXLI in wet AMD. The trial is evaluating the safety and efficacy of AXPAXLI dosed every 6 months versus aflibercept (2 mg) every 8 weeks. Subjects who have been screened and enrolled will now be treated with standard of care anti-VEGF treatment and evaluated during a loading phase with the goal of randomizing at least 555 subjects. The primary endpoint of SOL-R is to demonstrate non-inferiority in mean change in best corrected visual acuity (BCVA) from baseline between the AXPAXLI and on-label aflibercept (2 mg) arms at Week 56. The trial is 90% powered to detect a non-inferiority margin of -4.5 letters of mean BCVA when compared to aflibercept (2 mg) dosed every 8 weeks.

"Wet AMD continues to be a leading cause of blindness in the U.S., underscoring the need for more durable and sustainable treatments that offer improved long-term outcomes," said **Arshad M. Khanani, MD, MA, FASRS, Director of Clinical Research at Sierra Eye Associates in Reno, Nevada**. "The rapid enrollment in the SOL trials highlights the retina community's strong enthusiasm for AXPAXLI and its potential to fulfill this unmet need. The complementary SOL-1 and SOL-R trials are designed to answer key questions about AXPAXLI's durability, flexibility, and repeatability, and build on existing monotherapy data to provide further insights into the drug's activity. If approved, AXPAXLI could significantly reduce the treatment burden for patients with wet AMD and potentially improve long-term vision outcomes."

The FDA has agreed that together, SOL-1 and SOL-R could constitute two adequate and well-controlled trials to support a potential New Drug Application (NDA) and label for AXPAXLI in wet AMD. These complementary trials were designed in alignment with FDA guidance and validated through a Special Protocol Assessment (SPA) agreement for SOL-1, and written responses for SOL-R received in 2024. Pending positive results from SOL-1 and SOL-R, Ocular plans to submit an NDA for FDA review following 56-week data from SOL-R.

"SOL-1 and SOL-R were intentionally designed as complementary trials to provide a comprehensive evaluation of AXPAXLI, while strictly adhering to FDA guidance," said **Peter K. Kaiser, MD, Chief Development Officer** of Ocular Therapeutix. "Consistent with FDA recommendations for adequately masked and controlled trials, neither trial uses sham injections, and this mitigates the potential for bias from inadequate masking. Through thoughtful and innovative patient selection criteria and complementary trial designs, we aimed to de-risk each study population. Given the rigorous enrollment criteria, we're especially pleased with the rapid pace of enrollment across both trials. We are confident that this strategic approach not only positions us strongly for potential regulatory approval but also sets the stage for AXPAXLI to become a differentiated treatment in retinal disease."

About AXPAXLI
AXPAXLI™ (also known as OTX-TKI) is an investigational, bioresorbable, intravitreal hydrogel incorporating axitinib, a small

molecule, multi-target, tyrosine kinase inhibitor (TKI) with anti-angiogenic properties, being evaluated for the treatment of wet AMD, diabetic retinopathy, diabetic macular edema, and other retinal diseases.

About the SOL-R Study
The registrational Phase 3 SOL-R trial (NCT06495918) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (2:2:1), three-arm study that involves approximately 100 sites located in the U.S., Argentina, India, and Australia. The trial is intended to randomize approximately 555 subjects who are treatment-naïve or were newly diagnosed with wet AMD in the study eye within about four months prior to enrollment.

This non-inferiority trial reflects a patient enrichment strategy over the six months prior to randomization that includes three screening doses of any anti-VEGF therapy, excluding brolucizumab-dbll, and monitoring to exclude those subjects with significant retinal fluid fluctuations. Subjects that continue to meet eligibility criteria will enter a run-in period and receive two loading doses of aflibercept (2 mg) prior to Day 1. Subjects in the first arm receive a single dose of AXPAXLI at Day 1 and are re-dosed at Weeks 24, 48, and 72. Subjects in the second arm receive aflibercept (2 mg) on-label every eight weeks. Subjects in the third arm receive a single dose of aflibercept (8 mg) at Day 1 and are re-dosed at Weeks 24, 48, and 72, aligned with the AXPAXLI treatment arm for adequate masking. Subjects will be followed for safety until the end of Year 2. Throughout the study, subjects are assessed monthly. Trial subjects and designated study personnel will remain masked through the end of Year 2. Subjects in any arm that meet pre-specified rescue criteria will receive a supplemental dose of aflibercept (2 mg). The pre-specified rescue criteria include loss of ≥ 10 Early Treatment Diabetic Retinopathy Study (ETDRS) letters of BCVA from baseline or a combination of worsening anatomical measures and BCVA loss.

The primary endpoint of SOL-R is to demonstrate non-inferiority in mean BCVA change from baseline between the AXPAXLI and on-label aflibercept (2 mg) arms at Week 56. As per the protocol agreed to by the FDA, the non-inferiority margin for the lower bound is -4.5 letters of mean BCVA when compared to aflibercept (2 mg) dosed every eight weeks. In a written Type C response received in August 2024, and a subsequent written response received in December 2024, the FDA agreed that the SOL-R repeat dosing wet AMD study, with a primary endpoint at Week 56, should be appropriate as an adequate and well-controlled study in support of a potential New Drug Application and product label for wet AMD.

About the SOL-1 Study
The registrational Phase 3 SOL-1 trial (NCT06223958) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (1:1), parallel group study that involves more than 100 clinical trial sites located in the U.S. and Argentina. In December 2024, the trial completed randomization of 344 evaluable treatment-naïve subjects with a diagnosis of wet AMD in the study eye.

The superiority study has an eight-week loading segment prior to randomization. During the loading segment, subjects who have 20/80 vision or better and who satisfy other enrollment criteria receive two doses of aflibercept (2 mg) at Week -8 and Week -4. Eligible subjects who achieve best corrected visual acuity (BCVA) of 20/20 at Day 1 or gain at least 10 ETDRS letters at Day 1 are then randomized to receive a single dose of AXPAXLI or a single dose of aflibercept (2 mg). At Week 52 and at Week 76, all subjects are re-dosed with their respective initial treatment of AXPAXLI or aflibercept (2 mg). Subjects will be followed for safety until the end of Year 2. Throughout the study, subjects are assessed monthly. Trial subjects and designated study personnel will remain masked through the end of Year 2. The clinical trial protocol requires that, during the study, subjects in either arm meeting pre-specified rescue criteria will receive a supplemental dose of aflibercept (2 mg).

The primary endpoint of SOL-1 is the proportion of subjects who maintain visual acuity, defined as a loss of <15 ETDRS letters of BCVA, at Week 36. Subjects will continue to be evaluated for durability up to Week 52. The study is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

About Wet AMD
Wet age-related macular degeneration (wet AMD) is a leading cause of severe, irreversible vision loss affecting approximately 14.5 million individuals globally and 1.7 million in the United States alone (2024 Market Scope® Retinal Pharmaceuticals Market Report). Wet AMD causes vision loss due to abnormal new blood vessel growth and hyperpermeability and associated retinal vascularity in the macula, which is primarily stimulated by local upregulation of vascular endothelial growth factor (VEGF). Without prompt and continuous treatment to control this exudative activity, patients develop irreversible vision loss. With proper treatment, patients may maintain visual function for a period of time and may temporarily regain lost vision. Challenges with current therapies include pulsatile, repeated intraocular injections, treatment-related adverse events and up to 40% patient discontinuation within one year of initiating treatment with continued disease progression. Taken together, these factors lead to undertreatment and a lack of long-term vision improvement for patients.

About Ocular Therapeutix, Inc.
Ocular Therapeutix, Inc. is a fully-integrated biopharmaceutical company committed to redefining the retina experience. AXPAXLI™ (also known as OTX-TKI), Ocular's investigational product candidate for retinal disease, is an axitinib intravitreal hydrogel based on its ELUTYX™ proprietary bioresorbable hydrogel-based formulation technology. AXPAXLI is currently in Phase 3 clinical trials for wet age-related macular degeneration (wet AMD).

Ocular's pipeline also leverages the ELUTYX technology in its commercial product DEXTENZA®, an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery in adults and pediatric patients and ocular itching associated with allergic conjunctivitis in adults and pediatric patients aged two years or older, and in its investigational product candidate PAXTRAVA™ (also known as OTX-TIC), which is a travoprost intracameral hydrogel that is currently in a Phase 2

clinical trial for the treatment of open-angle glaucoma or ocular hypertension.

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Forward-Looking Statements
Any statements in this press release about future expectations, plans, and prospects for the Company; the development, regulatory status of and regulatory submissions regarding the Company's product candidates; the design of, and the timing of the screening, enrollment and randomization of patients in and the availability of data from the Company's SOL-1 and SOL-R Phase 3 clinical trials of AXPAXLI (also known as OTX-TKI) for the treatment of wet AMD; the Company's plans to advance the development of AXPAXLI; the potential utility or adoption, if approved, of any of the Company's product candidates; and other statements containing the words "anticipate", "believe", "estimate", "expect", "intend", "designed", "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 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 any product or product candidate that receives regulatory approval; the ability to retain regulatory approval of any product or product candidate that receives regulatory approval; the initiation, design, timing, conduct and outcomes of ongoing and planned clinical trials; the risk that fewer enrolled patients than expected will ultimately be randomized into the SOL-R clinical trial; the risk that the FDA will not agree with the Company's interpretation of the written agreement under the Special Protocol Assessment for the SOL-1 trial; the risk that the FDA may not agree that the protocol and statistical analysis plan of SOL-R or that the data generated by the SOL-1 and SOL-R trials support marketing approval, even if the trials are successful; the risk that the Company and the FDA may not agree on the registrational pathway for any of its product candidates; 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, whether preliminary or interim data from a clinical trial (including masked safety or masked rescue data from the Company's SOL-1 trial) will be predictive of final data from such trial, or whether data from a clinical trial assessing a product candidate for one indication will be predictive of results in other indications; availability of data from clinical trials and expectations for regulatory submissions and approvals; the Company's scientific approach and general development progress; 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 may 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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