Ocular Therapeutix™ Achieves Target Randomization of 555 Subjects in SOL-R

November 4, 2025

SOL-R, the second registrational trial of AXPAXLI™ in wet AMD, remains on track for topline data in 1H 2027

Together with SOL-1, these complementary trials are expected to form the basis of a potential NDA submission for AXPAXLI in wet AMD

BEDFORD, Mass., Nov. 04, 2025 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular"), an integrated biopharmaceutical company committed to redefining the retina experience, today announced that its SOL-R registrational trial of AXPAXLI™ (also known as OTX-TKI) in wet age-related macular degeneration (wet AMD) has achieved its randomization target of 555 subjects. Ocular will continue to allow randomization of previously enrolled subjects currently in the loading phase of the trial to maintain its commitment to both patients and investigators, with topline data remaining on track for the first half of 2027.

"Reaching target randomization in SOL-R marks another significant milestone for Ocular and reflects the remarkable speed and execution of our clinical team, along with the overwhelming enthusiasm and engagement from investigators across the world. The exceptional pace and scale of recruitment across our SOL program underscore the strong demand among retina specialists and patients for more durable therapies like AXPAXLI that can potentially deliver better long-term outcomes while reducing the treatment burden," said **Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer** of Ocular Therapeutix. "SOL-1 and SOL-R were intentionally developed to complement each other: SOL-1 is designed to demonstrate AXPAXLI's true durability up to 12 months and enable what could become the first superiority label versus a single dose of anti-VEGF therapy, while SOL-R is designed to provide data supporting the immediate adoption of AXPAXLI into clinical practice with predictable every six-month dosing. Across both trials, we have thoughtfully de-risked our approach to optimize patient selection and ensure rigor in execution. SOL-R is the first trial of its kind to include an extensive six-month screening and loading phase specifically designed to exclude subjects with early persistent fluid or significant retinal fluid fluctuations which can otherwise introduce variability and disrupt non-inferiority trials. This deliberate approach should result in the randomization of a more uniform patient population, thereby de-risking the study and strengthening the reliability of its data. We deeply appreciate the trust and collaboration of the patients, investigators, and study sites who are helping us advance toward what we believe could become a new standard-of-care in retinal disease."

SOL-R is a Phase 3, multi-center, double-masked, randomized (2:2:1) trial evaluating AXPAXLI dosed every 6 months versus aflibercept (2 mg) dosed every 8 weeks in treatment-naïve wet AMD patients. Subjects for SOL-R are enrolled across approximately 100 sites in the U.S., Argentina, India, and Australia. The primary endpoint is to demonstrate non-inferiority in mean change in best corrected visual acuity (BCVA) from baseline at Week 56. SOL-R is 90% powered to detect a non-inferiority margin of -4.5 letters. A singular Week 56 primary endpoint in SOL-R is potentially favorable as subjects will have received their most recent aflibercept or AXPAXLI injection eight weeks prior, at Week 48.

"The complementary SOL-1 and SOL-R trials are thoughtfully designed to jointly address the key questions that matter most to clinicians and patients," said **Mark R. Barakat, MD, Director of Research at Retina Macula Institute of Arizona and Clinical Assistant Professor at the University of Arizona College of Medicine, Phoenix**. "Retina specialists are looking for a therapy that truly delivers long-term durability without compromising outcomes. Patients desire that same durability to reduce the burden of frequent injections. Even with our most advanced options today, vision usually declines over time. If both studies succeed, AXPAXLI will have shown greater durability than aflibercept (2 mg) and sustained benefit at a predictable, low frequency of dosing, providing the confidence we need to treat patients with potentially better outcomes. The rapid pace of enrollment across the SOL program underscores the strong enthusiasm for AXPAXLI's potential to transform long-term management of wet AMD and other retinal diseases."

SOL-1, Ocular's first registrational trial in wet AMD, is a superiority study evaluating a single injection of AXPAXLI versus a single aflibercept (2 mg) injection with topline data expected in the first quarter of 2026. SOL-1 and SOL-R are complementary trials 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 a New Drug Application (NDA) for FDA review following 56-week topline data from SOL-R. The FDA has agreed that, together, SOL-1 and SOL-R could constitute two adequate and well-controlled trials to support a potential NDA and label for AXPAXLI in wet AMD.

Wet AMD remains a leading cause of blindness worldwide, affecting approximately 14.5 million individuals globally and 1.8 million in the United States alone. Despite advances in anti-VEGF therapy, many patients require frequent injections to maintain vision, and up to 40% discontinue treatment within the first year, leading to disease progression and vision loss. AXPAXLI is being developed to address this unmet need with the potential to extend dosing intervals to every 6 to 12 months and potentially provide

superior and sustainable long-term visual outcomes.

About AXPAXLI
AXPAXLI™ (also known as OTX-TKI) is an investigational, bioresorbable, intravitreal hydrogel incorporating axitinib, a small molecule, multi-target, tyrosine kinase inhibitor with anti-angiogenic properties, being evaluated for the treatment of wet AMD, diabetic retinopathy, 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 includes 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 diagnosed with wet AMD in the study eye within about four months prior to enrollment. Further, to qualify for screening, a subject's study eye must have a BCVA ETDRS letter score of ≥34 (~20/200).

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 early persistent fluid or significant retinal fluid fluctuations. Subjects who continue to meet eligibility, defined as a CSFT of ≤350 µm at Week -12 and Week -8 with ≤35 µm CSFT increase from the lowest CSFT at any prior visit, 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 Day 1 and per label every eight weeks thereafter. 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 a >5-letter loss in visual acuity plus a ≥75 µm increase in CSFT.

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 a central subfield thickness (CSFT) of ≤500 µm receive two doses of aflibercept (2 mg) at Week -8 and Week -4. Subjects who achieve best corrected visual acuity (BCVA) of 20/20 at Day 1 or gain at least 10 early treatment diabetic retinopathy study (ETDRS) letters at Day 1 along with a CSFT of ≤350 µm 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 1.8 million in the United States alone. 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 an 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), with a Phase 3 clinical program for non-proliferative diabetic retinopathy

(NPDR) planned to be initiated imminently.

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 OTX-TIC, which is a travoprost intracameral hydrogel that has completed a Phase 2 clinical trial for the treatment of open-angle glaucoma or ocular hypertension. Ocular is currently evaluating next steps for the OTX-TIC program.

Explore the Company's new corporate branding and follow the Company on its website, LinkedIn, or X.

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, the timing, design, enrollment, randomization, conduct and retention of subjects in the Company's clinical trials, including 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 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 initiation, design, timing, conduct and outcomes of ongoing and planned clinical trials, including the SOL-1 trial, the SOL-R trial; the risk that the FDA will not agree with the Company's interpretation of the written agreements under the Special Protocol Assessments for AXPAXLI, including 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 find that the data generated by the trial supports potential marketing approval; the risk that the FDA might not agree to the Company's design, protocol, and statistical analysis plan of the SOL-R trial; 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 or SOL-R 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; uncertainties regarding the potential commercial advantages and/or position of the Company's product candidates; 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; 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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