# Ocular Therapeutix™ Announces First Patient Enrolled in SOL-X Long-Term Extension Trial for AXPAXLI™ in Wet AMD

April 29, 2026

*SOL-X long-term extension trial in wet AMD enrolled the first subject in April 2026 who had successfully completed the two-year SOL-1 trial*

*Subjects who have completed the two-year follow-up in either SOL-1 or SOL-R have an opportunity to enroll in the SOL-X trial for an additional three years*

*SOL-X is designed to build on AXPAXLI's successful SOL-1 Phase 3 trial by exploring the potential to improve long-term visual outcomes with a dramatically reduced treatment burden*

BEDFORD, Mass., April 29, 2026 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular"), an integrated biopharmaceutical company committed to redefining the retina experience, today announced that the first patient has been enrolled in the SOL-X long-term extension trial for AXPAXLI (also known as OTX-TKI) for the treatment of wet age-related macular degeneration (wet AMD).

"The initiation of SOL-X reflects our continued outstanding execution and unwavering commitment to redefining the retina experience. Following the remarkable results from SOL-1, where AXPAXLI demonstrated unmatched durability and sustained disease control, SOL-X is designed to extend that story into the long-term outcomes that matter most to patients and retinal specialists," said **Pravin U. Dugel, MD, Executive Chairman, President and CEO** of Ocular Therapeutix. "We believe continuous VEGF suppression with AXPAXLI has the potential not only to maintain vision, but to fundamentally alter the trajectory of disease by reducing the risk of fibrosis and atrophy associated with pulsatile therapies used to treat wet AMD today. By starting AXPAXLI treatment early and sustaining disease control over multiple years, we have the opportunity to potentially improve long-term outcomes, reduce treatment burden, and significantly expand the number of patients who remain on therapy. SOL-X represents the next critical step in demonstrating that AXPAXLI is not just a durable therapy, but a transformative one."

The SOL-X open-label wet AMD extension trial is intended to evaluate the long-term safety of AXPAXLI and explore its ability to improve long-term outcomes. Subjects who have completed their two-year follow-up in either SOL-1 or SOL-R have an opportunity to enroll in the SOL-X study for an additional three years. SOL-X outcomes may further expand AXPAXLI's potential by highlighting the need to start AXPAXLI treatment early or risk worse long-term visual outcomes due to potential fibrosis and atrophy that may be seen with pulsatile treatments. By reducing the treatment burden and improving long-term outcomes, Ocular believes the data from SOL-X could increase both short-term and long-term patient retention significantly, thereby expanding the market opportunity.

"In clinical practice, we see firsthand the consequences of inconsistent disease control over time, including progressive damage that can ultimately limit long-term visual outcomes. What is particularly compelling about AXPAXLI is the ability to deliver continuous, sustained VEGF suppression – something we have not achieved historically, including with currently approved short-acting therapies," commented **Dilsher S. Dhoot, MD**, **of California Retina Consultants**. "The results from SOL-1 have demonstrated exceptional durability and disease control, and SOL-X provides an important opportunity to evaluate how that translates over multiple years, and its likely implications for the real world. If we can maintain that level of disease control long term, especially when initiated earlier in the disease course, AXPAXLI has the potential to meaningfully improve outcomes for our patients while reducing treatment burden. That combination is exactly what I believe the field has been waiting for."

**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 and diabetic retinal disease.

**About the SOL-X Trial**
The SOL-X trial (NCT07516132) is a multi-center, 36-month open-label extension trial designed to evaluate the long-term safety, efficacy, and disease modifying potential of AXPAXLI in wet AMD for subjects who have successfully completed their two-year safety follow-up visits in either the SOL-1 or SOL-R trials. The first subject enrolled in the study in April 2026.

According to the trial design, all subjects will be given AXPAXLI every 24 weeks, starting at Day 1 (after completion of the Week 104 visit in SOL-1, or Week 96 visit in SOL-R), and again at Weeks 24, 48, 72, 96, and 120. Subjects are assessed at Week 4, Week 12, and then every 12 weeks thereafter. Additional visits can be conducted with supplemental anti-VEGF injection administered based on investigator discretion.

The primary objectives of SOL-X are to evaluate the long-term safety of AXPAXLI; to explore long-term visual outcomes, including visual acuity and the incidence and/or progression of fibrosis and macular atrophy; and to evaluate the impact of delayed initiation of AXPAXLI in patients who initially were randomized to receive aflibercept in either SOL-1 or SOL-R.

**About Wet AMD**
Wet age-related macular degeneration (wet AMD) is a leading cause of severe, irreversible vision loss affecting approximately 14.8 million individuals globally and 1.7 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) and diabetic retinal disease, including non-proliferative diabetic retinopathy (NPDR).

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.

Follow the Company on its website, LinkedIn, or X.



**Forward-Looking Statements**
This press release contains forward-looking statements of the Company regarding its future expectations, plans, and prospects; statements regarding the development status of the Company's product candidate AXPAXLI (also known as OTX-TKI); statements regarding AXPAXLI's potential to improve long-term visual or other outcomes for patients; statements regarding the commercial potential, potential utility and/or adoption of AXPAXLI, if approved; and other statements containing the words "anticipate", "believe", "estimate", "expect", "intend", "designed", "goal", "may", "might", "plan", "position", "predict", "project", "target", "potential", "will", "would", "could", "should", "continue", and similar expressions, all of which 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, uncertainties regarding the initiation, design, timing, conduct and outcomes of the Company's ongoing clinical trials; the risk that the Company and the FDA may not agree on the registrational pathway for AXPAXLI; the risk that the Company may not be able to obtain FDA approval for AXPAXLI; risks related to the availability of data from clinical trials and expectations for regulatory submissions and approvals; uncertainty as to what restrictions, if any, may be imposed on the label for AXPAXLI, if approved, pending the receipt of additional clinical data or otherwise; 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 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; uncertainty as to the Company's ability to retain regulatory approval of any product or product candidate that receives regulatory approval; uncertainty as to whether data from the Company's SOL-X trial will demonstrate additional clinically meaningful, long-term benefits; uncertainties regarding the potential commercial advantages and/or position of the Company's product candidates; the timing and costs involved in commercializing any product or product candidate that receives regulatory approval; risks inherent to 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; 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.

**Investors & Media**
Ocular Therapeutix, Inc.
Bill Slattery
Vice President, Investor Relations
bslattery@ocutx.com