Ocular Therapeutix™ Announces Additional Positive Week 52 Data from Landmark SOL-1 Phase 3 Trial of AXPAXLI™ in Wet AMD

April 13, 2026

New SOL-1 post-hoc analyses presented at VBS reinforce AXPAXLI's unmatched durability in wet AMD with sustained disease control

AXPAXLI demonstrated robust CSFT control with a median time of 39 weeks and 46 weeks to ≥30 and ≥75 uM increases from Week 8

In all AXPAXLI subjects who had a vitreous floater AE, drug particles are no longer visible (mean time of 20 weeks)

Subjects treated with AXPAXLI generally maintained loading phase visual acuity gains up to Week 52 across quartile subgroups based on BCVA at screening

Company remains on track to submit NDA based on SOL-1 alone, subject to planned formal discussions with the U.S. FDA, consistent with recent FDA public commentary

BEDFORD, Ma., April 13, 2026 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular"), an integrated biopharmaceutical company committed to redefining the retina experience, today announced additional positive Week 52 data from the SOL-1 Phase 3 superiority trial of AXPAXLI (also known as OTX-TKI), its investigational product candidate for the treatment of wet age-related macular degeneration (wet AMD). The additional post-hoc analyses, presented at the 14th Annual Vit-Buckle Society (VBS) Meeting, reinforce the superior durability, strong sustained disease control, and generally well-tolerated safety seen with AXPAXLI in SOL-1.

"The new analyses of the SOL-1 Phase 3 data further strengthen our conviction in AXPAXLI's potential to redefine retina treatment. A clear drug profile has emerged for AXPAXLI: a product candidate with durability that is unmatched in the wet AMD space while demonstrating excellent sustained disease control," said **Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer of Ocular Therapeutix**. "Several analyses presented at VBS reinforce this profile. As retina specialists, anatomic control measured with OCT guides our treatment decisions. The time-to-CSFT increase analyses provide powerful additional evidence of AXPAXLI's efficacy. After Week 8, it takes a median of 39 weeks to reach a clinically meaningful increase of ≥30 uM in CSFT, and even longer to reach ≥75 uM. This is simply an unprecedented level of sustained disease control and allows us to re-imagine the management of wet AMD for patients. These data continue to increase our confidence that AXPAXLI may be adopted broadly and immediately, if approved. Most importantly, we remain on track to submit our NDA based on SOL-1 alone, subject to planned formal U.S. FDA discussions. The FDA Commissioner recently noted that the Agency expects this new default framework for approval based on a single pivotal trial to be phased in over the next six months or so, aligning with our goal of bringing AXPAXLI to patients as soon as possible."

Highlights from the data presented at VBS include:

- **Strong overall efficacy profile with unmatched durability:** Achieved statistical significance in the first three of five key secondary endpoints tested in hierarchical order. In addition, six other pre-specified secondary endpoints measuring clinically significant functional and anatomic outcomes were met with statistical significance.

- **Sustained disease control (post-hoc analysis):** Subjects in the AXPAXLI arm had significantly lower risk in anatomic worsening from Week 8 compared to the aflibercept (2 mg) arm. Week 8 was chosen to give both arms adequate time from the last aflibercept (2 mg) injection and start at a similar reference timepoint.

    - The median time to ≥30 uM Central Subfield Thickness (CSFT) increase from Week 8 was 39 weeks in the AXPAXLI group and 16 weeks in the aflibercept (2 mg) group, a 23-week difference. An estimated hazard ratio of 0.7 indicates that, at any time from Week 8 to Week 52, subjects in the treatment group experienced a 30% lower risk of the event (descriptive p=0.0028) compared with the control group.

    - The median time to ≥75 uM CSFT increase from Week 8 was 46 weeks in the AXPAXLI group and 24 weeks in the aflibercept (2 mg) group, a 22-week difference. An estimated hazard ratio of 0.5 indicates that, at any time from Week 8 to Week 52, subjects in the treatment group experienced a 50% lower risk of the event (descriptive p<0.0001) compared with the control group.

- **Sustained visual outcomes (post-hoc analysis):** Visual acuity gains achieved during the loading phase were generally maintained up to Week 52 with AXPAXLI across screening BCVA quartile subgroups. The magnitude of vision improvements was influenced by BCVA at screening. For example, AXPAXLI subjects in the lowest vision quartile group at screening had the greatest visual gains with +11.8 ETDRS letters compared to +8.5 letters in the aflibercept (2 mg) arm at Week 52. The mean vision at screening in this arm is similar to baseline BCVA in prior wet AMD studies. In comparison, subjects in the best vision quartile at screening had essentially no change in vision at Week 52 (-0.5 vs +1.1 letters; AXPAXLI vs aflibercept) as they started with almost 20/20 vision.

- **Sustained visual outcomes in rescue-free subjects (post-hoc analysis):** Observed difference for change in BCVA from baseline at Week 24 in the rescue-free subjects was -1.9 ETDRS letters in the AXPAXLI arm (+7.5 letters from screening) vs -2.6 letters in the aflibercept arm (+6.0 letters from screening). Of note, 81% of the AXPAXLI subjects were rescue-free at Week 24. At Week 36, 75% of AXPAXLI subjects remained rescue-free and lost <1 additional letter from Week 24 (+6.6 letters from screening).

- **Well-tolerated profile:** For all AXPAXLI subjects with a vitreous floater adverse event reported, drug particles are no longer visible (mean time of 20 weeks). Further analysis continues to illustrate the appearance of floaters corresponds closely to expected hydrogel bioresorption and drug elution without adversely affecting vision.

Andrew A. Moshfeghi, MD, MBA, FASRS, USC Roski Eye Institute commented**,** “What matters most to patients is preserving their vision - not just measuring change - and subjects treated with AXPAXLI in SOL-1 maintained excellent visual acuity throughout the study. The durability we are seeing is exceptional, with 75% of AXPAXLI subjects remaining rescue-free at 9 months and 66% at 12 months. The quartile analysis presented at VBS, demonstrating that BCVA improvements achieved during the pre-randomization loading phase were generally maintained by AXPAXLI across quartiles stratified by screening BCVA, is particularly striking. In the real world, we often find patients with excellent baseline visual acuity lose vision despite regular treatment. In contrast, the SOL-1 results illustrate AXPAXLI’s potential to generally maintain the benefits seen with loading doses across the four quartiles. Further, the SOL-1 data suggests the drug delivery and hydrogel bioresorption are behaving exactly as expected, providing the sustained disease control we had hoped for. Importantly, the observed safety profile has been reassuring, with no significant adverse events, such as endophthalmitis or vasculitis, and floaters resolving without impacting the patients’ vision. If approved, these results support meaningful clinical adoption of AXPAXLI.”

Ocular Therapeutix remains on track to submit its New Drug Application (NDA) for AXPAXLI in wet AMD based on the SOL-1 trial alone, subject to planned formal discussions with U.S. FDA. This planned submission is consistent with recent FDA commentary, including a February 2026 New England Journal of Medicine editorial indicating that a single well-controlled Phase 3 trial is expected to become the new default standard for approval. In early-April, 2026, the FDA Commissioner further noted that this framework is anticipated to be phased in over the next six months, highlighting that the same statistical power can be achieved with a well-designed, well controlled, appropriately powered, single pivotal trial. These recent comments further reinforce the Company’s confidence in NDA acceptability based on SOL-1 alone, aligning with its goal of bringing AXPAXLI to patients as quickly as possible.

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-1 Trial
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 trial that involves more than 100 clinical trial sites located in the U.S. and Argentina. In December 2024, the trial completed randomization of 344 treatment-naïve subjects with a diagnosis of wet AMD in the study eye. Two randomized subjects withdrew from the trial prior to receiving Day 1 treatment.

The superiority trial 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 (baseline) or gain at least 10 Early Treatment Diabetic Retinopathy Study (ETDRS) letters at Day 1 along with a CSFT of ≤350 µm were then randomized to receive a single dose of AXPAXLI (0.45 mg) 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 (0.45 mg) or aflibercept (2 mg). Subjects will be followed for safety until the end of Week 104.

Throughout the trial, subjects are assessed monthly. Trial subjects and designated trial personnel will remain masked through the end of Week 104. The clinical trial protocol requires that, during the trial, subjects in either arm meeting the pre-specified rescue criteria, which includes a BCVA loss of ≥15 ETDRS letters from baseline or new vision-threatening macular hemorrhage, will receive a supplemental dose of aflibercept (2 mg). The protocol provides that after the first rescue injection, rescue therapy may be provided at investigator discretion per their clinical judgement.

The primary endpoint of SOL-1 is the proportion of subjects who maintain visual acuity, a loss of <15 ETDRS letters of BCVA from baseline, at Week 36. Predefined statistical rules were applied to adjust for treatment discontinuation or deviation as per the

pre-specified statistical analysis plan. The trial remained masked following Week 36 and subjects were evaluated for treatment durability at Week 52. The trial is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

In February 2026, Ocular reported positive SOL-1 Week 52 topline data. The superiority primary endpoint was met with 74.1% of subjects in the AXPAXLI (0.45 mg) arm maintaining vision at Week 36, a 17.5% risk difference (p=0.0006), compared to aflibercept (2 mg) arm. 65.9% of subjects treated with AXPAXLI (0.45 mg) maintained vision at Week 52, a 21.1% risk difference (p<0.0001), compared to aflibercept (2 mg) arm.

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.

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Forward-Looking Statements
Any statements in this press release about future expectations, plans, and prospects for the Company, including statements regarding the development and regulatory status of the Company's product candidates, including the Company's intention to submit a New Drug Application (NDA) for AXPAXLI based on data from the Company's SOL-1 trial, subject to planned formal discussions with the FDA, 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; statements regarding the potential utility or adoption, if approved, of any of the Company's product candidates, including AXPAXLI; and other statements containing the words "anticipate", "become", "believe", "estimate", "expect", "intend", "designed", "goal", "may", "might", "plan", "position", "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 design, timing, conduct and outcomes of ongoing and planned clinical trials, including the SOL-R trial and the second year of the SOL-1 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; uncertainty as to whether the FDA will accept a NDA for AXPAXLI on the basis of a single pivotal clinical trial, namely SOL-1; uncertainty as to the minimum clinical data required to demonstrate the safety of a proposed product candidate such as AXPAXLI, even if the FDA recognizes that only one pivotal clinical trial may be required to demonstrate efficacy; 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 and submitted by the Company are sufficient to demonstrate the safety and efficacy of AXPAXLI to the degree necessary to support marketing approval for wet AMD; uncertainty as to whether the Company will be able to timely satisfy the FDA's other requirements for regulatory approval of AXPAXLI, including the FDA's Chemistry, Manufacturing and Control's requirements, even if the Company can satisfy the FDA's clinical requirements to demonstrate safety and efficacy; 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; 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, including AXPAXLI; 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; uncertainty as to whether preliminary or interim data from a clinical trial will be predictive of final data from such trial; 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 annual or quarterly 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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