Ocular Therapeutix™ Announces Positive Pre-NDA Meeting with U.S. FDA for AXPAXLI™ in Wet AMD

September 15, 2026

Consistent with prior Type C Meeting, the Pre-NDA Meeting confirms Ocular's plan to submit AXPAXLI NDA based on SOL-1 Week 52 efficacy and safety, interim SOL-R safety, and confirmatory evidence

AXPAXLI NDA submission for wet AMD remains on track for 4Q 2026

NDA submission to include subjects that have received multiple AXPAXLI injections in support of the Company's application for repeat dosing

Commercial readiness accelerates ahead of potential 2027 launch as AXPAXLI is well positioned to potentially be the first TKI approved for wet AMD

BEDFORD, Mass., Sept. 15, 2026 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular"), an integrated biopharmaceutical company committed to redefining the retina experience, today announced the successful completion of its Pre-New Drug Application (NDA) Meeting with the U.S. Food and Drug Administration (FDA) for its investigational product candidate AXPAXLI™ (also known as OTX-TKI) for the treatment of wet age-related macular degeneration (wet AMD). Based on the Pre-NDA Meeting, the Company's expectations for the AXPAXLI NDA package remain consistent with prior FDA communications, including the May 2026 Type C Meeting. Ocular remains on track to submit the NDA in the fourth quarter of 2026.

"Following our successful Pre-NDA Meeting with the FDA, we are on track for our planned AXPAXLI NDA submission in the fourth quarter of 2026. We are immensely grateful to the FDA for their collaboration throughout this process and will continue to follow their guidance as we advance AXPAXLI through NDA submission, review, and potential approval," said **Pravin U. Dugel, M.D., Executive Chairman, President and CEO of Ocular Therapeutix**. "Consistent with the FDA Type C Meeting minutes we previously communicated, our NDA submission will continue to be based on efficacy and safety data from SOL-1, interim safety data from SOL-R, and supporting confirmatory evidence. Our submission will include subjects that have received multiple AXPAXLI injections in support of our application for repeat dosing. From the outset, we have sought to thoughtfully balance risk and speed through methodical clinical trial design and consistent interactions with the FDA, always placing patients and physicians at the forefront of our decisions. That approach has served us well and has brought us to a position where AXPAXLI has the potential to be not only the first TKI to market for wet AMD, if approved, but also the only novel product candidate supported by a positive Phase 3 superiority trial against an approved anti-VEGF. We believe physicians will have all the data they need from SOL-1 to begin using AXPAXLI immediately following potential approval, due to the unmatched durability and level of sustained disease control observed in SOL-1 that is simply unprecedented in this space. Our commercial preparation efforts are well underway, and we look forward to bringing AXPAXLI to the wet AMD community as quickly as possible."

The positive Pre-NDA Meeting represents the latest in a series of successful clinical and regulatory milestones for AXPAXLI. The registrational Phase 3 SOL-1 superiority trial was designed and conducted under a Special Protocol Assessment (SPA) agreement with the FDA and, in February 2026, met its pre-specified primary endpoint with high statistical significance. In May 2026, the Company completed a positive Type C Meeting with the FDA, with subsequent meeting minutes supporting an NDA based on Week 52 efficacy and safety data from SOL-1, interim safety data from the ongoing Phase 3 SOL-R trial, and supporting confirmatory evidence. The September 2026 Pre-NDA Meeting further confirmed alignment with the FDA on the content and format of the planned NDA submission under the 505(b)(2) pathway, which has the potential to shorten the FDA review timeline by up to 60 days as compared to the traditional 505(b)(1) pathway for a new molecular entity. Ocular remains on track to conduct the interim SOL-R safety analysis and submit the AXPAXLI NDA in the fourth quarter of 2026.

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 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 1.8 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), 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 and regulatory status of the Company's investigational product candidate AXPAXLI (also known as OTX-TKI), including the Company's intention to submit a new drug application for AXPAXLI for the treatment of wet AMD based on Week 52 efficacy and safety data from the Company's SOL-1 Phase 3 clinical trial, Week 52 data from an interim safety analysis to be conducted in the Company's SOL-R clinical trial, and confirmatory evidence; statements regarding the timing, design, enrollment, randomization, conduct and retention of subjects in the Company's ongoing and planned clinical trials for AXPAXLI; statements regarding the commercial potential of AXPAXLI and the potential commercialization of AXPAXLI; statements regarding the Company's plans to leverage the Section 505(b)(2) pathway and its potential to accelerate the review timeline of the Company's planned NDA submission; 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", "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, including the Company's SOL-1 trial, SOL-R trial, HELIOS-3 trial, and SOL-X trial; the timing and costs involved in commercializing any product or product candidate that receives regulatory approval; the risk that the U.S. Food and Drug Administration, or 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, of the minutes of the Company's Type C meeting with the FDA or of the outcome of the Company's Pre-New Drug Application meeting with the FDA; uncertainty as to whether the FDA will accept a new drug application for AXPAXLI on the basis of a single pivotal clinical trial, notwithstanding discussions the Company has had with the FDA regarding its planned NDA submission; 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 and accepts the Company's NDA submission; 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; the risk that the FDA might not agree to the Company's design, protocol, and statistical analysis plan of any of its clinical trials for which the Company has not obtained a Special Protocol Assessment, including the SOL-R trial; the risk that the Company and the FDA may not agree on, or maintain agreement with respect to, the registrational pathway for any of its product candidates, including AXPAXLI; 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 whether the Company's NDA will qualify for, or whether the FDA will agree to review the NDA, if accepted for filing, under the 505(b)(2) pathway, notwithstanding discussions the Company has had with the FDA regarding its planned regulatory pathway, and whether the 505(b)(2) pathway will provide any time-savings as compared to the traditional 505(b)(1) pathway; 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 or post-hoc analyses of clinical data 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; uncertainty regarding the implementation and impact of most-favored-nation and other reference pricing regimes on the commercial potential of AXPAXLI, especially in markets outside the United States; 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; 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