February 25, 2026

Opus Genetics Announces FDA Acceptance of Supplemental New Drug Application for Phentolamine Ophthalmic Solution 0.75% for the Treatment of Presbyopia

FDA PDUFA Goal Date Set for October 17, 2026

RESEARCH TRIANGLE PARK, N.C., Feb. 25, 2026 (GLOBE NEWSWIRE) -- Opus Genetics, Inc. (Nasdaq: IRD) ("Opus Genetics" or the "Company"), a clinical-stage biopharmaceutical company developing gene therapies to restore vision and prevent blindness in patients with inherited retinal diseases (IRDs), today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the supplemental New Drug Application (sNDA) for phentolamine ophthalmic solution 0.75% for the treatment of presbyopia. The FDA has assigned a PDUFA goal date of October 17, 2026.

Presbyopia is an age-related condition that affects the ability to focus on near objects and impacts millions of adults worldwide, often requiring reading glasses or other visual aids. If approved, phentolamine ophthalmic solution 0.75% has the potential to offer a pharmacologic treatment option for patients seeking improved visual acuity without reliance on corrective lenses. The condition affects approximately 90% of adults in the U.S. over the age of 45.

"The FDA's acceptance of our sNDA marks an important milestone in expanding the potential use of phentolamine ophthalmic solution as a differentiated approach to managing presbyopia," said George Magrath, M.D., Chief Executive Officer, Opus Genetics. "Phentolamine is targeted to improve near vision while preserving distance vision, with a sustained effect on pupil diameter of up to 20 hours. Our team continues to make tremendous progress in advancing our mission to bring meaningful new ophthalmic treatment options to patients."

Phentolamine ophthalmic solution 0.75% is a preservative-free, topical ophthalmic formulation designed to modulate pupil dynamics and improve visual acuity through a sympatholytic mechanism of action that avoids engaging the ciliary muscle.

The sNDA is supported by data from a pivotal Phase 3 clinical program, including two trials, VEGA-2 and VEGA-3. Both trials demonstrated positive efficacy results for this investigational non-invasive treatment option for presbyopia, meeting the primary and all key secondary endpoints, with no treatment-related serious adverse events. The Company

intends to have data from VEGA-3 presented at the American Society of Cataract and Refractive Surgery (ASCRS) meeting in April 2026 in Washington, D.C. and the Association for Research in Vision and Ophthalmology (ARVO) meeting in May 2026 in Denver, Colorado. Phentolamine ophthalmic solution 0.75% is also being investigated across additional ophthalmic indications.

Ryzumvi ® (phentolamine ophthalmic solution 0.75%) is currently approved in the U.S. for the treatment of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents, and is the only commercially available FDA-approved product for this use. The sNDA seeks to expand the indication to include presbyopia.

Opus Genetics and Viatris, Inc. (Viatris) (through its affiliate) are parties to a global licensing agreement which provides for the development of phentolamine ophthalmic solution 0.75% and grants exclusive rights to Viatris to commercialize phentolamine ophthalmic solution 0.75% in the U.S.

RYZUMVI® IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Uveitis: RYZUMVI is not recommended to be used in patients with active ocular inflammation (e.g., iritis).

Potential for Eye Injury or Contamination: To avoid the potential for eye injury or contamination, care should be taken to avoid touching the vial tip to the eye or to any other surface.

Use with Contact Lenses: Contact lens wearers should be advised to remove their lenses prior to the instillation of RYZUMVI and wait 10 minutes after dosing before reinserting their contact lenses.

Adverse Reactions

The most common adverse reactions that have been reported are instillation site discomfort (16%), conjunctival hyperemia (12%), and dysgeusia (6%).

Please see Full **Prescribing Information**.

About Phentolamine Ophthalmic Solution 0.75%

Phentolamine ophthalmic solution 0.75% is a non-selective alpha-1 and alpha-2 adrenergic antagonist to reduce pupil size, administered as an eye drop. It works by blocking alpha-1 adrenergic receptors on the iris dilator muscle. Phentolamine ophthalmic solution 0.75% is designed to reduce pupil diameter through a sympatholytic mechanism of action that avoids engaging the ciliary muscle, potentially reducing risks such as retinal tears or detachment associated with parasympathomimetic agents. Phentolamine ophthalmic solution 0.75% is currently approved in the U.S. for the treatment of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents; and has successfully completed a Phase 3 program for presbyopia (VEGA clinical program), and is being evaluated in a Phase 3 program for the treatment of

dim (mesopic) light vision disturbances (sometimes referred to as DLD) after keratorefractive surgery (LYNX clinical program).

About Opus Genetics

Opus Genetics is a clinical-stage biopharmaceutical company developing gene therapies to restore vision and prevent blindness in patients with inherited retinal diseases (IRDs). The Company is developing durable, one-time treatments designed to address the underlying genetic causes of severe retinal disorders. The Company's pipeline includes seven AAV-based programs, led by OPGx-LCA5 for LCA5-related mutations and OPGx-BEST1 for BEST1-related retinal degeneration, with additional candidates targeting RHO, CNGB1, RDH12, NMNAT1, and MERTK. Opus Genetics is also advancing Phentolamine ophthalmic solution 0.75%, an approved small-molecule therapy for pharmacologically induced mydriasis, with additional potential indications in presbyopia and low-light visual disturbances following keratorefractive surgery. The Company is based in Research Triangle Park, NC. For more information, visit www.opusgtx.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements related to the clinical development, clinical results, preclinical data, and future plans for Phentolamine ophthalmic solution 0.75% and expectations regarding us, our business prospects, and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading "Risk Factors" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, our subsequent Quarterly Reports on Form 10-Q, and in our other filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. These forward-looking statements are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "aim," "may," "ongoing," "plan," "potential," "predict," "project," "should," "strive," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise.

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