



FDA Accepts Viatriis Supplemental New Drug Application for MR-141 (Phentolamine Ophthalmic Solution 0.75%) for the Treatment of Presbyopia

February 25, 2026

FDA PDUFA Goal Date Set for October 17, 2026

PITTSBURGH, Feb. 25, 2026 /PRNewswire/ -- [Viatriis Inc.](#) (Nasdaq: VTRS), a global healthcare company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the supplemental New Drug Application (sNDA) for MR-141 (phentolamine ophthalmic solution 0.75%) for the treatment of presbyopia. The FDA has assigned a PDUFA goal date of October 17, 2026. Presbyopia is the age-related progressive loss of the ability to focus on close objects that results in blurred near vision and eye strain. The condition affects approximately 90% of adults in the U.S. over the age of 45.

"FDA's acceptance of this supplemental New Drug Application for phentolamine ophthalmic solution 0.75% for presbyopia is evidence of the continued execution of our innovative pipeline," said [Philippe Martin](#), Viatriis Chief R&D Officer. "We are confident in the strength of the clinical data supporting our submission. Phentolamine offers a physiological approach that relaxes the iris dilator muscle to improve near vision without engaging the ciliary muscle, which helps preserve distance vision. We look forward to working with the FDA during the review as we pursue a new treatment option for the millions of patients who face blurred near vision."

The sNDA is supported by data from the pivotal Phase 3 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. Data from VEGA-3 will be presented at the American Society of Cataract and Refractive Surgery (ASCRS) meeting in April in Washington, D.C. and the Association for Research in Vision and Ophthalmology (ARVO) meeting in May in Denver, Colorado.

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 Viatriis (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 Viatriis to commercialize phentolamine ophthalmic solution 0.75% in the U.S.

About Presbyopia

Presbyopia is the gradual loss of near focusing ability due to aging, that typically becomes noticeable in the early to mid-40s. It is a nearly universal condition that, when uncorrected, contributes significantly to vision-related disability. Presbyopia leads to symptoms like eye strain and blurred near vision, impacting daily tasks and productivity. It affects nearly 128 million people in the United States—about 90% of adults over the age of 45. By age 50, most Americans require some form of near-vision correction, such as reading glasses or multifocal lenses. Globally, an estimated 1.8 billion people were presbyopic in 2015, projected to rise to 2.1 billion by 2030.

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 Viatriis

[Viatriis Inc.](#) (Nasdaq: VTRS) is a global healthcare company uniquely positioned to bridge the traditional divide between generics and brands, combining the best of both to more holistically address healthcare needs globally. With a mission to empower people worldwide to live healthier at every stage of life, we provide access at scale, currently supplying high-quality medicines to approximately 1 billion patients around the world annually and touching all of life's moments, from birth to the end of life, acute conditions to chronic diseases. With our exceptionally extensive and diverse portfolio of medicines, a one-of-a-kind global supply chain designed to reach more people when and where they need them, and the scientific expertise to address some of the world's most enduring health challenges, access takes on deep meaning at Viatriis. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at [viatriis.com](#) and [investor.viatriis.com](#), and connect with us on [LinkedIn](#), [Instagram](#), [YouTube](#) and [X](#).

Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include statements that the FDA has accepted for review the supplemental New Drug Application (sNDA) for MR-141 (phentolamine ophthalmic solution 0.75%) for the treatment of presbyopia; the FDA has assigned a PDUFA goal date of October 17, 2026; FDA's acceptance of this sNDA for phentolamine ophthalmic solution 0.75% for presbyopia is evidence of the continued execution of our innovative pipeline; we are confident in the strength of the clinical data supporting our submission; we look forward to working with the FDA during the review as we pursue a new treatment option for the millions of patients who face blurred near vision; 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; data from VEGA-3 will be presented at the American Society of Cataract and Refractive Surgery (ASCRS) meeting in April in Washington, D.C. and the Association for Research in Vision and Ophthalmology (ARVO) meeting in May in Denver, Colorado; 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. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: the uncertainties inherent in research and development, including the outcomes of clinical trials; the ability to meet anticipated clinical endpoints; the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from clinical studies; actions and decisions of healthcare and pharmaceutical regulators; our ability to comply with applicable laws and regulations; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; any regulatory, legal or other impediments to Viatri's ability to bring new products to market; products in development and/or that receive regulatory approval may not achieve expected levels of market acceptance, efficacy or safety; longer review, response and approval times as a result of evolving regulatory priorities and reductions in personnel at health agencies; Viatri's or its partners' ability to develop, manufacture, and commercialize products; the scope, timing and outcome of any ongoing legal proceedings, and the impact of any such proceedings on Viatri's; Viatri's failure to achieve expected or targeted future financial and operating performance and results; goodwill or impairment charges or other losses; any changes in or difficulties with the Company's manufacturing facilities; risks associated with international operations; changes in third-party relationships; the effect of any changes in Viatri's or its partners' customer and supplier relationships and customer purchasing patterns; the impacts of competition; changes in the economic and financial conditions of Viatri's or its partners; uncertainties regarding future demand, pricing and reimbursement for the Company's products; uncertainties and matters beyond the control of management, including but not limited to general political and economic conditions, potential adverse impacts from future tariffs and trade restrictions, inflation rates and global exchange rates; and the other risks described in Viatri's filings with the Securities and Exchange Commission ("SEC"). Viatri's routinely uses its website as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Viatri's undertakes no obligation to update these statements for revisions or changes after the date of this press release other than as required by law.



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