Viatris Announces Positive Top-Line Results from Second Pivotal Phase 3 VEGA-3 Trial of MR-141 in Presbyopia

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MR-141 Met Primary And All Secondary Endpoints, Demonstrating Rapid And Sustained Improvement In Near Visual Acuity Without Compromising Distance Vision

Safety Profile Consistent With Previous Clinical Trials And No Treatment-Related Serious Adverse Events Reported In This Study

Targeting Application To U.S. FDA In Second Half of 2025

PITTSBURGH, June 26, 2025 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced positive top-line results from VEGA-3, the second pivotal Phase 3 trial evaluating MR-141 (phentolamine ophthalmic solution 0.75%) in treating presbyopia. Presbyopia is the progressive loss of the ability to focus on close objects that results in blurred near vision and eye strain, particularly in dim lighting conditions.

The VEGA-3 Phase 3 trial is a randomized, placebo-controlled, double-blind study, with a total of 545 patients who were randomized 3:2 to receive either MR-141 or placebo, once daily in the evening. In summary:

- Significantly more patients treated in the MR-141 arm achieved the primary endpoint of Early Treatment Diabetic Retinopathy Study (ETDRS) (≥3-line) gain in binocular distance-corrected near visual acuity (DCNVA) and with less than 5 letters of loss in binocular best-corrected distance visual acuity (BCDVA) from baseline at 12 hours post-dose on Day 8, compared to placebo ($p<0.0001$).
- Significantly more patients treated in the MR-141 arm achieved ≥15-letters ETDRS (≥3-line) gain in DCNVA and with less than 5 letters of loss in BCDVA at 1-hour post-dose on Day 1 compared to those receiving placebo ($p=0.0002$).
- Significant patient-reported functional benefit at Days 3, 8, and Week 6 were observed with patients reporting satisfaction with near vision upon awakening ($p<0.0001$) and satisfaction with their improvement in near vision ($p<0.0001$).
- Patient reported significant improvement in near vision in dim/low light at Days 3, 8 and Week 6 compared with placebo ($p<0.0001$).
- No evidence of tachyphylaxis was observed during 6-week follow up.
- MR-141 demonstrated a safety profile consistent with previous trials, with no new safety signal identified and no treatment-related serious adverse events reported in this study. The most common (≥5%) treatment-emergent adverse events included conjunctival hyperemia, instillation site irritation, and dysgeusia and were predominantly mild. Low rate of headache (2.6%) was reported over the study period.

Viatris Chief R&D Officer Philippe Martin said, "Presbyopia is a very common condition affecting approximately 90 percent of adults in the U.S. over the age of 45, who often experience blurred near vision and eye strain. We are pleased with the positive results from the second pivotal Phase 3 trial, which reinforce our confidence in MR-141 and its benefit-risk profile as a potential, non-invasive option to support the millions of patients impacted by this condition."

VEGA-3 patients will continue to be monitored for long-term safety over 48 weeks. For more information on the VEGA-3 study design, refer to ClinicalTrials.gov (NCT06542497).

Opus Genetics and 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.

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. The condition is associated with reduced quality of life, functional independence, and work efficiency. It affects nearly 128 million people in the United States—about 90% of adults over 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. With global productivity losses estimated at $11–25 billion due to uncorrected cases, there is significant economic consequences from

lost productivity and increased healthcare utilization. Timely access to affordable near-vision correction is essential to reducing its impact.

About Viatris

Viatris 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 Viatris. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at viatris.com and investor.viatris.com, and connect with us on LinkedIn, Instagram, YouTube and X (formerly Twitter).

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 about the outcome of clinical trials; that MR-141 met primary and all secondary endpoints, demonstrating rapid and sustained improvement in near visual acuity without compromising distance vision; safety profile consistent with previous clinical trials and no treatment-related serious adverse events reported in this study; targeting application to U.S. FDA in second half of 2025; and we are pleased with the positive results from the second pivotal Phase 3 trial, which reinforce our confidence in MR-141 and its benefit-risk profile as a potential, non-invasive option to support the millions of patients impacted by this condition . 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 Viatris' 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; Viatris' 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 Viatris; Viatris' 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 Viatris' or its partners' customer and supplier relationships and customer purchasing patterns; the impacts of competition; changes in the economic and financial conditions of Viatris 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 Viatris' filings with the Securities and Exchange Commission ("SEC"). Viatris 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). Viatris 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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