Viatris Announces Positive Top-Line Results from Phase 3 LYNX-2 Trial of MR-142 in Keratorefractive Patients With Visual Disturbances Under Mesopic, Low-Contrast Conditions

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MR-142 Achieved Primary Endpoint of ≥15-letter (≥3-line) Gain in Mesopic Low Contrast Distance Visual Acuity in Comparison to Placebo

Results Showed Patient-Reported Functional Benefit in Treating Significant Chronic Night Driving Impairment in Keratorefractive Patients With Reduced Mesopic Vision, a Condition With No Current FDA-Approved Therapies

No Evidence of Tachyphylaxis Was Observed In This Study Over The 6-Week Period

Study Was Conducted Under FDA Special Protocol Assessment And Fast-Track Designation

PITTSBURGH, June 2, 2025 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced positive top-line results from LYNX-2, a pivotal Phase 3 trial evaluating MR-142 (phentolamine ophthalmic solution 0.75%) in treating significant, chronic night driving impairment in keratorefractive patients with reduced mesopic vision. This study was conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (U.S. FDA).

The LYNX-2 Phase 3 trial consisted of a randomized, placebo-controlled, double-masked study, with a total of 199 patients who were randomized to receive either MR-142 or placebo, self-administered in both eyes, nightly, treated and observed over 6 weeks. In summary:

- Significantly more patients treated in the MR-142 arm achieved the primary endpoint of ≥15-letter Early Treatment Diabetic Retinopathy Study (ETDRS) (≥3-line) gain in Mesopic Low Contrast Distance Visual Acuity (mLCVA) at Day 15, compared to placebo ($p<0.05$).[1]
- Patient-reported functional benefit was observed at Day 15 in difficulty of seeing the road because of oncoming headlights in patients dosed with MR-142 compared to placebo ($p<0.05$); and in difficulty seeing due to glare when driving at dawn or dusk in patients dosed with MR-142 compared to placebo ($p<0.05$) when assessed by the validated Vision and Night Driving Questionnaire (VND-Q).
- As per the pre-specified testing, no evidence of tachyphylaxis out to Week 6 of dosing.[2]
- MR-142 demonstrated a safety profile consistent with previous trials, with no new safety signal identified.
- LYNX-2 patients will continue to be monitored for long-term safety over 48 weeks.

Viatris Chief R&D Officer Philippe Martin said, "Our eye care pipeline is designed to address a broad range of ophthalmic conditions. We believe that these positive results confirm the potential of MR-142 to meet a critical need for keratorefractive patients experiencing glare and reduced functional vision in mesopic, low-contrast environments, including night driving, for which there are no currently FDA-approved options."

Viatris Chief Commercial Officer Corinne Le Goff said, "The positive Phase 3 results of MR-142, a potential first-in-class treatment option, are a promising step forward in our commitment to enhancing eye and vision health. We are excited by the potential to leverage our existing eye care infrastructure to introduce complementary product offerings that make a meaningful impact for patients and healthcare professionals alike."

The U.S. FDA granted Fast Track designation to MR-142 for the treatment of significant, chronic night driving impairment with concomitant increased risk of motor vehicle accidents and debilitating loss of best spectacle corrected mesopic vision in keratorefractive patients with photic phenomena (e.g., glare, halos, starbursts). Fast Track designation has the potential to accelerate the development and review of new drugs intended to treat serious conditions with unmet medical needs. For more information on the LYNX-2 study design, refer to ClinicalTrials.gov NCT06349759. A second pivotal study, LYNX-3 is anticipated to start shortly with results expected in the first half of 2026.

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.

[1] The primary endpoint was defined as the percentage of all randomized patients who took at least one dose of study drug (mITT Population) achieving a ≥15-letter ETDRS (≥3-line) improvement in mesopic low contrast distance visual acuity (mLCVA). The mITT Population was used for the primary endpoint analysis and to analyze efficacy endpoints.

[2] The study is also designed to examine tachyphylaxis of the therapeutic response to MR-142 for mLCVA. This was to be achieved by comparing change from Baseline at Week 6 in the MR-142 group to the best change from baseline achieved during the first month of treatment for mLCVA.

About LYNX-2
The LYNX-2 trial was conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration. The LYNX-2 Phase 3 trial consisted of a randomized, placebo-controlled, double-masked study, with a total of 199 patients who were randomized to receive either MR-142 or placebo, self-administered in both eyes, nightly, treated and observed over 6 weeks. Patients from both arms in LYNX-2 will be followed for a total of 48 weeks to evaluate long-term safety. For more information on the LYNX-2 study design, refer to ClinicalTrials.gov NCT06349759.

About Mesopic Vision and MR-142 (Phentolamine Ophthalmic Solution 0.75%)
Mesopic vision is defined as vision in dim light (interface of bright light and night vision) conditions that leverages both rod and cone photoreceptors. Decreased low contrast visual acuity under mesopic conditions occurs when the pupil dilates in low-light conditions allowing peripheral unfocused rays of light to enter the eye. The total diagnosed prevalence of Night Vision Disturbance (NVD) across the 7 Major Markets (United States, United Kingdom, Germany, France, Italy, Spain, and Japan) was estimated to be nearly 55 million in 2023, with the U.S. representing approximately 45% of cases. The condition is particularly common in patients with increased ocular aberrations and ocular scatter from keratorefractive surgery (including Laser-Assisted In Situ Keratomileusis (LASIK), Photorefractive Keratectomy (PRK), Small-Incision Lenticule Extraction (SMILE), and Radial Keratotomy (RK)). It is estimated that approximately 800,000 refractive surgeries are performed in the U.S. each year, with 25% of patients suffering from visual aberrations (e.g., glare, halos, starburst) at 1-month. There are currently no FDA-approved treatments.

The U.S. Food and Drug Administration granted Fast Track designation to MR-142 for the treatment of significant, chronic night driving impairment with concomitant increased risk of motor vehicle accidents and debilitating loss of best spectacle corrected mesopic vision in keratorefractive patients with photic phenomena (e.g., glare, halos, starburst). Fast Track designation has the potential to accelerate the development and review of new drugs intended to treat serious conditions with unmet medical needs.

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 regarding the outcome of clinical trials; that our eye care pipeline is designed to address a broad range of ophthalmic conditions; we believe that these positive results confirm the potential of MR-142 to meet a critical need for keratorefractive patients experiencing glare and reduced functional vision in mesopic, low-contrast environments, including night driving, for which there are no currently FDA-approved options; the positive Phase 3 results of MR-142, a potential first-in-class treatment option, are a promising step forward in our commitment to enhancing eye and vision health; we are excited by the potential to leverage our existing eye care infrastructure to introduce complementary product offerings that make a meaningful impact for patients and healthcare professionals alike; the U.S. FDA granted Fast Track designation to MR-142 for the treatment of significant, chronic night driving impairment with concomitant increased risk of motor vehicle accidents and debilitating loss of best spectacle corrected mesopic vision in keratorefractive patients with photic phenomena (e.g., glare, halos, starbursts); Fast Track designation has the potential to accelerate the development and review of new drugs intended to treat serious conditions with unmet medical needs; a second pivotal study, LYNX-3 is anticipated to start shortly with results expected in 1H 2026; and there are currently no FDA-approved treatments for mesopic vision. 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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