# Viatris Announces Positive Top-Line Results from Two Pivotal Phase 3 Studies of Novel Fast-Acting Meloxicam (MR-107A-02) for the Treatment of Moderate-to-Severe Acute Pain

May 8, 2025

*All Primary and Secondary Endpoints Were Met in Both Phase 3 Studies*

*In Both Acute Pain Models, MR-107A-02 Demonstrated Statistically Significant and Clinically Meaningful Improvement in Pain Compared to Placebo, Significant Reduction in Opioid Usage and Superior Pain Control Versus the Opioid Arm*

*Targeting New Drug Application Submission to U.S. FDA by End of 2025*

PITTSBURGH, May 8, 2025 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced positive results from its Phase 3 program of the novel fast-acting formulation of meloxicam (MR-107A-02) for the treatment of moderate-to-severe acute pain. The Phase 3 program consisted of two randomized, double-blind, placebo-(double-dummy) and active-controlled trials – one following herniorrhaphy surgery (NCT06215859) and one following bunionectomy surgery (NCT06215820). Both trials evaluated the efficacy and safety of MR-107A-02 versus placebo and included an opioid comparator arm (tramadol 50mg q6h) to confirm the sensitivity of the pain model.

The primary endpoint in both trials was defined by the Sum of Pain Intensity Difference (SPID) based on the Numeric Rating Scale measured over 0-48 hours ($SPID_{0\text{-}48h}$). Both trials evaluated the reduction in opioid usage that was defined by number of mean doses of opioid rescue medication and proportion of opioid-free patients over the combined in- and out-patient treatment phases.

In both studies, MR-107A-02 demonstrated statistically significant and clinically meaningful results. In particular:

- Treatment with MR-107A-02 led to improvement in pain versus baseline compared to placebo (herniorrhaphy: LS mean difference in $SPID_{0\text{-}48h}$ between MR-107A-02 and placebo = 50.1 (95% CI: 35.4, 64.8; $p<0.001$); bunionectomy: LS mean difference in $SPID_{0\text{-}48h}$ between MR-107A-02 and placebo = 82.7 (95% CI: 62.0, 103.4; $p<0.001$)).

- MR-107A-02 demonstrated notable reduction in opioid usage over the entire treatment phase by reducing opioid use versus placebo and by showing a higher number opioid-free patients than placebo (herniorrhaphy: MR-107A-02 treatment group had 72.6% opioid-free patients versus 58.6% in the placebo arm ($p=0.002$); bunionectomy: MR-107A-02 treatment group had 56.9% opioid-free patients versus 33.1% in the placebo arm ($p<0.001$)).

- Post-hoc analyses demonstrated significantly superior pain control ($SPID_{0\text{-}48}$) of MR-107A-02 versus the opioid arm in both surgical models, which was supported by time to perceptible and time to meaningful pain relief. Significantly shorter time to perceptible and meaningful pain relief was observed for MR-107A-02 versus placebo and shorter or comparable to tramadol.

- MR-107A-02 was generally well tolerated. In both studies, incidence of treatment emergent adverse events (TEAEs) was comparable to placebo in a post-surgical setting. Few severe TEAEs and severe adverse events (SAEs) were reported with a rate consistent with placebo. No TEAEs leading to death were reported.

"Building on an established mechanism of action and well-characterized safety profile, the efficacy and benefit-risk profile observed in these two pivotal studies optimally positions our fast-acting meloxicam for potential first-line treatment of moderate-to-severe acute pain," said Viatris Chief R&D Officer Philippe Martin. "The data observed in two surgical models – herniorrhaphy and bunionectomy – is a critical step in the development of a safe and effective non-opioid option to address an important public health need."

"I have accompanied this project since the Phase 2 dental pain study in 2022, and it is rare to see such positive data replicated in three different trials," said Dr. Todd Bertoch, a board-certified anesthesiologist, and the Chief Medical Officer for Pain Research at CenExel. "The efficacy and safety data of the novel, fast-acting meloxicam (MR-107A-02) from two Phase 3 studies in both bony and soft tissue pain models supports its potential use as a powerful, first-line, non-opioid analgesic option for patients with moderate-to-severe acute pain – potentially eliminating opioid use altogether for many patients."

The Company is targeting to submit a New Drug Application to the U.S. Food and Drug Administration (FDA) by the end of 2025 based on the positive data from these two Phase 3 studies and the supportive positive Phase 2 dose range finding data in dental pain.

Full results from both Phase 3 studies will be submitted for presentation at future congresses, including the upcoming PAINWeek 2025 conference in September.

Additional information about the positive Phase 3 studies will be made available in the Company's Q1 2025 Earnings Presentation that can be found at https://investor.viatris.com/events-and-presentations.

**Phase 3 Trial Design for Herniorrhaphy (NCT06215859) and Bunionectomy (NCT06215820)**
Post-operative herniorrhaphy and bunionectomy patients aged 18 or older who experienced moderate-to-severe pain following surgery were eligible to participate in the trials, NCT06215859 and NCT06215820, respectively. 579 herniorrhaphy subjects and 410 bunionectomy subjects were randomized and received doses of either MR-107A-02, tramadol or placebo every six hours during the inpatient phase (0-48h, 8 doses of study drug). To maintain the blind, subjects in the inpatient MR-107A-02 group received MR-107A-02 active and MR-107A-02 placebo alternately to allow for a six-hour dosing regimen of all subjects. During the outpatient phase, subjects continued to receive dose of the study drug twice daily (5 days, 10 doses of study drug). Subjects randomized to receive tramadol during the inpatient phase received placebo in the outpatient phase.

**About Acute Pain**
Acute pain is defined as pain of sudden onset associated with a known cause—such as surgery, trauma, or acute illness—and is typically self-limiting, resolving within 30 days to three months. It affects more than 80 million individuals in the U.S. each year and is a primary driver of emergency department visits and postoperative morbidity. Clinically, it contributes to delayed recovery, impaired physical function, poor sleep, and reduced quality of life. Economically, the burden of acute pain is substantial, including both direct medical expenses and indirect costs such as lost productivity and disability. Societally, inadequate pain control affects patient satisfaction and rehabilitation outcomes, contributes to opioid prescribing and potential misuse. Despite the widespread impact, more than half of surgical patients report inadequate pain relief, reflecting a significant unmet need for effective, non-opioid treatment options with rapid onset and favorable safety profiles.

**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 outcomes of clinical trials; in both acute pain models, MR-107A-02 demonstrated statistically significant and clinically meaningful improvement in pain compared to placebo, significant reduction in opioid usage and superior pain control versus the opioid arm; targeting new drug application submission to FDA by end of 2025; building on an established mechanism of action and well-characterized safety profile, the efficacy and benefit-risk profile observed in these two pivotal studies optimally positions our fast-acting meloxicam for potential first-line treatment of moderate-to-severe acute pain; the data observed in two surgical models – herniorrhaphy and bunionectomy – is a critical step in the development of a safe and effective non-opioid option to address an important public health need; it is rare to see such positive data replicated in three different trials; the efficacy and safety data of the novel, fast-acting meloxicam (MR-107A-02) from two Phase 3 studies in both bony and soft tissue pain models supports its potential use as a powerful, first-line, non-opioid analgesic option for patients with moderate-to-severe acute pain – potentially eliminating opioid use altogether for many patients; the Company is targeting to submit a New Drug Application to the FDA by the end of 2025 based on the positive data from these two Phase 3 studies and the supportive positive Phase 2 dose range finding data in dental pain; and full results from both Phase 3 studies will be submitted for presentation at future congresses, including the upcoming PAINWeek 2025 conference in September. 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: 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 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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