U.S. FDA Accepts Viatris New Drug Application for Fast-Acting Meloxicam for the Treatment of Moderate-to-Severe Acute Pain

May 18, 2026

FDA PDUFA Goal Date Set for Dec. 27, 2026

PITTSBURGH, May 18, 2026 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for MR-107A-02 (fast-acting meloxicam), a non-opioid, for the treatment of moderate-to-severe acute pain. The FDA has assigned a PDUFA goal date of Dec. 27, 2026. Acute pain affects more than 80 million individuals in the United States each year, where opioids remain a commonly used treatment option.[1,2]

"FDA's acceptance of the New Drug Application for investigational fast-acting meloxicam takes us one step closer to bringing a potential non-opioid first-line treatment option to patients with moderate-to-severe acute pain, which will help address an important public health need in the United States," said Philippe Martin, Viatris Chief R&D Officer. "Fast-acting meloxicam is one of several value-added medicines in our pipeline. We are proud of the strength of the clinical profile supporting this program, which includes a fast speed of onset of action, strong and sustained analgesic efficacy with a significant reduction in opioid usage, together with an established mechanism of action and well characterized safety profile."

The NDA is supported by data from the Phase 3 program which was presented at PAINWeek 2025. 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 Phase 3 trials evaluated the efficacy and safety of fast-acting meloxicam versus placebo and included an opioid 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 ($SPID_{0-48h}$) versus placebo. 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, fast-acting meloxicam met primary and secondary endpoints and demonstrated a safety profile consistent with the well-characterized safety profile of this mechanism of action.

Viatris is pursuing several value-added medicines, including fast-acting meloxicam, to drive high value products through life cycle optimization including new formulations, delivery technologies and indications.

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 acute 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 during the inpatient phase (0-48h). During the outpatient phase, subjects continued to receive the 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 United States. 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 Fast-Acting Meloxicam
Fast-acting meloxicam (MR-107A-02) is an investigational, novel fast-acting oral formulation of meloxicam being developed by Viatris for the treatment of moderate-to-severe acute pain. Meloxicam is a non-steroidal anti-inflammatory drug (NSAID), and this formulation was designed to enable more rapid dissolution and absorption than currently approved oral meloxicam products. Viatris has reported positive results from two pivotal Phase 3 studies of MR-107A-02 in acute post-surgical pain models following bunionectomy and herniorrhaphy. MR-107A-02 has been submitted to the U.S.

Food and Drug Administration for review under the 505(b)(2) regulatory pathway and has not been approved by any regulatory authority.

References

1. Lopez et al. "A real-world database analysis of the prevalence of pain medication use in the United States." *Pain Reports*, vol. 11, 2026, e1396.
2. Centers for Disease Control and Prevention. About Prescription Opioids. Accessed April 2026.

About Viatris

Viatris Inc. (Nasdaq: VTRS) is a global healthcare company whose mission is to empower people worldwide to live healthier at every stage of life. We meet the needs of patients around the world by acting decisively with ingenuity and resolve. Whether we're developing new medicines, working to maintain a resilient supply of needed therapies, or pursuing bold innovation, we strive to deliver solutions that are effective at scale and built to endure. We're purpose-built to make an impact with a dynamic portfolio that spans generics, established brands and innovative medicines that address areas of significant unmet need. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai, China, and Hyderabad, India. Learn more at viatris.com and investor.viatris.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 FDA has accepted for review the NDA for MR-107A-02 (fast-acting meloxicam), a non-opioid, for the treatment of moderate-to-severe acute pain; the FDA has assigned a PDUFA goal date of Dec. 27, 2026; FDA's acceptance of the NDA for investigational fast-acting meloxicam takes us one step closer to bringing a potential non-opioid first-line treatment option to patients with moderate-to-severe acute pain, which will help address an important public health need in the United States; fast-acting meloxicam is one of several value-added medicines in our pipeline; we are proud of the strength of the clinical profile supporting this program, which includes a fast speed of onset of action, strong and sustained analgesic efficacy with a significant reduction in opioid usage, together with an established mechanism of action and well characterized safety profile; information about clinical trials; in both studies, fast-acting meloxicam met primary and secondary endpoints and demonstrated a safety profile consistent with the well-characterized safety profile of this mechanism of action; Viatris is pursuing several value-added medicines, including fast-acting meloxicam, to drive high value products through life cycle optimization including new formulations, delivery technologies and indications. 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; failure to achieve the intended benefits of our strategic initiatives and priorities; goodwill or impairment charges or other losses; any changes in or difficulties with the Company's manufacturing facilities; failure to achieve expected or targeted future financial and operating performance and results; Viatris' or its partners' ability to develop, manufacture, and commercialize products; 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; actions and decisions of healthcare and pharmaceutical regulators; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; the scope, timing and outcome of any ongoing legal proceedings, and the impact of any such proceedings on Viatris; any significant breach of data security or data privacy or disruptions to our IT systems; 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.

View original content to download multimedia:https://www.prnewswire.com/news-releases/us-fda-accepts-viatris-new-drug-application-for-fast-acting-meloxicam-for-the-treatment-of-moderate-to-severe-acute-pain-302774276.html

SOURCE Viatris Inc.

Media: + 1.724.514.1968, Communications@viatris.com; Jennifer Mauer, Jennifer.Mauer@viatris.com; Matt Klein, Matthew.Klein@viatris.com; Investors: +1.724.514.1813, InvestorRelations@viatris.com; Bill Szablewski, William.Szablewski@viatris.com