Viatris Provides Pipeline Update on Four Regulatory Milestones

December 18, 2025

- *Receives U.S. Food and Drug Administration (FDA) Approval for Generic Version of Sandostatin® LAR Depot (Octreotide Acetate for Injectable Suspension)*
- *U.S. FDA Accepts New Drug Application for Low Dose Estrogen Weekly Patch for Contraception*
- *U.S. FDA Clears Investigational New Drug Application for MR-146 in Neurotrophic Keratopathy*
- *Japan Pharmaceuticals and Medical Devices Agency Accepts Japanese New Drug Application Filing for Pitolisant in Obstructive Sleep Apnea Syndrome*

PITTSBURGH, Dec. 18, 2025 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced four recent regulatory milestones spanning across all stages of its global pipeline:

- **Octreotide Acetate for Injectable Suspension:** The U.S. Food and Drug Administration (FDA) has approved the Company's octreotide acetate for injectable suspension, a generic version of Sandostatin® LAR Depot. The therapy is indicated for treatment in patients who have responded to and tolerated Sandostatin Injection subcutaneous injection for acromegaly, severe diarrhea/flushing episodes associated with metastatic carcinoid tumors, and profuse watery diarrhea associated with Vasoactive Intestinal Peptide secreting tumors.
- **Low Dose Estrogen Weekly Patch:** The U.S. FDA has accepted for review the New Drug Application (NDA) for the Company's investigational low dose estrogen weekly patch (150 mcg norelgestromin and 17.5 mcg ethinyl estradiol) for contraception. The NDA is accepted under the FDA's 505(b)(2) regulatory pathway, and the FDA has assigned a target action date (PDUFA) of July 30, 2026.
- **MR-146:** The U.S. FDA has cleared the Company's Investigational New Drug (IND) application for MR-146, an Enriched Tear Film™ (ETF) Adeno-Associated Virus (AAV) gene therapy candidate targeted to treat people with neurotrophic keratopathy (NK). The Company plans to initiate a Phase 1 / 2 clinical trial, CORVITA, for MR-146 in patients with NK in the first half of 2026.
- **Pitolisant**: The Japan Pharmaceuticals and Medical Devices Agency (PMDA) has accepted the Company's Japanese New Drug Application (J-NDA) for pitolisant in obstructive sleep apnea syndrome (OSAS). The Company remains on track to submit a J-NDA for narcolepsy by the end of the year.

"We are proud of these recent regulatory achievements, which culminate a year of significant R&D advancement in 2025," said Viatris Chief R&D Officer Philippe Martin. "These important milestones not only demonstrate the strength of our scientific and regulatory capabilities, but also our dedication to addressing areas of significant unmet medical need for patients. We look forward to continuing to work closely with health authorities around the world as we progress our pipeline in 2026 and beyond."

About Octreotide Acetate for Injectable Suspension
Octreotide acetate for injectable suspension is a long-acting medication used to help manage the symptoms of certain rare conditions, including acromegaly (a disorder in adults that causes abnormal growth of bones, organs and tissues) and complications associated with specific cancerous tumors. It is the Company's first approved injectable using microsphere technology.

This approval marks the Company's fourth injectable FDA approval in 2025 – joining iron sucrose, paclitaxel and liposomal amphotericin B – underscoring the Company's ability to successfully navigate complex regulatory pathways and strategy to expand its generics portfolio with technically complex, high-value products.

About Low Dose Estrogen Weekly Patch for Contraception
The investigational treatment is a once-weekly transdermal contraceptive patch being developed for women of childbearing potential with a BMI below 30 kg/m² who are appropriate candidates for combined hormonal contraception and who prefer a non-invasive, reversible option with a lower estrogen dose. The patch delivers approximately 150 mcg of norelgestromin and 17.5 mcg of ethinyl estradiol per day and is applied once weekly for three weeks, followed by a one-week patch-free period.

The planned 505(b)(2) NDA is supported by results from the Phase 3 Luminous Study, which demonstrated a favorable efficacy and safety profile and strong patch adhesion performance.

The patch represents the potential to meet an important unmet medical need for women seeking alternatives to regular estrogen dose and long-acting contraception treatments. This investigational treatment option builds upon the Company's established capability in transdermal drug delivery and represents a lifecycle advancement of the contraceptive patch Xulane® (norelgestromin and ethinyl estradiol transdermal system) 150/35 mcg per day.

About MR-146 for Neurotrophic Keratopathy
NK is a rare but potentially sight-threatening corneal disease, which impacts approximately 73,000 people in the United States. It is a degenerative disease that causes progressive damage to the cornea. The most common causes of the disease are viral infections (herpes simplex, varicella zoster [shingles]), diabetes, multiple sclerosis, chemical burns, dry eye disease and corneal surgeries.

MR-146 utilizes an ETF™ AAV gene therapy platform, a first-of-its-kind approach designed to be delivered directly to the lacrimal gland via a single injection, using non-replicating DNA delivery transporters for the production and delivery of human Nerve Growth Factor (hNGF) protein to the cornea via tears. NK is the first indication of many that could be treated with this platform.

About Pitolisant
Pitolisant is a selective histamine H3 receptor antagonist/inverse agonist that modulates the brain's sleep–wake pathways.

The J-NDA application is supported by positive Phase 3 data in Japanese patients. The Phase 3 trial evaluated the effect of pitolisant in Japanese patients with OSAS who were experiencing residual Excessive Daytime Sleepiness (EDS) despite treatment with CPAP therapy. At the end of the 12-week treatment period, patients receiving pitolisant scored lower on the Epworth Sleepiness Scale used to measure EDS compared to those in the placebo group, and this difference was statistically significant (p=0.007). Additionally, safety and tolerability were consistent with results from global clinical studies.

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.

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 Viatris provides pipeline update on four regulatory milestones; receives FDA approval for generic version of Sandostatin® LAR Depot (octreotide acetate for injectable suspension); FDA accepts NDA for low dose estrogen weekly patch for contraception; FDA clears IND application for mr-146 in neurotrophic keratopathy; Japan Pharmaceuticals and Medical Devices Agency accepts J-NDA new drug application filing for pitolisant in obstructive sleep apnea syndrome; the NDA is accepted under the FDA's 505(b)(2) regulatory pathway, and the FDA has assigned a target action date (PDUFA) of July 30, 2026; Viatris plans to initiate a Phase 1 / 2 clinical trial, CORVITA, for MR-146 in patients with NK in the first half of 2026; the Company remains on track to submit a J-NDA for narcolepsy by the end of the year; we are proud of these recent regulatory achievements, which culminate a year of significant R&D advancement in 2025; these important milestones not only demonstrate the strength of our scientific and regulatory capabilities, but also our dedication to addressing areas of significant unmet medical need for patients; we look forward to continuing to work closely with health authorities around the world as we progress our pipeline in 2026 and beyond; octreotide acetate for injectable suspension is the Company's first approved injectable using microsphere technology; this approval marks the Company's fourth injectable FDA approval in 2025 – joining iron sucrose, paclitaxel and liposomal amphotericin B – underscoring the Company's ability to successfully navigate complex regulatory pathways and strategy to expand the generics portfolio with technically complex, high-value products; the planned 505(b)(2) NDA is supported by results from the Phase 3 Luminous Study, which demonstrated a favorable efficacy and safety profile and strong patch adhesion performance; the patch represents the potential to meet an important unmet need for women seeking alternatives to regular estrogen dose and long-acting contraception treatments; this investigational treatment option builds upon the Company's established capability in transdermal drug delivery and represents a lifecycle advancement of the contraceptive patch Xulane® (norelgestromin and ethinyl estradiol transdermal system) 150/35 mcg per day; NK is the first indication of many that could be treated with this candidate; the J-NDA application is supported by positive Phase 3 data in Japanese patients; at the end of the 12-week treatment period, patients receiving pitolisant scored lower on the Epworth Sleepiness Scale used to measure EDS compared to those in the placebo group and this difference was statistically significant (p=0.007); additionally, safety and tolerability were consistent with results from global clinical studies. 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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