Viatris Announces Positive Results from Phase 3 Study of Investigational XULANE LO™ Low Dose Patch for Birth Control in Women of Childbearing Potential

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Treatment With XULANE LO Low Estrogen Dose Achieved Primary and All Secondary Efficacy and Safety Endpoints

Results Demonstrated Potential Best-In-Class Patch Performance

New Drug Application Submission to U.S. FDA Anticipated in the Second Half of 2025

PITTSBURGH, May 8, 2025 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced positive results of its Phase 3 study (NCT05139121) evaluating the contraceptive efficacy and safety of investigational XULANE LO low dose weekly dermal patch of 150 mcg norelgestromin and 17.5 mcg ethinyl estradiol per day in women of childbearing potential. The study evaluated women of childbearing potential (N=1,272) for up to 13 cycles (12,591 safety evaluable cycles and 9,105 efficacy evaluable cycles) across 81 investigative sites throughout the U.S., Puerto Rico and Canada.

In this study, XULANE LO demonstrated a favorable efficacy and safety profile with no new safety concerns identified as well as a potential best-in-class patch performance profile. In particular:

- With a Pearl Index (PI) of 4.14, the study demonstrated contraceptive efficacy. This primary efficacy endpoint was measured in eligible women aged 16 to 35 with a body mass index <30 mg/m^2 and at least one efficacy evaluable cycle. Additionally, the cumulative probability of pregnancy over 13 cycles was 3.7%.
- A favorable safety and tolerability profile was observed with most treatment emergent adverse events (TEAEs) reported as mild-to-moderate. Favorable cycle control was also observed with generally low unscheduled bleeding and spotting events.
- The study demonstrated a potential best-in-class patch adhesion profile with very few patches (1.3%) completely detaching over the seven-day wearing period and <1% of subjects reporting severe local application site reactions.

"We are pleased with the profile our investigational XULANE LO low dose patch demonstrated in this Phase 3 study," said Viatris Chief R&D Officer Philippe Martin. "The data underscores our confidence in the potential of XULANE LO to address an important need for women seeking a reversible birth control method that offers a lower dosage of estrogen in a weekly patch with potential best-in-class adhesion performance."

The Company plans to submit a New Drug Application to the U.S. Food and Drug Administration (FDA) in the second half of 2025.

About the Phase 3 Study Design (NCT05139121)
The multicenter, open-label, single-arm study, evaluated the contraceptive efficacy of investigational XULANE LO low dose patch when used over thirteen 28-day cycles in 1,272 healthy, post-menarcheal, pre-menopausal, heterosexually active female subjects of childbearing potential who are at least 16 years of age.

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; NDA submission to FDA anticipated in the second half of 2025; XULANE LO demonstrated a favorable efficacy and safety profile with no new safety concerns identified as well as a potential best-in-class patch performance profile; and the data underscores our confidence in the potential of XULANE LO to address an important need for women seeking a reversible birth control method that offers a lower dosage of estrogen in a weekly patch with potential best-in-class adhesion performance. 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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