Viatris Receives U.S. FDA Approval for Gwyn Lo™, a Once-Weekly Contraceptive Patch

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New Patch Will Provide Low-Dose Estrogen Combined Hormonal Contraceptive Option

Approval Marks an Important Milestone in Viatris' Efforts to Advance Women's Health

PITTSBURGH, July 29, 2026 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced that the U.S. Food and Drug Administration (FDA) has approved Gwyn Lo™ (norelgestromin and ethinyl estradiol transdermal system). Gwyn Lo is a new combined hormonal contraceptive (CHC) patch with low-dose estrogen. The patch has demonstrated contraceptive efficacy for women of childbearing potential with a body mass index (BMI) below 30 kg/m² who are appropriate candidates for CHC. The Gwyn Lo dosage is norelgestromin 220 mcg/day and ethinyl estradiol 20 mcg/day.

"Gwyn Lo will provide a discreet option for women seeking a reversible, non-invasive, once-weekly contraception patch with a low dose of estrogen," said Philippe Martin, Viatris Chief R&D Officer. "Building on our expertise in transdermal drug delivery systems and legacy in women's health, we are pleased that the approved label for this new patch reflects the strength of our clinical program. This includes demonstrated efficacy in women with a BMI of 25 to less than 30 kg/m², with no BMI-based limitation of use in this population."

The approval was granted under the FDA's 505(b)(2) regulatory pathway and was supported by results from the Phase 3 Luminous Study (NCT05139121), which demonstrated contraceptive efficacy, a well-characterized safety profile and robust patch adhesion performance. Key outcomes of the Phase 3 study included:

- The primary efficacy endpoint was the Pearl Index (PI), defined as the number of pregnancies per 100 woman-years of exposure in the efficacy evaluable population (women aged 18 to 35 years), which was 4.14 (95% CI: 2.77 to 5.95).
- The study demonstrated robust patch adhesion under real-world conditions, with only 1.3% of the 39,790 transdermal systems applied during the year-long trial fully detaching.
- The most common adverse reactions (2% or greater) reported during the study were application site irritation (4.8%), application site erythema (3.7%), application site pruritus (3.7%), intercycle bleeding (3.9%), heavy withdrawal bleeding (2.0%), and nausea (2.0%).
- Cycle control improved over time, as rates and duration of unscheduled bleeding or spotting decreased from 34.5% and a mean of 3.2 days in Cycle 1 to 20.0% and 2.4 days by Cycle 13.

Data from four Phase 1 studies investigating various application sites and conditions demonstrated consistent drug delivery under conditions including sauna, whirlpool, treadmill exercise and cold-water bath.

Unintended pregnancy remains a significant public health issue in the United States, accounting for 41.6% of pregnancies in 2019.[1] Women's contraceptive needs and preferences also vary: in a 2023 CDC survey, 18.1% of women who had used a contraceptive method changed or stopped a method within the previous 12 months.[2] Among those women, 42.8% reported that they did not like the method they had been using.[2] These findings underscore the continued need for a range of contraceptive options that can align with individual needs and preferences. Gwyn Lo helps address this need by offering a non-invasive, reversible, low-estrogen-dose CHC option for women who prefer once-weekly administration.

The Company expects Gwyn Lo to be commercially available later this year and will provide additional information during its upcoming financial results call.

About Gwyn Lo
Gwyn Lo is a once-weekly transdermal contraceptive patch 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 low estrogen dose. The patch is applied once weekly for three consecutive weeks, followed by one patch-free week, and delivers norelgestromin and ethinyl estradiol over each seven-day wear interval.

Gwyn Lo is a multilayer matrix type transdermal system. The active ingredients and adhesive are contained in a matrix between a backing layer, which consists of a flexible film that provides structural support to the patch, and a release liner that protects the matrix and is removed just prior to application. Upon application to the skin, the system provides controlled delivery of norelgestromin 220 mcg/day and ethinyl estradiol 20 mcg/day throughout the wear interval.

Gwyn Lo is a trademark of Mylan Pharmaceuticals Inc., a Viatris company.

INDICATION AND USAGE
Gwyn Lo is indicated for the prevention of pregnancy in women with a body mass index (BMI) < 30 kg/m2 for whom a combined hormonal contraceptive is appropriate.

IMPORTANT SAFETY INFORMATION
Gwyn Lo is contraindicated in women who smoke and are over 35 years of age due to an increased risk of serious cardiovascular events. Gwyn Lo is contraindicated in women with a BMI ≥ 30 kg/m2. The risk of VTE may be greater with Gwyn Lo in women with a BMI > 30 kg/m2 compared to women with a lower BMI. Patients should discuss their medical history and risk factors with their healthcare provider before using Gwyn Lo.

Please see Full Prescribing Information.

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 broad portfolio that spans generics, value-added medicines, 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.

References

1. Rossen LM, Hamilton BE, Abma JC, Gregory ECW, Beresovsky V, Resendez AV, et al. Updated methodology to estimate overall and unintended pregnancy rates in the United States. National Center for Health Statistics. Vital Health Stat 2(201). 2023. doi:10.15620/cdc:124395
2. NCHS Rapid Surveys Systems. Contraception Use. National Center for Health Statistics. Available from: www.cdc.gov/nchs/rss/round2/contraception-use.html.

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 about FDA approval for Gwyn Lo; approval marks an important milestone in Viatris' efforts to advance women's health; Gwyn Lo will provide a discreet option for women seeking a reversible, non-invasive, once-weekly contraception patch with a low dose of estrogen; building on our expertise in transdermal drug delivery systems and legacy in women's health, we are pleased that the approved label for this new patch reflects the strength of our clinical program; and the Company expects Gwyn Lo to be commercially available later this year, and will provide additional information during its upcoming financial results call. 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.

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