Viatris Advances Innovative Portfolio with Approval of Effexor® in Japan for Adults with Generalized Anxiety Disorder (GAD)

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Addresses a Significant Unmet Need in Japan as First and Only Approved Treatment Option for GAD

PITTSBURGH, March 23, 2026 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved Effexor® SR 37.5 mg / 75 mg capsules (venlafaxine hydrochloride), a serotonin-noradrenaline reuptake inhibitor (SNRI), for the treatment of adults with generalized anxiety disorder (GAD). Following the MHLW's decision, Effexor® becomes the first and only approved treatment option in Japan for adults living with GAD, addressing a long-standing unmet medical need in mental health and enabling new access to care. Effexor® is currently approved in Japan for the indication of major depressive disorder in adults, and with this approval, is now available to patients with GAD.

GAD is among the most prevalent and highly disabling mental health conditions, negatively impacting patients' quality of life and disrupting activities of daily living. A recent study reported the prevalence of probable GAD in Japan as 7.6% of the general population.[1]

"The approval of Effexor® in Japan for generalized anxiety disorder demonstrates the successful execution of our strategy to advance a differentiated and increasingly innovative portfolio in Japan, bringing forward value-added therapies that address a significant unmet need," said Philippe Martin, Viatris Chief R&D Officer. "This approval also reflects our ability to effectively implement an optimized lifecycle strategy for our established brands and to leverage our deep local expertise."

"This approval marks the introduction of a new treatment option for adults in Japan living with GAD," said Corinne Le Goff, Viatris Chief Commercial Officer. "We look forward to leveraging our strong infrastructure and deep expertise in central nervous system therapies in Japan to bring access to this much needed treatment to patients."

The approval of Effexor® for GAD is based on a Phase 3 placebo-controlled, randomized, double-blind, multicenter study of venlafaxine in patients with GAD conducted in Japan (Study B2411367), which achieved its primary objective of superiority of anxiolytic effects of venlafaxine compared to placebo at 8 weeks, based on the change in the Hamilton Anxiety Rating Scale (HAM-A) total score from baseline (two-sided p-value=0.012). All seven secondary efficacy endpoints as defined by the trial protocol were met. Effexor® was generally well tolerated with a profile consistent with its known safety profile in non-Japanese patients. In particular:

- Low discontinuation rates due to treatment emergent adverse events (TEAEs) were seen (7.3% vs 1.7% in placebo) with 3.9% vs 0.6% assessed as related to treatment.
- No serious TEAEs or TEAEs with severe intensity were observed (0% vs 1.1% and 0.6%, respectively, in placebo).

These results and the results of a long-term extension study of venlafaxine in Japanese outpatients with GAD were included as part of the applications for approval. Effexor® is currently approved to treat GAD in more than 80 countries outside of Japan.

About Generalized Anxiety Disorder (GAD)
Generalized Anxiety Disorder (GAD) is a mental health disorder whose central symptom is chronic and uncontrollable "anxiety" or "worry" about everyday life events or activities. Other symptoms include difficulty to get enough sleep, muscle tension/stiffness, feeling restless, irritable, or finding it difficult to concentrate, which may cause impairment in social, occupational, or other areas of functioning. In Japan, the World Health Organization reports that 2.6% of the population will suffer from GAD in their lifetime. A recent study in Japan reported the prevalence of probable GAD is 7.6%[1], suggesting that this condition may be significantly underdiagnosed.

About Viatris' Innovative Portfolio in Japan
Viatris' portfolio of innovative products in Japan includes approved products such as Spydia® Nasal Spray (diazepam) for the treatment of status epilepticus. The company's pipeline in Japan includes investigational products such as pitolisant for the treatment of excessive daytime sleepiness associated with obstructive sleep apnea syndrome and narcolepsy, and products in pivotal Phase 3 trials which are currently ongoing, such as selatogrel in acute myocardial infarction (AMI), Nefecon in IgA nephropathy, and cenerimod in systemic lupus erythematosus (SLE).

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 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.

References:

1. Matsuyama S, Otsubo T, Nomoto K, Higa S, Takashio O. Prevalence of Generalized Anxiety Disorder in Japan: A General Population Survey. Neuropsychiatr Dis Treat. 2024;20:1355-1366.

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 advances innovative portfolio with approval of Effexor® in Japan for adults with GAD; addresses a significant unmet need in Japan as first and only approved treatment option for GAD; the approval of Effexor® in Japan for generalized anxiety disorder demonstrates the successful execution of our strategy to advance a differentiated and increasingly innovative portfolio in Japan, bringing forward value-added therapies that address a significant unmet need; this approval also reflects our ability to effectively implement an optimized life cycle strategy for our established brands and leverage our deep local expertise; we look forward to leveraging our strong infrastructure and deep expertise in central nervous system therapies in Japan to bring access to this much needed treatment to patients; and the outcome of clinical trials. 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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