Viatris Files Supplemental New Drug Applications to Japan's Ministry of Health, Labor and Welfare for the Approval of EFFEXOR® for the Treatment of Generalized Anxiety Disorder

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Aiming to address a significant unmet need for which no other approved treatment option is available for generalized anxiety disorder patients in Japan

PITTSBURGH, April 21, 2025 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced it has filed applications to the Ministry of Health, Labor and Welfare (MHLW) for approval of Effexor SR Capsules (venlafaxine hydrochloride), a serotonin-noradrenaline reuptake inhibitor (SNRI) to treat adults with generalized anxiety disorder (GAD), an indication for which no other treatment option is currently approved in Japan.

As previously announced, our Phase 3 placebo-controlled, randomized, double-blind, multicenter study of venlafaxine in patients with GAD conducted in Japan (Study B2411367) 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. These results and results from a long-term extension study of venlafaxine in Japanese outpatients with GAD were included as part of the applications.[1]

"The filing of our supplemental New Drug Applications is a key milestone as we move one step closer to bringing the first available treatment option for generalized anxiety disorder to adults in Japan," said Viatris Chief R&D Officer Philippe Martin. "Positive results from our previously announced Phase 3 efficacy and safety studies laid the foundation for our applications with the MHLW. Effexor for GAD is among a number of novel assets we are advancing through our diversified pipeline to address significant unmet needs."

Patients with GAD can experience persistent, excessive and uncontrollable anxiety or worry about everyday life activities. Other symptoms include difficulty to get enough sleep, muscle tension/stiffness, feeling restless, irritable, or finding it difficult to concentrate, which may impair patients' social, occupational, or other areas of functioning.[2] In Japan, the World Health Organization reports that 2.6% of the population will suffer from GAD in their lifetime.[3] A recent study using a screening tool (GAD-7 ≧ 10) reported the prevalence of probable GAD in Japan is 7.6%.[4] This data suggests that GAD may be significantly underdiagnosed in Japan.

Outside of Japan, selective serotonin reuptake inhibitors (SSRIs) and SNRIs are recommended as first-line drug therapies for patients diagnosed with GAD. EFFEXOR® is currently approved in Japan for the indication of major depressive disorder in adults. EFFEXOR® has also been approved for the indication of GAD in more than 80 countries outside of Japan.

References

[1] Viatris Announces Positive Top-line Results from Phase 3 Study of EFFEXOR® in Japanese Adults with Generalized Anxiety Disorder (GAD)

[2] Takahashi, Saburo et al., supervisor of translation; II. Diagnostic Criteria and Code 5 Anxiety Disorders/Generalized Anxiety Disorder (p242-246): DSM-5-TR Diagnostic and Statistical Manual of Mental Disorders, Igaku-Shoin

[3] Stein DJ, Kazdin AE, Ruscio AM, et al. Perceived helpfulness of treatment for generalized anxiety disorder: a World Mental Health Surveys report. BMC Psychiatry. 2021;21(1):392.

[4] 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 Jun 26;20:1355-1366. doi: 10.2147/NDT.S456272. PMID: 38947368; PMCID: PMC11214750.

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 using a screening tool (GAD-7 ≧ 10) reported the prevalence of probable GAD in Japan is 7.6%.

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 receipt or timing of regulatory approvals; the outcome of clinical trials; the filing of our supplemental New Drug Applications is a key milestone as we move one step closer to bringing the first available treatment option for generalized anxiety disorder to adults in Japan; and Effexor for GAD is among a number of novel assets we are advancing through our diversified pipeline to address significant unmet needs. 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; 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; 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 and matters beyond the control of management, including but not limited to general political and economic conditions, tariffs and trade policies, 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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