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

October 9, 2024

Treatment with once-daily EFFEXOR® met primary and all secondary efficacy endpoints in outpatient adults with GAD

EFFEXOR® was generally well tolerated, consistent with its known safety profile

Pharmaceuticals and Medical Devices Agency (PMDA) submission targeted for 2025

PITTSBURGH and TOKYO, Oct. 9, 2024 /PRNewswire/ -- Viatris Inc. (NASDAQ: VTRS), a global healthcare company, today announced positive top-line results of its Phase 3 study (B2411367) in Japan evaluating the safety and efficacy of EFFEXOR® (venlafaxine) in adults with generalized anxiety disorder (GAD).

The study 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, which confirmed superiority compared to placebo.

In this study, 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).
- Incidence of new suicidal ideation was lower in the EFFEXOR® treatment group than in placebo (2.8% vs 5.1%).
- Commonly observed TEAEs like nausea and somnolence were reported at a lower rate than outside of Japan.

"We are very pleased with these top-line results, which consistently demonstrate the efficacy and safety of EFFEXOR® for the treatment of generalized anxiety disorder in Japanese patients with moderate to severe disease. The benefit-risk profile observed with EFFEXOR® in this study underscores its potential as a meaningful treatment option for patients with GAD in Japan, a condition which currently does not have any approved treatments available," said Viatris Chief R&D Officer Philippe Martin. "This significant life cycle opportunity is yet another proof point of our diversified base business pipeline, which includes more than 70 novel products in development or under regulatory review. Our focused execution of this robust pipeline gives us confidence in our ability to continue to grow our base business and address unmet medical needs."

"Despite generalized anxiety disorder being well-recognized globally, there is a large, general public awareness gap of GAD in Japan. Exacerbating this gap, is the absence of national clinical practice guidelines for treating the disease, signaling a large unmet need in Japan for those living with and treating excessive anxiety and worry," said Sun-A Kim, Country Manager of Viatris Japan. "Viatris Japan remains committed to meeting the needs of patients living with mental health disorders, and we are pleased to see that the results from this study signal the potential of EFFEXOR® to further reach patients as a possible treatment of GAD, for which there are currently no approved therapies in Japan."

Outside of Japan, selective serotonin reuptake inhibitors (SSRIs) and serotonin–norepinephrine reuptake inhibitors (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.

The Company expects to present the full results from this Phase 3 study at a future medical congress.

About Phase 3 Study B2411367
The study was a randomized, double-blind, placebo-controlled, multicenter Phase 3 study that was conducted in Japan to evaluate the efficacy and safety of venlafaxine in 357 Japanese outpatients with GAD based on the Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 diagnostic criteria and assessed with a Hamilton Anxiety Rating Scale (HAM-A) total score ≥ 20.

Patients were randomized equally to a flexible dose of 75-225 mg/day venlafaxine or placebo (once-daily, oral dosing) for an 8-week treatment period. The primary objective of the study was to show superiority over placebo in terms of the anxiolytic effects of venlafaxine, based on the change in the HAM-A total score from baseline at 8 weeks. The secondary objective was to evaluate the safety and tolerability of venlafaxine.

Key secondary endpoints were defined as absolute score/change from baseline at 8 weeks in:

- HAM-A psychic anxiety factor
- HAM-A somatic anxiety factor
- Clinical Global Impressions-Severity of Illness (CGI-S)

- Clinical Global Impressions-Global Improvement (CGI-I)
- Generalized Anxiety Disorder 7 (GAD-7)
- Zung Self-Rating Anxiety Scale (ZSRAS)
- Sheehan Disability Scale (SDISS)

Viatris is also conducting an open-label, multicenter, long-term extension (over 52 weeks) study to evaluate the safety and efficacy of venlafaxine in Japanese outpatients with GAD who completed study B2411367. Results from this study are scheduled to be delivered in 2025.

About Generalized Anxiety Disorder (GAD)
GAD is defined by the World Health Organization as persistent and excessive worry about daily activities or events. An estimated 4% of the global population currently experience an anxiety disorder.[1] GAD is among the most prevalent and highly disabling mental health conditions that negatively impacts patient's quality of life and disrupts activities of daily living.[2]

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; positive top-line results of its Phase 3 study (B2411367) in Japan evaluating the safety and efficacy of EFFEXOR® (venlafaxine) in adults with generalized anxiety disorder (GAD); Pharmaceuticals and Medical Devices Agency (PMDA) submission targeted for 2025; the benefit-risk profile observed with EFFEXOR® in this study underscores its potential as a meaningful treatment option for patients with GAD in Japan, a condition which currently does not have any approved treatments available; this significant life cycle opportunity is yet another proof point of our diversified base business pipeline, which includes more than 70 novel products in development or under regulatory review; our focused execution of this robust pipeline gives us confidence in our ability to continue to grow our base business and address unmet medical needs; the Company expects to present the full results from this Phase 3 study at a future medical congress; Viatris is also conducting an open-label, multicenter, long-term extension (over 52 weeks) study to evaluate the safety and efficacy of venlafaxine in Japanese outpatients with generalized anxiety disorder who completed study B2411367 and results from this study are scheduled to be delivered in 2025. 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; 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, including but not limited to "at-risk" launches; 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; the possibility that Viatris may be unable to realize the intended benefits of, or achieve the intended goals or outlooks with respect to, its strategic initiatives; the possibility that Viatris may be unable to achieve intended or expected benefits, goals, outlooks, synergies, growth opportunities and operating efficiencies in connection with divestitures, acquisitions, other transactions or restructuring programs, within the expected timeframes or at all; goodwill or impairment charges or other losses related to the divestiture or sale of businesses or assets; Viatris' failure to achieve expected or targeted future financial and operating performance and results; the potential impact of public health outbreaks, epidemics and pandemics; any significant breach of data security or data privacy or disruptions to our information technology systems; risks associated with international operations; the ability to protect intellectual property and preserve intellectual property rights; 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 general economic conditions, inflation and exchange rates; failure to execute stock repurchases consistent with current expectations; stock price volatility; 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.

References

1. World Health Organization. Anxiety Disorders Fact Sheet. 27 Sept. 2023, www.who.int/news-room/fact-sheets/detail/anxiety-disorders.
2. 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.

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