Viatris Announces Approval of WAKIX® (Pitolisant) in Japan, a First-in-Class Treatment for Narcolepsy and Excessive Daytime Sleepiness Associated With Obstructive Sleep Apnea Syndrome

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Approval Addresses High Unmet Medical Need and Further Advances Viatris' Innovative Portfolio in Japan

PITTSBURGH, Sept. 16, 2026 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced that Japan's Ministry of Health, Labour and Welfare has granted approval for WAKIX® (pitolisant) for the treatment of excessive daytime sleepiness (EDS) associated with obstructive sleep apnea syndrome (OSAS) in patients receiving treatment for airway obstruction, and approval for narcolepsy (type 1 and 2 – with and without cataplexy). WAKIX is the first histamine H3 receptor antagonist/inverse agonist approved in Japan for these indications.

"As Japan's first approved histamine H3 receptor antagonist/inverse agonist for these conditions, WAKIX offers a much-needed novel treatment option for patients," said Philippe Martin, Viatris Chief R&D Officer. "This milestone marks an important advancement for sleep medicine in Japan and brings forward a treatment option that is not classified as a controlled substance. We continue to strengthen Viatris' innovative medicines portfolio in this strategically important market by investing in differentiated therapies for patients."

EDS is a shared and clinically significant symptom of both OSAS and narcolepsy and remains an area of unmet medical need in Japan. In patients with OSAS, EDS can adversely affect daily functioning, work productivity, and quality of life and may persist despite treatment of airway obstruction. Narcolepsy is a chronic neurological disorder characterized by EDS and an impaired ability to maintain wakefulness. The condition can also have a significant impact on patients' daily lives and is often associated with delays in diagnosis. Narcolepsy includes both type 1, which is associated with cataplexy (sudden muscle weakness), and type 2, which is not associated with cataplexy.

The approval of Viatris' WAKIX was supported by positive data from domestic Phase 3 clinical trials in Japan as well as multiple international clinical studies evaluating WAKIX in patients with narcolepsy and patients with OSAS experiencing EDS despite treatment with continuous positive airway pressure (CPAP) therapy.

About WAKIX (Pitolisant)
WAKIX (pitolisant) is an orally administered histamine H3 receptor antagonist/inverse agonist that modulates the brain's sleep–wake pathways. WAKIX is licensed to Viatris for the Japan market only. WAKIX was discovered by Bioprojet (Paris, France) and has previously received approvals for narcolepsy in more than 38 countries, including the United States and countries across Europe, and for OSAS-related excessive daytime sleepiness in more than 29 European countries. WAKIX is not classified as a controlled substance and has been designated as an orphan drug in Japan for narcolepsy.

WAKIX is a registered trademark of Bioprojet Europe, Ltd., licensed to Viatris.

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.

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 approval of WAKIX® (Pitolisant) in Japan, a first-in-class treatment for narcolepsy and excessive daytime sleepiness associated with obstructive sleep apnea syndrome; approval addresses high unmet medical need and further advances Viatris' innovative portfolio in Japan; as Japan's first approved histamine H3 receptor antagonist/inverse agonist for these conditions, WAKIX offers a much-needed novel treatment option for patients; this milestone marks an important advancement for sleep medicine in Japan and brings forward a treatment option that is not classified as a controlled substance; we continue to strengthen Viatris' innovative medicines portfolio in this strategically important market by investing in differentiated therapies for patients. 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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