Vanda Pharmaceuticals Announces FDA Approval of NEREUS™ (tradipitant) for the Prevention of Vomiting Induced by Motion: A Historic Scientific Milestone in the Prevention of Motion Sickness

December 30, 2025

WASHINGTON, Dec. 30, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that the U.S. Food and Drug Administration (FDA) has approved NEREUS™ (tradipitant), an oral neurokinin-1 (NK-1) receptor antagonist, for the prevention of vomiting induced by motion. This approval marks the first new pharmacologic treatment in motion sickness in over four decades, representing a significant advancement in the understanding and management of this debilitating physiologic response that affects a substantial portion of the population and has long been recognized as a factor affecting military operational readiness.

"This approval underscores the strong scientific evidence in the antiemetic effects of NEREUS™ in motion sickness," said Mihael H. Polymeropoulos, M.D., President, CEO and Chairman of the Board of Vanda Pharmaceuticals. "For the first time in over 40 years, patients have access to a novel therapy grounded in modern neuropharmacology, offering effective prevention without the limitations of existing options. We are proud of this historic milestone and grateful to the Vanda researchers, patients, investigators, and regulators who contributed to this achievement."

The efficacy of NEREUS™ is supported by robust data from three pivotal clinical trials—two Phase 3 real-world provocation studies conducted or boats (Motion Syros and Motion Serifos) and one additional supporting study—with participants who had documented histories of motion sickness. In Motion Syros (n=365), vomiting incidence was 18.3–19.5% with NEREUS™ versus 44.3% with placebo ($p<0.0001$).[1] In Motion Serifos (n=316), vomiting rates were 10.4–18.3% with NEREUS™ versus 37.7% with placebo ($p\leq0.0014$), representing risk reductions of over 50–70%.[2] Across the pivotal program, NEREUS™ consistently demonstrated significant reductions in vomiting and a favorable safety profile consistent with acute use.

Motion sickness has been recognized as a critical factor in military operations since World War II, most notably during the D-Day invasion of Normandy in 1944, where severe seasickness impaired the effectiveness of troops, including paratroopers of the 101st Airborne Division deployed in rough Channel crossings and airborne drops. The condition was elevated to a strategic imperative, prompting early research into antiemetic therapies to ensure operational readiness during large-scale troop deployments by sea, air, and land.

Today, motion sickness remains prevalent in civilian life, with approximately 25–30% of adults[3] —roughly 65–78 million people in the U.S.—experiencing symptoms during common travel modes such as cars, planes, or boats. Globally, up to one-third of individuals are highly susceptible.[4] While most cases are mild, an estimated 5–15% of the population experiences severe, recurrent symptoms that can significantly impact quality of life. This severe segment comprises two key groups: those whose illness is inadequately controlled by existing therapeutic options, leaving them with persistent debilitating symptoms despite treatment, and those whose illness is so severe that it leads to avoidance of engaging in motion-provoking activities altogether, resulting in altered travel plans, missed opportunities, or complete abstention from certain modes of transportation or experiences. Tens of millions seek pharmacologic treatment annually, primarily through over-the-counter options, though many patients opt for prescription therapies when escalating care. Motion sickness arises from a sensory conflict between visual, vestibular, and proprioceptive inputs, triggering the release of substance P and activation of NK-1 receptors in the central nervous system, leading to nausea and vomiting. NEREUS™'s mechanism of action—potent and selective antagonism of NK-1 receptors—directly addresses this pathway.

The approval of NEREUS™ for the prevention of vomiting induced by motion validates its pharmacological profile and paves the way for further exploration of NK-1 antagonism in related vomit-inducing conditions. Vanda is advancing tradipitant in clinical development for gastroparesis, a chronic disorder characterized by delayed gastric emptying and persistent nausea/vomiting, as well as for the prevention of nausea and vomiting induced by GLP-1 receptor agonists—a common side effect impacting adherence in the rapidly growing obesity and diabetes treatment landscape.

Vanda anticipates launching NEREUS™ for the prevention of vomiting induced by motion in the coming months and remains committed to expanding its therapeutic potential across indications driven by substance P-mediated pathways.

References

1. Polymeropoulos VM, Kiely L, Bushman ML, Sutherland EB, Goldberg AR, Pham AX, Miller CR, Mourad R, Davis TR, Pham NV, Morgan DB, Giles AK, Xiao C, Polymeropoulos CM, Birznieks G, Polymeropoulos MH. Motion Syros: tradipitant effective in the treatment of motion sickness; a multicenter, randomized, double-blind, placebo-controlled study. Front Neurol. 2025 Mar 4;16:1550670. doi: 10.3389/fneur.2025.1550670. PMID: 40103934; PMCID: PMC11913704, available here.
2. Vanda Pharmaceuticals Inc., "*Vanda Pharmaceuticals Reports Positive Results from a Second Phase III Study of Tradipitant in Motion Sickness*" [Press Release], May 16, 2024, available here.
3. Turner M, Griffin MJ. Motion sickness in public road transport: passenger behavior and susceptibility. Ergonomics. 1999: 42: 444-461, available here.
4. Golding, J. F. (2016). "Motion sickness". *Neuro-Otology*. Handbook of Clinical Neurology. Vol. 137. pp. 371–390. doi:10.1016/B978-0-444-63437-5.00027-3. ISBN 978-0-444-63437-5. ISSN 0072-9752. PMID 27638085, available here.

About Vanda Pharmaceuticals Inc.

Vanda is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com and follow us on X @vandapharma.

About NEREUS™

NEREUS™ (tradipitant) is a neurokinin-1 receptor antagonist licensed by Vanda from Eli Lilly and Company. NEREUS™ is approved for the acute prevention of vomiting induced by motion in adults, and is currently in clinical development for a variety of indications, including gastroparesis and the

prevention of nausea and vomiting induced by GLP-1 receptor agonists.

INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

NEREUS™ is a substance P/neurokinin-1 (NK-1) receptor antagonist indicated for the prevention of vomiting induced by motion in adults.

Important Safety Information

In placebo-controlled clinical trials, somnolence (6%, 12%) and fatigue (6%, 8%) were adverse reactions reported in subjects who took a single dose of 85 mg or 170 mg NEREUS™, respectively. NEREUS™ may impair the mental and/or physical abilities required for driving a motor vehicle or operating heavy machinery. Concomitant use of other drugs that cause central nervous system depression and strong CYP3A4 inhibitors may increase this effect. If concomitant use is unavoidable, warn patients against driving and other activities requiring complete mental alertness.

Available data from clinical trials with NEREUS™ use in pregnant women are insufficient to inform a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.

Lactation studies have not been conducted to assess the presence of tradipitant or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Tradipitant has been found to be present in rat milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Monitor breastfed infants for somnolence.

The safety and effectiveness of NEREUS™ have not been established in pediatric patients.

Tradipitant has not been studied in subjects with severe renal impairment (eGFR ≤ 29 mL/min/1.73m2). Avoid use of NEREUS™ in patients with severe renal impairment.

Tradipitant has not been studied in patients with any degree of hepatic impairment (Child-Pugh Class A to C). Avoid NEREUS™ in patients with mild, moderate, or severe hepatic impairment.

CONTRAINDICATIONS

None.

DRUG INTERACTIONS

Tradipitant is a CYP3A4 substrate. Strong CYP3A4 inhibitors may increase tradipitant exposure, which may increase the risk of adverse reactions to NEREUS™.

Full Nereus™ Prescribing Information can be found at https://www.nereus.us.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding patient access to NEREUS™, the prevalence of motion sickness, Vanda's further clinical development plans for NEREUS™, Vanda's commercial launch plans for NEREUS™ and the timing thereof, and Vanda's plans to expand the therapeutic potential of NEREUS™ across additional indications driven by substance P-mediated pathways are "forward-looking statements" under the securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others, Vanda's ability to successfully execute the commercial launch of NEREUS™ in the coming months, the accuracy of the estimates of the prevalence of motion sickness, Vanda's ability to continue to advance tradipitant in gastroparesis and the prevention of nausea and vomiting induced by GLP-1 receptor agonists, and Vanda's ability to develop NEREUS™ as a safe and effective treatment for additional indications driven by substance P-mediated pathways. Therefore, no assurance can be given that the results or developments anticipated by Vanda will be realized, or even if substantially realized, that they will have the expected consequences to, or effects on, Vanda. Forward-looking statements in this press release should be evaluated together with the various risks and uncertainties that affect Vanda's business and market, particularly those identified in the "Cautionary Note Regarding Forward-Looking Statements", "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's most recent Annual Report on Form 10-K, as updated by Vanda's subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

All written and verbal forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda makes or that are made on its behalf. The information in this press release is provided only as of the date of this press release, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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