Vanda Pharmaceuticals Announces Positive Results from Study 3601 of NEREUS™ (tradipitant) for Prevention of GLP-1-Induced Vomiting

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NEREUS™ significantly reduced semaglutide induced vomiting including frequent multi-day and extreme vomiting

Key Results

- **Any vomiting** (primary) 43.0% (61/142) vs 58.5% (96/164) placebo (p=0.006); 27% relative reduction
- **Vomiting + severe nausea** (key secondary): 33.1% (47/142) vs 50.6% (83/164) (p=0.002); 35% relative reduction
- **Frequent multi-day vomiting** (>2 episodes on more than one day): 6.3% (9/142) vs 15.9% (26/164) (p=0.008); 60% relative reduction
- **Extreme vomiting** (>10 total episodes): 2.8% (4/142) vs 14.6% (24/164) (p=0.0003); 81% relative reduction

WASHINGTON, Oct. 27, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Nasdaq: VNDA) today announced positive results from Study 3601 (VP-VLY-686-3601), a Phase III randomized, placebo-controlled study evaluating NEREUS™ (tradipitant), an oral neurokinin-1 (NK-1) receptor antagonist, for the prevention of vomiting associated with GLP-1 receptor agonist therapy. The study showed significant reduction in overall vomiting episodes (27% p=0.006 as well as reduction of frequent (60% p=0.008) and extreme vomiting (81% p=0.0003) episodes.

Based on the totality of data from the Phase II and Phase III programs, Vanda intends to discuss the results with the U.S. Food and Drug Administration (FDA) and is planning a supplemental New Drug Application (sNDA) to support the use of NEREUS™ for the prevention of vomiting associated with GLP-1 receptor agonist therapy.

Primary Endpoint (any vomiting)
NEREUS™ reduced the incidence of any vomiting. Vomiting occurred in 43.0% of NEREUS™-treated participants (61/142) compared with 58.5% on placebo (96/164) (p=0.006, adjusted for site), a 27% relative reduction.

Key Secondary Endpoint (severe nausea and vomiting)
The key secondary endpoint of any vomiting together with worst nausea ≥3 occurred in 33.1% of participants on NEREUS™ (47/142) versus 50.6% on placebo (83/164) (p=0.002, adjusted for site), a 35% relative reduction.

Higher-Burden Vomiting
Exploratory analyses examined higher-intensity vomiting patterns. The proportion of participants with frequent vomiting—defined as more than 2 episodes on more than one day—was 6.3% with NEREUS™ versus 15.9% with placebo (p=0.008, site-adjusted), a 60% relative reduction. The proportion with extreme vomiting (greater than 10 total episodes) was 2.8% with NEREUS™ versus 14.6% with placebo (p=0.0003, site-adjusted), corresponding to an 81% relative reduction. These analyses are post hoc and are presented as supportive evidence of a reduction in higher-burden vomiting. A similar approximately 80% relative reduction in extreme vomiting was observed in the Phase II study.

Time Course
Almost all vomiting episodes in either group occurred by Day 2. Vomiting rates peaked on Day 1, and the absolute separation between NEREUS™ and placebo was greatest on Days 1 and 2. After Day 2, few additional participants began vomiting. These observations indicate that early prevention —dosing prior to initiation or dose escalation and in the first days after dosing of the GLP-1 analog—is the most impactful window for reducing vomiting.

Study Design and Dosing

The Phase III study tested NEREUS™ under conditions that produce a high rate of vomiting. Participants received a single 1 mg dose of semaglutide without the gradual titration used in clinical practice. This design provides a rigorous test of prevention when the emetogenic stimulus is strong. A pooled exposure–response analysis of the Phase 2 and Phase 3 data showed that the reduction in vomiting probability with NEREUS™ remained stable across the observed semaglutide concentration range, with no evidence that the treatment effect diminished at lower exposures, supporting extrapolation of the effect to real-world dosing of semaglutide.

Mechanism of Action
NEREUS™ is an NK-1 receptor antagonist that acts at the vomiting center, including the area postrema (AP) and nucleus tractus solitarius (NTS). By blocking substance P signaling in these central pathways, NEREUS™ is expected to be applicable across all available GLP-1 receptor agonist therapies.

The Problem and Market Context
Nausea and vomiting are among the most common reasons patients discontinue or fail to reach therapeutic doses of GLP-1 receptor agonists.[1,2,3,4] Real-world studies show that roughly half of patients discontinue GLP-1 therapy within one year, with gastrointestinal side effects among the leading reasons.[1] The global GLP-1 receptor agonist market exceeds $50 billion and continues to expand.[5] Improving tolerability could enable more patients to initiate and remain on therapy.

Next Steps
Vanda plans to discuss the results with the FDA and intends to submit an sNDA for NEREUS™ for the prevention of vomiting associated with GLP-1 receptor agonist therapy.

Safety
NEREUS™ was generally well tolerated, with a safety profile consistent with previous studies. No new safety signals were observed.

"These results demonstrate that NEREUS can meaningfully reduce vomiting and frequent multi-day vomiting induced by GLP-1 therapy, which are key contributors to treatment discontinuation," said Dr. Mihael H. Polymeropoulos, President, CEO and Chairman of the Board of Vanda. "The consistency and magnitude of the effects observed across this program could offer significant benefit to the millions of people seeking or using GLP1 therapies."

About NEREUS™
NEREUS™ (tradipitant) is an oral NK-1 receptor antagonist approved in December of 2025 for the prevention of motion-induced vomiting.

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.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including but not limited to statements regarding the therapeutic potential of NEREUS™; the estimates of patient discontinuation rates and the size and projected growth of the GLP-1 receptor agonist market; the possibility that NEREUS™ could improve patient adherence and broaden utilization of GLP-1 therapies; Vanda's plans and expectations regarding the regulatory path for NEREUS™ for the treatment of GLP-1-induced nausea and vomiting; and Vanda's commercial plans for NEREUS™ for this indication 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, the ability of NEREUS™ to mitigate nausea and vomiting in patients being treated with GLP-1 therapies across all available GLP-1 receptor agonist therapies; the accuracy of the estimates of patient discontinuation rates and the size and growth of the GLP-1 receptor agonist market; the ability of NEREUS™ to improve patient adherence and drive broader utilization of GLP-1 therapies; the sufficiency of the clinical trial data to support the filing of an sNDA for NEREUS™ for this indication; the FDA's willingness to meet with Vanda to discuss and provide feedback on Vanda's proposed sNDA submission during 2027; Vanda's ability to gain alignment with the FDA on the regulatory path for NEREUS™ and to obtain FDA approval of NEREUS™ for the treatment of GLP-1-induced nausea and vomiting; Vanda's ability to use the currently approved NEREUS™ product for this indication, if approved; and the ability of Vanda's existing commercial infrastructure to support the commercialization of NEREUS™ for this indication. 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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