



Vanda Pharmaceuticals Reports Positive Results for Tradipitant in Preventing GLP-1 Induced Nausea and Vomiting

November 17, 2025

Vanda's Tradipitant Study Success Positions it as Key Adjunct in \$50B+ Global GLP-1 Agonist Market

WASHINGTON, Nov. 17, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA), a leading biopharmaceutical company focused on the development and commercialization of innovative therapies, today announced positive topline results from its randomized controlled clinical study (VP-VLY-686-2601) evaluating tradipitant, an oral neurokinin-1 (NK-1) receptor antagonist, for the prevention of nausea and vomiting induced by GLP-1 receptor agonist Wegovy® in overweight and obese adults.

This study, which pre-treated patients with either tradipitant or placebo before administering a 1 mg injection of Wegovy®, a dose that normally takes 9 weeks of titration to reach, succeeded and met its primary endpoint, with only 29.3% of tradipitant-treated participants (17/58) experiencing vomiting compared to 58.6% on placebo (34/58) (p=0.0016), representing a 50% relative reduction. The study also met the key secondary endpoint of the proportion of participants with vomiting and significant nausea at 22.4% in the tradipitant group (13/58) versus 48.3% on placebo (28/58) (p=0.0039).

Tradipitant demonstrated a favorable safety profile consistent with previous studies with no new safety signals observed.

| Endpoint | Placebo (N=58) | Tradipitant (N=58) | P-value |
|---|----------------|--------------------|---------|
| Proportion with vomiting* | 58.6% (34/58) | 29.3% (17/58) | 0.0016 |
| Proportion with vomiting and worst nausea $\geq 3^{**}$ | 48.3% (28/58) | 22.4% (13/58) | 0.0039 |

*Primary endpoint

**Key secondary endpoint, nausea of ≥ 3 denotes moderate or worse on a 0-5 point scale of severity

"These results demonstrate tradipitant's potential to mitigate GLP-1 induced nausea and vomiting which are key contributors of the 30-50% real-world discontinuation rates for GLP-1 agonists, often before therapeutic doses are reached," said Mihael H. Polymeropoulos, M.D., President, CEO and Chairman of Vanda. "Tradipitant's effect in reducing nausea and vomiting could significantly improve GLP-1 agonist adherence enabling more people to receive the full therapeutic benefit."^{1,2,5}

The observed efficacy is consistent with tradipitant's demonstrated performance in motion sickness in multiple studies, where it reduced vomiting by more than 50% in randomized studies with over 800 individuals. These results position tradipitant as a potentially transformative adjunct in the rapidly expanding global GLP-1 agonist market, which is currently greater than \$50 billion through the first nine months of 2025.^{3,4}

Early discontinuations due to gastrointestinal side effects impose substantial costs on patients and payors. Patients forgo meaningful weight loss (15-20% with sustained use) and reductions in complications like diabetes progression and cardiovascular events, diminishing health outcomes. Payors face wasted spending on unused prescriptions without benefits, plus ongoing costs from unmanaged obesity, including hospitalizations.

The randomized, double-blind, placebo controlled trial studied 116 healthy overweight or obese adults (BMI 25-40 kg/m²) without prior GLP-1 agonist experience. Participants were injected with 1 mg Wegovy®, a dose that normally takes 9 weeks of titration to reach under current prescribing guidelines. Participants were pretreated with tradipitant 85 mg twice daily or placebo for 1 week, followed by 1 week of continued treatment post-dosing. Outcomes were measured using daily patient-reported assessments.

Vanda will evaluate an efficient development path towards obtaining regulatory approval for this unmet need. A Phase III program is anticipated to initiate in the first half of 2026, positioning tradipitant as a key adjunct to improve outcomes in GLP-1 agonist treatments.

References

1. Blue Health Intelligence. (2024, May). Real-world trends in GLP-1 treatment persistence and prescribing for weight management [Issue brief]. Blue Cross Blue Shield Association. https://www.bcbs.com/media/pdf/BHI_Issue_Brief_GLP1_Trends.pdf
2. Samuels JM, Ye F, Irlmeier R, Silver H, Srivastava G, Spann M. Real-world titration, persistence & weight loss of semaglutide and tirzepatide in an academic obesity clinic. *Diabetes Obes Metab*. 2025 Nov;27(11):6200-6209. doi: 10.1111/dom.70004. Epub 2025 Aug 5. PMID: 40762026; PMCID: PMC12515774.
3. Eli Lilly and Company. (2025, October 30). Lilly reports third-quarter 2025 financial results, highlights R&D pipeline momentum and raises 2025 guidance [Press release]. PR Newswire. <https://investor.lilly.com/news-releases/news-release-details/lilly-reports-third-quarter-2025-financial-results-highlights-rd>
4. Novo Nordisk A/S. (2025, November 5). Financial results for the third quarter of 2025 [Press release]. Novo Nordisk Investor Relations. <https://www.novonordisk.com/investors/financial-results.html>
5. Rodriguez PJ, Zhang V, Gratzl S, et al. Discontinuation and Reinitiation of Dual-Labeled GLP-1 Receptor Agonists Among US Adults With Overweight or Obesity. *JAMA Netw Open*. 2025;8(1):e2457349. doi:10.1001/jamanetworkopen.2024.57349

About Tradipitant

Tradipitant is a neurokinin-1 receptor antagonist licensed by Vanda from Eli Lilly and Company. Tradipitant is currently in clinical development for gastroparesis and GLP-1 induced nausea and vomiting. It is also under review by the U.S. Food and Drug Administration (FDA) for motion sickness with a Prescription Drug User Fee Act (PDUFA) target action date of December 30, 2025.

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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including but not limited to statements regarding the therapeutic potential of tradipitant in the GLP-1 agonist market, the possibility that tradipitant could significantly improve patient adherence, the estimates of patient discontinuation rates and the size and projected growth of the GLP-1 agonist market, Vanda's plans to evaluate an efficient development path to regulatory approval for tradipitant, and Vanda's further clinical development plans for tradipitant 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 tradipitant to mitigate GLP-1 induced nausea and vomiting, the ability of tradipitant to significantly improve patient adherence and allow patients to receive the full therapeutic benefit of the GLP-1 agonist, the accuracy of the estimates of patient discontinuation rates and the size and projected growth of the GLP-1 agonist market, and Vanda's ability to identify an efficient development path for tradipitant, initiate a Phase III program in the first half of 2026, complete the clinical development and obtain FDA approval of tradipitant for the prevention of GLP-1 induced nausea and vomiting. 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.

Corporate Contact:

Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

Jim Golden / Jack Kelleher / Dan Moore
Collected Strategies
VANDA-CS@collectedstrategies.com

Follow us on X @vandapharma

 View original content to download multimedia: <https://www.prnewswire.com/news-releases/vanda-pharmaceuticals-reports-positive-results-for-tradipitant-in-preventing-glp-1-induced-nausea-and-vomiting-302617739.html>

SOURCE Vanda Pharmaceuticals Inc.