Vanda Pharmaceuticals Announces Initiation of The Thetis Study, a Clinical Trial of NEREUS™ for the Prevention of Vomiting Induced by GLP-1 Receptor Agonists

April 8, 2026

WASHINGTON, April 8, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced the initiation of Thetis, a clinical trial evaluating NEREUS™ (tradipitant) for the prevention of vomiting in patients receiving glucagon-like peptide-1 (GLP-1) receptor agonist therapies. NEREUS™ was recently approved for the prevention of vomiting induced by motion[1].

GLP-1 receptor agonists, including semaglutide and tirzepatide, have transformed the treatment of type 2 diabetes and obesity. However, gastrointestinal side effects, particularly nausea and vomiting, remain a significant challenge for many patients and are a leading cause of treatment discontinuation or dose reduction. Recent studies and approvals in the GLP-1 space further underscore this. Last month, a "high dose" of Wegovy was approved by the U.S. Food and Drug Administration (FDA) on the basis of providing additional weight-loss benefits, yet it comes with the tradeoff that the top two reported adverse effects of nausea and vomiting for this high dose are of increased frequency compared to the previously approved Wegovy maximum dose.[2]

"GLP-1 receptor agonists offer significant benefits, but vomiting and nausea can severely impact patient adherence and quality of life," said Mihael H. Polymeropoulos, M.D., President CEO and Chairman of the Board of Vanda Pharmaceuticals. "NEREUS™ has demonstrated potent antiemetic effects in prior clinical studies. We are excited to advance this program, which has the potential to improve tolerability and allow more patients to fully benefit from these important therapies."

The Thetis study is a multicenter, randomized, double-blind, placebo-controlled trial that will evaluate the efficacy and safety of oral tradipitant in patients initiated at a high dose of a GLP-1 receptor agonist. The primary endpoint is the proportion of patients free from vomiting episodes during the treatment period.

The Phase 2 study, as previously announced in Vanda's press release dated November 15, 2025, was similar in design where patients were pre-treated with either tradipitant or placebo before administering a 1 mg injection of Wegovy®, a dose that normally takes 9 weeks of titration to reach. The phase 2 study 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).[3]

Vanda expects topline results from the Thetis study by Q4 2026. Following completion of the Thetis study, additional study data may be required prior to approval of a New Drug Application (NDA).

References

1. *See* full U.S. NEREUS Prescribing Information, available at: www.nereus.us.
2. *See* full U.S. Wegovy Prescribing Information, available at: https://www.novo-pi.com/wegovy.pdf.
3. *See* Vanda Pharmaceuticals Reports Positive Results for Tradipitant in Preventing GLP-1 Induced Nausea and Vomiting, available at: https://www.prnewswire.com/news-releases/vanda-pharmaceuticals-reports-positive-results-for-tradipitant-in-preventing-glp-1-induced-nausea-and-vomiting-302617739.html.

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

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 design, objectives and potential outcomes of the Thetis clinical trial; the potential benefits, effectiveness and safety of NEREUS™ (tradipitant) for the prevention of vomiting in patients receiving GLP-1 receptor agonist therapies; the significance of results from prior clinical studies; the expected timing of topline results from the Thetis study; and the risk that additional study data may be required prior to approval of an NDA, are "forward-looking statements" within the meaning of 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 on 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, risks inherent in clinical development, including the risk that the Thetis trial may not demonstrate efficacy or safety consistent with prior studies, may not meet its primary or secondary endpoints, or may experience delays; variability in patient response to therapy; regulatory considerations affecting the development of NEREUS™ for additional indications; and the risk that additional study data may be required prior to approval of an NDA. 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 risks and uncertainties

described in the sections titled "Cautionary Note Regarding Forward-Looking Statements," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in 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 forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements set forth herein. Vanda cautions investors not to place undue reliance on forward-looking statements. The information contained in this press release is provided as of the date hereof, and Vanda undertakes no obligation, and expressly disclaims any obligation, to update or revise 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-announces-initiation-of-the-thetis-study-a-clinical-trial-of-nereus-for-the-prevention-of-vomiting-induced-by-glp-1-receptor-agonists-302737472.html

SOURCE Vanda Pharmaceuticals Inc.