FDA Lifts Partial Clinical Hold on Tradipitant for Motion Sickness

December 4, 2025

WASHINGTON, Dec. 4, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Nasdaq: VNDA) today announced that the U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold on protocol VP-VLY-686-3403, which until today limited the protocol to a maximum of 90 doses of tradipitant.

The lift followed Vanda's formal dispute resolution request and an expedited re-review conducted by CDER leadership under the collaborative framework established between Vanda and the FDA in October 2025.

The FDA agreed with Vanda's position that motion sickness is an acute, self-limiting physiologic response rather than a chronic or chronic-intermittent condition. The Agency therefore concluded that the use of tradipitant in motion sickness represents an acute, event-driven therapy, eliminating the need for an additional six-month dog toxicity study and rendering the partial clinical hold unnecessary.

This decision allows Vanda to extend clinical studies of tradipitant in motion sickness. Separately, the ongoing review of the pending, fully completed New Drug Application for tradipitant for the prevention of vomiting induced by motion remains on track, with a PDUFA target action date of December 30, 2025, positioning tradipitant as potentially the first new pharmacologic treatment for motion sickness in over 40 years.

"The swift and favorable resolution of this issue highlights the effectiveness of our collaborative framework with the FDA," said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda. "We thank the Agency for its thorough and expedited scientific review and look forward to continued constructive dialogue."

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 Tradipitant

Tradipitant is a neurokinin-1 receptor antagonist licensed by Vanda from Eli Lilly and Company. Tradipitant is currently in clinical development for a variety of indications, including gastroparesis, motion sickness, and the prevention of nausea and vomiting induced by GLP-1 receptor agonists.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding Vanda's further clinical development plans for tradipitant, Vanda's pursuit of FDA approval of tradipitant for the prevention of vomiting induced by motion, the potential commercialization of tradipitant for such indication, and Vanda's future interactions with the FDA 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 FDA's ability to complete its review of the NDA for tradipitant for the prevention of vomiting induced by motion by December 30, 2025, the FDA's assessment of the evidence supporting the safety and efficacy of tradipitant for the prevention of vomiting induced by motion, and the ability of the FDA and Vanda to continue to work together collaboratively. 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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