Vanda Pharmaceuticals Provides Regulatory Update on Tradipitant for Motion Sickness

November 28, 2025

- *FDA requests, and Vanda agrees to, a brief extension (to December 5, 2025) for the expedited re-review of the partial clinical hold on long-term studies*
- *Separately, FDA recently issued labeling comments, and labeling discussions have formally begun for the New Drug Application of tradipitant for the prevention of vomiting induced by motion (PDUFA target action date remains December 30, 2025)*

WASHINGTON, Nov. 28, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA), today announced the following updates regarding tradipitant for motion sickness:

Partial Clinical Hold Re-Review Timeline

Under the collaborative framework announced on October 1, 2025, the U.S. Food and Drug Administration (FDA) is conducting an expedited re-review of the partial clinical hold that currently restricts long-term clinical studies of tradipitant in motion sickness. The original target completion date was November 26, 2025. At the FDA's request, and with Vanda's agreement, the target completion date has been extended to December 5, 2025 to accommodate recent personnel and leadership transitions within the Center for Drug Evaluation and Research (CDER). All other provisions of the collaborative framework remain unchanged.

New Drug Application (NDA) Progress

Separately, review of the NDA for tradipitant for the prevention of vomiting induced by motion continues according to schedule, with an unchanged PDUFA target action date of December 30, 2025. The FDA has recently issued comments on the proposed labeling, and labeling discussions between the FDA and Vanda have now formally commenced. Vanda looks forward to potentially delivering the first new pharmacologic treatment for motion sickness in over four decades.

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 the FDA's re-review of the partial clinical hold on tradipitant, the FDA's continuing review of the tradipitant NDA and the related timeline, the status of the label for tradipitant for the treatment of motion sickness, and the potential commercialization of tradipitant for such 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 FDA's ability to complete its re-review of the partial clinical hold on tradipitant by December 5, 2025, the FDA's ability to complete its review of the NDA for tradipitant for the treatment of motion sickness by December 30, 2025, the outcome of the labeling discussions between Vanda and the FDA, and the FDA's assessment of the evidence supporting the safety and efficacy of tradipitant for the treatment of motion sickness. 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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