Vanda Announces FDA Grants Landmark Hearing for HETLIOZ® in Jet Lag Disorder, the First Drug Approval Hearing in Over 40 Years

March 3, 2026

WASHINGTON, March 3, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that the U.S. Food and Drug Administration (FDA) has granted the company's request for a formal evidentiary public hearing to review the Center for Drug Evaluation and Research's (CDER) proposal to refuse approval of Vanda's supplemental new drug application (sNDA) for HETLIOZ® (tasimelteon) in the treatment of jet lag disorder.

The FDA confirmed the decision to grant a hearing in a letter from the Office of the Commissioner dated March 2, 2026. The hearing will proceed under 21 CFR Part 12, after which the presiding officer will issue an initial decision pursuant to 21 CFR § 12.120.

Granting a formal evidentiary public hearing in response to a proposed refusal to approve a drug application is a rare and highly significant regulatory step. Publicly available records and historical accounts indicate that the FDA has not granted such a hearing under 21 CFR Part 12 in the context of drug approvals for decades—potentially over 40 years—underscoring the gravity of the legal and scientific issues raised by Vanda.

"We are encouraged by the FDA's decision to grant a formal evidentiary hearing on the proposed refusal of our jet lag application for HETLIOZ®," said Mihael H. Polymeropoulos, M.D., President, Chief Executive Officer, and Chairman of the Board of Vanda Pharmaceuticals. "This procedural victory reflects Vanda's 7-year persistence in advocating for fairness and the rigorous pursuit of scientific truth on behalf of patients. At the same time, it represents a significant reform step by the FDA toward greater transparency—the first such formal drug approval hearing in over 40 years."

This development follows Vanda's prior success in *Vanda Pharmaceuticals Inc. v. FDA*, case no. 24-1049, before the U.S. Court of Appeals for the D.C. Circuit. In August 2025, the court set aside the FDA's earlier refusal to approve HETLIOZ® for jet lag disorder. The ruling held that the FDA unlawfully failed to adequately engage with Vanda's evidence—despite statistically significant results from clinical trials—and criticized the agency's cursory treatment of expert, evidence-based submissions. The court remanded the matter, directing the FDA to finally resolve Vanda's sNDA or commence a hearing.

HETLIOZ® is currently approved in the United States for Non-24-Hour Sleep-Wake Disorder and nighttime sleep disturbances associated with Smith-Magenis syndrome. The pending sNDA seeks to expand approval to treat jet lag disorder, a condition that affects millions of travelers worldwide — including business travelers, athletes, and rapidly deployed troops — for which there is currently no FDA-approved therapeutic.

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 HETLIOZ®

HETLIOZ® (tasimelteon) is a melatonin-receptor agonist, approved in the United States for the treatment of Non-24-Hour Sleep-Wake Disorder and nighttime sleep disturbances associated with Smith-Magenis Syndrome. For full U.S. Prescribing Information for HETLIOZ®, including indications and Important Safety Information, visit www.hetlioz.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding the upcoming formal evidentiary hearing, 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 outcome of the formal evidentiary hearing. 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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