Vanda Pharmaceuticals Announces Receipt of FDA Decision Letter on HETLIOZ® Supplemental New Drug Application for Jet Lag Disorder

January 8, 2026

WASHINGTON, Jan. 8, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that it has received a decision letter from the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) concluding that the supplemental New Drug Application (sNDA) for HETLIOZ® (tasimelteon) for the treatment of jet lag disorder cannot be approved in its current form. This letter stems from CDER's agreed re-review of the jet lag application under the October 1 collaborative framework agreement.

The FDA acknowledged positive efficacy from Vanda's controlled clinical trials, however, the FDA concluded that these data do not provide substantial evidence of effectiveness for jet lag disorder, primarily on the grounds that controlled phase advance protocols (5-hour and 8-hour bedtime shifts) are not sufficiently analogous to actual jet travel, which according to the FDA involves additional factors such as reduced oxygen pressure, physical constraints, noise, and lighting changes.

Vanda respectfully disagrees with this interpretation. Phase advance models are widely accepted in circadian rhythm research as valid and reliable surrogates for simulating the core circadian misalignment underlying eastward jet lag—the primary driver of the disorder's hallmark symptoms per ICSD-3 criteria. These models reproducibly induce the essential features of jet lag without the confounders of variable travel conditions which are unrelated to jet lag. The convergent evidence from Vanda's studies including simulated and actual transatlantic travel demonstrates tasimelteon's meaningful benefits on sleep duration, latency to persistent sleep, and next-day alertness.

Tasimelteon's safety profile is also well-established, with predominantly mild adverse events and a market experience of over 10 years in chronic approved indications. Vanda maintains that the submitted dataset meets the statutory standard for substantial evidence of effectiveness on clinically relevant endpoints, for jet lag disorder.

Procedural Status

As previously announced, in August 2025 the D.C. Circuit set aside a prior FDA refusal to approve HETLIOZ® for jet lag disorder, describing Vanda's evidence as "specific, reasoned, and rooted in evidence" and the FDA's prior review as "cursory," while noting statistically significant improvements on primary endpoints across trials.

Following that ruling, Vanda and the FDA entered a collaborative framework agreement in October 2025, under which the FDA committed to an expedited re-review of the sNDA by January 7, 2026, including consideration of narrowed, sleep-focused indications.

Vanda appreciates the FDA's engagement but believes the current decision does not fully reflect the collaborative spirit or address the Court's concerns regarding meaningful engagement with the evidence. Vanda remains committed to working constructively with the FDA while pursuing all appropriate avenues to advance approval of HETLIOZ® for jet lag disorder and make this important therapy available to travelers.

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® 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 Vanda's commitment to working with the FDA while pursuing appropriate avenues to advance approval of HETLIOZ® in jet lag disorder, and the potential commercial availability of HETLIOZ® for the treatment of jet lag disorder 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 willingness to work with Vanda and meaningfully engage with the evidence, the results of Vanda's efforts to advance and obtain FDA approval of HETLIOZ® in jet lag disorder, and Vanda's ability to successfully execute a commercial launch of HETLIOZ® for the treatment of jet lag disorder if approved. 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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