



Vanda Pharmaceuticals Announces Positive Phase III Results for HETLIOZ®(tasimelteon) in Delayed Sleep-Wake Phase Disorder

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- Study met its primary endpoint: timing of sleep onset shifted 37.1 minutes earlier versus placebo ($p=0.022$)
- 60% of HETLIOZ® treated participants shifted sleep at least 30 minutes earlier, compared to 15% of the placebo arm

WASHINGTON, Sept. 29, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Nasdaq: VNDA) today announced positive topline results from its pivotal Phase III study of HETLIOZ® (tasimelteon) 20 mg in adults with Delayed Sleep-Wake Phase Disorder (DSWPD). Vanda intends to discuss these data with the U.S. Food and Drug Administration (FDA) and to submit a supplemental New Drug Application (sNDA) seeking approval of HETLIOZ® for DSWPD. If approved, HETLIOZ® would be the first FDA-approved medicine indicated for this condition.

HETLIOZ® is already an approved circadian regulator. The FDA first approved it in 2014 to treat Non-24-Hour Sleep-Wake Disorder in adults, and in 2020 to treat nighttime sleep disturbances in people with Smith-Magenis Syndrome. The DSWPD program would extend that same medicine, at the same 20 mg dose, to a third circadian sleep-wake disorder.

Delayed Sleep-Wake Phase Disorder (DSWPD)

DSWPD is a body-clock disorder, and not simply being a "night owl." In a typical night owl, late bedtimes are a preference. In DSWPD, the internal clock is stably set too late. People with the disorder often cannot fall asleep until the early morning hours even when they get into bed at a conventional time, then cannot wake for work, school, or family life the next morning — even if they allow a full night in bed¹. Estimated prevalence in adults is 0.2% to 1.5%, or roughly 0.5 to 4.1 million adults in the United States.^{2,3} The condition is often comorbid with other common psychiatric disorders.^{4,5}

Clinical Study results

VP-VEC-162-3502 (NCT04652882) was a multicenter, double-blind, randomized, placebo-controlled Phase III study.⁶ Adults 18 to 75 years of age with a confirmed clinical diagnosis of DSWPD received once-daily oral tasimelteon 20 mg or matching placebo for 28 days. The study evaluated over 260 individuals and enrolled a total of 43 patients with DSWPD across 26 clinical sites in the US and Europe for a period of over 5 years.

The study met its primary endpoint. HETLIOZ® 20 mg ($n=20$) shifted the time of sleep onset 42.5 minutes earlier, compared with a 5.4-minute shift on placebo ($n=20$) — a 37.1-minute difference from placebo ($p=0.022$). The primary endpoint was the start time of the sleep episode, measured by sleep diary.

In an exploratory responder analysis, 60% of tasimelteon-treated participants (12/20) advanced their sleep timing onset by at least 30 minutes, compared with 15% on placebo (3/20) ($p=0.008$).

Endpoint	Placebo (N=20)	Tasimelteon 20 mg (N=20)	P-value
Sleep onset timing change, mean (min)*	5.4	42.5	0.022
≥30-minute sleep timing advance**	15% (3/20)	60% (12/20)	0.008

*Primary endpoint: change of sleep onset timing (as compared to placebo).

**Exploratory responder analysis defined as people with at least 30 minutes of advance of the sleep onset timing. P-value is from Fisher's exact test.

Safety over the 28-day controlled period was consistent with the established HETLIOZ® label. No new safety signals were identified.

"People with DSWPD often remain undiagnosed and undertreated especially because of the absence of a proven approved treatment," said Mihael H. Polymeropoulos, M.D., President, CEO and Chairman of the Board. "This study extends our knowledge of the clinical properties of HETLIOZ® as a versatile circadian regulator. We look forward to discussing these data with the FDA and pursuing a new indication for HETLIOZ® as the first ever approved treatment for DSWPD."

Vanda plans to file an sNDA for HETLIOZ® in DSWPD. The application is expected to include this Phase III study together with Vanda's prior studies in related disorders and more than a decade of use in two approved circadian indications.

About HETLIOZ® (tasimelteon)

HETLIOZ® is a dual melatonin MT1 and MT2 receptor agonist. It is FDA-approved for the treatment of Non-24-Hour Sleep-Wake Disorder in adults (approved 2014) and for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (approved 2020; capsules in patients 16 years and older and HETLIOZ LQ® oral suspension in patients 3 to 15 years of age).⁷ It is not currently approved for DSWPD.

About Vanda Pharmaceuticals Inc.

Vanda is a leading 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 HETLIOZ®, see the full Prescribing Information.

References

1. American Academy of Sleep Medicine. *International Classification of Sleep Disorders*, 3rd ed., Text Revision (ICSD-3-TR). Darien, IL: AASM;

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2. Nesbitt AD. Delayed sleep-wake phase disorder. *J Thorac Dis.* 2018;10(Suppl 1):S103-S111.
3. US Census Bureau, Vintage 2025 population estimates, age 18 and older.
4. Takaesu Y, Inoue Y, Murakoshi A, et al. Prevalence of circadian rhythm sleep-wake disorders and associated factors in euthymic patients with bipolar disorder. *PLoS One.* 2016;11(7):e0159578. doi:10.1371/journal.pone.0159578 (PLOS One, PubMed 27442503)
5. Reis C, Paiva T. *Sleep Sci.* 2019;12(3):203-213.
6. ClinicalTrials.gov NCT04652882.
7. HETLIOZ® Prescribing Information

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including but not limited to statements regarding Vanda's plans to submit an sNDA for HETLIOZ® in DSWPD and the likelihood of receiving regulatory approval of HETLIOZ® for the treatment of DSWPD 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, uncertainties relating to the timing and outcome of the regulatory approval process for HETLIOZ® for the treatment of DSWPD. 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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