



Vanda Pharmaceuticals Announces FDA Update for supplemental NDA for HETLIOZ® in the Treatment of Insomnia

February 5, 2024

WASHINGTON, Feb. 5, 2024 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that on February 4, 2024, it received a notification from the U.S. Food and Drug Administration (FDA) stating that as part of its ongoing review of Vanda's supplemental New Drug Application (sNDA) for HETLIOZ® (tasimelteon) in the treatment of insomnia characterized by difficulties with sleep initiation, the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. No deficiencies were disclosed by the FDA in the notification, and the FDA stated that the notification does not reflect a final decision on the information under review. In a letter to Vanda dated July 17, 2023, the FDA had assigned a Prescription Drug User Fee Act target date of March 4, 2024 for the completion of its review of the sNDA.

Vanda has extensively studied the efficacy of HETLIOZ® in the treatment of insomnia characterized by difficulties with sleep initiation. A Phase III, multi-center, placebo-controlled, 4-week trial evaluated patients with chronic primary insomnia. Two transient insomnia studies induced by phase advance of the sleep-wake cycle were also conducted with five-hour and eight-hour phase advance, which showed a significant effect the first night in improving sleep parameters.

Vanda believes that the timing of the FDA's communication is part of an ongoing violation of the Federal Food Drug, and Cosmetic Act (FDCA). The FDCA requires the FDA to either approve a new drug application or provide an opportunity for a hearing within 180 days after the filing of an application.¹ Because Vanda submitted the sNDA on May 4, 2023, the FDA's deadline under the FDCA was October 31, 2023. The FDA has not complied with the statute and has not timely approved the application or provided an opportunity for a hearing within the statutorily prescribed timeframe. Vanda is also challenging the FDA's approvals of several generic versions of HETLIOZ®, which have been marketed since 2023.

Vanda remains committed to its efforts to hold the FDA accountable to the law, ensuring predictable regulatory conduct.

References

1. 21 U.S.C. § 355(c)(1)

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 Twitter @vandapharma.

About HETLIOZ®

For full U.S. Prescribing Information for HETLIOZ®, including indication and Important Safety Information, visit www.hetlioz.com.

Corporate Contact:

Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

 View original content to download multimedia: <https://www.prnewswire.com/news-releases/vanda-pharmaceuticals-announces-fda-update-for-supplemental-nda-for-hetlioz-in-the-treatment-of-insomnia-302053260.html>

SOURCE Vanda Pharmaceuticals Inc.