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

March 6, 2024

WASHINGTON, March 6, 2024 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that on March 4, 2024, it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) 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.

In July 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. As previously reported, on February 4, 2024, the FDA provided a notification stating that it identified deficiencies that precluded discussion of labeling and postmarketing requirements/commitments. Consistent with that notification, the FDA has issued a CRL, indicating that the FDA cannot approve the sNDA in its present form.

Vanda is reviewing the CRL and evaluating its next steps.

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®

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

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