Vanda Pharmaceuticals Announces Notice of Opportunity for an FDA Hearing on the sNDA for HETLIOZ® In Jet Lag Disorder

September 7, 2022

WASHINGTON, Sept. 7, 2022 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced the notice of opportunity for an FDA hearing on Vanda's Supplemental New Drug Application (sNDA) for HETLIOZ® (tasimelteon) to treat jet lag disorder.

On August 19, 2019, Vanda reported that it had received a Complete Response Letter from the FDA for Vanda's sNDA for HETLIOZ® for the treatment of jet lag disorder. On July 1, 2022, Vanda submitted a request for an opportunity for a hearing under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) on the question of whether the sNDA is approvable. On August 26, 2022, Vanda received a notice of opportunity for hearing from the FDA. The FDA has indicated that it will publish the notice in a forthcoming issue of the Federal Register, but has not indicated when. Vanda is making the notice available to the public here.

Vanda has provided the FDA with four clinical studies that Vanda believes are adequate and well controlled and provide substantial evidence of efficacy for HETLIOZ® in the treatment of jet lag disorder. Vanda does not agree with the FDA's characterization of these studies and the conclusions reached by the FDA with respect to the sufficiency of its evidence to meet the standard of substantial evidence of efficacy. Vanda welcomes further administrative proceedings and remains committed to obtaining FDA marketing approval for HETLIOZ® for the treatment of jet lag disorder in order to address this significant unmet medical need.

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

Elizabeth Van Every
Head of Corporate Affairs
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

View original content:https://www.prnewswire.com/news-releases/vanda-pharmaceuticals-announces-notice-of-opportunity-for-an-fda-hearing-on-the-snda-for-hetlioz-in-jet-lag-disorder-301619811.html

SOURCE Vanda Pharmaceuticals Inc.