Vanda Pharmaceuticals FDA Update for HETLIOZ® in the Treatment of Jet Lag Disorder

August 19, 2019

WASHINGTON, Aug. 19, 2019 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that on August 16 2019, 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) for the treatment of Jet Lag Disorder (JLD).

As Vanda previously reported on May 23, 2018, JLD patients reported sleeping nearly three hours longer over the three nights following their transatlantic trip when treated with Hetlioz® than they did over the three nights following their untreated transatlantic trip, consistent with Vanda's jet lag simulation studies. In the CRL, the FDA asserted that these measures demonstrating improved sleep are of unclear clinical significance.

Vanda is perplexed by this conclusion, given that millions of travelers who experience JLD every year recognize that JLD is characterized by disruption of nighttime sleep and/or sleepiness during the day due to rapid travel across time zones. Consistent with this, the *American Academy of Sleep Medicine* lists disturbed sleep and daytime sleepiness as essential features of Jet Lag Disorder (International Classification of Sleep Disorders, 3rd Edition, 2011).

JLD sufferers attempt to treat the condition with unapproved remedies, which do not address either the symptoms or the underlying cause of JLD. Additionally, these treatments are replete with potentially dangerous side effects when used. To date, there are no treatments approved by the FDA for JLD, a public health issue experienced by millions of people every year.

The FDA's conclusions regarding the clinical significance of improved sleep in JLD are not the FDA's only observations made with respect to the sNDA. The CRL contains additional observations on various aspects of Vanda's sNDA. Vanda intends to consider each observation as it plans for continued engagement with the FDA on this matter.

"We are deeply disappointed to have not received approval at this time, given our previous discussions with the FDA on this program," said Mihael H. Polymeropoulos, M.D. Vanda's President and CEO. "Vanda remains committed to obtaining FDA marketing approval for tasimelteon in Jet Lag Disorder in order to address this significant unmet medical need."

About Vanda Pharmaceuticals Inc.
Vanda is a 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.

Forward Looking Statements
Various statements in this release are "forward-looking statements" under the securities laws. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include Vanda's discussion and potential resolution of the deficiencies that the FDA believes are contained in the sNDA along with the other matters identified by the FDA in the CRL and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2018 and quarterly report on Form 10-Q for the quarter ended June 30, 2019, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, other unknown or unpredictable factors also could affect Vanda's results. There can be no assurance that the actual 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. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

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 release is provided only as of the date of this 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.

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