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

July 22, 2019

WASHINGTON, July 22, 2019 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that on July 19, 2019, 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) for the treatment of Jet Lag Disorder, 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 this notification, and the FDA stated that this notification does not reflect a final decision on the information under review. In a letter dated December 19, 2018, the FDA had assigned a Prescription Drug User Fee Act ("PDUFA") target date for completion of its review by August 16, 2019.

Vanda has extensively studied the efficacy of the circadian regulator Hetlioz® on Jet Lag Disorder (JLD), which occurs following rapid eastward transmeridian travel and can result in significant and impairing symptoms. The majority of eastward transmeridian travelers will experience JLD. More than 30 million Americans travel across five or more eastward time zones annually.

Hetlioz® was shown to be well tolerated prior to its first approval by the FDA in 2014. Since its commercial launch in 2014, thousands of patients with Non-24-Hour Sleep-Wake Disorder have been exposed to Hetlioz®, many for periods of several years and on a daily basis.

In addition, Vanda has studied Hetlioz® for almost 15 years in different settings and conditions, and Hetlioz® has consistently demonstrated robust biological effects and clinical benefits.

Vanda anticipates receiving additional communication from the FDA identifying specific deficiencies in the sNDA. Vanda hopes that it will be able to work expeditiously with the FDA to resolve any such deficiencies.

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 the Company's forward-looking statements include the Company's discussion and potential resolution of the deficiencies that the FDA believes are contained in the sNDA 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 the Company'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 March 31, 2019, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be set forth in those sections of the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2019, to be filed in the third quarter of 2019. In addition to the risks described above and in the Company's annual report on Form 10-K and quarterly reports on Form 10-Q, other unknown or unpredictable factors also could affect the Company's results. There can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, the Company. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

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