



## **Vanda Receives Innovation Award from the National Organization for Rare Disorders for Development of HETLIOZ®**

May 26, 2015

WASHINGTON, May 26, 2015 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today announced that it has received the 2015 Industry Innovation Award from the National Organization of Rare Disorders (NORD) in recognition of Vanda's work in developing HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24). This award was presented to Vanda at the 2015 Portraits of Courage Gala in Washington D.C. on May 18<sup>th</sup>.

"We are proud to be recognized by NORD for our work on HETLIOZ for the treatment of Non-24 and view this award as another opportunity to bring attention to those individuals who are struggling to live with this debilitating condition," said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda. "We thank NORD for their support of Non-24 patients and others in the U.S. who live with rare disorders."

HETLIOZ® was approved by the U.S. for the treatment of Non-24 in January of 2014. In April 2015, the European Medicines Agency's Committee for Medicinal Products for Human Use adopted a positive opinion for HETLIOZ® for the treatment of Non-24. A final decision is expected by the end of the second quarter of 2015.

Established in 1983, NORD is the primary nonprofit organization representing all patients and families affected by rare diseases in the U.S. NORD is committed to the identification, treatment and cure for all 7,000 rare diseases that affect 30 million Americans. NORD provides programs of advocacy, education, research and patient/family services to improve the lives of all people living with rare diseases.

### **About Non-24-Hour Sleep-Wake Disorder**

Non-24 was first described more than 60 years ago, and is a chronic, circadian rhythm disorder resulting from the misalignment of the endogenous master body clock to the 24-hour day, disrupting the sleep-wake cycle. The sleep disturbance causes significant distress or impairment in social, occupational and other important areas of functioning. Non-24 affects the majority of totally blind individuals and it has been estimated that approximately 80,000 people in the U.S. have the disorder.

### **About HETLIOZ®**

HETLIOZ® is a melatonin receptor agonist. HETLIOZ® has been approved by the U.S. Food and Drug Administration for the treatment of Non-24. For full U.S. prescribing information, please visit [www.hetlioz.com](http://www.hetlioz.com).

### **U.S. Indication and Important Safety Information About HETLIOZ®**

#### **Indication**

HETLIOZ® is indicated for the treatment of Non-24.

#### **Important Safety Information**

HETLIOZ® may cause somnolence: After taking HETLIOZ®, patients should limit their activity to preparing for going to bed, because HETLIOZ® can impair the performance of activities requiring complete mental alertness.

The most common adverse reactions (incidence >5% and at least twice as high on HETLIOZ® than on placebo) were headache, increased alanine aminotransferase, nightmares or unusual dreams, upper respiratory or urinary tract infection. The risk of adverse reactions may be greater in elderly (>65 years) patients than younger patients because exposure to HETLIOZ® is increased by approximately 2-fold compared with younger patients.

Use of HETLIOZ® should be avoided in combination with fluvoxamine or other strong CYP1A2 inhibitors, because of a potentially large increase in exposure of HETLIOZ®, and a greater risk of adverse reactions. HETLIOZ® should be avoided in combination with rifampin or other CYP3A4 inducers, because of a potentially large decrease in exposure of HETLIOZ®, with reduced efficacy.

There are no adequate and well-controlled studies of HETLIOZ® in pregnant women. Based on animal data, HETLIOZ® may cause fetal harm. HETLIOZ® should be used during pregnancy only if the potential benefit justifies the potential risks. Caution should be exercised when HETLIOZ® is administered to a nursing woman.

HETLIOZ® has not been studied in patients with severe hepatic impairment and is not recommended in these patients.

Safety and effectiveness of HETLIOZ® in pediatric patients have not been established.

**Full U.S. HETLIOZ® Prescribing Information can be found at: [www.hetlioz.com](http://www.hetlioz.com).**

### **About Vanda Pharmaceuticals Inc.**

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. For more on Vanda, please visit [www.vandapharma.com](http://www.vandapharma.com).

### **CAUTIONARY NOTE REGARDING 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, among others, Vanda's assumptions regarding the regulatory status of

HETLIOZ® in the European Union 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, 2014, which is on file with the SEC and available on the SEC's website at [www.sec.gov](http://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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