Seventy Percent of Totally Blind Individuals With Sleep Complaints Suffer From Chronic Circadian Rhythm Sleep Disorder

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Vanda presents new data at SLEEP 2012 26th Annual Meeting of the Associated Professional Sleep Societies

BOSTON, June 11, 2012 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (NASDAQ: VNDA), a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders, announced today that data presented at SLEEP, the 26th annual meeting of the Associated Professional Sleep Societies (APSS), show that seventy percent (70%) of totally blind people with sleep complaints suffer from Non-24-Hour Disorder (Non-24). Non-24 is a circadian rhythm disorder characterized by a chronically misaligned body clock. The results underscore the need for a new therapy that can regulate the circadian clock and keep it synchronized with the 24-hour day. There are currently no FDA approved medications for the treatment of Non-24.

"Blind individuals who have no light perception do not receive the normal cues from daylight and darkness that regulate our sleep and wake cycles," said Dr. Phyllis Zee, Professor of Neurology, Neurobiology & Physiology and Director, Sleep Disorders Program at Northwestern University Feinberg School of Medicine in Chicago, Illinois. "The current study revealed that these patients' circadian cycles delay by an average of about thirty minutes each day, robbing them of their ability to stay in sync with a normal 24-hour schedule. Over time, patients will cycle in and out of phase resulting in frequent bouts of nighttime sleeplessness and daytime napping, which can negatively impact their day to day functioning."

In a poster presentation entitled, "Seventy Percent of Totally Blind People with Sleep Complaints Are Not Entrained to the 24-Hour Clock," data were reported on the endogenous circadian period (T) for the first 143 subjects enrolled in the ongoing SET study (Safety and Efficacy of Tasimelteon to Treat Non-24), a Phase III clinical trial in totally blind patients. Circadian period was calculated by measuring a urinary melatonin metabolite and secretion rates, collected weekly for 48 hours (at 4-8 hour intervals), for each of the four collection periods. Vanda used this objective evaluation of melatonin secretion by the pineal gland to determine circadian period.

Of the 143 totally blind subjects with sleep complaints in the study, 70% were found to not be entrained to a 24-hour day and, as a result, diagnosed with Non-24. Circadian period (T) in Non-24 patients ranged from 24.08 to 25.34, with a median tau of 24.45 (24 hours and 27 minutes), meaning study subject's internal clocks delay a median of 27 minutes every day. The effect is cumulative, putting subjects to sleep later and later each day until they cycle around the clock and begin again.

"The high prevalence of Non-24 in totally blind individuals with sleep complaints, coupled with frequent underdiagnoses, signals an urgent need to raise awareness in the blind community and with health professionals about the condition," said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda Pharmaceuticals. "At Vanda, we are committed to providing education and developing a therapeutic option to address the needs of people living with Non-24."

Vanda is currently studying the efficacy of tasimelteon in Non-24 in two multi-national Phase III studies, SET and RESET, which are ongoing and expected to be completed by the end of 2012.

The posters presented at SLEEP will be archived for 30 days on the Vanda website at http://www.vandapharma.com/

About Non-24-Hour Sleep Disorder

Non-24-Hour Disorder (Non-24) is a chronic circadian rhythm sleep disorder that affects a majority of totally blind individuals in the U.S., or between 65,000 and 95,000 people. Non-24 occurs almost entirely in individuals who are totally blind and lack the light sensitivity necessary to entrain, or synchronize, the brain's circadian rhythms with the 24-hour day-night cycle. Most people have a circadian clock that naturally runs somewhat longer than 24-hours, and light is the environmental cue that resets it back to 24-hours each day. Non-24 sufferers essentially "free-run" on their own internal clock time, putting them to sleep later and later each day, turning night into day and day into night, until the cycle starts all over again. The sleep condition is highly disruptive, making it difficult to do well in school, hold down a job or maintain relationships. For more information on Non-24, please visit http://24sleepwake.com/.

About Tasimelteon

Tasimelteon is the first compound in development for the treatment of Non-24Disorder. Tasimelteon is a specific and potent agonist of the human MT1 and MT2 receptors. Compounds that selectively bind to melatonin receptors are thought to be able to regulate the body clock, which may be useful to treat circadian rhythm disorders. Tasimelteon is being studied in both Non-24 and Major Depressive Disorder (MDD).

About the SET Study

Vanda Study 3201 is designed to investigate the efficacy and safety of 20 mg tasimelteon versus placebo in totally blind individuals with Non-24. The study includes a 6-month treatment period and an optional open-label extension. The primary endpoint of the study is "entrainment" to the 24 hour clock, assessed via a laboratory measure of the synchronization between the internal body clock and the 24-hour environmental light/dark cycle. The study will also measure parameters of improvement in Total Sleep Time (TST) during the night and a reduction in daytime sleep. Vanda expects to report top-line results for this trial in the fourth quarter of 2012. For more information on the SET study, please visit http://clinicaltrials.gov/.

About the RESET Study

RESET is a randomized withdrawal study designed to demonstrate the maintenance effect of 20 mg tasimelteon in the treatment of Non-24. Twenty totally blind individuals with no light perception and diagnosed as having a body clock period of greater than 24 hours, will be treated with tasimelteon for three months during a run-in phase. Patients who respond to tasimelteon treatment during the run-in phase, as measured by the resetting and

alignment of their body clock to the 24-hour day, will then be randomized either to receive placebo or to continue receiving tasimelteon for 2 months. During the post-randomization phase, patients will be re-evaluated. For more information on the RESET study, please visit http://clinicaltrials.gov/.

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 Pharmaceuticals Inc., please visit http://www.vandapharma.com/.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this release are "forward-looking statements" under the securities laws. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "project," "target," "goal," "likely," "will," "would," and "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. 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, among others: the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives; Vanda's ability to successfully commercialize Fanapt® outside of the U.S. and Canada; delays in the completion of Vanda's clinical trials; a failure of Vanda's products, product candidates or partnered products to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products, product candidates or partnered products or to comply with ongoing regulatory requirements; a lack of acceptance of Vanda's products, product candidates or partnered products in the marketplace, or a failure to become or remain profitable; Vanda's expectations regarding trends with respect to its costs and expenses; Vanda's inability to obtain the capital necessary to fund additional research and development activities; Vanda's failure to identify or obtain rights to new products or product candidates; Vanda's failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; limitations on Vanda's ability to utilize some or all of its prior net operating losses and research and development credits; a loss of any of Vanda's key scientists or management personnel; losses incurred from product liability claims made against Vanda; a loss of rights to develop and commercialize Vanda's products or product candidates under its license and sublicense agreements 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, 2011 which is on file with the SEC and available on the SEC's website at 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.

COMPANY CONTACT:
Cristina Murphy
Senior Communications Manager
Vanda Pharmaceuticals Inc.
(301) 803-8481
cristina.murphy@vandapharma.com

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