



Clinical Trial Results on the Sleep-Promoting Effects of Vanda Pharmaceuticals' Circadian Regulator Tasimelteon (VEC-162) Published in The Lancet

December 2, 2008

ROCKVILLE, Md., Dec. 1 /PRNewswire-FirstCall/ -- Vanda Pharmaceuticals Inc. (Nasdaq: VNDA) reports publication in The Lancet, one of the world's leading medical journals, results of clinical trials of its novel circadian regulator, experimental compound tasimelteon (VEC-162). The publication by Rajaratnam et al(1) is entitled "Melatonin agonist tasimelteon (VEC-162) for transient insomnia after sleep-time shift: two randomised controlled multicentre trials." Results are reported from two clinical trials that demonstrate the sleep-promoting effects of tasimelteon, a novel circadian regulator that acts by resetting the body clock. The internal body clock is a complex molecular machinery that governs the rhythm of many body functions, the most well described of which is the sleep-wake cycle.

In the same issue of The Lancet, in an accompanying editorial, "Let there be sleep -- on time," Cardinali and Golombek(2) discuss the implications of the circadian regulatory and sleep-promoting effects of tasimelteon. They also point to the need for public health education and a move towards more effective agents that do not present the safety issues encountered with current sleep treatments.

The article by Rajaratnam et al(1) presents results from two clinical studies with more than 400 volunteers, who were asked to initiate sleep five hours before their usual bedtimes. Tasimelteon was shown to reset the molecular machinery of the circadian clock and restore the sleep-wake cycle by improving both the ability to initiate and to maintain sleep as compared to placebo-treated patients.

The body's circadian clock plays significant roles in regulating sleep, mood as well as cardiovascular and metabolic processes.(3)(4) Circadian rhythm sleep disorders include insomnia associated with shift work (overnight, rotating and early riser), travel across time zones, delayed sleep phase syndrome, advanced phase syndrome and the non-24-hour sleep-wake syndrome in the blind. These disorders represent a large public health problem and, as presented in the 2006 Institute of Medicine (IOM) report on sleep disorders(5), the annual economic impact of sleep problems due to night shift work alone is estimated to exceed \$65 billion.

The novel circadian regulator tasimelteon holds promise for the treatment of patients with misalignments of the body clock. The work presented in The Lancet examines the potential application in sleep disorders. Additional clinical trials will have to be conducted to examine the role of circadian regulators in the treatment of other disorders such as depression, nondipper hypertension(3)(4), and others.

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," "targets," "likely," "will," "would," and "could," 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. Vanda is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in the company's forward-looking statements include, among others: delays in the completion of Vanda's clinical trials; a failure of Vanda's product candidates to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products or to comply with ongoing regulatory requirements; a lack of acceptance of Vanda's product candidates in the marketplace, or a failure to become or remain profitable; Vanda's inability to obtain the capital necessary to fund its research and development activities; Vanda's failure to identify or obtain rights to new product candidates; Vanda's failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; 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 under its license and sublicense agreements and other factors that are described in the "Risk Factors" section (Part II, Item 1A) of Vanda's quarterly report on Form 10-Q for the quarter ended September 30, 2008 (File No. 000-51863). In addition to the risks described above and in Part II, Item 1A of Vanda's quarterly report 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.

(1) Rajaratnam, Shantha M.W.; et al. "Melatonin agonist tasimelteon (VEC-162) for transient insomnia after sleep-time shift: two randomized controlled multicentre trials." www.thelancet.com. 2008.

(2) Cardinali, Daniel P.; Golombek, Diego A. "Let There Be Sleep - On Time." Letter. www.thelancet.com. 1 December 2008.

(3) Bunney, Jennifer N.; Potkin, Steven G. "Circadian abnormalities, molecular clock genes and chronobiological treatments in depression." *British Medical Bulletin*. 2008; 86 (1): 23-32.

(4) Perez-Lloret, Santiago; Garcia Aguirre, Alejandro; Cardinali, Daniel P.; Toblli, Jorge E. "Disruption of Ultradian and Circadian Rhythms of Blood Pressure in Nondipper Hypertensive Patients." *Hypertension*. 2004; 44: 311-315.

(5) Colten, Harvey R.; Altevogt, Bruce M. Institute on Medicine. Committee on Sleep Medicine and Research. *Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem*. 2006.

SOURCE Vanda Pharmaceuticals Inc.

-0- 12/01/2008

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CO: Vanda Pharmaceuticals Inc.; The Lancet

ST: Maryland

IN: MTC HEA BIO MAG PUB

SU: TRI SVY

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