

# VANDA PHARMACEUTICALS' VEC-162 DEMONSTRATES POSITIVE RESULTS IN A PHASE III TRANSIENT INSOMNIA CLINICAL TRIAL

Vanda Pharmaceuticals

*PR Newswire Europe, November 16, 2006*

Vanda Pharmaceuticals Inc. , a biopharmaceutical company focused on the development and commercialization of clinical-stage product candidates for central nervous system disorders, announced positive top-line results from the company's Phase III clinical trial evaluating VEC-162, a balanced melatonin receptor agonist, in transient insomnia. VEC-162 demonstrated statistically significant improvements at all three tested doses compared to placebo ( $p < 0.001$ ) in the primary endpoint of the trial, Latency to Persistent Sleep (LPS), a measure of sleep onset. VEC-162 also produced statistically significant improvements relative to placebo in Latency to Non-Awake (LNA), another measure of sleep onset, Wake After Sleep Onset (WASO), a measure of sleep maintenance, and Total Sleep Time (TST). VEC-162 was also demonstrated to be safe and well-tolerated.

The Phase III trial was a randomized, double-blind, placebo-controlled, multi-center study that enrolled 412 adults in a sleep laboratory setting using a phase-advance, first-night assessment model of induced transient insomnia. The trial examined VEC-162 dosed 30 minutes before bedtime at 20, 50 and 100 mg versus placebo.

Vanda Pharmaceuticals Inc.

VEC-162 achieved statistically significant results in multiple endpoints captured using polysomnography (PSG) including:

\* Latency to Persistent Sleep (LPS): Improvement compared with placebo of 21.5 ( $p < 0.001$ ), 26.3 ( $p < 0.001$ ), and 22.8 ( $p < 0.001$ ) minutes at 20, 50, and 100 mg respectively.

\* Latency to Non-Awake (LNA): Improvement compared with placebo of 11.1 ( $p < 0.006$ ), 14.3 ( $p < 0.001$ ), and 12.3 ( $p < 0.002$ ) minutes at 20, 50, and 100 mg respectively.

\* Wake After Sleep Onset (WASO): Improvement compared with placebo of 24.2 ( $p < 0.02$ ), 33.7 ( $p = 0.001$ ), and 17.5 ( $p = 0.081$ ) minutes at 20, 50, and 100 mg respectively.

\* Total Sleep Time (TST): Improvement compared with placebo of 33.7 ( $p < 0.002$ ), 47.9 ( $p < 0.001$ ) and 29.6 ( $p < 0.005$ ) minutes at 20, 50, and 100 mg respectively.

The trial also demonstrated that VEC-162 was well-tolerated.

"We are extremely pleased with the positive results of this Phase III clinical trial," stated Paolo Baroldi, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Vanda. "This study demonstrates VEC-162's ability to induce and maintain sleep. Also because VEC-162 is a balanced melatonin receptor agonist that works through the natural sleep/wake cycle, it appears to lack the side effects associated with hypnotics and sedatives and should not be scheduled as a controlled substance."

Mihael Polymeropoulos, M.D., President and CEO of Vanda, added that "VEC-162 may be an effective new treatment for sleep disorders in general, and also may be able to treat an important subset of sleep disorder patients for whom there is currently no available, effective drug treatment. These patients have Circadian Rhythm Sleep Disorders, or CRSD. CRSDs are sleep disorders arising from a misalignment of the circadian rhythm, where a person's internal sleep/wake cycle does not match his or her desired sleep

time. Examples include shift worker sleep disorder, delayed sleep phase syndrome, and jet lag. We believe VEC-162 is the only compound with a proven ability to modify the sleep/wake cycle and could be an important treatment for the large number of CRSD patients."